



MONASH University

Prevention of unintended pregnancy  
among female sex workers  
in low- and middle-income countries

---

Frances Halliday Ampt

MBBS, BA, MPH

A thesis submitted for the degree of Doctor of Philosophy at

Monash University in 2020

School of Public Health and Preventive Medicine

Melbourne, Australia

## Copyright notice

© Frances Ampt (2020).

I certify that I have made all reasonable efforts to secure copyright permissions for third-party content included in this thesis and have not knowingly added copyright content to my work without the owner's permission.

# Table of Contents

Copyright notice.....	ii
Abstract.....	v
List of tables.....	vii
List of figures.....	viii
Research outcomes during candidature .....	ix
Thesis including published works declaration .....	xii
Abbreviations .....	xvi
Acknowledgements.....	xvii
<b>Chapter 1: Introduction.....</b>	<b>1</b>
1.1 Sex work and female sex workers.....	1
1.2 Female sex workers in low- and middle income countries are at high risk of unintended pregnancy.....	3
1.3 Global burden of unintended pregnancy.....	4
1.4 Contraception and unmet need .....	5
1.5 Determinants of contraceptive use and unintended pregnancy among female sex workers.....	8
1.6 Behavioural interventions to increase contraceptive use and prevent unintended pregnancy .....	16
1.7 Promotion of sexual and reproductive health using mobile phones.....	20
1.8 Research context .....	25
1.9 Thesis overview .....	31
<b>Chapter 2: Systematic review of the incidence of unintended pregnancy among female sex workers .....</b>	<b>34</b>
2.1 Background.....	34
<b>Chapter 3: Development of an mHealth Intervention for female sex workers .....</b>	<b>64</b>
3.1 Background.....	64
<b>Chapter 4: Protocol for the WHISPER or SHOUT cluster-randomised controlled trial .....</b>	<b>83</b>
4.1 Background.....	83

<b>Chapter 5: Use of long-acting reversible contraceptives among female sex workers in Kenya .....</b>	<b>94</b>
5.1    Background.....	94
<b>Chapter 6: Impact of the WHISPER mobile phone intervention for female sex workers on unintended pregnancy .....</b>	<b>106</b>
6.1    Background.....	106
<b>Chapter 7: Integrated discussion.....</b>	<b>137</b>
7.1    Key findings and their implications.....	137
7.2    Methodological implications of measuring unintended pregnancy incidence .....	149
7.3    Strengths and limitations.....	151
7.4    Implementation challenges.....	158
7.5    Recommendations .....	161
7.6    Conclusion.....	171
<b>References.....</b>	<b>173</b>
<b>Appendices.....</b>	<b>198</b>
Appendix 1: WHISPER intervention messages.....	198
Appendix 2: London Measure of Unplanned Pregnancy adapted for the WHISPER or SHOUT study.....	218



## Abstract

Female sex workers (FSWs) in low- and middle-income countries are at high risk of unintended pregnancy, yet this issue has been largely neglected in sexual health research and programming. Many FSW populations have high unmet need for contraception, particularly long-acting reversible contraception (LARC). Condom use is often inconsistent, particularly with non-paying emotional sex partners, and use of condoms consistently along with another effective contraceptive method (dual method use) is uncommon. Knowledge of contraceptive options is often poor and misconceptions are widespread. In addition, FSWs work in a criminalised environment with endemic gender-based violence and stigma from both health providers and the general community.

My thesis aims to address the knowledge gaps around this issue, and to improve the sexual and reproductive health of FSWs in Kenya, by developing and evaluating a mobile phone-based (mHealth) intervention for FSWs to improve contraceptive use and prevent unintended pregnancy. Previous research indicates that FSWs in Kenya are heavily dependent on their mobile phones, making this an ideal modality for connecting with this hard-to-reach population.

The first study in this thesis, a systematic review and meta-analysis, found that pregnancy incidence among FSWs has rarely been measured. Available estimates were highly heterogeneous and of low methodological quality. The pooled estimate of unintended pregnancy incidence in the three studies best designed to measure this was 27 per 100 person-years, considerably higher than available estimates in the general population.

The remainder of my research centred on the WHISPER or SHOUT trial, conducted with FSWs in Mombasa, Kenya. The WHISPER SMS intervention was based on health promotion theory and developed using participatory methods, and the qualitative research from that process is reported in this thesis. The content and behaviour change techniques in the messages resonated strongly with the target population.

The intervention was tested in an equal-attention cluster-randomised controlled trial, in which recipients of WHISPER messages were compared to those receiving nutrition messages (SHOUT) for one year. Analysis of trial data at baseline examined the prevalence of LARCs, finding that implant use was considerably higher than anticipated, which was most likely attributable to a parallel increase in implant use in the Kenyan population. In contrast, intrauterine device (IUD) use was very rare.

Assessment of the effectiveness of the WHISPER intervention found that it had no impact on unintended pregnancy incidence (the primary outcome) or LARC use. However, the intervention did result in modest improvement in contraceptive knowledge and use of dual contraceptive methods.

Overall, my research suggests that mHealth interventions used in isolation may have the potential to change short-term user-controlled behaviours, but have limited impact on use of longer-term methods or behaviours that are more subject to external and structural influences. Multi-faceted pregnancy prevention is needed for FSWs, which integrates both supply- and demand-side elements, and addresses structural influences on FSWs' health and wellbeing. The use of SMS for contraceptive promotion is highly feasible and acceptable and could have greater impact on this important health and social issue if integrated into a broader prevention program for FSWs.

# List of tables

## Chapter 1

Table 1: Selected characteristics of contraceptive methods.....	6
Table 2: Potential determinants of unintended pregnancy among FSWs.....	10
Table 3: Typology of mHealth intervention characteristics.....	24

## Chapter 2

Table 1: Characteristics of studies included in the systematic review.....	39
Table 2: Results of included studies reporting pregnancy incidence.....	44
Table 3: Incidence of abortion and birth in included studies.....	48

## Chapter 3

Table 1: Example messages and role model story episode from WHISPER.....	71
Table 2: Role model stories developed from peer educator consultation.....	73
Table 3: Example on-demand messages and links to on-demand content.....	74
Table 4: Outcome expectations raised by workshop participants.....	79

## Chapter 4

Table 1: Number, length and timing of messages for each study arm.....	104
Table 2: Schedule of assessments for the WHISPER or SHOUT trial.....	106

## Chapter 5

Table 1: Demographic, sex work and health characteristics of the study participants.....	114
Table 2: Contraceptive use characteristics of the sample population.....	115
Table 3: Bivariate and multivariate logistic regression analyses of LARC use.....	116

## Chapter 6

Table 1: Participant characteristics by intervention group at baseline.....	138
Table 2: The effect of the WHISPER intervention on the primary outcome .....	139
Table 3: The effect of the WHISPER intervention on secondary outcomes.....	140
Table 4: True/False statements included in the knowledge scale.....	141

## List of figures

### Chapter 1

Figure 1: Contraceptive method mix in Kenya .....	8
Figure 2: Social ecological model of health for determinants of unintended pregnancy.....	9
Figure 3: Map of Mombasa showing sub-counties prior to 2012 redistribution.....	27

### Chapter 2

Figure 1: PRISMA flow diagram of search results and inclusion of studies after review.....	38
Figure 2: Incidence rates for studies reporting unintended pregnancy.....	45
Figure 3: Forest plot of unintended pregnancy incidence rates by intervention status.....	46
Figure 4: Forest plot of unintended pregnancy incidence rates by study design.....	46
Figure 5: Forest plot of unintended pregnancy incidence rates by study duration.....	47
Figure 6: Forest plot of pregnancy incidence rates by geographic region.....	47

### Chapter 3

Figure 1: WHISPER program logic.....	70
--------------------------------------	----

### Chapter 4

Figure 1: Logic model for the SRH intervention (WHISPER).....	103
Figure 2: Logic model for the nutrition intervention (SHOUT).....	104

### Chapter 5

Figure 1: Flow diagram showing recruitment of the study population.....	113
---	-----

### Chapter 6

Figure 1: Trial profile.....	142
Figure 2: Mean knowledge score by intervention group at each time point .....	143
Figure 3: Probability of LARC use by intervention group at each time point.....	144
Figure 4: Probability of dual method use by intervention group at each time point.....	145

### Chapter 7

Figure 1: Contraceptive method mix in Kenya and among FSWs from WHISPER or SHOUT.....	154
Figure 2: WHISPER program logic.....	159
Figure 3: Social ecological model of health illustrating influences on condom use.....	160

## Research outcomes during candidature

A list of publications and oral presentations during my PhD candidature is presented below. Presenters of oral presentations are indicated by underlining.

### Peer-reviewed publications contained within this thesis

**Ampt FH**, Willenberg L, Agius PA, Chersich M, Luchters S, Lim MSC: Incidence of unintended pregnancy among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *BMJ Open* 2018, 8(9):e021779.

**Ampt FH**, L'Engle K, Lim MSC, Plourde KF, Mangone E, Mukanya CM, Gichangi P, Manguro G, Hellard M, Stoové M, Chersich MF, Jaoko W, Agius PA, Temmerman M, Wangari W, Luchters S: A Mobile Phone–Based Sexual and Reproductive Health Intervention for Female Sex Workers in Kenya: Development and Qualitative Study. *JMIR Mhealth Uhealth* 2020, 8(5):e15096.

**Ampt FH**, Mudogo C, Gichangi P, Lim MSC, Manguro G, Chersich M, Jaoko W, Temmerman M, Laini M, Comrie-Thomson L, Stoové M, Agius PA, Hellard M, L'Engle K, Luchters S: WHISPER or SHOUT study: protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017, 7(8):e017388.

**Ampt FH**, Lim MSC, Agius PA, Chersich MF, Manguro G, Gichuki CM, Stoové M, Temmerman M, Jaoko W, Hellard M, Gichangi P, Luchters S: Use of long-acting reversible contraception in a cluster-random sample of female sex workers in Kenya. *International Journal of Gynecology & Obstetrics* 2019, 146(2):184-191.

**Ampt FH**, Lim MSC, Agius PA, L'Engle K, Manguro G, Gichuki C, Gichangi P, Chersich M, Jaoko W, Temmerman M, Stoové M, Hellard M, Luchters S: Impact of the WHISPER mobile phone intervention for female sex workers on unintended pregnancy: a cluster-randomised controlled trial in Kenya. *Lancet Glob Health* (in press).

### Additional peer-reviewed publications

Bowring AL, **Ampt FH**, Schwartz S, Stoové MA, Luchters S, Baral S, Hellard M: HIV pre-exposure prophylaxis for female sex workers: ensuring women's family planning needs are not left behind. *Journal of the International AIDS Society* (in press).

**Ampt FH**, El Hayek C, Agius PA, Bowring AL, Bartnik N, Van Gemert C, Fairley CK, Chow EPF, Bradshaw CS, Stephens N, Lim MSC, Hellard ME: Anorectal swabs as a marker of male-to-male

sexual exposure in STI surveillance systems. *Epidemiology and Infection* 2017, 145(12):2530-2535.

Luchters S, Bosire W, Feng A, Richter ML, King'ola N, **Ampt F**, Temmerman M, Chersich MF: "A baby was an added burden": predictors and consequences of unintended pregnancies for female sex workers in Mombasa, Kenya: a mixed-methods study. *PLoS ONE* 2016, 11(9):e0162871.

## Oral presentations

**Ampt FH**, Lim MSC, Manguro G, Gichuki CM, Gichangi P, L'Engle KL, Chersich MF, Agius PA, Temmerman M, Jaoko W, Stoové M, Hellard M, Luchters S: Impact of a mobile phone-based sexual and reproductive health intervention on unintended pregnancy and contraceptive use among female sex workers *10th Asia Pacific Conference on Reproductive and Sexual Health and Rights: 2020 (accepted)*; Siem Reap, Cambodia; 2020 (accepted).

**Ampt FH**, Lim MSC, Manguro G, Gichuki C, Gichangi P, L'Engle K, Chersich M, Agius PA, Temmerman M, Jaoko W, Stoové M, Hellard M, Luchters S: Impact of a mobile phone-based sexual and reproductive health intervention on unintended pregnancy and contraceptive use among female sex workers in Mombasa, Kenya. *Alfred Research Alliance Early-Mid Career Researchers Symposium*. Melbourne; 2019.

**Ampt F**, Lim M, Willenberg L, Agius P, Chersich M, Luchters S: Incidence of unintended pregnancy among female sex workers in low- and middle-income countries: a systematic review and meta-analysis. *15th World Congress on Public Health*. Melbourne; 2017.

**Ampt F**, Lim M, Agius P, Chersich M, Gichangi P, Hellard M, Temmerman M, Jaoko W, L'Engle K, Stoove M, Manguro G, Gichuki C, Luchters S: Long-acting reversible contraceptive use among female sex workers in Kenya. *Australasian Epidemiological Association Scientific Meeting*. Sydney; 2017.

## Poster presentations

Traeger M, **Ampt F**, Stoové M, Manguro G, Jaoko W, Gichangi P, Luchters S: HIV Incidence and Pre-Exposure Prophylaxis Awareness and Uptake Among a Random Sample of Female Sex Workers in Mombasa, Kenya. *13th INTEREST Workshop*. Accra; 2019.

Manguro G, Gichuki C, **Ampt F**, Temmerman M, Chersich M, Luchters S, Gichangi P, WHISPER/SHOUT Clinical Trial Group: Forty percent reduction in HIV prevalence among randomly sampled female sex workers in Mombasa, Kenya following intensive prevention programmes. *22nd International AIDS Conference*. Amsterdam; 2018.

L'Engle K, Mangone E, **Ampt F**, Mudogo C, Plourde K, Lim M, Gichangi P, Luchters S, WHISPER Study Investigators: “Dear Mrembo [Beautiful]”: Development, testing, and finalization of a theory-driven, human-centered mobile phone intervention to prevent pregnancy and HIV/STI among female sex workers (FSW) in Mombasa, Kenya. *9th IAS Conference on HIV Science*. Paris; 2017.

**Ampt F**, Mangone E, Plourde K, Mukanya CM, Gichangi P, Lim M, Luchters S, Hellard M, Stoové M, Chersich M, Temmerman M, Jaoko W, L'Engle K: “The phone is your office”: Development of an mHealth intervention for female sex workers in Mombasa, Kenya. *21st International AIDS Conference*. Durban; 2016.

## Thesis including published works declaration

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes four original papers published in peer reviewed journals and one submitted publications. The core theme of the thesis is unintended pregnancy among female sex workers in low- and middle-income countries. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the student, working within the Department of Epidemiology and Preventive Medicine under the supervision of Associate Professor Stanley Luchters and Dr Megan Lim.

The inclusion of co-authors reflects the fact that the work came from active collaboration between researchers and acknowledges input into team-based research.

In the case of Chapters Two to Six, my contribution to the work involved the following:

Thesis chapter	Publication title	Status	Nature and % of student contribution	Co-author name(s), nature and % of co-author's contribution*	Co-authors, Monash student Y/N
Two	Incidence of unintended pregnancy among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis	Published	70%. Study design, literature search, screening and data extraction, analysis and interpretation, manuscript preparation and revision	Lisa Willenberg: duplicate screening and extraction, manuscript review 10% Paul A. Agius: statistical advice, manuscript review 5% Matthew Chersich: manuscript review 3% Stanley Luchters: study design and manuscript review 6% Megan S. C. Lim: study design and manuscript review 6%	N
Three	A Mobile Phone–Based Sexual and Reproductive Health Intervention for Female Sex Workers	Published	50%. Study design, intervention development, project management, analysis, interpretation,	Kelly L'Engle: study design, intervention development, analysis, interpretation, manuscript preparation and revision 30% Megan SC Lim: interpretation of results and manuscript review 2%	N



	in Kenya: Development and Qualitative Study		manuscript preparation and revision	Kate F. Plourde: intervention development and manuscript review 2% Emily Mangone: intervention development, analysis and manuscript review 3% Collins Mudogo Mukanya: project management, manuscript review 1% Peter Gichangi, Griffins Manguro, Margaret Hellard, Mark Stoové, Matthew F Chersich, Walter Jaoko, Paul A Agius and Marleen Temmerman (collectively): study design and manuscript review 8% Winnie Wangari: data collection and manuscript review 1% Stanley Luchters: manuscript development and review 3%	
Four	WHISPER or SHOUT study: protocol of a cluster- randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya	Published	50%. Study design, literature review, manuscript preparation and revision	Collins Mudogo: literature review, manuscript preparation 30% Peter Gichangi, Megan S.C. Lim, Griffins Manguro, Walter Jaoko, Marleen Temmerman, Marilyn Laini, Liz Comrie-Thomson, Mark Stoové, Margaret Hellard, Kelly L'Engle (collectively): study design and manuscript review 9% Paul A. Agius: study design, statistical analysis and manuscript review 2% Matthew Chersich study design and manuscript preparation 2% Stanley Luchters: study design and manuscript preparation 7%	N
Five	Use of long- acting reversible contraception in a cluster- random sample of female sex	Published	70%. Study design, project management, data analysis and interpretation, manuscript preparation	Megan S.C. Lim and Stanley Luchters (collectively): study design and manuscript review 10% Paul A. Agius: statistical advice and manuscript review 3% Matthew F. Chersich: study	N

	workers in Kenya		and revision	design and manuscript review 3%, Griffins Manguro and Peter Gichangi (collectively): project management and manuscript review 6% Caroline M. Gichuki: project management, data collection and manuscript review 3% Mark Stoové, Marleen Temmerman, Walter Jaoko and Margaret Hellard (collectively): study design and manuscript review 5%	
Six	Impact of the WHISPER mobile phone intervention for female sex workers on unintended pregnancy: a cluster-randomised controlled trial in Kenya	Accepted	70%. Study design, project management, data analysis and interpretation, manuscript preparation and revision	Megan S.C. Lim: study design, interpretation and manuscript review 4% Paul A. Agius: data analysis and manuscript review 4% Griffins Manguro and Peter Gichangi (collectively): project management and manuscript review 6% Caroline Gichuki: project management, data collection and manuscript review 3% Kelly L'Engle, Matthew Chersich, Walter Jaoko, Marleen Temmerman, Mark Stoové, Margaret Hellard (collectively): study design, interpretation and manuscript review 8% Stanley Luchters: study design, interpretation and manuscript review 5%	N

I have renumbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

**Student name:** Frances Ampt

**Date:** 12 Feb 2020

I hereby certify that the above declaration correctly reflects the nature and extent of the student's and co-authors' contributions to this work. In instances where I am not the responsible author I have consulted with the responsible author to agree on the respective contributions of the authors.

**Main Supervisor name:** Stanley Luchters

**Date:** 12 Feb 2020

## Abbreviations

FSW	Female sex worker
HIC	High-income country
HIV	Human immunodeficiency virus
IUD	Intra-uterine device
IVR	Interactive voice response
LARC	Long-acting reversible contraceptive
LMIC	Low- and middle-income country
mCPR	Modern contraceptive prevalence rate
OR	Odds ratio
RCT	Randomised controlled trial
SMS	Short message service
SRH	Sexual and reproductive health
STI	Sexually transmitted infection

## Acknowledgements

In the first instance I would like to acknowledge the financial support I received to undertake this research: from an Australian Postgraduate Award and the Burnet Institute in the initial year, and a National Health and Medical Research Post Graduate Scholarship thereafter.

I would like to sincerely thank my supervisors, Stanley and Megan, for providing guidance, support and insight through this journey, and remaining so responsive and connected throughout several periods of personal, bureaucratic and geographic upheaval. Stanley, I am so grateful for your calmness and optimism, both as an academic supervisor and project manager. You always found a way to make things work and somehow reassured me when everything seemed irresolvable! Thanks for giving me so much autonomy to lead this work, while also providing decisiveness and leadership when it was needed.

Megan, thank you for being both an excellent supervisor and supportive partner-in-maternity. It was very special (and convenient!) to go through the pregnancy journey together and to have a supervisor who was so understanding of the challenges of early parenthood. Your sharp eye, insights into reading phone network data, and calm approach helped keep me on track.

I am indebted to the hard work, perseverance and enthusiasm of the team in Mombasa, who never lost their humour through some very stressful times. Griffins provided calm oversight and direction and was a much-needed sounding board. Millicent and Betty were inspirational leaders who managed to balance dedication to the study with passionate advocacy for the women who took part. I am particularly grateful to our study coordinator extraordinaire, Caroline. Your intelligence, good judgment and compassion made the whole project possible, and your friendship, advice on Kenyan cooking and bowls of pojo kept me going! I'd also like to thank the staff at ICRH for welcoming me so warmly, and being patient and tolerant with my overly direct Australian manner (including the 'cursing')! Irene, Sophie, and Aggrey, thank you for your friendship and humour and giving me greater cultural understanding.

I am so lucky to have been surrounded by many friendly and supportive colleagues on level 3 at Burnet. Thank you to my pod mates for making days in the office interesting and fun, and all the PhD students past and present who have made Burnet such a warm and inclusive place to undertake this journey. You have been particularly thoughtful and generous during these final thesis-writing weeks. Thanks to Anna, Vanessa and Kat for the much-needed and well-timed adventures in South Africa, and Minh for tidying up the loose ends of WHISPER while I was on leave.

I am very grateful to my parents for fostering in me a strong sense of both intellectual curiosity and social justice, which have driven me to take on this work and have stayed with me throughout my candidacy (and life). You have both been amazing role models by being brave and creative enough to reinvent your own careers and encouraging me to pursue what feels right in mine. And somehow your recent PhD endeavours weren't enough to warn me off my own! Thank you for your emotional support, knowing me so well, and really 'getting' what this work is like.

My deepest thanks go to my husband Priyantha and daughter Molly. Pri, your warmth and encouragement have been a fixture during this period, and your confidence in me kept me going many times when mine failed. I've lent on your wisdom and intuition many times, and learnt so much from you about people, management and myself. Thanks in particular for the many hours of debriefing during the earlier years, and the many patient Molly dinners and bedtimes you have undergone in my absence more recently! Molly, you are a total delight and your arrival gave me more perspective than I could have hoped for. Thank you for being a constant reminder of the important things in life, making me laugh and forcing me to stay in the moment and forget about work.

Finally, I would like to thank all the women that took part in this research and acknowledge the patience, time and trust that it required of you. Throughout this process, I was constantly struck by your tenacity and optimism, often in the face of great hardship. I hope that you can find peace, happiness, and the freedom and security to manage your own lives the way you want to.

# Chapter 1: Introduction

## 1.1 Sex work and female sex workers

Sex work is the provision of sex for money or other form of payment. It involves an explicit agreement between the parties that the service is commercial and limited to the sexual act.[1] In contrast, transactional sex involves an implied rather than necessarily explicit exchange, and is widespread and socially acceptable in many cultures, particularly in sub-Saharan Africa.[2, 3] The use of the terms 'sex work' and 'sex worker', reflect the view of many sex workers and their organisations that what they do is a legitimate paid activity that can be viewed through a labour rights framework.[4] These terms are used in this thesis in preference to more judgmental terminology such as prostitution, which carries historical connotations of immoral activity and character, and reduces sex workers' agency.

Because this research addresses the biological risk of pregnancy, it concerns cisgender rather than transgender women<sup>1</sup>. Transgender men, who can be biologically able to conceive, were not excluded from the research presented in this thesis, but nor were they specifically targeted, as they face different types of risks and may not be receptive to health promotion activities that address people who identify as women. The term female sex worker (FSW) is used throughout this thesis for ease of description.

Sex work takes a range of different forms depending on the location and context, including formal brothel-based work, selling sex from public places or one's home, or practicing from informal locations such as bars, hotels, beauty parlours or entertainment venues. Paid sex may take place in the same location as solicitation of clients, or at a different agreed location,[5] and solicitation is increasingly taking place via mobile phone or internet rather than in-person.[6-8] Sex work may be full or part time, and is often used by economically marginalised women to supplement other forms of informal paid employment. This may be described as 'indirect' when women use other employment, such as working in a massage parlour, to find sex clients. Non-venue based sex workers, and those working part-time or 'indirectly', face higher risks and are often harder to reach with traditional health programs than those working full time and from specific venues.[5, 9, 10]

---

<sup>1</sup> 'Cisgender women' refers to people of female biological sex who identify as women. Transgender women are people who were born with male sex and identify as women. Transgender men, conversely have female sex and male gender identity.

My research focuses on FSWs in low- and middle income countries (LMICs), with Kenya taken as a case study. In these contexts, health systems are often weak, with additional barriers to health care access for marginalised groups like FSWs. While sex work is criminalised at least partially in almost all jurisdictions, the negative impact on sex workers may be greater in countries with weaker rule of law, because of arbitrary and corrupt enforcement.[11, 12] For these reasons, health and social risks associated with sex work are greater in LMICs. In high-income countries, FSWs still face significant risk and social stigma, but there are more structural elements in place to counter these, for example comprehensive primary health services, employment law, and human rights protections. The specific context of sex work in Kenya is discussed in 1.8.

### **1.1.1 Pregnancy intention and childrearing among female sex workers**

This thesis specifically focuses on unintended pregnancy among FSWs, rather than pregnancy per se. It is important to note that in many contexts a large majority of FSWs have children[13] and their pregnancy intentions are similar to other women, contrary to widely held myths.[14-16] Just like other women, they are also subject to sociocultural pressure to bear children.[17] Strong gendered beliefs exist in Kenya and other societies that FSWs are immoral and make bad mothers.[18, 19] This influences FSWs' sense of legitimacy in child-rearing and may impact internalised stigma and health-seeking behaviour if they become pregnant. It also affects the behaviour of health providers who may discriminate against pregnant sex workers or their children.[17] Antenatal care and other maternal and children's health services that specifically cater to sex workers or their children, are rare.[13, 20]

Many women have ambivalent or conflicting intentions and emotional responses to pregnancy.[21] For FSWs, conflicted feelings about pregnancy may be heightened by conflicting stigmas (against sex workers as mothers and against childless women) and different intentions for different sex partners. Measures of intention that take account of this nuance may be more useful than simple dichotomous measures of whether a pregnancy is wanted or not.[22]

Scholarship on contraception and pregnancy risks among FSWs must not assume that motherhood is not desired or inherently inappropriate, and programs must be wary of pressuring FSWs to use specific contraceptive methods, especially in light of historical reproductive coercion of socially or economically marginalised women.[23-25] Rather, the emphasis should be on providing the opportunity and resources for FSWs to prevent pregnancy in the way that they desire, or to plan it at their preferred time and circumstances.



## 1.2 Female sex workers in low- and middle income countries are at high risk of unintended pregnancy

FSWs in LMICs face multiple sexual and reproductive health (SRH) risks, resulting from frequent exposures to multiple partners within an adverse social, economic and legal environment. The risk of sexually transmitted infections (STIs), particularly HIV, is well documented. A meta-analysis of HIV prevalence studies found that 10.4% of FSWs are living with HIV across LMICs, and prevalence is much higher in sub-Saharan Africa,[26] for example 26% in Kenya according to the most recent national survey.[27]

HIV prevention programs for sex workers have been implemented and evaluated in many countries. These include both demand generation through community- and facility-based peer education, and supply-side approaches, including testing and treatment services, improving access to condoms through outreach and at sex work venues, community drop-in centres specifically targeted to sex workers, and more recently, access to pre-exposure prophylaxis.[28, 29] While major barriers remain in terms of modifying HIV risk for this population, significant gains have been made and resources allocated to this issue.[26]

In contrast, the risk of unintended pregnancy in this population has been largely neglected in both research and programming, despite sharing many risk factors with HIV and being amenable to similar programmatic approaches, including peer education and outreach. HIV and STI prevention programs target unsafe or unprotected sex, which may positively impact on unintended pregnancy through increased condom use. However, they rarely specifically target unintended pregnancy or consider contraceptive methods other than condoms.[30] These programs have had considerable success at increasing condom use with clients[28] but not emotional partners,[31] leaving FSWs at risk of both STIs and pregnancy from their boyfriends, husbands, or other non-paying partners. Qualitative research in Kenya and Uganda indicates that avoiding unintended pregnancy is a high priority for FSWs[32] and may be perceived as a greater threat than HIV.[33] Similarly, three-quarters of FSWs in a study in Madagascar felt that pregnancy prevention was very important to them and 81% worried about getting pregnant.[34]

FSWs report very high rates of unintended pregnancy in their lifetime, for example 30% in Afghanistan,[35] 38% in West Africa[36] and 45% in Uganda.[37] Lifetime estimates of induced abortion vary widely, depending on availability of services and the legal context, but have been reported as 21% in Kenya,[38] 44% in China[39] and 90% in Pakistan,[40] and are frequently higher than national averages.[41] Very few studies have measured unintended pregnancy

incidence, but available estimates from sub-Saharan Africa range from 7[42] to 52[43] per 100 person-years.

### 1.3 Global burden of unintended pregnancy

Unintended pregnancy (including any pregnancy which is unwanted, mistimed or unplanned) is highly prevalent and has substantial global impact, with unintended pregnancies accounting for 44% of pregnancies worldwide. Incidence rates are higher in developing than developed countries (65 compared to 45 unintended pregnancies per 1000 women per year, respectively). Rates are higher still in Sub-Saharan Africa, particularly East Africa, where the incidence is 112 per 1000 women.[44] Available data suggests that unintended pregnancy incidence among FSWs in East Africa is higher than among the general population.[38]

#### 1.3.1 Consequences of unintended pregnancy

Unintended pregnancy has significant negative consequences for maternal and newborn health, as well as for psychological and emotional wellbeing, relationship stability, and socioeconomic status[45]. For women who choose to continue an unintended pregnancy, it is associated with increased odds of having a premature or low birth weight baby.[46] Less robust evidence indicates that unintended pregnancy is also associated with higher rates of stillbirth and neonatal death, reducing uptake and duration of breastfeeding, and delays in seeking perinatal care.[47, 48]

Over half of all unintended pregnancies worldwide are estimated to end in abortion. Women who choose to terminate an unintended pregnancy face substantial barriers in accessing safe and legal abortion in most parts of the world, including Kenya, where abortion is only permitted when the woman's health is in danger.[49] In developing regions, almost a third of women live in countries where abortion is either completely prohibited or is only legal when the woman's life is at risk, and 20 million abortions (more than half of all those performed) are unsafe.[50] Complications of unintended pregnancy and abortion are estimated to account for 70,000 maternal deaths and 500,000 newborn deaths annually.[51]

The social, economic and health impacts of unintended pregnancy differ depending on social norms around family size, single parenting, and pre-marital sex, as well as a country's economic development and stage of demographic transition.[48] Given their social context, unintended pregnancy may be a greater burden for FSWs than for other women. Being visibly pregnant may generate additional community disapproval, exacerbating existing sex work-related stigma.

FSWs often describe entering and continuing in sex work for survival reasons, in particular to provide for their children.[52] Having additional children is likely to exacerbate poverty and may further entrench their dependence on sex work.[53] Furthermore, being pregnant affects FSWs capacity to earn money and provide for their dependents, both because of the physical demands of the work, and being potentially less attractive to clients.[33, 38]

## 1.4 Contraception and unmet need

Insufficient use of contraception among FSWs is a major contributor to their high risk of unintended pregnancy. Estimates of use vary widely depending on which methods are included and whether consistency of use is accounted for, and will be discussed in subsequent sections.

In this thesis, the term *contraception* is used to refer to methods or devices specifically used to prevent pregnancy. *Family planning* is used to refer to the broader notion of pregnancy intention, pregnancy planning, birth spacing, and contraceptive methods.

Modern methods of contraception described in this thesis are classified according to a 2015 World Health Organization and USAID technical consultation. Rather than simply being a temporal definition, modern methods are those that have: “a sound basis in reproductive biology, a precise protocol for correct use and existing data showing that the method has been tested in an appropriately designed study to assess efficacy”.[54] Table 1 presents the key characteristics of specific modern and traditional contraceptive methods.

**Table 1: Selected characteristics of contraceptive methods, ordered by effectiveness**

	Typical-use pregnancy rate *	Modern or traditional	Duration of action	Hormonal	Level of program support required
<b>Very effective</b>					
Implant	0.1	Modern	Long	Yes	High
Vasectomy	0.15	Modern	Permanent	No	High
Female sterilisation	0.5	Modern	Permanent	No	High
Hormonal IUD	0.7	Modern	Long	Yes	High
Copper IUD	0.8	Modern	Long	No	High
<b>Effective</b>					
Emergency contraceptive pill	1 <sup>#</sup>	Modern	Short	Yes	Low
LAM <sup>§</sup>	2	Modern	Medium	No	Medium
Injectables	3-4	Modern	Medium	Yes	Medium
Oral contraceptive pill	7	Modern	Short	Yes	Low
Patch	7	Modern	Short	Yes	Low
Vaginal ring	7	Modern	Short	Yes	Low
<b>Moderately effective</b>					
Standard Days Method <sup>§</sup>	12	Modern	Short	No	Medium
Male condom	13	Modern	Short	No	Low
TwoDay Method <sup>§</sup>	14	Modern	Short	No	Medium
Diaphragm with spermicide	17	Modern	Short	No	Low
<b>Less effective</b>					
Withdrawal	20	Traditional	Short	No	None
Female condom	21	Modern	Short	No	Low
Rhythm/calendar method <sup>§</sup>	Unknown	Traditional	Short	No	None

IUD: intrauterine device; LAM: Lactational Amenorrhoea Method

Adapted from [55] and [54]

\* Number of pregnancies among 100 women using method for one year (as method is commonly used, rather than consistent and correct use).

<sup>#</sup> Estimated rate after one act of unprotected intercourse; different methodology than studies of other methods

<sup>§</sup> Fertility awareness-based methods with clear, replicable protocols and evidence base are considered modern, whereas user-defined rhythm and calendar methods are traditional and vary in their implementation

### 1.4.1 Long-acting reversible contraceptives

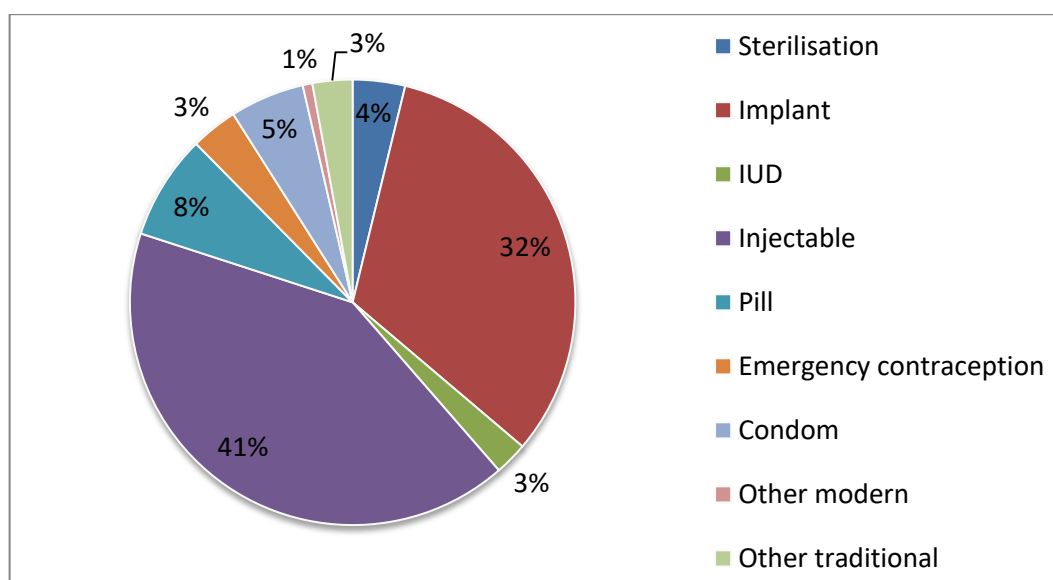
Long-acting reversible contraceptives (LARCs), including intra-uterine devices (IUDs) and contraceptive implants, offer a number of benefits over other forms of contraception. They are not user- or coitus- dependent, last for up to 12 years, are as effective as permanent methods, and fertility returns immediately after discontinuation.[54] As presented in table 1, they do have greater system requirements than less effective methods; trained skilled providers and clinic infrastructure are required for both insertion and removal, so unlike injectables, they cannot be distributed by community outreach workers. However, LARCs are among the most cost-effective methods because of the long duration of coverage between health provider contacts.[56]

There is evidence that LARCs are also more acceptable to users than other methods. Rates of discontinuation and switching to a different method are considerably lower for LARCs than for other methods. For example, among countries in the global FP2020 partnership, discontinuation within one year is around 40% for injectables, pills and condoms, compared to 12% for IUDs and 8% for implants.[57] The main reason for stopping LARCs is bleeding disturbances, with copper IUDs frequently causing heavy menstrual bleeding and IUDs causing irregular or prolonged bleeding.[58, 59] Short-acting methods are frequently discontinued not only because of side effects, but also for logistical or convenience reasons.[58, 60]

### 1.4.2 Contraceptive use and unmet need in Kenya

Of the 1.6 billion women of reproductive age living in developing regions, 885 million want to avoid pregnancy, and of these, 214 million are either not using any method of contraception, or using a traditional method. Overall, 13% have an unmet need for modern contraception. In sub-Saharan Africa, unmet need is estimated at 21%, higher than any other region.[61] In Kenya, where this research is conducted, 20% of women who are married or in a union have an unmet need for modern contraception.[57]

An estimated 43% of all women in Kenya were using a modern method of contraception in 2018 (modern contraceptive prevalence rate (mCPR)), [57] with injectable contraceptives accounting for over 40% of users (Figure 1). [62] Use of implants has increased dramatically in Kenya over the last decade. Their share of the contraceptive method mix increased from 5% in 2008 to 32% in 2017, representing a prevalence of approximately 14% of all women of reproductive age. In contrast, IUD use has remained persistently low, fluctuating between 2 and 6% of contraceptive users over the same period. [62-66]



**Figure 1: Contraceptive method mix in Kenya[62]**

'Other modern' includes lactational amenorrhoea and standard days methods.

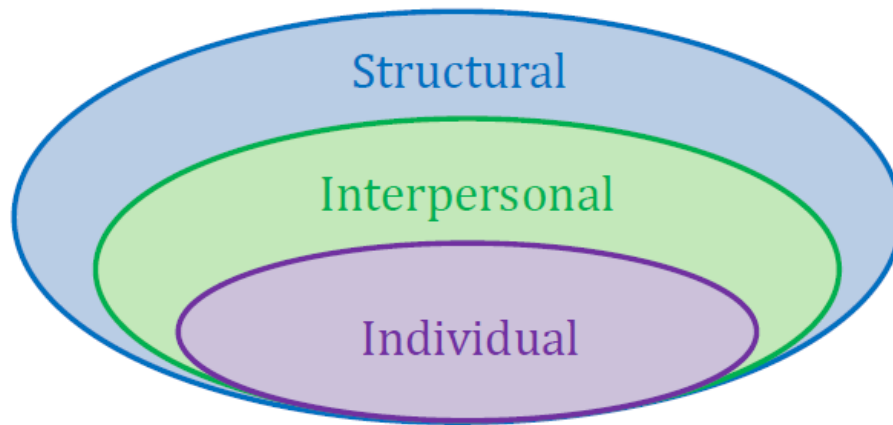
Estimates of modern contraceptive use among FSWs in Kenya vary and are not directly comparable to the prevalence data presented above, so it is difficult to know how use compares to the general population. A convenience sample of FSWs in Mombasa found modern contraceptive use to be 57% in 2007,[38] higher than the national estimate of 45% among sexually active women at around the same time,[63] however these estimates include different measures of condom use. Regardless of actual use, FSWs' need for contraception is greater because they typically have sex more frequently and with multiple partners. When FSWs desire children, it is usually with one partner in mind as father, so contraception is still required for other partners.[ref]

The family planning service system in Kenya, and services for FSWs, are described in sections 1.8.3 and 1.8.4.

## 1.5 Determinants of contraceptive use and unintended pregnancy among female sex workers

Many interrelated factors operating at multiple levels contribute to FSWs' use of contraception and risk of unintended pregnancy. These can be examined using a social ecological model as adopted by White et al,[67] from Brofenbronner's theory of health promotion[68] (Figure 2; Table 2). Social ecological models/theories posit that an individual's health is influenced directly and indirectly by a spectrum of factors from proximal to distal. Proximal factors are

those close to the individual – for example, individual genetic and behavioural characteristics. Distal factors refer to broader structural conditions of the society, culture and body politic. Similar models have been used to assess determinants of contraceptive use in other populations,[69-71] and HIV prevention interventions for FSWs.[28]



**Figure 2: Social ecological model of health to describe determinants of contraceptive use and unintended pregnancy among FSWs**

**Table 2: Potential determinants of unintended pregnancy among FSWs operating at different ecological levels**

Ecological level	Category	Determinant
Individual	Demographic	Age
		Level of education
		Religion
		Income
		Gravidity and number of children
	Behavioural	Correct, consistent use of condoms, non-barrier methods and dual methods
		Use of alcohol and other drugs
	Knowledge, attitudes and experience	Ambivalent or fluctuating pregnancy intention
		Knowledge of contraceptives and effective use
		Knowledge of reproductive cycle and conception
		Misconceptions and myths about contraceptive methods
		Personal experience of contraceptive use and side effects
		Low self-efficacy for contraceptive use
Interpersonal/ social	Behavioural	Frequency of sex
		Number of sex partners (paying and non-paying)
		Sex with non-paying emotional partner (e.g. husband or boyfriend)
		Partners' correct use of contraception
		Negotiation and communication with sex partners
		Relationship control
		Partner & community violence
	Knowledge, attitudes and experience	Partners' pregnancy intention
		Partners' knowledge and experience of contraceptive use
		Partner attitudes and refusal to use contraception
		Community knowledge and experience of contraceptive use
		Social norms around contraceptive use
Structural	Programmatic	Formal programs for FSWs
		Physical and financial access to contraception and abortion
		Available method mix
	Occupational	Safety and privacy of sex work environment
		Sex work venue location – proximity to services
	Economic	Local sex market conditions, e.g. incentives to not use condoms and accept low pay
		Economic status discrepancy between sex worker and client
	Sociocultural	Societal expectations of women as mothers
		Social and institutional stigma towards FSWs
		Social status of women
		National/sub-national modern contraceptive prevalence rate
		National/sub-national total fertility rate
		Empowerment and solidarity of sex work community
		Gender-based violence: prevalence and norms
	Regulatory	Legal status of sex work, abortion and gender-based violence and implementation of laws
		Local by-laws impacting sex work, e.g. loitering



### 1.5.1 Individual determinants

At the individual level, FSWs tend to be younger and have lower education and income than other women, and these demographic factors are also associated with lower contraceptive use[72] and higher risk of unintended pregnancy.[38, 73, 74] FSWs aged under 24 years have lower rates of condom use and other risk behaviours than their older counterparts, with greatest risks facing girls under 18 years.[75]

Frequent intercourse with a large number of both paying and non-paying sex partners, combined with inconsistent use of condoms and other forms of contraception, put FSWs in many settings at high risk of unintended pregnancy.[2, 76] In Africa, this is often on a background of common partner concurrency among the general population.[2]

Estimates of modern contraceptive use vary depending on the methodology used. For example, use of any non-barrier method has been estimated at 28% in China,[39] 67% in Zambia,[53] 65% in Kenya[77] and 72% in India.[78] Studies differ in terms of whether they include women who want to get pregnant, and what contraceptive methods they capture. Estimates of mCPR are much higher when condoms are included and the consistency of condom use is not accounted for; for example, 93% in both China[39] and Kenya.[79] In another Kenyan study that only included *consistent* condom use in the modern method calculation, mCPR was 57%. Only 10% of FSWs in that study used condoms consistently as well as another method (dual method use), which is recommended to prevent both pregnancy and STIs.[38] Dual method use was found to be similarly low among FSWs in Swaziland (8%)[80] and China (7%).[39] A study in Uganda found a comparatively high rate of dual method use (58%) but included any condom use (not specifically consistent use) in the definition.[81]

As well as inconsistent condom use, condom breakage or slippage is common. This has been attributed to lack of availability of lubricant, forceful or violent sexual interactions, incorrect use by both FSWs and their clients, and deliberate tampering by clients.[76, 82, 83] The critical influence of male partners on whether and how condoms are used highlights the interplay between individual- and interpersonal-level factors, and the need for FSWs to have access to female-controlled methods so that negative partner influence has less impact.

In addition to problems with condom use, FSWs report incorrect use of non-barrier contraception, for example missing or delaying 3-monthly progestin injections and daily pills.[79] This is likely to be due to a combination of misinformation (for example, mistakenly believing that pills need only be taken after intercourse), forgetfulness and chaotic lifestyles due to the nature of sex work, and financial or logistical barriers to repeated dosing, such as long wait

times for services.[38, 84] Because of the tendency to forget or use them incorrectly, short-term, user-controlled methods have been linked to pregnancy incidence among women in microbicide trials that enrolled FSWs and other women with multiple sex partners.[85] Issues with incorrect and inconsistent use of short-acting and user controlled methods highlight the potential benefits of LARCs for FSWs.

Contraceptive behaviour and risk taking during sex is also influenced by substance use, which is common among FSWs worldwide. In parts of Asia, Latin America and Europe, many women who sell sex also inject drugs, which exacerbates their risk of blood-borne viruses and their financial dependence on sex work.[26, 86, 87] Alcohol use is common in many FSW populations, particularly in sub-Saharan Africa.[2, 88] Drinking is important for finding and interacting with clients and boosting confidence, and also assists with coping with aggressive or unfriendly clients, and past trauma[2, 89, 90]. Several studies have described the impact of heavy drinking on remembering to take contraceptive pills,[79] negotiation and correct use of condoms,[91] STIs,[92] and pregnancy.[93]

FSWs' knowledge of both contraceptive methods and reproductive biology is low, and myths about contraceptives, particularly LARCs, are widespread. In formative research in Mombasa in 2015, FSWs described how IUDs could harm a developing foetus, be felt by partners or displaced during rough sex, or cause infertility, and how IUDs and implants could migrate around the body. Similar concerns have been voiced in qualitative studies with sex workers[79, 84] and other women in Kenya,[94, 95] and are reported in other sub-Saharan African countries.[96]

While adverse effects like infertility have been mistakenly attributed to contraception, FSWs are also legitimately concerned about known adverse effects which they or their peers have experienced, and which impact them in different ways to other women. Diminished libido from hormonal contraception, and disrupted or heavy bleeding from implants, injections or copper IUDs, have a detrimental impact on their ability to work and their perceived attractiveness to clients.[38, 84] However, lack of knowledge and corresponding structural support from health providers means that FSWs may inflate the risk of side effects or don't realise that better options are available to them.[30, 32, 56, 97, 98]

### **1.5.2 Interpersonal and social determinants**

The individual attitudes and knowledge gaps described above are reinforced by strongly-held beliefs and norms in FSWs' wider communities. Strong normative expectations of women as child-bearers and mothers exist in most cultures,[99] often alongside cultural and spiritual

beliefs around methods of preventing and terminating pregnancy. These expectations and beliefs are in turn common within sex workers' families and communities. Although women shoulder the responsibility for family planning and pregnancy,[84] they are still subject to assumptions around male control of both decision-making and women's behaviour.[99-101] In many sub-Saharan African cultures, women have an obligation to bear children, sometimes associated with a dowry or bride price.[102] Men are often resistant to contraceptive use because of social pressures to have large families, particularly in sub-Saharan Africa,[103, 104] and fears that their wives' use of contraception will encourage them to seek extra-marital sex, tying in with enduring stigmas that attach contraceptive use to promiscuity.[99, 101]

These norms may be more forceful for women who exist at the margins of society, like FSWs, both because they have a greater need to be accepted in the mainstream, and because they may be more vulnerable to male partner pressure to comply. They are answerable not only to their non-paying sexual partners but also to clients and pimps, and need to remain competitive in an often crowded market. Numerous studies have reported sex workers feel real or implied pressure to forgo condom use to retain a client or earn more money, and price premiums incentivise condomless sex and other risky activities, such as anal sex.[105, 106]

The powerful influence of male partners on condom use was highlighted in the previous section, and this influence is not restricted to clients. FSWs' use of both condoms and other contraceptive methods is repeatedly found to be lower within emotional relationships than with clients.[41, 107-109] A study of Kenyan FSWs who did not want to get pregnant found that having an emotional partner was associated with non-use of modern contraception, and was an independent predictor of unintended pregnancy.[38] Having a non-paying partner was also associated with unintended pregnancy for Caribbean FSWs[73] and women in microbicide trials, who were predominantly sex workers or had multiple partners.[85] Infrequent condom use with emotional partners, even when pregnancy is not desired, may be a consequence of men's greater control in the relationship, but may also reflect both women's and men's need for sexual intimacy.[110] Unprotected sex has symbolic meaning and may be used by FSWs to psychologically demarcate clients from non-paying emotional partners, even when an emotional partner is known to have sex with others.[76, 108, 111]

Male partners' influence on contraceptive use has been noted in research with both sex workers and other couples, and communication between partners seems to be a moderator of use. A study in Egypt found that women were more likely to continue to use IUDs if their husband knew that they had started contraception than if they didn't know.[58] Similarly, male partners

of FSWs who are aware of their sex work status are more likely to use condoms consistently than men who do not know their partners are sex workers.[112]

Violence is a pressing and widespread issue for FSWs. Violence hampers FSWs' ability to negotiate condom use, and is often viewed as a more urgent priority than other health concerns.[33, 90] Physical, verbal and sexual abuse are common, as well as economic violence and coercion, such as being robbed by clients.[89, 113] The perpetrators include not only clients, but also non-commercial sex partners and police. Violence perpetrated by emotional partners may be just as prevalent as for other partner types[114] and has been identified as an independent predictor of unsafe sex for FSWs in Kenya.[115]

### 1.5.3 Structural determinants

Structural determinants are the physical, political, legal, cultural and economic structures that govern how people live and work and that can constrain or facilitate individuals' and communities' ability to protect their own health.[116] Structural factors can operate at different proximities to the individuals affected. For example, national laws governing the sale of sex operate at a distal or 'macrostructural' level to impede sex workers' ability to work safely, whereas management practices within the 'microenvironment' of the sex work hotspot have a more proximal impact on FSWs' safety and security.[29, 117, 118]

Gender-based violence can be viewed as a structural determinant operating at an interpersonal or community level (its interpersonal dimension is described in 1.5.2) because it is a manifestation of broader currents of gender inequality, and constrains women's ability to freely make reproductive health choices.[117] FSWs experience the effects of legal frameworks and social stigmas guiding the use of their own bodies in a more invasive way than other women, and this can be seen as a form of structural violence. The criminalisation of sex work, with its associated violence and mistreatment by police,[113] is a critical barrier to sex workers' empowerment and adoption of safer behaviours, and has been described as the most important structural determinant of HIV among FSWs.[29, 119]

FSWs are highly stigmatised both by the general public and within institutions such as health services and the justice system. This is not only because their behaviour is illegal, but also because it is antithetical to conceptions of morality and socially-sanctioned femininity. In addition, poverty and low social class frequently reinforce the stigmatisation and marginalisation attached to sex work.[52, 120] The low status of women more broadly is particularly felt by young women and intersects with sex work stigma to curtail FSWs' power to improve their own health.[121] The experience of multiple intersecting stigmas (in this case

relating to sexual behaviour, gender, HIV status and poverty) is known to significantly impact health-promoting behaviours and worsen health outcomes, and has been identified as a key driver of the HIV epidemic.[122] Multiple intersecting stigmas can have a multiplicative rather than simply additive effect.[123]

Stigmatisation by health providers against FSWs may take the form of refusal of services, inappropriate care, low quality care or abuse. Perceived and internalised stigma also affects FSWs' decision to seek care or disclose health needs and risk behaviours.[41, 124, 125] FSWs who agree with or internalise negative attitudes towards sex work may suffer greater distress from discriminatory treatment than those who reject the premise that sex work is inherently 'bad'; the latter being associated with greater self-esteem and control.[126]

In addition to stigma-related barriers, FSWs often face logistical barriers to accessing reproductive health care. Health facilities, particularly in the public sector, are often open inconvenient hours and have long waiting times.[32, 120, 127] Waiting many hours for an appointment is not financially feasible for many women as it represents time away from seeking clients.[84, 125] Other health care-associated costs, whether for contraceptive commodities, services (such as implant or IUD insertion) or transport, are also a significant deterrent.[125]

Even when health facilities are accessible and non-stigmatising for FSWs, they may not offer sufficient contraceptive options to meet their needs. Contraceptive method mix has been identified as a key driver of uptake, and on a country level, contraceptive prevalence rates increase significantly as more methods become available.[128] LARCs, particularly IUDs, are less widely available than shorter acting methods in sub-Saharan Africa, and are subject to frequent stock-outs.[129] Even where LARCs are available, poor knowledge and insufficient training among providers may lead to them not being offered to FSWs, due to lack of confidence with their insertion, or misconceptions about side effects or medical eligibility criteria.[130, 131] Lack of utilisation by providers reduces commodity supply, which in turn diminishes the likelihood of uptake.

The degree to which FSWs and their communities are empowered also has a structural influence on their sexual health. Empowerment can be defined as a process in which individuals and communities gain control over their lives and the issues that most affect them. Multiple indicators of different types of empowerment, at individual, interpersonal and community levels, have been associated with increases in contraceptive use.[132] Among FSWs, community empowerment and sex-worker solidarity has been associated with multiple improvements in behavioural and clinical outcomes,[133] including HIV prevalence.[134] Community mobilisation to empower sex workers is one of the key determinants of success attributed to

large sex worker programs in India.[133, 135] For example, the Sonagachi project in South India initially focused on articulating and advocating sex worker rights. Internalisation of these rights by the sex work community drove empowerment, collectivisation, and community-led structural initiatives including literacy and microfinancing programs.[136] Other programs in Africa have supported sex workers to exercise their legal rights and seek justice despite sex work being criminalised.[137, 138]

## **1.6 Behavioural interventions to increase contraceptive use and prevent unintended pregnancy**

To date, there have been no trials evaluating behavioural interventions among FSWs to prevent unintended pregnancy or increase use of contraceptives apart from condoms. While determinants of contraceptive use operate at multiple ecological levels, many of the individual barriers identified above could be conducive to behaviour change interventions that aim to increase demand for contraception, and in turn influence contraceptive behaviours. Such interventions could also potentially influence some interpersonal and structural barriers. For example, they could include skill-building to improve intra-couple communication, encourage FSWs to discuss SRH with their peers, which could influence social norms and build solidarity, inform them about their rights, or link to FSW-friendly services in their area.

Because FSWs need to account for different partner types and varied contexts in which they have sex, their need for comprehensive information and education on method types may be greater than for other women. They may also place a higher priority on obtaining contraceptive information than other women, because the risk of pregnancy from multiple partners is a more pressing reality. Therefore, FSWs may be more receptive to behaviour change interventions, and they may have greater impact, than for other women.

There is a large body of evidence showing the effectiveness of behavioural interventions to improve condom use, including among FSWs. Interventions to modify other contraceptive behaviours have not been evaluated among FSWs, but there is growing evidence of their effectiveness in other populations.

### **1.6.1 Interventions addressing condom use**

A 2014 systematic review of reviews concluded that there is a large and strong body of evidence showing that behavioural interventions are effective in promoting condom use and related

sexual behaviours in varied populations, and reducing STI transmission.[139] However, intervention content tended to emphasise prevention of HIV and STIs rather than pregnancy, and very few studies measured pregnancy as an outcome. The review found that interventions that were tailored to the characteristics of recipients, and aimed to improve recipients' skills in negotiating and using condoms, were more successful. None of these studies specifically targeted sex workers and few were conducted in LMICs.

Another review did specifically focus on FSWs in sub-Saharan Africa,[31] and found sufficient evidence to conclude that behavioural interventions for this population are effective in improving correct and consistent condom use with clients. Results for condom use with emotional partners were less conclusive. Similar improvements with clients, but not emotional partners, have been observed in Mexico,[140] and with female entertainment workers in LMICs.[141]

However, most of the papers describing interventions with FSWs provide insufficient details about intervention content to know if they explicitly addressed condom use with non-paying partners. It is conceivable that they focused exclusively on clients, or at least placed greatest emphasis on clients. It is unreasonable to assume that participants would translate lessons about behaviour with clients to behaviour with non-paying emotional partners, given the very different types of relationships and contexts in which they occur. Interventions for FSWs should therefore directly target different partner types.

Only one study was located that reported an improvement in condom use with non-paying partners: a community-based program of peer-based education combined with supply-side and other structural initiatives covering most of Karnataka state in India. The odds of condom use with regular partners among FSWs exposed to the program increased by 80% over approximately six years, compared to no change in the unexposed group.[142] This change had not been apparent at the earlier survey after three years of program operation,[143] suggesting that influencing condom use with non-paying partners takes longer than the duration of most intervention studies.

Only one RCT has been identified that measured the effect of a condom promotion intervention for FSWs on pregnancy incidence.[74] It found that clinic-based risk reduction counselling alongside peer education for Malagasy FSWs improved condom use with clients and STI prevalence, but had no impact on pregnancy incidence (compared to peer education alone).

### 1.6.2 Interventions addressing use of non-barrier contraceptive methods

Far fewer studies have been conducted on interventions to change non-barrier contraceptive behaviour than condom use. Belaid et al identified 20 studies that tested interventions to generate demand for contraception among men and women in low- and middle-income countries.[144] These interventions consisted mostly of community- or facility-based counselling and education, and increased the odds of current contraceptive use by over 50% (pooled odds ratio (OR) 1.57; 95% CI 1.46-1.69; 12 included studies). There was weaker evidence for the impact on knowledge and attitudes towards contraception. However, the seven interventions conducted in Africa did not have a significant pooled impact on contraceptive use (OR 1.04; 95% CI 0.94-1.15) or knowledge. Many of the studies were of low quality or published more than ten years prior.

Other systematic reviews have examined the impact of contraceptive behaviour change interventions in relation to specific populations or approaches, for example theory-based interventions or those aimed at adolescents, and these will be outlined in the subsequent paragraphs. The vast majority of the interventions described were conducted in high-income countries, and evaluations were of low or moderate quality. Many studies included in these reviews or conducted subsequently have utilised digital media, particularly mobile phones, to deliver behaviour change messaging; these are discussed in the next section.

Very few behavioural interventions have been trialled to specifically improve dual-method contraceptive use, with only four included in a 2014 review.[145] This is surprising given the shared risk factors for unintended pregnancy and STIs, and the concern about condom 'migration' with increased use of other methods.[146] One intervention in this review was effective at improving dual method use, among adolescents in the USA, and remained effective at 6 months after the intervention ended.[147] This was a youth development intervention based on social cognitive theory that utilised both one-on-one case management and group sessions. It addressed structural and interpersonal, as well as individual, contributors to sexual risk. This approach is likely to be logistically complex in more dispersed and hard to reach populations like FSWs, and too resource-intensive to be used at scale.

Other, less resource-intensive contraceptive interventions have been developed based on health promotion theory, and there is reasonable evidence for the effectiveness of social cognitive and motivational interviewing-based approaches, in particular.[148] Health promotion theories can provide a useful and consistent framework for developing interventions that resonate with their target populations, and there is some evidence that they are more effective than those with no theoretical basis.[148]



Face-to-face counselling has been found to improve continuation of short-term contraceptive methods, and decrease rates of discontinuation due to menstrual disturbances.[149] Even one-off counselling sessions may be effective when based on sound theory and carefully adapted to the needs of the target population, as demonstrated by an individual community counselling intervention tailored to specific migrant communities in Spain.[150] Motivational interviewing-based counselling has also been shown to increase LARC uptake among post-abortion clients in the USA.[151]

Non-targeted communication ('broadcasting'), usually implemented via mass media, has historically been successful at influencing contraceptive behaviour at a population level, including in sub-Saharan Africa.[152, 153] However, this approach is neither feasible nor appropriate for a minority or marginalised population like FSWs. Furthermore, the impact of mass communication diminishes with increasing contraceptive prevalence, and is likely to have lesser yield now that contraceptive prevalence is well above 25% in most countries.[57, 152]

### **1.6.3 Interventions for improving contraceptive use in specific populations**

Many interventions have aimed at preventing unintended pregnancy among adolescents and young women, and these may be relevant to young sex worker populations. Oringanje et al reviewed interventions for adolescents, most of which were school or community-based group programs.[154] These interventions show most promise when they combine both educational, skills building and contraceptive supply components. Addressing contraceptive supply alone, for example by providing a longer supply of contraceptive pills in advance, had an impact on contraceptive use but not pregnancy. The finding that multiple reinforcing components are most effective in improving contraceptive use is reflected in a comprehensive program for young married couples in India. The most effective aspect of this program was home visits to women by community health workers, however the impacts on contraceptive use were even greater when both members of the couple were targeted with parallel interventions.[155]

While these studies provide useful insights, they tend to be fairly resource-intensive, particularly those conducted in high-income countries that depend on existing infrastructure. In addition, a non-targeted community approach may not be effective or ethical for FSWs, within the context of stigma, violence and the need to maintain privacy and anonymity.

Studies aiming to improve contraceptive use among HIV positive women may be more relevant to FSWs than adolescents or other women in the general population, because they face similar sexual risks and stigma. A 2016 review found 10 such studies, all in Africa.[156] Most involved family planning promotion integrated into HIV services, and some included both demand-side

(for example counselling for behaviour change) and supply-side (provision of contraceptive methods) components. The evidence was generally positive for their impact on contraceptive use. An intervention in Kenya for HIV serodiscordant couples, which included facility strengthening, provision of free contraceptive methods and counselling for both women and their male partners, not only improved contraceptive use but also resulted in reduced pregnancy incidence.[157]

#### **1.6.4 Characteristics of successful behaviour-change interventions**

While the approaches taken are highly varied and need to be specific to the needs of target populations, overall the evidence suggests that behaviour-change interventions are more effective at improving contraceptive use and preventing pregnancy when they use interpersonal communication and comprise multiple complementary components. Examples include use of individual as well as group counselling, combining information with skill-building activities, and addressing supply as well as demand. In addition, tailoring to both communities and individuals, using participatory approaches to develop interventions, and incorporating health promotion theory to guide development, are common aspects of successful interventions.

Most studies assess contraceptive use (any method) or condom use as the outcome measure. Only three studies in the reviews described above specifically measured the impact of behavioural interventions on LARC uptake or use,[151, 158, 159] and only one was effective, a post-abortion counselling intervention in the USA.[151] While there were many studies that measured pregnancy as an outcome, most of these were assessing school- or community-based interventions for adolescents in HICs.[154, 160, 161] The exception was the multi-component intervention in Kenya which impacted pregnancy incidence among HIV serodiscordant couples, described in 1.6.3.[157]

### **1.7 Promotion of sexual and reproductive health using mobile phones**

Digital media, including SMS, digital applications for computer or mobile phone, and social networking sites, offer potentially low-cost, private and scalable means of reaching women with information and education to change contraceptive behaviour. Mobile telephones in particular are increasingly being used to deliver health interventions (known as mHealth interventions) including to change SRH behaviours.

Mobile coverage has increased dramatically in the last two decades, including in developing countries, with an estimated 107 mobile telephone subscriptions for every 100 people

worldwide in 2018.[162] Mobile phones offer some specific benefits over traditional means of delivering health information. They are private, usually unique to each individual, and allow information to be stored or shared easily among peers. Technologies such as digital apps and short message service (SMS, or text messaging) are low cost to implement and can be used to target geographically diverse or mobile populations. These qualities make mHealth potentially well-suited to hard-to-reach, marginalised populations and those less engaged with formal health services.[163, 164]

### **1.7.1 mHealth for female sex workers in Kenya**

Mobile phones may be a feasible and effective way of reaching FSWs, providing them with information on unintended pregnancy and contraceptive methods, and motivating them to address barriers to contraceptive uptake. FSWs could particularly benefit from the privacy offered by mobile phones, and the avoidance of logistical issues such as transportation costs and waiting times associated with accessing prevention information in person.[165]

In Kenya, where this research takes place, mobile coverage was 96% in 2018, considerably higher than the African region overall (76%).[162] A popular mobile money system known as mPesa means most people in Kenya maintain the same unique phone subscription.[166] This makes issues such as multiple subscriptions, rapid turnover over of SIM cards and sharing phones, that have been problematic for some mHealth programs,[167] less prevalent in Kenya. In fact, Kenya is one of the countries in which mHealth interventions have most proliferated, particularly for HIV prevention and treatment adherence.[153]

Formative research from Mombasa indicates that FSWs depend on mobile phones to conduct their work, using them to take payments, arrange meetings and stay in contact with clients, and keep track of peers' whereabouts to ensure they are safe. This is consistent with the experience of both female and male sex workers globally, who are increasingly using mobile phones for solicitation. In some cases, this has replaced venue-based sex work.[6, 165]

### **1.7.2 mHealth interventions to address contraceptive use and unintended pregnancy**

mHealth interventions to improve contraceptive use and reduce unintended pregnancy have not been evaluated for FSWs, but there is some evidence of their effectiveness in other populations. Many mobile phone applications have also been developed to assist users to prevent pregnancy, but have not been formally evaluated.[168] Here I review only those interventions for which health outcomes have been evaluated in the scientific literature.

A systematic review in 2015 found only five mHealth interventions aimed at improving contraceptive use,[169] three of which were effective in either improving continuation of short-acting methods[170, 171] or increasing effective contraceptive use post-abortion.[172] The latter took place in Cambodia and the other four were in high-income countries. The interventions that were not effective comprised simple reminders to take oral contraceptive pills, without additional education or behavioural strategies.[173, 174] In contrast, the effective interventions were multi-faceted and more intensive; for example, they incorporated an educational component in addition to simply providing information.[149, 170, 171] The post-abortion intervention in Cambodia was the only mHealth intervention identified that significantly improved LARC use compared to controls, and this impact was sustained at 12 months. The intervention was a three-month interactive phone counselling service which recipients were prompted to access via interactive voice response (IVR) messages.[172]

Publications on this topic have subsequently become more common, particularly in LMICs. Six trials of mHealth interventions in LMICs have been published since the 2015 review,[175-180] and another four in the USA.[181-184] Most of these interventions used SMS and were unidirectional (involving messages being sent to the participant only, without the opportunity for interaction). Those that used a bidirectional SMS modality and/or frequent messaging for at least two months tended to have greater impact on contraceptive knowledge[175], contraceptive use[176, 177], and pregnancy.[175] All ten were theory-based and involved the target population in intervention development, suggesting a growing awareness of the need for rigorous and inclusive design processes for mHealth. Several improved contraceptive knowledge but not behaviours; these tended to involve shorter or less frequent exposure,[179, 180, 183] with the exception of a 3-month SMS intervention for young women in Palestine.[178]

Harrington[176] provides an example of an effective bidirectional intervention in Kenya. Text messages were sent to pregnant women from 28 weeks' gestation to 6 months postpartum. They were able to reply and interact with a dedicated nurse by SMS. This is one of the few contraceptive interventions in which male partners could also participate (if referred by the woman). The intervention was tailored to method of contraception used and type of recipient (woman or couple). It resulted in increased use of any highly effective contraception, but not LARCs.

The impact of mHealth interventions on condom use has been assessed in several systematic reviews,[163, 185, 186] locating surprisingly few relevant studies.[187-192] None had a significant impact on condom use in comparison to controls, but three interventions for high-risk young women in the USA had promising results. All three were theory-based, with two

using bidirectional SMS[187, 190] and one using a weekly smart-phone based video that aimed to subvert adolescent sex scripts.[188] Suffoletto et al tested a weekly theory-based SMS conversation that assessed risk behaviours, provided tailored feedback, and prompted goal-setting. After 12 weeks, there was a significant increase in condom use in the intervention group and minimal change in the control group.[187]

### 1.7.3 Characteristics of successful mHealth interventions

Similar to other types of behaviour change interventions, the evidence shows that mHealth interventions are more effective when they involve the target population in development, are tailored to individual characteristics or preferences, and comprise multiple components. The latter may include a combination of informative and skill-building content, incorporating bidirectional ('push' and 'pull') messaging, and using mHealth to facilitate or reinforce in-person counselling or services.

These general principles have been highlighted by reviews of mHealth interventions in other health domains. For example, a review of physical activity interventions found mobile-based interventions more effective when combined with additional delivery modalities.[193]

Table 3 lists the main characteristics of mHealth interventions (based on the typology by Gibson et al,[153] and the options for each that have the greatest potential to impact health outcomes. While there is insufficient evidence to clearly determine which types of intervention are most effective,[169] all characteristics will depend on the preferences and needs of the target population (particularly scheduling, phrasing and modality), as well as the availability of financial, human and technological resources. For example, in their multi-country intervention, McCarthy et al found that Bolivian youth preferred motivational, informal style messages, while Palestinians found informative, scientific texts to be more trustworthy. Formative research for an intervention in rural Malawi found low phone ownership but high rates of sharing. Young people were happy to receive mHealth messages via a friend, so messages were scheduled at times that were most convenient for sharing.[194]

Effective components of other types of behaviour-change interventions could be adapted to mHealth, for example by incorporating techniques from motivational interviewing into text messages, or role-modelling healthy sexual health behaviours through stories relayed over multiple short episodes.[195]

**Table 3: Typology of mHealth intervention characteristics**

Characteristic	Options	Preferred
Modality	SMS	Differs by target community preference and need SMS most common, lowest cost and frequently preferred IVR overcomes literacy barriers Phone calls allow for more interactivity and support
	IVR	
	Phone calls	
	Mobile-based applications	
Direction	Provider-initiated unidirectional ('push' messages)	Bidirectional
	Client-initiated ('pull')	
	Bidirectional (combination of push and pull, or element of interaction)	
Tailoring	Community	Any/all may improve the resonance of messages
	Individual	
	Condition (e.g. changed content when new contraceptive method adopted)	
Scheduling, frequency and duration	Specific times/days	Timing should suit participants' schedules; can differ by individual or group. Minimum frequency and duration may be required (evidence suggests more than weekly for 2+ months). High frequency may lead to saturation and disinterest.
	As-needed (pull messaging)	
	Brief or prolonged	
Phrasing/tone	Informational	Differs by target community preference and content. Combination may be preferred to appeal to different sub-groups.
	Motivating/persuasive	
	Formal/authoritative	
	Informal/friendly	
Content	Information	Mixed
	Skill-building	
	Linkage to services	
	Role-modelling	
	Narrative-based	

#### 1.7.4 Risks and limitations of mHealth interventions

Most studies that examine mobile phone use for health promotion find them to be feasible to implement and highly acceptable. Young people in particular have repeatedly expressed interest and enthusiasm with receiving contraceptive information via mobile phone.[171, 196-198]

However, there are limitations associated with this medium. Technical issues such as incomplete network coverage can interrupt interventions and social practices around number switching and phone sharing can result in dilution, contamination and lost contact with participants.[167] Limited phone ownership and literacy can impact the distribution and equity of access to mHealth. For example, a Cambodian study of a post-abortion intervention had to exclude over 20% of women who were approached because they didn't own a phone.[172] Interventions that rely on internet and computer literacy may worsen the 'digital divide' which mirrors socioeconomic inequities[199]; hence it is preferable to consider simpler intervention delivery options relevant to the population of interest to minimise exclusion. Furthermore, there is evidence that more privileged groups selectively engage in mHealth interventions, and those in minority groups or at higher risk may be less engaged.[179, 187]

While mobile phones are generally a private medium, there is a real risk of others viewing intervention content on a recipient's phone. For sensitive reproductive health interventions, this can have serious consequences, ranging from shame or embarrassment, to unintended disclosure, to violence. Reiss et al developed an IVR intervention for women to increase LARC uptake following menstrual regulation in Bangladesh. Despite the intervention being carefully targeted, and a checking procedure being implemented at enrolment to ensure recipients were comfortable with the level of privacy, the intervention was associated with an increase in physical intimate partner violence.[180] The authors emphasise the need to measure potential adverse outcomes such as violence in any mobile phone-based SRH intervention. The risk of unwanted disclosure and violence is of particular relevance to FSWs, who already face high levels of sex work-related stigma and violence.

As with any contraceptive promotion activity, there is a risk that over-emphasising pregnancy prevention at the expense of HIV/STI prevention will result in 'migration' from condoms to non-barrier methods, and increase STI transmission. For example, an SMS intervention in Ghana resulted in fewer pregnancies among sexually active adolescent girls, but more instances of condomless sex.[175] This reinforces the importance of promoting and measuring dual method contraceptive use in any SRH intervention, particularly in populations with high HIV prevalence.

## 1.8 Research context

### 1.8.1 Sex work in Mombasa, Kenya

The research presented in this thesis predominantly focuses on the population of female sex workers in Mombasa, Kenya.

Kenya is a lower-middle income country in East Africa with a population of 51 million,[200] and an estimated 133,675 women engaged in sex work.[201] This is thought to account for approximately 5% of the population of reproductive-aged women, higher than estimates in other sub-Saharan African countries.[202-204] Nine percent of Kenyan men aged between 15 and 49 years report ever having paid for sex.[64]

Sex work is illegal in Kenya, however a harm reduction approach has been adopted by the national government with the recognition that sex work was likely to be the initial source of HIV transmission and continues to play a key role in the epidemic.[205] Kenya's HIV and AIDS Prevention and Control Act, 2006, provides the legal framework for persons at risk of HIV infection to receive treatment counselling and care.[206] Moreover, in response to findings in 2009 that key populations including FSWs contributed to one-third of new HIV infections, the government prioritised targeted prevention approaches for these populations.[206] HIV programs have been scaled up in most counties in Kenya,[207] and now provide prevention and treatment services for the majority of FSWs.[208] Nonetheless, FSWs in Kenya continue to face frequent arbitrary arrests, police harassment and violence,[90, 209] and significant risks to their health and wellbeing, including harmful alcohol use,[91] inadequate contraceptive use[38] and inconsistent condom use, particularly with emotional partners.[110]

Mombasa is the second-largest city in Kenya and a transport, tourism and industry hub for East Africa, with a large port and international airport linking long-distance truck routes.[32] Consequently, there is a substantial market for commercial sex from men working in the city and visiting for work or tourism.[52] Many female migrant workers also come to Mombasa searching for work, contributing to the pool of underemployed women in the city[32] and part-time sex work is a particularly feature of the sex market in Mombasa.[9, 38] The most recent population mapping exercise, conducted in 2014, estimated that 11,777 female sex workers operated in the city, from 1025 locations (sex work 'hotspots') across four sub-counties.[210]<sup>2</sup> Hotspots range from higher-end bars, international hotels and night clubs, to brew dens (single-operator stalls selling homemade palm wine), and public locations such as street corners and beaches. Brothels, or other venues specifically catering to sex with no bar attached, are rare. As in other parts of sub-Saharan Africa[2], most FSWs in Mombasa work independently of managers or pimps, although they may have arrangements with venue staff or taxi drivers to assist them in finding clients.[211]

---

<sup>2</sup> Boundaries were changed in 2012, with Mombasa divided into six sub-counties. The enumeration conducted by Cheuk et al refers to the earlier four sub-counties.



My research takes place in Kisauni and Changamwe, the areas<sup>3</sup> of Mombasa with the highest numbers of FSWs (5,081 and 3,435, respectively; unpublished data from E. Cheuk). Kisauni includes both international hotels and tourist facilities located along the coast, and extensive informal housing settlements further inland. Sex work takes place around the late-night drinking culture in this area, predominantly in local brew dens, but also in bars, restaurants and higher-end international hotels. In contrast, Changamwe is an industrial area which includes the port and international airport. Sex workers tend to service men who work in the area, including truck drivers and other itinerant populations from throughout Kenya and neighbouring countries,[212] in bars and other drinking venues that may or may not have hotel rooms on the premises.



**Figure 3: Map of Mombasa showing sub-counties prior to 2012 redistribution**

Courtesy of Wiki Voyage[213]

<sup>3</sup> In this thesis, Kisauni refers to the area to the north of Mombasa Island bordered by Tudor Creek and the Indian Ocean, which now includes the sub-counties Kisauni and Nyali. Changamwe refers to body of land to the west of Mombasa Island, which now includes the sub-counties Changamwe and Jomvu.

### 1.8.2 Services and programs for female sex workers in Kenya

In response to a 2009 study which highlighted the critical role of key populations (FSWs, men who have sex with men, including male sex workers, and people who inject drugs) in HIV transmission in Kenya, the government adopted a renewed focus on preventing HIV in key populations.[208, 214] This drove a national enumeration of the FSW population and hotspots in 2012 to better implement and monitor programs at the community level. Recognising that a combination prevention approach was required to impact on plateauing incidence rates, the 2014-2019 National Strategy defined a package of biomedical, behavioural and structural interventions to be scaled up among FSWs and other key populations.[206]

Community-led outreach by sex worker peer educators is a critical component of this strategy, and is directed by national guidelines.[215] National peer education programs were scaled up rapidly from 2013 to 2016, to be able to reach 85% of FSWs at least once per quarter.[208] Peer educators provide risk-reduction information, skills and commodities at their usual hotspot/s and are expected to have contact with 60-80 FSWs monthly, using a micro-planning approach to organise their work and monitor local data. As well as aiming to change risky behaviours, such as unprotected sex, peer educators link FSWs to services, for example by promoting quarterly visits to program clinics which provide HIV and STI counselling and testing, and linking with volunteer paralegals and violence recovery services. Recent work has focused on increasing peer educator to sex worker ratios, as this has been associated with improved outcomes including HIV testing coverage.[208]

While Kenya has demonstrated a sustained commitment to addressing sexual health for sex workers, and established a national framework for engagement with FSWs, policies and programs, and their evaluations, focus on improving condom use and decreasing HIV transmission.[77] As discussed in section 1.5, there is evidence for integrating family planning into HIV services for women living with HIV,[156] and a similar approach to HIV prevention and treatment programs for FSWs could significantly benefit this population.

### 1.8.3 Family planning programs in Kenya

Kenya established a national family planning program in the 1960s, and was the first sub-Saharan African country to do so.[216] Despite considerable initial success, with a drop in the fertility rate from around eight to five births per woman between the mid-1970s and mid-1990s, government commitment to family planning subsequently fluctuated. Redirection of funding in the 1990s in response to the worsening HIV/AIDS epidemic, largely driven by international donors, resulted in a plateauing of contraceptive use and fertility rates.[216-218]

Renewed advocacy from the mid-2000s led to national political and budget commitments to reduce the need for donor dependence,[217, 219] and contraceptive coverage and equity increased dramatically between 2003 and 2009.[220]

Plateauing rates of long-acting and permanent method use prompted a national strategy to increase coverage of these methods in 2008, which included training health workers, equipping health facilities and improving commodity security. In addition to this national commitment, a multi-component, population-level intervention to increase the use of long-acting and permanent methods was implemented in three large urban centres.[221] These efforts resulted in large increases in implant use (from 5% to 19% of method mix between 2008 and 2014) but little change in IUD use or permanent methods.[64] The increase in implants can be partly attributed to the Implant Access program and increased emphasis on this method in counselling[218].

Kenya joined the FP2020 partnership in 2012 and has led the upward trend in contraceptive use in Eastern and Southern Africa, with an increase in the mCPR from 35 to 43%.[57] While there was a shortfall in county budget allocations following recent constitutional devolution,[222] Kenya reaffirmed its FP2020 commitment in 2017 by pledging that all counties will have family planning budget lines and costed implementation plans by 2020.[223]

A large proportion of health facilities throughout Kenya offer family planning, with 74% of hospitals, health centres, clinics and dispensaries offering at least 5 modern methods.[65] In addition, oral contraceptive pills and emergency contraceptives are available from pharmacies and condoms from multiple sources including retail outlets. Community health volunteers offer short-acting methods as well as contraceptive information through outreach services, but these are varied in implementation and reliability.[224] Method mix differs substantially between public and private facilities, particularly for LARCs. In a 2018 national survey, IUDs were available and in stock in 66% of public facilities compared to only 16% of private facilities. Implants were available in 80% of public, and 21% of private facilities. The difference was also pronounced for injectables (80% versus 46%).[65]

Contraceptive methods are available for free at public health facilities in Kenya, with the exception of early removal of IUDs and implants (personal communication with C. Gichuki, October 2019). Approximately 5% of public facilities report charging user fees, however it is not clear whether this is only for LARC removal or also for other services.[65] Estimates for fees charged by private providers vary widely,[65, 225] and are complicated by poor availability of data from the private sector.[224] Contraception is not covered by the National Health Insurance Fund or private insurers.[224]

Contraceptives can be difficult to obtain for girls under 18 years, which places additional burden on girls involved in commercial or transactional sex.[226] Young women and girls aged 15-24 years are more likely to obtain contraceptives from private than public facilities,[227] and this may partly be due to fears of legal repercussions or refusal of services in the public sector.

#### **1.8.4 Family planning services for female sex workers**

National guidelines and standards for programming with sex workers include family planning as part of their package of services for HIV prevention, and highlight the need for integration of HIV and reproductive health services, or strong referral networks for FSWs to access 'sex-worker friendly' services.[211, 228] It is recommended that peer educators provide family planning education and contraceptive commodities to their FSW peers, however the extent to which this occurs in practice is unclear, as evaluations of peer education programs have not described their family planning activities.[208, 229, 230]

Some sex worker drop-in-centres provide family planning as part of integrated services. This was the case in Kisauni and Changamwe, the Mombasa sub-counties where this PhD research took place, although the Changamwe drop-in centre was not constructed until after the study commenced. However, the Changamwe study clinic was located at a nearby municipal community health centre that was known to provide family planning services to FSWs.

