DIETARY INTERVENTION AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS: AN e-APPROACH

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DIETARY INTERVENTION AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS: AN e-APPROACH

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Notice 1

Notice 2

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In accordance with Monash University Doctorate Regulation 17/ Doctor of Philosophy and Master of Philosophy (MPhil) regulations the following declarations are made:

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.

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ABSTRACT

*my*DIDeA was a 12-months two-armed randomised controlled trial conducted in three tertiary public hospitals in Klang Valley, Malaysia. The primary outcome was the Dietary Knowledge, Attitude and Behaviour (DKAB) score, while the secondary outcomes included measures of food intake, anthropometry measurements, blood pressure and resting heart rate, some blood biomarkers and the Dietary Stages of Change (DSOC) score. The study was designed according to the recommendations of the CONSORT statement for randomised trials of non-pharmacologic treatment.

The study commenced in November 2009 after obtaining the ethical approvals from relevant authorities, and the trial has been registered with Clinicaltrials.gov (NCT01246687). After being screened for eligibility, 128 patients with Type 2 Diabetes Mellitus (T2DM) from the outpatient clinics at these hospitals were recruited with informed consent, and then randomised into the e-intervention (n=66) or the control (n=62) group. The e-intervention group received an intensive six-month dietary intervention through the study website, which was developed based on various established guidelines and recommendations but personalised according to the participants' DSOC, in addition to the usual standard treatment at the outpatient clinics. In contrast, the control group continued their usual standard treatment for patients with T2DM in the hospitals. Data were collected at baseline, six months post-intervention and at 12 months follow-up. A pre-tested and validated questionnaire was used for this purpose. The anthropometry measurements, blood pressure and resting heart rate were measured at data collection, while details on the blood biomarkers were obtained from the hospital medical records. All data were analysed with IBM® PASW® Statistics 17.0.

On average, each participant logged into the website once a week and spent 11 minutes at the website per visit. *my*DIDeA was found to be a successful intervention programme to improve the

overall DKAB score, due to the improvement in the knowledge and attitude sub-domains. Additionally, the intervention programme also successfully improved the DSOC score of the intervention group, which suggests participants were also making small but significant progress in changing their dietary behaviour. Some additional improvements in diet quality (reduction in carbohydrate and protein intake), glycaemic control and total cholesterol were also detected.

*my*DIDeA is one of few web-delivered dietary interventions for patients with chronic disease. The reach, flexibility, accessibility and conversion of established guidelines into a more user-friendly format have contributed to the success of this intervention programme. Future related studies are suggested to emphasise on the interactivity, familiarise the participants with the system prior to the intervention, encourage self-monitoring and built the intervention on a strong theoretical background.

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LIST OF ABBREVIATIONS

DM	Diabetes Mellitus
FBG	Fasting blood glucose
T2DM	Type 2 Diabetes Mellitus
TTM	Transtheoretical Model
SOC	Stages of Change
HbA1c	Glycosylated haemoglobin
NHMS	National Health Morbidity Survey
2HPPG	Two hour postprandial blood glucose
RCT	Randomised-controlled trial
DKAB	Dietary Knowledge, Attitude and Behaviour
DSOC	Dietary Stages of Change
UKPDS	United Kingdom Prospective Diabetes Study
MCPG	Malaysian Clinical Practice Guidelines
OHA	Oral hypoglycaemic agent
SMBG	Self-monitoring blood glucose
TG	Triglyceride
LDL	Low density lipoprotein
LCD	Low carbohydrate diet
GI	Glycaemic index
GL	Glycaemic load
HDL	High density lipoprotein
CVD	Cardiovascular disease

SF	Saturated fat
TF	Trans fat
MUFA	Monounsaturated fatty acid
VLDL	Very low density lipoprotein
PUFA	Polyunsaturated fatty acid
TC	Total cholesterol
IM	Intervention mapping
DKAB-Q	Dietary Knowledge, Attitude and Behaviour Questionnaire
DSOC-Q	Dietary Stages of Change Questionnaire
BMI	Body Mass Index
WC	Waist circumference
ICC	Intraclass correlation coefficient
CA	Cronbach’s Alpha
MET	Metabolic equivalent

LIST OF PUBLICATIONS AND CONFERENCE PRESENTATIONS

Journal publication

Ramadas A, Quek KF, Oldenburg B, Chan CKY & Zanariah H (2011). Randomised-Controlled Trial of a Web-based Dietary Intervention for Patients with Type 2 Diabetes Mellitus: Study Protocol of *my*DIDeA*. BMC Public Health*. 11:359. doi:10.1186/1471-2458-11-359

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Ramadas A, Quek KF, Chan CKY, Oldenburg B & Zanariah H (2009). Development Of An Interactive Nutrition Education Website For Patients With Type 2 Diabetes Mellitus. 19th International Congress of Nutrition, Bangkok, Thailand [4th – 9th October 2009]. *Annals of Nutrition & Metabolism*. 2009; 55 (suppl 1): 376.

Ramadas A, Quek KF, Chan CKY, Oldenburg B & Zanariah H (2009). Development of a Website-based Dietary Education for Patients with Type 2 Diabetes Mellitus: a theory based approach. 24th Scientific Conference and Annual General Meeting, Nutrition Society of Malaysia, Kuala Lumpur, Malaysia [27th - 28th March 2009].

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CHAPTER 1

INTRODUCTION

1.1 Background

Diabetes mellitus (DM) is a metabolic disorder of multiple aetiology characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both (1). The World Health Organisation sets the diagnostic criteria for diabetes through a single raised glucose reading with symptoms, otherwise raised values on two occasions, of either fasting blood glucose (FBG) ≥ 7.0 mmol/l or with a blood glucose ≥ 11.1 mmol/l after a glucose tolerance test (2). Type 2 Diabetes Mellitus (T2DM) is the most common form of diabetes and is characterised by disorders of insulin action and insulin secretion, either of which may be the predominant feature. Although T2DM could be inherited, modifiable factors such as body composition and nutrition also play important role in the aetiology of T2DM (3).

A wide range of interventions aimed at improving the provision of diabetes care and achieving better metabolic control for patients with diabetes have been implemented (4). Although multifaceted interventions seem to be effective, researchers are rarely able to isolate the exact component of the interventions that actually works. Besides, poor implementation of complex intervention may undermine the power and the validity of the entire study.

Theory and evidence-based behaviour interventions are long hailed to be the ideal approach towards successful health behaviour changes. Although no agreement exists as to the best theories for health promotion purposes, the Transtheoretical Model (TTM) (5) has become one of the most popular behaviour change model used in health promotion now. Besides the construct of Stages of Change (SOC), where the participants are classified into one of the five distinct stages; pre-contemplation, contemplation, preparation, action, and maintenance (6); processes of change, decisional balance, and self-efficacy measures also have been evaluated (7). The TTM and the SOC construct grew on the understanding on how people change their behaviour. Although the TTM has been subjected to criticism (8-9), it is still widely applied by clinicians and practitioners in various fields of health behaviour change.

TTM has been applied in health promotion studies on tobacco use (10), cancer screening behaviour (11), addictive substances, exercise (12) and dietary habits (13) among other health behaviours. Out of 25 intervention studies which were reviewed, 19 supported the use of SOC model in dietary interventions (13). The TTM has been mostly applied to describe dietary fat, fruits and vegetable intakes compared to any other dietary behaviour.

The TTM is also widely used in web-based interventions, especially those focusing on improving dietary and lifestyle behaviours (14-15). In a large but short Dutch web-based study, fruit intake increased significantly between pre- and post-test in contemplators, but not in precontemplators (14). TTM was also applied in a Korean web-based intervention to enhance the levels of physical activity and better control of FBG and glycosylated haemoglobin (HbA1c) in patients with T2DM. This has strengthened the need for more research on web-based studies using TTM (15).

A number of randomised-controlled trials (RCT) and quasi-experimental studies utilising the Internet for self-management of DM has been reported previously (16-18). By the mode of delivery, Internet interventions was found to have a positive impact on patient-centred outcomes (19). Beside self-management, web-based interventions also were successfully implemented in improving other health behaviour such as physical activity (15, 20) and weight management (21-22) in adults with T2DM.

Behavioural interventions have been proven to assist the management of T2DM and websites were found to be a feasible medium for the delivery of such interventions. Constant tracking of participants, personal goal-setting, self-monitoring, peer support and use of other technology as complimentary to the website are some measures that should be taken into account when such web-based interventions are conducted.

Taking these factors into consideration, this study aims investigate if a stage-personalised web-delivered dietary intervention will improve the dietary knowledge, attitude and behaviour, anthropometric measurements, dietary practices and biomarkers of patients with T2DM.

1.2 Problem statement

DM is an increasingly important medical and public health issue. The prevalence of diabetes in adults worldwide has been estimated to rise from 171 million in the year 2000 to 366 million in the year 2030 (23). The major part of this increase is expected to occur in urban areas in developing countries. The majority of diabetic patients in developing countries are expected to be in the range of 45-64 years, as opposed to more than 65 years in the developed countries (24).

The similar scenario can be seen in Malaysia, where DM has now become a growing concern. The first Malaysian National Health and Morbidity Survey (NHMS I) which was carried out in 1986 estimated the prevalence of DM to be 6.3%. Yet, the prevalence rose up to 8.3% in the NHMS II and the latest NHMS report (2007) stated the prevalence of T2DM in people above 30 years old of between 11% and 14% (25-27).

Poor metabolic control results in irreversible tissue damage and this accounts for 3.2 million deaths per annum (2). T2DM accounts for a huge burden of morbidity and mortality through microvascular and macrovascular complications (28-29). Long-term damages include damage and dysfunction of the cardiovascular system, eyes and nerves.

Increasing prevalence and disease burden has led to an increasing demand of programmes and studies focused on dietary and lifestyle habits, and chronic diseases such as T2DM. Besides, studying T2DM would be a good model for the care of many other chronic diseases that share almost similar risk factors.

1.3 Significance of the study

As in all cultures, diet plays a central role in the social and cultural aspects of the life of Malaysians. The ethnic variation in the Malaysian population and the ongoing diet transition from a traditional rice-fish-vegetable based one to a Western style one have resulted in the fusion of dietary habits of all Malaysians today. Changes in food preferences and food preparation methods have modified the dietary patterns of urban Malaysians in particular.

Those with T2DM may be extremely receptive towards improving their diet and physical activity behaviours and this offers the researcher a captive or "teachable moment" to promote behavioural change which may ultimately prevent complications due to DM. Besides, the probability of success in intervention or programmes related to dietary behaviour modification increases as the interventional strategies more aptly address the diversity of racial, ethnic, cultural, linguistic, religious and social factors in a community. Thus, a dietary intervention that is personalised and modified to suit the local content would be able to leave much greater impact than the general guidelines.

Although diet has been a part of lifestyle intervention in large studies such as The Finnish Diabetes Prevention Study (30), interventions focusing solely on the dietary component are scant. One of such few studies that looked into the aspect of diet and nutrition found that a reduced-fat diet intervention in those with glucose intolerance successfully reduced the body weight and lowered FBG (31). A Japanese study which was specifically designed to reduce total energy intake at dinner also successfully reduce the 2-hour post-prandial plasma glucose (2HPPG) level after one year intervention (32).

To date, there is no published study focused on dietary behaviour change in adults with T2DM via a website-based system. However, a pilot study on diabetes prevention resulted in a significant difference in the consumption of dietary fat (33). Dietary modification has been incorporated as a component of a web-based weight-loss programme in prevention of T2DM in adults (22). Behavioural e-counselling with calorie counting component also have significantly reduced the weight of adults at risk for T2DM (21). Improving Control with Activity and Nutrition (ICAN), a 12-month RCT which tested the efficacy of physical activity and nutrition behaviour changes in improving glycaemic control found favourable results as well (34).

The success of an Internet-based intervention relies heavily on the log-on rates, usability, and personalisation (35). Regular reinforcement by using the e-mail as a reminder service to encourage the subjects to log-in to a nutrition education website has been successful in increasing the log-in rates (36). Content development in local language may improve the usability of Internet in the locals seeking health information (37).

Although there are limited trials conducted to test the effectiveness of web-based intervention in subjects with T2DM, there is an improvement in outcomes for individuals using web-based interventions to increase nutritional knowledge and improve the glycaemic control (38). The web-based interventions have demonstrated some level of favourable outcomes, provided they are further enhanced with appropriate e-research strategies (35).

1.4 Research objectives

1.4.1 Primary objective

The primary objective of this study is to evaluate the effect of a 6-months dietary e-intervention on Dietary Knowledge, Attitude and Behaviour (DKAB) in patients with T2DM.

1.4.2 Secondary objectives

The secondary objectives of this study are:

1. To describe the baseline characteristics of study participants focusing on:
    a) Socio-demography and medical history
    b) Dietary Knowledge, Attitude and Behaviour (DKAB) score
    c) Dietary Stages of Change (DSOC) score
    d) Food intake (food groups and supplement intake)
    e) Anthropometric measurements (height, body weight, body mass index (BMI), waist circumference (WC), and body fat percentage)
    f) Blood pressure (systolic and diastolic) and resting heart rate
    g) Blood biomarkers (FBG, HbA1c and lipid profile)
    h) Other measures (smoking and drinking habit, and level of physical activity)

2. To compare between-groups and within-group changes in DKAB score at 6-months post-intervention and 12-months follow-up.

3. To compare between-groups and within-group changes in DSOC score at 6-months post-intervention and 12-months follow-up.

4. To compare between-groups and within-group changes in food intake (food groups and supplement intake) at 6-months post-intervention and 12-months follow-up.

5. To compare between-groups and within-group changes in anthropometry measurements (body weight, BMI, WC and body fat percentage) at 6-months post-intervention and 12-months follow-up.

6. To compare between-groups and within-group changes in blood pressure (systolic and diastolic) and resting heart rate at 6-months post-intervention and 12-months follow-up.

7. To compare between-groups and within-group changes in blood biomarkers (FBG, HbA1c and lipid profile)and resting heart rate at 6-months post-intervention and 12-months follow-up.

8. To conduct process evaluation of the website.

1.5 Research Question

Does a stage-personalised web-delivered dietary intervention improve the DKAB, anthropometry measurements, dietary practices and biomarkers of patients with T2DM?

CHAPTER 2

LITERATURE REVIEW

2.1 Background

2.1.1 Type 2 Diabetes Mellitus

Diabetes Mellitus (DM) is a metabolic disorder of multiple aetiology characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both (2).

Type 2 Diabetes Mellitus (T2DM) is the most common form of diabetes, accounting for about 80% of all diabetes cases mostly after the age of 30 (39). T2DM is characterised by three basic abnormalities – insulin resistance, impaired insulin secretion and increased hepatic glucose production, either of which may be the predominant feature (40-41). This results in a disorder of carbohydrate, fat, protein and or mineral metabolism.

Although T2DM could be inherited, modifiable factors such as body composition and nutrition play important roles in the aetiology of T2DM (3). Obesity is the main feature of T2DM as fat tissues are relatively resistant to the effect of insulin and this could eventually lead to elevation of glucose in the blood (42). According to the Nurses' Health Study, 91% of women with T2DM could be attributed to a BMI of more than 23, sedentary and unhealthy lifestyle (43).

The World Health Organisation has defined the diagnostic criteria for diabetes through a single raised glucose reading with symptoms, otherwise raised values on two occasions, of either fasting blood glucose (FBG) ≥ 7.0 mmol/l or with a blood glucose ≥ 11.1 mmol/l after a glucose tolerance test (2). In diabetes management, nearly all T2DM related research outcomes aiming for a reduction in glycosylated haemoglobin (HbA1c) and report from the United Kingdom Prospective Diabetes Study (UKPDS) has recommended HbA1c to be maintained below 7.1% to minimise T2DM related complication (44).

It has been shown that individuals from primitive societies, where the incidence of T2DM is low whom then move to societies where food is too readily available, often progress to develop diabetes (45). Although many people with T2DM could be managed by dietary modification alone, eventually they may require insulin therapy due to its progressive nature.

2.1.2 The burden of Type 2 Diabetes Mellitus

T2DM is an increasingly important medical and public health issue, which is becoming more common among the younger age group (45). While the prevalence of diabetes in adults worldwide was estimated to rise from 171 million in the year 2000 to 366 million in the year 2030, and the major part of this increase is expected to occur in the developing countries, concentrating in the urban areas (23). In addition to that, the majority of diabetic patients in the developing countries are expected to be in the range of 45-64 years, as opposed to more than 65 years in the developed countries (24).

According to International Diabetes Federation (IDF), the South East Asia region is projected to have the highest number of deaths due to diabetes of all the regions in 2010 (46). The regional diabetes prevalence in South-East Asia stood at 7% in the year 2010, and this figure is expected to increase to 8.4% in the year 2030. The IDF also expected the number of people with diabetes to almost double from 58.7million to 101.0million, and the health expenditure related to diabetes complications is set to rise from USD3.1million to USD5.3million in the next 20 years.

The similar scenario can be seen in Malaysia, where T2DM has become a growing concern. In the year 2000, the first Malaysian Burden of Disease and Injury Study estimated diabetes to be the seventh leading cause of burden of disease in Malaysia, accounting for 2,261 deaths and 3.7% of total disability adjusted life years.

The first National Health Morbidity Survey (NHMS I), which was carried out in 1986 estimated the prevalence of diabetes to be 6.3%. Yet, the prevalence rose to 8.3% in the NHMS II and the latest NHMS report (2007) stated the prevalence of T2DM in people above 30 years old of between 11% and 14% (25-27). Among newly diagnosed diabetes, the prevalence also increased from 2.5% (NHMS II) to 5.5% (NHMS III).

There was an increase in the prevalence with age and the highest prevalence of 20.8% to 26.2% was recorded among 50-64 years age group (27). The overall prevalence was significantly higher in the urban areas compared to the rural areas (12.1% vs. 10.5%). While NHMS III did not report difference in prevalence between gender and income status, there was a significantly high prevalence of diabetes in those with primary education or less, and among Indians (19.9%). The prevalence of people with known diabetes and newly diagnosed diabetes was 7.0% and 4.5% respectively.

The trend is further burdened with the disease complications. There is irreversible tissue damage mainly from poor metabolic control, which results in about 3.2 million deaths per annum from diabetes with six deaths every minute (47). Taking this into consideration, the Malaysian Clinical Practice Guidelines (MCPG) for T2DM recommends people with T2DM to be screened for complications at the diagnosis and thereafter at yearly intervals (48).

Apart from acute complication such as hypoglycaemia, lactic acidosis, diabetic ketoacidosis and hyperosmolar hyperglycaemic state, T2DM also accounts for a huge burden of morbidity and mortality through micro- and macrovascular complications (28-29). Microvascular complications include eye and renal diseases, while common macrovascular complications are hypertension, dyslipidaemia, obesity, peripheral vascular and cerebrovascular diseases.

The burden is evident among Malaysians, as the NHMS III has reported that 4.3% of people with known diseases to having had lower limb amputations, 3.4% had strokes and 1.6% was on dialysis or had kidney transplants due to diabetes. The percentage of strokes was highest in the Chinese (5.5%), nearly twice of that in the Malays (2.9%). For dialysis or kidney transplants, the Chinese and Indians reported almost double the percentage seen amongst the Malays (49).

This rising trend has been tied to many factors such as population growth, aging, urbanisation and increasing prevalence of obesity and physical inactivity (23). In view of this trend, there is an increasing need for more rigorous prevention and management of diabetes, especially programmes and studies that are focused on dietary and lifestyle habits.

2.1.3 Management of Type 2 Diabetes Mellitus

T2DM is managed via a step-wise approach based on the FBG and HbA1c level. Each step comprises of lifestyle modifications with monotherapy or combination therapy of antidiabetics (48). The goal of management is to achieve the glycaemic control and to reduce the risk and the incidence of complications due to T2DM, as the UKPDS has shown better glycaemic control lowers the risk of these complications (44).

During the continuing care, the health care providers aim for relief of acute symptoms, optimising the glycaemic control and other risk factors for complication, and treating the existing complications (48). The MCPG for T2DM recommends glycaemic targets to be individualised but targeted to achieve HbA1c less than 6.5% to reduce the risk of micro- and macrovascular complications. In order to achieve this, an individual with diabetes should aim for FBG or pre-prandial plasma glucose targets of 4.4 to 6.1 mmol/L and 2-hour post-prandial plasma glucose (2HPPG) targets of 4.4 to 8.0 mmol/L.

There are two important aspects in the management of T2DM – the pharmacological and non-pharmacological treatment.

2.1.3.1 Pharmacological management of T2DM

Oral hypoglycaemic agents (OHA) and/or insulin therapy are the most prevalent form of pharmacological management of T2DM. The MCPG for T2DM recommends the initiation of OHA if glycaemic targets are not achieved (HbA1c < 6.5%, FBG < 6 mmol/L) with lifestyle modification within 3 months. There are five distinct oral drug classes available for the treatment of T2DM – α-glucosidase inhibitors, biguanides, dipeptidyl peptidase-4 (DPP-4) inhibitors, insulin secretagogues and thiazolidinediones. Most of these agents lower the HbA1c level by 1% to 2% despite demonstrating different mechanism of action (50).

As the first line of therapy, metformin from the class of biguanide is the preferred choice of OHA due to its effectiveness in significantly reducing myocardial infarction and diabetes-related deaths (51-52). Metformin also has resulted in a lower incidence of hypoglycaemia, lack of weight gain and better effect on lipid profile compared to other OHA (53). If monotherapy failed, combination of OHAs is usually recommended (54). Combination of OHA and insulin also could be recommended in newly diagnosed patients with HbA1c >10%, FBG > 13 mmol/L or in patients who did not achieve glycaemic target (HbA1c <6.5%) after 3 – 6 months on optimal doses of combination therapy (48).

On the other hand, insulin such as, regular insulin, rapid-acting, intermediate-acting and long-acting insulin are also used to as the pharmacological treatment of T2DM (48). There are several types of insulin regimens, such as combination OHA with basal or premixed insulin, metformin with premixed insulin and metformin with basal and prandial insulin. Insulin is usually administered subcutaneously via insulin pen or pump. However, intravenous route can be also used in certain clinical conditions. Meanwhile, the insulin doses are titrated based on the FBG and “treat to target” schedule for the best glycaemic control.

2.1.3.2 Non pharmacological management of T2DM

Diabetes education is an integral part of management of T2DM and is effective for improving clinical outcomes and quality of life. It has since progressed from one-to-one teaching to group learning (55), and diabetes education programmes were advised to be structured towards decision making and problem solving. Diabetes education delivered by a team of educators, with reinforcement at additional points of contact, may provide the best improvements in patient outcomes (56). DESMOND, DAFNE and Diabetes X-PERT Programme are few of the most widely cited structured education programmes.

Diabetes education is vital in empowering the patients to self-manage their disease. Azimah et al. (57) found an urgent need to improve the overall diabetic education especially in areas of complications, exercise and diet, and emphasised the importance of the T2DM patients to discuss dietary habit with a dietician. It is recommended that diabetes education to be advocated to all patients with T2DM in Malaysia (48) (Figure 2.1).

Diet and lifestyle changes as well as self-monitoring blood glucose (SMBG) are important aspects of diabetes education, with dietary changes being the forefront of diabetes education programmes. The nature of dietary changes varies according to individual nutritional and clinical priorities, habitual diet and lifestyle, and prevalence of risk factors (58). There are three important stages in dietary management of diabetes – assessment, education and progress monitoring. In the assessment stage, the nutritionist decides on the dietary aspects that need to be changed and weigh the pros and cons of the possible changes after analysing the dietary background of the patient. In the following stage, patients are assisted to make dietary and lifestyle changes to optimise glycaemic control through tailored dietary education. In the third and final stage, the patients are followed up for review at specified interval. Specific dietary factors in diabetes management will be discussed in detail in Section 2.2.

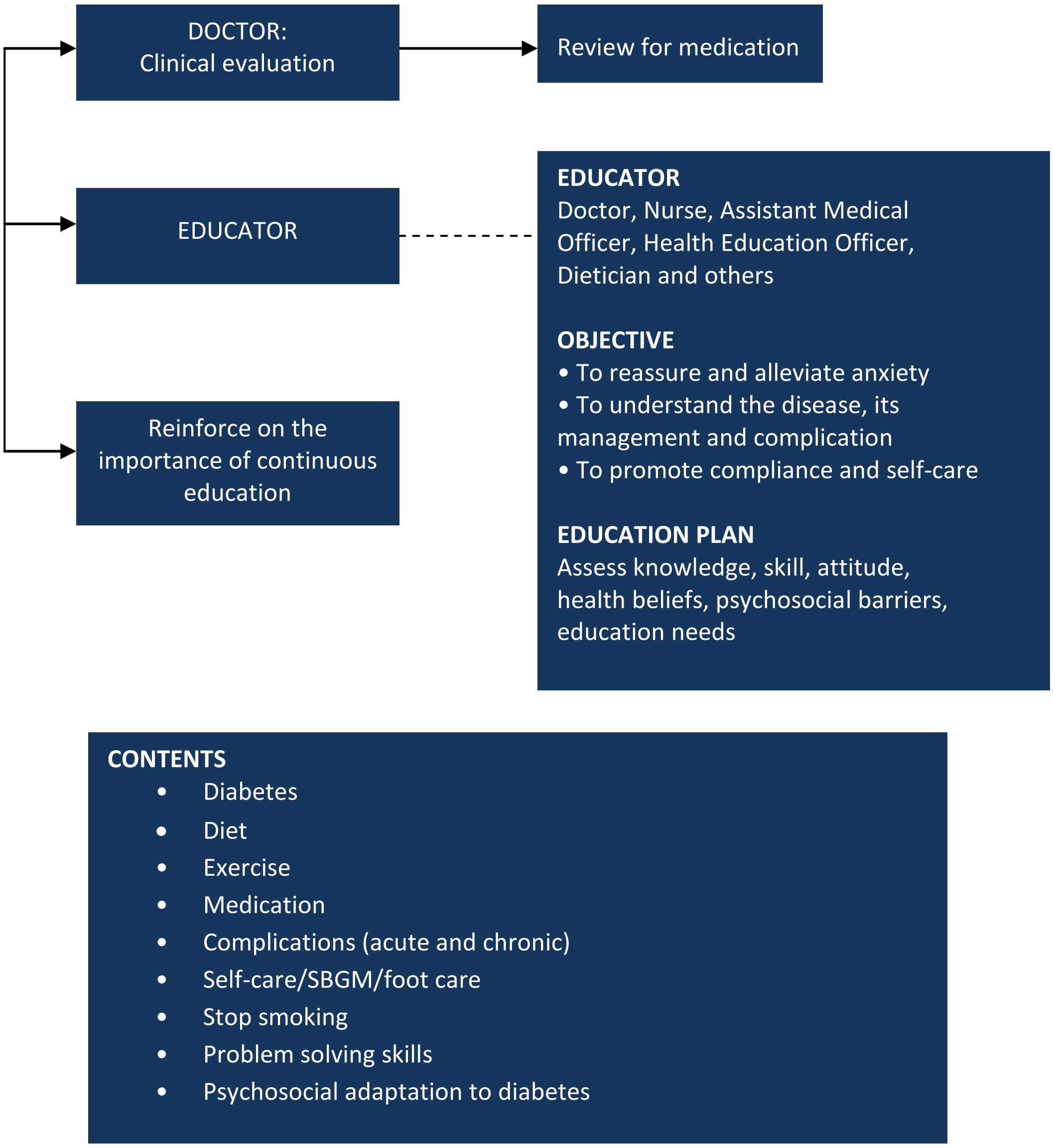


Figure 2.1: Education Strategies Algorithm (adapted from Malaysian Clinical Practice Guidelines for Type 2 Diabetes Mellitus (48)).

Physical activity is found to be beneficial to people with T2DM as it results in a better glycaemic control (59), and reduces visceral adipose tissue and plasma triglycerides (TG) (60). Specifically, vigorous aerobic exercise results in greater reductions in HbA1c and low-density lipoprotein (LDL), greater increase in maximal oxygen uptake (VO2 max) and greater increase in insulin sensitivity (61-63). Resistance training also could be an effective intervention to help glycaemic control (64). Recent evidences appear that a structured exercise training of more than 150 minutes per week is associated with greater HbA1c declines than that of 150 minutes or less per week (65). The review by Umpierre and colleagues (65) on 47 RCTs also suggested physical activity advice to be associated with lower HbA1c, but only when combined with dietary advice.

Although there are evidences suggesting SMBG is useful for patients with T2DM (66), the benefit of self-monitoring in patients who are not on insulin treatment is often debated (67-68). However, SMBG has been suggested to be tailored to the needs of the individuals in insulin therapy and poor glycaemic controls, and to be integrated into a wider educational strategy (69-73).

Diabetes education, diet, lifestyle modification and SMBG are vital components of diabetes education. Although some aspects of these components are still being debated, the benefits of non-pharmacological management should not be underestimated.

2.2 Nutrition and Diabetes

Diet is one of the main control key of T2DM and integral component of diabetes education (48, 74). The goals of Medical Nutrition Therapy in people with diabetes are to achieve and maintain normal blood glucose, lipid and lipoprotein and blood pressure levels; prevent or slow the development of complications; address the nutritional needs and maintain the pleasure of eating (74-75). A range of dietary factors is considered in the dietary management of T2DM and these factors are discussed in the following section.

2.2.1 Dietary factors in diabetes management

2.2.1.1 Carbohydrate

A recommended dietary pattern for people with diabetes includes carbohydrate from various sources for good health and monitoring carbohydrate is a key strategy in achieving glycaemic control (74). According to the American Diabetes Association, the amount and the source of carbohydrate are important determinants of postprandial glucose (76). However, Thomas (77) claimed that the distinction between complex and simple carbohydrate has not reliably showed the glycaemic effect of food. He explained that the postprandial glycaemia is influenced by many aspects of foods and cannot be predicted from its sugar content alone.

People with diabetes commonly adopt low carbohydrate diets (LCDs) and recent studies have shown the effectiveness of LCDs in improving the blood glucose control (78-86). Most of the reported trials are short-term in nature (84-85) , though a longer study by Haimoto et al. (78) reported a remarkable reduction in HbA1c levels after a 30% carbohydrate diet over 6 months. In an another intervention among overweight patients with T2DM, LCDs was suggest to be so effective that diabetes medications were discontinued or reduced in most participants (86). Meta-analysis of 13 studies showed that HbA1c and FBG, improved with intake of LCDs in patients with diabetes (87).

Carbohydrate restriction has not only resulted in better glycaemic control, but has also shown to improve dyslipidaemia in people with T2DM (79-80, 82, 85, 87-89). Plasma TG levels of these patients have been shown to decrease after LCD trials (87). A LCD diet with calorie limitation is effective in increasing HDL levels compared to high carbohydrate diets with calorie restriction (80).

The LCDs were also found to be beneficial in weight management of T2DM patients (80, 83, 90-91). A review by Dyson et al. (92) investigated the effects of hypocaloric reduced carbohydrate diets in patients with T2DM and found all studies reported reductions in body weight and HbA1c. Although studies are few and small in sample sizes, LCDs are found to be safe and effective over short term for patients with T2DM.

However, there are reports that did not support the use of LCDs in patients with T2DM for the purpose of glycaemic control (93-94). In addition, Kirk et al. (87) could not find a clear overall effect on body weight. Daly also reported an increase in relative SF intake despite the short-term weight loss achieved by the patients (91). Review by Chandler (95) suggested that LCDs can increase the risk of glycogen depletion, dehydration, elevate circulating LDL and loss of metabolically active muscle tissue besides increase in body fat levels beyond what they were initially once the LCD is discontinued.

In summary, the evidence supporting the use of LCD generally outweighs the any evidence suggesting the opposite. The lack of negative effects, improved glucose control and a positive nitrogen balance suggest beneficial effects for patients with T2DM (96). Patients with T2DM are regarded as an ideal target group for LCD, but insulin requirement during the diet need to be reviewed closely (97). As the LCDs can be very effective at lowering blood glucose, patients on diabetes medication who use this diet should be under close medical supervision or capable of adjusting their medication (86). There is a need for RCTs of low carbohydrate diets in patients with diabetes to be conducted to evaluate the sustainability of outcomes and long-term safety (87).

2.2.1.2 Glycaemic index

Glycaemic Index (GI) ranks carbohydrate-containing foods according to their effect on postprandial glycaemia (98-99). GI is a measure of the increase in blood glucose two hours after consumption of the food of interest, with reference to glucose or white bread. Glycaemic load (GL), a product of GI and amount of carbohydrate in the food, is another measure of glycaemic response to carbohydrate-containing foods, and could improve the evaluation of glycaemic response to a diet (76). Foods with low GI such as parboiled rice, barley, oats and legumes lower the postprandial hyperglycaemia, while high GI foods such as white bread, potatoes, white rice and commercial breakfast cereals will show the opposite effect (74, 100).

