



MONASH University

**Weekend allied health services in patients
undergoing elective lower limb joint
replacement surgery**

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Abstract

Background:

Elective hip and knee joint replacement surgery are high volume and high cost procedures. Postoperative allied health is an important aspect of the recovery process. Effective and efficient allied health service models for this population has the potential to improve both patient and service outcomes. Provision of weekend allied health services may potentially increase the quantity of therapy provided and/or commence therapy earlier. A systematic review conducted as part of this thesis demonstrated a weekend physiotherapy service and earlier commencement produced favourable outcomes. However, no studies examining the effect of a weekend allied health team of professionals were identified. This doctoral research program aimed to investigate the provision of an acute weekend allied health service following hip and knee joint replacement.

Methods:

A research program consisting of four studies was nested within a broader project consisting of two stepped wedge cluster randomised trials. An interrater agreement study (chapter 3) was conducted to assess the level of agreement between patient self-report and therapist-assessed performance of mobility using the de Morton Mobility Index (DEMMI). Health professionals providing acute care to patients following hip and knee replacement surgery were interviewed to gain an in-depth understanding of the allied health service at this location (chapter 4). Two quasi-experimental studies were then conducted to investigate the effect of an acute weekend allied health service compared to no service on short-term outcomes (chapter 5) and compared to the provision of a weekend allied health service provided in the sub-acute setting on medium-term outcomes (chapter 6).

Participants consisted of patients undergoing hip and knee replacement surgery recruited from an outpatient preadmission clinic and health professionals treating these patients in the acute hospital setting following surgery. The intervention examined was an acute weekend allied health service following hip and knee joint replacement surgery. A comprehensive battery of patient and service outcomes was examined. Participants were interviewed preoperatively, four days postoperatively and six weeks postoperatively.

Results:

334 participants were assessed preoperatively, 242 at four days postoperatively and 262 at six weeks postoperatively. Twenty-five health professionals providing acute care following hip and knee replacement surgery participated in semi-structured focus groups. High agreement between therapist-rated and patient self-report scores of the DEMMI was demonstrated. Health professionals perceived potential to optimise the allied health service provided to patients in the acute phase following hip and knee replacement surgery, particularly to facilitate mobilisation on the day of surgery. At four days postoperatively, the acute weekend allied health service increased patient mobility and the likelihood of discharge directly home at the expense of a longer acute length of stay and patient-perceived helpfulness of hospitalisation. At six weeks postoperatively, there was no comparative advantage or disadvantage of transferring weekend allied health services from the acute to sub-acute setting.

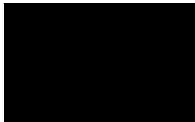
Conclusions:

Patient self-report of mobility using the DEMMI can be used to assess mobility remotely for patients undergoing hip and knee joint replacement surgery. The net effect of the acute weekend allied health service remains unclear. Further research is needed to examine the cost-effectiveness of this service in the longer term and compared to alternate allied health service models for this population. Further work to encourage implementation of early mobilisation evidence into practice at the study hospital is also recommended.

Declaration

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.

Signature:



Print Name: Romi Haas

Date: 10 December, 2017

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 two original papers published in peer-reviewed journals and three submitted publications. The core theme of the thesis is weekend allied health services in patients undergoing elective lower limb joint replacement surgery. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of myself, the student, working within the Faculty of Medicine, Nursing and Health Sciences (Department of Physiotherapy) under the supervision of Professor Terry Haines, Associate Professor Lisa O'Brien and Dr Kelly-Ann Bowles.

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 1, 3, 4, 5 and 6 my contribution to the work involved the following:

Thesis Chapter	Publication Title	Status (<i>published, in press, accepted or returned for revision, submitted</i>)	Nature and % of student contribution	Co-author name(s) Nature and % of Co-author's contribution*	Co-author(s), Monash student Y/N*
Chapter 1.2	Early commencement of physical therapy in the acute phase following lower limb arthroplasty produces favorable outcomes: a systematic review	Published	Led conception of the study and data collection, led data analysis and synthesis, drafted and prepared the manuscript for publication: 75%	Sarkies, K. contributed independent data extraction, manuscript preparation: 5%	Yes
		Osteoarthritis and Cartilage		Bowles, KA. contributed to study conception, assisted in drafting of the manuscript: 5%	No

Thesis Chapter	Publication Title	Status (<i>published, in press, accepted or returned for revision, submitted</i>)	Nature and % of student contribution	Co-author name(s) Nature and % of Co-author's contribution*	Co-author(s), Monash student Y/N*
	and meta-analysis examining allied health service models			O'Brien, L. contributed to study conception, assisted in drafting of the manuscript: 5%	No
				Haines, TP. contributed to study conception, assisted with data analysis, assisted in drafting of the manuscript: 10%	No
Chapter 3.2	Patient and therapist agreement of performance-rated ability using the de Morton Mobility Index	Published Archives of Physical Medicine and Rehabilitation	Led conception of the study and data collection, led data analysis and synthesis, drafted and prepared the manuscript for publication: 80%	Bowles, KA. contributed to study conception, assisted in drafting of the manuscript: 5%	No
				O'Brien, L. contributed to study conception, assisted in drafting of the manuscript: 5%	No
				Haines, TP. contributed to study conception, assisted with data analysis, assisted in drafting of the manuscript: 10%	No
Chapter 4.2	Health professionals' perceptions of the allied health role in the acute setting following hip and knee joint replacement surgery: a qualitative study	Under Review Disability and Rehabilitation	Led conception of the study and data collection, led data analysis and synthesis, drafted and prepared the manuscript for publication: 70%	Bowles, KA. contributed to study conception, assisted in drafting of the manuscript: 5%	No
				O'Brien, L. contributed to study conception, assisted with data collection and analysis, assisted in drafting of the manuscript: 15%	No
				Haines, TP. contributed to study conception, assisted with data analysis, assisted in drafting of the manuscript: 10%	No
Chapter 5.2	Effectiveness of a weekend allied health service on short-term outcomes following hip and knee joint replacement surgery	Under Review Clinical Rehabilitation	Contributed to study design, led data collection, led data analysis and synthesis, drafted and prepared the manuscript for publication: 75%	Bowles, KA. contributed to study conception, assisted with data extraction, assisted in drafting of the manuscript: 10%	No
				O'Brien, L. contributed to study conception, assisted in drafting of the manuscript: 5%	No

Thesis Chapter	Publication Title	Status (<i>published, in press, accepted or returned for revision, submitted</i>)	Nature and % of student contribution	Co-author name(s) Nature and % of Co-author's contribution*	Co-author(s), Monash student Y/N*
				Haines, TP. contributed to study conception, assisted with data analysis, assisted in drafting of the manuscript: 10%	No
Chapter 6.2	Transferring weekend allied health services from the acute to sub-acute setting: Does it make a difference to patient or service outcomes following lower limb joint replacement?	Under Review Disability and Rehabilitation	Contributed to study design, led data collection, led data analysis and synthesis, drafted and prepared the manuscript for publication 75%	Bowles, KA. contributed to study conception, assisted with data extraction, assisted in drafting of the manuscript: 10% O'Brien, L. contributed to study conception, assisted in drafting of the manuscript: 5% Haines, TP. contributed to study conception, assisted with data analysis, assisted in drafting of the manuscript: 10%	No No No

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

Student signature:

Date: 17 December, 2017

The undersigned 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 signature:



Date: 20/12/17

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Oral and poster presentations by candidate

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Haas R, Bowles KA, O'Brien L and Haines T. Is it more effective to provide weekend physiotherapy services in the acute or sub-acute setting following total hip and knee replacement? A comparison of patient and service outcomes. 2nd Victorian Allied Health Research Conference, Melbourne, March 2017.

Haas R, Bowles KA, O'Brien L and Haines T. Association between allied health delivery characteristics and patient outcomes following total hip and knee replacement. 4th Annual Monash Physiotherapy Research & Innovation Conference, Melbourne, September 2016.

Haas R, Sarkies MN, Bowles KA, O'Brien L and Haines T. Early commencement of therapy in the acute phase following elective lower limb arthroplasty produces favorable outcomes. 11th National Allied Health Conference, Melbourne, November 2015.

Poster presentations

Haas R, Bowles KA, O'Brien L and Haines T. Comparison of patient and service outcomes post-arthroplasty when weekend allied health services are transferred from the acute to sub-acute setting. Monash Health Research Week, Melbourne, November 2016.

Sarkies MN, Bowles KA, Skinner EH, Mitchell D, **Haas R**, Salter K, Ho M and Haines T. Disinvestment research in high-risk clinical populations: weekend allied health services to acute medical and surgical ward tracheostomy patients – a pilot nonrandomised controlled clinical trial. 11th National Allied Health Conference, Melbourne, November 2015.

Publications during enrolment

Peer reviewed publications related to thesis

Haines TP, Bowles KA, Mitchell D, O'Brien L, Markham D, Plumb S, May K, Philip K, **Haas R**, Sarkies MN, Ghaly M, Shackell M, Chiu T, McPhail S, McDermott F and Skinner EH (2017): Impact of disinvestment from weekend allied health services across acute medical and surgical wards: Two stepped-wedge, cluster randomised controlled trials. *PLoS Medicine* 14(10):e1002412.

O'Brien L, Mitchell D, Skinner EH, **Haas R**, Ghaly M, McDermott F, May K and Haines T (2017): What makes weekend allied health services effective and cost-effective (or not) in acute medical and surgical wards? Perceptions of medical, nursing, and allied health workers. *BMC Health Services Research* 17(1):345-358.

Haas R, Bowles KA, O'Brien L, and Haines T (2016): Patient and therapist agreement on performance rated ability on the de Morton Mobility Index. *Archives of physical medicine and rehabilitation* 97(12):2157-2165.

Haas R, Sarkies M, Bowles KA, O'Brien L and Haines T (2016): Early commencement of physical therapy in the acute phase following elective lower limb arthroplasty produces favorable outcomes: a systematic review and meta-analysis examining allied health service models. *Osteoarthritis and Cartilage* 24(10):1667-1681.

Sarkies M, Bowles KA, Skinner EH, **Haas R**, Mitchell D, O'Brien L, May K, Ho M and Haines T (2016): Do daily ward interviews improve measurement of hospital quality and

safety indicators? A prospective observational study. *Journal of Evaluation in Clinical Practice* 22(5):792-798.

Haines T, O'Brien L, Mitchell D, Bowles KA, **Haas R**, Markham D, Plumb S, Chiu T, May K, Philip K, Lescai D, McDermott F, Sarkies M, Ghaly M, Shaw L, Juj G and Skinner EH (2015): Study protocol for two randomized controlled trials examining the effectiveness and safety of current weekend allied health services and a new stakeholder-driven model for acute medical/surgical patients versus no weekend allied health services. *Trials* 16:133-146.

Sarkies M, Bowles KA, Skinner EH, Mitchell D, **Haas R**, Ho M, Salter K, May K, Markham D, O'Brien L, Plumb S and Haines T (2015): Data collection methods in health services research. *Applied Clinical Informatics* 18:6(1):96-101.

Peer reviewed publications unrelated to thesis

Sarkies MN, Bowles KA, Skinner EH, **Haas R**, Lane H and Haines TP (2017): The effectiveness of research implementation strategies for promoting evidence-informed policy and management decisions in healthcare: A systematic review. *Implementation Science* 12(1):132-152.

Haas R, Mason W and Haines T (2014): Twelve month follow up of a falls prevention program in older adults from diverse populations in Australia: a qualitative study. *Archives of Gerontology and Geriatrics* 58(2):283-92.

Haas R, Mason W and Haines T (2014): Difficulties experienced in setting and achieving goals by participants of a falls prevention programme: A mixed-methods evaluation. *Physiotherapy Canada* 66(4):413-422.

Publications under journal review

Haas R, O'Brien L, Bowles K, Haines T (2017): Effectiveness of a weekend physiotherapy service on short-term outcomes following hip and knee joint replacement surgery.

Haas R, Bowles K, O'Brien L, Haines T (2017): Transferring weekend physiotherapy services from the acute to sub-acute setting: Does it make a difference to patient or service outcomes following lower limb joint replacement?

Haas R, O'Brien L, Bowles K, Haines T (2017): Health professionals' perceptions of the allied health role in the acute setting following hip and knee joint replacement surgery: a qualitative study

O'Brien L, Sarkies M, **Haas R**, Bowles K, Haines T (2017): Are patients' perceptions of service quality influenced by the presence of a weekend allied health service on acute hospital wards?

Farlie M, Robins L, **Haas R**, Keating J, Molloy E, Haines T (2017): Program frequency, type, time and duration do not explain the effects of balance exercise in older adults: a systematic review with a meta-regression analysis.

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Chapter 1 – Introduction

This thesis reports the findings of a research program that commenced in 2013, which arose from a passion to explore whether or not current allied health services are provided effectively after joint replacement surgery. Health care should be built on evidence based research to enable “those managing health services to determine the mix of services and procedures that will give the greatest benefit to the population served” (Muir Gray, 1997). It is defined as the conscientious use of current best evidence in making decisions about the delivery of health services (Cochrane, 2005) and is the motivation for this thesis. This research was conducted in an Australian tertiary public hospital service and was specifically concerned with examining whether or not there is evidence of effectiveness for weekend allied health services during the acute postoperative period following elective hip and knee replacement surgery.

This chapter provides the relevant background information and rationale behind this research program. The first section discusses: the burden of elective lower limb joint replacement; how the provision of allied health services may assist in the postoperative recovery process; research suggesting that outcomes for patients admitted to hospital on the weekend are worse than for those admitted on a weekday; how this may apply to patients following elective hip and knee replacement; and the concept of a weekend in the hospital environment. Finally, the multi-dimensional nature of allied health is discussed with specific focus on two additional factors (allied health quantity and timing of commencement) that could potentially mediate the effectiveness of weekend allied health services on outcomes following joint replacement surgery.

The second section of this chapter presents the findings of a published systematic literature review evaluating available evidence relating to the timing of commencement, total dose, and effect of weekend allied health services in the acute phase following elective lower limb joint replacement. This chapter concludes with the overall thesis aim, the individual research questions that have guided this PhD research program and an overview of the subsequent chapters.

1.1 Background

1.1.1 Burden of osteoarthritis and elective joint replacement surgery

Osteoarthritis is the most common form of arthritis (Reginster, 2002) and a significant cause of chronic disability in Australia and globally. It affects approximately 2.2 million people in Australia (Ackerman, Bohensky, Pratt, Gorelik, & Liew, 2016), 8 million people in the United Kingdom (Arthritis Research UK, 2013) and 30 million people in the United States (Arthritis Foundation, 2017). The burden of hip and knee osteoarthritis in terms of disability adjusted life years is ranked 38th in the world and 23rd in Australasia (which includes Australia and New Zealand) (Cross et al., 2014). This is projected to increase to become one of the top ten leading causes of disability adjusted life years in developed regions by 2020 (Murray & Lopez, 1997). In Australia, the direct health costs associated with osteoarthritis were estimated to be over \$2.1 billion in 2015 and are forecast to exceed \$2.9 billion by 2030 (Ackerman et al., 2016). By 2032, the number of Australians with osteoarthritis is projected to increase by 58% to 3 million people (Arthritis and Osteoporosis Victoria, 2013).

Total joint replacement or arthroplasty is a surgical procedure performed to relieve pain and disability associated with arthritis, particularly of the hip and knee. Clinical guidelines in Australia recommend joint replacement surgery as a cost effective intervention for people with severe osteoarthritis who are unresponsive to medication and exercise (Brand, Osborne,

Landgren, & Morgan, 2007). Significant increases in lifetime risk of total knee and hip replacement have been observed internationally over a 10-year period from 2003 to 2013 (Ackerman, Bohensky, de Steiger, Brand, Eskelinen, Fenstad, Furnes, Garellick, et al., 2017; Ackerman, Bohensky, de Steiger, Brand, Eskelinen, Fenstad, Furnes, Graves, et al., 2017). In Australia, in 2016, 46,224 hip replacement procedures and 59,905 knee replacement procedures were performed (Australian Orthopaedic Association National Joint Replacement Registry, 2017), an increase of 213% and 318.3% respectively since the 1998-99 financial year (Graves, Davidson, & Ingerson, 2000). Although there has been documentation of joint replacement overutilisation (Riddle, Jiranek, & Hayes, 2014), the rates of total hip and knee joint replacement surgery are expected to continue to rise. This is due to an ageing population (Brody, 1985), an increasing prevalence of obesity (Vasarhelyi & MacDonald, 2012), public expectations for improved quality of life (Iorio et al., 2008) and expanded indications for total joint replacement surgery (Losina, Thornhill, Rome, Wright, & Katz, 2012). Younger patients than previously may be considered candidates for surgery since newer prosthetic components are thought to last longer (Rodriguez, Bhende, & Ranawat, 2001) and younger age and better preoperative health are associated with more favourable outcomes (Fortin et al., 2002). There may also be a growing demand amongst younger patients who wish to maintain or resume higher levels of physical activity (Kurtz et al., 2009).

Although total joint replacement is deemed a cost effective procedure from the clinical and patients' perspective (Daigle, Weinstein, Katz, & Losina, 2012; Kamaruzaman, Kinghorn, & Oppong, 2017), the increasing demand for such surgery is placing pressure on health care resources internationally. The direct hospital costs associated with total joint replacement are estimated to be approximately AU\$1 billion (Peel et al., 2015), £852 million (A. Chen, Gupte, Akhtar, Smith, & Cobb, 2012) and US\$42.3 billion (Murphy & Helmick, 2012) per

year in Australia, the United Kingdom and United States of America respectively. A significant component this expense is related to staffing costs during the inpatient hospital stay (D. A. Haas & Kaplan, 2017). The rising prevalence and cost of joint replacement surgery combined with limited health care resources is placing increasing emphasis on the need for effective and efficient postoperative models of care.

1.1.2 Allied health services following elective joint replacement surgery

Allied health professionals deliver evidence-based practice to clients in order to protect, restore and maintain optimal physical, sensory, psychological, cognitive, social and cultural function (Duckett & Bredon, 2014). Allied health interventions such as physiotherapy and occupational therapy are a core component of postoperative rehabilitation following joint replacement surgery in the hospital setting. Although the term allied health covers a broad range of health professionals that do not include medicine or nursing (Allied Health Professions Australia, 2014), anecdotally physiotherapists and occupational therapists with support from an allied health assistant are typically the main allied health professionals involved in patient rehabilitation following joint replacement surgery in the hospital setting. The role of physiotherapists and occupational therapists is to facilitate independence in mobility and self-care activities such as toileting, washing and dressing in preparation for discharge (College of Occupational Therapists, 2012; Department of Health, 2010). Allied health professionals are also involved in providing education necessary for patients to demonstrate awareness of postoperative precautions and to conduct a home exercise program independently (Enloe, Shields, Smith, Leo, & Miller, 1996). Inpatient multidisciplinary interventions including physiotherapy and occupational therapy have been shown to reduce length of stay and improve outcomes for people undergoing joint replacement in both the acute and sub-acute hospital settings (Khan, Ng, Gonzalez, Hale, & Turner-Stokes, 2008). Despite high use of postoperative allied health services following hip and knee joint

replacement (Jaglal, Mackay, & Corrigan, 2004), they remain a significantly understudied component of care (Rankin, Alarcón, Chang, & Cooney Jr, 2004).

The provision of allied health services on the weekend in the acute setting following elective lower limb joint replacement is the central focus of this thesis. Health care providers have a responsibility to provide health care that is accessible, available, acceptable, equitable, and of good quality to all communities (World Health Organization, 2003). There is reason to suggest outcomes following hip and knee replacement may be particularly sensitive to the provision of allied health services and that from an equity perspective there should be equal access to these services throughout the week. However, there is also reason to question the cost-effectiveness of weekend allied health services since these services cost more to provide compared to weekday services. A permanent, full-time, allied health staff member in Victoria, Australia receives a 1.5 times pay loading to work weekend-hours if a part of their regular 38 hour week and 2.0 times pay loading if this work is in addition to their regular 38 hour week (Fair Work Australia, 2012).

The following sections summarise background research suggesting outcomes for patients admitted to hospital on the weekend may be worse than for those admitted on weekdays, and outline factors that may potentially compromise the effectiveness of weekend allied health services following hip and knee replacement surgery.

1.1.3 The “weekend effect”

There is a growing body of evidence suggesting that health outcomes are worse amongst patients admitted to hospital on the weekend compared to during the week, known as “the weekend effect”. Although this is a controversial topic with some questioning its existence (Bray et al., 2016; Li & Rothwell, 2016), two recent systematic literature reviews both

containing over 50 million patients have demonstrated an increased risk of mortality for weekend versus weekday hospital admissions (Hoshijima et al., 2017; Pauls et al., 2017). This effect has been observed in most developed countries across a variety of different conditions including cancer (Cram, Hillis, Barnett, & Rosenthal, 2004), cardiovascular disease (Gallerani et al., 2011; Kostis et al., 2007), stroke (Palmer, Bottle, Davie, Vincent, & Aylin, 2012), cervical spine trauma (Nandyala, Marquez-Lara, Fineberg, Schmitt, & Singh, 2013), acute epiglottitis (Bell & Redelmeier, 2001), pulmonary embolism (Bell & Redelmeier, 2001), ruptured aortic aneurysm (Bell & Redelmeier, 2001), hip fracture (Thomas, Smith, Uzoigwe, & Braybrooke, 2014), acute exacerbation of chronic obstructive pulmonary disease (Barba et al., 2012) and childbirth (Gould, Qin, Marks, & Chavez, 2003).

Proposed explanations for this weekend effect predominantly revolve around two possibilities: 1) a lower quality of weekend clinical services due to reduced staffing levels and/or experience and unavailability of tests or procedures and 2) a selection bias whereby the patients admitted to hospitals over the weekend may be more severely ill than those admitted during the working week. Evidence exists in support of both of these hypotheses (Aylin, Alexandrescu, Jen, Mayer, & Bottle, 2013; Aylin, Yunus, Bottle, Majeed, & Bell, 2010; Freemantle et al., 2012; Tarnow-Mordi, Hau, Warden, & Shearer, 2000). Although it is likely that a combination of both exists depending on the diagnostic group (Concha, Gallego, Hillman, Delaney, & Coiera, 2014), there is some evidence to suggest patients admitted for weekend elective surgery may be healthier than their weekday counterparts (Aylin et al., 2013). Therefore, quality of weekend care may be a more plausible contributing factor if a weekend effect does exist in patients undergoing elective lower limb joint replacement.

There is evidence suggesting the weekend effect exists in elective surgical admissions (Aylin et al., 2013; Glance et al., 2016; McIsaac, Bryson, & van Walraven, 2014; Mohammed, Sidhu, Rudge, & Stevens, 2012) although it remains unclear as to whether or not this pertains specifically to patients undergoing joint replacement surgery. Two large retrospective cohort studies have demonstrated a higher risk of death within 30 days among elective surgical patients (including hip and knee joint replacement) who underwent surgery on a weekend compared to during the week (Aylin et al., 2013; McIsaac et al., 2014). In the study conducted by Aylin et al (2013) amongst patients undergoing elective surgery in English public hospitals, this effect was seen in a low-risk subgroup [where hip and knee replacement comprised two of the seven low-risk procedures (n=555,635 admissions)] only for those undergoing surgery on a Friday as opposed to the weekend. The higher mortality risk was not statistically significant in either the hip or knee replacement subgroup in the study conducted by McIsaac et al (2014) in acute care hospitals in Ontario, Canada. It is possible that neither of these studies were adequately powered to detect a significant difference in mortality in weekend compared to weekday admissions amongst these subgroups, given the lower surgical rates observed over the weekend compared to during the week. It is also possible that outcome measures indicative of physical function or health service costs may be more appropriate than mortality to evaluate the existence of a weekend effect in patients undergoing joint replacement surgery given the relatively low risk of mortality observed in these populations.

Comparisons between day of week of surgery and health outcomes or length of hospital stay in patients undergoing elective joint replacement surgery have yielded inconsistent results. Some studies have found a relationship between day of surgery and outcomes (mainly length of hospital stay) (Boylan et al., 2017; Chaurasia, Garson, Kain, & Schwarzkopf, 2014; Husted, Holm, & Jacobsen, 2008; Mathijssen, Verburg, van Leeuwen, Molenaar, &

Hannink, 2016; Muppavarapu et al., 2014; Newman et al., 2017) whereas others have not (Briggs, Guevel, McCaskie, & McDonnell, 2017; Dall, Ohly, Ballantyne, & Brenkel, 2009; Gibbs, Tafazal, Handley, & Newey, 2012; Raut, Mertes, Muniz-Terrera, & Khanduja, 2012). Variable results regarding a possible “weekend effect” have even been found within a single study amongst different outcome measures (Heck, Robinson, Partridge, Lubitz, & Freund, 1998). This prospective, observational cohort investigation of 563 patients following primary knee replacement in the USA demonstrated a lower likelihood of complications if their surgery was performed mid-week but that those who had their surgery on a Monday, Friday or Saturday experienced better physical improvement at two year follow-up. The one consistency observed amongst these studies is that most have attempted to explain the presence or absence of an association between surgery day of week and outcomes following elective joint replacement surgery by differences in weekend staff availability (particularly physiotherapists) compared to during the working week (Boylan et al., 2017; Briggs et al., 2017; Chaurasia et al., 2014; Dall et al., 2009; Husted et al., 2008; Mathijssen et al., 2016; Muppavarapu et al., 2014; Newman et al., 2017).

The major limitation of cohort studies demonstrating an association between weekend staff availability and postoperative outcomes is that, by nature of their design, they are only able to demonstrate the existence of a relationship between two variables and this does not infer causation. These associations may be explained by additional confounding factors. It therefore remains unclear as to whether a “weekend effect” exists in patients undergoing elective joint replacement surgery. In particular, previous research has raised the possibility that the existence or absence of a “weekend effect” may differ according to level of preoperative function (Heck et al., 1998), complexity of the patient and/or surgery (Chaurasia et al., 2014) and amount and timing of allied health provided postoperatively

(Gibbs et al., 2012; Husted et al., 2008). Future research in this area should therefore have the capacity to investigate and account for these factors.

1.1.4 Concept of a weekend in a hospital environment

According to definition, hospitals are required to deliver medical, nursing and related services 24 hours per day, seven days per week (World Health Organization, 2017), but this is not always the case. The introduction of legislation limiting the number of hours worked per week internationally (Lee, McCann, & Messenger, 2007) has made weekend services more expensive, and has cemented an expectation amongst society that the weekend should be devoted to rest. A dichotomy is created by the need for hospital services to be provided during the weekend at a time of traditional rest. This particularly applies to hospital staff dealing with health issues that are perceived as non-urgent.

There is evidence to suggest that hospitals function differently on a weekend compared to during the week. This has implications for the provision of effective and efficient postoperative models of allied health service delivery. Quantity and seniority of healthcare staffing is reduced on the weekend in both the hospital and community (Marco et al., 2010; The College of Emergency Medicine, 2013) as a result of the less desirable nature of weekend work and the higher cost per hour of employing staff on the weekend (Fair Work Australia, 2012). This has the potential to affect the quality of care provided within the hospital and the ability to discharge patients home with support services.

Although there may be fewer elective joint replacement surgeries conducted on the weekend compared to during the week, the need for postoperative allied health services on the weekend for those undergoing surgery late in the working week should theoretically be similar to those undergoing surgery earlier in the working week. However, allied health

staffing levels are reduced in quantity and seniority on the weekend compared to the working week. A survey of tertiary care hospitals in Canada reported that although weekend physiotherapy services were provided in the majority of facilities, there were fewer physiotherapists working fewer hours over the weekend than during the week (L. Campbell et al., 2010). This was calculated to represent an 88% reduction in quantity of services available on the weekend relative to the working week. In this survey, 69% of facilities did not require staff to have previous clinical experience in order to work on the weekend. Similarly, an Australian study found physiotherapy services provided on the weekend were significantly less in duration than those provided during business hours from Monday to Friday (Shaw, Taylor, & Brusco, 2012). In the only known study examining the availability of other allied health professions on the weekend in the acute setting, a survey of acute care community hospitals in Canada reported allied health assistants, social work and occupational therapy services were offered on the weekend at 71%, 24% and 16% of hospitals respectively (Ottensmeyer et al., 2012).

There is substantial variation in the delivery of allied health services within and between inpatient settings over the weekend. An Australian cross-sectional survey found variation in the provision of weekend physiotherapy services according to hospital funding source (private or public), hospital location (metropolitan or regional) and hospital size (Shaw et al., 2012). In particular, 60% of acute wards provided a weekend physiotherapy service compared to only 30% of sub-acute wards. Variability in availability of and eligibility criteria for weekend physiotherapy services has also been described in Canada (L. Campbell et al., 2010; Ottensmeyer et al., 2012). For example, a survey of acute-care community hospitals found the presence of a weekend physiotherapy service varied from 30% to 93% in different regions (Ottensmeyer et al., 2012). Variation in clinical practice that cannot be explained by type or severity of illness or patient preference (unwarranted variation) has

been associated with inconsistencies in outcomes and unnecessary healthcare costs in other populations and addressing this has become a priority for health care systems internationally (Duggan, Koff, & Marshall, 2005; P. J. Kennedy, Leathley, & Hughes, 2010; Love, Ehrenberg, & Group, 2014).

Changes in the functioning of a hospital on the weekend combined with unwarranted variation in weekend allied health services have the potential to compromise the effectiveness of weekend allied health services provided to patients following hip and knee replacement. This thesis will therefore explore the provision of weekend allied health services following hip and knee joint replacement surgery including an evaluation of the sufficiency and rigor of evidence in support of these services. In particular, it will evaluate whether there is evidence of effectiveness to justify the provision of real-life weekend allied health services in the acute postoperative phase.

1.1.5 Multi-dimensional nature of allied health

There are different dimensions of allied health to consider and potential relationships between these dimensions of allied health that warrant consideration when examining the effect of weekend allied health service provision on outcomes following elective lower limb joint replacement surgery. This thesis focuses on the effect of an acute weekend allied health service on outcomes following hip and knee replacement surgery by considering the additional effect on timing of therapy commencement and therapy quantity. It should be noted there are additional dimensions such as the different allied health professions that have not been considered in this thesis. Therapy quantity has been considered as an overall dimension but not divided into contributing dimensions such as therapy frequency and duration.

Provision of earlier and higher intensities of allied health services has been shown to improve outcomes for a range of patient populations in hospitals (Beder, 2008; Cifu, Kreutzer, Kolakowsky-Hayner, Marwitz, & Englander, 2003; Oldmeadow et al., 2006; Peiris, Taylor, & Shields, 2011; Schweickert et al., 2009). However, there is evidence to suggest there may be caveats to these guidelines and that earlier and more therapy may not always be advantageous or efficient. For example, an observational dose-response study in patients undergoing inpatient stroke rehabilitation demonstrated diminished marginal improvement with increasing levels of physiotherapy service provision (T. P. Haines, Kuys, Clarke, Morrison, & Bew, 2011). This suggests the efficiency of physiotherapy resource allocation reduces at higher quantities. Recently, a large international pragmatic randomised controlled trial also demonstrated that very early, more frequent and higher dose mobilisation therapy may result in poorer functional outcomes three months after stroke compared with lower dose usual care (Bernhardt et al., 2015). It therefore seems there may be an optimal timing of commencement and quantity of allied health that is specific to different patient populations and/or therapy types.

The availability of allied health services on the weekend has the potential to directly affect the quantity of allied health provided and the time at which therapy commences following surgery for those undergoing surgery late in the working week or on the weekend. For example, a patient undergoing surgery on a Saturday at a hospital that does not provide a weekend allied health service will commence therapy at the earliest on the second postoperative day (Monday). In comparison, a patient undergoing surgery on a Saturday at a hospital that does provide a weekend allied health service could theoretically commence therapy as early as the day of surgery (Saturday). Assuming a constant rate of therapy each day, the time at which therapy commences following surgery also has the capacity to directly affect the total dose of therapy provided. That is, if therapy commences earlier

postoperatively and continues at the same rate throughout the inpatient stay, a higher overall quantity or dose of therapy will be provided.

The potential relationships between the allied health dimensions of weekend allied health, early allied health initiation, and allied health quantity, and the mechanisms by which they may affect outcomes of care are presented in Figure 1.1. The multi-dimensional nature of allied health therapy has been incorporated into the research program in order to be able to isolate the effect of a weekend allied health service on outcomes following hip and knee replacement. In particular, this thesis considers the effect of a weekend allied health service on timing of initiation and quantity of therapy provided and the effect of these relationships combined and in isolation on outcomes of care following elective lower limb joint replacement.

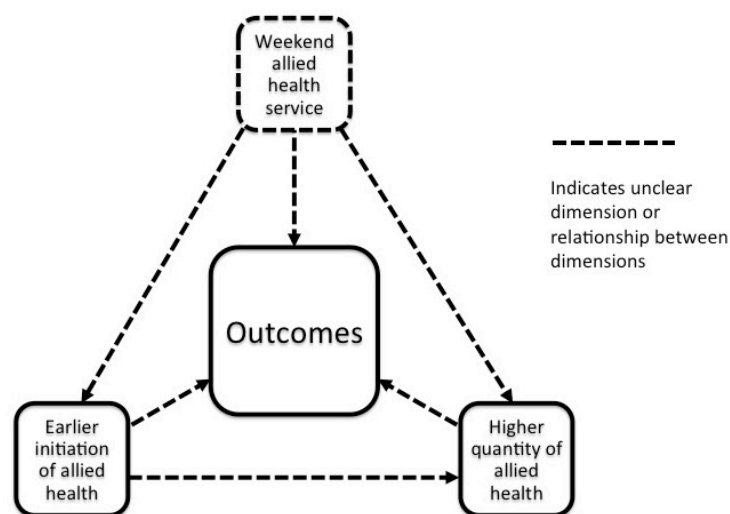


Figure 1.1: Potential relationships between allied health dimensions and outcomes of care

1.2 Preface to systematic literature review

The provision of limited weekend allied health services could potentially affect quality of care by impacting the timing of postoperative therapy initiation and the overall quantity of allied health provided. This concept is the subject of the following section, which presents

the findings of a systematic literature review examining the evidence-base related to quantity, timing of commencement and provision of weekend allied health services following elective lower limb joint replacement. It has been adapted, with permission of Elsevier, from a published manuscript:

Haas R, Sarkies M, Bowles K-A, O'Brien L and Haines T. Early commencement of physical therapy in the acute phase following elective lower limb arthroplasty produces favorable outcomes: a systematic review and meta-analysis examining allied health service models. *Osteoarthritis Cartilage*. 2016; 24: 1667-81.

A copy of the published article and copyright clearance is provided in Appendix A.

1.3 Early commencement of physiotherapy in the acute phase following elective lower limb joint replacement produces favourable outcomes: a systematic review and meta-analysis examining allied health service models

1.3.1 Abstract

Background

Temporal and dose-response relationships between allied health and recovery in the acute phase following lower limb joint replacement are unclear. This systematic review investigates whether early commencement, additional therapy and/or weekend allied health affects length of stay and patient outcomes in the acute phase following lower limb joint replacement.

Methods

Electronic databases were searched in February 2015. Studies were included if they evaluated any of the following aspects of allied health for adults following lower limb joint replacement in the acute phase: Early compared to later therapy commencement; Additional therapy; or a 6- or 7-day service compared to a lesser service.

Results

Twenty-four studies met the inclusion criteria, of which 19 investigated effects of physiotherapy alone. Earlier physiotherapy reduced length of stay [Weighted Mean Difference (WMD) = -1.23 days; 95% CI, -2.16 to -0.30] and resulted in higher probability of discharge directly home (relative risk = 1.45; 95% CI, 1.26-1.67). Addition of weekend physiotherapy reduced length of stay (WMD = -1.04 days; 95% CI, -1.66 to -0.41) and improved function [Standardised Mean Difference (SMD) = 0.37; 95% CI, 0.02-0.73]. Increasing physiotherapy from once to twice daily did not affect length of stay (WMD = -0.35 days; 95% CI, -0.96–0.26) or function (SMD=0.31; 95% CI, -0.06-0.71).

Discussion

Early physiotherapy commencement and a weekend service may produce favorable outcomes following lower limb joint replacement when baseline length of stay is 4 days or more. Redistributing physiotherapy resources to commence as early as day of surgery regardless of weekday may accelerate postoperative recovery. Current, high quality research is needed to confirm these findings.

1.3.2 Introduction

Clinical guidelines recommend joint replacement surgery as a cost effective intervention for people with severe osteoarthritis who are unresponsive to medication and exercise (Brand et al., 2007). Rates of knee and hip joint replacement have risen drastically over the last two decades (Weinstein et al., 2013; Wolford, Palso, & Bercovitz, 2015) and are expected to continue to rise. Between 2005 and 2030, primary total hip and knee replacement surgeries are projected to grow by 174% and 673% respectively in the United States (Kurtz, Ong, Lau, Mowat, & Halpern, 2007). Increasing demand for such surgery is placing pressure on scarce healthcare resources. Maximising postoperative recovery has the potential to improve quality of life, save money and increase capacity to perform additional surgeries by increasing patient flow.

Allied health professionals facilitate independent mobility and self-care in preparation for discharge following joint replacement (College of Occupational Therapists, 2012; Department of Health, 2010). Postoperative allied health may improve range of motion, quality of life, gait and balance and reduce hospital length of stay (A. F. Chen, Stewart, Heyl, & Klatt, 2012; Freburger, 2000; Khan et al., 2008; Labraca et al., 2011). However, the temporal (how soon post-surgery should therapy commence?) and dose-response relationships (by how much does the outcome improve if the amount of therapy is increased?) are unclear. Clinical guidelines prescribing exact timing and dose of therapy following lower limb joint replacement are absent despite general recommendations specifying early commencement of both physiotherapy (Department of Health, 2010) and occupational therapy (College of Occupational Therapists, 2012) where practicable.

Evidence from other populations suggests allied health should commence early enough and be of sufficient quantity to accelerate and maximise postoperative recovery but not too early or of too high a quantity so as to utilise allied health resources inefficiently or have detrimental effects on recovery (Lele, 2015; Saini, Kundnani, Patni, & Gupta, 2010; Wu & Tang, 2013). Timing of therapy commencement has the potential to affect the total quantity of therapy provided assuming a constant length of stay. Likewise, availability of weekend allied health can potentially affect both quantity and time of therapy commencement following lower limb joint replacement, especially when surgery occurs later in the working week or on the weekend. A recent review found weak evidence to suggest a benefit to weekend physiotherapy in reducing length of stay following total knee replacement (Kolber, Hanney, Lamb, & Trukman, 2013). However, it concluded early therapy initiation and the total sum of visits might be more influential than actual day of week during which treatment is received. This finding is logical given potential inter-relationships between availability of

a weekend allied health service, timing of therapy commencement post-surgery and therapy quantity, and deserves further investigation.

This study has been conducted from a service model perspective to inform decision-making by healthcare policy makers and managers. The aim was to systematically evaluate the available evidence relating to the timing of commencement, total dose, and effect of weekend allied health services, in the acute phase following elective lower limb joint replacement. Key outcomes were length of stay, rate of adverse events, discharge destination, cost and physical function.

This review required several aims to be addressed concurrently due to the multidimensional nature of allied health service models. The research questions were:

1. Does earlier commencement of allied health therapy result in reduced length of stay and improved outcomes compared to later commencement?
2. Is a greater quantity of allied health in the acute postoperative phase following lower limb joint replacement more beneficial in terms of patient and hospital outcomes compared to a lesser quantity?
3. What is the effectiveness of acute weekend allied health services in patients following lower limb joint replacement?
4. Are there differences in the evidence relating to timing of commencement, total dose and effectiveness of weekend allied health provision for patients undergoing total knee replacement compared to total hip replacement?

1.3.3 Methods

Study identification and selection

This review was performed and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Liberati et al., 2009). Full holdings of the Cochrane Central Register of Controlled Trials (CENTRAL), AMED, CINAHL plus, Embase, OVID Medline, Scopus and ProQuest (ProQuest Health & Medical Complete, ProQuest Nursing and Allied Health Source, ProQuest Social Science Journals) were searched electronically by the lead investigator (RH) on 16th February 2015. Publications were limited to English and no publication date limit was imposed. Boolean operators “AND” and “OR” were used to combine search terms relating to each domain in a PICO (Population, Intervention, Comparison and Outcomes) model (Richardson, Wilson, Nishikawa, & Hayward, 1995) and to provide additional terms with similar meaning respectively. Keywords included terms relevant to lower limb joint replacement AND allied health services AND weekend allied health OR early therapy OR increased dose AND joint replacement outcomes (Appendix B). Search terms relating to a comparison intervention were not identified. Truncation (*) was used where variations of search terms existed. The search strategy was first piloted and then refined for each database (Appendix C for AMED search).

Titles and abstracts were independently screened for relevance and cross-checked (VonVille, 2015) by two investigators (RH, MS). First, a random sample of 66 titles and abstracts were screened. Both reviewers were blinded to author and journal title, and reached strong agreement (Cohen's $\kappa = 0.84$) (McHugh, 2012). The two investigators then independently screened all titles and abstracts, and removed those that did not meet the inclusion criteria (Figure 1.2). The full text of all remaining articles, along with those where eligibility was uncertain, were obtained for review. Two investigators independently reviewed these to

ascertain eligibility for inclusion. Studies were excluded if the full text was unavailable or appropriate data was not collected as per the published methodology. Disagreements were resolved by discussion and where agreement could not be met, a third investigator (KAB) was consulted. Reference lists of included studies were searched using SCOPUS database (Elsevier, New York, USA) to identify additional relevant studies. This method has been shown to be as valid and more efficient than the traditional manual search approach (Chapman, Morgan, & Gartlehner, 2010). The reference list of each systematic review deemed eligible for full text review was scanned for relevant papers. Potentially relevant papers were then crosschecked against findings of the original search strategy to identify any further studies.

<p>Inclusion Criteria</p> <p><i>Design</i></p> <ul style="list-style-type: none"> • Experimental, quasi-experimental and observational study designs as long as a comparison intervention was evaluated in terms of a relevant outcome measure • Published in English <p><i>Participants</i></p> <ul style="list-style-type: none"> • Adults undergoing elective lower limb arthroplasty in a surgical facility and requiring admission to an acute health service <p><i>Intervention</i></p> <ul style="list-style-type: none"> • The effect of additional allied health therapy in terms of time, frequency or number of sessions provided compared to a lesser amount of therapy • The effect of early commencement of allied health therapy determined by time since surgery compared to a delayed commencement • Allied health therapy provided on the weekend with a 6- or 7-day service compared to that provided during the week with a lesser service • Allied health included physiotherapy, occupational therapy, speech therapy, dietetics, social work, orthotics or prosthetics • Allied health intervention to focus on service models rather than individual treatment modalities <p><i>Outcome Measures</i></p> <ul style="list-style-type: none"> • Length of stay, adverse events, unplanned readmission, discharge destination, function, mobility, joint range of motion, quality of life, pain, cost.

Figure 1.2: Inclusion criteria for systematic literature review

In an attempt to use the best available evidence, it was decided a priori that experimental, quasi-experimental and observational study designs would be included since previous

reviews in similar fields have identified few randomised controlled trials (Kolber et al., 2013; Nikitovic & Ontario, 2014).

Data Extraction

Two reviewers (RH, MS) independently extracted data related to study participants, exclusion criteria, study design, control and intervention (therapy type, timing, frequency and duration of therapy), outcomes, follow-up period, results and the PEDro (Physiotherapy Evidence Database) scale. Differences in data extracted were resolved by discussion and a third investigator (KAB) was consulted where consensus was not achieved. Attempts were made to contact authors of studies where collected data was not reported or where clarification was required.

Critical Appraisal

All studies underwent an independent quality assessment by two investigators (RH, MS) using the PEDro scale (Maher, Sherrington, Herbert, Moseley, & Elkins, 2003). PEDro assesses trials for quality according to 11 criteria, of which 10 are summed to form a final score. Although the PEDro scale was developed to assess randomised controlled trial quality, these criteria (Maher et al., 2003) have been applied in this review to provide a standardised quality assessment of all study designs. Random allocation is a criterion in the PEDro scale and therefore non-randomised studies receive a lower quality rating in accordance with the hierarchy of evidence (Silagy, Rubin, Henderson-Smart, & Gross, 1998). The PEDro database was consulted to confirm quality scores for previously assessed randomised controlled trials. A third reviewer (KAB) was consulted where discrepancies existed between the PEDro database and the reviewers of the present study. Additional potential sources of risk of bias for each study were also considered.

Data Analysis

Statistical analysis was undertaken using Stata (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP). DerSimonian and Laird (1986) random-effects meta-analyses were used to estimate the pooled effect of each service model (timing of commencement, dose and weekend service) where there was more than one study evaluating a similar outcome. Meta-analyses were not conducted on studies investigating multiple service models simultaneously. However, a study could be included in multiple service model meta-analyses if supporting data and outcomes confirming the inter-relationship was available. For example, a study investigating the effect of a weekend allied health service could also be included in a meta-analysis investigating the effect of early therapy commencement if there was adequate data confirming the weekend service resulted in earlier therapy commencement. The effect of each service model was estimated using: standardised mean differences (SMD) for functional outcomes and pain; weighted mean differences (WMD) for length of stay and range of motion; and relative risk (RR) for discharge destination, unplanned hospital readmissions and adverse events. SMD strength was determined according to Cohen (J. Cohen, 1977), with 0.2 considered small, 0.5 moderate and 0.8 a large effect size. Heterogeneity between studies was quantified using the I-squared statistic, with values of more than 50% representing substantial levels (Higgins, Thompson, Deeks, & Altman, 2003). Subgroup analyses and random effects univariate and multivariate meta-regression were performed where possible to explore the role of potential sources of heterogeneity. These included surgery type, study design, study quality (PEDro individual criteria) and intervention differences. Tau-squared, I-squared residual and adjusted R-squared values were used to investigate potential sources of heterogeneity. P-values generated through meta-regression analyses were used to determine if a covariate explained a significant amount of heterogeneity in the meta-analysis results.

Disease specific scales such as the Knee Society Score (KSS) and Iowa Level of Assistance Scale (ILOA) were pooled and categorised as functional outcome measures along with walking distance. In studies where multiple functional outcome measures were evaluated, the outcome most relevant during the inpatient period was chosen. For example, independence in functional mobility was deemed more relevant at this time than the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score because the WOMAC includes functional tasks such as heavy household duties that are not relevant during the inpatient period. In studies where outcomes were measured at multiple time points, the time closest to the mean discharge of that study group was used to calculate SMDs. This was to allow therapy to have its effect over the entire acute hospitalisation but no later to avoid subjecting data to other confounding variables occurring after hospital discharge. Where subscales were reported, summing the items for all subscales and pooling the subscale standard deviations created a total scale score.

Where study results were reported as medians and ranges or interquartile ranges, authors were contacted to obtain means and standard deviations. Where this data was not available, the methods of Wan et al (2014) were used to convert results into means and standard deviations. A sensitivity analysis was undertaken to re-assess the effect of excluding these studies in the meta-analysis. Sensitivity analyses were also undertaken to test robustness of findings including studies subject to substantial risk of bias (PEDro <7) and those examining the effect of allied health professions additional to physiotherapy on the results obtained. Additionally, sensitivity analyses were conducted to confirm results where outcome data were available at different time points and where baseline length of stay was greater than current averages.

1.3.4 Results

Study Selection

Figure 1.3 displays search, screening and eligibility findings. The search strategy identified four systematic literature reviews. From these, an additional three relevant studies (Holden & Daniele, 1987; Lenssen et al., 2006; Rapoport & Judd-Van Eerd, 1989) of which one (Lenssen et al., 2006) was subsequently included in this review (Appendix D).

Characteristics of Included Trials

Table 1-1 depicts characteristics of included papers. Of the 25 that met the inclusion criteria, there were six randomised controlled trials, 17 cohort designs, one cross-sectional and one cost-effectiveness paper. The cost-effectiveness paper (Larsen, Hansen, Thomsen, Christiansen, & Søballe, 2009) was based on one of the randomised controlled trial's (Larsen, Sørensen, Hansen, Thomsen, & Søballe, 2008), and was therefore treated as the same study. All studies evaluated the effect of physiotherapy following lower limb joint replacement with four evaluating the additional effect of occupational therapy (Isaac et al., 2005; Larsen, Hvass, Hansen, Thomsen, & Søballe, 2008; Larsen, Sørensen, et al., 2008; Robbins et al., 2014) and one social work (den Hertog, Gliesche, Timm, Mühlbauer, & Zebrowski, 2012). The effect of weekend physiotherapy and early commencement on quantity of therapy were documented in three and one study respectively (Figure 1.4).

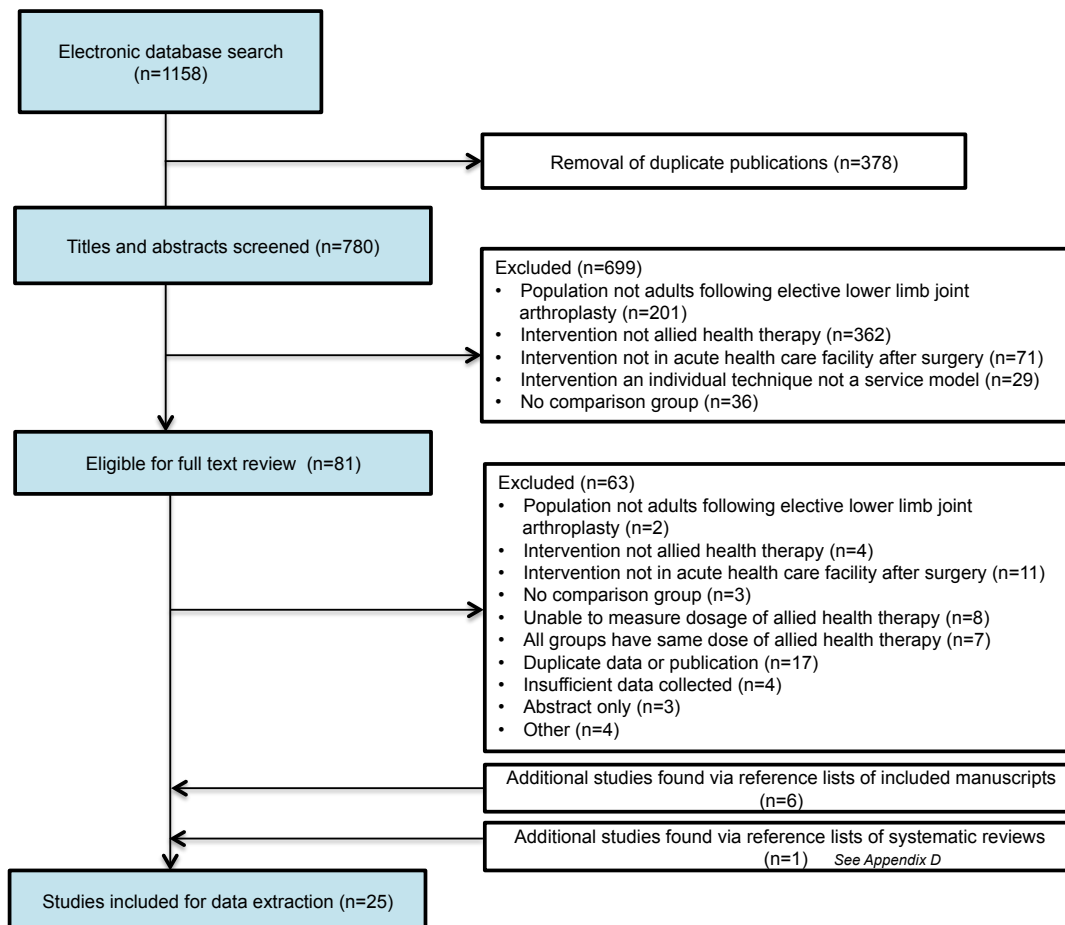


Figure 1.3: Flow of studies

Table 1-1: Characteristics of included studies

Abbreviations: RCT, randomised controlled trial; THR, total hip replacement; TKR, total knee replacement; C, control group; I, intervention group; SD, standard deviation; PT, physiotherapy; POD, postoperative day; LOS, length of stay; KSS, Knee Society Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; ROM, range of motion; SF-36, Short Form 36 Health Survey; SPS, single point stick; 4PS, 4 point stick; ILOA, Iowa Level of Assistance; CPM, continuous passive motion; mins, minutes

Author (year)	Study Design	Participant Details	Control Group	Intervention Group	Outcome Measures
Bottros et al 2010	Retrospective cohort (historical control group)	103 THR C n=73; Mean age (range) 58.7 (16-85) I n=30; Mean age (range) 59.6 (14-82)	Commence PT on POD 1 and ambulation on POD 2	Commence PT on POD 0, abductor sparing surgical approach & pain management	LOS, discharge destination. Distance walked & pain on POD 0, 1, 2 & 3. Hip Harris score on weeks 4 & 12.
Boxall et al 2004	Prospective cohort (historical control group matched by sex and age)	240 acute orthopaedic patients C n=120; Mean age 68.03 (variance not reported) I n=120; Mean age 67.97 (variance not reported)	Weekday PT service	7 day PT service	LOS, days to independent transfers, days to independent mobility, reasons for delayed discharge, discharge destination
Chen et al 2012	Prospective cohort (control group – PT commence on POD 1)	136 TJR (58 THR; 78 TKR) C n=111; Mean age (SD) 62.29 (11.05) I n=25; Mean age (SD) 58.0 (9.4)	Commence PT on POD 1	Commence PT on POD 0	LOS, pain on POD 0, functional status after first PT session (ie remain in bed, out of bed to chair or ambulating) & discharge destination
den Hertog et al 2012	RCT	147 TKR C n=73; Mean age (SD) 68.25 (7.91) I n=74; Mean age (SD) 66.58 (8.21)	Standard rehabilitation (1hr PT/day, mobilisation commenced on POD 2)	Fast-track rehabilitation - PT 2hr/day, commence on POD 0, focus on ADL & individual case management, positive messages and use of competitive care, expected discharge on POD 6	LOS, adverse events. AKSS, WOMAC & weighted consumption of analgesic medication on POD -1, 5-7, 15-23, 6 weeks & 3 months
Freburger J 2000	Cross Sectional	7495 THR Mean age (range) 64 (12-105)			Dependent variables - total cost care<expected, increased probability of discharge home Independent variable – physical therapy utilisation
Hughes et al 1993	Prospective cohort (historical control group)	73 THR C n=27; I n=46 64 TKR C n=26; I n=38 Age results reported as n/decade (unable to calculate mean, SD or range but majority of participants aged 60-80)	Weekday PT service	7 day PT service	LOS, PT treatment on weekend following surgery
Isaac et al 2005	Prospective cohort (control group – different surgeon, same hospital)	130 TKR C n=80; mean age (range) 71.3 (42-84) I n=50; mean age (range) 72.3 (50-88)	PT commence on POD 1	PT commence on POD 0 (4hrs postop), infiltration of bupivacaine & adrenaline, modification to surgery technique, multidisciplinary D/C planning, education re: expect shorter LOS	LOS, discharge delays & complications, blood loss postoperatively. Pain levels on POD 0, 1, 2, 3, 4, 5, 6, 7 & 14. AKSS, active knee ROM & Oxford functional rating score preoperatively and 6 weeks postoperatively
Juliano et al 2011	Retrospective cohort (historical control group matched by week of surgery)	408 THR C n=204; Mean age (range) 60.4 (27-82) I n=204; Mean age (range) 60.2 (32-83)	PT commence on POD 1 with 4 day expected LOS	PT commence on POD 0 with 3 day expected LOS	LOS and level of assisted required for transfers, ambulation with cane and negotiating stairs at discharge

Author (year)	Study Design	Participant Details	Control Group	Intervention Group	Outcome Measures
Klika et al 2009	Retrospective cohort (historical control group)	116 TKR C n=62; Mean age (range) 64.8 (48-84) I n=54; Mean age (range) 63.5 (45-86)	Traditional PT – bed rest POD 0, dangling at edge of bed POD 1 & ambulation POD 2.	Rapid recovery – improved pain management, quadriceps sparing approach & PT protocol commencing on POD 0	LOS, discharge destination. Distance walked, flexion ROM and pain on POD 1, 2, 3, & 4. Knee Society Scores 4 weeks postoperatively.
Labraca et al 2011	RCT	306 TKR C n=153; Mean age (SD) 66.36 (5.03) I n=153; Mean age (SD) 65.48 (4.83)	PT commence within 48-72 hours post surgery	PT commence within 24 hours of surgery	LOS. Pain, flexion & extension ROM, flexion & extension strength, Barthel Index & Tinetti test on day of discharge.
Lang C 1998	Prospective cohort (historical control group)	92 THR C n=57; Mean age (SD) 71.6 (14.7) I n=35; Mean age (SD) 64.7 (15.3) 48 TKR C n=23; Mean age (SD) 67.6 (11.2) I n=25; Mean age (SD) 68.9 (10.6)	6 day/week PT service (11 PT sessions/week)	7 day/week PT service (12 PT sessions/week)	LOS & discharge destination. Independence in don/doff lower extremity brace, moving in/out of bed, transfers, gait and ascending/descending stairs on day of discharge.
Larsen, Hvass et al., 2008	Prospective before-after cohort	139 THR & 108 TKR C n=63 THR & 42 TKR; Mean age (SD) 65 (11) I n=76 THR & 66 TKR; Mean age (SD) 65 (11)	Traditional rehabilitation – PT commence on POD 1	Accelerated rehabilitation – PT commence on POD 0, preoperative assessment, optimisation of oral nutrition	LOS. Hospital readmissions and adverse events within 3 months postoperatively.
Larsen, Sorensen et al., 2008	RCT	58 THR & 28 TKR C n=30 THR & 13 TKR; Mean age (SD) 65 (11.0) I n=28 THR & 15 TKR; Mean age (SD) 65 (11.0)	Standard rehabilitation – PT/OT commence on POD 1, 4hrs out of bed/day	Accelerated and intensive rehabilitation – PT/OT commence on POD 0, 8hrs out of bed/day, preoperative education, standardised pain relief, optimisation of oral nutrition.	LOS. Hospital readmissions and adverse events within 3 months postoperatively
Larsen, Hansen et al., 2009	Cost-effectiveness study based on RCT above	As above	As above	As above	Incremental cost within 12 months postoperatively
Lenssen et al., 2006	RCT	43 TKR C n=22; Mean age (SD) 67 (7) I n=21; Mean age (SD) 70 (8.5)	PT once/day, 20mins each session	PT twice/day, 20mins each session	LOS. Flexion & extension passive & active ROM, KSS, pain & satisfaction on POD 4, 6 weeks and 3 months postoperatively. WOMAC & perceived effect of surgery 6 weeks & 3 months postoperatively.
Liang et al., 1987	Prospective cohort (historical control group)	200 THR & TKR Group 1 n=50; Mean age (SD) 66.4 (7.3) Group 2 n=50; Mean age (SD) 66.2 (7.3) Group 3 n=50; Mean age (SD) 64.1 (7.1) Group 4 n=50; Mean age (SD) 67.8 (7.2)	Group 4 - Weekday PT service, once/day & weekend priority cases	Group 1 – 7 day PT service, twice/day (premerger) Group 2 - 7 day PT service, twice/day (postmerger) Group 3 – 7 day PT service, at least once/day	LOS. Functional Mobility Index on day of discharge. Intensity of physical therapy services provided during hospital stay. Complications within 6 months postoperatively.
Liebs et al., 2012	RCT	280 THR C n=142; Mean age (SD) 69.1 (9.8) I n=129; Mean age (SD) 66.7 (10.3) 185 TKR I n=87; Mean age (SD) 68.5 (8.6)	Commenced aquatic therapy on POD 14	Commenced aquatic therapy on POD 6	WOMAC function, pain & stiffness, SF-36, Lequesne-Hip/Knee Score & patient satisfaction at 3, 6, 12 & 24 months postoperatively.
Maidment et al., 2014	Prospective cohort (historical control group)	91 TKR C n=40; Mean age (IQR) 70.5 (68-78) I n=51; Mean age (IQR) 69 (65-75)	5 day PT service	7 day PT service	Hospital & PT LOS

Author (year)	Study Design	Participant Details	Control Group	Intervention Group	Outcome Measures
		54 THR C n=19; Mean age (IQR) 69 (66-77) I n=35; Mean age (IQR) 69 (65-75)			
Peck et al., 2006	Retrospective cohort (concurrent control from different hospital matched by age, sex and body mass)	96 THR Standard incision routine PT n=26; Mean age (SD) 70 (9.6) Minimal incision routine PT n=29; Mean age (SD) 71 (10) Standard incision intensive PT n=19; Mean age (SD) 70 (11.3) Minimal incision intensive PT n=22; Mean age (SD) 71 (9.7)	Standard incision and minimal incision routine PT - Once daily 5 day service	Standard incision and routine incision intensive PT - Twice daily 7 day service	LOS. Blood loss on POD 1. Scar length at a mean of 17 months postoperatively. Oxford hip score at 10-17 months postoperatively. Complications (not documented at what time this was measured).
Pua et al., 2011	Prospective cohort (historical control group)	229 TKR or unicompartmental knee arthroplasty C Group A n=82; Mean age (SD) 66.3 (8) C Group B n=74; Mean age (SD) 66.9 (9.3) I n=73; Mean age (SD) 65.4 (7.3)	Control Group A – 6 day PT service (once daily) 4 months prior to intervention Control Group B – 6 day PT service (once daily) 1 year prior to intervention	7 day PT service (once daily)	LOS and discharge knee outcomes (ROM knee flexion, ability to straight leg raise and proportion of patients who ambulated safely with SPS or 4PS)
Raphael et al., 2011	Prospective cohort (historical control group)	88 THR and 112 TKR C n=31 THR & 69 TKR; Mean age (SD) 69 (8) I n=57 THR & 43 TKR; Mean age (SD) 65 (9)	Standard rehabilitation – PT commence on POD 1 (as tolerated)	Fast-track rehabilitation – PT commence on POD 0, preoperative education, standardised preemptive and postoperative analgesia	LOS and transfer to tertiary hospital/emergency department visits during inpatient stay. Pain & postoperative nausea & vomiting on POD 0 & 1. Readmission to hospital within 30 days
Renkawitz et al., 2010	Prospective cohort (parallel control group)	143 TKR C=76; Mean age (SD) 68.1 (11.1) I=67; Mean age (SD) 67 (9)	Standard accelerated clinical pathway – mobilisation on POD 1, PT 1/day, weekends on demand, CPM 2/day	Optimised accelerated clinical pathway – Patient-controlled regional analgesia, ultra-early (POD 0)/doubled PT, once on weekend	Max. non-stop walking distance, number stairs, thigh circumference, KSS, Pain at rest & at mobilisation, knee ROM, time out of bed & opioid consumption on POD 5 & 8.
Robbins, Beirbaum et al., 2009	Retrospective cohort (concurrent control group – PT on POD 1)	40 THR; Mean age (range) 63.4 (32-82) C n=20; I n=20	Commence PT on POD 1	Commence PT on POD 0	LOS, discharge destination. Ability to ascend/descend stairs & ambulate 25 feet on POD 2.
Robbins, Casey et al., 2014	Retrospective cohort (concurrent control group – PT on POD 1)	590 THR C n=400; I n=190 Participant's ages not reported	Standard protocol – commence PT on POD 1	Accelerated protocol – commence PT on POD 0, preoperative education emphasising 24-48hr LOS, specialised hospital unit.	LOS, discharge destination. Complications that extended hospital LOS & hospital readmissions (timeframe unknown)
Stockton & Mengersen 2009	RCT	57 THR C n=27; Mean age (SD) 68.2 (10.6) I n=30; Mean age (SD) 68.3 (9.3)	PT once/day from POD 1	PT twice/day from POD 1	LOS & discharge destination. ILOA on POD 3 & 6.

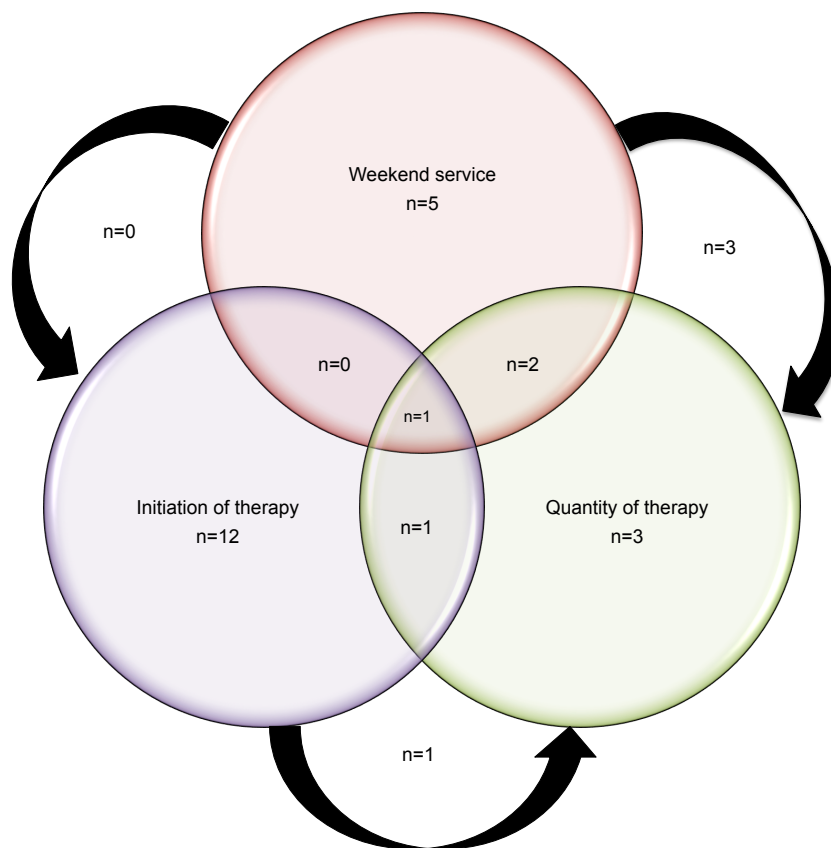


Figure 1.4: Intervention type of the included studies

Arrows depict possible relationships between different service models and number of studies where this was collected.

All studies meeting the inclusion criteria originated in developed nations. In 10 studies (Boxall, Sayers, & Caplan, 2004; A. F. Chen et al., 2012; Hughes, Kuffner, & Dean, 1993; Lang, 1998; Larsen, Hvass, et al., 2008; Larsen, Sørensen, et al., 2008; Liang et al., 1987; Liebs et al., 2012; Maidment, Hordacre, & Barr, 2014; Raphael, Jaeger, & van Vlymen, 2011), the population comprised patients undergoing total hip and knee replacement (three of these (A. F. Chen et al., 2012; Liang et al., 1987; Raphael et al., 2011) did not differentiate between joints), while seven studies included a population of total hip replacement (Bottros et al., 2010; Freburger, 2000; Juliano et al., 2011; Peck, Foster, & McLauchlan, 2006; Robbins, Bierbaum, & Ward, 2009; Robbins et al., 2014; Stockton & Mengersen, 2009) or

total knee replacement (den Hertog et al., 2012; Isaac et al., 2005; Klika et al., 2009; Labraca et al., 2011; Lenssen et al., 2006; Pua, Ong, Chong, & Lo, 2011; Renkawitz et al., 2010) only. In one study (Boxall et al., 2004), the population included a ward of acute orthopaedic patients where data was stratified by diagnostic group; only the patients following total hip or knee replacement were included in the present analyses. Data from a total of 4031 participants (mean 168, range 40-590) were included in meta-analyses, 2217 undergoing total hip replacement and 1814 undergoing total knee replacement.