Qualitative research with FSWs in Kenya shows that FSWs have mixed preferences regarding where to access family planning services. Public facilities are generally preferred because of low costs and more specialised services, but they usually have long wait times. While only 5% of public facilities surveyed in 2018 reported charging user fees for family planning,[65] reports from FSWs suggest that service fees are incurred much more frequently. In client interviews in Mombasa, 41% of FSWs paid for SRH services which are notionally available for free; however median cost was low (0.25 Euro).[32] Private facilities are more expensive but have long opening hours, are often perceived to be of higher quality, and tend to be more conveniently located, often strategically placed near sex work hotspots, so are more widely used.[32, 120, 127] FSWs report particular difficulties in accessing abortion and post-abortion care, female condoms, lubricant, and advice on managing side effects of contraception from all services.[32, 120]

Sex work-related stigma, discriminatory treatment and abuse from health professionals,[120] along with internalised stigma, are an issue at all mainstream facilities. In contrast, FSWs report being treated with respect at sex-worker specific drop-in-centres, and these are therefore the

most acceptable service model; however, the range of available services is not always sufficient.[127]

## 1.9 Thesis overview

### 1.9.1 Rationale

The research presented in this thesis arose out of the recognition that FSWs in Kenya face high risks of unintended pregnancy and its consequences, and that very little has been done to address this issue despite it being a major concern for the women affected. The structural barriers outlined in this chapter are complex and can only be addressed by broad social and programmatic changes, but many of the individual and even some interpersonal barriers to contraceptive use could be amenable to modification by a mobile phone health promotion intervention. Given ubiquitous mobile phone carriage in this population and existing evidence for the effectiveness of mHealth in other populations, such an intervention could be feasible and acceptable and could have considerable impact. This chapter has summarised the existing literature and highlighted some key research gaps that will be addressed in the upcoming chapters. These include understanding the magnitude of unintended pregnancy among FSWs in LMICs, how to effectively prevent unintended pregnancy in this population, and the development and evaluation of mHealth interventions for FSWs. The following section will outline the aims and objectives of this thesis and how each of these will be addressed.

### 1.9.2 Aims and objectives

#### *Overall aim*

To improve the sexual and reproductive health and wellbeing of FSWs in LMICs by better understanding the risks of unintended pregnancy in this population and developing and testing a mobile phone-based health promotion intervention (mHealth intervention) for FSWs in Mombasa, Kenya, aimed at preventing unintended pregnancy.

#### *Objectives:*

1. To quantify the incidence of unintended pregnancy among FSWs in LMICs and examine the correlates and predictors of unintended pregnancy, and the rates of pregnancy, induced abortion and birth, in this population.
2. To develop an mHealth intervention for FSWs aimed at preventing unintended pregnancy, and validate the intervention among FSWs in Mombasa, Kenya.

3. To assess the effectiveness of the mHealth intervention at reducing rates of unintended pregnancy among FSWs, by testing the intervention in a cluster-randomised controlled trial in Mombasa.
4. To assess the prevalence and correlates of long-acting reversible contraceptive use among FSWs in Mombasa using baseline data from the cluster-randomised controlled trial.

### 1.9.3 Thesis outline

This thesis comprises an introductory chapter and literature review (this chapter) five chapters presenting original research in the form of submitted or published manuscripts (described below), and an integrated discussion (Chapter 7) which summarises the main findings, strengths and limitations of my research and provides recommendations based on these findings.

#### *Chapter 2*

This chapter consists of a published systematic review and meta-analysis on the incidence of unintended pregnancy among FSWs in LMICs, addressing objective 1.

#### *Chapter 3*

This chapter describes the development of an mHealth intervention for FSWs (the WHISPER intervention) in a published paper. It includes a qualitative exploration of FSWs' responses to pilot testing the intervention in Mombasa, an assessment of its feasibility and acceptability, and a description of the final intervention content and structure. This chapter addresses objective 2.

#### *Chapter 4*

This chapter outlines the study design and methods of a cluster-randomised controlled trial to be conducted with FSWs in Mombasa, which tests both the WHISPER intervention for preventing unintended pregnancy, and a nutrition intervention (SHOUT) for reducing anaemia. This is presented in the form of a published protocol for the 'WHISPER or SHOUT' study, contributing to objective 3 and 4.

While the nutritional health of FSWs is not the focus of this thesis, the published study protocol in this chapter places equal emphasis on both the WHISPER and SHOUT arms of the trial, reflecting its equal-attention control design.

*Chapter 5*

This chapter consists of a cross-sectional analysis of the WHISPER or SHOUT study cohort at enrolment. A published paper presents eligibility data and baseline characteristics of participants, and analyses the prevalence, correlates and patterns of use of LARCs in the cohort, addressing objective 4.

*Chapter 6*

This chapter reports the final results of the WHISPER or SHOUT trial. An analysis of the effectiveness of the WHISPER intervention at preventing unintended pregnancies, as well as its impact on secondary outcomes, in a manuscript that has been accepted by the Lancet Global Health. This chapter addresses objective 3.

## Chapter 2: Systematic review of the incidence of unintended pregnancy among female sex workers

### 2.1 Background

The literature review in Chapter 1 established that FSWs in LMICs are exposed to many factors that put them at risk of unintended pregnancy, but that the magnitude of this risk is not well understood. In response to this gap, and to address objective 1 of this thesis, I conducted a systematic review and meta-analysis on the incidence of unintended pregnancy among FSWs in LMICs. The review confirmed that few studies have measured pregnancy incidence among FSWs, despite many studies being located that examined other aspects of FSWs' sexual and reproductive health.

This chapter consists of the following published manuscript:

Ampt FH, Willenberg L, Agius PA, Chersich M, Luchters S, Lim MSC. Incidence of unintended pregnancy among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *BMJ Open* 2018; 8(9): e021779.

The paper is followed by the published supplementary file containing the search strategy and quality assessment tool.

The protocol for this review was registered with the international prospective register of systematic reviews: PROSPERO 2016 CRD42016029185

([https://www.crd.york.ac.uk/PROSPERO/display\\_record.php?RecordID=29185](https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=29185))



# BMJ Open Incidence of unintended pregnancy among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis

Frances H Ampt,<sup>1,2</sup> Lisa Willenberg,<sup>1</sup> Paul A Agius,<sup>1,3</sup> Matthew Chersich,<sup>4</sup> Stanley Luchters,<sup>1,2,5</sup> Megan S C Lim<sup>1,2,6</sup>

**To cite:** Ampt FH, Willenberg L, Agius PA, *et al.* Incidence of unintended pregnancy among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *BMJ Open* 2018;**8**:e021779. doi:10.1136/bmjopen-2018-021779

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2018-021779>).

Received 22 January 2018  
Revised 14 May 2018  
Accepted 11 June 2018



© Author(s) (or their employer(s)) 2018. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

## Correspondence to

Professor Stanley Luchters;  
[stanley.luchters@burnet.edu.au](mailto:stanley.luchters@burnet.edu.au)

## ABSTRACT

**Objectives** To determine the incidence of unintended pregnancy among female sex workers (FSWs) in low-income and middle-income countries (LMICs).

**Design** We searched MEDLINE, PsychInfo, Embase and Popline for papers published in English between January 2000 and January 2016, and Web of Science and Proquest for conference abstracts. Meta-analysis was performed on the primary outcomes using random effects models, with subgroup analysis used to explore heterogeneity.

**Participants** Eligible studies targeted FSWs aged 15–49 years living or working in an LMIC.

**Outcome measures** Studies were eligible if they provided data on one of two primary outcomes: incidence of unintended pregnancy and incidence of pregnancy where intention is undefined. Secondary outcomes were also extracted when they were reported in included studies: incidence of induced abortion; incidence of birth; and correlates/predictors of pregnancy or unintended pregnancy.

**Results** Twenty-five eligible studies were identified from 3866 articles. Methodological quality was low overall. Unintended pregnancy incidence showed high heterogeneity ( $I^2 > 95\%$ ), ranging from 7.2 to 59.6 per 100 person-years across 10 studies. Study design and duration were found to account for heterogeneity. On subgroup analysis, the three cohort studies in which no intervention was introduced had a pooled incidence of 27.1 per 100 person-years (95% CI 24.4 to 29.8;  $I^2 = 0\%$ ). Incidence of pregnancy (intention undefined) was also highly heterogeneous, ranging from 2.0 to 23.4 per 100 person-years (15 studies).

**Conclusions** Of the many studies examining FSWs' sexual and reproductive health in LMICs, very few measured pregnancy and fewer assessed pregnancy intention. Incidence varied widely, likely due to differences in study design, duration and baseline population risk, but was high in most studies, representing a considerable concern for this key population. Evidence-based approaches that place greater importance on unintended pregnancy prevention need to be incorporated into existing sexual and reproductive health programmes for FSWs.

**PROSPERO registration number** CRD42016029185

## Strengths and limitations of this study

- This is the first study to systematically review and analyse the incidence of pregnancy or unintended pregnancy among female sex workers (FSWs) in low-income and middle-income countries.
- Broad inclusion criteria meant that the review allowed for the inclusion of a large proportion of the studies that have collected data on pregnancy or unintended pregnancy rates in this population.
- However, limitations of broad inclusion criteria are that only one study had an a priori objective of measuring pregnancy incidence, and studies were highly varied in terms of their methodology, settings and study populations.
- High heterogeneity prevented pooled analysis of all studies but allowed for subgroup analysis for cohort studies and for studies in which no intervention was introduced.
- Pregnancy rates among FSWs could not be compared with the background general population rates because of the lack of availability of those data.

## INTRODUCTION

Unintended pregnancy affects a large number of women in low-income and middle-income countries (LMICs) and can have significant impacts on maternal and child health.<sup>1–3</sup> Unintended pregnancy is a high priority issue for many female sex workers (FSWs)<sup>4 5</sup> who usually have dependents to support and for whom pregnancy may increase financial dependence on sex work and add to already high levels of stigmatisation.<sup>5</sup> This has been confirmed by consultation with FSWs in Kenya<sup>1</sup> and workshops with FSWs to inform development of a pregnancy prevention intervention.<sup>6</sup> Participants expressed considerable

<sup>1</sup>Our research group has worked closely with a local NGO (International Centre for Reproductive Health, Kenya) which has a long history of collaborating with and providing services for sex workers in Mombasa.

fear and anxiety about pregnancy, related personal and peer experiences of pregnancy scares and emphasised the importance of improving knowledge of family planning in their community (unpublished qualitative data, Mombasa, Kenya).

FSWs can face elevated risks of unintended pregnancy due to a high frequency of intercourse and a high number of sexual partners.<sup>7 8</sup> Risks are exacerbated by concurrent paying and non-paying partnerships<sup>8</sup> and by sexual and gender-based violence, gender inequalities and stigma towards sex work, which reduce women's power to negotiate within sexual relationships.<sup>9–11</sup> While gains have been made in terms of condom use with paying clients,<sup>12</sup> rates of condom and other contraceptive use are consistently lower with emotional (non-paying) partners.<sup>5 13 14</sup> In many countries, particularly in sub-Saharan Africa, few FSWs use long-acting reversible contraceptives (intrauterine devices and implants), and methods such as injections, condoms and pills may be used inconsistently or incorrectly, rendering them less effective.<sup>5 15</sup> Limited knowledge and misunderstandings, particularly in relation to contraceptive side effects and impacts on fertility, are significant demand-side barriers to contraceptive uptake.<sup>4 5 16</sup>

Family planning services are often neglected as part of FSW-specific service provision, which have focused largely on preventing HIV and other sexually transmitted infections (STIs).<sup>12 17–19</sup> Stigma of health workers towards sex workers can also limit access to contraception.<sup>20 21</sup> FSWs have the same reproductive rights as all women, and their desires and needs in relation to pregnancy have often been neglected,<sup>22–24</sup> similar to other marginalised populations, which have historically been subjected to reproductive coercion.<sup>25 26</sup> It is important that those who do desire pregnancy are provided with non-judgemental care and that those who do not are given the opportunity and resources to prevent it. Moreover, many FSWs who become pregnant may be reluctant to enter maternal health services, given their previous experiences of discrimination and abuse from health workers.<sup>20</sup> FSW programmes need to make concerted efforts to facilitate timely attendance of FSW at antenatal clinic and childbirth services. Importantly, FSWs often have remarkably high levels of HIV, and maternal health services are a key entry point for them to access antiretroviral treatment, which secures their health and reduces HIV in infants.

Despite a clear rationale for addressing unintended pregnancy in this population, it is important to acknowledge that intention is a problematic concept, which is more accurately represented as a spectrum than a dichotomy.<sup>3 27</sup> Indeed, many women feel positive about pregnancy despite not intending to conceive, or may simultaneously desire both pregnancy and its avoidance, for different reasons. The degree to which women accept or welcome a pregnancy once it has occurred has been hypothesised to be a more important predictor of adverse outcomes than prepregnancy intentions.<sup>27</sup> Fertility preferences are also likely to be less stable over time in LMICs

undergoing fertility transition compared with high-income countries.<sup>3</sup> FSWs' intentions also differ between types of partner, requiring them to adapt contraceptive use accordingly.<sup>22</sup> Furthermore, as a stigmatised group, FSWs may feel pressure not to disclose their intention. Despite these limitations, we have continued to use the term 'unintended pregnancy' in this paper for the sake of consistency with other literature and the lack of a feasible alternative.

The primary objective of this study was to determine the pooled incidence of unintended pregnancy among FSWs in LMICs. Given the expected low number of eligible studies, we also aimed to determine the incidence of pregnancy where intention is not known. Secondary aims were to examine the correlates and predictors of pregnancy and the incidence of induced abortion and childbirth in this population.

## METHODS

All stages of this systematic review and meta-analysis have been reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.<sup>28</sup> The protocol for this review was registered with the international prospective register of systematic reviews (PROSPERO): number CRD42016029185.

## Inclusion and exclusion criteria

Studies were included if they met key criteria in terms of population, outcomes and study design. FSWs had to account for at least two-thirds of the sample, unless data could be disaggregated by sex work status. We employed a broad definition of sex work, including women who self-identified as sex workers, those who engaged in transactional sex or part-time sex work and communities of women known to practice commercial or transactional sex. Study participants had to live or work in an LMIC<sup>29</sup> and be of reproductive age (15–49 years). Studies targeting women with reduced fertility (eg, women in the first 6 months postpartum and those exclusively breast feeding or undergoing fertility treatment) were excluded.

Studies had to measure or report one of the following primary outcomes:

1. Cumulative incidence (proportion of women who became pregnant in a defined time period) or incidence rate (per person-time) of unintended pregnancy.
2. Cumulative incidence or incidence rate of pregnancy (where intention is not measured).

Unintended pregnancy was defined as any pregnancy considered by the woman to be not planned, intended or desired at the time of conception,<sup>30</sup> as reported either prior to pregnancy or retrospectively. Such pregnancies may be described by the authors as unintended, unwanted, undesired, unplanned or mistimed.

Any study design that was able to measure one or more of the primary outcomes was considered, including both observational and intervention studies. Case studies, ecological

studies, qualitative studies, editorials and commentaries were excluded. We planned to expand the inclusion criteria if insufficient studies measuring the primary outcomes were identified to include studies reporting prevalence of pregnancy in the previous 12 months. Cross-sectional studies were included in the initial screen for this purpose but were subsequently excluded as there were sufficient longitudinal studies measuring incidence. The addition of period prevalence in the last 12 months as an outcome would have required additional subanalyses; in addition, measurement of retrospective pregnancy intention in cross-sectional studies differs from prospective measurement as women may change their minds during the course of their pregnancy. Only studies published in English since 1 January 2000 were included.

### Search strategy

A systematic electronic search of MEDLINE, Embase, PsychINFO and Popline was undertaken to identify relevant peer-reviewed articles. Search syntax included, as both subject headings and keywords: synonyms for 'sex work'; list of LMICs from the World Bank<sup>29</sup> and synonyms for 'low- and middle-income'; and study design and descriptor terms, for example, 'cohort studies' or 'controlled trials' (full search strategy in online supplementary file).

A search for unpublished grey literature was also undertaken, including conference proceedings and abstracts (via Web of Science and Proquest databases), research theses and the websites of relevant non-government organisations, including the Population Council, FHI 360 and Guttmacher Institute.

The last search was performed on 20 January 2016. Up to two attempts were made to contact authors when further information was required. Eligible studies recommended by contacted authors were also included.

### Screening and data extraction

Screening of all abstracts, removal of duplicates and selection of full-text articles was conducted by one researcher, with a random selection of 10% screened in duplicate. Data from a random sample of 50% of included full-text manuscripts were extracted in duplicate. Discrepancies in eligibility and data extraction were resolved by discussion, with a third researcher arbitrating when necessary.

Summary estimates were sought rather than individual subject data. Data were extracted relating to: eligibility criteria; study aims, population and methods; setting and participant characteristics at baseline; primary and secondary outcome data for each time point reported; and quality assessment criteria. In addition to the primary outcomes, the following secondary outcomes were extracted: incidence of induced abortion (termination of pregnancy); incidence of birth; and correlates/predictors of pregnancy or unintended pregnancy. Authors were contacted to provide data relating to the primary outcome when it was not reported in the paper, for example, the total person-years of exposure.

### Quality assessment

Methodological quality of the included studies was assessed using a modified version of the Joanna Briggs Institute Prevalence Critical Appraisal Tool<sup>31</sup> (online supplementary file). This tool was designed to assess studies measuring prevalence or incidence and can be applied to multiple study designs. The tool was modified to address specific methodological concerns of our research question. Given measurement bias could result from infrequent or irregular pregnancy detection methods, items on these methods were specifically included. We also documented whether pregnancy incidence was an a priori study objective.

Quality assessment was undertaken in duplicate for 50% of studies, with discrepancies resolved by discussion. Studies were given a score out of 15 if they measured unintended pregnancy incidence, and a score out of 14 if they measured pregnancy incidence (the latter did not include an item on measurement of intention). Scores were then reported as percentages.

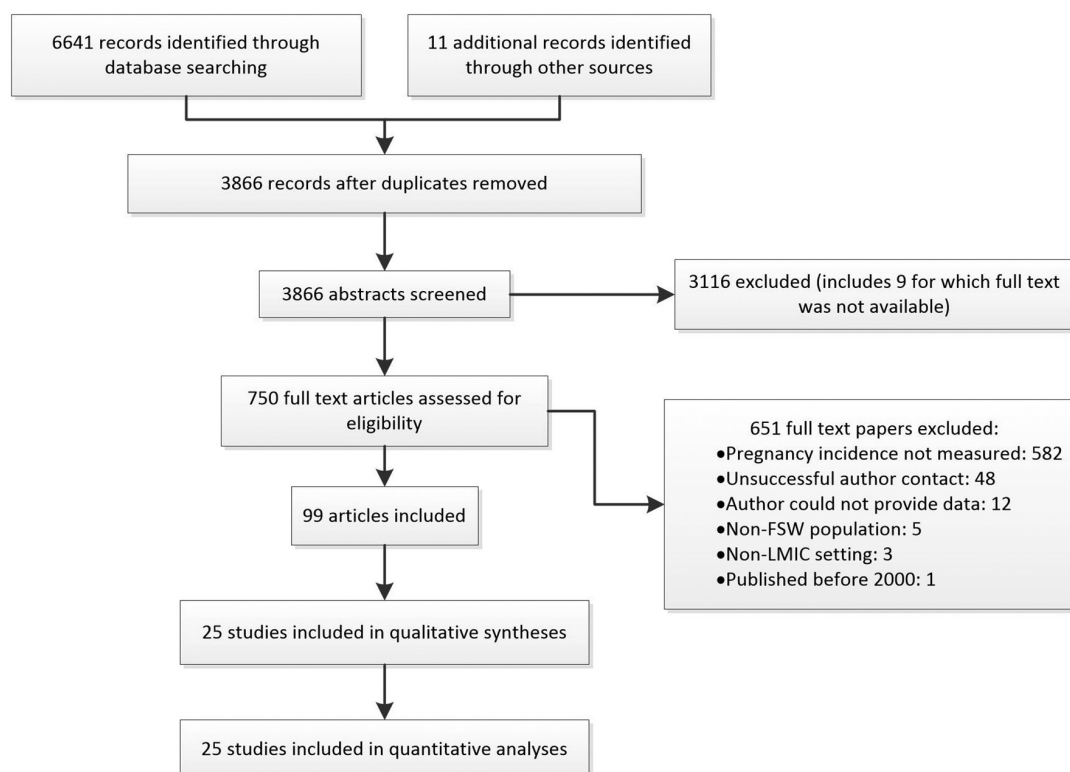
### Analysis

We undertook a qualitative narrative synthesis of both primary and secondary outcomes and quantitative analysis of primary outcomes using Stata V.13.1.

Incidence rate (per 100 person-years) was taken as the unit of analysis. In studies reporting only cumulative incidence, we estimated person-time, censoring women at their first pregnancy and assuming that they became pregnant halfway through the study.

The Mantel-Haenszel  $I^2$  statistic was over 95% for both primary outcomes, so meta-analysis and meta-regression were not performed for all eligible studies, as had been planned. Instead, sources of heterogeneity were explored using subgroup analyses, and pooled incidence rates were calculated using DerSimonian & Laird random effects models for subgroups containing more than two studies and with  $I^2$  of less than 75%. The explored subgroups were clustered as covariates that may explain heterogeneity (geographic region and intervention vs non-intervention) and potential methodological explanations of heterogeneity: study design (cohort vs randomised controlled trial (RCT)); study duration; and frequency of pregnancy measurement (measured regularly vs only when indicated). Interventions included any introduced by the study with the aim of improving sexual and reproductive health, including contraceptive provision and behavioural or biomedical interventions to prevent HIV/STIs.

We assessed study quality as a source of heterogeneity by examining scatter plots and Pearson correlation coefficients of quality score against incidence rate. We also qualitatively explored characteristics of different studies, including the following baseline population characteristics that may have impacted on pregnancy rates: age; contraceptive prevalence; consistent condom use; number of sex partners; coital frequency; STI prevalence; indicators of gender-based violence; and alcohol and other drug use.



**Figure 1** PRISMA flow diagram of search results and inclusion of studies after review.<sup>28</sup> FSWs, female sex workers; LMICs, low-income and middle-income countries; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

### Patient and public involvement

The research question and outcome measures were informed by previous qualitative work with FSWs conducted by the International Centre for Reproductive Health, Kenya. This confirmed that unintended pregnancy was an important issue for this population group. Patients and members of the public were not otherwise involved in the design or conduct of this study.

### RESULTS

The initial search yielded 6523 peer-reviewed and 118 grey literature articles and 11 identified by hand-searching (eg, due to recommendations from contacted authors). After removal of duplicates, this resulted in 3866 articles (figure 1). Based on title and abstracts, 750 manuscripts remained for full-text screening.

Pregnancy incidence was reported in 12 studies and was obtained for a further 13 studies after contacting authors. These 25 studies were reported in 99 papers. Ten studies measured *unintended* pregnancy (outcome 1), and 15 studies measured pregnancy *without specifying intention* (outcome 2); none measured both outcomes.

Fourteen cohort studies and 11 RCTs were included (table 1). Pregnancy incidence was not an a priori primary objective for any but was a secondary objective for a Rwandan HIV incidence study.<sup>32</sup> The majority of studies aimed to test interventions to prevent HIV or STIs (n=11) or measure HIV incidence (n=8). Six

undertook substudies in which they reported pregnancy incidence.<sup>33–38</sup> Thirteen studies included any intervention: three involved provision of diaphragms or female condoms,<sup>39–41</sup> and 10 studies were biomedical or behavioural interventions to prevent HIV/STIs (table 1). The latter included four studies that reported providing contraceptive counselling<sup>35 36 42 43</sup> and one which offered free contraception when needed.<sup>44</sup>

Most RCTs in this review required women to remain non-pregnant for continuation.<sup>36 40 42 44–48</sup> The majority of studies (n=19) took place in sub-Saharan Africa, most frequently in Kenya (n=8; table 1). There were also studies from the Americas (Mexico and the Caribbean) and East Asia (China, Thailand and Cambodia). All except three<sup>36 44 49</sup> took place in urban settings. The study areas were frequently informal housing settlements, low-income areas or environments known for sex work and/or drug use.

Sex work was mainly defined as exchange of sex for money or goods (n=12) or money alone (n=4). In five studies, sex workers were self-identified, in two studies they were members of communities or working in areas known for commercial sex work<sup>36 46</sup> and in two studies no definition was provided.<sup>48 50</sup> Eighteen studies involved FSWs exclusively; the remainder targeted women with high-risk sexual practices or at high risk of HIV. These studies either reported pregnancy incidence in the sex work subgroup<sup>36 42 44 51</sup> or FSWs constituted more than





Table 1 Characteristics of included studies

Study (first author, year)	Additional sources	Country	Year started	Design	Aim	Population	N (FSWs) at baseline	Age (median)†	Current contraceptive use‡ (%)	Consistent condom use§	Number of sex partners/frequency of sex¶	Gender-based violence (GBV)/alcohol/other risk factor	HIV/STI prevalence
Outcome 1: unintended pregnancy													
Behets, <sup>39</sup> 2005		Madagascar	2004	Prospective cohort (with intervention).	Assess acceptability and feasibility of diaphragm use.	FSWs who use condoms inconsistently.	91	28	Any: 47% LARC or permanent: <1%.	0% with clients in last month (inconsistent use was an inclusion criterion).	Five partners. Six sex acts.	N/A.	Vaginitis/Pelvic inflammatory disease (PID): 8%. TP (RPR): 27%.
Behets, <sup>40</sup> 2008	Author†† Khan <i>et al</i> <sup>4</sup> Penman-Aguilar <i>et al</i> <sup>72</sup>	Madagascar	2005	RCT (pilot).	Assess acceptability and feasibility of diaphragm and microbicide use for STI prevention.	Women with high-risk sex behaviours (sex work self-reported: 81% current, 100% ever).	192	29	Any (excl. condoms): 24%. Permanent: 0%.	0% in last 2 weeks (inconsistent use was an inclusion criterion).	Six casual partners. 10 sex acts.	Ever violence from casual partner suggesting condom: 21%. Ever received more money for no condom: 38%.	N/A.
Braunstein, <sup>32</sup> 2011	Braunstein <i>et al</i> <sup>3</sup>	Rwanda	2006	Prospective cohort.	Measure HIV incidence (secondary aim: measure pregnancy incidence).	HIV-uninfected women at high risk of HIV exposure (94% reported current sex work).	397	24	Any: 91% LARC or permanent: 0%.	21% with clients 18% with non-paying partners.	90 partners in past 3 months. 10 clients per week. 40 vaginal sex acts in last month.	Forced sex ever: 19%. Alcohol before sex: 52%.	CT: 5%. GN: 12%. TV: 17%. TP (RPR+TPHA pos): 7%. HSV2: 54%.
Chersich, <sup>34</sup> 2014	Author†† Luchters <i>et al</i> <sup>5</sup>	Kenya (Mombasa)	2006	Prospective cohort.	Assess HIV incidence and microbicide trial feasibility. This study: investigate links between alcohol use, and unsafe sex and incident HIV infection.	HIV-uninfected FSWs.	386	Mean 25.1	Any (incl. consistent condom use): 57.1% LARC: 3.0%. Permanent: 0%.	21.3% in last 3 months.	N/A.	Hazardous or harmful drinking: 26.8%. Ever had abortion: 21%.	N/A.
Deschamps, <sup>33</sup> 2016	Deschamps <i>et al</i> <sup>14</sup>	Haiti, Puerto Rico and Dominican Republic	2009	Prospective cohort.	Assess feasibility of establishing a high-risk cohort for HIV vaccine trials. This study: assess retention, HIV and pregnancy incidence and risk behaviours.	HIV-uninfected FSWs.	634	24††	Permanent: 10.0% (excluded from pregnancy analysis). Others not reported.	0.5% in last 6 months.	447 partners in last 6 months††.	Forced sex by client in last 6 months: 37.1%. Heavy drinker: 38.8%. Drug use: 14.0%.	N/A.
Gaffoor, <sup>42</sup> 2013	Author†† Skoler-Karpoft <i>et al</i> <sup>13</sup>	South Africa (one site of a multisite trial)	2004	RCT (phase 3, double blind, placebo-controlled).	Test safety and efficacy of the microbicide, Carraguard for HIV prevention. This study: describe prevalence and associations of forced sex.	HIV-uninfected sexually active women (3% FSWs).	41	§§	§§	N/A.	§§	N/A.	§§
Lara, <sup>41</sup> 2009	Author††	Dominican Republic	2006	Prospective cohort (with intervention).	Assess acceptability of the female condom and diaphragm, determinants of use, and impact on unprotected sex.	FSWs.	243	58.8% aged 20-29 years	Any (excl. condoms): 22.2%. Permanent: 0%.	66% in last month.	N/A.	Ever had abortion: 70%.	HIV: 1%. CT: 13%. GN: 2%. TP (VDRL): 8%.
McClelland, <sup>45</sup> 2008	Author†† Martin <i>et al</i> <sup>76</sup> McClelland <i>et al</i> <sup>17</sup> McClelland <i>et al</i> <sup>18</sup>	Kenya (Mombasa)	2003	RCT (placebo-controlled, nested in an open cohort study).	Test efficacy of monthly periodic presumptive antibiotic treatment at reducing incidence of vaginal infections and promoting vaginal Lactobacillus colonisation.	HIV-uninfected FSWs.	310	32	Any (excl. condoms): 35.5% LARC: 3.6%. Permanent: 2.9%.	Median 100% coverage of sex acts in past week.††	One partner. One sex act.††	N/A.	GN: 0.3%. TV: 1%. Cervicitis (microscopy): 0.6%. HSV2: 74%. BV: 34.5%.

Continued

Table 1 Continued

Study (first author, year)	Additional sources	Country	Year started	Design	Aim	Population	N (FSWs) at baseline	Age (median)†	Current contraceptive use‡ (%)	Consistent condom use§	Number of sex partners/ frequency of sex¶	Gender-based violence (GBV)/ alcohol/other risk factor	HIV/STI prevalence
Peterson, <sup>48</sup> 2007	Author†† MacQueen et al <sup>48</sup>	Ghana, Cameroon and Nigeria	2004	RCT (phase 2, double blind, placebo controlled).	Investigate safety and preliminary effectiveness of tenofovir disoproxil fumarate in preventing HIV infection.	HIV-uninfected women who work in hotels, bars, markets in high HIV transmission areas (areas known for sex work).	936	Mean 23.6††	Any (excl. condoms): 7.22% LARC: <2% Permanent: <2%.	N/A	Mean 21 partners in 30 days. Mean 12 coital acts per week.	N/A.	Any STI in last 6 months (self-reported): 41.2%.
Watson-Jones, <sup>44</sup> 2008	Author†† Oduola et al <sup>49</sup>	Tanzania	2004	RCT (double blind, placebo controlled).	Determine whether HSV2 suppressive therapy reduces the risk of HIV acquisition and genital shedding of HIV.	Female workers at food and recreational facilities at risk of HIV (38% FSWs).	499	§§	§§	§§	§§	§§	§§
Outcome 2: pregnancy (intention undefined)													
Bazzi, <sup>54</sup> 2015	Author†† Svendsen et al <sup>50</sup>	Mexico	2010	Prospective cohort.	Identify time varying risk factors for STI acquisition within FSWs' intimate partnerships.	FSWs with drug use history and their steady male partners.	212	33	Any (excl. condoms): 53.3% LARC: 12.3% Permanent: 25.5%.	Often or always: 56%.	N/A.	In last year: physical assault by partner: 41% Sexual coercion in TP (active): 1.4% In last 6 months: hazardous drinking: 23% Intravenous drug use: 62%.	HIV: 2.6% CT: 5.9% GN: 1.2% TP (active): 1.4% Any STI: 8%.
Pagi, <sup>38</sup> 2013	Author†† Duff et al <sup>65</sup> Couture et al <sup>61</sup>	Cambodia	2009	Prospective cohort.	Estimate HIV and STI prevalence, incidence and associated factors. This substudy: describe contraceptive utilisation and correlates of incident pregnancy.	Young women 220 who practice SW and/or have multiple partners (all those recruited had practiced SW).	220	60.3% aged 25–29 years	Any hormonal (not LARC): 10.8% LARC: <1.0%.	N/A	Four partners in last month.	In last year: physical or sexual violence by client: 26.0% Intimate partner: 20.1% In last 3 months: stimulant drug use: 27.0% Abortion: 11.3%.	HIV: 16.2%.
Feldblum, <sup>35</sup> 2007	Feldblum et al <sup>67</sup> Hoke et al <sup>62</sup>	Madagascar	2001	RCT.	Assess impact of two condom promotion interventions. This substudy: estimate pregnancy incidence rate and predictive factors.	FSWs.	935	Mean 28.3	Any highly effective (excl. condoms): 16.3%.	No unprotected sex with any partners: 13.2%.	Mean 5–6 partners.	N/A.	CT: 14.6% GN: 21.7% TV: 11.7% Any STI: 36.1% ‡‡
Kaewkungwal, <sup>36</sup> 2013	Reks-Ngarm et al <sup>63</sup>	Thailand (two provinces)	2003	RCT (multisite double blind placebo controlled).	Assess the efficacy of two vaccines to prevent HIV. This substudy: determine the qualities and outcomes of women's participation.	HIV-uninfected women (5% FSWs).	318	N/A	N/A	§§	N/A.	§§	N/A.
Kaul, <sup>47</sup> 2004	Yadav et al <sup>64</sup> Fonck et al <sup>65</sup>	Kenya (Nairobi)	1998	RCT (double blind placebo controlled).	Assess impact of monthly PPT on HIV and STI incidence.	HIV-uninfected FSWs.	430	28.6††	Any hormonal (not LARCs): 39.1%.	17.2% with casual partner.††	15.4 partners.‡‡	Daily alcohol: 47.6% Ever intravenous drug use: 4.1% HSV2: 73.9% BV: 51.1%.	CT: 9.9% GN: 10.3% TV: 12.2% TP: 4.4% HSV2: 73.9% BV: 51.1%.

Continued



Table 1 Continued

Study (first author, year)	Additional sources	Country	Year started	Design	Aim	Population	N (FSWs) at baseline	Age (median)†	Current contraceptive use‡ (%)	Consistent condom use§	Number of sex partners/ frequency of sex¶	Gender-based violence (GBV)/ alcohol/other risk factor	HIV/STI prevalence
Liu, <sup>53</sup> 2015	Author††	China	2009	Cluster RCT.	Assess the impact of a preventive intervention for FSWs on condom use with clients and partners.	FSWs.	750	Mean 27.8††	LARC: 29.9%.	43.6% in past month.	Mean 8.3 clients.††	N/A.	CT: 14.0%. GN: 3.3%. TP: 1.3%. Any STI: 16.9%.
McClelland, <sup>37</sup> 2011	Author†† Martin <i>et al</i> †‡ McClelland <i>et al</i> ‡§	Kenya (Mombasa)	1993	Open cohort.	Assess HIV-1 incidence and relationships between hormonal contraception, STIs and HIV. This substudy: examine relationship between risk behaviour and biologic outcomes (STI, pregnancy, seminal fluid deposition) among HIV-positive FSWs.	HIV-infected FSWs.	898	31	Any (excl. condoms): 43.0%. LARC: 2.34%. Permanent: 2.67%.	55% in past week.	One partner. Two sex acts.	N/A.	N/A.
Price, <sup>49</sup> 2012	Author††	Kenya (Nairobi, Kilifi)	2005	Prospective cohort.	Describe populations at risk of HIV, including HIV incidence, in preparation for HIV trials.	HIV-uninfected women and men at risk of HIV (75% of women were FSWs).	515	§§	N/A.	N/A.	N/A.	§§	Any non-ulcerative STI: 9.1%. Genital ulcers: 1.5%. TP: 0.6%. Any STI: 10.6%.
Priddy, <sup>56</sup> 2011		Kenya (Nairobi)	2008	Prospective cohort.	Assess HIV risk behaviour and incidence, STI prevalence, vaginal practices and retention.	HIV-uninfected FSWs.	200	Mean 28	Any non-barrier method: 52.0%. LARC: 3.0%. Permanent: 1.0%.	N/A (only reported sometimes/always use).	Mean per day: 2.4 regular clients. 1.9 casual clients.	Sexual/physical violence related to sex work (SW) in last month: 19.5%. Sometimes/always paid more for no condom: 29.0%. Sometimes/always has sex while intoxicated: 31.5%.	CT: 5.5%. GN: 6.0%. TV: 9.0%. TP: 2.5%. HSV2 (antibody): 72.0%. BV: 38.0%.
Robb, <sup>51</sup> 2016	Author†† Rono <i>et al</i> ‡†	Kenya, Tanzania and Uganda	2009	Prospective cohort.	Describe the trajectory of acute HIV infection.	HIV-uninfected women and men at high risk for HIV (64% FSWs).	1463	N/A	Any hormonal (incl. implant): 36.5%. IUD: 0.5%. Permanent: 0.5%.	32.6% with clients. 20.3% with non-paying partners.	N/A.	Abortion in last 3 months: 0.43%.	N/A.
Strathdee, <sup>42</sup> 2013	Author†† Vera <i>et al</i> ‡§ Gaines <i>et al</i> ‡§	Mexico	2008	RCT (four-arm factorial).	Determine effectiveness of two behavioural interventions to reduce sexual and injecting risk.	HIV-uninfected FSWs who inject drugs.	584	33	Any (excl. condoms): 39.3%. LARC: 25.3%. Permanent: 17.8%.	14.9% with regular clients. 11.7% with casual clients.	30 clients per month. 51 paid sex acts per month.	N/A.	CT: 12.0%. GN: 2.2%. TV: 33.6%. TP (active): 8.4%.
Van Damme, <sup>48</sup> 2002	Author†† Vandeboosch <i>et al</i> ‡§ Ramjee <i>et al</i> ‡†	Benin, Cote d'Ivoire, South Africa and Thailand	1996	RCT (multisite triple blind placebo-controlled; open cohort design).	Determine effectiveness of noroxynol-9 microbicide in prevention of HIV-1.	HIV-uninfected FSWs.	892	26	N/A.	N/A (only reported use of condom in >50% of sex acts).	Three partners per day.	N/A.	CT: 4.4%. GN: 5.1%. TV: 3.5%. TP: 11.2%.

Continued



Table 1 Continued													
Study (first author, year)	Additional sources	Country	Year started	Design	Aim	Population	N (FSWs) at baseline	Age (median)†	Current contraceptive use‡ (%)	Consistent condom use§	Number of sex partners/ frequency of sex¶	Gender-based violence (GBV)/ alcohol/other risk factor	HIV/STI prevalence
van Loggelenberg, <sup>52</sup> 2008	Author†† Nackler <i>et al</i> <sup>52</sup>	South Africa (Durban)	2004	Prospective cohort.	Understand HIV-1 subtype C acquisition, pathogenesis and disease progression. This substudy: describe cohort characteristics (79%) and/or HIV-incidence rates, and report challenges in establishing and maintaining the cohort.	HIV-uninfected women who practice SW (79%) and/or have multiple partners.	193	Mean 34.3	N/A	53.9% with casual partners. 20.4% with steady partners.	Two partners per week.	N/A.	Any STI (CT, GN, TV, MG, TP, HSV2): 31.3%.
Vandepitte, <sup>53</sup> 2013	Author†† Vandepitte <i>et al</i> <sup>54</sup>	Uganda (urban slum).	2008	Prospective cohort.	Understand dynamics of HIV and STI infections among FSWs. This substudy: investigate patterns of clearance and recurrence of untreated <i>Mycoplasma genitalium</i> infection.	FSWs.	1027	Mean 26	N/A	59.8% in last month.	At least daily sex for money: 50.5%.	Problem drinking: 55.7%.	MG: 14%.
Vielot, <sup>55</sup> 2015	Author††	Kenya (Nairobi)	2009	Prospective cohort.	Compare the duration of high risk HPV infection among FSWs by exposure to STIs, using a highly sensitive biomarker assay.	FSWs.	350	28	LARC: 15.5%. Permanent: 2.1%.	Most of the time/always: 73.8% with clients. 24.6% with non-paying partners.	10 partners per week.	N/A.	HIV: 24.0%. CT: 3.8%. GN: 2.3%. TV: 7.3%. MG: 12.8%.

†Median unless specified.

‡Any=modern contraceptive method including condoms, unless specified; LARC=long-acting reversible contraception (implants or IUDs); Permanent=any method of permanent contraception, for example, tubal ligation or hysterectomy. §Always uses condoms (unless specified).

¶Median number per week unless specified. Sex partners may be paying, non-paying, regular or casual, unless specified.

††'Author' indicates additional data were obtained from the author. Other references listed here reported on the same study and were used for data extraction.

‡‡Reported results segregated by sub-group; data presented here are overall estimates.

§§Not disaggregated by sex work status.

|||Bacterial vaginosis; CT, *Chlamydia trachomatis*; FSW, female sex worker; HSV2, herpes simplex virus type 2; MG, *Mycoplasma genitalium*; N/A, not measured or reported, data not available from author; NG, *Neisseria gonorrhoeae*; RCT, randomised controlled trial; STI, sexually transmitted infection; TP, *Treponema pallidum* (syphilis); TV, *Trichomonas vaginalis*.



two-thirds of the sample.<sup>32 40 49 52</sup> Fourteen studies were restricted to women without HIV at baseline, and one study to women living with HIV.<sup>37</sup>

Most studies (n=15) were conducted for 1–2 years, although they ranged from a 1 month pilot RCT<sup>40</sup> to a 15-year open cohort study.<sup>37</sup> The studies reporting pregnancy (intention undefined) tended to be of longer duration than those reporting unintended pregnancy (median duration 24 and 12 months, respectively; [table 2](#)).

### Baseline population characteristics

Most study populations had a median of 5–8 years of education, and the majority of women were supporting at least one financial dependent (data not shown). Median duration in sex work was 3–5 years for most study populations, with one notable exception of 14 years in a study in Mexico.<sup>43</sup> Concurrent non-paying sex partners were common, reported by 30%–100% of women in 12 studies.

Permanent and long-acting reversible contraceptive use was around 1% in most studies in Africa, with only one study in Kenya reporting significantly higher coverage (17.5%).<sup>50</sup> By contrast, coverage of these methods was greater than 30% in China<sup>53</sup> and Mexico.<sup>43 54</sup> Consistent condom use was measured using diverse metrics but was generally low and very low with non-paying partners. Most studies reported frequent sex with multiple partners, and few reported a median of less than five partners per week.<sup>37 45 52 55</sup> High rates of gender-based violence were noted in all studies in which this was measured, as well as physical or financial pressure not to use condoms.<sup>40 56</sup>

While the factors described generally contributed to high baseline pregnancy risk, several studies included FSW with notably lower risk profiles. For example, two studies were part of a large Kenyan open cohort, in which participants had few partners and sex acts per work, and older median age and lower STI prevalence than the other studies.<sup>37 45</sup> In addition, a number of studies provided insufficient information to assess population risk for pregnancy.

HIV prevalence was reported in four studies and varied from 24 % in Kenya<sup>50</sup> to less than 3 % in Mexico<sup>54</sup> and Dominican Republic.<sup>41</sup> STIs other than HIV were prevalent, with one study reporting up to 36% of the study population having at least one STI on biological testing.<sup>35 57</sup>

### Methodology and quality assessment

Quality scores, as percentages of the available total, are presented in [table 2](#). The median quality score was 40% (IQR=36%–50%). Four studies scored 60% or greater; three of these measured unintended pregnancy<sup>32–34</sup> and one measured pregnancy (undefined).<sup>53</sup> Most studies scored poorly in the external validity and selection bias categories.

Measurement bias was an issue for some studies. Pregnancy was tested regularly in all but one<sup>44</sup> of the unintended pregnancy studies; in contrast, five pregnancy

(undefined) studies only measured it if suspected by the clinician or participant. Five of the pregnancy (undefined) studies measured pregnancy using self-report rather than a biological test.

### Incidence of pregnancy

Incidence rate was reported by 14 studies and calculated for the remainder based on the available data, with the number of women who became pregnant as the numerator and person-years as the denominator. Women were censored at the time they became pregnant. The one exception was Deschamps *et al.*,<sup>33</sup> who counted multiple pregnancies and subtracted pregnancy time from total person-time.

Unintended pregnancy incidence rate (outcome 1) varied widely between studies, ranging from 7.2 to 59.6 pregnancies per 100 person-years ([table 2](#); [figure 2](#)). The median rate of the 10 studies was 26.8, and seven reported a rate of greater than 20 per 100 person-years.

Incidence rate of pregnancy (intention undefined – outcome 2) also varied widely, but rates were lower overall than unintended pregnancy, ranging from 2.0 to 23.4 per 100 person-years ([table 2](#)). The median rate of the 15 studies was 13.5, and only two reported a rate of greater than 20 per 100 person-years.

### Meta-analyses

Random effects meta-analyses were performed for the two primary outcomes. Heterogeneity was high, with  $I^2$  statistic over 95% for both outcomes.

### Incidence of unintended pregnancy

Explored covariates that may explain the high heterogeneity of unintended pregnancy incidence showed that geographical region did not explain this, whereas presence/absence of an intervention seemed important. The three cohort studies that did not involve an intervention had very low heterogeneity ( $I^2=0\%$ ), and the pooled estimate for these studies was 27.1 unintended pregnancies per 100 person-years (95% CI 24.4 to 29.8; [figure 3](#)). These three studies scored at least 60% on quality assessment ([table 2](#)).

Assessment of potential methodological explanations showed that study design (RCT vs cohort) and study duration seemed important sources of heterogeneity, while pregnancy measurement method did not explain the high heterogeneity. The cohort studies were more homogenous than the RCTs ( $I^2=63.9\%$  and  $96.8\%$  respectively), and had higher pooled incidence of unintended pregnancy ([figure 4](#)). The three studies of less than 1 year duration were more homogenous ( $I^2=59.1\%$ ) and had higher incidence (44.5 per 100 person-years) than longer studies ([figure 5](#)).

Quality was not found to be a source of heterogeneity, as no relationship was demonstrated between study quality score and unintended pregnancy incidence rate (Pearson correlation coefficient 0.01; scatter plot not shown).



## Open access

**Table 2** Results of included studies reporting unintended pregnancy and pregnancy (intention undefined) in ascending order of incidence

Study	Incidence rate (per 100 person-years)	95% CI	Person-years of exposure	Duration (months)	Measurement of pregnancy	Frequency of measurement	Quality (%)
Unintended pregnancy							
McClelland <i>et al</i> <sup>77</sup>	7.2	4.5 to 10.9	305.4	12	Urine test	Monthly	40
Watson-Jones <i>et al</i> <sup>44</sup>	11.8	9.7 to 14.5	796	30	Urine test	Quarterly on suspicion only	53
Gaffoor <i>et al</i> <sup>42</sup>	13.4	6.1 to 25.4	67.2	24	Urine test	Quarterly	20
Behets <i>et al</i> <sup>40</sup>	20.7	4.3 to 60.5	14.5	1	Urine test	Weekly	27
Braunstein <i>et al</i> <sup>32</sup>	26.3	21.9 to 30.7	528.5	24	Serum test	6 monthly for 1 year+1 measurement in second year	60
Deschamps <i>et al</i> <sup>33</sup>	27.3	23.3 to 31.7	615.6	18	Test (unspecified)	6 monthly	67
Chersich <i>et al</i> <sup>34</sup>	28.0	22.6 to 34.3	335.8	12	Urine test	Quarterly	60
Peterson <i>et al</i> <sup>46</sup>	51.7	44.9 to 59.3	400	12	Urine test	Monthly	40
Behets <i>et al</i> <sup>39</sup>	53.0	21.0 to 110.0	13.2	2	Urine test	Monthly	40
Lara <i>et al</i> <sup>41</sup>	59.6	41.7 to 82.5	60.4	4	Urine test	Monthly	40
Pregnancy (intention undefined)							
Robb <i>et al</i> <sup>51</sup>	2.0	1.4 to 2.9	1619.6	24	Self-report	Quarterly on suspicion only	21
McClelland <i>et al</i> <sup>37</sup>	2.7	2.1 to 3.5	2259.3	15-year open cohort *	Urine test	Monthly on suspicion only	21
Bazzi <i>et al</i> <sup>54</sup>	3.3	1.4 to 5.2	359.6	24	Self-report	6 monthly	43
Strathdee <i>et al</i> <sup>43</sup>	5.9	4.1 to 8.4	540.1	12	Self-report	4 monthly	36
van Loggerenberg <i>et al</i> <sup>52</sup>	8.5	5.6 to 11.5	376.5	24	Urine test	Monthly on suspicion only	36
Van Damme <i>et al</i> <sup>48</sup>	8.6	6.7 to 10.8	837.5	≤24*	Urine test	Quarterly	29
Vielot <i>et al</i> <sup>50</sup>	12.6	9.7 to 16.1	500.8	24	Urine test	Quarterly on suspicion only	50
Kaul <i>et al</i> <sup>47</sup>	13.5	11.3 to 16.1	968.0	≤48*	N/A	N/A	21
Priddy <i>et al</i> <sup>56</sup>	14.2	7.6 to 24.3	91.5	6	Urine test	Quarterly	36
Price <i>et al</i> <sup>49</sup>	14.5	12.0 to 17.5	784.0	48	Urine test	Quarterly	43
Liu <i>et al</i> <sup>53</sup>	15.2	10.4 to 21.5	210.3	6	Self-report	Quarterly	71
Kaewkungwal <i>et al</i> <sup>36</sup>	15.8	13.0 to 19.0	721.0†	42	Urine test	N/A	43

Continued

Table 2 Continued

Study	Incidence rate (per 100 person-years)	95% CI	Person-years of exposure	Duration (months)	Measurement of pregnancy	Frequency of measurement	Quality (%)
Vandepitte <i>et al</i> <sup>93</sup>	18.3	16.2 to 20.6	1467.0	≥24*	Urine test	N/A	50
Page <i>et al</i> <sup>38</sup>	22.0	16.3 to 30.1	186.4	12	Self-report	Quarterly	50
Feldblum <i>et al</i> <sup>35</sup>	23.4	20.6 to 26.5	1067.5	18	Urine test	6 monthly on suspicion only	43

\*Duration varied for different participants.

†Person-time estimated by:  $(n_{\text{FSWs}} \times \text{yrs} \times \text{retention}) - (n_{\text{preg}} \times \text{yrs}/2)$ ; where:  $n_{\text{FSWs}}$ , number of FSWs enrolled; yrs, study duration in years; retention, retention rate;  $n_{\text{preg}}$ , number of women who became pregnant. We could not use the approach advocated by Vandembroucke *et al*<sup>95</sup> as average follow-up time among FSWs was not known.

FSWs, female sex workers; N/A, not measured or reported, data not available from author.

### Incidence of pregnancy (intention undefined)

Subgroup analyses showed that study duration and geographic region were sources of heterogeneity for rates of pregnancy where intention was not known. Pregnancy measurement method and study design characteristics did not account for any heterogeneity for this outcome.

There were only two studies of less than 1-year duration<sup>53 56</sup> ( $I^2$  0%). As with the unintended pregnancy outcome, these studies had a higher pooled incidence than studies of more than 1 year duration (14.9 vs 11.4 per 100 person-years).

A subanalysis of geographic region showed that studies from Asia and the Americas (both in Mexico) were more homogenous ( $I^2$ =29.8% and 68.1%, respectively) than those from sub-Saharan Africa ( $I^2$ =98.3%). The pooled incidence of pregnancy was higher in Asia (16.8 per 100

person-years) and lower in Mexico (4.8 per 100 person-years; figure 6).

A scatter plot demonstrated a weak positive relationship between quality score and incidence rate (plot not shown; Pearson correlation coefficient 0.55).

### Secondary outcomes

Three studies assessed pregnancy outcomes for FSWs (table 3). In two of the studies, outcomes were unknown for about 25% of pregnancies (in the Caribbean<sup>33</sup> and Madagascar,<sup>35</sup>) resulting in underestimates of birth and abortion incidence. Abortion accounted for less than 20% of pregnancies with known outcomes. In contrast, in the third study, a multicountry study,<sup>48</sup> 62 abortions were recorded as adverse events (author correspondence), compared with only 10 reported as withdrawing from the

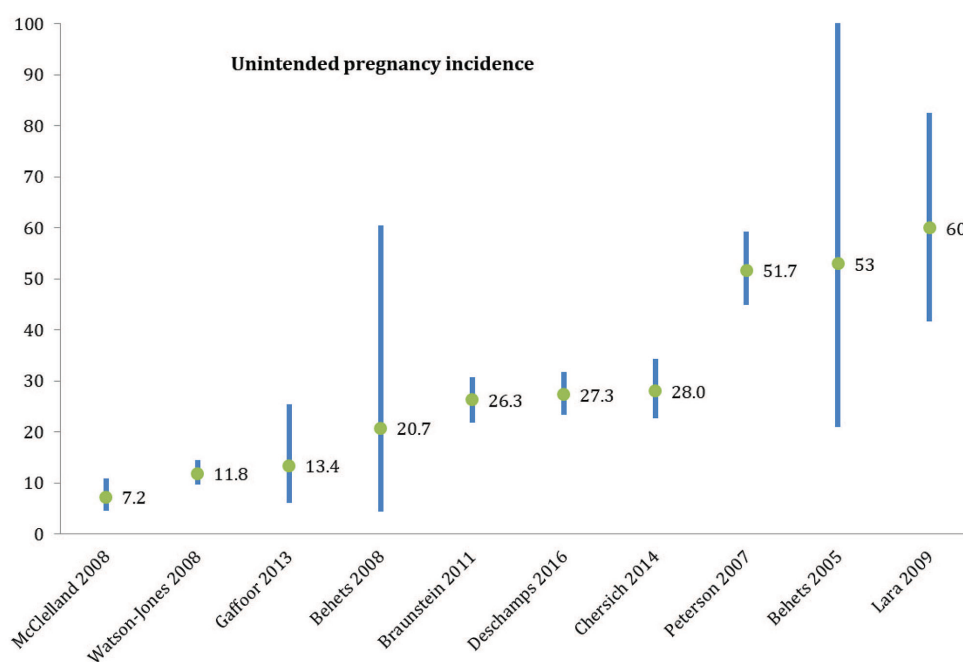
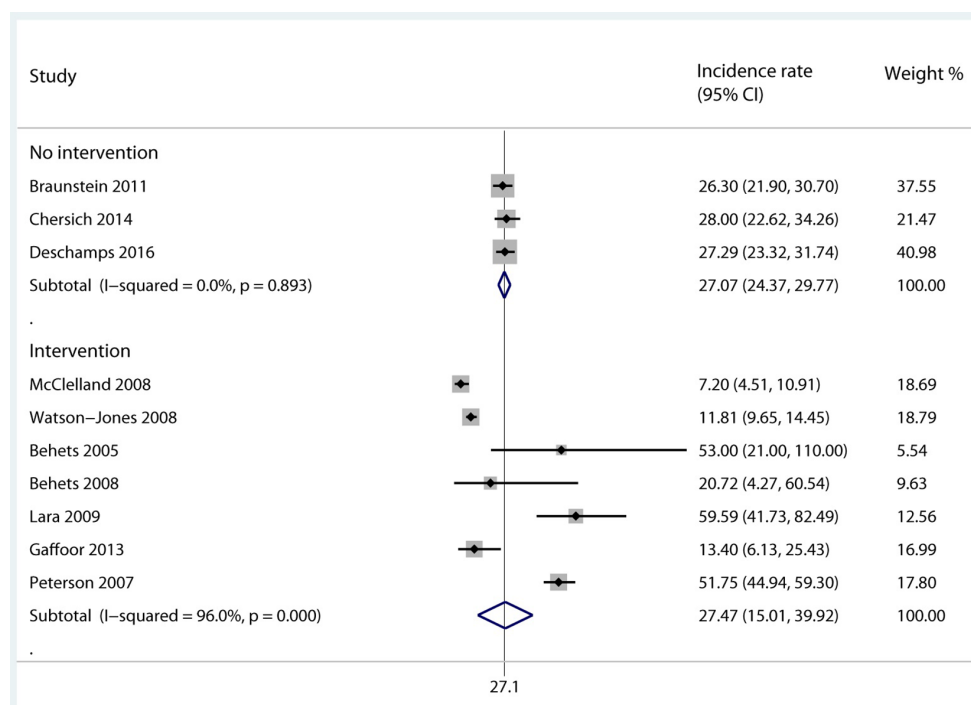


Figure 2 Incidence rates (per 100 person-years) for studies reporting unintended pregnancy.

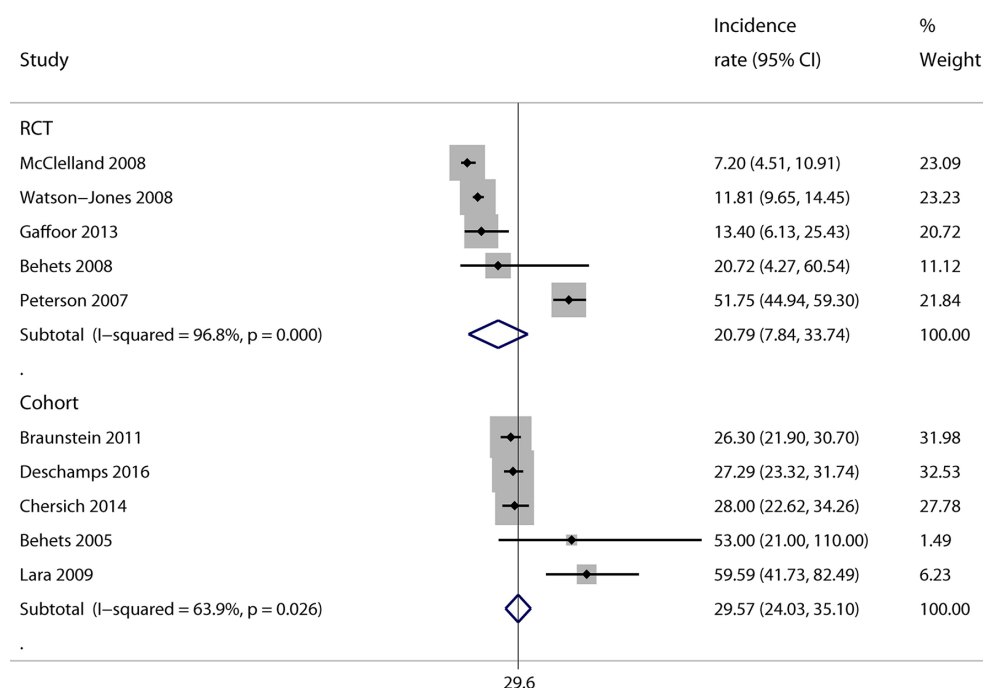


**Figure 3** Forest plot showing subgroup analysis of unintended pregnancy incidence rates (per 100 person-years) by intervention versus no intervention.

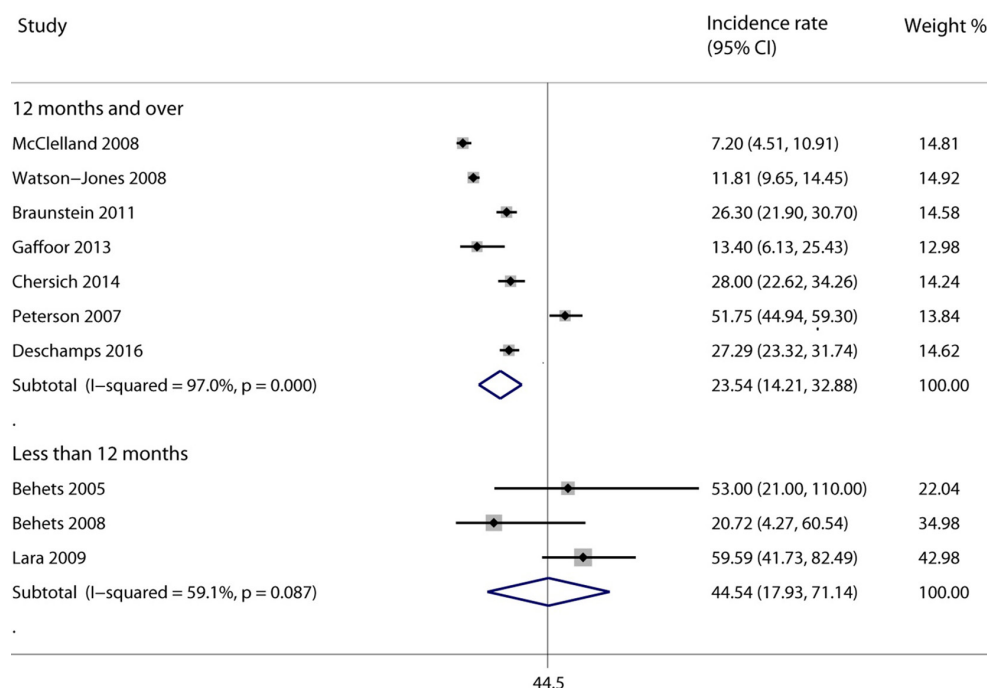
study due to pregnancy, suggesting that over 85% of the total women who became pregnant reported an abortion.

Four studies developed multivariate regression models to determine the predictors of pregnancy<sup>35 37</sup> or unintended pregnancy.<sup>5 33</sup> Common findings were that

younger age was associated with higher pregnancy incidence<sup>5 33 35</sup> and that highly effective contraceptive use<sup>35</sup> and consistent condom use<sup>35 37</sup> were protective; however, one study in Kenya found that using condoms at the exclusion of other methods was a risk factor.<sup>5</sup> Having a



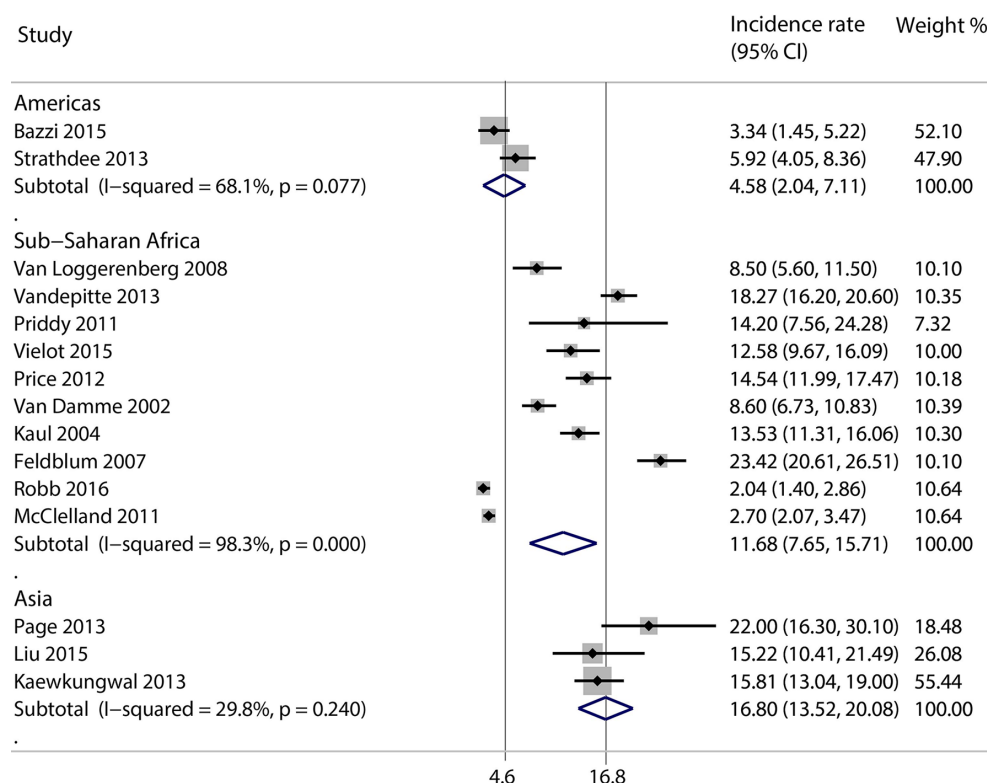
**Figure 4** Forest plot showing subgroup analysis of unintended pregnancy incidence rates (per 100 person-years) by RCT versus cohort study design. RCT, randomised controlled study.



**Figure 5** Forest plot showing subgroup analysis of unintended pregnancy incidence rates (per 100 person-years) by study duration (cut-off 1 year).

main or emotional partner increased the odds of unintended pregnancy<sup>5 33</sup> but not of pregnancy (intention undefined).<sup>35 37</sup> Deschamps *et al* noted some additional

associations, including recreational drug use and male partners having other sex partners being protective against pregnancy. Only one study assessed reproductive



**Figure 6** Forest plot showing subgroup analysis of pregnancy (intention undefined) incidence rates (per 100 person-years) by geographic region.

**Table 3** Incidence of abortion and birth

Study	Site	Outcome	Incidence of pregnancy	Incidence of birth	Incidence of abortion	Abortion (as proportion of pregnancies with known outcome)
Deschamps <i>et al</i> <sup>33</sup>	Haiti, Puerto Rico and Dominican Republic	Unintended pregnancy	27.3	15.1	3.1	16%
Feldblum <i>et al</i> <sup>35</sup>	Madagascar	Pregnancy (intention undefined)	23.4	11.9	3.0	17%
Van Damme <i>et al</i> <sup>48</sup>	Benin, Cote d'Ivoire, South Africa and Thailand	Pregnancy (intention undefined)	8.6	Not measured	7.4	>85%

history and income,<sup>5</sup> and none considered HIV status as potential predictors or confounders.

## DISCUSSION

This review found that of the many studies examining FSWs' sexual and reproductive health in LMICs, very few have measured pregnancy and even fewer have assessed pregnancy intention. While incidence varies widely between the included studies, it is sufficiently high in most low-income and middle-income contexts to constitute a significant health and social issue for FSWs.

Study design impacted on unintended pregnancy rates, with a lower rate seen in RCTs (20.8 per 100 person-years) than cohort studies (29.6 per 100 person-years). Most of the RCTs in this review required women to remain non-pregnant for continuation<sup>36 40 42 44–48</sup> and although only six RCTs specifically mentioned providing contraceptive counselling or methods, others may have offered a larger package of services that was not reported.

To better understand the influence of services provided by studies, we compared studies that provided any intervention with those that did not and found that the three studies in the latter category had very low heterogeneity and high pooled unintended pregnancy incidence (27 per 100 person-years). As non-intervention cohort studies with quality scores of at least 60%, these were arguably the best designed to answer the review question.

The included studies may have underestimated population incidence of pregnancy, for several reasons. First, studies that only tested for pregnancy on suspicion could have missed early pregnancies or failed to ascertain the need to test. Second, pregnancies occurring between study visits and ending in spontaneous or induced abortion may have been missed. Third, social desirability bias is likely to influence self-reporting of pregnancy in studies using that measure. Fourth, participants may have joined some studies in order to access services, potentially receiving superior family planning services than would otherwise be accessible.<sup>58</sup> Finally, there may be selective loss to follow-up among women who become pregnant, particularly in drug trials requiring women

to remain non-pregnant for continuation.<sup>36 40 42 44–48</sup> It is possible that these factors were more prominent in the studies measuring pregnancy without defining intention, contributing to the surprising finding that this outcome had generally lower incidence rates than unintended pregnancy.

Some 'unintended' pregnancies may in fact have been intended, because women may have been unsure about their intention or it changed over time.<sup>27</sup> Only one study assessed intention repeatedly,<sup>34</sup> and none used a validated instrument designed to measure this complex latent construct.<sup>59</sup> Some participants may have wanted a pregnancy but felt pressure to say otherwise, depending on the social environment, external and internal stigma and the study design, for example, if they wanted to access HIV prevention and other services through the study but inclusion was restricted to those not wanting to get pregnant.

Conversely, it is likely that most women in the undefined intention category (outcome 2) who became pregnant may not have intended to do so. During recruitment for a pregnancy prevention intervention trial with FSWs in Kenya,<sup>6</sup> less than 1% of those interested in taking part were planning to get pregnant in the next year (unpublished data). Similarly, in a cohort study included in this review, only 4% of participants expressed an intention to get pregnant at some point during the 12-month follow-up.<sup>5 34</sup> A study in South Africa found a higher proportion (10%) wishing to conceive, but this is still a small minority of FSWs. While immediate pregnancy intentions may be low, however, future fertility preferences may be comparable with other women,<sup>60</sup> and several authors have highlighted the need for appropriate services that promote safe conception and address FSWs' need for different forms of protection with different partners.<sup>22–24 60</sup>

Quality scores were low, but it is important to note that we were assessing how well the studies answered *our* research question, rather than their own stated objectives. However, there was a notable absence of well-described sampling and recruitment techniques, suggesting that



study populations may have been poorly representative of local FSW populations. This may have underestimated pregnancy incidence, as more marginalised members of the population, who are at greater sexual risk, are harder to reach and recruit by convenience or snowball methods. Indeed, the only study to use a random sampling approach found moderately high incidence of pregnancy (intention undefined; 15 per 100 person-years), despite 30% IUD coverage in this population.<sup>53</sup> Furthermore, inclusion criteria limiting more than half of the studies to HIV negative women contributed to selection bias, particularly in sub-Saharan African studies, where HIV prevalence among FSWs is estimated at 37%.<sup>61</sup> This may partly explain the observation that pregnancy incidence in sub-Saharan Africa was lower than Asia, despite the fact that total population fertility rates are lower in Asia. Higher quality scores seen in the Asian studies may also account for this discrepancy.

Quantitative analysis identified study duration as a clear contributor to heterogeneity in both outcomes. Incidence was lower in shorter studies and decreased over time within studies that reported incidence at multiple time points.<sup>32 35</sup> This is due in part to the analytical approach, taken by all but one study,<sup>33</sup> of censoring women's person-time when they first become pregnant. As study subjects at highest risk fall pregnant early, they are censored early and cannot contribute additional pregnancies to the numerator. The remaining lower risk women are less likely to experience the outcome. The same phenomenon has been observed in closed cohorts with the outcome of HIV incidence.<sup>62</sup> In addition, sexual risk behaviours often reduce over time in longitudinal studies, because of social desirability bias or health education from study participation,<sup>33 36</sup> or attrition bias,<sup>63</sup> which may have been a factor for 12 studies in this review with low or unreported retention rates among FSWs.

While measurement bias did not emerge as a significant source of heterogeneity, there was ambiguity in the reporting of pregnancy measurement, and it was often dependent on authors' recollections. There was a weak positive association between study quality and incidence rates in the pregnancy (intention undefined) group. The lack of a clear relationship may be because quality issues can result in either an underestimate or overestimate of incidence.

### Limitations

This review had a number of limitations. Foremost was the inclusion of studies in which (unintended) pregnancy incidence was not an *a priori* objective, which was the case for all but one. This likely resulted in methodological issues affecting participant selection and pregnancy measurement.

We also adopted a broad approach to other inclusion criteria. Several studies conducted in the late 1990s and early 2000s were included, which may be problematic as family planning coverage has grown and fertility rates declined since that time. The heavy reliance on authors

to provide unreported data was a limitation and may have introduced bias, and older data often could not be accessed.

We used a broad definition of sex work, which may have increased the heterogeneity of the outcomes. However, this definition reflects the reality that there are many reasons for women to sell sex, which depend on local laws, culture and economies, and to arbitrarily limit to full-time sex workers, for example, may exclude studies of 'hidden' FSWs who are often especially vulnerable.<sup>64 65</sup>

Our analysis was limited by high heterogeneity, which prevented us from pooling overall rates or performing meta-regression to tease out the influence of different variables. Heterogeneity was not fully explained by explorative subanalyses and may in part be due to the low number of studies, low quality and incomplete data on risk factors. It should be noted that interpretation of these descriptive heterogeneity statistics require a certain level of caution, specifically where the number of cases is small. Variations in baseline population risk probably contributed significantly to heterogeneity, but these could not be quantified due to the incomplete and/or inconsistent measurement of risk factors between studies. Cultural, legal and economic contexts, such as cultural norms around motherhood and abortion law, also vary considerably between the different settings in which the studies took place, and influence fertility preferences, expression of pregnancy intention and access to prevention methods and abortion. These contextual factors could not be accounted for in our analysis.

Another limitation was that we were unable to directly compare rates of pregnancy between FSWs and other populations. Very high pregnancy incidence has been observed in HIV studies among women not categorised as sex workers<sup>66 67</sup>; however, these women were at high risk for HIV for other reasons (eg, multiple partners). Among the general population, unintended pregnancy incidence is estimated at 5.4 per 100 person-years in the developing world, and eight in Africa,<sup>68</sup> substantially lower than the rates among FSWs presented here. Of the three studies in this review, which reported incidence for a broader study population as well as an FSW subgroup, two reported higher incidence<sup>36 42</sup> and one reported approximately equal incidence<sup>44</sup> in the FSW subgroup compared with the whole study population.

### CONCLUSION

Ultimately, this review demonstrates a concerning lack of research on an issue which is a priority for many FSWs in low-resource settings. This is surprising as we found many studies on HIV incidence and prevention in this population, for which unintended pregnancy is both relevant to the primary outcome and may indicate overall sexual risk. There has been

## Open access

a modest increase in family planning availability for women in many countries since the early 2000s<sup>69 70</sup>; however, this has not been accompanied by research on whether these additional services have reached FSW populations or impacted on pregnancy rates. Access to family planning, particularly long-acting reversible contraceptives, may be improved by better targeting of FSWs through mobile outreach<sup>71</sup> and integration with existing FSW-specific HIV prevention services, and by careful training of health workers and community workers in contraceptive counselling and follow-up.<sup>71</sup> Also, it is important that concerted efforts are made to link FSWs who become pregnant with maternal health services, including services for antiretroviral treatment and preventing HIV transmission to infants.

This review found that studies measuring pregnancy incidence among FSWs were of low overall methodological quality and had highly varied results but that unintended pregnancy incidence was high overall and, based on available data, higher than the general population. There is an urgent need for quality research on unintended pregnancy incidence, the effectiveness of interventions to reduce it and the best models of reproductive health service provision for this large and stigmatised population.

## Author affiliations

<sup>1</sup>Burnet Institute, Melbourne, Victoria, Australia

<sup>2</sup>Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia

<sup>3</sup>Judith Lumley Centre, La Trobe University, Melbourne, Victoria, Australia

<sup>4</sup>Faculty of Health Sciences, Wits Reproductive Health and HIV Institute, University of the Witwatersrand, Johannesburg, South Africa

<sup>5</sup>Department of Obstetrics and Gynaecology, International Centre for Reproductive Health, Universiteit Gent, Ghent, Belgium

<sup>6</sup>Melbourne School of Global and Population Health, University of Melbourne, Melbourne, Victoria, Australia

**Acknowledgements** We would like to acknowledge the many study authors who responded to our queries, in particular the following who provided additional data (in alphabetical order): Daniela Abramovitz, Kathy Baisley, Frieda Behets, Liviana Calzavara, Putu Duff, Paul Feldblum, James Iveniuk, Rupert Kaul, Diana Lara, Qun Li, Kate MacQueen, R. Scott McClelland, Mark Milazzo, Kimberly Page, Matt Price, Barbra Richardson, Merlin L. Robb, Steffanie Strathdee, Douglas Taylor, Abigail Norris Turner, Lut Van Damme, Francois Van Loggelenberg, Judith Vandepitte, Nadja Alexandra Vielot, Handan Wand, Deborah Watson-Jones and Helen Weiss. We would also like to thank senior librarian Lorena Romero at the Ian Potter library, who assisted with building the search strategy, and Professor Rory Wolfe, who provided additional statistical advice.

**Contributors** FHA, SL and MSCL conceived of and designed the study. All authors contributed to the protocol. FHA performed the search, screening, data extraction and analysis and drafted the manuscript. MC advised on search strategy. LW performed duplicate screening and extraction. PAA advised on analytical methods. All authors reviewed drafts and approved the final manuscript.

**Funding** This work was supported by the Australian National Health and Medical Research Council, which provided funding for the study (Project Grant GNT 1087006), a Career Development Fellowship for SL and a Postgraduate Scholarship for FHA.

**Competing interests** None declared.

**Patient consent** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** There are no additional data available.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

## REFERENCES

1. Singh S, Darroch JE, Ashford LS. *Adding it up: the costs and benefits of investing in sexual and reproductive health*. New York: Guttmacher Institute, 2014.
2. Hall JA, Benton L, Copas A, *et al*. Pregnancy intention and pregnancy outcome: systematic review and meta-analysis. *Matern Child Health J* 2017;21:670–704.
3. Gipson JD, Koenig MA, Hindin MJ. The effects of unintended pregnancy on infant, child, and parental health: a review of the literature. *Stud Fam Plann* 2008;39:18–38.
4. Khan MR, Turner AN, Pettifor A, *et al*. Unmet need for contraception among sex workers in Madagascar. *Contraception* 2009;79:221–7.
5. Luchters S, Bosire W, Feng A, *et al*. "A Baby was an added burden": predictors and consequences of unintended pregnancies for female sex workers in mombasa, kenya: a mixed-methods study. *PLoS One* 2016;11:e0162871.
6. Ampt FH, Mudogo C, Gichangi P, *et al*. WHISPER or SHOUT study: protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017;7:e017388.
7. Morineau G, Neilsen G, Heng S, *et al*. Falling through the cracks: contraceptive needs of female sex workers in Cambodia and Laos. *Contraception* 2011;84:194–8.
8. Scorgie F, Chersich MF, Ntaganira I, *et al*. Socio-demographic characteristics and behavioral risk factors of female sex workers in sub-saharan Africa: a systematic review. *AIDS Behav* 2012;16:920–33.
9. Okal J, Stadler J, Ombidi W, *et al*. Secrecy, disclosure and accidental discovery: perspectives of diaphragm users in Mombasa, Kenya. *Cult Health Sex* 2008;10:13–26.
10. Okal J, Chersich MF, Tsui S, *et al*. Sexual and physical violence against female sex workers in Kenya: a qualitative enquiry. *AIDS Care* 2011;23:612–8.
11. Erickson M, Goldenberg SM, Ajok M, *et al*. Structural determinants of dual contraceptive use among female sex workers in Gulu, northern Uganda. *Int J Gynaecol Obstet* 2015;131:91–5.
12. Yam EA, Okal J, Musyoki H, *et al*. Kenyan female sex workers' use of female-controlled nonbarrier modern contraception: do they use condoms less consistently? *Contraception* 2016;93:222–5.
13. Maher L, Mooney-Somers J, Phlong P, *et al*. Condom negotiation across different relationship types by young women engaged in sex work in Phnom Penh, Cambodia. *Glob Public Health* 2013;8:270–83.
14. Chow EP, Muessig KE, Yuan L, *et al*. Risk behaviours among female sex workers in China: a systematic review and data synthesis. *PLoS One* 2015;10:e0120595.
15. Lim MS, Zhang XD, Kennedy E, *et al*. Sexual and reproductive health knowledge, contraception uptake, and factors associated with unmet need for modern contraception among adolescent female sex workers in China. *PLoS One* 2015;10:e0115435.
16. Williamson LM, Parkes A, Wight D, *et al*. Limits to modern contraceptive use among young women in developing countries: a systematic review of qualitative research. *Reprod Health* 2009;6:3.
17. Dhana A, Luchters S, Moore L, *et al*. Systematic review of facility-based sexual and reproductive health services for female sex workers in Africa. *Global Health* 2014;10:46.
18. Moore L, Chersich MF, Steen R, *et al*. Community empowerment and involvement of female sex workers in targeted sexual and reproductive health interventions in Africa: a systematic review. *Global Health* 2014;10:47.
19. Slabbert M, Venter F, Gay C, *et al*. Sexual and reproductive health outcomes among female sex workers in Johannesburg and Pretoria, South Africa: Recommendations for public health programmes. *BMC Public Health* 2017;17:442.
20. Scorgie F, Nakato D, Harper E, *et al*. 'We are despised in the hospitals': sex workers' experiences of accessing health care in four African countries. *Cult Health Sex* 2013;15:450–65.
21. Mtetwa S, Busza J, Chidiya S, *et al*. "You are wasting our drugs": health service barriers to HIV treatment for sex workers in Zimbabwe. *BMC Public Health* 2013;13:698.