Given the importance of glycaemic control, GI-based dietary education has been suggested to be a useful tool in diabetes management (101-102). A dose-dependent relationship between dietary GI and GL with HbA1c was found in South Italy, where patients with diabetes with highest GI and GL had the highest HbA1c levels (103). Miller and Gutschall (104) reported a nine-week nutrition education regarding GI and GL which improved dietary intake, knowledge, outcome and efficacy expectations, and empowerment for diabetes management. Although GI could lead to a better dietary intake in people with diabetes, only few organisations recommended the use of low GI diets (48, 105-106).

Inclusion of low GI diet has resulted in improved glycaemic control of patients with T2DM (107-111). Significant improvements have been seen in HbA1c and/or FBG (108-111), insulin sensitivity (108) and serum fructosamine (110) with low GI diets. The role of GI diets in glycaemic control has been confirmed by few meta-analyses and reviews (100, 112-113). However, there is a lack of studies on the technology assisted low GI interventions, and only one feasibility nutritionist-delivered, PDA-assisted low-GI dietary intervention by Ma et al. (114) has been discovered.

Low GI diets also have been shown to have favourable impact on lipid profile and reduction in cardiovascular risk of patients with T2DM (109, 115-118). Studies have reported significant increase in HDL (111), and decrease in TC (108) and LDL (108, 119-120). Besides the cholesterol levels, a low GI or GL diet may be preferred for the dietary management of T2DM because of sustained reductions in c-reactive protein (121) and the increase in the plasma adiponection concentrations (122).

There is also evidence showing the positive impact of low GI diet on other health outcomes in people with diabetes. Low GI diet could assist with the weight management programme in patients with diabetes (117, 120). For example, Yusoff and colleagues (110) reported a significant reduction in waist circumference in Asian patients after 4 months of following a low GI diet. In addition, Low GI diet accompanied with exercise programme was found to improve cardiovascular health (123) and protect against exercise-induced hypoglycaemia in T2DM patients (124). Low GI diet has also generally results in better cognitive performance in adults with T2DM and reduces their dependency on diabetes medication (119, 125) .

Interestingly, there were studies that did not support the role of GI in diabetes management (120, 126-128). In one of such studies, low GI diet with calorie restriction in overweight patients with T2DM did not find any significant reduction in HbA1c (120). Data derived from the Atherosclerosis Risk in Communities study suggest high GL intake to be a coronary heart disease risk factor only among Whites without diabetes and not in individuals with diabetes (127). Cheong et al. (128) concluded addition of a low GI diet did not improve anthropometric or metabolic outcomes in diabetic patients. However, a review by Barojek and Morello (129) has identified short coming in terms of power of the study and confounders, which could have affected otherwise positive findings in these studies.

It can be concluded that, there is overwhelming evidence that supports low GI diet as an effective approach for weight management, glycaemic control and favourable lipid profile in people with T2DM. However, the concept of GI should not be used in isolation, but to be used as an adjunct treatment to existing lifestyle management of T2DM in fine-tuning the glycaemic control (126, 130).

2.2.1.3 Dietary fibre

A fibre-rich diet is usually based on legumes, whole-grains, vegetables, fruits, and high-fibre cereal products. Dietary fibre is constantly recommended for patients with diabetes, due to its effect on various cardiovascular risk factors (113, 131). Whole-grains, for example, have potential benefits in reducing mortality and cardiovascular risk in women with T2DM (132).

Various types of fibre-containing foods and supplements have been investigated on its glycaemic response and cardiovascular health. Psyllium is only of such desirable fibre supplement to be used in trials to determine the effectiveness of fibre in improving health of T2DM patients. Psyllium treatment was found to reduce postprandial plasma glucose and HbA1c (129), and plasma TG (133) in patients with T2DM, especially in those with poor glycaemic control (129). Fibre-containing nutrition bar has been shown to reduce postprandial glucose, insulin and C-peptive response (134), besides being an useful tool in weight management of T2DM as it increased fullness and decreased hunger in overweight and obese adults with T2DM (135).

Besides various method of fibre supplementation, Giacco et al. (136) demonstrated that it was possible to increase the dietary fibre with natural foods and it is possible to lower the HbA1c, reduce the hypoglycaemic episodes and improve cardiovascular profile of people with diabetes. This finding has been supported by other studies (lipids (137-141).

Consumption of a high fibre diet resulted in early attainment of normoglycaemia and improved glycaemic control, decreased hyperinsulinaemia and plasma lipids (121, 137-138). Mediterranean diet, which has the highest intake of dietary fibre and unsaturated-saturated ratio resulted in greater improvements in FBG and insulin levels (139). Intake of soluble dietary fibre from whole grains and fruits may have favourable impact on glycaemic control and lipid profile (140), as well as protective effect against occurrence of metabolic syndrome in patients with diabetes (141).

The overall evidence supports the beneficial effect of including high fibre diet in intervention for patients with T2DM. However, high fibre diets have shown to have a small impact on calcium and phosphorus balance in diabetic patients (142). It is vital to ensure adequate intake of these minerals in those consuming high fibre diet.

2.2.1.4 Dietary fat

Dietary fat is one of the most important dietary aspects in the management of T2DM, considering patients with T2DM to be high in risk for cardiovascular diseases (CVD). This has prompted low fat diet to be recommended to reduce the CVD risk (76). Besides reduction in CVD risk, the American Diabetes Association recommends low fat diets for weight loss as fat has higher calorie content than carbohydrate and protein (74). According to the MCPG for T2DM (48), only 25 – 30% energy should be obtained from fat and this percentage should be individualised based on lipid goals. Patients are also required to limit the intake of saturated fat (SF), trans fat (TF) and cholesterol. However, there are limited evidence based on trials on patients with T2DM and most of the recommendations on dietary fat intake are based on trials on non-diabetic or healthy individuals (143).

Diet rich in monounsaturated fatty acids (MUFA) is seen as a good alternative to high carbohydrate diet in T2DM patients (144-147). A meta-analysis by Garg (144) suggest MUFA-rich diet to improve glycaemic control and lipid profile by resulting in greater reduction in FBG, plasma TG and very low density lipoprotein (VLDL) and modest increase in HDL. The author recommended MUFA-rich diet accompanied with calorie restriction for weight management in patients with T2DM. Similarly, Wolever et al. (145), 12% reduction in serum TG level and a significant reduction in LDL size in T2DM patients consuming diet rich in MUFA. Moreover, high MUFA diet has favourable effect on LDL oxidative resistance and metabolic control in diabetic patients (146) and the mechanism of high MUFA diets in assisting in weight loss has been attributed to its higher oxidation rate compared to SF (147).

Besides MUFA, there are other types of fatty acids that may have a role in diabetes management. One of such fatty acids, the oleic acid has been showed to reduce LDL and protect from LDL oxidation, but without increasing HDL (148). Increase in dietary omega-6 polyunsaturated fatty acids (PUFAs) and SF intake are significantly associated with fasting hyperinsulinaemia and sub-clinical inflammation, which could contribute to high prevalence of insulin resistance, the metabolic syndrome and T2DM among Asians (149). In contrast, dietary omega-3 PUFAs improves lipid profile and may have beneficial effect on insulin resistance in this group. Regular consumption of oily fish and plant sources of dietary omega-3 PUFAs will help to ensure adequate intake of this fatty acid (150).

Studies by Gerhard et al. (151) and Ben Avraham et al. (139), however, did not support these findings. Although Gerhard et al. demonstrated a greater weight loss in diabetic patients consuming a low fat diet, the reduction in weight is lesser than those in the high-MUFA diet. They also did not find any difference in HbA1c and cholesterol levels in both groups. Ben Avraham and colleagues concluded low fat diet to be less beneficial when it comes to glycaemic control and lipid profile. However, low fat vegan diet may be superior to a conventional low fat diet. Such diet has been shown to improve postprandial glycaemia and lipid profile, and reduce dependency on medication and neuropathic symptoms in patients with T2DM (152).

Unfortunately, the contradicting evidence has made it difficult to conclude that low fat diet should be advocated for T2DM patients, and more high quality evidence is required before such conclusion can be made. For the time being, dietary recommendation on dietary fat intake for general population should be recommended for patients with T2DM.

2.2.1.5 Dietary protein

Studies have demonstrated relationship between intake of dietary protein and the development of diabetes (153); however, its role in diabetes management is under-researched. Most of the existing guidelines suggest dietary protein intake to be equivalent to the ones recommended to non-diabetic population, which is between 10 – 20% of total energy intake (48, 150, 154). Protein has neutral effects on postprandial glucose and there are very few studies that investigated this further (155-156).

High protein diet has been shown to improve the glycaemic control of people with diabetes (157-158). Besides consumption of high protein diet, eating protein-containing food before a carbohydrate-containing meal could reduce the postprandial glycaemia in patients with T2DM by stimulating insulin and incretin hormone secretion and slow the gastric emptying (159). The increased insulin response stimulates plasma glucose disposal and reduces postprandial glucose concentrations (160).

Besides, glycaemic control, Pomerleau and colleagues (158) have also reported significant decrease in body weight with moderate and high protein diet in T2DM patients with microalbuminuria. Increasing protein content of diet of these patients at the expense of carbohydrate actually reduces the 24-hour integrated plasma glucose concentration, independent of medication and without affecting their renal function (161). This could be a suitable method to empower patients to reduce hyperglycaemia.

Soy is a type of protein-rich food that has been investigated in relation to T2DM. It contains various beneficial components that may affect cardio-metabolic abnormalities (162-163), CVD risk and kidney-related biomarkers in diabetic patients with nephropathy (164-167). Despite lacking of human trials, fermented Korean soybean products also have shown to prevent or attenuate the progression of T2DM(168). The positive effect of soy proteins has been attributed to its glycine and arginine content which reduce the blood insulin levels, and fibre content which has insulin-moderating effect (169).

However, there are studies that did not support this evidence (170-171). Sargrad et al. (170) demonstrated significant decrease in HbA1c and FBG, an increase in insulin sensitivity amidst a small decrease in HDL in high carbohydrate group as compared to high protein group in a RCT among obese patients with T2DM. In another study, soy protein did not significantly affect FBG, postprandial glucose or insulin, HbA1c, insulin sensitivity and resistance, and the researchers concluded lack of support for the use of soy protein in dietary management of T2DM (171).

In contrast to high protein intake, low protein diet could significantly reduce depressive symptoms in young-old T2DM patients with renal failure (172). Low protein diet in T2DM patients with nephropathy is beneficial, as it reduces low-grade inflammatory state, proteinuria, albuminuria besides other renal markers (173).

The use of protein in diabetes management is still debatable. Similar to the dietary fat, the dietary recommendation for protein intake should be maintained as for the general public until future evidence shows otherwise.

2.2.1.6 Micronutrients and phytochemicals

Fruits, vegetables and herbs are traditionally used for management of T2DM. There are growing scientific evidence supporting the addition of these food groups in dietary management of T2DM. A review of popular commercially available Chinese herbs and herbal preparation suggest these herbs achieve hypoglycaemic effect by increasing insulin secretion, enhancing glucose uptake by adipose and muscle tissues, inhibiting glucose absorption from intestine and inhibiting glucose production from heptocytes (174). African patients with T2DM reported a reduced risk of metabolic syndrome due to regular intake of vegetables rich in antioxidants, specifically cassava leaves and dried red beans (175). The authors added that these findings supports for recommendations to consume fruits and vegetables rich in antioxidants.

Recent studies which are focused on studying the micronutrients and phytochemical compounds in fruits and vegetables, which may have advantageous effect. For example, decrease in amount of β-carotene and increase in urine and blood retinol-binding protein reported in patients with diabetes (176). The researchers found the β-carotene to be inversely correlated with FBG.

Various types of phytochemicals-containing fruits and vegetables have been suggested to be beneficial to people with diabetes (177-180). Polyphenols, which are found in fruits, vegetables, berries, beverages and herbal medicines can modify imbalanced lipid and glucose homeostasis thereby reducing the risk of the metabolic syndrome and type 2 diabetes complications (177). Cranberries, a rich source of polyphenols have exhibit a reduction in atherosclerotic cholesterol profiles, including LDL and TC levels, as well as TC: HDL ratio in patients with T2DM (178). Beside fresh fruits, unsweetened low-calorie cranberry juice also could be useful to promote fruits consumption in T2DM due to its favourable metabolic response (179). Similarly, consumption of commercial tomato juice increase plasma lycopene levels, decrease plasma c-reactive protein and resistance of LDL to oxidation as effect as high vitamin E supplementation in T2DM patients (180).

Inverse association between fruits and vegetable intake, serum carotenoids and insulin sensitivity has been shown by epidemiological studies (181-182). For example, the Botnia Dietary Study demonstrated favourable association between carotenoids, a marker of fruits and vegetable intake, and glucose metabolism in men with risk for T2DM (182). The EPIC-Norfolk Study, a population-based cohort study of diet and chronic disease, also reported similar finding (181). Fruits and vegetable intake also has been found to be inversely related to oxidative stress, while plasma carotenoids were inversely correlated with inflammation in patients with T2DM (183). The study suggests an increased intake of fruits and vegetables to be beneficial in these patients, especially when diabetic patients are shown to have raised oxidative stress and inflammation.

However, Bose & Agarwal (184) reported no significant lipid lowering effect in T2DM patients after consumption of tomato lycopene though it was found to be a good source of antioxidant. Likewise, a 12-weeks antioxidant supplementation trial in patients with T2DM did not find effect on glycaemic control or oxidative stress or inflammation, despite the increase in plasma concentration of antioxidants (185). The authors explained this could be due to the enrolment well-controlled study subjects with high intake of fruit and vegetable and high levels of plasma antioxidants, biomarkers of oxidative stress and inflammatory markers at baseline.

As opposed to other macronutrients such as carbohydrates, there is little evidence available to support the protective effect of fruits and vegetables, and even lesser intervention studies which investigated the effect of plant-rich dietary pattern. This could be an area for active investigation in the future.

2.2.1.7 Mineral: Sodium

People with both diabetes and hypertension have approximately twice the risk of CVD as nondiabetic people with hypertension, and hypertensive diabetic patients are also at increased risk for diabetes-specific complications including retinopathy and nephropathy (74). Lowering blood pressure to less than 130/80mmHg is the primary goal in the management of the hypertensive diabetic patients (186). Given the fact that the prevalence of hypertension is higher among people with diabetes, there is a need to study this link further.

There is established epidemiological evidence linking salt and hypertension (187) and the MCPG for T2DM (48) recommends a reduced sodium intake (less than 2,400 mg sodium/day or 6 g of salt a day) with a diet high in fruits, vegetables, and low-fat dairy products lowers blood pressure for normotenstive and hypertensive T2DM patients. Although national guidelines have recommended salt restriction, a report by Ekinchi et al. (188) found that most patients with T2DM do not meet Australian National Heart Foundation's sodium or potassium intake guidelines, and they suggested the development of hypertension and resistance to blood pressure lowering therapies to be attributed to diets high in sodium but low in potassium. Vedovato et al (189) reported a comparison study to measure the effect of sodium intake on blood pressure and albuminuria in T2DM patients with and without albuminuria. High salt intake increases blood pressure and albuminuria in type 2 diabetic patients with microalbuminuria. Salt taste perception is impaired in those with T2DM and it is significant associated with their blood pressure (190). The impairment of salt perception could be one of the explanations for the pathogenesis of hypertension in T2DM.

Low sodium diet potentiates the antihypertensive and antiproteinuria effects of losartan in patients with T2DM (191). The reduction in blood pressure due to the addition of low sodium diet to losartan was similar of what could be predicted from an addition of a second antihypertensive drug. Meta-analysis of 13 studies of salt restriction found a greater reduction in blood pressure of normotensive patients with diabetes, possibly due to greater decrease in salt intake (192). The salt restriction reduced blood pressure by 6.90 $\pm$ 2.87mm/Hg in T2DM patients, prompting the authors to recommend reduction of salt intake to at least less than 5-6g/day and may consider lowering it further.

Although the available evidence is limited, the studies have shown overwhelming support to a reduced-salt intake in people with T2DM. Considering the available evidence and recommendation of salt restriction, such recommendation should be incorporated in dietary intervention programme for all patients with T2DM.

2.2.2 Dietary strategies in Type 2 Diabetes Mellitus

Dietary change in patients with T2DM is best achieved by a series of small changes with an extent and pace desirable and acceptable by the patient (77). As opposed to total lifestyle change or self-monitoring, there are fewer studies focusing solely on dietary management of T2DM reported (31-32). This has resulted in a vacuum in available evidences to support the effect of dietary modification in the management of this disease, although dietary intervention personalised to local community may produce favourable results. However, there are many successful components that could be applied in future research.

A review of literature on healthy eating interventions within diabetes care published from 1999 to 2007 suggests inclusion of other health components of exercise and peer support may beneficial (193). Some studies require longer duration (more than 6 months) but some interventions have been shown to be successful with shorter duration. Dietary education was also more likely to be effective if it focused on specific food- and nutrition-related behaviours or community and social practices and used appropriate theory and research evidence for designing interventions (194-195). Personalised dietary education followed up by telephone, was effective in educating diabetic patients in adhering to dietary recommendation and improving glycaemic control and lipid concentrations (196).

The delivery of the dietary programme itself is important aspect to be investigated. The skill of translating the pathophysiology of diabetes to practice is possessed by nutritionists and this makes them the key personnel in translation of nutritional evidence to patients with T2DM (197). The report described nutritionists to be the best health professionals to deliver dietary education as they work in the real community setting and have demonstrated excellent practical understanding and creativity to find novel approaches to improving dietary and physical activity behaviours among people with diabetes. These healthcare professionals also have a good grasp of community-based data-gathering techniques including interviews, focus group discussions, and household food inventory checklists among others.

In Malaysia, a dietary study on T2DM patients showed the intake of energy was inadequate and the women participants did not meet the recommended requirement of several micronutrients and more than 80% of the patients interviewed were overweight or obese (198). This demonstrated a need for intensive dietary education programmes for people with T2DM in Malaysia. Nutrition education has showed to increase dietary knowledge, which could improve the dietary behaviour (199).

Various mediating factors and barriers have to be addressed for a dietary programme to be successful. Diabetes knowledge of T2DM patients' influence the eating patterns and dietary self-efficacy, social support, and time management were identified as mediating factors which can influence dietary behaviours (200). Lack of support from the family and health services, low income, neighbourhood insecurity, misleading information are key barriers for behavioural change in T2DM patients, primarily of those related to diet modification (201). High dropout rate is also a factor that needs to be encountered so that it does not interfere with the programme effectiveness (202).

It can be concluded that, there are diverse kinds of diets that can be 'prescribed' to people with diabetes – including low-carbohydrate diets, low glycaemic-index diets, low-fat vegan diets, conventional low-fat diets, and high-protein and high–monounsaturated fat diets (155). However, there is no clear indication of which diet may work better than the other is. The best strategy is the one that can be adopted easily and maintained long term. Future research with adequate sample size should also validate and refine the existing dietary management model of T2DM by focusing on initiation and maintenance of dietary behaviour change (193, 200).

2.3 The Theory-based Approach

2.3.1 Behavioural theories in health promotion

Theory-driven behaviour interventions are long hailed to be the ideal approach towards various successful health behaviour changes (203). Theory-based interventions focus on the key aspects of the programme and suitable evaluation methods based on the understanding of the behaviour. Thus, the outcomes of such an intervention programme will be reliable enough to be generalised to populations sharing a similar sociodemographic background. Figure 2.2, adapted from Nutbeam & Harris (2004) illustrates the importance and utilisation of behavioural theories at every stage of planning, implementation and evaluation of an intervention programme.

In recent years, there is an increase in the interest shown in the use of behavioural theories in health promotion programmes. Theories can be grouped into two major categories - explanatory theory and change theory (204). Explanatory theories describe the reasons why a problem exists and guides the search for the factors that contribute to the problem, while change theories guide the development of health interventions by specifying the concepts, programme messages and strategies, and offers a basis for programme evaluation.

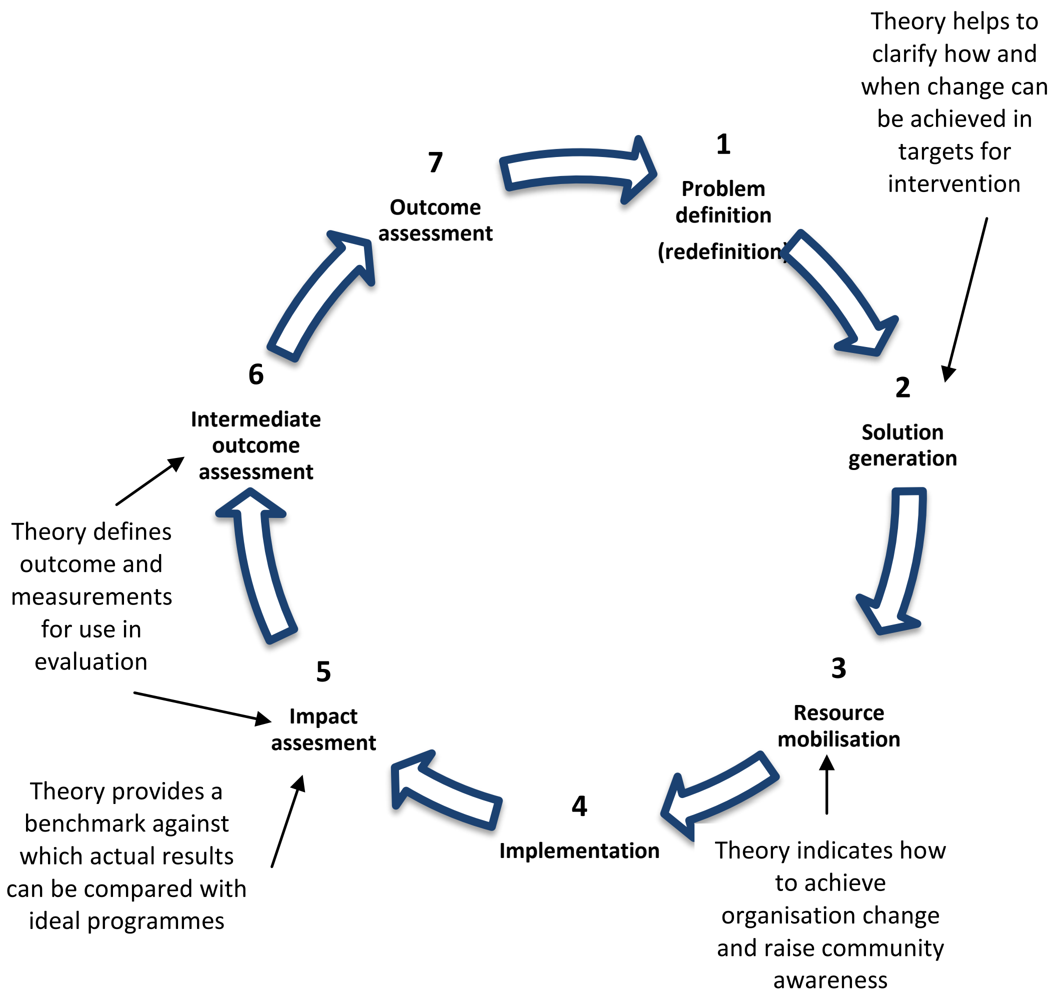


Figure 2.2: Health promotion planning and evaluation cycle (adapted from Nutbeam & Harris, 2004 (205)).

Although no agreement exists as to the best theories for health promotion purposes, the Transtheoretical Model (TTM)(5), Health Belief Model (206) and Theory of Reasoned Action or Theory of Planned Behaviour (207-209) are the most commonly applied theories to explain health behaviour and health behaviour change at individual levels (210). Both social and environmental factors influencing the target population's behaviour have to be investigated for the researchers to gather enough information to decide on a suitable behavioural theory. The decision on the theory should also take the aim of the intervention into consideration.

The Health Belief Model (HBM)(206) is one of the first social cognition models at individual level (210). It contains primary concepts that predict why people will take action to prevent, to screen for, or to control illness. These include perceived susceptibility, seriousness, benefits and barriers to a particular behaviour, cues to action and self-efficacy. A review on HBM-based studies published a decade after its introduced, suggested HBM was successfully used in the studies focusing on preventive behaviours and sick-role behaviours (211). However, the theory proposes an ideal behaviour, instead of a real behaviour and this limitation could interfere with the intention of this study, which is to improve the real behaviour of the participants.

The Theory of Reasoned Action (TRA) or the upgraded Theory of Planned Behaviour (TPB)(207-209) a theory that tries to link attitude and behaviour. The theory states that attitude toward behaviour, subjective norms, and perceived behavioural control, together shape an individual's behavioural intentions and behaviours (212). However, the theory did not consider the social factor, while social support is one of the factors integrated into the development of this intervention program.

The TTM was the behavioural theory that was used in development of this intervention programme, and is discussed in details in the following sections.

2.3.2 Transtheoretical Model

Introduced in the 80s, the TTM (5) has become one of the most popular behaviour change models used in health promotion. Besides the construct of Stages of Change (SOC), processes of change, decisional balance, and self-efficacy measures have also been described (7).

In the SOC, the participants are classified into one of the five distinct stages; pre-contemplation, contemplation, preparation, action, and maintenance (6) as shown in Figure 2.3. These stages are not considered to occur in a linear mode, but rather in a dynamic process, with the individual moving back and forth between stages possibly several times before progressing to the action and maintenance stages (213). The model also examines how the individual weighs up the costs or barriers, and benefits of a particular behaviour. It suggests that individuals at different SOC will focus differentially on either the costs/barriers or the benefits of a behaviour.

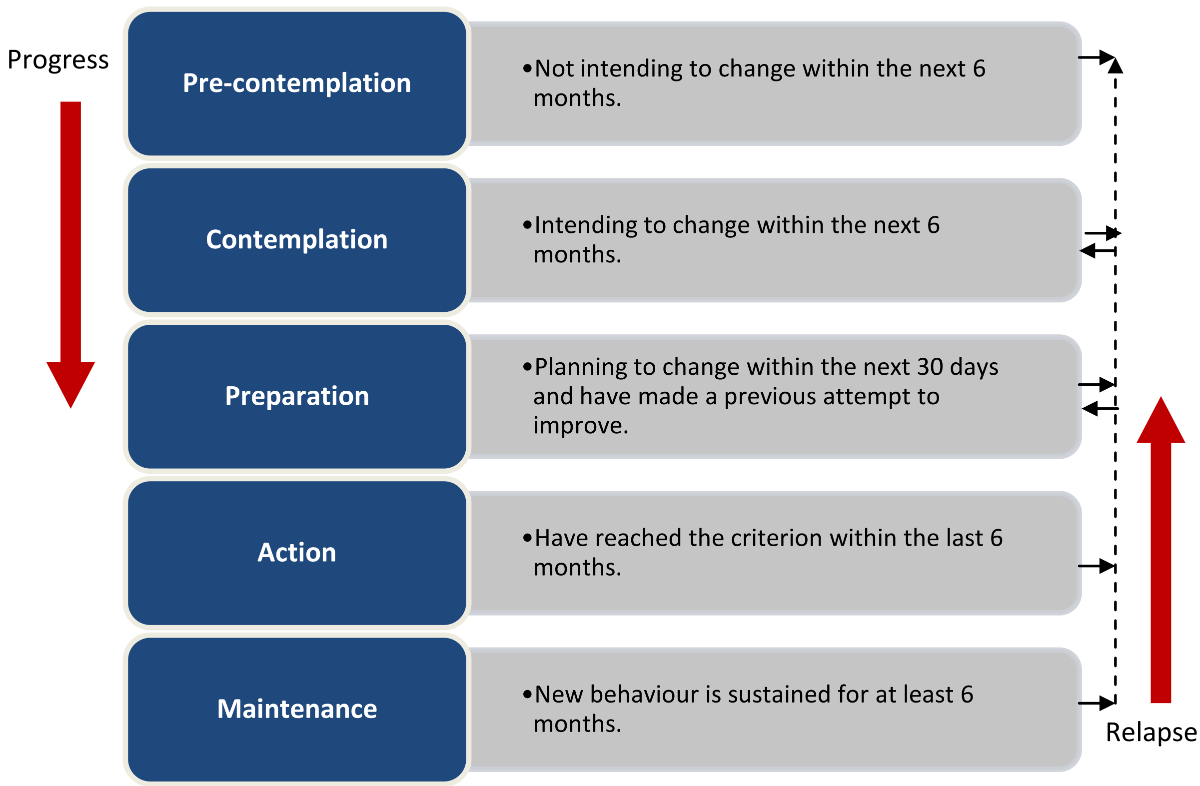


Figure 2.3: The characteristics of each Stages of Change.

The TTM is widely applied by clinicians and practitioners in various fields of health behaviour change due to its effective short-term behaviour change. A review of tailored interventions found TTM to be the most commonly applied theory and SOC as the most commonly used critical characteristics (214). TTM has been applied in health promotion studies on tobacco use (10), cancer screening behaviour (11), exercise (12) and dietary habits (13) among other health behaviours.

The TTM and the SOC construct focus on understanding how people change their behaviour. Nevertheless, the TTM has been subject to criticisms the staging validity, the use of it to explain complex behaviour and lack of long-term measures (8-9). In addition, there are published systematic reviews that have found no strong evidence of TTM being more effective than other theories or non-stage based interventions (12, 215-218). However, Prochaska argued that the methodological flaws in the study e.g. small sample sizes, poor recruitment rates, or high loss to follow-up may have resulted in that finding (219-220). Prochaska also explained that many unsuccessful interventions only utilised the SOC component of the TTM, rather than incorporating all four dimensions of TTM (221). For example, the processes of change components of the TTM may actually prove to be the most useful, yet have been under-researched (222).

The TTM has since came a long way to be one of the most used behavioural theory in health promotion. Utilisation of all dimensions of TTM such as SOC, decisional balance, processes of change and self-efficacy could possibly result in better findings than using SOC alone. However, the use of other constructs of TTM is subjected to the need and nature of the intervention programmes.

The next sections will narrow down the use of TTM in dietary interventions, interventions for people with T2DM and in Internet-based lifestyle interventions.

2.3.3 Transtheoretical Model in dietary interventions

Nineteen out of twenty-five intervention studies reviewed used the SOC model in dietary interventions (13). The most common strategy to categorise people into SOC are based on self-perception or self-rated diet or using a behavioural criterion based on an independent measure of nutrient intake (223). However, using the nutrient intake criteria is not encouraged as it has methodological issues and could mask clinically important changes. SOC construct is suggested to be most useful when the target behaviour is defined using a self-rated diet, and the action and maintenance stages should be interpreted as the time for developing and maintaining cognitive and behavioural vigilance about healthful food choice.

The TTM has been mostly applied with valid and reliable staging algorithms to the areas of fruit and vegetable consumption and dietary fat reduction. An example of a successful dietary intervention study is Eat Well, Live Well Nutrition (224), a stage-matched intervention with 12 counselling sessions to reduce the risk for T2DM. Although the study did not find any significant reductions in BMI, the intervention groups significantly adopted a low-fat dietary pattern at the end of the programme.

Ideally, an effective dietary intervention should speed up the movement from pre-action stages into the action and maintenance stages, and people moving up the stages should be able to make predictable changes in their dietary behaviour(223). Studies based on the TTM have tailored interventions for participants in each SOC, and have been effective in changing the health behaviour even among those in the pre-contemplation stage (225). Tailored messages, for example were found to be more effective for dietary fat reduction as compared to non-tailored intervention or controls (226-228).

Those in the precontemplation stage would require specific stage-tailored materials that emphasise on raising awareness level, self-re-evaluation and dramatic relief, as well as focusing on the benefits of change to get them to think about their problem enables them to move toward contemplation (229). On the other hand, individuals in the contemplation stage should be encouraged to reduce barriers to change in order to start making small dietary changes. The use of behavioural strategies for those in the preparation and action stages is to reduce temptation using traditional dietary change strategies. Prevention of relapse should be the priority for those in the action stage, as the risk for relapse in the maintenance stage is relatively low (230).

There are studies, which do not support the use of TTM in dietary intervention. One such study by Seiro and colleagues suggested that substantial changes in the nutrition behaviour can be achieved in a socio-economically deprived population via interactive group nutrition education independent to the SOC (231). Although SOC was not applicable in the study, the role of TTM in dietary behaviour change could not be brushed aside as the other constructs of the model were not investigated. Recently, Armitage has highlighted that though few studies have shown that process of change can account for transitions between SOC, no studies have tested if the process of change can account for changes in behaviour (232). Pros (pro-change behaviour), fruit intake and self-efficacy have been shown to predict forward stage transition from precontemplation, while self-efficacy alone predicted forward stage transition from contemplation (233). Assessment of SOC, processes of change and fruit intake of a cohort of 735 adults indicated that the Transtheoretical processes of change predicts stage transitions for fruit intake (234).