Outcome measures extracted from included studies were length of stay (n=21), function (n=9), range of motion (n=5), strength (n=1), pain (n=5), adverse events (n=2), hospital readmissions (n=3), quality of life (n=1), patient satisfaction (n=2), discharge destination (n=8) and financial cost (n=2). The studies evaluating the effect on patient satisfaction, cost and adverse events examined different service models so results were not pooled in a meta-analysis.

Study quality

PEDro ratings (excluding eligibility criterion) ranged from 3 to 8 with an average score of 5.1 (Table 1-2). Blinding of subjects, therapists and assessors (criterion 5-7) were the poorest scoring criteria. Two of five studies that had an existing PEDro rating on the PEDro database, were given a different score by the reviewers in this study. In each case, the rating was maintained following consultation with a third reviewer.

Effects of allied health service models on outcomes

Table 1-3 demonstrates the results of meta-analyses, sub-group and sensitivity analyses investigating the effect of changes in timing of therapy commencement, a weekend physiotherapy service and physiotherapy frequency.

Table 1-2: Methodological quality of included studies using the PEDro Scale

Author, year	1	2	3	4	5	6	7	8	9	10	11	Total	Confounders	Other sources of bias
Bottros <i>et al.</i> , 2010	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Abductor sparing surgical approach & pain management	LOS was part of intervention
Boxall <i>et al.</i> , 2004	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5		Organisational delays affected LOS
Chen <i>et al.</i> , 2012	✓	×	×	✓	×	×	×	✓	×	✓	✓	4		Selection bias; only 18% of cohort received PT on POD 0
den Hertog <i>et al.</i> , 2012	✓	✓	✓	✓	×	×	×	✓	✓	✓	✓	7	Case manager, competitive care, discharge scheduling	
Freburger J., 2000	✓	×	×	×	×	×	×	✓	×	✓	✓	3		Use of secondary database
Hughes <i>et al.</i> , 1993	✓	×	×	×	×	×	×	✓	×	✓	✓	3		Did not control for day of week of surgery
Isaac <i>et al.</i> , 2004	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Analgesics technique, surgical technique, multidisciplinary D/C planning, education re: shorter LOS	
Juliano <i>et al.</i> , 2011	✓	×	×	✓	×	×	×	✓	×	✓	✓	4		Potential selection bias, LOS an intervention & outcome.
Klika <i>et al.</i> , 2009	✓	×	×	✓	×	×	×	✓	×	✓	✓	4	Pain management, quadriceps sparing surgical approach	
Labraca <i>et al.</i> , 2011	✓	✓	✓	✓	×	×	✓	✓	×	✓	✓	7		Pre-op differences in pain & extension ROM
Lang C 1998	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5		Most surgery on a Mon, Tues or Wed.
Larsen <i>et al.</i> , 2008	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Multi-modal intervention	Surgery moved to beginning of wk in intervention group
Larsen, Hansen <i>et al.</i> , 2009	✓	✓	✓	✓	×	×	✓	✓	✓	✓	✓	8	Multi-modal intervention	
Larsen, Sorensen <i>et al.</i> , 2009	✓	✓	✓	✓	×	×	✓	✓	✓	✓	✓	8	Multi-modal intervention	
Lenssen <i>et al.</i> , 2006	✓	✓	✓	✓	×	×	×	✓	✓	✓	✓	7		
Liang <i>et al.</i> , 1987	✓	×	×	✓	×	×	×	✓	×	✓	✓	4		Potential selection bias; study conducted nearly 30yrs ago
Liebs <i>et al.</i> , 2012	✓	✓	✓	✓	×	×	×	✓	✓	✓	✓	7		
Maidment <i>et al.</i> , 2014	×	×	×	✓	×	×	×	✓	✓	✓	✓	5		
Peck <i>et al.</i> , 2006	×	×	×	✓	×	×	×	×	×	✓	✓	3		
Pua <i>et al.</i> , 2011	✓	×	×	✓	×	×	×	✓	×	✓	✓	4		
Raphael <i>et al.</i> , 2011	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Preoperative education, standardised analgesia	Potential selection bias
Renkowitz <i>et al.</i> , 2010	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Patient-controlled analgesia pump	Intervention group had surgery in am
Robbins, Beirbaum <i>et al.</i> , 2009	✓	×	×	×	×	×	×	✓	×	✓	✓	3		Potential selection bias
Robbins, Casey <i>et al.</i> , 2014	✓	×	×	×	×	×	×	✓	×	✓	✓	3	Preoperative education, multidisciplinary training re: protocol	Potential selection bias
Stockton & Mengersen 2009	✓	✓	✓	✓	×	×	✓	✓	✓	✓	✓	8		

Criteria: 1. Eligibility criteria specified. 2. Random subject allocation. 3. Concealed allocation. 4. Groups were similar at baseline. 5. Blinding of all subjects. 6. Blinding of all therapists. 7. Blinding of all assessors. 8. Measures obtained from more than 85% of initial subjects. 9. All subjects received treatment or control. If not, data was analyzed by intention to treat. 10. Results of between-group comparisons reported for at least one key outcome. 11. Provides both point measures and measures of variability for one key outcome. PEDro item 1. Eligibility criteria specified is not used to calculate the total PEDro score.

Effects of earlier therapy commencement

Fourteen studies evaluated the effect of early therapy commencement of which, 11 compared therapy commencing on day of surgery to postoperative day one. Eight of these evaluated the effect of a fast-track protocol, a process that optimises perioperative care and may include additional interventions such as standardised analgesic practices. Nine studies compared the effect of earlier physiotherapy commencement; four studies considered the additional effect of occupational therapy and one the additional effect of social work.

When considering the effect of allied health (physiotherapy in combination with occupational therapy or social work), earlier initiation demonstrated evidence of a reduction in length of stay in 11 studies among 2362 participants [Figure 1.5 (a)] and higher probability of discharge directly home (five studies, n=985) following total hip and knee replacement. Following total knee replacement, an increase in range of knee flexion (two studies, n=422) was also evident in those experiencing earlier therapy commencement. No evidence of change in function (three studies, n=684), pain (three studies, n=545) hospital readmissions (two studies, n=333) or adverse events (one study, n=86) was observed. Sensitivity analyses utilising outcome measures collected at different time points did not alter results.

When considering the effect of physiotherapy only, earlier initiation demonstrated evidence of a length of stay reduction in seven studies among 1309 participants [Figure 1.5 (b)] and higher probability of discharge directly home (four studies, n=395) following total knee but not hip replacement. No evidence of change in function (three studies, n=577) or adverse events (one study, n=86) was observed.

There was a large degree of heterogeneity (96.9%) between studies in length of stay analysis. This reduced to 0% by restricting to randomised controlled trials or those with a PEDro score

of seven or greater. In univariate meta-regression analyses (Table 1-4), higher PEDro scores and multidisciplinary interventions were the only variables significantly associated with a greater reduction in length of stay. Multivariable meta-regression using all PEDro criteria as predictor variables revealed studies with random allocation, concealed allocation and intention-to-treat analysis were significantly associated with greater reduction in length of stay, accounting for 71.42% of between-study variance.

One study investigated cost-effectiveness of an accelerated perioperative rehabilitation protocol (including physiotherapy and occupational therapy commencement on day of surgery) following total hip and knee replacement from a societal perspective (Larsen et al., 2009). This showed the accelerated protocol to be significantly less expensive than standard protocol, with an average cost reduction of 18,880 Danish kroner (approximately US\$4000).

Effects of increasing therapy dosage

Of the seven studies directly evaluating the effect of increasing therapy dosage, all considered the effect of physiotherapy alone and six compared once-daily to twice-daily physiotherapy. Total dosage over length of stay was not reported in these studies. Only three studies evaluated the sole effect of therapy quantity on outcomes following lower limb joint replacement, two of which were included in a meta-analysis. Analysis of the pooled effect of two studies (n=100) increasing physiotherapy from once to twice daily revealed no evidence of a change in length of stay [Figure 1.5 (c)] or function. The remaining study was a cross-sectional design investigating the relationship between physiotherapy utilisation and outcomes following total hip replacement (Freburger, 2000). Physiotherapy use was directly related to total cost of care that was less than expected and to an increased probability of discharge home.

Table 1-3: Meta-analyses, sub-group and sensitivity analyses investigating the effect of early initiation of allied health post-surgery, twice compared to once daily physiotherapy and introduction of a weekend physiotherapy service provided in the acute phase following lower limb joint replacement

Service Model	Outcome	Total	THR	TKR	PT only (no multi-disciplinary input)	RCT only	PEDro ≥ 7	No estimations	Allied health therapy only (no fast-track rehabilitation)	Average LOS < 4 days in control group
Early allied health initiation	Length of stay	-1.98 (-2.77, -1.19) $I^2=97\%$	-1.55 (-2.70, -0.41) $I^2=95.8\%$	-2.50 (-3.62, -1.39) $I^2=93.5\%$	-1.23 (-2.16, -0.30) $I^2=97.7\%$	-2.07 (-2.43, -1.71) $I^2=0\%$	-2.07 (-2.43, -1.71) $I^2=0\%$	-1.54 (-2.36, -0.73) $I^2=96.5\%$	-0.99 (-1.95, -0.04) $I^2=94.8\%$	-0.80 (-1.51, -0.08) $I^2=90.1\%$
	Function	0.11 (-0.09, 0.31) $I^2=24.2\%$	0.19 (-0.36, 0.73) $I^2=73.5\%$	0.13 (-0.12, 0.37) $I^2=0\%$	All PT only	1 study	1 study	0.11 (-0.09, 0.31) $I^2=24.2\%$	1 study	1 study
	ROM		No studies	14.49 (9.32, 19.66) $I^2=50.3\%$	All PT only	1 study	1 study (same as RCT)	14.49 (9.32, 19.66) $I^2=50.3\%$	1 study	No studies
	Pain	-0.54 (-1.18, 0.10) $I^2=84\%$	1 study	1 study	All PT only	1 study	1 study	-0.54 (-1.18, 0.10) $I^2=84\%$	-0.53 (-1.41, 0.35) $I^2=91.9\%$	1 study
	Discharge destination	RR=1.45 (1.26, 1.67) $I^2=44.6\%$	1.52 (1.41, 1.65) $I^2=0\%$	1 study	All PT only	No studies	No studies	RR=1.45 (1.26, 1.67) $I^2=44.6\%$	RR=1.25 (1.04, 1.49) $I^2=0\%$	1 study
	Readmissions	RR=0.85 (0.31, 2.37) $I^2=0\%$	0.6 (0.18, 2.65) $I^2=4.7\%$	1.33 (0.31, 7.38) $I^2=0\%$	No studies	1.39 (0.18, 10.63) $I^2=0\%$	RR=0.85 (0.31, 2.37) $I^2=0\%$	RR=0.85 (0.31, 2.37) $I^2=0\%$	No studies	No studies
Twice vs once daily PT	Length of stay	-0.35 (-0.95, 0.26) $I^2=0\%$	1 study	1 study	All PT only	-0.35 (-0.95, 0.26) $I^2=0\%$	-0.35 (-0.95, 0.26) $I^2=0\%$	-0.35 (-0.95, 0.26) $I^2=0\%$	N/A	No studies
	Function	0.31 (-0.08, 0.71) $I^2=0\%$	1 study	1 study	All PT only	0.31 (-0.08, 0.71) $I^2=0\%$	0.31 (-0.08, 0.71) $I^2=0\%$	0.31 (-0.08, 0.71) $I^2=0\%$	N/A	No studies
	ROM	1 study	No studies	1 study		1 study	1 study	1 study		
	Pain	1 study	No studies	1 study		1 study	1 study	1 study		
	Discharge destination	1 study	1 study	No studies		1 study	1 study	1 study		
	Readmissions	No studies	No studies	No studies		No studies	No studies	No studies		
Provision of weekend PT service	Length of stay	-1.04 (-1.66, -0.41) $I^2=90.5\%$	-1.22 (-2.72, 0.28) $I^2=48.9\%$	-0.87 (-1.05, -0.70) $I^2=0\%$	All PT only	No studies	No studies	-1.14 (-1.87, -0.42) $I^2=89.9\%$	N/A	No studies
	Function	0.37 (0.02, 0.73) $I^2=30\%$	0.18 (-0.34, 0.69) $I^2=21.6\%$	0.55 (0.13, 0.97) $I^2=13.1\%$	All PT only	No studies	No studies	SMD=0.37 (0.02, 0.73) $I^2=30\%$	N/A	No studies
	ROM	1 study								
	Pain	No studies								
	Discharge destination	1 study								
	Readmissions	No studies								

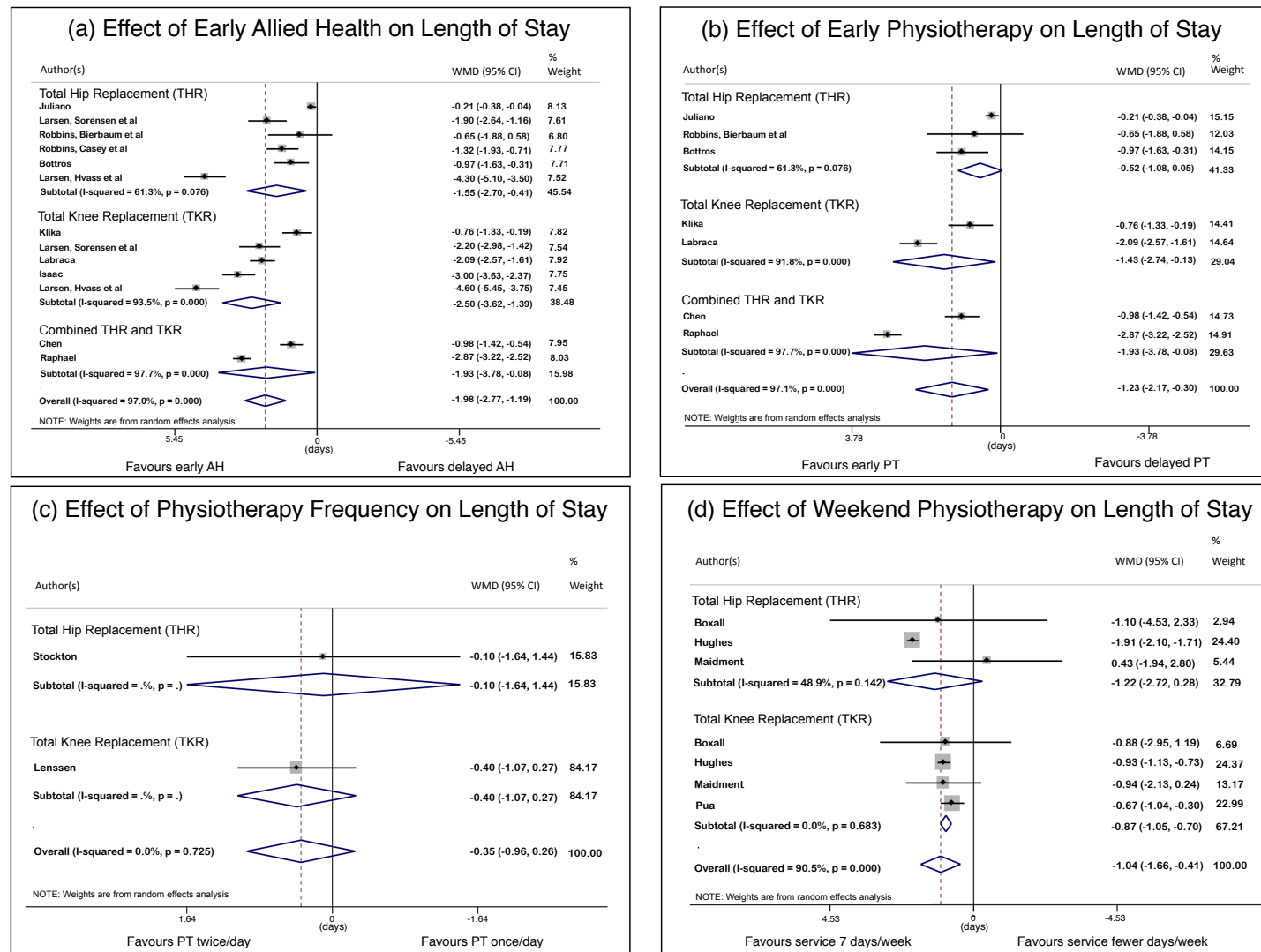


Figure 1.5: Forest plot of the effect of (a) early allied health, (b) early physiotherapy, (c) increased physiotherapy frequency and (d) a weekend physiotherapy service on length of stay in the acute phase following lower limb joint replacement

Effects of a weekend service

Of the eight studies evaluating the effect of a weekend allied health service, all considered the effect of physiotherapy alone and five compared a 5-day to a 7-day service (Boxall et al., 2004; Hughes et al., 1993; Liang et al., 1987; Maidment et al., 2014; Peck et al., 2006). Two studies compared a six to a 7-day service (Lang, 1998; Pua et al., 2011) while one compared a 5 to a 6-day service (Renkawitz et al., 2010). The addition of weekend physiotherapy demonstrated evidence of a reduction in length of stay [Figure 1.5 (d)] and a small standardised effect size increase in function (2 studies, n=206) in patients following knee but not hip replacement.

Table 1-4: Association between surgery type, study quality and intervention covariates in studies evaluating earlier compared to later commencement of therapy following lower limb joint replacement

Covariate	Coefficient (95% confidence interval)	p value	Proportion of between-study variance explained (Adjusted R-squared)	% residual variation due to heterogeneity (I-squared residual)	Estimate of between-study variance (tau-squared)
Base Model	-1.980 (-2.811, -1.14863)	0.000		96.96%	1.754
Surgery Type	0.428 (-0.787, 1.642)	0.455	-4.37%	97.22%	1.831
Study Design	0.634 (-0.378, 1.646)	0.195	7.2%	96.38%	1.628
Study Quality	-0.470 (-0.875, -0.064)	0.027	33.56%	94.86%	1.165
Time of allied health initiation (intervention group)	-0.119 (-3.367, 3.13)	0.937	-10.10%	97.10%	1.931
Multidisciplinary intervention	-1.627 (-3.018, -0.237)	0.026	33.39%	95.92%	1.169
Multimodal intervention	-1.426 (-3.069, 0.217)	0.082	19.19%	93.87%	1.418

1.3.5 Discussion

This review identified 24 studies examining the effect of early allied health commencement, additional therapy and/or a weekend service on outcomes following lower limb joint replacement. All studies investigated the effect of physiotherapy with four evaluating the

additional effect of occupational therapy and one social work. There is therefore insufficient evidence from which to draw conclusions regarding the sole effect of professions other than physiotherapy on outcomes following lower limb joint replacement. Based on the physiotherapy only studies, there appears to be a beneficial effect for early commencement and a weekend service following knee but not hip replacement. There appears to be an additional effect following total hip replacement for early therapy commencement in studies that examined physiotherapy in combination with other allied health professions are also considered. There was no evidence to suggest that providing allied health intervention as early as the day of surgery increased pain levels, rate of adverse events, or hospital readmissions. No studies evaluated the effect of a weekend physiotherapy service on detrimental outcomes. There are insufficient data available from which to adequately investigate a potential dose-response relationship between allied health and outcomes following lower limb joint replacement.

These results suggest that acute physiotherapy may be more effective following knee replacement than following hip replacement surgery. This is plausible given the greater scope for improvement in pain and function evident in patients undergoing knee replacement compared to hip replacement (Bachmeier et al., 2001; Beswick, Wylde, Gooberman-Hill, Blom, & Dieppe, 2012; O'Brien, Bennett, Doran, & Beverland, 2009). Likewise, the greater reduction in length of stay observed amongst patients undergoing knee replacement compared to hip replacement could be a function of the baseline length of stay which in the present review was 0.62 days shorter following total hip replacement (nearly 10% of hip replacement length of stay).

These results of this review support and extend upon findings of previous reviews which found weak evidence to support an acute weekend physiotherapy service following lower

limb joint replacement but no evidence to support an increase in physiotherapy frequency from once to twice daily in the acute postoperative phase (Kolber et al., 2013; Nikitovic & Ontario, 2014). This is in contrast to a previous subgroup meta-analysis that found an extra 19 minutes physiotherapy per day reduced length of stay by one day in acute settings (Peiris et al., 2011). However, this study included a mixed patient population. It is also difficult to directly compare the present study's results to the above meta-analysis in terms of additional physiotherapy provided since only three studies in the present review provided sufficient data to quantify the amount of additional physiotherapy provided by different service models. The key contribution of this systematic literature review is the provision of preliminary evidence to suggest that timing of therapy commencement in the acute postoperative phase may be more important than therapy quantity provided following lower limb joint replacement. This has potential implications for health care managers in terms of organising staffing availability around surgery timetables.

Commencing therapy on day of surgery has practical and financial implications for the development of efficient allied health service models. These results suggest that providing an additional physiotherapy session on the day of surgery is likely to be cost effective (even if this is provided “out of hours” or on the weekend) given the demonstrated concomitant reduction in length of stay by more than one day. The practicalities of routinely providing therapy on the day of surgery will however require careful consideration in terms of patient expectations and pre-operative education; minimisation of postoperative pain, nausea, vomiting and hypotension to facilitate therapy participation; therapist access to patients; and the likely need to extend therapy provision beyond traditional “business” hours. Despite these potential barriers, previous research in a variety of settings supports feasibility of commencing therapy on day of surgery (Christelis et al., 2015; Pearse, Caldwell, Lockwood, & Hollard, 2007; T. Smith, McCabe, Lister, Christie, & Cross, 2012; Tayrose et al., 2013).

In this review, studies with greater control over inclusion/exclusion criteria and intervention/control provision (that could be characterised as efficacy studies) demonstrated stronger effect sizes than studies that could be argued as being effectiveness studies given their lesser control over these factors. This raises the question whether health services are likely to see the same magnitude of benefit as observed in efficacy studies when they replicate these interventions in real life. Further research is required to understand the impact of allied health service models in this population using more pragmatic research designs (Haines et al., 2015).

Limitations

This review has limitations related to methodology and the evidence base upon which it was conducted. The search was limited to English publications. The risk of publication bias was not investigated due to inappropriateness of funnel plots when there are less than ten studies in the meta-analysis (Higgins & Green, 2008) or substantial heterogeneity present (Terrin, Schmid, Lau, & Olkin, 2003). The evidence base focused predominantly on physiotherapy following lower limb joint replacement and did not consider other allied health professions or the role of assistants sufficiently. Therefore, conclusions have focused predominantly on the effect of physiotherapy.

The data were drawn from a pool of studies with average length of stay greater than current averages (7.15 versus just under four days following total hip replacement (Wolford et al., 2015) and 7.77 versus 3.3 days following total knee replacement (Barad, Howell, & Tom, 2015)). A more modest length of stay reduction (0.8 days) was observed following therapy initiation on day of surgery in the three studies with an average length of stay in the control group of less than 4 days. However, there were no studies investigating provision of weekend physiotherapy or increased physiotherapy frequency with a baseline length of stay

comparable to current averages. It is plausible a weekend physiotherapy service may have a greater effect following surgery performed later in the week where the baseline length of stay is shorter. Research to-date investigating the effect of weekend physiotherapy has not accounted for surgery day of week. However, this may be an important factor influencing effectiveness of weekend physiotherapy in light of a demonstrable relationship between day of surgery and length of stay (Chaurasia et al., 2014; Dall et al., 2009; Husted et al., 2008).

High between-study heterogeneity was evident in studies investigating earlier therapy commencement following lower limb joint replacement. Meta-regression found greater length of stay reduction in studies with higher quality, which seems to lend further support to the conclusion that early postoperative therapy is beneficial. Meta-analyses were also based on variable quality research, with some studies of particularly low quality. However, sensitivity analyses with removal of low quality studies and those investigating multidisciplinary and multimodal interventions revealed largely consistent findings, which give credence to the findings drawn from the larger pool of studies.

The studies included in this review have not adequately investigated the multi-dimensional nature of allied health service models. The effect of weekend physiotherapy and early commencement on quantity of therapy was documented in only three and one study respectively. This data was confounded by length of stay in all but one study and was not linked to individual outcomes. The effect of weekend physiotherapy on timing of therapy commencement was not investigated. This review also focused on the effects of different allied health service models and did not attempt to investigate the effect of individual physiotherapy modalities such as continuous passive motion or bed exercises.

Research implications

Currently, there are gaps in the understanding of the optimal timing and quantity of allied health provided in the acute phase following lower limb joint replacement. Further high quality research investigating all dimensions of allied health service delivery (that is, the timing of commencement, quantity in terms of session length and frequency and out of hours therapy) at constant timepoints or by calculating rate of therapy per inpatient day is indicated. This research should focus on individual elements of service models (e.g., vary timing of therapy commencement, but hold the quantity constant) so that understanding of each element can improve without confounding from other elements. Further research in this area should also account for surgery day of week.

Most of the research in this area has investigated the effect on acute hospital outcomes. Further research considering outcomes following discharge home may also be useful. Additionally, investigation of therapy cost-effectiveness following lower limb joint replacement should consider the role of physiotherapy and occupational therapy assistants/aides given the established role of these personnel and lesser pay rate compared to allied health professionals (Bureau of Labor Statistics, 2015a, 2015b).

1.3.6 Conclusion

Earlier physiotherapy commencement and weekend provision may produce favorable outcomes following lower limb joint replacement (especially total knee replacement) when baseline length of stay is four days or more. Redistributing allied health resources to commence therapy on day of surgery regardless of day of week may accelerate postoperative recovery. Current, high quality research is needed to confirm these findings and examine cost-effectiveness, particularly when considering the multidisciplinary effect of allied health.

1.4 Statement of the problem

The development of effective allied health service models following hip and knee joint replacement surgery is central to this thesis. The systematic literature review identified a number of limitations in the available evidence related to quantity, timing of commencement and provision of weekend allied health services following elective lower limb joint replacement. First, all studies examining the effect of a weekend service focused on physiotherapy only. Second, the multi-dimensional nature of the weekend service models was not accounted for; meaning the effects observed could be mediated by earlier commencement and/or increased quantity. Third, a need to examine real-world weekend allied health services that are often reduced in quantity compared to that provided on weekdays was identified. These limitations have influenced the design and aims of the subsequent research program reported in this thesis.

1.5 Thesis aims and overview

The overarching aim of this thesis was to examine the effect of a real-world acute weekend allied health service on patient and hospital outcomes following lower limb joint replacement surgery. In doing this, it was also considered necessary to understand what allied health services are provided and the basis for these services following lower limb joint replacement.

A research program of three studies (studies two, three and four) was conducted to address the thesis aims with an additional study (Study 1) conducted to evaluate proposed methods for assessing patient mobility in studies three and four. The specific research questions were:

- 1) What is the level of agreement between patient self-report and therapist-assessed performance of mobility using the de Morton Mobility Index (DEMMI) in participants

undergoing preadmission assessment prior to elective lower limb joint replacement surgery?

- 2) What is the role of the allied health team during the acute phase following elective lower limb joint replacement surgery as perceived by health professionals?
- 3) What is the effect of a real-world acute weekend allied health service on short-term patient and hospital outcomes following hip and knee replacement surgery, compared to no weekend service?
- 4) Is the effect of a weekend allied health service mediated by earlier therapy commencement and/or increased quantity?
- 5) What is the effect of transferring weekend allied health services from the acute to sub-acute setting on medium-term patient and service outcomes following hip and knee replacement surgery?

The relationship between each study, the research question being addressed and the relevant thesis chapter are presented in Figure 1.6.

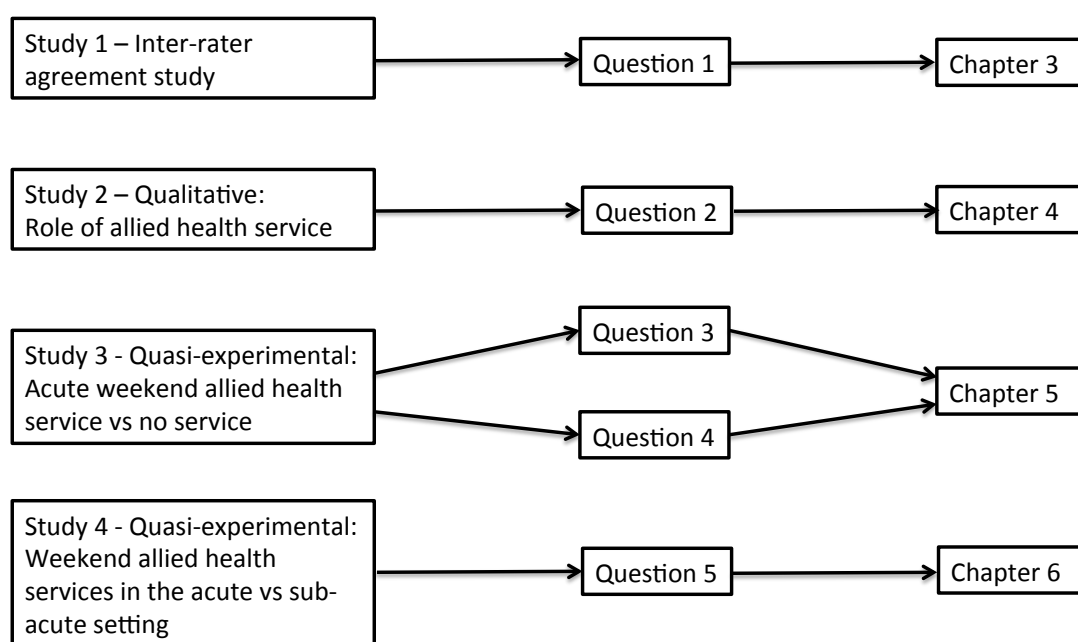


Figure 1.6: Research program and thesis structure

This thesis comprises the following chapters: Chapter 2 will provide background information of the parent trials in which the research studies of this thesis were nested, followed by the rationale underpinning the research design and an overview of the research methods used. Chapter 3 will present a published study (Study 1) conducted to inform the method of assessing patient self-reported mobility within this thesis. Chapters 4 to 6 present the findings of three studies (studies two to four) conducted to address the remaining thesis aims. Each of these studies have been prepared and submitted for publication and is currently under journal review. Chapter 7 integrates the main findings of this research program, discusses its strengths and limitations, and suggests avenues for further research.

Chapter 2 – Methods

2.1 Chapter overview

The present chapter describes the research methods used to address the thesis aims. It provides an overview of the methods used for the four studies conducted in this PhD research program: an interrater agreement study (Study 1); a qualitative descriptive study (Study 2); and two quasi-experimental studies (studies three and four). This chapter describes how these studies are related to the parent trials in which they are nested; the participants and setting; the intervention being evaluated; the outcome measures, data collection procedures, and data analysis techniques utilised; the timeline for this research program; and the ethical considerations. Further specific methods are provided within the methods section of each of the associated manuscripts (studies 2 to 5 in chapters 3 to 6, respectively).

2.2 Methods of studies conducted in this PhD research program

2.2.1 Parent trials

The four studies conducted as part of this thesis were nested within two parent trials investigating the effectiveness and safety of current weekend allied health services and a new stakeholder-driven model for acute medical and surgical patients compared to having no weekend allied health service. The protocol and results of these parent trials have been published and are provided in appendices E and F respectively. These trials consisted of two stepped-wedge cluster randomised trials where the existing allied health services were sequentially removed from acute wards, one ward at a time per month (Trial 1) followed by the introduction of a new stakeholder-driven model of weekend allied health service delivery to acute wards in the same order as in Trial 1 (Trial 2) (Figure 2.1). These parent trials included a total of 27,508 patients across 12 acute medical and surgical wards from two sites

(six wards at each site) in Melbourne, Australia. This PhD research program studied a subgroup of patients and health professionals drawn from Cluster 6 at one site (two orthopaedic wards) of the parent trials (highlighted box in Figure 2.1). This research focused on patients undergoing elective hip and knee joint replacement surgery and the health professionals providing their care.

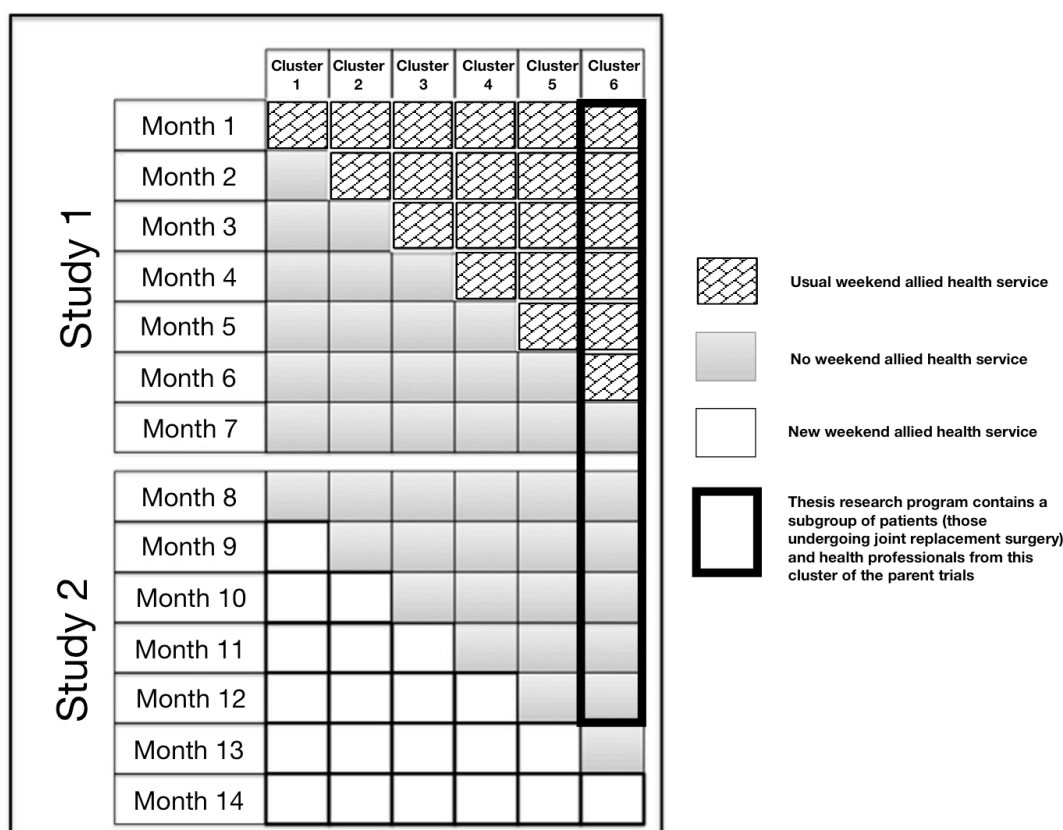


Figure 2.1: Two stepped-wedge cluster randomised trials in which this thesis was nested (i.e. parent trials).

Adapted with permission from "Study protocol for two randomised controlled trials examining the effectiveness and safety of current weekend allied health services and a new stakeholder-driven model for acute medical/surgical patients versus no weekend allied health services" by Haines et al, 2015, *Trials*, 16:133. Copyright 2015 by Terry Haines.

NB. Trial 1 of the parent trials was the sequential disinvestment from weekend allied health services (grey). Trial 2 was the new stakeholder-driven model of weekend allied health service delivery (white).

2.2.2 Rationale for study designs

Overall, this thesis used a mixed methods approach, incorporating both quantitative and qualitative methods to address the study aims. Mixed methods research focuses on collecting, analysing, and combining both quantitative and qualitative data in a single study or a series of studies (Creswell & Clark, 2007) and is advocated when addressing complex,

multifaceted issues such as health service interventions (Tariq & Woodman, 2013). This methodological approach was considered important in this context in order to integrate an understanding of the health service intervention (weekend allied health) with the effect it may have on a broad range of potential patient, staff and service outcomes.

Study 2 (Chapter 3) presents a qualitative descriptive study conducted using semi-structured focus groups to describe health professionals' perceptions of the role of allied health during the acute phase following elective lower limb joint replacement surgery. Qualitative description can help to focus on the experience of health professionals and their views on the organisation of the health care system (Neergaard, Olesen, Andersen, & Sondergaard, 2009). This approach was chosen to enable a richer understanding of the weekend allied health service that was provided within the complex environment of the health care system.

Studies 3 and 4 (chapters 5 and 6, respectively) are both quasi-experimental study designs investigating the effect of a six-month period of an acute weekend allied health service on short-term (Study 3) and medium-term (Study 4) outcomes following hip and knee joint replacement surgery. The acute orthopaedic wards at one site of the parent trials were the final cluster randomised to have their weekend allied health services temporarily discontinued and reallocated to a sub-acute orthopaedic ward providing rehabilitation (Cluster 6 in Figure 2.1). Consequently, this created a six-month period of existing acute weekend allied health service provision followed by a subsequent six months when these services were transferred to the sub-acute setting. This means in the subsequent six months there was no weekend allied health service available on the acute wards. Study 3 examined short-term outcomes on day four postoperatively. The comparison group was the period of no weekend allied health service provision in the acute setting due to an expected acute length of stay of only three to four days for this population. In Study 4, the comparison group

was the period of sub-acute weekend allied health provision because this study examined medium-term outcomes at six weeks postoperatively during which time patients may have been transferred to the sub-acute orthopaedic ward. It is important to note that the cluster-randomised nature of the parent trials dictated the timing of intervention and control conditions in studies 3 and 4 of this thesis, rather than the allocation of individual participants to these conditions. This research design is therefore considered quasi-experimental or nonrandomised (Harris et al., 2006). The individual study designs are presented in further detail in each chapter.

2.2.3 Setting

All studies conducted in this thesis were conducted in the same setting at Dandenong Hospital, Melbourne, Australia. This is a 520-bed public tertiary hospital situated in the south-eastern suburbs of Melbourne, Victoria and is part of the Monash Health network. In 2014-15, 290 and 183 total knee and hip replacement surgeries respectively were performed over six days a week (Monday to Saturday) at Dandenong Hospital (Australian Institute of Health and Welfare, 2017). All patients undergoing elective hip and knee joint replacement surgery attended a preoperative outpatient clinic where they were assessed by the multidisciplinary team, educated about the postoperative process and allocated to a recovery pathway based on the Risk Assessment and Prediction Tool (Oldmeadow, McBurney, & Robertson, 2003). Scores between six and nine indicated that four to seven days of inpatient rehabilitation were anticipated following the acute stay (Pathway B); and scores less than six indicated that an extended period (eight days or more) of inpatient rehabilitation was likely to be required (Pathway C). The recovery pathway could be modified postoperatively subject to health professional assessment, although in practice this is uncommon.

At the time of this research program, Dandenong Hospital provided a specialist orthopaedic unit, which had six surgical registrars, assisted by three junior residents and was led by a Director of Orthopaedic Services. This service was further staffed with 13 sessional consultant surgeons. Postoperatively, patients were generally admitted to one of two acute orthopaedic wards (containing 48 beds) following surgery. A team of three physiotherapists (totaling 2.8 EFT), three occupational therapists (2.8 EFT), and three physiotherapy allied health assistants (1.35 EFT) were part of the orthopaedic acute unit. An additional occupational therapy allied health assistant (1 EFT) was shared amongst the seven acute wards of the study hospital. Patients admitted to an acute orthopaedic unit also had access to other allied health services (e.g. social work, dietetics and speech therapy) on an as needs basis. The acute admission could be followed by admission to a sub-acute ward for rehabilitation (either onsite or offsite) depending on clinical need.

2.2.4 Participants

Participants for this PhD research program were patients undergoing elective lower limb joint replacement and the medical, nursing and allied health professionals involved in the acute care to these patients working on two specialist orthopaedic wards at the study hospital.

Surgery types considered for inclusion were total hip replacement, total knee replacement and revision total hip or knee replacement. Exclusion criteria were patients less than 18 years old, patients undergoing joint replacement immediately following trauma and patients with moderate or severe cognitive impairment assessed as less than or equal to 5/10 on the Short Portable Mental Status Questionnaire (Pfeiffer, 1975). In the quasi-experimental studies examining the effect of the acute weekend allied health service (studies three and four), participants were also excluded if they were exposed to both models of weekend allied

health service delivery during their hospital admission (i.e. admission included dates in July and August 2014).

2.2.5 Intervention

The intervention examined was acute weekend allied health service provision to patients following hip and knee joint replacement surgery. This was explored qualitatively using focus groups in Study 2 and quantitatively in studies 3 and 4. In the quantitative studies, Phase 1 intervention comprised existing weekend allied health services (including physiotherapy, occupational therapy, dietetics, speech pathology and interventions provided by allied health assistants) provided in two acute orthopaedic study wards. Services delivered were the same as those during weekdays although fewer hours of service were available on the weekend (approximately 30% of weekday services for physiotherapy; less for other professions). Weekend allied health services were allocated to individual patients according to a hospital-specific priority tool based on clinical urgency and proximity to discharge.

During Phase 2, these services were transferred to the orthopaedic sub-acute ward in the same hospital. Thus, the comparison group for Study 3 (which examined short-term outcomes) consisted of patients admitted when an acute weekend allied health service was not available. The comparison group for Study 4 (which examined medium-term outcomes) was a cost-neutral weekend allied health service reallocated from the acute to the sub-acute setting. Patients admitted during this time period therefore had weekend allied health services available during their sub-acute (but not acute) admission. The weekday allied health service remained unchanged throughout this time. Further details for each intervention are provided in the relevant chapter.

2.2.6 Outcome measures

A comprehensive range of patient, staff and service outcomes was examined according to the United Kingdom Medical Research Council guidance for the evaluation of complex interventions (P. Craig et al., 2008). This stipulates that a single primary outcome may not make best use of data and that a range of measures is needed, including those that capture possible unintended consequences. The weekend allied health service is classified as a complex intervention due to the number of interacting components, the number and difficulty of behaviours required by the staff delivering and patients receiving the service, the degree of tailoring of the intervention and the number and variability of potential outcomes. The allied health service staff and managers of the study hospital were consulted to assist the decision-making process around appropriate selection of outcome measures.

Length of stay

Hospital length of stay is a key determinant of hospital costs (Organisation for Economic Co-operation and Development, 2013) and was considered to be important, particularly from the health service provider perspective as an indicator of hospital efficiency (Organisation for Economic Co-operation and Development, 2011). The measurement of both acute and total hospital length of stay in this thesis allowed the perspective of both the acute and sub-acute (rehabilitation) health services to be considered. Minimising length of stay has the potential to reduce cost of care per patient and assist patient flow by facilitating bed availability to provide care for more patients, as long as it does not compromise quality of care or lead to higher rates of adverse events or readmissions. Acute length of stay was defined as the number of days (to two decimal points) from admission to discharge in the acute hospital setting. Total length of stay was defined as the number of days (to two decimal points) from acute hospital admission to discharge from either the acute or sub-acute hospital setting, whichever was longer.

Adverse events

Adverse events for each participant were documented as a marker of unintended detrimental patient events that may lead to poorer patient health outcomes, higher hospital costs and longer hospital length of stay (Hoogervorst-Schilp, Langelaan, Spreeuwenberg, de Bruijne, & Wagner, 2015). Events included in-hospital falls, Medical Emergency Team calls, pulmonary emboli, deep vein thromboses, death, hospital-acquired pressure injuries, and intensive care unit admissions.

Discharge destination

Discharge destination (home versus inpatient rehabilitation) was considered a marker of patient outcome and an indicator of additional costs to health service providers. Although patients discharged directly home to the community are likely to require access to outpatient rehabilitation, this has been shown to be a cheaper option compared to inpatient rehabilitation (Zeidler, Mittendorf, Vahldiek, Zeidler, & Merkesdal, 2008).

Unplanned hospital readmission within six weeks of discharge

This data was used as an indicator of treatment effectiveness, discharge planning and patient readiness for discharge (Kossovsky et al., 2000). Unplanned hospital readmission can also increase the overall cost on the health service and be a sign of detrimental patient outcomes. An “all-cause” definition of hospital readmission was utilised, meaning the cause of readmission did not need to be related to the surgery (McIlvennan, Eapen, & Allen, 2015).

Functional independence

Functional independence was measured using participant self-report on the Modified Barthel Index (Shah, Vancley, & Cooper, 1989). This scale assesses an individual’s ability to care for him/herself based on 10 activities of daily living. It is scored from zero indicating total dependency, to 100 indicating complete functional independence. The activities within the

Modified Barthel Index include behaviours relating to self-care (feeding, grooming, bathing, dressing, bowel and bladder care and toilet use) and behaviours relating to mobility (ambulation, transfers and stair climbing). The Modified Barthel Index was chosen as an outcome measure in this thesis because it does not require credentialing or specialised training and has been validated in a self-report format (Collin, Wade, Davies, & Horne, 1988) and using telephone interview (Shinar et al., 1988). It has demonstrated adequate reliability and validity in patients diagnosed with a lower limb orthopaedic condition and referred to an inpatient occupational therapy program (Fricke & Unsworth, 1997).

Mobility

Mobility was assessed using the De Morton Mobility Index (DEMMI) (de Morton, 2010). The DEMMI rates ability to perform 15 hierarchical mobility activities ranging from sitting unsupported to tandem stand with eyes closed. Rasch analysis has been used to construct an interval level scoring system out of 100 from the 15 ordinal items. The DEMMI has demonstrated reliability and validity across the full spectrum of mobility and clinical settings (acute, sub-acute and community), in which patients undergoing joint replacement are commonly seen (Davenport & de Morton, 2011; de Morton, Brusco, Wood, Lawler, & Taylor, 2011; de Morton, Davidson, & Keating, 2008, 2010; de Morton & Lane, 2010; Jans et al., 2011).

The DEMMI was chosen as a mobility specific outcome measure particularly because of its broad scale width, which was anticipated to be useful when examining patients preoperatively, and at four days and six weeks postoperatively. This scale is also relatively quick to administer in the clinical setting taking between five and nine minutes to complete (Davenport & de Morton, 2011). A minimum change of between 10 and 13 points (depending on the setting) is likely to overcome measurement error (with 90% confidence)

and represent a clinically important change in patient mobility (Davenport & de Morton, 2011; de Morton et al., 2011; de Morton et al., 2010; de Morton & Lane, 2010).

The DEMMI was originally developed using therapist assessment of patient performance but this requires face-to-face contact and is therefore limited in its use. The following chapter (Study 1) addresses the research question “what is the level of agreement between patient self-report and therapist-assessed performance using the DEMMI in participants undergoing preadmission assessment prior to elective hip and knee replacement surgery?” The results of this study will be used to directly inform the method of assessing mobility in studies three and four of this thesis.

Pain

Patient perceived pain levels were assessed using the Quadruple Visual Analogue Pain Scale (Von Korff, Deyo, Cherkin, & Barlow, 1993), which is based on the Visual Analogue Scale of pain intensity. The pain Visual Analogue Scale is a unidimensional measure of pain intensity that has been widely used in diverse populations, including those with preoperative and postoperative arthritic conditions (Hawker, Mian, Kendzerska, & French, 2011). The Visual Analogue Scale asks participants to rate their pain severity at a particular timepoint (most commonly at the time of response or within the last 24 hours) on a line 10 centimetres in length ranging from no pain at one extreme to the worst possible pain at the other extreme. The Quadruple Visual Analogue Scale allows for a more comprehensive pain picture within a unit of time by asking each participant to rate their pain severity from zero to 10 under four conditions: right now, typical/average, and at best and worst over the past week. In this thesis, participants were asked to rate their pain over the past 24 hours at four days postoperatively instead of the past week. This was because surgery was conducted within the past week and it was anticipated pain intensity would increase following surgery. Use of

prescription opioid analgesics (e.g. oxycodone) was also documented for each participant as this can affect pain intensity levels (Angst, Brose, & Dyck, 1999).

The Visual Analogue Scale, upon which the Quadruple Visual Analogue is based, has been shown to be a reliable and valid method of pain measurement (Bijur, Silver, & Gallagher, 2001; Downie et al., 1978). It has been specifically validated in patients following total hip and knee replacement (Boeckstyns & Backer, 1989; de Nies & Fidler, 1997), and internal construct validity of the Visual Analogue Scale has been demonstrated using Rasch analysis in patients waiting for hip and knee replacement surgery (Kersten, White, & Tennant, 2014). The pain Visual Analogue Scale is also simple and quick to administer and score and has demonstrated patient acceptability (Joyce, Zutshi, Hrubes, & Mason, 1975).

Clinically significant changes in pain vary amongst studies and may be related to the baseline pain measure (Bird & Dickson, 2001; Farrar, Young, LaMoreaux, Werth, & Poole, 2001; Jensen, Chen, & Brugger, 2003). A change of approximately 30% has been advocated as a clinically significant change (Farrar et al., 2001; Jensen et al., 2003). This is consistent with another study that demonstrated a minimal clinically important improvement of 40% and 32% change for knee and hip osteoarthritis respectively (Tubach et al., 2005).

Quality of life

Health-related quality of life was assessed using the EQ-5D which consists of a descriptive system (EQ-5D-5L) and a visual analogue scale (EQ-VAS) (Oemar & Janssen, 2013). The descriptive system comprises five domains of health including mobility, self-care, usual activities, pain/discomfort and anxiety/depression across five levels. This can be presented as a health profile or converted to a single summary index number (utility) reflecting health state preferences. The EQ-VAS component can be used as a quantitative measure of health

outcome that reflects the patient's own judgement. It asks patients to rate their overall health status (on the day of assessment) on a scale from 0 to 100 ranging from "the worst health you can imagine" to "the best health you can imagine".

The EQ-5D (base tool) is a generic (non disease-specific) instrument that provides a standardised measure of health status applicable to a wide range of health conditions and treatments (The EuroQol Group, 1990). It was originally developed with three levels across each health domain (EQ-5D-3L) but has more recently been expanded to include five levels of severity across each health domain (EQ-5D-5L). The EQ-5D-5L has been demonstrated as a valid extension of the EQ-5D-3L with improved measurement properties (Janssen et al., 2013). It is quick and simple to administer and was chosen in this context for its ability to provide a single index of utility by using data from the general population (Sakthong, Charoenvisuthiwongs, & Shabunthom, 2008). This index can then be used to calculate a cost-utility ratio in an economic analysis. The EQ-5D-5L was converted to a corresponding single index value using the crosswalk link function (Van Hout et al., 2012).

The EQ-5D-5L has demonstrated decreased ceiling and floor effects and increased discriminatory power compared to the original three-level version (EQ-5D-3L) in a cohort of pre and postoperative total hip replacement patients (Greene et al., 2015). It has shown satisfactory ease of use, patient acceptability, internal consistency and reliability in patients attending a preoperative clinic prior to total knee replacement surgery (Brazier, Harper, Munro, Walters, & Snaith, 1999). Intraclass coefficients ranging from 0.61 to 0.77 for the five dimensions and 0.87 for the index measure have been shown in patients with osteoarthritis referred for hip and knee replacement (Conner-Spady et al., 2015).

Patient satisfaction

Patient satisfaction was measured as an indicator of health care quality (Prakash, 2010) and patient-centred care. Patient-centred care is one of the six domains of health care quality defined as health care that is respectful of, and responsive to, individual patient preferences, needs and values, and ensuring that patient values guide all clinical decisions (Institute of Medicine, 2001). Although patient satisfaction has not been consistently defined in the literature, a common denominator is that it evaluates health services from the patients' point of view and may include their attitudes, emotions and/or perceptions of healthcare services (Al-Abri & Al-Balushi, 2014).

In this thesis, patient satisfaction was measured using three questions from the Victorian Patient Satisfaction Monitor (State Government of Victoria Australia, 2011-2012). This survey aims to elicit patients' perceptions about their health care experience so as to provide hospitals with information that will inform health service quality improvement. The first question provided a measure of overall patient satisfaction by asking, "Thinking about all aspects of your hospital stay, how satisfied were you?" The second question related to the effect of the stay in hospital by asking, "How much do you actually think you were helped by your stay in the hospital?" These questions were answered using a five-point Likert scale ranging from "not at all satisfied" to "very satisfied" for the first and from "not at all" to "a great deal" for the second question. The third question measured patient perception of the appropriateness of their length of stay by asking, "Was the length of time you spent in hospital too long, too short or the right amount?"

Global rating of change

A global rating of change scale provides an opportunity for patients to combine all components of their experience (e.g. pain relief, improvements in functioning) into one overall evaluative measure of the treatment they receive (Dworkin et al., 2005). Such

measures are often used as an external anchor from which to determine clinically important change since the patients make a subjective judgement about the meaning of change to them following treatment or surgery (Katz, Paillard, & Ekman, 2015).

The Patients' Global Impression of Change scale (Hurst & Bolton, 2004) was used as the global rating of change scale in this thesis. This scale evaluates overall change in health status since surgery as perceived by the patient using a seven-point single-item ordinal scale with the following options: "No change or worse; Almost the same, hardly any change at all; A little better, but no noticeable change; Somewhat better, but the change has not made any real difference; Moderately better, and a slight but noticeable change; Better, and a definite improvement that has made a real and worthwhile difference; and A great deal better, and a considerable improvement that has made all the difference". It has been used to define the level of change in pain intensity that represents a clinically important difference in a mixed cohort of patients (Farrar et al., 2001).

Compensatory health service measures

The removal of one part of a health service can potentially impact the remainder of the health service. In particular, the removal of a weekend allied health service has the potential to compromise early allied health intervention, early mobilisation (since physiotherapists are primarily concerned with patient mobility), and quantity of allied health sessions provided during the acute hospital period. Therefore, the timing of allied health commencement, the timing of first postoperative transfer out of bed (both relative to time of return to ward postoperatively) and allied health quantity (session rate per inpatient day) were collected in this thesis. These variables were collected for each separate allied health profession and also totalled for allied health in general. Sitting on edge of the bed was not considered a transfer nor was transferring with a mechanical aid (e.g. hoist). The profession of staff assisting with

first postoperative transfer out of bed was also collected, as this was a potential compensatory effect of the removal of weekend allied health services.

Qualitative outcomes

Semi-structured focus groups were conducted to gain an in-depth understanding of the role of the allied health team during the acute phase following elective lower limb joint replacement surgery in Study 2. Group dynamics play a significant role within any organisation (Scandiffio, 1990) and, as care provision for these patients is essentially a team activity, it was considered this was important to observe amongst the ward staff when examining the role of allied health following hip and knee replacement. Focus groups were also chosen to encourage participants to challenge their own ideas in order to facilitate discussion (Kitzinger, 1994). All focus groups followed a semi-structured format to allow for flexibility in the order of topics covered and so that issues raised could be explored in further detail.

Focus groups were designed to elicit and discuss staff perceptions regarding the aims and roles of allied health therapy in the acute phase following lower limb joint replacement, how these services are currently provided and how these services could better be provided. Related issues of optimal timing, quantity and provision of these services on the weekend were also explored (Appendix G).

2.2.7 Procedure

Data collection occurred concurrently for all four studies in this research program. Specific details concerning individual study procedures are provided throughout the respective chapters. A consecutive sampling approach for patient recruitment was adopted, with all patients undergoing preoperative assessment for hip or knee replacement at the study

hospital clinic approached for consent in order of presentation. Participant assessment occurred preoperatively (at time of consent), at four days and six weeks postoperatively. A professional language interpreter was employed for culturally and linguistically diverse participants upon their request.

During the preoperative assessment, baseline data for the quasi-experimental studies (studies three and four) were collected. This included participant self-report of functional independence, mobility, quality of life and pain. These same measures were assessed at four days and six weeks postoperatively. In addition, patient satisfaction using questions relating to overall patient satisfaction and the effect of the hospital stay from the Victorian Patient Satisfaction Monitor was assessed at four days postoperatively. Participant ratings of appropriateness of total length of time spent in hospital (from the Victorian Patient Satisfaction Monitor) and the global degree of change since surgery were also assessed at six weeks postoperatively.

Data collection for the interrater agreement study (Study 1) was also conducted at the preoperative assessment. Each participant completed a therapist-assessed performance of mobility using the DEMMI in addition to patient self-report. These two methods of mobility assessment were completed in a random order. Participants completing the self-report followed by the therapist-directed assessment were asked to rate their performance again after having recently attempted all tasks on the DEMMI.

For the quasi-experimental studies (studies three and four), participants were exposed to study conditions based on their surgery date and the subsequent dates of hospitalisation. Surgery dates were not allocated until after preoperative assessment. Notification of all planned surgeries at the beginning of each week was received during the study period. These dates were then used to calculate postoperative interview dates.

Survey data were entered into SurveyMonkey Inc. (Palo Alto, California, USA) and exported to Microsoft Excel. Hospital outcomes were extracted into Microsoft Excel after study completion from: i.PatientManager (i.PM) (DXC.technology, Macquarie Park, NSW, Australia), the hospital electronic patient management program; Scanned medical records; and RiskMan (RiskMan International Pty Ltd, Southbank, Victoria, Australia), the incident reporting database. The following information was obtained from i.PM: a) date and time of admission and discharge from acute and sub-acute wards (in order to calculate acute and total length of stay); b) date and profession of each occasion of allied health service; and c) dates of any hospital readmissions within six weeks of discharge. Scanned medical records were accessed to extract: date and time at which each participant returned to their designated ward following surgery; first postoperative allied health intervention; first transfer postoperatively; and verification of hospital admission and discharge dates. Falls, Medical Emergency Team calls and pressure areas were obtained from RiskMan reports while death and intensive care unit admissions were taken from i.PM. Reports generated from health information services identified any cases of postoperative deep vein thrombosis or pulmonary embolus using associated International Classification of Diseases codes.

Multiple methods were employed to verify data accuracy (Sarkies et al., 2016) (Figure 2.2). Allied health occasions of service were reconciled against hospital admission dates. Admission and discharge dates extracted from i.PM were confirmed by consulting scanned medical records. In cases of discrepancy, medical records were hand-searched used daily ward handover forms and participant interviews to triangulate and manually adjust data.

Daily staff interview and nursing handover forms collected as part of the parent trials were used to verify adverse events and identify additional events. Hospital readmission

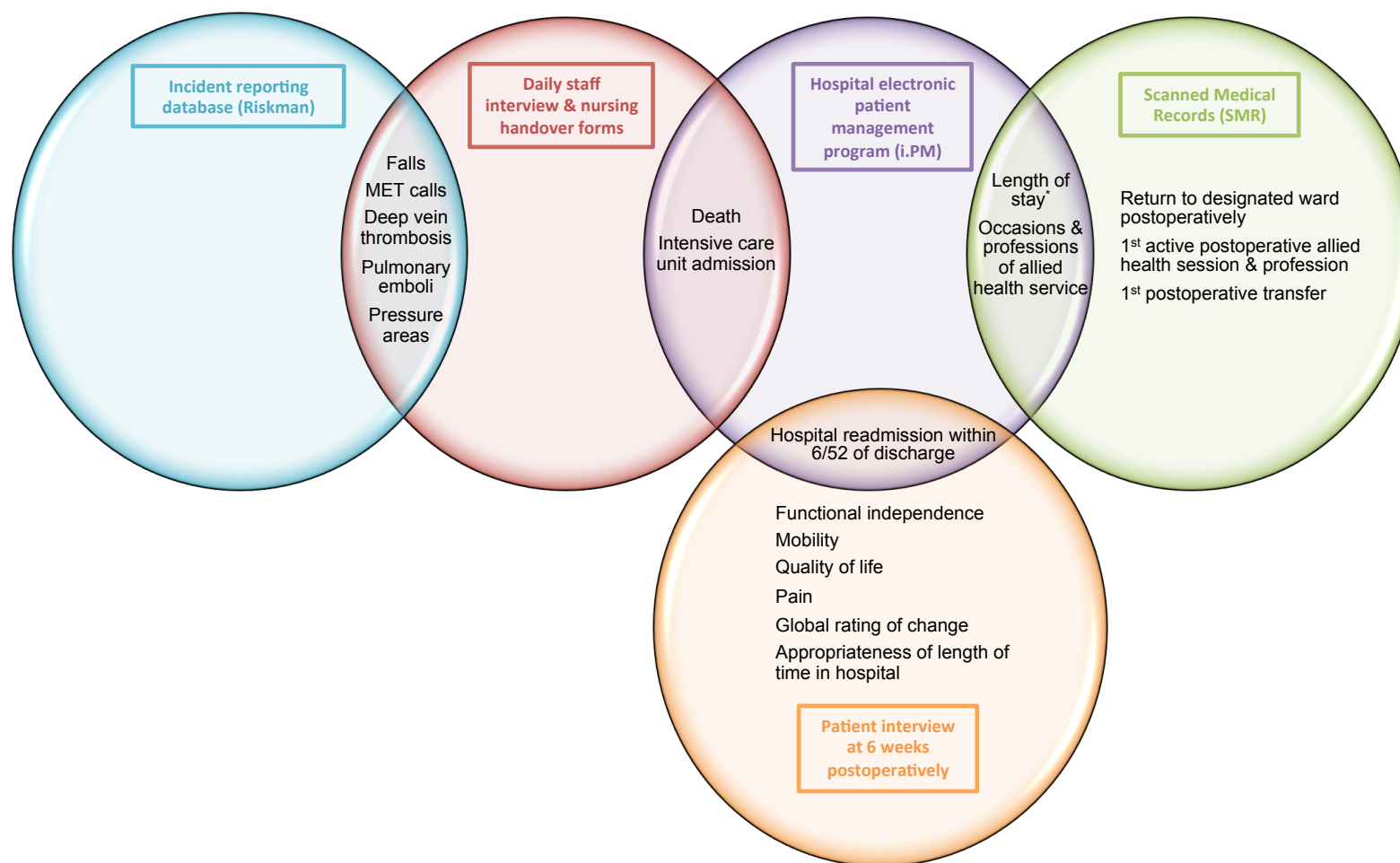


Figure 2.2: Example of triangulation of data extracted from hospital databases and ward records

information was sought during the six-week postoperative interview and reconciled with information from i.PM in order to identify unplanned admissions to a non-study hospital.

Semi-structured focus groups were conducted with health professionals involved in the acute care of patients following hip and knee joint replacement surgery in July 2014 prior to the removal of weekend allied health services in the acute orthopaedic wards (Study 3, Chapter 4). A purposive sampling strategy (total population) was used to ensure all health professional staff currently working on the study wards were invited to participate in this study. All investigators were appropriately trained in qualitative and participatory action research prior to conducting the focus groups. All groups included a facilitator and a note-taker. The same investigative team attended each focus group although the role of facilitator rotated. This was to allow all investigators to gain experience in all roles.

All manuscripts were written in accordance with their respective study design guidelines. The systematic literature review was written according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) (Liberati et al., 2009). Study 1 (interrater agreement) was written according to Guidelines for Reporting Reliability and Agreement Studies (GRRAS) (Kottner et al., 2011). Study 2 (qualitative descriptive) was written in accordance with COnsolidated criteria for REporting Qualitative research (COREQ) (Tong, Sainsbury, & Craig, 2007). Studies three and four (quasi-experimental) were written according to the Transparent Reporting of Evaluations with Non- randomised Designs statement (TREND) (Des Jarlais, Lyles, & Crepaz, 2004).

2.2.8 Data analysis approach

A range of quantitative and qualitative data analysis techniques were utilised throughout this thesis. Quantitative analyses included random effects meta-analyses (systematic literature

review), Bland-Altman plots (Study 1), univariate and multivariable linear and logistic regression (studies three and four), intention-to-treat analyses (studies three and four) and contamination-adjusted intention-to-treat analyses (Study 4). Qualitative data was analysed using thematic analysis (Study 2). Individual data analysis techniques are presented within each chapter separately. All statistical analyses were performed with STATA SE (STATACorp, College Station, TX, USA) version 13.0. NVivo computer software (version 10, QSR International Ltd, Doncaster, Victoria, Australia) was utilised to facilitate the thematic analysis conducted in Study 2.

2.2.9 Timeline

The timeline for this research program is presented in Figure 2.3. Work was conducted over five phases - a preparatory, data collection, data extraction, manuscript preparation and thesis finalisation phase. The preparatory phase involved study conception and ethics approval processes. Recruitment and data collection for all four studies occurred concurrently over 14 months from February 2014 until March 2015. Data extraction and cleaning occurred from February 2015 until June 2015. Data analysis, synthesis and manuscript submission occurred sequentially for each study during the manuscript preparation phase from July 2015 until July 2017. Study 2 (qualitative descriptive design) was an exception to this where data collection and analysis occurred in an iterative manner during July and August 2014 prior to the manuscript preparation. This was to allow for themes emerging from the data to be explored further in subsequent focus groups (Srivastava & Hopwood, 2009).

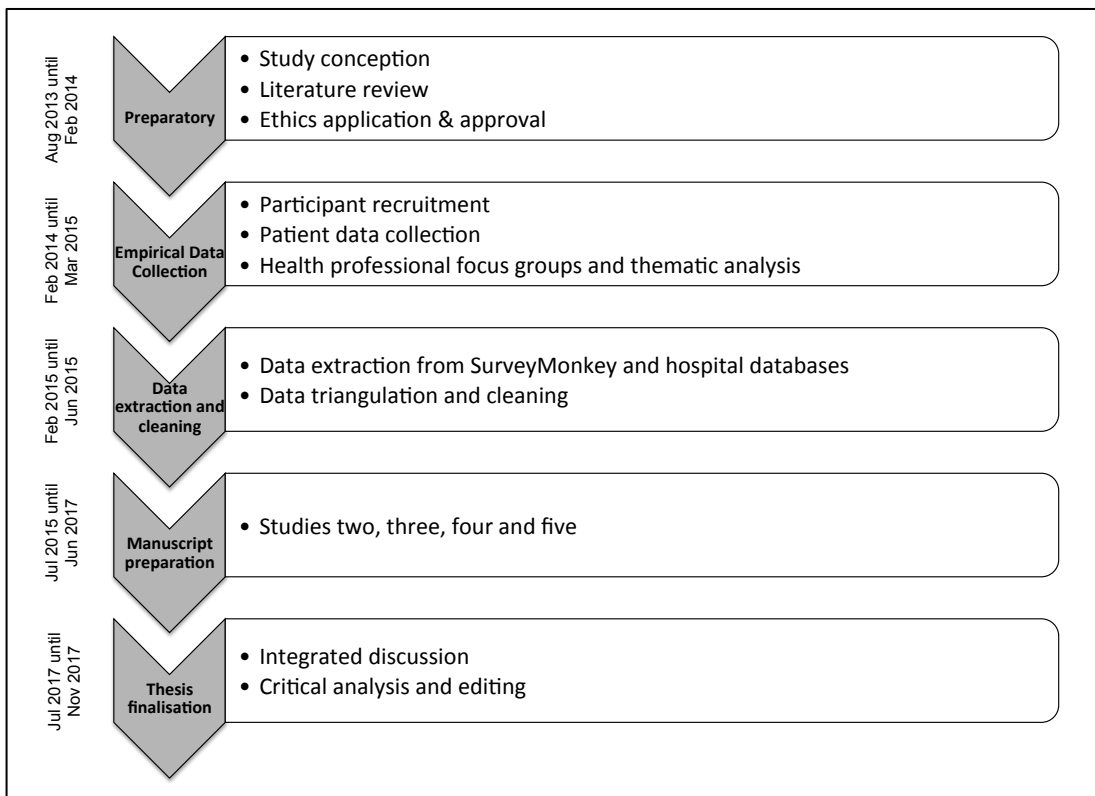


Figure 2.3: Research program timeline

2.2.10 Ethical and study registration considerations

Prior approval to conduct all studies conducted in this thesis was obtained from Monash Health Human Research Ethics Committee (Reference Number 13327B) (Appendix H). All study participants (including patients and hospital staff members) provided written informed consent (appendices I and J for patients and staff respectively) and the rights of the subjects were protected. All research was conducted according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia (2007 (Updated May 2015)). The parent trials in which this study was nested were registered with the Australian New Zealand Clinical Trials Registry [Registration number: ACTRN12613001231730 (Trial 1) and ACTRN12613001361796 (Trial 2)]. Use of the EQ-5D-5L for the studies conducted was registered with the EuroQol office (Appendix K).