22. Beckham SW, Shembilu CR, Brahmabhatt H, *et al.* Female sex workers' experiences with intended pregnancy and antenatal care services in southern Tanzania. *Stud Fam Plann* 2015;46:55–71.
23. Center for Health and Gender Equity. *All women, all rights, sex workers included*. Washington, DC: CHANGE, 2016.
24. Duff P, Shoveller J, Feng C, *et al.* Pregnancy intentions among female sex workers: recognising their rights and wants as mothers. *J Fam Plann Reprod Health Care* 2015;41:102–8.
25. Kendall T, Albert C. Experiences of coercion to sterilize and forced sterilization among women living with HIV in Latin America. *J Int AIDS Soc* 2015;18:19462.
26. Zampas C, Lamačková A. Forced and coerced sterilization of women in Europe. *Int J Gynaecol Obstet* 2011;114:163–6.
27. Aiken AR, Borrero S, Callegari LS, *et al.* Rethinking the pregnancy planning paradigm: unintended conceptions or unrepresentative concepts? *Perspect Sex Reprod Health* 2016;48:147–51.
28. Moher D, Liberati A, Tetzlaff J, *et al.* Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *BMJ* 2009;339:b2535.
29. The World Bank Group. World bank country and lending groups. 2016 <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519> (accessed 10 Jan 2016).
30. Santelli J, Rochat R, Hatfield-Timajchy K, *et al.* The measurement and meaning of unintended pregnancy. *Perspect Sex Reprod Health* 2003;35:94–101.
31. Munn Z, Moola S, Riitano D, *et al.* The development of a critical appraisal tool for use in systematic reviews addressing questions of prevalence. *Int J Health Policy Manag* 2014;3:123–8.
32. Braunstein SL, Ingabire CM, Kestelyn E, *et al.* High human immunodeficiency virus incidence in a cohort of Rwandan female sex workers. *Sex Transm Dis* 2011;38:385–94.
33. Deschamps MM, Metch B, Morgan CA, *et al.* Feasibility of identifying a female sex worker cohort at high risk of HIV infection in the Caribbean for HIV vaccine efficacy trials: longitudinal results of HVTN 907. *J Acquir Immune Defic Syndr* 2016;71:70–7.
34. Chersich MF, Bosire W, King'ola N, *et al.* Effects of hazardous and harmful alcohol use on HIV incidence and sexual behaviour: a cohort study of Kenyan female sex workers. *Global Health* 2014;10:22.
35. Feldblum PJ, Nasution MD, Hoke TH, *et al.* Pregnancy among sex workers participating in a condom intervention trial highlights the need for dual protection. *Contraception* 2007;76:105–10.
36. Kaewkungwal J, Pitisuttithum P, Rerks-Ngarm S, *et al.* Issues in women's participation in a phase III community HIV vaccine trial in Thailand. *AIDS Res Hum Retroviruses* 2013;29:1524–34.
37. McClelland RS, Richardson BA, Wanje GH, *et al.* Association between participant self-report and biological outcomes used to measure sexual risk behavior in human immunodeficiency virus-1-seropositive female sex workers in Mombasa, Kenya. *Sex Transm Dis* 2011;38:429–33.
38. Page K, Stein E, Sansothly N, *et al.* Sex work and HIV in Cambodia: trajectories of risk and disease in two cohorts of high-risk young women in Phnom Penh, Cambodia. *BMJ Open* 2013;3:e003095.
39. Behets F, Turner AN, Van Damme K, *et al.* Acceptability and feasibility of continuous diaphragm use among sex workers in Madagascar. *Sex Transm Infect* 2005;81:472–6.
40. Behets FM, Turner AN, Van Damme K, *et al.* Vaginal microbicide and diaphragm use for sexually transmitted infection prevention: a randomized acceptability and feasibility study among high-risk women in Madagascar. *Sex Transm Dis* 2008;35:818–26.
41. Lara DK, Grossman DA, Muñoz JE, *et al.* Acceptability and use of the female condom and diaphragm among sex workers in Dominican Republic: results from a prospective study. *AIDS Educ Prev* 2009;21:538–51.
42. Gaffoor Z, Wand H, Daniels B, *et al.* High risk sexual behaviors are associated with sexual violence among a cohort of women in Durban, South Africa. *BMC Res Notes* 2013;6:532.
43. Strathdee SA, Abramovitz D, Lozada R, *et al.* Reductions in HIV/STI incidence and sharing of injection equipment among female sex workers who inject drugs: results from a randomized controlled trial. *PLoS One* 2013;8:e65812.
44. Watson-Jones D, Weiss HA, Rusizoka M, *et al.* Effect of herpes simplex suppression on incidence of HIV among women in Tanzania. *N Engl J Med* 2008;358:358–1560–71.
45. McClelland RS, Richardson BA, Hassan WM, *et al.* Improvement of vaginal health for Kenyan women at risk for acquisition of human immunodeficiency virus type 1: results of a randomized trial. *J Infect Dis* 2008;197:1361–8.
46. Peterson L, Taylor D, Roddy R, *et al.* Tenofovir disoproxil fumarate for prevention of HIV infection in women: a phase 2, double-blind, randomized, placebo-controlled trial. *PLoS Clin Trials* 2007;2:e27.
47. Kaul R, Kimani J, Nagelkerke NJ, *et al.* Monthly antibiotic chemoprophylaxis and incidence of sexually transmitted infections and HIV-1 infection in Kenyan sex workers: a randomized controlled trial. *JAMA* 2004;291:2555–62.
48. Van Damme L, Ramjee G, Alary M, *et al.* Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomised controlled trial. *Lancet* 2002;360:971–7.
49. Price MA, Rida W, Mwangome M, *et al.* Identifying at-risk populations in Kenya and South Africa: HIV incidence in cohorts of men who report sex with men, sex workers, and youth. *J Acquir Immune Defic Syndr* 2012;59:185–93.
50. Vielot N, Huddgens MG, Mugo N, *et al.* The role of chlamydia trachomatis in high-risk human papillomavirus persistence among female sex workers in Nairobi, Kenya. *Sex Transm Dis* 2015;42:305–11.
51. Robb ML, Eller LA, Kibuuka H, *et al.* Prospective study of acute HIV-1 infection in adults in East Africa and Thailand. *N Engl J Med* 2016;374:2120–30.
52. van Loggerenberg F, Mlisana K, Williamson C, *et al.* Establishing a cohort at high risk of HIV infection in South Africa: challenges and experiences of the CAPRISA 002 acute infection study. *PLoS One* 2008;3:e1954.
53. Liu J, Calzavara L, Mendelsohn JB, *et al.* Impact evaluation of a community-based intervention to reduce risky sexual behaviour among female sex workers in Shanghai, China. *BMC Public Health* 2015;15:147.
54. Bazzi AR, Rangel G, Martinez G, *et al.* Incidence and predictors of HIV and sexually transmitted infections among female sex workers and their intimate male partners in Northern Mexico: a longitudinal, multilevel study. *Am J Epidemiol* 2015;181:723–31.
55. Duff P, Evans JL, Stein ES, *et al.* High pregnancy incidence and low contraceptive use among a prospective cohort of female entertainment and sex workers in Phnom Penh, Cambodia. *BMC Pregnancy Childbirth* 2018;18:128.
56. Priddy FH, Wakasiaka S, Hoang TD, *et al.* Anal sex, vaginal practices, and HIV incidence in female sex workers in urban Kenya: implications for the development of intravaginal HIV prevention methods. *AIDS Res Hum Retroviruses* 2011;27:1067–72.
57. Feldblum PJ, Hatzell T, Van Damme K, *et al.* Results of a randomised trial of male condom promotion among Madagascar sex workers. *Sex Transm Infect* 2005;81:166–73.
58. Stadler J, Scorgie F, van der Straten A, *et al.* Adherence and the Lie in a HIV prevention clinical trial. *Med Anthropol* 2016;35:503–16.
59. Hall J, Barrett G, Mbwana N, *et al.* Understanding pregnancy planning in a low-income country setting: validation of the London measure of unplanned pregnancy in Malawi. *BMC Pregnancy Childbirth* 2013;13:200.
60. Rao A, Baral S, Phaswana-Mafuya N, *et al.* Pregnancy intentions and safer pregnancy knowledge among female sex workers in Port Elizabeth, South Africa. *Obstet Gynecol* 2016;128:15–21.
61. Baral S, Beyrer C, Muessig K, *et al.* Burden of HIV among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *Lancet Infect Dis* 2012;12:538–49.
62. Heyward WL, Osmanov S, Saba J, *et al.* Preparation for phase III HIV vaccine efficacy trials: methods for the determination of HIV incidence. *AIDS* 1994;8:1285–91.
63. Graham SM, Raboud J, McClelland RS, *et al.* Loss to follow-up as a competing risk in an observational study of HIV-1 incidence. *PLoS One* 2013;8:e59480.
64. Hawken MP, Melis RD, Ngombo DT, *et al.* Part time female sex workers in a suburban community in Kenya: a vulnerable hidden population. *Sex Transm Infect* 2002;78:271–3.
65. Manopaiboon C, Prybylski D, Subhachaturas W, *et al.* Unexpectedly high HIV prevalence among female sex workers in Bangkok, Thailand in a respondent-driven sampling survey. *Int J STD AIDS* 2013;24:34–8.
66. MacQueen KM, Johnson L, Alleman P, *et al.* Pregnancy prevention practices among women with multiple partners in an HIV prevention trial. *JAIDS Journal of Acquired Immune Deficiency Syndromes* 2007;PAP:32–8.
67. Halpern V, Lie CC, Feldblum P, *et al.* Predictors of pregnancy in microbicide trials. *Contraception* 2011;83:436–40.
68. Sedgh G, Singh S, Hussain R. Intended and unintended pregnancies worldwide in 2012 and recent trends. *Stud Fam Plann* 2014;45:301–14.
69. Wang W, Wang S, Pullum T, *et al.* How family planning supply and the service environment affect contraceptive use: findings from four East African Countries. *DHS Analytical Studies* 2012:26.
70. Ross J, Smith E. Trends in national family planning programs, 1999, 2004 and 2009. *Int Perspect Sex Reprod Health* 2011;37:125–33.

71. Rees H, Pillay D, Mullick S, *et al.* Strengthening implant provision and acceptance in South Africa with the 'Any woman, any place, any time' approach: An essential step towards reducing unintended pregnancies. *S Afr Med J* 2017;107:939–44.
72. Penman-Aguilar A, Legardy-Williams J, Turner AN, *et al.* Effect of treatment assignment on intravaginal cleansing in a randomized study of the diaphragm with candidate microbicide. *J Womens Health* 2011;20:187–95.
73. Braunstein SL, Ingabire CM, Geubbels E, *et al.* High burden of prevalent and recently acquired HIV among female sex workers and female HIV voluntary testing center clients in Kigali, Rwanda. *PLoS One* 2011;6:e24321.
74. Deschamps MM, Zorrilla CD, Morgan CA, *et al.* Recruitment of Caribbean female commercial sex workers at high risk of HIV infection. *Rev Panam Salud Publica* 2013;34:92–8.
75. Skoler-Karpoft S, Ramjee G, Ahmed K, *et al.* Efficacy of Carraguard for prevention of HIV infection in women in South Africa: a randomised, double-blind, placebo-controlled trial. *Lancet* 2008;372:1977–87.
76. Martin HL, Nyange PM, Richardson BA, *et al.* Hormonal contraception, sexually transmitted diseases, and risk of heterosexual transmission of human immunodeficiency virus type 1. *J Infect Dis* 1998;178:1053–9.
77. McClelland RS, Richardson BA, Graham SM, *et al.* A prospective study of risk factors for bacterial vaginosis in HIV-1-seronegative African women. *Sex Transm Dis* 2008;35:617–23.
78. McClelland RS, Richardson BA, Hassan WM, *et al.* Prospective study of vaginal bacterial flora and other risk factors for vulvovaginal candidiasis. *J Infect Dis* 2009;199:1883–90.
79. Odutola A, Baisley K, Hayes RJ, *et al.* Pregnancy and contraceptive use among women participating in an HIV prevention trial in Tanzania. *Sex Transm Infect* 2012;88:436–43.
80. Syvertsen JL, Robertson AM, Abramovitz D, *et al.* Study protocol for the recruitment of female sex workers and their non-commercial partners into couple-based HIV research. *BMC Public Health* 2012;12:1–16.
81. Couture MC, Sansothy N, Saphon V, *et al.* Young women engaged in sex work in Phnom Penh, Cambodia, have high incidence of HIV and sexually transmitted infections, and amphetamine-type stimulant use: new challenges to HIV prevention and risk. *Sex Transm Dis* 2011;38:33–9.
82. Hoke TH, Feldblum PJ, Van Damme K, *et al.* Temporal trends in sexually transmitted infection prevalence and condom use following introduction of the female condom to Madagascar sex workers. *Int J STD AIDS* 2007;18:461–6.
83. Rerks-Ngarm S, Pitisuttithum P, Nitayaphan S, *et al.* Vaccination with ALVAC and AIDSVAX to prevent HIV-1 infection in Thailand. *N Engl J Med* 2009;361:2209–20.
84. Yadav G, Saskin R, Ngugi E, *et al.* Associations of sexual risk taking among Kenyan female sex workers after enrollment in an HIV-1 prevention trial. *J Acquir Immune Defic Syndr* 2005;38:329–34.
85. Fonck K, Kaul R, Kimani J, *et al.* A randomized, placebo-controlled trial of monthly azithromycin prophylaxis to prevent sexually transmitted infections and HIV-1 in Kenyan sex workers: study design and baseline findings. *Int J STD AIDS* 2000;11:804–11.
86. McClelland RS, Graham SM, Richardson BA, *et al.* Treatment with antiretroviral therapy is not associated with increased sexual risk behavior in Kenyan female sex workers. *AIDS* 2010;24:891–7.
87. Rono K, Sanga E, Sekiziyivu A, *et al.* RV 217: The early capture HIV cohort study (ECHO): a prospective study of acute HIV infection among high risk populations. *AIDS Research and Human Retroviruses* 2010;26:A33.
88. Vera A, Abramovitz D, Lozada R, *et al.* Mujer Mas Segura (Safer Women): a combination prevention intervention to reduce sexual and injection risks among female sex workers who inject drugs. *BMC Public Health* 2012;12:653.
89. Gaines TL, Rudolph AE, Brouwer KC, *et al.* The longitudinal association of venue stability with consistent condom use among female sex workers in two Mexico-USA border cities. *Int J STD AIDS* 2013;24:523–9.
90. Vandebosch A, Goetghebeur E, Ramjee G, *et al.* Acceptability of COL-1492, a vaginal gel, among sex workers in one Asian and three African cities. *Sex Transm Infect* 2004;80:241–3.
91. Ramjee G, Williams B, Gouws E, *et al.* The impact of incident and prevalent herpes simplex virus-2 infection on the incidence of HIV-1 infection among commercial sex workers in South Africa. *J Acquir Immune Defic Syndr* 2005;39:333–9.
92. Naicker N, Kharsany AB, Werner L, *et al.* Risk factors for HIV acquisition in high risk women in a generalised epidemic setting. *AIDS Behav* 2015;19:1305–16.
93. Vandepitte J, Weiss HA, Kyakuwa N, *et al.* Natural history of Mycoplasma genitalium infection in a cohort of female sex workers in Kampala, Uganda. *Sex Transm Dis* 2013;40:422–7.
94. Vandepitte J, Bukkenya J, Weiss HA, *et al.* HIV and other sexually transmitted infections in a cohort of women involved in high-risk sexual behavior in Kampala, Uganda. *Sex Transm Dis* 2011;38:1–23.
95. Vandenbroucke JP, Pearce N. Incidence rates in dynamic populations. *Int J Epidemiol* 2012;41:1472–9.

**Supplementary File*****Incidence of unintended pregnancy among female sex workers in low- and middle-income countries: a systematic review and meta-analysis*****1. Complete search strategy****Medline search 19 Jan 2016**

1. exp cohort studies/ or exp controlled before-after studies/ or exp cross-sectional studies/ or exp historically controlled study/ or exp interrupted time series analysis/ or exp feasibility studies/ or exp pilot projects/ or exp control groups/ or exp cross-over studies/ or exp double-blind method/ or exp random allocation/ or exp single-blind method/
2. exp clinical trial/ or exp observational study/ or exp comparative study/ or exp evaluation studies/ or exp multicenter study/
3. exp Sex Workers/
4. exp Prostitution/
5. prostitut\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
6. Commercial sex.mp.
7. sex work\*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
8. (sex\* adj2 (sell\* or transact\* or trade or trading)).mp.
9. 3 or 4 or 5 or 6 or 7 or 8
10. Developing Countries/
11. (Afghanistan\* or Albania\* or Algeria\* or Angola\* or Argentina\* or Armenia\* or Azerbaijan\* or Bangladesh\* or Belarus\* or Beliz\* or Benin\* or Bhutan\* or Bolivia\* or Bosnia\* or Herzegovin\* or Botswana\* or Brazil\* or Bulgaria\* or Burkina\* or Burundi\* or Cabo Verde\* or Cape Verde\* or Cambodia\* or Cameroon\* or Central African or Chad\* or China or Chinese or Colombia\* or Comor\* or Congo\* or Costa Rica\* or Cote d'Ivoire\* or Ivory Coast or Cuba\* or Djibouti\* or Dominica\* or Ecuador\* or Egypt\* or El Salvador\* or Eritrea\* or Ethiopia\* or Fiji\* or Gabon\* or Gambia\* or Georgia\* or Ghana\* or Grenad\* or Guatemala\* or Guinea\* or Guyan\* or Haiti\* or Honduras\* or Hungary\* or India\* or Indonesia\* or Iran\* or Iraq\* or Jamaica\* or Jordan\* or Kazakhstan\* or Kenya\* or Kiribati\* or Korea\* or Kosov\* or Kyrgyz Republic or Lao\* or Leban\* or Lesotho\* or Liberia\* or Libya\* or Macedonia\* or Madagascar\* or Malawi\* or Malaysia\* or Maldiv\* or Mali\* or Marshall Island\* or Mauritania\* or Mauriti\* or Mexic\* or Micronesia\* or Moldova\* or Mongolia\* or Montenegro\* or Morocco\* or Mozambi\* or Myanmar\* or Burmese or Namibia\* or Nepal\* or Nicaragua\* or Niger\* or Nigeria\* or Pakistan\* or Palau\* or Panama\* or Papua New Guinea\* or Paraguay\* or Peru\* or Philippines or Filipino or Romania\* or Rwanda\* or Samoa\* or Sao Tome\* or Senegal\* or Serbia\* or Seychell\* or Sierra Leon\* or Solomon Island\* or Somalia\* or South Africa\* or Sudan\* or Sri Lanka\* or St Lucia\* or St Vincent or Grenadines or Surinam\* or Swazi\* or Syria\* or Tajikistan\* or Tanzania\* or Thai\* or Timor\* or Togo\* or Tonga\* or Tunisia\* or Turk\* or Turkmenistan\* or Tuvalu\* or Uganda\* or Ukrain\* or Uzbekistan\* or Vanuatu\* or Venezuela\* or Vietnam\* or West Bank or Gaza or Yemen\* or Zambia\* or Zimbabwe\*).mp.
12. exp africa/ or exp caribbean region/ or exp central america/ or latin america/ or exp south america/ or asia/ or exp asia, central/ or exp asia, southeastern/ or exp asia, western/ or exp indian ocean islands/ or pacific islands/ or exp melanesia/ or exp micronesia/ or exp west indies/
13. (africa\* or asia\* or caribbean or central america\* or latin america\* or south america\* or melanesia\* or micronesia\* or polynesia\*).mp.

14. (resource-limit\* or resource-poor or low-resource\* or limited-resource\* or resource-constrain\* or constrain\*-resource\* or under-resource\* or poor\*-resource\* or resource-scarce\* or scarce\*-resource\* or low-income or middle-income or lowincome or middleincome or LMIC\*).mp.
15. ((developing or underdeveloped or under-developed or emerging or less-developed or least-developed or less-economically developed or least-economically developed or less-affluent or least-affluent) adj (country or countries or nation or nations or region or regions or economy or economies)).mp.
16. ((developing or underdeveloped or under-developed or less-developed or least-developed) adj world).mp.
17. (third-world\* or thirdworld\* or 3rd-world\*).mp.
18. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. 9 and 18
20. Cohort analy\*.mp.
21. ((doubl\* or singl\* or trebl\* or tripl\*) adj blind\*).mp.
22. Cross sectional.mp.
23. ((random\* or clinical or control\*) adj (trial\* or study or studies)).mp.
24. ((cohort or follow-up or followup or observational or prospective or retrospective or evaluation or intervention or comparative) adj (study or studies)).mp.
25. 1 or 2 or 20 or 21 or 22 or 23 or 24
26. 19 and 25
27. 26
28. limit 27 to (english language and yr="2000 -Current")

### PsychInfo search 18 Jan 2016

1. Cohort analy\*.mp.
2. ((doubl\* or singl\* or trebl\* or tripl\*) adj blind\*).mp.
3. Cross sectional.mp.
4. ((random\* or clinical or control\*) adj (trial\* or study or studies)).mp.
5. ((cohort or follow-up or followup or observational or prospective or retrospective or evaluation or intervention or comparative) adj (study or studies)).mp.
6. experimental design/ or exp between groups design/ or exp clinical trials/ or exp cohort analysis/ or exp followup studies/ or exp hypothesis testing/ or exp longitudinal studies/ or exp repeated measures/ or exp experiment controls/ or exp quasi experimental methods/
7. exp Evaluation/ or exp Program Evaluation/
8. exp observation methods/
9. "sampling (experimental)"/ or exp random sampling/
10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
11. exp Prostitution/
12. prostitut\*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
13. Commercial sex.mp.
14. sex work\*.mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures]
15. (sex\* adj2 (sell\* or transact\* or trade or trading)).mp.
16. Developing Countries/
17. (Afghanistan\* or Albania\* or Algeria\* or Angola\* or Argentina\* or Armenia\* or Azerbaijan\* or Bangladesh\* or Belarus\* or Beliz\* or Benin\* or Bhutan\* or Bolivia\* or Bosnia\* or Herzegovin\* or Botswan\* or Brazil\* or Bulgaria\* or Burkina\* or Burundi\* or Cabo Verde\* or Cape Verde\* or Cambodia\* or Cameroon\* or Central African or Chad\* or China or Chinese or Colombia\* or Comor\* or Congo\* or Costa Rica\* or Cote d'Ivoir\* or Ivory Coast or Cuba\* or Djibouti\* or Dominica\* or Ecuador\* or Egypt\* or El Salvador\* or Eritrea\* or Ethiopia\* or Fiji\* or Gabon\* or Gambia\* or Georgia\* or Ghana\* or Grenad\* or Guatemala\* or Guinea\* or Guyan\* or Haiti\* or Hondura\* or Hungar\* or India\* or Indonesia\* or Iran\* or Iraq\* or Jamaica\* or Jordan\* or Kazakhstan\* or Kenya\* or Kiribati\* or Korea\* or Kosov\* or Kyrgyz Republic or Lao\* or Leban\* or Lesotho\*

or Liberia\* or Libya\* or Macedonia\* or Madagascar\* or Malawi\* or Malaysia\* or Maldiv\* or Mali\* or Marshall Island\* or Mauritania\* or Mauriti\* or Mexic\* or Micronesia\* or Moldova\* or Mongolia\* or Monteneg\* or Morocc\* or Mozambi\* or Myanma\* or Burmese or Namibia\* or Nepal\* or Nicaragua\* or Niger\* or Nigeria\* or Pakistan\* or Palau\* or Panama\* or Papua New Guinea\* or Paraguay\* or Peru\* or Philippines or Filipino or Romania\* or Rwanda\* or Samoa\* or Sao Tome\* or Senegal\* or Serbia\* or Seychell\* or Sierra Leon\* or Solomon Island\* or Somalia\* or South Africa\* or Sudan\* or Sri Lanka\* or St Lucia\* or St Vincent or Grenadines or Surinam\* or Swazi\* or Syria\* or Tajikistan\* or Tanzania\* or Thai\* or Timor\* or Togo\* or Tonga\* or Tunisia\* or Turk\* or Turkmenistan\* or Tuvalu\* or Uganda\* or Ukrain\* or Uzbekistan\* or Vanuatu\* or Venezuela\* or Vietnam\* or West Bank or Gaza or Yemen\* or Zambia\* or Zimbabwe\*).mp.

18. (africa\* or asia\* or caribbean or central america\* or latin america\* or south america\* or melanesia\* or micronesia\* or polynesia\*).mp.

19. (resource-limit\* or resource-poor or low-resource\* or limited-resource\* or resource-constrain\* or constrain\*-resource\* or under-resource\* or poor\*-resource\* or resource-scarce\* or scarce\*-resource\* or low-income or middle-income or lowincome or middleincome or LMIC\*).mp.

20. ((developing or underdeveloped or under-developed or emerging or less-developed or least-developed or less-economically developed or least-economically developed or less-affluent or least-affluent) adj (country or countries or nation or nations or region or regions or economy or economies)).mp.

21. ((developing or underdeveloped or under-developed or less-developed or least-developed) adj world).mp.

22. (third-world\* or thirdworld\* or 3rd-world\*).mp.

23. 16 or 17 or 18 or 19 or 20 or 21 or 22

24. 11 or 12 or 13 or 14 or 15

25. 10 and 23 and 24

### Embase search 18 Jan 2016

1. (Afghanistan\* or Albania\* or Algeria\* or Angola\* or Argentina\* or Armenia\* or Azerbaijan\* or Bangladesh\* or Belarus\* or Beliz\* or Benin\* or Bhutan\* or Bolivia\* or Bosnia\* or Herzegovin\* or Botswan\* or Brazil\* or Bulgaria\* or Burkina\* or Burundi\* or Cabo Verde\* or Cape Verde\* or Cambodia\* or Cameroon\* or Central African or Chad\* or China or Chinese or Colombia\* or Comor\* or Congo\* or Costa Rica\* or Cote d'Ivoir\* or Ivory Coast or Cuba\* or Djibouti\* or Dominica\* or Ecuador\* or Egypt\* or El Salvador\* or Eritrea\* or Ethiopia\* or Fiji\* or Gabon\* or Gambia\* or Georgia\* or Ghana\* or Grenad\* or Guatemala\* or Guinea\* or Guyan\* or Haiti\* or Hondura\* or Hungar\* or India\* or Indonesia\* or Iran\* or Iraq\* or Jamaica\* or Jordan\* or Kazakhstan\* or Kenya\* or Kiribati\* or Korea\* or Kosov\* or Kyrgyz Republic or Lao\* or Leban\* or Lesotho\* or Liberia\* or Libya\* or Macedonia\* or Madagascar\* or Malawi\* or Malaysia\* or Maldiv\* or Mali\* or Marshall Island\* or Mauritania\* or Mauriti\* or Mexic\* or Micronesia\* or Moldova\* or Mongolia\* or Monteneg\* or Morocc\* or Mozambi\* or Myanma\* or Burmese or Namibia\* or Nepal\* or Nicaragua\* or Niger\* or Nigeria\* or Pakistan\* or Palau\* or Panama\* or Papua New Guinea\* or Paraguay\* or Peru\* or Philippines or Filipino or Romania\* or Rwanda\* or Samoa\* or Sao Tome\* or Senegal\* or Serbia\* or Seychell\* or Sierra Leon\* or Solomon Island\* or Somalia\* or South Africa\* or Sudan\* or Sri Lanka\* or St Lucia\* or St Vincent or Grenadines or Surinam\* or Swazi\* or Syria\* or Tajikistan\* or Tanzania\* or Thai\* or Timor\* or Togo\* or Tonga\* or Tunisia\* or Turk\* or Turkmenistan\* or Tuvalu\* or Uganda\* or Ukrain\* or Uzbekistan\* or Vanuatu\* or Venezuela\* or Vietnam\* or West Bank or Gaza or Yemen\* or Zambia\* or Zimbabwe\*).mp.

2. exp Africa/ or exp caribbean/ or exp caribbean islands/ or exp "South and Central America"/ or exp Asia/ or exp indian ocean/ or exp pacific ocean/

3. exp developing country/

4. (africa\* or asia\* or caribbean or central america\* or latin america\* or south america\* or melanesia\* or micronesia\* or polynesia\*).mp.

5. (resource-limit\* or resource-poor or low-resource\* or limited-resource\* or resource-constrain\* or constrain\*-resource\* or under-resource\* or poor\*-resource\* or resource-scarce\* or scarce\*-resource\* or low-income or middle-income or lowincome or middleincome or LMIC\*).mp.

6. ((developing or underdeveloped or under-developed or emerging or less-developed or least-developed or less-economically developed or least-economically developed or less-affluent or least-affluent) adj (country or countries or nation or nations or region or regions or economy or economies)).mp.
7. ((developing or underdeveloped or under-developed or less-developed or least-developed) adj world).mp.
8. (third-world\* or thirdworld\* or 3rd-world\*).mp.
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. prostitut\*.mp.
11. exp prostitution/ or exp transactional sex/
12. Commercial sex.mp.
13. sex work\*.mp.
14. (sex\* adj2 (sell\* or transact\* or trade or trading)).mp.
15. 10 or 11 or 12 or 13 or 14
16. ((cohort or follow-up or followup or observational or prospective or retrospective or evaluation or intervention or comparative) adj (study or studies)).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
17. ((random\* or clinical or control\*) adj (trial\* or study or studies)).mp.
18. Cross sectional.mp.
19. ((doubl\* or singl\* or trebl\* or tripl\*) adj blind\*).mp.
20. Cohort analy\*.mp.
21. exp cohort analysis/ or exp control group/ or exp correlational study/ or exp cross-sectional study/ or exp crossover procedure/ or exp double blind procedure/ or exp "early termination of clinical trial"/ or exp experimental design/ or exp nonequivalent control group/ or exp parallel design/ or exp pretest posttest control group design/ or exp pretest posttest design/ or exp single blind procedure/ or exp triple blind procedure/
22. exp comparative study/ or exp experimental study/ or exp feasibility study/ or exp observational study/ or exp pilot study/ or exp prevention study/ or exp quasi experimental study/
23. exp time series analysis/
24. exp clinical trial/ or exp "clinical trial (topic)"/ or exp community trial/ or exp intervention study/ or exp longitudinal study/ or exp major clinical study/ or exp open study/ or exp postmarketing surveillance/ or exp prospective study/ or exp retrospective study/
25. exp evaluation study/
26. 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
27. 9 and 15 and 26
28. limit 27 to (english language and yr="2000 -Current")

#### **POPLINE search 20 Jan 2016**

(( ( Keyword:SEX WORKERS ) OR ( Keyword:TRANSACTIONAL SEX ) )

OR

(( ("sex work\*" OR "Commercial sex" OR prostitut\* OR "sell sex\*" OR "transact\* sex\*" OR "sex\*transact\*" OR "sex\* trade" OR "sex\* trading" OR "trade sex\*" OR "trading sex\*" ) ) )

AND

(( ( Keyword:COHORT ANALYSIS OR Keyword:CLINICAL TRIALS OR Keyword:CONTROL GROUPS OR Keyword:CROSS SECTIONAL ANALYSIS OR Keyword:DOUBLE-BLIND STUDIES OR Keyword:FOLLOW-UP STUDIES OR Keyword:PROSPECTIVE STUDIES OR Keyword:RETROSPECTIVE STUDIES OR Keyword:REPEATED ROUNDS OF SURVEY OR Keyword:LONGITUDINAL STUDIES OR Keyword:PILOT PROJECTS OR Keyword:HEALTH SERVICES EVALUATION OR Keyword:PRE-POST TESTS OR Keyword:FAMILY PLANNING PROGRAM EVALUATION OR Keyword:PERIOD ANALYSIS OR Keyword:PROGRAM EFFECTIVENESS ) )

OR

## CHAPTER 2

(( (cohort OR follow\up OR followup OR "follow up" OR observational OR prospective OR retrospective OR evaluation OR intervention OR comparative OR random\* OR clinical OR control\*) study ~0 )

OR

(( (cohort OR follow\up OR followup OR "follow up" OR observational OR prospective OR retrospective OR evaluation OR intervention OR comparative OR random\* OR clinical OR control\*) studies ~0 )

OR

(( (random\* OR clinical OR control\*) trial~0 ) OR ((doubl\* OR singl\* OR trebl\* OR tripl\*) adj blind\* ) OR (cross\sectional OR "cross sectional" ) OR ("cohort analy\*" ) ) )

AND

(( ( Region/Country:Central America OR Region/Country:South America OR Region/Country:Caribbean OR Region/Country:Oceania OR Region/Country:Africa OR Region/Country:Europe Southeastern OR Region/Country:Asia Central OR Region/Country:Asia Southeastern OR Region/Country:Asia Southern OR Region/Country:Asia Southwestern OR Region/Country:China OR Region/Country:Democratic People's Republic of Korea OR Region/Country:Mongolia OR Region/Country:Belarus OR Region/Country:Moldova OR Region/Country:Ukraine OR Region/Country:Mexico OR Region/Country:Gaza OR Region/Country:Iran OR Region/Country:Iraq OR Region/Country:Jordan OR Region/Country:Lebanon OR Region/Country:Syria OR Region/Country:West Bank OR Region/Country:Yemen ) ) )

AND ( ( Language:English ) AND ( Years:[2000 TO \*] ) )

### Conference abstracts: Web of Science 22 Jan 2016

#16	#15 AND #9 AND #3 DocType=All document types; Language=All languages;
#15	#14 OR #13 OR #12 OR #11 OR #10 DocType=All document types; Language=All languages;
#14	(TS=("Cross sectional")) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#13	(TS=("Cohort analy*")) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#12	(TS=((cohort OR "follow up" OR followup OR observational OR prospective OR retrospective OR evaluation OR intervention OR comparative) near/0 (study OR studies))) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#11	(TS=((random* OR clinical OR control*) near/0 (trial* OR study OR studies))) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#10	(TS=((doubl* OR singl* OR trebl* OR tripl*) near/0 (blind*))) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#9	#8 OR #7 OR #6 OR #5 OR #4 DocType=All document types; Language=All languages;
#8	(TS(("developing" OR "underdeveloped" OR "under developed" OR "less developed" OR "least developed") NEAR/0 ("world"))) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#7	(TS(("developing" OR "underdeveloped" OR "under-developed" OR emerging OR "less-developed" OR "least-developed" OR "less-economically developed" OR "least-economically developed" OR "less-affluent" OR "least-affluent") near/0 (country OR countries OR nation OR nations OR region OR regions OR economy OR economies))) AND LANGUAGE: (English)

	DocType=All document types; Language=All languages;
#6	(TS=(("resource-limit*" or "resource-poor" or "low-resource*" or "limited-resource*" or "resource-constrain*" or "constrain*-resource*" or "under-resource*" or "poor*-resource*" or "resource-scarce*" or "scarce*-resource*" or "low-income" or "middle-income" or lowincome or middleincome or LMIC*)) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#5	(TS=(africa* or asia* or caribbean or "central america*" or "latin america*" or "south america*" or melanesia* or micronesia* or polynesia*)) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#4	(TS=(Afghanistan* or Albania* or Algeria* or Angola* or Argentina* or Armenia* or Azerbaijan* or Bangladesh* or Belarus* or Beliz* or Benin* or Bhutan* or Bolivia* or Bosnia* or Herzegovin* or Botswan* or Brazil* or Bulgaria* or Burkina* or Burundi* or "Cabo Verde*" or "Cape Verde*" or Cambodia* or Cameroon* or "Central African" or Chad* or China or Chinese or Colombia* or Comor* or Congo* or "Costa Rica*" or "Cote d'Ivoire*" or "Ivory Coast" or Cuba* or Djibouti* or Dominica* or Ecuador* or Egypt* or "El Salvador*" or Eritrea* or Ethiopia* or Fiji* or Gabon* or Gambia* or Georgia* or Ghana* or Grenad* or Guatemala* or Guinea* or Guyan* or Haiti* or Hondura* or Hungar* or India* or Indonesia* or Iran* or Iraq* or Jamaica* or Jordan* or Kazakhstan* or Kenya* or Kiribati* or Korea* or Kosov* or "Kyrgyz Republic" or Lao* or Leban* or Lesotho* or Liberia* or Libya* or Macedonia* or Madagascar* or Malawi* or Malaysia* or Maldiv* or Mali* or "Marshall Island*" or Mauritania* or Mauriti* or Mexic* or Micronesia* or Moldova* or Mongolia* or Monteneg* or Morocc* or Mozambi* or Myanma* or Burmese or Namibia* or Nepal* or Nicaragua* or Niger* or Nigeria* or Pakistan* or Palau* or Panama* or "Papua New Guinea*" or Paraguay* or Peru* or Philippines or Filipino or Romania* or Rwanda* or Samoa* or "Sao Tome*" or Senegal* or Serbia* or Seychell* or "Sierra Leon*" or "Solomon Island*" or Somalia* or "South Africa*" or Sudan* or "Sri Lanka*" or "St Lucia*" or "St Vincent" or Grenadines or Surinam* or Swazi* or Syria* or Tajikistan* or Tanzania* or Thai* or Timor* or Togo* or Tonga* or Tunisia* or Turk* or Turkmenistan* or Tuvalu* or Uganda* or Ukrain* or Uzbekistan* or Vanuatu* or Venezuela* or Vietnam* or "West Bank" or Gaza or Yemen* or Zambia* or Zimbabwe*)) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#3	#2 OR #1 DocType=All document types; Language=All languages;
#2	(TS=(sex* near/1 (sell* or transact* or trade or trading))) AND LANGUAGE: (English) DocType=All document types; Language=All languages;
#1	(TS=(prostitut* or "sex work*" or "commercial sex" )) AND LANGUAGE: (English) DocType=All document types; Language=All languages;

### Conference abstracts: Proquest 22 Jan 2016

(  
 (sex\* NEAR/2 (sell\* OR transact\* OR trade OR trading)) OR prostitut\* OR "Commercial sex" OR "sex work\*"  
 )  
 AND  
 (  
 ((doubl\* OR singl\* OR trebl\* OR tripl\*) PRE/0 blind\*)  
 OR  
 ((random\* OR clinical OR control\*) PRE/0 (trial\* OR study OR studies))  
 OR  
 ((cohort OR "follow up" OR followup OR observational OR prospective OR retrospective OR evaluation OR  
 intervention OR comparative) PRE/0 (study OR studies))  
 OR  
 ("Cohort analy\*")  
 OR  
 ("Cross sectional")  
 )  
 AND  
 (



## CHAPTER 2

(Afghanistan\* OR Albania\* OR Algeria\* OR Angola\* OR Argentina\* OR Armenia\* OR Azerbaijan\* OR Bangladesh\* OR Belarus\* OR Belize\* OR Benin\* OR Bhutan\* OR Bolivia\* OR Bosnia\* OR Herzegovina\* OR Botswana\* OR Brazil\* OR Bulgaria\* OR Burkina\* OR Burundi\* OR Cabo Verde\* OR Cape Verde\* OR Cambodia\* OR Cameroon\* OR Central African OR Chad\* OR China OR Chinese OR Colombia\* OR Comoros\* OR Congo\* OR Costa Rica\* OR Cote d'Ivoire\* OR Ivory Coast OR Cuba\* OR Djibouti\* OR Dominica\* OR Ecuador\* OR Egypt\* OR El Salvador\* OR Eritrea\* OR Ethiopia\* OR Fiji\* OR Gabon\* OR Gambia\* OR Georgia\* OR Ghana\* OR Grenada\* OR Guatemala\* OR Guinea\* OR Guyana\* OR Haiti\* OR Honduras\* OR Hungary\* OR India\* OR Indonesia\* OR Iran\* OR Iraq\* OR Jamaica\* OR Jordan\* OR Kazakhstan\* OR Kenya\* OR Kiribati\* OR Korea\* OR Kosovo\* OR Kyrgyz Republic OR Lao\* OR Lebanon\* OR Lesotho\* OR Liberia\* OR Libya\* OR Macedonia\* OR Madagascar\* OR Malawi\* OR Malaysia\* OR Maldives\* OR Mali\* OR Marshall Island\* OR Mauritania\* OR Mauritius\* OR Mexico\* OR Micronesia\* OR Moldova\* OR Mongolia\* OR Montenegro\* OR Morocco\* OR Mozambique\* OR Myanmar\* OR Burmese OR Namibia\* OR Nepal\* OR Nicaragua\* OR Niger\* OR Nigeria\* OR Pakistan\* OR Palau\* OR Panama\* OR Papua New Guinea\* OR Paraguay\* OR Peru\* OR Philippines OR Filipino OR Romania\* OR Rwanda\* OR Samoa\* OR Sao Tome\* OR Senegal\* OR Serbia\* OR Seychelles\* OR Sierra Leone\* OR Solomon Island\* OR Somalia\* OR South Africa\* OR Sudan\* OR Sri Lanka\* OR St Lucia\* OR St Vincent OR Grenadines OR Suriname\* OR Swaziland\* OR Syria\* OR Tajikistan\* OR Tanzania\* OR Thai\* OR Timor\* OR Togo\* OR Tonga\* OR Tunisia\* OR Turkey\* OR Turkmenistan\* OR Tuvalu\* OR Uganda\* OR Ukraine\* OR Uzbekistan\* OR Vanuatu\* OR Venezuela\* OR Vietnam\* OR West Bank OR Gaza OR Yemen\* OR Zambia\* OR Zimbabwe\*)

OR

((developing OR underdeveloped OR "under developed" OR "less developed" OR "least developed") PRE/0 (world))

OR

((developing OR underdeveloped OR "under developed" OR "less developed" OR "least developed" OR "less economically developed" OR "least economically developed" OR "less affluent" OR "least affluent") PRE/0 (country OR countries OR nation OR nations OR region OR regions OR economy OR economies))

OR

("third world\*" OR thirdworld\* OR "3rd-world\*")

OR

("resource limit\*" OR "resource poor" OR "low resource\*" OR "limited resource\*" OR "resource constrain\*" OR "constrain\* resource\*" OR "under resource\*" OR "poor\* resource\*" OR "resource scarce\*" OR "scarce\* resource\*" OR "low income" OR "middle income" OR lowincome OR middleincome OR LMIC\*)

OR

(africa\* OR asia\* OR caribbean OR "central america\*" OR "latin america\*" OR "south america\*" OR melanesia\* OR micronesia\* OR polynesia\*)

)

### Open grey22 Jan 2016

lang:"en"

((sex\* NEAR/2 (sell\* OR transact\* OR trade OR trading)) OR prostitut\* OR "Commercial sex" OR "sex work\*")

AND

(

(Afghanistan\* OR Albania\* OR Algeria\* OR Angola\* OR Argentina\* OR Armenia\* OR Azerbaijan\* OR Bangladesh\* OR Belarus\* OR Belize\* OR Benin\* OR Bhutan\* OR Bolivia\* OR Bosnia\* OR Herzegovina\* OR Botswana\* OR Brazil\* OR Bulgaria\* OR Burkina\* OR Burundi\* OR Cabo Verde\* OR Cape Verde\* OR Cambodia\* OR Cameroon\* OR Central African OR Chad\* OR China OR Chinese OR Colombia\* OR Comoros\* OR Congo\* OR Costa Rica\* OR Cote d'Ivoire\* OR Ivory Coast OR Cuba\* OR Djibouti\* OR Dominica\* OR Ecuador\* OR Egypt\* OR El Salvador\* OR Eritrea\* OR Ethiopia\* OR Fiji\* OR Gabon\* OR Gambia\* OR Georgia\* OR Ghana\* OR Grenada\* OR Guatemala\* OR Guinea\* OR Guyana\* OR Haiti\* OR Honduras\* OR Hungary\* OR India\* OR Indonesia\* OR Iran\* OR Iraq\* OR Jamaica\* OR Jordan\* OR Kazakhstan\* OR Kenya\*

OR Kiribati\* OR Korea\* OR Kosov\* OR Kyrgyz Republic OR Lao\* OR Leban\* OR Lesotho\* OR Liberia\*  
 OR Libya\* OR Macedonia\* OR Madagascar\* OR Malawi\* OR Malaysia\* OR Maldiv\* OR Mali\* OR Marshall  
 Island\* OR Mauritania\* OR Mauriti\* OR Mexic\* OR Micronesia\* OR Moldova\* OR Mongolia\* OR  
 Monteneg\* OR Morocco\* OR Mozambi\* OR Myanma\* OR Burmese OR Namibia\* OR Nepal\* OR Nicaragua\*  
 OR Niger\* OR Nigeria\* OR Pakistan\* OR Palau\* OR Panama\* OR Papua New Guinea\* OR Paraguay\* OR  
 Peru\* OR Philippines OR Filipino OR Romania\* OR Rwanda\* OR Samoa\* OR Sao Tome\* OR Senegal\* OR  
 Serbia\* OR Seychell\* OR Sierra Leon\* OR Solomon Island\* OR Somalia\* OR South Africa\* OR Sudan\* OR  
 Sri Lanka\* OR St Lucia\* OR St Vincent OR Grenadines OR Surinam\* OR Swazi\* OR Syria\* OR Tajikistan\*  
 OR Tanzania\* OR Thai\* OR Timor\* OR Togo\* OR Tonga\* OR Tunisia\* OR Turk\* OR Turkmenistan\* OR  
 Tuvalu\* OR Uganda\* OR Ukrain\* OR Uzbekistan\* OR Vanuatu\* OR Venezuela\* OR Vietnam\* OR West  
 Bank OR Gaza OR Yemen\* OR Zambia\* OR Zimbabwe\*)

OR

((developing OR underdeveloped OR "under developed" OR "less developed" OR "least developed" OR "less  
 economically developed" OR "least economically developed" OR "less affluent" OR "least affluent") NEAR/0  
 (country OR countries OR nation OR nations OR region OR regions OR economy OR economies))

OR

((developing OR underdeveloped OR "under developed" OR "less developed" OR "least developed") NEAR/0  
 (world))

OR

("third world\*" OR thirdworld\* OR "3rd-world\*")

OR

("resource limit\*" OR "resource poor" OR "low resource\*" OR "limited resource\*" OR "resource constrain\*" OR  
 "constrain\* resource\*" OR "under resource\*" OR "poor\* resource\*" OR "resource scarce\*" OR "scarce\*  
 resource\*" OR "low income" OR "middle income" OR lowincome OR middleincome OR LMIC\*)

OR

(africa\* OR asia\* OR caribbean OR "central america\*" OR "latin america\*" OR "south america\*" OR  
 melanesia\* OR micronesia\* OR polynesia\*)

)

## 2. Quality assessment tool

Adapted from the Joanna Briggs Institute Prevalence Critical Appraisal Tool<sup>1</sup>. Modified version provided by the author (Munn) on 21/3/16. Adjustments as per Bowring 2016<sup>2</sup>. Further modifications specific to research question made by review authors.

<b>DOMAIN 1: EXTERNAL VALIDITY</b>	
<i>Is the sample representative of the population of interest?</i>	
<b>1.1 Was an appropriate sampling frame used?</b>	
1	Enumeration/estimate of FSWs, or clear description of source population (demographics, location, and time period), and rationale for use
0	No sampling frame, or inappropriate population for research question
<b>1.2 Was an appropriate sampling method used?</b>	
1	Probability-based sample (including: simple random, systematic, stratified, cluster, two-stage and multi-stage sampling) RDS or properly described time-location/venue sampling (if analysed appropriately)
0	Non-random sample (including purposive, quota, convenience and snowball), or sampling not described
<b>1.3 Were inclusion and exclusion criteria explicit and appropriate to the research question?</b>	
1	Yes, e.g. women only, FSWs, all reproductive ages, etc
0	No: limited by HIV status or other characteristic that would affect generalisability

<b>DOMAIN 2: SELECTION (NON-RESPONSE) BIAS</b>	
<i>Was there incomplete outcome data (due to non-response, refusal or exclusion), and how did it affect the outcome?</i>	
<b>2.1 Were (FSW) study participants recruited and enrolled in an appropriate way?</b>	
1	Well described methods of recruitment and enrolment; appropriate staff expertise/training; appropriate seed selection for RDS; appropriate venue/location coverage
0	Poorly described; potential source of bias due to recruitment methods
<b>2.2 Was there selective participation in the study?</b>	
1	>=80% of those invited to participate were screened <80% participation rate, but sociodemographic/sex work characteristics not significantly different between participants and non-participants
0	<80% participation rate and significantly different characteristics likely to affect outcome Participation rate not reported or differences not assessed
<b>2.3 What was the retention rate?</b>	
Closed cohort/RCT: what proportion of participants who commenced the study contributed data at the final follow up visit? (If choosing an earlier endpoint, use retention rate up to this point)	
Open cohort: what proportion attended at least one follow up visit, and was retention well described?	
2	>=80% and sociodemographic/sex work characteristics compared and not significantly different
1	>=80% and sociodemographic/sex work characteristics either significantly different or not compared
0	<80%

<b>DOMAIN 3: MEASUREMENT BIAS</b>	
<b>3.1 Was a valid tool used for the identification of the condition (pregnancy)?</b>	
1	Serum or urine test for beta HCG
0	Self-reported or observed by study personnel
<b>3.2 Was the condition (pregnancy) measured in a standard, reliable way for all FSWs?</b>	
1	Pregnancy measured systematically (eg every study visit); data collectors appropriately trained
0	Unclear/inconsistent methods; lack of training for data collectors; nonsystematic measurement or recording (eg pregnancy only tested on participant request or clinician suspicion)
<b>3.3 Was pregnancy intention measured systematically using a valid tool?</b>	
1	Prospective question about intention asked at appropriate intervals (at least every 12months); or LMUP
0	Intention assumed, infrequently measured or unreliable retrospective question
N/A	Intention not measured

<b>DOMAIN 4: INTERNAL VALIDITY</b>	
<i>How likely could the result be due to chance? What is the level of precision?</i>	
<b>4.1 Was the person-years of observation adequate for calculating pregnancy incidence?</b>	
1	FSWs followed for at least 100 woman-years, or reasonable justification of smaller size
0	<100 woman-years
<b>4.2 Was the study conducted for a sufficient period of time to calculate pregnancy incidence?</b>	
1	Closed cohort or trial: at least 6 months' follow-up time Open cohort: median follow up time per participant >6 months?
0	Insufficient observation period, or not reported
<b>4.3 Was there appropriate statistical analysis?</b>	
1	Detailed statistical methods described Primarily consider the measure of risk that will be used in the meta-analysis – i.e. incidence rates, and/or incidence proportion if measured over 1 year For proportions (cumulative incidence): denominator and numerator explicitly reported and appropriate/justified For incidence rates: calculation of person-years, including estimate of conception date and approach to censoring of pregnancy, explicitly reported and appropriate/justified (should not count pregnant time towards total person-years) If calculated based on data from author: sufficient data provided for accurate calculation
0	Methods not sufficiently described; inappropriate technique

<b>DOMAIN 5: OTHER ISSUES</b>	
<b>5.1 Was pregnancy incidence an objective of the study?</b>	
1	Yes (consider objectives of overall study, not sub-study/specific paper)
0	No (e.g. cohort may have been originally designed to measure HIV incidence, but they also published a paper on incidental pregnancy incidence)
<b>5.1 Were there any other issues that may have introduced bias or affected the validity of the estimates?</b>	

## CHAPTER 2

1	No issues
0	<p>Study design issues, e.g. highly variable/skewed follow up times in open cohort study; very long follow-up period during which true incidence in the population likely to have changed</p> <p>Selective use or reporting of data (e.g. only reporting pregnancy incidence in one subgroup or at one time point without justification)</p> <p>Intervention may impact on pregnancy incidence e.g. testing diaphragm use, or FP counselling (not just standard of care condom counselling)</p>

### Scoring

#### **Studies that measure unintended pregnancy**

Domain	Raw score out of:
External validity	3
Selection bias	4
Measurement bias	3
Internal validity	3
Other issues	2
<b>Total</b>	<b>15</b>

#### **Studies that measure pregnancy (undefined)**

Domain	Raw score out of:
External validity	3
Selection bias	4
Measurement bias	2
Internal validity	3
Other issues	2
<b>Total</b>	<b>14</b>

### **References**

1. Munn Z, Moola S, Riitano D, Lisy K. The development of a critical appraisal tool for use in systematic reviews addressing questions of prevalence. *International Journal of Health Policy and Management* 2014; **3**: 123+.
2. Bowring AL, Veronese V, Doyle JS, Stooze M, Hellard M. HIV and Sexual Risk Among Men Who Have Sex With Men and Women in Asia: A Systematic Review and Meta-Analysis. *AIDS and Behavior* 2016: 1-23.

## Chapter 3: Development of an mHealth Intervention for female sex workers

### 3.1 Background

Chapters 1 and 2 described and quantified the risks of unintended pregnancy faced by FSWs, and highlighted the lack of programs or interventions aimed at addressing this issue. Chapter 1 described how interventions to increase FSWs' demand for contraception (particularly LARCs), for example by utilising mobile phones, could be effective at preventing unintended pregnancy incidence.

In response to this issue, our group developed an mHealth intervention for FSWs to promote contraceptive use and address other factors that contribute to their SRH risks, incorporating elements of mHealth interventions that were shown to be more effective in Chapter 1. I played a central role in the process of drafting the messages, pilot testing them with FSWs, and finalising the structure and content of the intervention.

This chapter describes the development of the intervention (known as the 'WHISPER' intervention), addressing objective 2. It includes a qualitative exploration of FSWs' responses to pilot testing the intervention in Mombasa, an assessment of its feasibility and acceptability, and a description of the final intervention content and structure.

The full intervention, including all messages, is included in the thesis appendix (Appendix 1).

This chapter consists of the following published paper:

Ampt FH, L'Engle K, Lim MSC, Plourde KF, Mangone E, Mukanya CM, Gichangi P, Manguro G, Hellard M, Stoové M, Chersich MF, Jaoko W, Agius PA, Temmerman M, Wangari W, Luchters S: A Mobile Phone-Based Sexual and Reproductive Health Intervention for Female Sex Workers in Kenya: Development and Qualitative Study. *JMIR Mhealth Uhealth* 2020, 8(5):e15096.

A supplementary file containing the Template for Intervention Description and Replication (TIDieR) checklist also follows the manuscript.

## Original Paper

# A Mobile Phone–Based Sexual and Reproductive Health Intervention for Female Sex Workers in Kenya: Development and Qualitative Study

Frances H Ampt<sup>1,2\*</sup>, MPH; Kelly L'Engle<sup>3\*</sup>, PhD; Megan S C Lim<sup>1,2</sup>, PhD; Kate F Plourde<sup>4</sup>, MPH; Emily Mangone<sup>5</sup>, MSc; Collins Mudogo Mukanya<sup>6</sup>, MA; Peter Gichangi<sup>7,8,9</sup>, PhD; Griffins Manguro<sup>9</sup>, MPH; Margaret Hellard<sup>1,10</sup>, PhD; Mark Stoové<sup>1,2</sup>, PhD; Matthew F Chersich<sup>8,11</sup>, PhD; Walter Jaoko<sup>12</sup>, PhD; Paul A Agius<sup>1,2</sup>, MSc; Marleen Temmerman<sup>8,9,13</sup>, PhD; Winnie Wangari<sup>9</sup>, BA; Stanley Luchters<sup>1,2,8,13</sup>, PhD

<sup>1</sup>Burnet Institute, Melbourne, Australia

<sup>2</sup>Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Australia

<sup>3</sup>University of San Francisco, San Francisco, CA, United States

<sup>4</sup>FHI 360, Durham, NC, United States

<sup>5</sup>School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC, United States

<sup>6</sup>mHealth Kenya, Nairobi, Kenya

<sup>7</sup>Technical University of Mombasa, Mombasa, Kenya

<sup>8</sup>Department of Public Health and Primary Care, International Centre for Reproductive Health, Ghent University, Ghent, Belgium

<sup>9</sup>International Centre for Reproductive Health, Mombasa, Kenya

<sup>10</sup>Department of Infectious Diseases, The Alfred Hospital, Melbourne, Australia

<sup>11</sup>Wits Reproductive Health and HIV Institute, University of the Witwatersrand, Johannesburg, South Africa

<sup>12</sup>University of Nairobi, Nairobi, Kenya

<sup>13</sup>Aga Khan University, Nairobi, Kenya

\* these authors contributed equally

## Corresponding Author:

Frances H Ampt, MPH

Burnet Institute

85 Commercial Rd

Melbourne, 3004

Australia

Phone: 61 2 9282 2111

Email: [frances.ampt@burnet.edu.au](mailto:frances.ampt@burnet.edu.au)

## Abstract

**Background:** Female sex workers (FSWs) have high rates of both unintended pregnancy and HIV, but few health promotion interventions address their contraceptive needs or other sexual and reproductive health and rights (SRHR) concerns. A broader approach integrates contraceptive promotion with HIV and sexually transmitted infection (STI) prevention and management, alcohol awareness, gender-based violence and rights, and health care utilization. The Women's Health Intervention using SMS for Preventing Pregnancy (WHISPER) mobile phone intervention uses a participatory development approach and behavior change theory to address these high-priority concerns of FSWs in Mombasa, Kenya.

**Objective:** This paper aimed to (1) describe the process of development of the WHISPER intervention, its theoretical framework, key content domains and strategies and (2) explore workshop participants' responses to the proposed intervention, particularly with regard to message content, behavior change constructs, and feasibility and acceptability.

**Methods:** The research team worked closely with FSWs in two phases of intervention development. First, we drafted content for three different types of messages based on a review of the literature and behavior change theories. Second, we piloted the intervention by conducting six workshops with 42 FSWs to test and refine message content and 12 interviews to assess the technical performance of the intervention. Workshop data were thematically analyzed using a mixed deductive and inductive approach.

**Results:** The intervention framework specified six SRHR domains that were viewed as highly relevant by FSWs. Reactions to intervention content revealed that social cognitive strategies to improve knowledge, outcome expectations, skills, and self-efficacy resonated well with workshop participants. Participants found the content empowering, and most said they would share the messages with others. The refined intervention was a 12-month SMS program consisting of informational and motivational messages, role model stories portraying behavior change among FSWs, and on-demand contraceptive information.

**Conclusions:** Our results highlight the need for health promotion interventions that incorporate broader components of SRHR, not only HIV prevention. Using a theory-based, participatory approach, we developed a digital health intervention that reflects the complex reality of FSWs' lives and provides a feasible, acceptable approach for addressing SRHR concerns and needs. FSWs may benefit from health promotion interventions that provide relevant, actionable, and engaging content to support behavior change.

(*JMIR Mhealth Uhealth* 2020;8(5):e15096) doi: [10.2196/15096](https://doi.org/10.2196/15096)

## KEYWORDS

sex work; mobile health (mHealth); unintended pregnancy; qualitative research

## Introduction

HIV prevention programs for female sex workers (FSWs) utilizing peer educators, drop-in-centers, and mobile outreach have been implemented in sub-Saharan Africa [1,2] and have shown promise in improving condom use, HIV and sexually transmitted infection (STI) prevalence, and HIV testing [3-5]. However, the broader sexual and reproductive health and rights (SRHR) needs of this population have been largely neglected by a narrow focus on HIV [6], potentially limiting the effectiveness of prevention programs [7] and prompting calls for greater integration of family planning, community empowerment, gender-based violence, and antenatal care services into existing programs [1,8-12].

Pregnancy prevention is a particular area of need for FSWs, with high rates of unintended pregnancy and low uptake of highly effective contraception and dual method use among those wanting to avoid pregnancy [13,14]. Research with FSWs in Mombasa, a port city and transport hub on Kenya's East Coast with a large FSW population [15], documented that over 1 year, 24% had an unintended pregnancy and only 57% were using a modern contraceptive method [16].

Limited knowledge of long-acting reversible contraceptives (LARCs), fear of side effects, and social and gender norms that limit the use of family planning are common among FSWs in this setting [11,16-19] and women in sub-Saharan Africa more generally [20,21]. This indicates a critical need for messaging that addresses family planning knowledge, attitudes, and behaviors in the context of sex work. Mobile phones offer a promising medium for such communication, as they are increasingly used to arrange sex work encounters and solicit clients [22], can reach marginalized populations with low engagement in formal services, and mobile coverage is high in most countries (eg, 96% in Kenya) [23].

Mobile phones have been used to deliver health promotion in a variety of contexts, and this approach has been effective in improving knowledge, use, and continuation of contraception [24], as well as impacting preventive behaviors for other health domains [25]. Mobile health (mHealth) interventions have not been implemented with FSWs, but they have been evaluated with young people and postpartum women in sub-Saharan

Africa, and have successfully impacted contraceptive outcomes in these contexts [26-28].

We developed a mobile phone intervention for FSWs in Mombasa to promote contraceptive use—particularly LARCs—and other behaviors related to SRHR. This intervention, called the Women's Health Intervention using SMS for Preventing Pregnancy (WHISPER), is being tested in a cluster-randomized controlled trial (RCT) to assess its impact on unintended pregnancy [29].

The intervention was developed using a participatory design approach. FSWs in Mombasa were involved in the initial conception of the intervention and in formal workshoping and testing. Participation by the target community in intervention design [30] and the development of health programs [31] may lead to greater health impacts. However, participatory design methods for mHealth interventions with minority populations such as FSWs are rarely explicitly described [32].

In this paper, we aim to (1) describe the development of the WHISPER intervention and present its theoretical framework, key content domains, and strategies, and (2) explore workshop participants' responses to the proposed intervention, particularly with regard to message content and behavior change constructs. Finally, we present the schedule and approach for intervention implementation and delivery.

## Methods

### Summary

Methods for the development of WHISPER have been described by Ampt et al [29] and generally follow the steps outlined by L'Engle et al [33]. The intervention was developed in two phases: first, to design the intervention framework and draft content; and second, to pilot the intervention with FSWs, refine the messages based on the results, and finalize the intervention structure and content.

### Phase 1: Developing the Framework and Draft Content

The framework for intervention content, and the drafting of initial messages, was informed by the following: review of the literature on motivators and barriers to FSWs' adoption of healthy SRHR behaviors; consideration of health promotion



theory, specifically transtheoretical [34] and social cognitive [35] theories; and consultation with FSWs who formed part of the research team. These women were experienced peer educators at the International Center for Reproductive Health's drop-in centers and came from the targeted FSW communities. We incorporated messaging from existing mHealth repositories and previous programs developed by the investigators [36-38] and aligned the content with relevant Kenyan and global guidelines for family planning [39,40] tailored to the specific needs of sex workers including their high risk of STIs and HIV [41]. We drafted and tested the messages in English rather than Kiswahili following advice from the Kenyan research team and peer educators.

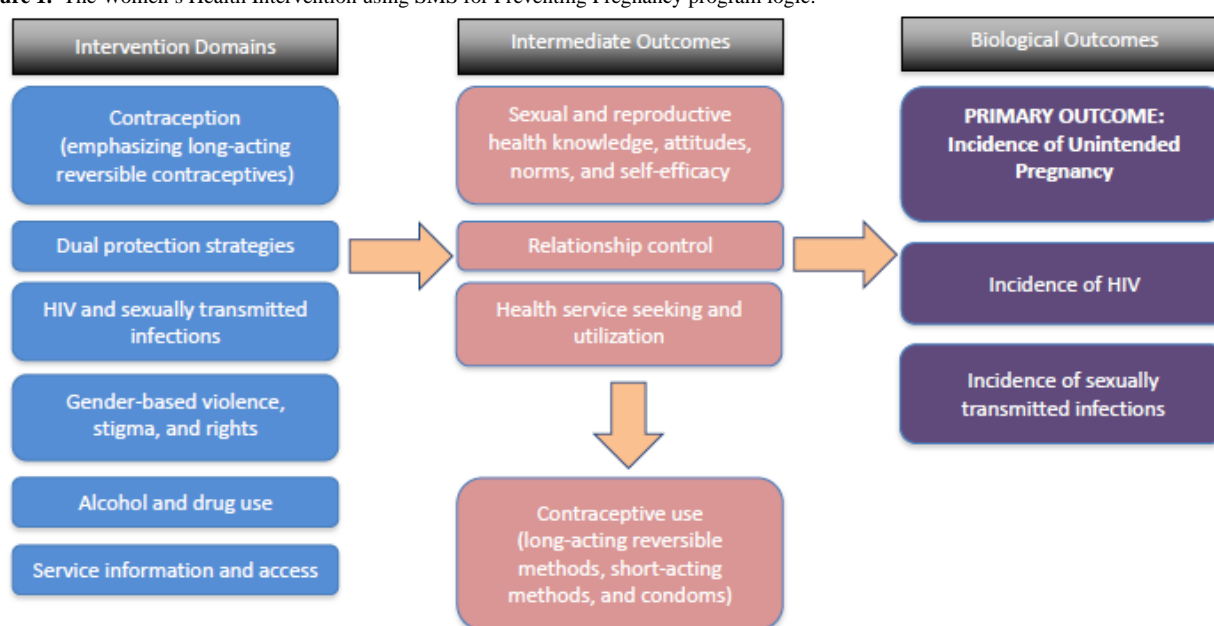
### Intervention Framework

A review of the literature and behavior change theory highlighted key content domains and corresponding behavioral

factors that impact the risk of unintended pregnancy, STIs, and HIV.

These domains and factors were confirmed as important and relevant to FSWs during consultations with peer educators and were incorporated into a logic model (Figure 1) that guided content development. The peer educators agreed that pregnancy prevention was a high priority and also identified conflicting attitudes to family planning in the community, due to fear of side effects and myths about the effects of some methods, particularly intrauterine devices (IUDs). The use of condoms for STI and HIV prevention was recognized as important, but a number of barriers to correct and consistent use were identified. Violence from clients and other partners, as well as heavy alcohol use, were also highlighted.

**Figure 1.** The Women's Health Intervention using SMS for Preventing Pregnancy program logic.



### Intervention Strategies

The intervention was designed to incorporate specific cognitive strategies from behavior change communication theory [42,43] and appeal to women at different stages of change [34] (Table 1). Three different types of messages were used: discrete messages of less than 160 characters *pushed* to participants' phones on a predetermined schedule; role model stories, consisting of narratives about FSWs negotiating SRH risks, sent to participants' phones over several messages (episodes); and on-demand (*pull*) messages that participants could access at any time by replying to messages with specific codes.

### Push Messages

These messages provided specific information in less than 160 characters (1 standard SMS) and used strategies to motivate and educate participants. In the precontemplative stage, more of the messages aimed at the women were developed to be sent early in the intervention, with greater emphasis on action and maintenance later on. However, there was a mixture throughout, given the anticipated diversity of stages of change of participants. The sequencing of role model stories also reflected this approach. Push messages were delivered on alternating months to role model stories. Examples of push messages and their associated behavior change strategies are provided in Table 1.

**Table 1.** Example messages and a role model story episode mapped to behavior change theory and strategies.

Intervention domain	Example message <sup>a</sup>	Stage of change and definition	Cognitive strategies
<b>Stand-alone push messages</b>			
Contraception	We have something important to tell you. Family planning lets you have sex without getting pregnant. That's what WHISPER is all about.	Precontemplation: not yet thinking about changing behavior	Increase awareness of risk; set positive outcome expectations; attract attention, <i>brand</i> recognition (social marketing strategy); frame subsequent messages
Dual protection	Husband or boronga (type of client)? (No matter who they are, they should be wearing a condom if they want to be with you). Hugs and kisses from WHISPER.	Precontemplation	Improve knowledge; use a friendly and personal tone to provide positive encouragement and social support; use humor to highlight desired behavior
Contraception	Most women who use family planning continue to have a normal sex drive. If you find one method leaves you without a sexual appetite, there are many other options.	Contemplation and preparation: thinking about making changes in behavior	Improve knowledge; challenge outcome expectations (related to fears of side effects); address specific concerns; provide an alternative strategy
HIV and STIs	Did you know you can take a rapid test for HIV? You get the result straight away, so you don't have to come back later! Reply 100 for services that do testing.	Contemplation and preparation	Set positive outcome expectations; motivate; provide specific action strategy
Gender-based violence, stigma, and rights	Violence against women is not ok, and it's not your fault. If you experience violence, remember you are not alone and can get help. Hugs, WHISPER.	Contemplation and preparation	Change social norms and model empowerment; provide social support; build self-efficacy for getting help; encourage help-seeking behavior
Alcohol and drug use	You can reduce your drinking: ask for beer bottles filled with water, add water to mixed drinks, secretly dump some out, drink soda, drink slow. WHISPER.	Preparation and action: preparing to act or taking actions to change behavior	Build skills and self-efficacy by breaking down behavior into components; develop action plans; encourage goal setting
Service information and access	If you have a bad experience with a health care provider, don't give up—ask your peer educator for clinic recommendations. Kisses and hugs.	Action and maintenance: taking actions to change behavior, for 6 months or more (maintenance)	Improve self-efficacy by overcoming setbacks; build skills to prevent or address relapse; provide alternative strategies
<b>Role model story (episode 1)</b>			
Contraception	Karibu tujienjoy [Welcome, let's have fun]! I'm Ciku from WHISPER. I'm new to town: I left my village because my husband drank a lot and was violent. I might be young, but I know I deserve better. I have some mpenzi [lovers] who help me out but I've had a couple of scares at the clinic, if you know what I mean. I need a better way to prevent pregnancy!	The character moving from precontemplation to contemplation in this episode.	Personalize, set scene; model self-efficacy and empowerment (leaving a violent relationship); present negative outcome expectations (risks of current behavior)

<sup>a</sup>Example messages contain final content, including any modifications made during phase 2.

### Role Model Stories

Role modeling healthy behaviors through stories about relatable peers constitute a recognized social-cognitive strategy for behavior change [42] but have rarely been used in mHealth. The WHISPER role model stories were intended to be delivered as multiple episodes, describing FSWs who overcome barriers to contraceptive use by modeling healthy social norms and

behaviors. To develop the stories, peer educators workshopped common and engaging scenarios that highlighted FSWs' risk of pregnancy (Table 2). The research team used these as the basis for developing and testing six stories, each promoting the use of LARCs integrated with other relevant themes. Peer educators also provided ideas about character names, language, and narrative, which were incorporated into the stories to ensure their relevance to the FSW community.

**Table 2.** Role model stories developed from peer educator consultation.

Scenarios from FSW <sup>a</sup> peer educators	Character	Key LARC <sup>b</sup> method in story	Other content in the story
Moving to the city to escape a violent husband and starting in sex work	Ciku	Implant	Intimate partner violence, inconsistent protection, pregnancy, and STI scares
Main partner (husband or boyfriend) resisting the use of condoms and other contraception	Sandra	Implant	Part-time sex work, STI transmission from boyfriend, condom negotiation with boyfriend, contraceptive pill
Pressure to drink alcohol before sex with a client, and resulting adverse consequences	Lynette	IUD <sup>c</sup>	Sexual risk-taking while intoxicated, strategies for reducing drinking.
Experiencing unintended pregnancy, concern about side effects preventing the use of contraception	Olivia	IUD	Unintended pregnancy and fetal loss, rumors about different contraceptive methods
Being arrested and unable to access emergency contraception	Mimi	IUD	Summary of different contraceptive methods from friends and peer educator
Difficulty negotiating condom use with a client, and making assumptions about his STI <sup>d</sup> or HIV status	Joslyn	Implant	Dual method use with clients, STI myths

<sup>a</sup>FSW: female sex worker.

<sup>b</sup>LARC: long-acting reversible contraceptive.

<sup>c</sup>IUD: intrauterine device.

<sup>d</sup>STI: sexually transmitted infection.

### On-Demand Messages

Previous research has indicated that messages about reproductive health that are accessible at any time via an on-demand menu are appealing and motivational to women in East Africa [33,37]. Furthermore, interventions that are bidirectional (involving both push and pull components) may have a greater impact than unidirectional messaging [26,44]. The WHISPER on-demand

menu was designed to be accessed by participants sending a code via SMS at any time. They could then obtain more information about contraceptive methods and available health services in their area. On-demand messages, along with the linking and functionality of the code menu, were tested during interviews. Example on-demand messages relating to contraceptive implants are provided in Table 3.

**Table 3.** Example message providing a link to on-demand content, SMS codes, and corresponding on-demand messages.

Push message linking to on-demand menu <sup>a</sup> and code to trigger message (sent via SMS)	Corresponding on-demand message <sup>a</sup>
<b>WHISPER Alert: Mimi found out that the implant protects you from pregnancy for 3 to 5 years! Want to know more about the implant? Reply 11 to this text</b>	
11	Implants are small rods placed under the skin of a woman's arm. Highly effective for 3 to 5 years. It can be removed anytime. For married and singles. May cause light irregular bleeding. When removed, you can become pregnant with no delay. No infertility or birth defects. WHISPER main menu, reply 00. For more information, reply 12.
12	Implants: Benefits 13, Side effects 14, Bleeding side effects 15, True facts 16, Insertion/Removal 17, WHISPER main menu 00.
15	Implant bleeding side effects: Monthly bleeding may be lighter and irregular during the first year, then lighter, more regular, and infrequent. Monthly bleeding may stop for some women. If bleeding stops it is not harmful—blood does not build up inside the womb.

<sup>a</sup>Example messages contain final content, including any modifications made during phase 2.

### Phase 2: Testing and Refining Messages

The second phase involved testing and refining draft messages based on detailed feedback from FSWs in 6 workshops and 12 interviews. A semistructured workshop guide covered responses to specific messages, overall feedback on the program, and preferences for program structure, timing, delivery, and vernacular. A female researcher who had experience working with FSWs was employed to moderate the workshops rather

than an FSW peer educator because this provided more anonymity and privacy to participants. Also, experienced facilitating groups was considered necessary to cover content efficiently but in a sensitive way. A note-taker was also present.

Workshop participants were recruited through purposive sampling of sex work venues (*hotspots*) by FSW peer educators. Peer educators with connections to different hotspots across two subcounties of Mombasa (Kisauni and Changamwe) were

selected to be recruiters. Recruiters sought participants with a range of ages and education levels. To be eligible for the workshops, women had to be at least 16 years old, have received money or goods in exchange for sex in the previous 6 months, self-report that they were not currently pregnant or planning a pregnancy in the next year, and own and use a mobile phone. These criteria were consistent with those in the subsequent RCT [29].

We modified the intervention based on the results of the workshops and tested it in 12 one-on-one interviews with participants who met the same eligibility criteria. Interviews tested the technical performance of the SMS system, reactions to the use of on-demand (*pull*) messages, and interpretation of specific messages where there was uncertainty about meaning.

Workshops and interviews were audio-recorded, and detailed notes taken during the sessions were augmented with data from the recordings and translated into English, where necessary, by research assistants. A mixed deductive and inductive thematic approach to analysis was adopted [45]. A list of predetermined codes was used to obtain specific information about message delivery, wording, and preferred content domains. Other codes emerged from the data and were analyzed thematically, particularly in relation to how FSWs responded to the content of different messages and related this to their own experiences, and how behavior change strategies employed by the messages resonated with participants. We analyzed the data using NVivo 11 (QSR International Pty Ltd).

Participants of both workshops and interviews provided written consent before proceeding. They were provided with refreshments and given 500 Kenyan shillings (approximately US \$5) to reimburse them for their time and travel costs. The study was approved by the Monash University Human Research Ethics Committee (Australia) and the University of Nairobi and Kenyatta Hospital Ethics Committee (Kenya).

Following data analysis, we refined the intervention further by making recommended wording changes, emphasizing certain content, finalizing the structure (order, timing, and frequency of messages), and resolving technical implementation issues.

## Results

### Workshop Participant Characteristics

We held 6 workshops, each with 7 FSWs, in November 2015 to test the draft messages and refine the intervention. Workshops A and E were held solely with women who had experienced unintended pregnancy to allow open discussion of this issue. Most participants were in their mid-20s (median age 24 years, IQR 20-30) with some secondary education (secondary: 20/42, 48%; primary 15/42, 36%; tertiary: 7/42, 17%) and at least 1 child (34/42, 81%). They worked from a range of hotspots, with half working from bars or nightclubs. Just over half of participants owned a smartphone (the remainder had feature or basic mobile phones), and almost all used SMS at least daily. It was common for participants to share text messages (35/42, 83%), mostly with friends, and some also with family, boyfriends, and clients.

## Responses to Message Content

### Importance of Topics and Relevance

Participants felt that the topics covered were high priorities for FSWs and would be useful to their community. They confirmed that unintended pregnancy was an important issue that caused fear and stress, and relayed personal experiences of getting pregnant unintentionally. They particularly liked messages that gave general pregnancy prevention advice and information about IUDs.

*Many sex workers fear getting pregnant [more] than HIV. [Age 19, Kisauni, workshop F]*

*Message 2 is important...as female sex workers we must use family planning because we have many clients and we need to protect ourselves from becoming pregnant. [Age 20, Kisauni, workshop E]*

There was a strong positive response to messages on rights, violence, and alcohol use, particularly when violence hotlines were provided, and practical tips were given to reduce alcohol-related harms:

*Many sex workers do not know their rights so by sharing with them [these] messages they will be informed. [Age 24, Changamwe, workshop D]*

Messages were considered highly relevant and spoke to participants' real experiences, particularly the role model stories, with which participants strongly identified.

*This information talks about what sex workers go through. [Age 19, Changamwe, workshop F]*

Many women volunteered personal stories that echoed message content. Common scenarios were pregnancy scares, difficulty negotiating condom use, experiences of violence, and contraceptive side effects. Role model stories in which the character gets drunk and then needs to use emergency contraception, and in which a woman overcomes contraceptive myths to use an IUD prompted the most discussion and personal anecdotes.

*It is realistic. I had the experience when the condom busted and I was unable to access e-pills on time, therefore I conceived a baby and I had no option of aborting, therefore I carried pregnancy to term. [Age 35, Kisauni, workshop E]*

*This thing happens to sex workers and it has happened to me, too. [Referring to unprotected sex while drunk; age 36, Kisauni, workshop C]*

### Appeal and Tone

Most women found the messages interesting and appealing, and several commented that the messages stimulated an interest in them to find out more. The majority in all groups agreed that they felt inspired by the role model stories.

*It is inspirational especially when Sandra [character in a story] visits a health center for screening and also consults friends on STI prevention. [Age 40, Changamwe, workshop B]*

*I am inspired. It shows us different family planning methods for example depo, IUD. [Age unknown, Kisauni, workshop E]*

Positive tone also contributed to the appeal. When specifically asked about tone, the most common responses were that the messages were friendly (mentioned 21 times), educational (16), and polite (9). Six women also commented spontaneously that the messages were caring:

*They are friendly because they let you know that there is someone who cares for you. [Age 44, Changamwe, workshop B]*

*It is friendly. The message is like peers talking to me. It is not official. [Age 35, Kisauni, workshop E]*

Participants were asked if FSWs would trust the information provided. Most agreed they would, because the messages were caring and relevant to sex workers, and their community had been involved in developing them.

*They will trust [the information] because somebody is caring for them. [Age 22, Changamwe, workshop F]*

*This information is good and they will accept it and also [because] we have been involved. [Age 24, Changamwe, workshop B]*

### Responses to Behavior Change Strategies

Behavior change strategies adopted from social cognitive theory that were used to develop messages resonated with women. Strategies that were most strongly echoed in their responses were the provision of knowledge, change in outcome expectations, self-efficacy and skill development, and empowerment.

#### Knowledge Gain

A large number of participants reflected that the messages taught them new and useful information. This was the response to both the program overall and specific topics, particularly messages on contraceptive options and side effects, IUDs, condoms, HIV, and alcohol. Participants from workshop A, who were less educated than other groups, were particularly keen to learn more.

*I would like to learn more so I would enroll [in the program]. [Age 23, Changamwe, workshop A]*

*Friends would want to know more...Yes I will be taught then share the information, especially among sex workers on unwanted pregnancies. [Age 22, Kisauni, workshop D]*

Specific knowledge gaps were identified as negatively affecting individual participants and their community. Knowledge gaps in HIV transmission were mentioned 4 times, condom usage techniques 3 times, side effects of family planning twice, appropriateness of using IUD with multiple partners twice, menstrual cycles twice, and alcohol and rights once each.

Women frequently mentioned how messages challenged prevalent myths about contraception, particularly about side effects and appropriate use of IUDs:

*I did not know that one can use a coil [IUD] and still have many partners. [Age 23, Changamwe, workshop A]*

*I can relate to this episode because I knew with sperms my sitting allowance [buttocks] would increase and my side mirror [hips] would expand, but that was a myth. I have learnt. [Referring to myth that sperm in the vagina is beneficial; age 19, Kisauni, workshop F]*

However, some described incorrect ideas that they or their peers still held about contraception:

*The coil is not good for sex workers because of the nature of work. We have different men of different [penis] sizes. [Age 38, Kisauni, workshop E]*

Only 2 participants stated that they did not learn anything new, indicating that the level of information was generally well targeted to participants' background knowledge.

#### Outcome Expectations

Outcome expectations refers to the beliefs one holds about the outcomes that will result from a specific behavior [42]. Many messages triggered participants to think about the outcomes of their behaviors, both positive and negative, particularly in relation to family planning. They were also prompted to think about the outcomes of heavy alcohol use, STI prevention, and service utilization. Examples of the outcomes they reflected on are presented in Table 4.