Assessment of change in the targeted dietary behaviour has been the focal point of TTM-based dietary intervention programmes, with less focus on the mediating factors by which programme effects are obtained. Only one dietary intervention related to the mediating factors of SOC has been published (235). The study reported SOC to account for 72% and 31% of the intervention effect in the multiple-mediator and single-mediator models, respectively.

Dimensions of TTM and mediating factors in TTM-based dietary intervention could be an area of future research interest. Given the positive outcomes demonstrated in most reported interventions, TTM may be the single most useful behavioural theory for dietary intervention, provided all constructs of TTM are well researched and applied according to the needs of the intervention programme.

2.3.4 Transtheoretical Model in interventions for people with Type 2 Diabetes Mellitus

In the process of complex behaviour change, patients may fall anywhere along the dynamic continuum of readiness to change, and the physician is expected to assist the patients to move towards the next SOC (236). In patients with diabetes, TTM was shown to enhance individualised assessment, collaborative goal setting and skill building, the three constructs of Resources and Support for Self-Management (RSSM), and facilitate the adoption of good diabetes self-management behaviours (237). Diabetes education programme has been shown to effectively move patients to more advanced stages of self-care behaviour and more effective in those with a shorter duration of diabetes (238).

Patients with diabetes vary in their adherence to different type of health behaviours (236). Adherence to a single behaviour (e.g. diet) is a poor predictor of adherence to others (e.g. physical activity or SMBG). Hence, it is best to assess and work on one type of behaviour at a time. Complex behaviour change may be best built on more than one behavioural theory. The existing evidence supports the use of a combination of behavioural theory and cognitive theory in facilitating modification of targeted dietary habits, weight, and cardiovascular and diabetes risk factors (239). For example, a community based diabetes education programme incorporating Social Cognitive Theory and SOC resulted in positive impacts on knowledge, health beliefs and self-reported behaviours (240). The study concluded that the improvement in diabetes knowledge is important to move the patients to the action or maintenance stage, and to improve their self-efficacy in diabetes management.

Diabetes SOC has been shown to be associated with clinical markers such as the HbA1c. It has independently predicted the change in HbA1c for patients with high but not for patients with low functional health status (241). The SOC can be determined by clinical tools and it was significantly associated with clinical improvements in HbA1c, which persisted for at least 12 months (242). The participants in the preparation and action stages achieved significantly larger reductions in HbA1c in a shorter time compared to those in the precontemplation-contemplation stage.

The role of TTM in diabetes-related dietary studies has been demonstrated previously. Patients with T2DM were found to be at different SOC of diabetes-affected dietary habits, and the stage varied according to dietary areas and dietary behaviours (243). Specifically, the SOC for fat and fibre were found to be significantly associated with positive dietary behaviours in people with or at risk for diabetes (244). The study also found that those receiving support intervention based on the stages were more likely to move forward compared to the controls.

People with T2DM have been shown to exhibit different dietary behaviours according to their SOC. A study by Vallis and colleagues indicated that T2DM patients in the action stages display healthier eating behaviours (245). T2DM patients in the action stages were also more likely to be female, and have a better quality of life. Precontemplators were a heterogeneous group and may need individually tailored interventions. Demographic and psychosocial factors were found to be the mediating factors in the pre-contemplators. A large scale telephone-based intervention on 1,029 patients with type 1 diabetes mellitus (T1DM) or T2DM resulted in an improved SOC to the action or maintenance stages, decrease of energy intake from fat, higher daily vegetable and fruit intake, and decreased HbA1C for those in the action stage (246). The intervention also found a significant treatment effect for stage-targeted healthy eating compared to usual intervention.

Despite these encouraging findings, a review by Salmela and colleagues revealed a lack of stage-based dietary counselling studies on T2DM prevention and treatment in primary care settings (216). Total and monounsaturated fat intake, diastolic blood pressure, health status and wellbeing were the long-term positive outcomes of the studies. However, the quality of the studies was only moderate to weak, and existing data supporting the benefits of TTM are inconclusive.

Most of the TTM based dietary interventions have primarily focused on the SOC construct and not on diabetes-specific decision-making and self-efficacy. TTM measures of SOC, decisional balance and self-efficacy are useful for making decisions on tailored intervention for diet adherence in patients with T2DM (247). This is an important finding as patients with diabetes have exhibited less motivation for diet adherence than patients with other chronic diseases (248).

Besides focusing on patients with diabetes, future studies could also give more attention to the skill building of the healthcare providers, especially in terms of the efficacy of nutrition counselling (246). High-quality diabetes intervention studies with focus on the training of intervention providers and process evaluation, standardised study evaluation tools for providers and patients are needed (216). The stages of change model, motivational interviewing and behavioural techniques are relevant to build the skill in counselling for behaviour change in staff working in diabetes care (249). Time constraints, the strength of existing staff routines and the patients' readiness to change may restrict the application of such training for the staff.

2.3.4 Transtheoretical Model in Internet-based lifestyle interventions

With increasing access to the Internet and awareness on its benefit, there is an increase in demand for web-delivered theory-backed intervention programmes. Evers et al. (250) in their review of online interventions, identified 16% of the theory-based interventions as being based on stage theories (TTM). An editorial by Dombrowski (251) reported that TTM accounted for 47% RCTs which applied behavioural theory in their intervention programme. SOC is one of the most commonly used tailoring criteria in interventions related to nutrition and physical activity (252).

The TTM is most commonly applied in web-delivered physical activity programmes and these programmes have shown similar results with face-to-face physical activity interventions (253). Besides websites, some of these physical activity interventions have utilised e-mails for the intervention delivery (254-255). Although website delivered physical activity intervention is found to be especially effective among the younger community (256-257), there were some successful physical activity interventions conducted among people with T2DM (15, 258). However, some studies reported inconclusive findings ((259-262). Nevertheless, the tailored advice was more read, printed and discussed with others than the standard advice, and most of the participants in the e-mail group indicated to be satisfied about the number, frequency and usefulness of the stage-based e-mails (262).

Interestingly, dietary web-based and stage-tailored interventions were suggested to be more successful than physical activity interventions. Veverka and colleagues (263) suggested dietary tailored e-intervention to have more beneficial effects on weight, BMI and body fat as opposed to a tailored exercise programme for healthy individuals. Cook et al. (264) also reported TTM-based dietary online programme to be more effective compared to print materials, but same could not be said with web-delivered stress management and physical activity interventions.

Similarly, the Internet was reported to be a successful medium to deliver stage-tailored dietary education to educate college females on folic acid supplementation (265). Despite the issues of penetration and self-selection, Internet-based intervention has also been effective in changing eating habits and assisting with weight reduction of individuals in worksite settings, besides improving their SOC (266). A large online TTM-based nutrition programme has shown to be well received, convenient, easy to disseminate, and was associated with sustained dietary change (267).

Similar to physical activity interventions, there were studies, which did not support the effectiveness of TTM-based dietary intervention delivered via the Internet. Heartweb, a web-based intervention nutrition counselling and social support intervention built on TTM, failed to show positive effects on the outcomes (268). This could be due to the low uptake of the intervention and the researchers proposed improvements in reach and frequency of site use to increase the effectiveness of the web-based interventions. A large Dutch Internet research and “F&V Express Bites”, a web-based dietary intervention did not find any specific benefit of using stage-tailored (269-270).

The findings have strengthened the need for more studies testing the model using new media with increasing use of websites. Interactive web sites can facilitate behaviour change, more efficient and cost-effective delivery method interventions (253, 271). More research is needed to investigate the mediators of web interventions or the mechanisms through which behaviour change happened. There is also a need to engage and retain the interest of the study participants using interactive elements of new media and personalised tailoring. There is a need for broader research on how people respond to this medium of programme delivery as well as more specific studies on website usage patterns (261).

2.4 The Internet opportunity

2.4.1 Internet and e-health

The Internet has emerged as a strong communication tool besides being an important source of health information. Rapid development of the technology has led to the progression from the generation of printed modules from computer and CD-ROMs to 'live' interaction of patients with the system and/or researchers via the Internet. The Internet penetration rate stood at 65.7% and an impressive 24.8 per 100 household having broadband access as of June 2009 in Malaysia (272). Website-delivered interventions have the potential to reach broad population, as it is available 24 hours, and could be hosted by both government and non-governmental agencies. Despite this, there is a lack of research, which investigated the effectiveness of the Internet as a delivery medium of behavioural intervention in this country.

There are limited trials conducted to investigate the efficacy of web-based intervention in people with T2DM. However, web-based interventions have shown to improve the nutrition knowledge and diabetic control of people with T2DM compared to non web-based interventions (38), especially if the web-based programmes gives participants flexibility in accessing the website. A review of recently published RCTs on web-based interventions among patients with T2DM has been published by the research team (35). The review concluded that goal-setting, personalised coaching, interactive feedback and online peer support groups were some of the successful approaches that were applied in e-interventions to manage T2DM. The article is available as Appendix I and an excerpt of the article is discussed here.

2.4.2 The Internet as an effective intervention delivery medium

2.4.2.1 Self-monitoring e-interventions

Self-management behaviour was one of the most commonly intervened factors, besides lifestyle habits in e-interventions among patients with T2DM. Appropriate self-management behaviour is one of the key determinants of successful blood glucose control. Diabetes self-management education is the process of providing a person with diabetes the knowledge and skills needed to perform self-care, manage crises, and make lifestyle changes required to successfully manage this disease (273).

There were few published reviews on technology-driven trials on the self-management of diabetes. A review on computer-assisted interventions reported six interventions with moderate to large significant declines in HbA1c levels compared with controls (274). There were also improvements in health care utilisation, behaviours, attitudes, knowledge, and skills. Graziano & Gross (275) reviewed eight isolated telephone interventions on glycaemic control and found no concrete evidence. However, a meta-analysis published the following year, showed intensive telephone follow-up may have better effects on glycaemic control (276).

Self-management or self-monitoring is a well-researched area in the management of T2DM. Although the self-management e-interventions were not based on behavioural theories, they were all found to be successful (19, 277-286). Six studies reported reduced levels of HbA1c in the intervention group (277-286) while Lee et al. (19) reported decreases in both HbA1c and FBG.

The success of these e-interventions are determined by many factors such as frequent contact between the intervention participants and the physician; weekly therapeutic changes; training on the website usage; interactive and individualised approach; online group discussion and integration of medical data (19, 277-278, 280, 284). All e-interventions focusing on self-monitoring were conducted for a period of 6 – 12 months. The core of the programme and intervention approach were the other crucial factors in determining the success of a self-monitoring intervention. This may suggest that web-based self-monitoring interventions have more impact on the blood glucose control but the sustainability of positive findings of these studies is questionable as only one intervention had follow-up.

2.4.2.2 Physical activity e-intervention

The number of internet-based behavioural interventions targeting physical activity/exercise is rather limited. To date, only two RCTs and two pilot RCTs have been published (15-16, 287-289). A previously reported systematic review on Internet-based physical activity interventions suggested that added values such as increased contact with the facilitator, tailored information and use of behavioural theories would improve the effectiveness of these interventions (290). This is an important aspect which needs to be focused in future studies, as declining usage could well affect the outcome of the e-interventions.

D-Net was a major physical activity e-intervention study that could only show moderate improvement in physical activity levels (16, 20, 287, 291). Similarly, a pilot study by Richardson et al. (288) did not show significant difference after the intervention, despite an increase in pedometer use and satisfaction level. By contrast, a web-based physical activity intervention in Korea was successful and has resulted in a better glucose control (15). A Canadian pilot RCT also showed improvement in the total minutes spent on vigorous and moderate physical activity, and behavioural capacity (289).

Website-based physical activity interventions, just like any other behavioural interventions have a problem with sustainability. For example, the participant website usage of D-Net was found to decrease over time, despite the additions of self-management and peer-support components (16). There could be also an issue of self-selection, as the response to the recruitment was greater in younger and newly diagnosed patients (291) than in older patients and those who had diabetes for many years.

2.4.2.3 Dietary e-interventions

To date, there is no published study that focused on dietary behaviour change in adults with T2DM via a website-based system. A pilot study conducted in 2006 tested the effectiveness of a nutrition education website to prevent diabetes in youths reported a significant improvement only in the consumption of dietary fat (33). Dietary modification has been incorporated as a component of a web-based weight loss programme in prevention of T2DM in adults (22). Calorie count as a part of behaviour e-counselling intervention also significantly reduced the weight of the adults at risk for T2DM (21). ICAN, a 12-month RCT which tested the efficacy of physical activity and nutrition behaviour changes in improving diabetic control found favourable results as well (34).

2.4.2.4 Multifaceted e-interventions

Multifaceted or combined interventions usually include diet, physical activity and/or self-monitoring of the patients' blood glucose. There were two combined interventions reported on a lifestyle intervention in the management of T2DM (34, 292). Wolf and co-authors (34) reported a low cost lifestyle intervention which combined physical activity and dietary behaviour has resulted in the improvement of anthropometrical measurements, HbA1c and health-related quality of life when compared with the group which received the usual care for patients with T2DM. Holbrook and co-workers (292) on the other hand, focused their intervention on various factors associated with diabetes and successfully improved the clinical and process composite score.

Although multifaceted intervention seems to be effective and has been reported to be helpful (293), there is always a limitation where researchers cannot always identify the component that contributes to the effectiveness of the intervention. Besides, poor implementation of complex intervention may undermine the power and the validity of the entire study. This may be one reason why there is a lack of combined interventions in preventing or managing T2DM.

2.4.3 Characteristics of e-interventions

2.4.3.1 Use of behavioural theories

Based on the review of the recent evidence (35), the number of studies applying a behavioural theory in their intervention was found to be rather limited. Intervention studies which focused on self-monitoring of blood glucose did not report any specific theory or model in their design of intervention, website or recommendations except for Ralston et al. (284) who used Wagner's Chronic Care Model. The use of behavioural theories to support the physical activity e-interventions among T2DM patients was found to be fruitful. Interventions guided by Self-efficacy Theory and Social Support Theory (16, 20, 287, 291), Health Belief Model (288), TTM (15) and Social Cognitive Theory (289) were all found to result in behavioural change and better glycaemic control.

So far, the evidence is not sufficient for any recommendation on the most suitable theory or model for future interventions. The decision on the most relevant theory, therefore, should be made based on the objective of the e-intervention and the factor to be intervened.

2.4.3.2 Intervention providers

The interventions were mainly provided by the researchers or research staff members appointed for the study (282-284, 287-289). Physicians (19, 277), study nurses (281, 285), dieticians (34) and endocrinologists (282-283) were also engaged in providing intervention to the patients. MyCare Team intervention had a larger group of healthcare personnel involved in the delivery of the intervention programme (278), while the latest intervention by Noh et al. (286) relied totally on the system to deliver automatic responses to the patients when they logged in their blood data.

2.4.3.3 Usage of other technology

E-mail and short messaging service (SMS) technologies were commonly used together with the websites to reinforce the intervention. E-mails were used as a component of the intervention, with the researchers sending weekly recommendations or as communication method between providers and patients (281, 284, 289). Richardson et al. (288) on the other hand, only used the e-mail component to contact the participants before and after the intervention programme.

SMS was used by the researchers to send warning messages to the participants if they did not log into the website for a stipulated time (15, 278). Some studies also used SMS as a part of the intervention programme by requesting the participants to send their blood sugar readings to the website via SMS (282-283) or by sending recommendations and feedback to the participants (19). Noh et al. (286) made their intervention web to be accessible both by cellular phone and computer-based Internet.

Sending automated e-mails whenever the website is updated and warning e-mails or SMS whenever the participant did not log in for a stipulated time is encouraged for more frequent engagement to the website throughout the intervention. In summary, the use of other technologies was found to be an excellent method of reinforcing web-based interventions.

2.4.3.4 Optimal duration of intervention

The duration of the intervention ranged between 12 and 52 weeks, with an average of 27.2 $\pm$ 18.3 weeks. The physical activity based e-interventions were conducted with an average of 9.5 $\pm$ 3.0 weeks with only the D-Net study reporting a 10-months follow-up (16). Only relatively longer studies (12 weeks) reported positive findings (15, 289). Combined interventions also were successful after a duration of 6 and 12 months (34).

The findings suggest that behavioural interventions require a longer duration to yield positive results as compared to self-monitoring e-interventions. Although the interventions are feasible in the short-term, a longer follow-up is essential to investigate the sustainability of the web-based interventions.

2.4.3.5 Outcome measures

Blood biomarkers e.g. HbA1c, FBG, 2HPPG and/or TC remained the most commonly reported outcome measures of web-based interventions in the management of T2DM. The majority to the self-monitoring interventions reported solely the blood biomarkers (19, 277-278, 280, 282-284, 286). Bond and co-authors (281) reported the blood biomarkers, body weight and psychosocial well-being as their primary outcome measures.

Besides blood biomarkers, there were few other outcome measures reported by these interventions. The D-Net study (16, 287) and Liebreich et al. (289) measured the level of physical activity, while another pilot RCT on Internet-mediated walking (288) measured the bouts of steps. Blood biomarkers and anthropometrical measurements were also used as outcome measures for a lifestyle e-intervention (34). Holbrook et al. (292) reported a composite score of clinical and process scores.

The majority of the studies included the blood biomarkers especially HbA1c as their primary outcome measure. However, some studies incorporated other outcome measures such as scoring, dietary or physical activity data corresponding to their objectives.

2.4.3.6 The 'reach' of the interventions

In this review, the 'reach' of the web-based interventions is determined by the participation rate and recruitment setting (294). The participation rate of these RCTs varied between 32% and 83%, with a mean of 58%. The hospital setting remains to be the most common ground to recruit subjects (15, 277-278, 283-284, 286, 291) although some studies have recruited subjects via health system or health care providers (279, 281, 285, 292) advertisements in mass media, distribution of flyers (288) and mixed mediums (289).

2.4.4 Limitation of e-interventions

The limitations of these interventions include the restriction to Internet access (15), which may decrease website usage over time (287) and non-responses (20). Distribution of weekly newsletters via the e-mail ensured the number of login remained high throughout the study. However, other telecommunication methods such as SMS have also been used together with websites to re-emphasize the intervention (15, 282-283) and this has proven to be successful.

The success of a web-based intervention relies heavily on the website login rates, usability, and personalisation. Regular reinforcement by using the e-mail as a reminder service to encourage the subjects to log-in to a nutrition education website has been successful in increasing the log-in rates (36). Content development in the local language may improve the usability of the Internet among locals seeking health information (37).

Generally, the self-monitoring e-interventions yielded better results than the behavioural e-interventions, although this could also be due to a higher number of self-management e-interventions that was reported. The availability of a care manager in the form of a clinical researcher, physician and/or nurse appears to strengthen the intervention programme and increase the compliance. The use of other technology such as the mobile phone was also found to be an important aspect of successful interventions. Therefore, web-based intervention programmes have the potential to reach and educate diabetic patients and further exploration in this area is warranted.

2.5 The conceptual framework

The conceptual framework of the study explains the underlying facts and rationale of the study design (Figure 2.4). Twelve dietary lesson plans in the intervention package were personalised according to the patients' DSOC and was expected to improve their DKAB and assist them to progress in their respective DSOC. The improvement in DKAB and progress in DSOC were expected to be reflected in the patients' dietary practices. Changes in anthropometric measurements and biomarkers are considered as indicators of adoption of healthy dietary practices.

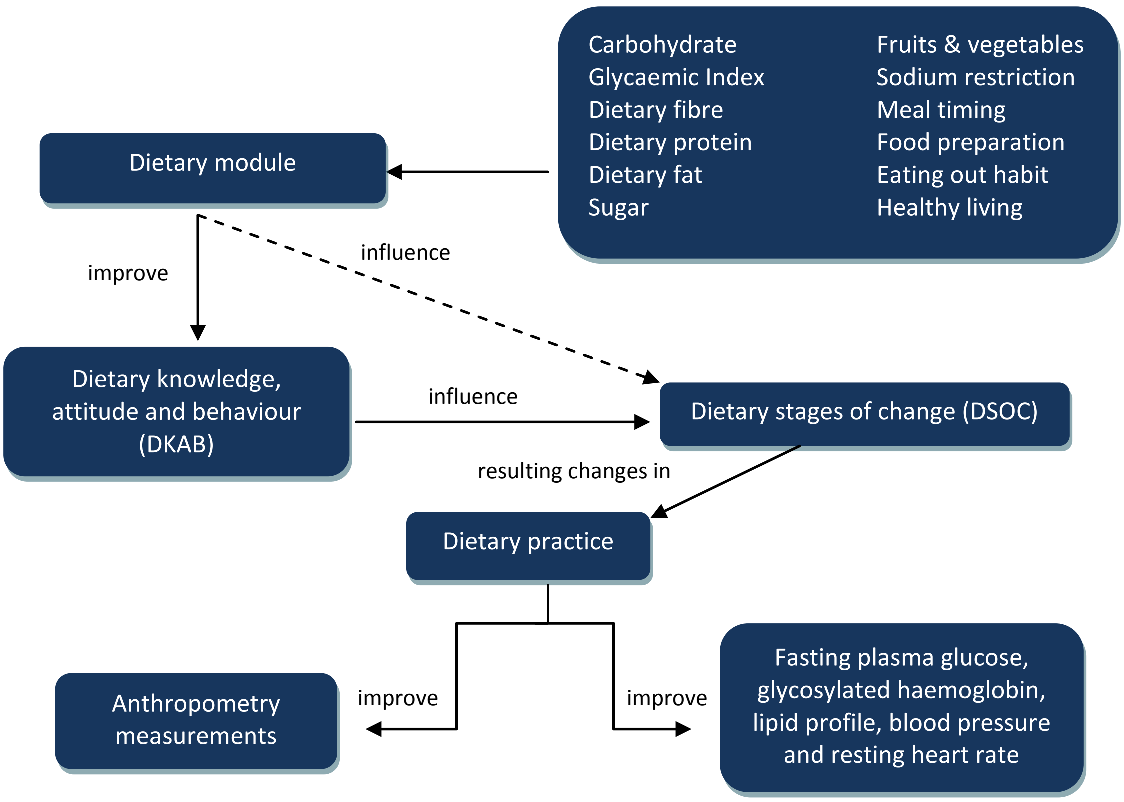


Figure 2.4: Conceptual framework of the intervention

CHAPTER 3

METHODOLOGY

3.1 Study design

A two-armed randomised-controlled trial (RCT) scheduled for 12 months (Figure 3.1) was conducted among patients with Type 2 Diabetes Mellitus (T2DM). The primary outcome is the Dietary Knowledge, Attitude and Behaviour (DKAB) score, while the secondary outcomes include the food intake, anthropometry measurements, blood pressure and resting heart rate, blood biomarkers and the Dietary Stages of Change (DSOC) score.

The study was designed according to the recommendations of the CONSORT statement for randomised trials of non-pharmacologic treatment (295).

3.2 Ethics approval and trial registration

The study has received ethics approval from Malaysian Ethics Research Committee (NMRR-09-303-3416) (Appendix A-1) and Monash University Human Research Ethics Committee (CF09/1583 – 2009000877) (Appendix A-2). The trial has been registered with Clinicaltrials.gov (NCT01246687). The study commenced in mid-November 2009 after the ethics approval was obtained.

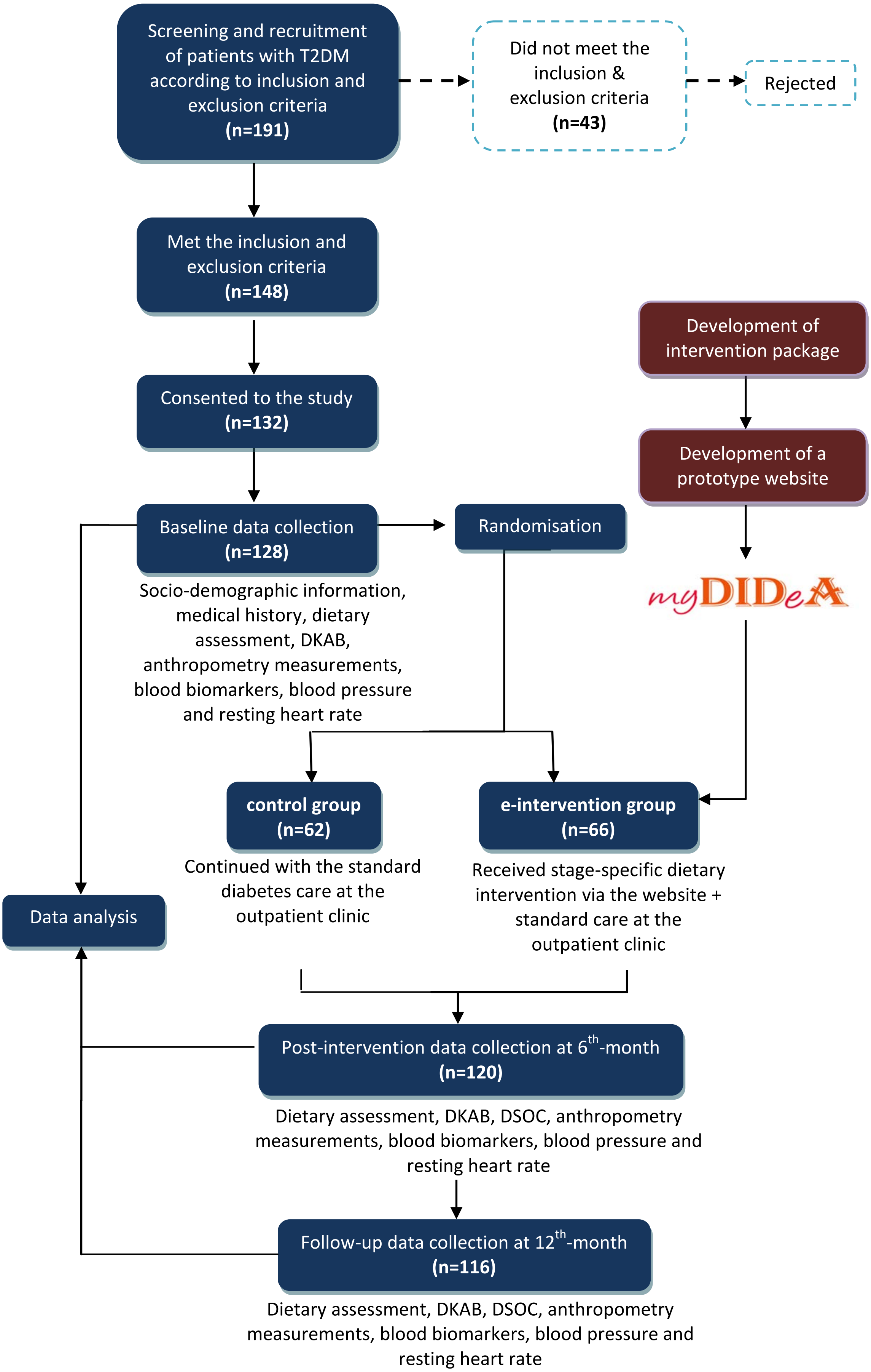


Figure 3.1: Flow chart of the study.

3.3 Study sample

3.3.1 Sample size

The sample size calculation, which was carried out using GPower software (296) was based on a difference in fat and fibre-related behaviour score as reported by a previous computer assisted dietary intervention study in people with type 2 diabetes (297). Using a reduction in the mean behaviour score from 1.93 (SD=0.50) (baseline) to 1.69 (SD=0.40) (post intervention), 31 patients were needed in each group to detect this difference with a two-sided alpha of 0.05 and a power of 80%. Based on 30% attrition rate for one year, a minimum of 41 participants were required in each group.

3.3.2 Study location

This was a multi-centre RCT, in which the recruitment of subjects, screening and data collections for this study were conducted in three public hospitals in Klang Valley, namely Putrajaya, Serdang and Selayang Hospital (Figure 3.2). Permission from relevant authorities was obtained for this purpose.

(a) Putrajaya Hospital

(b) Serdang Hospital

(c) Selayang Hospital

Figure 3.2: The study locations.

3.3.3 Recruitment process

The eligibility screening, recruitment of study participants and data collections were conducted in the outpatient medical clinic of the three urban hospitals. Diabetic nurses provided assistance in identifying potential study participants according to the eligibility criteria (Table 3.1). If a potential patient was identified, he/she was recruited using written informed consent. For this purpose, the patient information sheets and consent forms were prepared in both *Bahasa Malaysia* and English versions(Appendix B1 – B4). However, they were excluded from the study if the baseline DKAB score was more than 50% (average score that can be achieved). This was done to ensure the dietary intervention was targeted at those with poorly controlled diabetes and in dire need for dietary intervention.

Table 3.1: Eligibility criteria used in the screening for the participants.

Inclusion	Exclusion
• Men and women who are $\geq$ 18 years old.	• Pregnant, lactating or intend to become pregnant during the study period.
• Literate with a fair command of English and/or *Bahasa Malaysia.*	• Diagnosed with T2DM or Gestational Diabetes Mellitus
• Have access to the Internet at home, work or public place.	• Body Mass Index (BMI) of more than $50kg/m^2$.
• Willing to access the study website at least once every fortnight.	• Any pre-existing conditions or severe complications that could compromise the quality of life or ability to participate according to protocol.
• Have been confirmed of having HbA1c of $\geq$7.00%.	• Enrolled in other clinical studies.
	• Having DKAB score more than 50% at baseline.

3.4 Randomisation and treatment allocation

Eligible patients with T2DM who have consented to participate were randomised to either e-intervention or control group.

3.4.1 Control group

This group received the usual standard treatment (diabetic control and management) given to patients with T2DM. This includes the provision of oral medication and insulin, and routine medical consultation with health professionals. Although the controls had access to the Internet, they received neither the website login information, nor any reinforcement via e-mail or SMS.

3.4.2 e-Intervention group

This group received an intensive dietary intervention through the study website, personalised according to the participants' DSOC, in addition to the usual standard treatment at the outpatient clinics.

3.5 Intervention programme

The development of the dietary intervention programme can be described in a systematic six-step planning approach (Figure 3.3). A simplified Intervention Mapping (IM) protocol (298) was used to assist with the intervention programme planning. IM is a systematic approach in the development of intervention based on theory and evidence. It is a planning process and it enables health educators to create a feasible programme that is most likely to be effective.

The first step was to conduct a needs assessment based on the literature and existing guidelines. Twelve dietary lesson plans were then developed based on the outcome. The third step was to evaluate various behavioural theories for its relevance and suitability to the theme. Programme components were then developed based on the modules and selected theory. In the fifth step, a website was developed to deliver the intervention programme. Finally, the web-delivered intervention programme was evaluated with effect and process evaluation. The following sections describe the steps in detail.

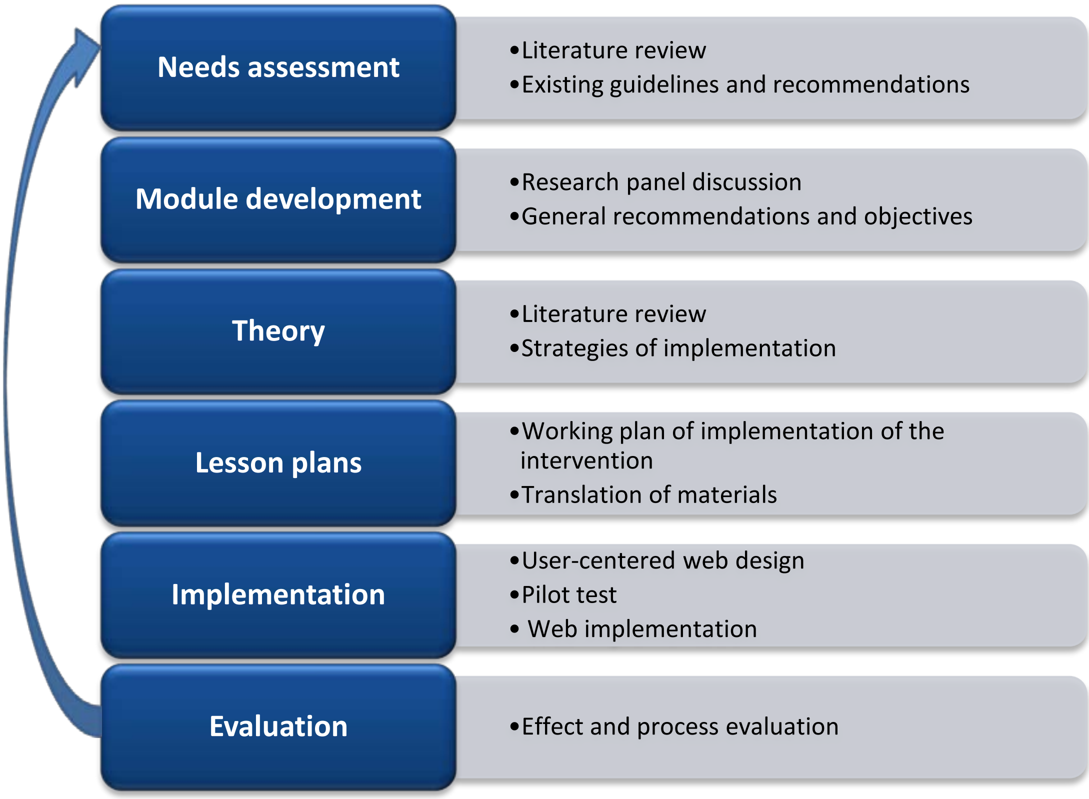


Figure 3.3: A six-step approach for intervention design reporting.