2.2.11 Amendment to planned study methods

Economic evaluation of the impact of removing acute weekend allied health services for patients following hip and knee joint replacement surgery was initially planned and patient reported data at six weeks postoperatively was collected accordingly. At this stage, the randomisation of the parent trials had not been conducted so the exact timing of the removal of the weekend allied health services from the orthopaedic wards was not known. An economic evaluation incorporating use of downstream inpatient, home-based or outpatient rehabilitation services could not be conducted once it became known that the orthopaedic wards had been randomised to Cluster 6. This is because the protocol of the parent trials stipulated that the acute weekend allied health service would be reallocated to an acute medical unit until saturation and then to the sub-acute ward in which the orthopaedic patients were preferentially admitted for rehabilitation. Saturation of acute weekend allied health services to the acute medical unit occurred during Cluster 4. This meant that by Cluster 6 all acute weekend allied health services were reallocated to the sub-acute setting. Therefore patients admitted for lower limb replacement surgery during phase 2 when acute weekend allied health services were not available, were eligible to receive a weekend allied health service in the sub-acute setting if receiving inpatient rehabilitation. This had the ability to confound the effect of an acute weekend allied health service compared to no service at six weeks postoperatively. A study investigating the effect of transferring weekend allied health services from the acute to sub-acute setting on medium-term patient and service outcomes following hip and knee replacement surgery (Study 4) was subsequently planned instead.

Chapter 3 – Establishing method of measuring mobility

3.1 Preface

The following section presents the findings of Study 2. It has been adapted from the following published article: Haas R, Bowles K-A, O'Brien L and Haines T. Patient and therapist agreement on performance rated ability on the de Morton Mobility Index. *Arch Phys Med Rehabil*. 2016; 97(12): 2157-2165.

A copy of the published article and copyright clearance is provided in Appendix L.

3.2 Study 1 – Patient and therapist agreement on performance-rated ability using the de Morton Mobility Index

3.2.1 Abstract

Objective: To determine the level of agreement between patient self-report and therapist-assessed performance of mobility using the de Morton Mobility Index.

Design: Interrater agreement study.

Setting: Outpatient hospital clinic.

Participants: Consecutive sample of patients (N=128) undergoing preoperative assessment for elective lower limb joint replacement.

Interventions: Participants completed a therapist-directed assessment of the DEMMI followed by self-report of performance. A random subsample (n=62, 48%) also completed a self-report of anticipated performance before the therapist-directed assessment. Both raters (participant and therapist) were blinded to the scores obtained from the other rater.

Main Outcome Measures: Interrater agreement between patient self-report and therapist-directed assessment of the total DEMMI scores was calculated using the intraclass correlation coefficient model 2,1 (ICC_{2,1}) with a 95% confidence interval. The Bland-Altman plots were also used to illustrate the agreement between the two raters.

Results: The intraclass correlation coefficient (ICC) between patient self-report after performance and therapist-directed assessment of the total DEMMI score was 0.967 (95% confidence interval, 0.952 to 0.977). The ICC between patient self-report of anticipated performance and therapist-directed assessment of the total DEMMI score was 0.830 (95% confidence interval, 0.730 to 0.894). The Bland-Altman plots depicted higher levels of agreement among participants with impaired levels of mobility (≤ 74 out of 100) than did those with near-maximum DEMMI scores.

Conclusion: Patient self-report of anticipated performance is an acceptable proxy for DEMMI scores derived from therapist rating of performance. Caution should be exercised when interpreting self-report scores of patients with near-maximum levels of mobility. Further research is required to establish whether these results can be generalised across a range of patient populations and to clinicians with differing backgrounds and expertise.

3.2.2 Introduction

Poor mobility is associated with reduced independence in activities of daily living (Hirvensalo, Rantanen, & Heikkinen, 2000), cardiovascular deconditioning (Welmer, Angleman, Rydwick, Fratiglioni, & Qiu, 2013), increased falls risk (Barker, Nitz, Low Choy, & Haines, 2012; Lord et al., 2003), reduced quality of life (Groessl et al., 2007), institutionalisation (von Bonsdorff, Rantanen, Laukkanen, Suutama, & Heikkinen, 2006), and mortality (Hirvensalo et al., 2000). The *International Classification of Functioning, Disability and Health* (World Health Organization, 2001)^(p138) defines *mobility* as “moving by changing body position or location or by transferring from one place to another, by carrying, moving or manipulating objects, by walking, running or climbing, and by using various forms of transportation”. Restricted mobility is the most common disability type in the United States, with one in eight adults reporting serious difficulty walking or climbing stairs (Courtney-Long et al., 2015).

The ability to reliably and accurately measure mobility is necessary to identify those in need of treatment and to measure treatment effects. The de Morton Mobility Index (DEMMI) is an instrument that has been shown to be valid, reliable, and robust across the mobility spectrum and clinical settings (T. Braun et al., 2015; de Morton et al., 2011; de Morton, Davidson, et al., 2008; de Morton et al., 2010; de Morton & Lane, 2010; de Morton et al., 2015; Jans et al., 2011). It has been designed as a performance-based assessment that relies on clinician observation and performance rating of 15 hierarchical mobility activities, ranging from sitting unsupported to tandem stand with eyes closed. A problem with this approach is that it requires face-to-face contact or observation mediated through video.

The ability to use patient self-report of perceived performance ability in addition to performance-based assessment of the DEMMI has the potential to aid future clinical practice and research by eliminating the cost burden (clinician time, patient time, travel) of face-to-face assessment. Previous researchers have reported that a similar measure, the modified Barthel Index, was quicker to complete as a self-reported rather than therapist-assessed measure (Rehabilitation Measures Database, 2010) and argued that it could be administered either via in-person interview or by telephone (Collin et al., 1988). Self-reported walking ability has also been demonstrated as an accurate predictor of mobility performance (Alexander et al., 2000; Sayers et al., 2004). However, substitution of therapist-assessed with self-report outcomes is only acceptable if there are high agreement levels between therapists and patients, and this may not always be the case (McPhail, Beller, & Haines, 2008). For example, 31% to 63% of older adults undergoing inpatient rehabilitation have been shown to underestimate personal fall risk as compared to clinician-rated functional ability (Mihaljcic, Haines, Ponsford, & Stolwyk, 2015).

The primary aim of this study was to determine the level of agreement between patient self-reported mobility and therapist-assessed performance using the DEMMI. Both anticipated self-report (assessed before physically attempting the tasks) and self-report postperformance (assessed after DEMMI performance) were examined. Secondary aims were to examine whether the agreement level was affected by age, sex, or linguistic background of the sample or whether actual performance or patient self-report preperformance affected patient self-report postperformance using the DEMMI.

3.2.3 Methods

Study design

This was an interrater agreement study design whereby patient self-report of perceived ability before and after actual performance was compared with therapist-assessed performance using the DEMMI.

Participants and setting

Consecutive patients undergoing preoperative assessment for elective lower limb joint replacement surgery were recruited between August 7, 2014, and December 4, 2014, as part of a larger study investigating the timing and dose of allied health intervention in the acute postoperative phase following joint replacement surgery. Adults older than 18 years undergoing elective lower limb joint replacement at a 520-bed public teaching hospital situated in the southeastern suburbs of Melbourne, Australia, were approached for consent. The types of joint replacement considered for inclusion were total hip replacement, total knee replacement, and revision total hip or knee replacement. Exclusion criteria were patients undergoing joint replacement surgery immediately after trauma (e.g. fracture) and patients with a moderate cognitive impairment assessed as ≤ 5 out of 10 on the Short Portable Mental Status Questionnaire (Pfeiffer, 1975). A professional interpreter was employed for participants upon request as part of their preoperative assessment.

Measurement

In this study, the DEMMI was used to assess mobility of patients undergoing preoperative assessment for elective lower limb joint replacement. The DEMMI was developed to overcome ceiling and floor effects demonstrated in other mobility instruments used in clinical populations (de Morton, Berlowitz, & Keating, 2008) and has face validity for measuring patients ranging from those who are bedbound to those with high levels of independence (de Morton, Davidson, et al., 2008). Rasch analysis has been used to construct an interval level scoring system out of 100 from the 15 ordinal items (Belvedere & de Morton, 2010). The DEMMI has been widely used and validated in mixed populations (including lower limb joint replacement) across the full mobility spectrum and clinical settings (acute, subacute, community), in which this patient population is commonly seen (T. Braun et al., 2015; de Morton et al., 2011; de Morton et al., 2010; de Morton & Lane, 2010; de Morton et al., 2015; Jans et al., 2011; Parker, Hill, Cobden, Davidson, & McBurney, 2015).

Procedure

This study was performed and reported in accordance with Guidelines for Reporting Reliability and Agreement Studies (Kottner et al., 2011). Approval to conduct this study was obtained from Monash Health Human Research Ethics Committee (reference number 13327B). A consecutive sampling methodology was adopted whereby all patients attending preoperative assessment before lower limb joint replacement were approached for consent in the order of presentation. Written informed consent was obtained from all consenting participants.

A computer generated randomisation process (SurveyMonkey Palo Alto, California, United States) was used to allocate participants to one of two groups. One group (Group 1) was

asked to self-rate their perceived mobility level using the DEMMI without actually attempting any of these tasks (anticipated performance). The investigator (R.H.) conducting the performance-based assessment of the DEMMI was blinded to participant's self-report. This group then undertook a therapist-directed assessment of the DEMMI during which the investigator (R.H.) rated their ability as they performed each task. Participants were not informed of the rating made by the investigator. These participants were then asked to again rate their performance using the DEMMI, having recently attempted all tasks (self-report postperformance). Participants allocated to Group 2 were not asked to self-rate perceived mobility before completing the therapist-directed assessment. These participants completed only the therapist-directed assessment and then rated their performance on the DEMMI. They were also blinded to the investigator rating. This second group allowed us to examine whether there was a potential confounding effect of completing self-report of anticipated performance on postperformance ratings.

Therapist-directed assessment was conducted according to the DEMMI handbook (de Morton, 2010). Items were scored at the lowest score if a participant declined to attempt a task or was deemed unsafe to do so. Participants were provided with the same verbal explanation as in the DEMMI handbook when they were completing their self-reported assessments. The investigator conducting the therapist-directed assessments was a physiotherapist who has worked in geriatric settings for 15 years (R.H.).

Data analysis

Interrater agreement between performance-based and self-reported (both anticipated and postperformance) total DEMMI scores was assessed separately using the intraclass correlation coefficient model 2,1 (ICC_{2,1}) with a 95% confidence interval. Agreement between self-report of anticipated performance and therapist-directed assessment included

only those participants who were randomly allocated to rate their anticipated performance before the therapist-directed assessment. Agreement between self-report postperformance and therapist-directed assessment included all study participants. Bland Altman plots (Bland & Altman, 1986) were also used to illustrate agreement between the 2 measurement techniques. Interrater agreement between performance-based and self-report ratings of each individual DEMMI task was determined using the κ statistic and intraclass correlation coefficient (ICC).

A known limitation of κ is that it is affected by the prevalence of the findings under observation (Feinstein & Cicchetti, 1990; Krippendorff, 2011; Viera & Garrett, 2005). For rare findings, low values of κ may not necessarily reflect low rates of the overall agreement. Percent total agreement, percent “able” agreement and percent “unable” agreement were therefore also calculated (Cicchetti & Feinstein, 1990) to account for this paradox.

Paired *t*-tests were conducted to investigate the presence of systematic bias. Agreement statistics were compared between participant subgroups for age, sex, and request for an interpreter during preoperative assessment. Finally, the effect of performing the DEMMI tasks on participant self-reported scores by comparing the anticipated scores obtained before performance with the self-report scores obtained after performance were examined. Total scores were compared using paired *t*-tests and item level ratings were compared using the Wilcoxon signed-rank test. The effect of completing self-report of anticipated performance using the DEMMI on self-report postperformance scores was also investigated. An unpaired *t*-test of self-report scores postperformance between those participants who did (Group 1) and did not (Group 2) complete self-report of anticipated performance was conducted.

Sample size consideration

A post hoc analysis demonstrated a sample size of 62 patients provided 80% power of finding a significant ICC as low as 0.33 (assuming two raters and $\alpha = 0.05$)²⁷ for the agreement analysis between ratings derived from therapist-directed assessment and patient self-report of anticipated performance on the DEMMI. A sample size of 128 patients provided 80% power of finding a significant ICC as low as 0.22 (assuming two raters and $\alpha = 0.05$) (Walter, Eliasziw, & Donner, 1998) for the agreement analysis between ratings derived from therapist-directed assessment and patient self-report after DEMMI performance.

3.2.4 Results

Study participants

One hundred twenty-eight of 149 patients undergoing preoperative assessment for lower limb joint replacement during the recruitment period consented to participate in this study. In total, there were 318 DEMMI observations (62 anticipated self-report, 128 therapist-directed and 128 self-report post-performance) derived from 128 participants and 2 raters (therapist, participant). The characteristics of those who consented and those who did not are summarised in Table 3-1. Of the 21 patients undergoing preoperative assessment who did not consent to participate, 12 could not be approached for consent during the clinic; two declined surgery; one had impaired cognition and six declined to participate. Reasons for declining consent included apprehension (n=1, 17%), previous hospital experience (n=1, 17%), “not feeling well” (n=2, 33%) and carer report of impaired cognition (n=2, 33%).

Table 3-1: Participant and nonparticipant characteristics

Characteristic	Participants who consented (n=128)	Those who did not consent (n=21)
Female, n (%)	78 (61)	14 (67)
Age in years, mean (SD)	68.5 (9.3)	70.0 (12.3)
Request for interpreter, n (%)	18 (14)	8 (38)
Surgery type, n (%)	TKR, 82 (64) THR, 42 (33) Revision TKR, 1 (0.7) Revision THR, 3 (2.3)	TKR, 13 (62) THR, 6 (28) Revision TKR, 1 (5) Revision THR, 1 (5)
DEMMI total, median (range)	74 (39-100)	
Pathway*, n (%)	A, 46 (36) B, 57 (44) C, 24 (19) (1 missing)	A, 3 (14) B, 7 (33) C, 9 (43) (2 missing)
Comorbidities†, n (%)	Cardiovascular, 34 (27) Neurological, 7 (5) Diabetes, 33 (26) Mental health, 17 (13) Malignancy, 17 (13) Pulmonary, 18 (14)	Cardiovascular, 7 (33) Neurological, 3 (14) Diabetes, 11 (52) Mental health, 3 (14) Malignancy, 1 (5) Pulmonary, 6 (28)

* Pathway indicates expected postoperative recovery pathway. A indicates 4 day length of stay with discharge directly home from acute facility. B indicates 3-day acute length of stay with inpatient rehabilitation 4-7 days. C indicates inpatient rehabilitation \geq 14 days.

† Participants may have multiple comorbidities.

Comparison of self-report of anticipated performance with therapist-assessed performance

In the 62 participants who randomly completed self-report of anticipated performance before therapist-directed assessment, the ICC between the total DEMMI scores was 0.830 (95% confidence interval 0.730-0.894). The Bland-Altman plot (Figure 3.1) depicts that participants overestimate their actual ability on average; however, this overestimation was by <1 out of 100 points on the DEMMI scale and considered insignificant (de Morton et al., 2010). The relatively wide limits of agreement (-19.773, 18.063) appear to be largely driven by four data points. Further inspection of individual data revealed that there were discrepancies in two or three DEMMI items for each of these outliers, all of which were in high-end tasks. Removal of these outliers from this analysis reduced the 95% limits of agreement to -14.750 and 14.715.

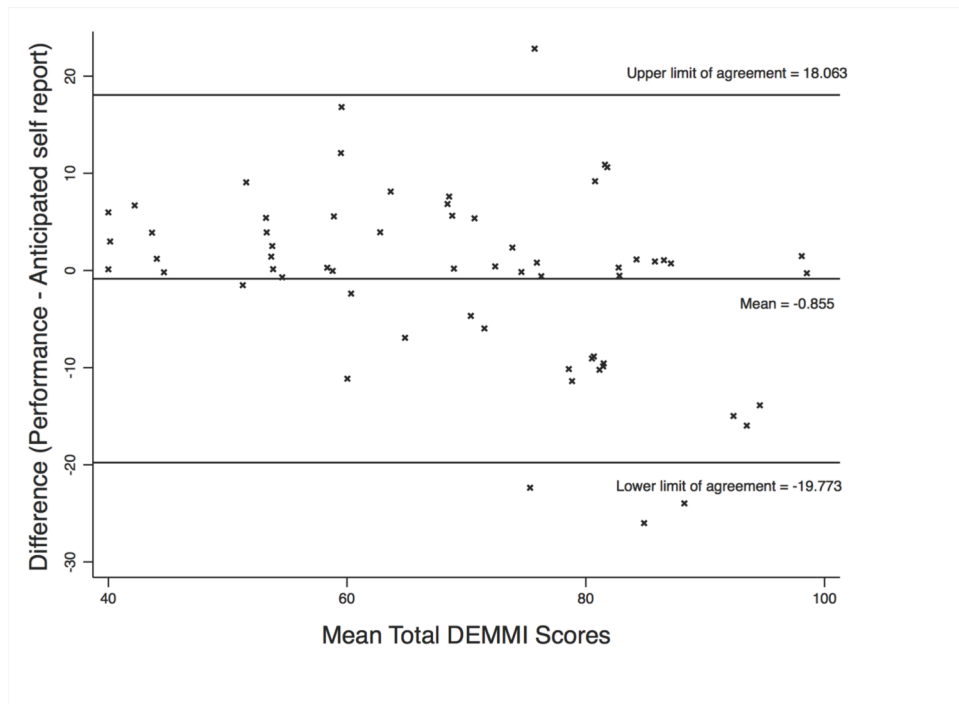


Figure 3.1: Bland-Altman plot comparing total DEMMI scores using therapist-directed assessment and patient self-report of anticipated performance

Agreement statistics between participant self-report of anticipated performance and therapist-directed assessment of individual DEMMI tasks are listed in Table 3-2. Total agreement in all tasks was >85%. A ceiling effect and consequent lack of range in scores for eight of the lower-end tasks limits the interpretation of κ and ICC values for these tasks (Feinstein & Cicchetti, 1990; Krippendorff, 2011; Viera & Garrett, 2005). In these tasks, the proportion of assessments where both raters categorised participants as “able” was >85%. This rendered chance-corrected agreement statistics low or unable to be calculated. In the remaining seven tasks, κ values ranged from 0.6482 to 0.9086.

Table 3-2: Agreement between therapist-directed assessment and patient self-report of anticipated performance for individual DEMMI tasks

DEMMI task	Kappa	ICC (95% CI)	Percent total agreement	% Responses in majority category	Percent 'able' agreement	Percent 'partially able' agreement	Percent 'unable' agreement
Sit unsupported in chair*	N/A	N/A	62/62= 100%	62/62= 100%	1	N/A	Not a number
Bridge*	0.0000	0.000 (-0.238, 0.242)	59/62=95.16%	59/62=95.16%	0.975	N/A	0
Stand unsupported*	0.0000	0.000 (-0.233, 0.239)	58/62=93.55%	58/62=93.55%	0.967	N/A	0
Sit to stand from chair*	0.0000	0.000 (-0.248, 0.248)	61/62=98.39%	61/62=98.39%	0.992	0	Not a number
Roll onto side*	N/A	N/A	62/62= 100%	62/62= 100%	1	N/A	Not a number
Lying to sitting*	0.659	0.663 (0.498, 0.782)	61/62=98.39%	60/62= 96.77%	0.992	0.667	Not a number
Stand feet together*	0.5709	0.515 (0.307, 0.677)	58/62=93.55%	55/62=88.71%	0.965	N/A	0.6
Pick up pen from floor	0.8484	0.850 (0.764, 0.907)	58/62=93.55%	41/62=66.13%	0.953	N/A	0.895
Walk 4 steps backwards	0.8066	0.768 (0.637, 0.835)	57/62=91.94%	46/62=74.19%	0.948	N/A	0.815
Walking distance**†	1.000	1.000 (1.000, 1.000)	62/62=100%	60/62=96.77%	1	1	Not a number
Sit to stand without arms	0.7748	0.778 (0.645, 0.863)	56/62=90.32%	40/62=64.52%	0.930	N/A	0.842
Walking independence	0.9066	0.840 (0.747, 0.900)	59/62=95.16%	32/62=51.61%	0.955	0.945	0.5
Jump	0.8287	0.831 (0.734, 0.895)	59/62=95.16%	50/62=80.65%	0.857	N/A	0.971
Stand on toes	0.7120	0.715 (0.567, 0.818)	54/62=88.10%	37/62=59.68%	0.902	N/A	0.810
Tandem stand with eyes closed	0.6482	0.652 (0.481, 0.775)	54/62=88.10%	43/62=69.35%	0.733	N/A	0.915

Tasks displayed in hierarchical order from easiest to hardest

* Indicates tasks with a ceiling effect in which more than 85% of participants both self-reported and could actually perform the task.

† Maximum score achieved if able to walk 50 metres

Comparison of participant self-report post-performance with therapist-assessed performance

All 128 participants completed self-report of the DEMMI after the therapist-directed assessment. The ICC between participant self-report postperformance and therapist-directed assessment of the total DEMMI scores was 0.967 (95% confidence interval, 0.952-0.977). The Bland-Altman plot (Figure 3.2) depicts a similar mean difference but narrower limits of agreement than in the comparison between self-report of anticipated performance and therapist-assessed performance.

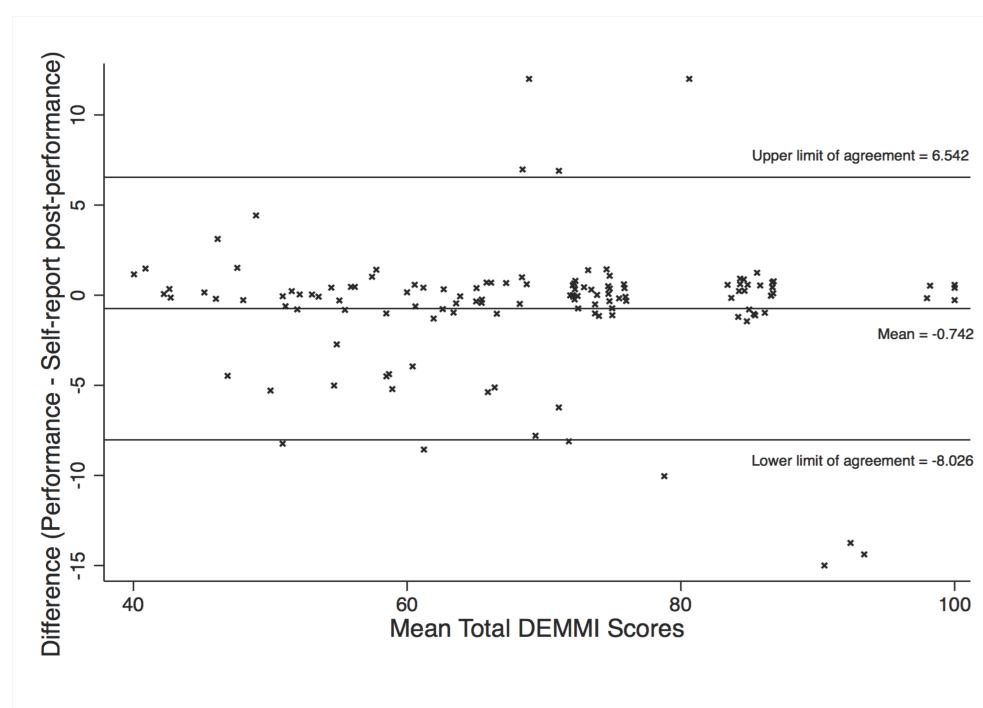


Figure 3.2: Bland-Altman plot comparing total DEMMI scores using therapist-directed assessment and patient self-report postperformance

Agreement statistics between participant self-report postperformance and therapist-directed assessment of individual DEMMI tasks are listed in Table 3-3. Total agreement in all tasks was > 90% with a ceiling effect as seen previously in the same eight tasks. κ values ranged from 0.7826 to 1.0000 in the remaining seven tasks.

Comparison of self-report of anticipated performance with self-report post-performance

There was no difference in participant self-report scores completed before (mean, 69.71 ± 17.87) and after (mean, 69.10 ± 14.30) the therapist-directed assessment ($t_{61} = 0.4758$; $P = 0.6359$). Of the 62 participants who self-reported before and after the therapist-directed assessment, 49 individual rating disagreements (in 36 participants) were evident between participant self-report of anticipated performance and therapist-directed assessment. Of these, only 11 rating disagreements (in nine participants) were maintained in the self-report postperformance.

The comparisons of participant self-report of anticipated performance and self-report postperformance for each individual DEMMI task are presented in Table 3-4. Participants overestimated their ability in anticipated self-report in one task (tandem stand with eyes closed) but underestimated their ability in two others (sit to stand without arms, stand on toes).

Comparison of self-report postperformance between participants who self-reported anticipated performance and those who did not

There was no difference in participant self-report scores after the therapist-directed assessment in participants who self-reported anticipated performance (mean, 69.29 ± 14.29) and those who did not (mean, 70.48 ± 14.71) ($t_{126} = -0.4655$; $P = 0.6424$).

Table 3-3: Agreement between therapist-directed assessment and patient self-report post-performance for individual DEMMI tasks

DEMMI task	Kappa	ICC (95% CI)	Percent total agreement	% Responses in majority category	Percent 'able' agreement	Percent 'partially able' agreement	Percent 'unable' agreement
Sit unsupported in chair*	0.0000	0.000 (-0.173, 0.173)	127/128=99.22%	127/128=99.22%	0.996	N/A	0
Bridge*	N/A	N/A	128/128=100%	128/128=100%	1	N/A	Not a number
Stand unsupported*	0.663	0.665 (0.556, 0.751)	127/128=99.22%	126/128=98.44%	0.996	N/A	0.667
Sit to stand from chair*	N/A	N/A	128/128=100%	128/128=100%	1	Not a number	Not a number
Roll onto side*	N/A	N/A	128/128=100%	128/128=100%	1	N/A	Not a number
Lying to sitting*	1.000	1.000 (1.000, 1.000)	128/128=100%	127/128=99.22%	1	1	Not a number
Stand feet together*	0.919	0.920 (0.888, 0.943)	127/128=99.22%	121/128=94.53%	0.996	N/A	0.923
Pick up pen from floor	1.000	1.000 (1.000, 1.000)	128/128=100%	94/128=73.44%	1	N/A	1
Walk 4 steps backwards	1.000	1.000 (1.000, 1.000)	128/128=100%	105/128=82.03%	1	N/A	1
Walking distance*†	1.000	1.000 (1.000, 1.000)	128/128=100%	124/128=96.88%	1	1	Not a number
Sit to stand without arms	0.818	0.820 (0.753, 0.869)	119/128=92.97%	90/128=70.31%	0.952	N/A	0.866
Walking independence	0.9517	0.953 (0.934, 0.967)	125/128=97.66%	75/128=58.59%	0.987	0.971	0
Jump	1.000	1.000 (1.000, 1.000)	128/128=100%	107/128=83.59%	1	N/A	1
Stand on toes	0.8848	0.886 (0.842, 0.918)	121/128=94.53%	75/128=58.59%	0.955	N/A	0.929
Tandem stand with eyes closed	0.7826	0.784 (0.706, 0.843)	117/128=91.41%	88/128=68.75%	0.841	N/A	0.941

Tasks displayed in hierarchical order from easiest to hardest.

* Indicates tasks with a ceiling effect in which more than 85% of participants both self-reported and could actually perform the task.

† Maximum score achieved if able to walk 50 metres

Table 3-4: Wilcoxon signed-rank test comparing participant self-report of anticipated performance to self-report postperformance for individual DEMMI tasks

DEMMI task	z-score	p-value
Sit unsupported in chair	no adjusted variance	
Bridge	-1.732	0.0833
Stand unsupported	-1.732	0.0833
Sit to stand from chair	-1.000	0.3173
Roll onto side	no adjusted variance	
Lying to sitting	-1.000	0.3173
Stand feet together	-0.535	0.5930
Pick up pen from floor	-1.000	0.3173
Walk 4 steps backwards	-1.633	0.1025
Walking distance†	no adjusted variance	
Sit to stand without arms	-2.714	0.0067*
Walking independence	-0.017	0.9868
Jump	1.732	0.0833
Stand on toes	-2.000	0.0455*
Tandem stand with eyes closed	3.138	0.0017*

Tasks displayed in hierarchical order from easiest to hardest.

* p<0.05 considered statistically significant

† Maximum score achieved if able to walk 50 metres

Subgroup analyses

Paired *t*-tests, ICCs, and 95% confidence intervals for the subgroup analyses are reported in Table 3-5 and Table 3-6. The mean difference between therapist-directed assessment and participant self-report did not exceed > 2 out of 100 points for any subgroup analysis. The only factor demonstrating a difference between subgroups was sex, where there was a mean difference of < 1 out of 100 points on the DEMMI between therapist-directed assessment (mean, 67.49±14.12) and self-report post-performance (mean, 68.23±14.33) for women ($t_{77} = -2.1893$; $P = 0.0316$). However, this small difference is considered clinically insignificant (de Morton et al., 2010).

Table 3-5: Paired t-test, intraclass correlation coefficients (ICC2,1) and 95% confidence intervals for subgroup analyses comparing therapist-directed assessment to participant self-report of anticipated performance

Demographic			Therapist-directed DEMMI scores Mean (SD)	Self-report of anticipated performance Mean (SD)	Paired t-test	ICC (95% CI)
Age	≤68	n=33	70.58 (13.92)	71.70 (17.37)	p=0.5157	0.809 (0.648, 0.901)
	>68	n=29	66.90 (14.54)	67.45 (18.46)	p=0.7496	0.850 (0.705, 0.927)
Gender	Male	n=27	71.56 (13.30)	71.26 (15.66)	p=0.8636	0.819 (0.640, 0.913)
	Female	n=35	66.77 (14.73)	68.51 (19.54)	p=0.3060	0.835 (0.700, 0.913)
Interpreter	No	n=52	70.35 (14.09)	71.75 (17.96)	p=0.3097	0.813 (0.696, 0.888)
	Yes	n=10	61.1 (12.84)	59.1 (13.66)	p=0.3653	0.876 (0.599, 0.967)

Table 3-6: Paired t-test, intraclass correlation coefficients (ICC2,1) and 95% confidence intervals for subgroup analyses comparing therapist-directed assessment to patient self-report postperformance

Demographic			Therapist-directed DEMMI scores Mean (SD)	Self-report post-performance Mean (SD)	Paired t-test	ICC (95% CI)
Age	≤68	n=65	72.8 (13.67)	73.62 (14.13)	p=0.1187	0.954 (0.926, 0.972)
	>68	n=63	65.22 (13.77)	65.89 (13.87)	p=0.0881	0.975 (0.959, 0.985)
Gender	Male	n=50	71.54 (14.08)	72.28 (14.50)	p=0.2504	0.950 (0.914, 0.971)
	Female	n=78	67.49 (14.12)	68.23 (14.33)	p=0.0316*	0.977 (0.963, 0.985)
Interpreter	No	n=110	69.81 (13.85)	70.34 (14.00)	p=0.0853	0.973 (0.961, 0.982)
	Yes	n=18	64.56 (15.73)	66.61 (17.22)	p=0.1412	0.937 (0.840, 0.976)

* p<0.05 considered statistically significant

3.2.5 Discussion

Agreement between ratings of therapist-assessed performance on the DEMMI and participant self-report both before and after performance observed in this study is interpreted as almost perfect (Landis & Koch, 1977). Interrater agreement is higher when participants self-reported their perceived ability after, rather than before, the therapist-directed assessment. Agreement also appears higher amongst participants with DEMMI scores reflecting some level of mobility dysfunction, that is, ≤ 74 out of 100 (corresponding to the raw score of ≤ 17 out of 19). In both scenarios, there is a slight overall tendency for participants to overestimate their ability compared to therapist ratings, though the magnitude of this is small. Individual DEMMI task agreement is interpreted as moderate (McHugh, 2012) or higher and is highest among functional activities of daily living such as walking independence. The high level of agreement was maintained regardless of participant's sex, age group, or use of an interpreter.

To the author's knowledge, this is the first use of DEMMI self-report. The high rating of agreement observed is consistent with a similar study (Collin et al., 1988) comparing patient self-report to therapist-assessed measurements of the Barthel Index but not with two other studies (McGinnis, Seward, DeJong, & Osberg, 1986; Sinoff & Ore, 1997). One of these studies (Sinoff & Ore, 1997) demonstrated a mean difference between self-report and therapist-assessed performance (90.4 ± 14.6 vs 88.3 ± 14.5 , respectively, out of 100) comparable to the results of the present study but with low κ scores (range 0.103 to 0.398). This difference is unlikely to be clinically important (De Morton, Keating, & Jeffs, 2007), and it should be noted that high Barthel scores have been associated with a ceiling effect (De Morton et al., 2007), of which the subsequent low variability in scores is a known limitation of the κ statistic (Feinstein & Cicchetti, 1990; Krippendorff, 2011; Viera & Garrett, 2005). This study (Sinoff & Ore, 1997) may also have introduced additional disagreement by using

multiple observers to rate performance and multiple interviewers to assist with self-reporting. Unlike the results of the present study, McGinnis et al (1986) found that patients underestimated their performance. However, this study was conducted immediately before discharge home from inpatient rehabilitation when therapists may be keen to demonstrate treatment effectiveness. In addition, patients may have felt anxious about their impending discharge and/or have rated their independence during Barthel index tasks on the basis of acceptance of available assistance in hospital rather than perceived ability. In contrast to existing literature (Crandall, 1969; Deaux & Farris, 1977; Merrill, Seeman, Kasl, & Berkman, 1997) demonstrating men tend to overestimate whereas women tend to underestimate their performance, the results of this study do not depict a sex difference in agreement level between patient self-report and therapist-assessed performance using the DEMMI.

The present results demonstrate lesser agreement in participants with high-level mobility. It is possible these results may be a consequence of the total DEMMI score calculation approach based on Rasch analysis. This approach gives a much higher penalty for disagreement in one category at the higher end of the mobility spectrum than at the middle or lower end. For example, there is a 15-point penalty for disagreement in one category at the maximum score of 100 compared to only two points at a score of 41 out of 100 (de Morton, 2010). It was data from participants at this high-end of mobility that drove the wider 95% limits in each of the comparisons examined. This may mean that these different methods of assessing the DEMMI may have narrower limits of agreement if the participant population has poorer mobility than the sample considered in this study. This is possibly not surprising given the DEMMI was originally developed in the inpatient older adult population, which is likely to have poorer mobility than the preoperative sample.

This study's results suggest that actually performing the DEMMI may affect participant self-report postperformance in cases where there was an initial discrepancy between self-report of anticipated performance and the rating obtained from the therapist-directed assessment. This is consistent with previous experimental findings (Sprangers & Hoogstraten, 1989) and a cross-sectional study (Daltroy, Larson, Eaton, Phillips, & Liang, 1999) supporting the notion that actual performance has the capacity to affect self-report postperformance, presumably by providing participants with information that enables them to better assess their level of functioning. This is also evident in the results of the present study demonstrating that the individual DEMMI tasks with the least agreement (tandem stand with eyes closed, stand on toes) are those least likely to be performed in a functional context.

The ability to use self-report of perceived ability as a proxy to therapist ratings of DEMMI performance, as demonstrated in this study, has both clinical and research implications. Reassessment of the DEMMI using self-report after discharge home from hospital could be used to identify those requiring additional support in the absence of clinical contact. It could also assist in standardising follow-up methodology, which has been identified as a limitation in investigating the effect of follow-up telephone calls in reducing post discharge problems (Mistiaen & Poot, 2006). In addition, the ability to conduct standardised patient assessment remotely after discharge home could aid research practices by promoting recruitment and convenience and reducing cost and nonresponse bias caused by loss to follow-up (Kim, Lonner, Nelson, & Lotke, 2004).

There are potential limitations associated with the present work and its generalisability. First, the study sample is specific to cognitively intact older adults undergoing preoperative assessment before lower limb joint replacement. The extent to which these findings are generalisable to other patient populations, particularly those who may have experienced a

recent change in mobility, requires further investigation. Previous research (McGinnis et al., 1986) suggests that self-report may be inappropriate for those with cognitive impairment. Secondly, an experienced clinician conducted the therapist-directed assessment of the DEMMI in this study. A clinician with less experience may plausibly have lower agreement with patient self-report. Establishing whether the results observed in this study apply to clinicians with differing backgrounds and levels of expertise is therefore warranted.

3.2.6 Conclusion

A high level of agreement was observed between patient self-report and therapist-assessed performance using the DEMMI. However, self-report of the DEMMI should be interpreted with caution for those with near-maximum mobility scores, because this is where small discrepancies in item ratings can lead to large total score differences. These results suggest that there is potential to use DEMMI self-report to reassess mobility after hospital discharge in the absence of clinical contact and to use this information for providing additional support and/or for research purposes.

This study provides support for using patient self-reported mobility (as assessed by the de Morton Mobility Index) as a proxy for therapist-assessed mobility performance in studies 3 and 4 of this thesis.

Chapter 4 – Role of allied health services following hip and knee joint replacement: health professionals’ perceptions of current versus ideal practice

4.1 Preface

This chapter presents a qualitative study that aimed to describe health professionals’ perceptions of the role of the allied health team during the acute phase following elective lower limb joint replacement surgery and how these services are delivered. This study was designed to gain a deeper understanding of the health service being investigated in this thesis, that is, allied health service provision following elective hip and knee joint replacement surgery. It specifically enabled the research team to understand the weekend allied health service in the context of the broader service to these patients. Section 3.2 reports on a manuscript that has been prepared for publication and is currently under review.

4.2 Study 2 – Health professionals’ perceptions of the role of acute allied health services following hip and knee joint replacement surgery: a qualitative study

4.2.1 Abstract

Purpose:

To describe health professionals’ perceptions of the role of allied health during the acute phase following elective lower limb joint replacement surgery.

Methods:

This was a qualitative descriptive study involving semi-structured focus groups and thematic analysis. Participants were 25 medical, nursing and allied health professionals working on two orthopaedic wards in a tertiary hospital in Victoria, Australia. Focus groups elicited staff perceptions regarding the aims and roles of acute allied health intervention following hip and

knee replacement, how these services are currently provided and how these services can best be provided. This study was undertaken alongside two stepped wedge cluster randomised controlled trials during which existing weekend allied health services were to be temporarily removed with opportunity to contribute to a stakeholder-driven model of these services.

Results:

The main theme that emerged was a sense of unrealised potential amongst health professionals in terms of patient outcomes following hip and knee joint replacement surgery arising from tension between perceptions of actual versus ideal allied health practice. Assessing function and planning for discharge accordingly was perceived to be a higher priority than intervening to improve functional independence.

Conclusion:

Prioritising allied health intervention to low functioning and complex patients could be a more efficient use of allied health expertise in patients following lower limb replacement surgery than current practice in this setting that prioritises discharge.

4.2.2 Introduction

Joint replacement of the hip and knee are amongst the most common surgeries performed in developed nations (Arthroplasty Clinical Outcomes Registry, 2015; Canadian Institute for Health Information, 2015; Murphy & Helmick, 2012). Both the increasing demand (Kurtz et al., 2007) and rising costs (Steiner, Andrews, Barrett, & Weiss, 2014) associated with joint replacement have created ongoing and increasing strain on health care resources around the world. In Australia, the cost of total joint replacements is estimated to exceed \$1 billion AU per year (Peel et al., 2015). The majority of this expense is related to inpatient hospital costs with personnel costs among the highest of these (D. A. Haas & Kaplan, 2017). Efficient allied health service models in the acute phase postoperatively have the potential to improve patient outcomes and reduce length of stay and the associated costs. A recent systematic

review conducted from an allied health service model perspective concluded current, high quality research was needed to confirm findings that early physiotherapy commencement and a weekend service may produce favourable outcomes in the acute setting following hip and knee replacement (R. Haas, Sarkies, Bowles, O'Brien, & Haines, 2016). It was also noted that this review yielded insufficient evidence from which to draw conclusions relating to professions other than physiotherapy despite knowledge that inter-professional comprehensive care models including other allied health professions (e.g. occupational therapy) lead to improved patient outcomes in the acute care setting (Grimmer et al., 2015).

Defining roles and responsibilities of health professionals within a team environment is an essential ingredient of collaborative patient-centred care (Suter et al., 2009). The role of physiotherapy and occupational therapy in the acute setting has been widely discussed (Britton, Rosenwax, & McNamara, 2015; Curtis & Martin, 1993; Griffin & McConnell, 2001; Jette, Brown, Collette, Friant, & Graves, 2009; Masley, Havrilko, Mahnensmith, Aubert, & Jette, 2011). Roles that are commonly described as being performed by allied health staff include functional retraining and education, however the predominant role described in the acute setting is their contribution to accurate and appropriate discharge planning in a time pressured environment (G. Craig, Robertson, & Milligan, 2004; B. A. Smith, Fields, & Fernandez, 2010). It has been argued that the knowledge, clinical reasoning skills, decision-making capabilities, and professional responsibilities of allied health staff facilitate timely, patient-focused holistic assessment, intervention and complex discharge planning for patients in the acute care setting (Masley et al., 2011). However, it is unclear what roles therapy staff are actually filling in the clinical setting following elective joint replacement and whether these roles require the specialist skills that allied health staff possess. This issue is important as it can lead to inefficient use of hospital resources and job dissatisfaction for the staff involved if they perceive they are performing only generic roles

that do not require specialist skills and are not being adequately challenged by their work (N. Campbell, McAllister, & Eley, 2012).

The aim of this qualitative study was to describe the role of allied health services during the acute phase following elective lower limb joint replacement surgery as perceived by health professionals. In particular, this study compared and contrasted health professionals' perceptions of actual versus ideal allied health service delivery with the ultimate aim to inform efficient allied health service models following joint replacement.

4.2.3 Methods

Design

This qualitative descriptive study (Neergaard et al., 2009) was conducted during the first of two stepped wedge cluster randomised controlled trials seeking to determine the effectiveness, cost-effectiveness and safety of the current weekend allied health service model and a new stakeholder-driven model of weekend allied health service delivery on acute medical and surgical wards compared to having no weekend allied health services (Haines et al., 2017; Haines et al., 2015). In this work, the model of weekend allied health service delivery provided on the participating wards was removed sequentially, following the stepped-wedge design. It was replaced seven months later by a stakeholder-developed model of weekend allied health service provision.

The semi-structured focus groups used to generate data in this study were conducted prior to the removal of weekend allied health services in the acute orthopaedic wards at one site and before the development of the new stakeholder-driven model. The investigators felt the impending discontinuation of weekend allied health services and reintroduction of a stakeholder-driven model of these services provided an opportunity for health professionals

to partake in a rich discussion regarding actual versus ideal allied health service model delivery for patients undergoing hip and knee joint replacement. Health professionals have specialist training in service provision and critical thinking (McKendry, 2015) and are therefore in a key position to evaluate their own practices with the view to developing efficient allied health service models.

Participants and setting

Study participants were health professionals involved in the acute care of patients undergoing hip and knee replacement working in two specialist orthopaedic wards at a 520-bed public tertiary hospital in the southeastern suburbs of Melbourne, Australia. In the 2014-15 financial year, 290 and 183 total knee and hip replacement surgeries respectively were performed at this hospital from Monday to Saturday (Australian Institute of Health and Welfare, 2017). The staff invited to participate had professional backgrounds in medicine, surgery, nursing, physiotherapy, occupational therapy, allied health assistance, speech pathology, dietetics and social work.

Some important contextual notes in this setting are that i) all patients undergo preoperative assessment by the multidisciplinary team prior to surgery, ii) patients are educated about the postoperative process during the preoperative consultation, and iii) patients undergo assessment preoperatively using the Risk Assessment and Prediction Tool (Oldmeadow et al., 2003) to allocate them to a recovery pathway. Scores greater than nine out of twelve indicate patients should be able to be discharged directly home from the acute facility (referred to as Pathway A). Scores between six and nine indicate that four to seven days of inpatient rehabilitation are anticipated following the acute stay (Pathway B); and scores less than six indicate that an extended period (\geq eight days) of inpatient rehabilitation is likely to be required (Pathway C). Recovery pathway could be modified but required health professional assessment and intervention during the early postoperative phase to do so. All

patients allocated to Pathway A are referred for follow-up outpatient physiotherapy at the preoperative consultation. This is routinely provided at a geographically convenient hospital or community-based outpatient clinic but referrals to private practice are made at a patient's request.

Measurements

Focus groups were chosen as the data collection technique and aimed to encourage participants to challenge their own ideas in order to facilitate discussion (Kitzinger, 1994). Group dynamics play a significant role within any organisation (Scandiffio, 1990) and it was felt this was important to observe when examining the role of allied health following hip and knee replacement since care provision for these patients is essentially a team activity.

All focus groups followed a semi-structured format to allow for flexibility in the order of topics covered and so that issues raised could be explored in further detail. Focus groups were designed to elicit and discuss staff perceptions regarding the aims and roles of allied health therapy in the acute phase following lower limb joint replacement, how these services are currently provided and how these services can best be provided. Related issues of optimal timing, quantity and provision of these services on the weekend were also explored (Appendix G).

Procedure

Prior approval to conduct this study was obtained from Monash Health Human Research Ethics Committee (Reference Number 13327B). A purposive sampling strategy was used to ensure all health professional staff currently working on the study wards were invited to participate in this study. Focus groups were scheduled either immediately before or after

departmental staff meetings in order to be convenient to most staff members who wanted to attend. All potential participants were provided with a project description and invited to participate in person during the departmental meeting in the week prior to the scheduled focus group. Relevant departmental meetings included individual ward meetings along with profession specific meetings. Written informed consent was gained prior to participation.

Investigators experienced in qualitative and participatory action research facilitated each face-to-face focus group (R.H. and L.O.B.). All groups included a facilitator and a note taker. The same investigative team attended each focus group although the role of facilitator rotated. The semi-structured interview guide (Appendix 1) was used to facilitate each focus group and additional prompts were added as required to allow deeper exploration of emerging themes. The investigative team discussed emerging themes after each focus group and group consensus was used to decide whether each emerging theme and sub-theme had been confirmed during subsequent focus groups. Each focus group was recorded on a digital voice recorder. Audio files and file notes were uploaded to NVivo (version 10, QSR International Pty Ltd, Doncaster, Victoria, Australia) and key quotes were transcribed.

Data analysis

Data analysis and collection occurred in an iterative manner to allow for themes emerging from the data to be explored further in subsequent focus groups (Srivastava & Hopwood, 2009). Data were analysed according to professional group and individual participants within the group in order to compare and contrast perceptions amongst staff members with differing professional backgrounds.

Thematic analysis was used to provide a systematic framework for coding the data, and for then using that coding to identify patterns across the dataset in relation to describing actual

and ideal allied health practice in the acute phase following joint replacement (V. Braun & Clarke, 2014). Six phases of thematic analysis were conducted: familiarising ourselves with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes and producing the report (V. Braun & Clarke, 2006).

Two investigators (R.H and L.O.B.) independently listened to each focus group and developed initial codes in an inductive manner. They then met to compare the coding, develop a consistent codebook from which to code further focus groups and define emerging themes. Themes were reviewed with the investigative team when the research team agreed that no new themes had been identified from the previous focus group. NVivo computer software was used to facilitate the coding of data and collating of codes into themes.

Member checking was conducted with the orthopaedic multidisciplinary team members in person. An investigator (R.H.) presented the preliminary findings, including examples of data coding and emergent themes and invited participants to comment on whether the coding and themes adequately represented their perceptions. There were no disagreements during this process.

The use of multiple investigators, a reflexive diary recording the development of codes and themes, regular reflections of the principal investigator, and the documentation of investigator background and pre-study expectations was used to foster reflexivity and aid trustworthiness (D. Cohen & Crabtree, 2006). Study participants were aware that all investigators were concurrently involved in the parent trial investigating the effectiveness and safety of current weekend allied health services versus no weekend allied health services in acute medical/surgical patients (Haines et al., 2015). All investigators had a background in

allied health, two physiotherapists (R.H. and T.H.), one occupational therapist (L.O.B.) and one exercise physiologist (K.A.B.). These investigators had prior experience working in the hospital system but had not worked clinically in the study hospital. This experience was drawn upon in devising the interview guide. The principal investigator (R.H.) was a PhD candidate with clinical experience in providing physiotherapy to patients following hip and knee joint replacement in a sub-acute setting. All other investigators were working as researchers at the time of the study and held PhD qualifications. Preconceptions of the investigators were that the main role of allied health in this population would be to improve functional independence and that the health professionals interviewed would advocate for a more comprehensive weekend allied health service than that currently provided.

4.2.4 Results

Three focus groups (including allied health, medical and orthopaedic ward staff respectively) were conducted with a total of 25 hospital staff (seven medical, three physiotherapy, two occupational therapy, one allied health assistant, one social worker and eleven nursing staff). Focus groups ranged in duration from 36 to 49 minutes (mean 41 minutes) and contained between six and 12 participants (mean eight participants). The health professionals' level of experience varied from recently qualified to more than ten years clinical experience in the orthopaedic setting. Weekday and weekend staff were represented for each profession. All health professionals available to attend a focus group consented.

Participants provided a relatively homogenous account as to the roles undertaken by allied health staff within and between the focus groups and the purpose behind these roles. In situations where there was initial disagreement, the group forum was used to clarify opinions and challenge views. Group consensus appeared to have been achieved by the completion of each focus group with the exception that there were differing opinions regarding the role of

specific professions in facilitating early mobilisation. This will be expanded upon in the results section. All themes raised in the first focus groups were confirmed in subsequent focus groups. No new themes were identified during the third focus group.

The health professional's perceptions of actual versus ideal allied health practice in this population is conceptualised in Figure 4.1. In summary, the main theme that emerged from the data was a sense of unrealised potential in terms of patient outcomes following hip and knee joint replacement surgery arising from tension between perceptions of actual versus ideal allied health practice. Adherence to the organisation's priority tool, role boundaries and risk aversion were perceived as the predominant factors influencing actual practice. Evidence, benchmarking and equity principles were viewed as the main factors influencing perceptions of ideal practice.

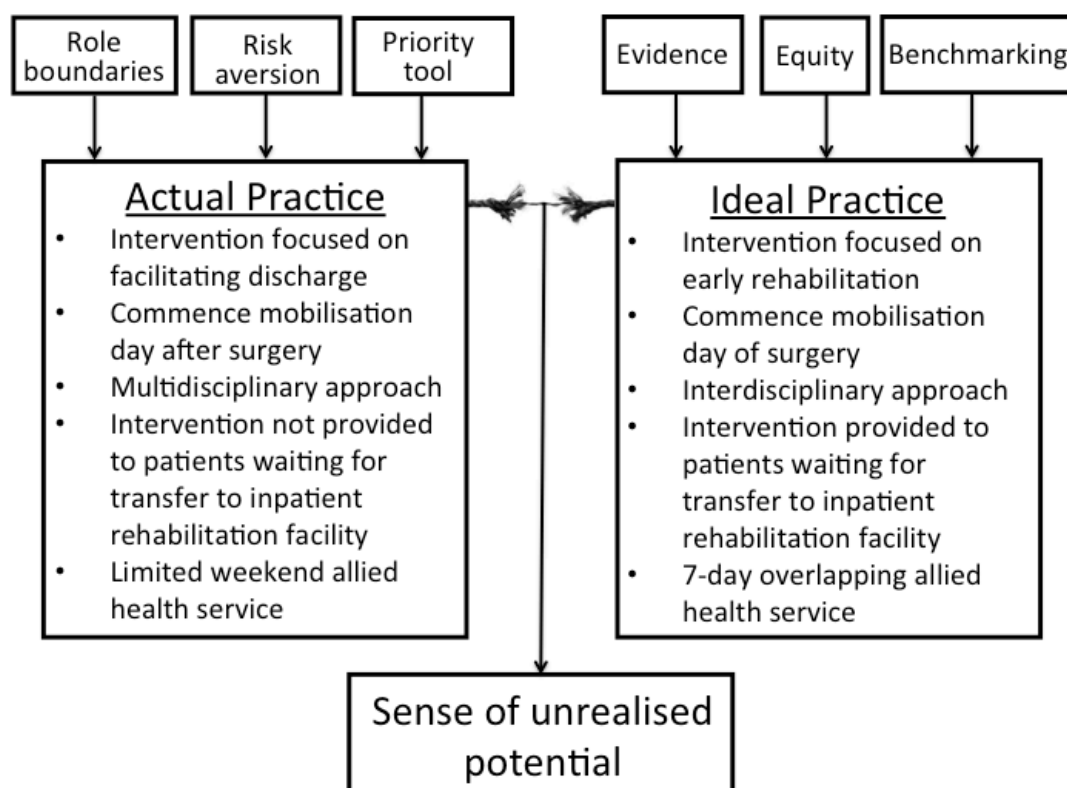


Figure 4.1: Conceptualisation of health professional's perceptions of actual and ideal allied health practice

Table 4-1 depicts the development of the central theme of unrealised potential from each of the areas of practice that were identified and its related codes. This theme and the underpinning data will now be presented in detail commencing with actual practice and the associated roles of allied health following elective lower limb joint replacement.

Table 4-1: Central theme and coding

Main Theme	Area of Practice	Codes
Sense of unrealised potential in terms of patient outcomes	<ul style="list-style-type: none"> Aims of allied health after joint replacement 	<ul style="list-style-type: none"> Challenges Limited resources It's all about discharge Prioritisation based on clinical need Organisational vs patient goals
	<ul style="list-style-type: none"> Facilitation of early mobilisation 	<ul style="list-style-type: none"> Evidence of effectiveness Day of surgery mobilisation Patient safety Setting patient expectations before admission Surgeon's postoperative orders
	<ul style="list-style-type: none"> Intervention to patients awaiting inpatient rehabilitation 	<ul style="list-style-type: none"> Patient's not seen after decision made to transfer to rehabilitation facility
	<ul style="list-style-type: none"> Professional roles 	<ul style="list-style-type: none"> Interdisciplinary Role boundaries Teamwork
	<ul style="list-style-type: none"> Overlapping 7-day allied health service versus limited weekend service 	<ul style="list-style-type: none"> Weekend Equal availability/access Benchmarking Overlapping service Handovers

Actual practice

All health professional groups commented that practice was predominantly driven by department priority tools, which were reflective of the organisation's goals and imperatives. They perceived the highest priority of acute allied health care in patients following joint replacement was to facilitate rapid discharge from the acute setting. Organisational priority tools stipulated that staff resources should be directed toward activities believed to be essential to support patient discharge. Such activities included equipment provision, functional assessment to check safety prior to discharge, patient education and referrals for

follow-up care. Patients were usually seen in order of expected time of discharge commencing with those perceived to be most likely to be discharged within the shortest timeframe.

“It’s always focused on prioritising discharge first.” (Occupational therapist 2)

“From my perspective, allied health services are more directed at discharge planning to allow patient flow. Resources currently are more focused toward getting people home than providing a rehabilitation service”. (Physiotherapist 1)

The next priority of physiotherapy and occupational therapy intervention respectively was to assist a patient to mobilise for the first time postoperatively and to provide occupational therapy assessment and education to ensure safe discharge and timely community referrals for patients with expected discharge in less than 24 hours. Patient mobility for the first time postoperatively was routinely commenced the day after surgery.

“Priority 2 is to mobilise a patient for the first time.” (Physiotherapist 2)

“Current practice at this hospital is to commence mobilisation the day after surgery.” (Physiotherapist 1)

“Generally occupational therapy is commenced day 2 onwards depending on how they recover and when discharge is expected.” (Occupational therapist 2)

There appeared to be a cultural belief that physiotherapists were primarily responsible for facilitating patient mobilisation for the first time following surgery. Nursing and medical staff rather than physiotherapists articulated this belief. Doctors raised concern that nurses were not adequately trained for this role whereas nurses lacked confidence in performing this role as it wasn’t part of their routine practice. This appeared to be influenced by perceptions

of firm role boundaries in some cases.

“Having a physiotherapist to get them out of bed in the morning, they build the confidence in the patient, they know exactly what they’re doing, so they’re the ones that will get them out of bed and maybe walk them to the shower & know they’re capabilities, know exactly what to do with that patient.” (Nurse 1)

“As the physios get them out the first time they’re explaining everything, you know the hip precautions and it’s not a brand new thing, the patient’s are not as anxious, they’re more confident it just flows really quickly the second time because they’ve (the physiotherapists) spent that time the first time.” (Nurse 2)

“And the reality is I don’t think they’re (nurses) trained to teach the patient how to use crutches or a frame. It’s just based on necessity to get to the toilet or use a pan and then just back on the bed but not actually to get them up to rehabilitate them. I think it’s different”. (Doctor 1)

In other cases perceived risk of an adverse event influenced nurse’s decisions regarding whether to mobilise a patient postoperatively.

“If they’re really quite difficult then we run the risk of dislocating the leg and things like that. Then we won’t put a patient at risk.” (Nurse 3)

The role of allied health at the preoperative assessment was thought to be particularly important in setting patient’s expectations regarding early mobilisation.

“I think the biggest benefit is actually telling the patient before the surgery what the surgery entails and getting their mind, their psyche sorted out for the surgery and what will happen after. The patients get it in their head that they’re going to get up and get moving day 1.” (Doctor 4)

It was noted that allied health interventions for patients awaiting rehabilitation at an inpatient facility were unlikely to be provided as these interventions were categorised as low priority on the physiotherapy and occupational therapy priority tools.

*“Certainly once they get to day two or three postop and they’re waiting for rehabilitation, then they do drop down our priority list so they’re not getting the therapy as opposed to the people who aren’t waiting for rehabilitation.”
(Occupational therapist 1)*

Actual practice also included the provision of a limited weekend allied health service where intervention was based on handovers received from allied health professionals working on a Friday and/or referrals received from nursing or medical staff over the weekend. Referrals were prioritised based on proximity to expected discharge in a similar process to the weekday priority tool. Fewer allied health staff were employed on the weekend compared to during weekdays for the same number of patients. As a consequence, only the highest priority patients (those for which intervention was perceived to facilitate immediate discharge) could be seen on the weekend. Facilitating postoperative mobilisation (priority two) for higher functioning patients only was a task usually completed by physiotherapists during the working week but transferred to nursing staff on the weekend.

“On weekends, we have less staffing for the same number of patients. The exact quantity is slightly different for different professions. And the way we normally prioritise is dependent on whether they (the patients) are going to go home over the weekend.” (Occupational therapist 1)

“With the higher function population (Pathway A) we don’t actually see them on a weekend so we can hopefully direct our resources to the patients that will be more challenging from a mobilisation perspective. The nursing staff on this ward are very capable of assisting these patients out of bed for the first time on the weekend.” (Physiotherapist 1)

Allied health staff perceived the sessional nature of the weekend service to be inefficient due to the time-consuming handover process.

“There’s a lot of time spent familiarising yourself with the patients on the weekend and working out your priorities and then if there’s been any new admissions since Friday and then where do they fit in with the priority system. And then at the end of that day, on the Saturday, then you have to do a handover for the Sunday, for another different person, This can take maybe one hour and a half or two hours of your allocated time.” (Physiotherapist 2)

Ideal practice and sense of unrealised potential

Health professionals involved in the acute care of patients following joint replacement surgery identified five areas where they perceived allied health service provision could potentially achieve a more efficient and/or equitable service: 1) Focus on early rehabilitation as well as facilitating discharge; 2) Commence mobilisation on the day of surgery; 3) Incorporate an interdisciplinary approach; 4) Provide rehabilitation opportunities to patients waiting for transfer to an inpatient rehabilitation facility; and 5) Redistribute current allied health resources to achieve an overlapping 7-day allied health service with staggered starts to the working week to ensure equity.

1) Physiotherapists, occupational therapists and medical staff ideally wanted the allied health service to address early intensive rehabilitation in addition to facilitating early discharge.

“It’s very challenging to provide more than just a discharge assessment because the length of stay is so short that there’s always that pressure to get somebody home. So you’re sending someone home less independent than you would like somebody of their age to be or needing more help at home or more support services at home than is ideal and you think in one or two more days they wouldn’t need that. I think that’s a challenge we all have.” (Occupational therapist 1)

“I still think it’s important to concentrate on discharge planning but we’d like to be able to commence early rehabilitation.” (Physiotherapist 1)

“Priority should be given to those with recent surgery to promote early mobilisation.” (Doctor 3)

2) Evidence regarding the benefits of commencing mobilisation on the day of surgery and risks of delayed postoperative mobilisation influenced the perception amongst medical staff and physiotherapists that commencing postoperative mobilisation on the day of surgery was ideal.

“Current practice at this hospital is to mobilise the day after surgery. There’s evidence available to suggest that length of stay in hospital is shorter for those patients in the arthroplasty population who mobilise day zero, that is the day of surgery. That’s obviously something we would like to change but given our limited resources, that’s a challenge we do have.” (Physiotherapist 1)

“There’s evidence that getting out of bed soon after surgery is important for the prevention of deep vein thrombosis and hospital acquired pneumonia.” (Doctor 2)

3) Allied health professionals believed incorporating an interdisciplinary approach to rehabilitation would be beneficial. In particular, having an allied health assistant who specialised in orthopaedics rather than either physiotherapy or occupational therapy was a suggested improvement to the current model of care.

“I think allied health is moving towards more of an interdisciplinary approach. And I think the expectation that we’re all sort of sitting within our own silos I think that’s quite limited....I think interdisciplinary is the way to go.” (Physiotherapist 1)

“It works so well. There’s a lot of stuff that’s similar and I think from an AHA (allied health assistant) point of view they really enjoy the mix of it.”
(Occupational therapist 1)

Physiotherapists also felt their expertise in facilitating early mobilisation was only required for the more complex patients and that in most cases nurses or other staff (e.g. allied health assistants) were capable of assisting in this process.

“The staff (nurses) up on this ward are fantastic in that where they are comfortable doing it, they will mobilise patients for us, they’ll get them up, they’ll try to get them walking to the bathroom as part of what they should be doing in relation to their progress and their functional level. So I think from that perspective they do a really good job.” (Physiotherapist 1)

“It’s the difficult ones to get up and moving that’s most challenging. That’s where physiotherapists are best placed to use their expertise.” (Physiotherapist 2)

4) The health professionals interviewed also perceived there was potential to reduce overall hospital length of stay and optimise the allied health service by providing intensive intervention to patients waiting for transfer to an inpatient rehabilitation facility.

“So essentially we could get them home a lot quicker if we continued providing intensive rehabilitation while they (the patients) were waiting for a bed in a rehabilitation facility. In some cases, inpatient rehabilitation may no longer be necessary.” (Occupational therapist 2)

5) Focus groups were conducted in the context of evaluating evidence regarding the effectiveness of the current weekend allied health service. In the absence of evidence supporting this service, health professionals relied on benchmarking with other organisations and the principle of equity to inform their belief that an overlapping seven-day allied health service was warranted.

“There’d be the potential to be able to do a lot more functional rehabilitation tasks on the weekend because you don’t have to wait for the patients to get bloods taken and go down for X-ray and waiting for handovers to finish. However because you’ve got less time (on the weekend), all the time is used to discharge patients that need to go home so your focus is slightly different to what it could potentially be.” (Occupational therapist 1)

“If it was a staggered working week, a seven- day working week with overlapping, I think that would work better for patient flow rather than having unfamiliar staff on the weekends. So with three staff members across the ward, you could have someone Monday to Friday, someone Sunday to Thursday, someone Tuesday to Saturday and then you’d get the overlap so there’d always be a consistent staff member at all times.” (Physiotherapist 2)

“If it’s accepted that we have physios and OTs (occupational therapists) during weekdays then they should continue on weekends because we’re doing exactly the same work. I mean we’re doing four joint replacements on a Saturday.” (Doctor 3)

“It (the amount of therapy provided) should be equal, regardless of what day you have surgery.” (Nurse 1)

“I look at our service compared to other networks. They (another network) have a discharge home rate of 85% elective joint replacement surgery patients compared to our rate of 55% so I think there’s definitely scope to improve the service we provide. They’ve also shown a shorter length of stay for both hip and knee replacement compared to ours with a similar cohort of patients. I think modeling what we do on this network would be good and they do provide that seven-day service with an overlap of staff on a Tuesday or Wednesday where it’s almost as well resourced on a Saturday and Sunday as during the week.” (Physiotherapist 1)

4.2.5 Discussion

The role of the allied health team during the acute phase following elective lower limb joint

replacement surgery was essentially perceived to centre on patient assessment and discharge planning with little time for treatment other than facilitating early postoperative mobilisation. While the allied health professionals in this study were primarily concerned with functional independence, as anticipated, they spent more time assessing function and planning for discharge accordingly, rather than intervening to improve functional independence. Although the ultimate purpose of this study was to inform the development of efficient allied health service models, equity was also a key consideration for the health professionals interviewed. This study also highlighted an apparent discord between needs of the acute health service and the patient. The health professionals described a constant pressure to discharge patients quickly in order to facilitate patient flow and reduce acute care costs; this was not always perceived to be in the best interests of their patients.

Ethical dilemmas of allied health professionals have been previously described (Barnitt, 1998; Barnitt & Partridge, 1997) with conflict of loyalty between employers and patients termed “the dilemma of the double agent” (Bruckner, 1987). Limitations of the public health system in meeting inpatient and outpatient rehabilitation demand following total hip and knee replacement have also been described as a barrier to patient recovery (Westby & Backman, 2010). However, to the author's knowledge, this is the first study to describe these limitations in the acute inpatient setting. The role of allied health in the acute setting following elective joint replacement described in this study differed to that previously described in the general acute setting in that it focused more on following processes than complex problem solving. The health professionals in this study did not appear to describe a dynamic clinical reasoning process focused on discharge planning that required the ability to integrate medical information with profession specific knowledge (Britton et al., 2015; Masley et al., 2011; B. A. Smith et al., 2010). Instead, a more predictable role was described whereby patients followed a linear and predetermined pathway with a reliance on

preoperative planning and intervention. This is not surprising given the common use of clinical pathways and models of care designed to standardise clinical care before and after lower limb joint replacement (Barbieri et al., 2009; Department of Health, 2010).

In this study, postoperative mobilisation routinely commenced on day one following surgery. However, the health professionals recognised current evidence supports commencement of mobilisation on the same day of surgery following elective joint replacement surgery (Guerra, Singh, & Taylor, 2014) and suggested this as a potential improvement to the service currently offered. In the present study, while it was agreed that physiotherapists are specialists in mobility and best qualified to perform this role in low functioning or complex patients, there was also a belief that other health professionals were capable of assisting in this role in high functioning and uncomplicated patients (and in fact already do this on the weekend). This discrepancy between weekday and weekend practice suggests there may be more scope for nurses to be involved in promoting early postoperative mobilisation following joint replacement surgery. Guidelines stipulating which staff should perform this role or whether or not this requires designation to a specific profession do not currently exist, though similar perceptions of role boundaries between nurses and physiotherapists have been expressed in a qualitative study across medical and surgical wards at the same hospital as the present study (O'Brien et al., 2017). An interdisciplinary approach to early mobilisation whereby team members work collaboratively to achieve common and shared goals was advocated by the health professionals in this study and could be beneficial. Previous research has demonstrated success in the development of interdisciplinary early mobilisation clinical practice guidelines involving surgeons, anaesthesiologists, physiotherapists, occupational therapists and nurses working collaboratively with the patient to achieve mobilisation on the day of surgery (Yager & Stichler, 2015).