**Table 4.** Outcome expectations raised by workshop participants and corresponding quotes.

Outcome expectations	Example quotes
An outcome of using family planning is not getting pregnant and hence avoiding related stress	<ul style="list-style-type: none"> <li>• “If I am with a client and I am on family planning, I will not fear issues of pregnancy.” (Age 24, Changamwe, workshop B)</li> <li>• “When she [character in a role model story] uses coil, she is free and does not have fear of getting pregnant.” (Age 23, Kisauni, workshop D)</li> </ul>
Some contraceptive methods cause negative outcomes in the form of side effects but these are less severe than many perceive and can be addressed	<ul style="list-style-type: none"> <li>• “These contraceptives have different effects: they lie to the body that you are pregnant [due to amenorrhea], but if you know the effects there is need not to worry.” (Age 20, Kisauni, workshop D)</li> <li>• “It has inspired me, because I can use a coil and when I want a baby I can return to fertility and conceive.” (Age 19, Kisauni, workshop E)</li> </ul>
Getting drunk results in increased risk and bad business	<ul style="list-style-type: none"> <li>• “If I get drunk when I go to the hotspot I will not be able to negotiate well with the client and I might be violated. I will not be able to get what I wanted.” (Age 19, Changamwe, workshop F)</li> <li>• “When I am sober I will take care of myself from drama and keep myself safe, as sometimes men take advantage if one is drunk; he may refuse to pay you, steal your money and phone, or even not use a condom.” (Age 36, Kisauni, workshop C)</li> </ul>
If one accesses a service, they can expect to be provided with good quality care	<ul style="list-style-type: none"> <li>• “When I go the clinic I can get help for an implant or STI treatment.” (Age 20, Changamwe, workshop A)</li> <li>• “I have learnt that a health worker can listen to a sex worker and give advice.” (Age 24, Changamwe, workshop D)</li> </ul>

Role model stories appeared particularly well suited to supporting changes in outcome expectations and triggered responses in which women reflected on the behaviors of the characters, and the outcomes of their own behaviors and those of peers:

*Yes; Lynette [character in story] was drunk and did not have a family planning method, if she had coil the situation could have been avoided.* [Age 30, Kisauni, workshop C]

*My friend had a fear of using a coil, but when she went to hospital she was given advice and more information and she ended up using it, and it is not disturbing her.* [Age 30, Kisauni, workshop E]

### Self-Efficacy, Skills, and Action

Participants' comments indicated a belief that they or their peers are capable of adopting certain behaviors, demonstrating self-efficacy for healthy behavior. They also reflected that some of the messages improved their skills and confidence to adopt new behaviors. Messages that provided specific skills and techniques to lower drinking risk, and specific tips on condom use, were particularly well-received:

*I can talk to the waiter and exchange beer with water.* [Age 26, Kisauni, workshop C]

Violence and rights messages prompted statements reflecting increased self-efficacy for recognizing rights, seeking help, and negotiating with clients:

*I know now I am the boss and I can negotiate for payment with clients.* [Age 22, Kisauni, workshop F]

*These messages will teach them their rights, and how they can negotiate and report cases if violated.* [Age 18, Kisauni, workshop F]

Messages on what to expect from service providers also prompted a response that suggested women felt capable of accessing services:

*It is true—the job of the health care is to give services, and I can find a clinic where I am comfortable.* [Age 26, Kisauni, workshop C]

Participants liked messages that suggested specific actions or plans, and they were triggered to think about what they should do in different situations and how they could make the best use of the messages:

*I will put a reminder on the message that I have received, for example when I am at the hotspot.* [Age 19, Kisauni, workshop F]

*If one contraceptive is not good for you, change to another one.* [Age 22, Kisauni, workshop D]

*When I go out I should have a friend or talk to the receptionist at the hotspot to check on my security, and not go with the money in the room.* [Age 30, Kisauni, workshop C]

### Empowerment

Empowerment refers to a process in which individuals and communities gain control over their lives and the issues that most affect them, and includes the development of self-confidence and self-reliance [46-48]. The responses of women indicate that they found the messages empowering to both themselves and their community, particularly messages about violence and rights:

*It is about me, myself and I. I deserve to be happy and know my rights. Yes I like this message [about rights of sex workers].* [Age 24, Changamwe, workshop D]

*We should visit people who can listen to our voice or our complaints, and health workers should not stigmatize us when we go for services.* [Age 23, Kisauni, workshop D]

There was a sense that the messages prompted improved morale and inspired them to take action. A number of women

specifically mentioned the importance of being in control, particularly in response to role model stories. Stories about the use of LARCs also prompted a sense of being free from the fear of getting pregnant:

*They give me morale to use condoms.* [Age 31, Changamwe, workshop A]

*Dual methods remove fear. I have total control when I have the implant and use condoms.* [Age 23, Changamwe, workshop A]

Participants were overwhelmingly in favor of sharing the messages with other sex workers and friends, and to a lesser extent, with family members, boyfriends, clients, and health workers. Almost all said they would share messages when asked directly, and many said that they would do so without prompting, consistent with the existing practice of frequent sharing. The desire to share influenced their preferences for message delivery. Participants in workshop E preferred SMS because it is an easy format to share. Those in workshops A and B wanted to receive the messages before starting work, to allow time to discuss them with others at the hotspot. Many indicated that it was important for both sex workers and the broader community to have access to this information, and that, as holders of the messages, they would be empowered to provide it. There was a real enthusiasm expressed for teaching others:

*My friends do not have this information, therefore I will reach out to them and share with them.* [Age 31, Changamwe, workshop A]

*I will share with 15 and 16 year age groups, because they do not know about family planning and they are already engaging in sex.* [Age 20, Kisauni, workshop E]

*I will share with my clients so that they can reach their spouses.* [Age 33, Kisauni, workshop E]

*By teaching others these messages they will help me to remember.* [Age 16, Changamwe, workshop F]

### Risks of the Program

One workshop participant thought that she could contact WHISPER to receive emergency assistance (“If am assaulted I can send message or call to get help”; age 40, Kisauni, workshop C). As WHISPER is an automated system, such requests cannot be followed up, and it was concerning that the women may have thought they could depend on the program in this way. This was addressed in subsequent changes to the program (described below).

Breach of privacy was also raised as a potential risk. Participants in 3 workshops discussed the risk that someone else would see the messages and would assume that they were sex workers and/or HIV positive. Some were afraid that this could cause conflict with their boyfriends.

*It will bring conflict between me and my boyfriend who might be nosy especially on information on STIs.* [Age 24, Changamwe, workshop B]

*It depends on the person and the relationship you have with them. For example, if a parent sees information about a condom he or she will react, but*

*you can explain. If a client or a boyfriend sees information on HIV he will panic.* [Age 19, Kisauni, workshop F]

However, not all agreed, and there was a discussion about how the messages might be good for other people, including their boyfriends, illustrated in this interaction:

*Even the boyfriends want to plan a family, so they cannot deter us from using this service.* [Age 35, Changamwe, workshop B]

*These messages will be good for both parties—man and woman.* [Age 40, Changamwe, workshop B]

Others felt that the messages would be socially acceptable. For example, workshop A participants thought friends and health care workers would be impressed that they were *careful with their lives*:

*My boyfriend, family or friend will say I am informed.* [Age 23, Changamwe, workshop A]

Another risk is that the program would not overcome barriers to healthy behaviors in sex work. Responses illustrated how some barriers cannot be overcome by an individually targeted intervention alone. For example, a role model story about a client offering to pay extra for no condom prompted discussion in workshop F about the need to balance conflicting outcome expectations of different courses of action. This reflected sex workers’ need to continually assess risk, and the fact that money and immediate safety are often higher priorities than pregnancy and STI prevention.

*The client of Joslyn [character in the story] in this case was polite, because he said he will call next week, but most clients will become abusive if you refuse to not use condoms.* [Age 19, Changamwe, workshop F]

*The issue is money. That is why female sex workers risk going without a condom—so that she might get a client.* [Age 19, Kisauni, workshop F]

*I had a friend who had the same issue. She judged the guy with looks because the guy had money. She did not negotiate for condom before. The money was huge. The lady refused because this guy insisted no condom.* [Age 22, Kisauni, workshop F]

### Response to On-Demand Messages

Interview participants were sent messages with a link to the on-demand system. In all, 7 of 12 participants found it *very easy* to access messages on demand. Others had minor difficulties, and 2 had genuine difficulty and had to be directed by the interviewer. These women had lower education than other participants.

Many women liked having the option to retrieve more information and the interactive aspect of the system. They talked about the ease of getting detailed information on their phones rather than having to seek it out from health professionals, and the ability to refer back to such messages later. A number of women did not feel the initial message on a topic contained new information, but obtaining more detail allowed them to gain a greater understanding.

*It has motivated me since I can get instant replies and can be helped instantly.* [Age 26, Changamwe]

*It is like revision [on] family planning when I am reading I am being enlightened more and remembering, it is easy.* [Age 33, Changamwe]

Messages about health services were considered very useful to participants and their peers as they provided information that was not easy to obtain and saved the time and resources needed to find appropriate services. The emergency message (developed in response to workshop feedback—described below) was particularly popular and seen as important.

*When I need help, or having an emergency, they have provided a number which I can call for free in case of violence and has given me a whisper menu too. In short they have not left me hanging from the situation I may be experiencing.* [Age 30, Kisauni]

There were some technical issues during interviews, including delayed receipt of messages and (erroneous) warnings received from network providers, which deterred some women from continuing. Despite these challenges, most interview participants were very engaged in the process of retrieving pull messages, and those who had initial difficulty still enjoyed the process. When asked directly, all agreed that they would like to continue using the system.

## Intervention Structure and Final Delivery

### Intervention Delivery Preferences

Workshop participants had generally consistent preferences regarding how the intervention should be delivered. The majority were in favor of text rather than voice modality and preferred push messages to retrieving content via a pull system. Most women reported that their texting practices involved a mixture of English and Swahili, and they favored English for health messages, with some keywords or phrases in Swahili. Participants wanted to receive messages several times a week for at least 1 year and preferred to receive them in the late morning on set days to align with their typical work schedules.

### Refinement of the Intervention

A number of changes were made to the intervention content and form based on findings. To minimize the risk of women expecting emergency assistance from WHISPER, a message was included on what to do in an emergency, specifically around violence. An *error* message was also developed that was triggered if they tried to send content other than the prespecified codes. These were well received on testing in the interviews.

The other key concern identified was the risk of sex work status being discovered by clients or boyfriends viewing the messages. In response to this, we minimized overt references to sex work and clients wherever possible.

Suggestions were adopted from participants regarding the use of specific words and terms, in both Swahili and English. Terms of endearment like *mrembo* (beautiful) and *darling* were incorporated into the messages, and *family planning* was adopted consistently as FSW's preferred term for pregnancy prevention.

A number of strategies were adopted to address the technical challenges encountered using the on-demand system. These included testing the system with each participant during their enrolment and incorporating introductory messages that explained how to use the on-demand menu.

### Final Intervention Schedule

The intervention components and delivery schedule were finalized based on workshop and interview results. Over a 12-month intervention period, participants received SMS 2 to 3 times per week, alternating push messages with role model stories every month. A total of 82 push messages were developed for the intervention (see examples in Table 1). In addition, 7 reminders for study visits and 19 alerts linking to the pull system (Table 2) were sent to participants. Six role model stories were sent, each with 4 or 5 episodes (Table 1). Messages were scheduled for mornings on set days, in line with participant preferences.

## Discussion

We provide the first description of the development of a digital health intervention for FSWs that uses a comprehensive SRHR framework. The participatory approach enabled FSWs to influence the range and content of topics included in the intervention [49] and to enhance the relevance and salience of messages, and the participants themselves confirmed that their involvement improved the perceived trustworthiness of the messages. The benefits of a co-design approach have been observed in other mHealth studies [32]. Co-design is critical for handling sensitive content matter that may be interpreted differently by different communities [50].

Furthermore, health behavior change interventions are more effective when they are based on social and behavioral science theory, and the use of multiple theories may increase intervention effectiveness [51,52]. WHISPER utilizes multiple theories to guide the intervention framework and specify intermediate behavior change outcomes [42,43]. Notably, the adopted strategies from Bandura's social cognitive theory [35] were frequently highlighted by workshop participants, confirming the applicability and utility of theory for guiding intervention design.

The messages increased participants' feelings of empowerment [46-48] and social support [43]. There was a strong sense of being part of a community; many women reflected on how messages would help their friends, or how they could share the knowledge they had gained, rather than focusing solely on how it would help them as individuals. These findings suggest that WHISPER may capitalize on and enhance community cohesion. Social cohesion has been linked to safer sex behaviors [53] and is important for the success of community empowerment interventions, which may otherwise be undermined by mistrust and competition among FSWs for scarce resources [7]. The desire to share messages with peers and the broader community suggests that social diffusion is also likely to contribute to the effectiveness of the intervention [43].

Participants reinforced the importance of the selected SRHR topics and confirmed that unintended pregnancy is a major



concern for sex workers. The team was careful to ensure that scenarios were not overly optimistic and appropriately represented known barriers. Content addressing family planning myths was stated in different ways and different formats (push and pull messages and role model stories) to maximize the potential that participants would engage with and learn from the WHISPER content so that myths would no longer represent barriers to participants.

In addition to family planning, alcohol use and gender-based violence were viewed as important. Strategies for reducing drinking provided in the text messages were adapted from effective harm reduction interventions [54], and this practical emphasis resonated strongly with participants. Experiences of violence were frequently described and noted as a barrier to adopting safer sexual practices. Although an individual health promotion intervention cannot address the structural causes of violence or change the behavior of perpetrators, participant responses indicate that messages about violence improved knowledge of rights, were empowering, and provided much-needed advice about how to reduce risks and access services.

The intervention was highly acceptable to both workshop and interview participants. Women were interested and engaged in both the content and the format of delivery, with role model stories eliciting particularly enthusiastic discussion, and SMS confirmed as the preferred technology. Workshop and interview participants demonstrated familiarity and comfort using SMS, and desire to learn more, suggesting that it is feasible for SRHR messages to be sent regularly over a year to this population. Testing during interviews confirmed the feasibility of the on-demand system. Most participants could retrieve pull messages with relative ease; however, women who are less educated or have less experience with mobile phones may experience difficulty using this system.

There were some technical issues, including a network warning that could not be deactivated. Similar problems have been identified by other implementers of mHealth programs [55,56], highlighting the importance of real-time testing and the need to consider how to overcome aspects of mobile platforms designed for commercial rather than public health applications.

We have demonstrated that WHISPER is feasible to implement and acceptable to the target audience; however, this may not translate to sufficient participant engagement to produce better health outcomes. Engagement with a digital health program

incorporates not only the subjective and cognitive responses that are triggered (which are explored in this paper) but also the extent of use [57] (eg, the number and frequency of messages received), which will be measured during the trial. The evaluation of engagement in digital health interventions has not been well characterized and is an important area for further research [57].

Our research revealed several risks to participation in a digital health SRHR intervention. First, participants believed that they could receive emergency assistance from WHISPER. It is possible that the friendly and personal tone—while effective in generating intervention engagement [58]—creates an expectation that participants are interacting with real people rather than an automated system. Revisions were made to minimize this risk.

Second, disclosure of sensitive messages could result in increased conflict with boyfriends or clients, although it also has the potential to improve communication with partners. Disclosure risk has been explored during the development of mHealth interventions for HIV [58–60], and an increase in intimate partner violence was an unintended consequence of a contraceptive mHealth program in Bangladesh [61]. However, few studies report on the potential harms from women's participation in SRHR digital health programs, and this is an important area for further research [61,62].

This study had some important limitations. We used purposive sampling and cannot ensure that workshop participants were representative of the larger FSW population. In addition, our approach to data collection and analysis was highly directive, and some messages were not tested because they were from preexisting mHealth interventions [37]. This approach to data collection yielded the specific information needed to develop the intervention, but it was not designed to reach data saturation, and it is possible that some critical feedback was not obtained.

This research provides a clear illustration of the many issues that preoccupy FSWs in their day-to-day lives—beyond the traditional biomedical focus on HIV risk and transmission. Our results support the need for health promotion interventions that utilize a participatory approach to intervention development and are based on social and behavioral science to increase their relevance and effectiveness. The resulting WHISPER digital health intervention reflects the complex reality of FSWs' daily lives and provides a feasible, engaging, and confidential approach for addressing their SRHR concerns and needs.

---

## Acknowledgments

This work was supported by the National Health and Medical Research Council Australia (NHMRC) under Project Grant GNT 1087006, NHMRC Career Development Fellowships for SL and MS, and an NHMRC Postgraduate Scholarship for FA. The authors would like to acknowledge the FSW peer educators and research assistants who contributed to this work. We also gratefully acknowledge the contribution to this work of funding from the Victorian Operational Infrastructure Support Program received by the Burnet Institute.

---

## Conflicts of Interest

None declared.

---

## References

<https://mhealth.jmir.org/2020/5/e15096>

JMIR Mhealth Uhealth 2020 | vol. 8 | iss. 5 | e15096 | p. 11  
(page number not for citation purposes)

1. Dhana A, Luchters S, Moore L, Lafort Y, Roy A, Scorgie F, et al. Systematic review of facility-based sexual and reproductive health services for female sex workers in Africa. *Global Health* 2014 Jun 10;10:46 [FREE Full text] [doi: [10.1186/1744-8603-10-46](https://doi.org/10.1186/1744-8603-10-46)] [Medline: [24916010](https://pubmed.ncbi.nlm.nih.gov/24916010/)]
2. National AIDS/STD Control Programme of the Kenya Ministry of Public Health and Sanitation. Bar Hostess Empowerment & Support Programme (BHESP). 2010 Sep. Standards for Peer-Education and Outreach Programs for Sex Workers URL: <https://tinyurl.com/y7j5kjnx> [accessed 2020-03-10]
3. Luchters S, Chersich MF, Rinyiru A, Barasa M, King'ola N, Mandaliya K, et al. Impact of five years of peer-mediated interventions on sexual behavior and sexually transmitted infections among female sex workers in Mombasa, Kenya. *BMC Public Health* 2008 Apr 29;8:143 [FREE Full text] [doi: [10.1186/1471-2458-8-143](https://doi.org/10.1186/1471-2458-8-143)] [Medline: [18445258](https://pubmed.ncbi.nlm.nih.gov/18445258/)]
4. Chersich MF, Luchters S, Ntaganira I, Gerbase A, Lo YR, Scorgie F, et al. Priority interventions to reduce HIV transmission in sex work settings in sub-Saharan Africa and delivery of these services. *J Int AIDS Soc* 2013 Mar 4;16:17980 [FREE Full text] [doi: [10.7448/IAS.16.1.17980](https://doi.org/10.7448/IAS.16.1.17980)] [Medline: [23462140](https://pubmed.ncbi.nlm.nih.gov/23462140/)]
5. Lafort Y, Geelhoed D, Cumba L, Lázaro CD, Delva W, Luchters S, et al. Reproductive health services for populations at high risk of HIV: Performance of a night clinic in Tete province, Mozambique. *BMC Health Serv Res* 2010 May 28;10:144 [FREE Full text] [doi: [10.1186/1472-6963-10-144](https://doi.org/10.1186/1472-6963-10-144)] [Medline: [20507644](https://pubmed.ncbi.nlm.nih.gov/20507644/)]
6. Yam EA, Okal J, Musyoki H, Muraguri N, Tun W, Sheehy M, et al. Kenyan female sex workers' use of female-controlled nonbarrier modern contraception: do they use condoms less consistently? *Contraception* 2016 Mar;93(3):222-225. [doi: [10.1016/j.contraception.2015.11.010](https://doi.org/10.1016/j.contraception.2015.11.010)] [Medline: [26656841](https://pubmed.ncbi.nlm.nih.gov/26656841/)]
7. Cornish F, Campbell C. The social conditions for successful peer education: a comparison of two HIV prevention programs run by sex workers in India and South Africa. *Am J Community Psychol* 2009 Sep;44(1-2):123-135. [doi: [10.1007/s10464-009-9254-8](https://doi.org/10.1007/s10464-009-9254-8)] [Medline: [19521765](https://pubmed.ncbi.nlm.nih.gov/19521765/)]
8. Petrune T, Minichiello SN, McDowell M, Wilcher R. Meeting the contraceptive needs of key populations affected by HIV in Asia: An unfinished agenda. *AIDS Res Treat* 2012;2012:792649 [FREE Full text] [doi: [10.1155/2012/792649](https://doi.org/10.1155/2012/792649)] [Medline: [22991656](https://pubmed.ncbi.nlm.nih.gov/22991656/)]
9. Moore L, Chersich MF, Steen R, Reza-Paul S, Dhana A, Vuylsteke B, et al. Community empowerment and involvement of female sex workers in targeted sexual and reproductive health interventions in Africa: a systematic review. *Global Health* 2014 Jun 10;10:47 [FREE Full text] [doi: [10.1186/1744-8603-10-47](https://doi.org/10.1186/1744-8603-10-47)] [Medline: [24916108](https://pubmed.ncbi.nlm.nih.gov/24916108/)]
10. Slabbert M, Venter F, Gay C, Roelofsen C, Lalla-Edward S, Rees H. Sexual and reproductive health outcomes among female sex workers in Johannesburg and Pretoria, South Africa: Recommendations for public health programmes. *BMC Public Health* 2017 Jul 4;17(Suppl 3):442 [FREE Full text] [doi: [10.1186/s12889-017-4346-0](https://doi.org/10.1186/s12889-017-4346-0)] [Medline: [28832290](https://pubmed.ncbi.nlm.nih.gov/28832290/)]
11. Beckham SW, Shembilu CR, Brahmabhatt H, Winch PJ, Beyrer C, Kerrigan DL. Female sex workers' experiences with intended pregnancy and antenatal care services in southern Tanzania. *Stud Fam Plann* 2015 Mar;46(1):55-71 [FREE Full text] [doi: [10.1111/j.1728-4465.2015.00015.x](https://doi.org/10.1111/j.1728-4465.2015.00015.x)] [Medline: [25753059](https://pubmed.ncbi.nlm.nih.gov/25753059/)]
12. Global Health Council. Washington, DC: The Center for Health and Gender Equity; 2016 Aug 5. REPORT: All Women, All Rights, Sex Workers Included: US Foreign Assistance and the Sexual and Reproductive Health and Rights of Female Sex Workers URL: <https://tinyurl.com/y8zk6tft> [accessed 2020-03-10]
13. Ampt FH, Willenberg L, Agius PA, Chersich M, Luchters S, Lim MS. Incidence of unintended pregnancy among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *BMJ Open* 2018 Sep 17;8(9):e021779 [FREE Full text] [doi: [10.1136/bmjopen-2018-021779](https://doi.org/10.1136/bmjopen-2018-021779)] [Medline: [30224388](https://pubmed.ncbi.nlm.nih.gov/30224388/)]
14. Sutherland EG, Alaii J, Tsui S, Luchters S, Okal J, King'ola N, et al. Contraceptive needs of female sex workers in Kenya - a cross-sectional study. *Eur J Contracept Reprod Health Care* 2011 Jun;16(3):173-182. [doi: [10.3109/13625187.2011.564683](https://doi.org/10.3109/13625187.2011.564683)] [Medline: [21413869](https://pubmed.ncbi.nlm.nih.gov/21413869/)]
15. Cheuk E, Becker M, Mishra S, Blanchard J, Isac S, Kingola N, et al. Understanding Female Sex Workers' Early HIV Risk and the Implications for HIV Epidemic Control (Transitions Study): Mapping and Estimating the Population Size of Female Sex Workers in Mombasa, Kenya and Dnipropetrovsk, Ukraine. In: Proceedings of the 24th Annual Canadian Conference on HIV/AIDS Research. 2015 Presented at: CAHR'15; April 30 - May 3, 2015; Toronto, Ontario URL: [https://www.cahr-acrv.ca/wp-content/uploads/2012/10/InfDis\\_26\\_SB\\_MarApr2015\\_Final.pdf](https://www.cahr-acrv.ca/wp-content/uploads/2012/10/InfDis_26_SB_MarApr2015_Final.pdf)
16. Luchters S, Bosire W, Feng A, Richter ML, King'ola N, Ampt F, et al. 'A baby was an added burden': predictors and consequences of unintended pregnancies for female sex workers in Mombasa, Kenya: a mixed-methods study. *PLoS One* 2016;11(9):e0162871 [FREE Full text] [doi: [10.1371/journal.pone.0162871](https://doi.org/10.1371/journal.pone.0162871)] [Medline: [27689699](https://pubmed.ncbi.nlm.nih.gov/27689699/)]
17. Khan MR, Turner AN, Pettifor A, van Damme K, Rabenja NL, Ravelomanana N, Mad STI Prevention Group, et al. Unmet need for contraception among sex workers in Madagascar. *Contraception* 2009 Mar;79(3):221-227 [FREE Full text] [doi: [10.1016/j.contraception.2008.09.011](https://doi.org/10.1016/j.contraception.2008.09.011)] [Medline: [19185677](https://pubmed.ncbi.nlm.nih.gov/19185677/)]
18. Boudreau CL. Assessing the contraceptive needs of female sex workers in Kigali, Rwanda. *Ann Glob Health* 2015;81(1):217. [doi: [10.1016/j.aogh.2015.02.997](https://doi.org/10.1016/j.aogh.2015.02.997)]
19. Okal J, Stadler J, Ombidi W, Jao I, Luchters S, Temmerman M, et al. Secrecy, disclosure and accidental discovery: perspectives of diaphragm users in Mombasa, Kenya. *Cult Health Sex* 2008 Jan;10(1):13-26. [doi: [10.1080/13691050701519730](https://doi.org/10.1080/13691050701519730)] [Medline: [18038278](https://pubmed.ncbi.nlm.nih.gov/18038278/)]

20. Williamson LM, Parkes A, Wight D, Petticrew M, Hart GJ. Limits to modern contraceptive use among young women in developing countries: a systematic review of qualitative research. *Reprod Health* 2009 Feb 19;6:3 [FREE Full text] [doi: [10.1186/1742-4755-6-3](https://doi.org/10.1186/1742-4755-6-3)] [Medline: [19228420](https://pubmed.ncbi.nlm.nih.gov/19228420/)]
21. Sedgh G, Hussain R, Bankole A, Singh S. Guttmacher Institute. New York: Guttmacher Institute; 2007 Jun. Women With an Unmet Need for Contraception in Developing Countries and Their Reasons for Not Using a Method URL: <https://www.guttmacher.org/sites/default/files/pdfs/pubs/2007/07/09/or37.pdf> [accessed 2020-03-10]
22. Thomas B, Closson EF, Biello K, Menon S, Navakodi P, Dhanalakshmi A, et al. Development and open pilot trial of an HIV-prevention intervention integrating mobile-phone technology for male sex workers in Chennai, India. *Arch Sex Behav* 2017 May;46(4):1035-1046 [FREE Full text] [doi: [10.1007/s10508-015-0665-3](https://doi.org/10.1007/s10508-015-0665-3)] [Medline: [26714684](https://pubmed.ncbi.nlm.nih.gov/26714684/)]
23. Information and Communication Technology (ICT). 2018. Statistics URL: <http://www.itu.int/en/ITU-D/Statistics/Pages/stat/default.aspx> [accessed 2019-07-09]
24. Smith C, Gold J, Ngo TD, Sumpter C, Free C. Mobile phone-based interventions for improving contraception use. *Cochrane Database Syst Rev* 2015 Jun 26(6):CD011159 [FREE Full text] [doi: [10.1002/14651858.CD011159.pub2](https://doi.org/10.1002/14651858.CD011159.pub2)] [Medline: [26115146](https://pubmed.ncbi.nlm.nih.gov/26115146/)]
25. Badawy SM, Kuhns LM. Texting and mobile phone app interventions for improving adherence to preventive behavior in adolescents: a systematic review. *JMIR Mhealth Uhealth* 2017 Apr 19;5(4):e50 [FREE Full text] [doi: [10.2196/mhealth.6837](https://doi.org/10.2196/mhealth.6837)] [Medline: [28428157](https://pubmed.ncbi.nlm.nih.gov/28428157/)]
26. Rokicki S, Cohen J, Salomon JA, Fink G. Impact of a text-messaging program on adolescent reproductive health: a cluster-randomized trial in Ghana. *Am J Public Health* 2017 Feb;107(2):298-305. [doi: [10.2105/AJPH.2016.303562](https://doi.org/10.2105/AJPH.2016.303562)] [Medline: [27997236](https://pubmed.ncbi.nlm.nih.gov/27997236/)]
27. Harrington EK, Drake AL, Matemo D, Ronen K, Osoti AO, John-Stewart G, et al. An mHealth SMS intervention on postpartum contraceptive use among women and couples in Kenya: a randomized controlled trial. *Am J Public Health* 2019 Jun;109(6):934-941. [doi: [10.2105/AJPH.2019.305051](https://doi.org/10.2105/AJPH.2019.305051)] [Medline: [31067089](https://pubmed.ncbi.nlm.nih.gov/31067089/)]
28. Johnson D, Juras R, Riley P, Chatterji M, Sloane P, Choi SK, et al. A randomized controlled trial of the impact of a family planning mHealth service on knowledge and use of contraception. *Contraception* 2017 Jan;95(1):90-97. [doi: [10.1016/j.contraception.2016.07.009](https://doi.org/10.1016/j.contraception.2016.07.009)] [Medline: [27421767](https://pubmed.ncbi.nlm.nih.gov/27421767/)]
29. Ampt FH, Mudogo C, Gichangi P, Lim MS, Manguro G, Chersich M, et al. WHISPER or SHOUT study: protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017 Aug 18;7(8):e017388 [FREE Full text] [doi: [10.1136/bmjopen-2017-017388](https://doi.org/10.1136/bmjopen-2017-017388)] [Medline: [28821530](https://pubmed.ncbi.nlm.nih.gov/28821530/)]
30. O'Mara-Eves A, Brunton G, McDaid D, Oliver S, Kavanagh J, Jamal F, et al. Community engagement to reduce inequalities in health: a systematic review, meta-analysis and economic analysis. *Pub Health Res* 2013;1(4) [FREE Full text] [Medline: [25642563](https://pubmed.ncbi.nlm.nih.gov/25642563/)]
31. Cyril S, Smith BJ, Possamai-Inesedy A, Renzaho AM. Exploring the role of community engagement in improving the health of disadvantaged populations: a systematic review. *Glob Health Action* 2015;8:29842 [FREE Full text] [doi: [10.3402/gha.v8.29842](https://doi.org/10.3402/gha.v8.29842)] [Medline: [26689460](https://pubmed.ncbi.nlm.nih.gov/26689460/)]
32. Eyles H, Jull A, Dobson R, Firestone R, Whittaker R, Te Morenga L, et al. Co-design of mHealth delivered interventions: a systematic review to assess key methods and processes. *Curr Nutr Rep* 2016;5(3):160-167. [doi: [10.1007/s13668-016-0165-7](https://doi.org/10.1007/s13668-016-0165-7)]
33. L'Engle K, Plourde KF, Zan T. Evidence-based adaptation and scale-up of a mobile phone health information service. *Mhealth* 2017;3:11 [FREE Full text] [doi: [10.21037/mhealth.2017.02.06](https://doi.org/10.21037/mhealth.2017.02.06)] [Medline: [28567408](https://pubmed.ncbi.nlm.nih.gov/28567408/)]
34. Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983 Jun;51(3):390-395. [doi: [10.1037//0022-006x.51.3.390](https://doi.org/10.1037//0022-006x.51.3.390)] [Medline: [6863699](https://pubmed.ncbi.nlm.nih.gov/6863699/)]
35. Bandura A. Social Foundations of Thought and Action: A Social Cognitive Theory. Englewood Cliffs, NJ: Prentice Hall; 1986.
36. Lim MS, Hocking JS, Aitken CK, Fairley CK, Jordan L, Lewis JA, et al. Impact of text and email messaging on the sexual health of young people: a randomised controlled trial. *J Epidemiol Community Health* 2012 Jan;66(1):69-74. [doi: [10.1136/jech.2009.100396](https://doi.org/10.1136/jech.2009.100396)] [Medline: [21415232](https://pubmed.ncbi.nlm.nih.gov/21415232/)]
37. L'Engle KL, Vahdat HL, Ndakidemi E, Lasway C, Zan T. Evaluating feasibility, reach and potential impact of a text message family planning information service in Tanzania. *Contraception* 2013 Feb;87(2):251-256. [doi: [10.1016/j.contraception.2012.07.009](https://doi.org/10.1016/j.contraception.2012.07.009)] [Medline: [22935322](https://pubmed.ncbi.nlm.nih.gov/22935322/)]
38. Vahdat HL, L'Engle KL, Plourde KF, Magaria L, Olawo A. There are some questions you may not ask in a clinic: providing contraception information to young people in Kenya using SMS. *Int J Gynaecol Obstet* 2013 Nov;123(Suppl 1):e2-e6 [FREE Full text] [doi: [10.1016/j.ijgo.2013.07.009](https://doi.org/10.1016/j.ijgo.2013.07.009)] [Medline: [24012514](https://pubmed.ncbi.nlm.nih.gov/24012514/)]
39. World Health Organization. Family Planning - A Global Handbook for Providers. Baltimore and Geneva: CCP and WHO; 2011.
40. Ministry of Public Health and Sanitation. National Family Planning Guidelines for Service Providers: Updated to reflect the 2009 Medical Eligibility Criteria of the World Health Organization. Nairobi: Division of Reproductive Health, Ministry of Public Health and Sanitation; 2010.

41. Ministry of Public Health Sanitation. National guidelines for HIV/STI programs for sex workers. Nairobi, Kenya: Ministry of Public Health Sanitation; 2010.
42. Maibach E, Cotton D. Moving people to behaviour change. In: Maibach EW, Parrott RL, editors. *Designing Health Messages: Approaches from Communication Theory and Public Health Practice*. Thousand Oaks: Sage publications; 1995.
43. National Cancer Institute. Division of Cancer Control and Population Sciences. Bethesda, MD: National Institutes of Health; 2005. Theory at a Glance: A Guide for Health Promotion Practice URL: [https://cancercontrol.cancer.gov/brp/research/theories\\_project/theory.pdf](https://cancercontrol.cancer.gov/brp/research/theories_project/theory.pdf) [accessed 2020-03-10]
44. Armanasco AA, Miller YD, Fjeldsoe BS, Marshall AL. Preventive health behavior change text message interventions: a meta-analysis. *Am J Prev Med* 2017 Mar;52(3):391-402. [doi: [10.1016/j.amepre.2016.10.042](https://doi.org/10.1016/j.amepre.2016.10.042)] [Medline: [28073656](https://pubmed.ncbi.nlm.nih.gov/28073656/)]
45. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006 Jan;3(2):77-101. [doi: [10.1191/1478088706qp063oa](https://doi.org/10.1191/1478088706qp063oa)]
46. Wallerstein N. Powerlessness, empowerment, and health: implications for health promotion programs. *Am J Health Promot* 1992;6(3):197-205. [doi: [10.4278/0890-1171-6.3.197](https://doi.org/10.4278/0890-1171-6.3.197)] [Medline: [10146784](https://pubmed.ncbi.nlm.nih.gov/10146784/)]
47. Canadian International Development Agency. Cida's Policy On Gender Equality. Quebec: CIDA; 1999.
48. Varkey P, Mbbs, Kureshi S, Lesnick T. Empowerment of women and its association with the health of the community. *J Womens Health (Larchmt)* 2010 Jan;19(1):71-76. [doi: [10.1089/jwh.2009.1444](https://doi.org/10.1089/jwh.2009.1444)] [Medline: [20088661](https://pubmed.ncbi.nlm.nih.gov/20088661/)]
49. World Health Organization. Community Participation in Local Health and Sustainable Development: Approaches and Techniques. Copenhagen: World Health Organization Regional Office for Europe; 2002.
50. McCarthy OL, Wazwaz O, Calderon VO, Jado I, Saibov S, Stavridis A, et al. Development of an intervention delivered by mobile phone aimed at decreasing unintended pregnancy among young people in three lower middle income countries. *BMC Public Health* 2018 May 2;18(1):576 [FREE Full text] [doi: [10.1186/s12889-018-5477-7](https://doi.org/10.1186/s12889-018-5477-7)] [Medline: [29716571](https://pubmed.ncbi.nlm.nih.gov/29716571/)]
51. Glanz K, Bishop DB. The role of behavioral science theory in development and implementation of public health interventions. *Annu Rev Public Health* 2010;31:399-418. [doi: [10.1146/annurev.publhealth.012809.103604](https://doi.org/10.1146/annurev.publhealth.012809.103604)] [Medline: [20070207](https://pubmed.ncbi.nlm.nih.gov/20070207/)]
52. Lopez LM, Grey TW, Chen M, Tolley EE, Stockton LL. Theory-based interventions for contraception. *Cochrane Database Syst Rev* 2016 Nov 23;11:CD007249 [FREE Full text] [doi: [10.1002/14651858.CD007249.pub5](https://doi.org/10.1002/14651858.CD007249.pub5)] [Medline: [27879980](https://pubmed.ncbi.nlm.nih.gov/27879980/)]
53. Lippman SA, Donini A, Díaz J, Chinaglia M, Reingold A, Kerrigan D. Social-environmental factors and protective sexual behavior among sex workers: the Encontros intervention in Brazil. *Am J Public Health* 2010 Apr 1;100(Suppl 1):S216-S223 [FREE Full text] [doi: [10.2105/AJPH.2008.147462](https://doi.org/10.2105/AJPH.2008.147462)] [Medline: [19762673](https://pubmed.ncbi.nlm.nih.gov/19762673/)]
54. L Engle KL, Mwarogo P, Kingola N, Sinkela W, Weiner DH. A randomized controlled trial of a brief intervention to reduce alcohol use among female sex workers in Mombasa, Kenya. *J Acquir Immune Defic Syndr* 2014 Dec 1;67(4):446-453. [doi: [10.1097/QAI.0000000000000335](https://doi.org/10.1097/QAI.0000000000000335)] [Medline: [25197826](https://pubmed.ncbi.nlm.nih.gov/25197826/)]
55. Chernick LS, Stockwell MS, Wu M, Castaño PM, Schnall R, Westhoff CL, et al. Texting to increase contraceptive initiation among adolescents in the emergency department. *J Adolesc Health* 2017 Dec;61(6):786-790 [FREE Full text] [doi: [10.1016/j.jadohealth.2017.07.021](https://doi.org/10.1016/j.jadohealth.2017.07.021)] [Medline: [29056437](https://pubmed.ncbi.nlm.nih.gov/29056437/)]
56. McCarthy OL, Zghayyer H, Stavridis A, Adada S, Ahamed I, Leurent B, et al. A randomized controlled trial of an intervention delivered by mobile phone text message to increase the acceptability of effective contraception among young women in Palestine. *Trials* 2019 Apr 23;20(1):228 [FREE Full text] [doi: [10.1186/s13063-019-3297-4](https://doi.org/10.1186/s13063-019-3297-4)] [Medline: [31014358](https://pubmed.ncbi.nlm.nih.gov/31014358/)]
57. Perski O, Blandford A, West R, Michie S. Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis. *Transl Behav Med* 2017 Jun;7(2):254-267 [FREE Full text] [doi: [10.1007/s13142-016-0453-1](https://doi.org/10.1007/s13142-016-0453-1)] [Medline: [27966189](https://pubmed.ncbi.nlm.nih.gov/27966189/)]
58. Odeny TA, Newman M, Bukusi EA, McClelland RS, Cohen CR, Camlin CS. Developing content for a mHealth intervention to promote postpartum retention in prevention of mother-to-child HIV transmission programs and early infant diagnosis of HIV: a qualitative study. *PLoS One* 2014;9(9):e106383 [FREE Full text] [doi: [10.1371/journal.pone.0106383](https://doi.org/10.1371/journal.pone.0106383)] [Medline: [25181408](https://pubmed.ncbi.nlm.nih.gov/25181408/)]
59. Nachega JB, Skinner D, Jennings L, Magidson JF, Altice FL, Burke JG, et al. Acceptability and feasibility of mHealth and community-based directly observed antiretroviral therapy to prevent mother-to-child HIV transmission in South African pregnant women under Option B+: an exploratory study. *Patient Prefer Adherence* 2016;10:683-690 [FREE Full text] [doi: [10.2147/PPA.S100002](https://doi.org/10.2147/PPA.S100002)] [Medline: [27175068](https://pubmed.ncbi.nlm.nih.gov/27175068/)]
60. Ronen K, Unger JA, Drake AL, Perrier T, Akinyi P, Osborn L, et al. SMS messaging to improve ART adherence: perspectives of pregnant HIV-infected women in Kenya on HIV-related message content. *AIDS Care* 2018 Apr;30(4):500-505 [FREE Full text] [doi: [10.1080/09540121.2017.1417971](https://doi.org/10.1080/09540121.2017.1417971)] [Medline: [29254362](https://pubmed.ncbi.nlm.nih.gov/29254362/)]
61. Reiss K, Andersen K, Pearson E, Biswas K, Taleb F, Ngo T, et al. Unintended consequences of mHealth interactive voice messages promoting contraceptive use after menstrual regulation in Bangladesh: intimate partner violence results from a randomized controlled trial. *Glob Health Sci Pract* 2019 Sep;7(3):386-403 [FREE Full text] [doi: [10.9745/GHSP-D-19-00015](https://doi.org/10.9745/GHSP-D-19-00015)] [Medline: [31558596](https://pubmed.ncbi.nlm.nih.gov/31558596/)]
62. Jennings L, Gagliardi L. Influence of mHealth interventions on gender relations in developing countries: a systematic literature review. *Int J Equity Health* 2013 Oct 16;12:85 [FREE Full text] [doi: [10.1186/1475-9276-12-85](https://doi.org/10.1186/1475-9276-12-85)] [Medline: [24131553](https://pubmed.ncbi.nlm.nih.gov/24131553/)]



## Abbreviations

**FSW:** female sex worker  
**IUD:** intrauterine device  
**LARC:** long-acting reversible contraceptive  
**NHMRC:** National Health and Medical Research Council Australia  
**RCT:** randomized controlled trial  
**SRHR:** sexual and reproductive health and rights  
**STI:** sexually transmitted infection  
**WHISPER:** Women's Health Intervention using SMS for Preventing Pregnancy

*Edited by G Eysenbach; submitted 19.06.19; peer-reviewed by C Lyons, A Ermias, D Opoku, S Badawy; comments to author 30.09.19; revised version received 24.11.19; accepted 03.02.20; published 29.05.20*

*Please cite as:*

Ampt FH, L'Engle K, Lim MSC, Plourde KF, Mangone E, Mukanya CM, Gichangi P, Manguro G, Hellard M, Stoové M, Chersich MF, Jaoko W, Agius PA, Temmerman M, Wangari W, Luchters S  
*A Mobile Phone-Based Sexual and Reproductive Health Intervention for Female Sex Workers in Kenya: Development and Qualitative Study*

*JMIR Mhealth Uhealth* 2020;8(5):e15096

URL: <https://mhealth.jmir.org/2020/5/e15096>

doi: [10.2196/15096](https://doi.org/10.2196/15096)

PMID:

©Frances H Ampt, Kelly L'Engle, Megan S C Lim, Kate F Plourde, Emily Mangone, Collins Mudogo Mukanya, Peter Gichangi, Griffins Manguro, Margaret Hellard, Mark Stoové, Matthew F Chersich, Walter Jaoko, Paul A Agius, Marleen Temmerman, Winnie Wangari, Stanley Luchters. Originally published in JMIR mHealth and uHealth (<http://mhealth.jmir.org>), 29.05.2020. This is an open-access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in JMIR mHealth and uHealth, is properly cited. The complete bibliographic information, a link to the original publication on <http://mhealth.jmir.org/>, as well as this copyright and license information must be included.

## The TIDieR (Template for Intervention Description and Replication) Checklist\*:

Information to include when describing an intervention and the location of the information

Manuscript title: “I now know I’m the boss”: Development of mobile phone-based sexual and reproductive health intervention for female sex workers in Kenya

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
1.	<b>BRIEF NAME</b> Provide the name or a phrase that describes the intervention.	Introduction, p2	_____
2.	<b>WHY</b> Describe any rationale, theory, or goal of the elements essential to the intervention.	Methods: Intervention framework, p4	_____
3.	<b>WHAT</b> Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Examples of intervention content: tables 1 and 3.	Details of intervention structure in published protocol <sup>1</sup>

<sup>1</sup> Ampt FH, Mudogo C, Gichangi P, et al. WHISPER or SHOUT study: protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open*. 2017;7(8):e017388.

4.	<p>Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.</p> <p><b>WHO PROVIDED</b></p> <p>5. For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.</p> <p><b>HOW</b></p> <p>6. Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.</p> <p><b>WHERE</b></p> <p>7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.</p>	<p>Processes:</p> <p>Types of messages and health promotion strategies described in “Methods: Intervention strategies”, p5, and Table 1</p> <p>N/A</p> <p>Methods: Intervention strategies, p5</p> <p>N/A</p>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
8.	<p><b>WHEN and HOW MUCH</b></p> <p>Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.</p> <p><b>TAILORING</b></p>	<p>Results: Final intervention schedule, p19</p>	<hr/>

			INTERVENTION DEVELOPMENT
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. <b>MODIFICATIONS</b>	N/A	_____
10.*	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). <b>HOW WELL</b>	N/A	_____
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	To be reported in results paper	_____
12.*	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	To be reported in results paper	_____

\*\* **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use ‘?’ if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

\* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

\* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see [www.consort-statement.org](http://www.consort-statement.org)) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see [www.spirit-statement.org](http://www.spirit-statement.org)). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see [www.equator-network.org](http://www.equator-network.org)).



## Chapter 4: Protocol for the WHISPER or SHOUT cluster-randomised controlled trial

### 4.1 Background

The previous chapter described the development, content and structure of the WHISPER intervention, and confirmed that it was highly acceptable to FSWs and Mombasa, and feasible to implement in that context. In order to determine the effectiveness of the WHISPER intervention, we conducted a cluster-randomised controlled trial, called “WHISPER or SHOUT”, with FSWs in Mombasa. The trial tested two interventions in parallel: the WHISPER intervention for preventing unintended pregnancy, and a nutrition intervention (SHOUT) for reducing anaemia. I was primarily responsible for developing the study protocol and associated study documents including consent forms and questionnaires, and coordinating the initiation and implementation of the study, which included establishing processes in the field, supervising field staff, and generating the digital intervention and data collection tools, monitoring data, and liaising with study investigators.

This chapter contributes to objectives 3 and 4 of this thesis. It consists of the following published study protocol, which describes the methods and rationale for the WHISPER or SHOUT study, and provides a detailed description of both interventions:

Ampt FH, Mudogo C, Gichangi P, Lim MSC, Manguro G, Chersich M, Jaoko W, Temmerman M, Laini M, Comrie-Thomson L, Stoové M, Agius PA, Hellard M, L'Engle K, Luchters S: WHISPER or SHOUT study: protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017, 7(8):e017388.

# BMJ Open WHISPER or SHOUT study: protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya

Frances H Ampt,<sup>1,2</sup> Collins Mudogo,<sup>3</sup> Peter Gichangi,<sup>3,4,5</sup> Megan S C Lim,<sup>1,2</sup> Griffins Manguro,<sup>3</sup> Matthew Chersich,<sup>6</sup> Walter Jaoko,<sup>4</sup> Marleen Temmerman,<sup>3,5,7</sup> Marilyn Laini,<sup>3</sup> Liz Comrie-Thomson,<sup>1</sup> Mark Stoové,<sup>1</sup> Paul A Agius,<sup>1,2,8</sup> Margaret Hellard,<sup>1</sup> Kelly L'Engle,<sup>9</sup> Stanley Luchters<sup>1,2,5</sup>

**To cite:** Ampt FH, Mudogo C, Gichangi P, *et al.* WHISPER or SHOUT study: protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017;7:e017388. doi:10.1136/bmjopen-2017-017388

► Prepublication history for this paper is available online. To view these files please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2017-017388>).

FHA and CM contributed equally.

Received 20 April 2017  
Revised 23 June 2017  
Accepted 30 June 2017



CrossMark

For numbered affiliations see end of article.

## Correspondence to

Professor Stanley Luchters;  
[stanley.luchters@burnet.edu.au](mailto:stanley.luchters@burnet.edu.au)

## ABSTRACT

**Introduction** New interventions are required to reduce unintended pregnancies among female sex workers (FSWs) in low- and middle-income countries and to improve their nutritional health. Given sex workers' high mobile phone usage, repeated exposure to short messaging service (SMS) messages could address individual and interpersonal barriers to contraceptive uptake and better nutrition.

**Methods** In this two-arm cluster randomised trial, each arm constitutes an equal-attention control group for the other. SMS messages were developed systematically, participatory and theory-driven and cover either sexual and reproductive health (WHISPER) or nutrition (SHOUT). Messages are sent to participants 2–3 times/week for 12 months and include fact-based and motivational content as well as role model stories. Participants can send reply texts to obtain additional information. Sex work venues (clusters) in Mombasa, Kenya, were randomly sampled with a probability proportionate to venue size. Up to 10 women were recruited from each venue to enrol 860 women. FSWs aged 16–35 years, who owned a mobile phone and were not pregnant at enrolment were eligible. Structured questionnaires, pregnancy tests, HIV and syphilis rapid tests and full blood counts were performed at enrolment, with subsequent visits at 6 and 12 months. **Analysis** The primary outcomes of WHISPER and SHOUT are unintended pregnancy incidence and prevalence of anaemia at 12 months, respectively. Each will be compared between study groups using discrete-time survival analysis.

**Potential limitations** Contamination may occur if participants discuss their intervention with those in the other trial arm. This is mitigated by cluster recruitment and only sampling a small proportion of sex work venues from the sampling frame.

**Conclusions** The design allows for the simultaneous testing of two independent mHealth interventions for which messaging frequency and study procedures are

identical. This trial may guide future mHealth initiatives and provide methodological insights into use of reciprocal control groups.

**Trial registration number** ACTRN12616000852459; Pre-results.

## INTRODUCTION

### Female sex work

Despite sex work being very common in sub-Saharan Africa, with 1 in 20 women estimated to have exchanged sex for money, goods or other favours,<sup>1</sup> it remains a highly stigmatised and mostly criminalised practice, including in Kenya.<sup>1,2</sup> The hostile politico-legal and social environment limits sex workers' access to health services, especially for sexual and reproductive health (SRH) and for preventing and treating HIV and other sexually transmitted infections (STIs).<sup>3</sup> Strategies such as providing peer education and outreach services are often unable to overcome the myriad structural, personal and financial challenges that female sex workers (FSWs) face.<sup>4</sup> This complex situation calls for new interventions that complement the current package of services and improve health and social outcomes for sex workers.

### Unintended pregnancies among female sex workers

In many low-income countries, increased provision of low-cost contraceptive methods has raised contraception coverage in the general population,<sup>5,6</sup> but such gains remain inequitably distributed within countries,<sup>7</sup> and they have not translated into improvements

### Strengths and limitations of this study

- ▶ Use of a cluster-RCT with reciprocal controls allows for the simultaneous testing of two mHealth interventions, for which message frequency and study processes are identical; only the content of the messages differs. The design mitigates biases from unequal attention in trial groups, positive expectations and non-blinding. Moreover, the approach is efficient, using considerably fewer resources than two independent trials.
- ▶ Contamination may occur if women receiving SRH messages share them or discuss their content with women in the nutrition arm, and vice versa. Contamination would diminish the ability to detect a difference in effectiveness between the two groups. Cluster-based intervention allocation could limit this, though FSWs often work from multiple venues. In addition, we recruited only a small proportion of sex workers across a large geographic area (up to 106 of 760 hot spots, and 860 of an estimated 8,516 FSWs), which diminishes the chances of interaction between trial arms.
- ▶ A further limitation of this design is that the outcomes of the interventions may interact. While the two health domains were chosen due to the minimal overlap between behaviours, there are some plausible points of influence between the arms. For example, higher rates of pregnancy in the nutrition arm may lower haemoglobin and iron levels in these women. More generally, those receiving messages on one aspect of health may improve their health behaviours across multiple health domains, potentially diluting the effect measures of the comparison between the study arms.
- ▶ The SRH intervention aims to increase demand for contraceptives, and translating demand into raised coverage may be limited by deficiencies in the health system (supply-side issues). Supply-side issues may also influence outcomes in the nutrition group, for example, if a limited range of foods is available in the household, or area more generally
- ▶ The use of both push and pull technologies is a novel and potentially powerful approach, but their simultaneous use may make it difficult to determine the size of their independent effects.

for FSWs.<sup>8</sup> This is due to a combination of *individual* barriers to uptake, such as side effects of some contraceptive methods that impact sex work and myths and misconceptions about particular methods<sup>9 10</sup>; *interpersonal* barriers, including peer norms and pressure from partners not to use contraception<sup>8</sup> and *structural* barriers, such as stigmatising treatment of FSWs in the health system.<sup>11 12</sup>

Most programs established to improve the health of FSWs focus primarily on HIV and other STIs and overlook FSWs' broader reproductive needs.<sup>8 13 14</sup> A systematic review of SRH projects aimed at FSWs in Africa found that few provided pregnancy testing or contraceptive services other than condoms, and few specifically promoted dual method use (the concurrent use of condoms and another effective contraceptive method).<sup>15</sup>

Available data indicate that use of contraception other than condoms by FSWs in sub-Saharan Africa is variable, but generally low, ranging from around 15% to 50%.<sup>8 16–18</sup> Dual method use is rarely measured, but estimated at 10% in one study in Mombasa, Kenya.<sup>8</sup> The most popular modern method, injectable progestin,<sup>19</sup> is

prone to discontinuation and contraceptive failure due to incorrect use.<sup>20 21</sup> In contrast, highly effective and low maintenance long-acting reversible contraceptives (LARCs; intrauterine devices and subdermal implants) are underused, with only 7% of a sample of FSWs in Mombasa reporting ever using these methods.<sup>8</sup>

While few studies have aimed specifically to measure unintended pregnancy among FSWs, HIV prevention studies among FSWs have reported unexpectedly high rates of pregnancy, with 12 month cumulative incidence of 24% in Kenya,<sup>8</sup> 23% in Madagascar,<sup>17</sup> 27% in Rwanda<sup>22</sup> and 23% in the Caribbean.<sup>23</sup> Unintended pregnancy exposes women to significant health and social risks, such as unsafe (and often illegal) abortion, high maternal and infant morbidity and mortality for those who continue with the pregnancy<sup>24</sup> and increased financial dependence on sex work, which in turn increases their risk of HIV, other STIs, violence and repeat pregnancies.

### Nutrition and nutritional status among female sex workers

Urban food insecurity is a growing public health problem in sub-Saharan Africa and disproportionately affects poor populations, who are more exposed to nutritional risks and have less capacity to adopt effective coping strategies.<sup>25</sup> Also, as a result of rapid urbanisation in low-income and middle-income countries—and associated changes in diet, leading to over-reliance on non-home prepared food that tends to be high in energy, sugar and salt and low in nutrients—undernutrition and micronutrient deficiencies are increasingly occurring alongside overnutrition, overweight and obesity.<sup>25–27</sup> Both undernutrition and overnutrition are risk factors for poor health and mortality globally.<sup>28</sup> In women of reproductive age, micronutrient deficiency leads to pregnancy complications and greater child and maternal morbidity and mortality.<sup>29</sup> Anaemia, predominantly caused by iron deficiency, is endemic among women in sub-Saharan Africa; in Kenya, 36% of pregnant women and 25% of non-pregnant women are estimated to be anaemic.<sup>30</sup>

While there are no published data on malnutrition among FSWs in Kenya, lack of physical activity, chaotic lifestyles and poor diet may lead to unhealthy weight gain, at the same time contributing to their risk of micronutrient deficiency. Equally, food insecurity and hunger have been identified as key push factors for women to initiate and continue sex work.<sup>31 32</sup> In one study of sex workers in the Lagos metropolitan area in Nigeria, 35% of respondents had entered sex work in response to food insecurity.<sup>33</sup>

### mHealth interventions

Mobile phones have the potential to effectively engage FSWs, provide information, improve knowledge and address individual and interpersonal barriers to contraception use and nutritional health. Mobile phone coverage is over 80% in Kenya<sup>34</sup> and close to ubiquitous among FSWs, who constitute a large mobile population that relies on mobile phones for maintaining social and

business networks (unpublished formative research from Mombasa). mHealth interventions allow for repeated, theory-driven, user-centred and low-cost exposure, which are known to be important for securing behaviour change.<sup>35</sup>

Several systematic reviews have shown that short messaging service (SMS) technology can influence health behaviour.<sup>36–39</sup> There are, however, few randomised controlled trials (RCTs) addressing SRH behaviour through SMS.<sup>40–42</sup> Two trials in Australia demonstrated improvements in health-seeking behaviour and sexual health outcomes, particularly among young women.<sup>41 42</sup> Non-randomised trials and programme evaluations have also had positive findings.<sup>43 44</sup> With regard to nutrition, trials in USA and Iran have demonstrated the efficacy of SMS for changing eating behaviours<sup>45</sup> and knowledge and attitudes towards iodine consumption,<sup>46</sup> respectively. SMS interventions targeting overnutrition have also been tested,<sup>47–51</sup> some of which were associated with significant weight reduction.<sup>47–49</sup>

Overall, however, research is failing to keep up with the rapid proliferation of mHealth interventions.<sup>58</sup> Despite the potential gains, there remains a lack of rigorous research on SRH promotion initiatives in LMICs,<sup>52</sup> and within the field of nutrition, the lack of rigorous data is even more pronounced. Furthermore, among populations like FSWs from low-resource settings, who tend to have lower health knowledge and fewer resources for obtaining health information, intervention impact may be greater than that observed in high-income countries, but this has yet to be demonstrated empirically.

### WHISPER and SHOUT interventions

The Women's Health Intervention using SMS for Preventing Unintended Pregnancy (WHISPER) study was developed in response to the substantial SRH needs of FSWs in Kenya, the potential benefits of increasing demand for family planning among FSWs through mHealth, and the research gaps in this field. If found to be effective, mHealth for SRH could complement and increase the effectiveness of the current service packages provided for sex workers.

Similarly, the need to improve nutrition for women in poor and vulnerable settings, and the paucity of data on FSWs' nutritional health, led to the development of the SMS intervention to improve nutritional health outcomes (SHOUT). The SHOUT trial will provide important preliminary data on this underinvestigated issue and explore whether mHealth is an effective means of reducing malnutrition and anaemia in this population.

This paper presents the protocol for the WHISPER or SHOUT study. Recruitment and enrolment took place from September 2016 to May 2017, and 12-month data collection is anticipated to finish by June 2018.

## METHODS AND ANALYSIS

This is a two-arm cluster RCT, which will examine the effectiveness of parallel interventions, addressing SRH and nutrition, delivered via mobile phone among FSWs in Mombasa, Kenya. As each intervention addresses a unique set of specific issues, and the mode of delivery and level of exposure is the same, each trial arm serves as a control group for the other.<sup>53 54</sup>

### Study objectives and outcomes

The overall aim is to improve the health and well-being of FSWs in resource-constrained settings. Specifically, the study will assess the effectiveness of two independent 12-month mobile phone-delivered interventions in improving: (1) SRH outcomes for FSWs receiving the WHISPER intervention, compared with women receiving a nutrition intervention and (2) nutritional status for FSWs receiving the SHOUT intervention compared with women receiving an SRH intervention.

The feasibility and acceptability of the interventions will also be assessed, using a combination of quantitative methods (structured questionnaires at 6 and 12 months) and qualitative methods (in-depth interviews at 12 months).

### WHISPER

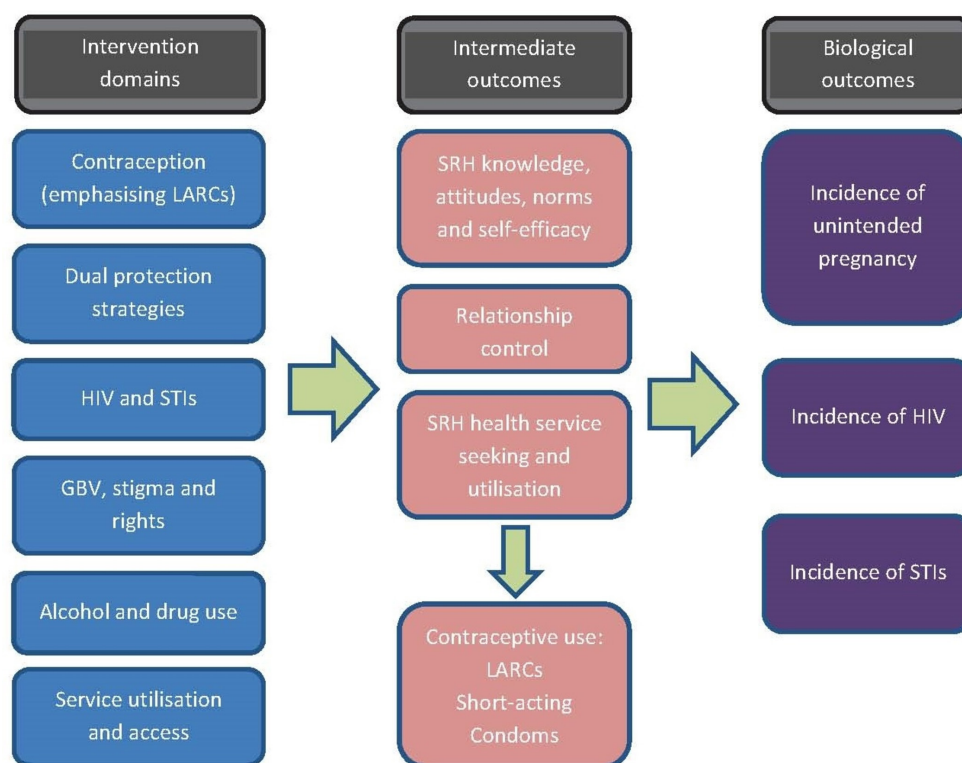
The primary study outcome for WHISPER is the incidence of unintended pregnancy over 12 months of follow-up. Unintended pregnancy is defined as pregnancy that is mistimed, unplanned or unwanted at the time of conception.<sup>55</sup> Women in the study are asked about their pregnancy intentions for the forthcoming 6 months at enrolment and at the 6-month and 12-month visits. A psychometrically-validated six-item questionnaire (London Measure of Unintended Pregnancy) will also be used to score pregnancy intention when pregnancy occurs during study follow-up.<sup>56</sup> Pregnancy events are defined as either a positive result on urine pregnancy screening at the 6-month or 12-month visits (or at unscheduled visits at the study clinics, should these occur) or a self-reported pregnancy that occurs between study visits (captured by the follow-up questionnaire).

Secondary outcomes are being measured at baseline and 6 and 12 months and include incidence of HIV and syphilis measured by point-of-care testing. Self-reported secondary outcomes, assessed by structured questionnaire, include SRH knowledge, behaviour (prevalence of LARC and dual method use) and service utilisation.

### SHOUT

The primary study outcome for SHOUT is the prevalence of anaemia at 12 months of follow-up. This outcome is measured using a certified laboratory-based haematology machine at baseline and 12 months and is defined as haemoglobin (Hb) level below 12.0 g/dL, consistent with the WHO definition.<sup>30</sup> A point-of-care haemoglobinometer will also be used to enable immediate management of anaemia, but the laboratory measure will be used to calculate the primary outcome.





**Figure 1** Logic model for the SRH intervention (WHISPER). LARCs, long-acting reversible contraceptives; SRH, sexual and reproductive health; STIs, sexually transmitted infections; GBV, gender-based violence.

Secondary outcomes include mean Hb levels at 12 months, prevalence of malnutrition (measured by body mass index and mid-upper arm circumference (MUAC) at baseline and 6 and 12 months) and self-reported nutritional knowledge and behaviour (assessed by structured questionnaire at baseline and 6 and 12 months).

### Study intervention

#### Development of WHISPER or SHOUT study interventions

Changes in attitudes and behaviours are most likely to occur when communication interventions are theory-driven, interactive and follow best practice in design and implementation.<sup>57</sup> Furthermore, sustainable positive behaviour change among individuals and communities occurs as a process, supported by carefully designed interventions, and not as a single event.<sup>58 59</sup>

The WHISPER and SHOUT interventions were therefore developed following a predefined protocol and in a systematic and participatory manner, ensuring that the intervention was grounded in evidence, was relevant and acceptable to the study population and followed a logical process of behaviour change based on staged and social cognitive theoretical approaches.<sup>60</sup> An extensive review of the literature and consideration of health behaviour change theory informed the development of logic models for both study arms (figures 1 and 2) and the subsequent drafting of messages. Participatory and user-centred design and testing of the mobile phone intervention<sup>61–63</sup> was conducted with the target population in 4 informal

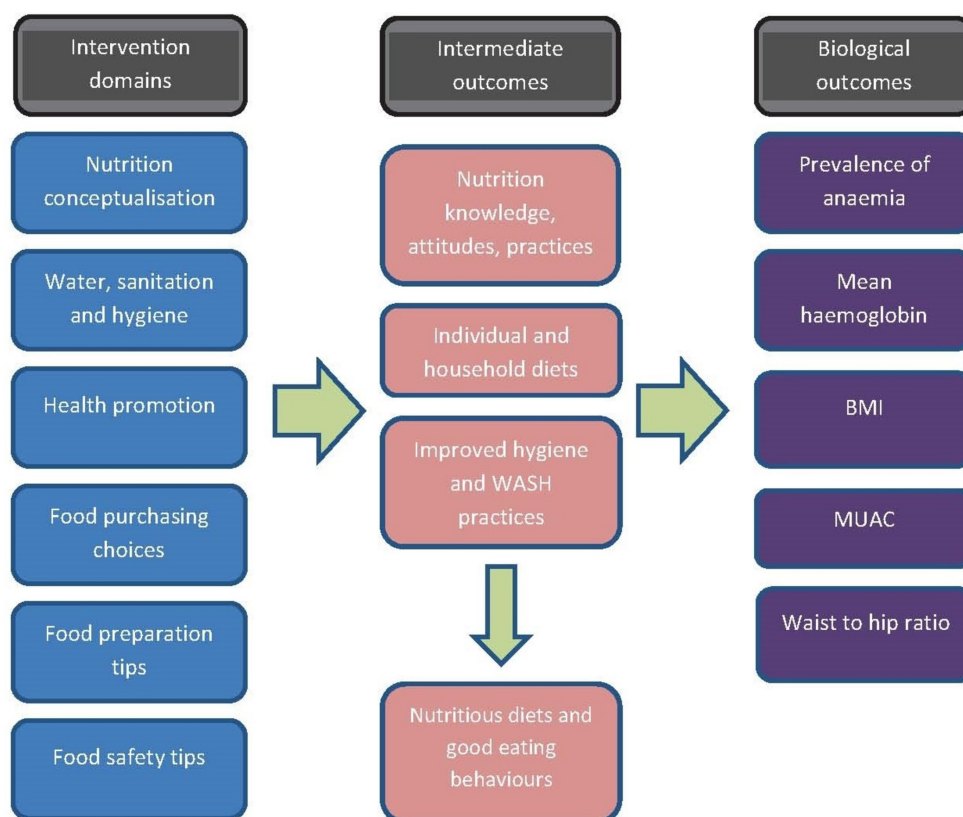
consultative meetings, 12 formal workshops and 24 usability testing interviews. FSWs were involved in identifying important issues that affect them, developing messages and role model stories, reviewing and refining the content and suggesting changes to the intervention architecture.

#### Structure and delivery of the intervention

Both the SRH and nutrition intervention consist of SMS (text) messages sent to participants two to three times per week for 12 months. The intervention includes the following components:

- ▶ ‘push’ texts covering the main content domains, providing simple information, motivational messages and strategies to prompt action;
- ▶ ‘role model stories’ about FSWs modelling healthy social norms and sent in 4–5 instalments in 1 month (alternating months with stand-alone messages) and
- ▶ a ‘pull’ or on-demand menu that participants can access by texting into the system to obtain more information on high-priority topics and local services.

The intervention is being delivered by the VOTO mobile (<https://www.votomobile.org/>) online platform. All messages are loaded onto the system in a predetermined order and sent automatically to each cluster of participants at the scheduled time (calculated from each cluster’s start date). Participants are able to text assigned codes at any time during the study to access the pull messages, with SMS



**Figure 2** Logic model for the nutrition intervention (SHOUT). BMI, body mass index; MUAC, middle-upper arm circumference.

costs incurred by the study (no charge for participants). Content is only accessible to enrolled participants in the relevant intervention group, so that those in the nutrition arm cannot directly access SRH messages and vice versa.

Table 1 presents a summary of the structure of the interventions, showing that they are essentially equivalent in all structural components except the on-demand

system. This discrepancy is due to additional pull messages in WHISPER that provide information about SRH services, allowing participants to link in with local sex worker-sensitive providers. This was deemed important on ethical grounds given the sensitive content of the WHISPER intervention and because promotion of contraception can only impact pregnancy

**Table 1** Number, length and timing of messages for each study arm

Message type	Number of messages	Length	Timing
Push messages	82 (both arms)	Up to 160 characters (1 SMS 'screen')*	Three per week (Monday, Wednesday and Saturday mornings) during months 1, 3, 5, 7, 9, 11, 13 <sup>†</sup>
Interview reminders and study information (push messages)	7 (both arms)	160–480 characters (1–3 screens)	Months 6, 7, 13
Role model stories (push messages)	26 (SRH); 27 (nutrition) (covering six stories for each arm)	160–640 characters (1–4 screens) per message	Two per week (sent Monday and Friday mornings) during months 2, 4, 6, 8, 10, 12
'Alerts': push messages linking participants to the pull system	19 (SRH); 18 (nutrition)	160–320 characters (1–2 screens)	
Pull (on-demand) messages	80 (SRH); 49 (nutrition)	160–640 characters (1–4 screens)	User determined

\*Messages are charged per 160 characters (one screen). Messages longer than this will appear as one long SMS on most phones, but may be split into multiple messages on older phones.

<sup>†</sup>There are 13 blocks of 4 weeks each, making up 12 calendar months in total. SMS, short messaging service; SRH, sexual and reproductive health.

rates if delivered alongside accessible services that provide the methods in question. In contrast, the promotion of healthy eating does not require an intermediate service utilisation step to result in improved nutritional outcomes. Furthermore, low-cost or free nutrition services are not widely available in Mombasa, and screening asymptomatic non-pregnant women for anaemia is rarely practised, so we were unable to reliably list relevant services for SHOUT.

### Setting and participants

Eligible women were recruited from mapped sex work venues by well-established peer outreach workers. Sex work venues consist of fixed-site businesses including nightclubs, bars, brothels and hotels as well as public spaces such as street corners and beaches, where sex is known to be bought and sold. The study is being conducted in two areas of Mombasa, a major economic centre in Kenya and East Africa, with busy port, rail and industrial enterprises. The local implementing partner, International Centre for Reproductive Health (ICRH; a WHO Collaborating Centre for Reproductive Health in Mombasa) has a research track record in the area dating back to 2002, including many trials and other prospective intervention studies with FSWs<sup>64–66</sup> and numerous non-interventional studies.<sup>67–70</sup>

### Inclusion and exclusion criteria

To be eligible for participation, women had to: (1) be aged 16 to 35 years; (2) report having engaged in sex work (received money in exchange for sex) at the site of recruitment in the last 6 months; (3) not be pregnant or planning pregnancy within 12 months; (4) reside within the study area for the duration of the study; (5) have a personal mobile phone with Safaricom or Airtel subscription, and be willing to provide the phone number to the researchers to receive the intervention messages; (6) report being SMS literate (ie, able to read text messages in English); (7) be willing to return for follow-up after 6 and 12 months; (8) be willing to provide contact information (eg, home address) to enable contact or a visit from a member of the research team in the community to remind them to attend follow-up visits and (9) be able and willing to give written informed consent for enrolment in the study.

Exclusion criteria included participation in another mHealth intervention study or in the formative research for this study and having a medical or non-medical condition detected through screening that hinders study participation, as confirmed by the local principal investigator.

### Randomisation and sampling strategy

ICRH and collaborators conducted a two-stage geographic mapping and enumeration exercise of FSWs in 2014, estimating that 11 777 (range 9265–14 290) FSWs operate from 1053 venues across four subcounties of Mombasa County.<sup>62</sup>

We are recruiting FSW from two of these areas: Changamwe (where an estimated 3435 FSWs work from 285

venues) and Kisauni (where an estimated 5081 FSWs work from 475 venues).<sup>62</sup>

A two-stage sampling process was adopted, drawing on this sampling frame. At the first stage, FSW venues were selected with a probability proportionate to the enumerated size of the sex worker population at the venue and randomised to either the WHISPER or SHOUT arm. Each venue was considered to be a separate cluster. At the second stage, 10 FSWs were consecutively selected from each venue, based on an estimated mean cluster size of 11.<sup>62</sup> At venues where less than 10 FSWs were active, all FSWs from the selected venue were invited to participate in the study. Sampling of FSW venues continued until the required sample size was achieved.

Cluster randomisation (allocation of each cluster to either WHISPER or SHOUT) was done centrally by the statistician and prior to recruitment commencing, involving an equal number of clusters in both arms. The participants and study team were blinded to allocation until after cluster enrolment was completed and all baseline questionnaires had been administered for that cluster.

Overall, our approach aimed for optimal (as random as possible) sampling from the FSW population, while minimising the potential intervention dilution effects of message sharing that might occur with individual-level randomisation.

### Recruitment and enrolment

Community mobilisers and peer educators employed by the study applied minimum prescreening criteria at the site of recruitment to identify potential study participants. Potentially eligible women received a card with a unique, anonymous *referral card number* (made up of cluster number and sequential participant number for that cluster). They were asked to attend the nearest study clinic for full eligibility screening, consenting and enrolment within the next 3 days. The study clinics are open 5 days a week and are embedded in existing facilities: an ICRH-run sex-worker drop-in centre in Kisauni and a municipal community health centre in Changamwe. The number of sex workers approached and referral cards disbursed at each cluster was documented as well as reasons for ineligibility at prescreening.

Volunteers had to bring their referral card number with them to undergo the screening process to ensure that only volunteers selected by the random sampling process were enrolled. Women who consented to participate and successfully completed full screening had their study identification number assigned and were then formally enrolled.

### Data collection

Study visits were conducted at enrolment and will be repeated after 6 and 12 months at the study clinics. All study staff, including clinicians, research assistants, community mobilisers and peer educators were trained in the study procedures during a 5-day workshop and undertake additional targeted sessions where required.

**Table 2** Schedule of assessments for the WHISPER or SHOUT trial

Assessments	Month 0	Month 6	Month 12
Structured questionnaire	✓	✓	✓
Clinical examination	✓	✓	✓
Urine pregnancy testing	✓	✓	✓
Point-of-care HIV and syphilis testing (including pretest and post-test counselling)	✓	✓	✓
Haemoglobin measured by haemoglobinometer	✓		✓
Full blood count	✓		✓
In-depth interviews (subgroup of participants from sexual and reproductive health arm)			✓

Enrolment procedures include collecting informed consent, administering the baseline questionnaire and performing clinical examination, urine pregnancy test, point-of-care blood tests for HIV, syphilis and Hb level and venepuncture for full blood count (haemogram: Hb, haematocrit, mean cell volume and white blood count). Follow-up assessments are presented in [table 2](#).

Questionnaires were developed in English and translated into Kiswahili and were based on previously validated measurement tools wherever possible. The questionnaire captures detailed sociodemographic information including education, literacy, employment, income, family and living circumstances, health and illness and sex work history. SRH enquiries cover previous pregnancy(ies); 6-month pregnancy intention; contraception and condom use (including dual protection); reasons for discontinuation or non-use of contraception; contraceptive self-efficacy; SRH seeking and service utilisation; sexual risk behaviours; SRH knowledge and attitudes and relationship control and joint-decision-making with non-paying emotional partners. Participants are asked about whether they have recent STI-related symptoms, which are classified and treated as per syndromic STI guidelines.<sup>71</sup> Nutrition questions gather data on nutrition-related health seeking and service utilisation; food and hygiene-related knowledge and behaviours; dietary intake and preparation and food purchasing.

Clinical examination is performed by study clinicians and includes STI syndromic management and anthropometric measurements to assess nutritional status (ie, weight, height, waist circumference, hip circumference and MUAC).

The results of rapid diagnostic tests are communicated to the participants at the time of the visit. Participants newly diagnosed with HIV are referred for treatment at specialised centres. Those with positive syphilis rapid test are treated with benzathine penicillin at the study visit. Participants with anaemia receive 1 month of iron and folic acid supplementation and a referral to a health facility for follow-up.

Following enrolment, each participant was registered in the VOTO online platform. No identifying details apart from mobile phone number were entered. Intervention allocation was performed by data management

staff independent of the study team and occurred after enrolment was completed for each cluster. The intervention commenced simultaneously for all participants of one cluster in the week following completed cluster-level enrolment.

## Data analyses

### Analysis of primary endpoints

Primary analysis for WHISPER and SHOUT will compare the primary endpoints (unintended pregnancy incidence and anaemia prevalence, respectively) between groups at 12 months. The data analysis team will be blinded to the allocation of participants. Given the interval-censored nature of unintended pregnancy incidence, discrete-time survival models using generalised linear modelling will be used to compare unintended pregnancy incidence between the two trial arms. Comparison of differences in prevalence of anaemia between study arms will be undertaken using multilevel generalised linear modelling.

These analyses will, where appropriate, provide estimates with robust SEs for FSW venue clustering. Standardised probability weighting will be applied in population-averaged analyses to account for any sampling bias where achieved sample cluster sizes vary. Also, where randomisation is not effective in removing allocation bias, adjusted models will be specified. In all analyses, associations will be considered statistically significant at the 5% level.

### Sample size

The sample size was calculated to obtain sufficient power to examine the effects of the SRH intervention. Based on a 12-month incidence of unintended pregnancy of 24% in the control group (data from previous research in the study population),<sup>8</sup> enrolment of 860 participants from a minimum of 86 FSW venues would enable detection of a relative reduction in annual unintended pregnancy incidence of 37% (hazard risk=0.63), at 80% power and 5% significance level. This estimate was adjusted for an expected 10% attrition rate (based on previous experience with this population<sup>8</sup>) and an estimated inflation in SE due to cluster randomisation (design effect=1.18; estimated intracluster correlation coefficient=0.02, with a cluster size of 10).<sup>72</sup>



Sample size could not be reliably calculated for the SHOUT trial as estimates of anaemia in the local sex work population are not available. However, if we assume a prevalence of 25% (as per the national estimate for non-pregnant women<sup>30</sup>), the calculated sample size of 860 would allow for detection of an approximate 42% reduction in odds of anaemia prevalence, with inflation in SE and attrition rate adjustments applied as above.

## ETHICS AND DISSEMINATION

Written informed consent has been obtained from every study participant. Women aged 16 and 17 years are considered mature minors and able to consent without involving parents and guardians, due to the sensitive nature of the subject matter. Informed consent forms are available in both Kiswahili and English and describe the purpose of the study, the procedures to be followed and the risks and benefits of participation. Most importantly, we are aware of the risk that others seeing the messages may infer that the participant is a sex worker. It is important to mitigate this risk of unintentional disclosure of sex work status and consequent stigma or other adverse events for participants.<sup>73</sup> Participants have been counselled about the need for care to be taken to ensure that others do not have access to their phones. The study team also asks that participants report instances of unintentional disclosure. Such reporting allows us to provide support to the women concerned and, through understanding the events surrounding the case, try to find ways to avoid future occurrences.

Ethical approvals have been obtained for protocol version 1.2, dated 22 August 2016 from the Monash University Human Research Ethics Committee (MUHREC—CF16/1552—2016000812) and the Kenyatta National Hospital, University of Nairobi Ethics and Research Committee (KNH-UoN ERC—KNH-ERC/RR/493).

Several dissemination activities are planned, including to health workers and the district office, Kenyan policy-makers, at local and international conferences and in academic publications.

## Potential impact and significance

The WHISPER study responds to the pressing need for effective and evidence-informed interventions to prevent unintended pregnancies among vulnerable women in resource-constrained settings. Persistent unmet need for family planning contributed to inadequate progress towards reducing child mortality and improving maternal health (Millennium Development Goals 4 and 5) and to the need for the 2010 Global Strategy for Women's and Children's Health.<sup>7</sup> The ability to decide on the number and timing of children, free from coercion and violence, is a fundamental human right. During the 2012 London Summit on Family Planning,<sup>74</sup> the Kenyan Government committed to increasing funding and contraception coverage by 2015. Despite this supply-side commitment, questions remain about the optimum mechanism to increase demand,

particularly among marginalised populations. The WHISPER trial will assess an innovative, sustainable and scalable approach to address some of these gaps.

Study outcomes will be used to inform future policies and public health interventions aimed at increasing uptake of family planning as well as other SRH services, among vulnerable populations in a range of similar settings, particularly in LMICs. The rigorous research design and extensive local experience of our team will support advocacy and guide mobile technology services for health promotion as outlined in the 2010 Kenyan Government's Family Planning Guidelines.<sup>75</sup> If found to be effective, this intervention could be sustainably scaled up across East Africa.

With regard to nutritional health, there are renewed efforts to design and implement action-oriented research, but the role of mHealth in these initiatives remains uncertain.<sup>76</sup> The SHOUT study will go some way towards clarifying whether SMS technology is a useful way of responding to a long-recognised, but poorly characterised and neglected problem. Indeed, if shown to be effective in this trial, mHealth could be incorporated into broader nutrition strategies for FSWs in Africa and elsewhere and has the potential to be scaled up for use with other women at a population level.