3.5.1 Needs assessment

Needs assessment was done before the beginning of the actual intervention planning, where the severity of the health problem, relevant health behaviour and other conditions were assessed. The literature was reviewed to determine the important dietary factors to be addressed in the management of T2DM (75, 299-300). Existing dietary guidelines and recommendations for patients with T2DM were also reviewed to extract suitable guidelines to be developed further for the intervention programme. For this purpose, the Nutrition

Recommendations and Interventions for Diabetes by American Diabetes Association (74), Malaysian Clinical Practice Guidelines (MCPG) for T2DM (48), Malaysian Medical Nutrition Therapy Guidelines for Type 2 Diabetes (154) and recommendations by the National Diabetes Institute (301) were assessed.

3.5.2 Development of the module

Step 2 of the IM provides the foundation for the intervention by specifying who and what will change because of the intervention. The selected guidelines were translated into a more defined set of modules and objectives that were aimed for each lesson plan. The research panel that comprised of nutritionist, behavioural scientists, endocrinologist and epidemiologist reviewed these guidelines to develop the content for the intervention. The content of each guidelines extracted was studied for its relevance to the local community and tailored to suit local context. A set of general recommendations based on the extracted guidelines was developed, and two to three intervention objectives were constructed for each lesson plan (Table 3.2).

3.5.3 Theoretical approach

In the third step of the IM protocol, theory-inspired methods and strategies to change the health behaviour were explored. Although no agreement exists as to the best theories for health promotion purposes, the Transtheoretical Model (TTM) (5), Health Belief Model (206) and Theory of Reasoned Action or Theory of Planned Behaviour (209) are the most commonly applied theories. A literature review of behavioural theories used for dietary and Internet-based interventions were conducted, and TTM was found to be the most suited theory to our context. The TTM's Stages of Change (SOC) construct was used to develop the intervention structure. The stages, its characteristics and matching strategies by Kendra (2010) that were adopted in this study are presented in Table 3.3 (302).

Table 3.2: General recommendations, intervention and patient's objectives for each lesson plan.

Lesson plan	General recommendation	Intervention objective	Patient's objective
Carbohydrate intake	• 50 – 60% energy from carbohydrate preferably from whole grain, fruits & vegetables, legumes and low-fat milk. • Consistent portions of carbohydrate in daily main meals.	• Educate on refined and complex carbohydrates. • Guide the patient to substitute refined carbohydrates with complex carbohydrates. • Count serving sizes of carbohydrate containing foods for each meal.	• Eat lesser refined carbohydrate and more of complex carbohydrate. • Increase whole grains, fruits, vegetables, legumes and low fat milk. • Eat consistent portion of carbohydrate for each meal.
Glycaemic Index	• Eat lesser of high GI foods. • Shift to low GI diet.	• Educate patients on GI. • Improve the quality of foods consumed in terms of GI.	• Eat lesser of high-GI based food. • Aim for an average dietary GI if low GI is not possible.
Dietary fibre	• Achieve 20-30g fibre/day or 5-7 servings/day of vegetables, fruits, legumes and whole grain cereals.	• Increase the intake of high fibre foods in each meal. • Able to mix and match various types of high fibre foods to create a variety in food intake.	• Understand serving sizes of high fibre foods. • Include more servings of high fibre foods to achieve the recommended intake (5 – 7 servings/day).
Dietary protein	• 15 – 20% energy from protein-based sources, preferably those low in fat.	• Educate on serving sizes and proper cooking methods of protein-rich foods. • Provide options for vegetarians or for those preferring plant-based protein.	• Consume at least one serving of fish, low-fat meal or plant-based protein source at every meal.
Dietary fat	• 25 – 30% energy from fat and individualised based on lipid goals.	• Educate on various types of fatty acids - trans fat (TF), saturated fat (SF), polyunsaturated fatty acid (PUFA) and monounsaturated fatty acid (MUFA). • Provide alternative cooking methods to reduce fat intake with healthier cooking method.	• Identify and avoid foods high in cholesterol, TF and SF. • Identify and increase intake of foods high in PUFA and MUFA.

Table 3.2: General recommendations, intervention and patient's objectives for each lesson plan (continued).

Lesson plan	General recommendation	Intervention objective	Patient's objective
Sugar	• Total free sugar not > 10% unless if the glucose level is under control. • Sugar replacements or artificial sweeteners are allowed.	• Educate on various other forms of sugar in food products. • Emphasise on homemade foods with less or no sugar.	• Able to identify and reduce consumption of common food products that are high in hidden sugar.
Fruits & vegetables	• 5 – 7 servings of fruits and vegetables a day. • Fruits and vegetables to contribute natural micronutrients without the need for supplements.	• Consume fruits and vegetables as whole whenever possible. • Educate and advocate fruits and vegetables as the main source of vitamins and minerals.	• Include fruits and vegetables in main meals or as snacks to achieve the recommended servings per day.
Sodium restriction	• Salt intake to be kept less than 1 teaspoon a day.	• Educate on the hidden sodium found in processed foods. • Give emphasis to use of alternatives to salt in cooking.	• Substitute salt in cooking with other natural flavouring and spices. • Consume more fresh foods instead of processed and preserved foods high in sodium.
Meal timing	• Consistent meal time every day.	• Emphasise the importance of having meals at the same time.	• Not to skip any main meals, especially breakfast. • Make it a habit to eat main meals 4 – 5 hours apart and around the same time every day.
Food preparation	• Health cooking methods to replace unhealthy cooking methods.	• Encourage cooking methods that use less oil, salt and sugar.	• Learn what good cooking method could do to the same type of meat/protein food.

Table 3.2: General recommendations, intervention and patient's objectives for each lesson plan (continued).

Lesson plan	General recommendation	Intervention objective	Patient's objective
Eating out habit	• Maintaining healthy eating outside home.	• Encourage to choose sugar-free or sugar-less meals. • Keep the total calorie intake low when eating out.	• Reduce consumption of artificial flavouring such as sauces, dressings, salt or sugar when eating out. • Learn to pick low calorie foods when dining out.
Healthy living	• Engaged in healthy lifestyle (physically active, stress management, quit smoking/drinking).	• Embrace healthy lifestyle that includes exercises, quitting smoking/drinking, consumption of sufficient water and stress management.	• Engaged in gentle to medium intensity exercise. • Quit smoking/drinking. • Drink a lot of water or sugar-less tea (green or Chinese tea). • Manage stress.

Table 3.3: The characteristics of Stages of Change and matching strategies for each stage (302).

Stage	Characteristics	Strategies
Precontemplation	• Denial • Ignorance of the problem	• Encourage individual to rethink their behaviour • Encourage self-analysis • Explain the risks of current behaviour
Contemplation	• Ambivalence • Conflicted emotion	• Weigh the pros and cons of changing behaviour • Confirm readiness to change and encourage confidence in their abilities • Address possible barriers to change
Preparation	• Experimenting with small changes • Collecting information about change	• Goal setting • Prepare an action plan • Make a list of motivating statements
Action	• Taking direct action towards achieving a goal	• Reward their success • Seek social support • Make a list of motivating statements
Maintenance	• Maintaining new behaviour • Avoiding temptation	• Develop coping strategies to deal with temptation • Reward them for success

3.5.4 Development of lesson plans

Step 4 involves description of scope and sequence of the components of the intervention, programme materials and protocols. Based on Step 2 and Step 3, a working plan of the intervention programme that will be delivered via the Internet was developed. Patients were required to log in to a website, where they are given a set of five validated SOC questions for each module (Section 3.10). The score was then calculated based on the algorithm and patients were subsequently directed to a recommendation page that corresponded to the score. Each lesson plan was translated to *Bahasa Malaysia*, the national language of Malaysia and back translated to English by a qualified translator.

3.5.5 Implementation of the programme

The fifth step of the IM framework is focused on programme adoption and implementation. The intervention programme is delivered via a website developed for the RCT, Dietary Intervention among Patients with Type 2 Diabetes Mellitus: An e-Approach (*my*DIDeA). The e-intervention group will be given access to the personalised website (matched with their stage of motivation) for 6 months and followed-up for another 6 months. The website development is explained in detail in the following sub-sections.

3.5.5.1 Web design process

User-centred web design approach was used in the development of the website. User-centred design (UCD) refers to the web design process that meets the needs of the user (303). UCD approach uses the Technology Acceptance Model, which gives importance to ease of use and usefulness of the technology in its approach (304).

3.5.5.2 User analysis

Discussions were held between the professional webmaster and the research team on the needs and functions of the website. The usability, level of knowledge, demography of the patients were also taken into consideration.

3.5.53 Paper prototype

Based on the user analysis, the webmaster created a site map diagram of the website on paper. The organisation and navigation were developed at this stage. Discussion was held again based on the proposed prototype drawn on the paper. Once the design has been finalised, a mock prototype was created.

3.5.5.4 Mock prototype

A mock prototype website was created using the tunnel design, where the user follows a page-by-page approach (305). After ensuring the system was responding well to the queries, the design was further developed into a hybrid design (Figure 3.4). It is a mix and match design created in combining few tunnel designs. For example, the staging question and recommendation pages were based on the tunnel design as there was a series of sequential steps, and these pages were parts of a larger site.

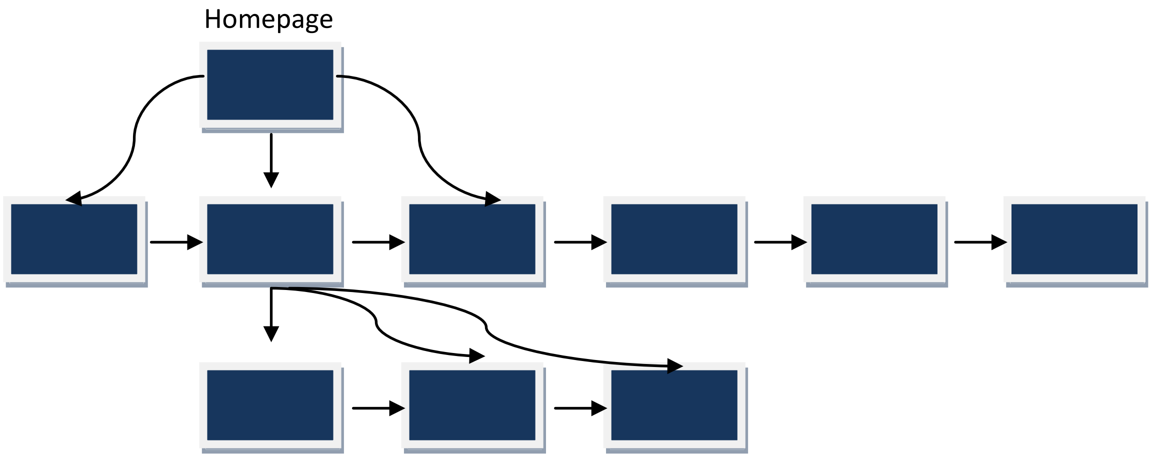


Figure 3.4: Hybrid design schematic (305).

3.5.5.5 Technical consideration

In this stage, the idea on web usage details such as fonts, colours, use of graphics and navigation bars were conceived. Issues that were taken into consideration were bandwidth, latency and document-caching capabilities to ensure the proposed system can be used effectively across the Local Area Network (LAN) or wireless environment. In addition, database constraints, which included concurrency, data integrity and consistency, were also considered. Since the system was developed as a web-based system, those issues were taken into account when evaluating the identified tools and implementation strategies.

The application exported certain required data in Extensible Markup Language (XML) format as well, to enable any integration by third parties, or to allow third party to make use of the data exported. This was done by function calling using Application Programming Interfaces.

The website development team used Object Oriented Programming approach. This enabled the webmaster to reuse functions created earlier, and for third party component developments. The system was built using Hypertext Preprocessor (PHP), an open source web scripting and powered by MySQL, another open source database table type (Figure 3.5). The core engine and related plug-ins, web application language PHP (compatible with version 5.1x above) and open source MySQL database were used in the development of the website.

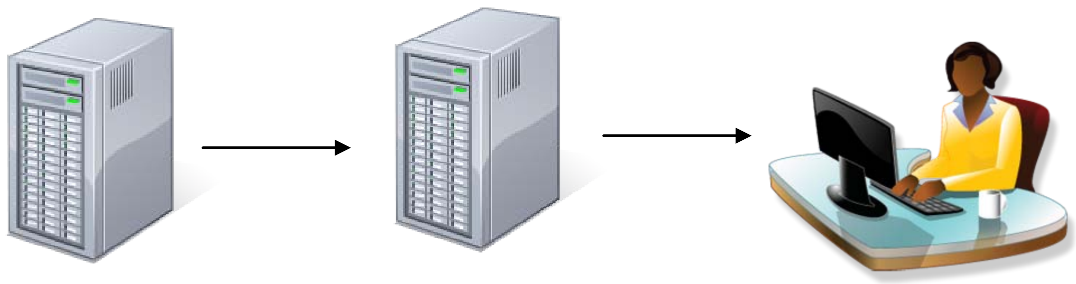


Figure 3.5: Illustration of the system.

3.5.5.6 Pilot study

A pilot test was then conducted to assess the acceptability and user-friendliness of the intervention structure and web design. For this purpose, the web design expert developed a prototype website consisting of a standard homepage, two sample lesson plans (carbohydrate intake, and fruit and vegetable Intake), factsheets on diabetes and the patient's personal profile. A group of patients with T2DM (n=30) was requested to go through the factsheets and personal profile, and answer the staging questions to be directed to the corresponding recommendation page. The patients were then requested to provide their feedback on the user-friendliness of the website in terms of navigation, loading time, overall outlook and layout, font size, colour combinations and language used. Changes were made according to the feedback received.

3.5.5.7 Web implementation

The final website (*my*DIDeA) was uploaded to the domain www.mydidea.com. The website was developed for each lesson plan in simple understandable form in two languages i.e. *Bahasa Malaysia* and English. Figure 3.6 shows the structure of the final website. Sample screenshots of *my*DIDeA are available in Appendix C1 to Appendix C5. At the landing page, the participants were required to login with their unique username and password. In the same page, a short description of the research was made available in both languages. Upon logging in, participants were taken to the homepage, where they were provided with short instruction on how to navigate the site. Twelve lesson plans were made available to the patients one after another over the period of 6 months, with updates every fortnight.

*my*DIDeA was tailored according to the participants' DSOC as described previously. The staged-tailored recommendations were aimed to address the barriers and motivate the participants according to the lesson plan and stage. Relevant photographs and illustrations were added to enhance the understandability of the lesson plans. Factsheets and statistics on diabetes, links to existing diabetes resources and an example of ideal health profile also were included.

The participants were briefed on *my*DIDeA, and were provided with unique username and password via e-mail or SMS after the randomisation. No training was given prior to the commencement of the intervention. However, participants who had difficulty to login or navigate the website were given support via the phone. Login reminders were sent to their e-mail each time *my*DIDeA is updated with new lesson plan. The participants were also encouraged to send their queries to the study nutritionist via the website.

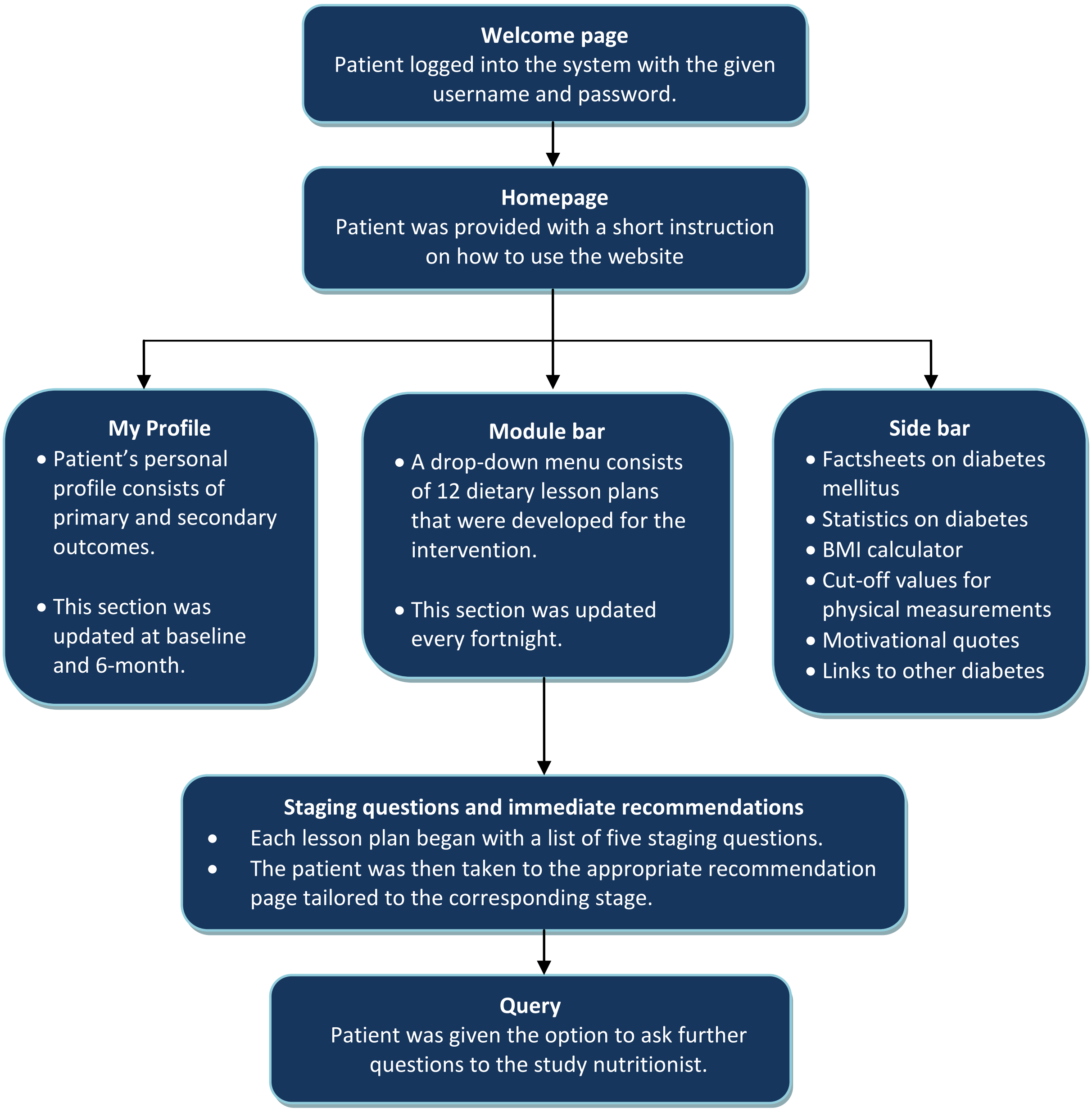


Figure 3.6: Structure of *my*DIDeA.

3.5.6 Programme evaluation

In Step 6, effect evaluation and process evaluation were conducted to determine the effectiveness of the intervention programme. The effect evaluation involved baseline and post-data collection primarily to measure the changes in DKAB score in study participants. The impact of the intervention on the dietary practices, physical measurements and blood biomarkers of the participants was also assessed. Process evaluation was conducted in the e-intervention group to determine the adherence to the programme, and to assess the content satisfaction, usability and acceptability of the web-delivered dietary intervention programme.

3.6 Outcome assessment

All assessments (Table 3.4) were conducted at the clinical settings by trained enumerators. A pre-tested and structured questionnaire was used to record the information obtained during the interview. A set of structured questionnaire in English or *Bahasa Malaysia* was used to interview the participants. The data collection process is illustrated in Figure 3.7, and all the questionnaires used in this study are available in Appendix D1 to Appendix D4.

3.6.1 Primary outcome

The primary outcome was assessed using a validated interviewer-administered Dietary Knowledge, Attitude and Behaviour Questionnaire (DKAB-Q). The development and psychometric evaluation of the DKAB-Q is described in Section 3.9.

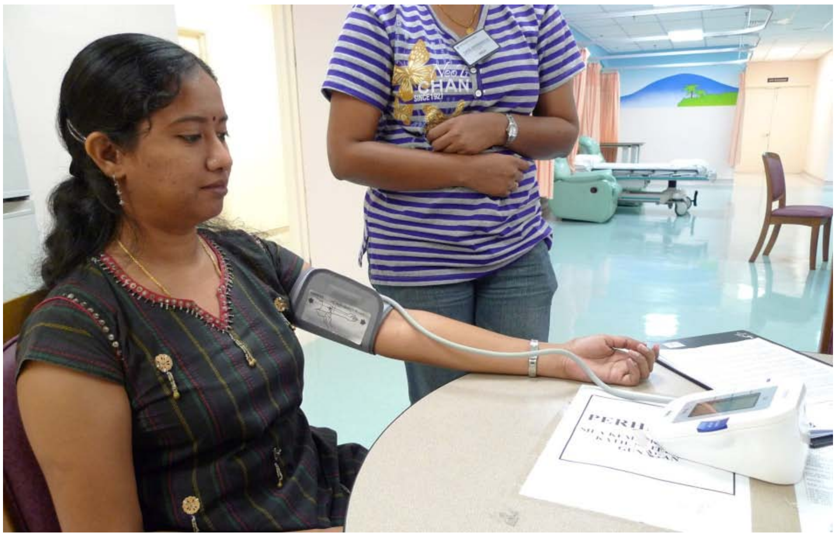
Table 3.4: Assessments that were carried out in the study.

Outcome	Measure	Instrument
Primary	DKAB related to T2DM	DKAB-Q*
Secondary	Dietary practices	SFFQ* Supplement intake
	Height	Body meter
	Weight and body composition	Four-point digital weighing scale
	Waist circumference	Non-elastic measuring tape
	Systolic and diastolic blood pressure	Automatic blood pressure monitor
	FBG, HbA1c and lipid profile	Medical record
Others /Covariates	Socio-demographic characteristics Medical history Smoking and alcohol drinking habit	Pretested questionnaire
	Physical activity	IPAQ (306)
	SOC	DSOC-Q*

*validated instrument

(a) Measuring the height using a body meter

(a) Measuring weight and body composition using a four-point weighing scale



(c) Measuring the blood pressure and resting heart rate using an automatic blood pressure monitor

Figure 3.7: The data collection process.

3.6.2 Secondary outcomes

Changes in the Stages of Change were determined via a validated Dietary Stages of Change Questionnaire (DSOC-Q). The development and psychometric evaluation of the DSOC-Q is described in Section 3.10.

A semi-food frequency questionnaire (SFFQ) was used to record the subjects' dietary intake (307). Participants were required to select the frequency of consumption of the specified food item in the SFFQ, which was recorded daily, weekly or monthly. The corresponding serving size of each food items was also recorded. The serving sizes were then calculated to consumption of each food groups of interest by participants. Besides SFFQ, frequencies of consumption of supplements, which include herbs, vitamins, minerals, and other food supplements for the past one month were also recorded. The SFFQ was pretested and validated against a three-day 24-hour dietary recall (data not shown) in patients with T2DM prior to its inclusion in the study questionnaire.

Anthropometry measurements (weight, body mass index (BMI), waist circumference (WC) and body fat percentage), blood pressure and resting heart rate were taken during the interview sessions. The subjects were barefooted and in light clothing when the measurements were taken. Height was measured using SECA 213 portable stadiometer (measured to 0.1m), while a four-point digital weighing scale (Omron HBF 356) was used to record the weight (measured to 0.1kg) and percentage of body fat (measured to 0.1%). The scale uses Bioelectrical Impedence method to calculate the body fat percentage (body fat (%) = (body fat mass (kg) / body weight (kg)) *100).

Height and weight of the subjects were then used to calculate the BMI. The WC was measured to 0.1cm using a non-elastic measuring tape (SECA 201). Obesity classification for Asians was used to classify BMI (308) and WC (309) of the participants. The classification developed by a previously published study (310) was used to categorise the participants according to their body fat percentage. Blood pressure and resting heart rate were measures using automatic blood pressure monitor (Omron Automatic Blood Pressure Monitor IA2). The results of participants' blood biomarkers were obtained from their medical record.

3.6.3 Process evaluation

Adherence to the intervention was assessed by the number of logins and duration spent in the website. Besides, the participants' satisfaction of the intervention was assessed by self-administered questionnaire at post-intervention.

3.6.4 Other assessments

The socio-demographic characteristics, medical history, and smoking and drinking habits were recorded in a structured questionnaire. International Physical Activity Questionnaire (IPAQ) was used to determine the level of physical activity of the participants (306).

3.7 Blinding

It was not possible to blind study nutritionist, webmaster and the participants. The enumerators trained to collect the data, however, were blinded during the data collection.

3.8 Statistical analysis

All statistical analyses were performed with IBM® PASW® Statistics 17.0. Chi square (χ^2) or equivalent was used to determine the association between categorical variables, while independent *t*-test was used to determine the mean differences of continuous variables. As this was a prospective RCT involving repeated measures, the General Linear Model (multivariate and ANOVA repeated measures) was applied to observe significant differences within the study groups. The evaluation of the intervention was based on an intention-to-treat analysis, with the p=0.05.

3.9 Validation of Dietary Knowledge, Attitude and Behaviour Questionnaire

3.9.1 Draft development

A 72-item questionnaire with 24 items for each domain – knowledge, attitude and behaviour was initially drafted using the same guidelines used for the development of the intervention (48, 74, 154, 301). The draft questionnaire was then subjected to content and face validity.

3.9.2 Content and face validity

The content validity of the draft questionnaire was determined by the research panel. The content of the questionnaire was studied for each individual item for its clarity and relevance to the community. The number of items was further reduced to 36 with 12 items in each domain, but care was taken to ensure there was one item per lesson plan in each domain.

The shortened draft's face validity was determined by 10 patients with T2DM. The patients were asked on the difficulties as well as user-friendliness of the questionnaire. Questions were rephrased and restructured to convey the intended message based on feedback received during face validation. Terminologies such as "high glycaemic index foods" were changed to "foods that rapidly increase your blood sugar".

3.9.3 Finalisation of the questionnaire

The Flesch-Kincaid Grade Level score was used to estimate the readability of the questionnaire (311). The Flesch Reading Ease score was 74.6% suggesting the questions to be fairly easy to be understood. The Flesch-Kincaid Grade Level yielded a score of 5.6, suggesting the participants have to be at least between 5th and 6th grade to understand the questions.

The final DKAB-Q consists of 36 items sectioned in three domains. The first domain, Knowledge, measured patients' understanding of important dietary aspects. The 12 items in this domain were measured using responses of “True”, “False” and “Don’t know”. Each correct response was given one point, whilst incorrect responses as well as “Don’t know” responses were given zero points. The second domain, Attitude, measured the attitude of patients when it comes to diet and diabetes. Five items (item 17, 18, 20, 23 and 24) in this domain were scored using Likert scale responses: strongly agree = 5 to strongly disagree = 1, while seven reversed items (item 13 – 16, 19, 21 and 22) scored from strongly agree = 1 to strongly disagree = 5. The third domain, Behaviour, measured the actual dietary behaviour of the patients. Responses to twelve items in this domain were scored as “Yes”, “No” and “Not sure”. The scoring is similar to that of the Knowledge domain.

The final version of the DKAB-Q was subjected to psychometric evaluation.

3.9.4 Psychometric evaluation

The evaluation was carried out among patients with T2DM undergoing follow-up treatment in three government hospitals (Putrajaya, Serdang and Selayang) in Malaysia. Healthy individuals accompanying non-diabetic patients seeking outpatient treatment in the same hospitals were recruited into the control group. The controls were matched to the patients with T2DM for age (±5 years), ethnicity and gender. Sixty subjects (30 patients with T2DM and 30 healthy individuals) were recruited into the validation study.

The questionnaires were administered by trained enumerators (DKAB-Q1) at the hospitals between December 2009 and February 2010. The same questionnaire was re-administered via phone call approximately after 2 weeks of the first interview, and this was noted as DKAB-Q2. The questionnaire took approximately 10 minutes to be completed.

The detailed result of DKAB-Q validation is presented in Appendix E. This validation study showed good internal consistency and reliability as showed by Cronbach’s Alpha (CA) and Intraclass Correlation Coefficient (ICC) of more than 0.70. The item discrimination showed a better item-to-total correlation of the items in diabetic patients compared to healthy individuals. Among patients with T2DM, the questionnaire attained item discrimination between 0.12 and 0.53, CA of 0.72 and ICC between 0.70 and 0.92 ($p<0.05$) suggesting good internal consistency and test-retest reliability.

The mean scores of DKAB-Q and each domain within and between groups were compared to determine the construct validity. There were no significant differences in mean scores within diabetic group or between groups ($p<0.05$). The patients with T2DM were found to have better consistency in the mean scores of domains and total DKAB scores compared to the controls.

3.10 Validation of Dietary Stages of Change Questionnaire

3.10.1 Draft development

Similar to the development phase of DKAB-Q, the existing evidence-based dietary guidelines and recommendations were reviewed in the development of the DSOC-Q. Ten behavioural questions were initially drafted for each lesson plan, making it a 120-item questionnaire.

3.10.2 Content and face validity

The content validity was assessed by the research team, which included a nutritionist. Face validity was determined by 15 patients with T2DM, where each individual item was studied for its clarity and relevance. Based on the feedback received, the number of questions was reduced to five per component. The questions were rephrased and restructured to convey the intended message based on the feedback received.

3.10.3 Finalisation of the questionnaire

The Flesch-Kincaid Grade Level score was used to estimate the readability of the questionnaire (311). The Flesch Reading Ease score was 68.2% suggesting the questions were fairly easy to understand. The Flesch-Kincaid Grade Level yielded a score of 6.6, suggesting the subjects need at least to be between 6th and 7th grade to understand the questions.

The final D-SOCQ consists of 60 questions sectioned in 12 dietary components. Five-point, Likert scale response was used for all the questions. The items were scored from 5 (strongly agree) to 1 (strongly disagree), except for 15 items (item 1, 4, 9, 21, 22, 30, 32, 36, 38, 39, 41, 46, 54, 56 and 57) which were scored on reverse. Other items in the questionnaire included demographic information. The final version of the D-SOCQ was subjected to psychometric evaluation.

3.10.4 Psychometric evaluation

The sample for this study was drawn from patients with T2DM undergoing follow-up treatment in three government hospitals (Putrajaya, Serdang and Selayang Hospitals) in Malaysia. Healthy respondents were those who accompanied the outpatients for treatment in the same hospitals and they belonged to the control group. The controls were matched to the diabetic patients for age (±5 years), ethnicity and gender.

The 60-item questionnaire (DSOC-Q1) was administered by trained enumerators at the hospital between March and June 2010. The questionnaire was administered verbally in English during one-to-one interviews. The same questionnaire was re-administered via phone call approximately after 4 weeks after the administration of DSOC-Q1, and this was noted as DSOC-Q2. The questionnaire took approximately 15 minutes to complete.

Ninety-six DSOC-Q1 was administered in patients with T2DM (n=48) and matching healthy controls (n=48). Eighty DSOC-Q2 were successfully completed after 4 to 5 weeks with 40 respondents in each study group (response rate=83%).

The detailed result of DKAB-Q validation is presented in Appendix F. It is important to note that the T2DM patients scored better than the healthy individuals did when it comes to the reliability of the items. Using a cut-off of 0.70, all items were found to be reliable when tested in patients, though there were items scored less than 0.70 among healthy controls. Among patients with T2DM, the questionnaire attained item discrimination between 0.12 and 0.49, CA of 0.79 and Intraclass Correlation Coefficient (ICC) between 0.69 and 0.90 ($p<0.05$), suggesting good internal consistency and test-retest reliability. The mean scores of DSOC-Q and each lesson plan within and between groups were compared to determine the construct validity. There were no significant differences in mean scores within diabetic group. The mean score difference was also found to be significantly lower in the diabetic group as compared to the healthy individuals ($p<0.05$). Based on this finding, DSOC-Q was found to be a suitable measure specifically for patients with T2DM.