The concept of equity was fundamental to this study. Equity in healthcare is defined as the absence of socially unjust or unfair health disparities (Whitehead, 1992) but there is widespread inconsistency in how this may be operationalised (Lane, Sarkies, Martin, & Haines, 2017) and this was evident in this study. Health professionals perceived access to allied health services should be equal throughout the seven-day week or relative to time of surgery. However, the concept of prioritising services according to the perceived ability of the intervention to achieve discharge from the acute hospital setting was also described. This suggests equity was implicitly operationalised based on perceived potential to benefit from the organisation's perspective in terms of facilitating discharge. Previous authors have criticised this approach from an ethical and practical perspective and have advocated for urgency of need to be the dominant principle for prioritisation of healthcare resources with some capacity to include potential to benefit as a sub criteria so as not to compromise the effectiveness of the service (Brown & Pirotta, 2011; Evans & Price, 1999; Lane et al., 2017). Prioritising allied health service provision to patients with high functional impairment and perceived high capacity to benefit could potentially address many of the concerns raised from this study. It could assist in using the specialist skills of allied health staff more efficiently by ensuring allied health professionals target those patients with low functional independence, leaving support staff to assist in the rehabilitation of higher functioning patients. This approach could also ensure patients waiting for transfer to an inpatient rehabilitation facility may be prioritised and that allied health may be accessible to patients who need intervention regardless of the day of week. Furthermore, this might encourage benefit to be perceived in terms of the entire health system rather than the acute health service in isolation and in doing so, could partially overcome the conflict of loyalty between the patient and the employer observed in this study.

The main limitation of this study is that it has limited generalisability to settings with different service delivery models or patient cohorts to those in the present study. The allied health service model in this hospital was similar to others in terms of providing a limited weekend service whereby patients were prioritised for intervention according to urgency of need and potential to benefit in terms of facilitating discharge (L. Campbell et al., 2010; Shaw et al., 2012). It is however possible that this setting may differ from others with respect to the day in which postoperative mobilisation is routinely commenced and/or availability of inpatient rehabilitation. This study was also performed in the context of an impending temporary disinvestment from weekend allied health services so the difference between weekend and weekday services was a particularly sensitive topic at the time of these focus groups and it is likely this challenge was amplified. However, the opportunity to redesign a weekend allied health service for patients following hip and knee replacement revealed perceived weekday inefficiencies in the current allied health service model that may not have otherwise surfaced. Additional research is warranted to inform role delineation and identify ways to promote greater collaboration amongst interdisciplinary team members to facilitate mobilisation on the day of surgery following joint replacement; to explicitly operationalise equity in this context; to inform evidence-based allied health interventions and service delivery models following lower limb joint replacement; and ultimately to develop and evaluate the effect of prioritisation guidelines on patient and service outcomes in this population. Patient discharge procedures and responsibilities for discharge decision-making were beyond the scope of this qualitative study. Further research could examine this concept to provide insight as to whether or not allied health intervention is needed to routinely facilitate hospital discharge following joint replacement surgery.

4.2.6 Conclusion

Allied health intervention in the acute phase following elective hip and knee joint replacement needs to achieve a balance between facilitating inpatient flow and using evidence-based practice to facilitate patient functional improvement. Allied health intervention targeted to low functioning and/or complex patients could be a more efficient use of allied health expertise than the observed current practice of prioritising service delivery according to its perceived potential to facilitate patient discharge.

Chapter 5 – Investigating the effect of an acute weekend allied health service on short-term outcomes

5.1 Preface

This chapter reports on the third study conducted as part of this PhD research program. Building on the high level of agreement demonstrated between patient self-report and therapist-assessed performance (Chapter 3), it uses the de Morton Mobility Index to assess patient self-reported mobility. It also uses the improved understanding of the perceived role of allied health team in the acute phase following joint replacement (Chapter 4) to evaluate the effect of an acute weekend allied health service on patient and hospital outcomes following joint replacement.

This quasi-experimental study addressed the research question, “what is the effect of a real-world acute weekend allied health service on short-term outcomes following elective hip and knee joint replacement, compared to no service?” It also addressed the question, “is the effect of this weekend allied health service mediated by earlier therapy commencement and/or increased quantity?” Section 4.2 is an adaptation of a manuscript that has been prepared for publication and is currently under journal review.

5.2 Study 3 – Effectiveness of a weekend allied health service on short-term outcomes following hip and knee joint replacement surgery

5.2.1 Abstract

Objective: To investigate the effect of an acute weekend allied health service on short-term outcomes following lower limb joint replacement, compared to no weekend service.

Design: Pre-post, exploratory study nested within two stepped-wedge clustered randomised controlled trials.

Setting: Public tertiary hospital in Melbourne, Australia.

Participants: Consecutive patients undergoing hip and knee replacement.

Interventions: This study analysed a subgroup of one cluster of the broader parent trials where acute weekend allied health services were sequentially discontinued in a random order from one cluster at a time. Intervention (at the ward level) included six-months of existing acute weekend allied health services (Phase 1) (n=130) followed by six-months when these services were discontinued (Phase 2) (n=146).

Main measures: Acute hospital length of stay and other short-term patient and hospital measures.

Results: Availability of weekend allied health was associated with increased odds of discharge directly home [OR (95% CI): 3.401 (1.050 to 11.010) p=0.041] and improved mobility [coefficient 3.861 (1.065 to 6.658), p=0.007]. However, hospitalisation was perceived as less helpful [coefficient -1.792 (-2.518 to -1.067), p<0.001], and acute length of stay was longer (only in multivariable analyses) [coefficient 1.145 (0.095 to 2.194), p=0.033] than when weekend allied health services were unavailable. Similar results were observed when examining data according to receipt of weekend allied health services (contamination-adjusted intention-to-treat) rather than the intervention phase to which each patient was allocated (intention-to-treat).

Conclusion: The weekend allied health service appears to have had beneficial impacts on discharge destination and patient mobility that may outweigh unfavourable impacts on patient perceived helpfulness of hospitalisation and acute length of stay.

5.2.2 Introduction

Total hip and knee replacement are high volume and high cost surgical procedures that are placing substantial burden on health care systems internationally (A. Chen et al., 2012; Peel

et al., 2015). Allied health intervention (e.g. physiotherapy and occupational therapy) is an important aspect of the early postoperative period following lower limb joint replacement and has been shown to improve patient outcomes and reduce hospital length of stay (Khan et al., 2008). In particular early compared to later initiation of allied health, (particularly physiotherapy) postoperatively appears to be associated with favourable outcomes following hip and knee replacement (R. Haas, Sarkies, et al., 2016; Masaracchio, Hanney, Liu, Kolber, & Kirker, 2017). A weekend allied health service can potentially assist in providing earlier postoperative therapy for patients undergoing surgery late in the working week or on the weekend, though the effectiveness of such services remains unclear.

A recent meta-analysis found the addition of a weekend physiotherapy service reduced length of stay and had a small improvement on function following lower limb joint replacement (R. Haas, Sarkies, et al., 2016). This review, however, was based on five prospective cohort studies with average acute length of stays greater than current averages and was limited to the effect of only physiotherapy rather than the allied health team. Furthermore, most studies in this meta-analysis provided weekend physiotherapy services that were comparable to those provided during the working week yet in practice weekend allied health services often provide fewer hours and/or employ less experienced clinicians compared to weekday services (L. Campbell et al., 2010; Ottensmeyer et al., 2012; Shaw et al., 2012). Numerous logistical difficulties associated with the delivery of effective and cost-effective weekend allied health services have also been identified (Mitchell, O'Brien, Bardoel, & Haines, 2017; O'Brien et al., 2017). Additional up-to-date research is therefore needed to establish the effectiveness of weekend allied health services following lower limb joint replacement in real-world circumstances.

The aim of this study was to examine the effect of a real-world acute weekend allied health service on a range of patient-relevant and hospital-relevant early outcomes following hip and

knee replacement. A secondary aim was to examine whether or not the effects observed were mediated by earlier therapy commencement and/or increased therapy session rate. These findings will inform future research investigating optimal allied health service delivery models following hip and knee replacement.

5.2.3 Methods

Study design

This study was a pre-post exploratory, secondary, subgroup analysis of patients undergoing joint replacement surgery within cluster six of two multicenter stepped-wedge cluster randomised trials (Figure 5.1). In the two parent trials, existing weekend allied health services were sequentially removed from acute medical/surgical wards, one ward per month followed by the sequential introduction of a new stakeholder driven weekend allied health service delivery model. Approval to conduct this study was obtained from Monash Health Human Research Ethics Committee (Reference Number 13327B). The parent trials were registered with the Australian New Zealand Clinical Trials Registry [Registration number: ACTRN12613001231730 (first study) and ACTRN12613001361796 (second study)] and the study protocol (Haines et al., 2015) (Appendix E) and results (Haines et al., 2017) (Appendix F) are reported elsewhere. Clinical exceptions and stopping rules were in place within the parent trials to ensure safety (Haines et al., 2015).

The parent trials included a total of 27,508 patients across twelve acute medical and surgical wards from two sites. The present study included a subset of patients (those undergoing lower limb joint replacement) in one cluster at one site (276 out of 2450 patients in cluster six at site one). The parent trials generated a two group pre-post research design whereby a six-month period (3rd February 2014 till 31st July 2014) of existing weekend allied health services was compared to a subsequent six-months (1st August 2014 till 31st January 2015

but remaining in hospital till 28th February 2015) when these services were not available for acute orthopaedic patients (see highlighted Cluster 6 in Figure 5.1).

The order in which weekend allied health services were to be discontinued for each cluster within the parent trials were determined randomly by an investigator blinded to ward identity (Haines et al., 2015). It is important to note that the randomised nature of the parent trials dictated the timing of intervention and control conditions rather than the allocation of individual patients to these conditions. The present research design is therefore considered quasi-experimental or nonrandomised (Harris et al., 2006).

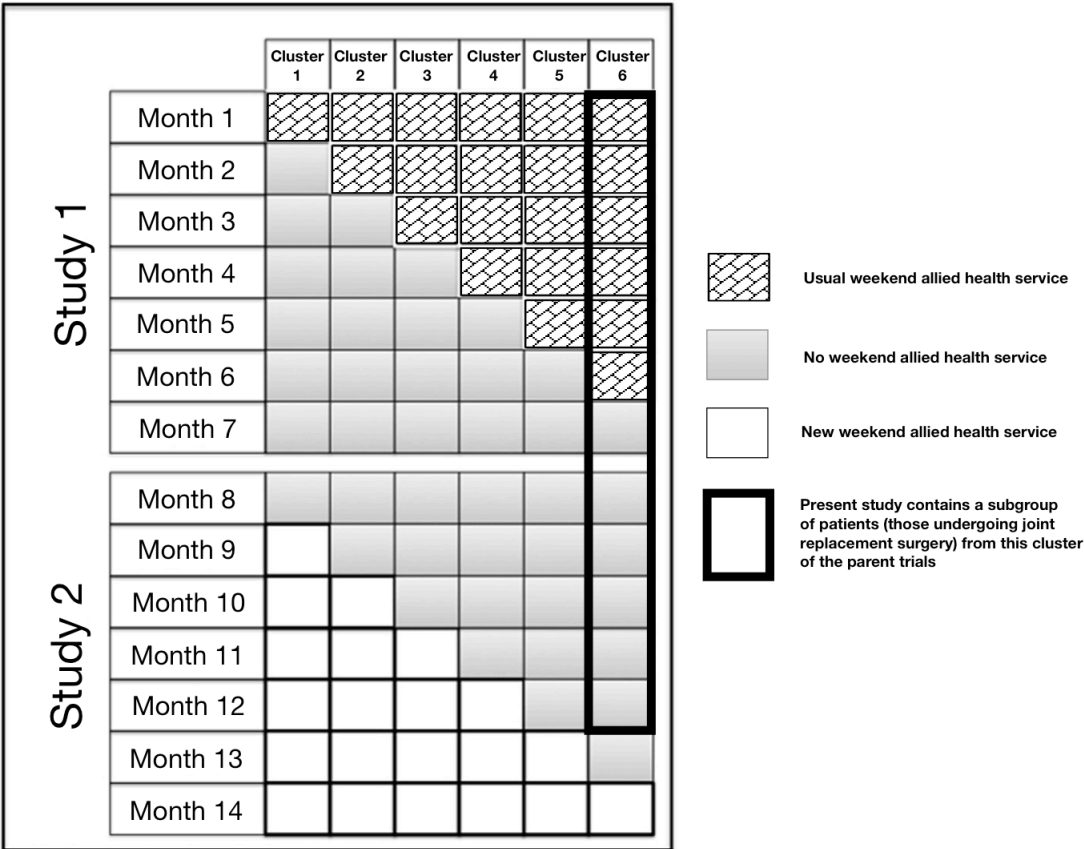


Figure 5.1: Two stepped-wedge randomised controlled trials in which this study was nested (i.e. parent trials).

Adapted from “Study protocol for two randomized controlled trials examining the effectiveness and safety of current weekend allied health services and a new stakeholder-driven model for acute medical/surgical patients versus no weekend allied health services” by Haines et al, 2015, *Trials*, 16:133. Copyright 2015 by Terry Haines. Adapted with permission.
 NB. Trial 1 of the parent trials was the sequential disinvestment from weekend allied health services (grey). Trial 2 was the new stakeholder-driven model of weekend allied health service delivery (white).

Participants and setting

This study was conducted at a 520-bed public tertiary hospital situated in southeastern Melbourne, Australia and included consenting patients who underwent lower limb joint replacement between 3rd February 2014 and 31st January 2015. This patient subgroup was thought to be important because patients undergoing hip and knee joint replacement are known to receive allied health routinely in the acute postoperative phase and anecdotally this subgroup received the largest weekend allied health input in this setting. Participants undergoing surgery at the study hospital were admitted to one of two acute orthopaedic wards (containing 48 beds) following surgery. Depending on clinical need, this may be followed by admission to a sub-acute ward for rehabilitation. Participant inclusion and exclusion criteria are presented in Figure 5.2.

<i>Inclusion Criteria</i>
<ul style="list-style-type: none">• Total hip replacement• Total knee replacement• Revision total hip replacement• Revision total knee replacement
<i>Exclusion Criteria</i>
<ul style="list-style-type: none">• Patients less than 18 years of age• Patients undergoing joint replacement immediately following trauma (eg. fracture)• Patient with moderate to severe cognitive impairment (assessed as less than or equal to 5/10 on the Short Portable Mental Status Questionnaire)• Patients exposed to both models of weekend allied health service delivery during their hospital admission (i.e. admission included dates in July and August 2014)

Figure 5.2: Study inclusion and exclusion criteria

Interventions

Details of the weekend allied health service (including physiotherapy, occupational therapy, dietetics, speech pathology and intervention provided by allied health assistants) available during Phase 1 are provided according to the TIDieR guidelines (Hoffmann et al., 2014) (Table 5-1). Weekday allied health services remained unchanged throughout this study. Weekend allied health services provided on the acute orthopaedic wards (Cluster 6 in Figure

5.1) during Phase 1 were removed in Phase 2 and reallocated to a sub-acute ward within the study hospital.

Outcome measures

Hospital administrative data were examined to measure acute length of stay, number of adverse events during acute hospitalisation for each participant, and discharge destination. Hospital length of stay was considered important from the health service provider perspective as a key determinant of hospital costs (Organisation for Economic Co-operation and Development, 2013). Adverse events were documented as a marker of unintended and detrimental patient outcomes that may lead to poorer patient health outcomes, increase cost and length of stay (Hoogervorst-Schilp et al., 2015). Events included in-hospital falls, Medical Emergency Team calls, pulmonary emboli, deep vein thromboses, death, hospital-acquired pressure injuries, and intensive care unit admissions. Discharge destination (community versus inpatient rehabilitation) was considered a marker of patient outcome and additional costs to health service providers (Zeidler et al., 2008).

Table 5-1: Intervention conditions according to TIDieR criteria

TIDieR criteria	Phase 1 intervention
Brief name	Acute weekend allied health services available
Why	Weekend allied health practitioners cost more to employ than their weekday counterparts. The acute orthopaedic wards (ward 6 in Figure 5.1) have the highest budget allocated to weekend allied health services in this hospital based on the organisational imperative to minimise length of stay. The service is provided for fewer hours/day and by different practitioners than those during the working week. The effectiveness of such a service has not been previously investigated.
What (materials)	No additional physical or informational materials are used in this intervention. Discretion of individual therapists' guide materials used in day-to-day clinical practice and these should be the same as those used by allied health professionals during the week.
What (procedures)	Allied health professionals provided weekend allied health services provided by physiotherapy, occupational therapy, social work, dietetics, speech pathology professionals and/or allied health assistants. Services delivered were the same as those during weekdays although fewer hours of service were available on the weekend. On average, allied health hours of service on the weekend were approximately 30% of those provided on weekdays to both orthopaedic wards (a specific amount was not allocated to joint replacement patients). Services commonly included functional retraining, transfer and gait retraining, discharge planning and assessment and prescription of aids and equipment.
Who provided	All allied health professionals held a bachelor degree qualification at minimum. Weekend therapists were employed at a grade 2 level indicating they could work autonomously. During the working week, therapists were employed at a grade 1 (40%), 2 (20%) and 3 (40%) level. Grade 1 allied health therapists were employed on a rotating basis and did not have specialist orthopaedic knowledge or experience. The grade 2 therapist during the week was deemed to have specialist orthopaedic knowledge and the grade 3 therapist had expert knowledge in this field and provided operational leadership of the orthopaedic allied health staff. Staff providing weekend allied health services were employed on either a part-time or casual basis by the health service.
How	Face to face individual patient interaction
Where	Either of two acute orthopaedic wards or their associated gymnasium.
When and how much	Individual patients received variable amounts of weekend allied health service delivery. The intensity of services was at the discretion of the treating therapist(s) and was allocated according to a hospital-specific priority tool based on clinical urgency and proximity to discharge. Services were referred from either allied health professionals on a Friday or nursing, medical or allied health staff throughout the weekend. 1.84 and 0.98 allied health sessions per participant hospitalised day were provided on weekdays and weekends respectively during Phase 1.
Tailoring	All weekend allied health services were tailored according to the individual needs of patients being treated. This was based upon clinical judgement and determined by the individual practitioners at the time.
Modifications	The intervention was not modified during the course of the study.
How well (planned)	Research assistants from the larger stepped-wedge trial in which this study was nested, were present on study wards daily to monitor adherence to the study protocol. Patient contact statistics recorded by allied health staff daily were used to monitor intervention fidelity, defined as the number of participants in each phase adhering to study protocol.
How well (actual)	10 allied health sessions (all physiotherapy) were provided on a weekend to 5 participants of this study during the "no weekend therapy" phase. These services were provided to participants who had been transferred to a high dependency ward.

Patient outcomes were collected at four days postoperatively. These included functional independence, mobility, health-related quality of life, patient satisfaction, pain, and prescription opioid use. Functional independence and mobility were measured using participant self-report on the Modified Barthel Index (Shah et al., 1989) and De Morton Mobility Index (DEMMI) (de Morton, Davidson, et al., 2008) respectively. These scales have been validated in orthopaedic populations across different clinical settings (de Morton & Lane, 2010; Fricke & Unsworth, 1997). Self report formats have been developed for the Modified Barthel Index (Collin et al., 1988) and are considered an acceptable proxy for the DEMMI (R. Haas, Bowles, O'Brien, & Haines, 2016). Health-related quality of life was assessed using the EuroQol questionnaire (EQ-5D-5L and visual analogue scale) (Oemar & Janssen, 2013). Patient perceived pain levels were assessed using the Quadruple Visual Analogue Pain Scale (Von Korff et al., 1993). Use of prescription opioid analgesics (e.g. oxycodone) were also documented for each participant. Patient satisfaction was measured using the following two questions from the Victorian Patient Satisfaction Monitor (State Government of Victoria Australia, 2011-2012): 'Thinking about all aspects of your hospital stay, how satisfied were you?' and 'How much do you actually think you were helped by your stay in the hospital?' Both questions were answered using a five-point Likert scale.

Additional outcomes were captured through searching of patients' scanned medical records. These included time between patient return to the ward postoperatively and first postoperative transfer out of bed along with the profession of the staff who assisted this task. These outcomes were collected as previous research has demonstrated benefits from early mobilisation in this population (Guerra et al., 2014). Sitting on edge of the bed was not considered a transfer nor was transferring with a mechanical aid (e.g. hoist). Timing of allied health commencement following surgery and daily session rate during acute hospitalisation were collected as they were considered useful covariates when trying to isolate the effect of

weekend allied health service provision. Day of week and profession of each allied health service occasion were also identified to determine whether or not each participant received an acute weekend allied health service, and which profession provided this service. Anticipated recovery pathway (A, B or C where A was the least complex) was also recorded as a covariate. This was identified at the preoperative assessment based upon the Risk Assessment and Prediction Tool (Oldmeadow et al., 2003).

Procedure

All patients undergoing preoperative assessment for hip or knee replacement at the hospital clinic were consecutively approached for written informed consent. Participant assessment occurred preoperatively (at time of consent) and four days postoperatively. A professional language interpreter was employed for culturally and linguistically diverse participants upon request. Participants were exposed to study conditions based on their surgery date and the subsequent dates of hospitalisation but were not allocated a surgery date until after preoperative assessment.

Data was entered into SurveyMonkey Inc. (Palo Alto, California, USA) and exported to Microsoft Excel. Hospital outcomes were extracted into Microsoft Excel after study completion using multiple data sources (hospital databases, staff interview and nursing handover forms) for verification (Sarkies et al., 2016).

Data analysis

Occasions of allied health service were summed for each participant according to profession and totaled. Average duration of each allied health session was not reliably collected during the trial, but was generally considered to be 30 minutes. Acute allied health session rate per day for each participant was calculated as total number of services divided by acute length of

stay. Number of allied health sessions provided per day of hospitalisation was calculated for each day of week in each phase. Participant demographics and baseline clinical measures were compared between intervention groups using the chi-square test for categorical variables and the Mann-Whitney U test for continuous variables.

Data were examined using intention-to-treat and contamination-adjusted intention-to-treat analyses. Intention-to-treat estimated the effect of availability of weekend allied health services by analysing all participants according to the intervention phase to which they were allocated regardless of whether or not weekend allied health intervention was received. Contamination-adjusted intention-to-treat analyses estimated the effect of receiving weekend allied health services since not all patients received the weekend service when it was available (Sussman & Hayward, 2010).

Intention-to-treat analyses were examined using ordinary least squares (linear) regression for continuous dependent variables, ordered logistic regression for ordinal-scaled dependent variables, and logistic regression for those with dichotomous scaling. Several multivariable regression analyses were performed to adjust for potential confounding characteristics based on previous research (Kinoshita, Momosaki, Kakuda, Okamoto, & Abo, 2016). The first model was an unadjusted univariate regression analysis. The second model included patient age, gender, preoperative mobility and respective baseline measure as these characteristics have been demonstrated as key predictors of outcomes following lower limb joint replacement (D. M. Kennedy, Hanna, Stratford, Wessel, & Gollish, 2006; Nilsdotter & Lohmander, 2002). In this model, adjustment was also performed for differences between groups in patient characteristics and discharge destination was adjusted for predicted recovery pathway. The third model included time of postoperative allied health commencement and acute allied health session rate due to the potential relationship between

weekend allied health provision and these variables. The fourth model included patient and allied health variables from models two and three. The contamination-adjusted intention-to-treat analyses were only undertaken using the variables included for in model four. Variance inflation factors were calculated to check for collinearity among covariates in the multivariable regression analyses. All values were lower than two, indicating a lack of collinearity among variables (Hair, Black, Babin, Anderson, & Tatham, 1998).

Associations between allied health characteristics (i.e. weekend allied health provision, time of commencement and allied health intensity) were examined using linear regression analyses. Logarithmic transformations ($x+1$ transformation (Lachin et al., 2011)) for acute length of stay was conducted because the assumption of normally distributed residuals was not met. EQ-5D-5L was converted to a corresponding single index value using a crosswalk link to EQ-5D-3L scale values (Van Hout et al., 2012). Data were clustered to account for multiple admissions of individual participants, and robust variance estimates employed (Rogers, 1994). Tests for interaction between subgroups and each dependent variable were conducted based on surgery type (hip or knee replacement) and recovery pathway (A, B or C where A was expected to be the least complicated). One-way sensitivity analyses were undertaken to limit analyses: to participants undergoing surgery on a Thursday, Friday or Saturday since the weekend allied health service is most likely to assist in commencing earlier postoperative allied health for these participants; and to consider the effect of physiotherapy only since previous research has been limited to this area rather than the effect of an allied health team (R. Haas, Sarkies, et al., 2016). All statistical analyses were performed with STATA SE (STATACorp, College Station, TX, USA) version 13.0.

Sample size

A post hoc power analysis was conducted to examine the power this study had for comparing acute length of stay between the two study phases. Based upon the observed standard deviations and sample sizes, this study had 90% power to detect at least a one-day difference in the intention-to-treat analysis. The observed sample sizes were also deemed sufficient to adjust for the number of independent variables in the fourth multivariable regression model (VanVoorhis & Morgan, 2007).

5.2.4 Results

Study participants and fidelity

Two hundred and seventy-six participants underwent surgery during the study period, 130 during Phase 1 and 146 during Phase 2. Participant flow and reasons for loss to follow-up are presented (Figure 5.3). Age, gender, surgery type and expected recovery pathway of participants who did not consent were similar to those who consented in each phase. More participants who did not consent (28%) requested an interpreter compared to those who consented (11%). Some differences between groups in participant demographics and baseline measures were noted (Table 5-2). Seventy percent (92/130) of participants received a weekend allied health service during Phase 1 and 99% (272/276) received a weekday service. On weekdays and weekends respectively, 1.84 and 0.98 allied health sessions per participant hospitalised day were provided (Figure 5.4). In Phase 2, treatment fidelity was achieved for 96.5% of participants.

Weekend allied health following hip and knee replacement surgery

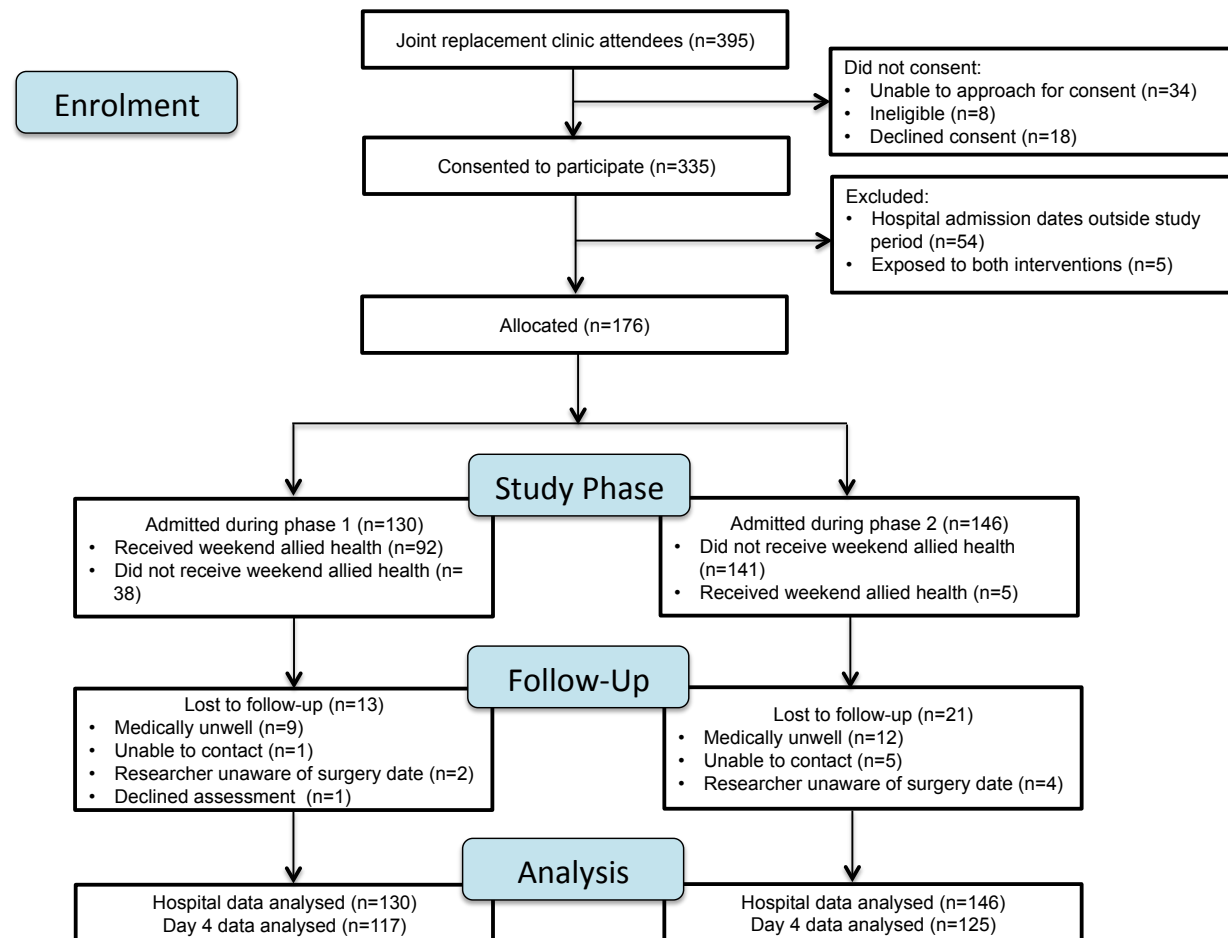


Figure 5.3: Flow of participants

Table 5-2: Participant demographics and baseline clinical measures

Characteristic	Intention-to-treat		Contamination-adjusted Intention-to-treat	
	Phase 1 Acute weekend allied health services available (n=130)	Phase 2 Acute weekend allied health services NOT available (n=146)	Received acute weekend allied health (n=97)	Did not receive acute weekend allied health (n=179)
Age, mean (SD), years	67.77 (10.62)	68.58 (10.29)	67.99 (11.35)	68.31 (9.93)
Female, n (%)	75 (58%)	90 (62%)	59 (61%)	106 (59%)
Request for interpreter, n (%)	12 (9%)	14 (10%)	8 (8%)	18 (10%)
Surgery type, n (%)				
Total knee replacement	68 (52%)	92 (63%)	53 (55%)	107 (60%)
Total hip replacement	58 (45%)	45 (31%)	39 (40%)	64 (36%)
Revision knee replacement		3 (2%)		3 (1%)
Revision hip replacement	4 (3%)	6 (4%)	5 (5%)	5 (3%)
Surgery day of week, n (%)				
Monday	8 (6%)	10 (7%)	1 (1%)	17 (10%)*
Tuesday	18 (14%)	12 (8%)	6 (6%)	24 (13%)
Wednesday	9 (7%)	21 (14%)	7 (7%)	23 (13%)
Thursday	31 (24%)	21 (14%)*	30 (31%)	22 (12%)*
Friday	17 (13%)	30 (21%)	21 (22%)	26 (15%)
Saturday	47 (36%)	52 (36%)	32 (33%)	67 (37%)
Time from preoperative assessment to surgery, median (IQR), days	23 (15-35)	37 (23-58)*	21 (15-35)	35 (22-55)*
Pathway†, n (%)				
A	63 (48)	54 (37)	41 (42)	76 (42)
B	43 (33)	64 (44)	34 (35)	73 (41)
C	24 (19)	28 (19)	22 (23)	30 (17)
Comorbidities‡, n (%)				
Cardiovascular	24 (18%)	34 (23%)	19 (20%)	39 (22%)

Weekend allied health following hip and knee replacement surgery

Characteristic	Intention-to-treat		Contamination-adjusted Intention-to-treat	
	Phase 1 Acute weekend allied health services available (n=130)	Phase 2 Acute weekend allied health services NOT available (n=146)	Received acute weekend allied health (n=97)	Did not receive acute weekend allied health (n=179)
Neurological	12 (9%)	9 (6%)	9 (9%)	12 (7%)
Diabetes	22 (17%)	32 (22%)	15 (15%)	39 (22%)
Mental Health	17 (13%)	22 (15%)	14 (14%)	25 (14%)
Malignancy	10 (8%)	15 (10%)	9 (9%)	16 (9%)
Pulmonary	4 (3%)	22 (15%)*	3 (3%)	23 (13%)*
Obesity (BMI>35)	8 (6%)	17 (12%)	3 (3%)	22 (12%)*
Prior joint replacement	46 (35%)	44 (30%)	36 (37%)	54 (30%)
Preoperative DEMMI total, median (IQR)	62 (53-74)	67 (57-74)*	62 (50.5-74)	67 (57-74)*
Preoperative Modified Barthel index, median (IQR)	100 (95.75-100)	100 (98-100)	100 (95-100)	100 (98-100)
Preoperative EQ5D Utility Index, median (IQR)	0.54 (0.31-0.67)	0.55 (0.30-0.70)	0.55 (0.29-0.69)	0.55 (0.31-0.70)
Preoperative EQ5D VAS, median (IQR)	70 (50-80)	70 (50-80)	70 (50-80)	70 (50-80)
Preoperative pain now, median (IQR)	5 (2-7)	5 (1.875-7)	4.5 (1-6)	5 (2-7)
Preoperative pain average, median (IQR)	6 (5-7)	5 (5-7)	6 (5-7)	5.5 (5-7)
Preoperative pain best, median (IQR)	3.75 (0-5)	3 (0-5)	3.5 (0-5)	3.5 (0-5)
Preoperative pain worst, median (IQR)	8 (7-10)	9 (7.5-10)	8.5 (7.5-10)	9 (7.5-10)
Preoperative opioid use, n (%)	42 (32%)	65 (45%)	14 (29%)	67 (43%)

Abbreviations: n, number of hospital admissions; DEMMI, de Morton Mobility Index; EQ5D, EuroQol five dimensions; VAS, Visual Analogue Scale.

* Indicates difference between groups is statistically significant for this variable

† Pathway indicates expected postoperative recovery pathway. A indicates discharge directly home from acute facility. B indicates acute length of stay with inpatient rehabilitation 4-7 days. C indicates inpatient rehabilitation ≥ 14 days

* Participants may have multiple comorbidities

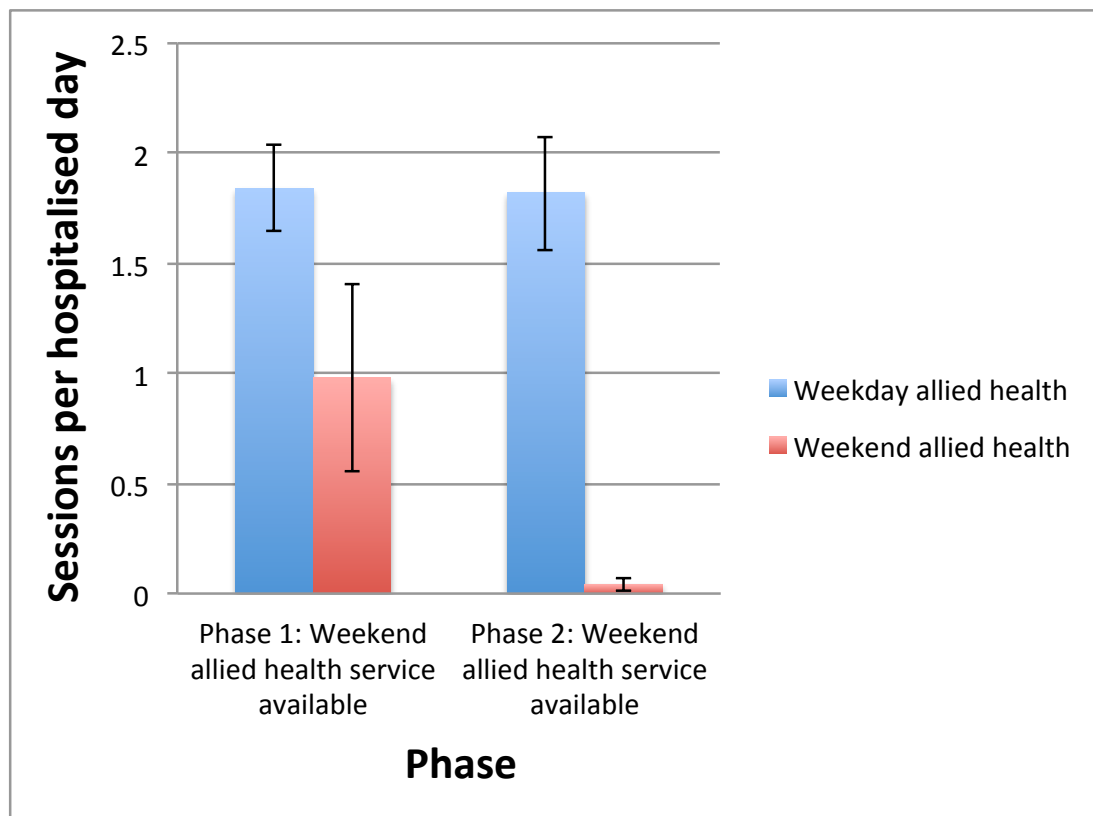


Figure 5.4: Number of acute allied health sessions per hospitalised day

Error bars represent standard deviation

Relationships between physiotherapy service delivery characteristics

Participants in Phase 1 commenced allied health at 0.91 (0.75-1.08) days postoperatively compared to those in phase 2 who commenced allied health at 1.74 (0.88-2) days postoperatively [coefficient -0.77 (-0.64 to -0.97), <0.001]. Participants in Phase 1 received 1.82 (1.38-2.25) allied health sessions per inpatient day compared to those in Phase 2 who received 1.31 (0.98-1.71) sessions per day [coefficient 0.45 (0.31-0.60), <0.001]. These relationships were stronger when acute weekend physiotherapy services were based on receipt of intervention rather than phase of admission. Those who commenced physiotherapy earlier also received a higher rate of allied health services [coefficient 0.31 (0.22 to 0.40), <0.001].

Intention-to-treat analyses

Data for all outcomes are presented (Table 5-3). The majority of allied health sessions received by this population were from physiotherapists, occupational therapists and allied health assistants. Acute length of stay was longer when weekend allied health services were available though this was only statistically significant in models including adjustments for allied health session rate and timing of commencement. Patients perceived their hospitalisation as less helpful when weekend allied health services were available. However, odds of discharge directly home were greater and mobility increased when these services were available (Table 5-4).

Twenty-four percent (16/67) of participants predicted to require inpatient rehabilitation (Pathway B and C) were discharged directly home in Phase 1 compared to 11% (10/92) in Phase 2. Similarly, 3% (2/63) of participants predicted to be discharged directly home (Pathway A) were admitted for inpatient rehabilitation in Phase 1 compared to 9% (5/54) in Phase 2. First postoperative transfer commenced earlier [-0.16 (-0.31 to -0.01), 0.036] when weekend allied health services were available. Nurses were also less likely to assist with first postoperative transfer [OR=0.529 (0.282 to 0.990), 0.046] when these services were available. These effects were only evident in statistical models without adjustment for allied health timing and intensity suggesting they may be related to the earlier commencement and/or the greater intensity of allied health rather than the day(s) of week when therapy was available.

Table 5-3: Raw data

Outcome Measure	Intention-to-treat				Contamination-adjusted Intention-to-treat			
	Phase 1 Acute weekend allied health services available		Phase 2 Acute weekend allied health services NOT available		Received acute allied health		Did not receive acute weekend allied health	
Acute length of stay (days), mean (SD), days	4.87 (3.10)	n=130	4.38 (1.74)	n=146	5.42 (3.44)	n=97	4.17 (1.60)	n=179
Log (x+1) acute length of stay (days), mean (SD)	1.70 (0.34)	n=130	1.64 (0.29)	n=146	1.78 (0.36)	n=97	1.60 (0.27)	n=179
Acute Adverse Events*, n (%)	18 (14%)	n=130	15 (10%)	n=146	16 (16%)	n=97	17 (9%)	n=179
Discharge destination, n (%)		n=130		n=146		n=97		n=179
Home	77 (59%)		59 (40%)		52 (54%)		84 (47%)	
Inpatient rehabilitation	53 (41%)		87 (60%)		45 (46%)		95 (53%)	
Time till first postoperative transfer, median (IQR), days	0.96 (0.8-1.1)	n=130	1.03 (0.91-1.67)	n=146	0.97 (0.82-1.12)	n=97	1.01 (0.88-1.32)	n=179
Profession of staff assisting first postoperative transfer, n (%)		n=130		n=146		n=97		n=179
Physical therapist	104 (80%)		95 (65%)		81 (84%)		118 (66%)	
Nurse	26 (20%)		51 (35%)		16 (16%)		61 (34%)	
Acute allied health session rate, median (IQR), sessions per inpatient day	1.82 (1.38-2.25)	n=130	1.31 (0.98-1.71)	n=146	1.81 (1.46-2.11)	n=97	1.39 (1-1.89)	n=179
Time till first postoperative allied health session, median (IQR), days	0.91 (0.75-1.08)	n=130	1.74 (0.88-2)	n=146	0.89 (0.74-1.01)	n=97	1.66 (0.87-1.97)	n=179
Day 4 Outcomes								
Modified Barthel Index, median (IQR)	85 (74.5-96)	n=117	87 (70-96)	n=125	84 (73-96)	n=88	88.5 (72-96)	n=154
DEMMI, median (IQR)	44 (37.5-48)	n=117	41 (30-48)	n=125	44 (36-48)	n=88	44 (33-48)	n=154
EQ5D utility, median (IQR)	0.29 (0.22-0.38)	n=117	0.26 (0.17-0.36)	n=125	0.29 (0.21-0.37)	n=88	0.27 (0.19-0.37)	n=154
EQ5D VAS, median (IQR)	70 (50-80)	n=117	70 (50-80)	n=125	70 (50-80)	n=88	70 (50-80)	n=154
Overall satisfaction, n (%)		n=117		n=125		n=88		n=154
Very dissatisfied	1 (1%)				1 (1%)			

Outcome Measure	Intention-to-treat				Contamination-adjusted Intention-to-treat			
	Phase 1 Acute weekend allied health services available		Phase 2 Acute weekend allied health services NOT available		Received acute allied health		Did not receive acute weekend allied health	
Dissatisfied	2 (2%)		1 (1%)		2 (2%)		1 (1%)	
Neutral	4 (3%)		5 (4%)		2 (2%)		7 (5%)	
Satisfied	46 (39%)		39 (31%)		35 (40%)		50 (32%)	
Very satisfied	64 (55%)		80 (64%)		48 (55%)		96 (62%)	
Helpfulness of hospitalisation, n (%)		n=117		n=125		n=88		n=154
Not at all	3 (3%)				3 (3%)			
A little	1 (1%)		1 (1%)		1 (1%)		1 (1%)	
Somewhat	15 (13%)		3 (2%)		8 (9%)		10 (6%)	
Quite a bit	45 (38%)		19 (15%)		34 (39%)		30 (19%)	
Great deal	53 (45%)		102 (82%)		42 (48%)		113 (73%)	
Pain now, median (IQR)	3.5 (1-5)	n=117	3 (1-5)	n=125	3.25 (0.25-5)	n=88	3 (1-5)	n=154
Pain average, median (IQR)	4 (2.75-5)	n=117	5 (2.5-5.25)	n=125	4 (3-5.38)	n=88	4.5 (2.5-5)	n=154
Pain best, median (IQR)	2 (0-4)	n=117	2 (0-4)	n=125	2 (0-4)	n=88	2 (0-4)	n=154
Pain worst, median (IQR)	7 (5-8)	n=117	7.5 (4.75-9)	n=125	7 (5-8)	n=88	7 (4.5-9)	n=154
Opioid use, n (%)	95 (81%)	n=117	103 (82%)	n=125	66 (75%)	n=88	131 (85%)	n=154
Acute allied health sessions, n (% total sessions)		n=130		n=146		n=97		n=179
Physiotherapy	500 (46%)		415 (47%)		401 (45%)		514 (46%)	
Occupational therapy	198 (18%)		214 (24%)		149 (18%)		262 (24%)	
Allied health assistant	396 (36%)		252 (29%)		325 (37%)		324 (30%)	
Speech pathology	0 (0%)		1 (<1%)		1 (<1%)		0 (0%)	
Social work	3 (<1%)		3 (<1%)		3 (<1%)		3 (<1%)	
Dietetics	3 (<1%)		5 (<1%)		3 (<1%)		5 (<1%)	

Abbreviations: n, number of hospital admissions: DEMMI, de Morton Mobility Index: EQ5D, EuroQol five dimensions: VAS, Visual Analogue Scale.

* Participants who experienced 1 or more adverse events.

Table 5-4: Intention-to-treat analyses

Outcome Measure	Model 1 Unadjusted [†] Regression Coefficient (95% CI), p value	Model 2 Adjusted [†] Regression Coefficient (95% CI), p value	Model 3 Adjusted [‡] Regression Coefficient (95% CI), p value	Model 4 Adjusted [§] Regression Coefficient (95% CI), p value
Acute length of stay	0.492 (-0.111 to 1.096), 0.109	0.667 (-0.123 to 1.458), 0.098	0.781 (0.024 to 1.538), 0.043	1.145 (0.095 to 2.194), 0.033
Acute length of stay – log(x+1) transformed	-0.060 (-0.135 to 0.015), 0.119	-0.076 (-0.161 to 0.009), 0.078	0.099 (0.009 to 0.187), 0.032	0.135 (0.030 to 0.239), 0.012
Acute Adverse Events [¶]	0.085 (-0.045 to 0.215), 0.198	0.091 (-0.101 to 0.282), 0.352	0.13 (-0.023 to 0.283), 0.096	0.129 (-0.114 to 0.371), 0.296
Discharge directly home	OR=2.142 (1.336 to 3.435) 0.002	OR=2.258 (0.842 to 6.060) 0.106	OR=2.321 (1.372 to 3.925) 0.002	OR=3.401 (1.050 to 11.010) 0.041
Timing of first postoperative transfer	-0.16 (-0.30 to -0.03), 0.02	-0.16 (-0.31 to -0.01), 0.036	0.063 (-0.064 to 0.189), 0.332	0.047 (-0.085 to 0.181), 0.482
First transfer assisted by nurse	OR=0.466 (0.269 to 0.807), 0.006	OR=0.529 (0.282 to 0.990), 0.046	OR=0.860 (0.462 to 1.601), 0.635	OR=0.969 (0.472 to 1.99), 0.931
Day 4 Outcomes				
Modified Barthel Index	2.670 (-1.456 to 6.797), 0.204	2.395 (-1.354 to 6.143), 0.209	1.265 (-3.11 to 5.64), 0.569	2.74 (-0.972 to 6.451), 0.147
DEMMI	3.134 (-0.266 to 6.002), 0.032	4.158 (1.444 to 6.873), 0.003	4.737 (1.763 to 7.712), 0.002	3.861 (1.065 to 6.658), 0.007
EQ5D utility	0.017 (-0.038 to 0.071), 0.548	0.014 (-0.041 to 0.070), 0.613	0.020 (-0.04 to 0.079), 0.518	0.031 (-0.029 to 0.092), 0.305
EQ5D VAS	0.612 (-4.172 to 5.395), 0.801	-0.570 (-5.377 to 4.237), 0.816	1.462 (-3.923 to 6.846), 0.593	1.163 (-4.674 to 7.00), 0.695
Satisfaction	-0.377 (-0.896 to 0.1141), 0.154	-0.536 (-1.102 to 0.029), 0.063	-0.519 (-1.096 to 0.057), 0.077	-0.599 (-1.205 to 0.008), 0.053
Helpfulness of hospitalisation	-1.686 (-2.255 to -1.116), <0.001	-1.624 (-2.256 to -0.922), <0.001	-1.807 (-2.451 to -1.162), <0.001	-1.792 (-2.518 to -1.067), <0.001
Pain now	-0.084 (-0.743 to 0.574), 0.801	0.033 (-0.655 to 0.720), 0.925	-0.316 (-1.039 to 0.408), 0.391	-0.274 (-1.018 to 0.470), 0.469
Pain average	-0.127 (-0.659 to 0.404), 0.638	-0.078 (-0.608 to 0.452), 0.772	-0.321 (-0.938 to 0.296), 0.307	-0.405 (-1.016 to 0.207), 0.194
Pain best	-0.183 (-0.763 to 0.397), 0.534	-0.153 (-0.728 to 0.423), 0.602	-0.354 (-0.989 to 0.28), 0.272	-0.459 (-1.109 to 0.191), 0.166
Pain worst	-0.192 (-0.939 to 0.556), 0.614	-0.245 (-1.035 to 0.544), 0.541	-0.523 (-1.384 to 0.338), 0.232	-0.752 (-1.654 to 0.150), 0.102
Opioid use	OR=1.075 (0.510 to 2.263), 0.850	OR=1.674 (0.638 to 4.394), 0.295	OR=0.673 (0.278 to 1.632), 0.381	OR=1.436 (0.525 to 3.931), 0.481

Abbreviations: n, number of hospital admissions; DEMMI, de Morton Mobility Index; EQ5D, EuroQol five dimensions; VAS, Visual Analogue Scale.

Untransformed data presented since data transformations made no difference to significance of results

Regression coefficient indicates greater or lesser unit of outcome measure (depending on positive or negative value respectively) for participants who had acute weekend allied health services available compared to those participants who did not have these services available

[†] Model 1 - Unadjusted

[‡] Model 2 - Adjusted for time from preoperative assessment till surgery, surgery day of week, preoperative mobility, pulmonary comorbidities, age, gender and respective baseline value if applicable. Discharge destination was also adjusted for anticipated recovery pathway.

[§] Model 3 - Adjusted for time till first postoperative allied health session and acute allied health session rate. Discharge destination was also adjusted for anticipated recovery pathway.

^{||} Model 4 - Adjusted for preoperative assessment till surgery, surgery day of week, preoperative mobility, pulmonary comorbidities, age, gender, respective baseline value if applicable, time till first postoperative allied health session and acute allied health session rate. Discharge destination was also adjusted for anticipated recovery pathway.

^{||} Indicates association is statistically significant

[¶] Participants who experienced 1 or more adverse events.

Contamination-adjusted intention-to-treat analyses

Short-term outcomes were similar when contamination-adjusted intention-to-treat-analyses were conducted (Table 5-5). Acute length of stay was longer [2.178 (1.095 to 3.262), <0.001] when weekend allied health services were received. The effect of receiving weekend allied health services on mobility and helpfulness of hospitalisation could not be estimated because the study phase was correlated with the error term from the regression model. More acute adverse events were observed [0.220 (0.015 to 0.425), 0.035] amongst participants who received acute weekend allied health services compared to those who did not. Of the 26 adverse events occurring in 16 participants who received weekend allied health services, 22 occurred before the weekend allied health service suggesting adverse events may be an indicator for receipt of weekend allied health services rather than vice versa.

Subgroup and sensitivity analyses

No interaction effects across surgery type or recovery pathway subgroups were observed. Results remained unchanged when weekend allied health services were limited to include physiotherapy only. Some between-group differences were not observed when analyses were limited to participants undergoing surgery on a Thursday, Friday or Saturday, possibly due to fewer participants (n=198) and a consequent reduction in statistical power.

Table 5-5: Contamination-adjusted intention-to-treat analyses

Outcome Measure	Association between residuals & instrument	Model 4 Adjusted* Regression Coefficient (95% CI), p value
Acute length of stay	-0.003 (-0.029 to 0.024), 0.854	2.178 (1.095 to 3.262), <0.001†
Acute length of stay – log(x+1) transformed	-0.068 (-0.282 to 0.146) 0.532	0.301 (0.202 to 0.399), <0.001†
Acute Adverse Events‡	0.001 (-0.115 to 0.115), 0.998	0.220 (0.015 to 0.425), 0.035†
Discharge directly home	Risk difference = 0.128 (-0.065 to 0.320), 0.192	Risk difference = 0.136 (0.021 to 0.251), 0.021†
Timing of first postoperative transfer	-0.049 (-0.157 to 0.060), 0.378	-0.127 (-0.276 to 0.022), 0.094
First transfer assisted by nurse	Risk difference = 0.029 (-0.113 to 0.171), 0.686	Risk difference = -0.140 (-0.255 to -0.024), 0.018†
Day 4 Outcomes		
Modified Barthel Index	0.004 (-0.001 to 0.009), 0.118	-3.085 (-7.383 to 1.212), 0.159
DEMMI	0.006 (0.001 to 0.013), 0.049†	Not calculated as assumption ii not met
EQ5D utility	0.131 (-0.176 to 0.437), 0.402	-0.012 (-0.069 to 0.043), 0.651
EQ5D VAS	0.001 (-0.002 to 0.005), 0.550	-1.868 (-7.691 to 3.954), 0.529
Satisfaction	-0.039 (-0.136 to 0.058), 0.433	-0.175 (-0.409 to 0.060), 0.144
Helpfulness of hospitalisation	-0.101 (-0.187 to -0.015), 0.022†	Not calculated as assumption ii not met
Pain now	-0.001 (-0.026 to 0.027), 0.988	-0.518 (-1.285 to 0.249), 0.185
Pain average	-0.015 (-0.047 to 0.017), 0.365	-0.044 (-0.673 to 0.586), 0.892
Pain best	-0.012 (-0.042 to 0.018), 0.443	-0.221 (-0.920 to 0.478), 0.535
Pain worst	-0.009 (-0.032 to 0.013), 0.405	-0.422 (-1.324 to 0.479), 0.358
Opioid use	RD=0.046 (-0.138 to 0.230), 0.626	RD=-0.125 (-0.271 to 0.021), 0.093

Abbreviations: n, number of hospital admissions; DEMMI, de Morton Mobility Index; EQ5D, EuroQol five dimensions; VAS, Visual Analogue Scale.

Untransformed data presented since data transformations made no difference to significance of results

Regression coefficient indicates greater or lesser unit of outcome measure (depending on positive or negative value respectively) for participants who received acute weekend allied health services compared to those participants who did not receive acute weekend allied health services

* Model 4 - Adjusted for time from preoperative assessment till surgery, surgery day of week, preoperative mobility, pulmonary and obesity comorbidities, age, gender, respective baseline value if applicable, time till first postoperative allied health session and acute allied health session rate. Discharge destination was also adjusted for anticipated recovery pathway.

† Indicates association is statistically significant

‡ Participants who experienced 1 or more adverse events

5.2.5 Discussion

This study suggests that provision of an acute weekend allied health service may increase mobility following hip and knee joint replacement surgery and the odds of discharge directly home without subsequent inpatient rehabilitation. However, this may be at the expense of patients rating their hospital admission as less helpful and a possible longer acute length of stay. Furthermore, the removal of weekend allied health services during Phase 2 may have created a stimulus for nurses to be more involved in promoting early postoperative transfers but this occurred approximately four hours later post-surgery compared to when weekend services were available. Further experimental research using a priori hypotheses with stakeholder-relevant outcome measures is required to identify the net effect for patients, health organisations and funders of these contrasting results.

The results of this study are consistent with previous research relating to mobility (Boxall et al., 2004; Maidment et al., 2014; Pengas, Khan, Bennett, & Rankin, 2015) but discordant for acute length of stay (Boxall et al., 2004; Hughes et al., 1993; Maidment et al., 2014; Pua et al., 2011). None of these studies examined the effect of weekend physiotherapy on discharge destination; without this it is not possible to compare the present study's results comprehensively since discharge destination may confound length of stay and vice versa (Carter & Potts, 2014; Forrest, Roque, & Dawodu, 1999). To the author's knowledge, only one study has investigated the effect of a weekend physiotherapy service on discharge destination and no difference in discharge destination or length of stay between patients hospitalised during a six and seven-day physiotherapy service was evident, although statistical power was low (Lang, 1998). In the present study, patients rated their hospitalisation as less helpful (but not unhelpful) when weekend allied health services were available. Previous studies have examined the effect of a weekend physiotherapy service on patient satisfaction but not specifically ratings of helpfulness and these studies were

conducted in patients following coronary artery bypass surgery (van der Peijl et al., 2004) or in inpatient rehabilitation settings (Peiris, Taylor, & Shields, 2012; Ruff, Yarnell, & Marinos, 1999). This finding appears counter-intuitive but could be related to unwelcome pain associated with early physiotherapy commencement due to a weekend service or patient expectations for a particular recovery pathway. This is because more participants in Phase 1 than Phase 2 exceeded their expected recovery pathway and were discharged directly home without inpatient rehabilitation. It is also possible the patients perceived the quality of the service provided by casual staff on the weekend was lower than that provided during the week by regular staff who were known to the patients.

The present study differed from previous studies in that the cumulative effect of allied health (predominantly physiotherapy, occupational therapy and care provided by allied health assistants) was considered rather than physiotherapy only. In addition, the weekend service in the present study was removed rather than added. This service also reflected real-world practice where the weekend allied health service provided on the weekends was less in quantity than that provided on weekdays (approximately 60% less) and predominantly provided by casual staff. A key strength of this study is that a broad range of short-term effects of a weekend allied health service was examined in a controlled manner. Other strengths are that this study had a high follow-up rate (88%), a high fidelity rate (adherence to intervention protocol) and the analysis considered the potential confounding relationship of allied health intensity and time to allied health commencement postoperatively.

Previous research has demonstrated early mobilisation following hip and knee replacement is beneficial (Guerra et al., 2014) and that a multidisciplinary approach is integral to effective rehabilitation (Khan et al., 2008). The present study suggests that although there might be more scope for nurses to be involved in assisting patients to mobilise postoperatively, the

weekend allied health service appears to be important in improving patient mobility and promoting earlier postoperative mobilisation. This is consistent with research demonstrating although nurses have the expertise to impact early mobilisation through the development of and adherence to standardised mobility protocols (Pashikanti & Von Ah, 2012), nursing practice is primarily focused on patient safety rather than rehabilitation goals (Kneafsey, Clifford, & Greenfield, 2013). Further research is required to identify areas for greater collaboration within multi or interdisciplinary team members to promote mobility.

To the author's knowledge, this is the first study to investigate potential relationships between allied health characteristics and gain insight into the potential mechanisms of impact of a weekend allied health service. The present findings demonstrate acute weekend allied health is associated with earlier allied health commencement postoperatively and increased inpatient allied health intensity. Previous studies have reported increased allied health quantity in groups receiving weekend services (Boxall et al., 2004; Liang et al., 1987; Maidment et al., 2014), however, these studies quantified total allied health dose and may therefore be confounded by length of stay. The findings of this study also suggest the observed effects on length of stay, discharge destination, mobility and helpfulness of hospitalisation are independent of timing of commencement and quantity. This differs to a previous review proposing early therapy initiation and total sum of visits may be more influential than day of week during which treatment is received though this was a post-hoc hypothesis rather than an investigation (Kolber et al., 2013). It is possible a 7-day allied health service promotes mobility improvement through consistency of therapy without allowing functional decline during breaks in therapy over the weekend, although this premise requires further investigation.

The results of this study highlight the importance of assessing a range of potential outcomes when conducting health services research. This is consistent with guidelines from the United Kingdom Medical Research Council on the evaluation of complex interventions (P. Craig et al., 2008). To explore the economic implications of our findings, we compared the average cost of an inpatient rehabilitation admission for this cohort [AUD\$1011 per day (Independent Hospital Pricing Authority, 2017) multiplied by average length of stay of eight days (range 6-12 days)] to the incremental cost of an additional half to one-day acute length of stay (AUD\$1050, range \$550-\$1600 (National Health Performance Authority, 2015)). From this, we estimate a net cost saving of between AUD\$4466-\$11582 (average AUD\$7038) per patient discharged directly home with an increased acute length of stay. This suggests the costs saved from avoiding an inpatient rehabilitation admission are likely to outweigh the costs associated with the increase in acute length of stay observed with the availability of a weekend physiotherapy service in this study. However, these costs did not include downstream costs following hospitalisation such as home-based or outpatient allied health services or the cost of providing the weekend physiotherapy service. Longer-term economic evaluation of these results is therefore warranted.

Although this study attempted to control for differences in patient cohorts between the service models investigated, the principal limitation is that the findings may be influenced by unmeasured differences between patient cohorts. While a patient level randomised controlled trial would control for this, it would not allow the broader health service compensations to be considered. Multi-site parallel cluster or stepped-wedge randomised controlled trials with cost-effective analyses are recommended to further inform optimal allied health service delivery models. Setting a priori hypotheses based on the results of this exploratory study would also allow the clinical importance of observed effects to be considered. Another limitation was that allied health rate was measured using occasions of service instead of

minutes. Although the demographics and average length of stay of the participants in this study are comparable to those undergoing lower limb joint replacement in Australia and other developed nations (Arthroplasty Clinical Outcomes Registry, 2015; Hart et al., 2015; Jonas, Smith, Blair, Dacombe, & Weale, 2013), care should be taken generalising these results to other health care systems with different allied health service models.

5.2.6 Conclusion

This study demonstrates that the weekend allied health service appears to have had beneficial impacts on discharge destination and patient mobility that may outweigh the unfavourable impacts on patient perceived helpfulness of hospitalisation and acute length of stay. These observed effects were independent of timing of allied health commencement and session rate. Although there might be more scope for nurses to be involved in assisting patients to mobilise postoperatively following joint replacement surgery, the weekend allied health service appears to be important in promoting earlier postoperative mobilisation and improving patient mobility. These effects are likely to be mediated by earlier allied health commencement and/or increased quantity achieved with the provision of a weekend allied health service. Multi-site parallel cluster or stepped-wedge randomised controlled trials with economic and process evaluation are recommended to further inform optimal physiotherapy service model delivery following hip and knee replacement surgery.

Chapter 6 – Alternate allied health service models

6.1 Preface

As health care resources are limited, it is essential that healthcare interventions demonstrate effectiveness and cost-effectiveness. The previous chapter (Chapter 5) demonstrated mixed effects from the weekend allied health service at the study hospital. A potential alternative to providing weekend allied health services following total hip and knee replacement surgery in the acute setting is to transfer these services to the sub-acute setting. An Australian economic evaluation alongside a randomised controlled trial suggests the provision of a weekend allied health service (including physiotherapy and occupational therapy) in the sub-acute setting for a mixed cohort of patients undergoing inpatient rehabilitation is cost-effective for up to 12 months following surgery (Brusco, Watts, Shields, & Taylor, 2015). This chapter reports on a comparative effectiveness study examining the effect of transferring a cost-neutral weekend allied health service from the acute to sub-acute setting on medium-term outcomes (six weeks postoperatively) following total hip and knee joint replacement surgery. Section 5.2 is an adaptation of a manuscript that has been prepared for publication and is currently under review.

6.2 Study 4 - The effect of transferring weekend allied health services from the acute to sub-acute setting in patients following lower limb joint replacement

6.2.1 Abstract

Purpose:

To investigate the effect of transferring a real-world weekend allied health service from the acute to sub-acute setting on patient and service outcomes following hip and knee replacement.

Methods:

This was a quasi-experimental research design nested within two stepped-wedge cluster randomised controlled trials. Acute weekend allied health services were sequentially discontinued and reallocated in a random order from one ward at a time within the broader trial. Patient and service outcomes for participants undergoing hip and knee replacement (N=247) were compared during six-months of acute weekend allied health services (Phase 1, n=117) followed by six-months of sub-acute services (Phase 2, n=130). Outcomes included total hospital length of stay, adverse events, unplanned hospital readmission, mobility, functional independence, quality of life, pain, patient ratings of hospital length of stay appropriateness and patient-perceived degree of change since surgery.

Results:

The intervention had a negligible effect on medium-term outcomes. The only statistically significant difference observed was slightly higher patient ratings of “worst pain experienced over the past week” [coefficient 0.865 (0.123 to 1.606), $p=0.022$] during Phase 2. No interaction effects were observed despite a 2.4-day reduction in total length of stay amongst complex patients during Phase 2.

Conclusions:

No comparative advantage or disadvantage was observed by allocating a weekend allied health budget to the sub-acute rather than the acute setting following hip and knee replacement. Further research investigating the cost-effectiveness of weekend allied health services in the sub-acute setting may be warranted for complex patients.

6.2.2 Introduction

Hospitals are required to provide continuous care to patients 24 hours a day, seven days a week for 365 days a year. There is a growing body of evidence to suggest health outcomes are worse amongst patients admitted to hospital on the weekend compared to during the week (known as ‘the weekend effect’) and that this may apply to patients undergoing

elective surgery such as hip or knee joint replacement (Aylin et al., 2013; Mohammed et al., 2012; Newman et al., 2017; Ruiz, Bottle, & Aylin, 2015). Reduced quantity and seniority of staff on the weekend relative to weekdays could be a contributing factor to the weekend effect (Aylin et al., 2010; Freemantle et al., 2015; Ozdemir et al., 2015; Tarnow-Mordi et al., 2000), although the cause is likely to be related to a complex cluster of different causal pathways that differs according to diagnostic group (Concha et al., 2014).

Total hip and knee replacement is a surgical procedure frequently performed to relieve pain and disability associated with arthritis. Patients with multiple risk factors (such as age, comorbidities and a disadvantaged social environment) are commonly referred directly from the acute hospital to a sub-acute setting for inpatient rehabilitation following hip and knee replacement in countries such as Australia, Switzerland and the United States (Buhagiar et al., 2017; Khan et al., 2008). Inpatient allied health (e.g. physiotherapy and occupational therapy) is a core component of postoperative rehabilitation, and has been shown to reduce length of stay and improve patient outcomes in both the acute and sub-acute settings (A. F. Chen et al., 2012; Khan et al., 2008). However, the quantity of weekend allied health services provided is often reduced relative to those provided during the working week and/or provided by less experienced clinicians (L. Campbell et al., 2010; Ottensmeyer et al., 2012; Shaw et al., 2012) and these factors may compromise the effectiveness of a weekend allied health service.

There is substantial variation in the delivery of allied health services within and between inpatient settings over the weekend. An Australian cross-sectional survey found variation in the provision of weekend physiotherapy services with respect to funding source (private or public), hospital location (metropolitan or regional) and hospital size (Shaw et al., 2012). In particular, 60% of acute wards provided a weekend physiotherapy service compared to only 30% of sub-acute wards. Unwarranted practice variation that cannot be explained by type or

severity of illness or patient preference has been associated with outcome variability and unnecessary healthcare costs in other populations. Addressing unwarranted variation in clinical practice has become a priority for health care systems (Duggan et al., 2005; P. J. Kennedy et al., 2010; Love et al., 2014).

Evidence supporting the effectiveness of weekend allied health services in improving service or patients outcomes following hip and knee joint replacement is limited in both the acute (R. Haas, Sarkies, et al., 2016; Pengas et al., 2015) and sub-acute (Brusco, Shields, Taylor, & Paratz, 2007; Caruana, Kuys, Clarke, & Bauer, 2016; Peiris, Shields, Brusco, Watts, & Taylor, 2013) settings and has predominantly focused on physiotherapy. To the author's knowledge, the effectiveness of allied health services provided in the acute hospital setting has not been compared to those provided in the sub-acute setting. The primary aim of this study was to investigate the effect of transferring a real-world weekend allied health service from the acute to sub-acute setting on patient and service outcomes following hip and knee replacement. A secondary aim was to establish whether there were any subgroup effects based on surgery type (hip or knee replacement) and/or anticipated recovery pathway (A, B or C from least to most complex).