The design mitigates biases from unequal attention in trial groups, positive expectations and non-blinding.<sup>53 54</sup> The innovative approach described herein has never been used to prevent unintended pregnancies or improve nutrition among key risk populations in LMICs. A similar methodology in which the effects of SRH text messages were compared with a control SMS intervention was adopted in Australia with a sun safety control group,<sup>41</sup> and in USA with a nutrition control group,<sup>44</sup> although the latter did not measure nutrition outcomes, unlike our trial. This trial will thus set standards for the mHealth field in LMICs, for both interventions and trial methodology. Lessons learnt about optimising SMS technology for both WHISPER and SHOUT could have considerable impact in Kenya and similar countries, for a range of health priorities outside of those examined here.<sup>69</sup>

In conclusion, FSWs constitute a large, vulnerable, hard-to-reach population that could be amenable to mHealth interventions given their high mobile phone coverage and utilisation. FSWs are at considerable risk of unintended pregnancies and could benefit markedly from interventions that increase uptake of contraception, with an emphasis on long-acting reversible technologies and dual method use. Similarly, the nutrition arm of the trial responds to the paucity of quality data on rates of malnutrition among sex workers and of effective interventions to improve their nutritional status and metabolic health.

A cluster RCT with an equal-attention control and objective biological primary endpoints (unintended pregnancy and anaemia) is the most robust study design to test the effectiveness of the planned

interventions. It is anticipated that the trial will contribute important evidence to mHealth initiatives among vulnerable populations and provide useful methodological insights into the use of reciprocal control groups within such trials.

#### Author affiliations

<sup>1</sup>Burnet Institute, Melbourne, Australia

<sup>2</sup>Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Australia

<sup>3</sup>International Centre for Reproductive Health (ICRH), Mombasa, Kenya

<sup>4</sup>University of Nairobi, Mombasa, Kenya

<sup>5</sup>Department of Obstetrics and Gynaecology, International Centre for Reproductive Health (ICRH), Ghent University, Ghent, Belgium

<sup>6</sup>Wits Reproductive Health and HIV Institute, University of the Witwatersrand, Johannesburg, South Africa

<sup>7</sup>Aga Khan University, Nairobi, Kenya

<sup>8</sup>Judith Lumley Centre, La Trobe University, Melbourne, Australia

<sup>9</sup>University of San Francisco, San Francisco, California, USA

**Acknowledgements** The authors gratefully acknowledge the contribution to this work of funding from the Victorian Operational Infrastructure Support Programme received by the Burnet Institute.

**Contributors** The following authors were investigators on the trial from the outset: FHA, CM, PG, MSCL, MC, WJ, MT, ML, LC-T, MS, PAA, MH, KL SL. GM more recently joined the trial site in Kenya, leading work in that site. The paper draws from the trial protocol, which was written collectively, under the leadership of the Principal Investigator SL. The final version of the paper was read and approved by all authors.

**Funding** Australia's National Health and Medical Research Council (NHMRC) provided funding for Project Grant GNT 1087006, Career Development Fellowships for SL and MS, and a Postgraduate Scholarship for FHA. The sponsor did not have any contribution to the study design, data collection, management, analysis or interpretation.

**Competing interests** None declared.

**Patient consent** Obtained.

**Ethics approval** Monash University (MUHREC) in Australia and Kenyatta National Hospital Ethics and research committee in Kenya.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** Data presented in this paper are available from the corresponding author on request.

**Open Access** This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>

© Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2017. All rights reserved. No commercial use is permitted unless otherwise expressly granted.

#### REFERENCES

- Vandepitte J, Lyerla R, Dallabetta G, *et al.* Estimates of the number of female sex workers in different regions of the world. *Sex Transm Infect* 2006;82 Suppl 3(Suppl 3:iii18):iii18–iii25.
- Odek WO, Githuka GN, Avery L, *et al.* Estimating the size of the female sex worker population in Kenya to inform HIV prevention programming. *PLoS One* 2014;9:e89180.
- The Global Fund. Key Populations Action Plan 2014–2017. Geneva: the Global Fund to fight AIDS, tuberculosis and malaria. 2013.
- Kerrigan D, Kennedy CE, Morgan-Thomas R, *et al.* A community empowerment approach to the HIV response among sex workers: effectiveness, challenges, and considerations for implementation and scale-up. *Lancet* 2015;385:172–85.
- Kyalo J, Jurczynska K, Kundu F. *ImpactNOW application in Kenya: policy brief*. Washington: Health Policy Project & National Council for Population and Development, 2015.
- Ross J, Stover J. Use of modern contraception increases when more methods become available: analysis of evidence from 1982–2009. *Glob Health Sci Pract* 2013;1:203–12.
- Temmerman M, Khosla R, Bhutta ZA, *et al.* Towards a new global strategy for Women's, Children's and Adolescents' Health. *BMJ* 2015;351:h4414.
- Luchters S, Bosire W, Feng A, *et al.* "A Baby Was an Added Burden": Predictors and Consequences of Unintended Pregnancies for Female Sex Workers in Mombasa, Kenya: A Mixed-Methods Study. *PLoS One* 2016;11:e0162871.
- Khan MR, Turner AN, Pettifor A, *et al.* Unmet need for contraception among sex workers in Madagascar. *Contraception* 2009;79:221–7.
- Sutherland EG, Alaii J, Tsui S, *et al.* Contraceptive needs of female sex workers in Kenya – a cross-sectional study. *Eur J Contracept Reprod Health Care* 2011;16:173–82.
- Scorgie F, Nakato D, Harper E, *et al.* 'We are despised in the hospitals': sex workers' experiences of accessing health care in four African countries. *Cult Health Sex* 2013;15:450–65.
- Mannava P, Durrant K, Fisher J, *et al.* Attitudes and behaviours of maternal health care providers in interactions with clients: a systematic review. *Global Health* 2015;11:36.
- Schwartz S, Papworth E, Thiam-Niangoin M, *et al.* An urgent need for integration of family planning services into HIV care: the high burden of unplanned pregnancy, termination of pregnancy, and limited contraception use among female sex workers in Côte D'Ivoire. *J Acquir Immune Defic Syndr* 2015;68:S91–S98.
- Weldegebreal R, Melaku YA, Alemayehu M, *et al.* Unintended pregnancy among female sex workers in Mekelle city, northern Ethiopia: a cross-sectional study. *BMC Public Health* 2015;15:40.
- Dhana A, Luchters S, Moore L, *et al.* Systematic review of facility-based sexual and reproductive health services for female sex workers in Africa. *Global Health* 2014;10:46–.
- Erickson M, Goldenberg SM, Ajok M, *et al.* Structural determinants of dual contraceptive use among female sex workers in Gulu, northern Uganda. *Int J Gynaecol Obstet* 2015;131:91–5.
- Feldblum PJ, Nasution MD, Hoke TH, *et al.* Pregnancy among sex workers participating in a condom intervention trial highlights the need for dual protection. *Contraception* 2007;76:105–10.
- McClelland RS, Richardson BA, Cherutich P, *et al.* A 15-year study of the impact of community antiretroviral therapy coverage on HIV incidence in Kenyan female sex workers. *AIDS* 2015;29:2279–86.
- Darroch JE, Singh S. Trends in contraceptive need and use in developing countries in 2003, 2008, and 2012: an analysis of national surveys. *Lancet* 2013;381:1756–62.
- Baumgartner JN, Morroni C, Mlobeli RD, *et al.* Timeliness of contraceptive reinjections in South Africa and its relation to unintentional discontinuation. *Int Fam Plan Perspect* 2007;33:066–74.
- Smit JA, Beksinska ME. Hormonal contraceptive continuation and switching in South Africa: implications for evaluating the association of injectable hormonal contraceptive use and HIV. *J Acquir Immune Defic Syndr* 2013;62:363–5.
- Braunstein SL, Ingabire CM, Kestelyn E, *et al.* High human immunodeficiency virus incidence in a cohort of rwandan female sex workers. *Sex Transm Dis* 2011;38:385–94.
- Deschamps MM, Metch B, Morgan CA, *et al.* HVTN 907 Study Team. Feasibility of identifying a female sex worker cohort at high risk of HIV infection in the Caribbean for HIV vaccine efficacy trials: longitudinal results of HVTN 907. *J Acquir Immune Defic Syndr* 2016;71:70–7.
- Singh S, Darroch JE, Ashford LS. *Adding it up: the costs and benefits of investing in sexual and reproductive health*. New York: Guttmacher Institute, 2014.
- Kimani-Murage EW, Schofield L, Wekesah F, *et al.* Vulnerability to food insecurity in urban slums: experiences from Nairobi, Kenya. *J Urban Health* 2014;91:1098–113.
- van 't Riet H, den Hartog AP, Hooftman DA, *et al.* Determinants of non-home-prepared food consumption in two low-income areas in Nairobi. *Nutrition* 2003;19(11–12):1006–12.
- van't Riet H, den Hartog AP, van Staveren WA. Non-home prepared foods: contribution to energy and nutrient intake of consumers living in two low-income areas in Nairobi. *Public Health Nutr* 2002;5:515–22.
- Oldewage-Theron WH, Kruger R, Egal AA. Socio-Economic variables and Nutrient Adequacy of Women in the Vaal Region of South Africa. *Ecol Food Nutr* 2014;53:514–27.
- United Nations Children's Fund, United Nations University, World Health Organization. Iron deficiency anaemia, assessment, control and prevention: a guide for programme managers. 2010.
- World Health Organization. *The global prevalence of anaemia in 2011*. Geneva, 2015.

31. Fielding-Miller R, Mnisi Z, Adams D, *et al.* "There is hunger in my community": a qualitative study of food security as a cyclical force in sex work in Swaziland. *BMC Public Health* 2014;14:79.
32. Kunnuji M. Basic deprivation and involvement in risky sexual behaviour among out-of-school young people in a Lagos slum. *Cult Health Sex* 2014;16:727–40.
33. Oyefara JL. Food insecurity, HIV/AIDS pandemic and sexual behaviour of female commercial sex workers in Lagos metropolis, Nigeria. *Sahara J* 2007;4:626–35.
34. International Telecommunication Union. Information and Communication Technology (ICT) Statistics. 2016 <http://www.itu.int/en/ITU-D/Statistics/Pages/stat/default.aspx> (accessed 10 Sep 2016).
35. Mwaikambo L, Speizer IS, Schurmann A, *et al.* What works in family planning interventions: a systematic review. *Stud Fam Plann* 2011;42:67–82.
36. Cole-Lewis H, Kershaw T. Text messaging as a tool for behavior change in disease prevention and management. *Epidemiol Rev* 2010;32:56–69.
37. Fjeldsoe BS, Marshall AL, Miller YD. Behavior change interventions delivered by mobile telephone short-message service. *Am J Prev Med* 2009;36:165–73.
38. Free C, Phillips G, Watson L, *et al.* The effectiveness of mobile-health technologies to improve health care service delivery processes: a systematic review and meta-analysis. *PLoS Med* 2013;10:e1001363.
39. Armanasco AA, Miller YD, Fjeldsoe BS, *et al.* Preventive Health Behavior Change text message interventions: a Meta-analysis. *Am J Prev Med*. In Press. 2017;52:391–402.
40. Tsur L, Kozar E, Berkovitch M. The effect of drug consultation center guidance on contraceptive use among women using isotretinoin: a randomized, controlled study. *J Womens Health* 2008;17:579–84.
41. Gold J, Aitken CK, Dixon HG, *et al.* A randomised controlled trial using mobile advertising to promote safer sex and sun safety to young people. *Health Educ Res* 2011;26:782–94.
42. Lim MS, Hocking JS, Aitken CK, *et al.* Impact of text and email messaging on the sexual health of young people: a randomised controlled trial. *J Epidemiol Community Health* 2012;66:69–74.
43. L'Engle KL, Vahdat HL, Ndakidemi E, *et al.* Evaluating feasibility, reach and potential impact of a text message family planning information service in Tanzania. *Contraception* 2013;87:251–6.
44. Juzang I, Fortune T, Black S, *et al.* A pilot programme using mobile phones for HIV prevention. *J Telemed Telecare* 2011;17:150–3.
45. Brown ON, O'Connor LE, Savaiano D. Mobile MyPlate: a pilot study using text messaging to provide nutrition education and promote better dietary choices in college students. *J Am Coll Health* 2014;62:320–7.
46. Mehran L, Nazari P, Delshad H, *et al.* Does a text messaging intervention improve knowledge, attitudes and practice regarding iodine deficiency and iodized salt consumption? *Public Health Nutr* 2012;15:2320–5.
47. Haapala I, Barengo NC, Biggs S, *et al.* Weight loss by mobile phone: a 1-year effectiveness study. *Public Health Nutr* 2009;12:2382–91.
48. Lombard C, Deeks A, Jolley D, *et al.* A low intensity, community based lifestyle programme to prevent weight gain in women with young children: cluster randomised controlled trial. *BMJ* 2010;341:c3215.
49. Joo NS, Kim BT. Mobile phone short message service messaging for behaviour modification in a community-based weight control programme in Korea. *J Telemed Telecare* 2007;13:416–20.
50. Patrick K, Raab F, Adams MA, *et al.* A text message-based intervention for weight loss: randomized controlled trial. *J Med Internet Res* 2009;11:e1.
51. Shapiro JR, Bauer S, Hamer RM, *et al.* Use of text messaging for monitoring sugar-sweetened beverages, physical activity, and screen time in children: a pilot study. *J Nutr Educ Behav* 2008;40:385–91.
52. Lim MS, Hocking JS, Hellard ME, *et al.* SMS STI: a review of the uses of mobile phone text messaging in sexual health. *Int J STD AIDS* 2008;19:287–90.
53. Hartinger SM, Lanata CF, Hattendorf J, *et al.* Improving household air, drinking water and hygiene in rural Peru: a community-randomized-controlled trial of an integrated environmental home-based intervention package to improve child health. *Int J Epidemiol* 2016;45:dyw242.
54. Hartinger SM, Lanata CF, Hattendorf J, *et al.* Impact of a child stimulation intervention on early child development in rural Peru: a cluster randomised trial using a reciprocal control design. *J Epidemiol Community Health* 2017;71:217–24.
55. US Centers for Disease Control and Prevention. Unintended Pregnancy Prevention 2015 <https://www.cdc.gov/reproductivehealth/unintendedpregnancy/> (accessed 22 Dec 2016).
56. Hall J, Barrett G, Mwana N, *et al.* Understanding pregnancy planning in a low-income country setting: validation of the London measure of unplanned pregnancy in Malawi. *BMC Pregnancy Childbirth* 2013;13:200.
57. Noar SM, Palmgreen P, Chabot M, *et al.* A 10-year systematic review of HIV/AIDS mass communication campaigns: Have we made progress? *J Health Commun* 2009;14:15–42.
58. WIC Programme. *WIC programme nutrition education guidance*, 2006.
59. California WIC Programme. *How to evaluate a WIC Nutrition education program*, 2002.
60. US Department of Health and Human Services. *Making health communication programs work*. Washington, DC: US Department of Health and Human Services, 2004.
61. Zhang D, Adipat B, Challenges AB. Challenges, methodologies, and issues in the Usability Testing of Mobile applications. *Int J Hum Comput Interact* 2005;18:293–308.
62. Cheuk E, Becker M, Mishra S, *et al.* Understanding female sex workers' Early HIV Risk and the Implications for HIV Epidemic Control (Transitions Study): Mapping and Estimating the Population Size of Female Sex Workers in Mombasa, Kenya and Dnipropetrovsk:Ukraine. 24th Annual Canadian Conference on HIV/AIDS Research. *Can J Infect Dis Med Microbiol* 2015;78B.
63. Yardley L, Morrison L, Bradbury K, *et al.* The person-based approach to intervention development: application to digital health-related behavior change interventions. *J Med Internet Res* 2015;17:e30.
64. Luchters S, Chersich MF, Jao I, *et al.* Acceptability of the diaphragm in Mombasa Kenya: a 6-month prospective study. *Eur J Contracept Reprod Health Care* 2007;12:345–53.
65. Thomsen SC, Ombidi W, Toroitich-Ruto C, *et al.* A prospective study assessing the effects of introducing the female condom in a sex worker population in Mombasa, Kenya. *Sex Transm Infect* 2006;82:397–402.
66. L'Engle KL, Mwarogo P, Kingola N, *et al.* A randomized controlled trial of a brief intervention to reduce alcohol use among female sex workers in Mombasa, Kenya. *J Acquir Immune Defic Syndr* 2014;67:446–53.
67. Chersich MF, Luchters SM, Malonza IM, *et al.* Heavy episodic drinking among kenyan female sex workers is associated with unsafe sex, sexual violence and sexually transmitted infections. *Int J STD AIDS* 2007;18:764–9.
68. Luchters S, Chersich MF, Rinyiru A, *et al.* Impact of five years of peer-mediated interventions on sexual behavior and sexually transmitted infections among female sex workers in Mombasa, Kenya. *BMC Public Health* 2008;8:143.
69. Luchters S, Richter ML, Bosire W, *et al.* The contribution of emotional partners to sexual risk taking and violence among female sex workers in Mombasa, Kenya: a cohort study. *PLoS One* 2013;8:e68855.
70. Pack AP, L'engle K, Mwarogo P, *et al.* Intimate partner violence against female sex workers in Mombasa, Kenya. *Cult Health Sex* 2013.
71. World Health Organization. Guidelines for the management of sexually transmitted infections. 2004.
72. Cai Y, Shi R, Shen T, *et al.* A study of HIV/AIDS related knowledge, attitude and behaviors among female sex workers in Shanghai China. *BMC Public Health* 2010;10:377.
73. Rodrigues R, Poongulali S, Balaji K, *et al.* 'The phone reminder is important, but will others get to know about my illness?' Patient perceptions of an mHealth antiretroviral treatment support intervention in the HIVIND trial in South India. *BMJ Open* 2015;5:e007574.
74. Carr B, Gates MF, Mitchell A, *et al.* Giving women the power to plan their families. *Lancet* 2012;380:80–2.
75. *National Family Planning guidelines for Service Providers*. Kenya: Reproductive Health Division, 2010.
76. Beratarrechea A, Moyano D, Irazola V, *et al.* mHealth Interventions to Counter Noncommunicable Diseases in developing countries: still an Uncertain Promise. *Cardiol Clin* 2017;35:13–30.

## Chapter 5: Use of long-acting reversible contraceptives among female sex workers in Kenya

### 5.1 Background

Chapter 1 discussed the importance of LARC use, low rates among FSWs, and the necessity of improving uptake of these highly effective methods in order to make any inroads into improving FSWs SRH. The WHISPER or SHOUT study provides recent, externally valid cross-sectional data from a large sample of FSWs in Kenya, which is ideal for assessing the prevalence of LARC use among this population and examining the correlates and patterns of use of LARCs.

This chapter presents these cross-sectional analyses, using enrolment data from the WHISPER or SHOUT study, and addressing objective 4 of this thesis. It also presents eligibility data from the trial and weighted prevalence estimates of characteristics of the participants at baseline. The analyses finds that the prevalence of implant use is considerably higher than expected (23%), but that IUD use is very low (2%), and FSWs in Mombasa continue to face substantial SRH risks including unintended pregnancy. LARC use was found to be associated with several personal characteristics, most markedly gravidity.

This chapter consists of the following published paper:

Ampt FH, Lim MSC, Agius PA, Chersich MF, Manguro G, Gichuki CM, Stoové M, Temmerman M, Jaoko W, Hellard M, Gichangi P, Luchters S: Use of long-acting reversible contraception in a cluster-random sample of female sex workers in Kenya. *International Journal of Gynecology & Obstetrics* 2019, 146(2):184-191.



# Use of long-acting reversible contraception in a cluster-random sample of female sex workers in Kenya

Frances H. Ampt<sup>1,2</sup> | Megan S.C. Lim<sup>1,2,3</sup> | Paul A. Agius<sup>1,2,4</sup> | Matthew F. Chersich<sup>5,7</sup> |  
Griffins Manguro<sup>6</sup> | Caroline M. Gichuki<sup>6</sup> | Mark Stoové<sup>1</sup> | Marleen Temmerman<sup>6,7,8</sup> |  
Walter Jaoko<sup>9</sup> | Margaret Hellard<sup>1</sup> | Peter Gichangi<sup>6,9</sup> | Stanley Luchters<sup>1,2,7,8,\*</sup>

<sup>1</sup>Burnet Institute, Melbourne, Vic, Australia

<sup>2</sup>School of Public Health and Preventive Medicine, Monash University, Melbourne, Vic, Australia

<sup>3</sup>Melbourne School of Global and Population Health, University of Melbourne, Melbourne, Vic, Australia

<sup>4</sup>Judith Lumley Centre, La Trobe University, Melbourne, Vic, Australia

<sup>5</sup>Wits Reproductive Health and HIV Institute, University of the Witwatersrand, Johannesburg, South Africa

<sup>6</sup>International Centre for Reproductive Health, Mombasa, Kenya

<sup>7</sup>International Centre for Reproductive Health, Department of Primary Care and Public Health, Ghent University, Ghent, Belgium

<sup>8</sup>Aga Khan University, Nairobi, Kenya

<sup>9</sup>University of Nairobi, Nairobi, Kenya

## \*Correspondence

Stanley Luchters, 85 Commercial Road, Melbourne, Vic. 3004, Australia.  
Email: stanley.luchters@aku.edu

## Funding Information

Burnet Institute; Australia's National Health and Medical Research Council

## Abstract

**Objective:** To assess correlates of long-acting reversible contraceptive (LARC) use, and explore patterns of LARC use among female sex workers (FSWs) in Kenya.

**Methods:** Baseline cross-sectional data were collected between September 2016 and May 2017 in a cluster-randomized controlled trial in Mombasa. Eligibility criteria included current sex work, age 16–34 years, not pregnant, and not planning pregnancy. Peer educators recruited FSWs from randomly selected sex-work venues. Multiple logistic regression identified correlates of LARC use. Prevalence estimates were weighted to adjust for variation in FSW numbers recruited across venues.

**Results:** Among 879 participants, the prevalence of contraceptive use was 22.6% for implants and 1.6% for intra-uterine devices (IUDs). LARC use was independently associated with previous pregnancy (adjusted odds ratio for one pregnancy, 11.4; 95% confidence interval, 4.25–30.8), positive attitude to and better knowledge of family planning, younger age, and lower education. High rates of adverse effects were reported for all methods.

**Conclusion:** The findings suggest that implant use has increased among FSWs in Kenya. Unintended pregnancy risks remain high and IUD use is negligible. Although LARC rates are encouraging, further intervention is required to improve both uptake (particularly of IUDs) and greater access to family planning services.

## KEYWORDS

Cluster-randomized design; Complex sampling; Contraceptive implant; Intra-uterine device; Kenya; Long-acting reversible contraception; Sex work

## 1 | INTRODUCTION

Female sex workers (FSWs) in many countries have high rates of unintended pregnancy,<sup>1</sup> and experience many barriers to using highly effective contraception. They also have difficulties negotiating condom use with clients and non-paying partners, often facing

violence or financial incentives not to use condoms.<sup>2</sup> Therefore, use of condoms alongside a highly effective method is critical for pregnancy prevention.

Long-acting reversible contraceptives (LARCs) including intra-uterine devices (IUDs) and subdermal implants, are not user- or coital-dependent, and accord women greater control in the face of resistant

This is an open access article under the terms of the Creative Commons Attribution License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.

© 2019 The Authors. *International Journal of Gynecology & Obstetrics* published by John Wiley & Sons Ltd on behalf of International Federation of Gynecology and Obstetrics

male partners.<sup>1</sup> LARCs are considered safe for nulliparous women and women with multiple sexual partners, provided that those with a very high risk of sexually transmitted infections (STIs) receive STI screening or treatment at the time of IUD insertion.<sup>3–5</sup>

The use of LARCs among FSWs is low in many countries,<sup>6</sup> particularly in sub-Saharan Africa, where prevalence is reported as less than 5% in most studies.<sup>1,7</sup> Use of IUDs among FSWs varies considerably between regions, with higher levels in parts of Latin America and Asia.<sup>8,9</sup>

Access to family planning services has increased in parts of Africa in recent decades.<sup>10</sup> In Kenya, LARCs are offered at low or no cost in many public health facilities, and are used by approximately 22% of married women.<sup>11</sup> Uptake by FSWs, however, is unknown. Peer-based HIV-prevention programs for FSWs are common in HIV-endemic countries, but they seldom offer family planning or other sexual or reproductive health services.<sup>12,13</sup> Misconceptions and limited knowledge about contraception have further limited access.<sup>1</sup>

The WHISPER or SHOUT study evaluated the impact of a mobile phone intervention on knowledge and attitudes to contraception (with a focus on LARCs) and on unintended pregnancy rates in a population of FSWs.<sup>14</sup> Using baseline data from that trial, the aim of the present study was to assess the prevalence and correlates of LARC use, and explore patterns of use among FSWs in Mombasa, Kenya.

## 2 | MATERIAL AND METHODS

The present study analyzed data collected in the WHISPER or SHOUT trial<sup>14</sup> on contraceptive use among FSWs in Kenya between September 1, 2016, and May 31, 2017. The study was approved by the Kenyatta National Hospital, University of Nairobi Ethics and Research Committee, Kenya, and the Monash University Human Research Ethics Committee, Australia, and was registered with the Australian New Zealand Clinical Trial Registry (ACTRN12616000852459). All participants provided written informed consent.

The WHISPER or SHOUT study recruited women aged 16–34 years who self-reported sex work in the past 6 months, had a negative urine pregnancy test, and were not planning a pregnancy for the next 12 months. Peer educators recruited the women from sex work venues such as bars and hotels by using two-stage cluster-random sampling. First, 102 sex work venues (clusters) were randomly selected from a sampling frame of mapped venues.<sup>15</sup> The probability of a venue being selected was proportionate to the estimated number of FSWs at that venue. Next, peer educators consecutively recruited FSWs from the selected venues, aiming for 10 women from each. Additional venues were approached until at least 860 women were recruited (the target sample size).

After providing written informed consent, participants completed a clinical assessment, point-of-care testing for HIV, and a structured interviewer-administered questionnaire. Data were collected on electronic tablets using REDCap electronic data capture tools hosted at the Burnet Institute (Vanderbilt University, Nashville, TN, USA).<sup>16</sup>

The outcome of interest, LARC use, was defined as self-reported current use of either contraceptive implants or IUDs. Highly effective

contraception methods were defined as implant, IUD, injection, oral contraceptive pill, and permanent contraception methods (those with at least 90% typical use efficacy<sup>17</sup>). Full details of the study measures and variable categories are provided in Supplementary File S1. Knowledge about family planning was classified as high if participants answered at least five of six true-or-false statements correctly. They were considered to have a positive attitude to family planning if they agreed with at least three of four attitude statements. Self-efficacy and stigma were both measured on a 10-item scale,<sup>18,19</sup> each rated between one and four, with four representing greater self-efficacy or stigma. Two additional items measured contraception-specific self-efficacy, defined as high if participants agreed with both statements.

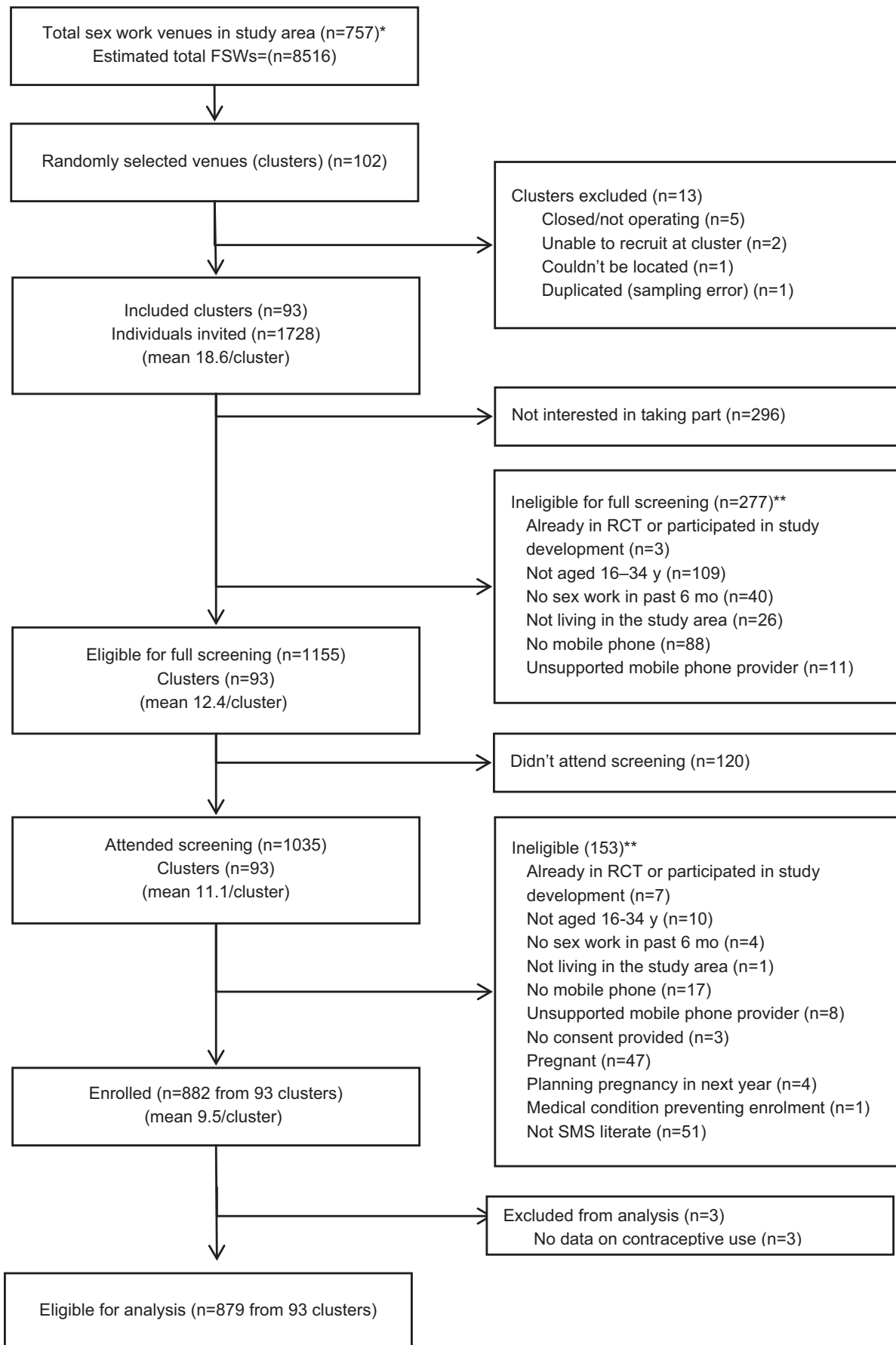
All analyses were undertaken in Stata version 13 (StataCorp, College Station, TX, USA). Correlates of LARC use were identified by using multiple logistic regression, with the level of statistical significance set at 0.05. Covariates were included in the model on the basis of empirical evidence from previous studies or an a priori theoretical basis for this relationship. Exploratory analyses examined the reasons for starting and ceasing use of implants and IUDs. The proportion of women who had experienced adverse effects was calculated, and bivariable logistic regression analyses were used to explore the association between cessation of implant use and experience of adverse effects.

Inverse probability sample weights were derived for each participant to account for variation in the number of FSWs recruited across sex-work venues. Given the non-independence of observations owing to sampling FSWs by venue, cluster sandwich variance estimation was used to produce corrected standard errors in logistic regression and univariate descriptive analyses.

## 3 | RESULTS

Among 1728 women invited to participate in the study, 1432 (82.8%) expressed an interest in participating; of these, 120 (8.4%) did not attend screening and 430 (30.0%) were deemed ineligible. The main reasons for ineligibility were age ( $n=119$ , 27.7%) and not owning a mobile phone ( $n=105$ , 24.4%) (Fig. 1). In total, 882 eligible women were enrolled from 93 venues. Three women were subsequently excluded from the analysis because they did not answer the questions on contraceptive use, resulting in a sample size of 879 women for the analysis.

The mean age of the participants was 25.4 years, and 494 (57.1%) women had a boyfriend or husband (non-paying emotional partner) (Table 1). A median of four clients in the past week was reported. Three-quarters of participants ( $n=675$ , 76.0%) had ever been pregnant, and 458 (51.3%) had ever had an unintended pregnancy, with 96 (10.8%) having had one in the previous year. The prevalence of HIV was 12.1% (95% confidence interval [CI], 9.7–14.9). One-quarter of women reported currently using a LARC, including 204 implant users (22.6%) and 13 IUD users (1.6%) (Table 2). Half the women reported using condoms consistently with all partners in the past month, with 235 (26.3%) doing so alongside another method. Binge drinking was common ( $n=176$ ,



**FIGURE 1** Flow diagram showing recruitment of the study population for the WHISPER or SHOUT trial as per the Consort 2010 statement: “extension to cluster randomized trials”.<sup>36</sup> Asterisk: total hotspots and number of FSWs per hotspot in the study area, as enumerated by Cheuk et al.<sup>15</sup> Double asterisk: one reason for ineligibility is reported per participant; criteria were determined in the order shown. Abbreviation: FSW, female sex worker.

**TABLE 1** Demographic, reproductive health, sex work, and alcohol use characteristics of the study participants.

Characteristic	Value (n=879) <sup>a</sup>	95% CI <sup>b</sup>
Demographic		
Mean age, y	25.4	25.0–25.9
Education (highest level attained)		
None or some primary	104 (11.4)	9.4–13.8
Primary or some secondary	463 (53.5)	49.8–57.2
Secondary or some tertiary	312 (35.1)	31.5–38.8
Religion		
Protestant	391 (44.1)	40.7–47.6
Catholic	310 (36.1)	32.4–40.0
Muslim	171 (18.9)	15.4–23.0
Other	5 (0.9)	0.3–2.3
Weekly income from sex work, shillings <sup>c</sup>		
<1000	146 (16.2)	13.2–19.8
1000–2000	215 (24.1)	21.1–27.3
>2000	515 (59.7)	55.0–64.3
Number of living children		
0	248 (28.8)	25.0–32.9
1	312 (35.8)	31.8–40.0
≥2	319 (35.4)	31.2–39.9
Current boyfriend/husband	494 (57.1)	52.9–61.1
Reproductive health		
Intimate partner violence in past 12 mo	531 (60.0)	55.3–64.5
Pregnancy history		
Ever pregnant	675 (76.0)	72.2–79.4
Ever had an unintended pregnancy	458 (51.3)	47.5–55.0
Unintended pregnancy in past 12 mo	96 (10.8)	8.9–13.2
Sex and sex work practices		
Main venue for meeting clients		
Bar with lodging	397 (44.2)	38.0–50.5
Bar without lodging	147 (16.9)	13.5–21.0
Lodging/guesthouse	140 (15.1)	10.9–20.5
Street/beach	86 (11.0)	7.7–15.5
Other <sup>d</sup>	109 (12.8)	9.2–17.5
Clients in past week	4 (3–6)	
Number of non-paying partners (boyfriends/husbands) in the past wk <sup>e</sup>		
0	40 (7.4)	5.1–10.7
1	399 (81.7)	77.1–85.5
≥2	54 (10.9)	8.0–14.7
Disclosure of sex work status to boyfriend/husband <sup>f</sup>	138 (28.6)	24.3–33.4

(Continues)

**TABLE 1** (Continued)

Characteristic	Value (n=879) <sup>a</sup>	95% CI <sup>b</sup>
Alcohol use		
High-risk drinking <sup>f</sup>	176 (19.9)	16.8–23.5
Sex without a condom while drunk in past week	104 (12.0)	9.8–14.7

<sup>a</sup>Values are given as median (interquartile range) or number (percentage) unless stated otherwise. Inverse probability-weighted percentages are shown (weighted percentages are similar, but not identical to those calculated from counts).

<sup>b</sup>Standard errors are corrected by cluster sandwich variance estimation.

<sup>c</sup>1000 Kenyan shillings is approximately US \$10.

<sup>d</sup>Includes brothel, casino, strip club, home, and other.

<sup>e</sup>Among those with a boyfriend/husband.

<sup>f</sup>Five or more alcoholic drinks on one occasion at least monthly.

19.9%), and 104 (12.0%) women had had sex without a condom while drunk in the previous week.

The multivariate logistic regression model included 14 variables (Table 3). There was no evidence of effect modification, so interaction terms were not added. In the multivariate analysis, current use of LARCs was correlated with gravidity. The odds of LARC use among women who reported one previous pregnancy was more than 10-fold higher than that of nulliparous women (adjusted odds ratio [aOR], 11.44; 95% CI, 4.25–30.83), and the association increased with number of pregnancies. Only six nulliparous women used LARCs (2.8%). A high level of family planning knowledge (aOR, 2.52; 95% CI, 1.78–3.56) and positive attitudes to family planning (aOR, 4.58; 95% CI, 2.62–8.00) were also associated with LARC use.

In multivariate analysis, LARC users were younger than non-users (aOR per year of age, 0.91; 95% CI, 0.86–0.96). Women with at least secondary education had a lower odds of LARC use (aOR, 0.42; 95% CI, 0.22–0.83) as compared with those who had not completed primary education. The odds of LARC use was nearly doubled for women whose friends used family planning (OR, 1.92; 95% CI, 1.41–2.61) and those with high contraceptive self-efficacy (OR, 1.86; 95% CI, 1.19–2.88) in bivariate analysis. However, both variables were strongly correlated with positive attitude to LARC and were not independently associated with LARC use after adjustment.

Further analyses explored the experiences of women who had ever used LARCs, including reasons for commencement and cessation, and adverse effects. Three hundred and two (34.2%) women had ever used implants. The most commonly reported reason for use was their effectiveness at preventing pregnancy (n=173, 56.6%), followed by perceived fewer adverse effects (n=49, 16.5%) and longer duration of action (n=49, 16.4%) relative to other contraceptives. Overall, 266 (88.8%) women reported adverse effects, most commonly irregular or



**TABLE 2** Contraceptive use characteristics of the sample population.

Contraceptive use	No. (%) <sup>a</sup>	95% CI <sup>b</sup>
Current contraceptive use		
Highly effective method (± condoms)	482 (54.6)	49.8–59.3
Other non-barrier method (± condoms)	53 (5.8)	4.2–7.9
Condoms only	336 (38.8)	34.2–43.5
None	8 (0.9)	0.4–1.9
Current methods of contraception <sup>c</sup>		
Condoms (any) <sup>d</sup>	845 (96.3)	94.1–97.7
Female condoms	14 (1.6)	0.9–2.6
IUD	13 (1.6)	0.9–2.7
Implant	204 (22.6)	19.2–26.3
Pill	68 (8.3)	6.3–10.9
Injection	199 (22.3)	19.3–25.7
Permanent	1 (0.1)	0.01–0.8
Emergency pill	34 (3.7)	2.6–5.1
Natural method (LAM, cycle beads, withdrawal)	23 (2.5)	1.6–3.9
Consistent condom use during all sex acts in past month		
With clients <sup>e</sup>	669 (76.4)	72.3–80.1
With boyfriends/husband <sup>f</sup>	157 (32.2)	28.1–36.6
With all partners	441 (50.4)	46.2–54.5
Dual method use (consistent condom use + another highly effective method)	235 (26.3)	22.6–30.5

Abbreviations: IUD, intra-uterine device; LAM, lactational amenorrhea method.

<sup>a</sup>Inverse probability-weighted percentage.

<sup>b</sup>Standard errors are corrected by cluster sandwich variance estimation.

<sup>c</sup>Categories are not mutually exclusive.

<sup>d</sup>Those reporting current use of male or female condoms, or stating use of condoms mostly/always in the past month.

<sup>e</sup>Among those who had sex with clients in the past month (n=874).

<sup>f</sup>Among those who had sex with a boyfriend or husband in the past month (n=486).

heavy bleeding (n=139, 45.6%), lighter or no bleeding (n=123, 42.0%), and pelvic pain (n=93, 30.8%). One-third of those who had ever used implants were no longer doing so (n=98, 34.1%), mostly because of adverse effects (n=81, 83.2%). The adverse effects most strongly associated with cessation were heavier bleeding (OR, 3.26; 95% CI, 1.70–6.28), nausea (OR, 3.73; 95% CI, 2.06–6.74), and weight loss (OR, 3.79; 95% CI, 2.22–6.47).

Overall, 40 (4.6%) women had ever used IUDs; the main reasons for commencing use were perceived fewer adverse effects (n=20, 51%) and effectiveness at preventing pregnancy (n=16, 38%). Three-quarters of IUD users reported adverse effects (n=30, 76%), predominantly pelvic pain (n=19, 50%), heavier bleeding (n=10, 26%), and irregular bleeding (n=8, 22%). Twenty-seven (65%) IUD users had ceased use; 17 of them cited adverse effects as the reason.

Similar to LARCs, adverse effects were common with other contraceptives, affecting 189 (90.0%) of pill users and 397 (87.4%) of injection users. Rates of cessation were also high with these methods: 66.0% for oral contraceptives and 57.0% for injections. Adverse effects and difficulty of use were the main reasons for ceasing these methods. Few women reported stopping male (n=11, 2%) or female (n=1, 6%) condoms.

Among the current implant users, implants had been obtained from government health centers (n=86, 42.1%), government hospitals (n=48, 23.7%), mobile outreach services (n=24, 11.9%), and private hospitals or clinics (n=23, 10.9%). Only 10 (5%) women reported obtaining them from sex-worker drop-in centers. A similar pattern was noted for IUDs. In contrast, injections were largely obtained from private hospitals or clinics (n=71, 36.0%), and contraceptive pills (n=31, 45%) and emergency contraceptives (n=3, 97%) from pharmacies. Male condoms were sourced from varied locations including pharmacies (n=217; 27.4%), government health centers (n=101, 13.4%) and sex-worker drop-in centers (n=86; 11.7%).

## 4 | DISCUSSION

The present study recruited a large representative sample of FSWs from 93 sites in Mombasa, Kenya. Encouragingly, implant use was approximately fourfold higher than, and the 1-year period prevalence of unintended pregnancy was approximately half of the values estimated in 2007<sup>1</sup> and 2008.<sup>7</sup> Although the two earlier studies did not use random sampling and included a wider age range, the magnitude of the differences suggests that the present findings are due to real changes in the FSW population. The present findings also suggest that implant use is more prevalent among FSWs (22.6%) than among the general population (11%).<sup>20</sup> Nevertheless, this population still faces considerable risks, owing to multiple paying and non-paying partners, low use of dual-method contraception, endemic intimate partner violence, and high-risk drinking with associated sexual risk-taking.

Improvements in implant coverage were not matched by the rate of IUD use (1.6%), which remained negligible and consistent with low estimates in the general population (3%).<sup>20</sup> Fewer public facilities provide IUDs as compared with other contraceptives.<sup>20</sup> Access is also limited by providers' misconceptions about IUDs<sup>21</sup> and interpretation of medical eligibility criteria, with many providers continuing to assume that higher-risk women are ineligible for IUD insertion.<sup>22</sup>

In the present study, gravidity was the strongest independent correlate of LARC use, reflecting similar results in non-sex-worker populations.<sup>23</sup> This may be because women decide to use longer-acting methods after completing their family or experiencing unintended pregnancy. However, it may also reflect an enduring assumption that LARCs are inappropriate for nulliparous women.<sup>21</sup>

Unexpectedly, younger age and lower education were independently associated with LARC use. Younger, less educated women may experience greater difficulty in returning to a clinic for short-acting methods, making LARCs more convenient.<sup>24</sup> An association between use of any contraceptive by FSWs and older age has been

**TABLE 3** Characteristics of the study population by LARC use, and bivariate and multivariate logistic regression analyses of LARC use.<sup>a</sup>

Variable	LARC use (95% CI) <sup>b</sup>	Unadjusted analysis		Adjusted analysis	
		OR (95% CI)	P value	OR (95% CI)	P value
Mean age, y	26.1 (25.3–26.8)	1.04 (1.00–1.08)	<0.05	0.91 (0.86–0.96)	<0.01
Education (highest level)					
None or some primary	28.0 (21.0–36.2)	Ref.		Ref.	
Primary or some secondary	29.5 (24.4–35.2)	1.08 (0.69–1.69)		0.95 (0.52–1.72)	
Secondary or some tertiary	14.6 (10.8–19.6)	0.44 (0.27–0.73)	<0.01	0.42 (0.22–0.83)	<0.05
Weekly sex work income, shillings					
<1000	23.2 (16.1–32.1)	Ref.		Ref.	
1000–2000	27.1 (21.4–33.6)	1.23 (0.70–2.17)		1.26 (0.65–2.46)	
>2000	23.2 (19.3–27.6)	1.00 (0.62–1.63)		1.06 (0.59–1.91)	
Total lifetime pregnancies					
0	2.75 (1.21–6.11)	Ref.		Ref.	
1	27.9 (22.4–34.2)	13.71 (5.54–33.89)	<0.001	11.44 (4.25–30.83)	<0.001
≥2	33.0 (28.1–38.3)	17.42 (7.32–41.42)	<0.001	17.21 (6.32–46.81)	<0.001
Knowledge, self-efficacy, and attitudes					
High FP knowledge score	38.7 (33.1–44.7)	3.29 (2.40–4.51)	<0.001	2.52 (1.78–3.56)	<0.001
Median general self-efficacy score	3.6 (3.2–3.9)	1.02 (0.71–1.48)		1.11 (0.72–1.70)	
High FP-specific self-efficacy	27.0 (23.2–31.2)	1.86 (1.19–2.88)	<0.01	1.43 (0.86–2.36)	
Positive attitude to FP use	34.7 (30.0–39.9)	5.65 (3.43–9.31)	<0.001	4.58 (2.62–8.00)	<0.001
Partner influence					
Current boyfriend/husband	23.0 (19.1–27.5)	0.87 (0.62–1.22)		0.97 (0.64–1.46)	
Intimate partner violence in last year	27.5 (23.7–31.8)	1.61 (1.16–2.23)	<0.01	1.20 (0.82–1.75)	
Social influence					
Friends use FP (most or all)	28.9 (24.6–33.6)	1.92 (1.41–2.61)	<0.001	1.25 (0.85–1.83)	
Median stigma score	2.8 (2.4–3.0)	0.88 (0.63–1.23)		1.03 (0.71–1.49)	
Health service experience					
Sought health services in past 6 mo	24.2 (20.3–28.5)	1.01 (0.72–1.40)		0.83 (0.56–1.22)	
Expect to be treated with respect by health worker	25.1 (21.6–28.9)	2.94 (1.04–8.25)	<0.05	1.12 (0.30–4.13)	

Abbreviations: CI, confidence interval; FP, family planning; OR, odds ratio.

<sup>a</sup>Sample size, n=858 women (21 women had missing values for at least one variable). The proportion using LARC did not differ significantly between those with and without complete data. Values are given as mean (95% CI), median (IQR), or percentage (95% CI).

<sup>b</sup>Inverse probability-weighted percentage. Standard errors are corrected by cluster sandwich variance estimation.

noted,<sup>1,25</sup> but it may reflect the predominance of condoms and short-acting methods in those studies, or the influence of gravidity. Studies examining LARC use in non-sex-worker populations have rarely found a clear association with age,<sup>23,24</sup> and have reported mixed results regarding education.<sup>23,26</sup>

Knowledge and positive attitude to family planning were correlates of LARC use, consistent with findings in other populations.<sup>26</sup> Social norms and contraceptive self-efficacy may lie on the same causal pathway as positive attitude, or may measure the same underlying construct. Education about LARCs has been found to improve attitude and uptake.<sup>21</sup> In the present sample, these individual factors had greater influence on LARC use than structural factors such as the presence of a boyfriend or husband, sex-work-related stigma, and violence. This is surprising given the known influence of structural

determinants on sexual health risks.<sup>2,25,27</sup> Structural determinants may have a greater influence on use of condoms and other user-dependent methods than on LARC use.

Adverse effects were experienced by most women for all highly effective contraceptive methods and seemed to be more common than reported elsewhere.<sup>28,29</sup> The rate of LARC discontinuation was high, but the duration of use was not known, preventing a comparison with other studies. There was a lower rate of cessation of implants as compared with IUDs, pills, or injections.<sup>30</sup> Reduced bleeding caused by implants may be beneficial for sex workers, because bleeding can interfere with work. Heavier bleeding was associated with implant cessation, consistent with other research.<sup>30</sup> Heavy bleeding caused by copper IUDs might negatively impact on sex work and exacerbate iron deficiency anemia, which is likely to be high in the present

population.<sup>14,31</sup> Future studies should investigate whether hormonal IUDs, with their tendency to suppress bleeding, would have a higher uptake than copper IUDs.<sup>32</sup> It would be particularly interesting to determine whether negative perceptions of the copper IUD are transferred to the hormonal one. Targeting additional resources at raising IUD uptake might help to overcome these barriers. It is possible, however, that such efforts might not raise uptake and that the method has low acceptability in this setting. If that is the case, then it may be better to target programmatic resources to other family planning priorities.

Pelvic pain was a frequently reported adverse effect and is also a symptom of cervicitis and pelvic inflammatory disease. The long-held misconception that IUDs cause pelvic inflammatory disease<sup>21</sup> may lead to their unnecessary removal, when in fact it is safe to leave them in situ while concurrent STIs are treated.<sup>4</sup>

Quality education and counseling on the benefits and adverse effects of LARCs can improve uptake and continuation rates<sup>21,23</sup> by managing expectations, countering common myths, and providing reassurance on the safety of bleeding disturbances.<sup>32</sup> However, counseling is likely to be insufficient or incomplete in many settings.<sup>30</sup> While Kenya has clear guidelines on contraceptive counseling,<sup>5</sup> one study noted that only 60% of women were counseled on adverse effects when they obtained contraception.<sup>11</sup> Further work is required to determine how guidelines are applied in practice, particularly for sex workers who are subject to discrimination by health workers.<sup>33</sup> Research in South Africa has indicated that, to improve uptake, LARCs need to be available from a wider range of trained service providers, including mobile outreach clinics for harder-to-reach populations such as FSWs, and counseling should be reoriented to emphasize LARCs as a "first-line" contraceptive method.<sup>34</sup> Only 20% of private facilities in Kenya supply LARCs, whereas more than 65% supply other methods<sup>20</sup> — an observation reflected in the present data. Sex worker drop-in-centers supplied very few contraceptives (other than male condoms). This highlights a missed opportunity for these acceptable and widely used centers<sup>33</sup> to improve access to all methods including LARCs.

The study has some important limitations. The data were collected by self-report, increasing the risk of recall bias and social desirability bias; however, it would not be possible or practicable to obtain such personal data by other means. Age was an inclusion criterion, so the results cannot be extrapolated to all ages. There are also limitations around the measurement of pregnancy intention, which may affect the reliability of these data. Some participants may not have intended to get pregnant, but nonetheless desired pregnancy for different reasons. FSWs often have mixed pregnancy intentions depending on their partners, so they must rely on short-acting methods with all partners except the desired father.<sup>35</sup> They may also prefer not to disclose a true intention owing to the stigma surrounding sex work and motherhood.

Interpretation of the analysis is also limited by the cross-sectional design. Correlates such as knowledge may follow rather than precede LARC use. Other variables that might be associated with the outcome were not included; for example, stigma from health workers may be an important structural determinant.<sup>33</sup> Because there were very few current users of IUDs, the results of the regression

were dominated by implant users. The low number of IUD users also precluded further examination of their adverse effects, patterns of use, and removal. The analysis of adverse effects had some limitations: there were no data on duration of bleeding, which is a predictor of cessation,<sup>30</sup> and prolonged bleeding may have been instead reported as heavy or irregular.

In conclusion, despite the multiple sexual risks and difficulties accessing services faced by FSWs in Kenya, implant use has increased and self-reported unintended pregnancy was lower as compared with previous estimates in this population. LARC use was strongly associated with gravidity, knowledge, and attitudes toward family planning. FSWs reported very high rates of contraceptive adverse effects. This population would benefit from interventions to improve uptake of LARCs, particularly IUDs, which are currently under-used.

## AUTHOR CONTRIBUTIONS

Under the leadership of the Principal Investigator (SL), FHA, PG, MSCL, MFC, WJ, MT, MS, PAA, and MH contributed to study design. GM and CG contributed to data acquisition in Kenya under the supervision of PG. FHA and PAA led the analyses. FHA and MSCL drafted the first manuscript. All authors contributed to data interpretation, provided critical input into the draft, and approved the final version of the manuscript.

## ACKNOWLEDGMENTS

The authors gratefully acknowledge the contribution of funding from the Victorian Operational Infrastructure Support Program received by the Burnet Institute. Australia's National Health and Medical Research Council provided funding for the WHISPER or SHOUT trial (Project Grant GNT 1087006), Career Development Fellowships for SL and MS, and a Postgraduate Scholarship for FHA. The sponsor did not contribute to study design; data collection, analysis, or interpretation; manuscript writing; or the decision to submit the article for publication.

## CONFLICTS OF INTEREST

The authors have no conflicts of interest.

## REFERENCES

1. Luchters S, Bosire W, Feng A, et al. "A baby was an added burden": Predictors and consequences of unintended pregnancies for female sex workers in Mombasa, Kenya: A mixed-methods study. *PLoS ONE*. 2016;11:e0162871.
2. Wirtz AL, Schwartz S, Ketende S, et al. Sexual Violence, Condom Negotiation, and Condom Use in the Context of Sex Work: Results From Two West African Countries. *J Acquir Immune Defic Syndr*. 2015;68:171–179.
3. World Health Organization Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center

- for Communication Programs. *Family planning: A global handbook for providers. Knowledge for Health Project*. Baltimore and Geneva: CCP and WHO. 2011.
4. World Health Organization. *Medical Eligibility Criteria for Contraceptive Use*. Geneva: World Health Organization; 2015.
  5. Aluisio A, Richardson BA, Bosire R, John-Stewart G, Mbori-Ngacha D, Farquhar C. Reply to male involvement in women and children's HIV prevention: Challenges in definition and interpretation. *J Acquir Immune Defic Syndr*. 2011;57:e116–e117.
  6. Lim MSC, Zhang X-D, Kennedy E, et al. Sexual and Reproductive Health Knowledge, Contraception Uptake, and Factors Associated with Unmet Need for Modern Contraception among Adolescent Female Sex Workers in China. *PLoS ONE*. 2015;10:e0115435.
  7. Sutherland EG, Alaii J, Tsui S, et al. Contraceptive needs of female sex workers in Kenya – a cross-sectional study. *Eur J Contracept Reprod Health Care*. 2011;16:173–182.
  8. Ampt FH, Willenberg L, Agius PA, Chersich M, Luchters S, Lim MSC. Incidence of unintended pregnancy among female sex workers in low-income and middle-income countries: A systematic review and meta-analysis. *BMJ Open*. 2018;8:e021779.
  9. Buhling KJ, Zite NB, Lotke P, Black K. Worldwide use of intrauterine contraception: A review. *Contraception*. 2014;89:162–173.
  10. Cleland JG, Ndugwa RP, Zulu EM. Family planning in sub-Saharan Africa: Progress or stagnation? *Bull World Health Organ*. 2011;89:137–143.
  11. PMA2020. PMA2016/KENYA-R5: Family planning brief. Country reports. Kenya: Performance Monitoring and Accountability 2020; 2017.
  12. Dhana A, Luchters S, Moore L, et al. Systematic review of facility-based sexual and reproductive health services for female sex workers in Africa. *Global Health*. 2014;10:46.
  13. Petrunev T, Minichiello SN, McDowell M, Wilcher R. Meeting the contraceptive needs of key populations affected by HIV in Asia: An unfinished agenda. *AIDS Res Treat*. 2012;2012:6.
  14. Ampt FH, Mudogo C, Gichangi P, et al. WHISPER or SHOUT study: Protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open*. 2017;7:e017388.
  15. Cheuk E, Becker M, Mishra S, et al. Understanding Female Sex Workers' Early HIV Risk and the Implications for HIV Epidemic Control (Transitions Study): Mapping and Estimating the Population Size of Female Sex Workers in Mombasa, Kenya and Dnipropetrovsk, Ukraine. 24th Annual Canadian Conference on HIV/AIDS Research: Can J Infect Dis Med Microbiol 2015: 78B.
  16. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research Electronic Data Capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42:377–381.
  17. Trussell J. Contraceptive efficacy. In: Hatcher RA, Trussell J, Nelson A, Cates W, Kowal D, Policar M, eds. *Contraceptive Technology*. New York: Ardent Media; 2011.
  18. Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In: Weinman J, Wright S, Johnston M, eds. *Measures in health psychology: A user's portfolio Causal and control belief*. Windsor, England: NFER-NELSON; 1995:35–37.
  19. Liu S-H, Srikrishnan AK, Zelaya CE, Solomon S, Celentano DD, Sherman SG. Measuring perceived stigma in female sex workers in Chennai, India. *AIDS Care*. 2011;23:619–627.
  20. PMA2020. PMA2015/KENYA-R4 SOI: Snapshot of indicators. Country reports. Kenya: Performance Monitoring and Accountability 2020; 2016.
  21. Black K, Lotke P, Buhling KJ, Zite NB. A review of barriers and myths preventing the more widespread use of intrauterine contraception in nulliparous women. *Eur J Contracept Reprod Health Care*. 2012;17:340–350.
  22. Luchowski AT, Anderson BL, Power ML, Raglan GB, Espey E, Schulkin J. Obstetrician-Gynecologists and contraception: Practice and opinions about the use of IUDs in nulliparous women, adolescents and other patient populations. *Contraception*. 2014;89:572–577.
  23. Hong R, Montana L, Mishra V. Family planning services quality as a determinant of use of IUD in Egypt. *BMC Health Serv Res*. 2006;6:79.
  24. Hubacher D, Olawo A, Manduku C, Kiarie J. Factors associated with uptake of subdermal contraceptive implants in a young Kenyan population. *Contraception*. 2011;84:413–417.
  25. Erickson M, Goldenberg SM, Ajok M, Muldoon KA, Muzaaya G, Shannon K. Structural determinants of dual contraceptive use among female sex workers in Gulu, northern Uganda. *Int J Gynecol Obstet*. 2015;131:91–95.
  26. Saavedra-Avendano B, Andrade-Romo Z, Rodriguez MI, Darney BG. Adolescents and Long-Acting Reversible Contraception: Lessons from Mexico. *Matern Child Health J*. 2016.
  27. Pitpitan EV, Kalichman SC, Eaton LA, Strathdee SA, Patterson TL. HIV/STI risk among venue-based female sex workers across the globe: A look back and the way forward. *Curr HIV/AIDS Rep*. 2013;10:65–78.
  28. Bahamondes L, Brache V, Meirik O, et al. A 3-year multicentre randomized controlled trial of etonogestrel- and levonorgestrel-releasing contraceptive implants, with non-randomized matched copper-intrauterine device controls. *Hum Reprod*. 2015;30:2527–2538.
  29. Bitzer J, Tschudin S, Alder J. the Swiss Implanon Study G. Acceptability and side-effects of Implanon in Switzerland: A retrospective study by the Implanon Swiss Study Group. *Eur J Contracept Reprod Health Care*. 2004;9:278–284.
  30. Tolley E, Loza S, Kafafi L, Cummings S. The impact of menstrual side effects on contraceptive discontinuation: Findings from a longitudinal study in Cairo, Egypt. *Int Fam Plan Perspect*. 2005;31:15 + .
  31. World Health Organization. *The global prevalence of anaemia in 2011*. Geneva: World Health Organization; 2015.
  32. Hubacher D, Masaba R, Manduku CK, Veena V. Uptake of the levonorgestrel intrauterine system among recent postpartum women in Kenya: Factors associated with decision-making. *Contraception*. 2013;88:97–102.
  33. Corneli A, Lemons A, Otieno-Masaba R, et al. Contraceptive service delivery in Kenya: A qualitative study to identify barriers and preferences among female sex workers and health care providers. *Contraception*. 2016;94:34–39.
  34. Rees H, Pillay Y, Mullick S, Chersich MF. Strengthening implant provision and acceptance in South Africa with the 'Any woman, any place, any time' approach: An essential step towards reducing unintended pregnancies. *S Afr Med J*. 2017;107:939–944.
  35. Beckham SW, Shembilu CR, Brahmabhatt H, Winch PJ, Beyrer C, Kerrigan DL. Female sex workers' experiences with intended pregnancy and antenatal care services in southern Tanzania. *Stud Fam Plann*. 2015;46:55–71.
  36. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: Extension to cluster randomised trials. *BMJ*. 2010;2012:345.

## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**File S1.** Study measures and scoring.

## Use of long-acting reversible contraception in a cluster-random sample of female sex workers in Kenya

### Supplementary appendix: Study measures and scoring

#### *Knowledge*

<b>Statement</b>	<b>Correct answer</b>
Implants can make your period lighter, or stop it altogether	True
One contraceptive injection, like Depo, will protect against pregnancy for 1 year	False
I don't need to use condoms if I'm already using another type of family planning	False
It is easy for most women to get pregnant soon after they stop using family planning	True
The IUD protects against pregnancy for up to 12 years	True
Family planning pills and injections provide some protection against HIV	False

Participants chose 'true' or 'false' for each statement. Answers were dichotomised into the following categories:

- High knowledge: 5-6 correct answers
- Low knowledge: 0-4 correct answers

#### *Attitude to family planning*

I think longer acting methods like IUDs and implants are the best contraceptive methods for me.
I have a lot of knowledge about contraceptive methods I can use to prevent pregnancy.
Side effects from using family planning usually disappear after a few months of use.
If you try one type of family planning and do not like it, there are many other types to try.

For each item, participants chose 'strongly agree', 'agree', 'disagree', or 'strongly disagree'. Answers were dichotomised into the following categories:

- Positive attitude: chose 'strongly agree' or 'agree' for 3-4 items
- Negative attitude: chose 'strongly disagree' or 'disagree' for 0-2 items

#### *General self-efficacy*

I can always manage to solve difficult problems if I try hard enough.
If someone opposes me, I can find the means and ways to get what I want.
It is easy for me to stick to my aims and accomplish my goals.
I am confident that I could deal efficiently with unexpected events.
Thanks to my resourcefulness, I know how to handle unforeseen situations.
I can solve most problems if I invest the necessary effort.
I can remain calm when facing difficulties because I can rely on my coping abilities.
When I am confronted with a problem, I can usually find several solutions.

If I am in trouble, I can usually think of a solution.
--

I can usually handle whatever comes my way.
---

For each item, participants received a score of 1-4, corresponding to the following responses:

<i>Response</i>	<i>Score</i>
Not at all true	1
Hardly true	2
Moderately true	3
Exactly true	4

These were added for a total score of 10-40, and divided by 10 for a mean score of 1-4 for each participant.

This scale was developed by Schwarzer and Jerusalem[1].

### *Contraceptive self-efficacy*

I am confident that I can use a family planning method if I want to
---

I am confident I can use family planning even if my partner/boyfriend does not approve
--

A mean score of 1-4 for each participant was calculated in the same way as for General Self-Efficacy

### *Sex-work related stigma*

I feel that if I disclosed being a sex worker to some people they would not talk to me anymore
--

I feel that if I disclosed being a sex worker to some people they would not talk to my family
---

I feel that if I disclosed being a sex worker to some people they would think I was immoral
---

I feel that if I disclosed being a sex worker to some people, I would be threatened with violence
---

I feel that if I disclosed being a sex worker to some people, they would treat me differently
---

I feel that if I disclosed being a sex worker to my husband/boyfriend, he would hit me
--

I feel that if I disclosed being a sex worker to my husband/boyfriend, he would not talk to me anymore
--

I feel that if I disclosed being a sex worker to my family, I would not be able to see my children
--

I feel that if I disclosed being a sex worker to my family, they would desert me
--

I feel that if I disclosed being a sex worker to my family, they would treat me differently
---

For each item, participants received a score of 1-4, corresponding to the following responses:

<i>Response</i>	<i>Score</i>
Strongly disagree	1
Disagree	2
Agree	3
Strongly agree	4

These were added for a total score of 10-40, and divided by 10 for a mean score of 1-4 per participant.

Adapted from the community-based Sex Worker Stigma index developed by Liu et al[2].

- [1] Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. In: Weinman J, Wright S, Johnston M, eds. Measures in health psychology: A user's portfolio Causal and control belief. Windsor, England: NFER-NELSON. 1995: 35-37.
- [2] Liu S-H, Srikrishnan AK, Zelaya CE, Solomon S, Celentano DD, Sherman SG: Measuring perceived stigma in female sex workers in Chennai, India. *AIDS Care* 2011;23(5): 619-627.



## Chapter 6: Impact of the WHISPER mobile phone intervention for female sex workers on unintended pregnancy

### 6.1 Background

This chapter reports the final results of the WHISPER or SHOUT trial, addressing objective 3 and building on the methods presented in Chapter 4, and the baseline results presented in Chapter 5. The primary outcome, incidence of unintended pregnancy, is analysed using discrete-time survival modelling, and selected secondary outcomes are analysed using multilevel modelling.

These analyses show that the WHISPER intervention was not effective at reducing the incidence of unintended pregnancy among FSWs, or increasing use of LARCs. However, it did have a positive impact on contraceptive knowledge and dual method contraceptive use. Results indicate that while SMS interventions for FSWs may be effective at modifying short-term or user-controlled contraceptive behaviour, they are unlikely to impact use of longer-term methods or behaviours that are more subject to structural influences, without being incorporated into pregnancy prevention approaches.

This chapter includes the following manuscript, which has been accepted by the Lancet Global Health:

Ampt FH, Lim MSC, Agius PA, L'Engle K, Manguro G, Gichuki C, Gichangi P, Chersich M, Jaoko W, Temmerman M, Stoové M, Hellard M, Luchters S: Impact of the WHISPER mobile phone intervention for female sex workers on unintended pregnancy: a cluster-randomised controlled trial in Kenya. *Lancet Glob Health* (in press).

A supplementary file, containing the statistical model output for each outcome, is appended to this manuscript.



## Impact of the WHISPER mobile phone intervention for female sex workers on unintended pregnancy: a cluster-randomised controlled trial in Kenya

*Lancet Global Health (in press)*

Frances Ampt, MPH<sup>1,2</sup>, Megan S.C. Lim, PhD<sup>1,2</sup>, Paul A. Agius, MSc<sup>1,2</sup>, Kelly L'Engle, PhD<sup>3</sup>, Griffins Manguro, MPH<sup>4</sup>, Caroline Gichuki, BSc<sup>4</sup>, Peter Gichangi, PhD<sup>4,5,6</sup>, Matthew Chersich, PhD<sup>6,7</sup>, Walter Jaoko, PhD<sup>8</sup>, Marleen Temmerman, PhD<sup>4,6,9</sup>, Mark Stoové, PhD<sup>1,2,10</sup>, Margaret Hellard, PhD<sup>1,2,11</sup>, Stanley Luchters\*, PhD<sup>1,2,6,9</sup>

1. Burnet Institute, Melbourne, Australia
2. Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Australia
3. University of San Francisco, San Francisco, California, USA
4. International Centre for Reproductive Health (ICRH), Mombasa, Kenya
5. Technical University of Mombasa, Mombasa, Kenya
6. Department of Public Health and Primary Care, International Centre for Reproductive Health (ICRH), Ghent University, Ghent, Belgium
7. Wits Reproductive Health and HIV Institute, University of the Witwatersrand, Johannesburg, South Africa
8. University of Nairobi, Nairobi, Kenya
9. Aga Khan University, Nairobi, Kenya
10. School of Psychology and Public Health, La Trobe University, Melbourne, Australia
11. Department of Infectious Diseases, The Alfred Hospital, Melbourne, Australia

\*Corresponding author

## Abstract

### Background

Female sex workers (FSWs) in low- and middle-income countries face high risks of unintended pregnancy. We developed a 12-month multi-faceted SMS intervention (“WHISPER”) for FSWs in Kenya, to prevent unintended pregnancy mainly by improving their contraceptive knowledge and behaviours.

### Methods

Our two-arm cluster-randomised controlled trial tested the effectiveness of the WHISPER intervention to reduce the incidence of unintended pregnancy, as compared to an equal-attention control group receiving nutrition-focussed messages. Participants, aged 16-34 years and not pregnant or planning pregnancy, were recruited from 93 randomly-selected sex work venues (clusters). Random cluster allocation (1:1) was concealed from participants and researchers until the intervention commenced. Unintended pregnancy was measured at six and 12 months. The primary intention-to-treat analysis compared unintended pregnancy incidence between groups using discrete-time survival analysis. Secondary outcomes (contraceptive knowledge, dual method contraception and long-acting reversible contraception (LARC)) were measured using multi-level models accounting for clustering by individual and cluster.

Australian New Zealand Clinical Trials Registry: ACTRN12616000852459.

### Findings

Recruitment occurred between September 2016 and May 2017. Four hundred and fifty-one women from 47 clusters were assigned to the intervention and 431 from 46 venues to the control group, with 401 and 385 respectively included in the analysis. Incidence of unintended pregnancy was 15.5 per 100 person-years in the intervention group and 14.7 in the control group. Primary analysis revealed no difference between the two groups (hazard ratio:0.98, 95%CI:0.69-1.39). The intervention improved knowledge and dual method use, but not LARC use.

### Interpretation

The intervention had no measurable impact on unintended pregnancy incidence, despite positive effects on knowledge and selected contraceptive behaviours. mHealth interventions,

even when acceptable and rigorously designed, are unlikely to have sufficient impact on behaviour among FSWs to change pregnancy incidence when used in isolation.

### **Funding**

National Health and Medical Research Council of Australia.

## **Panel: Research in context**

### **Evidence before this study**

We searched MEDLINE, Embase, PsychINFO and Popline on 20 January 2016, for peer-reviewed studies conducted with female sex workers (FSWs) in low- and middle-income countries (LMICs) since 2000. Search terms included “sex work”, “transactional sex” and related terms; list of countries defined by the World as LMICs; and synonyms for ‘low- and middle-income’. No studies were identified that tested interventions for FSWs in LMICs to increase non-barrier contraceptive use or prevent unintended pregnancy. Twenty-five studies measured unintended pregnancy incidence in this population, which was estimated at 27 per 100 person-years in a meta-analysis. Most studies focused exclusively on HIV or other sexually transmitted infections. Therefore, FSWs in LMICs are at high risk of unintended pregnancy, but interventions to reduce this risk have not been evaluated.

### **Added value of this study**

To our knowledge, this is one of only two trials of a behaviour change intervention for FSWs in a low- or middle-income country designed to prevent unintended pregnancy. Other trials in this population have been conducted to increase condom use but not other contraceptives, and to prevent HIV and STIs rather than pregnancy. Our intervention aimed to address known knowledge gaps and misconceptions about pregnancy prevention and related sexual and reproductive health (SRH) concerns, with a particular focus on long-acting reversible contraceptives (LARCs). It was delivered by mobile phone SMS, which was deemed an acceptable and widely used medium by FSWs. A two-arm, equal-attention, cluster-randomised controlled design was employed, with participants enrolled from randomly selected sex work venues (clusters) to minimise contamination. Retention was high (85%) and the intervention was well-received by participants. Our study did not show an impact on unintended pregnancy incidence or use of LARCs. The intervention did result in improvements in dual method contraceptive use and contraceptive knowledge.

## Implications of all the available evidence

This trial, along with prior research, has not identified effective strategies of preventing unintended pregnancy for FSWs. A repeat search of MEDLINE in September 2019 identified only one other intervention study, an RCT of an mHealth intervention in Cambodia, but results were not yet available.

Our trial confirmed that mobile phones are an important and acceptable means of engaging with this population, but SRH messages delivered via this medium, when used in isolation, did not have sufficient impact on contraceptive behaviour to modify biological outcomes. In view of the complex socioeconomic and structural barriers faced by FSWs, more comprehensive interventions, for example combining mHealth with supply-side initiatives, may be required.

## Introduction

Female sex workers constitute a large<sup>1</sup> and marginalised population in sub-Saharan Africa with multiple overlapping sexual and reproductive health (SRH) needs. High rates of HIV and other sexually transmitted infections (STIs) have long been recognised in this population and targeted by interventions such as peer education, mobile outreach and FSW-friendly health services.<sup>2</sup> In contrast, unintended pregnancy has received relatively little attention, despite being a high priority for FSWs<sup>3</sup> and having multiple adverse health and socioeconomic consequences,<sup>4-6</sup> including increased financial dependence on sex work.<sup>7,8</sup> A systematic review of 3,866 studies of FSWs found only ten in which unintended pregnancy incidence was measured, and the estimated incidence was 27 per 100 women-years.<sup>9</sup> Estimates of contraceptive use in this population are also low.<sup>7</sup> However, little emphasis has been placed on family planning as part of SRH services for FSWs, and effective interventions to prevent unintended pregnancy have not been identified.

There are multiple individual, interpersonal and structural barriers to FSWs' adoption and maintenance of effective contraception.<sup>10</sup> Myths and misconceptions, particularly in relation to long-acting reversible contraception (LARC), are especially common and salient. Lack of knowledge and fear of side effects have been noted as significant barriers for FSWs,<sup>7,11,12</sup> consistent with findings for young women more broadly,<sup>13</sup> which could be amenable to modification by an individually-focused mHealth intervention. Mobile phone coverage was approximately 87% in Kenya when we commenced this study,<sup>14</sup> and higher among FSWs, who rely on mobile phones for maintaining social and business networks.<sup>3</sup> Short messaging service

technology (SMS, or text messaging) is available on all phones, and has been shown to influence health behaviour.<sup>15,16</sup> However, while some randomised controlled trials (RCTs) have used SMS for promoting safer sex behaviours,<sup>17-19</sup> few have focused on improving contraceptive use.<sup>20-24</sup>

We developed an SMS health promotion intervention for FSWs in Kenya, to address their knowledge gaps and misconceptions around family planning, and prevent unintended pregnancy. The intervention was developed using a participatory, theory-based approach and was well received by the FSW community in the pilot phase.<sup>3</sup> Our two-arm cluster-RCT, named WHISPER or SHOUT,<sup>10</sup> assessed the effectiveness of the intervention to reduce the incidence of unintended pregnancy among FSWs in Kenya, as compared to an equal-attention control group receiving nutrition-focussed messages.

## Methods

### Study design

A full description of the study protocol is provided elsewhere.<sup>10</sup> In brief, the study was conducted in two sub-counties of Mombasa (Kisauni and Changamwe). Trained community mobilisers and peer educators, all of whom were current or former FSWs, recruited participants from pre-identified sex work venues. Venues ranged from nightclubs and brothels to informal drinking dens and public spaces. The sampling frame was based on an enumeration of sex workers conducted in 2014,<sup>25</sup> and consisted of 8516 FSWs working across 757 venues in the two study areas.

The sampling strategy was two-staged. First, sex work venues were randomly selected with a probability proportionate to the size (PPS) of their estimated FSW population. Second, at each venue, FSWs were consecutively invited to participate in the study, with a fixed target of 10 participants per venue (based on an estimated mean venue size of 11.2), until the required sample size of 860 FSWs was reached. The number of venues sampled was 102 plus an additional four, which were not approached because more than 860 FSWs had been recruited. The number of venues sampled was increased from 86 to 95 to account for some venues that had small FSW populations, and inflated 10% to account for anticipated lack of access (for example, due to venue closure or security concerns).

The study was approved by the Kenyatta National Hospital and University of Nairobi Ethics and Research Committee, Kenya (KNH-UoN ERC—KNH-ERC/RR/493) and the Monash University Human Research Ethics Committee, Australia (MUHREC—CF16/1552—2016000812).

## Participants

Women were eligible if they: were aged 16 to 34 years; self-reported receiving money in exchange for sex at the venue of recruitment in the previous six months; were not pregnant or planning pregnancy within 12 months; resided within the study area; reported being able to read text messages in English; and had a personal mobile phone with one of two phone networks (Safaricom or Airtel, which accounted for 71% and 18% of Kenyan mobile subscriptions respectively at the commencement of the trial). Participation in another mHealth study (including the formative research for this study) was an exclusion criterion. All women provided written informed consent to participate.

## Randomisation and masking

Before recruitment, each de-identified sex work venue was randomly allocated to either the intervention (WHISPER) or control (SHOUT) group by the study statistician using random sequence generation. Opaque envelopes with the randomisation assignment were kept at the research office in Mombasa for participant allocation. Allocation was concealed from both participants and researchers until baseline data collection was completed for each cluster. The study coordinator then assigned that cluster to the relevant arm via an online platform (operated by Viamo mobile; <https://viamo.io/>), and set the date for text messages to commence.

## Procedures

Women who met pre-screening criteria at their work venue attended one of two study clinics embedded in existing health facilities for full screening and data collection. Data collection included urine pregnancy testing (also used to assess eligibility), STI and HIV assessment, and a structured questionnaire administered by trained research assistants. Additional data collection procedures for the control arm are detailed in the protocol.<sup>10</sup> Data collection was repeated at six and 12 months after enrolment, with participants reminded to attend each follow up by automated SMS.

The WHISPER intervention and SHOUT control groups had identical structures, consisting of text messages in English delivered two to three times per week for 12 months (137 in total), as well as additional 'on-demand' messages that could be accessed at any time.<sup>10</sup> Members of each cluster were sent the same messages on the same days throughout the study period. Half of the messages were short stand-alone texts providing information, and the other half consisted of longer fictional narratives about FSWs showing healthy social norms and behaviours ('role

model stories'), recounted over several instalments. On-demand messages could be retrieved free-of-charge via SMS using a numeric code, and contained supplementary information and further options. Prompts to reply with numeric codes were included in many of the scheduled messages. The system and content were modelled on the m4RH service,<sup>26</sup> but with the addition of a directory of 12 local health facilities for FSWs, describing their location and available services.

WHISPER message content focused on promotion of contraception, particularly LARCs and dual method use. It also incorporated key domains of SRH known to influence pregnancy risk, including HIV and STI prevention, alcohol and substance use, stigma, and violence.<sup>10 26</sup> Message content and structure were informed by behaviour change theories including stages of change and social cognitive theory,<sup>27,28</sup> which posit that not only knowledge, but also personal factors such as self-efficacy and skill development are important influencers of behaviour;<sup>29</sup> hence these cognitive strategies were incorporated into messages. The intervention was co-designed and tested with FSWs from the target communities.<sup>3</sup> Data from the SMS provider was monitored regularly to detect errors in message delivery.

## Outcomes

All outcomes were measured at the individual rather than cluster level. The primary outcome of WHISPER was the incidence of unintended pregnancy measured at 6- and 12-months.

Pregnancy was defined as either a positive result on urine pregnancy test at the study clinic, or self-report by the participant when it occurred between study visits. Pregnancy intention was assessed using the London Measure of Unintended Pregnancy (LMUP)<sup>30</sup>, a six-item scale administered for every reported pregnancy. A pregnancy scoring less than 10 out of 12 on the LMUP was defined as unintended.<sup>31</sup>

We assessed three secondary outcomes: LARC use (current use of contraceptive implant or intrauterine device), dual contraceptive method use and contraceptive knowledge score. Dual method use was defined as use of effective non-barrier contraception (IUD, pill, implant or injection) as well as consistent use of condoms with all of their sexual partners (clients and/or boyfriends/husbands) in the last month. Contraceptive knowledge was measured as a score in which one point was given for each of six correctly answered statements (Table 4).

Serious adverse events and social events possibly related to SMS receipt (for example physical violence inflicted by a participant's partner resulting from her participation) were reported to the Kenyan ethics committee. Where appropriate, assistance was provided by arranging for urgent medical treatment, counselling and protection by community mobilisers.

## Statistical analysis

Our target sample size (430 women from at least 43 sex work venues in each group) was based on an estimated 12-month unintended pregnancy incidence of 24% in the control group, 37% relative reduction in hazard (hazard ratio=0.63) of unintended pregnancy attributable to the intervention, and an expected attrition of 10%<sup>7</sup> (80% power and 5% significance). This included adjustment for inflation in standard error due to the complex-sampling approach used (design effect=1.18; estimated intra-cluster correlation coefficient=0.02; mean cluster size=10).<sup>32</sup>

Retention rate was calculated using follow-up time by counting one year for each participant who attended their 12-month appointment, or 0.5 years for those who attended the six-month visit only. Unintended pregnancy incidence rate was calculated for descriptive purposes by counting only the first unintended pregnancy per woman, to allow comparison with other estimates.<sup>9</sup> Exposure time was calculated as time from enrolment visit to last menstrual period for women who became pregnant unintentionally, and total time in the study for those who did not. For those missing data on the timing of their pregnancy, this date was imputed by taking the mid-point between the current and last visits.

Primary pre-specified analysis was by intention-to-treat. As the primary outcome was interval-censored (measured in six-month intervals), discrete-time multiple-event survival analysis was performed, using a generalised linear mixed model with complementary log-log link function and binomial distribution. Up to two pregnancies per woman (one per six-month period of discrete time) could be incorporated, and a random intercept was specified for each participant to account for within-subject dependencies. This provided an estimate of the hazard ratio of unintended pregnancy incidence in the intervention group compared to the control group. The model included data from all time points, and was offset for the duration between interviews. Cluster robust standard errors accounted for clustering of participants by sex work venue.