CHAPTER 4

CHARACTERISTICS OF STUDY PARTICIPANTS

A total of 128 patients with T2DM were enrolled in this study after being screening for inclusion and exclusion criteria. The characteristics of the study participants at baseline are described here.

4.1 Demographic characteristics

The demographic characteristics of the study participants are presented in Table 4.1. There were 77 male and 51 female participants in this study. The mean age of the participants was 50.54 years old (SD=10.48) and the majority of the participants were in their 50's. The youngest participant was 19 and the oldest was 73 years old. Malays was the largest ethnic group participated in this study (73%) and more than half of the study participants had tertiary level education. More than 60% of the study participants were full-time employed. The mean personal income of the participants was RM5,166.85 per month, with the majority of them earning between RM3,001 and RM3,999. None of the demographic characteristics were significantly associated with the study groups.

Table 4.1: Demographic characteristics of the participants at baseline.

Demographic characteristics		e-intervention	control	$P^{(a)}$	Total
		n (%)	**n (%)**		**N (%)**
Gender	Male	41 (62.1)	36 (75.8)	0.639	77 (60.2)
	Female	25 (37.9)	26 (41.9)		51 (39.8)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Age (years)	<30	3 (4.5)	2 (3.2)		5 (3.9)
	30 – 39	8 (12.1)	6 (9.7)		14 (10.9)
	40 – 49	20 (30.3)	15 (24.2)		35 (27.3)
	50 – 59	23 (34.8)	22 (35.5)		45 (35.2)
	60 – 69	11 (16.7)	16 (25.8)		27 (21.1)
	>70	1 (1.5)	1 (1.6)		2 (1.6)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
	Mean + SD	49.61 + 10.67	51.52 + 10.27	0.304	50.54 + 10.48
	Range	19 – 73	19 – 71		19 – 73
Ethnic group	Malay	46 (69.7)	47 (75.8)	0.734	93 (72.6)
	Chinese	4 (6.1)	3 (4.8)		7 (5.5)
	Indian & others	16 (24.2)	12 (19.4)		28 (21.9)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Education status	Primary & lower secondary	4 (6.1)	6 (9.7)	0.625	10 (7.81)
	Higher secondary	21 (31.8)	22 (35.5)		43 (33.6)
	Tertiary	41 (62.1)	34 (54.8)		75 (58.6)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Occupation	Employed	45 (68.2)	34 (54.8)	0.280	79 (61.7)
	Unemployed or student	10 (15.1)	15 (24.2)		25 (19.5)
	Retired	11 (16.7)	13 (21.0)		24 (18.8)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Personal income (RM)	No income	16 (24.2)	22 (35.5)		38 (29.7)
	<2,000	3 (4.5)	6 (9.7)		9 (7.0)
	2,001 – 3,000	7 (10.6)	8 (12.9)		15 (11.7)
	3,001 – 4,000	10 (15.2)	9 (14.5)		19 (14.8)
	4,001 – 5,000	7 (10.6)	5 (8.1)		12 (9.4)
	5,001 – 6,000	12 (18.2)	3 (4.8)		15 (11.7)
	6,001 – 7,000	2 (3.0)	2 (3.2)		4 (3.1)
	7,001 – 8,000	2 (3.0)	0 (0.0)		2 (1.6)
	8,001 – 9,000	2 (3.0)	2 (3.2)		4 (3.1)
	9,001 – 10,000	1 (1.5)	0 (0.0)		1 (0.8)
	>10,001	4 (6.1)	5 (8.1)		9 (7.1)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
	Mean + SD	4837.18 + 2571.57	4813.28 + 4672.57	0.976	5,166.85 + 3,816.44
	Range	1,000 – 15,000	900 – 25,000		900 – 25,000

Notation: [(a)] Two-tailed Fisher's Exact test (categorical variables) or independent *t*-test (continuous variables).

4.2 Medical history and characteristics

The medical history of chronic diseases, especially diabetes and related information was recorded and reported in Table 4.2. Healthcare professionals such as doctors, nurses and dieticians were the most common source of health information (53.1%), followed by Internet resources (17.2%). Although it was not statistically significant, the e-intervention participants were found to rely more on the Internet for diabetes or health information compared to the control group (21.2% vs. 12.9%).

Almost half of the study participants were being treated with oral hypoglycaemic agent (OHA), with equal distribution in types of diabetes treatment in both groups. On the average, participants in this study have been diagnosed with T2DM eight years ago with disease duration ranging widely from one month to 38 years. There was no significant difference in mean disease duration between groups.

Slightly more than 80% of them did self-monitoring blood glucose (SMBG) at home, with majority monitoring it one to three times a week. A huge percentage (83.1%) of the participants had family history of diabetes. Based on the self-reported medical history, hypertension (53.1%), dyslipidaemia (46.1%) and previous history of heart diseases (10.2%) were the most common occurred conditions among the participants. Only one e-intervention participant and one control participant have reported previous kidney disease and foot ulcer, respectively.

Table 4.2: Medical history and characteristics of the participants at baseline.

Medical characteristics		e-intervention	control	$P^{(a)}$	Total
		n (%)	**n (%)**		**N (%)**
Source of health information	Internet	14 (21.2)	8 (12.9)	0.653	22 (17.2)
	Books and newspaper	6 (9.0)	7 (11.3)		13 (10.2)
	Health professionals	34 (51.5)	34 (54.8)		68 (53.1)
	Others	12 (18.2)	13 (21.0)		25 (19.5)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Diabetes medication	OHA	32 (48.5)	31 (50.0)	0.130	63 (49.3)
	Insulin only	7 (10.6)	2 (3.2)		9 (7.0)
	OHA + insulin	25 (37.9)	22 (35.5)		47 (36.7)
	Unknown	2 (3.0)	7 (11.3)		9 (7.0)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Disease duration (months)	$\leq$12	9 (13.6)	10 (16.1)		19 (14.8)
	13 – 36	12 (18.2)	10 (16.1)		22 (17.2)
	37 – 60	7 (10.6)	11 (17.7)		18 (14.1)
	61 – 84	7 (10.6)	8 (12.9)		15 (11.7)
	85 – 108	7 (10.6)	5 (8.1)		12 (9.4)
	109 – 120	6 (9.1)	10 (16.1)		16 (12.5)
	$\geq$120	18 (27.3)	8 (12.9)		26 (20.3)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
	Mean $\pm$ SD	111.07 $\pm$ 106.28	81.77 $\pm$ 69.89	0.069	96.88 $\pm$ 91.31
	Range	1 – 456	1 – 300		1 - 456
Family history of diabetes	Yes	56 (84.8)	51 (82.3)	0.692	107 (83.6)
	No	10 (15.2)	11 (17.7)		21 (16.4)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
SMBG	Daily	6 (9.1)	9 (14.5)	0.367	15 (11.7)
	4 – 6 times/week	9 (13.6)	1 (1.6)		2 (1.7)
	1 – 3 times/week	47 (71.2)	33 (53.2)		80 (62.5)
	Less than once a week	2 (3.0)	4 (6.5)		6 (4.7)
	No	10 (15.2)	15 (24.2)		25 (19.5)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Medical history					
Hypoglycaemia	Yes	5 (7.6)	2 (3.2)	0.442	7 (5.5)
	No	61 (92.4)	60 (96.8)		121 (94.5)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Heart disease	Yes	4 (6.1)	9 (14.5)	0.113	13 (10.2)
	No	62 (93.9)	53 (85.5)		115 (89.8)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**

Table 4.2: Medical history and characteristics of the participants at baseline (continued).

Medical characteristics		e-intervention	control	$P^{(a)}$	Total
		n (%)	n (%)		N (%)
Medical history					
Kidney disease	Yes	1 (1.5)	0 (0.0)	1.000	1 (0.8)
	No	65 (98.5)	62 (100.0)		127 (99.2)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Nerve disorder	Yes	2 (3.0)	5 (8.1)	0.263	7 (5.5)
	No	64 (97.0)	57 (91.9)		121 (94.5)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Foot ulcer	Yes	0 (0.0)	1 (1.6)	0.484	1 (0.8)
	No	66 (100.0)	61 (98.4)		127 (99.2)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Hypertension	Yes	36 (54.5)	32 (48.4)	0.740	68 (53.1)
	No	30 (45.5)	32 (51.6)		60 (46.9)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Dyslipidaemia	Yes	32 (48.5)	27 (43.5)	0.576	59 (46.1)
	No	34 (51.5)	35 (56.5)		69 (53.9)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**

Notation: [(a)] Two-tailed Chi -square (χ^2) or Fisher's exact test (categorical variables), and independent *t*-test (continuous variables).

4.3 Lifestyle characteristics

About one-third of the participants were current or past smokers (Table 4.3). About 17% of the participants disclosed that they were exposed to cigarette smoke at home or office (passive smoking), with more control participants admitting to be exposed (21.0% vs 13.6%). Only ten participants (7.8%) were alcohol drinkers and five participants (6.5%) were drinkers in the past. None of these characteristics was associated with the study groups.

Total metabolic equivalent (MET), a concept expressing the energy cost of physical activities as multiples of basal metabolic rate, was used to determine the level of physical activity (312). Physical activity, which was determined by the total MET per week, was mostly on the low level. Almost 44% of the participants scored low in their physical activity level, while only 21.0% of them reported to be engaged in high level of physical activity. The total MET/week was 1769.68 (SD = 2412.02) with e-intervention participants reporting slightly higher total MET/week than the control group. However, the difference in the total MET/week between the study groups was not significant.

Table 4.3: Lifestyle characteristics of the participants at baseline.

Lifestyle characteristics		e-intervention n (%)	control n (%)	$P^{(a)}$	Total N (%)
Smoking					
Current smoker	Yes	9 (13.6)	11 (17.7)	0.523	20 (15.6)
	No	57 (86.4)	51 (82.3)		108 (84.4)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Past smoker	Yes	11 (16.7)	9 (14.5)	0.738	20 (15.6)
	No	55 (83.3)	53 (85.5)		108 (84.4)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Passive smoker	Yes	9 (13.6)	13 (21.0)	0.272	22 (17.2)
	No	57 (86.4)	59 (95.2)		106 (82.8)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Alcohol drinking					
Current drinker	Yes	7 (10.6)	3 (4.8)	0.224	10 (7.8)
	No	59 (89.4)	59 (95.2)		118 (92.2)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Past drinker	Yes	4 (6.1)	1 (1.6)	0.366	5 (3.9)
	No	62 (93.9)	61 (98.4)		123 (96.1)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Physical activity level	Low	25 (37.9)	31 (50.0)	0.379	56 (43.8)
	Moderate	26 (39.4)	19 (30.6)		45 (35.2)
	High	15 (22.7)	12 (19.4)		27 (21.0)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Total MET/week	Median ± SEM	879.00 ± 269.54	620.25 ± 335.71	0.193[(b)]	733.00 ± 213.19
	Range	0 – 8,586	0 – 13,440		0 – 13,440

Notation: [(a)] Two-tailed Chi -square (χ^2) or Fisher's exact test (categorical variables), and independent *t*-test (continuous variables).
[(b)] Mann-Whitney U test (skewed data).

4.4 Dietary Knowledge, Attitude and Behaviour, and Dietary Stages of Change scores

Table 4.4 presents the Dietary Knowledge, Attitude and Behaviour (DKAB) and Dietary Stages of Changes (DSOC) scores of the participants at baseline. Out of the maximum of 12 points, the participants scored an average of 5.88 points (SD=1.91) for the knowledge, with an equal score between both study groups. Similarly, the attitude score was almost the same for both study groups at a mean of 23.36 points (SD=4.20) out of the maximum of 36 points. The behaviour score was lower than knowledge score with a mean of 4.70 (SD=1.90) out of the maximum of 12 points. The total DKAB score was 33.93 (SD=5.35), which was about 57% of total score of 60 points. The total DSOC score was 192.27 points (SD=15.36) out of a total possible score of 300 points. None of the scores significantly differed between study groups.

Table 4.4: Dietary Knowledge, Attitude and Behaviour, and Dietary Stages of Change scores of the participants at baseline.

Score		e-intervention (n=66)	control (n=62)	*P*[(a)]	Total (n=128)
Knowledge	Mean $\pm$ SD	5.83 $\pm$ 2.10	5.94 $\pm$ 1.70	0.764	5.88 $\pm$ 1.91
	Range	0 – 9	0 – 9		0 – 9
Attitude	Mean $\pm$ SD	23.69 $\pm$ 4.10	23.03 $\pm$ 4.31	0.395	23.36 $\pm$ 4.20
	Range	14 – 34	13 – 30		13 – 34
Behaviour	Mean $\pm$ SD	4.67 $\pm$ 1.80	4.73 $\pm$ 2.02	0.861	4.70 $\pm$ 1.90
	Range	1 – 8	0 – 10		0 – 10
Total DKAB score	Mean $\pm$ SD	34.15 $\pm$ 5.23	33.69 $\pm$ 5.50	0.630	33.93 $\pm$ 5.35
	Range	22 – 42	21 – 42		21 – 42
Total DSOC score	Mean $\pm$ SD	193.27 $\pm$ 14.60	191.20 $\pm$ 16.19	0.448	192.27 $\pm$ 15.36
	Range	160 – 242	158 – 247		158 – 247

Notation: [(a)] Independent *t*-test.

4.4 Food intake

The food intake of the participants is presented in the form of selected food groups (Table 4.5) and supplement intake (Table 4.6). The total average servings of carbohydrate intake were four and a half servings a day, with almost equal intake between the study groups. Average fruits intake was less than two servings a day while average vegetables intake was even lesser (1.35 servings/day). The average intake of protein-rich foods was 2.61 servings/day (SD=1.40), with the highest intake of six and a half servings a day. The intake of miscellaneous foods such as snacks was less than 1 serving/day.

Table 4.5: Intake of selected food groups by the participants at baseline.

Food groups		e-intervention (n=66)	control (n=62)	$P^{(a)}$	Total (n=128)
Carbohydrate	Mean ± SD	4.56 ± 2.36	4.53 ± 1.33	0.943	4.54 ± 2.32
	Range	1.28 – 12.00	0.47 – 10.92		0.47 – 12.00
Fruits	Mean ± SD	1.68 ± 1.31	1.65 ± 1.33	0.899	1.67 ± 1.32
	Range	0.00 – 5.36	0.00 – 7.00		0.00 – 7.00
Vegetables	Mean ± SD	1.33 ± 1.03	1.38 ± 1.17	0.795	1.35 ± 1.10
	Range	0.00 – 5.02	0.00 – 6.00		0.00 – 6.00
Protein	Mean ± SD	2.74 ± 1.42	2.48 + 1.37	0.294	2.61 ± 1.40
	Range	0.43 – 6.14	0.06 – 6.51		0.06 – 6.51
Miscellaneous	Mean ± SD	0.77 ± 0.94	0.61 ± 0.74	0.275	0.70 ± 0.85
	Range	0.00 – 3.57	0.00 – 3.21		0.00 – 3.57

Notation: [(a)] Independent *t*-test.

About 53% of the study participants reported intake of supplement and the majority of them were consuming multivitamin (21.1%) (Table 4.6). Vitamin C and B complex were the other commonly consumed supplements (10.9% and 8.6%, respectively). The e-intervention participants were consuming more calcium supplementation compared to the control participants (13.6% vs 4.8%). None of the control participants took fish oil supplementation, while almost 47% of total study participants reported no consumption of any type of supplements.

Table 4.6: Intake of supplements by the participants at baseline.

Supplement intake		e-intervention n (%)	control n (%)	$P^{(a)}$	Total N (%)
Multivitamin	Yes	16 (24.2)	11 (17.7)	0.368	27 (21.1)
	No	50 (75.8)	51 (82.3)		101 (78.9)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Vitamin B complex	Yes	6 (9.1)	5 (8.1)	0.836	11 (8.6)
	No	60 (90.9)	57 (91.9)		117 (91.4)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Vitamin C	Yes	3 (4.5)	8 (12.9)	0.092	14 (10.9)
	No	63 (95.5)	54 (87.1)		114 (89.1)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Calcium	Yes	9 (13.6)	3 (4.8)	0.088	12 (9.4)
	No	57 (86.4)	59 (95.2)		116 (90.6)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Iron	Yes	2 (3.0)	0 (0.0)	0.497	2 (1.6)
	No	64 (97.0)	62 (100.)		126 (98.4)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Fish oil	Yes	3 (4.5)	0 (0.0)	0.245	14 (10.9)
	No	63 (95.5)	62 (100.)		114 (89.1)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
Others	Yes	13 (19.7)	11 (17.7)	0.777	25 (19.5)
	No	53 (80.3)	51 (82.3)		103 (80.5)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**
None	Yes	29 (43.9)	31 (50.0)	0.492	60 (46.9)
	No	37 (56.1)	31 (50.0)		68 (53.1)
	Total	**66 (100.0)**	**62 (100.0)**		**128 (100.0)**

Notation: [a] Two-tailed Chi -square (χ^2) or Fisher's exact test.

4.5 Anthropometry measurements

Table 4.7 presents the various anthropometry measurements of the study participants. The mean weight of the participants was 79.48kg (SD=16.01), with e-intervention participants weighing slightly heavier than the control group. The mean height was 163.6cm with the shortest person measured 145.0cm and the tallest measured at 181.0cm. The average Body Mass Index (BMI) of all participants was 29.59kg/m^2 (SD=5.02). The participants' BMI was then categorised according to the Asian classification, and more than 80% of the participants were found to be obese (BMI $\geq$25.0). The problem of obesity among the participants was reconfirmed by the waist circumference (WC) and body fat percentage. The mean WC of the e-intervention group was 100.55cm (SD=9.64), which did not differ significantly than the control group 96.42cm (SD=12.94). Overwhelming 93.9% of the e-intervention participants and 82.3% of control group were classified as at risk for cardiovascular diseases based on their WC. The mean body fat was 32.75% (SD=6.50), and again almost 80% of them classified having high body fat percentage (>25% for males and >35% for females). There was no significant different in body fat percentage between groups.

Table 4.7: Anthropometry measurements of the participants at baseline.

Anthropometry measurements		e-intervention (n=66)	control (n=62)	$P^{(a)}$	Total (n=128)
Weight (kg)	Mean + SD	82.50 + 14.39	76.27 + 17.12	0.270	79.48 + 16.01
	Range	51.2 – 118.7	48.9 – 133.5		48.9 – 133.5
Height (cm)	Mean + SD	164.77 + 7.87	162.38 + 7.76	0.087	163.62 + 7.88
	Range	147.5 – 179.5	145.0 – 181.0		145.0 – 181.0
BMI (kg/m^2)[b]; n(%)	Normal (18.5 – 22.9)	4 (6.1)	8 (12.9)		12 (9.4)
	At risk (23.0 – 24.9)	4 (6.1)	8 (12.9)		12 (9.4)
	Obese 1 (25.0 – 29.9)	22 (33.3)	25 (40.3)		46 (35.9)
	Obese 2 (≥30.0)	36 (54.5)	21 (33.9)		57 (44.5)
	Total	**66 (100.0)**	**62 (100.0)**		
	Mean + SD	30.33 + 4.52	28.80 + 5.43	0.085	29.59 + 5.02
	Range	21.73 – 40.86	18.65 – 46.74		18.65 – 46.74
WC (cm)[c]; n(%)	Normal	4 (6.1)	11 (17.7)		15 (11.7)
	At risk	62 (93.9)	51 (82.3)		113 (88.3)
	Total	**66 (100.0)**	**62 (100.0)**		
	Mean + SD	100.55 + 9.64	96.42 + 12.94	0.420	98.55 + 11.50
	Range	76.0 – 120.0	76.0 – 140.0		76.0 – 140.0
Body fat (%); n(%)	Normal	1 (1.5)	3 (4.8)		4 (3.1)
	Slightly high	7 (10.6)	15 (24.2)		22 (17.2)
	High	58 (87.9)	44 (71.0)		102 (79.7)
	Total	**66 (100.0)**	**62 (100.0)**		
	Mean + SD	33.54 + 6.42	31.90 + 6.70	0.161	32.75 + 6.58
	Range	19.1 – 47.6	15.8 – 44.1		15.8 – 47.6

Notation: [a] Independent *t*-test.
[b] Categorisation done according to BMI for Asians (306).
[c] Categorisation done according waist circumference cut-off for Asians (307).

4.6 Blood biomarkers and blood pressure

The mean fasting blood glucose (FBG) and glycosylated haemoglobin (HbA1c) were 8.63 mmol/L (SD=3.45) and 9.01% (SD=1.95) respectively (Table 4.8). The mean of plasma triglyceride (TG), total cholesterol (TC), high-density lipoprotein (HDL) and low-density lipoprotein (LDL) were 1.86 mmol/L (SD=0.96), 4.82 mmol/L (SD=1.37), 1.11 mmol/L (SD=0.23) and 2.85 mmol/L (SD=1.11) respectively. There were no significant differences in all blood biomarkers between the study groups.

The mean systolic and diastolic blood pressure of the study participants were 136.42mm/Hg (SD=16.67) and 82.20mm/Hg (SD=10.49), respectively (Table 4.8). The blood pressure was almost equal between both groups. The mean resting heart rate was 79.60 beats/min (SD=10.31). None of these physical measurements differed between both groups.

Table 4.8: Blood biomarkers and physical measurements of the participants at baseline.

Biomarkers and physical measurements		e-intervention (n=66)	control (n=62)	$P^{(a)}$	Total (n=128)
FBG (mmol/L)	Mean ± SD	8.92 ± 3.92	8.30 ± 2.87	0.312	8.63 ± 3.45
	Range	4.20 – 20.50	4.60 – 17.65		4.20 – 20.50
HbA1c (%)	Mean ± SD	9.07 ± 2.03	8.94 ± 1.88	0.712	9.01 ± 1.95
	Range	7.00 – 15.90	7.00 – 16.40		7.00 – 16.40
TC (mmol/L)	Mean ± SD	4.95 ± 1.47	4.69 ± 1.25	0.293	4.82 ± 1.37
	Range	2.50 – 9.90	2.19 – 8.70		2.19 – 9.90
HDL (mmol/L)	Mean ± SD	1.09 ± 0.23	1.12 ± 0.24	0.530	1.11 ± 0.23
	Range	0.64 – 1.69	0.63 – 1.70		0.63 – 1.70
LDL (mmol/L)	Mean ± SD	2.92 ± 1.23	2.79 ± 0.99	0.506	2.85 ± 1.11
	Range	1.10 – 6.51	0.80 – 5.50		0.80 – 6.51
TG (mmol/L)	Mean ± SD	1.94 ± 0.93	1.78 ± 1.00	0.355	1.86 ± 0.96
	Range	0.50 – 4.50	0.42 – 5.10		0.42 – 5.10

Table 4.8: Blood biomarkers and physical measurements of the participants at baseline (continued).

Biomarkers and physical measurements		e-intervention (n=77)	control (n=51)	$P^{(a)}$	Total (n=128)
Systolic blood pressure (mm/Hg)	Mean ± SD Range	137.73 ± 16.70 88 – 169	135.03 ± 16.67 96 – 175	0.363	136.42 ± 16.67 88 – 175
Diastolic blood pressure (mm/Hg)	Mean ± SD Range	83.35 ± 11.23 52 – 107	80.97 ± 9.59 60 – 104	0.201	82.20 ± 10.49 52 – 107
Resting heart rate (beats/min)	Mean ± SD Range	80.29 ± 10.00 60 – 106	78.86 ± 16.68 59 – 103	0.437	79.60 ± 10.31 59 – 106

Notation: [(a)] Independent *t*-test.

CHAPTER 5

PRIMARY OUTCOMES

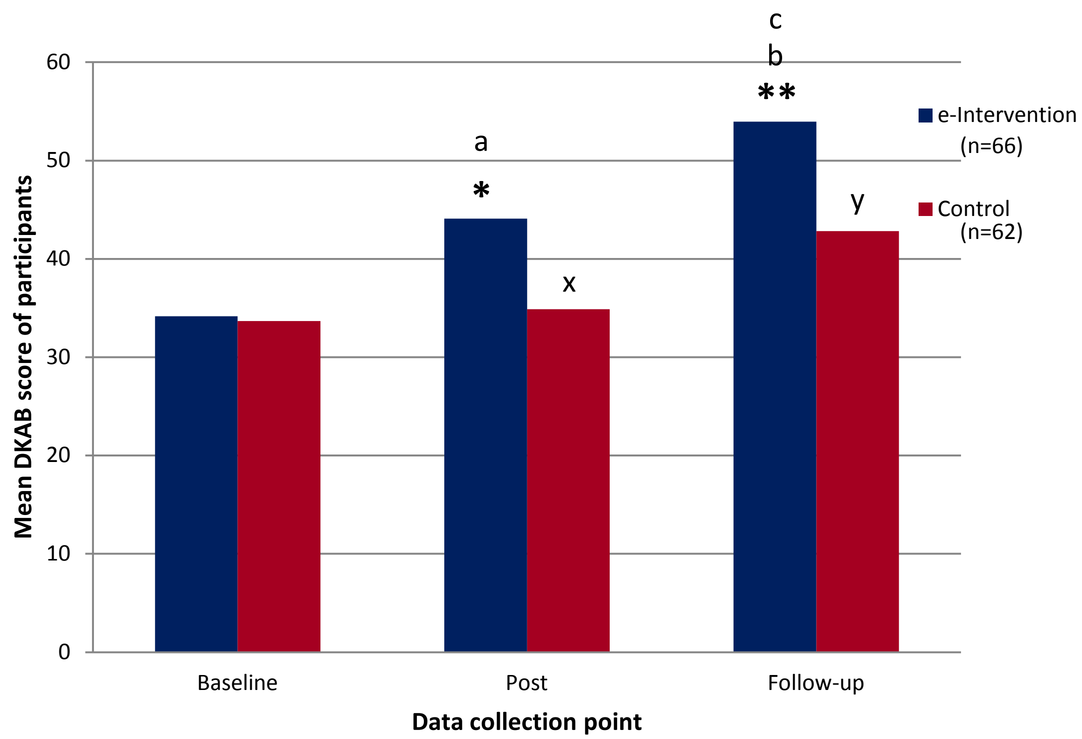
The Dietary Knowledge, Attitude, Behaviour (DKAB) score and its sub-domains were the independent variables, while the study groups (e-intervention and control) and data collection points (baseline, post-intervention and follow-up) were the between groups and within group factors, respectively.

All data were normally distributed. General linear model (multivariate and repeated measures) was used to analyse the within and between groups mean score differences. Data were adjusted for gender, age, education status, smoking and drinking habit, total MET/week, duration of the disease and type of diabetes treatment.

Intention-to-treat analysis was performed and the statistical significance was set at p=0.05. The detailed analyses of the primary outcomes are included in Appendix G.

5.1 Dietary Knowledge, Attitude and Behaviour score

Figure 5.1 presents the mean DKAB score of participants in the both groups at various data collection points. The DKAB score of the study participants were found to increase across the data collection points and there was a significant difference in the mean DKAB score between the study groups ($p<0.001$). Despite within group analysis showing an increase in the mean DKAB in both groups ($p<0.001$), Bonferroni post-hoc analysis between groups revealed significantly higher mean DKAB scores in e-intervention group at post-intervention ($p<0.01$) and follow-up ($p<0.001$), compared to baseline.



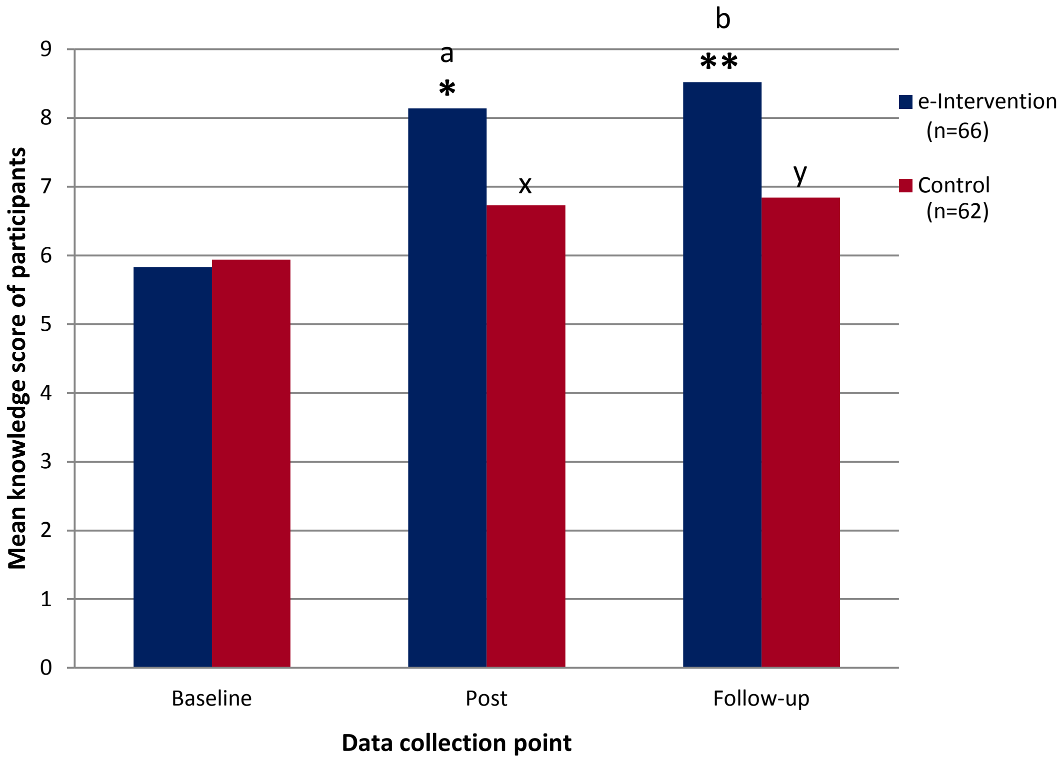
Notations:

* : p = 0.004; post-intervention vs. baseline changes between groups
** : p = 0.000; follow-up vs. baseline changes between groups
a : p = 0.000; post-intervention vs. baseline in e-intervention group
b : p = 0.000; follow-up vs. baseline in e-intervention group
c : p = 0.000; follow-up vs. post-intervention in the e-intervention group
x : p = 0.000; post-intervention vs. baseline in control group
y : p = 0.000; follow-up vs. baseline in control group

Figure 5.1: The mean Dietary Knowledge, Attitude and Behaviour scores of participants in the e-intervention and control groups at various data collection points.

5.2 Knowledge score

The DKAB score was analysed for its individual components. The knowledge score increased across the data collection points in both groups (Figure 5.2). Yet, the mean knowledge scores of e-intervention and control groups were found to be significantly different ($p<0.01$), and further analysis found that the post-intervention and follow-up scores of the e-intervention group to be significantly higher than the control group ($p<0.001$ and $p<0.01$, respectively).



Notations:

* : p = 0.003; post-intervention vs. baseline changes between groups

** : p = 0.000; follow-up vs. baseline changes between groups

a : p = 0.000; post-intervention vs. baseline in e-intervention group

b : p = 0.000; follow-up vs. baseline in e-intervention group

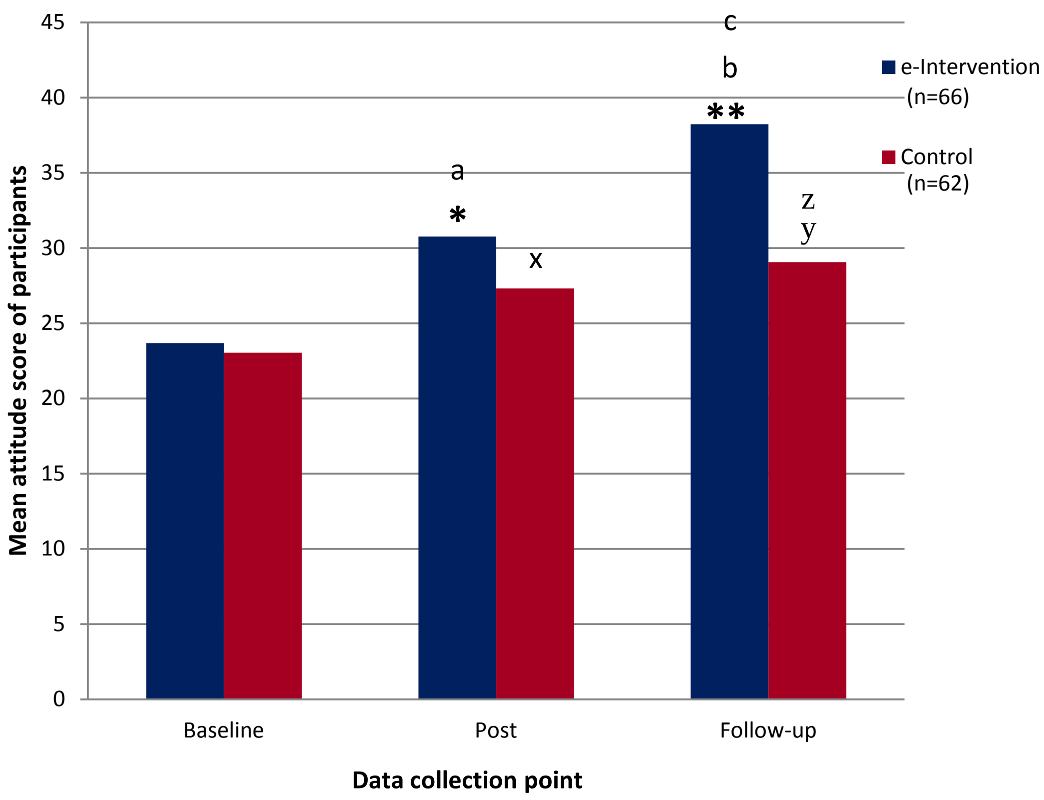
x : p = 0.002; post-intervention vs. baseline in control group

y : p = 0.001; follow-up vs. baseline in control group

Figure 5.2: The mean knowledge scores of participants in the e-intervention and control groups at various data collection points.