6.2.3 Methods

Study design

This study was a sub-analysis drawn from one cluster of two multi-centre, stepped-wedge, cluster randomised trials whereby existing weekend allied health services were sequentially removed from acute medical/surgical wards one ward at a time and reallocated to other wards (Haines et al., 2015). The acute orthopaedic wards at one site were the final cluster randomised to have their weekend allied health services discontinued and reallocated to a sub-acute orthopaedic ward providing rehabilitation. Consequently, this trial created a comparative effectiveness, before-after quasi-experimental research design whereby a six-

month period of existing acute weekend allied health services (Phase 1 - 3rd February till 31st July 2014) was compared to the subsequent six-months (Phase 2 - 1st August 2014 till 31st January 2015) when these services were transferred to a sub-acute ward providing rehabilitation (Figure 6.1).

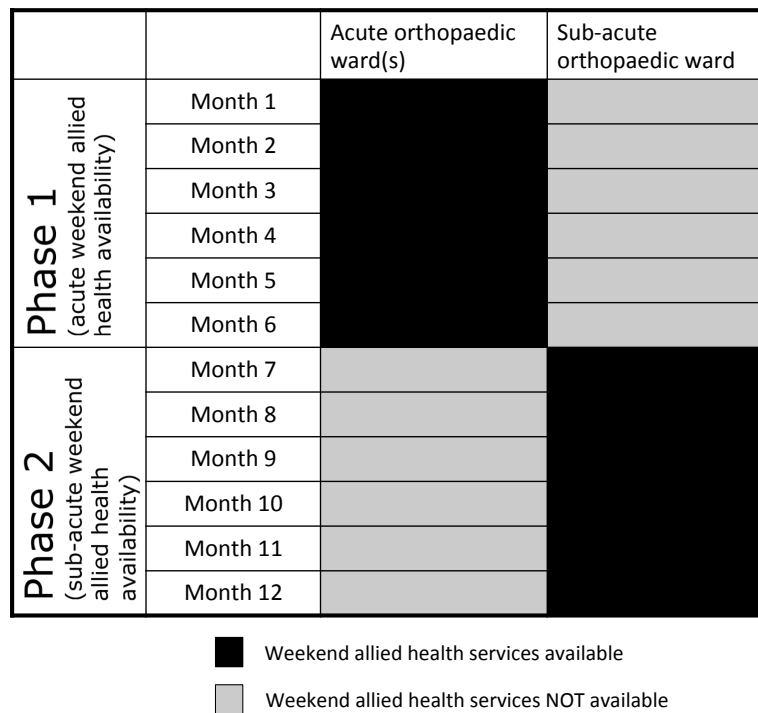


Figure 6.1: Weekend allied health services transferred from acute to sub-acute setting

Participants and setting

This study was conducted at a 520-bed public tertiary hospital situated in Melbourne, Australia and included all consenting patients who underwent elective lower limb joint replacement and were hospitalised in the designated study wards between 3rd February 2014 and 28th February 2015. Surgical procedures considered for inclusion were total hip replacement, total knee replacement and revision total hip or knee replacement. The study wards included two orthopaedic specific acute wards and one sub-acute ward where patients may be admitted following their acute stay for rehabilitation depending on clinical need. This sub-acute ward accepted orthopaedic admissions from acute wards locally including

those not involved in the trial and from other hospitals, however local admissions were usually given priority. Exclusion criteria were patients less than 18 years old, patients undergoing joint replacement immediately following trauma (e.g. fracture) and patients with moderate cognitive impairment assessed as less than or equal to 5/10 on the Short Portable Mental Status Questionnaire¹⁹. Participants were also excluded if they were admitted to an off-site ward for rehabilitation or exposed to both interventions (a weekend service in both the acute and sub-acute settings) during their hospital admission (i.e. admission dates included both July and August 2014).

Interventions

Details of each intervention are provided in Table 6-1 consistent with the TIDieR guidelines (Hoffmann et al., 2014). Phase 1 intervention comprised existing weekend allied health services (including physiotherapy, occupational therapy, dietetics, speech pathology and interventions provided by allied health assistants) provided in the two acute orthopaedic study wards. During Phase 2, these services were transferred to the orthopaedic sub-acute ward in the same hospital. Allied health services provided during weekdays remained unchanged throughout the study period.

Outcome measures

Patient- and service-related outcome measures were collected. A priori primary and secondary outcomes were not specified, as this study was part of a broader trial. Patient outcomes were assessed at six weeks postoperatively and included functional independence, mobility, pain, prescription opioid use, health-related quality of life and patient ratings of the appropriateness of length of time spent in hospital and the degree of change since surgery.

Table 6-1: Intervention conditions according to TIDieR criteria

TIDieR criteria	Phase 1 intervention	Phase 2 intervention
Brief name	Acute weekend allied health services	Sub-acute weekend allied health services
Why	The acute orthopaedic wards have the highest budget allocated to weekend allied health services in this hospital based on the organisational imperative to minimise length of stay. The service was developed in an 'ad hoc' manner and is provided for fewer hours/day and by different practitioners than those during the working week. The effectiveness of this real-world service has not been previously investigated.	Emerging evidence suggests allied health services (particularly physiotherapy and occupational therapy) provided on the weekend may be cost-effective in the rehabilitation setting but this has not been specifically investigated in patients undergoing elective lower limb joint replacement.
What (materials)	No additional physical or informational materials are used in this intervention. Discretion of individual therapists' guide materials used in day-to-day clinical practice and these should be the same as those used by allied health professionals during the week.	No additional physical or informational materials are used in this intervention. Discretion of individual therapists guide materials used in day-to-day clinical practice and these should be the same as those used by allied health professionals during the week.
What (procedures)	Allied health services may include services provided by physiotherapy, occupational therapy, social work, dietetics, speech pathology professionals and allied health assistants. Services delivered were the same as those during weekdays although fewer hours of service were available on the weekend. On average, 6 hours of physiotherapy, 4 hours of occupational therapy and 4 hours of allied health assistance were provided on each weekend day across the two acute orthopaedic wards during this phase. Services from other allied health professions were provided on an as needs basis and were shared amongst the other five acute wards. Services commonly included transfer and gait retraining, exercises to increase joint range of motion and muscle strength, discharge planning and assessment and prescription of aids and equipment.	Allied health services may include services provided by physiotherapy, occupational therapy, social work, dietetics, speech pathology professionals and allied health assistants. Services delivered were the same as those during weekdays although fewer hours of service were available on the weekend. The same budget was spent providing sub-acute weekend allied health services in this phase compared to that spent on providing acute services during Phase 1. Services commonly included transfer and gait retraining, exercises to increase joint range of motion and muscle strength, discharge planning and assessment and prescription of aids and equipment.
Who provided	All allied health professionals held a bachelor degree qualification at minimum. Weekend allied health professionals were employed on a casual or part-time basis at a grade 2 level indicating they could work autonomously. Allied health assistants do not require formal qualification but most possessed a certificate III or IV qualification(Australian Qualifications Framework Council, 2013) and all operate under the direction of an allied health professional.	The same allied health practitioners that provided weekend allied health services in the acute setting provided these services in the sub-acute setting during Phase 2 of the intervention.
How	Face to face individual patient interaction.	Face to face individual patient interaction.
Where	Either of two acute orthopaedic wards or their associated gymnasium.	The orthopaedic sub-acute ward or its associated gymnasium located in the same study hospital as the acute wards where weekend allied health services were provided during Phase 1 of the intervention.
When and how much	Individual patients received variable amounts of weekend allied health service delivery. The intensity of services was at the discretion of the treating therapist. Individual services	Individual patients received variable amounts of weekend allied health service delivery. The intensity of services was at the discretion of the

TIDieR criteria	Phase 1 intervention	Phase 2 intervention
	were allocated according to a hospital-specific priority tool based on clinical urgency and proximity to discharge. Services were referred from either allied health professionals on a Friday or nursing, medical or allied health staff throughout the weekend. 0.94 and 0.16 allied health sessions per participant hospitalised day were provided on weekends in the acute and sub-acute orthopaedic wards respectively during Phase 1. Intervention duration for each patient was not reliably collected. Treating therapists estimated intervention duration to be 30 minutes on average in the acute setting.	treating therapist. Individual services were allocated according to a hospital-specific priority tool based on clinical urgency and proximity to discharge. Services were referred from either allied health professionals on a Friday or nursing, medical or allied health staff throughout the weekend. 0.74 and 0.03 allied health sessions per participant hospitalised day were provided on weekends in the sub-acute and acute orthopaedic wards respectively during Phase 2. Intervention duration for each patient was not reliably collected. Treating therapists estimated intervention duration to be 45 minutes on average in the sub-acute setting.
Tailoring	All weekend allied health services were tailored according to the individual needs of patients being treated. This was based upon clinical judgement and determined by individual practitioners at the time.	All weekend allied health services were tailored according to the individual needs of patients being treated. This was based upon clinical judgement and determined by individual practitioners at the time.
Modifications	The intervention was not modified during the course of the study.	The intervention was not modified during the course of the study.
How well (planned)	Research assistants from the larger stepped wedge trial in which this study was nested, were present on study wards daily to monitor which wards should be receiving weekend allied health services and which should not. Patient contact statistics recorded by allied health staff daily were used to monitor intervention fidelity.	Research assistants from the larger stepped wedge trial in which this study was nested, were present on study wards daily to monitor which wards should be receiving weekend allied health services and which should not. Patient contact statistics recorded by allied health staff daily were used to monitor intervention fidelity.
How well (actual)	14 allied health sessions were provided to 9 participants in the sub-acute study ward on a weekend during the "acute weekend allied health" phase. This occurred as a result of the broader stepped-wedge cluster randomised trial in which this study was nested whereby other clusters commenced the reallocation process earlier than the orthopaedic wards.	7 acute allied health (all were physiotherapy) sessions were provided on a weekend to 3 study participants during the "sub-acute weekend allied health" phase. These services were provided to participants who had been transferred to a high dependency wards (e.g. intensive care unit) and were deemed to be too high risk to have these services withheld.

Functional independence was assessed using the Modified Barthel Index that rates a person's ability to care for him/herself based on ten activities of daily living (Shah et al., 1989). Mobility was assessed using the De Morton Mobility Index (DEMMI) which rates a person's ability to perform 15 hierarchical mobility activities ranging from sitting unsupported to tandem stand with eyes closed (de Morton, Davidson, et al., 2008). Participant self-report of perceived ability was used since strong agreement between this method and therapist rating of observed performance has been demonstrated for both these scales (Collin et al., 1988; R. Haas, Bowles, et al., 2016). Both the Modified Barthel Index and DEMMI have also been widely used and validated in orthopaedic populations across different clinical settings (T. Braun et al., 2015; de Morton et al., 2010; Ferrara et al., 2008; Fricke & Unsworth, 1997; Jans et al., 2011).

The Quadruple Visual Analogue Pain Scale (numerical rating scale) to indicate their perceived pain level right now, average pain, and pain at its best and worst over the past week on a visual analogue scale between zero and ten. Each participant was also asked whether or not they were taking prescription opioid analgesics (e.g. oxycodone) regularly.

The EuroQol questionnaire (EQ-5D-5L) (Oemar & Janssen, 2013) was used to provide a single index of utility which could then be used to calculate a cost-utility ratio in an economic evaluation. This scale is applicable to a wide range of health conditions including orthopaedics and provides a standardised measure of health status^{33, 34}. It rates five health domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) across five levels and also consists of a visual analogue scale (EQ-VAS) that rates overall health status from 0 to 100.

Patient rating of the appropriateness of total length of time spent in hospital was examined using the following question from the Victorian Patient Satisfaction Monitor (State Government of Victoria Australia, 2011-2012): ‘Was the length of time you spent in hospital too long, too short or the right amount?’ Patient rating of the degree of change since surgery was assessed using the Patients’ Global Impression of Change scale (Hurst & Bolton, 2004). This evaluates overall change in health status as perceived by the patient using a seven-point single-item scale ranging from ‘no change or worse’ to ‘a great deal better’.

Service outcomes included hospital length of stay, adverse events and unplanned hospital readmission. Total hospital length of stay (i.e. acute plus sub-acute) was measured for each participant because it has a large influence on hospital costs and is indicative of hospital efficiency (Organisation for Economic Co-operation and Development, 2013). Adverse events and unplanned hospital readmission within six weeks of discharge were also measured as markers of hospital efficiency since these are associated with detrimental patient outcomes and financial burden to the healthcare system (Axon & Williams, 2011; de Vries, Ramrattan, Smorenburg, Gouma, & Boermeester, 2008; Hoogervorst-Schilp et al., 2015). Unplanned hospital readmission may additionally be considered a sign of premature discharge and/or poor quality of care (Axon & Williams, 2011). In this study, adverse events included in-hospital falls, Medical Emergency Team calls, pulmonary embolus, deep vein thrombosis, death, hospital-acquired pressure area, and intensive care unit admission from the ward. An “all-cause” definition of hospital readmission was utilised, meaning the cause of readmission did not need to be related to the surgery (McIlvennan et al., 2015). Readmission was ascertained using the hospital database and patient interview at six weeks postoperatively to incorporate unplanned admissions to a non-study hospital.

The anticipated recovery pathway was also recorded. This was identified at the preoperative assessment based upon the Risk Assessment and Prediction Tool. This tool has been

validated as an accurate method of predicting a patient's risk of requiring extended inpatient rehabilitation after elective hip or knee replacement (Oldmeadow et al., 2003). Scores greater than 9 indicated anticipated discharge directly home from acute facility (Pathway A); between six and nine indicated acute length of stay with 4-7 day inpatient rehabilitation (Pathway B); and less than six predicted extended inpatient rehabilitation would be required (Pathway C).

Procedure

Approval to conduct this study was obtained from Monash Health Human Research Ethics Committee (Reference Number 13327B). Consecutive patients attending the hospital preoperative outpatient clinic for hip and knee joint replacement were approached for consent between 3rd February and 11th December 2014. All consenting participants provided written informed consent. Participant assessment occurred preoperatively at the time of consent and at six weeks postoperatively. Baseline measures were obtained for functional independence, mobility, health-related quality of life, pain and prescription opioid use. A professional interpreter was employed for participants upon request.

The month at which the transition between phases took place was determined randomly by an investigator blinded to ward identity as part of the broader trial in which this study was nested (Haines et al., 2015). One investigator developed pseudonyms for each ward in the broader study while another investigator blinded to the identity of each pseudonym used a computerised random number generator to allocate transition dates to each pseudonym. Participants were exposed to study conditions based on their surgery date and the subsequent dates of hospitalisation in the specific study wards but were not allocated a surgery date until after consent had been obtained. It was not possible to blind research assistants and clinicians to the intervention to which their patients were exposed.

Clinical exceptions and stopping rules were in place to ensure trial safety. A clinical exception was met if a participant fell and required post-fall review/intervention. Participants admitted to a high dependency ward during Phase 2 could also receive weekend allied services because these wards were not part of the parent trials. Stopping rules were established as part of the broader stepped wedge in which this trial was nested (Haines et al., 2015). These enabled data to be monitored monthly and the trial stopped if there was evidence of a lack of safety or efficacy associated with removing acute weekend allied health services (Ho, 1991).

Data was entered into SurveyMonkey Inc. (Palo Alto, California, USA) and exported to Microsoft Excel. Hospital outcomes were extracted into Microsoft Excel after study completion. Where possible, multiple methods (e.g. hospital databases, staff interview and nursing handovers) were employed to verify data accuracy (Sarkies et al., 2016).

Data analysis

Occasions of allied health service were summed for each participant according to profession and ward type (acute versus sub-acute). Number of allied health sessions provided per day of hospitalisation was calculated for each day of the week separately for each phase. Average duration of each allied health session was not reliably collected during the trial. Reasons for occasions where intervention fidelity was not maintained were explored using scanned medical records. Participant demographics and baseline clinical measures were compared between intervention groups using the chi-square test for categorical variables and the Mann-Whitney U test for continuous variables. EQ-5D-5L was converted to a corresponding single index value using a crosswalk link to EQ-5D-3L scale values³⁷.

Intention-to-treat data analysis was conducted. Comparisons between study phase and each outcome measure were examined separately using ordinary least squares (linear) regression

for continuous variables, ordered logistic regression for ordinal-scaled dependent variables and logistic regression for categorical variables. Two regression analyses were performed for each outcome. The first model was an unadjusted univariate regression analysis. The second model included patient age, gender, preoperative mobility and relevant baseline measure as these characteristics have been demonstrated as key predictors of outcomes following hip and knee joint replacement (D. M. Kennedy et al., 2006; Nilsson & Lohmander, 2002; Oldmeadow et al., 2003; Raut et al., 2012). In this model, adjustment was also performed for differences between groups in patient characteristics at baseline.

Patient ratings of appropriateness of total length of stay were analysed using logistic regression in two ways: 1) Comparison of “too short” versus “right amount” and “too long” and 2) comparison of “too long” versus “right amount” and “too short”. Logarithmic transformations ($x+1$ transformation (Lachin et al., 2011)) for the total length of stay outcome was conducted because the assumption of normally distributed residuals was not met. Data were clustered to account for multiple admissions of individual participants, and robust variance estimates employed (Rogers, 1994). Missing data from the six-week assessment was not included in analyses. Tests for interaction between subgroups and each dependent variable were conducted based on surgery type (hip or knee replacement) and recovery pathway (A, B or C where A was expected to be the least complicated). All statistical analyses were performed with STATA SE (STATA Corp, College Station, TX, USA) version 13.0.

Sample size

An a priori sample size was not calculated since the number of participants in this study was dependent on the number of surgeries conducted during this time. A post hoc power analysis revealed this study had 80% power to detect a 2-day difference in length of stay (Peiris et al., 2013) based on the observed standard deviations and sample sizes ($\alpha \leq 0.05$).

6.2.4 Results

Study participants

Participant flow through the study and loss to follow-up are presented (Figure 6.2). A total of 247 participants underwent surgery during the study period, 117 during Phase 1 (acute weekend allied health service availability) and 130 during Phase 2 (sub-acute weekend allied health service availability). There were differences between groups at baseline for surgery day of week, time from preoperative assessment till surgery, mobility and incidence of pulmonary conditions (Table 6-2).

Intervention fidelity

Seventy-one percent (83/117) of Phase 1 participants received acute weekend allied health services. During Phase 2, 70 out of 130 participants were discharged to the sub-acute setting where 53 of these (76%) received sub-acute weekend allied health services. The rate of allied health service provision per participant day in hospital across these settings and study phases is presented (

Figure 6.3). Intervention fidelity was achieved for 92.3% and 97.7% of participants in phases one and two respectively (Table 6-1).

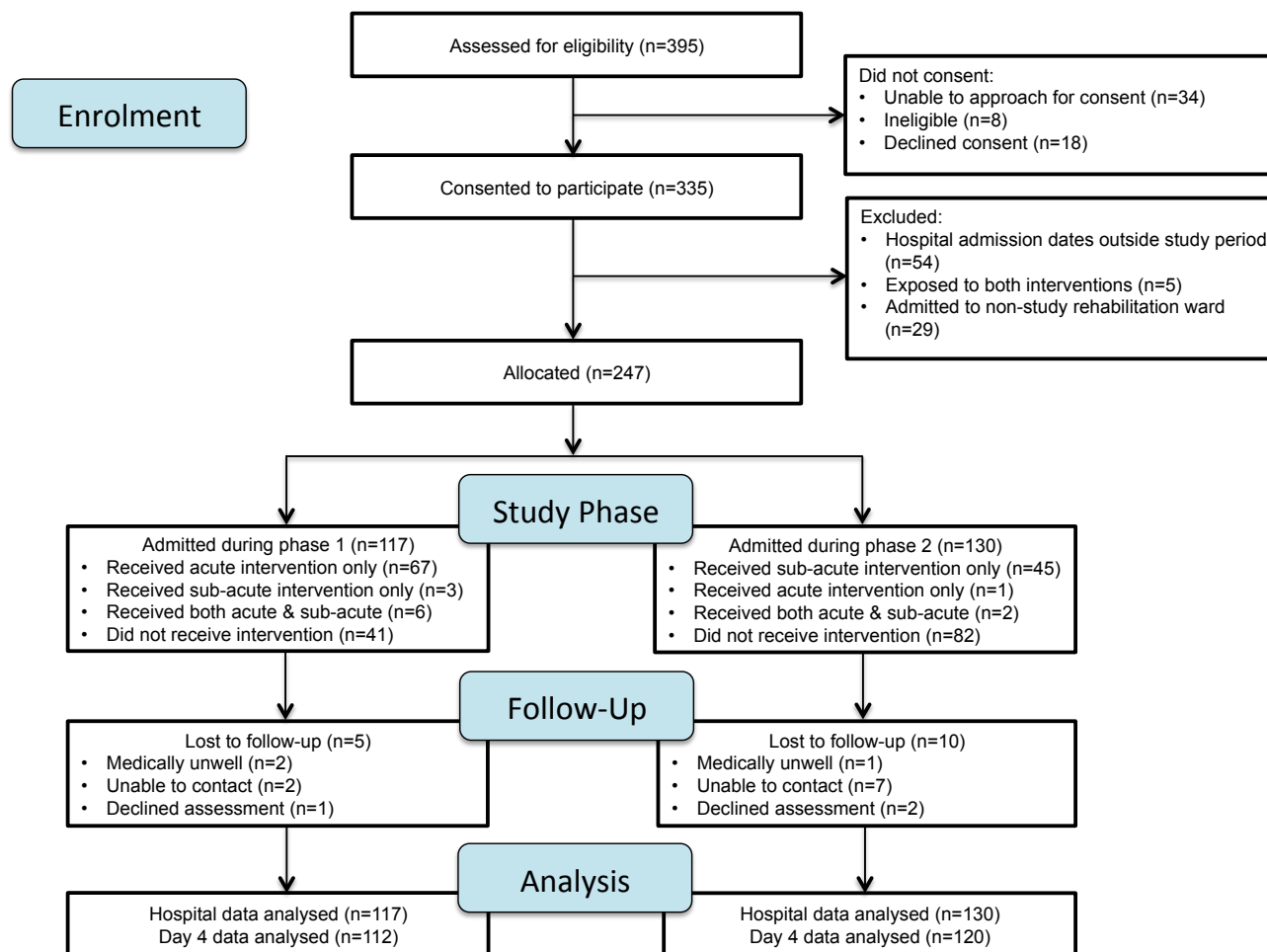


Figure 6.2: Flow of participants

Table 6-2: Participant demographics and baseline clinical measures

Characteristic	Phase 1 (n=117)	Phase 2 (n=130)
Age in years, mean (SD)	67.21 (10.99)	68.00 (10.34)
Female, n (%)	64 (55)	77 (60)
Request for interpreter, n (%)	7 (6)	13 (10)
Surgery type, n (%)		
Total knee replacement	58 (50)	81 (62)
Total hip replacement	55 (47)	42 (32)
Revision knee replacement		2 (2)
Revision hip replacement	4 (3)	5 (4)
Surgery day of week, n (%)		
Monday	8 (7)	10 (8)
Tuesday	14 (12)	11 (8)
Wednesday	9 (8)	19 (15)
Thursday	26 (22)	13 (10)*
Friday	14 (12)	26 (20)
Saturday	46 (39)	51 (39)
Time from preoperative assessment to surgery (days), median (IQR)	23.12 (15.23-35.20)	35.69 (22.35-58.34)*
Pathway†, n (%)		
A	63 (54)	54 (42)
B	39 (33)	60 (46)
C	15 (13)	16 (12)
Comorbidities‡, n (%)		
Cardiovascular	20 (17)	27 (21)
Neurological	10 (9)	6 (5)
Diabetes	19 (16)	29 (22)
Mental Health	15 (13)	18 (14)
Malignancy	7 (6)	14 (11)
Pulmonary	3 (3)	17 (13)*
Obesity (BMI>35)	8 (7)	14 (11)
Prior hip or knee joint replacement	40 (34)	39 (30)
Preoperative DEMMI total, median (IQR)	62 (53-74)	74 (57-85)*
Preoperative Modified Barthel index, median (IQR)	100 (96-100)	100 (98-100)
Preoperative EQ5D Utility Index, median (IQR)	0.548 (0.305-0.691)	0.554 (0.319-0.704)
Preoperative EQ5D VAS, median (IQR)	67 (50-80)	70 (50-80)
Preoperative pain now, median (IQR)	5 (1-7)	4.75 (1.375-6.125)
Preoperative pain average, median (IQR)	6 (5-7)	5 (4.5-7)
Preoperative pain best, median (IQR)	3.5 (0-5)	3 (0-5)
Preoperative pain worst, median (IQR)	8 (7.5-10)	9 (7.5-10)
Preoperative opioid use, n (%)	35 (30)	54 (42)

Abbreviations: n, number of hospital admissions; DEMMI, de Morton Mobility Index; EQ5D, EuroQol five dimensions; VAS, Visual Analogue Scale.

* Indicates difference between groups is statistically significant for this variable

† Pathway indicates expected postoperative recovery pathway. A indicates discharge directly home from acute facility. B indicates acute length of stay with inpatient rehabilitation 4-7 days. C indicates inpatient rehabilitation ≥ 14 days

‡ Participants may have multiple comorbidities

Intention-to-treat analyses

Raw values are presented in Table 6-3 and statistical analyses in Table 6-4. The majority of allied health sessions received by this population were from physiotherapists, occupational therapists and allied health assistants. At six weeks postoperatively, the “worst pain experienced over the past week” was higher in participants who had weekend allied health services available in the sub-acute compared to the acute setting [coefficient 0.865 (0.123 to 1.606), $p=0.022$].

Subgroup analyses

No interaction effects across surgery type or recovery pathway subgroups were observed.

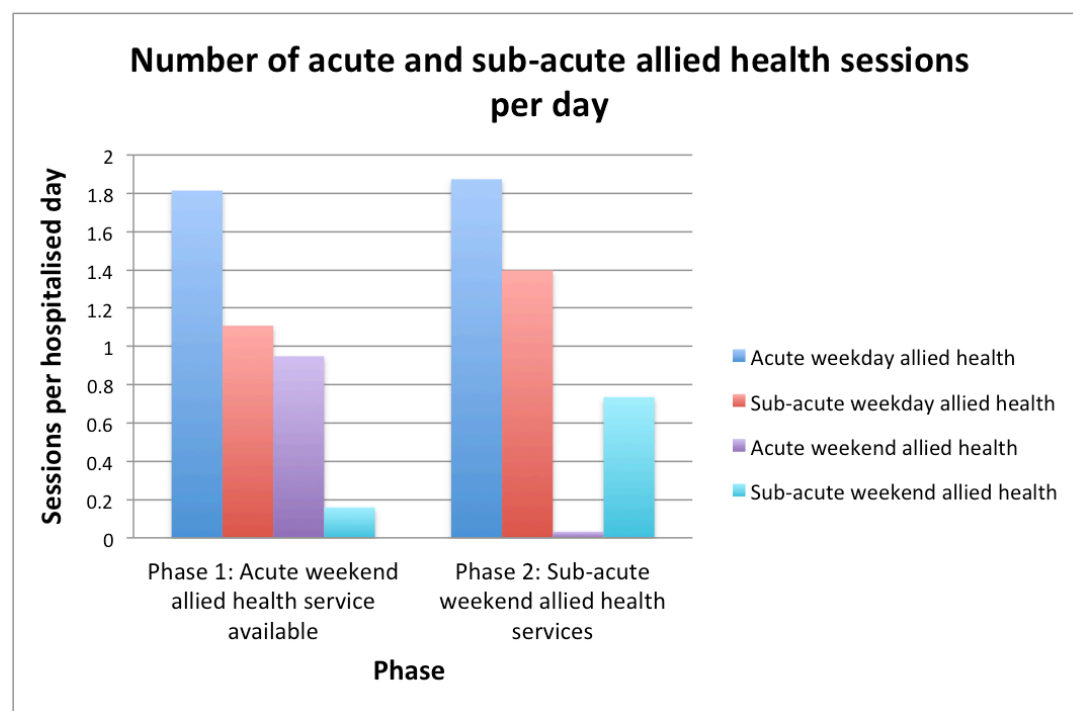


Figure 6.3: Number of allied health sessions per hospitalised day in each phase

Table 6-3: Raw data

Outcome Measure	Phase 1		Phase 2	
Total hospitalisation length of stay (days), mean (SD)	8.13 (7.12)	n=117	8.32 (5.23)	n=130
Log(x+1) total hospitalisation length of stay (days), mean (SD)	2.02 (0.58)	n=117	2.09 (0.53)	n=130
Pathway A* total length of stay, mean (SD)	4.88 (3.48)	n=63	4.56 (2.73)	n=54
Pathway B† total length of stay, mean (SD)	9.46 (5.28)	n=39	9.69 (2.87)	n=60
Pathway C‡ total length of stay, mean (SD)	18.28 (11.31)	n=15	15.86 (7.55)	n=16
Adverse Events§, n (%)	15 (12.82)	n=117	15 (11.54)	n=130
Unplanned hospital readmission, n (%)	12 (10.26)	n=117	14 (10.77)	n=130
6 week Outcomes				
Modified Barthel Index – median (IQR)	100 (98-100)	n=112	100 (100-100)	n=120
DEMMI – median (IQR)	67 (57-85)	n=112	67 (57-85)	n=120
EQ5D utility – median (IQR)	0.722 (0.641-0.826)	n=112	0.737 (0.631-0.837)	n=120
EQ5D VAS – median (IQR)	80 (70-90)	n=112	80 (70-90)	n=120
Pain now – median (IQR)	0 (0-2.375)	n=112	1.5 (0-3.5)	n=120
Pain average – median (IQR)	2 (0.25-3.375)	n=112	2.5 (0-4.5)	n=120
Pain best – median (IQR)	0 (0-0)	n=112	0 (0-2)	n=120
Pain worst – median (IQR)	4 (2-5.875)	n=112	5 (2-8)	n=120
Opioid – n (%)	33 (29)	n=112	39 (33)	n=120
Appropriateness of length of stay, n (%)		n=108		n=120
Too short	26 (24%)		19 (16%)	
Right amount	76 (70%)		96 (80%)	
Too long	6 (6%)		5 (4%)	
Degree of change since surgery, n (%)		n=112		n=120
No change or worse	9 (8%)		13 (11%)	
Almost the same	5 (4%)		5 (4%)	
A little better	3 (3%)		1 (1%)	
Somewhat better	8 (7%)		10 (8%)	

Outcome Measure	Phase 1		Phase 2	
Moderately better	12 (11%)	n=112	16 (13%)	n=120
Better and a definite improvement	29 (26%)		21 (18%)	
A great deal better	46 (41%)		54 (45%)	
Acute allied health sessions, n (% total sessions)		n=117		n=130
Physiotherapy	443 (45%)		361 (47%)	
Occupational therapy	184 (19%)		195 (25%)	
Allied health assistant	352 (36%)		217 (28%)	
Speech pathology	0 (0%)		1 (<1%)	
Social work	3 (<1%)		3 (<1%)	
Dietetics	3 (<1%)		5 (<1%)	
Sub-acute allied health sessions, n (% total sessions)		n=117		n=130
Physiotherapy	174 (54%)		350 (52%)	
Occupational therapy	79 (24%)		208 (31%)	
Allied health assistant	52 (16%)		97 (14%)	
Speech pathology	1 (<1%)		3 (<1%)	
Social work	16 (5%)		6 (1%)	
Dietetics	4 (1%)		12 (2%)	

Abbreviations: n, number of hospital admissions; DEMMI, de Morton Mobility Index; EQ5D, EuroQol five dimensions; VAS, Visual Analogue Scale.

* Pathway A indicates discharge directly home from acute facility

† Pathway B indicates acute length of stay with inpatient rehabilitation 4-7 days

‡ Pathway C indicates inpatient rehabilitation ≥ 14 days

§ Participants who experienced 1 or more adverse event

Table 6-4: Intention-to-treat analyses

Outcome Measure	Model 1 Unadjusted [‡] Regression Coefficient (95% CI), p value	Model 2 Adjusted [†] Regression Coefficient (95% CI), p value
Total hospitalised length of stay – log(1+x) transformed	0.076 (-0.062 to 0.213), 0.279	0.127 (-0.005 to 0.259), 0.059
Adverse Events [‡] , n (%)	-0.123 (-0.890 to 0.645), 0.754)	-0.247 (-1.341 to 0.847), 0.658
Unplanned hospital readmission, n (%)	OR=1.056 (0.478 to 2.332), 0.893	OR=0.844 (0.312 to 2.289), 0.740
Modified Barthel Index	0.176 (-0.527 to 0.879), 0.622	0.134 (-0.663 to 0.931), 0.741
DEMMI	0.328 (-3.375 to 4.031), 0.862	-2.079 (-5.772 to 1.614), 0.268
EQ5D utility	0.016 (-0.034 to 0.066), 0.525	-0.002 (-0.059 to 0.055), 0.943
EQ5D VAS	-2.207 (-6.163 to 1.748), 0.273	-2.765 (-6.938 to 1.409), 0.193
Pain now	0.616 (0.103 to 1.130), 0.019 [§]	0.355 (-0.229 to 0.939), 0.232
Pain average	0.489 (-0.007 to 0.985), 0.053	0.326 (-0.216 to 0.867), 0.237
Pain best	0.340 (-0.033 to 0.713), 0.073	0.390 (-0.060 to 0.840), 0.089
Pain worst	1.031 (0.303 to 1.759), 0.006 [§]	0.865 (0.123 to 1.606), 0.022 [§]
Opioid	OR=1.153 (0.678 to 1.959), 0.600	OR=1.299 (0.554 to 3.045), 0.547
Appropriateness of length of stay – “too short” vs “right amount” and “too long”	OR=0.593 (0.309 to 1.14), 0.117	OR=0.752 (0.362 to 1.559), 0.443
Appropriateness of length of stay – “too long” vs “right amount” and “too short”	OR=0.739 (0.245 to 2.234), 0.592	OR=0.729 (0.162 to 3.278), 0.681
Degree of change since surgery	0.002 (-0.455 to 0.46), 0.992	0.156 (-0.436 to 0.748), 0.605

Abbreviations: n, number of hospital admissions; DEMMI, de Morton Mobility Index; EQ5D, EuroQol five dimensions; VAS, Visual Analogue Scale.

Regression coefficient indicates greater or lesser unit of outcome measure (depending on positive or negative value respectively) for participants who had sub-acute weekend allied health services available compared to those participants who had acute weekend allied health services available

[‡] Model 1 - Unadjusted

[†] Model 2 - Adjusted for time from preoperative assessment till surgery, surgery day of week, preoperative mobility, pulmonary comorbidities, age, gender and corresponding baseline value if applicable.

[‡] Participants who experienced 1 or more adverse events.

[§] Indicates difference between groups is statistically significant for this variable.

6.2.5 Discussion

Higher patient ratings of “worst pain experienced over the past week” at six weeks postoperatively were observed in study participants hospitalised during Phase 2 (sub-acute weekend allied health service availability) rather than Phase 1 (acute weekend allied health service availability). However, one could question the clinical importance of this difference given the 8mm magnitude of change observed on the visual analogue scale is below the 30% estimated clinically significant change that has been previously reported (Farrar et al., 2001). No other differences in hospital or patient outcomes were observed between the two study groups, suggesting there was no comparative advantage or disadvantage achieved by allocating a weekend allied health budget to the sub-acute instead of the acute setting. Results were consistent across hip and knee joint replacement cohorts. A 2.4-day reduction in total hospital length of stay was observed amongst complex Pathway C patients during Phase 2 compared to Phase 1, although there was no interaction effect between expected recovery pathway and length of stay. Consistent with other studies (Klapwijk, Mathijssen, Van Egmond, Verbeek, & Vehmeijer, 2017; Van Egmond, Verburg, & Mathijssen, 2015), this study also demonstrated similar or improved patient functioning, pain and quality of life at six weeks postoperatively compared to preoperative values.

To the author’s knowledge, this is the first study to compare the effects of a weekend allied health service provided in a sub-acute versus an acute setting. Five previous studies (Brusco et al., 2007; Caruana et al., 2016; DiSotto-Monastero, Chen, Fisch, Donaghy, & Gomez, 2012; Hakkennes, Lindner, & Reid, 2014; Peiris et al., 2013) have compared the addition of a weekend allied health service to that of a weekday service in a sub-acute setting, of which

four have demonstrated favorable outcomes with respect to balance (Caruana et al., 2016), function (Caruana et al., 2016; DiSotto-Monastero et al., 2012; Hakkennes et al., 2014; Peiris et al., 2013), quality of life (Peiris et al., 2013), patient flow (DiSotto-Monastero et al., 2012; Hakkennes et al., 2014) and cost-effectiveness (Brusco, Watts, Shields, & Taylor, 2014). None of these studies demonstrated a statistically significant ($\alpha \leq 0.05$) difference in sub-acute length of stay despite mean differences favouring the weekend service group ranging between 1.5 and 3.2 days. The present study has extended this evidence base by examining the effect across the health care continuum (rather than focusing only on sub-acute length of stay) and finding no difference in total length of hospitalisation. However, the previous studies all compared the addition of a sub-acute weekend service to a weekday service alone (rather than an acute weekend service as in the present study). Most previous studies also examined the addition of a Saturday only service (Brusco et al., 2007; Caruana et al., 2016; Hakkennes et al., 2014; Peiris et al., 2013) as opposed to the two-day weekend service examined in the present study. Furthermore, the majority of previous studies examined an allied health service comparable to weekdays in amount of therapy provided (Brusco et al., 2007; DiSotto-Monastero et al., 2012; Peiris et al., 2013) and were conducted in a mixed rehabilitation unit that included only a small proportion of patients following hip and knee replacement. Only one previous study (DiSotto-Monastero et al., 2012) has examined the effect of a seven-day allied health service on subgroups of patients undergoing hip and knee replacement. However, this was a cross-sectional retrospective electronic data review where the results were not adjusted for individual patient characteristics and subject to bias.

The key contribution of this study is that it attempts to directly inform health care decision-making and resource allocation by comparing two accepted settings in which weekend allied

health services are provided following hip and knee replacement for which there is unknown superiority. No advantage or disadvantage with respect to the hospital or patients in this study was found by transferring weekend allied health services from the acute to the sub-acute setting. That is, investing the weekend allied health budget in the sub-acute setting was neither more nor less effective than investing it in the acute setting for patients following hip or knee joint replacement. This is not to say that these services are not effective when compared to no weekend allied health service provision.

In the present study, it was interesting to note that results for the more complex pathway C patients were trending towards favouring the sub-acute weekend allied health service provision model (Phase 2). According to the Risk Assessment and Prediction Tool used in this study, these complex patients are likely to have three or more of the following preoperative risk factors: over 75 years of age; male; housebound most of the time; require a frame to assist walking; receive community supports two or more times per week; and/or do not live with someone who can care for them postoperatively (Oldmeadow et al., 2003). Although analyses involving this subgroup were underpowered, a 2.4-day difference in total length of stay (Table 6-3) could improve patient flow and reduce costs by AUD\$2426 per patient (Independent Hospital Pricing Authority, 2017). Prioritising more complex patients post hip and knee replacement to receive weekend allied health services in a sub-acute setting is likely to reduce hospital length of stay without compromising patient outcomes. Further research examining the cost-effectiveness of sub-acute weekend allied health services for complex patients following hip and knee replacement is therefore warranted.

The main strengths of this study were the pragmatic nature of the interventions examined, that the same staff with similar resources provided the service in both settings, its high participant recruitment and retention rate and that patient-level outcomes at six weeks postoperatively were considered in addition to length of stay. Previous research has demonstrated length of stay may be influenced by different payment classifications and patient expectations regarding length of stay after elective surgery (Liu, Phillips, & Codde, 2001) and may therefore be subject to these factors rather than the interventions explored in this study. Baseline characteristics of those lost to follow-up were similar to those retained.

The principal limitation of this study was that the quantity of weekend allied health provision provided in the sub-acute setting during Phase 2 might have varied on a monthly basis according to the stepped-wedge of the broader trial in which this study was nested. This is because this study was nested within a broader trial whereby five other clusters (wards) also reallocated their weekend allied health services to the sub-acute orthopaedic ward though this only occurred after services were first reallocated and saturated in an acute assessment ward. On balance, intervention fidelity within the present study can be considered high given the quantities of allied health provided in the acute and sub-acute settings. There were fewer occasions of weekend allied health service provided per participant hospitalised during Phase 2 compared to Phase 1 (

Figure 6.3), but there were also fewer sub-acute compared to acute allied health sessions provided during the weekdays. It is possible this may have been partially influenced by a longer allied health session time in the sub-acute setting compared to the acute setting. This is supported by anecdotal evidence from the treating physiotherapists, occupational

therapists and allied health assistants in this study. Care should also be taken in generalising the results of this study to settings in which inpatient rehabilitation in the sub-acute setting following joint replacement are uncommon (Buhagiar et al., 2017).

6.2.6 Conclusion

Transferring weekend allied health services from the acute to the sub-acute setting did not substantially affect any of the observed patient or hospital outcomes following hip and knee replacement. Further research examining the cost-effectiveness of weekend allied health service models in the sub-acute setting may be warranted for complex patients undergoing hip or knee replacement.

Chapter 7 – Summary of findings and conclusion

7.1 Introduction

The quest to develop and provide evidence-based healthcare services to patients undergoing joint replacement surgery was central to this thesis. This body of research built on a background understanding that weekend hospital services are inherently different from those provided during the week and the body of evidence suggesting that health outcomes may be negatively impacted by the day of admission or surgery. The overarching aim of this thesis was to evaluate patient and hospital outcomes from provision of a ‘real-world’ weekend allied health service in the acute phase after lower limb joint replacement surgery. This chapter integrates key findings from the systematic literature review and the subsequent research described in this thesis and also considers the strengths and limitations of this research, and future research directions.

7.2 Patient and therapist interrater agreement of mobility

A high level of agreement was observed between patient self-report and therapist-assessed performance of mobility using the de Morton Mobility Index, especially for those with impaired levels of mobility. This suggests patient self-report of anticipated performance is an acceptable proxy for de Morton Mobility Index scores derived from therapist rating of performance and can therefore be used to measure mobility remotely when clinical contact is not feasible. Self-report of anticipated performance is especially likely to be an acceptable proxy for performance-based de Morton Mobility Index scores for patients during the early postoperative period following lower limb joint replacement since patients commonly

experience impaired mobility during this time (Klapwijk et al., 2017; Van Egmond et al., 2015). Studies 3 and 4 of this thesis (chapters 5 and 6 respectively) were the first known studies to use patient self-report of mobility using the de Morton Mobility Index.

7.3 Relationships between a weekend allied health service, quantity and timing of allied health commencement and outcomes following lower limb joint replacement

Allied health services are multi-dimensional and complex, with regard to composition of therapies, quantity of intervention and timing of commencement postoperatively. This section integrates the current knowledge relating to relationships between weekend allied health service provision, timing of allied health commencement and allied health quantity, and outcomes of care following hip and knee replacement (Figure 7.1).

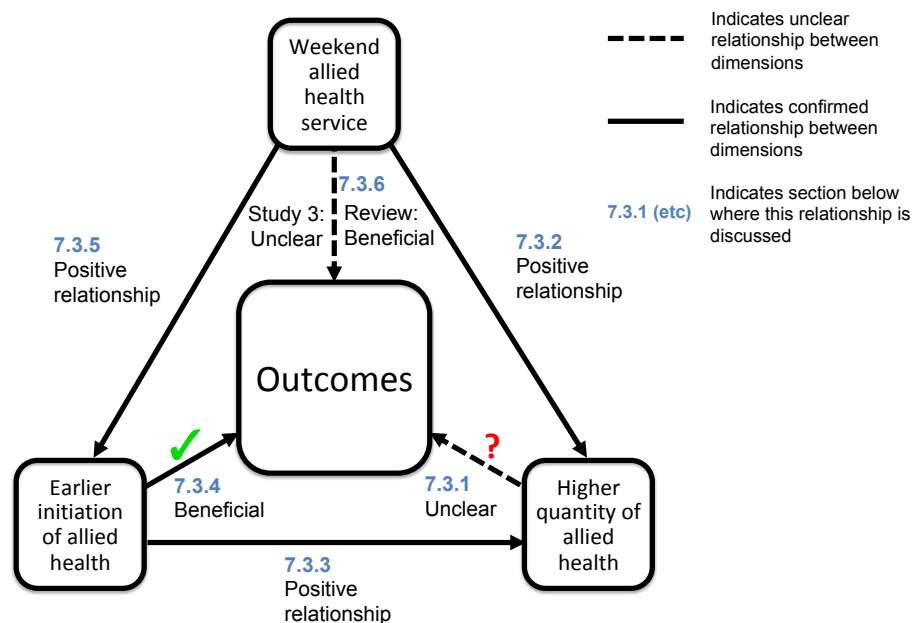


Figure 7.1: Findings within the context of multi-dimensional nature of allied health

7.3.1 Effect of increasing the quantity of allied health intervention on outcomes

The systematic literature review identified two randomised controlled trials that evaluated the effect of increasing physiotherapy frequency from once-daily to twice-daily following total hip and knee replacement. Although no effect on acute hospital length of stay or function was identified, there remains insufficient information from which to adequately investigate a potential dose-response relationship (7.3.1 on Figure 7.1). This is in contrast to a previous subgroup meta-analysis of a mixed patient cohort that found an extra 19 minutes of physiotherapy per day reduced length of stay by one day in acute settings (Peiris et al., 2011). However, the majority of participants in this meta-analysis conducted by Peiris et al were patients following stroke, and the additional therapy was achieved from a combination of increased duration, frequency and additional days (e.g. weekend).

7.3.2 Effect of a weekend allied health service on the quantity of allied health

The systematic literature review identified three studies that all found an increased quantity of physiotherapy during their acute length of stay (Boxall et al., 2004; Liang et al., 1987; Maidment et al., 2014) among patients who received an acute weekend physiotherapy service. However, the total quantities reported in these studies may be confounded by longer length of stay. In addition, the total quantity reported in one study was only reported descriptively (Liang et al., 1987). Study 3 (Chapter 5) demonstrated provision of a weekend allied health service was associated with a statistically significant increase in allied health session rate per inpatient day (7.3.2 on Figure 7.1). However, the magnitude of this difference was very small (less than 0.5 session per inpatient day). This finding is unlikely to

have any effect on outcomes following lower limb joint replacement since the review findings demonstrated no effect from increasing physiotherapy rate from once to twice daily (i.e. an increase of one session per day).

7.3.3 Effect of earlier postoperative commencement of allied health on allied health quantity

The systematic literature review identified one study that demonstrated a greater number of mean physiotherapy and occupational therapy visits per day of hospitalisation in the accelerated rehabilitation group compared to standard care (Robbins et al., 2014). However, this comparison was only reported descriptively. Study 3 (Chapter 5) of this thesis demonstrated patients who commenced allied health earlier received a significantly higher rate of allied health services throughout the acute hospitalisation (7.3.3 on Figure 7.1). However, the magnitude of this difference was very small (approximately 0.3 session per inpatient day), and unlikely to have any effect on lower limb joint replacement outcomes.

7.3.4 Effect of earlier postoperative commencement of allied health on outcomes

The systematic literature review demonstrated earlier commencement of physiotherapy reduced length of stay by more than one day and resulted in a higher probability of discharge directly home (7.3.4 on Figure 7.1). Since publication, two additional systematic reviews have supported these favourable results (Henderson, Wallis, & Snowdon, 2017; Masaracchio et al., 2017). A review by Masaracchio et al (2017) found early initiation of physiotherapy following total hip replacement, total knee replacement, or unicompartmental knee replacement was associated with a shorter length of stay (nine studies), a lower overall cost

(4 studies) and no evidence of an increased number of adverse reactions (11 studies). A review of randomised controlled trials by Henderson et al (2017) demonstrated accelerated physiotherapy regimens were the most effective active physiotherapy intervention in the acute hospital or inpatient rehabilitation setting for adults who have undergone total knee replacement (3 studies, n=447). In this review “accelerated physiotherapy”, defined as intervention commencing within 24 hours of surgery and occurring more than 24 hours prior to standard care, was associated with a shorter acute hospital length of stay by approximately three days.

The common treatment focus of all the studies included in the above systematic literature reviews is early mobilisation. Early mobilisation as opposed to early physiotherapy intervention following hip and knee joint replacement is supported in a previous systematic literature review (Guerra et al., 2014). In this review, a meta-analysis of five randomised controlled trials (n=622) found earlier compared to later mobilisation reduced acute length of stay by 1.8 days following hip and knee joint replacement surgery. In four out of the five trials the experimental group first sat out of bed within 24 hours and walked within 48 hours postoperatively. Early mobilisation is also recommended following an evidence-based review of clinical care for elective primary hip and knee replacements according to National Health and Medical Research Council (NHMRC) grades of recommendations, although it is noted that the optimal timing, intensity and frequency were under-investigated (Mak et al., 2014).

Another aspect of early mobilisation that has been under-investigated is which staff should perform this role and how this should be managed within an interdisciplinary team approach. Three of the five randomised controlled trials included in the systematic review conducted by Guerra et al (2014) examining the effect of early mobilisation on length of stay following joint replacement did not specify which staff were responsible for facilitating mobilisation. Physiotherapists were responsible for commencing day of surgery mobilisation in the other two trials included in this review. The research program in this thesis has provided some preliminary insights in this area, although further investigation is necessary before clear recommendations can be made. The findings of studies 2 and 3 (reported in chapters 4 and 5, respectively) suggest that although physiotherapists are considered specialists and are primarily responsible for patient mobility in the acute hospital setting, there may be scope for other professions to contribute to this shared postoperative goal following hip and knee replacement. In particular, Study 2 identified that health professionals perceived nurses were capable of assisting mobilisation for the first time postoperatively, especially in high functioning, uncomplicated patients. Study 3 identified that although the removal of weekend allied health services may have created a stimulus for nurses to be more involved in promoting early postoperative transfers, this occurred approximately four hours later post-surgery compared to when weekend allied health services were available. Although further investigation is required to determine if this is a clinically important delay, early mobilisation and allied health intervention are both associated with beneficial outcomes (Guerra et al., 2014; R. Haas, Sarkies, et al., 2016; Henderson et al., 2017; Masaracchio et al., 2017).

7.3.5 Effect of a weekend allied health service on timing of therapy commencement

No studies included in the systematic literature review examined the effect of a weekend physiotherapy service on timing of therapy initiation. Study 3 (Chapter 5) of this thesis demonstrated that participants hospitalised when an acute weekend allied health service was provided commenced allied health 0.8 days earlier than those hospitalised when this service was not provided (7.3.5 on Figure 7.1). This suggests an acute weekend allied health service may have favourable benefits mediated by the earlier commencement of therapy given that early allied health commencement is associated with beneficial outcomes following hip and knee replacement surgery. Based on these findings, the amount of benefit obtained from a weekend allied health service is likely to vary depending on whether or not joint replacement surgeries are performed on a Friday and Saturday. This has implications for scheduling allied health services around surgery timetables. In the current study setting, 58% of hip and knee replacement surgeries were conducted on a Friday or Saturday. Therefore, a weekend allied health service may be important in ensuring timely postoperative allied health commencement at this location.

7.3.6 Effect of a weekend allied health service on outcomes following hip and knee joint replacement

The systematic literature review identified that the addition of a weekend physiotherapy service resulted in a one-day reduction in length of stay and a small increase in function in patients following hip and knee joint replacement. However, it is possible that this effect may have been partially or completely mediated by earlier initiation of therapy.

The research conducted in Study 3 as part of this thesis generated findings that were not completely consistent with those derived from the systematic literature review. Study 3 demonstrated contrasting results in patients who were hospitalised during the provision of a weekend allied health service compared to those who were hospitalised when this service was temporarily withdrawn. In particular, the weekend allied health service appears to have had favourable impacts on discharge destination (greater likelihood of discharge directly home rather than to inpatient rehabilitation) and patient mobility but unfavourable impacts on patient-perceived helpfulness of hospitalisation and acute length of stay. Statistical adjustment demonstrated these effects were all independent of timing of therapy initiation and therapy quantity suggesting another mechanism may be responsible for these effects. Consistency was observed across univariate and multivariable models with all outcome measures with the exception of acute length of stay. The longer acute length of stay observed during the provision of the weekend allied health service was only statistically significant in models including adjustments for allied health session rate and timing of commencement. This is counter-intuitive given the positive relationship observed between the weekend allied health service and earlier timing of therapy commencement and increased therapy quantity, creating some ambiguity as to the causal relationships between these factors.

In Study 3, physiotherapists rather than nurses were more likely to assist with the first postoperative transfer when allied health services were available and this also occurred earlier. The earlier commencement may help to explain the small increase in mobility observed. These effects were only evident in statistical models without adjustment for allied health timing and intensity. This finding suggests these observed effects may be mediated by the earlier commencement and/or the greater intensity of allied health rather than the day(s)

of week when therapy was available. In light of previous research (including the systematic review conducted as part of this thesis), these results are more likely to be mediated by the earlier commencement of allied health rather than the increased quantity.

7.3.7 Potential explanations for discrepancies in findings

Differences in the effect of a weekend allied health service on outcomes following lower limb joint replacement surgery were observed between the systematic literature review and Study 3 (Chapter 5) conducted as part of this thesis. It is possible that the following variations in study conditions may explain these differences. Study 3 examined a real-world weekend allied health service where the quantity of allied health provided was approximately 30-40% of that provided on weekdays. In comparison, studies identified within the review provided a similar quantity of physiotherapy on the weekend as during the week. Study 3 was conducted in the context of the removal of a service rather than the addition, which was the case in the studies included in the review. Study 3 examined the effect of a weekend allied health team including physiotherapists, occupational therapists and allied health assistants rather than physiotherapists alone. It is possible the discharge planning processes may have been affected by having a greater number of professional disciplines involved. Study 2 identified that the all health professionals perceived the role of physiotherapists and occupational therapists to be able to assist with the discharge planning process. This may have manifested in multiple team members being asked to provide approval prior to discharging a patient home and subsequently could have increased acute length of stay by delaying discharge. Consistent with the findings of Study 3, it is possible that patients may have been more likely to be transferred to an inpatient rehabilitation facility when allied health professionals were not available on the weekend to approve

patient discharge home. Inpatient rehabilitation was also available at the same hospital site in Study 3; however, the availability and effect on inpatient rehabilitation was not considered in the studies identified within the systematic literature review.

The overall effect of the weekend allied health service (compared to no weekend service) remains unclear due to the combination of both favourable and unfavourable effects observed across different outcome measures. The next section gives context to the quantitative findings by describing the health professionals' perceptions of the allied health service provided following hip and knee replacement.

7.4 Health professionals' perceptions of the allied health service following joint replacement

The main theme that emerged from Study 2 was a sense of unrealised potential amongst health professionals in terms of patient outcomes following hip and knee joint replacement surgery. Interviewee responses suggest there may be several ways of optimising allied health service delivery models on both weekdays and weekends to improve patient outcomes. The health professionals interviewed in Study 2 identified the following five areas where they perceived allied health service provision could potentially achieve a more efficient and/or equitable service:

- Prioritise provision of early rehabilitation interventions in addition to facilitating discharge.
- Commence postoperative mobilisation on the day of surgery.
- Incorporate an interdisciplinary approach.

- Provide rehabilitation opportunities to patients waiting for transfer to an inpatient rehabilitation facility.
- Redistribute current allied health resources to achieve an overlapping 7-day allied health service with staggered starts to the working week to ensure patient equity.

The suggestion to commence postoperative mobilisation on the day of surgery following hip and knee replacement is evidence-based. Further work to encourage implementation of early mobilisation evidence into practice at the study hospital is recommended. The other suggestions are yet to be explored. However, in light of previous research and support for interdisciplinary teamwork to promote early mobilisation (Czaplijski, Marshburn, Hobbs, Bankard, & Bennett, 2014), 7-day healthcare models (Lapointe-Shaw & Bell, 2013), and the role of allied health to maximise functional independence (Duckett & Breadon, 2014), these suggestions warrant further investigation.

Overall, Study 2 found the role of allied health following elective surgery may be different to that following unplanned admission in the general acute setting, and may therefore require separate priority tools. It concluded allied health intervention targeted to low functioning and/or complex patients could be a more efficient use of allied health expertise than the observed current practice in this setting of prioritising service delivery according to its perceived potential to facilitate patient discharge.

7.5 Alternate allied health service models

No comparative advantage or disadvantage was observed by allocating a cost-neutral weekend allied health budget to the sub-acute rather than the acute setting for patients

undergoing hip and knee replacement surgery. This study was conducted from a health service model perspective rather than that of the individual patient. The results for the more complex Pathway C patients (who were more likely to be older, have significant mobility limitations and require community support preoperatively) were trending towards favouring the sub-acute weekend allied health service model. Although analyses involving this subgroup were underpowered (n=31, 13% of the cohort), total length of stay was 2.4 days shorter for these patients undergoing surgery when weekend allied health services were provided in the sub-acute setting. This difference could have substantial cost ramifications for hospitals [\$2426 per patient (Independent Hospital Pricing Authority, 2017)] and suggests that prioritising more complex patients (Pathway B and C) to receive weekend allied health services in the sub-acute setting following hip and knee replacement is likely to reduce hospital length of stay without compromising patient outcomes including functional independence, mobility, health-related quality of life and pain. The health professionals interviewed in study 2 also suggested prioritising these more complex patients in the acute setting.

7.6 Strengths and limitations of the research program

7.6.1 Strengths

The key strength of this PhD research program is that it extends previous research evaluating the effect of acute weekend allied health services on outcomes following elective hip and knee replacement surgery. It does this by addressing a number of the limitations identified from earlier studies included in the systematic literature review. First, this research program examined an acute weekend allied health service that is consistent with usual practice in countries such as Australia and Canada (L. Campbell et al., 2010; Ottensmeyer et al., 2012;

Shaw et al., 2012) and therefore more likely to represent contemporary care. Second, this research program examined the cumulative effect of the weekend allied health service rather than that of physiotherapy alone, which rarely exists in isolation. Third, this research program sought to understand the weekend allied health service within the context of the overall acute service provided to patients undergoing elective hip and knee replacement surgery. Fourth, this research program evaluated the effect of the weekend allied health service on timing of therapy commencement and quantity of therapy provided in order to determine whether any observed effects were mediated by these factors or a result of the weekend allied health service per se.

The novel research design is also an important strength. The stepped wedge cluster randomised controlled design of the parent trials in which this research program was nested allowed temporary disinvestment from a service with questionable effectiveness in a controlled manner while simultaneously generating evidence of the effect of the service. The high rates of intervention fidelity and participant recruitment and follow-up can also be considered strengths of this research program.

Finally, the mixed methods research approach enabled a comprehensive understanding of the effect of the acute weekend allied health service at this location to be gained. This design was essential for considering the complex nature of the intervention and the broad range of potential outcomes relevant to both patients and service providers.

7.6.2 Limitations

The limitations of each separate study have been discussed within the relevant chapters. The limitations across the whole program of research will now be discussed. The main limitation was that only quasi-experimental and observational studies were used to address the thesis research aims. This research program was nested within a broader study, which constrained the methods able to be employed. Ideally, to investigate the multidimensional nature of allied health service delivery, a series of trials should be conducted where only one aspect of service delivery is varied per study. For example, an investigation that purely examines the effect of a weekend allied health service would need to hold the total quantity of allied health service received per patient and timing of therapy commencement constant between groups.

An economic evaluation comparing the effect of an acute weekend allied health service to no service was not conducted due to limitations imposed by the parent trials and the inability to collect the use of downstream rehabilitation services in a robust manner (discussed in chapter 2.2.11). Instead the short-term economic implications of changes in acute and sub-acute length of stay based on the results of Studies 3 and 4 have been estimated from published costs. It was possible to have estimated these short-term costs based on data from this thesis but was not deemed worthwhile due to the quasi-experimental nature of the study design.

This research program was conducted in one clinical setting to gain a comprehensive understanding of a complex intervention within a contemporary health system. Care should therefore be taken in generalising these findings to other settings, especially to those where inpatient rehabilitation is not commonly available following lower limb joint replacement

surgery or to genuine 7-day allied health models of care where the services provided on the weekend are of the same quantity as during the working week.

A priori sample size calculations were not undertaken due to the exploratory nature of this research. Therefore, this research may have been underpowered to determine a statistically and clinically significant difference for each individual outcome measure. It could also be argued that the large number of outcomes measures examined may have increased the risk of identifying a spurious significant finding (Type 1 error). However, the Medical Research Council contends that complex multidimensional interventions should be evaluated across a range of outcomes to ensure the potential consequences and benefits are adequately identified (P. Craig et al., 2008).

The nature of the intervention provided (i.e. weekend allied health intervention) does not allow for blinding of participants and health professionals, meaning there is risk of assessor bias. This may have been heightened by the disinvestment nature of the parent trials where allied health professionals may have had a vested interest in protecting their role. However, acute length of stay did not increase when weekend allied health services were removed as expected (Mitchell et al., 2017; O'Brien et al., 2017). Instead, acute length of stay was lower when weekend allied health services were removed but there was an increased likelihood of discharge to inpatient rehabilitation. It is also possible the differences observed in discharge destination may have been influenced by seasonal trends. For example, discharge directly home may be more likely during the winter compared to summer months due to increased pressure for medical beds in the sub-acute wards. While the self-reported outcomes may be subject to bias because patients were not technically blinded, this is unlikely to be

problematic given patients were not explicitly made aware of the aim of the study and so would have been largely unaware of whether they were hospitalised during the intervention or control phases.

The use of databases to collect service-based outcome measures (such as hospital length of stay, adverse events, and hospital readmissions) is another potential source of bias. Fifty-two out of 282 discrepancies in acute length of stay between iPM and scanned medical records were observed and could be the result of a systematic error. In these cases, medical records, daily ward handover forms and participant day-four interviews were used to triangulate and manually amend length of stay data.

7.7 Future research directions

Ultimately, economic analysis alongside multi-site parallel cluster or stepped-wedge randomised controlled trials are recommended to examine the cost-effectiveness of different allied health service delivery models. The findings of this thesis have identified that length of stay, discharge destination (home versus inpatient rehabilitation) and patient reported mobility may be appropriate process and patient outcome measures when considering the effect of an acute weekend allied health service. Further stakeholder consultation (with patients, health organisations and funders) is recommended to confirm the appropriateness of these outcome measures. Adequately powered trials are also necessary to determine the effect of a weekend allied health service on different patient subgroups such as those undergoing hip replacement compared to knee replacement, and in particular the effect of a sub-acute weekend allied health service on complex patients following joint replacement surgery.

There is a need to examine a potential dose-response relationship between allied health therapy and outcomes following lower limb joint replacement. Until now, research in this area has focused on increasing session frequency but increasing session duration could also be considered. To do this, reliable data pertaining to the duration of allied health sessions will need to be collected. The suggestions made by health professionals in Study 2 for optimising the existing allied health service for patients following hip and knee joint replacement also warrant further investigation. In particular, qualitative research to identify how best to facilitate mobilisation on the day of surgery and the most efficient mix of health professionals required to achieve this goal is recommended. Methods of identifying and prioritising complex patients are additionally recommended. The effect of different prioritisation guidelines on patient and service outcomes for patients following elective surgery such as joint replacement compared to those for patients in the general acute setting also warrants further investigation.

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Appendix A

Published manuscript of systematic literature review

Copyright clearance has been obtained to submit this manuscript as part of this thesis (see below). This manuscript has been published in Archives of Physical Medicine and Rehabilitation, which is ranked in the top quartile of orthopaedic (3/76) and rheumatology (5/30) journals.



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Title: Early commencement of physical therapy in the acute phase following elective lower limb arthroplasty produces favorable outcomes: a systematic review and meta-analysis examining allied health service models

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Osteoarthritis and Cartilage



Review

Early commencement of physical therapy in the acute phase following elective lower limb arthroplasty produces favorable outcomes: a systematic review and meta-analysis examining allied health service models



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SUMMARY

Background: Temporal and dose–response relationships between allied health (AH) and recovery in the acute phase following lower limb (LL) arthroplasty are unclear. This systematic review investigates whether early commencement, additional therapy and/or weekend AH affects length of stay (LOS) and patient outcomes in the acute phase following LL arthroplasty.

Methods: Electronic databases were searched in February 2015. Studies were included if they evaluated any of the following aspects of AH for adults following LL arthroplasty in the acute phase: Early compared to later therapy commencement; Additional therapy; or a 6- or 7-day service compared to a lesser service.

Results: Twenty-four studies met the inclusion criteria, of which 19 investigated effects of physical therapy (PT) alone. Earlier PT reduced LOS (WMD = −1.23 days; 95% CI, −2.16 to −0.30) and resulted in higher probability of discharge directly home (relative risk = 1.45; 95% CI, 1.26–1.67). Addition of weekend PT reduced LOS (WMD = −1.04 days; 95% CI, −1.66 to −0.41) and improved function (SMD = 0.37; 95% CI, 0.02–0.73). Increasing PT from once to twice daily did not affect LOS (WMD = −0.35 days; 95% CI, −0.96–0.26) or function (SMD = 0.31; 95% CI, −0.06–0.71).

Discussion: Early PT commencement and a weekend service may produce favorable outcomes following LL arthroplasty when baseline LOS is 4 days or more. Redistributing PT resources to commence as early as day of surgery regardless of weekday may accelerate postoperative recovery. Current, high quality research is needed to confirm these findings.

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Introduction

Clinical guidelines recommend arthroplasty as a cost-effective intervention for people with severe osteoarthritis who are unresponsive to medication and exercise¹. Rates of knee and hip arthroplasty have risen drastically over the last two decades^{2,3} and are expected to continue to rise. Between 2005 and 2030, primary

total hip and knee arthroplasties are projected to grow by 174% and 673% respectively in the United States⁴. Increasing demand for such surgery is placing pressure on scarce healthcare resources. Maximizing postoperative recovery has potential to improve quality of life, save money and increase capacity to perform additional surgeries by increasing patient flow.

Allied health (AH) professionals facilitate independent mobility and self-care in preparation for discharge following arthroplasty^{5,6}. Postoperative AH therapy may improve range of motion, quality of life, gait and balance and reduce hospital length of stay (LOS)^{7–10}. However, the temporal (how soon post-surgery should therapy commence?) and dose–response relationships (by how much does the outcome improve if the therapy amount is increased?) are unclear. Clinical guidelines prescribing exact timing and dose of

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therapy following lower limb arthroplasty are absent despite general recommendations specifying early commencement of both physical therapy (PT)⁵ and occupational therapy (OT)⁶ where practicable.

Evidence from other populations suggests AH should commence early enough and be of sufficient quantity to accelerate and maximize postoperative recovery but not too early or of too high a quantity so as to utilize resources inefficiently or have detrimental effects on recovery^{11–13}. Timing of therapy commencement has the potential to affect the total therapy quantity assuming a constant LOS. Likewise, availability of weekend AH can potentially affect both quantity and time of therapy commencement following lower limb arthroplasty, especially when surgery occurs later in the working week or on the weekend. A recent review found weak evidence to suggest a benefit to weekend PT in reducing LOS following total knee arthroplasty (TKA)¹⁴. However, it concluded early therapy initiation and total sum of visits might be more influential than actual day of week during which treatment is received. This finding is logical given potential inter-relationships between availability of weekend AH, timing of therapy commencement post-surgery and therapy quantity, and deserves further investigation.

This study has been conducted from a service model perspective to inform decision-making by healthcare policy-makers and managers. The aim was to systematically evaluate the available evidence relating to the timing of commencement, total dose, and effect of weekend AH services, in the acute phase following elective lower limb arthroplasty. Key outcomes were LOS, rate of adverse events, discharge destination, cost and physical function.