Additional exploratory analysis was performed to examine the potential impact of intervention fidelity on the outcome (as-treated analysis). High exposure to the intervention was defined as more than 100 text messages successfully sent to the participant (reported by the SMS platform provider for participants with Safaricom subscriptions only). The primary analysis model was adjusted by including an interaction term of exposure by study group, to estimate whether the intervention effects differed across high and low levels of exposure.

Secondary outcomes were analysed using multi-level models. Mixed three-level models specifying random intercepts for both individual FSW and sex work venue were fitted for dual method use and contraceptive knowledge score, using generalised linear and linear regression



modelling, respectively. LARC use was assessed by a two-level random effects logistic regression model due to convergence issues with the three-level model. Correct standard errors were applied for clustering by venue. Joint inferential tests (Wald and likelihood ratio (LR)) were applied to determine whether there was an overall effect of the intervention on each outcome over time. For dual method use, the component outcomes (consistent condom use with clients, consistent condom use with boyfriends/husbands, and use of an effective non-barrier contraceptive method) were also analysed using generalised linear mixed models, to explore the effect of each component on the overall measure.

Contamination between trial arms was measured by asking about sharing of health-related text messages at 12 months. Contamination was considered to have occurred when the nominated topics of shared messages included those from the other study arm.

Feasibility and acceptability of the intervention was assessed by SMS provider data on the number of messages successfully sent to each participant and engagement of participants with the pull menu. Self-reported engagement with the intervention was assessed by follow-up questionnaires.

All analyses used a significance level of 5% and no adjustments were made for multiple testing on secondary or exploratory analyses. All analyses were performed in STATA version 14.2. The trial was registered in the Australian New Zealand Clinical Trials Registry (ACTRN12616000852459).

### Role of the funding source

The funder, Australian National Health and Medical Research Council (NHMRC), had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

## Results

Recruitment took place from 14 September 2016 to 16 May 2017, with follow-up completed by 31 July 2018. Of 102 venues sampled, nine sex work venues were excluded due to closure and other logistical reasons, resulting in a total of 93 venues accessed. Recruiters approached 1728 women to take part, of whom 1155 (67%) were eligible for full screening. Of the 1035 women who underwent screening, 882 (85%) were found to be eligible (Figure 1). Four hundred and

fifty-one women from 47 venues were allocated to the WHISPER intervention and 431 from 46 venues to the control group. At least one follow-up visit was attended by 786 women (89%). Retention rate was 85% of total person-time (intervention group 84%; control group 87%). Further details regarding recruitment, ineligibility and baseline characteristics, have been presented elsewhere.<sup>33</sup>

One woman left the study before enrolment procedures were completed, so 881 participants contributed to baseline data. Participant characteristics were similar between study arms (Table 1). Mean age was 25.4 years (SD:4.7). A large majority of participants had been pregnant before, with 45% having had at least two previous pregnancies. HIV prevalence was 12%.

One hundred and thirty-one participants became pregnant during the study, with a total of 145 pregnancies. Of these, 122 were classified as unintended. Fifty-seven women in the intervention group and 53 in the control group had at least one unintended pregnancy, across 368 and 361 person-years at risk, respectively. Last menstrual period was imputed for 32 women (29%). The resulting incidence rates were 15.5 per 100 person-years in the intervention group and 14.7 in the control group (Table 2).

There was no difference in unintended pregnancy incidence between the two groups in the primary intention-to-treat analysis (hazard ratio:0.98, 95%CI:0.69-1.39; Table 2). A time-to-first pregnancy survival analysis using generalised linear modelling showed similar results (AHR:1.06, 95%CI:0.75-1.51; not shown). The as-treated analysis revealed that the effect of the intervention was no different for those exposed to more messages (>100) compared to those exposed to fewer messages (test of joint effects Wald  $\chi^2(1)=0.58$ ,  $p=0.45$ ; Table 2). Other means of measuring exposure (whether or not the participant had accessed the pull menu, and whether they had changed phone number) were also explored, but similarly had no impact on the primary outcome. Full model outputs for both primary and secondary outcomes are available in Appendix 1.

There was a greater change in mean contraceptive knowledge score over time in the intervention group compared to the control group (LR  $\chi^2(2)=14.43$ ,  $p<0.001$ ; Figure 4). This effect was observed over the full 12 months (adjusted difference in knowledge score(b) :0.37, 95%CI:0.18-0.56,  $p<0.001$ ), but did not reach statistical significance in the first 6 months ( $p=0.11$ , Table 3). Most knowledge items were correctly answered at baseline, apart from those relating to duration of action of IUDs and injections (Table 4).

Approximately one quarter of participants used LARCs at all time points (Figure 3), and there was no significant difference in the use of LARCs over time between the two groups (Wald  $\chi^2(2)=3.35$ ,  $p=0.19$ ; Figure 2).

In contrast, the WHISPER intervention was associated with increased odds of dual method use relative to controls over time (LR  $\chi^2(2)=6.47$ ,  $p=0.039$ ). This effect was observed over 12 months (adjusted odds ratio (AOR):2.21, 95%CI:1.19-4.09,  $p=0.012$ ), but not in the first 6 months ( $p=0.18$ , Table 3). This result reflected a significant decline in dual method use between baseline and 12 months in the control group (AOR:0.36, 95%CI:0.23-0.56), compared to no significant change in the WHISPER intervention group (AOR:0.79, 95%CI:0.51-1.21; Figure 4).

More specifically, the different aspects of dual method use played out in different ways across the two arms. First, the use of effective non-barrier contraception declined over 12 months in the control group (AOR:0.58, 95%CI:0.38-0.89,  $p=0.011$ ) but not in the intervention group (AOR:1.09, 95%CI:0.72-1.67,  $p=0.659$ ). Second, consistent condom use with clients increased in the intervention group (AOR:1.79, 95%CI:1.17-2.72,  $p=0.007$ ), but remained unchanged in the control group (AOR:1.13, 95%CI:0.76-1.69,  $p=0.537$ ). Lastly, consistent condom use with boyfriends or husbands declined significantly in both groups (intervention: AOR:0.39, 95%CI:0.27-0.58; control: AOR:0.38, 95%CI:0.26-0.56). A current non-paying boyfriend or husband was reported by 58% of participants in the intervention group at baseline and 55% in the control group, and 67% in both groups at 12 months.

Only five women requested to stop receiving the SMS messages (Figure 1), and 55% accessed additional pull messages at least once during the study (55% in the intervention group and 54% in the control group). Reliable exposure data were available for 787 participants who used Safaricom throughout the study, and these women received a median of 127/137 messages each (IQR:106-133). Women who changed their phone number during the study ( $n=93$ , 11%, from SMS provider data) received a median of 80 messages (IQR:70-109). There were frequent reports of phones being misplaced or broken; one-quarter of participants reported that their phone was unavailable for at least one month. Despite these interruptions, perceived receipt of messages was high, with 86% stating that they had received messages at least twice per week. Of participants who were lost to follow up, 32 (33%) could not be contacted either by phone or by physical tracing.

A quarter of participants reported being shown messages by their peers ( $n=172$ ; 24%). Twenty-two of these were from women in the other trial arm. In addition, two participants were erroneously sent both WHISPER and SHOUT messages for two to three months, and one

participant gave her SIM card to her sister in the other trial arm. Therefore, the overall cross-arm contamination rate was 3% (25/786).

Five adverse events were reported to the Ethics committees. There was one death and one case of physical assault which were not related to the intervention. Two women reported that the messages had made their boyfriends angry, and in one case this exacerbated existing intimate partner violence; however, both women decided to remain in the study. There was one inadvertent breach of a participant's HIV status to a woman later found to be impersonating the participant, and mitigating strategies were subsequently implemented.

## Discussion

The WHISPER intervention had no detectable impact on the biological outcome of unintended pregnancy, despite the fact that it was rigorously designed in collaboration with FSWs, and well-received by participants.<sup>3</sup> The observed unintended pregnancy incidence of 15 per 100 person-years was much lower than anticipated based on previous research, particularly considering our sample was younger than other incidence studies.<sup>7,9</sup> This is consistent with a finding of higher-than expected implant use in the cohort at baseline,<sup>33</sup> and given the magnitude of the difference, it likely reflects a real change in LARC use and pregnancy incidence in the population over time. Alternatively, it is possible that previous studies overestimated incidence as they did not use random samples of sex workers.<sup>9</sup>

Because there were fewer unintended pregnancies than we expected, the standard error of the primary analysis estimate was larger than anticipated, widening the confidence interval (hazard ratio:0.98, 95%CI:0.69-1.39). Nonetheless, as the observed confidence interval excludes our expected intervention effect (hazard ratio = 0.63), this provides some evidence that the intervention was not effective in reducing unintended pregnancy incidence to a degree we defined as clinically meaningful. Despite this, we cannot exclude the possibility that a true difference of less than 37%, attributable to the intervention, is present in the population and that such a magnitude of effect might be considered meaningful.

The WHISPER intervention was associated with improved knowledge about contraceptives, particularly IUDs, as well as dual method contraceptive use. Positive changes were observed in consistent condom use with clients, and to a lesser extent effective non-barrier contraceptive use. This is a promising result as dual method use is a key behaviour related to pregnancy risk, and critical for maintaining STI prevention. The improvement in dual method use was not

sufficient to impact the primary outcome as hypothesised, in part because of the higher than expected baseline use of implants and lower unintended pregnancy incidence.

The observed decline in consistent condom use with boyfriends and husbands was partly an artefact of the larger proportion of women in these non-paying emotional relationships at follow-up than baseline. Regardless, at all time points, less than a third of women with husbands or boyfriends used condoms consistently in these sexual encounters, and this was not influenced by the intervention. This is concerning for a population known to be at greater risk of unintended pregnancy from emotional partners than paying clients.<sup>7</sup> Interventions that can successfully influence sexual risk behaviour within FSWs' emotional relationships have not yet been identified, though innovative models have been trialled.<sup>34</sup>

The fact that the WHISPER intervention was correlated with change in use of some methods but not LARCs, suggests that, contrary to our hypothesis, addressing knowledge barriers may translate to behaviour change in relation to short-acting and user-controlled methods only. A similar result was observed in a study of postpartum women receiving an SMS intervention in Kenya.<sup>22</sup> Improving knowledge of LARCs and associated individual determinants such as attitudes and self-efficacy may have little impact without addressing supply-side barriers such as lack of availability,<sup>35</sup> insufficient provider counselling,<sup>33</sup> and stigma from health workers.<sup>36</sup> Unlike short-acting methods, LARCs are mainly only available in public facilities in Kenya,<sup>37</sup> which tend to have longer waiting times than private facilities.<sup>36</sup> Baseline data from this study revealed that only male condoms were frequently supplied by FSW-targeted drop-in-centres,<sup>33</sup> despite these being the most acceptable health centres for FSWs.<sup>36</sup> Supply-side interventions have increased LARC uptake and reduced unintended pregnancy in the USA,<sup>38,39</sup> and a combined supply- and demand-side intervention increased LARC use in Kenya,<sup>40</sup> but similar approaches have not been adopted with FSWs.

Overall, the results suggest that provision of health education by mobile phone, in the absence of parallel interventions, is unlikely to result in substantial contraceptive behaviour change in a population with high baseline use of at least some form of contraception. A similar conclusion has been reached by other RCTs of SMS-based sexual health interventions.<sup>18,23</sup> In our case, this was despite concerted efforts in intervention design to maximise translation from knowledge to behaviour change, because increased knowledge alone is often insufficient to change behaviour or clinical outcomes.<sup>29</sup> We adopted strategies from health promotion theory,<sup>27,28</sup> such as role modelling and skill development;<sup>29</sup> and bidirectional messaging, with an on-demand menu that allowed greater engagement and included a directory of local SRH services.<sup>3</sup> Non-automated

bidirectional messaging with a health provider and tailoring of messages to individuals' current method may have had greater impact,<sup>22</sup> but were not feasible to adopt in this intervention.

The messages addressed contextual and structural issues, such as alcohol use, violence and rights; however, this may have resulted in too broad a scope and diluted the primary message of pregnancy prevention, or required a longer duration to have measurable impact. Further research using qualitative methodologies is needed to better understand why women could not or did not want to adopt safer contraceptive behaviours in response to this intervention.

Concurrent and complementary interventions may be needed so that women receive multiple reinforcing messages from different sources. A systematic review of mHealth for maternal and neonatal care in LMICs found that combining mHealth interventions with other interventions had promising results.<sup>41</sup> Similarly, a post-abortion intervention in Cambodia that utilised a combination of interactive voice response messages, contraceptive counselling by phone, and expedited links to LARC insertion services, is one of few mHealth interventions shown to improve LARC use.<sup>20</sup>

The need for combined approaches is likely to be greater for populations like FSWs that face entrenched supply-side and demand-side barriers to contraceptive use. We therefore recommend that the WHISPER intervention be adapted and trialled as part of a more comprehensive pregnancy prevention package for FSWs that addresses supply- as well as demand-side barriers.

This study demonstrates that mHealth interventions with FSWs are not only feasible, but can be highly acceptable. Despite interruptions due to phone problems, participants received a large proportion of the scheduled messages and the majority sought further information. Some simple strategies were instituted to minimise loss of participants, such as testing their number at registration, screening for number changes at follow-up visits, and periodically investigating participants with high SMS failure rates. The high rate of message sharing between participants is further evidence of their engagement with the intervention, and also confirms the appropriateness of the cluster design, which accommodated the intended interactions of women within sex work venues. Sharing of messages, because it was mostly done within study arms, is likely to have enhanced rather than diluted any intervention effects.

Our study had several limitations. Measurement of outcomes ceased at the same time as the intervention, so we may have missed some participants' transition from contemplation of message content into action, and its subsequent impact on biological outcomes.

The second stage of sampling may have introduced selection bias, as recruiters sampled FSWs consecutively until a target was reached, rather than randomly sampling or inviting all FSWs from each venue (i.e. using an intact second stage sampling unit). This was a pragmatic decision to ensure that participant selection was feasible and adapted to conditions in the field. The fixed number of second stage sampling units notionally provided a sample where FSWs were sampled with equal probability, despite the unequal probability selection at the first-stage. In addition, the number of venues and FSWs active in each venue may have changed between the enumeration in 2014 and recruitment for the study in 2016. This may have resulted in over-representation of some venues in the sample, and exclusion of new venues.

It is possible that we underestimated unintended pregnancy incidence due to selective loss of pregnant participants from the study. There were five anecdotal reports of women who were pregnant not returning for study visits, due to either changes in living circumstances or concerns that they would not be able to remain in the study following pregnancy, which may have reflected a misinterpretation of eligibility criteria.

Unreliable reporting from the Airtel network that could not be rectified during the study meant that we were limited to measuring exposure only among women who used Safaricom for the whole year. While this still accounted for 89% of participants, it may have hidden differences in successful delivery between the two networks. The ability to accurately monitor message and call delivery is an important consideration for future mHealth programs.

English-language SMS was utilised rather than Swahili text or voice messaging, based on the preferences of FSWs in our formative work<sup>3</sup>. However, a small minority of women did have difficulty with this format. Only 6% of women were found to be SMS illiterate on screening (data not shown), but the field team suspected that some women self-excluded on the basis of illiteracy before being screened. It may be preferable for future interventions to provide a voice message option to improve equity of delivery across literacy levels, and reach women at greater disadvantage. Other authors have noted the risk of mHealth interventions not reaching those at greatest need.<sup>20,23,42</sup>

Despite these issues, we have demonstrated that mobile phones are a feasible means of connecting with this population. Sex work is increasingly solicited via digital means, and models of health promotion and service delivery that are overly focused on physical locations will increasingly miss women who sell sex.<sup>43</sup> Mobile phones could be utilised to link to clinical and educational programs, create support networks between peers, and provide information, and will need to be part of the means of delivery to this population in the future.



This study is notable for being one of few RCTs conducted among FSWs in LMICs, for aiming to prevent unintended pregnancy, a critical but under-recognised issue in this population, and for adopting a novel reciprocal control design. We showed that an mHealth intervention in isolation may improve both contraceptive knowledge and dual method contraceptive use. However, mHealth needs to be incorporated into more comprehensive approaches, particularly those addressing the role of FSWs' emotional partners and the supply of longer-acting, more reliable contraception, to prevent unintended pregnancy and its associated detrimental impacts on the health and wellbeing of FSWs.

## Tables

**Table 1: Participant characteristics by intervention group at baseline. N=881 unless specified.**

	<b>WHISPER intervention group (n=450)</b>	<b>SHOUT control group(n=431)</b>
Age (n=877)	25·4 (4·5)	25·6 (4·8)
Marital status		
Married/cohabitating	29 (6%)	26 (6%)
Not married/cohabitating	421 (94%)	405 (94%)
Education		
None/some primary	60 (13%)	44 (10%)
Completed primary	225 (50%)	239 (55%)
Completed secondary	165 (37%)	148 (34%)
Religion (n=879)		
Protestant	190 (42%)	202 (47%)
Catholic	168 (37%)	142 (33%)
Muslim	89 (20%)	83 (19%)
Other	3 (0·7%)	2 (0·5%)
Gravidity		
0	117 (26%)	88 (20%)
1	136 (30%)	142 (33%)
2+	197 (44%)	201 (47%)
Location		
Kisauni sub-county	297 (66%)	273 (63%)
Changamwe sub-county	153 (34%)	158 (37%)
Sex work venue		
Bar with lodging	215 (48%)	183 (42%)
Bar without lodging	66 (15%)	81 (19%)
Lodging/guesthouse	76 (17%)	64 (15%)
Street/beach	38 (8%)	48 (11%)
Other	55 (12%)	55 (13%)
Duration in sex work (years; n=871)	4·5 (3·2)	4·9 (3·7)
HIV positive (n=876)	60 (13%)	47 (11%)
Currently has boyfriend/husband (n=879)	260 (58%)	235 (55%)
Boyfriend/husband wants pregnancy (n=494)		
Yes	68 (26%)	52 (22%)
No	114 (44%)	113 (48%)
Unsure or unknown	78 (30%)	69 (29%)
Total weekly income* (n=722)	€37·16 (€36·65)	€37·43 (€35·06)
Contraceptive use		
Any modern method* (n=878)	344 (77%)	346 (80%)
LARC (n=879)	107 (24%)	110 (26%)
Dual methods (n=873)	111 (25%)	124 (29%)

Data are in n (%) or mean (SD)

\*Data from 12-month visit as not asked at baseline. Conversion rate from Euros to Kenyan shillings as at 15 September 2016.

+IUD, implant, pill, injection or consistent condom use with all partners in the last month

**Table 2: The effect of the WHISPER intervention on the primary outcome, unintended pregnancy incidence (intention-to-treat and as-treated analyses)**

		Women with unintended pregnancy (n/N)	Incidence*	HR	95% CI	p-value
<b>Intention-to-treat (n=786)<sup>†</sup></b>						
Control group		53/385	14.7	1.00 (ref)		
Intervention group		57/401	15.5	0.98	0.69-1.39	0.89
<b>As-treated (n=700)<sup>†</sup></b>						
Low exposure	Control group	10/68	16.8	1.00 (ref)		
	Intervention group	9/75	13.0	0.71	0.29-1.71	0.44
High exposure	Control group	37/282	13.8	1.00 (ref)		
	Intervention group	40/275	15.7	1.05	0.66-1.65	0.84
Differential effect of exposure between groups <sup>#</sup>				1.48	0.54-4.10	0.45

Hazard ratios (HR), 95% confidence intervals (95%CI) and probability-values (p-values)

\*Time-to-first pregnancy analysis, per 100 person-years

+Discrete-time survival analysis including multiple pregnancies per woman. Generalised linear mixed model (complementary log-log link, binomial distribution, offset for log time between visits and random intercept for FSW), with cluster robust standard errors for FSW venue clustering

<sup>†</sup>As above, with addition of group-by-exposure interaction term

<sup>#</sup>Interaction term; represents the additional change in the outcome with increased exposure for the WHISPER group compared to the control group

**Table 3: The effect of the WHISPER intervention on secondary outcomes (LARC use, dual method contraceptive use and contraceptive knowledge)**

	Group comparison at each time point: intervention vs control			Differential effect over time (from baseline to follow up) of the intervention compared to control group <sup>#</sup>			Joint test of effect <sup>§</sup>
Knowledge score*							
	<i>b</i>	95% CI	p-value	<i>b</i>	95% CI	p-value	p-value
6 months	0.001	-0.21-0.21	1.00	0.154	-0.03-0.34	0.11	<0.001
12 months	<b>0.216</b>	<b>0.004-0.43</b>	<b>0.046</b>	<b>0.369</b>	<b>0.18-0.56</b>	<b>&lt;0.001</b>	
LARC use <sup>†</sup>							
	AOR	95% CI	p-value	AOR	95% CI	p-value	p-value
6 months	1.25	0.52-3.00	0.62	1.82	0.87-3.82	0.11	0.19
12 months	0.83	0.30-2.30	0.72	1.21	0.45-3.24	0.71	
Dual method use <sup>†</sup>							
	AOR	95% CI	p-value	AOR	95% CI	p-value	p-value
6 months	1.035	0.54-1.99	0.92	1.48	0.83-2.62	0.18	<b>0.039</b>
12 months	1.55	0.78-3.09	0.22	<b>2.21</b>	<b>1.19-4.09</b>	<b>0.012</b>	

Adjusted mean differences (b), adjusted odds ratios (AOR), 95% confidence intervals (95%CI), probability-values (p-values)

\*3-level linear mixed model with random intercepts for sex work venue and FSW

+2-level random effects logistic regression model with cluster robust standard errors for sex work venue (as a 3-level model exhibited convergence problems)

†3-level generalised linear mixed model with random intercepts for sex work venue and FSW

#Interaction terms from each model. Represent the additional change in the outcome over follow-up for the WHISPER group compared to the control group (mean difference for knowledge score and relative difference in odds for LARC and dual method use)

§ Likelihood ratio test for knowledge and dual method use; Wald test for LARC use.

**Table 4: True/False statements included in the knowledge scale and percent answered correctly at baseline and 12 months, by intervention group**

Statement and correct answer (true or false)	Percent answered correctly			
	Baseline		12 months	
	WHISPER intervention	SHOUT control	WHISPER intervention	SHOUT control
Implants can make your period lighter, or stop it altogether (true)	64.1	66.5	71.9	72.8
One contraceptive injection, like Depo, will protect against pregnancy for 1 year (false)	44.1	46.4	60.8	60.1
I don't need to use condoms if I'm already using another type of family planning (false)	71.8	73.0	76.0	75.1
It is easy for most women to get pregnant soon after they stop using family planning (true)	84.8	89.1	88.9	88.6
The IUD protects against pregnancy for up to 12 years (true)	45.2	45.5	<b>62.5</b>	<b>45.7***</b>
Family planning pills and injections provide some protection against HIV (false)	<b>76.7</b>	<b>83.0*</b>	88.6	89.8

Difference between groups at each time point: \*p<0.05; \*\*p<0.001

## Figures

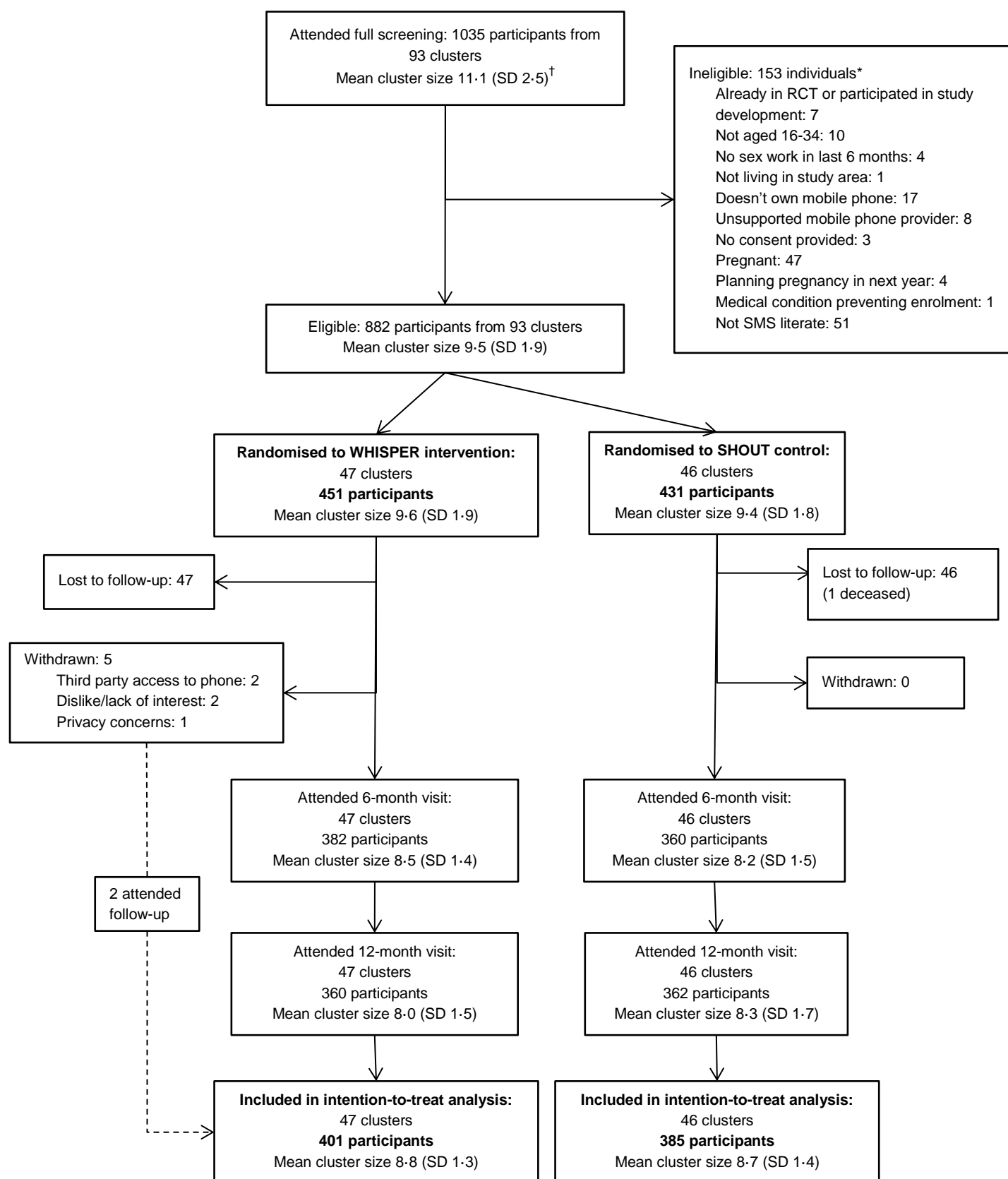


Figure 1: Trial profile

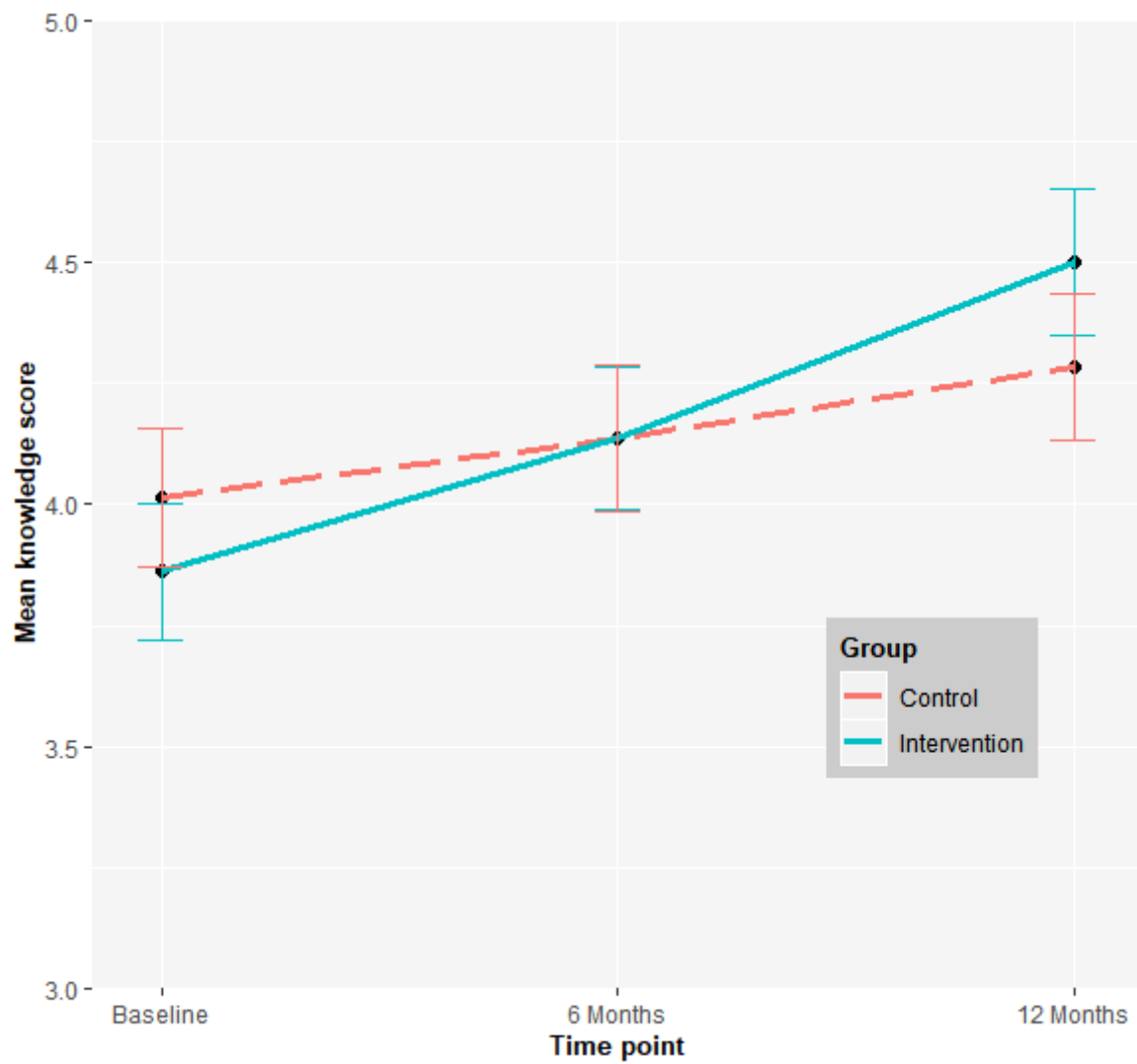
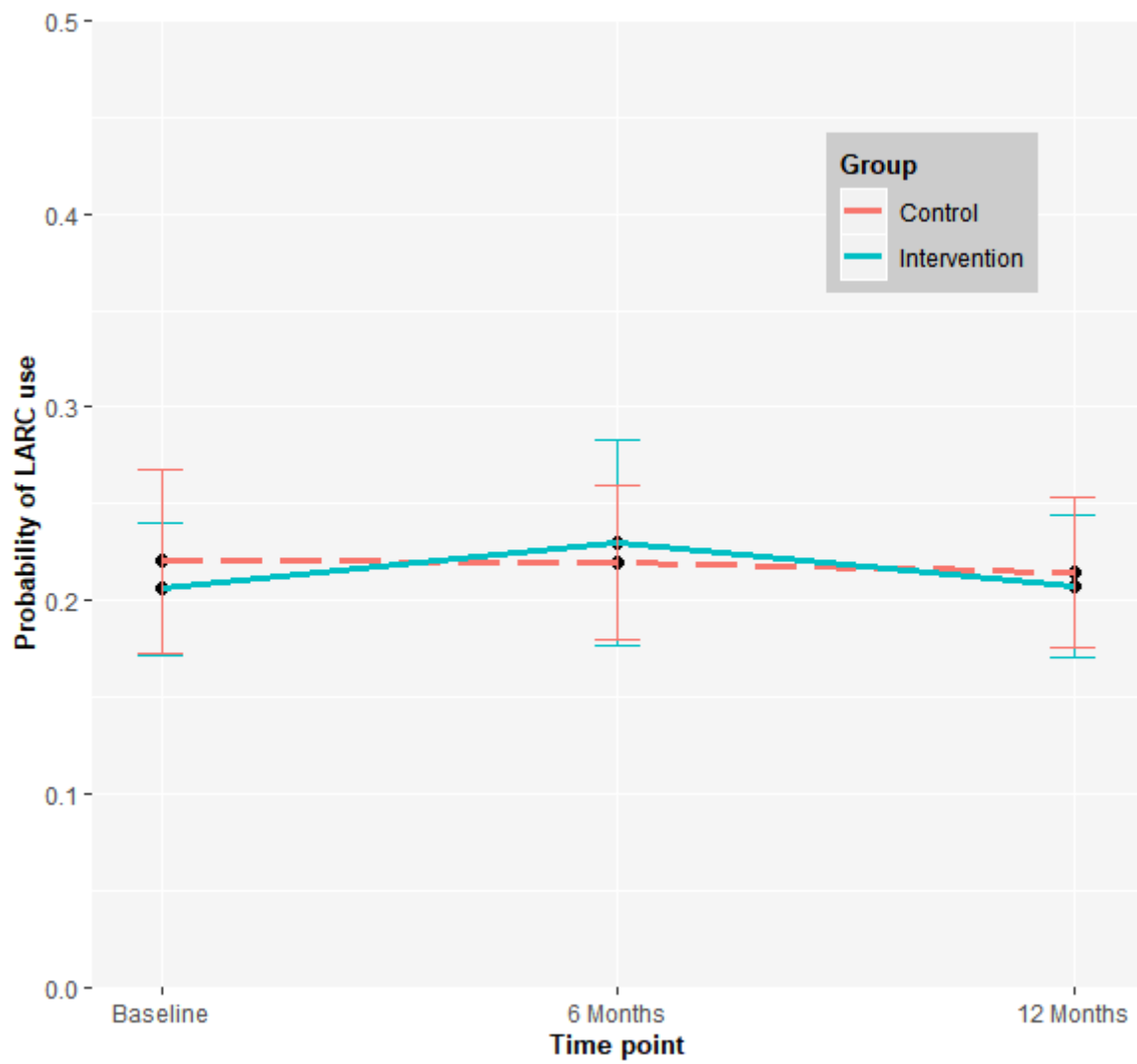
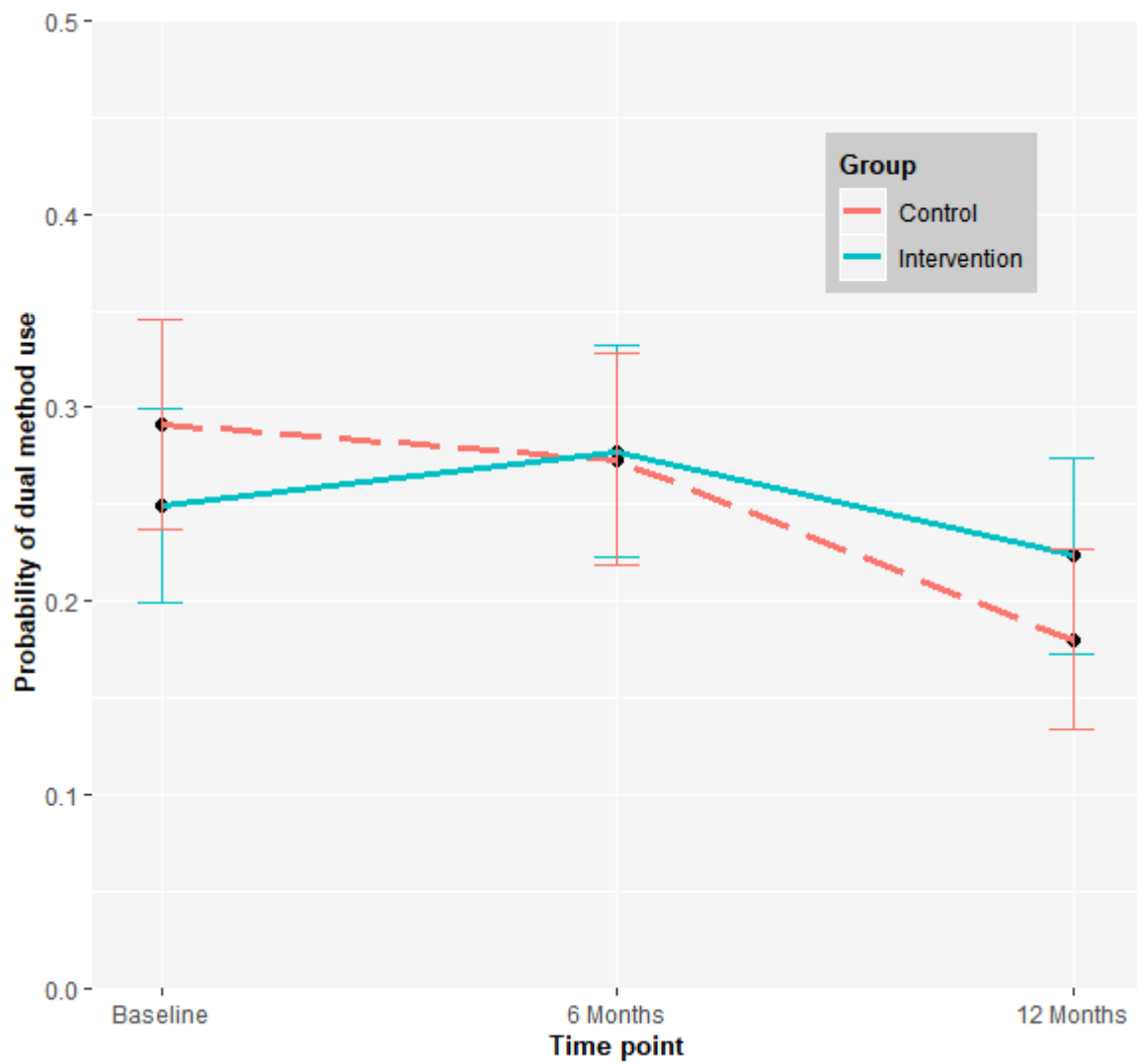


Figure 2: Mean knowledge score by intervention group at each time point, predicted by mixed linear regression model





**Figure 3: Probability of LARC use by intervention group at each time point, predicted by random effects logistic regression model**



**Figure 4: Probability of dual method use by intervention group at each time point, predicted by generalised linear mixed model**

## Declarations

### Contributors

SL is the Principal Investigator on the study. SL, FHA, PG, MSCL, MC, KL, WJ, MT, MS, PAA, and MH contributed to study design. GM and CG undertook trial coordination and data acquisition in Kenya under the supervision of PG. FHA, SL and MSCL conceptualised the manuscript. FHA and PAA did the statistical analyses. FHA wrote the first draft of the manuscript. All authors contributed to data interpretation, provided critical input, and approved the final version of the manuscript.

### Declaration of interests

We declare no competing interests.

### Acknowledgments

Australia's National Health and Medical Research Council provided funding for the WHISPER or SHOUT trial (Project Grant GNT 1087006), Career Development Fellowships for SL and MS, and a Postgraduate Scholarship for FHA. The authors gratefully acknowledge the contribution of funding from the Victorian Operational Infrastructure Support Program received by the Burnet Institute.

### Supplementary material

Appendix 1: Statistical model output for each outcome

### Data sharing statement

Data collected for the study cannot be made publically available. The study protocol, including statistical analysis plan, has been published and is available at <https://bmjopen.bmj.com/content/7/8/e017388>. Additional study documents (for example, informed consent forms and questionnaires) can be provided on request.

## References

1. Vandepitte J, Lyster R, Dallabetta G, Crabbé F, Alary M, Buvé A. Estimates of the number of female sex workers in different regions of the world. *Sex Transm Infect* 2006; **82 Suppl 3**: iii18-25.
2. Dhana A, Luchters S, Moore L, et al. Systematic review of facility-based sexual and reproductive health services for female sex workers in Africa. *Global Health* 2014; **10**(1): 46-.
3. Ampt F, L'Engle K, Lim MS, et al. "I now know I'm the boss": Development of a mobile phone-based sexual and reproductive health intervention for female sex workers in Kenya. *JMIR mHealth and uHealth* (in press).
4. Singh S, Darroch JE, Ashford LS. Adding it up: the costs and benefits of investing in sexual and reproductive health 2014. New York: Guttmacher Institute, 2014.
5. Hall JA, Benton L, Copas A, Stephenson J. Pregnancy intention and pregnancy outcome: systematic review and meta-analysis. *Matern Child Health J* 2017; **21**(3): 670-704.
6. Gipson JD, Koenig MA, Hindin MJ. The effects of unintended pregnancy on infant, child, and parental health: a review of the literature. *Stud Fam Plann* 2008; **39**(1): 18-38.
7. Luchters S, Bosire W, Feng A, et al. "A baby was an added burden": predictors and consequences of unintended pregnancies for female sex workers in Mombasa, Kenya: A mixed-methods study. *PLoS ONE* 2016; **11**(9): e0162871.
8. Reed E, Silverman JG, Stein B, et al. Motherhood and HIV risk among female sex workers in Andhra Pradesh, India: the need to consider women's life contexts. *AIDS Behav* 2013; **17**(2): 543-50.
9. Ampt FH, Willenberg L, Agius PA, Chersich M, Luchters S, Lim MSC. Incidence of unintended pregnancy among female sex workers in low-income and middle-income countries: a systematic review and meta-analysis. *BMJ Open* 2018; **8**(9): e021779.
10. Ampt FH, Mudogo C, Gichangi P, et al. WHISPER or SHOUT study: protocol of a cluster-randomised controlled trial assessing mHealth sexual reproductive health and nutrition interventions among female sex workers in Mombasa, Kenya. *BMJ Open* 2017; **7**(8): e017388.
11. Khan MR, Turner AN, Pettifor A, et al. Unmet need for contraception among sex workers in Madagascar. *Contraception* 2009; **79**(3): 221-7.
12. Boudreau CL. Assessing the contraceptive needs of female sex workers in Kigali, Rwanda. 6th Annual CUGH Conference, Consortium of Universities for Global Health: Mobilizing Research for Global Health 2015 26-28 March; Boston, MA United States; 2015. p. 217.
13. Williamson LM, Parkes A, Wight D, Petticrew M, Hart GJ. Limits to modern contraceptive use among young women in developing countries: a systematic review of qualitative research. *Reprod Health* 2009; **6**: 3.
14. Communications Authority of Kenya. Second quarter sector statistics report for the financial year 2016/2017 (October-December 2016), 2017.
15. Free C, Phillips G, Galli L, et al. The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. *PLoS Med* 2013; **10**(1): e1001362-e.
16. Armanasco AA, Miller YD, Fjeldsoe BS, Marshall AL. Preventive Health Behavior Change Text Message Interventions: A Meta-analysis. *Am J Prev Med* 2017; **52**(3): 391-402.
17. Gold J, Aitken CK, Dixon HG, et al. A randomised controlled trial using mobile advertising to promote safer sex and sun safety to young people. *Health Educ Res* 2011; **26**(5): 782-94.
18. Lim MSC, Hocking JS, Aitken CK, et al. Impact of text and email messaging on the sexual health of young people: a randomised controlled trial. *J Epidemiol Community Health* 2012; **66**(1): 69-74.
19. Jones R, Hoover DR, Lacroix LJ. A randomized controlled trial of soap opera videos streamed to smartphones to reduce risk of sexually transmitted human immunodeficiency virus (HIV) in young urban African American women. *Nurs Outlook* 2013; **61**(4): 205-15.e3.

20. Smith C, Ngo TD, Gold J, et al. Effect of a mobile phone-based intervention on post-abortion contraception: a randomized controlled trial in Cambodia. *Bull World Health Organ* 2015; **93**(12): 842-50A.
21. Tsur L, Kozer E, Berkovitch M. The effect of drug consultation center guidance on contraceptive use among women using isotretinoin: a randomized, controlled study. *J Womens Health (Larchmt)* 2008; **17**(4): 579-84.
22. Harrington EK, Drake AL, Matemo D, et al. An mHealth SMS intervention on postpartum contraceptive use among women and couples in Kenya: a randomized controlled trial. *Am J Public Health* 2019; **109**(6): 934-41.
23. Johnson D, Juras R, Riley P, et al. A randomized controlled trial of the impact of a family planning mHealth service on knowledge and use of contraception. *Contraception* 2017; **95**(1): 90-7.
24. de Tolly KM, Constant D. Integrating Mobile Phones into Medical Abortion Provision: Intervention Development, Use, and Lessons Learned From a Randomized Controlled Trial. *JMIR Mhealth Uhealth* 2014; **2**(1): e5.
25. Cheuk E, Isac S, Musyoki H, et al. Informing HIV prevention programs for adolescent girls and young women: a modified approach to programmatic mapping and key population size estimation. *JMIR Public Health Surveill* 2019; **5**(2): e11196-e.
26. L'Engle KL, Vahdat HL, Ndakidemi E, Lasway C, Zan T. Evaluating feasibility, reach and potential impact of a text message family planning information service in Tanzania. *Contraception* 2013; **87**(2): 251-6.
27. Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: Toward an integrative model of change. *J Consult Clin Psychol* 1983; **51**(3): 390-5.
28. Bandura A. Social foundations of thought and action: A social cognitive theory. Englewood Cliffs, NJ: Prentice Hall; 1986.
29. Maibach E, Cotton D. Moving people to behaviour change. In: Maibach E, Parrott RL, eds. *Designing Health Messages: Approaches from Communication Theory and Public Health Practice*. Thousand Oaks: Sage publications; 1995.
30. Hall J, Barrett G, Mbwana N, Copas A, Malata A, Stephenson J. Understanding pregnancy planning in a low-income country setting: validation of the London Measure of Unplanned Pregnancy in Malawi. *BMC Pregnancy and Childbirth* 2013; **13**.
31. Hall JA, Barrett G, Copas A, Stephenson J. London Measure of Unplanned Pregnancy: guidance for its use as an outcome measure. *Patient Relat Outcome Meas* 2017; **8**: 43-56.
32. Cai Y, Shi R, Shen T, et al. A study of HIV/AIDS related knowledge, attitude and behaviors among female sex workers in Shanghai China. *BMC Public Health* 2010; **10**: 377.
33. Ampt FH, Lim MSC, Agius PA, et al. Use of long-acting reversible contraception in a cluster-random sample of female sex workers in Kenya. *International Journal of Gynecology & Obstetrics* 2019; **146**(2): 184-91.
34. Beattie TS, Isac S, Bhattacharjee P, et al. Reducing violence and increasing condom use in the intimate partnerships of female sex workers: study protocol for Samvedana Plus, a cluster randomised controlled trial in Karnataka state, south India. *BMC Public Health* 2016; **16**: 660.
35. European Commission. Report of situational analysis of reproductive health services for general population women and female sex workers in India, Kenya, Mozambique and South Africa: European Commission FP7 DIFFER project, 2013.
36. Corneli A, Lemons A, Otieno-Masaba R, et al. Contraceptive service delivery in Kenya: a qualitative study to identify barriers and preferences among female sex workers and health care providers. *Contraception* 2016; **94**(1): 34-9.
37. PMA2020. PMA2015/Kenya-R4 SOI: snapshot of indicators: Performance Monitoring and Accountability 2020, 2016.
38. Harper CC, Rocca CH, Thompson KM, et al. Reductions in pregnancy rates in the USA with long-acting reversible contraception: a cluster randomised trial. *Lancet* 2015.
39. Secura GM, Madden T, McNicholas C, et al. Provision of no-cost, long-acting contraception and teenage pregnancy. *N Engl J Med* 2014; **371**(14): 1316-23.

40. Benson A, Calhoun LM, Corroon M, et al. Longitudinal evaluation of the Tupange urban family planning program in Kenya. *Int Perspect Sex Reprod Health* 2017; **43**(2): 75-87.
41. Sondaal SFV, Browne JL, Amoakoh-Coleman M, et al. Assessing the Effect of mHealth Interventions in Improving Maternal and Neonatal Care in Low- and Middle-Income Countries: A Systematic Review. *PLoS ONE* 2016; **11**(5): e0154664.
42. Suffoletto B, Akers A, McGinnis KA, Calabria J, Wiesenfeld HC, Clark DB. A sex risk reduction text-message program for young adult females discharged from the emergency department. *J Adolesc Health* 2013; **53**(3): 387-93.
43. Wilson D. HIV programs for sex workers: lessons and challenges for developing and delivering programs. *PLoS Med* 2015; **12**(6): e1001808.

## Appendix 1: Statistical model output for each outcome

**Supplementary Table 1: The effect of the WHISPER intervention on the primary outcome (unintended pregnancy incidence); full model output for intention-to-treat and as-treated analyses**

		Intention-to-treat* (n=786)			As-treated* (n=700)		
Factor		HR	95%CI	p-value	HR	95%CI	p-value
Allocation group: WHISPER intervention		0.98	0.69-1.39	0.89	0.71	0.29-1.71	0.44
Exposure level: high (>100 messages) <sup>§</sup>		N/A			0.82	0.39-1.74	0.61
Interaction of group (WHISPER) by exposure level (high) <sup>#</sup>		N/A			1.48	0.54-4.10	0.45
Follow-up	6-month	0.01	0.01-0.02	<0.001	0.01	0.005-0.02	<0.001
	12-month	0.01	0.01-0.02	<0.001	0.01	0.005-0.02	<0.001

Hazard ratios (HR), 95% confidence intervals (95%CI) and probability-values (p-values)

\* Generalised linear mixed model (complementary log-log link and binomial distribution) with cluster robust standard errors

§ Represents the change in the outcome for the control group (SHOUT) for high (vs low) exposure

# Represents the relative change in the hazard ratio of high vs low exposure for the WHISPER group, compared to the control group.

N/A not applicable

**Supplementary Table 2: The effect of the WHISPER intervention on secondary outcomes (LARC use, dual method contraceptive use and contraceptive knowledge); full model output for each outcome**

		LARC use <sup>*</sup> (n=881)			Dual method use <sup>+</sup> (n=881)			Knowledge score <sup>†</sup> (n=881)		
Factor		AOR	95%CI	p-value	AOR	95%CI	p-value	<i>b</i>	95%CI	p-value
Allocation group: WHISPER intervention		0.69	0.27-1.73	0.42	0.70	0.37-1.31	0.27	-0.15	-0.35-0.48	0.14
Follow-up <sup>§</sup>	6-month	0.98	0.52-1.84	0.95	0.86	0.57-1.29	0.47	0.12	-0.01-0.26	0.075
	12-month	0.87	0.39-1.93	0.73	0.36	0.23-0.56	<0.001	0.27	0.13-0.40	<0.001
Interaction of group (WHISPER) by time <sup>#</sup>	6-month	1.82	0.87-3.82	0.11	1.48	0.83-2.62	0.18	0.15	-0.03-0.34	0.11
	12-month	1.21	0.45-3.24	0.71	2.21	1.19-4.09	0.012	0.37	0.18-0.56	<0.001

Adjusted odds ratios (AOR), adjusted mean differences (*b*), 95% confidence intervals (95%CI), probability-values (p-values)

\*2-level random effects logistic regression model with cluster robust standard errors for sex work venue as a 3-level model exhibited convergence problems.

+3-level generalised linear mixed model with random intercepts for sex work venue and FSW

† 3-level linear mixed model with random intercepts for sex work venue and FSW

§ Represents the change in the outcome for the control group (SHOUT) across follow-up (baseline to 6 months, baseline to 12 months)

# Represents the additional change in the outcome over follow-up (baseline to 6 months, baseline to 12 months) for the WHISPER group compared to the control group (relative difference in odds for LARC and dual method use and mean difference for knowledge score).



## Chapter 7: Integrated discussion

This thesis aimed to improve FSWs' sexual and reproductive health, by addressing knowledge gaps about the risks of unintended pregnancy in this population, and developing and testing an mHealth intervention for FSWs in Kenya to prevent unintended pregnancy. In this thesis I have presented novel methods for understanding and addressing unintended pregnancy among FSWs. The systematic review in Chapter 2 represents the first attempt to develop a pooled estimate of unintended pregnancy incidence. WHISPER is the first reproductive health mobile phone intervention to be evaluated in this population, and the WHISPER or SHOUT study utilised an innovative design for testing an mHealth intervention, and for conducting randomised controlled trials in this population. This trial provided critical evidence of FSWs' contraceptive practices and needs, of methods to stimulate demand for contraception, and of the potential shortfalls of implementing single-modality demand-generating interventions in isolation. In this chapter, I present an integrated discussion of the key findings and implications of this research, and propose recommendations for addressing ongoing knowledge gaps and for improved models of care for FSWs that incorporate both prevention and service delivery components.

### 7.1 Key findings and their implications

#### 7.1.1 Female sex workers in Kenya had higher implant use, and lower unintended pregnancy incidence, than expected

The incidence of unintended pregnancy among WHISPER or SHOUT trial participants, presented in Chapter 6, was 15 per 100 person-years, which is certainly high by global and regional standards. Bearak et al., using a Bayesian hierarchical model, calculated an incidence of approximately 6.5 per 100 women-years among women in developing countries and 11.2 in East Africa in the period of 2010 to 2014.[44] These figures are now likely to be lower still, given downward trends.

Nonetheless, our measurement of incidence is considerably lower than the pooled estimate among FSWs calculated from the most relevant studies in the systematic review, 27.1 per 100 person-years (Chapter 2). The studies in this meta-analysis took place between 2006 and 2009, so it is reasonable to assume that incidence would have decreased since that time corresponding to the general population decrease, however the magnitude of the difference was unexpected. The WHISPER or SHOUT study provides a more accurate measure of incidence than

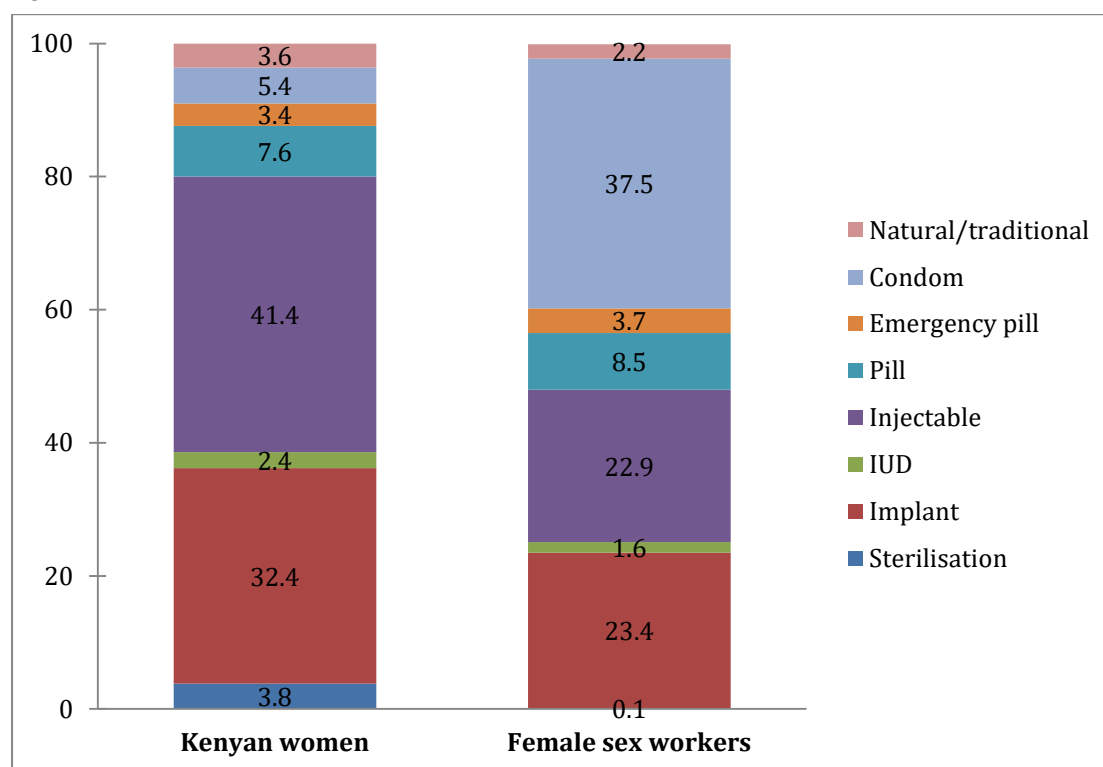
those in the systematic review, because of higher methodological quality. In particular, pregnancy incidence was the primary outcome measure, pregnancy intention was measured with a validated scale, and the sample was randomly selected, which were issues that affected the quality of studies in the systematic review.

The lower than expected unintended pregnancy rate in Kenyan FSWs may be attributable to a large increase in implant use in the last decade. In a cohort study conducted in Mombasa in 2006-2007, less than five percent of FSWs were using implants,[38] compared to 23% (weighted estimate) in our study at baseline in 2016-2017 (Chapter 5). Similarly, all but one[231] of the African studies in the systematic review reported very low LARC use (Chapter 2). Again, the WHISPER or SHOUT estimate is likely to be more externally valid due to the random sampling methodology, but the apparent fourfold increase occurred in parallel to a similar increase in the general population in Kenya over the same period, and a concerted effort by the Kenyan government to improve supply of long-acting methods (described in Chapter 1).

Comparison of method mix between FSWs and the general population reveals a similar distribution apart from a much higher reliance on condoms by FSWs. Figure 1 presents the distribution of methods among women currently using contraception from a national stratified cluster survey in Kenya in 2017[62, 232] and the WHISPER or SHOUT participants at enrolment.<sup>4</sup>

---

<sup>4</sup> Proportions and denominator for the WHISPER or SHOUT sample differ from the results in Chapter 5, as the latter reports prevalence of each method in the full sample rather than among women reporting current contraceptive use. Note that the Kenyan sample includes all women aged 15 to 49 years currently using contraception, regardless of pregnancy intention.



**Figure 1: Contraceptive method mix in Kenya in 2017[62] and among FSWs from the WHISPER or SHOUT study at enrolment (inverse probability-weighted percentages; n=852).**

Condom and emergency pill refer to those using only these methods. Natural/traditional includes both modern fertility awareness based methods and traditional methods (e.g. withdrawal, rhythm and herbal).

Implants have overtaken injections as the most used non-barrier method among FSWs, suggesting that FSWs both have a demand for long-acting methods, and are accessing family planning services that provide these methods. While the extensive use of condoms is understandable in a population with more partners and higher HIV risk than the general population, it is concerning that a substantial proportion of FSWs are relying on condoms alone for pregnancy prevention<sup>5</sup>.

<sup>5</sup> The women included in these data are those who nominated condoms as their only current method of contraception (n= 317). An additional 19 women reported not currently using contraception, but later stated that they had used condoms in the last month. The former measure of condom use was considered more appropriate for comparing method mix with the national survey, which asks about condoms used for the purpose of pregnancy prevention. The latter measure was used in the analysis presented in Chapter 5, accounting for the discrepancy between these two analyses.

### 7.1.2 Despite improvements, female sex workers continue to have substantial sexual and reproductive health needs

Although changes over time in implant use and unintended pregnancy are promising, demand for contraception remains high among FSWs in Kenya, with less than 1% of women who underwent screening for WHISPER or SHOUT reporting wanting to get pregnant in the next year (similar to the 4% planning pregnancy in an earlier study[38]). At baseline, over one-third relied on condoms alone for contraception, 55% were using modern contraceptives other than condoms or emergency pills, and only one quarter were using dual methods, indicating substantial ongoing unmet need (Chapter 5). While the use of short-acting methods and condoms increased with the WHISPER intervention (7.1.4), the magnitude of this increase was not sufficient to substantially reduce unmet need. The perspectives of FSWs captured during formative research for WHISPER (Chapter 3) confirmed that family planning and unintended pregnancy are considered high priorities by this population.

#### *Use of intrauterine devices*

IUDs are a glaring example of underuse of an effective and reliable method, with baseline estimates of only 2% of FSWs currently using IUDs (Chapter 5). IUD use remains similarly low in the general population in Kenya, accounting for 2.4% of women using contraception (Figure 1). Key opinion leaders in Kenya believe that the main barriers to IUD uptake are: myths about IUDs among both the general population and health providers; lack of training for providers; and insufficient commodities or clinical resources for insertion and removal.[56] Insufficient training for family planning providers, low knowledge, and provider bias have similarly been nominated as barriers by the Ministry of Health.[233] These views are reflected in qualitative work with FSWs[38] and support the hypothesis in Chapter 5 of this thesis that supply-side issues are critically impacting IUD uptake. Furthermore, IUDs were historically not supported in Africa, and the early domination of the method mix by injectables precluded the later adoption of less familiar methods (unless they are technologically novel, like implants[234]).[235] The rapid uptake of implants by FSWs over approximately the same period that they increased in the general population reflects the existing demand for longer acting methods among FSWs, and hints at the additional benefit that could be gained from increasing program support for IUDs.

The main disadvantage of the copper IUD is the risk of heavy bleeding[59], which could worsen existing risks of anaemia (Chapter 4). Therefore, the introduction of hormonal IUDs into the Kenyan method mix could be particularly beneficial,[236] with arguably greater benefit for sex workers for whom menstrual bleeding may interfere with work[56] (Chapter 5). A study of

postpartum women in Kenya found that the hormonal IUD was much more popular than the copper method when given the choice, and continuation was high.[237] Nonetheless, copper IUDs are cheap, popular in many countries,[235] and are less likely to cause irregular bleeding than implants,[59] and are a good option for women preferring to avoid hormonal contraception. FSWs in Kenya have voiced concerns about hormonal contraception because of the potential impact on libido.[38]

### *Condom use with non-paying emotional partners*

Less than one third of FSWs who had non-paying emotional partners (described as boyfriends or husbands in this study) were using condoms consistently with these partners at baseline. This is similar to rates in other studies,[2, 41, 107] and reflects the barriers outlined in Chapter 1, in particular the level of control over relationship decisions exerted by men, related intimate partner violence, and the desire of sex workers to demarcate emotional from commercial relationships in which condom use plays a symbolic role. It is disappointing that the WHISPER intervention did not influence this behaviour, given a deliberate attempt was made to illustrate its importance through SMS role model stories, and to address partner-level determinants such as couples' communication and violence. However, these attempts were clearly insufficient to influence an entrenched behaviour largely outside of FSWs' control, and our experience reflects that of other condom promotion studies.[31, 140, 141]

This is an ongoing and critical concern for FSWs which undermines their attempts to prevent STIs and pregnancy, regardless of how well they can adopt these behaviours with clients. It is particularly worrying given high rates of non-paying partner concurrency; 11% in this study reported sex with more than one boyfriend or husband in just the past week (Chapter 5), and their boyfriends are similarly likely to be engaged in relationships with others. Evidence from Kenya, India and Mexico indicates that emotional partners of sex workers have high rates of partner concurrency, with both commercial and non-commercial interactions.[110, 112, 238]

### *Other sexual and reproductive health needs*

In addition to contraceptive needs, the baseline analysis in Chapter 5 highlighted other areas of significant concern for FSWs in Kenya. In particular, violence was very common, with 60% reporting either physical violence or forced sex from any partner in the previous year. Alcohol use was also common and had a direct impact on sexual risk behaviour, with 12% of women reporting having unprotected sex while drunk in the previous week. It was therefore appropriate that content domains of WHISPER included alcohol and violence. The impact of the intervention on these measures is an important subject for future analyses.

### 7.1.3 SMS is a highly feasible and acceptable means of reaching female sex workers

Formative research described in Chapter 3 indicated that WHISPER content and format was acceptable, and that SMS was a feasible (and preferred) means of delivery. FSWs involved in the workshops and interviews were highly engaged, felt that the content reflected the reality of their experiences, and were prompted to spontaneously discuss the content. These findings were confirmed in the RCT. Acceptability was evident in the very low number of withdrawals (only two of whom did not want to receive the messages; the other three had to withdraw for privacy reasons), high rate of engagement with the on-demand system (55%) and frequent reports of sharing and discussing messages. It was also apparent from anecdotal reports from the research team, who received positive feedback from many participants. They were even approached in person by women who wanted to continue receiving messages when they had changed phones or experienced technical errors.

#### *Feasibility of delivering 'push' SMS*

It was feasible to deliver SMS to FSWs and to incorporate the different type of messages into the intervention. The main indicator of this was a high overall receipt of messages, with a median of 127 (out of a total of 137) being sent to each participant. Loss, breakage and theft, or change of phone number, did present a barrier, as has been described elsewhere[167, 239]; this is likely to be a particular issue for itinerant populations and those subject to greater risk of personal crime. However, even the women that changed phone numbers during the trial (11%) received a reasonably high median number of messages (80). Further, the cluster design meant that participants who missed messages could view them on the phones of peers from the same hotspot; it is conceivable that this occurred given the high rate of sharing.

#### *Feasibility of the interactive on-demand menu*

Arguably, the on-demand component of WHISPER was not feasible to operate for all participants. Nearly three-quarters made some attempt to engage but not all did so successfully. Half of all women sent a message consisting of text rather than one of the eligible numeric codes needed to elicit a response. In some cases this was a direct question or comment about the messages, and in others it was an incorrect attempt to retrieve a pull message (for example typing the letter 'O' instead of the number zero). These inputs triggered an error message which explained how to engage successfully and provided emergency contacts (the error message was incorporated as a result of iterative testing during intervention development; Chapter 3). This did seem to work for many women, as 60% of them went on to successfully use the pull system.

However, 19% of the whole sample only ever sent in erroneous text content. This suggests that the pull system required a greater level of SMS literacy than was possible for some women.

### *Technical complications*

There were a number of technical difficulties encountered with the SMS distribution platform which threatened the feasibility of the intervention and need to be considered in future mHealth programs; these are discussed in 7.4.1.

Nonetheless, the feasibility and acceptability data from this RCT support the use of SMS to engage with FSWs generally, and to provide SRH information specifically. While it is not perfect, it remains a critical way to reach this disparate and mobile population, particularly as mobile phones and internet are increasingly used for client solicitation.[6, 8]

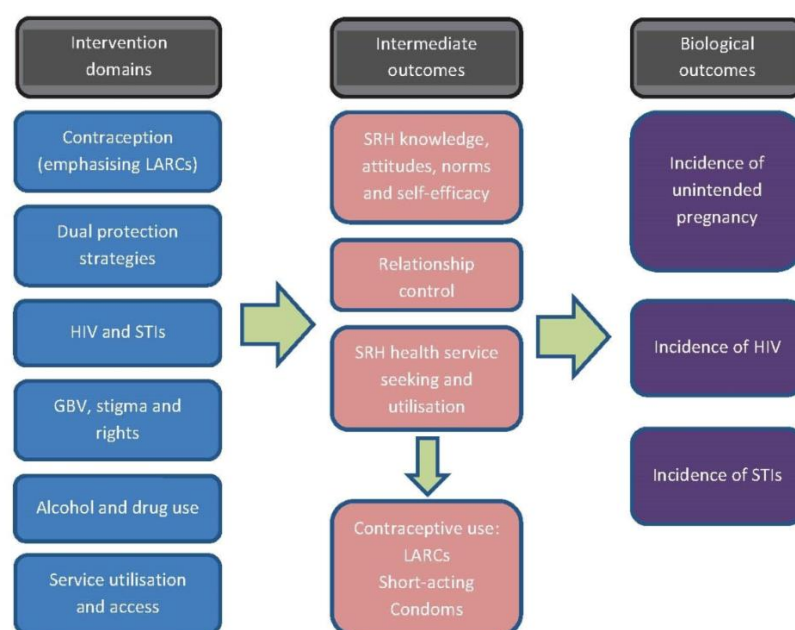
#### **7.1.4 SMS is effective at improving contraceptive knowledge and some behaviours**

Analysis of RCT results (Chapter 6) revealed that the WHISPER intervention resulted in improved contraceptive knowledge. Many SMS interventions with other populations have shown promise in increasing knowledge, including of contraception (Chapter 1), and this study confirms that the same impact is observed with FSWs in Kenya. The magnitude of the change was modest; based on modelled probabilities, the knowledge score increased from 3.9 to 4.5 (out of 6) in the intervention group compared to 4.0-4.3 in the control group. However, the knowledge questions were well answered at baseline and the scale may not have been a particularly sensitive measure for capturing knowledge. It is likely that we would have seen a change of greater magnitude had we used a more discriminating scale. However, few validated scales have been developed for measuring contraceptive knowledge. One has been validated in the USA,[240] but it is very specific to the method-mix and health system in that country and is not applicable to the Kenyan context.

As proposed by the WHISPER program logic (Figure 2) and underlying social cognitive theory, the improvements in knowledge in turn led to behaviour change, with greater improvement in dual method contraceptive use in the intervention group compared to controls. Notably, the behaviours that changed were short-term and largely within the woman's control: condom use with clients and use of shorter-acting non-barrier contraception (injections and pills). This suggests that knowledge, an individual-level determinant, can positively impact individual-level behaviours, but may be limited in impacting behaviours that are subject to strong influences at other social ecological levels, like condom use with non-paying partners and LARC use.

A preliminary assessment of the effect of exposure on secondary outcomes indicates that the effectiveness of WHISPER on both knowledge and dual method use was limited to women who received more than 100 messages, and was not significant for those who received 100 or fewer (not shown). This suggests that a further increase in duration or frequency of exposure may have resulted in greater improvements in these measures.

FSWs' reporting of contraceptive behaviours could have been influenced by social desirability bias. However, this is unlikely as only selected behaviours changed, and not those that were most strongly encouraged by the intervention (i.e. use of LARCs).

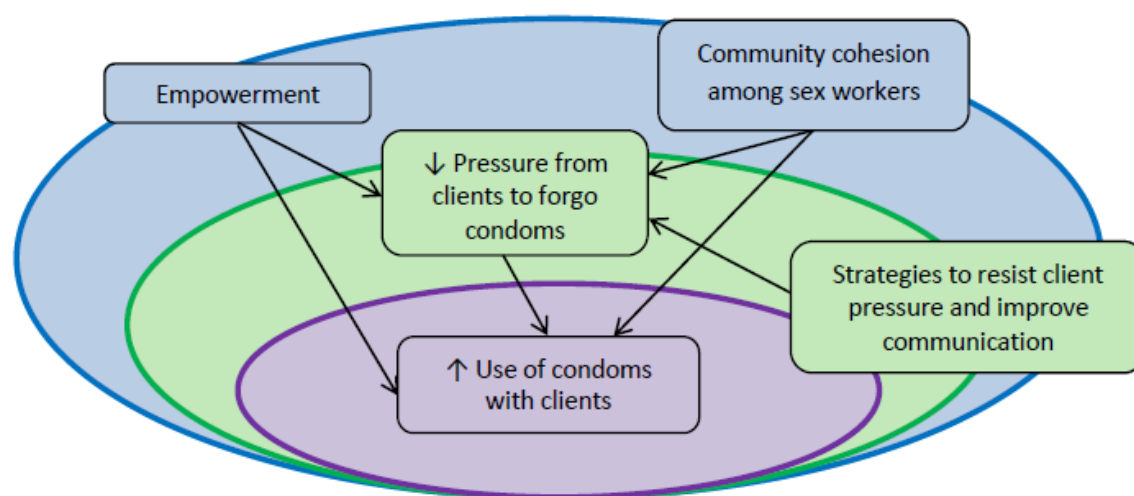


**Figure 2: WHISPER program logic**

It is possible that the intervention had some influence on higher-level determinants in the social ecological model described in Chapter 1 (section 1.5), just not sufficient to alter more resistant behaviours such as condom use with emotional partners and LARC use. At the interpersonal level, clients have significant physical and financial power over the commercial sex interaction, yet there are strategies that FSWs can use to counter this, and the promotion of these strategies in WHISPER messages may have worked to improve condom use with clients. For example, in one role model story the character defuses pressure to forgo condoms by introducing humour into the interaction. Other characters are firm but friendly with their clients and demand payment prior to sex. For more detail, see the full message schedule in the Appendix 1.



Several messages emphasise FSWs' right not to be subject to violence or sexual coercion. Messages about violence and rights played particularly well with women in the formative research phase of WHISPER and seemed to improve their self-efficacy and sense of empowerment (Chapter 3). This qualitative research also found that WHISPER messages triggered a sense of community, and they may well have enhanced community cohesion, operating at the structural level to counter the potentially divisive pressures from clients, partners and the broader community. Figure 3 illustrates how messages targeting different social-ecological strata could have impacted on condom use with clients.



**Figure 3: Social ecological model of health illustrating potential interpersonal-level (green) and structural-level (blue) influences on condom use with clients resulting from WHISPER**

In the next steps for this study, it will be important to examine other intermediate outcomes such as attitudes and self-efficacy, to see if they too were impacted by WHISPER and may have contributed to the observed changes in behaviour. It would also be instructive to analyse outcomes that reflect change on higher socio-ecological levels, such as relationship control and health service utilisation.

#### **7.1.5 WHISPER had no impact on long-acting reversible contraceptive use or unintended pregnancy, suggesting that there are limits to what can be achieved with an SMS health promotion program for female sex workers**

Despite the benefits of the SMS intervention on short-term user-controlled behaviours, there was no impact on LARC use, which was the main behavioural outcome of interest, or in turn on pregnancy incidence, the primary biological outcome. The as-treated analysis showed that receipt of more messages did not alter these results (Chapter 6). A perinatal mHealth

contraceptive intervention conducted in Kenya in 2016 was similarly successful in improving use of effective methods overall, but not LARCs specifically.[241]

While knowledge may impact on the decision to use contraception, the choice of which method to use may be driven more by accessibility of methods, control over their use, and the orientation of health services (in other words, more structural or distal factors). Choosing methods with lower effectiveness because they are easier to access, dramatically limits the potential to lower pregnancy rates (for example, pregnancy is around thirty times more likely among injection users than implant users in one year; Table 1, Chapter 1[55]). The changes in contraceptive behaviour by WHISPER participants were insufficient to modify their risk of unintended pregnancy over one year, not only because these changes consisted of modest uptake of relatively less effective methods, but also because pregnancy was relatively uncommon and conception is a time-critical event that can only be detected after several weeks.

The higher-than-expected implant use at baseline meant fewer women may have been receptive to the messaging about LARCs than predicted, and hence there was less potential for impact on LARC uptake. This raises the question of whether the intervention was effective for women not using LARCs at baseline (590 participants). However, an exploratory sub-analysis revealed that it was not, with no impact on unintended pregnancy in this group (hazard ratio for SRH group 0.88 CI 0.58-1.33;  $p=0.5$ ).

### *Supply-side barriers to long-acting reversible contraceptive access*

As described in Chapter 6, LARC use (like condom use with emotional partners) is more strongly affected by multi-level influences than shorter-term methods. Structural interventions, particularly those impacting on the supply of LARCs and their availability for FSWs, are needed alongside demand generation.

In the case of IUDs, this will necessarily involve addressing many of the barriers that affect IUD coverage in Kenya as a whole (described in 7.1.2), particularly provider bias against IUDs, insufficient provider training, and reliable commodity and equipment supply. For implants, the reasons for lack of uptake may be less obvious, but may include inability of providers to meet increasing demand, stigma towards sex workers, and inaccessibility of existing providers for FSWs. National facility data[65] combined with baseline findings from this study (Chapter 5) suggest that both implants and IUDs are mainly available from public health facilities and occasionally from private facilities. FSWs in our study obtained the more widely-available short-term methods from private suppliers, suggesting they are preferred to public facilities; this is

consistent with other research and may be due to more convenient locations, shorter wait times, and greater perceived quality of private providers.[32, 84, 120, 127]

Very few FSWs obtained any methods apart from male condoms from sex worker drop-in-centres, despite these centres previously being reported as the preferred way to access care,[127] and increasingly attended by FSWs in Mombasa and throughout Kenya, according to national surveys.[27] This suggests that drop-in-centres are not providing family planning services to the extent that is recommended or implied by national policy documents.[211, 228] The research team was informed that all methods were available from the drop-in centres in Mombasa, however later in the study this became less apparent and detailed information was difficult to obtain.

The result is that FSWs are largely restricted to obtaining LARCs through mainstream government services, where they may be subject not only to existing IUD-specific barriers, but also logistical barriers (e.g. long wait times), stigma towards sex workers,[120] and bias against providing LARCs for young or nulliparous women. These structural barriers are sufficient to prevent behaviour change even though WHISPER may have increased demand for LARCs. Unfortunately we did not collect data that would allow us to assess whether demand for LARCs increased, but qualitative research would be useful for determining whether this was indeed the case.

### *Experiences using contraception and the role of counselling*

Adverse effects were very common for all methods of contraception in the WHISPER or SHOUT cohort, reported by up to 90% of participants (Chapter 5). Cessation was also high and mainly as a result of adverse effects, in the order of 34% for implants and 60% for pills, injections and IUDs. Very different results were reported in the recently completed ECHO trial, which compared HIV and pregnancy incidence among women using implants, copper IUDs and injections in three African countries. Discontinuation due to side effects was low (4-9%) for all three study arms.[242] The difference is at least in part due to 3-monthly contraceptive counselling and clinical management of contraceptive side effects in the ECHO trial. A greater emphasis on counselling as a fundamental part of family planning service provision, to manage expectations of known side effects and how these can be addressed, could have significant positive impact on women's experience and contraceptive coverage and continuation.[97, 98, 243] Furthermore, this information could be reinforced with greater frequency by peer educators and digital technologies.

WHISPER messages provide an example of how to deliver this content digitally, particularly the pull menu, which includes detail on the side effects of each method (Appendix 1). However, it was not possible to analyse the extent to which access to such information in digital form was able to allay women's concerns or improve continuation. Most likely, personal contact is important in relaying this clinical information,[149, 150] at least at the outset. Digital information on side effects may be better provided in push form (to cover those women who were less able to access on-demand content) but tailored to the woman's method and circumstances, as was done by Harrington et al for postpartum women and couples in Kenya.[241]

Another approach that has been used to complement health provider counselling in the USA is mobile applications providing contraceptive information for women in family planning clinic waiting rooms. Sridhar et al[184] found that knowledge of contraception, and selection of LARCs, was the same among those who used an mHealth waiting room application compared to those who had a one-on-one health educator session prior to their physician appointment. A similar application was effective in improving knowledge of LARCs and intention to use them 3 months after the consultation, but did not impact LARC uptake.[183] While these were non-representative samples of women already seeking contraception, and not replicable in an LMIC context, the results suggests that mHealth alongside or in conjunction with face-to-face counselling could be an efficient way to provide sufficiently detailed information for FSWs to make informed and longer lasting choices.

### *Implications for mHealth interventions to increase long-acting reversible contraceptive use*

Digital interventions have been widely used to generate demand for health commodities and services, but are often implemented without measuring their health impacts.[153, 168] WHISPER or SHOUT remains a rare example of a rigorously conducted RCT that evaluates the impact of a digital intervention on stimulating demand for contraception in a low-income context. Given the modest results for short-acting methods and the lack of evidence for impact on LARCs and unintended pregnancy (despite high engagement with the intervention), this trial questions the rationale for mobile phone health promotion interventions conducted in isolation.

The literature review in Chapter 1 outlined aspects of previous mHealth interventions that have made them effective at modifying SRH behaviours: intensive frequency or duration of messaging, bidirectional modality, tailoring to personal characteristics, theoretical basis and participatory intervention development, illustrated by studies in Kenya,[176] Malawi[177] and the USA,[170] for example. There are a few exceptions of simpler interventions being effective, but these have taken place in high income countries with strong health service infrastructure,

and impacts have still been limited; for example, a short unidirectional SMS intervention in Australia impacted sexual health seeking, but not condom use, among young Australian women.[189] We made a concerted effort in intervention development to incorporate as many of the effective components listed above as possible into WHISPER. However, this was still insufficient to modify LARC behaviours. The only mHealth intervention identified that has been successful at improving LARC use was implemented with women post-abortion in Cambodia, and combined voice messaging with phone counselling and expedited links to LARC insertion services.[172] In other words, compared to WHISPER, it involved in-depth personal interaction and a supply-side initiative to improve access.

The combination of these findings indicates that any future mHealth interventions to increase LARC use among FSWs should:

1. Continue to utilise the more effective mHealth approaches that are already features of WHISPER, such as bidirectional messaging, longer duration and intensity, theoretical basis and participatory development;
2. Incorporate interaction with a real person, either via phone-based counselling or by stronger linkages to face-to face counselling; and
3. Be combined with other pregnancy prevention approaches that address both demand- and supply-side barriers.

The benefits of integrating mHealth with other prevention approaches will be greater for populations like FSWs that face entrenched supply-side and demand-side barriers to contraceptive use. Recommended models for a combined prevention approach are discussed below (7.5.3 and 7.5.4).

## 7.2 Methodological implications of measuring unintended pregnancy incidence

### 7.2.1 Measurement of pregnancy incidence

The primary outcome measure of the WHISPER trial required measurement of both pregnancy incidence and pregnancy intention. Pregnancy was defined by a combination of urine pregnancy testing and self-reporting of pregnancies that had occurred in the last six months. While self-reporting may underestimate pregnancy,[244] we only had the resources for 6-monthly urine tests, so chose to supplement these with self-reporting to detect interim miscarriages and

abortions. This also allowed women who attended their 12-month, but not 6-month, visit, to report pregnancies that had not been captured at six months; there were nine women in this category. Moreover, frequent urine testing may overestimate incidence by detecting early subclinical pregnancies,[245] so our combined outcome is likely to be a reasonable method of estimating the population incidence.