5.3 Attitude score

Similar to DKAB and knowledge score, attitude score was found to be significantly different between both groups at post-intervention (p<0.05) and follow-up (p<0.001). Again, although the mean scores increased significantly in both groups, the increase was more evident in e-intervention group, which scored higher than the control group (Figure 5.3).



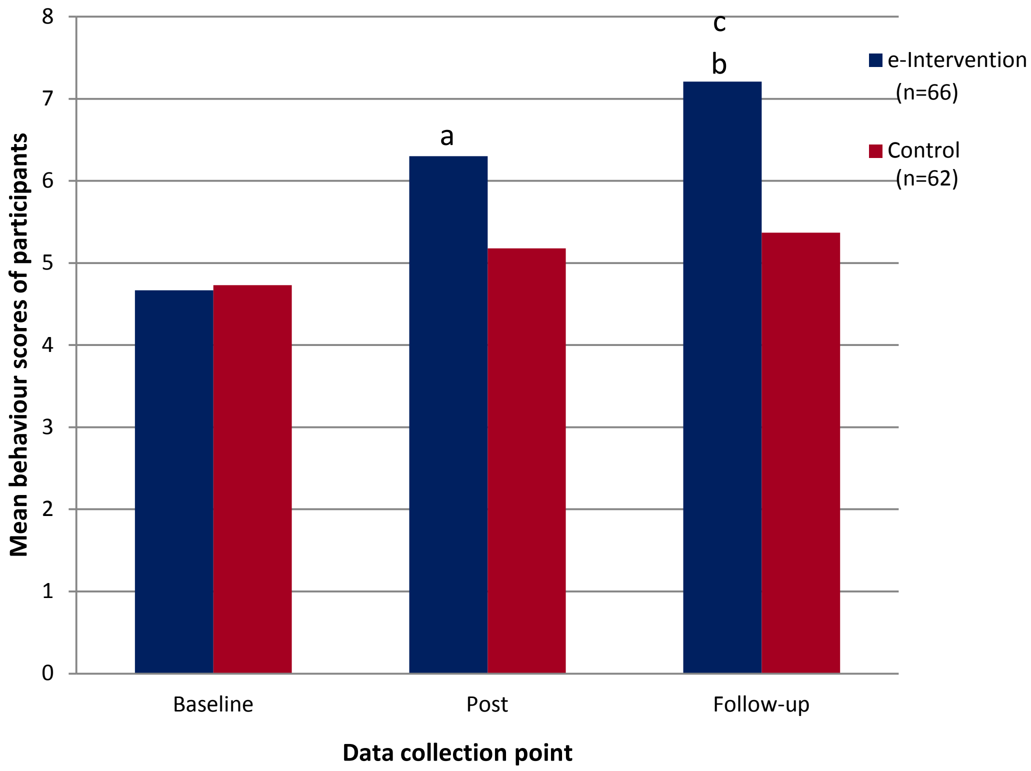
Notations:

*	: p = 0.011; post-intervention vs. baseline changes between groups
**	: p = 0.000; follow-up vs. baseline changes between groups
a	: p = 0.000; post-intervention vs. baseline in e-intervention group
b	: p = 0.000; follow-up vs. baseline in e-intervention group
c	: p = 0.000; follow-up vs. post-intervention in e-intervention group
x	: p = 0.002; post-intervention vs. baseline in control group
y	: p = 0.001; follow-up vs. baseline in control group
z	: p = 0.036; follow-up vs. post-intervention in control group

Figure 5.3: The mean attitude scores of participants in the e-intervention and control groups at various data collection points.

5.4 Behaviour score

In contrast to other component of DKAB, there was no significant difference between behaviour score between groups (p=0.119). However, there were significant differences between post-intervention (p<0.001) and follow-up (p<0.001) behaviour score compared to baseline in e-intervention group. Figure 5.4 presents the mean behaviour scores of participants in the e-intervention and control groups at various data collection points.



Notations:

a : p = 0.000; post-intervention vs. baseline in e-intervention group
b : p = 0.000; follow-up vs. baseline in e-intervention group
c : p = 0.000; follow-up vs. post-intervention in e-intervention group

Figure 5.4: The mean behaviour scores of participants in the e-intervention and control groups at various data collection points.

5.5 Summary

The GLM analyses revealed that the total DKAB, knowledge, attitude and behaviour score of the e-intervention group have improved significantly at post-intervention and follow-up, as compared to the baseline ($p<0.05$). The improvements in DKAB, knowledge and attitude score of the participants in e-intervention groups were significantly better than those in the control group ($p<0.05$). The mean behaviour score, however, did not differ between the study groups.

CHAPTER 6

SECONDARY OUTCOMES

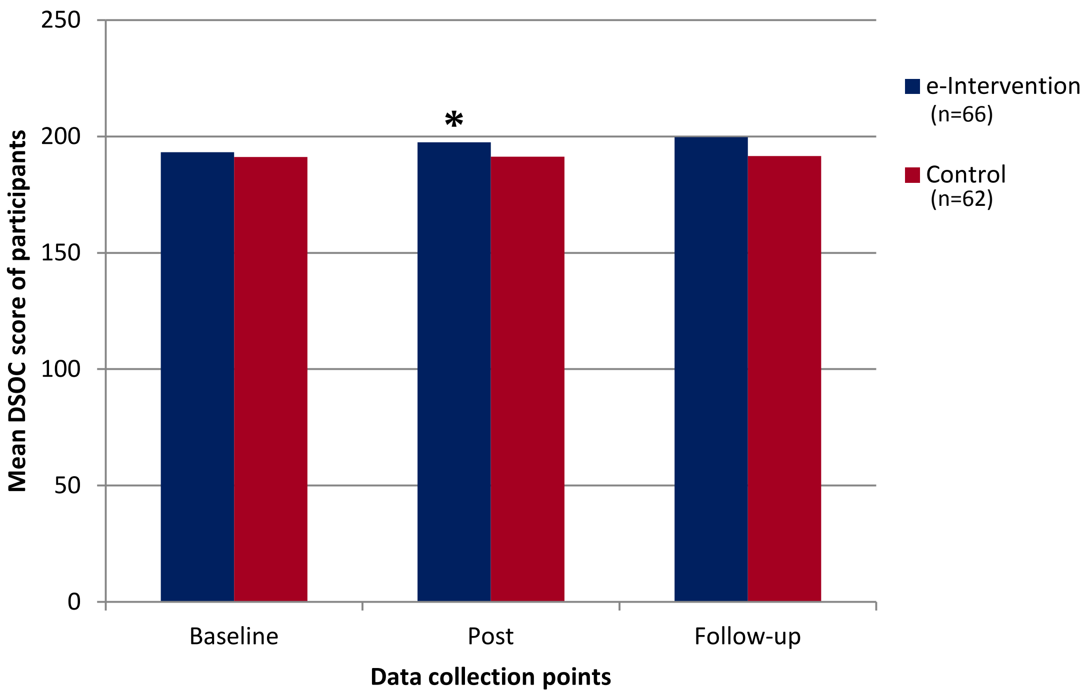
The secondary outcomes of this study are Dietary Stages of Change (DSOC) score, food and supplement intake, anthropometry measurements, blood biomarkers, blood pressure and resting heart rate.

All continuous variables were normally distributed. General linear model (multivariate and repeated measures) were used to analyse the within and between group mean differences, while Chi-square (χ^2) analysis was conducted to determine the association of categorical variables within groups. Data were adjusted for gender, age, education status, smoking and drinking habit, total MET/week, duration of the disease and type of diabetes treatment.

Intention-to-treat analysis was performed and the statistical significance was set at p=0.05. The detailed analyses of the secondary outcomes are included in Appendix H.

6.1 Dietary Stages of Change score

The mean DSOC score between groups was found to be significant different ($p<0.05$) at post-intervention. The Bonferroni post-hoc analysis showed the mean DSOC score of the e-intervention group to be significantly higher than the control group (199.65 $\pm$ 18.21 vs. 191.50 $\pm$ 15.06, $p<0.05$). The within group changes, however, was not statistically significant (Figure 6.1). The majority of the participants in both groups were in the action stage (Table 6.1).



Notations:
* : p = 0.025; post-intervention vs. baseline changes between groups

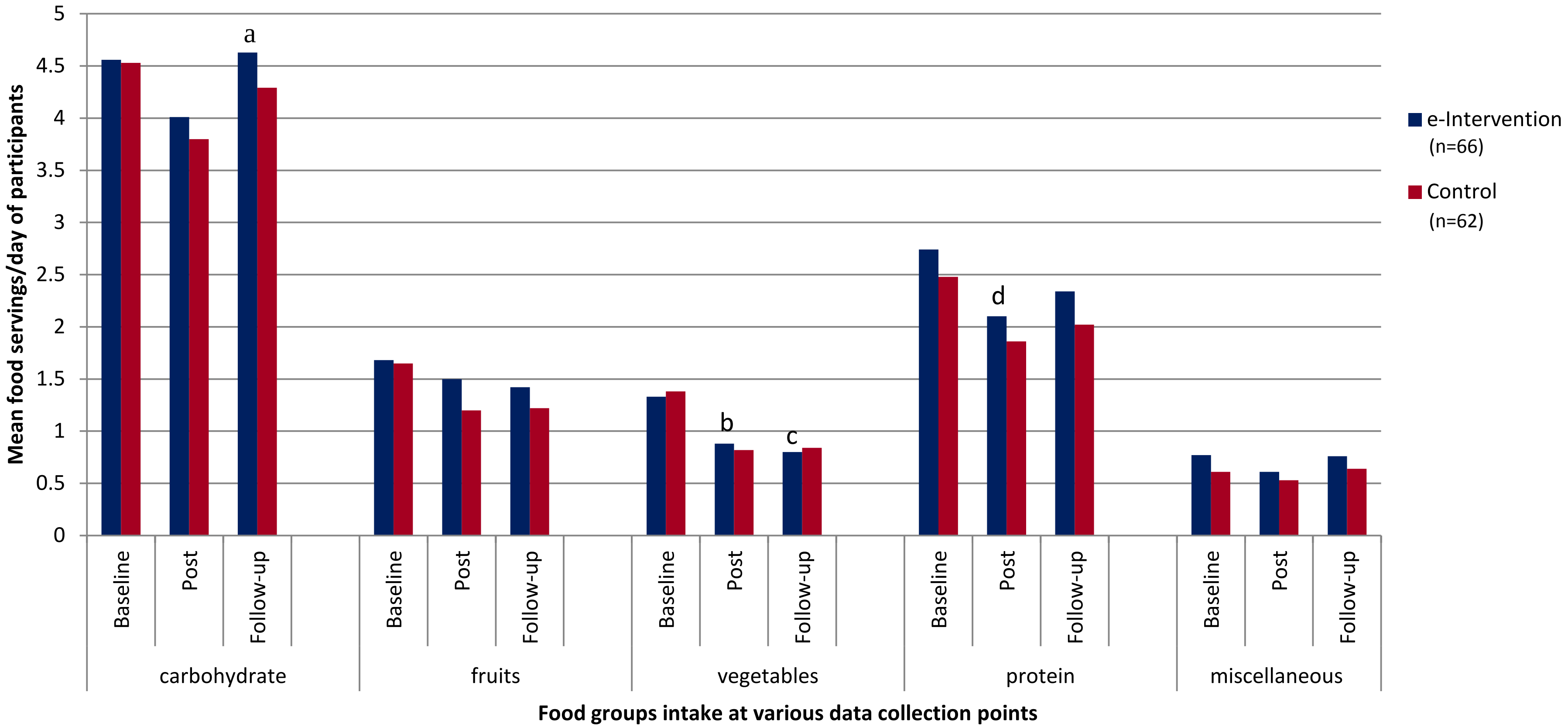
Figure 6.1: The mean Dietary Stages of Change score of participants in the e-intervention and control groups at various data collection points.

Table 6.1: Descriptive presentation of categories of Dietary Stages of Change score of the participants at various data collection points.

DSOC	e-Intervention			Control		
	Baseline n (%)	Post n (%)	Follow-up n (%)	Baseline n (%)	Post n (%)	Follow-up n (%)
Preparation	10 (15.2)	9 (13.6)	7 (10.8)	19 (30.6)	18 (29.0)	15 (24.2)
Action	55 (83.3)	56 (84.8)	56 (86.2)	42 (67.7)	43 (69.4)	46 (74.2)
Maintenance	1 (1.5)	1 (1.6)	2 (3.1)	1 (1.6)	1 (1.6)	1 (1.6)

6.2 Food intake

The mean servings of food groups of interest (carbohydrate, fruits, vegetables, protein and miscellaneous food items) were used to determine the general food consumption of the participants (Figure 6.2). There were no significant different in the mean intake of all food groups between the study groups. The consumption of carbohydrate-containing foods, however, showed a significant decrease at follow-up compared to post-intervention in e-intervention group ($p<0.05$). Unfortunately, there is a significant decrease in the mean servings of vegetables at post-intervention ($p<0.05$) and follow-up ($p<0.001$) compared to baseline in e-intervention group, while consumption of protein-containing foods decreased at post-intervention ($p<0.05$). There were no significant changes in supplement intake between the groups (Table 6.2).



Notations:

a : p = 0.003; follow-up vs. post-intervention within e-intervention group

b : p = 0.016; post-intervention vs. baseline within e-intervention group

c : p = 0.001; follow-up vs. baseline within e-intervention group

d : p = 0.016; post-intervention vs. baseline within e-intervention group

Figure 6.2: The mean food servings of participants in the e-intervention and control groups at various data collection points.

Table 6.2: Supplement intake by the participants at various data collection points.

Supplement	Data collection points		e-Intervention n (%)	Control n (%)	χ^2	P
All types	Baseline	Yes	37 (56.1)	31 (50.0)	0.472	0.492
		No	29 (43.9)	31 (50.0		
	Post-intervention	Yes	36 (54.5)	30 (51.6)	0.110	0.740
		No	30 (45.5)	32 (48.4)		
	Follow-up	Yes	33 (50.0)	31 (50.0)	0.000	1.000
		No	33 (50.0)	31 (50.0)		
Multivitamin	Baseline	Yes	16 (75.8)	11 (17.7)	0.812	0.368
		No	50 (24.2)	51 (82.3)		
	Post-intervention	Yes	17 (25.8)	15 (24.2)	0.042	0.838
		No	49 (74.2)	47 (75.8)		
	Follow-up	Yes	16 (24.2)	13 (21.0)	0.196	0.658
		No	50 (75.8)	48 (79.0)		
Vitamin B complex	Baseline	Yes	6 (9.1)	5 (8.1)	0.043	0.836
		No	60 (90.9)	57 (91.9)		
	Post-intervention	Yes	7 (10.6)	9 (14.5)	0.447	0.504
		No	59 (89.4)	53 (85.5)		
	Follow-up	Yes	4 (6.1)	9 (14.5)	2.505	0.113
		No	62 (93.9)	53 (85.5)		
Vitamin C	Baseline	Yes	3 (4.5)	8 (12.9)	2.843	0.092
		No	63 (95.5)	54 (87.1)		
	Post-intervention	Yes	8 (12.1)	9 (14.5)	0.159	0.690
		No	58 (87.9)	53 (85.5)		
	Follow-up	Yes	7 (10.6)	7 (11.3)	0.015	0.901
		No	59 (89.4)	55 (88.7)		
Calcium	Baseline	Yes	9 (13.6)	3 (4.8)	-	0.129[(a)]
		No	57 (86.4)	59 (95.2)		
	Post-intervention	Yes	5 (7.6)	7 (11.3)	0.519	0.471
		No	61 (92.4)	55 988.7)		
	Follow-up	Yes	5 (7.6)	7 (11.3)	0.519	0.471
		No	61 (92.4)	55 988.7)		

Table 6.2: Supplement intake by the participants at various data collection points (continued).

Supplement	Data collection points		e-Intervention n (%)	Control n (%)	χ^2	P
Iron	Baseline	Yes	2 (3.0)	0 (0.0)	-	0.497[(a)]
		No	64 (97.0)	62 (100.0)		
	Post-intervention	Yes	1 (1.5)	1 (1.6)	-	1.000[(a)]
		No	65 (97.0)	61 (98.4)		
	Follow-up	Yes	1 (1.5)	1 (1.6)	-	1.000[(a)]
		No	65 (97.0)	61 (98.4)		
Fish oil	Baseline	Yes	3 (4.5)	0 (0.0)	-	0.245[(a)]
		No	63 (95.5)	62 (100.0)		
	Post-intervention	Yes	6 (9.1)	6 (9.7)	0.013	0.909
		No	60 (90.9)	56 (90.3)		
	Follow-up	Yes	7 (10.6)	8 (12.9)	0.163	0.686
		No	59 (89.4)	54 (87.1)		
Others	Baseline	Yes	13 (19.7)	11 (17.7)	0.080	0.777
		No	53 (80.3)	51 (82.3)		
	Post-intervention	Yes	9 (13.6)	9 (14.5)	0.020	0.886
		No	57 (86.4)	53 (85.5)		
	Follow-up	Yes	13 (19.7)	11 (17.7)	0.080	0.777
		No	53 (80.3)	51 (82.3)		

Notation: [(a)]Two tailed Fisher's Exact Test.

6.3 Anthropometry measurements

6.3.1 Body weight

The mean body weight of the participants in both groups was almost equal across the data collection points (Figure 6.3). Although the mean body weight of e-intervention group seemed to be higher at all data collection points, the differences were not significant.

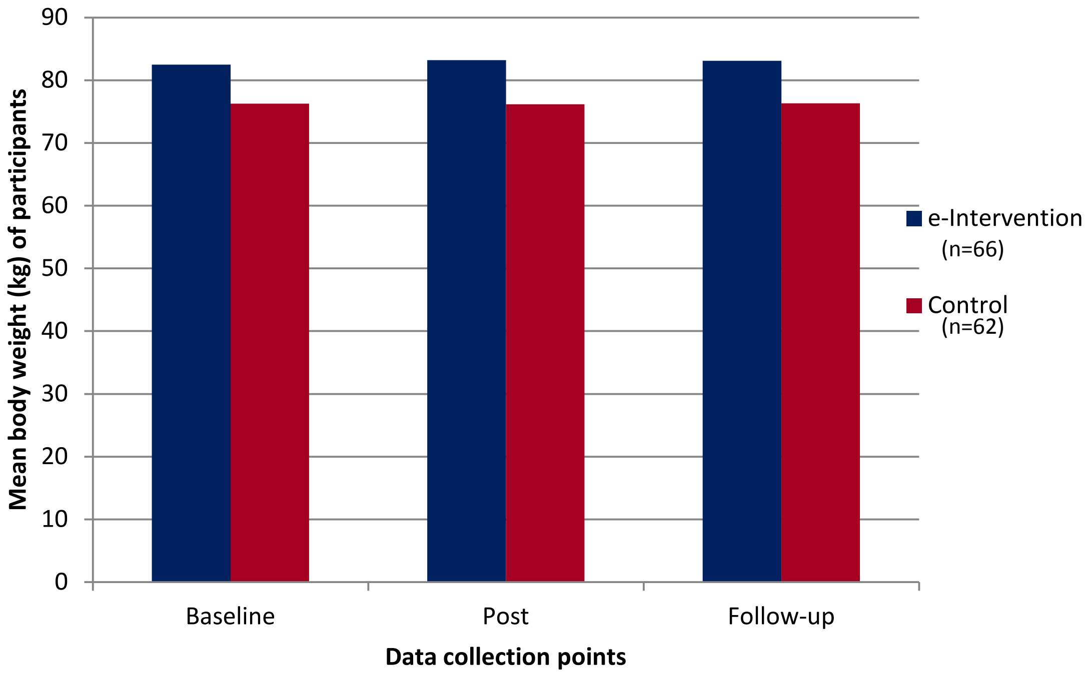


Figure 6.3: The mean body weight of participants in the e-intervention and control groups at various data collection points.

6.3.2 Body Mass Index

Similar to the body weight, the Body Mass Index (BMI) of e-intervention participants was slightly higher than the control group, but the difference was not statistically significant. There was no statistically significant change within group was found. Figure 6.4 presents the mean BMI of the participants at each data collection points. An alarming 88% of the e-intervention group and 77% of the control group participants were categorised to be obese at baseline (Table 6.3). The percentages remained almost the same at follow-up data collection.

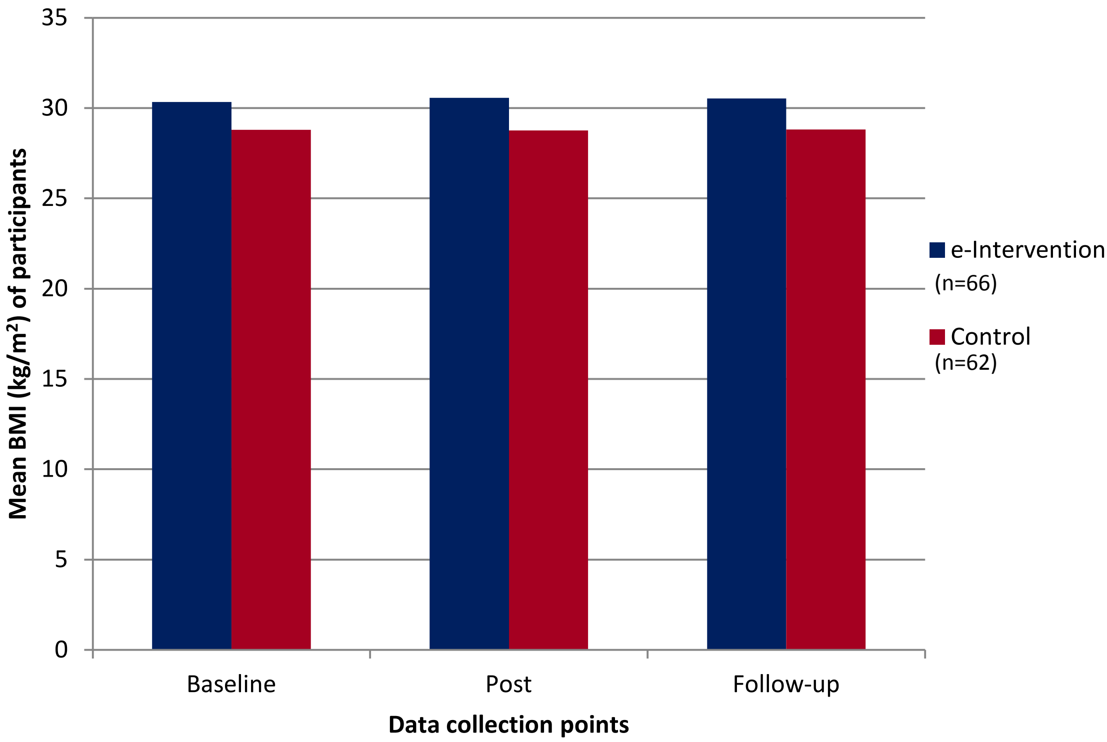


Figure 6.4: The mean Body Mass Index of participants in the e-intervention and control groups at various data collection points.

Table 6.3: Descriptive presentation of categories of Body Mass Index of the participants at various data collection points.

Category of BMI[(a)]	e-Intervention			Control		
	Baseline n (%)	**Post n (%)**	**Follow-up n (%)**	**Baseline n (%)**	**Post n (%)**	**Follow-up n (%)**
Normal (18.50 – 22.99 kg/m^2)	4 (6.1)	3 (4.5)	3 (4.5)	8 (12.9)	6 (9.7)	6 (9.7)
At risk (23.00 – 29.99 kg/m^2)	4 (6.1)	3 (4.5)	3 (4.5)	8 (12.9)	13 (21.0)	13 (21.0)
Obese 1 (25.00 – 29.99 kg/m^2)	22 (33.3)	26 (39.4)	26 (39.4)	25 (40.3)	23 (37.1)	23 (37.1)
Obese 2 ($\geq$30.00 kg/m^2)	36 (54.5)	34 (51.5)	34 (51.5)	21 (36.8)	20 (32.3)	20 (32.3)

Notation: [(a)]Categorisation done according to BMI for Asians (306).

6.3.3 Waist circumference

Although the mean waist circumference (WC) of the e-intervention participants found to be 4cm wider than the controls, the differences was not significantly different (p>0.05). The within group analysis also did not find any statistical difference in both groups (Figure 6.5). The percentages of participants in both groups were higher in those at risk category compared to normal category (Table 6.4).

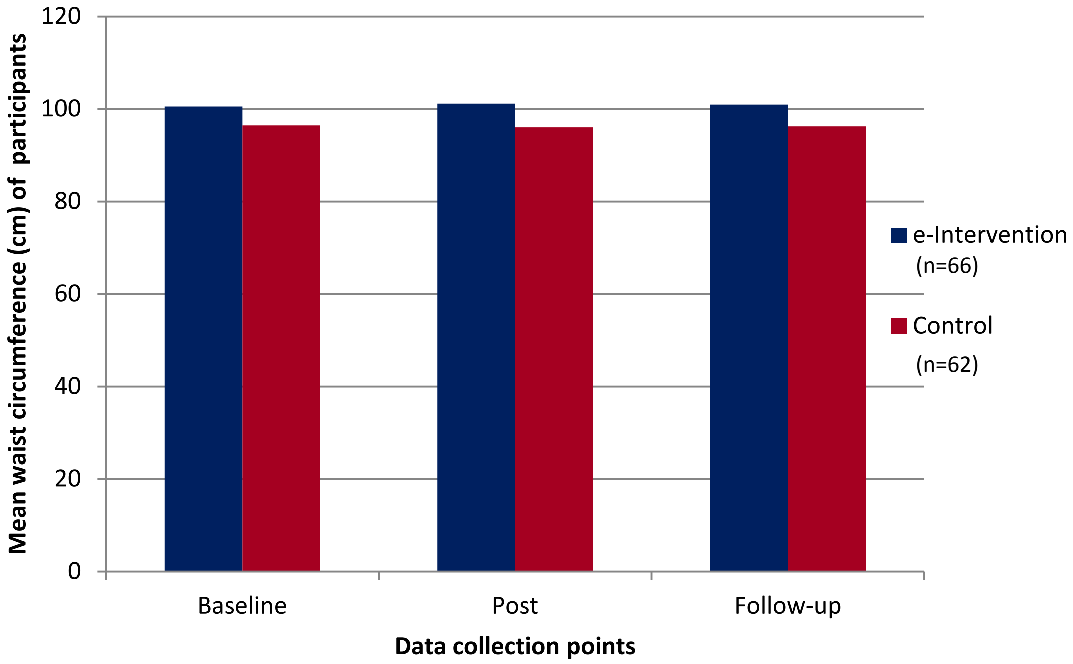


Figure 6.5: The mean waist circumference of participants in the e-intervention and control groups at various data collection points.

Table 6.4: Descriptive presentation of categories of waist circumference of the participants at various data collection points.

Category of WC[a]	e-Intervention			Control		
	Baseline n (%)	Post n (%)	Follow-up n (%)	Baseline n (%)	Post n (%)	Follow-up n (%)
Normal	4 (6.1)	5 (7.6)	5 (7.6)	11 (17.7)	14 (22.6)	14 (22.6)
At risk	62 (93.9)	61 (92.4)	61 (92.4)	51 (82.3)	48 (77.4)	48 (77.4)

Notations: [a] Categorisation done according waist circumference cut-off for Asians (307).

6.3.4 Body fat percentage

The mean body fat percentage of the participants (Figure 6.6) reflected the similar findings on the other anthropometry measurements. None of the within and between groups difference of mean body fat percentage were significant. There were 88% e-intervention participants and 71% of the control group with high body fat percentage at baseline, and the body fat remained consistently high until end of the study (Table 6.5).

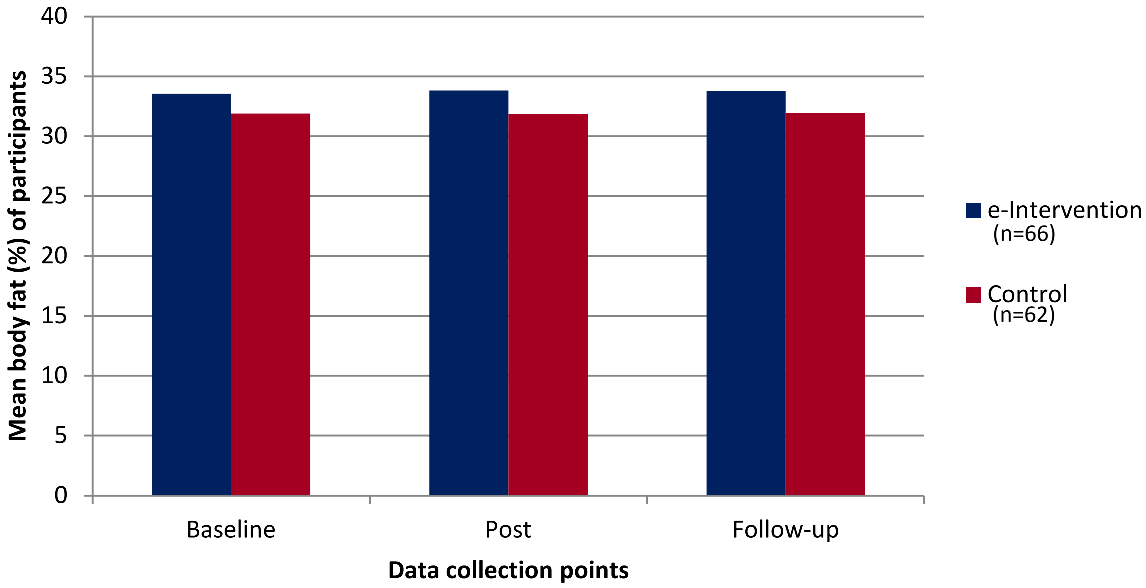


Figure 6.6: The mean body fat percentage of participants in the e-intervention and control groups at various data collection points.