This review required several aims to be addressed concurrently due to the multidimensional nature of AH service models. The research questions were:

1. Does earlier commencement of AH result in reduced LOS and improved outcomes compared to later commencement?
2. Is a greater quantity of AH in the acute postoperative phase more beneficial in terms of patient and hospital outcomes compared to a lesser quantity?
3. What is the effectiveness of acute weekend AH services in patients following lower limb arthroplasty?
4. Are there differences in the evidence relating to timing of commencement, total dose and effectiveness of weekend AH provision for patients undergoing TKA compared to total hip arthroplasty (THA)?

Methods

Study identification and selection

This review was performed and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines¹⁵. Full holdings of the Cochrane Central Register of Controlled Trials (CENTRAL), AMED, CINAHL plus, Embase, OVID Medline, Scopus and ProQuest (Health & Medical Complete, Nursing and Allied Health Source, Social Science Journals) were searched electronically by the lead investigator (RH) on 16th February 2015. Publications were limited to English and no publication date limit was imposed. Boolean operators “AND” and “OR” were used to combine search terms relating to each domain in a PICO (Population, Intervention, Comparison and Outcomes) model¹⁶ and to provide additional terms with similar meaning respectively. Keywords included terms relevant to lower limb arthroplasty AND AH services AND weekend AH therapy OR early therapy OR increased dose AND arthroplasty outcomes (Appendix

I). Search terms relating to a comparison intervention were not identified. Truncation (*) was used where variations of search terms existed. The search strategy was first piloted and then refined for each database (Appendix II for AMED search).

Titles and abstracts were independently screened for relevance and cross-checked¹⁷ by two investigators (RH, MS). First, a random sample of 66 titles and abstracts were screened. Both reviewers were blinded to author and journal title, and reached strong agreement (Cohen's $\kappa = 0.84$)¹⁸. The two investigators then independently screened all titles and abstracts, and removed those that did not meet the inclusion criteria (Box 1). The full text of all remaining articles were obtained for review. Two investigators independently reviewed these to ascertain eligibility for inclusion. Studies were excluded if the full text was unavailable or appropriate data was not collected as per the published methodology. Disagreements were resolved by discussion and where agreement could not be met, a third investigator (KAB) was consulted. Reference lists of included studies were searched using SCOPUS database (Elsevier, New York, USA) to identify additional relevant studies. This method has been shown to be as valid and more efficient than the traditional manual search approach¹⁹. The reference list of each systematic review deemed eligible for full text review was scanned for relevant papers. Potentially relevant papers were then cross-checked against findings of the original search strategy to identify any further studies.

Box 1

Inclusion criteria for systematic literature review

Inclusion Criteria

Design

- Experimental, quasi-experimental and observational study designs as long as a comparison intervention was evaluated in terms of a relevant outcome measure.
- Published in English

Participants

- Adults undergoing elective lower limb arthroplasty in a surgical facility and requiring admission to an acute health service.

Intervention

- The effect of additional allied health therapy in terms of time, frequency or number of sessions provided compared to a lesser amount of therapy
- The effect of early commencement of allied health therapy determined by time since surgery compared to a delayed commencement
- Allied health therapy provided on the weekend with a 6- or 7-day service compared to that provided during the week with a lesser service
- Allied health included physiotherapy, occupational therapy, speech therapy, dietetics, social work, orthotics or prosthetics
- Allied health intervention to focus on service models rather than individual treatment modalities

Outcome measures

- Length of stay, adverse events, unplanned readmission, discharge destination, function, mobility, joint range of motion, quality of life, pain, cost.

In an attempt to use the best available evidence, it was decided a priori that experimental, quasi-experimental and observational study designs would be included since previous reviews in similar fields have identified few RCTs^{14,20}.

Data extraction

Two reviewers (RH, MS) independently extracted data related to study participants, exclusion criteria, study design, control and intervention (therapy type, timing, frequency and duration), outcomes, follow-up period, results and the PEDro (Physiotherapy Evidence Database) scale. Differences in data extracted were resolved by discussion and a third investigator (KAB) was consulted where consensus was not achieved. Attempts were made to contact authors of studies where collected data was not reported or where clarification was required.

Critical appraisal

All studies underwent an independent quality assessment by two investigators (RH, MS) using the PEDro scale²¹. PEDro assesses trials for quality according to 11 criteria, of which 10 are summed to form a final score. Although the PEDro scale was developed to assess RCT quality, these criteria²¹ have been applied in this review to provide a standardized quality assessment of all study designs. Random allocation is a criterion in the PEDro scale and therefore non-randomised studies receive a lower quality rating in accordance with the hierarchy of evidence²². The PEDro database was consulted to confirm quality scores for previously assessed RCTs. A third reviewer (KAB) was consulted where discrepancies existed between the PEDro database and our reviewers. Additional potential sources of risk of bias for each study were also considered.

Data analysis

Statistical analysis was undertaken using Stata (StataCorp. 2013. Stata Statistical Software: Release 13. College Station, TX: StataCorp LP). DerSimonian and Laird random-effects meta-analyses²³ were used to estimate the pooled effect of each service model (timing of commencement, dose and weekend service) where there was more than one study evaluating a similar outcome. Meta-analyses were not conducted on studies investigating multiple service models simultaneously. However, a study could be included in multiple service model meta-analyses if supporting data and outcomes confirming the inter-relationship was available. For example, a study investigating the effect of weekend AH could also be included in a meta-analysis investigating the effect of early therapy commencement if there was adequate data confirming the weekend service resulted in earlier therapy commencement. The effect of each service model was estimated using: standardized mean differences (SMD) for functional outcomes and pain; weighted mean differences (WMD) for LOS and range of motion; and relative risk (RR) for discharge destination, unplanned hospital readmissions and adverse events. SMD strength was determined according to Cohen²⁴, with 0.2 considered small, 0.5 moderate and 0.8 a large effect size. Heterogeneity between studies was quantified using the I-squared statistic, with values of more than 50% representing substantial levels²⁵. Subgroup analyses and random effects univariate and multivariate meta-regression were performed where possible to explore the role of potential sources of heterogeneity. These included surgery type, study design, study quality (PEDro individual criteria) and intervention differences. Tau-squared, I-squared residual and adjusted R-squared values were used to investigate potential sources of heterogeneity. *P*-values generated through meta-regression analyses were used to

determine if a covariate explained a significant amount of heterogeneity in the meta-analysis results.

Disease specific scales such as the Knee Society Score (KSS) and Iowa Level of Assistance (ILOA) were pooled and categorized as functional outcome measures along with walking distance. In studies where multiple functional outcome measures were evaluated, the outcome most relevant during the inpatient period was chosen. In studies where outcomes were measured at multiple timepoints, the time closest to the mean discharge of that study group was used to calculate SMDs. This was to allow therapy to have its effect over the entire acute hospitalization but no later to avoid subjecting data to other confounding variables occurring after hospital discharge. Where subscales were reported, summing the items for all subscales and pooling the subscale standard deviations created a total scale score.

Where study results were reported as medians and ranges or interquartile ranges, authors were contacted to obtain means and standard deviations. Where this data was not available, the methods of Wan *et al.*²⁶ were used to convert results into means and standard deviations. A sensitivity analysis was undertaken to re-assess the effect of excluding these studies in the meta-analysis. Sensitivity analyses were also undertaken to test robustness of findings including studies subject to substantial risk of bias (PEDro <7) and those examining the effect of AH disciplines additional to PT on the results obtained. Additionally, sensitivity analyses were conducted to confirm results where outcome data were available at different timepoints and where baseline LOS was greater than current averages.

Results

Study selection

Figure 1 displays search, screening and eligibility findings. The search strategy identified four systematic literature reviews. From these, an additional three relevant studies were identified^{27–29} of which one²⁸ was subsequently included in this review (Appendix III).

Characteristics of included trials

Table 1 depicts characteristics of included papers. Of the 25 that met the inclusion criteria, there were six RCTs, 17 cohort designs, one cross-sectional and one cost-effectiveness paper. The cost-effectiveness paper³⁰ was based on one of the RCTs³¹, and was therefore treated as the same study. All studies evaluated the effect of PT following lower limb arthroplasty with four evaluating the additional effect of OT^{31–34} and one social work³⁵. The effect of weekend PT and early commencement on quantity of therapy were documented in three and one study respectively (Fig. 2).

All studies meeting the inclusion criteria originated in developed nations. In 10 studies^{9,31,33,36–42}, the population comprised patients undergoing THA and TKA (three of these^{9,38,42} did not differentiate between joints), while seven studies included a population of THA^{8,34,43–47} or TKA^{7,28,32,35,48–50} only. In one study³⁷, the population included acute orthopaedic patients where data was stratified by diagnostic group; only the patients following THA or TKA were included in our analyses. Data from a total of 4031 participants (mean 168, range 40–590) were included in our meta-analyses, 2217 undergoing THA and 1814 undergoing TKA.

Outcome measures extracted from included studies were LOS (*n* = 21), function (*n* = 9), range of motion (*n* = 5), strength (*n* = 1), pain (*n* = 5), adverse events (*n* = 2), hospital readmissions (*n* = 3), quality of life (*n* = 1), patient satisfaction (*n* = 2), discharge destination (*n* = 8) and cost (*n* = 2). The studies evaluating the effect on

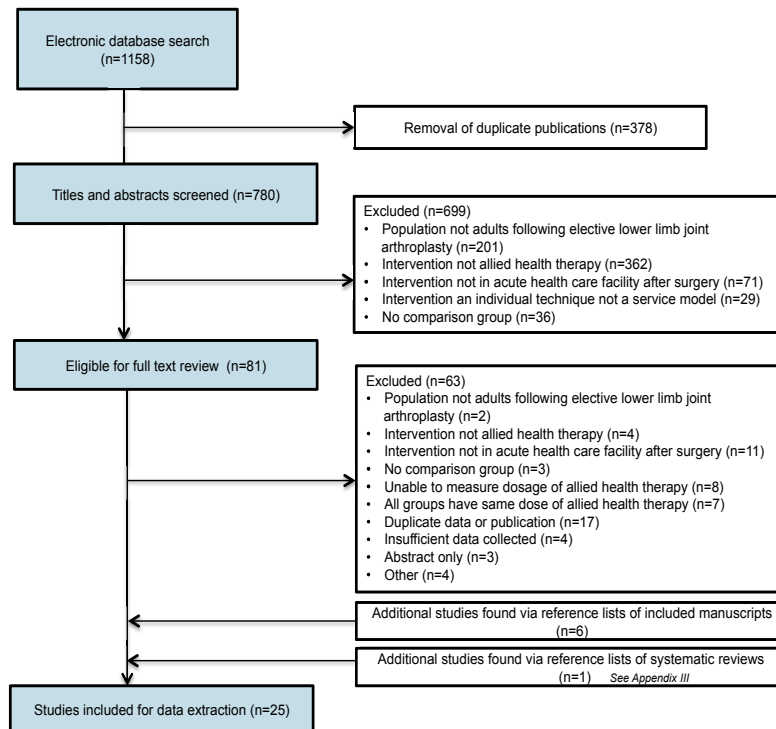


Fig. 1. Flow of studies.

patient satisfaction, cost and adverse events examined different service models so results were not pooled in a meta-analysis.

Study quality

PEDro ratings (excluding eligibility criterion) ranged from 3 to 8 with an average of 5.1 (Table II). Blinding of subjects, therapists and assessors (criterion 5–7) were the poorest scoring criteria. Two of five studies that had an existing PEDro rating on the PEDro database, were given a different score by our reviewers. In each case, we maintained our rating following consultation with our third reviewer.

Effects of AH service models on outcomes

Table III demonstrates the results of meta-analyses, sub-group and sensitivity analyses investigating the effect of changes in timing of therapy commencement, a weekend PT service and PT frequency.

Effects of earlier therapy commencement

Fourteen studies evaluated the effect of early therapy commencement of which, 11 compared therapy commencing on day of surgery to postoperative day one. Eight of these evaluated the effect of a fast-track protocol, a process that optimizes perioperative care and may include additional interventions such as standardized analgesic practices. Nine studies compared the effect of earlier PT commencement; four studies considered the additional effect of OT and one the additional effect of social work.

When considering the effect of AH (PT in combination with OT or social work), earlier initiation demonstrated evidence of a reduction in LOS in 11 studies among 2362 participants [Fig. 3(a)] and higher probability of discharge directly home (5 studies, $n = 985$) following THA and TKA. Following TKA, an increase in range of knee flexion (2 studies, $n = 422$) was also evident in those experiencing earlier therapy commencement. No evidence of change in function (3 studies, $n = 684$), pain (3 studies, $n = 545$), hospital readmissions (2 studies, $n = 333$) or adverse events (1 study, $n = 86$) was observed. Sensitivity analyses utilizing outcome measures collected at different timepoints did not alter results.

When considering the effect of PT only, earlier initiation demonstrated evidence of a LOS reduction in seven studies among 1309 participants [Fig. 3(b)] and higher probability of discharge directly home (4 studies, $n = 395$) following TKA but not THA. No evidence of change in function (3 studies, $n = 684$), pain (3 studies, $n = 545$), range of knee flexion (3 studies, $n = 577$) or adverse events (1 study, $n = 86$) was observed.

There was a large degree of heterogeneity (96.9%) between studies in LOS analysis. This reduced to 0% by restricting to RCT studies or those with a PEDro score of seven or greater. In univariate meta-regression analyses (Table IV), higher PEDro scores and multidisciplinary interventions were the only variables significantly associated with a greater reduction in LOS. Multivariable meta-regression using all PEDro criteria as predictor variables revealed studies with random allocation, concealed allocation and intention-to-treat analysis were significantly associated with greater reduction in LOS, accounting for 71.42% of between-study variance.

One study investigated cost-effectiveness of an accelerated perioperative protocol (including PT and OT commencement on day

Table 1
Characteristics of included studies

Author (year)	Study design	Participant details	Control group	Intervention group	Outcome measures
Bottros <i>et al.</i> , 2010 ⁴⁷	Retrospective cohort (historical control group)	103 THA C n = 73; Mean age (range) 58.7 (16–85) I n = 30; Mean age (range) 59.6 (14–82)	Commence PT on POD 1 and ambulation on POD 2	Commence PT on POD 0, abductor sparing surgical approach & pain management	LOS, discharge destination. Distance walked & pain on POD 0, 1, 2 & 3. Hip Harris score on weeks 4 & 12.
Boxall <i>et al.</i> , 2004 ³⁷	Prospective cohort (historical control group matched by sex and age)	240 acute orthopaedic patients C n = 120; Mean age 68.03 (variance not reported) I n = 120; Mean age 67.97 (variance not reported)	Weekday PT service	7 day PT service	LOS, days to independent transfers, days to independent mobility, reasons for delayed discharge, discharge destination
Chen <i>et al.</i> , 2012 ⁹	Prospective cohort (control group – PT commence on POD 1)	136 TJA (58 THA; 78 TKA) C n = 111; Mean age (SD) 62.29 (11.05) I n = 25; Mean age (SD) 58.0 (9.4)	Commence PT on POD 1	Commence PT on POD 0	LOS, pain on POD 0, functional status after first PT session (i.e., remain in bed, out of bed to chair or ambulating) & discharge destination
Den Hertog <i>et al.</i> , 2012 ³⁵	RCT	147 TKA C n = 73; Mean age (SD) 68.25 (7.91) I n = 74; Mean age (SD) 66.58 (8.21)	Standard rehabilitation (1 h PT/day, mobilization commenced on POD 2)	Fast-track rehabilitation – PT 2 h/day, commence on POD 0, focus on ADL & individual case management, positive messages and use of competitive care, expected discharge on POD 6	LOS, adverse events. KSS, WOMAC & weighted consumption of analgesic medication on POD –1, 5–7, 15–23, 6 weeks & 3 months
Freburger J 2000 ⁸	Cross Sectional	7495 THA Mean age (range) 64 (12–105)			Dependent variables – total cost care < expected, increased probability of discharge home Independent variable – physical therapy utilization
Hughes <i>et al.</i> , 1993 ³⁹	Prospective cohort (historical control group)	73 THA C n = 27; I n = 46 64 TKA C n = 26; I n = 38 Age results reported as n/decade (unable to calculate mean, SD or range but majority of participants aged 60–80)	Weekday PT service	7 day PT service	LOS, PT treatment on weekend following surgery
Isaac <i>et al.</i> , 2005 ³²	Prospective cohort (control group – different surgeon, same hospital)	130 TKA C n = 80; Mean age (range) 71.3 (42–84) I n = 50; Mean age (range) 72.3 (50–88)	PT commence on POD 1	PT commence on POD 0 (4 h postop), infiltration of bupivacaine & adrenaline, modification to surgery technique, multidisciplinary D/C planning, education re: expect shorter LOS	LOS, discharge delays & complications, blood loss postoperatively. Pain levels on POD 0, 1, 2, 3, 4, 5, 6, 7 & 14. KSS, active knee ROM & Oxford functional rating score preoperatively and 6 weeks postoperatively
Juliano <i>et al.</i> , 2011 ⁴⁶	Retrospective cohort (historical control group matched by week of surgery)	408 THA C n = 204; Mean age (range) 60.4 (27–82) I n = 204; Mean age (range) 60.2 (32–83)	PT commence on POD 1 with 4 day expected LOS	PT commence on POD 0 with 3 day expected LOS	LOS and level of assisted required for transfers, ambulation with cane and negotiating stairs at discharge
Klika <i>et al.</i> , 2009 ⁵⁰	Retrospective cohort (historical control group)	116 TKA C n = 62; Mean age (range) 64.8 (48–84) I n = 54; Mean age (range) 63.5 (45–86)	Traditional PT – bed rest POD 0, dangling at edge of bed POD 1 & ambulation POD 2.	Rapid recovery – improved pain management, quadriceps sparing approach & PT protocol commencing on POD 0	LOS, discharge destination. Distance walked, flexion ROM and pain on POD 1, 2, 3, & 4. Knee Society Scores 4 weeks postoperatively.
Labraca <i>et al.</i> , 2011 ⁷	RCT	306 TKA C n = 153; Mean age (SD) 66.36 (5.03) I n = 153; Mean age (SD) 65.48 (4.83)	PT commence within 48–72 h post surgery	PT commence within 24 h of surgery	LOS. Pain, flexion & extension ROM, flexion & extension strength, Barthel Index & Tinetti test on day of discharge.
Lang C 1998 ⁴¹	Prospective cohort (historical control group)	92 THA C n = 57; Mean age (SD) 71.6 (14.7) I n = 35; Mean age (SD) 64.7 (15.3)	6 day/week PT service (11 PT sessions/week)	7 day/week PT service (12 PT sessions/week)	LOS & discharge destination. Independence in don/doff lower extremity brace, moving in/out of (continued on next page)

Table 1 (continued)

Author (year)	Study design	Participant details	Control group	Intervention group	Outcome measures
Larsen, Hvass <i>et al.</i> , 2008 ³³	Prospective before-after cohort	48 TKA C n = 23; Mean age (SD) 67.6 (11.2) I n = 25; Mean age (SD) 68.9 (10.6) 139 THA & 108 TKA C n = 63 THA & 42 TKA; Mean age (SD) 65 (11) I n = 76 THA & 66 TKA; Mean age (SD) 65 (11)	Traditional rehabilitation – PT commence on POD 1	Accelerated rehabilitation – PT commence on POD 0, preoperative assessment, optimization of oral nutrition	bed, transfers, gait and ascending/descending stairs on day of discharge. LOS. Hospital readmissions and adverse events within 3 months postoperatively.
Larsen, Sorensen <i>et al.</i> , 2008 ³¹	RCT	58 THA & 28 TKA C n = 30 THA & 13 TKA; Mean age (SD) 65 (11.0) I n = 28 THA & 15 TKA; Mean age (SD) 65 (11.0)	Standard rehabilitation – PT/OT commence on POD 1, 4 h out of bed/day	Accelerated and intensive rehabilitation – PT/OT commence on POD 0, 8 h out of bed/day, preoperative education, standardized pain relief, optimization of oral nutrition.	LOS. Hospital readmissions and adverse events within 3 months postoperatively
Larsen, Hansen <i>et al.</i> , 2009 ³⁰ Lemssen <i>et al.</i> , 2006 ²⁸	Cost-effectiveness study based on RCT above RCT	As above 43 TKA C n = 22; Mean age (SD) 67 (7) I n = 21; Mean age (SD) 70 (8.5)	As above PT once/day, 20 min each session	As above PT twice/day, 20 min each session	Incremental cost within 12 months postoperatively LOS. Flexion & extension passive & active ROM, KSS, pain & satisfaction on POD 4, 6 weeks and 3 months postoperatively. WOMAC & perceived effect of surgery 6 weeks & 3 months postoperatively.
Liang <i>et al.</i> , 1987 ⁴²	Prospective cohort (historical control group)	200 THA & TKA Group 1 n = 50; Mean age (SD) 66.4 (7.3) Group 2 n = 50; Mean age (SD) 66.2 (7.3) Group 3 n = 50; Mean age (SD) 64.1 (7.1) Group 4 n = 50; Mean age (SD) 67.8 (7.2)	Group 4 – Weekday PT service, once/day & weekend priority cases	Group 1 – 7 day PT service, twice/day (premerger) Group 2 – 7 day PT service, twice/day (postmerger) Group 3 – 7 day PT service, at least once/day	LOS. Functional Mobility Index on day of discharge. Intensity of physical therapy services provided during hospital stay. Complications within 6 months postoperatively.
Liebs <i>et al.</i> , 2012 ⁴⁰	RCT	280 THA C n = 142; Mean age (SD) 69.1 (9.8) I n = 129; Mean age (SD) 66.7 (10.3) 185 TKA I n = 87; Mean age (SD) 68.5 (8.6)	Commenced aquatic therapy on POD 14	Commenced aquatic therapy on POD 6	WOMAC function, pain & stiffness, SF-36, Lequesne-Hip/Knee Score & patient satisfaction at 3, 6, 12 & 24 months postoperatively.
Maidment <i>et al.</i> , 2014 ³⁶	Prospective cohort (historical control group)	91 TKA C n = 40; Mean age (IQR) 70.5 (68–78) I n = 51; Mean age (IQR) 69 (65–75) 54 THA C n = 19; Mean age (IQR) 69 (66–77) I n = 35; Mean age (IQR) 69 (65–75)	5 day PT service	7 day PT service	Hospital & PT LOS
Peck <i>et al.</i> , 2011 ⁴⁴	Retrospective cohort (concurrent control from different hospital matched by age, sex and body mass)	96 THA Standard incision routine PT n = 26; Mean age (SD) 70 (9.6) Minimal incision routine PT n = 29; Mean age (SD) 71 (10) Standard incision intensive PT n = 19; Mean age (SD) 70 (11.3) Minimal incision intensive PT n = 22; Mean age (SD) 71 (9.7)	Standard incision and minimal incision routine PT – Once daily 5 day service	Standard incision and routine incision intensive PT – Twice daily 7 day service	LOS. Blood loss on POD 1. Scar length at a mean of 17 months postoperatively. Oxford hip score at 10–17 months postoperatively. Complications (not documented at what time this was measured).
Pua <i>et al.</i> , 2011 ⁴⁹	Prospective cohort (historical control group)	229 TKA or unicompartmental knee arthroplasty C Group A n = 82; Mean age (SD) 66.3 (8) C Group B n = 74; Mean age (SD) 66.9 (9.3) I n = 73; Mean age (SD) 65.4 (7.3)	Control Group A – 6 day PT service (once daily) 4 months prior to intervention Control Group B – 6 day PT service (once daily) 1 year prior to intervention	7 day PT service (once daily)	LOS and discharge knee outcomes (ROM knee flexion, ability to straight leg raise and proportion of patients who ambulated safely with SPS or 4PS)

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Raphael <i>et al.</i> , 2011 ³⁸	Prospective cohort (historical control group)	88 THA and 112 TKA C n = 31 THA & 69 TKA; Mean age (SD) 69 (8) I n = 57 THA & 43 TKA; Mean age (SD) 65 (9)	Standard rehabilitation – PT commence on POD 1 (as tolerated)	Fast-track rehabilitation – PT education, standardized preemptive and postoperative analgesia	LOS and transfer to tertiary hospital/emergency department visits during inpatient stay. Pain & postoperative nausea & vomiting on POD 0 & 1. Readmission to hospital within 30 days
Renkawitz <i>et al.</i> , 2010 ⁴⁸	Prospective cohort (parallel control group)	143 TKA C n = 76; Mean age (SD) 68.1 (11.1) I n = 67; Mean age (SD) 67 (9)	Standard accelerated clinical pathway – mobilization on POD 1, PT 1/day, weekends on demand, CPM 2/day	Optimised accelerated clinical pathway – Patient-controlled regional analgesia, ultra-early (POD 0)/doubled PT, once on weekend	Max. non-stop walking distance, number stairs, thigh circumference, KSS
Robbins, Beirbaum <i>et al.</i> , 2009 ⁴⁵	Retrospective cohort (concurrent control group – PT on POD 1)	40 THA; Mean age (range) 63.4 (32–82) C n = 20; I n = 20	Commence PT on POD 1	Commence PT on POD 0	Pain at rest & at mobilization, knee ROM, time out of bed & opioid consumption on POD 5 & 8.
Robbins, Casey <i>et al.</i> , 2014 ⁴⁴	Retrospective cohort (concurrent control group – PT on POD 1)	590 THA C n = 400; I n = 190 Participant's ages not reported	Standard protocol – commence PT on POD 1	Accelerated protocol – commence PT on POD 0, preoperative education emphasizing 24 h LOS, specialized hospital unit.	LOS, discharge destination. Ability to ascend/descend stairs & ambulate 25 feet on POD 2.
Stockton & Mengersen 2009 ³⁶	RCT	57 THA C n = 27; Mean age (SD) 68.2 (10.6) I n = 30; Mean age (SD) 68.3 (9.3)	PT once/day from POD 1	PT twice/day from POD 1	LOS, discharge destination. Complications that extended hospital LOS & hospital readmissions (timeframe unknown)

Abbreviations: RCT, randomised controlled trial; C, control group; I, intervention group; SD, standard deviation; POD, postoperative day; WOMAC, Western Ontario and McMasters Universities Osteoarthritis Index; ROM, range of motion; SF-36, Short Form 36 Health Survey; SPS, single point stick; 4PS, 4 point stick; CPM, continuous passive motion; mins, minutes; h, hours.

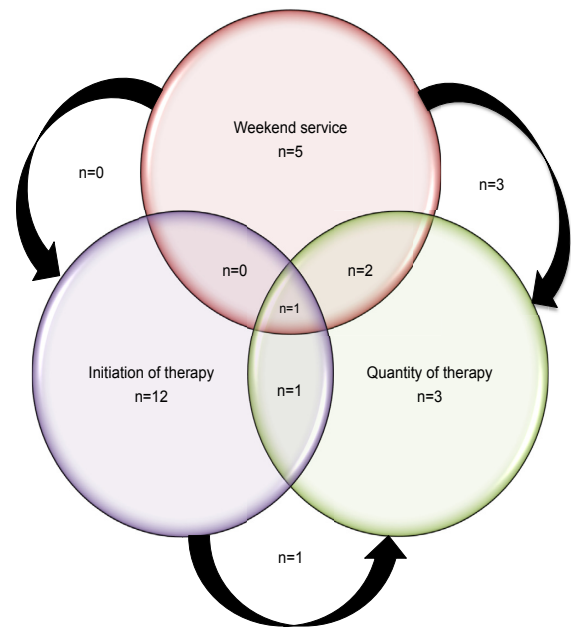


Fig. 2. Intervention type of the included studies. Arrows depict possible relationships between different service models and number of studies where this data was collected.

of surgery) following THA and TKA from a societal perspective³⁰. This showed the accelerated protocol to be significantly less expensive than standard protocol, with an average cost reduction of 18,880 Danish kroner (approximately US\$4000).

Effects of increasing therapy dosage

Of the seven studies directly evaluating the effect of increasing therapy dosage, all considered the effect of PT alone and six compared once-daily to twice-daily PT. Total dosage over LOS was not reported in these studies. Only three studies evaluated the sole effect of therapy quantity on outcomes following lower limb arthroplasty, two of which were included in a meta-analysis. Analysis of the pooled effect of two studies ($n = 100$) increasing PT from once to twice daily revealed no evidence of a change in LOS [Fig. 3(c)] or function. The remaining study was a cross-sectional design investigating the relationship between PT utilization and outcomes following THA⁸. PT use was directly related to total cost of care that was less than expected and to an increased probability of discharge home.

Effects of a weekend service

Of the eight studies evaluating the effect of a weekend AH service, all considered the effect of PT alone and five compared a 5-day to a 7-day service^{36,37,39,42,44}. Two studies compared a 6 to a 7-day service^{41,49} while one compared a 5 to a 6-day service⁴⁸. The addition of weekend PT demonstrated evidence of a reduction in LOS [Fig. 3(d)] and a medium standardized effect size increase in function (2 studies, $n = 206$) in patients following TKA but not THA.

Discussion

This review identified 24 studies examining the effect of early AH commencement, additional therapy and/or weekend service on

outcomes following lower limb arthroplasty. All studies investigated the effect of PT with four evaluating the additional effect of OT and one social work. There is therefore insufficient evidence from which to draw conclusions regarding the sole effect of professions other than PT on outcomes following lower limb arthroplasty. Based on the PT only studies, there appears to be a beneficial effect for early commencement and a weekend service following TKA but not THA. If we also consider studies that examined PT in combination with other AH professions, there appears to be an additional effect following THA for early therapy commencement. There was no evidence to suggest providing AH intervention as early as the day of surgery increased pain levels, rate of adverse events, or hospital re-admissions. No studies evaluated the effect of weekend PT on detrimental outcomes. There is insufficient data available from which to adequately investigate a potential dose–response relationship between AH therapy and outcomes following lower limb arthroplasty.

Our results suggest acute PT may be more effective following TKA than THA. This is plausible given the greater scope for

improvement in pain and function evident in patients undergoing TKA compared to THA^{51–53}. Likewise, the greater reduction in LOS observed amongst patients undergoing TKA compared to THA could be a function of the baseline LOS, which in our review was 0.62 days shorter following THA (nearly 10% of THA LOS).

These results support and extend upon findings of previous reviews which found weak evidence to support an acute weekend PT service following lower limb arthroplasty but no evidence to support an increase in PT frequency from once to twice daily in the acute postoperative phase^{14,20}. This is in contrast to a previous subgroup meta-analysis that found an extra 19 min PT per day reduced LOS by 1 day in acute settings⁵⁴. However, this study included a mixed patient population. We are also unable to directly compare our results to the above meta-analysis in terms of additional PT provided since only three studies in our review provided sufficient data to quantify the amount of additional PT provided by different service models. The key contribution of our review is the provision of preliminary evidence to suggest timing of therapy commencement in the acute postoperative phase may be more important than therapy

Table II
Methodological quality of included studies using the PEDro Scale

Author, year	1	2	3	4	5	6	7	8	9	10	11	Total	Confounders	Other sources of bias
Bottros <i>et al.</i> , 2010	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Abductor sparing surgical approach & pain management	LOS was part of intervention
Boxall <i>et al.</i> , 2004	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5		Organisational delays affected LOS
Chen <i>et al.</i> , 2012	✓	×	×	✓	×	×	×	✓	×	✓	✓	4		Selection bias; only 18% of cohort received PT on POD 0
Den Hertog <i>et al.</i> , 2012	✓	✓	✓	✓	×	×	×	✓	✓	✓	✓	7	Case manager, competitive care, discharge scheduling	
Freburger J., 2000	✓	×	×	×	×	×	×	✓	×	✓	✓	3		Use of secondary database
Hughes <i>et al.</i> , 1993	✓	×	×	×	×	×	×	✓	×	✓	✓	3		Did not control for day of week of surgery
Isaac <i>et al.</i> , 2004	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Analgesics technique, surgical technique, multidisciplinary D/C planning, education re: shorter LOS	
Juliano <i>et al.</i> , 2011	✓	×	×	✓	×	×	×	✓	×	✓	✓	4		Potential selection bias, LOS an intervention & outcome.
Klika <i>et al.</i> , 2009	✓	×	×	✓	×	×	×	✓	×	✓	✓	4	Pain management, quadriceps sparing surgical approach	
Labraca <i>et al.</i> , 2011	✓	✓	✓	✓	×	×	✓	✓	×	✓	✓	7		Pre-op differences in pain & extension ROM
Lang C 1998	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5		Most surgery on a Mon, Tues or Wed.
Larsen <i>et al.</i> , 2008	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Multi-modal intervention	Surgery moved to beginning of wk in intervention group
Larsen, Hansen <i>et al.</i> , 2009	✓	✓	✓	✓	×	×	✓	✓	✓	✓	✓	8	Multi-modal intervention	
Larsen, Sorensen <i>et al.</i> , 2009	✓	✓	✓	✓	×	×	✓	✓	✓	✓	✓	8	Multi-modal intervention	
Lenzen <i>et al.</i> , 2006	✓	✓	✓	×	×	×	×	✓	✓	✓	✓	7		
Liang <i>et al.</i> , 1987	✓	×	×	✓	×	×	×	✓	×	✓	✓	4		Potential selection bias; study conducted nearly 30 years ago
Liebs <i>et al.</i> , 2012	✓	✓	✓	✓	×	×	×	✓	✓	✓	✓	7		
Maidment <i>et al.</i> , 2014	×	×	×	✓	×	×	×	✓	✓	✓	✓	5		
Peck <i>et al.</i> , 2011	×	×	×	✓	×	×	×	×	×	✓	✓	3		
Pua <i>et al.</i> , 2011	✓	×	×	✓	×	×	×	✓	×	✓	✓	4		
Raphael <i>et al.</i> , 2011	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Preoperative education, standardized analgesia	Potential selection bias
Renkowitz <i>et al.</i> , 2010	✓	×	×	✓	×	×	×	✓	✓	✓	✓	5	Patient-controlled analgesia pump	Intervention group had surgery in morning
Robbins, Beirbaum <i>et al.</i> , 2009	✓	×	×	×	×	×	×	✓	×	✓	✓	3		Potential selection bias
Robbins, Casey <i>et al.</i> , 2014	✓	×	×	×	×	×	×	✓	×	✓	✓	3	Preoperative education, multidisciplinary training re: protocol	Potential selection bias
Stockton & Mengersen 2009	✓	✓	✓	✓	×	×	✓	✓	✓	✓	✓	8		

Criteria: 1. Eligibility criteria specified. 2. Random subject allocation. 3. Concealed allocation. 4. Groups were similar at baseline. 5. Blinding of all subjects. 6. Blinding of all therapists. 7. Blinding of all assessors. 8. Measures obtained from more than 85% of initial subjects. 9. All subjects received treatment or control. If not, data was analyzed by intention to treat. 10. Results of between-group comparisons reported for at least one key outcome. 11. Provides both point measures and measures of variability for one key outcome. PEDro item 1. Eligibility criteria specified is not used to calculate the total PEDro score.

Table III

Meta-analyses, sub-group and sensitivity analyses investigating the effect of early initiation of AH post-surgery, twice compared to once daily PT and introduction of a weekend PT service provided in the acute phase following lower limb arthroplasty

Service model	Outcome	Total	THA	TKA	PT only (no multi- disciplinary input)	RCT only	PEDro ≥ 7	No estimations	Allied health therapy only (no fast-track rehabilitation)	Average LOS < 4 days in control group
Early allied health initiation	Length of stay	-1.98 (-2.77, -1.19) $I^2 = 95.8\%$	-2.75 (-2.70, -0.41) $I^2 = 95.8\%$	-2.50 (-3.62, -1.39) $I^2 = 93.5\%$	-1.23 (-2.16, -0.30) $I^2 = 97.7\%$	-2.07 (-2.43, -1.71) $I^2 = 0\%$	-2.07 (-2.43, -1.71) $I^2 = 0\%$	-1.54 (-2.36, -0.73) $I^2 = 96.5\%$	-0.99 (-1.95, -0.04) $I^2 = 94.8\%$	-0.80 (-1.51, -0.08) $I^2 = 90.1\%$
	Function	0.11 (-0.09, 0.31) $I^2 = 24.2\%$	0.19 (-0.36, 0.73) $I^2 = 73.5\%$	0.13 (-0.12, 0.37) $I^2 = 0\%$	All PT only	1 Study	1 Study	0.11 (-0.09, 0.31) $I^2 = 24.2\%$	1 Study	1 Study
	ROM		No studies	14.49 (9.32, 19.66) $I^2 = 50.3\%$	All PT only	1 Study	1 Study (same as RCT)	14.49 (9.32, 19.66) $I^2 = 50.3\%$	1 Study	No studies
	Pain	-0.54 (-1.18, 0.10) $I^2 = 84\%$	1 Study	1 Study	All PT only	1 Study	1 Study	-0.54 (-1.18, 0.10) $I^2 = 84\%$	-0.53 (-1.41, 0.35) $I^2 = 91.9\%$	1 Study
	Discharge destination	RR = 1.45 (1.26, 1.67) $I^2 = 44.6\%$	1.52 (1.41, 1.65) $I^2 = 0\%$	1 Study	All PT only	No studies	No studies	RR = 1.45 (1.26, 1.67) $I^2 = 44.6\%$	RR = 1.25 (1.04, 1.49) $I^2 = 0\%$	1 Study
	Readmissions	RR = 0.85 (0.31, 2.37) $I^2 = 0\%$	0.6 (0.18, 2.65) $I^2 = 4.7\%$	1.33 (0.31, 7.38) $I^2 = 0\%$	No studies	1.39 (0.18, 10.63) $I^2 = 0\%$	RR = 0.85 (0.31, 2.37) $I^2 = 0\%$	RR = 0.85 (0.31, 2.37) $I^2 = 0\%$	No studies	No studies
Twice vs once daily PT	Length of stay	-0.35 (-0.95, 0.26) $I^2 = 0\%$	1 Study	1 Study	All PT only	-0.35 (-0.95, 0.26) $I^2 = 0\%$	-0.35 (-0.95, 0.26) $I^2 = 0\%$	-0.35 (-0.95, 0.26) $I^2 = 0\%$	N/A	No studies
	Function	0.31 (-0.08, 0.71) $I^2 = 0\%$	1 Study	1 Study	All PT only	0.31 (-0.08, 0.71) $I^2 = 0\%$	0.31 (-0.08, 0.71) $I^2 = 0\%$	0.31 (-0.08, 0.71) $I^2 = 0\%$	N/A	No studies
	ROM	1 Study	No studies	1 Study		1 Study	1 Study	1 Study		
	Pain	1 Study	No studies	1 Study		1 Study	1 Study	1 Study		
	Discharge destination	1 Study	1 Study	No studies		1 Study	1 Study	1 Study		
	Readmissions	No studies	No studies	No studies		No studies	No studies	No studies		
Provision of weekend PT service	Length of stay	-1.04 (-1.66, -0.41) $I^2 = 90.5\%$	-1.22 (-2.72, 0.28) $I^2 = 48.9\%$	-0.87 (-1.05, -0.70) $I^2 = 0\%$	All PT only	No studies	No studies	-1.14 (-1.87, -0.42) $I^2 = 89.9\%$	N/A	No studies
	Function	0.37 (0.02, 0.73) $I^2 = 30\%$	0.18 (-0.34, 0.69) $I^2 = 21.6\%$	0.55 (0.13, 0.97) $I^2 = 13.1\%$	All PT only	No studies	No studies	SMD = 0.37 (0.02, 0.73) $I^2 = 30\%$	N/A	No studies
	ROM	1 Study								
	Pain	No studies								
	Discharge destination	1 Study								
	Readmissions	No studies								

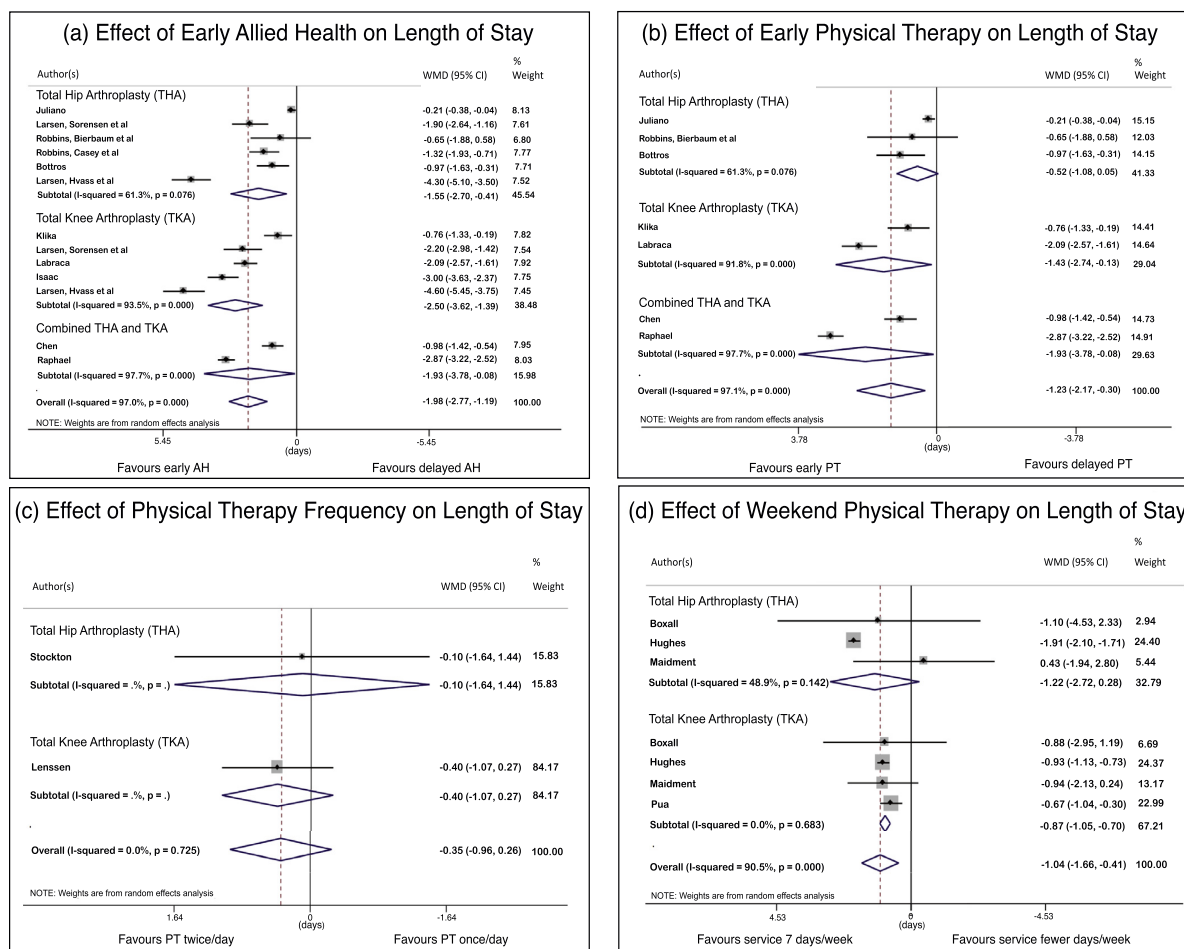


Fig. 3. Forest plot of the effect of (a) early AH, (b) early PT, (c) increased PT frequency and (d) a weekend PT service on LOS in the acute phase following lower limb arthroplasty.

Table IV

Association between surgery type, study design, study quality and intervention covariates in studies evaluating earlier compared to later commencement of therapy following lower limb arthroplasty

Covariate	Coefficient (95% confidence interval)	P value	Proportion of between-study variance explained (adjusted R-squared)	% Residual variation due to heterogeneity (I-squared residual)	Estimate of between-study variance (tau-squared)
Base model	-1.980 (-2.811, -1.14863)	0.000		96.96%	1.754
Surgery type	0.428 (-0.787, 1.642)	0.455	-4.37%	97.22%	1.831
Study design	0.634 (-0.378, 1.646)	0.195	7.2%	96.38%	1.628
Study quality	-0.470 (-0.875, -0.064)	0.027	33.56%	94.86%	1.165
Time of allied health initiation (intervention group)	-0.119 (-3.367, 3.13)	0.937	-10.10%	97.10%	1.931
Multidisciplinary intervention	-1.627 (-3.018, -0.237)	0.026	33.39%	95.92%	1.169
Multimodal intervention	-1.426 (-3.069, 0.217)	0.082	19.19%	93.87%	1.418

quantity provided following lower limb arthroplasty. This has potential implications for healthcare managers in terms of organizing staffing availability around surgery timetables.

Commencing therapy on day of surgery has practical and financial implications for the development of efficient AH service

models. Our results suggest providing an additional PT session on the day of surgery is likely to be cost-effective (even if this is provided 'out-of-hours' or on the weekend) given the demonstrated concomitant reduction in LOS by more than 1 day. The practicalities of routinely providing therapy on the day of surgery will however

require careful consideration in terms of patient expectations; minimization of postoperative pain, nausea, vomiting and hypotension to facilitate therapy participation; therapist access to patients; and the likely need to extend therapy provision beyond traditional 'business' hours. Despite these potential barriers, previous research in a variety of settings supports feasibility of commencing therapy on day of surgery^{55–58}.

In this review, studies with greater control over inclusion/exclusion criteria and intervention/control (that could be characterized as efficacy studies) demonstrated stronger effect sizes than studies that could be argued as being effectiveness studies given their lesser control over these factors. This raises the question whether health services are likely to see the same magnitude of benefit as observed in efficacy studies when they replicate these studies in real life. Further research is required to understand the impact of AH service models in this population using more pragmatic research designs⁵⁹.

Limitations

This review has limitations related to the methodology and evidence base from which it was conducted. The search was limited to English publications. The risk of publication bias was not investigated due to inappropriateness of funnel plots when there are less than 10 studies in the meta-analysis⁶⁰ or substantial heterogeneity present⁶¹. The evidence base focused predominantly on PT following lower limb arthroplasty and did not consider other AH professions or the role of assistants sufficiently. Therefore, we have focused our conclusions predominantly on the effect of PT.

Our findings were drawn from a pool of studies with average LOS greater than current averages (7.15 vs just under 4 days following THA³ and 7.77 vs 3.3 days following TKA⁶²). A more modest LOS reduction (0.8 days) was observed following therapy initiation on day of surgery in the three studies with an average LOS in the control group of less than 4 days. However, there were no studies investigating provision of weekend PT or increased PT frequency with a baseline LOS comparable to current averages. It is plausible a weekend PT service may have a greater effect following surgery performed later in the week where the baseline LOS is shorter. Research to-date investigating the effect of weekend PT has not accounted for surgery day of week. However, this may be an important factor influencing effectiveness of weekend PT in light of a demonstrable relationship between day of surgery and LOS^{63–65}.

High between-study heterogeneity was evident in studies investigating earlier therapy commencement following lower limb arthroplasty. Meta-regression found greater LOS reduction in studies with higher quality, which we believe lends further support to our conclusion that early postoperative therapy is beneficial. Meta-analyses were also based on variable quality research, with some studies of particularly low quality. However, sensitivity analyses with removal of low quality studies and those investigating multidisciplinary and multimodal interventions revealed largely consistent findings, which give credence to the findings drawn from the larger pool of studies.

Research in this review has not adequately investigated the multi-dimensional nature of AH service models. The effect of weekend PT and early commencement on quantity of therapy were documented in only three and one study respectively. This data was confounded by LOS in all but one study and was not linked to individual outcomes. The effect of weekend PT on timing of therapy commencement was not investigated. This review also focused on the effects of different AH service models and did not attempt to

investigate the effect of individual modalities such as continuous passive motion or bed exercises.

Research implications

Currently, there are gaps in our understanding of the optimal timing and quantity of AH provided in the acute phase following lower limb arthroplasty. Further high quality research investigating all dimensions of AH service delivery (that is, timing of commencement, quantity in terms of session length and frequency and out-of-hours therapy) at constant timepoints or by calculating rate of therapy per day is indicated. This research should focus on individual elements of service models (e.g., vary timing of therapy commencement, but hold the quantity constant) so our understanding of each element can improve without confounding from other elements. Further research in this area should also account for surgery day of week.

Most research in this area has investigated the effect on acute hospital outcomes. Further research considering outcomes following discharge home may also be useful. Additionally, investigation of therapy cost-effectiveness following lower limb arthroplasty should consider the role of PT and OT assistants/aides given the established role of these personnel and lesser pay rate compared to AH professionals^{66,67}.

Conclusion

Earlier PT commencement and weekend provision may produce favorable outcomes following lower limb arthroplasty (especially TKA) when baseline LOS is 4 days or more. Redistributing AH resources to commence therapy on day of surgery regardless of day of week may accelerate postoperative recovery. Current, high quality research is needed to confirm these findings and examine cost-effectiveness, particularly when considering the multidisciplinary effect of AH.

Contributions

RH, KAB, LOB and TH were involved in study conception and design. RH obtained the data. RH and MS screened and extracted data. Data analysis was performed by RH, KAB, LOB and TH. All authors were involved in data interpretation. RH wrote the first draft of the manuscript. All authors revised the manuscript and gave final approval for submission.

Competing interests

No competing interests have been declared.

Role of the funding source

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Appendix I. Search terms for systematic literature review

Population	Intervention 1	Intervention 2	Intervention 3	Intervention 4	Outcome
Hip replacement	Allied health	Weekend	Early ambulation	Intensive therap*	Length of stay
Knee replacement	Physiotherap*	After hour*	Initial therap*	Additional therap*	Quality of life
Hip arthroplasty	Physical therap*	'On call'	Early mobil*	Extra therap*	Mobility
Knee arthroplasty	Occupational therap*	Out of hour*	Enhanced total hip replacement	Frequent therap*	Function*
Total knee replacement	Speech	Saturday	Enhanced total knee replacement	Immediate therap*	Activit* of daily living
Total hip replacement	Nutrition	Sunday	Enhanced recovery pathway	Utili?ation	ADL*
Total knee arthroplasty	Dietetic*	6-day	Rapid recovery	Dose	discharge destination
Total hip arthroplasty	Dietitian	7-day	Accelerated rehab* protocol*		adverse event*
Total joint arthroplasty	Dietician		First walk*		Cost
	Social		Time to commence physiotherapy*		Econom*
	Orthotic*		Time to commence physical therap*		Outcome*
	Prosthetic*		Day 0		Benefit*
			Day 1		
			Fast track		

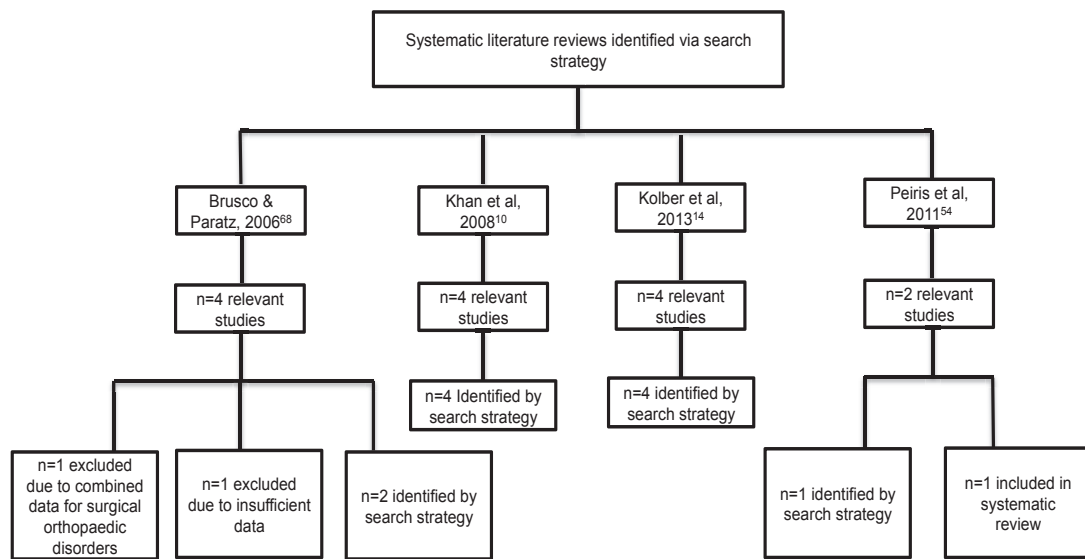
Population AND Intervention 1 AND (Intervention 2 OR Intervention 3 OR Intervention 4) AND Outcome.

Appendix II. Search Strategy for AMED

1	("hip replacement" or "total joint arthroplasty" or "knee replacement" or "hip arthroplasty" or "knee arthroplasty" or "total knee replacement" or "total hip replacement" or "total knee arthroplasty" or "total hip arthroplasty").mp.
2	(weekend or "after hour*" or "on call" or "out of hour*" or Saturday or Sunday or 6-day or 7-day).mp.
3	("early ambulation" or "immediate" or "early mobil*" or "enhanced total hip replacement" or "enhanced total knee replacement" or "enhanced recovery pathway" or "rapid recovery" or "accelerated rehab* protocol" or "first walk*" or "time to commence physiotherap*" or "time to commence physical therap*" or "initial therap*" or "day 0" or "day 1" or "fast track").mp.
4	("intensive therap*" or "additional therap*" or "extra therap*" or "frequent therap*" or "immediate therap*" or utili?ation or dose).mp.
5	("allied health" or physiotherap* or "physical therap*" or "occupational therap*" or speech or dietetic* or nutrition or dietitian or dietician or social or orthotic* or prosthetic*).mp.
6	("length of stay" or "quality of life" or mobility or function* or "activit* of daily living" or ADL* or "discharge destination" or "adverse event*" or cost or econom* or outcome* or benefit*).mp.
7	(#2 or #3 or #4).mp.
8	(#1 and #5 and #6 and #7).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]

Appendix III. Screening of systematic literature reviews identified from search strategy⁶⁸



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Appendix B

Search terms for systematic literature review

Population	Intervention 1	Intervention 2	Intervention 3	Intervention 4	Outcome
Hip replacement	Allied health	Weekend	Early ambulation	Intensive therap*	Length of stay
Knee replacement	Physiotherap*	After hour*	Initial therap*	Additional therap*	Quality of life
Hip arthroplasty	Physical therap*	'On call'	Early mobil*	Extra therap*	Mobility
Knee arthroplasty	Occupational therap*	Out of hour*	Enhanced total hip replacement	Frequent therap*	Function*
Total knee replacement	Speech	Saturday	Enhanced total knee replacement	Immediate therap*	Activit* of daily living
Total hip replacement	Nutrition	Sunday	Enhanced recovery pathway	Utili?ation	ADL*
Total knee arthroplasty	Dietetic*	6-day	Rapid recovery	Dose	discharge destination
Total hip arthroplasty	Dietitian	7-day	Accelerated rehab* protocol*		adverse event*
Total joint arthroplasty	Dietician		First walk*		Cost
	Social		Time to commence physiotherapy*		Econom*
	Orthotic*		Time to commence physical therap*		Outcome*
	Prosthetic*		Day 0		Benefit*
			Day 1		
			Fast track		

Population AND Intervention 1 AND (Intervention 2 OR Intervention 3 OR Intervention 4)

AND Outcome

Appendix C

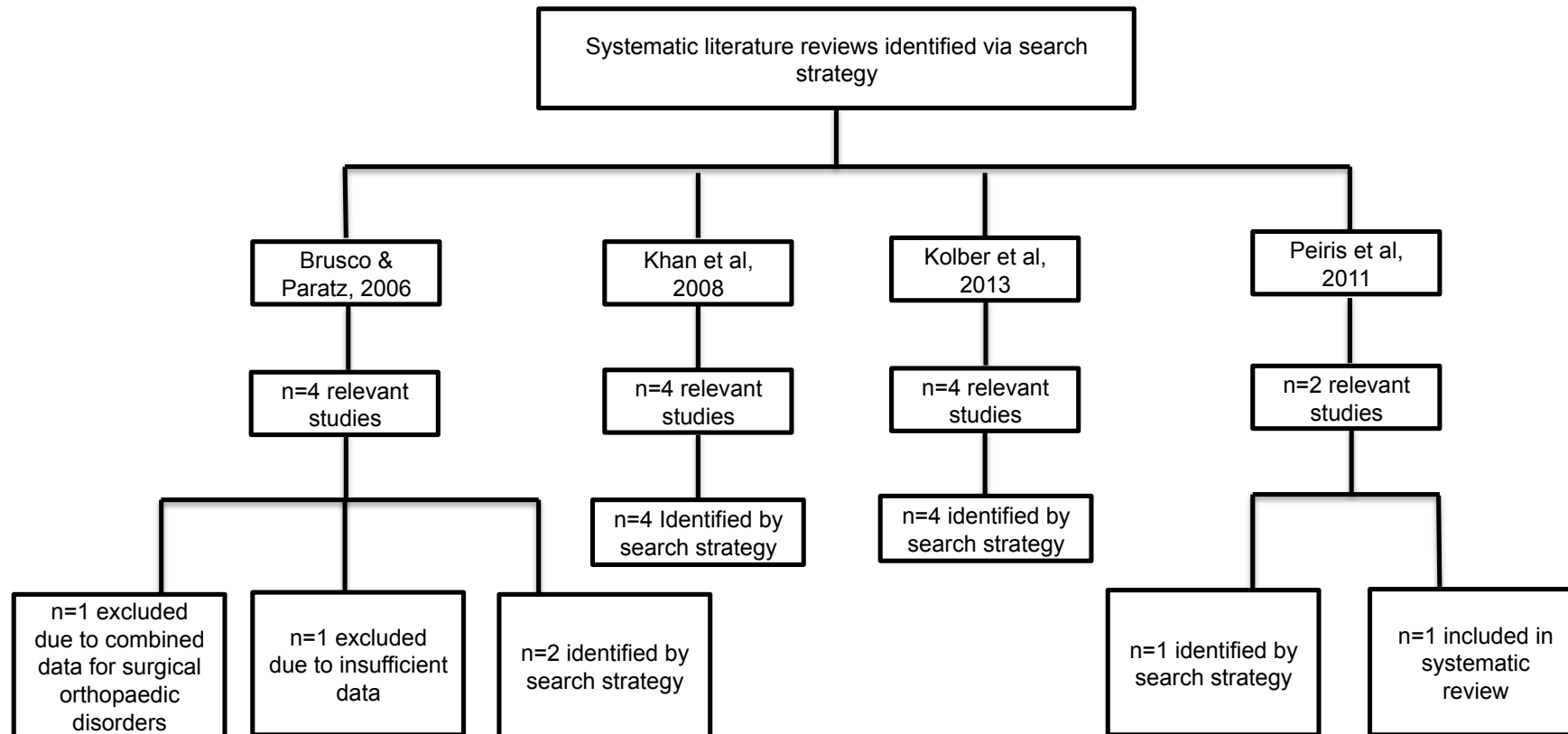
Search Strategy for Allied and complimentary MEDicine Database (AMED)

1	("hip replacement" or "total joint arthroplasty" or "knee replacement" or "hip arthroplasty" or "knee arthroplasty" or "total knee replacement" or "total hip replacement" or "total knee arthroplasty" or "total hip arthroplasty").mp.
2	(weekend or "after hour*" or "on call" or "out of hour*" or Saturday or Sunday or 6-day or 7-day).mp.
3	("early ambulation" or "immediate" or "early mobil*" or "enhanced total hip replacement" or "enhanced total knee replacement" or "enhanced recovery pathway" or "rapid recovery" or "accelerated rehab* protocol" or "first walk*" or "time to commence physiotherap*" or "time to commence physical therap*" or "initial therap*" or "day 0" or "day 1" or "fast track").mp.
4	("intensive therap*" or "additional therap*" or "extra therap*" or "frequent therap*" or "immediate therap*" or utili?ation or dose).mp.
5	("allied health" or physiotherap* or "physical therap*" or "occupational therap*" or speech or dietetic* or nutrition or dietitian or dietician or social or orthotic* or prosthetic*).mp.
6	("length of stay" or "quality of life" or mobility or function* or "activit* of daily living" or ADL* or "discharge destination" or "adverse event*" or cost or econom* or outcome* or benefit*).mp.
7	(#2 or #3 or #4).mp.
8	(#1 and #5 and #6 and #7).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]

Appendix D

Screening of systematic literature reviews identified from search strategy



Appendix E

Manuscript presenting protocol of parent trials

“Study protocol for two randomized controlled trials examining the effectiveness and safety of current weekend allied health services and a new stakeholder driven model for acute medical/surgical patients versus no weekend allied health services” by Haines et al is licensed under CC BY 4.0.

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STUDY PROTOCOL

Open Access

Study protocol for two randomized controlled trials examining the effectiveness and safety of current weekend allied health services and a new stakeholder-driven model for acute medical/surgical patients versus no weekend allied health services

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Abstract

Background: Disinvestment from inefficient or ineffective health services is a growing priority for health care systems. Provision of allied health services over the weekend is now commonplace despite a relative paucity of evidence supporting their provision. The relatively high cost of providing this service combined with the paucity of evidence supporting its provision makes this a potential candidate for disinvestment so that resources consumed can be used in other areas.

This study aims to determine the effectiveness, cost-effectiveness and safety of the current model of weekend allied health service and a new stakeholder-driven model of weekend allied health service delivery on acute medical and surgical wards compared to having no weekend allied health service.

Methods/Design: Two stepped wedge, cluster randomised trials of weekend allied health services will be conducted in six acute medical/surgical wards across two public metropolitan hospitals in Melbourne (Australia). Wards have been chosen to participate by management teams at each hospital. The allied health services to be investigated will include physiotherapy, occupational therapy, speech therapy, dietetics, social work and allied health assistants. At baseline, all wards will be receiving weekend allied health services. Study 1 intervention will be the sequential disinvestment (roll-in) of the current weekend allied health service model from each participating ward in monthly intervals and study 2 will be the roll-out of a new stakeholder-driven model of weekend allied health service delivery. The order in which weekend allied health services will be rolled in and out amongst participating wards will be determined randomly. This trial will be conducted in each of the two participating hospitals at a different time interval. Primary outcomes will be length of stay, rate of unplanned hospital readmission within 28 days and rate of adverse events. Secondary outcomes will be number of complaints and compliments, staff absenteeism, and patient discharge destination, satisfaction, and functional independence at discharge.

(Continued on next page)

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(Continued from previous page)

Discussion: This is the world's first application of the recently described non-inferiority (roll-in) stepped wedge trial design, and the largest investigation of the effectiveness of weekend allied health services on acute medical surgical wards to date.

Trial registration: Australian New Zealand Clinical Trials Registry.

Registration number: ACTRN12613001231730 (first study) and ACTRN12613001361796 (second study).

Was this trial prospectively registered?: Yes.

Date registered: 8 November 2013 (first study), 12 December 2013 (second study).

Anticipated completion: June 2015.

Protocol version: 1.

Role of trial sponsor: KP and DL are directly employed by one of the trial sponsors, their roles were: KP assisted with overall development of research design and assisted with overall project management; DL contributed to project management, administration and communications strategy.

Keywords: Disinvestment, Hospital, Effectiveness, Randomised trial, Allied health

Background

Allied health services (such as physiotherapy, occupational therapy, speech pathology, social work and dietetics) are now commonly provided on the weekend in hospitals internationally. A survey of tertiary-care hospitals in Canada reported that 97% of facilities provided weekend physiotherapy services [1]. This was at a lower intensity than during the week and there was high variability in the scope of services provided between hospitals. In an Australian study, 61% of hospitals provided physiotherapy on Saturdays, and 45% on Sundays [2]. There is little published information examining weekend services amongst other allied health disciplines. One survey of Australian public hospital emergency departments found that 6 out of 21 responding hospitals had rostered occupational therapy weekend services [3].

There is a body of indirect evidence indicating that provision of earlier and higher intensities of particular allied health services improves health outcomes for a range of hospital patient populations [4-8]. However, increasing service provision on weekends may not have the same effect as increasing services during the week. Staff who are employed in weekend roles may not have the same level of organisational knowledge/expertise/connection as staff who work during the week, which may affect patient health outcomes, discharge planning and subsequent organisational flow outcomes. Also, community support services that allied health services may refer patients to may not operate over the weekend, reducing their ability to facilitate discharges at this time.

There is scant evidence from well-designed studies that directly supports the effectiveness of allied health services provided over the weekend. A systematic review of experimental, quasi-experimental and observational studies concluded that research to date did not provide strong evidence that physiotherapy services provided on the weekend reduced length of stay, improved patient

discharge mobility status or discharge destination [9]. Subsequent research has focused on provision of physiotherapy ± occupational therapy on weekends in rehabilitation wards and has generated some support for service effectiveness in this context [10-13]. However, patients on rehabilitation wards are distinct from those in other hospital wards given their longer length of stay and higher need for rehabilitation therapy. Hence, it is difficult to extrapolate the findings of research conducted in rehabilitation settings to other hospital areas such as acute medical/surgical wards.

An additional factor that should influence whether allied health services are provided on weekends is that of economic efficiency. There are two key factors that may limit the cost-effectiveness of allied health services provided over the weekend, being: the higher cost per hour of employing staff over weekends compared to during the week, [14] and the possibility of diminishing marginal returns [15]. This latter principle suggests that the amount of additional benefit gained for each additional unit of service provision will decrease as the overall level of service provision increases, meaning that the cost-effectiveness ratio of these services will decrease with increasing levels of service provision (that is, there may be less benefit achieved from increasing allied health services from 5 to 7 days service per week than when increasing from 3 to 5 days of service per week). There is some evidence from an observation dose-response study indicating this principle applies to physiotherapy rehabilitation services [16].

Direct evidence of the economic efficiency of allied health services delivered on weekends is scant and inconsistent in its support of weekend allied health services. A partial economic evaluation (cost evaluation) of a weekend physiotherapy service provided to rheumatology patients in the United Kingdom found increased costs of service provision with no reduction in length of

stay (indeed, a non-significant increase of 0.5 days) associated with this programme [17]. A quasi-experimental, historical control group study found weekend physiotherapy provided to patients who had undergone a total hip or knee arthroplasty generated a cost saving to the health fund driven by a reduction in length of stay from 12.28 days to 10.84 days [18]. An observational study of a 7-day a week, 24-hour, on-call social work service provided in a hospital's emergency department suggested that the programme was operated at little cost to the hospital [19]. However, this study was purely an accounting exercise based on the estimated accounts paid and actual cost of the on-call services. An economic evaluation arising from a randomised controlled trial investigating the cost-effectiveness of additional Saturday physiotherapy and occupational therapy services on rehabilitation inpatients compared to those receiving usual Monday to Friday services had an incremental cost utility ratio of AUD 41,825 (95% confidence interval (CI) -2,817 to 74,620) per quality-adjusted life year (QALY) gained for the intervention group indicating this approach in this setting is likely to be cost-saving [20].

Clearly, there is uncertainty as to whether providing weekend allied health services is effective or cost-effective, particularly when provided on acute medical or surgical wards. Current widespread provision of these services complicates conduct of a traditional randomised trial as the intervention is already being provided as a part of usual care (the default control condition in pragmatic research). Our research team has recently devised a novel disinvestment research design that can be applied in the context where a health technology is being applied as a part of routine care, yet there is uncertainty as to the effectiveness, cost-effectiveness or safety of this health technology [21]. In this research, we will use this novel research approach to evaluate the effectiveness,

cost-effectiveness and safety of two models of weekend allied health service being provided on acute medical and surgical wards compared to having no weekend allied health service.

Methods/Design

Design

This research comprises two studies. Study 1 will consist of two hospital sites undertaking a novel, stepped wedge, roll-in, cluster randomised disinvestment trial whereby the current model of weekend allied health service delivery will be 'rolled back in' (withdrawn). Study 2 will consist of these same two hospital sites undertaking a conventional stepped wedge, roll-out, cluster randomised trial design in which a new stakeholder-driven model of weekend allied health service delivery will be rolled out to the same wards. Study 2 will commence immediately following completion of study 1.