One finding from the systematic review was that duration of study can influence the calculated incidence rate. In the meta-analysis, higher incidence was observed in studies of shorter duration, most likely because the women at highest risk of pregnancy fall pregnant early, and are then censored (removed from subsequent analyses), leaving a progressively lower risk group over time. This was the case in our study, although the effect was not particularly pronounced; an exploratory analysis revealed that the full cohort had an incidence of 16.3/100 person-years in the first six months, compared to 15.1 over the full 12 months.

### 7.2.2 Measurement of pregnancy intention

As discussed in the introduction to this thesis and the systematic review (Chapters 1 and 2), the intention to conceive is complex and subject to a woman's emotional, physical and financial readiness, as well as considerations of her partners' and families' expectations and desires. Contrary to implications of the categories 'planned/unplanned', 'intended/unintended' and 'wanted/unwanted', intentions can rarely be neatly categorised as positive or negative, and are often ambivalent or fluctuating.[21, 246] For FSWs, the presence of both paying and non-paying sex partners, the need for greater emotional and financial support which may be secured from the father of one's child, and contradictory stigmas against both motherhood and childlessness, further complicate this decision.[17, 38, 76, 108] The systematic review presented in Chapter 2 demonstrated that few studies of FSWs ask about their pregnancy intentions.

The field of research dedicated to measuring pregnancy intention is still relatively new. Most studies measure intention with a single retrospective survey question about whether the current or most recent pregnancy was wanted, derived from the Demographic and Health Surveys.[22] Women are more likely to retrospectively report their pregnancy as 'unplanned' than 'unwanted'[247], perhaps to rationalise regret or mixed feelings after becoming pregnant and giving birth. Asking about pregnancy intention prospectively may be less subject to bias and rationalisation,[247, 248] however this fails to acknowledge the fact that many women who unexpectedly become pregnant are genuinely happy with the event.[21] More nuanced measures of intention have been developed, for example the London Measure of Unplanned Pregnancy (LMUP), a scale that considers a woman's desires, use of contraception, communication with her partner and practical steps taken to prepare for pregnancy. The LMUP

was developed in a high-income setting,[249] but has been validated for use in India[250] and Malawi.[22] It had not been used with FSWs prior to the WHISPER or SHOUT study, but has since been used with FSWs in Uganda.[81]

We collected two forms of data on pregnancy intention: a prospective question asked at each time point for all non-pregnant women, and an adaptation of the LMUP asked for each reported pregnancy (Appendix 2). The LMUP was chosen to measure the primary outcome because it was considered to have greater internal validity, the data was more complete, and the prospective measure could have been asked up to five months before conception. Nonetheless, some of the sensitivity of the LMUP is likely to have been lost because a dichotomous measure was needed to classify intended and unintended pregnancies. This necessitated the use of an arbitrary cut-off point (between a score of nine and 10 out of 12) according to the advice of the developers of the LMUP (email communication with G. Barrett, October 2018).[251]

Fewer pregnancies were classified as unintended by the LMUP (84%) compared to the prospective measure (95% reported as unintended or fluctuation intentions). Future analyses could investigate the circumstances under which FSWs' intentions differed by the two measures, for example they may have been less discrepant if the prospective data was collected around the time of conception.

## 7.3 Strengths and limitations

### 7.3.1 Strengths of the study design

The key strengths of this research lie in the methods used to both design and evaluate the WHISPER intervention. As the first RCT to test an mHealth intervention with FSWs, and one of only two RCTs identified that has measured the impact of a contraceptive intervention for FSWs on pregnancy rates,[74] it is uniquely placed to provide insight into: the feasibility of using SMS with this population; the extent to which SMS can be effective at changing behaviour and biological outcomes; and the facilitators and barriers for reducing unintended pregnancy risk among FSWs. The protocol for this study was published (Chapter 4) to ensure transparency of reporting and to allow other researchers to replicate these methods or modify them as appropriate.



### *Random sampling*

The sampling strategy, in which sex work venues were randomly selected from a known sampling frame, was an innovative way of obtaining a representative sample of FSWs, which is notoriously difficult in hard-to-reach and mobile populations. As one of the few cluster-random samples of FSWs, prevalence estimates from the study at baseline are likely to be more representative of the FSW population than previous estimates, and will be useful for guiding programs, policies and service provision for FSWs in Kenya.

### *Clustering*

Cluster rather than individual randomisation has been recommended for conducting intervention studies with FSWs, to account for inevitable peer-to-peer interaction within sex work venues.[31] In our study, the random allocation of venues to either the WHISPER or SHOUT arm was effective in minimising contamination between the two groups, and facilitated social diffusion because women at each hotspot shared and discussed the same message content. While FSWs may have unstable housing arrangements[252] and need to travel frequently, their relative attachment to specific venues in Mombasa where they solicit and meet clients facilitated this methodology. This is a good model for other populations of sex workers that are predominantly venue-based, but would not be feasible where sex workers move more flexibly between sites or work predominantly from home.

### *Parallel interventions*

The use of two parallel mHealth interventions essentially allowed two RCTs to be conducted simultaneously; the impact of the SHOUT intervention on nutrition outcomes will be analysed in the near future. This represented an efficient way of assessing two priority health areas within this population that are both understudied. Utilising a parallel intervention is an ideal way of minimising the retention bias that can occur in mHealth trials when the control arm receives either no messages or fewer messages with non-consequential content. In our case, measures of engagement and acceptability (for example, use of pull messages) were equal across the two arms, indicating that WHISPER and SHOUT were equally interesting and relevant to participants, making the SHOUT arm an ideal comparator for WHISPER. A similar approach was used in Australia to compare sexual health and sun safety behaviours[192].

The challenge of this method is identifying health topics that are unrelated but of equal importance to the population of interest. SRH and nutrition are largely mutually exclusive, but there are some areas of potential overlap, in particular alcohol use. To minimise the risk of both



interventions influencing alcohol use, we chose to limit alcohol messaging to the WHISPER arm, because alcohol intake is a known strong determinant of sexual risk in this population.[91] Nonetheless, the high engagement in both trial arms (as well as anecdotal reports from field staff) confirmed that nutrition is as interesting to FSWs as SRH; had we chosen a comparison topic with less relevance, we would have risked differential attrition in the two arms.

### *Participatory design*

A key reason for the high acceptability of both WHISPER and SHOUT is the use of participatory research methods to design both interventions. In the case of WHISPER, qualitative research confirmed the relevance of the content, the feasibility of using different types of SMS messaging, and the resonance of behavioural strategies adopted from combining social cognitive and transtheoretical health promotion theories.[195] FSWs were instrumental in constructing role model stories, adding tone, colour and appropriate language to the messages, and modifying elements that were confusing, unrealistic or potentially risky.

#### **7.3.2 Strengths of the research team and utilisation of local networks**

Both the formative stage of this research and the trial itself capitalised on existing collaborations between the international research teams and local partners in Kenya, and utilised existing peer networks of sex workers. The study was implemented by the International Centre for Reproductive Health Kenya, a non-government organisation that manages a large peer education network and three drop-in-centres in Mombasa (expanded from two centres during the trial). Their relationship with sex worker peer networks enabled them to recruit two experienced community mobilisers to coordinate the recruitment and tracing of participants and manage other peer educators to do this. This was an onerous task which could not have been completed without the dedication of these two women, who remained with the project from the early design phase until the completion of the RCT, and were critical to facilitating data collection and ensuring clear communication between the study population and the research team.

The trust that was established among the sex worker community, a community that understandably feels some resistance to being involved in research that will not necessarily translate to positive change, was largely due to the established relationships and respect for the community mobilisers. The non-judgmental and respectful demeanour of the research staff, including one researcher who had past experience in sex work, also improved participant trust and confidence, which was important for minimising social desirability bias and improving internal validity.[253]

Capacity building for both peer educators and other local staff was an important part of the implementation of this project. The local research staff had not worked on an RCT previously and this provided an opportunity for them to expand their knowledge of research methods and epidemiology. I lived in Mombasa for five months to coordinate the initiation of the RCT and this provided an important opportunity to mentor and assist research staff in gaining new skills. While there was some staff turnover, there were several core members of the team who remained throughout, quickly developed many new competencies, and showed exceptional dedication to the project despite sometimes difficult working conditions and long hours.

### 7.3.3 Strengths of statistical methods

The statistical models for analysing outcomes were selected to allow inclusion of as much available data as possible, for example including more than one pregnancy per woman in the primary analysis and including secondary outcome data from all time points. This ensured a precise comparison of groups and minimised the risk of missing patterns in the data.

While the primary analysis measured instances of pregnancy within discrete time periods, the model was offset for the duration between participant interviews, in effect making the duration of these time periods flexible to account for late episodes of data collection for some participants. This was a useful tool for correcting for the inevitable logistical challenges of a mobile population attending at timely intervals despite multiple conflicting demands, particularly when external events like flooding intervened.

Multilevel modelling of secondary outcomes was important for identifying a difference in the *change* in each outcome over time between the two groups, allowing adjustment for small baseline differences between the groups and inclusion of all follow-up data. For example, contraceptive knowledge and dual method use were higher in the control group at baseline, and the models accounted for this disparity, employing data from all time points to determine overall trends. Were we to examine only the relative risk of dual method use at each time point, we could not have detected this overall pattern.

### 7.3.4 Limitations

#### *Power and sample size*

Fewer unintended pregnancies occurred in the study than expected, hence the event rate in the discrete time analysis was lower than in the sample size calculation, resulting in an increase of the standard error and widening of the confidence interval around the final estimate. In other words, the study had less power than intended to detect the pre-determined difference in

unintended pregnancy incidence of 37% between the two groups. As described in Chapter 6, the observed confidence interval (0.69-1.39) excludes a hazard ratio of 0.63, so we can be reasonably confident that the intervention is not effective at reducing incidence in the population by 37%, but it is possible that it would produce a smaller but nonetheless meaningful reduction. However, given the lack of signal for any intervention effect on the primary outcome (the point estimate was very close to one (hazard ratio 0.98) and there were no signs of an effect at different levels of exposure), it is highly unlikely that increasing the sample size would have resulted in the existing intervention having a significant result.

### *Timing of outcome measurement*

Measurement of outcomes commenced even before the first messages were sent (as we had to provide up to two weeks for all participants from a cluster to enrol before commencing their messages) and ceased at the same time as the messages. Some participants may have transitioned from contemplation to action later in the intervention period, with subsequent impact on biological outcomes not occurring until after the end of data collection. Extending follow-up to six or 12 months later would have detected such cases and may have provided evidence of greater impact.

### *Incidence calculation and methods for analysing the primary outcome*

We reported unintended pregnancy incidence, per 100 person-years, for each trial arm, with exposure time for pregnant women defined as time to last menstrual period. We asked pregnant women to estimate their gestation, but did not do so for self-reported interim pregnancies that had ended in abortion or miscarriage. These data had to be imputed for 29% of women who had an unintended pregnancy, resulting in uncertainty around the incidence rate estimates.

In retrospect, a better approach would have been to ensure that gestation data was collected for all pregnancies, and used not only for descriptive incidence calculation but also for the primary analysis. Using metric (continuous) time to compare 'survival' (i.e. duration of time to pregnancy) between the two groups, would have allowed for a more precise measure of incidence and more intuitive comparison between arms than the discrete-time model used, and is consistent with the approach taken by most studies to calculate incidence (for example, those in the systematic review). Instead, we used the pre-specified discrete-time model, to accommodate data collected at discrete intervals (i.e. every 6 months). Regardless, adopting a traditional metric time approach would not have altered the final results as rates were so similar between the two arms.

### *Potential attrition bias*

There was some indication of selective loss to follow up of pregnant women in the WHISPER or SHOUT study, which would have underestimated incidence if on a sufficient scale. A similar issue was identified in other pregnancy studies in the systematic review (Chapter 2). In two known cases this resulted from changed life circumstances (such as moving back to the family home), which would be expected to occur in any study of pregnancy and would not have differed between the study arms. However, the community mobilisers were able to establish three cases of women not wanting to return because of a mistaken belief that they could not continue the SMS program if they were pregnant, and we could not ascertain whether this was a widespread belief among participants. If so, it may well have affected those in the intervention group more than the control group, and could have biased the effectiveness analysis because of an underestimate of pregnancy in the intervention group. It also represents a possible ethical issue, as the consent process may not have sufficiently emphasised the participant's right to remain in the study (or leave it if desired), regardless of circumstance. We introduced a new process for reinforcing this aspect of consent at the 6-month visit, after the issue was identified.

### *Representativeness*

While the sample was randomly selected, it was not wholly representative of FSWs nationally because eligibility was restricted to ages 16-34 years. The mean (weighted) age in this study was 25, compared to the national mean of 29[27]. We may have missed some important dynamics of risk among young adolescent or older FSWs, however they would likely have constituted a small proportion of the study, as only 8% of those interested in taking part in the study were excluded due to age (Chapter 5).

The sample may not have been representative in terms of education and literacy, because eligibility was restricted to those who self-reported being able to read SMS (discussed in Chapter 6). Six percent of women who were screened were found not to be SMS literate. Some women may also have self-excluded on the basis of illiteracy before being screened, but we have no way of confirming this. In addition, 20% of women did report some difficulty with the English SMS format, which may have limited the effectiveness of the intervention for these women.

As noted in 7.3.1, venue-based sampling meant that the study sample did not represent FSWs who practice from their own homes or independently from locations that are not recognised sex work sites. While our sampling approach is reasonable in a predominantly site-based sex work culture like Mombasa, it would miss many FSWs in locations with less structured location-based

work. Time-location cluster sampling has been used in India[254] and Canada[15], where a large proportion of FSWs work outside, to capture the main clusters associated with time as well as location; in our case the sampling was limited to location only.

External validity was also limited in terms of lessons that can be drawn for FSWs in other countries. While there are similarities in sex work practice and SRH needs in most LMICs, as described in Chapter 1, cultural and behavioural differences and different family planning service contexts may impact the generalisability of the results. For example, in many countries outside of Africa, drug use is a large contributor to health risk among FSWs,[26, 255, 256] and would need to be considered in developing mHealth content. Similarly, the misconceptions about IUDs which were targeted by WHISPER would be less relevant in a country in which IUD use is common, such as Mexico[86] or China[257]. The WHISPER intervention used language and tone that appealed to FSWs living on the Kenyan coast; similar qualitative work and pilot testing would be needed if it were adapted to other locations, even elsewhere in Kenya or East Africa.

#### *Lack of corroborative data on health services and long-acting reversible contraceptive access*

Unfortunately, the research team was unable to obtain service data from local health services or sex-worker drop in centres relating to supply of contraceptive methods. This would have provided more insight into whether LARC use did not improve because of problems with the supply of implants and IUDs and their accessibility to FSWs, or because WHISPER was not able to stimulate sufficient demand.

The lack of relevant data on health services and LARC access also affected the interpretation of the cross-sectional analysis in Chapter 5. The published paper speculated that structural determinants may not have been as important as individual factors in influencing LARC use, however in light of subsequent trial findings this is probably not true. In reality, the lack of relevant data precluded the ability to analyse this relationship. The proxy measures for structural and interpersonal factors used in the cross-sectional analysis (sex-work stigma, presence of boyfriend, experience of violence) were insufficient to capture the extent of the impacts that the social and health service environment had on LARC use. Data from the questionnaire on experiences attending a health centre to obtain contraception may have shed light on this but could not be used in the multivariable analysis because one quarter of women had never obtained family planning at a health centre. Interestingly, subsequent bivariate analysis of this data (not shown) revealed that disclosure of sex work status to a health care worker was associated with obtaining all desired information about contraception, which was

in turn associated with more positive treatment experiences. These service-level dynamics require further exploration.

### *Realism of role-model stories depicting contraceptive access*

It is important that any health promotion intervention represents realistic (but also optimistic) scenarios for the target audience. This was one of the key reasons for taking a participatory design approach to the development of WHISPER, and testing messages in formative research with FSWs. However, it may not have been realistic for FSWs to access IUDs and implants in the way the role model stories described, because they may have been overly optimistic about health service and other structural barriers. This could have eroded trustworthiness in the intervention that could potentially have implications for how women responded to other topics. Qualitative research with participants would need to be conducted to determine whether this was the case.

## 7.4 Implementation challenges

### 7.4.1 Using mHealth in public health and research settings

We encountered a number of challenges implementing the WHISPER and SHOUT interventions which are likely to be common to other mHealth interventions. These largely stem from the fact that private enterprises have conflicting priorities to public health practitioners and researchers.[258] Mobile network providers have systems in place for commercial purposes that may create barriers to public health messaging. For example, use of the WHISPER on-demand menu triggered an automatic warning for many users indicating that they may be charged (despite all SMS costs being covered by the project). This deterred participants from replying to WHISPER messages during pilot testing. A similar issue was encountered by Chernick et al in the USA.[181] The network provider was not amenable to finding a technical solution to this issue, so we addressed it by enrolling participants in person in order for research assistants to deactivate the warning and provide reassurance. This direct personal involvement negates one of the benefits of mHealth – that participants can be enrolled remotely – and would be a particular issue with on-demand programs delivered at scale.

The SMS online platform provider, Viamo, was similarly orientated towards broadcasting campaigns rather delivering and monitoring public health programs. For example, there was a lack of understanding of the need for standardised SMS content delivery and for consistent and

detailed data, which has been encountered by other mHealth researchers partnering with private organisations.[258] Incorrect assumptions were made about the type of phone usage data that would be required by the researchers. Data anomalies were frequent and constant monitoring was required to detect and address these. For example, data extraction parameters changed between reports, and the status of messages changed without explanation so that it was difficult to know which reports were valid and to calculate correct totals. Issues with unreliable data were ongoing and could not be resolved with one of the two mobile network providers, and this meant that 11% of participants had to be excluded from the per-protocol analysis of the primary outcome.

While our RCT had the resources to monitor incoming data and follow up participants with frequent call failures, this would not be feasible in an mHealth program delivered at scale. These issues need to be considered in the design and conduct of mHealth programs, particularly those undergoing rigorous evaluation. Use of open source online platforms (for example, Verboice <https://verboice.instedd.org/>) or those with experience in research projects may be preferable to those with more of a focus on broad marketing campaigns. Finally, intervention delivery and trial retention can be impacted by mobile phone breakage, theft or loss (described in 7.1.3). These losses could be estimated based on data from studies like WHISPER and factored into sample size calculations in future trials.

#### 7.4.2 Environmental and political disturbances

The WHISPER or SHOUT study encountered several external events that delayed or interrupted study conduct, that are more frequent in LMICs than HICs and particularly affect vulnerable and mobile populations like FSWs. Mombasa experienced severe flooding in May 2017, causing damage to the Kisauni study clinic and paper study records, and prolonging recruitment by six weeks. The presidential election in August 2017 also created disturbances. The study clinics were closed during the election week, and in the preceding weeks many participants chose to minimise travel or leave Mombasa to avoid civil disturbance and potential violence. Aspects of our study design minimised the impact of these events on the primary outcome. For example, we adjusted for time of clinic visit in the survival model, so that participants who had to postpone their follow-up visit were still included in the primary analysis. Similarly, we introduced questions at 12 months that allowed us to collect data on pregnancy during the whole year for women who missed their 6-month appointment. It is important for research projects in similar contexts to acknowledge that such challenges are likely to occur, and to have the flexibility to be able to manage them.



### 7.4.3 Implementing research projects with key population peer educators

Peer educators for key populations at risk of HIV, including FSWs, tend to be volunteers with minimal financial or in-kind compensation, and have clearly defined health promotion roles embedded in HIV prevention programs. Understandably, they are rarely familiar with research, particularly the stringent requirements of randomised controlled trials. Utilising peer educators in a large RCT can be challenging, because of their lack of research training and orientation, as well as confusion regarding their dual and sometimes conflicting role as both community advocate and detached observer. Peer educators engaged with WHISPER or SHOUT experienced some of this role confusion early in the study, and the training required frequent emphasis on the importance of study procedures, the need for objectivity and the necessity of communicating any protocol deviations to the study coordinator.

The two lead community mobilisers were employed full time and six other peer educators were given a small monthly honorarium equivalent to that provided by a national HIV prevention program, LINKAGES,[259] with which they had previously been involved. The original intention had been for high-performing LINKAGES peer educators to continue in their role while taking on additional WHISPER or SHOUT duties, however there were disagreements about how this arrangement should be remunerated, and how to separate the program and research activities they conducted with their peers. It was regrettable that these issues could not be resolved, as this model would have allowed for capacity building and additional income for motivated peer educators (as was the case for the two senior community mobilisers), and strengthened links between existing HIV prevention programs and WHISPER or SHOUT. In retrospect, the peer educator appointments could have been better planned in collaboration with LINKAGES project staff, and early training could have better clarified the expectations of conducting research in this context.

This experience holds important lessons for other research projects taking place in the context of existing programs for key populations. It is important that human resource requirements are clearly mapped, options for engagement of peer educators decided by both research staff and programmers at the outset, and potential conflicts or confusion of roles anticipated and resolved before engaging peer educators. Models of remuneration for research staff have been found to influence whether research with FSWs is conducted ethically.[253] The model of engaging full time community mobilisers, who were themselves peer educators, was a successful one and could be adapted to other contexts. The demands of recruitment, participant tracing and engagement in a large RCT are significant, and having two experienced and committed members of the local sex worker community to take on this role and supervise the



other peer educators, was critical to the success of the study and mitigated against the problems described here.

## 7.5 Recommendations

### 7.5.1 Knowledge gaps and future research directions

This thesis has highlighted a number of outstanding knowledge gaps requiring further research. The systematic review revealed that very few studies have been conducted on the risks, incidence and correlates of unintended pregnancy among FSWs, and even fewer on interventions to reduce pregnancy incidence – only one was identified prior to our study.[74] More cohort and intervention studies are required that measure incidence over time and adopt nuanced measures of pregnancy intention, such as the LMUP, so that this important issue can be better understood and effective interventions identified.

Qualitative research is urgently needed to explore a number of outstanding research questions arising from this thesis, in particular how the WHISPER messages were received by participants and why they did not translate to behaviour change relating to LARCs. More broadly, interviews with FSWs outside of this study could improve our understanding of the persistent barriers they face to commencing and continuing LARCs. Attitudes to IUDs in particular need to be investigated, among not only FSWs but also other women in Kenya, to determine the extent to which low uptake is a result of service-level factors or low demand. If the latter, further research should explore the influence that misconceptions about IUDs continue to have on women's perceptions and decision-making.

The potential impact of enduring misconceptions about IUD use and eligibility among health providers also needs to be investigated, along with other service-level barriers such as resource availability and skill development.[130, 131] This could inform service-level efforts to improve clinician knowledge, expertise and skills, and address sex-worker and age-related biases.

Additional quantitative analyses of the WHISPER or SHOUT data would provide further insight into the influence of the messages. Secondary outcomes in addition to those presented in Chapter 6 should be analysed to determine the extent to which the intervention influenced individual factors (such as attitudes and self-efficacy for contraceptive use) and interpersonal factors (including relationship control with emotional partners and intimate partner violence). It would be useful to understand how these factors operated as mediators to contraceptive use. The impact on violence in particular is also critical to understand in its own right, as this is a

major problem for FSWs for which effective interventions are desperately needed. Given the small yet positive effect of WHISPER on condom use with clients, it would also be valuable to determine whether this in turn reduced sexually transmitted infection transmission or HIV incidence.

Finally, because it is more representative than most studies with FSWs, the WHISPER or SHOUT sample has utility for estimating SRH indicators among the FSW population in Kenya. Chapter 5 presented the results of prevalence estimates at baseline for contraceptive use, HIV, and intimate partner violence, among others. Future analyses could look at incidence of abortion, for example, and correlates of incident unintended pregnancy, abortion, and uptake of LARCs. Despite the limitations with using data from an intervention study for longitudinal descriptive analyses, the WHISPER or SHOUT study currently represents one of the best datasets for assessing these questions among FSWs in Kenya, and indeed East Africa.

### 7.5.2 The results of this trial point to the need for multi-level combination prevention models to impact unintended pregnancy among female sex workers

The modest impacts on knowledge and behaviour in this trial do not support immediate scale-up of the WHISPER intervention for FSWs. However, the trial has demonstrated that SMS can stimulate demand for (shorter-acting) contraception among FSWs, and SMS programs like WHISPER could play an important role *in combination* with other demand- and supply- side initiatives that influence multiple social ecological levels in parallel.

As outlined in Chapter 1, there is little other direct evidence for what works to reduce unintended pregnancies among FSWs. Nonetheless, a comprehensive pregnancy prevention model could be developed and tested, based on the following key findings from this thesis and existing evidence:

1. Multi-component behavioural interventions, including those delivered by mobile phone, are effective at improving knowledge and increasing **demand** for (short-acting) contraception among FSWs, as well as in other populations;
2. **Supply**-side interventions such as training of providers, LARC-focused counselling and commodity support are effective in improving the supply of LARCs and their uptake, although they have not been tested with FSWs;
3. Consistent condom use by FSWs is lower with emotional non-paying sex partners than clients, and emotional partners present barriers to FSWs' use of other contraceptive methods;

4. Rates of sexual and gender-based violence against FSWs are unacceptably high across countries and contexts;
5. A combination prevention approach, with a strong basis in structural change and FSW empowerment, is most effective at reducing FSWs' risk of HIV and other STIs.

Improving demand for and supply of contraception, engaging with non-paying male partners, and addressing structural determinants of unintended pregnancy (particularly violence) would therefore all be important components of a comprehensive prevention program for FSWs. Each of these is described in more detail below. A new model for pregnancy prevention is then proposed which would be based on combination prevention programs for HIV and incorporated into existing HIV and STI prevention infrastructure.

### 7.5.3 Components of comprehensive pregnancy prevention for female sex workers

#### *Increasing demand for contraception*

As described in Chapter 1, behavioural interventions to stimulate demand are more effective when they consist of multiple reinforcing components. WHISPER was developed with this principle in mind, incorporating bidirectional messaging, different styles of messages and a combination of cognitive techniques (for example educational messaging and role modelling). A more effective and sustainable approach would integrate WHISPER or a similar SMS intervention into other evidence-based behavioural interventions, such as interpersonal communications interventions. There is good evidence for community-based counselling and motivational interviewing, particularly when these are tailored to recipients' needs and aim to improve practical skills,[148-151] and mobile phone messages could be delivered to reinforce these interventions and increase exposure to the content.

Combining digital messaging with access to a real support person (i.e. peer educator or clinician) could have greater impact and allow for better tailoring of messaging (also discussed in 7.1.5). It would also meet the expectations of FSWs reflected in both the formative research for this study, in which participants often assumed they would be interacting with real people, and the trial itself, in which many women sent in text questions that could not be answered by the automated on-demand system. A combination of automated voice messages and phone counselling with a real counsellor was effective at improving LARC use after abortion among Cambodian women.[172] Another combined digital/in-person intervention is currently being trialled in Cambodia, in which female entertainment workers are linked to outreach workers and contraceptive counselling if they raise any questions or concerns.[260]

Peer educators could play a critical role in stimulating and maintaining demand for contraception and linking to clinical counselling, as part of the model proposed in 7.5.4. Community health volunteers could play a similar role, for example by sharing responsibilities with peer educators or taking community referrals from them. This cadre of workers have been integral to larger scale family planning programs in Kenya, with positive results,[261], provided they are given sufficient training and compensation.[262]

English SMS was the most popular medium for being contacted in our study population,[263], but may have created a literacy barrier for some women. Offering FSWs a choice of either SMS or interactive voice response messages would make future mHealth interventions more equitable, particularly considering associations noted between educational level and contraceptive use.[72]

Were WHISPER to be implemented at scale as part of a broader pregnancy prevention program (as described in 7.5.3 and 7.5.4), consideration would be needed as to translating the feasibility findings from an RCT to program context. The research team was able to institute a number of strategies that helped ensure a high receipt of messages in the trial, including actively tracing women who were lost to follow up, checking phone numbers at follow up visits, and investigating participants with high call failure rates based on phone network data. Some of these monitoring functions could be adapted to a program context, particularly if such a program used existing HIV peer education models for contraceptive promotion, but would necessarily be less rigorous than in an RCT and may result in higher attrition.

#### *Increasing supply of long-acting reversible contraception and other effective methods*

Multi-component demand-side programming should be accompanied by interventions to increase supply of contraception to FSWs, particularly LARCs. When demand creation is not matched by an equivalent increase in commodities and provider capacity, clients become frustrated and the success of the overall program is undermined. This has been identified as a problem in the national family planning program in Kenya,[233] and would also apply to the FSW population which arguably has greater latent demand than the general population. Evidence from HIV prevention with FSWs indicates that only when condom need is met with adequate supplies can programs determine other reasons for inconsistent use[264]; the same principle should apply to other contraceptive commodities.

Supply-side programming would be of greatest benefit to FSWs if it was incorporated into existing HIV prevention infrastructure and catered specifically to FSWs; this is discussed further

in 7.5.4. However, improved family planning programming for the general population would also increase FSWs' access to contraception and would be ideally implemented in parallel.

A number of challenges identified by the Kenyan Ministry of Health have impacted on successful delivery of family planning at the national level, such as commodity security and lack of sufficiently trained providers.[224] Addressing these to improve services for the general population, and linking FSW communities to these services through sensitisation or referral pathways, is an important strategy for improving FSWs' access. The fact that trends in use of both IUD and implants by FSWs have mirrored those in the general population suggests that improvements in family planning services generally would benefit FSWs. This is particularly important for IUDs, where supply-related issues on the national level appear to be impacting access for FSWs.

Improving method mix at national and local levels is important to increase access to IUDs in particular, and contraceptive uptake in general,[128] and allows for more stable provision of contraception in the case of price or availability fluctuation of specific methods.[218] While three-quarters of health facilities in Kenya offer at least five modern methods, this indicator has not improved over time.[65, 66] As described in Chapter 1, fewer facilities stock IUDs than other methods (66% of public facilities compared to 80% for injections and implants) and there are large discrepancies between public and private facilities. Supply chain strengthening is needed for IUDs in particular. Introducing subsidised hormonal IUDs to the available method mix could be particularly beneficial for FSWs (described in 7.1.2). While cost has been a barrier to doing this, newer products are becoming available that have equivalent or lower cost per couple-years of protection than other fully subsidised methods.[56] Emerging technologies, such as the dual-purpose vaginal ring for prevention of both pregnancy and HIV,[265] could hold promise for FSWs. However, such technologies are in the early stages of development, and structural changes to family planning infrastructure are nonetheless required that allow new products like these to be easily integrated in the future.

Training and supervision of family planning providers, ideally alongside other facility-strengthening measures, could have a substantial impact on supply, access and uptake. Cluster-randomised trials in the USA and Australia have found that training either family physicians or specialist providers in structured contraceptive counselling results in improvements in LARC use[266] and pregnancy incidence,[267] even though participants covered any clinical costs incurred. In the US study, the intervention included training for insertion and removal of LARCs, while in the Australian study, not all practitioners were trained to provide LARCs, but utilised a

rapid online referral pathway, which the authors hypothesised was an important reason for the high uptake of hormonal IUDs.[266]

Similar findings were reported in a study in Burkina Faso, where LARC use doubled after provision of both intensive provider training and free LARC commodities and equipment in primary care centres.[96] Other programs have been implemented in LMICs targeting provider training and capacity alongside other demand- and supply-side activities, but weaknesses in evaluation design[268] or reliance on program monitoring data alone[234, 269, 270] prevent an accurate assessment of their impact. For example, a health systems strengthening approach in Central Africa, which included provider training and support, supply chain security and demand generation, coincided with a dramatic rise in implants and subsequently IUDs, but no formal pre-post or control comparison was undertaken.[234, 271]

Quality family planning counselling, which is a key component of the studies described here, is likely to be critical to the effectiveness of supply-side interventions, as shown in 7.1.5. Counselling about a range of options in order of effectiveness, rather than making assumptions about what is appropriate, supports LARC uptake.[98] Discussing anticipated adverse effects, and providing ongoing support and management of any adverse effects that do occur, improves maintenance of LARCs,[98] but evidence suggests this is not well implemented in Kenya currently.[225] A much stronger emphasis on dual method use as part of family planning counselling will be critical for FSWs to reduce sexual risk. In parallel, HIV counselling should also reinforce dual method use, so the overlapping risks of HIV/STIs and pregnancy are not addressed in isolation.

Addressing cost barriers is critical to improving contraceptive access, especially for poor and marginalised women,[218] including FSWs. While the public system notionally provides family planning services for free in Kenya, public facilities do sometimes charge user fees[65] and these are often incurred by FSWs,[32] as discussed in Chapter 1. Auditing local family planning providers to determine the circumstances in which users are charged, and working with them to find ways to reduce costs or modify cost-recovery models, could assist FSWs accessing these services. At the national level, the policy of charging for early removal of LARCs may need to be abolished, because it disincentivises LARC use and may coerce women to remain on LARCs for longer than tolerated.

### *Involving non-paying sexual partners in pregnancy prevention*

This thesis has confirmed one of the most consistent and concerning findings in research with FSWs; that non-paying male sexual partners have a powerful negative influence on FSWs' use of

condoms and other contraceptive methods. The lack of impact of WHISPER (and other interventions in the literature) on consistent condom use with boyfriends and husbands points to an urgent need to find ways to engage with male partners, without compromising women's privacy and autonomy, or putting them at risk of violence by challenging men's role in the relationship. Given the inherent risks, multiple approaches that target men in different contexts and through different channels will be required.

Accessing men through their wives or girlfriends may be effective in some cases, and was found to be acceptable to the majority of FSWs and their intimate partners in a feasibility study in Mexico.[272] It has also been successfully trialled with postpartum women (not sex workers) who could choose to include their partners in an SMS contraceptive program.[176] However, inviting men through their female partners would not be appropriate for FSWs at high risk of intimate partner violence, and is unlikely to reach men who are unaware of their partner's sex work status, or more resistant to contraceptive use.

To reach more emotional partners of FSWs, community-based interventions aimed at men or couples without specific reference to sex work will be needed. 'Gender-transformative'[273] interventions in Malawi and South Africa have been successful at improving contraceptive use[274] and reducing gender-based violence,[275] respectively. In Malawi, male 'Motivators' promoted contraceptive use and challenged gender norms with their peers through home visits, and interspousal communication was an independent predictor of contraceptive use. Community sensitisation, particularly of men, was thought to be an important contributor to the success of a comprehensive program at increasing IUD uptake in the DRC, and women interviewed felt that gender-transformative interventions for men were important to improve shared decision making around contraceptive use.[271] If similar interventions were implemented in locations with high rates of sex work or high known sexual risk, they could indirectly impact FSWs' emotional relationships.

In addition to emotional partners such as husbands and boyfriends, casual non-paying partners may also contribute significantly to sexual risk.[210] Evidence suggests that young sex workers go to hotspots to meet casual and transactional sex partners as well as clients.[75] Therefore, interventions targeting men at hotspots may be a way to reach young casual partners of female sex workers. Such interventions would be generalised and opportunistic, thus removing the risk of their female partners being punished by association, and would simultaneously provide services and education to clients. Simple messages on pregnancy prevention and use of condoms with non-paying partners could be incorporated into existing initiatives providing

sexual health services to men at hotspots,[276] and these initiatives expanded if shown to be effective.

The Avahan program for FSWs in India is one of few examples where consistent condom use with non-paying partners has improved, as a result of comprehensive community-based HIV programming for FSWs, but changes took much longer than for commercial clients.[142] Therefore, it is likely that long-term structural and gender-transformative initiatives are required to have any impact on this behaviour because of its complex determinants that span notions of trust, masculinity, fertility and intimacy. Mobilisation to legitimise sex work in the broader community and promote disclosure to sex partners (where safe to do so) has been proposed[277]; this may not only improve sex worker rights but also couples' communication and contraceptive use with emotional partners, as men who are aware of their female partners' sex work status are more likely to use condoms consistently.[112]

### *Structural interventions to reduce unintended pregnancy*

Structural interventions aim to change the sociocultural, economic, political, or environmental forces that constrain individuals' and communities' ability to protect and improve their own health.[116, 117] There is a growing body of evidence showing that structural interventions reduce HIV transmission among FSWs.[29] Similar interventions are likely to positively impact unintended pregnancy rates, given the two health issues share many of the same structural risk factors, such as criminalisation of sex work, stigma and gender-based violence.

Modelling of structural interventions predicts that decriminalisation of sex work would have the greatest impact on HIV transmission. While it is rarely possible for health and community development programs to modify national laws or other 'macrostructural' elements,[29] structural interventions can also act at the interpersonal or individual level. Unlike behaviour change approaches, structural approaches address the factors constraining individual behaviour, rather than the behaviour itself.[117] For example, microcredit programs operating in sex work communities can't alter underlying financial arrangements that discriminate against sex workers, but they can provide alternative access to emergency finance that can reduce FSWs' dependency on high-risk sexual exchanges.

Activities to improve the supply of LARCs to FSWs, described above, are structural because they aim to remove economic, social and geographic access barriers for FSWs, modify their care environment, change norms of clinical and management practice within health facilities, and ultimately give the client (i.e. FSWs) greater power within the clinical interaction.



#### 7.5.4 Proposed combination prevention model tailored specifically for female sex workers

A combination HIV prevention model has been adopted in Kenya on a large scale, with key population prevention programs in 32 of the 47 counties,[206, 208] and is recommended globally by UNAIDS[278] and the World Health Organization.[279] This model combines evidence-based structural, behavioural and biomedical interventions acting on both supply of prevention technologies and testing and treatment services, and demand for these technologies and services, to prevent HIV among priority populations. Component interventions should be delivered within a framework of community empowerment that counters legal and sociocultural barriers, therefore addressing the structural determinants of HIV transmission.[28]

Combination prevention for unintended pregnancy should utilise existing HIV and STI prevention infrastructure, in particular sex worker drop-in centres and peer education. These programs have been very successful at reaching FSWs in Kenya; in national polling booth surveys, three-quarters of FSWs visited a drop-in centre or project clinic in the previous quarter and 88% were met by a peer educator in 2017, with increasing trends over time.[27] Family planning programming should capitalise on these high levels of engagement among a population traditionally disconnected from services. Peer-mediated interventions have been shown to improve consistent condom use with clients in Mombasa,[230] and use of other contraceptive methods could be impacted through similar channels.

Contraceptive promotion should be incorporated into peer education curricula to generate and maintain demand. Models of combining in-person and mobile phone-based approaches are recommended, as described in 7.5.3. For example, FSWs could link to their peer educator via an SMS system when they are interested in a method or want more information, and in-person counselling sessions from clinicians could be followed up by tailored peer educator-led messaging that reinforces information on methods of interest. SMS or interactive voice messages delivered to FSWs as part of this contraceptive promotion model should utilise the more effective features of mHealth interventions that are detailed in 7.1.5 and Chapter 1.

Contraceptive methods can be provided to FSWs via three clinical models: embedded in drop-in-centres, located on site at sex worker hotspots, or through outreach services,[7] Drop-in-centres are best placed to support more comprehensive family planning services. To increase contraceptive supply, drop-in-centres need to strengthen family planning provision using the approaches described in 7.5.3, with improved method mix, facilities for LARC insertion and

removal, structured counselling and regular training and supervision for providers. This will necessarily involve increasing staffing and expanding clinic spaces, and would benefit from stronger links, particularly referral pathways, to family planning services in the general community. Services located at hotspots could supply shorter-acting and emergency methods, and peer educators or other outreach workers (for example, community health volunteers) could also be upskilled to supply oral and self-injectable[280] contraceptives. Hotspot-based and outreach services need to have clear embedded referral pathways to drop-in centres or other health facilities to link clients with comprehensive counselling and the full range of methods.

Combination prevention models in Mombasa and elsewhere in Kenya already include structural components – for example, drop-in-centres were established not only for service provision but as a safe space and refuge for FSWs to counter structural problems such as housing and economic insecurity and foster solidarity.[29, 209] More recently, peer educators have been trained to act as paralegals to provide emergency assistance to their peers in the event of violence, link them to services, and assist with reporting to police.[229] These existing approaches could be strengthened and supplemented with structural innovations that specifically aim to reduce unintended pregnancy risk. Supply-side initiatives described above do this by modifying the programmatic environment, for example by reducing cost and transport barriers. Sensitising facilities to counter health provider stigma, and advocating for safer abortion services, are other possible approaches.

Integration of HIV and SRH prevention and treatment, as presented in this model, is in line with global and local thinking, with numerous advocates highlighting the dangers of vertical programming and calling for comprehensive SRH services to be prioritised in the era of widespread PrEP provision.[281-284] On the national level in Kenya, there has been a greater focus on integrating family planning into HIV programs and leveraging HIV prevention resources for this purpose since 2006, and the Ministry of Health attributes the increase in contraceptive use in the general population to this, among other factors.[233]

Kenya has historically been successful at both broadening comprehensive family planning programming, resulting in improved contraceptive use and fertility indices,[218] and rapidly scaling up combination HIV prevention programs for FSWs. There is therefore substantial potential for enhanced family planning programming to be extended to FSWs through existing health promotion and service delivery channels.

The proposed model outlined here needs to be developed in conjunction with FSWs, HIV program staff and family planning providers. A critical first step would be mapping and auditing

existing family planning services in the local area, both serving FSWs specifically and the general population. As a limitation of this research was a lack of service-level data, and this hampered efforts to harmonise messages with the realities of local service provision, it is important that strong collaborative relationships are built with service providers. Service auditing would determine what counselling and methods are being provided, when, where and by whom, and what are the barriers to expanding these and linking them to other components of prevention.

It is critical that any new model is evaluated in a way that provides reliable evidence of its effectiveness, particularly given the lack of current evidence for similar programs. The research design could be a cluster-randomised controlled trial (for example, randomising different sub-counties or comparable cities to receive the new program) or a less rigorous but more economical design such as pre-/post-intervention evaluation. A smaller research study could also be embedded in the larger program, ideally powered to measure unintended pregnancy incidence. Regardless of the methods chosen, it is critical that: evaluation is planned from the outset; outcomes as well as outputs are measured; qualitative methods are incorporated; and the evaluation is sufficiently resourced and data collection does not overly burden program staff or FSW clients.

## 7.6 Conclusion

This thesis makes a substantial contribution to the existing body of research on unintended pregnancy risks among FSWs in LMICs. My research found that estimates of unintended pregnancy incidence among FSWs are varied, but higher than the general population overall. Despite promising trends in unintended pregnancy incidence and implant use in Mombasa, use of contraception remains suboptimal, particularly dual methods and IUDs. The WHISPER SMS intervention was highly engaging for FSWs, and was effective at improving their knowledge of contraception and use of dual contraceptive methods, but not LARC use or condom use with non-paying emotional partners. Structural barriers, particularly limitations with the supply of LARCs, and interpersonal barriers relating to male partners' influence over contraceptive behaviour, are likely to have impaired FSWs' ability to reduce their risks. Future programs for FSWs should more fully integrate unintended pregnancy prevention into existing combination HIV prevention, for example by expanding family planning services available at sex-worker drop-in-centres, and contraceptive promotion by peer educators. The effectiveness of such programs could be enhanced by mHealth initiatives, which this research has demonstrated to be

feasible and acceptable in this population. The results of this thesis can inform future mHealth interventions for FSWs, other programs for reducing their risk of unintended pregnancy, and innovative research designs for testing these initiatives.

## References

1. UNAIDS: A situational analysis guide on sex work in West and Central Africa. 2000. [https://www.who.int/hiv/topics/vct/sw\\_toolkit/publications\\_situational\\_analysis.pdf](https://www.who.int/hiv/topics/vct/sw_toolkit/publications_situational_analysis.pdf).
2. Scorgie F, Chersich MF, Ntaganira I, Gerbase A, Lule F, Lo Y-R: Socio-demographic characteristics and behavioral risk factors of female sex workers in sub-saharan Africa: a systematic review. *AIDS Behav* 2012, 16(4):920-933.
3. Stoebenau K, Heise L, Wamoyi J, Bobrova N: Revisiting the understanding of "transactional sex" in sub-Saharan Africa: a review and synthesis of the literature. *Soc Sci Med* 2016, 168:186-197.
4. Das P, Horton R: Bringing sex workers to the centre of the HIV response. *Lancet* 2015, 385(9962):3-4.
5. Manopaiboon C, Prybylski D, Subhachaturas W, Tanpradech S, Suksripanich O, Siangphoe U, Johnston LG, Akarasewi P, Anand A, Fox KK *et al*: Unexpectedly high HIV prevalence among female sex workers in Bangkok, Thailand in a respondent-driven sampling survey. *Int J STD AIDS* 2013, 24(1):34-38.
6. Navani-Vazirani S, Solomon D, Gopalakrishnan, Heylen E, Srikrishnan AK, Vasudevan CK, Ekstrand ML: Mobile phones and sex work in South India: the emerging role of mobile phones in condom use by female sex workers in two Indian states. *Cult Health Sex* 2015, 17(2):252-265.
7. Thompson L, Bhattacharjee P, Anthony J, Shetye M, Moses S, Blanchard J: A systematic approach to the design and scale-up of targeted interventions for HIV prevention among urban female sex workers. Bangalore, India: Karnataka Health Promotion Trust, University of Manitoba and World Bank; 2012.
8. Wilson D: HIV programs for sex workers: lessons and challenges for developing and delivering programs. *PLoS Med* 2015, 12(6):e1001808.
9. Hawken MP, Dallabetta G, Temmerman M: Part time female sex workers in a suburban community in Kenya: a vulnerable hidden population. *Sex Transm Infect* 2002, 78(4):271-273.
10. Pitpitan EV, Kalichman SC, Eaton LA, Strathdee SA, Patterson TL: HIV/STI risk among venue-based female sex workers across the globe: a look back and the way forward. *Curr HIV/AIDS Rep* 2013, 10(1):65-78.
11. Reeves A, Steele S, Stuckler D, McKee M, Amato-Gauci A, Semenza JC: National sex work policy and HIV prevalence among sex workers: an ecological regression analysis of 27 European countries. *Lancet HIV* 2017, 4(3):e134-e140.

12. Overs C: Sex work and the law – it's complicated. *The Conversation*. 2017.  
<https://theconversation.com/sex-work-and-the-law-its-complicated-81316>.
13. Willis B, Welch K, Onda S: Health of female sex workers and their children: a call for action. *Lancet Glob Health* 2016, 4(7):e438-e439.
14. Rao A, Baral S, Phaswana-Mafuya N, Lambert A, Kose Z, Mcingana M, Holland C, Ketende S, Schwartz S: Pregnancy intentions and safer pregnancy knowledge among female sex workers in Port Elizabeth, South Africa. *Obstet Gynecol* 2016, 128(1):15-21.
15. Duff P, Shoveller J, Feng C, Ogilvie G, Montaner J, Shannon K: Pregnancy intentions among female sex workers: recognising their rights and wants as mothers. *J Fam Plann Reprod Health Care* 2015, 41(2):102-108.
16. Strathdee SA, Crago A-L, Butler J, Bekker L-G, Beyrer C: Dispelling myths about sex workers and HIV. *Lancet* 2015, 385(9962):4-7.
17. Beckham SW, Shembilu CR, Brahmbhatt H, Winch PJ, Beyrer C, Kerrigan DL: Female sex workers' experiences with intended pregnancy and antenatal care services in southern Tanzania. *Stud Fam Plann* 2015, 46(1):55-71.
18. LINKAGES: The nexus of gender and HIV among sex workers in Kenya. Durham, North Carolina: FHI 360; 2016.
19. Basu A, Dutta MJ: 'We are mothers first': localocentric articulation of sex worker identity as a key in HIV/AIDS communication. *Women Health* 2011, 51(2):106-123.
20. Center for Health and Gender Equity: All women, all rights, sex workers included. Washington, DC: CHANGE; 2016.
21. Aiken ARA, Borrero S, Callegari LS, Dehlendorf C: Rethinking the pregnancy planning paradigm: unintended conceptions or unrepresentative concepts? *Perspect Sex Reprod Health* 2016, 48(3):147-151.
22. Hall J, Barrett G, Mbwana N, Copas A, Malata A, Stephenson J: Understanding pregnancy planning in a low-income country setting: validation of the London Measure of Unplanned Pregnancy in Malawi. *BMC Pregnancy and Childbirth* 2013, 13.
23. Zampas C, Lamackova A: Forced and coerced sterilization of women in Europe. *Int J Gynaecol Obstet* 2011, 114(2):163-166.
24. Kendall T, Albert C: Experiences of coercion to sterilize and forced sterilization among women living with HIV in Latin America. *J Int AIDS Soc* 2015, 18(1):19462.
25. Gomez AM, Fuentes L, Allina A: Women or LARC first? Reproductive autonomy and the promotion of long-acting reversible contraceptive methods. *Perspect Sex Reprod Health* 2014, 46(3):171-175.

26. Shannon K, Crago AL, Baral SD, Bekker LG, Kerrigan D, Decker MR, Poteat T, Wirtz AL, Weir B, Boily MC *et al*: The global response and unmet actions for HIV and sex workers. *Lancet* 2018, 392(10148):698-710.
27. National AIDS & STI Control Programme, Ministry of Health: Third national behavioural assessment of key populations in Kenya: polling booth survey report. Nairobi: NASCOP; 2018.
28. Bekker L-G, Johnson L, Cowan F, Overs C, Besada D, Hillier S, Cates W: Combination HIV prevention for female sex workers: what is the evidence? *Lancet* 2015, 385(9962):72-87.
29. Shannon K, Strathdee SA, Goldenberg SM, Duff P, Mwangi P, Rusakova M, Reza-Paul S, Lau J, Deering K, Pickles MR *et al*: Global epidemiology of HIV among female sex workers: influence of structural determinants. *Lancet* 2015, 1(9962):55-71.
30. Dhana A, Luchters S, Moore L, Lafort Y, Roy A, Scorgie F, Chersich M: Systematic review of facility-based sexual and reproductive health services for female sex workers in Africa. *Global Health* 2014, 10(1):46-46.
31. Okafor UO, Crutzen R, Aduak Y, Adebajo S, Van den Borne HW: Behavioural interventions promoting condom use among female sex workers in sub-Saharan Africa: a systematic review. *Afr J AIDS Res* 2017, 16(3):257-268.
32. European Commission: Report of situational analysis of reproductive health services for general population women and female sex workers in India, Kenya, Mozambique and South Africa. European Commission FP7 DIFFER project; 2013.
33. Schoemaker J, Twikirize J: A life of fear: sex workers and the threat of HIV in Uganda. *Int J Soc Welf* 2012, 21(2):186-193.
34. Khan MR, Turner AN, Pettifor A, Van Damme K, Rabenja NL, Ravelomanana N, Swezey T, Williams D, Jamieson D, Behets F: Unmet need for contraception among sex workers in Madagascar. *Contraception* 2009, 79(3):221-227.
35. Todd CS, Nasir A, Raza Stanekzai M, Scott PT, Strathdee SA, Botros BA, Tjaden J: Contraceptive utilization and pregnancy termination among female sex workers in Afghanistan. *J Womens Health* 2010, 19(11):2057-2062.
36. Wirtz AL, Schwartz S, Ketende S, Anato S, Nadedjo FD, Ouedraogo HG, Ky-zerbo O, Pitche V, Grosso A, Papworth E *et al*: Sexual violence, condom negotiation, and condom use in the context of sex work: results From two West African countries. *J Acquir Immune Defic Syndr* 2015, 68:171-179.
37. Erickson M, Goldenberg SM, Ajok M, Muldoon KA, Muzaaya G, Shannon K: Structural determinants of dual contraceptive use among female sex workers in Gulu, northern Uganda. *Int J Gynaecol Obstet* 2015, 131(1):91-95.

38. Luchters S, Bosire W, Feng A, Richter ML, King'ola N, Ampt F, Temmerman M, Chersich MF: "A baby was an added burden": predictors and consequences of unintended pregnancies for female sex workers in Mombasa, Kenya: A mixed-methods study. *PLoS ONE* 2016, 11(9):e0162871.
39. Lim MS, Zhang XD, Kennedy E, Li Y, Yang Y, Li L, Li YX, Temmerman M, Luchters S: Sexual and reproductive health knowledge, contraception uptake, and factors associated with unmet need for modern contraception among adolescent female sex workers in China. *PLoS ONE* 2015, 10(1):e0115435.
40. Khan M, Unemo M, Zaman S, Lundborg C: Health-seeking behaviour of women selling sex in Lahore, Pakistan. *Int J STD AIDS* 2011, 22(7):376-380.
41. Ippoliti NB, Nanda G, Wilcher R: Meeting the reproductive health needs of female key populations affected by HIV in low- and middle-income countries: a review of the evidence. *Stud Fam Plann* 2017, 48(2):121-151.
42. McClelland RS, Richardson BA, Graham SM, Masese LN, Gitau R: A prospective study of risk factors for bacterial vaginosis in HIV-1-seronegative African women. *Sex Transm Dis* 2008, 35(6):617-623.
43. Peterson L, Taylor D, Roddy R, Belai G, Phillips P, Nanda K, Grant R, Clarke EE, Doh AS, Ridzon R *et al*: Tenofovir disoproxil fumarate for prevention of HIV infection in women: a phase 2, double-blind, randomized, placebo-controlled trial. *PLoS Clin Trials* 2007, 2(5):e27.
44. Bearak J, Popinchalk A, Alkema L, Sedgh G: Global, regional, and subregional trends in unintended pregnancy and its outcomes from 1990 to 2014: estimates from a Bayesian hierarchical model. *Lancet Glob Health* 2018, 6(4):e380-e389.
45. Sonfield A, Hasstedt K, Kavanaugh ML, Anderson R: The social and economic benefits of women's ability to determine whether and when to have children. New York: Guttmacher Institute; 2013.
46. Shah PS, Balkhair T, Ohlsson A, Beyene J, Scott F, Frick C: Intention to become pregnant and low birth weight and preterm birth: a systematic review. *Matern Child Health J* 2011, 15(2):205-216.
47. Hall JA, Benton L, Copas A, Stephenson J: Pregnancy intention and pregnancy outcome: systematic review and meta-analysis. *Matern Child Health J* 2017, 21(3):670-704.
48. Gipson JD, Koenig MA, Hindin MJ: The effects of unintended pregnancy on infant, child, and parental health: a review of the literature. *Stud Fam Plann* 2008, 39(1):18-38.
49. KELIN: Laws on abortion in Kenya.



50. Singh S, Remez L, Sedgh G, Kwok L, Onda T: Abortion worldwide: uneven progress and unequal access. Guttmacher Institute; 2017.  
<https://www.guttmacher.org/report/abortion-worldwide-2017>.
51. Singh S, Darroch JE, Ashford LS: Adding it up: the costs and benefits of investing in sexual and reproductive health 2014. New York: Guttmacher Institute; 2014.
52. Hampanda KM: The social dynamics of selling sex in Mombasa, Kenya: a qualitative study contextualizing high risk sexual behaviour. *Afr J Reprod Health* 2013, 17(2):141-149.
53. Chanda MM, Ortblad KF, Mwale M, Chongo S, Kanchele C, Kamungoma N, Barresi LG, Harling G, Barnighausen T, Oldenburg CE: Contraceptive use and unplanned pregnancy among female sex workers in Zambia. *Contraception* 2017, 96(3):196-202.
54. Festin MP, Kiarie J, Solo J, Spieler J, Malarcher S, Van Look PF, Temmerman M: Moving towards the goals of FP2020 - classifying contraceptives. *Contraception* 2016, 94(4):289-294.
55. World Health Organization Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs: Family planning: a global handbook for providers (2018 update). Baltimore and Geneva: CCP and WHO; 2018.
56. Rademacher KH, Solomon M, Brett T, Bratt JH, Pascual C, Njunguru J, Steiner MJ: Expanding access to a new, more affordable levonorgestrel intrauterine system in Kenya: service delivery costs compared with other contraceptive methods and perspectives of key opinion leaders. *Glob Health Sci Pract* 2016, 4 Suppl 2(Suppl 2):S83-S93.
57. FP2020: FP2020: catalyzing collaboration 2017–2018. 2018. <http://2017-2018progress.familyplanning2020.org/>.
58. Tolley E, Loza S, Kafafi L, Cummings S: The impact of menstrual side effects on contraceptive discontinuation: findings from a longitudinal study in Cairo, Egypt. *International Family Planning Perspectives* 2005, 31:15+.
59. Bahamondes L, Brache V, Meirik O, Ali M, Habib N, Landoulsi S, Bahamondes L, Bahamondes MV, Massai R, Montero JC *et al*: A 3-year multicentre randomized controlled trial of etonogestrel- and levonorgestrel-releasing contraceptive implants, with non-randomized matched copper-intrauterine device controls. *Hum Reprod* 2015, 30(11):2527-2538.
60. Hubacher D, Spector H, Monteith C, Chen PL, Hart C: Long-acting reversible contraceptive acceptability and unintended pregnancy among women presenting for

- short-acting methods: a randomized patient preference trial. *Am J Obstet Gynecol* 2017, 216(2):101-109.
61. Darroch JE, Audam S, Biddlecom A, Kopplin G, Riley T, Singh S, Sully E: Fact sheet: adding it up: investing in contraception and maternal and newborn health. New York: Guttmacher Institute; 2017.
  62. PMA2020: Survey Round 6, PMA2017/Kenya-R6: snapshot of indicators. Kenya and Baltimore, Maryland, USA.: International Centre for Reproductive Health Kenya (ICRHK) and The Bill & Melinda Gates Institute for Population and Reproductive Health at The Johns Hopkins Bloomberg School of Public Health; 2017.  
<https://pma2020.org/pma2017-kenya-round-6-soi-table>.
  63. Kenya National Bureau of Statistics, ICF Macro: Kenya demographic and health survey 2008-09. Calverton, Maryland: KNBS and ICF Macro; 2010.
  64. Kenya National Bureau of Statistics: Kenya demographic and health survey 2014. 2015.  
<http://microdata.worldbank.org/index.php/catalog/2544>.
  65. PMA2020: PMA2018/Kenya-R7: family planning brief. 2019.  
<https://www.pma2020.org/reports/pma2018-kenya-round-7-family-planning-brief>.
  66. PMA2020: PMA2015/Kenya-R4 SOI: snapshot of indicators. *Country reports - Kenya*. Performance Monitoring and Accountability 2020; 2016.  
<https://pma2020.org/research/country-reports/kenya>.
  67. White K, Ocampo M, Scarinci IC: A socio-ecological approach for examining factors related to contraceptive use among recent Latina immigrants in an emerging Latino state. *Women Health* 2017, 57(7):872-889.
  68. Brofenbrenner U: The ecology of human development: experiments by nature and design. Cambridge, MA: Harvard University Press; 1979.
  69. Koren A, Mawn B: The context of unintended pregnancy among married women in the USA. *J Fam Plann Reprod Health Care* 2010, 36(3):150.
  70. Vinh NT, Tuan PC: Factors Influencing Unintended Pregnancy and Abortion among Unmarried Youth in Vietnam :a Literature Review. *Tap chi y te cong cong* 2015, 3(2):3-16.
  71. Raneri LG, Wiemann CM: Social Ecological Predictors of Repeat Adolescent Pregnancy. *Perspect Sex Reprod Health* 2007, 39(1):39-47.
  72. Blackstone SR, Nwaozuru U, Iwelunmor J: Factors influencing contraceptive use in Sub-Saharan Africa: a systematic review. *Int Q Community Health Educ* 2017, 37(2):79-91.
  73. Deschamps MM, Metch B, Morgan CA, Zorilla CD, Donastorg Y, Swann E, Taina D, Patrice J, Pape WJ: Feasibility of identifying a female sex worker cohort at high risk of HIV

- infection in the Caribbean for HIV vaccine efficacy trials: longitudinal results of HVTN 907. *J Acquir Immune Defic Syndr* 2016, 71(1):70-77.
74. Feldblum PJ, Nasution MD, Hoke TH, Van Damme K, Turner AN, Gmach R, Wong EL, Behets F: Pregnancy among sex workers participating in a condom intervention trial highlights the need for dual protection. *Contraception* 2007, 76(2):105-110.
  75. NASCOP: Transitions study evidence brief, Kenya. Nairobi: National AIDS/STI Control Programme; 2017.
  76. Morineau G, Neilsen G, Heng S, Phimpachan C, Mustikawati DE: Falling through the cracks: contraceptive needs of female sex workers in Cambodia and Laos. *Contraception* 2011, 84(2):194-198.
  77. Yam EA, Okal J, Musyoki H, Muraguri N, Tun W, Sheehy M, Geibel S: Kenyan female sex workers' use of female-controlled nonbarrier modern contraception: do they use condoms less consistently? *Contraception* 2016, 93(3):222-225.
  78. Reed E, Erausquin JT, Biradavolu M, Servin AE, Blankenship KM: Non-barrier contraceptive use and relation to condom use behaviour by partner type among female sex workers in Andhra Pradesh, India. *J Fam Plann Reprod Health Care* 2017, 43(1):60-66.
  79. Sutherland EG, Alaii J, Tsui S, Luchters S, Okal J, King'ola N, Temmerman M, Janowitz B: Contraceptive needs of female sex workers in Kenya - a cross-sectional study. *Eur J Contracept Reprod Health Care* 2011, 16(3):173-182.
  80. Yam EA, Mnisi Z, Mabuza X, Kennedy C, Kerrigan D, Tsui A, Baral S: Use of dual protection among female sex workers in Swaziland. *Int Perspect Sex Reprod Health* 2013, 39(2):69-78.
  81. Bukenya JN, Wanyenze RK, Barrett G, Hall J, Makumbi F, Guwatudde D: Contraceptive use, prevalence and predictors of pregnancy planning among female sex workers in Uganda: a cross sectional study. *BMC Pregnancy and Childbirth* 2019, 19(1):121.
  82. Mukenge-Tshibaka L, Alary M, Geraldo N, Lowndes CM: Incorrect condom use and frequent breakage among female sex workers and their clients. *Int J STD AIDS* 2005, 16(5):345-347.
  83. Masvawure TB, Mantell JE, Tocco JU, Gichangi P, Restar A, Chabeda SV, Lafort Y, Sandfort TGM: Intentional and unintentional condom breakage and slippage in the sexual interactions of female and male sex workers and clients in Mombasa, Kenya. *AIDS Behav* 2018, 22(2):637-648.
  84. Ochako R, Okal J, Kimetu S, Askew I, Temmerman M: Female sex workers experiences of using contraceptive methods: a qualitative study in Kenya. *BMC Womens Health* 2018, 18(1):105-105.

85. Musekiwa A, Muchiri E, Manda SO, Mwambi HG: Pregnancy incidence and risk factors among women participating in vaginal microbicide trials for HIV prevention: systematic review and meta-analysis. *PLoS ONE* 2013, 8(10):e77014.
86. Strathdee SA, Abramovitz D, Lozada R, Martinez G, Rangel MG, Vera A, Staines H, Magis-Rodriguez C, Patterson TL: Reductions in HIV/STI incidence and sharing of injection equipment among female sex workers who inject drugs: results from a randomized controlled trial. *PLoS ONE* 2013, 8 (6) (no pagination)(e65812).
87. Deschamps MM, Zorrilla CD, Morgan CA, Donastorg Y, Metch B, Madenwald T, Joseph P, Severe K, Garced S, Perez M *et al*: Recruitment of Caribbean female commercial sex workers at high risk of HIV infection. *Rev Panam Salud Publica* 2013, 34(2):92-98.
88. Braunstein SL, Ingabire CM, Kestelyn E, Uwizera AU, Mwamarangwe L, Ntirushwa J, Nash D, Veldhuijzen NJ, Nel A, Vyankandondera J *et al*: High human immunodeficiency virus incidence in a cohort of Rwandan female sex workers. *Sex Transm Dis* 2011, 38(5):385-394.
89. Parcesepe AM, L'Engle KL, Martin SL, Green S, Sinkele W, Suchindran C, Speizer IS, Mwarogo P, Kingola N: The impact of an alcohol harm reduction intervention on interpersonal violence and engagement in sex work among female sex workers in Mombasa, Kenya: results from a randomized controlled trial. *Drug Alcohol Depend* 2016, 161:21-28.
90. Okal J, Chersich MF, Tsui S, Sutherland E, Temmerman M, Luchters S: Sexual and physical violence against female sex workers in Kenya: a qualitative enquiry. *AIDS Care* 2011, 23(5):612-618.
91. Chersich MF, Bosire W, King'ola N, Temmerman M, Luchters S: Effects of hazardous and harmful alcohol use on HIV incidence and sexual behaviour: a cohort study of Kenyan female sex workers. *Global Health* 2014, 10(1):22-22.
92. Priddy FH, Wakasiaka S, Hoang TD, Smith DJ, Farah B, Del Rio C, Ndinya-Achola J: Anal sex, vaginal practices, and HIV incidence in female sex workers in urban Kenya: implications for the development of intravaginal HIV prevention methods. *AIDS Res Hum Retroviruses* 2011, 27(10):1067-1072.
93. Sagtani RA, Bhattarai S, Adhikari BR, Baral D, Yadav DK, Pokharel PK: Alcohol use, HIV risk behavior and experience of sexually transmitted infections among female sex workers of Nepal. *Clin Epidemiol Glob Health* 2013, 1(2):73-78.
94. Ochako R, Mbondo M, Aloo S, Kaimenyi S, Thompson R, Temmerman M, Kays M: Barriers to modern contraceptive methods uptake among young women in Kenya: a qualitative study. *BMC Public Health* 2015, 15(1):1-9.

95. Mbuthia FW, Okumbe GM, Monda J, Ng'ang'a PM: Intrauterine device uptake among women seeking family planning services in Nairobi County, Kenya. *Afr J Midwifery Womens Health* 2017, 11(1):46-50.
96. Kientore S, Zoungrana Z, Zamane H, Kabore C, Ouedraogo A, Bonane B: Interventions to improve the use of long-acting reversible contraceptive methods at primary health centers in Burkina Faso. *Int J Gynaecol Obstet* 2019, 147(3):350-355.
97. Hubacher D, Masaba R, Manduku CK, Veena V: Uptake of the levonorgestrel intrauterine system among recent postpartum women in Kenya: factors associated with decision-making. *Contraception* 2013, 88(1):97-102.
98. Rees H, Pillay Y, Mullick S, Chersich MF: Strengthening implant provision and acceptance in South Africa with the 'any woman, any place, any time' approach: an essential step towards reducing unintended pregnancies. *S Afr Med J* 2017, 107(11):939-944.
99. Nalwadda G, Mirembe F, Byamugisha J, Fixelid E: Persistent high fertility in Uganda: young people recount obstacles and enabling factors to use of contraceptives. *BMC Public Health* 2010, 10:530-530.
100. Withers M, Dworkin SL, Zakaras JM, Onono M, Oyier B, Cohen CR, Bukusi EA, Grossman D, Newmann SJ: 'Women now wear trousers': men's perceptions of family planning in the context of changing gender relations in western Kenya. *Cult Health Sex* 2015, 17(9):1132-1146.
101. Onyango MA, Owoko S, Oguttu M: Factors that influence male involvement in sexual and reproductive health in western Kenya: a qualitative study. *Afr J Reprod Health* 2010, 14(4 Spec no.):32-42.
102. Bawah AA, Akweongo P, Simmons R, Phillips JF: Women's fears and men's anxieties: the impact of family planning on gender relations in northern Ghana. *Stud Fam Plann* 1999, 30(1):54-66.
103. Kabagenyi A, Jennings L, Reid A, Nalwadda G, Ntozi J, Atuyambe L: Barriers to male involvement in contraceptive uptake and reproductive health services: a qualitative study of men and women's perceptions in two rural districts in Uganda. *Reprod Health* 2014, 11(1):21.
104. May JF: The Politics of Family Planning Policies and Programs in sub-Saharan Africa. *Popul Dev Rev* 2017, 43:308-329.
105. Jakubowski A, Omanga E, Agot K, Thirumurthy H: Large price premiums for unprotected sex among female sex workers in Kenya: a potential challenge for behavioral HIV prevention interventions. *J Acquir Immune Defic Syndr* 2016, 72(1):e20-22.

106. Elmes J, Nhongo K, Ward H, Hallett T, Nyamukapa C, White PJ, Gregson S: The price of sex: condom use and the determinants of the price of sex among female sex workers in Eastern Zimbabwe. *J Infect Dis* 2014, 210(suppl 2):S569-S578.
107. Chow EP, Muessig KE, Yuan L, Wang Y, Zhang X, Zhao R, Sun P, Sun X, Tucker JD, Jing J *et al*: Risk behaviours among female sex workers in China: a systematic review and data synthesis. *PLoS ONE* 2015, 10(3):e0120595.
108. Maher L, Mooney-Somers J, Phlong P, Couture M-C, Kien SP, Stein E, Bates AJ, Sansothy N, Page K: Condom negotiation across different relationship types by young women engaged in sex work in Phnom Penh, Cambodia. *Glob Public Health* 2013, 8(3):270-283.
109. Musyoki H, Bhattacharjee P, Blanchard AK, Kioko J, Kaosa S, Anthony J, Javalkar P, Musimbi J, Malaba SJ, Olwande C *et al*: Changes in HIV prevention programme outcomes among key populations in Kenya: data from periodic surveys. *PLoS ONE [Electronic Resource]* 2018, 13(9):e0203784.
110. Luchters S, Richter ML, Bosire W, Nelson G, Kingola N, Zhang X-D, Temmerman M, Chersich MF: The contribution of emotional partners to sexual risk taking and violence among female sex workers in Mombasa, Kenya: a cohort study. *PLoS ONE* 2013, 8(8):e68855-e68855.
111. Warr DJ, Pyett PM: Difficult relations: sex work, love and intimacy. *Sociol Health Illn* 1999, 21(3):290-309.
112. Deering KN, Bhattacharjee P, Bradley J, Moses SS, Shannon K, Shaw SY, Washington R, Lowndes CM, Boily M-C, Ramesh BM *et al*: Condom use within non-commercial partnerships of female sex workers in southern India. *BMC Public Health* 2011, 11(6):S11.
113. Deering KN, Amin A, Shoveller J, Nesbitt A, Garcia-Moreno C, Duff P, Argento E, Shannon K: A systematic review of the correlates of violence against sex workers. *Am J Public Health* 2014, 104(5):42-55.
114. Panchanadeswaran S, Johnson SC, Sivaram S, Srikrishnan AK, Latkin C: Intimate partner violence is as important as client violence in increasing street-based female sex workers' vulnerability to HIV in India. *Int J Drug Policy* 2008:[7] p.
115. Wilson KS, Deya R, Yuhas K, Simoni J, Vander Stoep A, Shafi J, Jaoko W, Hughes JP, Richardson BA, McClelland RS: A prospective cohort study of intimate partner violence and unprotected sex in HIV-positive female sex workers in Mombasa, Kenya. *AIDS Behav* 2016:1-11.
116. Evans C, Jana S, Lambert H: What makes a structural intervention? Reducing vulnerability to HIV in community settings, with particular reference to sex work. *Glob Public Health* 2010, 5.

117. Gupta GR, Parkhurst JO, Ogden JA, Aggleton P, Mahal A: Structural approaches to HIV prevention. *Lancet* 2008, 372(9640):764-775.
118. Krusi A, Chettiar J, Ridgway A, Abbott J, Strathdee SA, Shannon K: Negotiating safety and sexual risk reduction with clients in unsanctioned safer indoor sex work environments: a qualitative study. *Am J Public Health* 2012, 102(6):1154-1159.
119. Platt L, Grenfell P, Meiksin R, Elmes J, Sherman SG, Sanders T, Mwangi P, Crago AL: Associations between sex work laws and sex workers' health: a systematic review and meta-analysis of quantitative and qualitative studies. *PLoS Med* 2018, 15(12):e1002680.
120. Scorgie F, Nakato D, Harper E, Richter M, Maseko S, Nare P, Smit J, Chersich M: 'We are despised in the hospitals': sex workers' experiences of accessing health care in four African countries. *Cult Health Sex* 2013, 15(4):450-465.
121. Williamson LM, Parkes A, Wight D, Petticrew M, Hart GJ: Limits to modern contraceptive use among young women in developing countries: a systematic review of qualitative research. *Reprod Health* 2009, 6:3.
122. Lyons CE, Schwartz SR, Murray SM, Shannon K, Diouf D, Mothopeng T, Kouanda S, Simplicie A, Kouame A, Mnisi Z *et al*: The role of sex work laws and stigmas in increasing HIV risks among sex workers. *Nat Commun* 2020, 11(1):773.
123. Turan JM, Elafros MA, Logie CH, Banik S, Turan B, Crockett KB, Pescosolido B, Murray SM: Challenges and opportunities in examining and addressing intersectional stigma and health. *BMC Med* 2019, 17(1):7.
124. Delany-Moretlwe S, Cowan FM, Busza J, Bolton-Moore C, Kelley K, Fairlie L: Providing comprehensive health services for young key populations: needs, barriers and gaps. *J Int AIDS Soc* 2015, 18(2 Suppl 1):19833.
125. Mtetwa S, Busza J, Chidiya S, Mungofa S, Cowan F: You are wasting our drugs: health service barriers to HIV treatment for sex workers in Zimbabwe. *BMC Public Health* 2013, 13:698.
126. Wong WCW, Holroyd E, Bingham A: Stigma and sex work from the perspective of female sex workers in Hong Kong. *Sociol Health Illn* 2011, 33(1):50-65.
127. Corneli A, Lemons A, Otieno-Masaba R, Ndiritu J, Packer C, Lamarre-Vincent J, Dulli L: Contraceptive service delivery in Kenya: a qualitative study to identify barriers and preferences among female sex workers and health care providers. *Contraception* 2016, 94(1):34-39.
128. Ross J, Stover J: Use of modern contraception increases when more methods become available: analysis of evidence from 1982–2009. *Glob Health Sci Pract* 2013, 1(2):203-212.

129. Choi Y, Safi S, Nobili J, PMA2020 Principal Investigators Group, Radloff S: Levels, trends, and patterns of contraceptive method availability: comparative analyses in eight sub-Saharan African countries. Performance Monitoring and Accountability 2020 methodological reports no. 5. Baltimore, Maryland: Bill & Melinda Gates Institute for Population and Reproductive Health, Johns Hopkins University Bloomberg School of Public Health; 2019.
130. Luchowski AT, Anderson BL, Power ML, Raglan GB, Espey E, Schulkin J: Obstetrician–gynecologists and contraception: practice and opinions about the use of IUDs in nulliparous women, adolescents and other patient populations. *Contraception* 2014, 89(6):572-577.
131. Black K, Lotke P, Buhling KJ, Zite NB: A review of barriers and myths preventing the more widespread use of intrauterine contraception in nulliparous women. *Eur J Contracept Reprod Health Care* 2012, 17(5):340-350.
132. Prata N, Fraser A, Huchko MJ, Gipson JD, Withers M, Lewis S, Ciaraldi EJ, Upadhyay UD: Women's empowerment and family planning: a review of the literature. *J Biosoc Sci* 2017, 49(6):713-743.
133. Moore L, Chersich MF, Steen R, Reza-Paul S, Dhana A, Vuylsteke B, Lafort Y, Scorgie F: Community empowerment and involvement of female sex workers in targeted sexual and reproductive health interventions in Africa: a systematic review. *Global Health* 2014, 10(1):47.
134. Kerrigan DL, Fonner VA, Stromdahl S, Kennedy CE: Community empowerment among female sex workers is an effective HIV prevention intervention: a systematic review of the peer-reviewed evidence from low- and middle-income countries. *AIDS Behav* 2013, 17(6):1926-1940.
135. Evans C, Lambert H: Implementing community interventions for HIV prevention: insights from project ethnography. *Soc Sci Med* 2008, 66(2):467-478.
136. Jana S, Basu I, Rotheram-Borus MJ, Newman Pa: The Sonagachi Project: a sustainable community intervention program. *AIDS Educ Prev* 2004, 16(5):405-414.
137. African Commission on Human and Peoples' Rights: HIV, the law and human rights in the African human rights system: key challenges and opportunities for rights-based responses. Banjul, The Gambia: UNAIDS and African Union; 2018.  
[https://www.unaids.org/en/resources/documents/2018/HIV\\_Law\\_AfricanHumanRightsSystem](https://www.unaids.org/en/resources/documents/2018/HIV_Law_AfricanHumanRightsSystem).
138. KELIN: How the constitution protects HIV related rights. Nairobi: Kenya Legal & Ethical Issues Network on HIV and AIDS; 2010.



139. von Sadowszky V, Draudt B, Boch S: A systematic review of reviews of behavioral interventions to promote condom use. *Worldviews Evid Based Nurs* 2014, 11(2):107-117.
140. Ulibarri MD, Strathdee SA, Lozada R, Staines-Orozco HS, Abramovitz D, Semple S, Martinez GA, Patterson TL: Condom use among female sex workers and their non-commercial partners: effects of a sexual risk intervention in two Mexican cities. *Int J STD AIDS* 2012, 23(4):229-234.
141. Lim RBT, Tham DKT, Cheung ONY, Wong ML: Efficacy of human immunodeficiency virus/sexually transmitted infection prevention interventions targeting female entertainment workers: a systematic review and meta-analysis. *AIDS Behav* 2017, 21(8):2341-2361.
142. Moses S, Ramesh BM, Isac S, Reza-Paul S, Alary M, Bradley J, Washington R, Beattie T, Blanchard J: O1-S09.01 Increased condom use and decreased HIV & STI prevalence among female sex workers following a targeted HIV prevention program in Karnataka, South India. *Sex Transm Infect* 2011, 87(Suppl 1):A44-A44.
143. Ramesh BM, Beattie TSH, Shajy I, Washington R, Jagannathan L, Reza-Paul S, Blanchard JF, Moses S: Changes in risk behaviours and prevalence of sexually transmitted infections following HIV preventive interventions among female sex workers in five districts in Karnataka state, south India. *Sex Transm Infect* 2010, 86(Suppl 1):i17-i24.
144. Belaid L, Dumont A, Chaillet N, Zertal A, De Brouwere V, Hounton S, Ridde V: Effectiveness of demand generation interventions on use of modern contraceptives in low- and middle-income countries. *Trop Med Int Health* 2016, 21(10):1240-1254.
145. Lopez LM, Chen M, Steiner Markus J, Gallo Maria F: Behavioral interventions for improving dual-method contraceptive use. *Cochrane Database Syst Rev* 2014(3).
146. Gallo MF, Warner L, Jamieson DJ, Steiner MJ: Do women using long-acting reversible contraception reduce condom use? A novel study design incorporating semen biomarkers. *Infect Dis Obstet Gynecol* 2011, 2011:107140-107140.
147. Sieving RE, McRee A-L, McMorris BJ, Beckman KJ, Pettingell SL, Bearinger LH, Garwick AW, Oliphant JA, Plowman S, Resnick MD *et al*: Prime Time: sexual health outcomes at 24 months for a clinic-linked intervention to prevent pregnancy risk behaviors. *JAMA Pediatr* 2013, 167(4):333-340.
148. Lopez LM, Grey TW, Chen M, Tolley EE, Stockton LL: Theory-based interventions for contraception. *Cochrane Database Syst Rev* 2016(11).
149. Mack N, Crawford TJ, Guise JM, Chen M, Grey TW, Feldblum PJ, Stockton LL, Gallo MF: Strategies to improve adherence and continuation of shorter-term hormonal methods of contraception. *Cochrane Database Syst Rev* 2019(4).