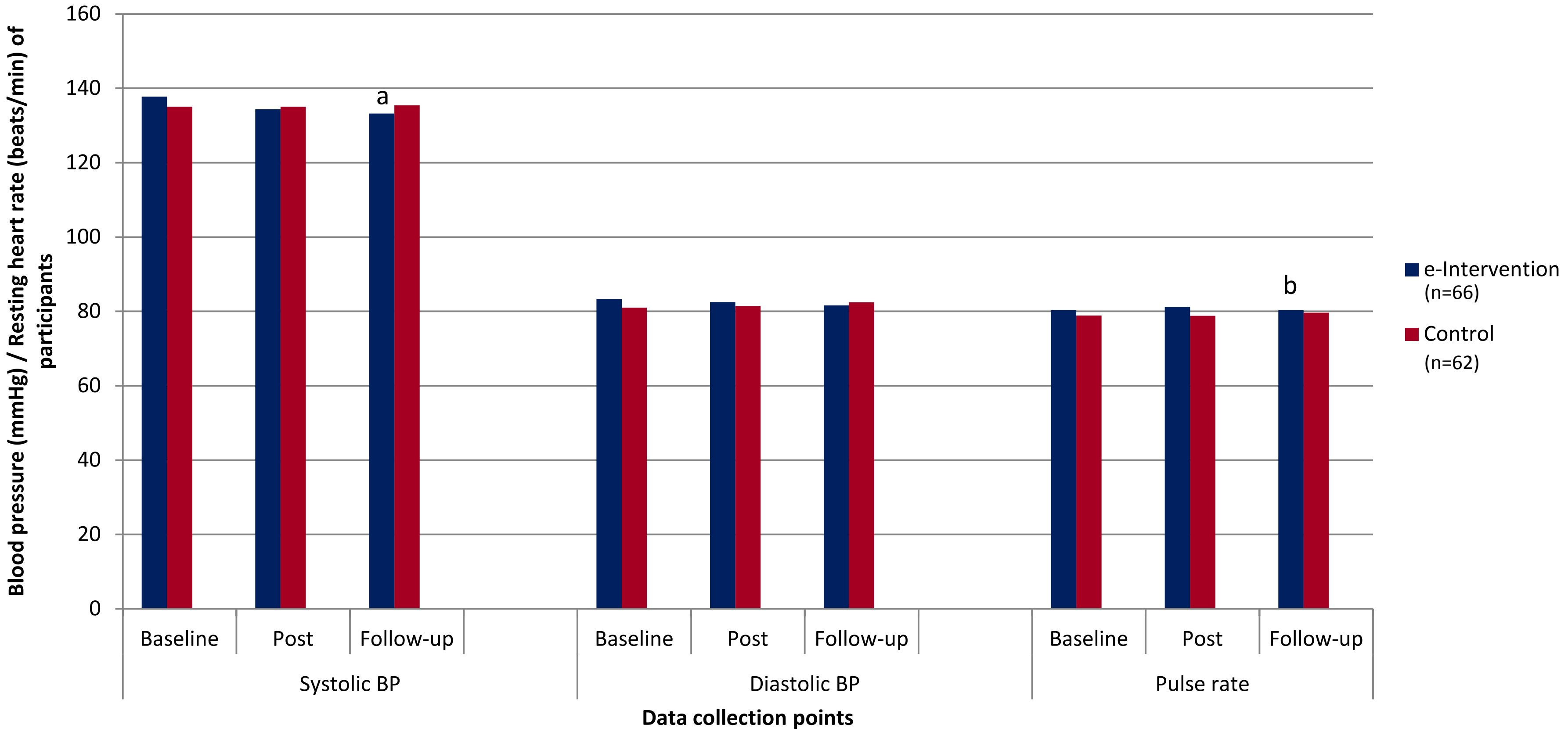
Table 6.5: Descriptive presentation of categories of body fat percentage of the participants at various data collection points.

Category of body fat percentage	**e-Intervention**			**Control**		
	Baseline n (%)	**Post n (%)**	**Follow-up n (%)**	**Baseline n (%)**	**Post n (%)**	**Follow-up n (%)**
Normal	1 (1.5)	0 (0.0)	0 (0.0)	3 (4.8)	4 (6.5)	4 (6.5)
Slightly high	7 (10.6)	7 (10.6)	8 (12.1)	15 (24.2)	13 (21.0)	13 (21.0)
High	58 (87.9)	59 (89.4)	58 (87.9)	44 (71.0)	45 (72.6)	45 (72.6)

Notations: Categorisation was done according to the classification by Gallaghar et al. (310)

6.4 Blood pressure and resting heart rate

The means systolic blood pressure of the participants in the e-intervention group showed a slight but significant decrease at follow-up compared to the post-intervention ($p<0.05$). There was no significant change in the diastolic blood pressure within and between both groups, but the resting heart rate of the e-intervention group reduced significantly at follow-up ($p<0.05$). Figure 6.7 presents the blood pressures and resting heart rate of the participants.



Notations:

a : p = 0.036; post-intervention vs. follow-up in e-intervention group

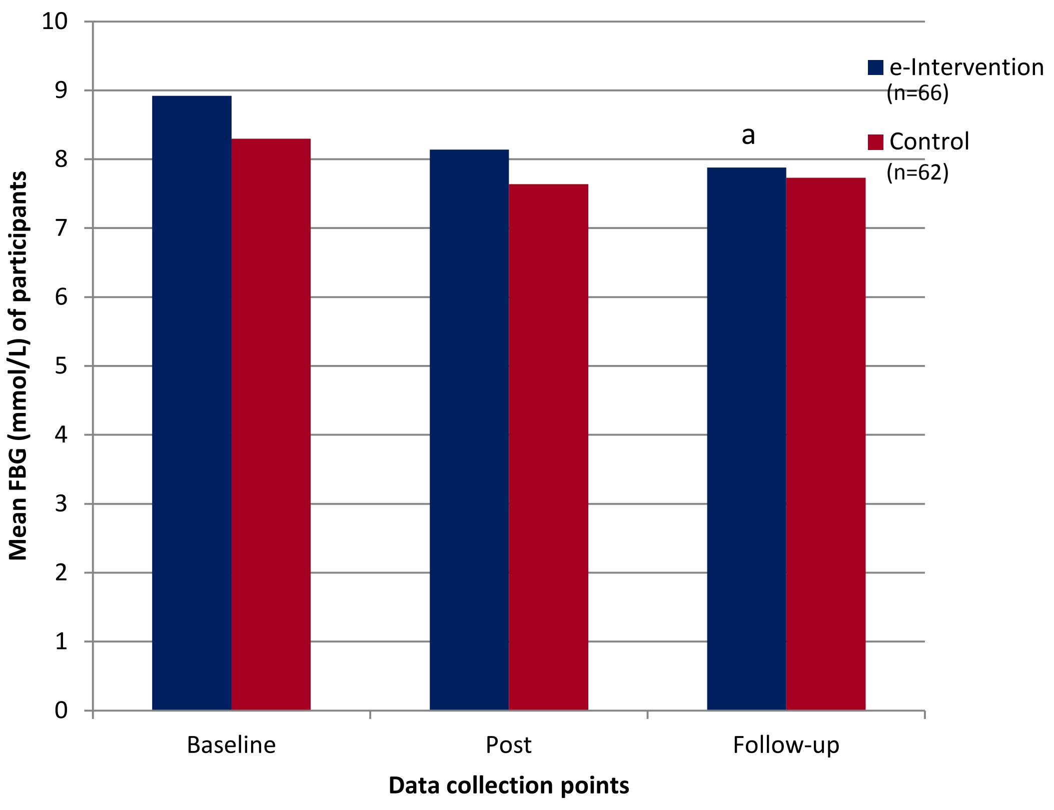
b : p = 0.043; post-intervention vs. follow-up in e-intervention group

Figure 6.7: The mean blood pressure and resting heart rate of participants in the e-intervention and control groups at various data collection points.

6.5 Blood biomarkers

6.5.1 Fasting Blood Glucose

There was decreasing trend in the mean fasting blood glucose (FBG) across the data collection points in both groups (Figure 6.8). The mean FBG has decreased from 8.92mmol/L (SD=3.92) at baseline to 7.88mmol/L (SD=2.47) at follow-up in the e-intervention group, and from 8.30 (SD=2.87) to 7.73 mmol/L (SD=2.62) in the control group. Although there was no significant change in FBG between the study groups, the Bonferroni post-hoc analysis showed a significant changes at follow-up compared to post-intervention in e-intervention group ($p<0.05$). No significant change was found within the control group.



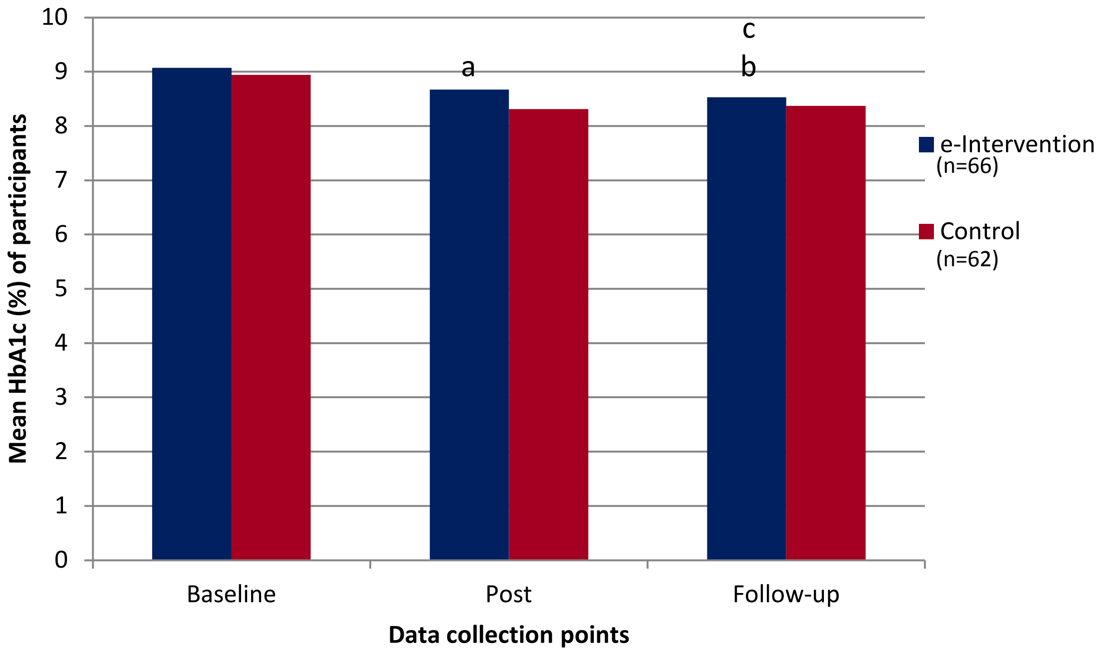
Notations:

a : p = 0.013; post-intervention vs. follow-up in e-intervention group

Figure 6.8: The mean fasting blood glucose of participants in the e-intervention and control groups at various data collection points.

6.5.2 Glycosylated haemoglobin

The glycosylated haemoglobin (HbA1c) showed a similar decreasing pattern to the FBG (Figure 6.9). The mean HbA1c of the *e*-intervention group has significantly decreased by 0.5% at post-intervention and 1.5% at follow-up as compared to the baseline ($p<0.05$). There was no significant difference in the changes between groups and within the control group.



Notations:

a : p = 0.013; post-intervention vs. baseline in e-intervention group
b : p = 0.025; follow-up vs. baseline in e-intervention group
c : p = 0.036; follow-up vs. post-intervention in e-intervention group

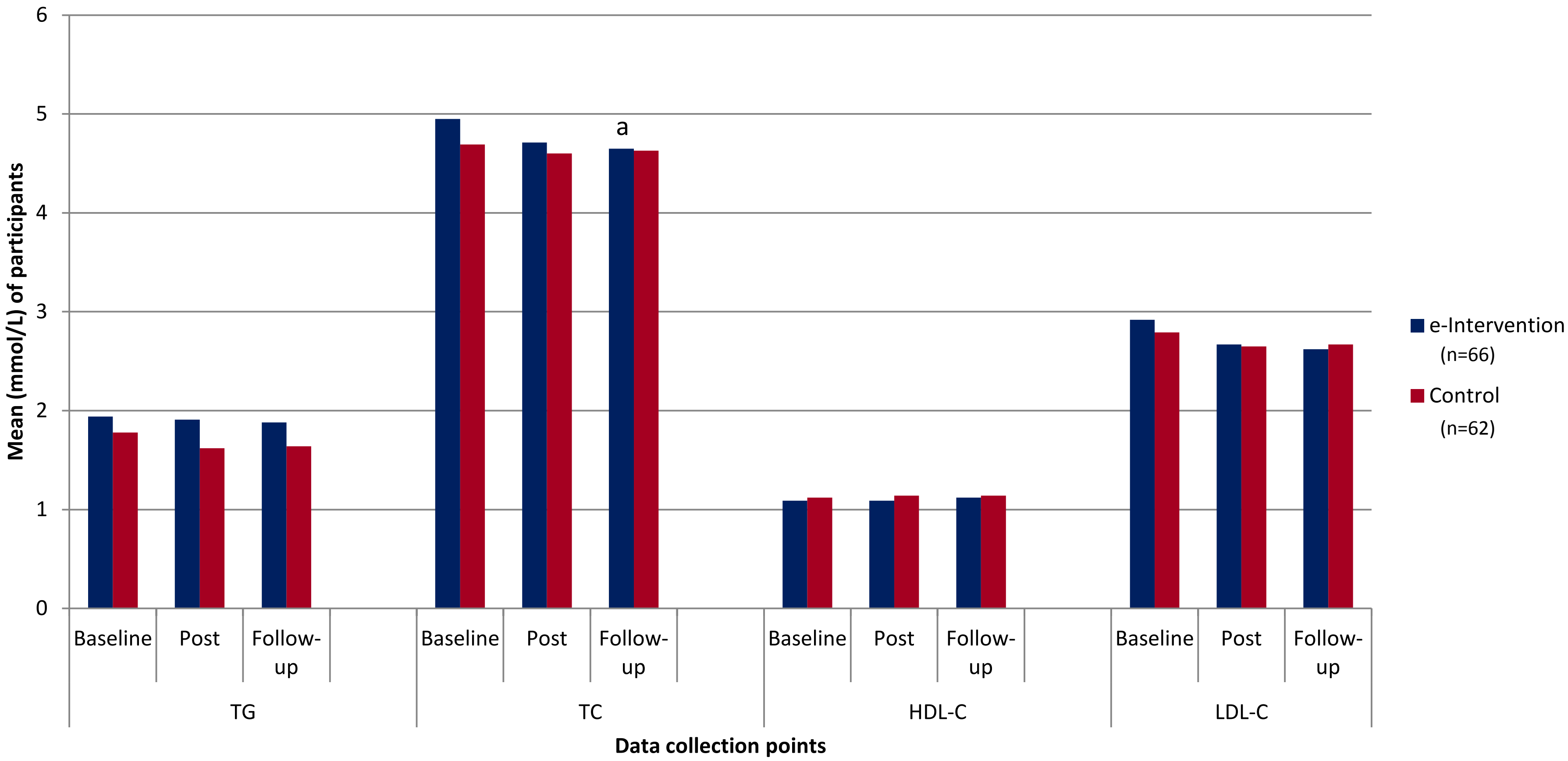
Figure 6.9: The mean glycosylated haemoglobin of participants in the e-intervention and control groups at various data collection points.

6.5.3 Lipid profile

There was no significant difference found between lipid profile of e-intervention group and control group (Figure 6.10). However, there was a significant difference in total cholesterol (TC) within e-intervention group at follow-up compared to the post-intervention ($p<0.05$). The triglyceride (TG) level in the control group increased slightly at follow-up compared to post-intervention ($p<0.05$).

6.6 Summary

The GLM analyses revealed that the mean DSOC score between groups was found to be significant different ($p<0.05$) at post-intervention. The consumption of protein and carbohydrate-containing foods, FBG and HbA1c however, showed a significant decrease at follow-up compared to post-intervention in e-intervention group ($p<0.05$). There were no significant changes in all anthropometry measurements between and within the study groups.



Notations:
a : p = 0.043; post-intervention vs. follow-up in *e*-intervention group

Figure 6.10: The mean lipid profile of participants in the e-intervention and control groups at various data collection points.

CHAPTER 7

PROCESS EVALUATION

Process evaluation was conducted in the e-intervention group at post intervention to evaluate the adherence of the intervention participants to the programme and their level of satisfaction towards the programme.

7.1 Adherence

The adherence to the intervention programme was measured by the frequency of logins and the duration spent in each module (Figure 7.1). There is a decrease in both the login frequency and minutes spent as time progressed. The mean frequency of login when the Module 1 (carbohydrate) was launched, was 1.9 (SD=0.2), with 13.1 minutes (SD=3.5) spent at the website. Gradually, the figures declined to 1.0 logins (SD=0.1), with 6.1 minutes (SD=2.5) spent at the website when the final module was launched. On the average, the login frequency was once, with about 11 minutes spent surfing the website.

7.2 Process evaluation

The evaluation was conducted on 58 participants who have logged into the website at least once every two weeks during the intervention period. The response rate for the process evaluation was 94%. The process evaluation of the website was sectioned into content satisfaction, acceptability and usability (Table 7.1).

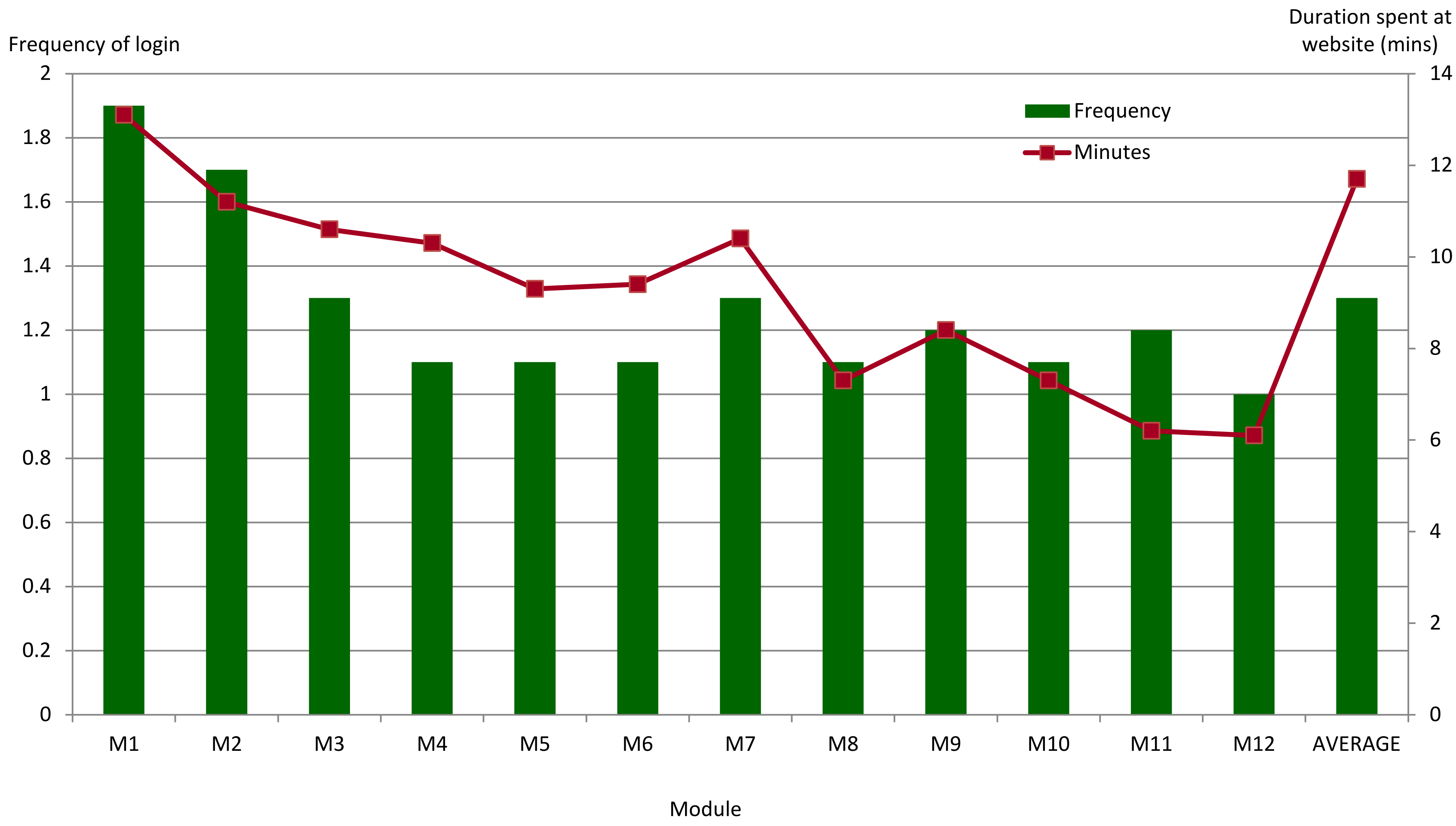


Figure 7.1: Frequency of logins and duration spent at the website.

Table 7.1: Scores of each sub-category of process evaluation of *my*DIDeA.

Process evaluation		Mean score + SD	Range
Content satisfaction	Performance expectancy	75.34 + 23.17	20 – 100
	Effort expectancy	55.17 + 14.02	35 – 100
	Patient – cantered factors	77.20 + 13.87	50 – 100
	Total	**69.24 + 8.32**	**48 – 85**
Acceptability	Attitude towards technology	72.20 + 22.75	20 – 100
	Anxiety	48.98 + 23.39	20 – 100
	Self-efficacy	73.90 + 24.71	20 – 100
	Behavioural intention	76.27 + 17.90	40 – 100
	Total	**66.97 + 9.32**	**49 – 89**
Usability	Facilitating conditions	85.59 + 10.38	70 – 100
	User-friendliness	82.80 + 12.40	55 – 100
	Total	**83.73 + 10.88**	**60 – 100**

Content satisfaction explored three factors (performance expectancy, effort expectancy and patient-centred factors) that could influence the participants' fulfilment of using the website. The average score for the content satisfaction was 69% with the 'patient-centred factors' scoring the highest (77%). The lowest score was for the effort expectancy (55%), which rated their satisfaction for effort they have to put to use the website. The participants rated the performance expectancy at 75%.

There were four factors explored to determine the acceptability of the website – attitude towards technology, anxiety, self-efficacy and behavioural intention. The acceptability of the website was rated at 67%. While the behavioural intention to use the website in the future scored highest (76%), the participants scored low in anxiety, which reflected their apprehensiveness in using the website (49%). The patients' attitude towards technology and self-efficacy in using *my*DIDeA scored 72% and 74%, respectively.

The usability of the website was rated highly (84%) based on the facilitating conditions and user-friendliness. The facilitating conditions of *my*DIDeA were scored at 86%, while the user-friendliness of the website was rated 83%.

In summary, the high rating of the content satisfaction, acceptability and usability supported the use of *my*DIDeA in disseminating dietary information and encouraging the dietary behaviour changes.

CHAPTER 8

DISCUSSION

8.1 Characteristics of the participants

There were 128 patients with Type 2 Diabetes Mellitus (T2DM) recruited into the randomised-controlled trial (RCT) (n=66 in e-intervention group and n=62 in control group). The recruitment of the study participants were conducted in outpatient clinic of three tertiary hospitals in Klang Valley. Clinical setting has been a common ground for the selection of study samples in diabetes-related studies, mainly for its convenience in capturing suitable study subjects.

The mean age of the participants was 50.5 years, with majority of them in their 50's, which is younger than the reported age group (60 - 64 years old) by the third National Health Morbidity Survey (NHMS III) (27). This is probably due to the nature of this study, which recruited only those with Internet access and generally, Internet users are of a younger age group. This was also shown in other web-based diabetes researches (288, 291). The study participants comprised by the majority Malay, the biggest ethnic group in Malaysia. Although the composition of the study sample is different compared to the ethnic composition reported in NHMS III (27), which reported the prevalence to be highest among Indian, the pattern is similar to other published clinical studies (313-314). This could be due to the fact that majority of the patients visiting the selected outpatient clinics consisted of mainly Malay community. The income was on the higher side, with average monthly income of more than MYR5,000 per month. However, the high income is consistent with the tertiary level education and the employment status of majority of the participants.

The average duration of diabetes was eight years, with almost 50% of them were being treated on oral hypoglycaemic agents (OHA). Fell et al. (291) reported similar characteristics of D-Net study participants, where the mean years of diagnosed was nine and a half years and 53% of them were taking OHA. More than three-quarter of the *my*DIDeA participants reported to monitor their blood glucose, revealing high awareness of the importance of self-monitoring blood glucose (SMBG) in diabetes management. However, only 11.7% of them self-monitor their blood glucose once daily. The percentage was lesser than the reported 16.5% of daily self-monitoring in Malaysians (315).

More than 80% of the participants had family history of diabetes among their immediate family members. There was high percentage of self-reported history of hypertension and dyslipidaemia among the study participants. This is reasonable, as family history is one of the unmodifiable risk factor of diabetes, while hypertension and dyslipidaemia are common co-morbidities in people with T2DM.

Only T2DM patients with access to the Internet were recruited into the study. However, the baseline data revealed only 17% of them used the Internet to seek for health-related information. This figure is far lower than the reported 52% of participants with diabetes using Internet to seek for health information in the United States (316). Based on previous study, physical illness and nutrition/fitness were the most common area of online search among patients who seeks health information in the Internet (317).

8.2 The primary outcome

The Dietary Knowledge, Attitude and Behaviour (DKAB) score was the primary outcome of this study. This section will first discuss the validation of the Dietary Knowledge, Attitude and Behaviour Questionnaire (DKAB-Q) which was used to score the participants. The DKAB score obtained by the participants and its sub-domains will be then discussed and finally, the findings from this study will be compared to the previous published studies.

A validated questionnaire (DKAB-Q) was used to record the score at baseline, post-intervention and follow-up. The 36-item questionnaire was sectioned to the sub-domains of knowledge, attitude and behaviour, which were analysed separately. The DKAB-Q was developed based on twelve dietary lesson plans identified to be important components in the dietary management of patients with T2DM. The validation process of DKAB-Q has been described in Section 3.9. The questionnaire has showed good internal consistency and reliability as showed by Cronbach's Alpha (CA) and Intraclass Correlation Coefficient (ICC) of more than 0.70. The DKAB-Q was concluded to be diabetes-specific, as there was a better item-to-total correlation and consistency in the mean DKAB and sub-domain scores in patients with T2DM compared to healthy individuals.

Although there are few valid and reliable psychometric tools for the measurement of outcomes of diabetes education (318), these tools are not dietary-specific. The lack of tools in assessing dietary management of diabetic patients supports the use of DKAB-Q as a vital instrument in assessing diabetic patients' perception on the role of diet in management of T2DM.

In this intervention study, significant increase in mean DKAB score in the e-intervention group, comparing baseline to post-intervention and follow-up was found. Similar pattern was shown by the control group, but the increase in the DKAB score was much higher in e-intervention group. Continuous education through the *my*DIDeA website on various lesson plans has shown a positive impact on the DKAB. The intervention programme had successfully assisted the participants to achieve a better DKAB score, possibly by accelerating the learning process. Recommendations based on the patients' current Stage of Changes (SOC) probably gives a more valid and do-able suggestions, leading to improvisation of the DKAB scores.

On the other hand, the control group could have possibly scored higher in the post-intervention and follow-up as the fact that they were being followed-up could have increased the likelihood of them seeking for health information on their own. Besides, this is also could be due to the usual diabetes care they were given at the hospital. Unfortunately, it could not be manipulated, as it would be unethical to restrict the control group from receiving any usual care and diabetes education given in the hospital. However, this should not be a matter of concern as the participants in the e-intervention would have also received and subjected to similar care and diabetes education in the hospital. The fact that the e-intervention group scored much higher DKAB score than the control suggests that, receiving additional education through *my*DIDeA could result in a better DKAB.

The sub-domains of dietary knowledge and attitude were also found to differ between groups and across the study period. Similar to the total DKAB score, the knowledge and attitude score of participants in both groups have increased, but those in the e-intervention group have shown a better increase in score compared to the control group. However, only the participants in the e-intervention group have shown significant improvement in the dietary behaviour score at post-intervention and follow-up. This demonstrates that although there were positive changes in knowledge and attitude in the control participants, it did not result in behavioural change.

However, most of the available diabetes Knowledge, Attitude and Behaviour (KAB) or Knowledge, Attitude and Practice (KAP) do not focus solely on diet. While this made the outcome comparison to be more difficult, it also showed the importance of administering a validated questionnaire solely to assess the dietary education for people with diabetes. The questionnaire, which was developed closely with *my*DIDeA's dietary module, measured the impact of the intervention on the primary aspects of dietary KAB.

The encouraging improvement in knowledge score of the e-intervention participants showed that the intervention was successful in conveying the necessary dietary information, comprehension and skill of the participants. The improvement in dietary knowledge was the first level of success for *my*DIDeA. The intervention programme was also found to improve the attitude score of the participants, which reflected on positive reaction to the knowledge provided. The improvement of behaviour score in the e-intervention group, further emphasize the success of *my*DIDeA and it shows that the web-based dietary intervention programme can propagate positive change in dietary behaviour.

A study by Ambikapathy et al. (313) found that an increase in knowledge would increase attitude, though it may not be reflected in the practice, and a better-structured diabetes educational programme is needed for this purpose. Similar finding was reported by Bazata et al. (319), who showed majority of the T2DM patients did not translate the existing dietary and lifestyle knowledge into behaviour. A more comprehensive dietary education programme that addressed barriers such as lack of support from family and health services, and dietary myths (201) could result in a better changes in dietary behaviour. A successful programme should also take into consideration factors such as meal planning, self-monitoring, dietary self-efficacy, social support and time management (196, 200, 320), and deliver it through trained professionals such as such as dieticians or nutritionists (57).

In summary, *my*DIDeA was a successful intervention programme to improve the overall DKAB score, aided by the improvement in the knowledge and attitude sub-domains. However, other issues such as addressing the barriers, altering the study duration, making use of other health components, inclusion of self-monitoring and more intense and individualised intervention would have made a difference in the behavioural aspect.

8.3 The secondary outcomes

8.3.1 Dietary Stages of Change score

The Dietary Stages of Change (DSOC) score was one of the secondary outcomes of this study. Similar to the primary outcome, this section will first discuss the validation of the Dietary Stages of Change Questionnaire (DSOC-Q). The DSOC score obtained by the participants will be then discussed and finally, the findings from this study will be compared to the previous published studies.

A validated questionnaire (DSOC-Q) was used to determine the changes in DSOC score of the participants. It was a 60-item questionnaire conceived based on the twelve dietary lesson plans developed for the intervention programme. The questions were designed so that it complements the recommendations given in the intervention. The validation process of DSOC-Q has been described in Section 3.10. The questionnaire has showed good internal consistency and reliability as showed by CA of more than 0.70, and ICC between 0.69 and 0.90 when it was tested in patients with T2DM. The construct validity also have shown the mean DSOC score differences to be lower in patients with T2DM, suggesting the DSOC-Q to be a suitable measure specifically for patients with T2DM.

The DSOC score was used to determine participants' SOC for each dietary lesson plan, and the recommendations given were strictly based on the score obtained. Based on the total DSOC, there was no participant in the pre-contemplation stage and less than 3% were in the maintenance stage at the follow-up. In addition, majority of the participants were in the action stage regardless of the study group. The DSOC score itself is a continuous measure of the participants' SOC. The e-intervention group had slightly higher DSOC score compared to control group at the baseline. However, as the study progressed, the DSOC of e-intervention participants exhibited greater increase than the control group.

The participants probably showed higher SOC as majority of them were educated with access to the Internet. It is highly likely that they were aware of the importance of dietary changes in T2DM and trying to change their dietary behaviour. However, without much guidance and intervention it might not be that easy to propagate further from the action stage. The increase in DSOC suggests the intervention, provided was effective in improving the participants' dietary behaviour, as a higher DSOC score reflects a higher level of SOC.

Although this study did not identify significant movement in DSOC, previous studies have reported significant movement in the SOC after the intervention programme. Significant improvement in the SOC was seen in herbs, sweeteners and carbohydrate consumption (240), and dietary fat intake (321) after dietary intervention programme in people with T2DM. Clark and colleagues (321) associated the movement in SOC with a trend towards decreased barriers to change but not with increased self-efficacy. However, Kasila et al. (243) highlighted that T2DM patients' SOC varies according to dietary areas and within the dietary habits. As such, studies would exhibit different outcome according these variability. The SOC construct will be more useful when used together with other TTM measures such as decisional balance and self-efficacy in developing a more well-rounded intervention programme (247).

In summary, the study did find an increasing DSOC score among intervention participants though the increase was not statistically significant. Excluding patients in the action or maintenance stage, and including only those in the pre-contemplation or contemplation stage could be a good option to focus the intervention on those absolutely needing it. Such measures would allow the researchers to investigate the possible movement in SOC. Besides, other domain of SOC such as process of change and decisional balance should also been taken into consideration in the development of the intervention.

8.3.2 Food intake

The food intake of the study participants were assessed based on the dietary and supplement intake. The dietary intake of the participants was determined based on the mean servings of selected food groups, while the supplement intake measured the consumption of addition vitamins, mineral and herbs. In this section, the food intake of the study participants will be discussed and compared with findings from the literature.

The e-intervention group showed a significant decrease in the consumption of vegetables carbohydrate- and protein-containing food at follow-up compared to baseline. Yet, no significant difference in the dietary intake was found between the e-intervention and control group. The study also did not find any significant change in supplement intake within and between the study groups.

The findings were consistent with the increase in the DKAB score among T2DM patients in the e-intervention group. However, dietary practices may require more time to show any significant changes between groups. The decrease in carbohydrate consumption in *my*DIDeA could be due to adoption of low carbohydrate diets (LCDs), which is common among people with diabetes and the awareness that simple carbohydrate may affect the blood glucose control. This could also be the reason why the intake of carbohydrate was lower than the general recommendation of five to six servings. The participants of *my*DIDeA, however, recorded a very low intake of fruits and vegetables at an average of two servings a day. This was far lesser than the usual recommended five to seven servings a day. Some participants revealed that they are still hesitant to consume fruits, especially due to the concern that it will raise their blood glucose level. It is also understandable that the intervention programme did not show an effect on the supplement intake, as the programme was not designed to assist any increase in supplement intake but rather improve the overall dietary practice.