Participants, therapists, centres

This research will take place across six acute medical or surgical wards from Dandenong Hospital and Western Hospital (Footscray), in Victoria, Australia. Both of these hospitals are major tertiary, metropolitan hospitals. The wards (Table 1) were selected by project investigators in consultation with managers and clinicians based at each site on the basis of currently having a weekend allied health service, the patient types being treated on that ward (medical or surgical patients, not rehabilitation), and not being anticipated to undergo major structural change (for example, substantive change of patient case-mix or refurbishment requiring ward shut-down) during the study period which would confound the trial design. High-risk wards such as intensive and coronary care units, emergency departments and paediatric wards were excluded. Each hospital will commence this research at

Table 1 Caseload in participating wards

Hospital	Ward	Description
Dandenong Hospital	SW3/W2 acute	Orthopaedic surgery
	SW4	Stroke unit
	West 3	Thoracic, Vascular, General surgical and medical units
	West 4	General medicine
	North Ward	Head and neck, Plastics
	North 3	Surgical
Western Hospital	2B	Medical
	2C	Medical
	2D	Infectious diseases; Respiratory medicine
	2 W ^a	Plastics; Head and neck surgery; ENT surgery
	3 W	General surgery; Colorectal; Breast; Endocrine; Urology
	3E	General surgery; Vascular surgery; Thoracic; Upper gastrointestinal

^aStudy 1 only.

different time points (Dandenong Hospital commencing February 2014 and Western Hospital (Footscray) commencing April 2014).

Data in this study will be collected from three groups of participants. Each group of participants is now described in detail.

Group 1

'All patients on participating wards.' This group will consist of patients admitted to acute medical or surgical wards involved in the trial who are over the age of 18 years. Paediatric patients will be excluded from this study as they are not routinely seen on the selected wards (none are paediatric units or have paediatric beds) and have different provisions for service delivery. It is anticipated, based on previous patient flow data, that each ward will have an average of 174 patient admissions per month during the trial. This means that 6 wards at 1 site will have 7,308 patient admissions during the 7 months of study 1 and 7,308 during the 7 months of study 2. This will lead to an anticipated total of 29,232 patient admissions during the overall study period.

Group 2

'Randomly selected subgroup of patients from participating wards'. A randomly selected subgroup of approximately 600 patients from participating wards will be recruited for additional data collection. Study data collectors will use a random number generator to randomly select wards on specific days during the study period that they will attend and approach all patients who are planned for discharge within the next 24 hours from that ward to consent to participate in this component of the study. These participants will be recruited to contribute data to secondary outcomes for this study.

Group 3

'Health professionals.' A volunteer subgroup of medical, nursing and allied health staff (four to twelve per participating ward) will be sought to participate in qualitative data collection approaches (group interviews and key informant interviews) being used as a part of the project process evaluation and planning for the intervention model to be used in study 2. This will include staff who work on the participating wards during the week and on the weekend. Three waves of data collection will take place with these health professionals (pre-study 1, between studies 1 and 2, and post-study 2).

Intervention/Control

We have provided a summary of our intervention conditions described according to the TIDieR guidelines [22]

in Table 2. Further elaboration of the intervention conditions is now provided according to study.

Study 1 intervention condition - current weekend allied health services

Current physiotherapy, occupational therapy, social work, dietetics, speech pathology and allied health assistant weekend service delivery on the participating wards will be the intervention for study 1 of this trial. During this study, the weekend allied health services of each participating ward (cluster) will be 'rolled in' sequentially using the stepped wedge design (Figure 1 and Additional file 1). The current model of weekend allied health service delivery in the hospitals participating in this study has not been developed systematically, rather in an '*ad hoc*' manner driven by decisions made by individual allied health managers. Thus, there is potential that this model is not currently tailored to the needs of individual wards and is, therefore, not delivering optimal outcomes. However, it is the prevailing model of care that in a pragmatic research design serves as an appropriate reference standard [23].

Design at Western Hospital (Footscray) is similar but with 5 wards involved in study 2 and a 13-month total study period. Black = current weekend allied health service. White = no weekend allied health service. Grey = new, stakeholder-driven weekend allied health service. Twelve months of pre-trial data collection at participating sites indicated that weekend allied health services at each site varied in terms of the number of disciplines involved, the amount of time allocated per ward and the total budgetary allocation to this activity. Steps will be taken during study 1 to ensure intervention fidelity relative to the pre-trial data collection. Allied health staff providing weekend services will be updated as to the amount of time spent on each ward per month and will have pre-trial data used as monthly targets to ensure that service provision levels within study 1 intervention periods are consistent with pre-trial data. Staff will be advised to continue performing tasks and prioritising patients in the same manner with which they had been doing so prior to trial commencement.

Study 1 - control condition - no weekend allied health services

The control condition will be characterised by the provision of no weekend allied health services unless a patient meets a 'clinical exception' criteria. A 'clinical exception' refers to circumstances where the trial treatment protocol is permitted to be violated due to the risk of harm to an individual or organisation. This is also intended to mitigate against possible protocol violations by staff and to ease their concerns regarding the health and well-being of patients given the novel research

Table 2 Intervention conditions according to TiDieR criteria

TiDieR criteria	Study 1 intervention	Study 2 intervention
Item 1. Brief name: provide the name or a phrase that describes the intervention	Usual care weekend allied health service	Stakeholder-driven weekend allied health service
Item 2. Why: describe any rationale, theory, or goal of the elements essential to the intervention	Usual care is the prevailing model of care in the research location that in a pragmatic research design serves as an appropriate reference standard. This model of care has developed incrementally over time and has largely been driven by decisions of individual allied health managers in an <i>'ad hoc'</i> manner	A new model of weekend allied health service will be developed where managers and staff of participating wards are engaged to identify the most important tasks that require completion on weekends that could be undertaken by allied health staff. It is anticipated that by directly engaging with these key stakeholders, a new model of care that better meets the needs of individual wards will be developed
Item 3. What (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	There are no specific materials used beyond those materials ordinarily used by allied health professionals during the week. It is left to the discretion of individual staff what materials they use in their clinical practice	There are no specific materials used beyond those materials ordinarily used by allied health professionals during the week. If the people involved in developing this model of care determine that additional materials are required, these will be identified and described at a later date
Item 4. What (procedures)? describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities	Allied health services may include services provided by physiotherapy, occupational therapy, social work, dietetics, speech pathology professionals and allied health assistants. Services delivered are the same as those performed on weekdays, although the intensity of weekend services is lower (fewer hours per ward) than weekday services. Services commonly include mobilisation, chest physiotherapy, discharge planning, assessment and prescription of aids and equipment, swallowing assessment, dietary analysis and prescription, and counselling	Services provided are likely to be similar to that of the usual care weekend allied health service. However, the people involved in developing this model will be able to inform the practitioners involved of the relative priority of the different tasks that they may be asked to perform on each ward
Item 5. Who provided?: for each category of intervention provider (for example, psychologist, nursing assistant), describe their expertise, background and any specific training given	All allied health professionals will have entry-level allied health degrees as a minimum. Orientation of new staff members to the health care organisation and wards that they work on is provided as a part of standard human resources procedures. Allied health assistants do not require formal qualification but must have a certificate III or IV [44] and all operate under the direction of an allied health professional	Services providers are likely to be similar to that of the usual care weekend allied health service. However, the people involved in developing this model will be able to decide which service providers are best positioned to undertake the tasks that require completion on the weekend, and will also decide if transdisciplinary training is required by individual practitioners
Item 6. How?: describe the modes of delivery (such as 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	Face to face individual patient interaction	Face to face individual patient interaction
Item 7. Where: describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	Hospital acute medical/surgical ward environment	Hospital acute medical/surgical ward environment
Item 8. When and how much?: 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	Individual patients will receive variable amounts of weekend allied health service delivery. The intensity of services provided is at the discretion of the allied health professional. The number of hours of weekend allied health service delivered per day will vary between wards within each site and between sites	Individual patients will receive variable amounts of weekend allied health service delivery. The intensity of services provided is at the discretion of the allied health professional. The number of hours of weekend allied health service delivered per day will vary between wards within each site and between sites
Item 9. Tailoring: if the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how	All weekend allied health services will be tailored to the needs of the patients being treated. This will be at the discretion of the treating allied health professional based upon their clinical judgement.	All weekend allied health services will be tailored to the needs of the patients being treated. This will be at the discretion of the treating allied health professional based upon their clinical judgement.
Item 10. Modifications: if the intervention was modified during the course of the study,	Not applicable for protocol	Not applicable for protocol

Table 2 Intervention conditions according to TIDieR criteria (Continued)

describe the changes (what, why, when, and how)

Item 11. How well (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

Research assistants will be present daily on study wards to both promote and monitor intervention fidelity in terms of which wards should be receiving weekend allied health services and which should not. Patient contact statistics are recorded by allied health professionals and are recorded in hospital administrative datasets. These datasets will be used by investigators to measure time spent by weekend allied health personnel with patients on each ward.

Research assistants will be present daily on study wards to both promote and monitor intervention fidelity in terms of which wards should be receiving weekend allied health services and which should not. Patient contact statistics are recorded by allied health professionals and are recorded in hospital administrative datasets. These datasets will be used by investigators to measure time spent by weekend allied health personnel with patients on each ward.

Item 12. How well (actual)? If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

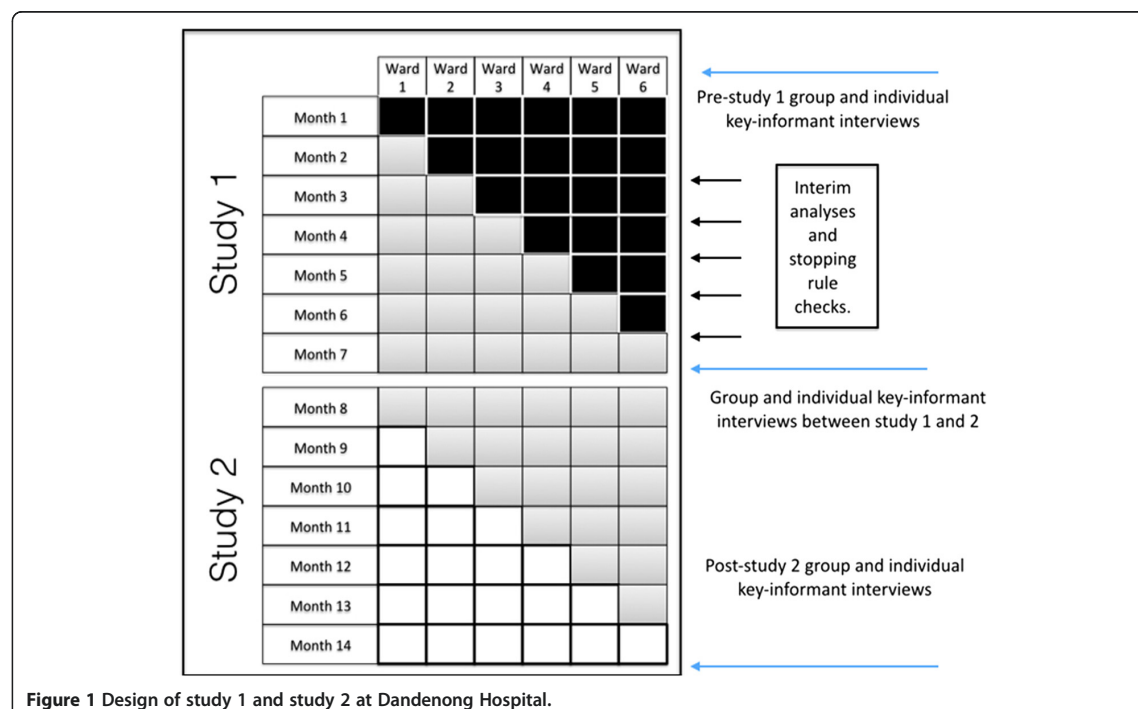
Not applicable for protocol

Not applicable for protocol

approach being used in this study [21]. Patients who meet one of these criteria will be permitted to see a weekend allied health staff member despite them being on a ward during a 'control' period. Local nursing or medical staff will identify if the patient meets the pre-determined set of criteria, which allows for them to be seen by an allied health professional over a weekend. This will be escalated to the site allied health director or project site liaison who will approve provision of the service following a final check against the 'clinical exception' criteria. These criteria will be suggested by ward-

level staff during pre-trial group interviews, and managers through key-informant and group interviews and will vary from site to site. Staff will be asked to provide evidence to support their request for a clinical exception criteria (for example, research papers, local incident reports, hospital policy), and project investigators will determine whether the strength of evidence presented warrants formation of a clinical exception criterion.

The frequency of clinical exceptions under each criterion will be recorded to monitor control condition fidelity. Project data collectors at each site will be present on



each ward each day of this project and will facilitate ongoing communication with ward staff regarding local clinical exception criteria.

Study 2 - control condition - no weekend allied health services

This will be identical to the study 1 control condition.

Study 2 - intervention condition - stakeholder-driven model of weekend allied health services

A criticism of using the current model of weekend allied health service provision as the intervention in study 1 is that it is possible that the sites involved may have constructed their prevailing model on an *ad hoc* basis, which may not reflect higher standards of service set in other hospitals. This is consistent with evidence already discussed that there is high variability in the amount and focus of allied health services already being delivered on weekends internationally [1]. However, there is no existent 'gold standard' for how a weekend allied health service delivery model should be structured (which services, how much, what activities) given the paucity of evidence regarding the comparative efficacy of different weekend allied health service delivery models. Developing such a standard across all medical and surgical wards may also be an impossibility, as different types of wards will have different patient casemix and different allied health service requirements.

Rather than conform to a non-existent 'standard' for what a weekend allied health service delivery model should look like, we have sought to standardise a process by which an 'optimal' site-specific service could be developed. Thus, the model of allied health service delivery used as the intervention in study 2 of this research is a complex intervention [24].

Our process for developing this site-specific weekend allied health service delivery model begins with extensive consultation with relevant stakeholders (medical, nursing and allied health staff and managers) on participating wards. These staff will be interviewed (group and individual, key informant) to drive development of this model; hence, we refer to this model as a stakeholder-driven model. Investigators experienced in conducting qualitative and participatory action research (LO, FM) will facilitate these interviews. These staff will not be asked to say which professional discipline they want to be employed on the weekends, rather, to identify and prioritise the tasks that they believe to be most important for allied health to perform on weekends both in terms of improving patient health outcomes, improving patient flow, and reducing readmissions. They will also be asked to reflect on the strengths and limitations of the current model of care, suggest areas for improvement and to examine patient incident and clinical

exception data gathered during the first study of the trial to inform their decisions. Allied health managers will be provided with this list of tasks and other feedback gathered, so that they can propose what the new, stakeholder-driven model of weekend allied health service delivery will be. Transdisciplinary, interdisciplinary and multidisciplinary models of care are all possible candidates for the model of care that will arise from this process. These managers will then be engaged in a Delphi process [25] to select the preferred model of care from the proposals generated.

Each site will hold constant the budgetary amount allocated to weekend allied health services between studies 1 and 2. During the second 'step' in the stepped wedge design of study 2, the first ward to resume provision of weekend allied health services using the stakeholder-driven model will be provided with a budgetary allocation that is the average per ward of study 1. During the third step, when a second ward resumes provision of weekend allied health services, the total budgetary allocation to be shared between the 2 wards that have resumed provision of the weekend service will be twice the average per ward of study 1. However, provisions within the stakeholder-driven model will be made to allow weekend allied health to distribute their time unequally between the two wards based on the task prioritisation framework provided to them by the stakeholders who designed this model. This provision recognises that an optimal service would target patients who are likely to receive the greatest benefit from this service, regardless of the ward they are physically being treated on.

Outcome measures

Current United Kingdom Medical Research Council guidance on the evaluation of complex interventions indicates that a single primary outcome may not make best use of data in these evaluations, rather, that a range of outcome measures will be needed including possible unintended consequences [23]. In this research, we plan to examine three domains of primary outcome with one domain being analysed in two ways, and another being measured as a composite outcome.

Primary outcome measure: 1) length of stay

Mean overall length of stay per patient who is treated on one of the targeted wards will be used as the primary outcome. This measure is often used as an indicator of hospital efficiency [26]. Length of stay is the key overall driver of inpatient costs and is the most readily available outcome to enable stopping rules to be checked during study 1. However, overall mean length of stay is limited as an outcome for this project as: i) these data can be skewed by highly influential outliers, ii) length of stay of longer-stay patients will not be known until they are

discharged (thus interim analyses for non-inferiority to check stopping rules may underestimate mean length of stay) and iii) patient admission casemix profile may vary over the study period (for example, a study ward may start admitting more patients who typically stay longer). To account for these limitations, we will also examine the proportion of patients who stay longer than their Australian Refined Diagnosis-Related Group average 'in-liner' length of stay according to data published from the previous year [27].

Primary outcome measure: 2) rate of unplanned hospital readmission within 28 days

This routinely collected measure will be used as a marker of treatment effectiveness, discharge planning and patient readiness for discharge [28].

Primary outcome measure: 3) rate of adverse events

Patient adverse events will be collected using a range of clinical data collection systems. The events quantified will be in-hospital falls, Code Blue/Medical Emergency Team calls, pulmonary embolus, deep vein thrombosis, death, hospital acquired pressure area, and intensive care unit admission from the ward. Rate of adverse events (events per person-time) will be considered as a single, composite end-point when considered as a primary outcome. A composite end point for this primary outcome domain was selected as a number of different clinical events may indicate a clinical failure, whereas the selection of only one type of clinical event as the end point may not present a comprehensive clinical picture [29].

Secondary outcome measure: 1) number of complaints

Complaints emanating from targeted wards (total and allied health specific) will be captured through the hospital administrative databases and local departmental datasets.

Secondary outcome measure: 2) number of compliments

Compliments emanating from targeted wards will be captured similarly to the number of complaints.

Secondary outcome measure: 3) patient discharge destination

Patient discharge destination will be classified into categories of: i) discharged to the community, ii) transferred to another acute ward, iii) transferred to intensive care, iv) transferred to rehabilitation, and v) discharged to residential aged care.

Secondary outcome measure: 4) patient satisfaction

Patient satisfaction with overall care will be measured using data from the 'overall hospital experience' domain of the Victorian Patient Satisfaction Survey [30]. These data will only be extracted from participant group 2

(randomly selected subgroup of patients from participating wards). These data will not be collected from patients with a diagnosis of dementia or cognitive impairment documented in their medical history.

Secondary outcome measure: 5) patient functional independence at discharge

Patient independence at discharge will be measured using participant self-report on the Modified Barthel Index [31]. These data will be collected from the same participant subgroup as secondary outcome measure: 4) patient satisfaction.

Secondary outcome measure: 6) patient health-related quality of life at discharge

Health-related quality of life at discharge from hospital will be measured using the European Quality of Life, 5 dimensions (EQ-5D-5 L) instrument [32]. These data will be collected from the same participant subgroup as secondary outcome measure: 4) patient satisfaction in study 2.

Secondary outcome measure: 7) staff absenteeism

Staff absenteeism (medical, nursing, allied health staff) will be collected through routine finance reporting. As allied health staff are not allocated to specific wards, but may work across a combination of wards with mixed exposure to intervention and control conditions, we will collect these data at only 3 time points: the first month of study 1, the final month of study 1 and the final month of study 2.

Process measure: 1) allied health hours of service

Number of occasions of allied health service provision to each patient on weekends and weekdays will be collected.

Process measure: 2) clinical exceptions

The frequency and reason for clinical exceptions taking place will be recorded by project research personnel.

Process measure: 3) proportion of patients discharged on a Saturday or Sunday

This outcome is a potential indicator of patient flow during the study. It is important to consider patient flow as a process measure to ensure that bed-block is not occurring on the weekend.

Economic outcome measure: 1) cost of inpatient treatment per patient

Hospital clinical costing data will be used to measure the costs attributed to each patient. If administrative data for a particular patient is unable to be extracted, costing based on the most recent National Weighted Activity Unit calculators [33] will be used. This will be based on the overall

patient admission, not just their time spent on a ward under an intervention or control condition.

Qualitative outcomes

Group and individual interviews will be conducted with staff members from each ward and weekend allied health staff at 3 time points (pre-study 1, between study 1 and study 2, and post-study 2) to explore their satisfaction with and experiences of the different weekend allied health service delivery models being examined.

Procedure

Approval to conduct this study has been obtained from the Monash Health Human Research Ethics Committee (EC00383 - representing Dandenong Hospital) and the Melbourne Health Human Research Ethics Committee (2013.283 - representing Western Hospital (Footscray)) and this trial has been registered with the Australian New Zealand Clinical Trials Registry (ACTRN12613001231730 (study 1) and ACTRN12613001361796 (study 2)). It is anticipated that data collection will commence in February 2014 and be completed in June 2015 with reports and publications finalised by June 2016. A multi-site project executive committee has been developed consisting of all project investigators. This executive committee has developed a project communications plan in consultation with representatives from the Victorian Government, Department of Health. Further pre-trial communications with relevant health services unions, local site clinicians, managers and executives will also be undertaken prior to trial commencement. Extensive staff engagement has been undertaken for this project at both study sites prior to trial commencement.

Randomisation and allocation concealment

The order in which weekend allied health services will be rolled in and out from each participating ward will be determined at random by an investigator blinded to ward identity. One investigator will develop pseudonyms for each ward while another investigator blinded to the true identity of each pseudonym will use a random number generator in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) to allocate ward number locations to each pseudonym. The first investigator will then be able to reveal which pseudonym represented which ward.

Masking

Research assistants collecting and entering data will not be blinded to the allocation of wards within the stepped wedge research designs. The randomly selected subgroup of patients from participating wards will not be informed of the purpose of the interview as being for the evaluation of a randomised controlled trial. However, we cannot say that all of these participants will be

blinded as to the intervention they were exposed to. Masking will be applied to the trial data analyst. Six mock codes representing different orders in which the wards may have progressed through the stepped wedge design (using a Latin Square approach) will be used to blind the statistician conducting the final quantitative analysis from the true identity of each ward and the time sequence in which each ward was randomised.

Trial safety

The process of disinvestment in allied health services has the potential to be detrimental to patient safety and/or organisational outcomes. The checking of stopping rules and development of clinical exceptions will, therefore, be used to ensure safety. A stopping rule allows data to be monitored and the trial to be stopped if there is evidence of a lack of safety or efficacy associated with the intervention [34]. During study 1, interim analyses will be conducted monthly to ensure that patient outcomes have not dropped below a pre-specified non-inferiority margin. This margin represents the maximum amount of gain anticipated if the amount of resources being saved were to be reallocated to another purpose. Discussion groups with clinicians and project investigators initially determined that the non-inferiority margin should be 0.8 multiplied by the standard deviation of the targeted outcome. This is equivalent to 'Cohen's large effect size' [35]. However, review of the standard deviations for the outcomes that these stopping rules would be applied to revealed that these margins were too wide to be acceptable to the management of participating hospitals. As a result of these consultations, the following stopping rules were developed:

1. The 95% CI of the effect (difference between means) of having no weekend allied health services exceeding a 1-day increase in mean length of stay.
2. The 95% CI of the effect (difference between proportions) of having no weekend allied health services exceeding an absolute change of 0.02 (2%) in the outcomes of the proportion of patients who stay longer than their average inlier Australian Refined Diagnosis-Related Group (ARD-RG), the proportion of patients who experience one or more of the previously specified adverse events, or the proportion of patients who are unexpectedly readmitted within 28 days.

Management at each site also reserved the right to review other study data (for example, the proportion of patients discharged on the weekend) in determining whether the study should continue at each site. Interim analysis will be conducted during each month of study 1 and reported back to the project executive committee.

The project executive committee will then forward their recommendations along with blinded data to an independent data-monitoring committee at each site to make a determination as to whether the project should be ceased on the basis of the analysis conducted.

Data will be collected in an identifiable form to allow data linkage with other project datasets but will then be de-identified for storage and analysis once linkages have been made.

Recruitment

A waiver of consent was requested and granted for researchers to access routinely collected, hospital administrative data (for example, length of stay, hospital readmission) covering these forms of data for participants in Group 1. Written consent will be obtained from all participants (where the waiver of consent does not apply). Written consent will be obtained from participants in Group 2 by a project team member (MS, MG) or research assistant. They will be identified as being potentially eligible for consent to participate by screening of ward handover sheets and communication with ward staff. Written consent will be obtained from participants in Group 3 by a project team member (ES, SP, LS, DM, LOB). They will be notified of the possibility of participating in this project by Email and verbal communication.

Data analysis

Sample size estimation

The sample size in this study is governed by the patient throughput on the participating wards over the trial

period. Non-inferiority trials do not preclude testing of superiority and can be done so without statistical penalty [36]; hence, we undertook power calculations for studies 1 and 2 from a superiority analysis perspective. Current data from study wards indicates there will be 7,308 patient admissions in total per study per site. We used the approach for conducting power analyses for stepped wedge trials advocated by Hussey and Hughes [37] based upon the Wald statistic. We applied this approach to 3 of our primary outcomes and demonstrated > 90% power in each case for study 1 and study 2 (Table 3). We reiterate that the actual sample size to be used in the trial has been determined primarily by practical considerations, particularly the availability of suitable wards at the participating sites.

Statistical analysis

Study 1 Both non-inferiority and superiority analyses will be conducted. For non-inferiority analyses, if the non-inferiority null hypothesis is to be rejected, the upper limit of the CI around the observed difference should be less than the non-inferiority margin. Multi-level, mixed-effects generalised linear model analyses will be used to construct the 95% CIs that compare effectiveness and safety outcomes between groups. These models will nest patient admissions within wards, treating both as random factors, to account for the clustered nature of these data. Weekend allied health service delivery model provided will be treated as a fixed factor. The distribution of the length of stay outcome will be examined (\pm transformations as indicated) as a part of model building as these data are commonly skewed. Data from

Table 3 Outcome of power analysis for three outcomes for each study at each site (assuming six wards per site), and for both sites combined

Outcome	Proportion 1 (weekend allied health services) ^a	Proportion 2 (no weekend allied health services)	Single site or both sites combined	Assumed coefficient of variation	Assumed number of patients per study	Power
Proportion of patients who stay longer than their AR-DRG average inlier length of stay	0.40	0.42	Single	0.4	n = 7,000 ^b	0.65
Proportion of patients who are readmitted within 28 days	0.10	0.12	Single	0.4	n = 7,000 ^b	0.96
Proportion of patients who experience at least one of the adverse events listed	0.10	0.12	Single	0.4	n = 7,000 ^b	0.96
Proportion of patients who stay longer than their AR-DRG average inlier length of stay	0.40	0.42	Both	0.4	n = 14,000 ^b	0.99
Proportion of patients who are readmitted within 28 days	0.10	0.12	Both	0.4	n = 14,000 ^b	>0.99
Proportion of patients who experience at least one of the adverse events listed	0.10	0.12	Both	0.4	n = 14,000 ^b	>0.99

AR-DRG, Australian Refined Diagnosis-Related Group.

^aBaseline proportions based on data drawn from administrative datasets at participating sites covering a 12-month period.

^bNote that for the single site analyses we assume there will be 7,308 per study, but use only 7,000 in the power analysis to allow for loss of patients during the transition phases between intervention and control conditions and for transfers between study wards. Correspondingly, we use 14,000 when considering the power of both sites combined.

patients who are exposed to both control and intervention conditions within each study will be excluded from the analyses. Analyses will be adjusted for index study ward (first study ward the patient was admitted to during that inpatient episode of care), calendar time using each step in the wedge design as a categorical covariate and for historical data collected for the outcome being examined from each site over the previous 2 years mapped against these steps to account for potential local seasonal variations in the outcomes collected.

Analyses will be conducted at a site-level with pre-planned meta-analyses across both sites using patient-level data from phase 1 and separately for phase 2. These meta-analyses will examine the main effect of the usual care weekend allied health service as opposed to the control condition across sites. A site-by-intervention interaction effect will also be examined to determine if there is heterogeneity in results between sites. This is plausible as a dose-response relationship may exist between the amount of resource allocated to the weekend allied health service and the study outcomes. In this study, local data collected prior to the study indicated that Dandenong Hospital allocated approximately four times as much resource to the acute medical and surgical wards participating in this research. Meta-regression will be employed using ward-level data, treating each ward over time as a pre-post intervention study to identify if the labour costs consumed on each ward for provision of the weekend allied health service explains variation in the change in each outcome within ward.

Patients who are exposed to both intervention and control conditions will be excluded from analyses to minimise potential contamination that is made possible by having the transition periods within the stepped wedge design.

Study 2 These analyses will be equivalent to the analyses conducted for study 1; however, non-inferiority analyses will not be conducted for this study.

A grand meta-analysis is planned, pooling results between studies 1 and 2 to examine whether there is a significant study-by-intervention interaction effect. This analysis will examine whether the effect of the stakeholder-driven model of weekend allied health service was significantly different to that of the usual care weekend allied health service delivery model.

Sensitivity analyses will be conducted if there are unit closures (for example, surgical unit closures over the Christmas holiday period) that are likely to affect the caseload on related wards at these times. Data within these cells of the stepped wedge design will be treated as missing in the sensitivity analyses.

Economic analysis The primary economic analysis will be a cost-effectiveness analysis from the hospital perspective that examines the incremental cost per patient admitted. These costs will include the 'total cost' of patients during their admission plus additional costs from an unplanned admission within 28 days. Data from patients who are transferred between wards in different study periods (that is one without access to allied health services, one with access to allied health services) will be excluded from the analyses as will data from patients who remain within the same ward over two or more weekends if they are allowed to access weekend allied health services during one weekend, and not allowed to access allied health services on another. Secondary economic evaluations will examine the incremental cost per difference in clinical outcome for the measures of functional independence (studies 1 and 2) and health-related quality of life (study 2).

Qualitative data analysis Both content and thematic analysis will be used for the analysis of qualitative data collected as a part of this study [38].

Analysis of workforce absenteeism outcome It was initially planned to analyse these data in a similar manner to other outcomes; however, it has become apparent that for some professional groups, staff operate over multiple wards that may be in the intervention or control periods during the study. Hence, we will only compare data collected from the first and last months of each study when all wards within the study are either completely in control or intervention periods.

Deviation from registered trial protocol

There have been two changes to the registered trial protocol. The first change was the withdrawal from both study 1 and study 2 of what was planned to be a third study site. Originally, a third site with five participating wards was planned to be involved and the appropriate ethics approval was gained. The ethics committee at this site retracted this approval due to subsequent opposition from senior medical staff. Project investigators met with these senior medical staff to discuss their concerns; however, agreement could not be reached regarding the issues raised to enable the trial to continue at this site.

The second change was that the broader health network, within which the Western Health (Footscray) site operates, decided to transfer some services from that site to another site within their network. This has resulted in only 5 wards being available to participate in study 2 at this site. This is likely to result in some changes to case-mix at the Western Health (Footscray) site during study 2. These changes are planned to take effect in early 2015 when the intervention phase of study 2 is in progress,

thus it was decided to make the changes to the study wards involved from the commencement of phase 2.

Discussion

Disinvestment from health services is becoming a growing priority for health care service providers due to increasing health care expenditure, budget cuts, an increasing burden of chronic disease and ageing in developed nations, and the ongoing introduction of new health technologies that render older technologies obsolete [39-41]. Paradigms for undertaking disinvestment are emerging but current processes rely upon the availability of evidence of effectiveness and cost-effectiveness [39,42,43]. This study uses a novel research design to demonstrate how health services can generate evidence regarding effectiveness, cost-effectiveness and safety during the disinvestment process [21]. The withdrawal of an intended study site due to opposition from senior medical staff despite prior ethics approval has demonstrated a clear barrier to conducting disinvestment research.

Trial status

Recruitment ongoing, anticipated completion June 2015.

Additional file

Additional file 1: SPIRIT 2013 Checklist: recommended items to address in a clinical trial protocol and related documents*.

Abbreviations

ARD-RG: Australian Refined Diagnosis-Related Group; EQ-5D-5 L: European Quality of Life, 5 dimensions; QALY: quality-adjusted life year; TIDieR: Template for Intervention Description and Replication.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

TPH: led development of research design and analysis plan and overall project management. LOB: assisted development of research design, led development of qualitative data collection methods and collection of qualitative data. DMi: site liaison for Monash Health, assisted with overall project management, led development of qualitative data collection methods and collector of qualitative data across all sites. KAB: led development of quantitative data collection methods, assisted with overall project management and collection of quantitative data across all sites. RH: development of local data collection methods and data collection at Monash Health. DMA: assisted development of overall research design, assisted overall project management and conduct of project at Dandenong Hospital. SP: site liaison for Melbourne Health, assisted with overall project management, assisted development of data collection plan at Melbourne Health. TC: assisted development of overall research design, assisted with overall project management, and conduct of project at Western Health. KM: assisted development of overall research design, assisted with overall project management, and conduct of project at Dandenong Hospital. KP: assisted with overall development of research design and assisted with overall project management. DL: contribution to project management, administration and communications strategy. FM: assisted with development of qualitative data collection approach and assistance with qualitative data collection. MS: assisted with development of quantitative data collection approach at Monash Health and data collection at this site. MG: assisted with development of quantitative data collection approach at Western Health and

data collection at this site. LS: site liaison for Melbourne Health, assisted with development of quantitative data approach at Melbourne Health. GJ: assisted with overall project management. ES: assisted with development of overall research design, site liaison for Western Health, assisted with development of quantitative data approach at Melbourne Health, assisted with data collection, assisted with overall project management. All authors have read and approved the trial manuscript and given approval for this version to be published.

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Access to trial data

TPH will have access to the final, de-identified trial dataset.

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Appendix F

Manuscript presenting results of parent trials

“Impact of disinvestment from weekend allied health services across acute medical and surgical wards: 2 stepped-wedge cluster randomised controlled trials” by Haines et al is licensed under CC BY 4.0.



RESEARCH ARTICLE

Impact of disinvestment from weekend allied health services across acute medical and surgical wards: 2 stepped-wedge cluster randomised controlled trials

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Abstract

Background

Disinvestment (removal, reduction, or reallocation) of routinely provided health services can be difficult when there is little published evidence examining whether the services are effective or not. Evidence is required to understand if removing these services produces outcomes that are inferior to keeping such services in place. However, organisational imperatives, such as budget cuts, may force healthcare providers to disinvest from these services before the required evidence becomes available. There are presently no experimental studies examining the effectiveness of allied health services (e.g., physical therapy, occupational therapy, and social work) provided on weekends across acute medical and surgical hospital wards, despite these services being routinely provided internationally. The aim of this study was to understand the impact of removing weekend allied health services from acute medical and surgical wards using a disinvestment-specific non-inferiority research design.

Methods and findings

We conducted 2 stepped-wedge cluster randomised controlled trials between 1 February 2014 and 30 April 2015 among patients on 12 acute medical or surgical hospital wards spread across 2 hospitals. The hospitals involved were 2 metropolitan teaching hospitals in

Postgraduate Award (RH and MS). KP worked for the Victorian Department of Health and Human Services and contributed to study design and manuscript preparation as an author. The funders had no other role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: I have read the journal's policy and the authors of this manuscript have the following competing interests: RH has been funded by an Australian Postgraduate Awards Scholarship. KM is a board member (volunteer/unpaid) for Wounds Australia and a member of Victorian Allied Health Leaders Council Executive (unpaid).

Melbourne, Australia. Data from $n = 14,834$ patients were collected for inclusion in Trial 1, and $n = 12,674$ in Trial 2. Trial 1 was a disinvestment-specific non-inferiority stepped-wedge trial where the 'current' weekend allied health service was incrementally removed from participating wards each calendar month, in a random order, while Trial 2 used a conventional non-inferiority stepped-wedge design, where a 'newly developed' service was incrementally reinstated on the same wards as in Trial 1. Primary outcome measures were patient length of stay (proportion staying longer than expected and mean length of stay), the proportion of patients experiencing any adverse event, and the proportion with an unplanned readmission within 28 days of discharge. The 'no weekend allied health service' condition was considered to be not inferior if the 95% CIs of the differences between this condition and the condition with weekend allied health service delivery were below a 2% increase in the proportion of patients who stayed in hospital longer than expected, a 2% increase in the proportion who had an unplanned readmission within 28 days, a 2% increase in the proportion who had any adverse event, and a 1-day increase in the mean length of stay. The current weekend allied health service included physical therapy, occupational therapy, speech therapy, dietetics, social work, and allied health assistant services in line with usual care at the participating sites. The newly developed weekend allied health service allowed managers at each site to reprioritise tasks being performed and the balance of hours provided by each professional group and on which days they were provided. Analyses conducted on an intention-to-treat basis demonstrated that there was no estimated effect size difference between groups in the proportion of patients staying longer than expected (weekend versus no weekend; estimated effect size difference [95% CI], p -value) in Trial 1 (0.40 versus 0.38; estimated effect size difference 0.01 [−0.01 to 0.04], $p = 0.31$, CI was both above and below non-inferiority margin), but the proportion staying longer than expected was greater with the newly developed service compared to its no weekend service control condition (0.39 versus 0.40; estimated effect size difference 0.02 [0.01 to 0.04], $p = 0.04$, CI was completely below non-inferiority margin) in Trial 2. Trial 1 and 2 findings were discordant for the mean length of stay outcome (Trial 1: 5.5 versus 6.3 days; estimated effect size difference 1.3 days [0.9 to 1.8], $p < 0.001$, CI was both above and below non-inferiority margin; Trial 2: 5.9 versus 5.0 days; estimated effect size difference −1.6 days [−2.0 to −1.1], $p < 0.001$, CI was completely below non-inferiority margin). There was no difference between conditions for the proportion who had an unplanned readmission within 28 days in either trial (Trial 1: 0.01 [−0.01 to 0.03], $p = 0.18$, CI was both above and below non-inferiority margin; Trial 2: −0.01 [−0.02 to 0.01], $p = 0.62$, CI completely below non-inferiority margin). There was no difference between conditions in the proportion of patients who experienced any adverse event in Trial 1 (0.01 [−0.01 to 0.03], $p = 0.33$, CI was both above and below non-inferiority margin), but a lower proportion of patients had an adverse event in Trial 2 when exposed to the no weekend allied health condition (−0.03 [−0.05 to −0.004], $p = 0.02$, CI completely below non-inferiority margin). Limitations of this research were that 1 of the trial wards was closed by the healthcare provider after Trial 1 and could not be included in Trial 2, and that both withdrawing the current weekend allied health service model and installing a new one may have led to an accommodation period for staff to adapt to the new service settings. Stepped-wedge trials are potentially susceptible to bias from naturally occurring change over time at the service level; however, this was adjusted for in our analyses.

Conclusions

In Trial 1, criteria to say that the no weekend allied health condition was non-inferior to current weekend allied health condition were not met, while neither the no weekend nor current weekend allied health condition demonstrated superiority. In Trial 2, the no weekend allied health condition was non-inferior to the newly developed weekend allied health condition across all primary outcomes, and superior for the outcomes proportion of patients staying longer than expected, proportion experiencing any adverse event, and mean length of stay.

Trial registration

Australian New Zealand Clinical Trials Registry [ACTRN12613001231730](https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=12613001231730) and [ACTRN12613001361796](https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=12613001361796)

Author summary

Why was this study done?

- This study was done to find out whether a health service that is routinely provided has the effect that it is intended to have.
- It considers whether it is worth continuing to provide this service when the resources we use to support this service could potentially be better used elsewhere in the health system.

What did the researchers do and find?

- We conducted 2 large trials across 6 acute medical and surgical wards in each of 2 hospitals.
- We removed the weekend allied health (e.g., physical therapy, occupational therapy, and social work) service in the first trial, redesigned it, and reintroduced it in the second trial.
- We found that removing the weekend allied health service had an uncertain impact on patient flow (the change in the percentage of patients who stayed longer than expected was +1% [95% CI: -1% to 4%]) and safety (the change in the percentage with any adverse event was +1% [95% CI: -1% to 3%]), but that having no weekend allied health service on these wards was no worse than having the newly developed service that was brought back in, and indeed was superior for some outcomes (the percentage who stayed longer than expected was 2% better [95% CI: 1% to 5%], and the percentage with any adverse event was 3% better [95% CI: 0% to 5%] with no weekend service).

What do these findings mean?

- These findings indicate that resources spent on providing allied health services on weekends across acute medical and surgical wards could possibly be better spent elsewhere in the healthcare system.

- This study also demonstrated that it is possible to undertake research of routinely provided services where it is uncertain whether they provide the benefits they are intended to.

Introduction

Disinvestment is the process of (partially or completely) withdrawing health resources from any existing healthcare practices, procedures, technologies, or pharmaceuticals that are deemed to deliver little or no health gain for their cost and thus are not efficient health resource allocations [1]. Governments and professional bodies around the world are introducing processes to eliminate or limit access to services and procedures known to deliver little or no health gain for their cost. Examples from the United States include the Choosing Wisely campaign driven by the American Board of Internal Medicine Foundation [2], and the Patients Before Paperwork initiative led by the American College of Physicians [3].

There is some controversy surrounding what the key motivation for these disinvestments should be. Commentators have expressed concern that the Choosing Wisely campaign is seen by some as a cost-cutting exercise, and feel that it would be more acceptable if the focus were placed on helping to avoid patient harm that may arise from unnecessary tests and ineffective interventions [2]. We would argue that disinvesting from ineffective services could be seen as being more virtuous and acceptable if entwined with an argument based on opportunity costs: that resources spent delivering ineffective services to one patient are the same resources that can no longer be used to deliver an effective service to improve health outcomes for another. This position is best seen from the perspective of healthcare administrators with finite budgets who must choose between competing services they can offer with their available funds.

Much of the debate thus far has centred on disinvestment from individual services that are known to be ineffective or unnecessary, particularly for certain patient subgroups. But what is to be done with classes of services that are routinely provided, but have unknown effectiveness or cost-effectiveness? Continued provision of these services, if ineffective, creates an opportunity cost that is wasteful and stops other patients from potentially benefitting from those same resources. If services are effective, cessation of provision creates a situation for potential patient harm and poorer health outcomes than what otherwise would have been achieved. Thus, decision makers are left in an unenviable position—by virtue of the absence of evidence relevant to guide their decision—of choosing between continued provision, cessation, or reduction, which each carry an element of risk for their patients. This situation is further complicated in circumstances where a service is provided by clinicians who believe it is effective, despite the absence of evidence to this effect. Planning to remove such a service may create fear of negative patient and/or provider outcomes in staff members, which can act as a barrier to practice change [4,5].

One such area of uncertainty is the delivery of allied health services on weekends to patients in acute medical and surgical units. Allied health services (such as physical therapy or social work) are now commonly provided on weekends in hospitals internationally, though not to the same extent as during the week [6–10]. These models appear to have increased in popularity following observational studies identifying a ‘weekend effect’—poorer patient and service outcomes associated with admissions or procedures taking place on weekends [11–15]. However, the efficacy of these services has not been established. A recent, methodologically

inclusive systematic review of these services amongst acute joint arthroplasty patients found some benefit in improving length of stay and function [16]. However, this finding was largely driven by findings of observational studies, and no randomised trials examining the efficacy of weekend allied health services in acute settings were identified. Links between allied health staffing levels and the weekend effect have not been established, and some have questioned the very existence of the weekend effect [17,18].

The aim of this study was to establish the impact of disinvesting from provision of allied health services on weekends across acute medical and surgical hospital wards.

Methods

Human Research Ethics Committee approval for this project was provided by the Monash Health (approval ref 13327B) and Melbourne Health (approval number: 2013.283) Human Research Ethics Committees.

Design

We have previously proposed an approach for use in the context of disinvestment from a service that has unknown effectiveness [4]. This approach is centred on simultaneous disinvestment from the health service in question while also generating the evidence examining the effectiveness of this service. In this research, we conducted 2 stepped-wedge cluster randomised controlled trials across each of 2 tertiary, metropolitan teaching hospitals, Dandenong Hospital and Footscray Hospital, in Victoria, Australia. Stepped-wedge trials are a form of cluster randomised trial with unidirectional crossover that are increasingly being used for health service evaluations [19]. Trial 1 was a disinvestment randomised trial where the 'current' weekend allied health service was removed from 1 ward per calendar month in an order determined at random. It contained examination of both non-inferiority and superiority hypotheses for each primary outcome examined, and superiority hypotheses for each secondary outcome examined. Testing non-inferiority hypotheses does not preclude testing of superiority hypotheses and can be done without statistical penalty [20]. Trial 2 was a conventional stepped-wedge randomised trial where a 'newly developed' weekend allied health service was reintroduced in a 180-degree rotated image of Trial 1 (Fig 1) [5]. This reintroduction of weekend allied health services in Trial 2 was considered necessary in the present context given the incremental and evolving development of the current weekend service delivery models that had taken place at the participating sites combined with heterogeneity in delivery models of these services internationally. The newly developed model that was reintroduced was intended to be a complex intervention that used a reproducible procedure for development. Its development involved gathering feedback from medical, nursing, and allied health staff working on the targeted wards. This feedback was reviewed by and discussed with local allied health managers in charge, who made the final decision as to the make-up of the newly developed model.

There were 3 deviations from the analysis plan and 1 change to the outcome measures described in our study protocol (S1 Text). First, a pre-planned meta-analysis that combined data from both sites and trials was not performed due to discordance in findings between Trial 1 and Trial 2 [21]. Second, a sensitivity analysis for Trial 1 was performed where a 1-month analysis washout period was introduced immediately following introduction of the 'no weekend allied health service' condition: the September 2014 block at Dandenong Hospital and the November 2014 block at Footscray Hospital served as the last block for this sensitivity analysis of Trial 1. Third, analyses without adjustment for monthly outcome data for the previous 2 years were undertaken. These analysis changes were inspired by peer-reviewers. The secondary

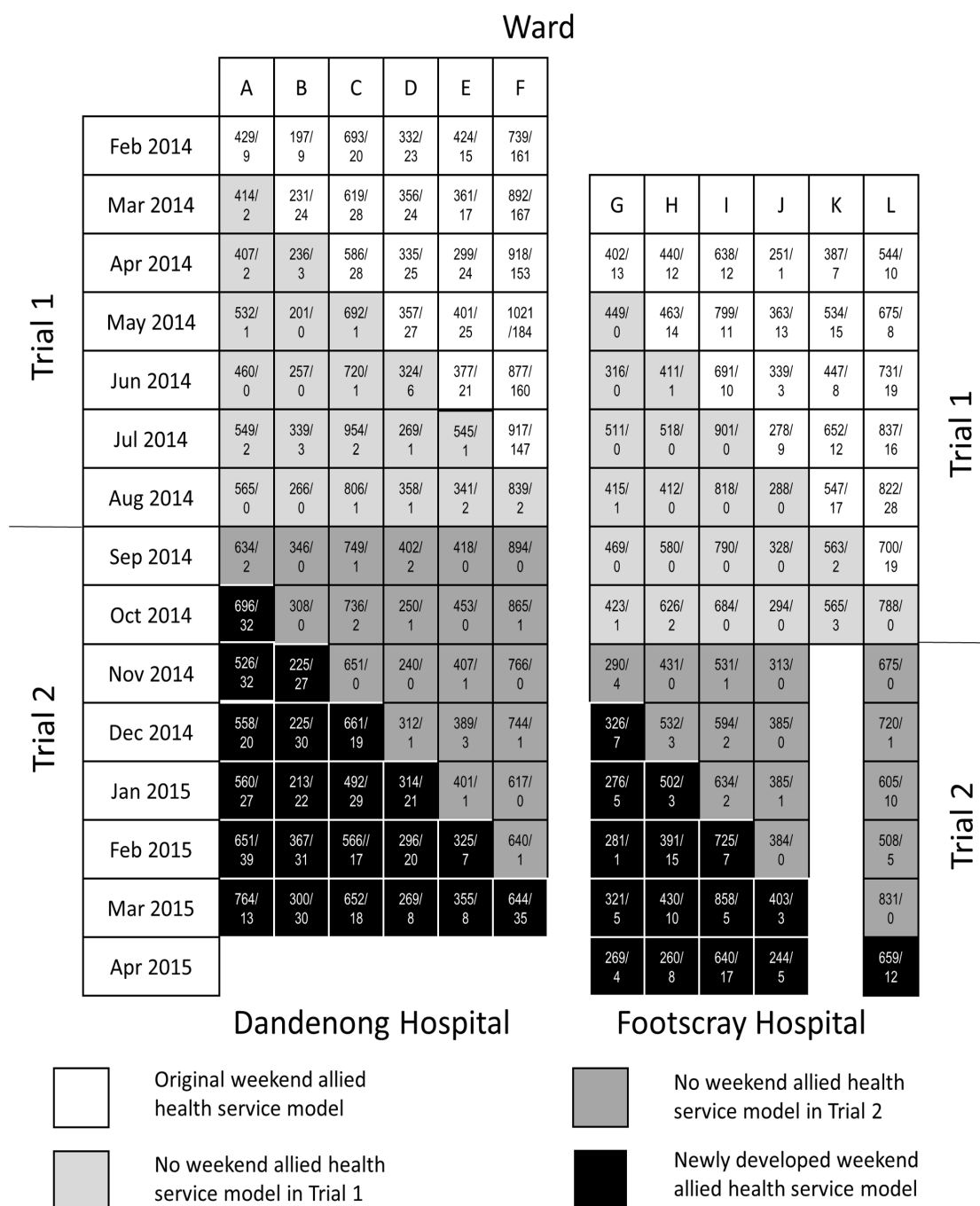


Fig 1. Trial design and occasions of allied health service delivery on weekdays and weekends within each month of the trial. Numbers in boxes indicate occasions of service provided by allied health team on weekdays/on weekends that month. These data include approved clinical exceptions during no weekend service periods.

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outcome of staff absenteeism could not be extracted in clinical units relevant for this trial, so was abandoned. A CONSORT checklist for this study is provided as [S2 Text](#).

Participants and setting

This research took place across 6 acute medical or surgical wards at Dandenong Hospital and 6 at Footscray Hospital, Victoria, Australia. Most of these wards were specialised in different areas of medical/surgical medicine and admitted different types of patients. At Dandenong Hospital, the ward specialties were orthopaedic surgery, stroke, thoracic/vascular/general surgery & medical, general medicine, head/neck/plastics, and surgical. At Footscray Hospital, the ward specialties were medical (2 wards), infectious diseases/respiratory, plastics/ENT/head/neck surgery, general surgery/colorectal/breast/endocrine/urology, and general surgery/vascular/thoracic/upper gastrointestinal. Patient allocation to wards was driven by patient specialty requirements and bed availability.

Patients who were exposed to the no weekend allied health service condition as well as either the current or newly developed weekend allied health service conditions were excluded to avoid research-design-induced contamination. The requirement to collect individual patient-level consent for researchers to access the primary and secondary outcomes reported in this paper was waived during the ethical approval process.

Randomisation and masking

Random allocation of wards at each site to starting position in the trial design was undertaken at public meetings at each site. Investigators (D. Mitchell and EHS) developed a list of pseudonyms to represent each ward and then provided these to another investigator (TPH) who was blinded to the meaning of each pseudonym. This investigator then used a random number generator command in Microsoft Excel to allocate wards to starting positions in the stepped-wedge trial design. From this point, staff and patients were not blinded to group allocations due to the practical need to notify staff when the weekend allied health service on their ward would cease.

Interventions

A detailed description of weekend allied health service models investigated in both of these trials (including TIDiER checklist [22]) and the process used to develop the newly designed model in Trial 2 was provided in our protocol [5]. Briefly, we undertook extensive consultation with relevant stakeholders (medical, nursing, and allied health staff and managers) on participating wards. These staff were interviewed (group interviews at the ward level and individual/key informant interviews) by investigators experienced in conducting qualitative and participatory action research (LO, FM). These staff were not asked to say which professional discipline they wanted to be employed on the weekends, rather, to identify and prioritise the tasks that they believe to be most important for allied health to perform on weekends in terms of improving patient health outcomes, improving patient flow, and reducing readmissions. They were also asked to reflect on the strengths and limitations of the current model of care, suggest areas for improvement, and examine patient incident and clinical exception data gathered during Trial 1 to inform their decisions. Allied health managers were provided with this list of tasks and other feedback gathered, so they could propose the new stakeholder-driven model of weekend allied health service they felt would work best. A Delphi meeting was used to facilitate this process separately at each hospital site [23]. This information was forwarded to each hospital's allied health director, who made the final decision.

Services delivered under the original (Trial 1) and newly developed models (Trial 2) at each site are presented in S3 and S4 Texts, which present the amount of service provided by each discipline group when the service was fully operational (first month of Trial 1 and last month of Trial 2).

The no weekend service condition entailed delivery of no allied health services on weekends to wards affected, unless criteria for a clinical exception had been met. A safety mechanism specified in our trial protocol was that a process be established whereby the trial protocol could be violated for an individual patient if specific, pre-planned criteria set by local clinicians and approved by local administrators were met (S5 Text).

Outcomes

The primary outcomes were indicators of the domains of patient flow through the hospital (length of stay measured in days, proportion of patients staying longer than their diagnosis-related group average inlier length of stay), failures in discharge planning (proportion of patients with unplanned readmissions within 28 days of discharge), and failures in patient care (proportion of patients experiencing any of the following adverse events: in-hospital fall, Code Blue call, Medical Emergency Team call, pulmonary embolus, deep vein thrombosis, death, hospital-acquired pressure area, or intensive care unit admission from the ward). We used 2 indicators of patient flow due to the inherent limitations of using the intuitively attractive indicator (length of stay measured in days) in the context of our stepped-wedge design. The results of a stepped-wedge trial can be biased if certain hospital wards, but not others in the same trial, change the types of patients (particularly those with greater or lesser lengths of stay) they tend to admit over time to cope with seasonal demands. Statistically adjusting for patient diagnosis and procedure type is a possible approach to dealing with this problem, but only if the number of meaningful diagnostic/procedural groupings is small enough to enable statistical models to be validly calculated (which is not the case in this context). Our alternate approach was to use the dichotomous outcome of whether each patient stayed longer than expected for their diagnosis/procedural-related grouping. In Australia, the Australian Refined Diagnosis Related Groups approach is employed. Hospital data coders classify patients into these groupings that are based on similarity of conditions and usage of hospital resources, using information in the hospital morbidity record such as the diagnoses, procedures, and demographic characteristics of the patient [24]. The primary outcomes were collected through hospital administrative data systems and checked daily by research assistants interviewing ward representatives and checking handover documentation.

Secondary outcomes collected across all participants included the proportion of patients discharged to residential aged care facilities, the cost (in Australian dollars) per patient to the healthcare system per admission, the proportion of patients discharged on a Saturday or Sunday, and the number of compliments and complaints (total and allied health specific). These outcomes were extracted from hospital administrative data systems at completion of the study. The cost of inpatient treatment per patient was extracted from hospital-based clinical costing systems in August 2016 to allow finalisation of hospital costing processes. It should be noted here that clinical costing data are largely driven by length of stay, and hence this outcome has the same limitations as described above for the length of stay outcome.

Process measures collected included the occasions of weekend allied health service delivery (i.e., the number of times an allied health professional went and saw a patient on the weekend) and reason for clinical exceptions taking place. Occasions of allied health service delivery were recorded by allied health staff, collected through routine hospital administrative data systems, and extracted at the end of the study. The frequency and reason for clinical exceptions taking

place were recorded by site investigators (KM, TC, and MS) who had local responsibility for approving these at the time of the exception being granted. Non-patient-related outcomes and qualitative, economic, subsample, and meta-regression analyses described in our protocol were reserved for further publications.

Procedure

An audit was conducted prior to the trial to establish the average amount of weekend service per ward and the financial costs of the overall service. During Trial 1, weekend services were titrated down according to pre-trial audit amounts. If a ward received 4 hours of physical therapy over a weekend prior to trial commencement, it is this amount that was removed when this service was ceased on this ward. For Trial 2, the service was reintroduced on a pro rata basis. So, if a hospital provided A\$2,400 in allied health staffing costs per weekend across 6 wards overall prior to the trial, then A\$400 worth of resources per ward was allowed to be reintroduced when the newly developed service was commenced. At the Dandenong Hospital site, managers reallocated their funds to increase the overall number of allied health hours provided by moving some hours to a Friday afternoon and Monday morning. This was intended to facilitate discharge planning prior to the weekend and immediately following and to maximise the total number of allied health hours. At the Footscray Hospital site, managers changed the personnel who provided the weekend allied health service from casual staff to allied health staff working in the intensive care unit and the Immediate Response Service, whose usual responsibility was to screen and assess presentations to the emergency department to prevent inappropriate admissions and facilitate discharge planning.

A CONSORT flow chart (Fig 2) provides study recruitment, data collection, and analysis details. Nursing staff managers on each ward were engaged prior to study commencement to identify which tasks usually performed by allied health staff on weekends could be modified, accelerated (to a Friday), delayed (to a Monday), or transferred to other staff who were present on weekends. They were also provided with the criteria for clinical exceptions on their wards. Study stopping rules and non-inferiority margins were also developed prior to trial commencement by hospital administrators and allied health managers at participating sites [5].

Project research assistant data collectors were present 7 days per week during the study period. They collected data through medical record review and interviews with hospital staff, enabling crosschecking of data collected between routine hospital administrative data systems and direct data collection approaches [25,26].

These trials were registered with the Australian New Zealand Clinical Trials Registry. Trial 1 was prospectively registered on 8 November 2013 (ACTRN12613001231730), and Trial 2 on 12 December 2013 (ACTRN12613001361796).

Statistical analysis

Multilevel, mixed-effects generalised linear model analyses were used to generate effect size estimates and 2-tailed 95% CIs and superiority hypothesis *p*-values. The 95% CIs were compared to the non-inferiority margins for each primary outcome measure to determine if they were completely below (indicating non-inferiority), completely above (indicating inferiority), or both above and below (indicating uncertain inferiority) the non-inferiority margin. The non-inferiority margins were an absolute difference of 2% in proportion outcomes (proportion of patients staying longer than the average inlier diagnosis-group-related length of stay, proportion with an unplanned readmission within 28 days, proportion experiencing 1 or more of the adverse events previously listed) and an absolute difference of 1 day for the mean length of stay outcome.

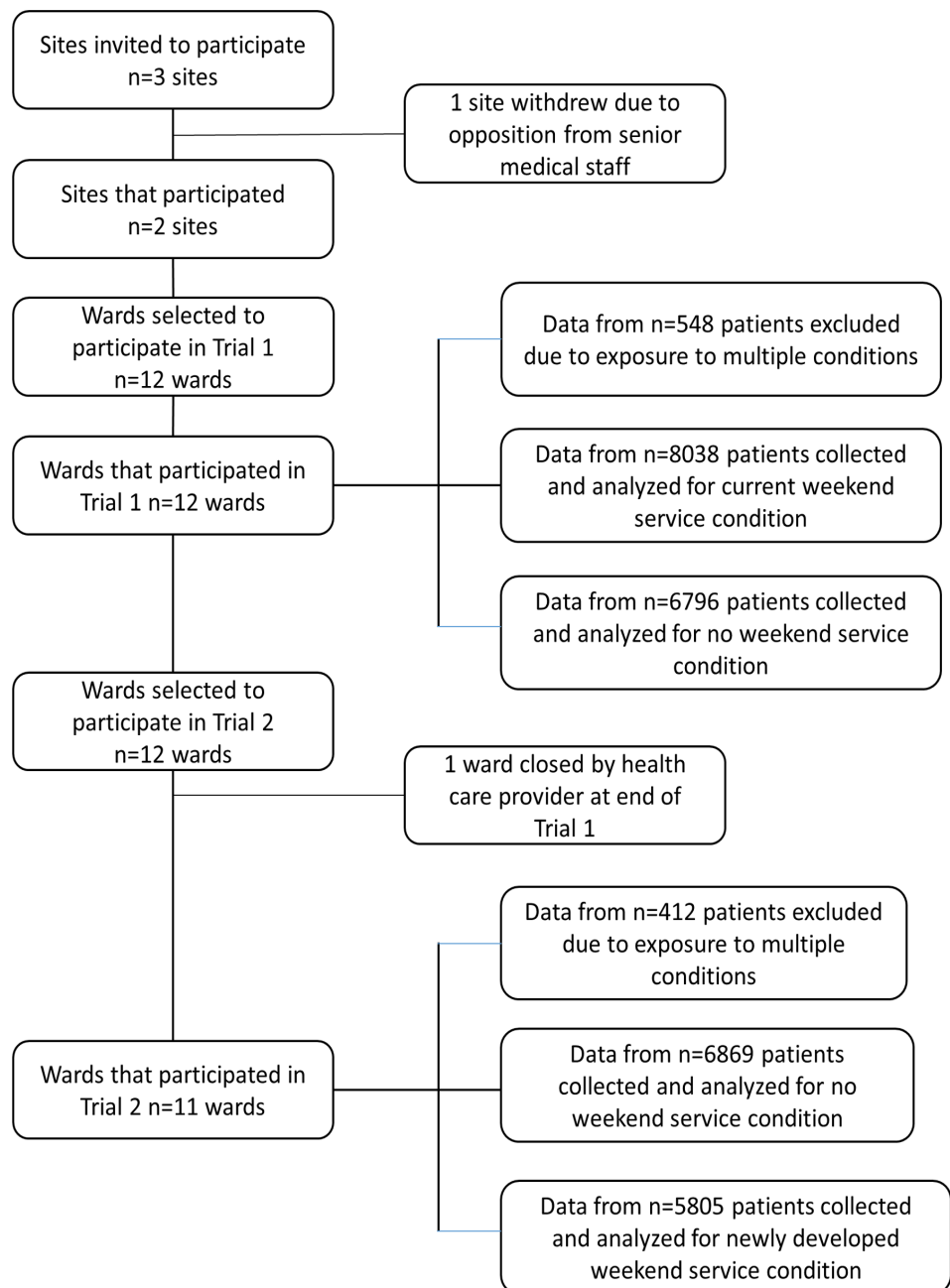


Fig 2. CONSORT flow chart of site, ward, and patient involvement in data collection and analysis.

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These analyses were conducted by a statistician (SM) independent to the research locations and blinded to ward allocation status through use of 6 mock codes representing different ward allocation patterns. An intention-to-treat analysis approach was employed. Models were

initially constructed using patient-level data nested within ward nested within hospital site. Patient admissions were coded against the first study ward of their admission and calendar month of their first admission to a study ward. Log natural transformation of length of stay data was planned due to the anticipated skewed distribution [5]. Effect estimates were generated using ward-month-level data if effect estimates could not be calculated using patient-level data (on account of inability to ascertain starting values for models with binary outcomes). All analyses were adjusted for study month and ward as categorical fixed factors in line with recommendations for analysis of stepped-wedge designs [19]. Adjustment was also made for monthly outcome data from the previous 2 years for primary outcomes to account for potential seasonal fluctuations that are consistent from year to year. The main effect of having no weekend service was calculated, followed by pre-planned 'no weekend service by site' interaction effects to determine if site-level analyses were required [27]. Analyses were undertaken using Stata MP v.14 (StataCorp, College Station, Texas).

Three post hoc exploratory analyses were undertaken. The first investigated potential differences in outcomes between the 2 weekend allied health service delivery models (current versus newly developed) directly. This analysis was considered important as there was no guarantee that the newly developed model would be superior to the current model despite this being the intent of redesigning the weekend allied health service. The second examined whether the results under the no weekend service condition were comparable between the 2 trials. Previous studies have reported substantial changes over time within health services in outcomes examined in this trial (e.g., falls [28]), making it important to consider whether the no weekend allied health service conditions in the 2 trials were comparable. Adjustment for study month was not used in these exploratory analyses as this would have led to collinearity with the independent variables of interest. The third post hoc analysis was a sensitivity analysis for Trial 1 whereby a 1-month washout period was applied to each ward following their transition to the no weekend allied health service condition. This meant that the month of data immediately following the transition in model of care was excluded from the analysis for each ward and that the final month included in the analysis of Trial 1 became September 2014 for the Dandemonong Hospital site and November 2014 for the Footscray Hospital site. This analysis was important as changes in practice can potentially affect hospital practices and processes in a way that is different to what happens once the change has had more time to become imbedded in practice.

Data were monitored by a committee drawn from senior clinical staff at participating sites who were not members of the study investigative team. Trial dates are provided (Fig 1), along with deviations from the registered trial protocol (Fig 2; inability to commence at 1 site and closure of 1 ward during Trial 2). Study data used in these analyses are provided (S1 and S2 Data). Study power analysis calculations are provided (S6 Text) and were described in our protocol paper [5].

Results

Trial dates of commencement and completion along with occasions of allied health service are presented (Fig 1). Demographic characteristics of trial participants (Trial 1, $n = 14,834$; Trial 2, $n = 12,674$) are presented (Table 1). There were 28 approved clinical exceptions in total (14 in each trial) during the no weekend allied health periods, of which the most common justification was a post-fall mobility review by a physiotherapist (16). The remaining occasions of service provision were not approved clinical exceptions during this period.

Data for primary and secondary outcomes for the full trial sample are presented (Table 2). Effect size estimates for each trial are presented (Table 3). The p -values presented in Table 3

Table 1. Participant demographics for each group within each trial.

Characteristic	Trial 1		Trial 2	
	Current weekend service	No weekend service	No weekend service	Newly developed weekend service
<i>N</i>	8,038	6,796	6,869	5,805
Age (years)—mean (SD)	59.5 (20.7)	60.8 (20.2)	59.7 (20.6)	59.8 (20.3)
Sex— <i>n</i> (%) male	4,225 (53.6%)	3,611 (53.1%)	3,587 (52.2%)	3,090 (53.2%)
Most common Australian Refined Diagnosis Related Groups— <i>n</i> (%)	Other digestive system disorders, 267 (3.3%); respiratory infections and inflammations, 214 (2.6%); heart failure and shock, 211 (2.6%); chronic obstructive airways disease, 208 (2.6%)	Chronic obstructive airways disease, 250 (3.7%); respiratory infections and inflammations, 248 (3.7%); other digestive system disorders, 202 (3.0%); septicaemia, 192 (2.8%)	Other digestive system disorders, 237 (3.5%); septicaemia, 198 (2.9%); chronic obstructive airways disease, 179 (2.6%); respiratory infections and inflammations, 178 (2.6%)	Other digestive system disorders, 194 (3.3%); chronic obstructive airways disease, 162 (2.8%); respiratory infections and inflammations, 153 (2.6%); laparoscopic cholecystectomy, 145 (2.4%)
Expected length of stay (days)*—mean (SD)	5.3 (5.1)	5.7 (5.1)	5.0 (4.5)	5.4 (5.6)

*Based on mean inlier Australian Refined Diagnosis Related Groups from Victoria in 2013.

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reflect the probability of the findings observed when the superiority null hypothesis is true, and were derived from multilevel, mixed-effects generalised linear model analyses. Length of stay was greater for the no weekend service condition in Trial 1, but shorter in Trial 2. The no weekend allied health condition was of uncertain inferiority in Trial 1 for this outcome (95% CI: 0.85 to 1.77), but non-inferior in Trial 2 (95% CI: −2.03 to −1.13) relative to the +1 day non-inferiority margin. The proportion of patients staying longer than their diagnosis-related group average inlier length of stay was lower for the no weekend service condition in Trial 2 compared to the newly developed weekend allied health service condition. The no weekend allied health service condition was of uncertain inferiority for the proportion of patients who stayed longer than expected (95% CI: −0.01 to 0.04), the proportion who had an unplanned readmission within 28 days (95% CI: −0.01 to 0.03), and the proportion who had 1 or more adverse events (95% CI: −0.01 to 0.03) in Trial 1 relative to a +2% absolute increase non-inferiority margin. However, the no weekend allied health service condition was non-inferior to the newly developed weekend allied health service condition for the proportion of patients who stayed longer than expected (95% CI: −0.05 to −0.01), the proportion who had an unplanned readmission within 28 days (95% CI: −0.02 to 0.01), and the proportion who had 1 or more adverse events (95% CI: −0.05 to −0.004). It was also superior for the proportion of patients staying longer than expected and the proportion who had 1 or more adverse event outcomes.