150. Díez E, López MJ, Marí-Dell'Olmo M, Nebot L, Pérez G, Villalbi JR, Carreras R: Effects of a counselling intervention to improve contraception in deprived neighbourhoods: a randomized controlled trial. *Eur J Public Health* 2017, 28(1):10-15.
151. Whitaker AK, Quinn MT, Munroe E, Martins SL, Mistretta SQ, Gilliam ML: A motivational interviewing-based counseling intervention to increase postabortion uptake of contraception: a pilot randomized controlled trial. *Patient Educ Couns* 2016, 99(10):1663-1669.
152. Babalola S, Figueroa M-E, Krenn S: Association of mass media communication with contraceptive use in Sub-Saharan Africa: a meta-analysis of demographic and health surveys. *J Health Commun* 2017, 22(11):885-895.
153. Gibson DG, Tamrat T, Mehl G: The state of digital interventions for demand generation in low- and middle-income countries: considerations, emerging approaches, and research gaps. *Glob Health Sci Pract* 2018, 6(Supplement 1):S49-S60.
154. Oringanje C, Meremikwu MM, Eko H, Esu E, Meremikwu A, Ehiri JE: Interventions for preventing unintended pregnancies among adolescents. *Cochrane Database Syst Rev* 2016(2).
155. Subramanian L, Simon C, Daniel EE: Increasing contraceptive use among young married couples in Bihar, India: evidence from a decade of implementation of the PRACHAR project. *Glob Health Sci Pract* 2018, 6(2):330-344.
156. Lopez LM, Grey TW, Chen M, Denison J, Stuart G: Behavioral interventions for improving contraceptive use among women living with HIV. *Cochrane Database Syst Rev* 2016(8).
157. Ngure K, Heffron R, Mugo N, Irungu E, Celum C, Baeten J: Successful increase in contraceptive uptake among Kenyan HIV-1-serodiscordant couples enrolled in an HIV-1 prevention trial. *AIDS* 2009, 23 Suppl(1):S89-S95.
158. Davidson AS, Whitaker AK, Martins SL, Hill B, Kuhn C, Hagbom-Ma C, Gilliam M: Impact of a theory-based video on initiation of long-acting reversible contraception after abortion. *Am J Obstet Gynecol* 2015, 212(3):310.e311-317.
159. Sarnquist CC, Moyo P, Stranix-Chibanda L, Chipato T, Kang JL, Maldonado YA: Integrating family planning and prevention of mother to child HIV transmission in Zimbabwe. *Contraception* 2014, 89(3):209-214.
160. Black MM, Bentley ME, Papas MA, Oberlander S, Teti LO, McNary S, Le K, O'Connell M: Delaying second births among adolescent mothers: a randomized, controlled trial of a home-based mentoring program. *Pediatrics* 2006, 118(4):e1087-1099.
161. Stanton B, Cole M, Galbraith J, Li X, Pendleton S, Cottrel L, Marshall S, Wu Y, Kaljee L: Randomized trial of a parent intervention: parents can make a difference in long-term

- adolescent risk behaviors, perceptions, and knowledge. *Arch Pediatr Adolesc Med* 2004, 158(10):947-955.
162. Information and Communication Technology (ICT) Statistics  
<http://www.itu.int/en/ITU-D/Statistics/Pages/stat/default.aspx>. Accessed: 9 July 2019.
  163. L'Engle KL, Mangone ER, Parcesepe AM, Agarwal S, Ippoliti NB: Mobile phone interventions for adolescent sexual and reproductive health: a systematic review. *Pediatrics* 2016, 138(3):e20160884.
  164. Gibson DG, Ochieng B, Kagucia EW, Were J, Hayford K, Moulton LH, Levine OS, Odhiambo F, O'Brien KL, Feikin DR: Mobile phone-delivered reminders and incentives to improve childhood immunisation coverage and timeliness in Kenya (M-SIMU): a cluster randomised controlled trial. *Lancet Glob Health* 2017, 5(4):e428-e438.
  165. Thomas B, Closson EF, Biello K, Menon S, Navakodi P, Dhanalakshmi A, Mayer KH, Safren SA, Mimiaga MJ: Development and open pilot trial of an HIV-prevention intervention integrating mobile-phone technology for male sex workers in Chennai, India. *Arch Sex Behav* 2017, 46(4):1035-1046.
  166. Suri T, Jack W, Stoker TM: Documenting the birth of a financial economy. *Proc Natl Acad Sci U S A* 2012, 109(26):10257-10262.
  167. Bullen P: Operational challenges in the Cambodian mHealth revolution. *J Mob Technol Med* 2013, 2(2):20-23.
  168. Mangone ER, Lebrun V, Muessig KE: Mobile phone apps for the prevention of unintended pregnancy: a systematic review and content analysis. *JMIR Mhealth Uhealth* 2016, 4(1):e6.
  169. Smith C, Gold J, Ngo Thoai D, Sumpter C, Free C: Mobile phone-based interventions for improving contraception use. *Cochrane Database Syst Rev* 2015(6).
  170. Castano PM, Bynum JY, Andres R, Lara M, Westhoff C: Effect of daily text messages on oral contraceptive continuation: a randomized controlled trial. *Obstet Gynecol* 2012, 119(1):14-20.
  171. Trent M, Thompson C, Tomaszewski K: Text messaging support for urban adolescents and young adults using injectable contraception: outcomes of the DepoText pilot trial. *J Adolesc Health* 2015, 57(1):100-106.
  172. Smith C, Ngo TD, Gold J, Edwards P, Vannak U, Sokhey L, Machiyama K, Slaymaker E, Warnock R, McCarthy O *et al*: Effect of a mobile phone-based intervention on post-abortion contraception: a randomized controlled trial in Cambodia. *Bull World Health Organ* 2015, 93(12):842-850A.

173. Hou MY, Hurwitz S, Kavanagh E, Fortin J, Goldberg AB: Using daily text-message reminders to improve adherence with oral contraceptives: a randomized controlled trial. *Obstet Gynecol* 2010, 116(3):633-640.
174. Tsur L, Kozer E, Berkovitch M: The effect of drug consultation center guidance on contraceptive use among women using isotretinoin: a randomized, controlled study. *J Womens Health (Larchmt)* 2008, 17(4):579-584.
175. Rokicki S, Cohen J, Salomon JA, Fink G: Impact of a text-messaging program on adolescent reproductive health: a cluster-randomized trial in Ghana. *Am J Public Health* 2017, 107(2):298-305.
176. Harrington EK: Evaluation of an mHealth SMS dialogue strategy to meet women's and couples' postpartum contraceptive needs in Kenya (Mobile WACH XY): a randomized controlled trial [dissertation]. University of Washington; 2017.
177. Laidlaw R: The design, development and evaluation of an SMS contraceptive behaviour change intervention – a case study in Chikwawa, Malawi [dissertation]. 2018.
178. McCarthy OL, Zghayyer H, Stavridis A, Adada S, Ahamed I, Leurent B, Edwards P, Palmer M, Free C: A randomized controlled trial of an intervention delivered by mobile phone text message to increase the acceptability of effective contraception among young women in Palestine. *Trials* 2019, 20(1):228.
179. Johnson D, Juras R, Riley P, Chatterji M, Sloane P, Choi SK, Johns B: A randomized controlled trial of the impact of a family planning mHealth service on knowledge and use of contraception. *Contraception* 2017, 95(1):90-97.
180. Reiss K, Andersen K, Pearson E, Biswas K, Taleb F, Ngo TD, Hossain A, Barnard S, Smith C, Carpenter J *et al*: Unintended consequences of mHealth interactive voice messages promoting contraceptive use after menstrual regulation in Bangladesh: intimate partner violence results from a randomized controlled trial. *Glob Health Sci Pract* 2019, 7(3):386-403.
181. Chernick LS, Stockwell MS, Wu M, Castaño PM, Schnall R, Westhoff CL, Santelli J, Dayan PS: Texting to Increase Contraceptive Initiation Among Adolescents in the Emergency Department. *J Adolesc Health* 2017, 61(6):786-790.
182. Bull S, Devine S, Schmiede SJ, Pickard L, Campbell J, Shlay JC: Text messaging, teen outreach program, and sexual health behavior: a cluster randomized trial. *Am J Public Health* 2016, 106(S1):S117-S124.
183. Hebert LE, Hill BJ, Quinn M, Holl JL, Whitaker AK, Gilliam ML: Mobile contraceptive application use in a clinical setting in addition to standard contraceptive counseling: a randomized controlled trial. *Contraception* 2018, 98(4):281-287.

184. Sridhar A, Chen A, Forbes ER, Glik D: Mobile application for information on reversible contraception: a randomized controlled trial. *Am J Obstet Gynecol* 2015, 212(6):774 e771-777.
185. Taylor D, Lunny C, Lolić P, Warje O, Geldman J, Wong T, Gilbert M, Lester R, Ogilvie G: Effectiveness of text messaging interventions on prevention, detection, treatment, and knowledge outcomes for sexually transmitted infections (STIs)/HIV: a systematic review and meta-analysis. *Systematic Reviews* 2019, 8(1):12.
186. Burns K, Keating P, Free C: A systematic review of randomised control trials of sexual health interventions delivered by mobile technologies. *BMC Public Health* 2016, 16(1):778.
187. Suffoletto B, Akers A, McGinnis KA, Calabria J, Wiesenfeld HC, Clark DB: A sex risk reduction text-message program for young adult females discharged from the emergency department. *J Adolesc Health* 2013, 53(3):387-393.
188. Jones R, Hoover DR, Lacroix LJ: A randomized controlled trial of soap opera videos streamed to smartphones to reduce risk of sexually transmitted human immunodeficiency virus (HIV) in young urban African American women. *Nurs Outlook* 2013, 61(4):205-215.e203.
189. Lim MSC, Hocking JS, Aitken CK, Fairley CK, Jordan L, Lewis JA, Hellard ME: Impact of text and email messaging on the sexual health of young people: a randomised controlled trial. *J Epidemiol Community Health* 2012, 66(1):69-74.
190. Cornelius JB, Dmochowski J, Boyer C, St Lawrence J, Lightfoot M, Moore M: Text-messaging-enhanced HIV intervention for African American adolescents: a feasibility study. *J Assoc Nurses AIDS Care* 2013, 24(3):256-267.
191. Berenson AB, Rahman M: A randomized controlled study of two educational interventions on adherence with oral contraceptives and condoms. *Contraception* 2012, 86(6):716-724.
192. Gold J, Aitken CK, Dixon HG, Lim MSC, Gouillou M, Spelman T, Wakefield M, Hellard ME: A randomised controlled trial using mobile advertising to promote safer sex and sun safety to young people. *Health Educ Res* 2011, 26(5):782-794.
193. Lau PW, Lau EY, Wong del P, Ransdell L: A systematic review of information and communication technology-based interventions for promoting physical activity behavior change in children and adolescents. *J Med Internet Res* 2011, 13(3):e48.
194. Laidlaw R, Dixon D, Morse T, Beattie TK, Kumwenda S, Mpemberera G: Using participatory methods to design an mHealth intervention for a low income country, a case study in Chikwawa, Malawi. *BMC Med Inform Decis Mak* 2017, 17(1):98.

195. Maibach E, Cotton D: Moving people to behaviour change. In: *Designing Health Messages: Approaches from Communication Theory and Public Health Practice*. Edited by Maibach E, Parrott RL. Thousand Oaks: Sage publications; 1995.
196. McCarthy OL, Wazwaz O, Osorio Calderon V, Jado I, Saibov S, Stavridis A, López Gallardo J, Tokhirov R, Adada S, Huaynoca S *et al*: Development of an intervention delivered by mobile phone aimed at decreasing unintended pregnancy among young people in three lower middle income countries. *BMC Public Health* 2018, 18(1):576.
197. L'Engle KL, Vahdat HL, Ndakidemi E, Lasway C, Zan T: Evaluating feasibility, reach and potential impact of a text message family planning information service in Tanzania. *Contraception* 2013, 87(2):251-256.
198. Vahdat HL, L'Engle KL, Plourde KF, Magaria L, Olawo A: There are some questions you may not ask in a clinic: providing contraception information to young people in Kenya using SMS. *Int J Gynaecol Obstet* 2013, 123 Suppl:e2-6.
199. Baum F, Newman L, Biedrzycki K: Vicious cycles: digital technologies and determinants of health in Australia. *Health Promot Int* 2014, 29(2):349-360.
200. The World Bank data: Kenya <https://data.worldbank.org/country/kenya>. Accessed: 25 September.
201. NASCOP: Kenya most at risk populations size estimate consensus report. Nairobi: National AIDS and STI Control Programme, Government of Kenya; 2013.
202. Vandepitte J, Lyerla R, Dallabetta G, Crabbé F, Alary M, Buvé A: Estimates of the number of female sex workers in different regions of the world. *Sex Transm Infect* 2006, 82 Suppl 3:iii18-25.
203. Khalid FJ, Hamad FM, Othman AA, Khatib AM, Mohamed S, Ali A, Dahoma MJ: Estimating the number of people who inject drugs, female sex workers, and men who have sex with men, Unguja Island, Zanzibar: results and synthesis of multiple methods. *AIDS Behav* 2014, 18 Suppl 1:S25-31.
204. Konstant TL, Rangasami J, Stacey MJ, Stewart ML, Nogoduka C: Estimating the number of sex workers in South Africa: rapid population size estimation. *AIDS Behav* 2015, 19(1):3-15.
205. NACC: Kenya national AIDS strategic plan 2009-2013: delivering on universal access to services. Nairobi: National AIDS Control Council; 2009.  
[http://www.nationalplanningcycles.org/sites/default/files/country\\_docs/Kenya/kenya\\_national\\_hiv\\_aids\\_strategic\\_plan\\_2009-2013.pdf](http://www.nationalplanningcycles.org/sites/default/files/country_docs/Kenya/kenya_national_hiv_aids_strategic_plan_2009-2013.pdf).
206. NACC: Kenya AIDS strategic framework 2014/15-2018/19. Nairobi: National AIDS Control Council; 2016.

207. Bhattacharjee P, Musyoki HK, Becker M, Musimbi J, Kaosa S, Kioko J, Mishra S, Isac SK, Moses S, Blanchard JF: HIV prevention programme cascades: insights from HIV programme monitoring for female sex workers in Kenya. *J Int AIDS Soc* 2019, 22(S4):e25311.
208. Bhattacharjee P, Musyoki H, Prakash R, Malaba S, Dallabetta G, Wheeler T, Moses S, Isac S, Steen R: Micro-planning at scale with key populations in Kenya: optimising peer educator ratios for programme outreach and HIV/STI service utilisation. *PLoS ONE* 2018, 13(11):e0205056.
209. Scorgie F, Vasey K, Harper E, Richter M, Nare P, Maseko S, Chersich MF: Human rights abuses and collective resilience among sex workers in four African countries: a qualitative study. *Global Health* 2013, 9(1):33.
210. Cheuk E, Isac S, Musyoki H, Pickles M, Bhattacharjee P, Gichangi P, Lorway R, Mishra S, Blanchard J, Becker M: Informing HIV prevention programs for adolescent girls and young women: a modified approach to programmatic mapping and key population size estimation. *JMIR Public Health Surveill* 2019, 5(2):e11196-e11196.
211. Ministry of Public Health and Sanitation: National guidelines for HIV/STI programs for sex workers. Nairobi, Kenya; 2010.
212. Okal J, Stadler J, Ombidi W, Jao I, Luchters S, Temmerman M, Chersich MF: Secrecy, disclosure and accidental discovery: perspectives of diaphragm users in Mombasa, Kenya. *Cult Health Sex* 2008, 10(1):13-26.
213. Wiki Voyage: Mombasa <https://en.wikivoyage.org/wiki/Mombasa>. Accessed: 25 September.
214. NACC: Kenya HIV prevention response and modes of transmission analysis, final report. Nairobi: National AIDS Control Council; 2009.  
<http://siteresources.worldbank.org/INTHIVAIDS/Resources/375798-1103037153392/KenyaMOT22March09Final.pdf>.
215. NASCOP: National guidelines for HIV/STI programming with key populations. Nairobi: National AIDS and STI Control Programme, Government of Kenya; 2014.  
<http://www.icop.or.ke/wpcontent/uploads/2016/10/KP-National-Guidelines-2014-NASCOP.pdf>.
216. Blacker J, Opiyo C, Jasseh M, Sloggett A, Ssekamatte-Ssebuliba J: Fertility in Kenya and Uganda: a comparative study of trends and determinants. *Population Studies* 2005, 59(3):355-373.
217. Bongaarts J, Hardee K: The role of public-sector family planning programs in meeting the demand for contraception in Sub-Saharan Africa. *Int Perspect Sex Reprod Health* 2017.

218. Askew I, Maggwa N, Obare F: Fertility transitions in Ghana and Kenya: trends, determinants, and implications for policy and programs. *Popul Dev Rev* 2017, 43(S1):289-307.
219. Crichton J: Changing fortunes: analysis of fluctuating policy space for family planning in Kenya. *Health Policy Plan* 2008, 23(5):339-350.
220. Fotso JC, Speizer IS, Mukiira C, Kizito P, Lumumba V: Closing the poor-rich gap in contraceptive use in urban Kenya: are family planning programs increasingly reaching the urban poor? *Int J Equity Health* 2013, 12(1):71.
221. Benson A, Calhoun LM, Corroon M, Lance P, O'Hara R, Otsola J, Speizer IS, Winston J: Longitudinal evaluation of the Tupange urban family planning program in Kenya. *Int Perspect Sex Reprod Health* 2017, 43(2):75-87.
222. Kyalo J, Jurczynska K, Kundu F: ImpactNOW application in Kenya: policy brief. Washington: Health Policy Project & National Council for Population and Development; 2015.
223. Government of Kenya: Family Planning 2020 commitment. FP2020; 2017. <https://www.familyplanning2020.org/kenya>.
224. Ministry of Health: Kenya national family planning costing implementation plan 2017-2020. 2017.
225. PMA2020: PMA2016/Kenya-R5: family planning brief. *Country reports - Kenya*. Performance Monitoring and Accountability 2020; 2017.
226. NASCOP: National implementation guidelines for HIV and STI programming among young key populations. Nairobi: National AIDS & STI Control Programme; 2018.
227. Mumah J, Kabiru C, Mukiira C, Brinton J, Mutua M, Izugbara C, Birungi H, Askew I: Unintended pregnancies in Kenya: a country profile. STEP UP research report. Nairobi: African Population and Health Research Center; 2014.
228. Programme NAASC: Standards for peer-education and outreach programs for sex workers. Kenya Ministry of Public Health and Sanitation; 2010. <https://www.bhesp.org/index.php/2015-08-24-17-52-33?download=2:standards-for-peer-education-and-outreach-program-for-sex-workers>.
229. McClarty LM, Bhattacharjee P, Isac S, Emmanuel F, Kioko J, Njiraini M, Gichangi P, Okoth CD, Musimbi-Mbole J, Blanchard JF *et al*: Key programme science lessons from an HIV prevention 'Learning Site' for sex workers in Mombasa, Kenya. *Sex Transm Infect* 2018, 94(5):346-352.
230. Luchters S, Chersich MF, Rinyiru A, Barasa M-S, King'ola N, Mandaliya K, Bosire W, Wambugu S, Mwarogo P, Temmerman M: Impact of five years of peer-mediated



- interventions on sexual behavior and sexually transmitted infections among female sex workers in Mombasa, Kenya. *BMC Public Health* 2008, 8:143-143.
231. Vielot N, Hudgens MG, Mugo N, Chitwa M, Kimani J, Smith J: The role of chlamydia trachomatis in high-risk human papillomavirus persistence among female sex workers in Nairobi, Kenya. *Sex Transm Dis* 2015, 42(6):305-311.
  232. PMA2020: PMA2017/Kenya-R6: family planning brief. *Country reports - Kenya*. Performance Monitoring and Accountability 2020; 2018.
  233. Ministry of Health: National family planning costed implementation plan 2012-2016. 2012.
  234. Rattan J, Noznesky E, Curry DW, Galavotti C, Hwang S, Rodriguez M: Rapid contraceptive uptake and changing method mix with high use of long-acting reversible contraceptives in crisis-affected populations in Chad and the Democratic Republic of the Congo. *Glob Health Sci Pract* 2016, 4(Supplement 2):S5-S20.
  235. Cleland J, Ali M, Benova L, Daniele M: The promotion of intrauterine contraception in low- and middle-income countries: a narrative review. *Contraception* 2017, 95(6):519-528.
  236. Hubacher D: The levonorgestrel intrauterine system: reasons to expand access to the public sector of Africa. *Glob Health Sci Pract* 2015, 3(4):532-537.
  237. Hubacher D, Masaba R, Manduku CK, Chen M, Veena V: The levonorgestrel intrauterine system: cohort study to assess satisfaction in a postpartum population in Kenya. *Contraception* 2015, 91(4):295-300.
  238. Robertson AM, Syvertsen JL, Rangel MG, Staines HS, Morris M, Patterson TL, Ulibarri MD, Strathdee SA: Concurrent sexual partnerships among female sex workers and their non-commercial male partners in Tijuana and Ciudad Juarez, Mexico. *Sex Transm Infect* 2013, 89(4):330-332.
  239. Pop-Eleches C, Thirumurthy H, Habyarimana JP, Zivin JG, Goldstein MP, de Walque D, MacKeen L, Haberer J, Kimaiyo S, Sidle J *et al*: Mobile phone technologies improve adherence to antiretroviral treatment in a resource-limited setting: a randomized controlled trial of text message reminders. *AIDS* 2011, 25(6):825-834.
  240. Haynes MC, Ryan N, Saleh M, Winkel AF, Ades V: Contraceptive knowledge assessment: validity and reliability of a novel contraceptive research tool. *Contraception* 2017, 95(2):190-197.
  241. Harrington EK, Drake AL, Matemo D, Ronen K, Osoti AO, John-Stewart G, Kinuthia J, Unger JA: An mHealth SMS intervention on postpartum contraceptive use among women and couples in Kenya: a randomized controlled trial. *Am J Public Health* 2019, 109(6):934-941.

242. Ahmed K, Baeten JM, Beksinska M, Bekker L-G, Bukusi EA, Donnell D, Gichangi PB, Heller KB, Hofmeyr GJ, Justman J *et al*: HIV incidence among women using intramuscular depot medroxyprogesterone acetate, a copper intrauterine device, or a levonorgestrel implant for contraception: a randomised, multicentre, open-label trial. *Lancet* 2019, 394(10195):303-313.
243. Higgins JA, Kramer RD, Ryder KM: Provider bias in long-acting reversible contraception (LARC) promotion and removal: perceptions of young adult women. *Am J Public Health* 2016, 106(11):1932-1937.
244. Stuart GS, Grimes DA: Social desirability bias in family planning studies: a neglected problem. *Contraception* 2009, 80(2):108-112.
245. Jarvis GE: Early embryo mortality in natural human reproduction: what the data say. *F1000Res* 2016, 5(2765):2765.
246. Barrett G, Wellings K: What is a 'planned' pregnancy? Empirical data from a British study. *Soc Sci Med* 2002, 55(4):545-557.
247. Moreau C, Bohet A, Le Guen M, Loilier AR, Bajos N: Unplanned or unwanted? A randomized study of national estimates of pregnancy intentions. *Fertil Steril* 2014, 102(6):1663-1670.
248. Kavanaugh ML, Schwarz EB: Prospective assessment of pregnancy intentions using a single- versus a multi-item measure. *Perspect Sex Reprod Health* 2009, 41(4):238-243.
249. Barrett G, Smith SC, Wellings K: Conceptualisation, development, and evaluation of a measure of unplanned pregnancy. *J Epidemiol Community Health* 2004, 58(5):426-433.
250. Rocca CH, Krishnan S, Barrett G, Wilson M: Measuring pregnancy planning: an assessment of the London Measure of Unplanned Pregnancy among urban, south Indian women. *Demographic Research* 2010, 23:293-333.
251. Hall JA, Barrett G, Copas A, Stephenson J: London Measure of Unplanned Pregnancy: guidance for its use as an outcome measure. *Patient Relat Outcome Meas* 2017, 8:43-56.
252. Reed E, Gupta J, Biradavolu M, Devireddy V, Blankenship KM: The role of housing in determining HIV risk among female sex workers in Andhra Pradesh, India: considering women's life contexts. *Soc Sci Med* 2011, 72(5):710-716.
253. Reed E, Khoshnood K, Blankenship KM, Fisher CB: Confidentiality, privacy, and respect: experiences of female sex workers participating in HIV Research in Andhra Pradesh, India. *J Empir Res Hum Res Ethics* 2014, 9(1):19-28.
254. Ramesh BM, Moses S, Washington R, Isac S, Mohapatra B, Mahagaonkar SB, Adhikary R, Brahman GNV, Paranjape RS, Subramanian T *et al*: Determinants of HIV prevalence among female sex workers in four south Indian states: analysis of cross-sectional surveys in twenty-three districts. *AIDS* 2008, 22 Suppl(5):S35-S44.

255. Page K, Stein E, Sansothy N, Evans J, Couture MC, Sichan K, Cockroft M, Mooney-Somers J, Phlong P, Kaldor J *et al*: Sex work and HIV in Cambodia: trajectories of risk and disease in two cohorts of high-risk young women in Phnom Penh, Cambodia. *BMJ Open* 2013, 3(9):e003095.
256. Bazzi AR, Rangel G, Martinez G, Ulibarri MD, Syvertsen JL, Bazzi SA, Roesch S, Pines HA, Strathdee SA: Incidence and predictors of HIV and sexually transmitted infections among female sex workers and their intimate male partners in northern Mexico: a longitudinal, multilevel study. *Am J Epidemiol* 2015, 181(9):723-731.
257. Liu J, Calzavara L, Mendelsohn JB, O'Leary A, Kang L, Pan Q, Myers T, Ren J, Cha Y, Shi G *et al*: Impact evaluation of a community-based intervention to reduce risky sexual behaviour in female sex workers in Shanghai, China. *BMC Public Health* 2015, 15:147.
258. Gold J, Hellard ME, Lim MS, Dixon H, Wakefield M, Aitken CK: Public-private partnerships for health promotion. *Am J Health Educ* 2013, 43(4):250-253.
259. LINKAGES: LINKAGES Kenya: summary of achievements, March 2016–October 2019. Durham (NC): FHI 360; 2019.
260. Brody C, Tuot S, Chhoun P, Swendenman D, Kaplan KC, Yi S: Mobile Link - a theory-based messaging intervention for improving sexual and reproductive health of female entertainment workers in Cambodia: study protocol of a randomized controlled trial. *Trials* 2018, 19(1):235.
261. Amo-Adjei J, Mutua M, Athero S, Izugbara C, Ezech A: Improving family planning services delivery and uptake: experiences from the “Reversing the Stall in Fertility Decline in Western Kenya Project”. *BMC Res Notes* 2017, 10(1):498.
262. Aseyo RE, Mumma J, Scott K, Nelima D, Davis E, Baker KK, Cumming O, Dreibelbis R: Realities and experiences of community health volunteers as agents for behaviour change: evidence from an informal urban settlement in Kisumu, Kenya. *Hum Resour Health* 2018, 16(1):53.
263. Ampt FH, L'Engle K, Lim MS, Plourde KF, Mangone E, Mukanya CM, Gichangi P, Manguro G, Hellard M, Stoové M *et al*: “I now know I’m the boss”: development of a mobile phone-based sexual and reproductive health intervention for female sex workers in Kenya. *JMIR Mhealth Uhealth* (in press).
264. Weiner R, Fineberg M, Dube B, Goswami P, Mathew S, Dallabetta G, Johnson S: Using a cascade approach to assess condom uptake in female sex workers in India: a review of the Avahan data. *BMC Public Health* 2018, 18(1):897-897.
265. Achilles SL, Hendrix CW, Poloyac SM, Hoesley CJ, Peda M, Gundacker H, Mensch BS, Marzinke MA, Devlin B, Nel AM *et al*: Safety and pharmacokinetics of dapivirine and levonorgestrel vaginal rings for multipurpose prevention of HIV and pregnancy

- (Abstract OA12.02LB). *HIV Research for Prevention (HIVR4P): October 21-25 2018; Madrid, Spain; 2018.*
266. Mazza D, Watson CJ, Taft A, Lucke J, McGeechan K, Haas M, McNamee K, Peipert JF, Black KI: Increasing long acting reversible contraceptives: the Australian Contraceptive ChOice pRoject (ACCORD) cluster randomized trial. *Am J Obstet Gynecol* 2019.
  267. Harper CC, Rocca CH, Thompson KM, Morfesis J, Goodman S, Darney PD, Westhoff CL, Speidel JJ: Reductions in pregnancy rates in the USA with long-acting reversible contraception: a cluster randomised trial. *Lancet* 2015.
  268. Rahman M, Haider MM, Curtis SL, Lance PM: The Mayer Hashi large-scale program to increase use of long-acting reversible contraceptives and permanent methods in Bangladesh: explaining the disappointing results. An outcome and process evaluation. *Glob Health Sci Pract* 2016, 4(Supplement 2):S122-S139.
  269. Blumenthal PD, Shah NM, Jain K, Saunders A, Clemente C, Lucas B, Jafa K, Eber M: Revitalizing long-acting reversible contraceptives in settings with high unmet need: a multicountry experience matching demand creation and service delivery. *Contraception* 2013, 87(2):170-175.
  270. Neukom J, Chilambwe J, Mkandawire J, Mbewe RK, Hubacher D: Dedicated providers of long-acting reversible contraception: new approach in Zambia. *Contraception* 2011, 83(5):447-452.
  271. Castle S, Schroffel H, Nzau Mvuezolo JJ, Mupenda B, Mumbere J, Shapiro R: Successful programmatic approaches to facilitating IUD uptake: CARE's experience in DRC. *BMC Womens Health* 2019, 19(1):104.
  272. Palinkas LA, Robertson AM, Syvertsen JL, Hernandez DO, Ulibarri MD, Rangel MG, Martinex G, Strathdee SA: Client perspectives on design and implementation of a couples-based intervention to reduce sexual and drug risk behaviors among female sex workers and their noncommercial partners in Tijuana and Ciudad Juarez, Mexico. *AIDS Behav* 2014, 18(3):583-594.
  273. Barker G, Ricardo C, Nascimento M: Engaging men and boys in changing gender-based inequity in health: evidence from programme interventions. Geneva: World Health Organization; 2007.
  274. Shattuck D, Kerner B, Gilles K, Hartmann M, Ng'ombe T, Guest G: Encouraging contraceptive uptake by motivating men to communicate about family planning: the Malawi Male Motivator project. *Am J Public Health* 2011, 101(6):1089-1095.
  275. Jewkes R, Nduna M, Levin J, Jama N, Dunkle K, Puren A, Duvvury N: Impact of stepping stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial. *BMJ* 2008, 337:a506.

276. Valente PK, Mantell JE, Masvawure TB, Tocco JU, Restar AJ, Gichangi P, Chabeda SV, Lafort Y, Sandfort TG: "I couldn't afford to resist": condom negotiations between male sex workers and male clients in Mombasa, Kenya. *AIDS Behav* 2019.
277. Fehrenbacher AE, Chowdhury D, Jana S, Ray P, Dey B, Ghose T, Swendeman D: Consistent condom use by married and cohabiting female sex workers in India: investigating relational norms with commercial versus intimate partners. *AIDS Behav* 2018, 22(12):4034-4047.
278. UNAIDS: HIV Prevention 2020 Road Map — Accelerating HIV prevention to reduce new infections by 75%. Geneva: Joint United Nations Programme on HIV/AIDS; 2017.
279. World Health Organization: Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations – 2016 update. Geneva: World Health Organization; 2016.
280. Burke HM, Chen M, Buluzi M, Fuchs R, Wevill S, Venkatasubramanian L, Dal Santo L, Ngwira B: Effect of self-administration versus provider-administered injection of subcutaneous depot medroxyprogesterone acetate on continuation rates in Malawi: a randomised controlled trial. *Lancet Glob Health* 2018, 6(5):e568-e578.
281. Bowring AL, Ampt FH, Schwartz S, Stoové MA, Luchters S, Baral S, Hellard M: HIV pre-exposure prophylaxis for female sex workers: ensuring women's family planning needs are not left behind. *J Int AIDS Soc* (in press).
282. Yam EA, Kidanu A, Burnett-Zieman B, Pilgrim N, Okal J, Bekele A, Gudeta D, Caswell G: Pregnancy experiences of female sex workers in Adama city, Ethiopia: complexity of partner relationships and pregnancy intentions. *Stud Fam Plann* 2017, 48(2):107-119.
283. UNFPA: The Glion Call to Action on Family Planning and HIV/AIDS in Women and Children, 3–5 May 2004. United Nations Population Fund; 2004.  
<https://www.unfpa.org/resources/glion-call-action-family-planning-and-hivaids-women-and-children#>.
284. Haberlen SA, Narasimhan M, Beres LK, Kennedy CE: Integration of family planning services into HIV care and treatment services: a systematic review. *Stud Fam Plann* 2017, 48(2):153-177.

## Appendices

### Appendix 1: WHISPER intervention messages

#### Push messages (includes role model stories)

Message number	Message	Day and time
Enrolment	Karibu mrembo! Register for WHISPER or SHOUT by replying '222' to this number. Try it now!	During enrolment
Month 1 <sup>6</sup>		
1	Welcome to WHISPER! WHISPER will help you take control of your life and your body by sending you inspiring information about reproductive health every week!	Mon 11am
2	Save this number as 'WHISPER' in your mobile phone contacts so you can always see who these important messages are from!	Wed 11am
3	We have something important to tell you. Family planning lets you have sex without getting pregnant. That's what WHISPER is all about.	Fri 4pm
4	If you are having sex and not using a family planning (FP) method you are at risk of becoming pregnant. WHISPER advice: Use FP! Add a condom to prevent HIV!	Mon 11am
5	Stuck on holiday with a client and no protection? Consider a longer acting FP method like IUD (coil) or implant to avoid a last minute crisis. Hugs, WHISPER	Wed 11am
6	Hi beautiful, short-term family planning is daily pills and the 3-month injectable. Implants and the IUD (coil) are longer-term and last 3 years or more-wow!	Fri 4pm
7	Condoms (male or female) protect against both pregnancy and STIs, including HIV. Use a condom to prevent STIs even if you use another family planning method.	Mon 11am
8	Some women don't have any side effects from FP; those who do find they are minor and go away quickly. Take control, find an FP method that works for you.	Wed 11am
9	Abortion is ending pregnancy before the baby is born. Abortion is unsafe when performed by non-skilled people. Use FP to avoid unintended pregnancy.	Fri 4pm
10	Did you know that a woman's period (bleeding cycle) is not regular? For this reason, counting days is not the best method to prevent pregnancy. Hugs and kisses!	Mon 11am
11	Hey, love. Long-term family planning (coil and implant) prevents pregnancy better than counting days and emergency contraception (e-pills).	Wed 11am
12	You can send messages with special codes to WHISPER to get more information. Try it now - it's free! Press reply, type 333 in your message, and press send.	Fri 4pm

<sup>6</sup> Intervention 'months' are of four weeks duration, not calendar months.

Month 2		
13	WHISPER Alert: Reply '00' to WHISPER at any time for FREE information about family planning (FP) and health services nearby that can help you take control!	Mon 11am
14	Ever thought about talking to your man about using family planning? Talking about each other's needs in the bedroom can make sex more fun and keep you safe ;-)	Wed 11am
15	Everyone, no matter your age, sex, gender, marital status, religious beliefs, or any other differences has the right to use family planning.	Fri 4pm
16	Having trouble replying to WHISPER? Try sending a text message to the number 22770. Type the code 00 in your message to get to the WHISPER menu!	Mon 11am
17	Karibu tujienjoy! I'm Ciku from WHISPER. I'm new to town: I left my village because my husband drank a lot and was violent. I might be young, but I know I deserve better. I have some mpenzi who help me out but I've had a couple of scares at the clinic, if you know what I mean. I need a better way to prevent pregnancy!	Wed 11am
18	WHISPER Alert: If you experience violence like Ciku and need urgent help, call 1195 (free) or go to Coast General Hospital emergency. Reply 110 for more info	Fri 4pm
19	Jambo! Ciku from WHISPER! I've been counting days and sometimes using condoms or e-pills with washefa, but keeping track is hard! I've gone to the clinic for STIs and pregnancy scares 4 times in 6 months! BUT I heard of a method called a contraceptive implant that is easy and prevents pregnancy for 3 years! More soon!	Mon 11am
20	Hello dear! Ciku from WHISPER again. I got my new implant! It's perfect for me because it lasts for at least 3 years but if I want a baby earlier, I can have it removed anytime. It works well so I won't get pregnant. Plus the nurse said it might stop or reduce my period. Now I can stay fresh and work whenever I want.	Thurs 11am
21	It's Ciku from WHISPER! I've felt so great the last week with my implant and business is good. I have also started using condoms with all guys and I just feel more safe, happy, and in control. I am going to save so much time and money now that I don't have to go to the clinic so often. Are you ready to take control?	Mon 11am
22	WHISPER Alert: Want to take control like Ciku? You can get family planning methods and condoms FREE or LOW COST at many health centres. Reply 100 for details	Thurs 11am
Month 3		
23	The IUD (Coil) and implants are the best methods to prevent pregnancy. They are private, long-lasting (3 years or more!), and don't interfere with sex :-)	Mon 11am
24	No matter what family planning method you use, always carry lots of condoms with you for dual protection against HIV/STIs AND pregnancy. For FP info reply 00	Wed 11am
25	Hi Dear! Use a new condom every time but only one at a time! Condoms are easy to find, cheap and easy to use with practice. Cheers! Reply 71 for more on condoms	Fri 4pm

26	Husband or boronga? No matter who they are, they should be wearing a condom if they want to be with you ;-) Hugs and kisses from WHISPER	Mon 11am
27	Hello beautiful, invest in your body—protect yourself from pregnancy, HIV and STIs by using a condom correctly every time, along with a long-term FP method.	Wed 11am
28	Female condoms can be put in up to 8 hours before sex. They protect against HIV, STI and pregnancy. Female and male condoms shouldn't be used at the same time	Fri 4pm
29	Hey Mrembo, Did you know anal sex increases your risk of HIV and STI infection? Use a condom and lubricant (KY Jelly) every time to protect yourself. Hugs!	Mon 11am
30	Being dry can make sex painful, cause a condom burst, and increase the risk of HIV and STIs. Use lubricant (KY Jelly) with a condom for comfort and safety!	Wed 11am
31	Some family planning methods can help make your period lighter; or stop your bleeding altogether. This is not unhealthy and some women really like it ;-)	Fri 4pm
32	Family planning won't cause cancer, infertility, or harm a baby if you're already pregnant. It's usually easy to get pregnant after you stop FP. Hugs, WHISPER	Mon 11am
33	Most women who use family planning continue to have a normal sex drive. If you find one method leaves you without sexual appetite, there are many other options	Wed 11am
34	Most family planning methods won't cause weight gain. If you are unhappy with your method for any reason you can try a different method. Love from WHISPER	Fri 4pm
Month 4		
35	WHISPER Alert: Would you like to know more about side effects of family planning? Reply 00 to get informed about different methods.	Mon 11am
36	Hey girl, I'm Sandra from WHISPER. I work at a make-up kiosk and take washefa on the side to support myself and my little boy. I hope to one day have my own shop—but girl, it takes money. My mpenzi Jay helps out sometimes. He's cool, but he can be a pain AND he wants a baby. I'm not ready for another baby right now!	Thurs 11am
37	Girlfriend, it's Sandra from WHISPER. I have had such a bad day. I had a rough weekend with lots of washefa and am in a lot of pain. Then Jay comes over this morning and starts harassing me because he found my daily pills and thinks they are unnatural. I know that's a rumor and that pills are perfectly safe, but sometimes I forget to take them on time and others, like Jay, might find them. There has to be a better way to prevent pregnancy! I gotta talk to my peer educator.	Mon 11am
38	Hey, it's Sandra from WHISPER again. My peer educator thinks I have an STI :-( She told me that STIs can cause pain that I thought was from rough sex. She told me to go to the drop-in center and that they will give me medication. She also said that antibiotics decrease the power of daily pills so I should use condoms as a backup method. I know I should use condoms every time I have sex to prevent STIs/HIV, but I am nervous to talk to Jay about using them. More soon.	Thurs 11am



39	WHISPER Alert: Sandra was nervous about asking her mpenzi to use condoms. Do you feel the same? Talk to a peer educator, or go to a drop-in centre - reply 160	Mon 11am
40	It's Sandra, from WHISPER. I went to the drop-in center last week and I did have an STI. I told the nurse that I was worried about talking to my partner about using condoms. She suggested that I try to make condoms more fun, and gave me flavored ones to try. She also said that there are FP methods that are private, like the contraceptive implant or coil. She said the implant works better than the pill, antibiotics will not reduce its power to prevent pregnancy, and it can prevent pregnancy for 3 to 5 years. I decided to try the implant. Insertion in my arm was quick and easy. I learned so much over the past few weeks! Kama kawa.	Thurs 11am
41	It's Sandra! Good news and bad news: good news is that my implant has been great and is my secret way to prevent pregnancy! Bad news is that once I had the implant, I didn't make Jay wear condoms and now I have ANOTHER STI. This boy is trouble. So this week we are both going to get tested and treated and from now on, I will insist on using condoms. My health is important and I don't have time to go to the clinic this often! Plus some STIs like HIV and HPV can't be cured and I have my little boy to think of. A man using condoms is showing me respect. I am empowered, in charge, and so sexy! Kisses and hugs, Sandra	Mon 11am
42	WHISPER Alert: Had sex without a condom like Sandra did? Take medicine called PEP within 72h to help prevent HIV. Reply 100 to find services that provide PEP.	Thurs 11am
Month 5		
43	Hi love, implants are small rods placed in a woman's arm. They are private, prevent pregnancy for 3-5 years and can be removed at any time. For more reply 11.	Mon 11am
44	Karibu mpenzi, IUD (coil) is a small device placed inside the womb by a health care provider. It can prevent pregnancy for up to 12 years! Isn't this amazing!	Wed 11am
45	If you want to get pregnant you can have the IUD (coil) removed at any time and can become pregnant with no delay. For more reply 21. Hugs and kisses, WHISPER!	Fri 4pm
46	Chonjo, did you know that IUDs (coil) can be used as emergency family planning? Get an IUD within 5 days of unprotected sex and it lasts for up to 12 years!	Mon 11am
47	If you have an IUD (coil) your partner will not be able to feel it and it won't move around in your body...no matter how big he is ;-). For more facts, reply 25	Wed 11am
48	Government health facilities provide IUDs, implants and other FP methods at low cost. For a list of government health centres near you, reply 150	Fri 4pm
49	Hi love, Drinking too much can lead to bad decisions, and problems with washefa. Drink less to save money and reduce drama. Stay sober and in control.	Mon 11am
50	Staying sober can help you take better care of your children, remember to use family planning, and avoid financial problems. It's better for your health. Hugs!	Wed 11am

51	Drinking less will keep you safer with washefa, help you negotiate a better price, get paid, and avoid getting robbed. Stay in control and keep your money.	Fri 4pm
52	Alcohol affects your emotions and makes it more likely that you will get into a fight. Stay sober, stay smart, stay safe. Love, WHISPER	Mon 11am
53	Don't accept alcohol or drugs as payment for sex. Remember that women get drunk faster than men and a drunk washefa takes a long time—No one wants that.	Wed 11am
54	You can reduce your drinking: ask for beer bottles filled with water, add water to mixed drinks, secretly dump some out, drink soda, drink slow. WHISPER.	Fri 4pm
Month 6		
55	Girl, it's Lynette from WHISPER. I have a hangover. I went out last night and it got way out of hand. I went to my usual bar and met a guy. I wasn't really interested, but he bought me drinks and I lost count. Later he asked to go for a shot. He seemed like bad news, but I wasn't thinking straight and so I said yes.....	Mon 11am
56	Lynette here...so about that bad news guy- I went with him and it was bad. He didn't use a condom, then took all my money when I was passed out. I had to beg a hotel guy for cash for the matatu. Now I am short on rent and worried about being pregnant and STIs. Not worth it, right?! I need a smarter strategy for next time. I've heard female condoms are good because you can put them in before going out and you don't have to rely on a guy. I also need to think about my drinking.	Thurs 11am
57	WHISPER Alert: It sounds like Lynette needs a backup plan. Reply 66 to learn about female condoms and 61 for emergency contraception (e-pills)	Mon 11am
58	Hey girl, Lynette again. I went to the pharmacist. He suggested a longer lasting family planning method like a coil. I have two kids already and am not ready for another one, so I listened up. He also gave me emergency FP (e-pills) and female condoms. Girlfriend! I am thinking about the coil. I can get it inserted by a health care provider at the clinic, and it can last 12 years! A peer educator also gave me the name of an alcohol counselor, to help me manage my drinking.	Thurs 11am
59	What's up, it's Lynette from WHISPER. I decided to make an appointment to get the coil. I went to the clinic and they gave me STI treatment, just in case, and then gave me the coil. It was fast and easy. I told friends about the shady washefa and my new coil. We also made a deal with the bartender at our usual hang out to bring us beer bottles filled with water. That way we can share the money the washefa is paying for beer and I can stay smart. Cheers to being in control!	Mon 11am
60	WHISPER Alert: Be smart like Lynette - find out more about the coil (IUD) by replying 21. For help with drinking, visit a health centre or ICRH drop-in centre.	Wed 11am
61	Great work girl, you've been part of WHISPER for almost 6 months now! Soon it will be time for your next interview and free tests. Check the white card we gave you to see the appointment date. Need more info? Call or text your friendly mobiliser on 0721858325	Fri 4pm

	(Chaani) or 0721935040 (Kisauni).	
62	WHISPER says: You should get tested for HIV every 3 months. HIV can take 3 months to be detected. Talk to a peer educator about your HIV risk. Hugs!	Mon 11am
63	Mrembo, kumbuka kurudi for your 6 month WHISPER visit. You'll have an interview and free tests, and we'll give you refreshments and money for transport. Cheers!	Wed 11am
64	Did you know you can take a rapid test for HIV ? You get the result straight away so you don't have to come back later! Reply 100 for services that do testing	Fri 4pm
Month 7		
65	Hi love. If you are living with HIV it is important to use condoms every time you have vaginal, oral, or anal sex for your health and your partners' health.	Mon 11am
66	Hey girl, have you come in for your 6-month WHISPER interview yet? We know you're busy, but ni muhimu and we can't do this without you! Any problems, call or text 0721858325 for Chaani, or 0721935040 for Kisauni.	Thurs 11am
67	People with HIV often lead normal lives by taking medicines called antiretrovirals (ARV). People on ARV can still transmit HIV, so condoms are still needed.	Mon 11am
68	Some people think herbs will prevent or cure HIV. This is not true. The only way to treat HIV is with ARVs (vidonge, wala nju, patco). Love from WHISPER	Thurs 11am
69	If you are taking the daily pill, set an alarm on your phone to help you remember to take it at the same time every day. Want to know more about pills? Reply 51	Mon 11am
70	Daily FP pills can reduce menstrual cramps, heavy periods, and pimples. When you are ready to get pregnant you can stop the pills any time. J Hugs, WHISPER	Wed 11am
71	Hello beautiful, carry daily pills with you wherever you go. Put them in a makeup bag with your condoms so you'll be hot and ready to go ;-)	Fri 4pm
72	Start new packs of daily pills on time. If you miss a pill, take it as soon as you remember and keep using condoms. For more advice on missed pills, reply 56	Mon 11am
73	Vomiting, diarrhea, and some medicines can make daily pills not work so well. If you use daily pills and are sick or taking medicine, use a backup FP method.	Wed 11am
74	Chonjo, the injection (Depo) is given in the arm or hip every three months by a provider to prevent pregnancy. Another good family planning method!	Fri 4pm
Month 8		
75	Injections are private, safe, and last for three months ;-). It is important to get injections on time to reduce the risk of pregnancy! Reply 41 to find out more	Mon 11am
76	Hello Mrembo, are you around? It's Olivia, from WHISPER. I just found out that I'm pregnant, again. I don't know how this happened! I've been counting my days and using condoms when I	Thurs 11am

	think I am unsafe. My friend Frieda tells me that there are better ways to prevent pregnancy. I have heard so many rumors about family planning that I am scared to use it. I don't know who the father is, and I don't know what to do next. I'm going to the clinic to get some advice. Chonjo!	
77	WHISPER Alert: Are you confused like Olivia? Worried about pregnancy? You can find out more about family planning, or services that can help, by replying 00.	Mon 11am
78	Hello, it's Olivia from WHISPER. I've had a difficult week. I lost the baby and I haven't felt well. But there is hope: I went to the clinic and they gave me good information- most of the rumors I had heard were wrong! For example I thought family planning caused cancer, make it hard to have a baby later, and leaves you without sexual appetite. It turns out this is all untrue! The implant, coil (IUD), and injection are better than counting days and have some great benefits. More soon!	Thurs 11am
79	WHISPER Alert: It can be very hard to lose a baby. If it happens, it's important to take care of yourself. You can visit a health centre anytime (reply 100), talk to a peer educator, or go to Coast Hospital Emergency if it's urgent.	Mon 11am
80	Olivia from WHISPER! I feel much better and less stressed. After going to the clinic I decided to get the coil. Now I won't worry about pregnancy until I'm ready—it lasts up to 12 years! I used to think that my partner might be able to feel the coil, or move it around if he was big. But it turns out that no matter how big your man is, that won't happen. Or did you hear that if you got pregnant with the coil your baby would come out holding it? Not true either!	Thurs 11am
81	Hi lovely, it's Olivia from WHISPER. I love my coil! I feel much safer. Counting days was tricky and easy to mess up. I had heavy bleeding at first, but now my periods are normal and it was worth it! None of my washefa have felt the coil. With my coil I won't get pregnant or lose another baby. I still use condoms with my partners because only condoms protect against STIs and HIV. My girlfriends are so impressed with me and I'm much happier. You should try it too! :-) Olivia	Mon 11am
82	WHISPER Alert: Worried you might be pregnant? Get a simple urine pregnancy test - reply 100 for a list of health services where you can get tested.	Thurs 11am
Month 9		
83	WHISPER says: Take Emergency Contraception (e-pills) up to 3 days after unprotected sex to prevent pregnancy. Works best when taken as soon as possible.	Mon 11am
84	Karibu mpenzi, E-pills are safe for all women. They will not harm an existing pregnancy or your ability to get pregnant in the future. Reply 61 for more info	Wed 11am
85	Hi love. If you use e-pills often, consider using an FP method like the IUD (coil) or implant to prevent these emergencies. Long-lasting and stress free!	Fri 4pm
86	Permanent family planning is surgery for men (vasectomy) or women (Tubal ligation) to prevent all future pregnancies. No effect on performance or appearance.	Mon 11am

87	Did you know that a woman's period is not always the same length? Counting days may not be dependable to prevent pregnancy. Try another FP method - reply 00	Wed 11am
88	Your job does not make you any less deserving of respect. All people have the right to healthy and happy lives with no violence. Including you! Hugs WHISPER	Fri 4pm
89	Violence includes physical force, threats and insults, forced sex and sexual violence. Everyone has the right to be safe. Hugs and kisses.	Mon 11am
90	Hi darling, call 0725333999 if you need help at a hotspot. To find out about the Gender-Based Violence Recovery Centre (GBVRC) reply 123.	Wed 11am
91	If anyone—including your mpenzi, husband or washefa —forces you to have sex or engage in sexual activity that you have not agreed to, it is against the law.	Fri 4pm
92	No one—NOT husbands, mpenzi, washefa, police officers, or anyone else -has the right to be violent toward you. Hugs and kisses from WHISPER	Mon 11am
93	Ask for payment and set your terms before you go with washefa. You are the boss. If you accept mobile money, move payment to another phone immediately.	Wed 11am
94	Violence against women is not ok and it's not your fault. If you experience violence remember you are not alone and can get help. Hugs, WHISPER.	Fri 4pm
Month 10		
95	If you experience rape, go to the GBVR centre at Coast General, or the hospital emergency. They can support you and help you report it to the police. Reply 123.	Mon 11am
96	WHISPER Alert: Peer educators are women just like you who have been trained to help you with pregnancy, STIs and violence. Find them at ICRH centres - reply 160	Thurs 11am
97	Hello pretty lady, I'm Mimi, from WHISPER. I had a crazy weekend. Friday, I got picked up by police and couldn't pay bail. Before they got me I was with a washefa and the condom burst! Normally I take emergency contraception (e-pills) to prevent pregnancy. e-pills can be taken up to 3 days after unprotected sex. E-pills are safe and won't cause an abortion if you are already pregnant. Because e-pills work best when taken right away, I was worried because I was stuck in jail all weekend without any. I'm ok this time, but what a scare! I need a more reliable family planning method so I'm going to visit a peer educator. Chat next week!	Mon 11am
98	Hi darling, it's Mimi from WHISPER. I talked to a peer educator about family planning. She said there are many different methods. She said contraceptive pills are taken once a day every day, at the same time. There is also the injection (Depo), given in the arm or hip, good for 3 months. There are even longer acting methods like the implant and coil. Implants are small rods put in the arm, good for 3-5 years; and the coil (IUD) is placed in the womb, good for up to 12 years.	Thurs 11am
99	WHISPER Alert: Mimi found out that the implant protects you from pregnancy for 3-5 years! Want to know more about the implant? Reply 11 to this text	Mon 11am

100	Mimi again! So I asked my girls about family planning methods they use and here's what I learned. My friend Tammy uses injectable contraception (Depo) because it's private and very good. She visits a clinic every 3 months and sets a reminder on her mobile. Her period changed at first but that's normal and went away. She gained a little weight, but men like her new shape! That sounds pretty good, but I'll tell you about another method that my friend Cici is using next week.	Thurs 11am
101	Dear Mrembo, it's Mimi from WHISPER. As I was saying, my friend Cici is using a coil (IUD, loop or tube). It lasts up to 12 years so she never worries about pregnancy. She is busy making money so it's a great method for her. If she wants a baby, she can have her coil removed and can get pregnant right away! She's still using condoms to prevent HIV. I want something that lasts longer, I have enough to worry about. I'm going to the clinic for a coil today! Cheers to protection!	Mon 11am
102	WHISPER Alert: Hi darling, there are so many choices for pregnancy prevention. Reply 00 to learn about every method and choose the one that is best for you!	Thurs 11am
<b>Month 11</b>		
103	WHISPER says: Everyone, especially you, has the right to health services that are accessible, affordable and good quality. Cheers!	Mon 11am
104	It's not ok for a health care provider to make you feel bad. Their job is to provide you a service & good advice. Find a clinic where you are comfortable.	Wed 11am
105	If you have a bad experience with a health care provider, don't give up – ask your peer educator for clinic recommendations. Kisses and hugs.	Fri 4pm
106	Most family planning methods are free of charge at ICRH drop-in centres. Government health centres provide FP methods at a small fee. Reply 100 for services	Mon 11am
107	Get free condoms from peer educators, government health centres or ICRH drop-in centres! Or buy them from chemists. Female condom info reply 66, male condom 71	Wed 11am
108	Be each other's keepers. Make sure you always tell a friend where you are going, carry your phone, and set up a plan for emergencies. Hugs, WHISPER	Fri 4pm
109	Hi love. Family planning does NOT make women infertile, affect existing pregnancies, cause birth defects, or cause cancer, diabetes or other health problems.	Mon 11am
110	If you use FP but are not getting your period, you can take a simple urine test at the health centre if you are worried about pregnancy. Kisses and hugs.	Wed 11am
111	Be careful girl! The injection only stops you getting pregnant for 3 months. Set an alarm on your phone to remind you when the next injection is due :-)	Fri 4pm
112	The IUD (coil) and implant are stress-free FP methods! Once you get one, you don't have to do anything else to prevent pregnancy for years! IUD 21, implants 11	Mon 11am
113	Hi mrembo, don't listen to rumours. Douching (washing the vagina) after a man has ejaculated (kushusha) does not prevent pregnancy!	Wed 11am

	For better methods reply 00	
114	There are many ways to protect yourself from becoming pregnant. Take control of your life and your body. Talk to a health care provider about FP.	Fri 4pm
Month 12		
115	Hi it's Joslyn, your friend from WHISPER. Girl, I have a story for you. Last night I was in a club and this Sonko sent me a drink. Of course I took it and we started talking. He said he would pay extra for no condom. Normally I use condoms, but he looked so good in that fancy suit, I figured he was clean. Plus I could use the money! So I agreed and we went back to his hotel room for a shot. When he took that suit off, he did not look so hot. Wait until I tell you next week.	Mon 11am
116	Jambo Mrembo! Joslyn again. So about this guy—under the suit, not so good. It looks like he has an STI- my implant won't protect me against that! So now I was in a difficult situation because I had already agreed to not use a condom. I felt bad because he bought me the drink and I was hoping I could stay in this nice hotel tonight. So I had to be clever. I told him I thought he was sexy, but I wanted to stick to my "no condom no sex" rule. You will never believe what he said!	Thurs 11am
117	Hey it's Joslyn. So I said we needed a condom.. He seemed a bit angry at first, but I stayed calm and explained! Condoms are the only method that prevents pregnancy and STIs including HIV. Some infections like HIV, herpes, and HPV can't be cured. Other infections might not have symptoms but can do harm, like causing infertility. So condoms protect BOTH of us and our other partners. Condoms are easy to use and cheap. I even had some in my bag. He said...I'll tell you next week!	Mon 11am
118	Joslyn here. So get this, the Sonko guy says using a condom won't feel as good and he would pay less. I told him he was underestimating my skills and if didn't kushusha, he could have 10% back. He laughed and finally agreed. He kushusha 2 times! ;-). Even though I won't get pregnant because I use the implant, I will never put myself at risk of STIs again. You never know what is under the suit, no matter how fancy the pants. "No Condom No Sex" is my new self-protection rule!	Thurs 11am
119	WHISPER Alert: Try talking to your washefa and wapenzi about using condoms like Joslyn did. Clear up their misconceptions! To find out the facts reply 70 or 76.	Mon 11am
120	Hi girl, it's Joslyn with one more bit of advice. I've heard all these crazy rumors about how having sperm in the vagina gives you smooth skin or changes the shape of your butt or hips. So I went to my peer educator and she set me straight! All those rumors are untrue and bad news. You know what gives you smooth, clear skin? Not having an STI! So use a condom, girlfriend, with ALL your men! I want you and all our friends to be safe and healthy. So tell our friends! :-). Joslyn	Thurs 11am
121	WHISPER Alert: Have you heard crazy rumours like Joslyn? If you're confused, talk to a peer educator or a health care worker. Reply 100	Mon 11am

	to find out where to go	
122	WHISPER Alert: It's a good idea to get regular tests for STIs and HIV, even if you don't have symptoms. Many STIs are easy to treat. Reply 100 for services.	Thurs 11am
Month 13		
123	Worried about last night? Did the condom burst, get stuck or did you have unprotected sex? Take e-pills to prevent pregnancy and PEP to reduce the risk of HIV.	Mon 11am
124	Don't forget you can also get an IUD (coil) up to 5 days after unprotected sex. It will stop you getting pregnant this time and for years to come! IUD: reply 21	Wed 11am
125	Some people say if you use emergency pills often it will be harder to get pregnant in the future. This is not true! Get the facts on e-pills by replying 61.	Fri 4pm
126	Some FP methods can change your period (cycle), but they affect people differently. If one method doesn't work for you, there's no harm in trying another.	Mon 11am
127	It's not harmful to have sex during your period. But if you don't like it, try using female condoms. They can catch the blood so it doesn't come out during sex.	Wed 11am
128	Dear Mrembo, always remember even if you are using family planning to prevent pregnancy you should still use a condom to protect yourself from STIs. Hugs!	Fri 4pm
129	Next week is the final week of WHISPER. We will be sad to go! Reply 00 to review the WHISPER menu. You won't be able to access it after next week, but you can store the messages on your phone for as long as you want :-). Talk to a peer educator or go to a drop-in-centre or health centre for more information and support.	Mon 11am
130	Great work girl, you've been part of WHISPER for almost a year now! Soon it will be time for your next interview and free tests. Check the white card we gave you to see the appointment date. Need more info? Call or text your friendly mobiliser on 0721858325 (Chaani) or 0721935040 (Kisauni).	Wed 11am
131	WHISPER hint: Male condoms have an amazing ability to stretch to any size. Don't believe us? Open a condom and pull it up your arm - you'll be surprised ;-)	Fri 4pm
132	Everyone has the right to use family planning and lead healthy lives free from violence. Your job does not make you any less deserving of respect! Love WHISPER	Mon 11am
133	Mrembo, kumbuka kurudi for your 12month WHISPER visit. You'll have an interview and free tests, and we'll give you refreshments and money for transport. Cheers!	Wed 11am
134	WHISPER says a HUGE thank you to you mrembo!! We hope you've enjoyed hearing about family planning and stories from women like Sandra, Olivia and Joslyn. By taking part in this trial you've helped us develop a program to help other women in the future. If you haven't had your last interview yet, please come in. We might also contact you soon to find out what you thought of the program. Lots of love and hugs, WHISPER :-)	Fri 4pm
Month 14		



135	Hello dear! The WHISPER team would love to see you for your last interview if you haven't come in yet. Need more info? Call or text your friendly mobiliser on 0721858325 (Chaani) or 0721935040 (Kisauni).	Wed 11am
Additional alerts (delivered at same time to all participants)		
136	Great news dear! ICRH now has a drop-in centre in Changamwe. All services are free. You can talk to peer educators there or just relax. For details, reply 141	5 Sep 2017 11am
137	WHISPER alert: We won't be open over Christmas. If you need to come in and see us, please come before 20th December or after 03rd Jan. Enjoy your holiday mrembo	14 Dec 2017 11am

## Pull messages (on-demand menu)

Name	Numeric access code	Message Content
Main menu	00	Welcome to WHISPER main menu. For implants reply 11, IUD (coil) 21, permanent 31, injectable 41, daily pills 51, emergency pills 61, female condoms 66, male condoms 71, natural family planning 81, LAM (breastfeeding method) 91. For health services reply 100.
Enrolment test	222	Hongera! You have registered for the WHISPER or DIVA study. You will start receiving messages soon.
Intro	333	Hongera darling, great work! You've accessed the WHISPER menu. Go to main menu at any time by replying 00. You can get more information there. And it's free!
Error - text	X	Pole, WHISPER can't receive messages. In an emergency go to Coast General hospital. For urgent help you can also call 1195 or 0725333999. WHISPER menu reply 00.
Error - numeric	#	Hi dear, you sent an incorrect code to WHISPER - check the number you sent and try again. For the WHISPER main menu, reply 00 to this message.
<b>Implants</b>		
Implant	11	Implants are small rods placed under skin of woman's arm. Highly effective for 3-5 years. Can be removed anytime. For married and singles. May cause light irregular bleeding. When removed, can become pregnant with no delay. No infertility or birth defects. Main menu reply 00. More information reply 12.
Implant more info	12	Implants: Benefits 13, Side Effects 14, Bleeding Side Effects 15, True Facts 16, Insertion/Removal 17, WHISPER main menu 00.
Implant benefits	13	Implant benefits: Discrete and very effective pregnancy prevention, long-lasting, reversible, does not interfere with sex. For single and married women of any age, even adolescents. If breastfeeding, can start implant 6 weeks after childbirth.
Implant side effects	14	Implant side effects: Abdominal pain, acne, breast tenderness, dizziness, headaches, nausea, and changes in mood or weight are common and not a cause for concern. Side-effects usually lessen or stop after 1 year or less. Some women don't have side effects. If concerned, see a health care provider.
Implant bleeding side effects	15	Implant bleeding side effects: Monthly bleeding may be lighter and irregular during the first year; then lighter, more regular and infrequent. Monthly bleeding may stop for some women. If bleeding stops it is not harmful - blood does not build up inside womb.
Implant true facts	16	Implants DO NOT make women infertile, delay pregnancy after removal, cause birth defects or ectopic pregnancy. Implants DO NOT cause cancer, high blood pressure, or diabetes and DO NOT move to other parts of the body.
Implant insertion/removal	17	Implant: On insertion, arm may swell, bruise or be sore for a few days. This will go away without treatment. Implant can be removed anytime. Must go to a health facility for removal - simple and fast procedure.
<b>IUD (Coil)</b>		

IUD	21	IUD (coil) is a small device placed inside the womb. Highly effective up to 12 years. Can be removed anytime. May increase monthly bleeding and cramps at first. When removed, can become pregnant with no delay. No infertility or birth defects; does not move around in body. Main menu reply 00. More information reply 22.
IUD more info	22	IUD (coil): Benefits 23, Side Effects 24, True Facts 25, Insertion/removal 26, main menu 00.
IUD benefits	23	IUD benefits: Discrete, very effective pregnancy prevention for 5 to 12 years. Does not interfere with sex. No hormones. When removed, can become pregnant with no delay. No action needed after insertion. Good for most women, including breastfeeding. Can be inserted right after baby is born, or later.
IUD side effects	24	IUDs have few side effects. Monthly bleeding may be irregular, heavy and longer during first 3 to 6 months. May have painful cramps. Wounding of the uterus is rare. Some women don't have side effects.
IUD true facts	25	IUDs (coils) DO NOT make women infertile, cause cancer or harm an existing pregnancy. They do not move in the body. Cannot attach to baby. IUDs (coils) DO NOT affect sex drive. Partner should not feel strings. Insertion is simple, does not require surgery.
IUD insertion/removal	26	IUD (coil): If you have an STI, it should be treated before inserting IUD. After insertion, some cramping and pain for a few days. This will go away without treatment. Wounding of the uterus from insertion is rare. IUD can be removed at any time. Must go to a health facility for removal - simple and fast procedure.
<b>Permanent Contraception</b>		
Permanent FP	31	Permanent family planning methods are simple surgery for men (vasectomy) or women (sterilization). For people who do not want more children. Get in clinic or hospital. Highly effective. No effect on sexual performance, appearance, or feelings. Main menu reply 00. More information reply 32.
Perm FP more info	32	Permanent family planning: Benefits 33, Side Effects 34, True Facts 35, main menu 00.
Perm FP benefits	33	Permanent family planning methods are very effective. No need to worry about FP when procedure is final (3 months for men, 1 week for women). Nothing to do or remember. No side effects.
Perm FP side effects	34	Permanent family planning has no side effects. Some pain and swelling after procedure.
Perm FP true facts	35	Permanent family planning DOES NOT mean removing uterus, ovaries or testicles, DOES NOT decrease sex drive, sexual performance, or make men or women weak. Men can still get erections (kusimika) and ejaculate (kushusha). Women will still have periods. Safe for all men and women.
<b>Injection</b>		
Injection	41	Injection (depo) in arm or hip. Effective for 1-3 months. Get re-injected on time, return even if late. Irregular or no monthly bleeding not harmful. May gain weight. For married and singles. After stopping may take a few months to get pregnant. No infertility or pregnancy loss. Private use. Main menu reply 00.

		More information 42.
Injection more info	42	Injection (depo): Benefits 43, Main Side Effects 44, Bleeding Side Effects 45, True Facts 46, Main menu 00.
Injection benefits	43	Injection benefits: Discrete and effective pregnancy prevention if get injections regularly, reversible, does not interfere with sex. For single and married women of any age, even adolescents. If breastfeeding can start 6 weeks after childbirth.
Injection side effects	44	Injection side effects: Abdominal pain, dizziness, headaches, changes in mood and weight gain, and less sex drive are all common and not a cause for concern. May take 4-9 months to get pregnant after last injection. Some women don't have side effects.
Injection bleeding side effects	45	Injection bleeding side effects: Monthly bleeding may be irregular and longer during first 3 to 6 months; then lighter, infrequent, or irregular. Monthly bleeding may stop for some women. If bleeding stops it is not harmful - blood does not build up inside womb.
Injection true facts	46	Injectables DO NOT make women infertile, disrupt existing pregnancy, cause birth defects, cancer, high blood pressure, or diabetes.
Daily Pills		
Daily pill	51	Daily pill: One pill is taken every day. Makes monthly bleeding lighter and regular. May reduce menstrual pains and acne. May have headaches and nausea at first. For married & singles. After stopping can become pregnant with no delay. No infertility or birth defects. Start new packs on time. Main menu reply 00. More information 52.
Daily pill more info	52	Daily pill: Benefits 53, Side Effects 54, True Facts 55, Missed Pills 56, main menu 00.
Daily pill benefits	53	Daily pill is very effective if taken daily. Reduces menstrual cramps, bleeding problems, and ovulation pain. Reduces excess hair on face or body and acne. Can be stopped at any time without provider help. For single and married women of any age, even adolescents.
Daily pill side effects	54	Daily pill side effects: Monthly bleeding may be lighter and irregular during the first few months then lighter, shorter and regular. Headaches, breast tenderness and weight change may occur but usually decrease or stop after first few months. Some women don't have side effects.
Daily pill true facts	55	Daily pill must be taken every day whether or not woman has sex. Pills DO NOT make women infertile, cause birth defects, multiple births, or disrupt existing pregnancy. DO NOT build up in the body or change a woman's sexual behavior. DO NOT cause cancer or diabetes.
Missed pills	56	Daily pills: Always take 1 missed pill immediately, then continue with pack. If missed 3 or more pills use condoms for 7 days (reply 71) and consider using emergency contraception (e-pills - reply 61). If missed 3 pills in week 3: take 1 missed pill immediately,

		then continue with pack until 7 pills remain, then throw away these 7 pills and start a new pack.
Emergency Contraception		
E-pills	61	Take emergency contraception (e-pills) up to 5 days after unprotected sex to prevent pregnancy. Most effective when taken as soon as possible. Safe for all women. Will not affect existing pregnancy. Does not affect future fertility. Get in pharmacies or clinics. Not recommended as regular contraception. Main menu reply 00. More information 62.
E-pills more info	62	Emergency pills (e-pills): Benefits 63, Side Effects 64, True Facts 65, main menu 00.
E-pills benefits	63	E-pills help protect against the risk of pregnancy following unprotected sex. Can be used as back-up birth control if daily pills are missed (reply 57) or condom is not used or breaks (reply 71).
E-pills side effects	64	E-pills side effects: Slight irregular bleeding for 1-2 days. Next monthly bleeding may be early or later than usual. Headache, dizziness, breast tenderness, nausea and vomiting possible. Some women don't have side effects.
E-pills true facts	65	E-pills DO NOT make women infertile, or harm your baby if you are already pregnant. E-pills do not cause risky sex and are not dangerous to a woman's health.
Female Condoms		
Female condoms	66	Female condoms: effective when used correctly every time with every partner. Put inside the vagina or anus up to 8 hrs before sex. Use a new condom every time. Easily used with practice, work best with lubricant (KY jelly). Best if discussed with partner. For married and singles. Condoms are the only method to prevent HIV, STIs, and pregnancy. More information reply 67. Main menu 00.
Fem cdm more info	67	Female condoms: Benefits 68, Side Effects 69, True Facts 70, main menu 00.
Fem cdm benefits	68	Female condoms are effective when used correctly every time. Also protects against STIs, including HIV. No hormonal side effects. Controlled by the woman, can put in place before meeting partner. Strong and soft. Can make sex more enjoyable for woman and man.
Fem cdm side effects	69	Female condoms have no side effects. However, they can be noisy. If they move during sex, try adding more lubricant (KY jelly). Breaking/tearing is rare.
Fem cdm true facts	70	Female condoms DO NOT get lost in woman's body, decrease sex drive or make women sick due to sperm not getting in. They DO NOT make men sterile, impotent, fat or weak. Both married and singles use condoms. May be slippery and tricky to use at first but easier with practice. CANNOT be used at same time as male condoms.
Male Condoms		

Male condoms	71	Male condoms are effective when used correctly every time with every partner. Condoms are the only method to prevent HIV, STIs, and pregnancy. Use a new condom every time. Easy to find, low cost. Easily used with practice. Best if discussed with partner. For married and singles. Main menu reply 00. More information 72.
Male cdm more info	72	Male condoms: Benefits 73, Side Effects 74, True Facts 75, Tips for correct use 76, Main menu 00.
Male cdm benefits	73	Male condoms are effective when used correctly every time. Also protects against STIs, including HIV. Do not affect hormones, easy to obtain, cheap, can be used without seeing a provider.
Male cdm side effects	74	Male condoms have no side effects. Condoms may break or burst, especially if dry or not used correctly (reply 76 for correct use). Use lubricant (KY jelly) to reduce breakage. Some people may be allergic to the latex in condoms – this is not common.
Male cdm true facts	75	Male condoms DO NOT decrease sex drive, get lost in woman's body, make men sick due to back-up of sperm. They DO NOT make men sterile, impotent, fat or weak. Both married and singles use condoms. Cannot be used at same time as female condoms (for female condoms reply 66)
Male cdm correct use	76	Tips for using male condoms: Put condom on before starting to have sex. Don't use teeth to open packet and keep away from sharp objects. Squeeze the tip while rolling it on the penis to stop air getting in. Make sure there is space at the tip when condom is on. When man has ejaculated (kushusha), hold condom on the base of penis while pulling out to stop semen spilling. Don't leave on for long after sex as semen can leak out.
Natural Family Planning		
NFP	81	Natural family planning (Standard Days Method): track your bleeding cycle to find out days when you can get pregnant. First day of bleeding is day 1. You can get pregnant on days 8-19 if your periods are one month apart. Use condoms or don't have sex on days 8-19. To protect against STIs or HIV you need to keep using condoms every time you have sex on all days of the cycle. Works well when used correctly. Partner support needed. More information 82. Main menu reply 00.
NFP more info	82	More info on natural family planning: Benefits 83, Side Effects 84, True Facts 85, main menu 00.
NFP benefits	83	Natural family planning helps a woman and her partner understand her body and fertility. Safe, natural, no hormones, procedures, or side effects.
NFP side effects	84	Natural family planning: no side-effects, but can be difficult to do correctly. Condoms only work well when used correctly. Male condoms 71, female condoms 66
NFP true facts	85	Natural FP: You are only protected from pregnancy if you use condoms or don't have sex on days 8-19. Men and women are not harmed if they don't have sex.
LAM		
LAM	91	LAM (breastfeeding method) works for 6 months after your baby is born IF your period has not returned AND you give your baby only breast milk. Doesn't protect against STIs or HIV so use

		condoms as well. Main menu reply 00. More information 92.
LAM more info	92	LAM (breastfeeding method): Benefits 93, Side Effects 94, True Facts 95, reminders 98. Main menu 00.
LAM benefits	93	LAM (breastfeeding method): Mother can start immediately after baby is born. Natural, no hormones, procedures, supplies, or side effects. Healthy for baby and mother. Can switch to another FP method whenever you want. Gives you time to decide which method to use when LAM ends.
LAM side effects	94	LAM has no side effects. Stops working when your period returns or you give your baby other food in addition to your breastmilk. Stops working after 6 months.
LAM true facts	95	Women with HIV can use LAM (breastfeeding method)- see a health care provider before starting.
Health Services		
Health Services	100	For emergency services reply 110. For health services in Island 120, Kisauni 130, Changamwe 140. For government services 150, ICRH services/drop-in centres 160.
Emergency Services	110	Free violence hotline: call 1195. Urgent help at a hotspot: call 0725333999. Free 24-hour care at Coast Provincial Hospital. The emergency department provides free care after rape/violence when Gender Based Violence Recovery Centre (GBVRC) is closed. For more info on GBVRC reply 123, hotlines 111, other services 100.
Island Health Services	120	For ICRH learning site (drop-in centre) 121, Tudor District Hospital 122, Gender Based Violence Centre 123, Coast Provincial Hospital 124. Other services 100.
Kisauni Health Services	130	For ICRH Kisauni drop-in centre reply 131, Kisauni Health Centre 132. For other services reply 100.
Changamwe Health Services	140	For ICRH Changamwe drop-in centre reply 141, Chaani health centre 142, Port Reitz Hospital 143, Magongo health centre 144, Mikindani health centre 145, Jomvu health centre 146. Other services 100.
Government Health Services	150	For government health service in Tudor 122, Kisauni 132, Chaani 141, Port Reitz 142, Magongo 143, Mikindani 144, Jomvu 145. Coast Hospital 124. Service menu 100
ICRH Health Services	160	ICRH learning site (drop-in centre) in Island reply 121, Kisauni drop-in centre 131, Changamwe drop-in centre 141, ICRH Gender Based Violence Recovery Centre (GBVRC) 123, other services 100.
Hotlines	111	1195 is a free national hotline that can help you if you have experienced violence. Or you can call 0725333999 for urgent help from peers in Mombasa. They can help with violence, or problems with police and difficult clients at a hotspot. They can't give financial support. For other emergency services reply 110.
ICRH Learning Site	121	ICRH learning site. Drop-in centre for sex workers, all services FREE. Behind Casablanca night club, Island. Ph 0702 565 550. Provides all family planning methods, condoms & lubricant, testing and treatment for HIV/STIs, care after rape/violence, post-exposure prophylaxis (PEP) to prevent HIV, emergency pills

		to prevent pregnancy. Also care after loss of pregnancy, cancer screening, alcohol/drug counseling, peer education. Safe and friendly space to relax. Open Mon-Thurs 8am-5pm, Fri 10am-7pm, Sat 2-7pm. Other services reply 100
Tudor District Hospital	122	Tudor District Hospital. Opposite Ziواني school of the deaf, Island. Ph 0700451193. Government health service. Provides family planning at low cost and condoms for free. Also provides HIV & STI testing and treatment, TB clinic, pregnancy care. Open 8am-8pm every day. Other services reply 100
ICRH GBVRC	123	ICRH Gender Based Violence Recovery Centre (GBVRC). At Coast Provincial General Hospital. Ph 0702141431 or 0736403311. All services are FREE for survivors of sexual violence. Provides medical, psychological and legal support to women after rape/sexual violence. Post-exposure prophylaxis (PEP) to prevent HIV, and emergency pills to prevent pregnancy. Testing for pregnancy, HIV, STIs. Open Mon-Fri 8am-5pm. After hours go to Coast General emergency department. Service menu: 100
Coast Provincial General Hospital	124	Coast Provincial General Hospital. Government hospital. Provides free 24-hour emergency care 7 days per week, also general medical care and surgery. Emergency department provides free care after rape/violence when Gender Based Violence Recovery Centre is closed. Other services reply 100
ICRH DIC Kisauni	131	ICRH Drop-in centre for sex workers, all services FREE. Bombolulu Estate, opposite Tunza clinic, Kisauni. Provides family planning, condoms & lubricant, HIV testing, peer education. Safe and friendly space to relax. Open Mon-Fri 8am-5pm, Sat 9.30-12pm. Other services reply 100
Kisauni Health Centre	132	Kisauni Health Centre. Frere town kisimani stage, opposite CDF hall, Kisauni. Government health service. Provides family planning at low cost and condoms for free. Also provides testing and treatment for HIV/STIs and general medical services. Free cervical cancer screening during in-reaches. Open Mon-Fri 8am-4.30pm.
ICRH DIC Changamwe	141	ICRH Drop-in centre for sex workers, all services FREE. PN Mashru road, opposite Salvation Army, Migadini. Provides family planning, condoms & lubricant, cervical cancer screening, HIV testing, STI treatment and other services. Safe and friendly space to relax. Open Mon-Fri 8am-5pm. Other services reply 100
Chaani Health Centre	142	Chaani Health Centre. Near ABC secondary school, Changamwe. Government health service. Provides family planning at low cost and condoms for free. Also testing and treatment for HIV/STIs, care after rape/violence, assistance with alcohol and drug use, pregnancy care and general medical services. Open Mon-Fri 8am-4.00pm.
Port Reitz District Hospital	143	Port Reitz District Hospital. Port Reitz mwisho, opposite Port Reitz Medical Training College, Changamwe. Ph 0720419492. Government health service. Provides family planning at low cost and condoms for free. Also testing and treatment for HIV/STIs, youth friendly health services. Post-exposure prophylaxis (PEP) to prevent HIV and e-pills to prevent pregnancy are available 24hrs



		7 days a week.
Magongo Health Centre	144	Magongo Health Centre, opposite Changamwe police station. Government health service. Provides family planning at low cost and condoms for free. Free cancer screening, TB, HIV testing and treatment. Also offer STI testing and treatment, general medical services. Open Mon-Fri 8am-4.30pm.
Mikindani Health Centre	145	Mikindani Health Centre. Near Kajembe secondary school, Changamwe. Government health service. Provides family planning at low cost and condoms for free. Also testing and treatment for HIV/STIs, post-exposure prophylaxis (PEP) to prevent HIV, care after rape/violence, general medical services. Open Mon-Fri 8am-4.30pm. Other services reply 100
Jomvu Health Centre	146	Jomvu model Health Centre. Before chief's camp, Changamwe-Mikanjuni. Government health service. Provides family planning at low cost and condoms for free. Also testing and treatment for HIV/STIs, care after rape/violence, pregnancy care, general medical services. Open Mon-Fri 8am-4.30pm. Other services reply 100

## Appendix 2: London Measure of Unplanned Pregnancy adapted for the WHISPER or SHOUT study

*Preamble: Now I am going to ask some questions about your circumstances and feelings around the time you became pregnant. We're talking about your CURRENT pregnancy.*

Questions	Score
In the month that you became pregnant, you and your partners:	
Were not using family planning	0
Were using family planning, but not on every occasion	1
Were using family planning, but it did not work on some occasions	1
Always used family planning	2
In terms of becoming a mother (first time or again), do you feel that your pregnancy happened at the:	
Right time	2
OK, but not quite right time	1
Wrong time	0
Think about the time just before you became pregnant. Would you say:	
You intended to get pregnant	2
Your intentions to get pregnant kept changing	1
You did not intend to get pregnant	0
Just before you became pregnant, would you say:	
You wanted to have a baby	2
You had mixed feelings about having a baby	1
You did not want to have a baby	2
Now think about you and your boyfriend/husband before you became pregnant. Would you say:	
You and your partner had agreed that you would like for you to be pregnant	2
You and your partner had discussed having children together, but hadn't agreed for you to get pregnant	1
You and your partner had never discussed having children together	0
N/A; no main partner at the time	0
Before you became pregnant, did you do any of the following things in preparation for pregnancy? (Multiple responses allowed)	
Took vitamins (e.g. iron or folic acid)	1 (1 action) 2 (2+ actions)
Stopped or cut down on smoking, drinking, or other drugs	
Changed your diet, such as by eating more healthy foods	
Sought medical or health advice or information about pregnancy	
Saved money for medical expenses	
Took some other action (please specify)	
You did not do any of these things before your pregnancy	0