Examination of site-by-intervention interaction effects identified an interaction for the proportion of patients with an unplanned readmission in Trial 1. The subsequent subgroup analyses indicated that at the Dandenong Hospital site the no weekend service condition had a higher proportion of unplanned readmissions (coefficient [95% CI]: 0.03 [0.01 to 0.05], $p = 0.01$), but this was not the case at the Footscray Hospital site (coefficient [95% CI]: −0.0002 [−0.03 to 0.02], $p = 0.86$).

Examination of superiority hypotheses for secondary outcomes demonstrated that there was difference between conditions in the proportion of patients discharged to residential aged care facilities. However, the cost to the healthcare system per admission was greater for the no weekend service condition in Trial 1, but less in Trial 2.

Examination of superiority hypotheses for the secondary outcome of the proportion of patients discharged on a Saturday or Sunday demonstrated that there was no difference

Table 2. Raw data for primary and secondary outcomes.

Outcome	Trial 1		Trial 2	
	Current weekend service	No weekend service	No weekend service	Newly developed weekend service
Length of stay—mean (SD)/median (IQR)	5.5 (7.5)/3.1 (1.5 to 6.4)	6.3 (9.4)/3.7 (1.7 to 7.2)	5.0 (5.9)/3.2 (1.6 to 6.1)	5.5 (8.3)/3.4 (1.6 to 6.9)
Patients staying longer than expected— <i>n</i> (%)	3,263 (40.2%)	2,608 (38.4%)	2,767 (40.3%)	2,288 (39.4%)
Patients with an unplanned readmission within 28 days— <i>n</i> (%)	788 (9.8%)	733 (10.8%)	671 (9.8%)	577 (9.9%)
Adverse events				
Any adverse event— <i>n</i> (%)	695 (8.5%)	665 (9.8%)	608 (8.9%)	506 (8.7%)
Fall— <i>n</i> people (%)/ <i>n</i> events	165 (2.1%)/212	140 (2.1%)/181	156 (2.3%)/218	88 (1.5%)/105
Code Blue/MET call— <i>n</i> people (%)/ <i>n</i> events	300 (3.7%)/400	323 (4.7%)/461	263 (3.8%)/345	274 (4.7%)/380
Pulmonary embolus— <i>n</i> people (%)/ <i>n</i> events	17 (0.2%)/17	11 (0.2%)/11	10 (0.2%)/10	4 (0.1%)/5
Deep vein thrombosis— <i>n</i> people (%)/ <i>n</i> events	8 (0.1%)/8	7 (0.1%)/8	8 (0.1%)/8	4 (0.1%)/5
Death— <i>n</i> (%)	143 (1.8%)	171 (2.5%)	135 (2.0%)	120 (2.1%)
Pressure area— <i>n</i> people (%)/ <i>n</i> events	80 (1.0%)/99	72 (1.1%)/78	58 (0.8%)/61	26 (0.5%)/28
ICU admission from the ward— <i>n</i> people (%)/ <i>n</i> events	154 (1.9%)/167	172 (2.5%)/197	146 (2.1%)/157	153 (2.6%)/173
Discharge destinations				
Home/private residence— <i>n</i> (%)	6,566 (81.7%)	5,468 (80.5%)	5,367 (78.1%)	2,758 (82.0%)
Acute care facility— <i>n</i> (%)	142 (1.8%)	159 (2.3%)	171 (2.5%)	137 (2.4%)
Other acute/extended care/rehab hospital— <i>n</i> (%)	693 (8.6%)	579 (8.5%)	683 (9.7%)	451 (7.8%)
Cost per patient to the healthcare system per admission*—mean (SD)/median (IQR)	8,446 (11,205)/5,095 (2,688 to 10,168)	9,501 (13,661)/5,550 (2,988 to 10,796)	8,233 (9,942)/5,223 (2,797 to 10,082)	9,442 (14,794)/5,334 (3,001 to 10,153)
Compliments				
Total	32 ^d	33 ^d	38 ^d	24 ^d
Allied health specific	1 ^e	3 ^e	2 ^e	0 ^e
Complaints				
Total	37 ^d	32 ^d	35 ^d	43 ^d
Allied health specific	0 ^e	0 ^e	1 ^e	1 ^e

* Cost in Australian dollars.

^d Data from first month of trial only.

^e Data from last month of trial only.

ICU, intensive care unit; MET, Medical Emergency Team.

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Table 3. Effect size estimates of main and trial-by-site interaction effects from each trial for primary and secondary outcomes.

Outcome	Trial 1				Trial 2			
	Main effect	Inferiority	Intervention-by-site interaction	ICC*	Main effect	Inferiority	Intervention-by-site interaction	ICC*
Primary								
Length of stay (days)	1.31 (0.85 to 1.77) $p < 0.001^{\text{E}}$	Uncertain inferiority	0.03 (−0.57 to 0.63) $p = 0.93$	S: 0.0001 W: 0.04 E: 0.91	−1.59 (−2.03 to −1.13) $p < 0.001^{\text{E}}$	Non-inferior	0.23 (−0.42 to 0.88) $p = 0.48$	S: <0.0001 W: 0.03 E: 0.88
Length of stay (log transformed)	0.09 (0.04 to 0.15) $p = 0.002$	N/A	−0.07 (−0.15 to 0.01) $p = 0.08$	S: <0.0001 W: 0.10 E: 0.91	−0.14 (−0.21 to −0.08) $p < 0.001$	N/A	−0.03 (−0.13 to 0.06) $p = 0.47$	S: 0.02 W: 0.08 E: 0.89
Proportion of patients staying longer than expected	0.01 (−0.01 to 0.04) $p = 0.30$	Uncertain inferiority	−0.02 (−0.06 to 0.02) $p = 0.34$	S: 0.83 W: 0.86	−0.02 (−0.05 to −0.01) $p = 0.04^{\text{E}}$	Non-inferior	−0.02 (−0.07 to 0.02) $p = 0.30$	S: 0.85 W: 0.88
Proportion with an unplanned readmission within 28 days	0.01 (−0.01 to 0.03) $p = 0.18$	Uncertain inferiority	−0.04 (−0.06 to −0.02) $p < 0.001^{\text{E}}$	S: <0.0001 W: 0.39	−0.01 (−0.02 to 0.01) $p = 0.62$	Non-inferior	−0.02 (−0.05 to 0.01) $p = 0.18$	S: <0.0001 W: 0.53
Proportion of patients with any adverse event	0.01 (−0.01 to 0.03) $p = 0.33$	Uncertain inferiority	−0.02 (−0.04 to 0.01) $p = 0.15$	S: <0.0001 W: 0.71	−0.03 (−0.05 to −0.004) $p = 0.02^{\text{E}}$	Non-inferior	0.02 (−0.01 to 0.05) $p = 0.24$	S: <0.0001 W: 0.70
Secondary								
Proportion of patients discharged to aged care facility	0.001 (−0.004 to 0.01) $p = 0.28$	N/A	−0.003 (−0.01 to 0.01) $p = 0.54$	S: 0.30 W: 0.65	−0.001 (−0.01 to 0.01) $p = 0.88$	N/A	0.008 (−0.01 to 0.01) $p = 0.99$	S: 0.12 W: 0.62
Cost to the healthcare system per admission (Australian dollars)	1,810 (1,094 to 2,525) $p < 0.001$	N/A	769 (−168 to 1,706) $p = 0.11$	S: <0.0001 W: 0.013 E: 0.76	−2,431 (−3,166 to −1,696) $p < 0.001^{\text{E}}$	N/A	−163 (−1,273 to 947) $p = 0.77$	S: <0.0001 W: 0.005 E: 0.88
Proportion of patients discharged on a Saturday or Sunday	0.01 (−0.01 to 0.03) $p = 0.33$	N/A	0.02 (−0.01 to 0.05) $p = 0.24$	S: <0.0001 W: 0.43	−0.02 (−0.05 to −0.002) $p = 0.03^{\text{E}}$	N/A	−0.01 (−0.04 to 0.02) $p = 0.69$	S: <0.0001 W: 0.47

Main effects are interpreted as the impact of being exposed to the 'no weekend' allied health condition compared to the 'current' or 'newly developed' weekend allied health conditions. Data in parentheses are 95% CIs.

*Intraclass correlation coefficients (ICCs) derived from mixed-effects generalised linear models partitioned at the site (S), ward (W), and patient episode (E) levels.

^EStatistically significant (superiority hypothesis, 2-tailed $p < 0.05$).

N/A, not applicable.

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between conditions in Trial 1, but proportion discharged on a Saturday or Sunday was marginally (2%) higher for the newly developed weekend service in Trial 2. This finding should be viewed in the context that length of stay was longer when a weekend allied health service was present in that trial.

Exploratory analyses (Table 4) indicated that patients in the no weekend service condition in Trial 1 had better outcomes across multiple domains than those in the no weekend service condition in Trial 2. Patients exposed to the original weekend allied health service delivery model did not experience different outcomes than those exposed to the newly developed model for the primary outcomes of the proportion staying in hospital longer than expected, the proportion who had an unplanned readmission within 28 days, and the proportion experiencing any adverse event when these patient groups were compared directly. There was

Table 4. Effect size estimates of main effects from the exploratory analyses.

Outcome	Weekend service: 'current' versus 'newly developed'		No weekend service: Trial 1 versus Trial 2		Sensitivity: Trial 1 with 1-month washout period		
	Effect size	ICC*	Effect size	ICC*	Effect size	Inferiority	ICC*
Primary							
Length of stay (days)	0.12 (−0.20 to 0.43) $p = 0.46$	S: 0.0002 W: 0.06 E: 0.89	1.03 (0.73 to 1.32) $p < 0.001^E$	S: <0.0001 W: 0.01 E: 0.91	0.30 (0.01 to 0.60) $p = 0.04^E$	Non-inferior	S: <0.0001 W: 0.05 E: 0.91
Length of stay (log transformed)	0.05 (0.01 to 0.09) $p = 0.02^E$	S: 0.0001 W: 0.12 E: 0.90	0.11 (0.07 to 0.15) $p < 0.001^E$	S: 0.0001 W: 0.06 E: 0.90	0.05 (0.02 to 0.09) $p = 0.005^E$	N/A	S: <0.0001 W: 0.01 E: 0.91
Proportion of patients staying longer than expected	0.01 (−0.01 to 0.04) $p = 0.31$	S: 0.83 W: 0.86	0.01 (−0.003 to 0.03) $p = 0.004^E$	S: 0.87 W: 0.89	0.03 (−0.004 to 0.06) $p = 0.09$	Uncertain inferiority	S: 0.83 W: 0.87
Unplanned readmission within 28 days	0.01 (−0.01 to 0.02) $p = 0.42$	S: <0.0001 W: 0.45	−0.001 (−0.02 to 0.01) $p = 0.95$	S: <0.0001 W: 0.50	0.01 (−0.01 to 0.03) $p = 0.31$	Uncertain inferiority	S: <0.0001 W: 0.39
Proportion of patients with any adverse event	−0.002 (−0.01 to 0.01) $p = 0.74$	S: 0.02 W: 0.68	0.02 (0.008 to 0.04) $p = 0.02^E$	S: <0.0001 W: 0.59	0.01 (−0.01 to 0.03) $p = 0.33$	Uncertain inferiority	S: <0.0001 W: 0.71
Secondary							
Proportion of patients discharged to aged care	−0.004 (−0.01 to 0.003) $p = 0.30$	S: 0.14 W: 0.58	−0.01 (−0.01 to 0.003) $p = 0.09$	S: 0.23 W: 0.63	−0.001 (−0.01 to 0.01) $p = 0.89$	N/A	S: 0.31 W: 0.70
Cost to the healthcare system per admission (Australian dollars)	−558 (−1,086 to −30) $p = 0.04^E$	S: 0.0001 W: 0.02 E: 0.86	1,224 (745 to 1,702) $p < 0.001^E$	S: 0.0001 W: 0.01 E: 0.76	952 (494 to 1,410) $p < 0.001^E$	N/A	S: 0.0001 W: 0.03 E: 0.79
Proportion of patients discharged on a Saturday or Sunday	−0.01 (−0.04 to 0.02) $p = 0.34$	S: <0.0001 W: 0.43	0.05 (−0.01 to 0.10) $p = 0.10$	S: <0.0001 W: 0.47	0.02 (−0.004 to 0.04) $p = 0.12$	N/A	S: <0.0001 W: 0.51

Main effects are interpreted as the impact of being exposed to the 'current' service, exposure to Trial 1, and exposure to the 'current' service for the three analyses, respectively. Data in parentheses are 95% CIs.

*Intraclass correlation coefficients (ICCs) derived from mixed-effects generalised linear models partitioned at the site (S), ward (W), and patient episode (E) levels.

^EStatistically significant (superiority hypothesis, 2-tailed $p < 0.05$).

N/A, not applicable.

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a difference for mean length of stay (log transformed) and total cost favouring the original weekend allied health service delivery model, though these outcomes did not account for differences in patient diagnosis categories between phases. The sensitivity analyses of Trial 1, with the washout period added, demonstrated that the no weekend allied health condition was non-inferior to the current weekend allied health condition (95% CI: 0.01 to 0.60) for the length of stay outcome, whereas there was uncertain inferiority for this outcome in the primary analysis. The other outcomes were largely unaffected in this sensitivity analysis.

Analyses without adjustment for monthly outcome data for the previous 2 years had some inconsistencies with main analyses, where the adjustment was made (S7 Text). Differences in the proportion of patients staying longer than expected and with any adverse event were no longer significant between the no weekend service and newly developed weekend allied health service conditions in Trial 2. However, the 95% CIs were still completely below the non-inferiority margin, meaning that the interpretation of these results from this perspective remains

unaffected. There were also site-by-intervention interaction effects for the log-transformed length of stay (Trial 1) and proportion of patients with any adverse event (Trial 2) outcomes. Here, the log-transformed mean length of stay was longer if exposed to the no weekend allied health service condition at the Dandenong Hospital (coefficient [95% CI]: -0.15 [0.07 to 0.23], $p < 0.001$), and the proportion of patients who experienced any adverse event was lower in the no weekend allied health service condition at Dandenong Hospital only (coefficient [95% CI]: -0.03 [-0.05 to -0.002], $p = 0.03$).

Discussion

In Trial 1, criteria to say that the no weekend allied health condition was non-inferior to current weekend allied health condition were not met, while neither the no weekend nor current weekend allied health condition demonstrated superiority. The result for the mean length of stay outcome from Trial 1 was sensitive to whether a 1-month washout period was applied in the analysis. When the washout period was applied, the no weekend allied health service condition was found to be non-inferior to the current weekend allied health service model. In Trial 2, the no weekend allied health condition was non-inferior to the newly developed weekend allied health condition across all primary outcomes, and superior for the proportion of patients staying longer than expected, proportion experiencing any adverse event, and mean length of stay.

The findings of this study were somewhat discordant with the only previously published randomised trial of the effect of weekend allied health services on patient and health service outcomes. This earlier trial reported no significant difference in length of stay or patient adverse events ($p > 0.05$) in those provided with a Saturday physical therapy service, in addition to a Monday to Friday service, on rehabilitation wards [29]. However, this trial did identify small benefits of the service in terms of improved functional independence and health-related quality of life attributable to the intervention, though these benefits were arguably below clinically meaningful thresholds [30–32]. It is difficult to directly compare these results given the differences in ward types and patient populations involved, the fact that the earlier study focused only on a physical therapy service, and the differences in the activities undertaken by allied health staff between acute and rehabilitation settings. Our study was the first to our knowledge to use this particular disinvestment research design to simultaneously disinvest from a routinely provided service with uncertain effectiveness while also developing evidence that had previously been missing as to the effectiveness of the intervention.

It should be noted that the models of care we examined in Trial 1 were limited to those in place at the outset of the trial at the study locations. However, the model of care in Trial 2 was a complex intervention, where the process used could be reproduced in other settings to develop models that are similarly tailored to local conditions. A strength of these two trials in addressing the research context area was their size, which led to narrow confidence intervals in our analyses and a high degree of certainty in the results. Our choice to investigate both the current weekend allied health service and a newly developed service also enhanced the generalisability of our findings to real world settings. However, these trials did not investigate the breadth of all possible permutations and combinations of weekend allied health service delivery models. Rather, we focused on the pragmatic scenario of what was currently being allocated and the budgetary envelope of this. Our study was limited in that we were unable to proceed with this research on 1 ward at 1 of our sites in Trial 2 due to closure of that clinical unit. We were also unable to proceed at a third site due to local opposition to participation in the study. This highlights some of the difficulties that can be encountered in conducting disinvestment research of this nature over an extended period of time. This study could have been

further strengthened by considering the healthcare costs consumed by patients after they were discharged from these acute wards. It is possible that allied health services not provided on weekends in the acute setting may still have been provided in another setting later in a patient's journey.

The scope of the clinical implications of our findings should be clearly defined. The study locations did not have all types of specialty wards (e.g., spinal, burns) that might be considered to be acute medical or surgical wards. The finding of no effect of weekend allied health services overall should not be extrapolated to weekday services. It is possible that variation in staffing profile and the lack of availability of community-based services on weekends that support patients upon discharge are an important difference. We also did not withhold weekend allied health services from those who met our clinical exception criteria. The low frequency of these exceptions may indicate that using staff from other areas that do have a weekend allied health service (e.g., intensive care unit) or using an on-call staffing model may be preferable to employing weekend allied health staff in fixed shifts to meet these patients' needs.

This study reported discordant findings for the mean length of stay and total cost outcomes between Trials 1 and 2. This can be explained by 5 potential mechanisms. First, these changes could be attributed to background variation in patient case mix not accounted for by these outcomes. Winter months in Australia, which largely coincided with the no weekend services condition in Trial 1, are associated with a 20% increase in demand for medical admissions primarily due to infectious diseases [33]. Second, it may be that the current weekend allied health service delivery model was superior to the newly developed model. Our exploratory analyses directly comparing these models did not support this explanation as the log-transformed length of stay outcome favoured the newly developed service when these conditions were directly compared. Third, the current service model could be argued to have had an unfair advantage in a direct comparison with the newly developed service model. The current service model had several years of refinement locally and integration into usual care before being subjected to this evaluation, whereas the newly developed service model was evaluated as soon as it was introduced and did not have the same opportunity to be refined and integrated. Fourth, the patient cohort or standard of usual care provided at study sites could have changed within the no weekend service periods across Trials 1 and 2. Our exploratory analyses identified multiple outcomes where differences favoured those exposed to the no weekend service condition during Trial 2 compared to Trial 1, which would support this hypothesis. The fifth potentially concurrent explanation is that both withdrawing the weekend allied health service model and installing a new one required an accommodation period for staff to adapt to the new service settings. This hypothesis would also be supported by the differences observed between Trials 1 and 2 within the no weekend service periods. Models of organisational lag have been formally investigated since the 1980s [34] and may indicate that our original research design should have included a washout period following the transition to the new model of care. Our sensitivity analyses, where we introduced a 1-time-period washout to Trial 1, identified that the length of stay in the no weekend service condition was non-inferior to the current weekend service condition (though other results were not substantially changed).

There is potential that naturally occurring change over time could confound the results of these stepped-wedge trials. Naturally occurring change over time (maturation) is a potential confounder in every longitudinal interventional research design. The important concern is whether this may have biased the intervention effect size estimates calculated from each trial. In a stepped-wedge design, this problem is prominent given the unidirectional crossover employed. This means that a stepped-wedge trial conducted within a system/organisation that naturally improves over time will favour the condition that is tested second, and vice versa. This problem was first described in detail by Hussey and Hughes [35]. Their solution to this

problem was to explicitly model the effect of each time period to eliminate this bias from the intervention effect estimate. We used this approach in every analysis presented in Table 3. Thus, our estimated effect sizes calculated from within Trial 1 and Trial 2 are statistically independent of the potentially confounding effects of change over time that occurred across the organisations involved, and can be considered to be free of bias from this source. The analyses that were not independent of these effects are the comparisons between Trial 1 and Trial 2 that are reported in Table 4. We could not use this approach in the comparisons between the 2 control periods, and in the direct comparisons of the current and the newly developed weekend services in Table 4 as these were not comparisons based on a stepped-wedge design. Rather, these were pre- versus post-intervention design comparisons with no overlap in time periods between the conditions being compared (thus a time covariate would directly confound the covariate of interest, which in this case was Trial 1 versus Trial 2). The washout sensitivity analysis model in Table 4 did use the approach described by Hussey and Hughes as this was a stepped-wedge design.

The key implication of this research is that resources being used to support weekend allied health service delivery to acute medical and surgical wards similar to those involved in this study could potentially be put to better use elsewhere in the healthcare system. Future research in the field of weekend allied health service delivery is warranted, particularly in other ward types and when examining higher dosage levels of service delivery. If higher dosage levels can demonstrate an effect on clinical or patient flow outcomes, they will still need to be justified economically. Future research using this disinvestment trial approach is also warranted. The value of a trial that finds a model of care that no longer includes a particular service to be non-inferior to one that includes it can be conceptualised as the future opportunity costs saved of no longer providing that service. Hence, commonly provided services that have a relative absence of evidence supporting their use and a high opportunity cost of delivery should be targeted.

Supporting information

S1 Data. Ward-level data.

(XLSX)

S2 Data. Patient-level data.

(XLSX)

S3 Data. Blinded statistician data.

(XLSX)

S1 Text. Trial protocol. Study protocol for 2 randomised controlled trials examining the effectiveness and safety of current weekend allied health services and a new stakeholder-driven model of weekend allied health services for acute medical/surgical patients versus no weekend allied health services.

(PDF)

S2 Text. CONSORT checklist.

(PDF)

S3 Text. TIDieR criteria.

(DOCX)

S4 Text. Hours of service by discipline. Hours of allied health service provision offered under current and newly developed weekend allied health service delivery models at each site.

(DOCX)

S5 Text. Clinical exceptions.

(DOCX)

S6 Text. Power analysis.

(DOCX)

S7 Text. Analyses unadjusted for monthly ward data from previous 2 years. Effect size estimates of main and trial-by-site interaction effects from each trial for primary and secondary outcomes. Main effects are interpreted as the impact of being exposed to the no weekend allied health condition compared to the current or newly developed weekend allied health conditions.

(DOCX)

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Appendix G

Study 2 interview guide

Aims and roles of allied health following hip and knee joint replacement:

What are the aims of allied health therapy in the acute phase following elective hip and knee replacement surgery?

What allied health roles are important for this patient group?

Who usually performs these roles?

Could any other members of staff perform these roles?

Current allied health service:

What is the availability of allied health throughout the week/weekend?

What are the advantages and disadvantages of the current service?

How are the current allied health services prioritised?

What sorts of patients benefit the most and least from the current service and why?

Ideal:


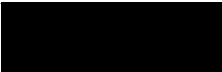
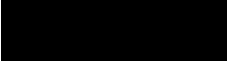

What do you think should be the aims of allied health intervention in the acute phase following elective hip and knee joint replacement surgery?

What do you think the ideal service model of allied health service delivery should look like for this patient group?

Prompts: how soon after surgery, how much therapy, weekend provision?

Appendix H

Ethics approval for all empirical thesis studies

	Research Directorate Monash Health Monash Medical Centre 	Postal address: 	Tel Fax 
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28 November 2013

A/Prof Terry Haines
Director Allied Health Clinical Research Unit
Allied Health Clinical Research Unit
Kingston Centre
Cheltenham Vic 3192

Dear A/Prof Haines

Study title: Weekend Allied Health Services On Acute Medical / Surgical Patients to Improve Efficiency and Safety of Patient Care
Monash Health HREC Ref: 13327B

The Monash Health HREC B reviewed the above application at the meeting held on 19 September 2013. In addition, the HREC is satisfied that the responses to our correspondence of 24 September 2013 have been sufficiently addressed.

The HREC approved the above application on the basis of the information provided in the application form, protocol and supporting documentation.

This reviewing HREC is accredited by the Consultative Council for Human Research Ethics under the single ethical review system.

Approval

The HREC and Site Specific Authorisation approval is from 28 November 2013.

Approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007)*. The HREC has ethically approved this research according to the Memorandum of Understanding between the Consultative Council and the participating organisations conducting the research.

Approval is given for this research project to be conducted at the following sites and campuses:

- Monash Health

You must comply with the following conditions:

The Chief Principal Investigator is required to notify the Research Directorate, Monash Health of the following:

1. Any change in protocol and the reason for that change together with an indication of ethical implications (if any)
2. Serious or unexpected adverse effects of project on subjects and steps taken to deal with them
3. Any unforeseen events that might affect continued ethical acceptability of the project
4. Any expiry of the insurance coverage provided in respect of sponsored trials
5. Discontinuation of the project before the expected date of completion, giving reasons
6. Any change in personnel involved in the research project including any study member resigning from Monash Health &/or the study team.

At the conclusion of the project or every twelve months if the project continues, the Principal Investigator is required to complete and forward an annual report to the Committee.

Annual report forms will be forwarded to the researcher.

Approved documents

Documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Clinical Trial Protocol	1.2	9 October 2013
Participant Information and Consent Form – Patients	1	26 August 2013
Authorised Person Information and Consent Form	1	26 August 2013
Participant Information and Consent Form – Staff	1	26 August 2013
Participant Information and Consent Form – Elective Orthopaedic Patient	1	29 August 2013

If you should have any queries about your project please contact Deborah Dell or Julie Gephart by email deborah.dell@southernhealth.org.au / julie.gephart@southernhealth.org.au

The HREC wishes you and your colleagues every success in your research.

Yours sincerely

Prof Andis Graudins
HREC Medical Administrator

cc: Ms Romi Haas
MUHREC

Checklist: Post-ethics approval requirements that must be met before a research project can commence at a study site.

Please ensure that as a PI (including the CPI) the following are completed at each study site.

Requirements	Yes/No/NA
Clinical Trial Research Agreement The PI must forward a fully executed copy of the agreement to the Research Directorate.	N/A
Indemnity The PI must forward a fully executed copy of the indemnity to the Research Directorate.	N/A
CTN notification The PI must sign the CTN and forward to the RGO so the authority approving the conduct of the trial, at that site, can complete and sign.	N/A
Radiation If applicable, the RGO must contact the Medical Physicist to notify DHS, Radiation Safety Section to list the project on the Institute's licence.	N/A
Other Commonwealth statutory requirements Ensure compliance with the following e.g. Office of the Gene Technology Regulator, NHMRC Licensing Committee, NHMRC Cellular Therapies Advisory Committee.	N/A

Appendix I

Participant information and consent form: Patients



Participant Information and Consent Form: Patients

Full Project Title: Evaluation of allied health services provided to elective joint replacement surgery patients treated on the acute orthopaedic ward at Dandenong Hospital.

Principal Researchers: Associate Professor Terry Haines, Donna Markham, Kerry May, Deb Mitchell, Associate Professor Fiona McDermott, Dr Lisa O'Brien, Dr Elizabeth Skinner, Samantha Plumb, Genevieve Juj, Timothy Chiu, Kathleen Phillip

PhD student: Romi Haas

1. Introduction

You are invited to take part in this research project. The aim of the project is to examine the effectiveness, cost-effectiveness and safety of allied health services on the acute orthopaedic ward at Dandenong Hospital provided to elective joint replacement surgery patients.

This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to participate in the research processes that are described;

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research project?

Allied Health services include services provided by health professionals such as physiotherapists, occupational therapists, speech pathologists, dieticians, social workers, podiatrists, exercise physiologists and psychologists. These services have evolved over time and vary across wards and facilities. The model of allied health service being provided on the acute orthopaedic ward at Dandenong Hospital is being changed over a period of 14 months. We would like to evaluate how this change may affect patient outcomes and satisfaction with the services they have received. Elective joint replacement surgery is one of the most common surgical procedures performed. This study aims to evaluate how changes in allied health service delivery model provided during the immediate postoperative period affect outcomes for patients undergoing

elective total joint replacement surgery at Dandenong Hospital. The results will be used to inform improvements in postoperative care provided to these patients.

The results of this research will be used by the Romi Haas to obtain a Doctor of Philosophy degree.

3. What does participation in this research project involve?

Participation in this project will involve answering some questions about your current abilities, pain levels and satisfaction with the care you received at Dandenong Hospital following your surgery. You will be asked to sign this consent form prior to any study assessments being performed.

Examples of questions that will be asked include:

1) "Please indicate on the scale provided how good or bad your own health is today?" and

2) "Thinking about all aspects of your hospital stay, how satisfied have you been?"

It is anticipated that the entire interview process will take approximately 30 minutes.

A researcher will perform these assessments at three different time points:

1) When you attend the pre-admission clinic

2) Four days following your surgery

3) Six weeks following your surgery

The first two assessments will be performed with a face-to-face interview and the six-week postoperative review will be conducted by telephone. If you have been discharged from Dandenong Hospital prior to the day 4 postoperative review, this will also be conducted by telephone. Each assessment will take up to 15 minutes.

As part of your involvement in this research project, we also request access to your Dandenong Hospital medical record in order to gain information about the postoperative care you receive. There are no costs to you associated with participating in this research project, nor will you be paid.

We are aiming to evaluate 250 people undergoing elective total joint replacement surgery at Dandenong Hospital over a 14-month period.

4. What are the possible benefits?

There will be no direct benefit to you from your participation in this research.

5. What are the possible risks?

We do not anticipate any risks, side effects or discomforts resulting from your participation in this study above that which you would normally encounter while being treated for your condition.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage without any consequence.

7. How will I be informed of the results of this research project?

Public presentations regarding the project outcomes will be made at your health service. If you wish to receive a summary of project findings, please provide your contact details on the consent form.



8. What else do I need to know?

• What will happen to information about me?

The information we collect will be stored in a de-identified manner in a password-protected file for a period of 7 years on the computer of the principal investigator. This is kept in a key-lockable office. All members of the investigative team will be able to access this information. After this time, the data will be destroyed. Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

Ethical guidelines

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of Monash Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

9. Who can I contact?

Who you may need to contact will depend on the nature of your query, therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have concerns about any aspect of your involvement in the project, you can contact the principal investigator, Terry Haines on [REDACTED] or [REDACTED].

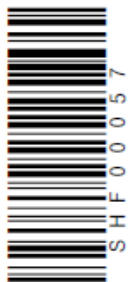
For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name: Ms Malar Thiagarajan

Position: Director of Research Services, Monash Health Research Directorate

Telephone: [REDACTED]



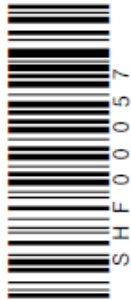
10. Consent

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I will be given a signed copy of this document to keep.



Participant's name (printed)

Signature

Date

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.*

Researcher's name (printed)

Signature

Date

Note: All parties signing the consent section must date their own signature.

If you wish to receive a summary of project findings, please provide the best contact information for this to be sent to you below:

E-mail: _____

OR

Postal address: _____

Appendix J

Participant information and consent form: Health service staff

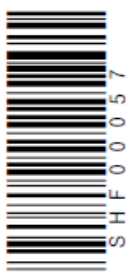


Participant Information and Consent Form: Health service staff

Full Project Title: Trial of weekend allied health services on acute medical / surgical wards

Principal Researchers: Associate Professor Terry Haines, Donna Markham, Kerry May, Associate Professor Fiona McDermott, Dr Lisa O'Brien, Dr Elizabeth Skinner, Samantha Plumb, Genevieve Juj, Tim Chiu, Kathleen Phillip, Kelly-Ann Bowles, Leonie Shaw

PhD student: Romi Haas and Deb Mitchell



1. Introduction

You are invited to take part in this research project. The aim of the project is to examine the effectiveness, cost-effectiveness and safety of existing weekend allied health services on acute medical and surgical units across three Victorian Hospitals compared to having no weekend allied health service on these wards.

This project will also examine the effectiveness, cost-effectiveness and safety of a new, stakeholder-driven model of weekend allied health service compared to having no weekend allied health service on these same wards.

This will involve acute medical and surgical units at Dandenong Hospital, Royal Melbourne Hospital, and Western Hospital Footscray.

This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to participate in the research processes that are described;

You will be given a copy of this Participant Information and Consent Form to keep.

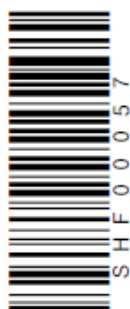
2. What is the purpose of this research project?

Weekend Allied Health services have evolved over time and vary across wards and facilities. They cost more per minute than ordinary weekday services and consume additional weekday service time as clinicians prepare referrals for the weekend staff. Little is published of the tasks that weekend allied health staff perform and there has been little discussion of the rationale behind why they perform these particular tasks.

You are invited to participate in this research project because you work on one of the wards participating in this research. Your participation will allow the researchers to

- 1) Better understand what is currently taking place in terms of weekend allied health service delivery
- 2) Help plan what the new, stake-holder driven model of weekend allied health service delivery will look like for your particular ward
- 3) Understand how your ward's involvement in this broader research project has affected your work and that of your co-workers

This research will be used by Romi Haas and Deb Mitchell towards completion of a PhD.



3. What does participation in this research project involve?

Participation in this project will involve being interviewed on up to three occasions. You will be asked for consent separately on each occasion; therefore this consent is relevant only for this interview. The interview/s will take place either in a "group-interview" format along with other staff members of the ward that you work on, or on a one-to-one basis. We anticipate that each interview will take approximately 45 minutes in duration.

Examples of questions that will be asked include:

1. "What are the tasks that Allied Health staff currently undertake on the weekend?"
2. "Which of these tasks can be completed prior to the weekend?"

The information you provide will help to shape the new, stakeholder-driven model of weekend allied health service that we will evaluate in the second half of this project. We will tape record your responses so that we can later write them out in full and analyse them. We will remove your name and contact details from these transcripts so that this data will be stored as text without any identifying information. This information therefore will not be accessible from any publications resulting from this research.

If you choose to participate in this research, you will be provided with one adult movie ticket each time you participate in an interview.

4. What are the possible benefits?

There will be no direct benefit to you from your participation in this research.

5. What are the possible risks?

We do not anticipate any risks, side effects or discomforts resulting from your participation in this study.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage without any consequence.

7. How will I be informed of the results of this research project?

Public presentations regarding the project outcomes will be made at your health service. If you wish to receive a summary of project findings, please provide your contact details on the consent form.

8. What else do I need to know?

• What will happen to information about me?

The information we collect will be stored in a de-identified manner in a password-protected file for a period of 7 years on the computer of the principal investigator. This

is kept in a key-lockable office. All members of the investigative team will be able to access this information. After this time, the data will be destroyed. Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

Ethical guidelines

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of Monash Health and Melbourne Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

9. Who can I contact?

Who you may need to contact will depend on the nature of your query, therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have concerns about any aspect of your involvement in the project, you can contact the principal investigator, Terry Haines on [REDACTED] or [REDACTED]

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name: Ms Deborah Dell

Position: Manager, Human Research Ethics Committees

Telephone: [REDACTED]

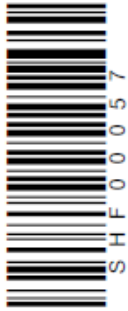
10. Consent

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I will be given a signed copy of this document to keep.



Participant's name (printed)

Signature

Date

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.*

Researcher's name (printed)

Signature

Date

Note: All parties signing the consent section must date their own signature.

If you wish to receive a summary of project findings, please provide the best contact information for this to be sent to you below:


E-mail: _____

OR

Postal address: _____

Appendix K

EuroQol registration

From: Mandy Oemar [REDACTED] 
Subject: EQ-5D registration
Date: 4 February 2014 8:17 pm
To: [REDACTED]



Dear Ms/Mr. Romi Haas,

Thank you for registering your research at the EuroQol Group Foundation's website.

As the study you registered involves low patient numbers (250) you may use the EQ-5D-5L instrument (Paper version) free of charge. Please note that separate permission is required if any of the following is applicable:

- Funded by a pharmaceutical company, medical device manufacturer or other profit-making stakeholder;
- Number of respondents over 5000
- Routine Outcome Measurement;
- Developing or maintaining a Registry;
- Digital representations (e.g. PDA, Tablet or Web)

Please find attached the English (Australia) EQ-5D-5L version (word format). A brief user guide is downloadable from the EuroQol website (www.euroqol.org).

Please note that currently we do not have value sets associated with the EQ-5D-5L system. Valuation studies to elicit values for the EQ-5D-5L are just beginning in a number of countries. In the meantime, the EuroQol Group has developed a "crosswalk" between the EQ-5D-3L value sets and the new EQ-5D-5L descriptive system, resulting in interim value sets for the new EQ-5D-5L descriptive system. Please find all information about the crosswalk from EQ-5D-5L data to the EQ-5D-3L value sets online at the EuroQol website (<http://www.euroqol.org/about-eq-5d/valuation-of-eq-5d/eq-5d-5l-value-sets.html>).

Kind regards,

Mandy Oemar
Communications Officer



W: www.euroqol.org



Australia (English) EQ-5D-5L.doc

Appendix L

Published manuscript of study 1

Copyright clearance has been obtained to submit this manuscript as part of this thesis (see below). This manuscript has been published in Archives of Physical Medicine and Rehabilitation, which is ranked in the top quartile of rehabilitation (5/65) and sports sciences (10/81) journals.



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ORIGINAL RESEARCH

Patient and Therapist Agreement on Performance-Rated Ability Using the de Morton Mobility Index



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Abstract

Objective: To determine the level of agreement between patient self-report and therapist-assessed performance of mobility using the de Morton Mobility Index (DEMMI).

Design: Interrater agreement study.

Setting: Outpatient hospital clinic.

Participants: Consecutive sample of patients (N = 128) undergoing preoperative assessment for elective lower limb (LL) arthroplasty.

Interventions: Participants completed a therapist-directed assessment of the DEMMI followed by self-report of performance. A random subsample (n = 62, 48%) also completed a self-report of anticipated performance before the therapist-directed assessment. Both raters (participant and therapist) were blinded to the scores obtained from the other rater.

Main Outcome Measures: Interrater agreement between patient self-report and therapist-directed assessment of the total DEMMI scores was assessed using the intraclass correlation coefficient model 2,1 (ICC_{2,1}) with a 95% confidence interval. The Bland-Altman plots were also used to illustrate the agreement between the 2 raters.

Results: The intraclass correlation coefficient (ICC) between patient self-report after performance and therapist-directed assessment of the total DEMMI score was .967 (95% confidence interval, .952–.977). The ICC between patient self-report of anticipated performance and therapist-directed assessment of the total DEMMI score was .830 (95% confidence interval, .730–.894). The Bland-Altman plots depicted higher levels of agreement among participants with impaired levels of mobility (≤ 74 out of 100) than did those with near-maximum DEMMI scores.

Conclusions: Patient self-report of anticipated performance is an acceptable proxy for DEMMI scores derived from the therapist rating of performance. Caution should be exercised when interpreting self-report scores of patients with near-maximum levels of mobility. Further research is required to establish whether these results can be generalized across a range of patient populations and to clinicians with differing backgrounds and expertise.

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Poor mobility is associated with reduced independence in activities of daily living,¹ cardiovascular deconditioning,² increased falls risk,^{3,4} reduced quality of life,⁵ institutionalization,⁶ and mortality.¹ The *International Classification of Functioning, Disability and Health*^{7(p138)} defines *mobility* as “moving by changing body position or location or by transferring from one place to another, by carrying, moving or manipulating objects, by walking, running or climbing, and by using various forms of

transportation.” Restricted mobility is the most common disability type in the United States, with 1 in 8 adults reporting serious difficulty walking or climbing stairs.⁸

The ability to reliably and accurately measure mobility is necessary to identify those in need of treatment and to measure treatment effects. The de Morton Mobility Index (DEMMI) is an instrument that has been shown to be valid, reliable, and robust across the mobility spectrum and clinical settings.⁹⁻¹⁵ It has been designed as a performance-based assessment that relies on clinician observation and performance rating on 15 hierarchical mobility activities ranging from sitting unsupported to tandem stand with eyes closed. A problem with this approach is that it requires face-to-face contact or observation mediated through video.

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The ability to use patient self-report of perceived performance ability in addition to performance-based assessment of the DEMMI has the potential to aid future clinical practice and research by eliminating the cost burden (clinician time, patient time, travel) of face-to-face assessment. Previous researchers have reported that a similar measure, the modified Barthel Index, was quicker to complete as a self-reported rather than therapist-assessed measure¹⁶ and argued that it could be administered via in-person interview or by telephone.¹⁷ Self-reported walking ability has also been demonstrated as an accurate predictor of mobility performance.^{18,19} However, substitution of therapist-assessed with self-report outcomes is acceptable only if there are high agreement levels between therapists and patients, and this may not always be the case.²⁰ For example, 31% to 63% of older adults undergoing inpatient rehabilitation have been shown to underestimate personal fall risk as compared to clinician-rated functional ability.²¹

The primary aim of this study was to determine the level of agreement between patient self-reported mobility and therapist-assessed performance using the DEMMI. Both anticipated self-report (assessed before physically attempting the tasks) and self-report postperformance (assessed after DEMMI performance) were examined. Secondary aims were to examine whether the agreement level was affected by age, sex, or linguistic background of our sample or whether actual performance or patient self-report preperformance affected patient self-report postperformance using the DEMMI.

Methods

Study design

This was an interrater agreement study design whereby patient self-report of perceived ability before and after actual performance was compared with therapist-assessed performance using the DEMMI.

Participants and setting

Consecutive patients undergoing preoperative assessment for elective lower limb (LL) arthroplasty were recruited between August 7, 2014, and December 4, 2014, as part of a larger study investigating the timing and dose of allied health intervention in the acute postoperative phase following arthroplasty. Adults older than 18 years undergoing elective LL arthroplasty at a 520-bed public teaching hospital situated in the southeastern suburbs of Melbourne, Australia, were approached for consent. The types of joint arthroplasty considered for inclusion were total hip arthroplasty, total knee arthroplasty, and revision total hip or knee arthroplasty. Exclusion criteria were patients undergoing arthroplasty immediately after trauma (eg, fracture) and patients with moderate cognitive impairment assessed as ≤ 5 out of 10 on the Short Portable Mental Status Questionnaire.²² A professional interpreter was employed for participants upon request as part of their preoperative assessment.

List of abbreviations:

DEMMI de Morton Mobility Index
ICC intraclass correlation coefficient
ICC_{2,1} intraclass correlation coefficient model 2,1
LL lower limb

Measurement

In this study, the DEMMI was used to assess mobility of patients undergoing preoperative assessment for elective LL arthroplasty. The DEMMI was developed to overcome ceiling and floor effects demonstrated in other mobility instruments used in clinical populations²³ and has face validity for measuring patients ranging from those who are bedbound to those with high levels of independence.¹¹ Rasch analysis has been used to construct an interval level scoring system out of 100 from the 15 ordinal items.²⁴ The DEMMI has been widely used and validated in mixed populations (including LL arthroplasty) across the full mobility spectrum and clinical settings (acute, subacute, community), in which this patient population is commonly seen.^{9,10,12-15,25}

Procedure

This study was performed and reported in accordance with Guidelines for Reporting Reliability and Agreement Studies.²⁶ Approval to conduct this study was obtained from Monash Health Human Research Ethics Committee (reference number 13327B). A consecutive sampling methodology was adopted whereby all patients attending preoperative assessment before LL arthroplasty were approached for consent in the order of presentation. Written informed consent was obtained from all consenting participants.

A computer-generated randomization process^a was used to allocate participants to 1 of 2 groups. One group was asked to self-rate their perceived mobility level using the DEMMI without actually attempting any of these tasks (anticipated performance). The investigator (R.H.) conducting the performance-based assessment of the DEMMI was blinded to participant's self-report. This group then undertook a therapist-directed assessment of the DEMMI during which the investigator (R.H.) rated their ability as they performed each task. Participants were not informed of the rating made by the investigator. These participants were then asked to again rate their performance using the DEMMI, having recently attempted all tasks (self-report postperformance). Participants allocated to the second group were not asked to self-rate perceived mobility before completing the therapist-directed assessment. These participants completed only the therapist-directed assessment and then rated their performance on the DEMMI. They were also blinded to investigator rating. This second group allowed us to examine whether there was a potential confounding effect of completing self-report of anticipated performance on postperformance ratings.

Therapist-directed assessment was conducted according to the DEMMI handbook.²⁷ Items were scored at the lowest score if a participant declined to attempt a task or was deemed unsafe to do so. Participants were provided with the same verbal explanation as in the DEMMI handbook when they were completing their self-reported assessments. The investigator conducting the therapist-directed assessments was a physiotherapist who has worked in geriatric settings for 15 years (R.H.).

Data analysis

Interrater agreement between performance-based and self-reported (both anticipated and postperformance) total DEMMI scores was assessed separately using the intraclass correlation coefficient model 2,1 (ICC_{2,1}) with a 95% confidence interval. Agreement between self-report of anticipated performance and

therapist-directed assessment included only those participants who were randomly allocated to rate their anticipated performance before the therapist-directed assessment. Agreement between self-report postperformance and therapist-directed assessment included all study participants. The Bland-Altman plots²⁸ were also used to illustrate agreement between the 2 measurement techniques. Interrater agreement between performance-based and self-report ratings of each individual DEMMI task was determined using the κ statistic and intraclass correlation coefficient (ICC).

A known limitation of κ is that it is affected by the prevalence of the findings under observation.²⁹⁻³¹ For rare findings, low values of κ may not necessarily reflect low rates of the overall agreement. Percent total agreement, percent “able” agreement, and percent “unable” agreement were therefore also calculated³² to account for this paradox.

Paired *t*-tests were conducted to investigate the presence of systematic bias. Agreement statistics were compared between participant subgroups for age, sex, and request for an interpreter during preoperative assessment.

Finally, we examined the effect of performing the DEMMI tasks on participant self-report scores by comparing the anticipated scores obtained before performance with the self-report scores obtained after performance. We compared total scores using paired *t*-tests and item level ratings using the Wilcoxon signed-rank test. We also investigated the effect of self-reporting anticipated performance on the DEMMI on self-report postperformance scores. We conducted an unpaired *t*-test of self-report scores postperformance between those participants who did (group 1) and did not (group 2) complete self-report of anticipated performance.

Sample size consideration

A post hoc analysis demonstrated that a sample of 62 patients provided 80% power of finding a significant ICC as low as .33 (assuming 2 raters and $\alpha = .05$)²⁷ for the agreement analysis between ratings derived from therapist-directed assessment and patient self-report of anticipated performance on the DEMMI. A sample of 128 patients provided 80% power of finding a significant ICC as low as .22 (assuming 2 raters and $\alpha = .05$)³³ for the agreement analysis between ratings derived from therapist-directed assessment and patient self-report after DEMMI performance.

Results

Study participants

One hundred twenty-eight of 149 patients undergoing preoperative assessment for LL arthroplasty during the recruitment period consented to participate in this study. In total, there were 318 DEMMI observations (62 anticipated self-report, 128 therapist-directed, 128 self-report postperformance) derived from 128 participants and 2 raters (therapist, participant). The characteristics of those who consented and those who did not are summarized in table 1. Of the 21 patients undergoing preoperative assessment who did not consent to participate, 12 could not be approached for consent during the clinic, 2 declined surgery, 1 had impaired cognition, and 6 declined to participate. Reasons for declining consent included apprehension ($n = 1$, 17%), previous hospital experience ($n = 1$, 17%), “not feeling well” ($n = 2$, 33%), and carer report of impaired cognition ($n = 2$, 33%).

Table 1 Participant and nonparticipant characteristics

Characteristic	Participants Who Consented (n = 128)	Participants Who Did Not Consent (n = 21)
Sex: female	78 (61)	14 (67)
Age (y)	68.5 ± 9.3	70.0 ± 12.3
Request for interpreter	18 (14)	8 (38)
Surgery type	TKR, 82 (64) THR, 42 (33) Revision TKR, 1 (0.7) Revision THR, 3 (2.3)	TKR, 13 (62) THR, 6 (28) Revision TKR, 1 (5) Revision THR, 1 (5)
DEMMI total score	74 (39–100)	
Pathway*	A, 46 (36) B, 57 (44) C, 24 (19) (1 missing)	A, 3 (14) B, 7 (33) C, 9 (43) (2 missing)
Comorbidities†	Cardiovascular, 34 (27) Neurologic, 7 (5) Diabetes, 33 (26) Mental health, 17 (13) Malignancy, 17 (13) Pulmonary, 18 (14)	Cardiovascular, 7 (33) Neurologic, 3 (14) Diabetes, 11 (52) Mental health, 3 (14) Malignancy, 1 (5) Pulmonary, 6 (28)

NOTE. Values are mean ± SD, n (%), or median (range).

Abbreviations: THR, total hip replacement; TKR, total knee replacement.

* Pathway indicates expected postoperative recovery pathway. A indicates 4-day length of stay with discharge directly home from acute facility. B indicates 3-day acute length of stay with inpatient rehabilitation for 4–7d. C indicates inpatient rehabilitation ≥14d.

† Participants may have multiple comorbidities.

Comparison of self-report of anticipated performance with therapist-assessed performance

In the 62 participants who randomly completed self-report of anticipated performance before therapist-directed assessment, the ICC between the total DEMMI scores was .830 (95% confidence interval, .730–.894). The Bland-Altman plot (fig 1) depicts that participants overestimate their actual ability on

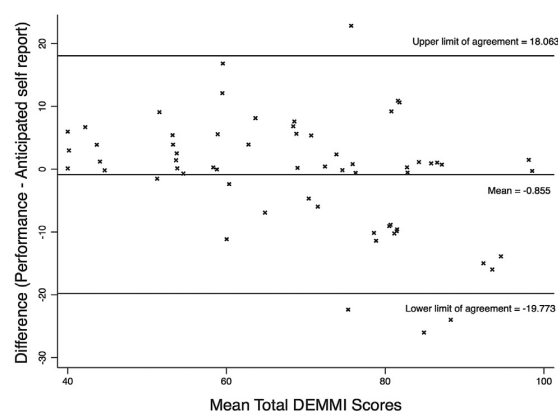


Fig 1 Bland-Altman plot comparing total DEMMI scores using therapist-directed assessment and patient self-report of anticipated performance.

Table 2 Agreement between therapist-directed assessment and patient self-report of anticipated performance for individual DEMMI tasks

DEMMI Task	κ	ICC (95% CI)	Total Agreement, n (%) [*]	Responses in the Majority Category, n (%) [*]	Percent "Able" Agreement	Percent "Partially Able" Agreement	Percent "Unable" Agreement
Sit unsupported in chair [†]	NA	NA	62 (100)	62 (100)	100	NA	NA
Bridge [†]	0.0000	0.000 (−0.238 to 0.242)	59 (95.16)	59 (95.16)	97.5	NA	0
Stand unsupported [†]	0.0000	0.000 (−0.233 to 0.239)	58 (93.55)	58 (93.55)	96.7	NA	0
Sit to stand from the chair [†]	0.0000	0.000 (−0.248 to 0.248)	61 (98.39)	61 (98.39)	99.2	0	NA
Roll onto side [†]	NA	NA	62 (100)	62 (100)	100	NA	NA
Lying to sitting [†]	0.659	0.663 (0.498–0.782)	61 (98.39)	60 (96.77)	99.2	66.7	NA
Stand with feet together [†]	0.5709	0.515 (0.307–0.677)	58 (93.55)	55 (88.71)	96.5	NA	60.0
Pick up a pen from the floor	0.8484	0.850 (0.764–0.907)	58 (93.55)	41 (66.13)	95.3	NA	89.5
Walk 4 steps backward	0.8066	0.768 (0.637–0.835)	57 (91.94)	46 (74.19)	94.8	NA	81.5
Walking distance ^{†,‡}	1.000	1.000 (1.000–1.000)	62 (100)	60 (96.77)	100	100	NA
Sit to stand without arms	0.7748	0.778 (0.645–0.863)	56 (90.32)	40 (64.52)	93.0	NA	84.2
Walking independence	0.9066	0.840 (0.747–0.900)	59 (95.16)	32 (51.61)	95.5	94.5	50.0
Jump	0.8287	0.831 (0.734–0.895)	59 (95.16)	50 (80.65)	85.7	NA	97.1
Stand on toes	0.7120	0.715 (0.567–0.818)	54 (88.10)	37 (59.68)	90.2	NA	81.0
Tandem stand with eyes closed	0.6482	0.652 (0.481–0.775)	54 (88.10)	43 (69.35)	73.3	NA	91.5

NOTE. Tasks displayed in hierarchical order from easiest to hardest.

Abbreviations: CI, confidence interval; NA, not applicable.

^{*} Number out of 62.

[†] Tasks with a ceiling effect in which >85% of participants both self-reported and could actually perform the task.

[‡] Maximum score achieved if able to walk 50m.

average; however, this overestimation was by <1 out of 100 points on the DEMMI scale and considered clinically insignificant.¹² The relatively wide limits of agreement (−19.773, 18.063) appear to be largely driven by 4 data points. Further inspection of individual data revealed that there were discrepancies in 2 or 3 DEMMI items for each of these outliers, all of which were in high-end tasks. Removal of these outliers from this analysis reduced the 95% limits of agreement to −14.750 and 14.715.

Agreement statistics between participant self-report of anticipated performance and therapist-directed assessment of individual DEMMI tasks are listed in table 2. Total agreement in all tasks was >85%. A ceiling effect and consequent lack of range in scores for 8 of the lower-end tasks limits the interpretation of κ and ICC values for these tasks.^{29–31} In these tasks, the proportion of assessments where both raters categorized participants as “able” was >85%. This rendered chance-corrected agreement statistics low or unable to be calculated. In the remaining 7 tasks, κ values ranged from .6482 to .9086.

Comparison of participant self-report postperformance with therapist-assessed performance

All 128 participants completed self-report of the DEMMI after the therapist-directed assessment. The ICC between participant self-report postperformance and therapist-directed assessment of the total DEMMI scores was .967 (95% confidence interval, .952–.977). The Bland-Altman plot (fig 2) depicts a similar mean difference but narrower limits of agreement than in the comparison between self-report of anticipated performance and therapist-assessed performance.

Agreement statistics between participant self-report postperformance and therapist-directed assessment of individual DEMMI tasks are listed in table 3. Total agreement in all tasks was >90%, with a ceiling effect as seen previously in the same 8 tasks. κ values ranged from .7826 to 1.0000 in the remaining 7 tasks.

Comparison of self-report of anticipated performance with self-report postperformance

There was no difference in participant self-report scores completed before (mean, 69.71±17.87) and after (mean, 69.10±14.30) the therapist-directed assessment ($t_{61}=.4758$; $P=.6359$). Of the 62

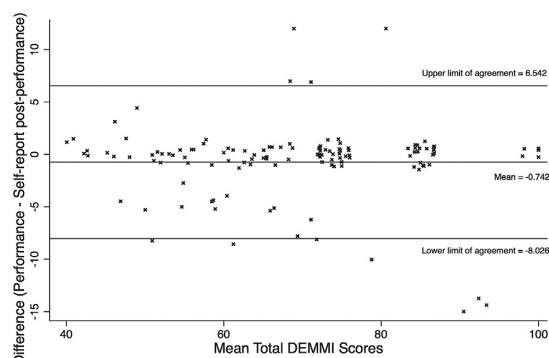


Fig 2 Bland-Altman plot comparing total DEMMI scores using therapist-directed assessment and patient self-report postperformance.

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participants who self-reported before and after the therapist-directed assessment, 49 individual rating disagreements (in 36 participants) were evident between participant self-report of anticipated performance and therapist-directed assessment. Of these, only 11 rating disagreements (in 9 participants) were maintained in the self-report postperformance.

The comparisons of participant self-report of anticipated performance and self-report postperformance for each individual DEMMI task are presented in table 4. Participants overestimated their ability in anticipated self-report in 1 task (tandem stand with eyes closed) but underestimated their ability in 2 others (sit to stand without arms, stand on toes).

Comparison of self-report postperformance between participants who self-reported anticipated performance and those who did not

There was no difference in participant self-report scores after the therapist-directed assessment in participants who self-reported anticipated performance (mean, 69.29±14.29) and those who did not (mean, 70.48±14.71) ($t_{126}=-.4655$; $P=.6424$).

Subgroup analyses

Paired t -tests, ICCs, and 95% confidence intervals for subgroup analyses are reported in tables 5 and 6. The mean difference between therapist-directed assessment and participant self-report did not exceed >2 out of 100 points for any subgroup analysis. The only factor demonstrating a difference between subgroups was sex, where there was a mean difference of <1 out of 100 points on the DEMMI between therapist-directed assessment (mean, 67.49±14.12) and self-report postperformance (mean, 68.23±14.33) for women ($t_{77}=-2.1893$; $P=.0316$). However, this small difference is considered clinically insignificant.¹²

Discussion

Agreement between ratings of therapist-assessed performance on the DEMMI and participant self-report both before and after performance observed in this study is interpreted as almost perfect.³⁴ Interrater agreement is higher when participants self-report their perceived ability after, rather than before, the therapist-directed assessment. Agreement also appears higher among participants with DEMMI scores reflecting some level of mobility dysfunction, that is, ≤74 out of 100 (corresponding to the raw score of ≤17 out of 19). In both scenarios, there is a slight overall tendency for participants to overestimate their ability compared to therapist ratings, though the magnitude of this is small. Individual DEMMI task agreement is interpreted as moderate³⁵ or higher and is highest among functional activities of daily living such as walking independence. The high level of agreement was maintained regardless of participant's sex, age group, or use of an interpreter.

To our knowledge, this is the first use of DEMMI self-report. Our high rating of agreement is consistent with a similar study¹⁷ comparing patient self-report to therapist-assessed measurements of the Barthel Index, but not with 2 other studies.^{36,37} One³⁷ of these studies demonstrated a mean difference between self-report and therapist-assessed performance (90.4±14.6 vs 88.3±14.5, respectively, out of 100) comparable to our results but with low κ scores (.103–.398). This difference is unlikely to be clinically important,³⁸ and it should be noted that high Barthel scores have been associated

Table 3 Agreement between therapist-directed assessment and patient self-report postperformance for individual DEMMI tasks

DEMMI Task	κ	ICC (95% CI)	Total Agreement, n (%) [*]	Responses in the Majority Category, n (%) [*]	Percent "Able" Agreement	Percent "Partially Able" Agreement	Percent "Unable" Agreement
Sit unsupported in the chair [†]	0.0000	0.000 (−0.173 to 0.173)	127 (99.22)	127 (99.22)	99.6	NA	0
Bridge [†]	NA	NA	128 (100)	128 (100)	100	NA	NA
Stand unsupported [†]	0.663	0.665 (0.556–0.751)	127 (99.22)	126 (98.44)	99.6	NA	66.7
Sit to stand from the chair [†]	NA	NA	128 (100)	128 (100)	100	NA	NA
Roll onto side [†]	NA	NA	128 (100)	128 (100)	100	NA	NA
Lying to sitting [†]	1.000	1.000 (1.000–1.000)	128 (100)	127 (99.22)	100	100	NA
Stand with feet together [†]	0.919	0.920 (0.888–0.943)	127 (99.22)	121 (94.53)	99.6	NA	92.3
Pick up a pen from the floor	1.000	1.000 (1.000–1.000)	128 (100)	94 (73.44)	100	NA	100
Walk 4 steps backward	1.000	1.000 (1.000–1.000)	128 (100)	105 (82.03)	100	NA	100
Walking distance ^{†,‡}	1.000	1.000 (1.000–1.000)	128 (100)	124 (96.88)	100	100	NA
Sit to stand without arms	0.818	0.820 (0.753–0.869)	119 (92.97)	90 (70.31)	95.2	NA	86.6
Walking independence	0.9517	0.953 (0.934–0.967)	125 (97.66)	75 (58.59)	98.7	97.1	0
Jump	1.000	1.000 (1.000–1.000)	128 (100)	107 (83.59)	100	NA	100
Stand on toes	0.8848	0.886 (0.842–0.918)	121 (94.53)	75 (58.59)	95.5	NA	92.9
Tandem stand with eyes closed	0.7826	0.784 (0.706–0.843)	117 (91.41)	88 (68.75)	84.1	NA	94.1

NOTE. Tasks displayed in hierarchical order from easiest to hardest.

Abbreviations: CI, confidence interval; NA, not applicable.

^{*} Number out of 128.

[†] Tasks with a ceiling effect in which >85% of participants both self-reported and could actually perform the task.

[‡] Maximum score achieved if able to walk 50m.

Table 4 Wilcoxon signed-rank test comparing participant self-report of anticipated performance with self-report post-performance for individual DEMMI tasks

DEMMI Task	z Score	P
Sit unsupported in the chair	No adjusted variance	
Bridge	-1.732	.0833
Stand unsupported	-1.732	.0833
Sit to stand from the chair	-1.000	.3173
Roll onto side	No adjusted variance	
Lying to sitting	-1.000	.3173
Stand with feet together	-0.535	.5930
Pick up a pen from the floor	-1.000	.3173
Walk 4 steps backward	-1.633	.1025
Walking distance*	No adjusted variance	
Sit to stand without arms	-2.714	.0067 [†]
Walking independence	-0.017	.9868
Jump	1.732	.0833
Stand on toes	-2.000	.0455 [†]
Tandem stand with eyes closed	3.138	.0017 [†]

NOTE. Tasks displayed in hierarchical order from easiest to hardest.

* Maximum score achieved if able to walk 50m.

[†] $P < .05$ considered statistically significant.

with a ceiling effect,³⁸ of which the subsequent low variability in scores is a known limitation of the κ statistic.²⁹⁻³¹ This study³⁷ may also have introduced additional disagreement by using multiple observers to rate performance and multiple interviewers to assist with self-reporting. Unlike our results, McGinnis et al³⁶ found that patients underestimated their performance. However, this study was conducted immediately before discharge home from inpatient rehabilitation when therapists may be keen to demonstrate treatment effectiveness. In addition, patients may have felt anxious about their impending discharge and/or have rated their independence during Barthel Index tasks on the basis of acceptance of available assistance in hospital rather than perceived ability. In contrast to existing literature³⁹⁻⁴¹ demonstrating men tend to overestimate whereas women tend to underestimate their performance, our results do not depict a sex difference in agreement level between patient self-report and therapist-assessed performance using the DEMMI.

Our results demonstrate lesser agreement in participants with high-level mobility. It is possible that these results may be a

consequence of the total DEMMI score calculation approach based on Rasch analysis. This approach gives a much higher penalty for disagreement in 1 category at the higher end of the mobility spectrum than at the middle or lower end. For example, there is a 15-point penalty for disagreement in 1 category at the maximum score of 100 compared to only 2 points at a score of 41 out of 100.²⁷ It was data from participants at this high-end of mobility that drove the wider 95% limits in each of the comparisons examined. This may mean that these different methods of assessing the DEMMI may have narrower limits of agreement if the participant population has poorer mobility than does the sample we considered. This is possibly not surprising given the DEMMI was originally developed in the inpatient older adult population, which is likely to have poorer mobility than does our preoperative sample.

Our results suggest that actually performing the DEMMI may affect participant self-report postperformance in cases where there was an initial discrepancy between self-report of anticipated performance and the rating obtained from the therapist-directed assessment. This is consistent with previous experimental findings⁴² and a cross-sectional study⁴³ supporting the notion that actual performance has the capacity to affect self-report postperformance, presumably by providing participants with information that enables them to better assess their level of functioning. This is also evident in our results demonstrating that the individual DEMMI tasks with the least agreement (tandem stand with eyes closed, stand on toes) are those least likely to be performed in a functional context.

The ability to use self-report of perceived ability as a proxy to therapist ratings of DEMMI performance, as demonstrated by our results, has both clinical and research implications. Reassessment of the DEMMI using self-report after discharge home from hospital could be used to identify those requiring additional support in the absence of clinical contact. It could also assist in standardizing follow-up methodology, which has been identified as a limitation in investigating the effect of follow-up telephone calls in reducing postdischarge problems.⁴⁴ In addition, the ability to conduct standardized patient assessment remotely after discharge home could aid research practices by promoting recruitment and convenience and reducing cost and nonresponse bias caused by loss to follow-up.⁴⁵

Study limitations

There are potential limitations associated with the present work and its generalizability. First, the study sample is specific to cognitively intact older adults undergoing preoperative assessment before LL

Table 5 Paired t -test, ICC_{2,1}, and 95% CIs for subgroup analyses comparing therapist-directed assessment with participant self-report of anticipated performance

Demographic Characteristic	Therapist-Directed DEMMI Scores	Self-Report of Anticipated Performance	Paired t -test	ICC (95% CI)
Age (y)				
≤68 (n=33, 47%)	70.58±13.92	71.70±17.37	.5157	.809 (.648-.901)
>68 (n=29, 53%)	66.90±14.54	67.45±18.46	.7496	.850 (.705-.927)
Sex				
Male (n=27, 44%)	71.56±13.30	71.26±15.66	.8636	.819 (.640-.913)
Female (n=35, 56%)	66.77±14.73	68.51±19.54	.3060	.835 (.700-.913)
Interpreter				
No (n=52, 84%)	70.35±14.09	71.75±17.96	.3097	.813 (.696-.888)
Yes (n=10, 16%)	61.1±12.84	59.1±13.66	.3653	.876 (.599-.967)

NOTE. Values are mean ± SD or as otherwise indicated.

Abbreviation: CI, confidence interval.

Table 6 Paired *t*-test, ICC_{2,1}, and 95% CIs for subgroup analyses comparing therapist-directed assessment with patient self-report postperformance

Demographic Characteristic	Therapist-Directed DEMMI Scores	Self-Report Postperformance	Paired <i>t</i> -test	ICC (95% CI)
Age				
≤68 (n = 65, 51%)	72.8±13.67	73.62±14.13	.1187	.954 (.926–.972)
>68 (n = 63, 49%)	65.22±13.77	65.89±13.87	.0881	.975 (.959–.985)
Sex				
Male (n = 50, 39%)	71.54±14.08	72.28±14.50	.2504	.950 (.914–.971)
Female (n = 78, 61%)	67.49±14.12	68.23±14.33	.0316*	.977 (.963–.985)
Interpreter				
No (n = 110, 86%)	69.81±13.85	70.34±14.00	.0853	.973 (.961–.982)
Yes (n = 18, 14%)	64.56±15.73	66.61±17.22	.1412	.937 (.840–.976)

NOTE. Values are mean ± SD or as otherwise indicated.

Abbreviation: CI, confidence interval.

* *P* < .05 considered statistically significant.

arthroplasty. The extent to which our findings are generalizable to other patient populations, particularly those who may have experienced a recent change in mobility, requires further investigation. Previous research³⁶ suggests that self-report may be inappropriate for those with cognitive impairment. Second, an experienced clinician conducted the therapist-directed assessment of the DEMMI in this study. A less experienced clinician may plausibly have lower agreement with patient self-report. Establishing whether the results observed in this study apply to clinicians with differing backgrounds and expertise level is therefore warranted.

Conclusions

A high level of agreement was observed between patient self-report and therapist-assessed performance using the DEMMI. However, self-report of the DEMMI should be interpreted with caution for those with near-maximum mobility scores, because this is where small discrepancies in item ratings can lead to large total score differences. These results suggest that there is potential to use DEMMI self-report to reassess mobility after hospital discharge in the absence of clinical contact and to use this information for providing additional support and/or for research purposes.

Supplier

a. SurveyMonkey.

Keywords

Mobility limitation; Rehabilitation; Self report; Task performance and analysis

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