Some of the findings of *my*DIDeA are supported by other studies. Reduction in carbohydrate consumption is also commonly reported in diabetes-related dietary education programme where EnBalance is one of such programme (322). Dissemination of dietary knowledge would lead to changes in dietary behaviour and this was shown by De Vriendt et al. (199) in a study among non-diabetic subjects. The findings from that study has emphasised on the importance of dietary education to improve the consumption of fruits and vegetables. Behavioural intervention programme delivered online also have shown to improve the consumption of fruits and vegetables (267).

*my*DIDeA has been successful in showing the positive trend in decreasing carbohydrate and protein intake. While the reduction in carbohydrate and protein-servings supported the web-based intervention programme, more vigorous intervention strategies are needed to improve the fruits and vegetables intake. Care should be taken to address the concern on the effect of fruits and vegetables on the blood glucose level, dealing with the popular myths surrounding fruits and vegetable intake, and diabetes.

8.3.4 Anthropometry measurements

The anthropometry measurements were taken at the baseline, post-intervention and follow-up intervention sessions. Body weight, body mass index (BMI), waist circumference (WC) and body fat percentage were the secondary outcomes of interest. In this section, the outcome of anthropometry assessments of the study participants will be discussed and compared with findings from the literature.

There were no significant changes in weight, BMI, WC or body fat percentage across the data collection points and between study groups. However, an alarming portion of the *my*DIDeA study participants was obese. Measured using BMI categorisation for Asians (308), more than three quarter of the participants were obese. This finding was re-confirmed by high percentage of them having WC and body fat more than normal levels.

It is possible that such effect could not be shown in *my*DIDeA as the study was not designed towards weight loss, and high percentage of the participants obese in the beginning of the intervention. Based on the National Health Morbidity Survey (NHMS III), the highest prevalence of obesity is in the 45 – 49 years and 50 – 54 years age groups (27). This is consistent with the demography of the study participants, who mostly belonged to these two age groups. Besides, the current diabetes treatment including all types of OHA except metformin, and insulin treatments are known to cause weight gain.

The high percentage of obesity among this study participants is supported by another Malaysian study by Ming and Rahman (198). The authors, using the WHO cut-offs for obesity, classified 66.8% to be overweight and 15.8% to be obese. An audit by Mohamed and Diabcare-Asia Study Group (323) of patients profile in the year 1998 and 2003 cohorts found 95% of them were diagnosed with T2DM and were obese. Interestingly similar non-significant impact of intervention programme on body weight was reported by a small pilot study by Yannakoulia et al. (202). However, this could be due to the high dropout rate reported at the one-year follow-up data collection in the study.

On the other hand, Veverka and colleagues (263) showed that dietary web-based and stage-tailored interventions have been shown to have beneficial effects on weight, BMI and body weight in healthy individuals. Combined or multifaceted web-based intervention had been successful towards weight loss in people with or at risk for diabetes (22, 34). Meta-analyses have shown beneficial effect of weight loss interventions in people with T2DM (324-325). Although small pooled weight loss of 1.7 kg was found, multi-component interventions including very low calorie diets or low calorie diets may result in a better weight loss in adults with T2DM (325).

While scope of *my*DIDeA was not focused on weight management, there is a potential for such study to be conducted in the future. Future study with emphasis on weight management among obese T2DM patients, along with a dietary education programme would be beneficial.

8.3.5 Blood pressure and blood biomarkers

Blood pressure and selected blood biomarkers were another group of secondary outcomes of this study. The blood pressure and resting heart rate were taken at the baseline, post-intervention and follow-up intervention sessions, while the blood biomarkers were obtained from the patients' medical records. Blood biomarkers – glycosylated haemoglobin (HbA1c), fasting blood glucose (FBG) and/or total cholesterol (TC) were the most commonly reported outcome measures of web-based interventions in the management of T2DM (35). In this section, blood pressure, resting heart rate, HbA1c, FBG and the lipid profile of the study participants will be discussed and compared with findings from the literature.

There were small but significant reductions in the FBG (-1.5mmol/L) and HbA1c (-0.5%) of the e-intervention participants at follow-up, though no significant changes were detected between groups. The TC was reduced by 0.30 mmol/L in the e-intervention group at follow-up, though no significant between group changes was detected. There were no significant changes in the other lipid markers. In addition to the blood biomarkers, the e-intervention group reported a slight drop in the systolic blood pressure and resting heart rate at follow-up. Yet, there was no difference found between groups.

The HbA1c is a known better indicator of glycaemic control than FBG as it shows the control over the past three months. Based on the outcome of *my*DIDeA, the participants of the e-intervention group have shown a clinically significant reduction in the HbA1c level. This shows that the e-intervention through *my*DIDeA website was able to help the participants to achieve better glycaemic control. Apart from that, concurrent slight reduction in FBG, TC, systolic blood pressure and resting heart rate also supports the role of e-dietary intervention in patients with T2DM. However, longer duration of intervention is necessary to show more clinically significant changes in the blood pressure and biomarkers. In addition, medication therapy and exercise also plays an important role in showing these changes.

Although there is no quality data to support the clinical efficacy of online dietary intervention in improving glycaemic control among people with T2DM, some reviews have suggested improvements in FBG, HbA1c and diabetes knowledge, besides reducing blood pressure, weight and need for medication (274, 299, 326) following the intervention programme. The reduction in FBG and HbA1c in *my*DIDeA is comparable to the findings from other web-based lifestyle interventions, which reported a reduction of 0.78mmol/L of FBG and 0.19% to 0.59% of HbA1c in patients with T2DM (15, 34). Website-based SMBG interventions have also suggested improvement in both glycaemic control and lipid markers (19, 281).

The decreasing trend in HbA1c, FBG and TC in *my*DIDeA is encouraging, and it can be anticipated that with longer duration of follow-up and regular reinforcement, better and clinically significant glycaemic control and improved lipid profile could be achieved.

8.4 Process evaluation

The adherence to the programme, and overall satisfaction and attitude towards the intervention were evaluated at post-intervention stage. The adherence to the intervention programme was measured by the frequency of logins and the duration spent in each module. In addition to adherence, process evaluation of the website was determined through a short questionnaire at post-intervention data collection. In this section, findings on the adherence and process evaluation of the website will be discussed and compared with the literature.

On the average, each participant logged in the website once a week and spent 11 minutes surfing the content. However, the login frequency and the time spent per visit declined over the time. This is understandable as the participants were inclined to read only the lesson plans as they progressed, as other pages were static. The satisfaction and attitude process evaluation supported *my*DIDeA in terms of content satisfaction, acceptability and usability.

Generally, web-based interventions showed positive effects on patients' empowerment (327). Published articles on the process evaluation of web-based interventions are scant. Such process evaluation has been conducted for the Australian Physical Activity Network (AusPAnet) (328). The process evaluation of the communication web portal was done by monitoring the e-mails created and by evaluating self-reported perception, satisfaction and usefulness of the web portal. Over the time, the portal experienced attrition and this could be captured by the evaluation.

McConnon et al. (329) reported the process evaluation of a website designed for weight control for obese participants. Similar to the findings of *my*DIDeA, the frequency of log-in and the average time spent on the website per visit have declined over the period of 12 months. The general satisfaction score for the website was positive with social support getting the lowest rating. Process evaluation of SHED-IT, another weight control website for men reported similar adherence and programme evaluation strategies(330).

There were process evaluations done on dietary and lifestyle web-intervention, though it was not confined to intervention in people with T2DM. Process evaluation of an healthy eating website promoting the Mediterranean diet also used the same measures of adherence and programme evaluation, but added another feature of focus group interview to obtain qualitative feedback on the programme (331). Similar focus group discussion was used by Steele et al. (332) besides the evaluation of satisfaction and usability of a physical activity website.

In summary, the process evaluation of the intervention programme was found to be sufficient and captured the details of web usage and programme satisfaction. The future studies should look into enhancement of such website by making it more interactive with platform for the participants to discuss their obstacles and success stories, share ideas and motivate each other in following the dietary advices. This also could stimulate their interest to login and stay longer in the website.

8.5 Summary of the findings

The module was designed according to the established guidelines and recommendations, while the study website was developed using standard and well-known methods. In comparison with the conceptual framework discussed earlier in Chapter 2, *my*DIDeA has successfully improved the DKAB of the intervention participants. While, the improvement in DKAB could have lead to the improvement in DSOC and dietary practices, there were no statistically significant trends observed. While restricting the intervention to those in the pre-contemplation stage and competition stage, and including other aspects of TTM, a better dietary practice could have achieved. Similarly, anthropometry measurements and biomarkers did not exhibit significant difference between the study groups, except for some improvement in blood biomarkers (FBG, HbA1c and TC) in the e-intervention group. However, with a longer, more intensive and weight management-focused intervention, these objectives could be achieved.

8.6 Strength of the study

The increasing government's effort to popularise high-speed broadband and Internet in general, has already resulted in an increasing Internet penetration in Malaysia. While the use of Internet to educate patients is fairly a new area of clinical and research interest in Malaysia, there is a wide scope for such education programme to be incorporated into the existing healthcare system.

Patients were recruited in the clinical setting and all data collections were carried out in the clinics when they turned up for their follow-up treatment. The participants were not required to come to the hospital specifically for data collection purpose, unless they have missed their appointment. This was to ensure lesser burden to the patients and this perhaps has resulted in better compliance to the intervention programme.

The selection of patients with DKAB score of less than 50% and HbA1c of more than 7% meant that only those in dire need of dietary education to improve their glycaemic control were included in this RCT. This offered a teachable moment for the researchers, and detection of significant changes in important outcome measures.

The intervention programme has merged four widely accepted guidelines and recommendations for patients with T2DM (48, 74, 154, 333). This has facilitated the researchers to diversify the content of the intervention by incorporating the international recommendations and local guidelines into one programme. Most of the dietary factors specified in the guidelines have been explored and included in the intervention programme without sounding 'too scientific'. The content of the intervention has also been adapted to suit the local culture. For example, various types of local dishes were included in the modules, while giving them culturally and religiously sensitive options.

This is one of the few web-delivered dietary interventions for patients with chronic disease. Being a web-based study, the intervention was flexible to the participants' time. Besides, the reinforcement with e-mail and subsequently SMS reminder has been helpful to keep the compliance high. This has paved the path for more studies focusing on dietary aspects in the future. The outcomes from this study could be used to strengthen the diabetes management and/or chronic disease management as whole.

8.7 Limitation of the study

The demography of patients may not reflect the country's population but is representative of the current scenario in public hospitals in Malaysia. Besides, the study only looked at one segment of the population with access to the Internet. However, the Internet boom is expected to happen in this country with government's initiative of introducing free WIFI in certain parts of the country, the high speed-broadband UNIFI and 4G technologies. Use of smart phones also have increased and webs could be accessed anywhere.

The web system only managed to track the login frequency and time spent in the website. Other feature such as 'e-Mail the Nutritionist' was not extensively used.

In *my*DIDeA, the improvement within the SOC is commendable, but the movement between SOC was not obvious due to the fact that no or few participants fell in the two extreme categories of SOC. While patients could have been screened to exclude those in the action and maintenance categories, this could have restricted the pool of study sample and made the recruitment more difficult.

The intervention programme development had only utilised the SOC in the intervention design. Other construct of Transtheoretical Model (TTM) could be used and these constructs have been shown to be more effective than using just SOC alone.

Based on the feedback received from the participants, the two weeks' gap between modules was considered too long. It was initially meant for the patients to adapt to the recommendations and make necessary changes before the next module and not to rush them.

As the questionnaire was designed to be interviewer-administered, some participants may not have honestly answered the questions. They might want to give answers that they feel appropriate or answers which they think the researchers needs. However, data enumerators independent to the research were recruited to collect the data to minimise the researcher-bias in this study.

As the study was conducted for a long period (12 months) among patients with uncontrolled diabetes, there is a possibility for changes to be made to the standard treatment given by the attending physician. While this may confound the study results, the randomised study design is expected to eliminate or control this possible confounder.

The analyses presented here have been controlled for all the possible confounding factors as identified in the literature. However, it is still possible that other nutritional or lifestyle factors have yet to be identified which may confound this relationship.

8.8 Directions for future research

Future web-delivered interventions should include more features to assess the usage of the web component. Clicks on the links and record of pages visited are examples of tracking system that could be included. The use of online forums would encourage the participants to discuss their dietary issues with their 'peers' and this could form a strong social support network. As the structure of this website did not encourage the use of other communication features such as 'e-Mail the Nutritionist', future studies should also encourage the communication between researchers and participants via the website.

While the anxiety of the participants in using a new system is understandable, the future researchers could prepare the participants to use the system by offering short workshop on the web usage at the beginning of the intervention. As the two weeks gap between the module updates was deemed too long, future studies following the similar style to *my*DIDeA could opt for a shorter break between updates.

Self-monitoring is one aspect that could determine the success of an intervention. Web-based interventions should include an option for the patients to input their blood sugar levels, dietary intake or other measures to encourage interactivity and self-monitoring behaviour.

*my*DIDeA has demonstrated that the intake of fruits and vegetables were below the recommendation. In the future studies, emphasis should be given on fruits and vegetables, as these are major sources of micronutrients and beneficial phytochemicals, the emphasis should be given in future studies.

Besides self-monitoring and emphasis on fruits and vegetables, inclusion of a component of weight loss in the intervention programme would have been appropriate in investigating for the impact of dietary changes in weight loss, and subsequently resulting in better glucose control in people with T2DM.

The use of behavioural theories is essential to ensure the intervention programme is scientifically sound. Besides using the SOC model, other constructs of TTM could be incorporated into the development of the intervention. Some complex studies have utilised more than one behavioural theory in their design, and this option could be explored as well.

CHAPTER 9

CONCLUSION

*my*DIDeA was a 12-months two-armed randomised controlled trial (RCT) conducted among 128 patients with Type 2 Diabetes Mellitus (T2DM) recruited from three tertiary public hospitals in Klang Valley, Malaysia. The study commenced in November 2009 after obtaining the ethical approvals from relevant authorities, and the trial has been registered with Clinicaltrials.gov (NCT01246687). The primary outcome was the Dietary Knowledge, Attitude and Behaviour (DKAB) score, while the secondary outcomes included the food intake, anthropometry measurements, blood pressure and resting heart rate, blood biomarkers and the Dietary Stages of Change (DSOC) score.

After being screened for eligibility and baseline data collection, the participants were randomised into the e-intervention (n=66) or the control (n=62) group. The e-intervention group received an intensive dietary intervention through the study website, personalised according to the participants' DSOC, in addition to the usual standard treatment at the outpatient clinics. In contrast, the control group received the usual standard treatment given to patients with T2DM, and did not receive the website login information, or any reinforcement via e-mail or SMS.

The average age of the participants was 50.5 years old, with majority of them in their 50's. The study participants comprised by the majority Malay. The average monthly income of the participants was almost RM5,200 and consistent with the tertiary level education and the employment status of majority of the participants. The average duration of diabetes was eight years, with almost 50% of them on oral hypoglycaemic agent (OHA) therapy. More than three-quarter of the participants reported self-monitoring of their blood glucose (SMBG). More than 80% of the participants had family history of diabetes among their immediate family members. There was high self-reported history of hypertension and dyslipidaemia among the study participants. Although only T2DM patients with access to the Internet were recruited into the study, the baseline data revealed only 17% of them used the Internet to seek for health-related information.

Although there were significant increases in the DKAB and all sub-domains within both groups, the participants in the e-intervention group had significantly higher score of DKAB, knowledge and attitude at post-intervention and follow-up. There was a significant increase in the dietary behaviour score in the e-intervention group, but not in the control group.

The DSOC score of the e-intervention group was significantly higher at follow-up compared to the controls. The majority of the participants in both groups were in the action stage and no obvious movement of SOC was seen. There was a significant decrease in the consumption of carbohydrate-containing food and protein at follow-up in the e-intervention group, but there was no significant between group changes.

There were no significant changes in body weight, BMI, WC or body fat percentage across the data collection points and between study groups. However, more than three quarter of the participants in both group reported to be obese. There was a slight decrease the systolic blood pressure and resting heart rate of the participants in the e-intervention group at follow-up. Reductions of FBG (-1.5mmol/L), HbA1c (-0.5%) and TC (-0.30 mmol/L) were seen in the e-intervention participants at follow-up, though no changes was detected between groups.

The process evaluation of the study website revealed that on the average each participant logged in the website once a week and spent 11 minutes at the website per visit. The usability (facilitating conditions) scored the highest, while the acceptability (anxiety) scored the lowest.

In summary, *my*DIDeA was successful in improving overall DKAB score by improving the diabetes-related dietary knowledge and attitude of the participants. Besides, the intervention programme also have successfully improved the DSOC score of the intervention group, suggesting the participants were indeed making small but significant progress in changing their dietary behaviour. Improvement in the diet quality (improvement in vegetable intake and reduction in carbohydrate and protein intake), glycaemic control and total cholesterol have added credibility to this web-delivered intervention. Finally, the process evaluation has further supported *my*DIDeA in terms of content satisfaction, acceptability and usability.

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APPENDIX A-1

PEJABAT TIMBALAN KETUA PENGARAH KESIHATAN
OFFICE OF THE DEPUTY DIRECTOR-GENERAL OF HEALTH
(PENYELIDIKAN & SOKONGAN TEKNIKAL)
(RESEARCH & TECHNICAL SUPPORT)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
Aras 12, Blok E7, Parsel E, Presint 1
Level 12, Block E7, Parcel E, Precinct 1
Pusat Pentadbiran Kerajaan Persekutuan
Federal Government Administrative Centre
62590 PUTRAJAYA

Tel : 03 88832543
Faks : 03 88895184

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur

Ruj. Kami : (2) KKM/NIHSEC/08/0804/P09-249

Tarikh : 21 Ogos 2009

Prof Madya Dr Quek Kia Fatt
Tan Sri Jeffrey Cheah School of Medicine
Monash University
Sunway Campus

Tuan

<u>NMRR-09-303-3416</u>
Dietary intervention among patients with type 2 diabetes mellitus : an e-approach

Dengan hormatnya perkara di atas adalah dirujuk.

2. Jawatankuasa Etika & Penyelidikan Perubatan (JEPP), Kementerian Kesihatan Malaysia (KKM) mengambil maklum bahawa projek tersebut adalah untuk memenuhi keperluan akademik Program Kedoktoran bagi Sdri Amutha Ramadas dan telah diluluskan oleh Universiti Monash.

3. Sehubungan dengan ini, dimaklumkan bahawa pihak JEPP KKM tiada halangan, dari segi etika, ke atas pelaksanaan projek ini. JEPP mengambil maklum bahawa kajian ini tidak melibatkan sebarang intervensi klinikal dan hanya akan menggunakan soal selidik, pengukuran antropometri dan analisa sampel darah yang diambil secara rutin bagi mengumpul data kajian. Segala rekod dan data adalah SULIT dan hanya digunakan untuk tujuan kajian dan semua isu serta prosedur mengenai *data confidentiality* mesti dipatuhi. Kebenaran daripada Pengarah Hospital yang terlibat mesti diperolehi terlebih dahulu sebelum kajian dijalankan. Pelajar perlu akur dan mematuhi keputusan tersebut.

4. Laporan tamat kajian dan sebarang penerbitan hasil dari kajian ini hendaklah dikemukakan kepada Jawatankuasa Etika & Penyelidikan Perubatan selepas tamatnya projek ini.

Sekian terima kasih.

BERKHIDMAT UNTUK NEGARA

Saya yang [redacted]

(DATO' DR CHANG KIAN MENG)
Pengerusi
Jawatankuasa Etika & Penyelidikan Perubatan
Kementerian Kesihatan Malaysia

APPENDIX A-2

MONASH University

Monash University Human Research Ethics Committee (MUHREC)
Research Office

Human Ethics Certificate of Approval

Date:	**24 July 2009**
Project Number:	**CF09/1583 - 2009000877**
Project Title:	**Dietary intervention among patients with Diabetes Mellitus: An e-approach (DIDeA)**
Chief Investigator:	**Associate Professor Quek Kia Fatt**
Approved:	**From: 24 July 2009 To: 24 July 2014**

Terms of approval

1. The Chief investigator is responsible for ensuring that permission letters are obtained, if relevant, and a copy forwarded to MUHREC before any data collection can occur at the specified organisation. **Failure to provide permission letters to MUHREC before data collection commences is in breach of the National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research**.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is the responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by SCERH.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash University letterhead and the Monash University complaints clause must contain your project number.
6. **Amendments to the approved project (including changes in personnel):** Requires the submission of a Request for Amendment form to MUHREC and must not begin without written approval from SCERH. Substantial variations may require a new application.
7. **Future correspondence:** Please quote the project number and project title above in any further correspondence.
8. **Annual reports:** Continued approval of this project is dependent on the submission of an Annual Report. This is determined by the date of your letter of approval.
9. **Final report:** A Final Report should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected date of completion.
10. **Monitoring:** Projects may be subject to an audit or any other form of monitoring by MUHREC at any time.
11. **Retention and storage of data:** The Chief Investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.

[redacted]

Professor Ben Canny
Chair, SCERH

cc: Professor Brian Oldenburg, Dr Carina Chan Ka Yee, Dr Zanariah Hussein, Ms Amutha Ramadas

Postal – Monash University, Vic 3800, Australia
Building 3E, Room 111, Clayton Campus, Wellington Road, Clayton
Telephone +61 3 9905 5490 Facsimile +61 3 9905 3831
Email muhrec@adm.monash.edu.au www.monash.edu/research/ethics/human/index/html
ABN 12 377 614 012 CRICOS Provider #00008C

APPENDIX B – 1

MONASH University

18th May 2009

Explanatory Statement

Title: **Dietary Intervention among Patients with Type 2 Diabetes Mellitus: An e-Approach (DIDeA)**

This information sheet is for you to keep.

My name is Amutha Ramadas and I am conducting a research project with Dr. Quek Kia Fatt an Associate Professor in the School of Medicine and Health Sciences towards a Doctor of Philosophy (Ph.D) at Monash University. This means that I will be writing a thesis which is the equivalent of a 300-page book. We have funding from Monash University to conduct the study.

Why did you choose this particular person/group as participants?
Your contact details were obtained from your physician with his/her permission. You are chosen to be a respondent of this study because you have met all the inclusion (mentally sound diabetic patient, at least 30 years old, literate, have access to the Internet and willing to access the web portal) and exclusion criteria (pregnant, lactating or intend to become pregnant during the study period, weighing more than 150% of the desired weight for height, has any pre-existing condition compromising macronutrient metabolism, quality of life or ability to participate according to protocol, have severe complications that would affect the ability to follow the tailored advice, or enrolled in other clinical studies)for this research project.

The aim/purpose of the research
The aim of this study is to evaluate the effect of a six month dietary e-intervention on knowledge, attitude and practice (KAP), anthropometrical measurements and biomarkers related to dietary and habits in patients with type 2 diabetes mellitus.

I am conducting this research to find out if a web-based education programme could improve the knowledge, attitude and practices (KAP) of the participants with regards to healthy diet habits, besides improving their selected anthropometric measurements and biomarkers.

Possible benefits
Besides immediate improvement in knowledge, attitude and behaviour (KAB) and clinical markers, the outcome of this study is expected to assist promotion of healthy diet to high-risk groups as well as Malaysian public in line with technology development.

What does the research involve?
The study involves interviewer-administered questionnaire at baseline, 3-month, 6-month, 9-month and 12-month.

How much time will the research take?
The study is scheduled to take 12 months to complete from the day baseline interview is done. The interviewer-administered questionnaire will take approximately 35 to 45 minutes to be completed.

Inconvenience/discomfort
The inconvenience and/or discomfort to you are expected to be minimal as the research will be conducted online at your pace and the interviews will be conducted at the clinical setting you are familiar with.

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Jalan Lagoon Selatan,
Bandar Sunway, 46150,
Selangor Darul Ehsan,
Malaysia
Telephone + +60 3 5514 6000 Facsimile +60 3 5514 6001 Email info@monash.edu.my Web http://www.med.monash.edu.my/
ABN 12 377 614 012 CRICOS provider number 00008C

Payment
There would not be any payment be given out as incentives.

Can I withdraw from the research?
Being in this study is voluntary and you are under no obligation to consent to participation. However, if you do consent to participate, you may only withdraw prior to the baseline questionnaire being submitted.

Confidentiality
To maintain the confidentiality of your details, only the research team will have access to the data that you provided. You will be also identified with a unique code in order to protect your identity.

Storage of data
Storage of the data collected will adhere to the University regulations and kept on University premises in a locked cupboard/filing cabinet for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report.

Use of data for other purposes
If applicable, your anonymous data may be used for other research purpose with your consent. However, because it is anonymous data, nobody will be named and you will not be identified in any way.

Results
If you would like to be informed of the aggregate research finding, please contact Amutha Ramadas on [redacted] or email [redacted] The findings are accessible for 5 years.

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigator:	If you have a complaint concerning the manner in which this research **"Dietary Intervention among Patients with Type 2 Diabetes Mellitus: An e-Approach"** is being conducted, please contact:
Dr. Quek Kia Fatt, **Associate Professor,** **School of Medicine and Health Sciences,** **Monash University, Sunway Campus,** **Jalan Lagoon Selatan,** **Bandar Sunway, 46150,** **Selangor Darul Ehsan,** **Malaysia**	**Ethics Committee,** **School of Medicine and Health Sciences,** **Monash University, Sunway Campus,** **Jalan Lagoon Selatan,** **461500 Bandar Sunway,** **Selangor Darul Ehsan.** **Tel: +603 5514600**

Thank you.

....
AMUTHA RAMADAS

APPENDIX B – 2

Consent Form

Title: Dietary Intervention among Patients with Type 2 Diabetes Mellitus: An e-Approach (DIDeA)

NOTE: This consent form will remain with the Monash University researcher for their records

I agree to take part in the Monash University research project specified above. I have had the project explained to me, and I have read the Explanatory Statement, which I keep for my records. I understand that agreeing to take part means that:

I agree to take part in the intervention study; to be interviewed to complete questionnaires asking me about my socio-demographic, dietary and lifestyle information; to be followed-up during the study duration and make myself available during the assessments.

I understand that my participation is voluntary, that I can choose not to participate in part or all of the project, and that I can withdraw prior to the baseline questionnaire being submitted, without being penalised or disadvantaged in any way.

I understand that any data that the researcher extracts from the questionnaire for use in reports or published findings will not, under any circumstances, contain names or identifying characteristics.

I understand that any information I provide is confidential, and that no information that could lead to the identification of any individual will be disclosed in any reports on the project, or to any other party.

I understand that data from the questionnaire will be kept in a secure storage and accessible to the research team. I also understand that the data will be destroyed after a 5 year period unless I consent to it being used in future research.

Name: ....

Signature : ....

Date : ....

APPENDIX B – 3

MONASH University

18 May 2009

Kenyataan Penjelasan

Tajuk: Intervensi Diet di Kalangan Pesakit Diabetes Mellitus Jenis 2: e-Pendekatan (DIDeA)

Lembaran maklumat ini untuk simpanan anda.

Nama saya ialah Amutha Ramadas dan saya sedang menjalankan satu projek kajian bersama Dr Quek Kia Fatt, Profesor Madya di Sekolah Perubatan dan Sains Kesihatan untuk memperoleh ijazah Doktor Falsafah (Ph.D) di Monash University. Ini bermakna saya akan menulis sebuah tesis yang bersamaan dengan buku bermukasurat 300. Kami mempunyai dana daripada Monash University untuk menjalankan kajian ini.

Mengapa anda pilih kumpulan/individu ini sebagai peserta?
Maklumat diri anda telah diperoleh daripada doktor anda dengan kebenaran beliau. Anda telah dipilih sebagai responden kerana anda telah memenuhi kriteria inklusi (pesakit diabetik yang waras, berumur sekurang-kurangnya 30 tahun, celik huruf, mempunyai akses kepada Internet dan sanggup mengakses laman web kajian sekurang-kurangnya sekali setiap 2 minggu) dan ekslusi (hamil, menyusu atau berhasrat untuk hamil dalam tempoh kajian, berat badan melebihi 150% daripada berat badan yang sesuai untuk tinggi, masalah kesihatan yang berkaitan dengan metabolisma macronutrien dan kualiti hidup, komplikasi serius yang menjejaskan pembabitan dalam kajian atau terlibat dengan kajian klinikal yang lain) kajian ini.

Tujuan kajian
Tujuan kajian ini dijalankan adalah untuk menilai kesan e-intervensi diet selama enam bulan terhadap pengetahuan, sikap dan amalan (PSA), ukuran antropometri dan biomarker-biomarker berhubung diet dalam pesakit diabetes mellitus jenis 2.

Saya sedang menjalankan kajian ini untuk mendapat tahu jika program pendidikan berasaskan laman web mampu memperbaiki pengetahuan, sikap dan amalan (PSA) tentang tabiat diet sihat para peserta, di samping memperbaiki ukuran antropometri dan biomarker-biomarker tertentu.

Manfaat yang mungkin diperoleh
Selain daripada kemajuan serta-merta dalam pengetahuan, sikap dan amalan (PSA) dan marker-marker klinikal, hasil kajian ini dijangka akan membantu mempromosikan amalan diet sihat di kalangan kumpulan berisiko tinggi dan rakyat Malaysia selaras dengan pembangunan teknologi.

Apakah yang dirangkumi oleh kajian ini?
Kajian ini merangkumi borang soal-selidik yang dilengkapkan oleh penemuramah pada awal kajian, dan selepas tempoh 3, 6, 9 dan 12 bulan.

Berapa lamakah tempoh masa yang akan diambil oleh kajian ini?
Kajian ini dijadualkan untuk mengambil masa 12 bulan dari tarikh permulaan. Borang soal-selidik yang akan dilengkapkan oleh penemuramah mengambil masa lebih kurang 35 hingga 45 minit.

Ketidakselesaan
Ketidakselesaan yang anda mungkin alami adalah minima kerana kajian akan dijalankan secara "online" mengikut keselesaan anda dan temuramah akan dijalankan di hospital yang anda kunjungi.

School of Medicine and Health Sciences,
Jalan Lagoon Selatan,
Bandar Sunway, 46150,
Selangor Darul Ehsan,
Malaysia
Telephone + +60 3 5514 6000 Facsimile +60 3 5514 6001 Email info@monash.edu.my Web http://www.med.monash.edu.my/
ABN 12 377 614 012 CRICOS provider number 00008C

Bayaran
Sebarang bayaran atau intensif tidak akan diberikan.

Bolehkah saya menarik diri daripada kajian ini?
Penyertaan dalam kajian ini adalah secara sukarela dan anda tidak mempunyai sebarang obligasi untuk mengambil bahagian. Walaubagaimanapun, anda hanya boleh menarik diri pada awal kajian sebelum melengkapkan borang soal-selidik asas.

Sulit
Untuk memastikan maklumat anda dirahsiakan, hanya para penyelidik mempunyai akses kepada data yang anda berikan. Anda akan diberikan kod unik untuk merahsiakan identiti anda.

Penyimpanan data
Data yang dikumpul akan disimpan mengikut peraturan Universiti dan disimpan di premis Universiti di dalam almari/kabinet berkunci selama 5 tahun. Sebuah laporan tentang kajian mungkin diterbitkan tetapi individu-individu yang terbabit tidak akan dikenalpasti.

Pengunaan data untuk tujuan lain
Jika perlu, data yang dikumpul mungkin digunakan untuk kajian yang lain dengan kebenaran anda. Walaubagaimanapun, tiada individu yang dinamakan dan anda tidak akan dikenalpasti sama sekali.

Hasil kajian
Jika anda ingin mengetahui seluruh hasil kajian, sila hubungi Amutha Ramadas di [redacted] or e-mel [redacted] Hasil kajian dapat diakses untuk 5 tahun.

Jika anda ingin menghubungi para penyelidik tentang sebarang aspek kajian ini, sila hubungi Penyelidik Utama:	Jika anda mempunyai sebarang aduan tentang cara kajian **"Intervensi Diet di Kalangan Pesakit Diabetes Mellitus Jenis 2: e-Pendekatan"** dijalankan, sila hubungi:
Dr. Quek Kia Fatt, Associate Professor, School of Medicine and Health Sciences, Monash University, Sunway Campus, Jalan Lagoon Selatan, Bandar Sunway, 46150, Selangor Darul Ehsan, Malaysia	**Ethics Committee, School of Medicine and Health Sciences, Monash University, Sunway Campus, Jalan Lagoon Selatan, 461500 Bandar Sunway, Selangor Darul Ehsan. Tel: +603 5514600**

Terima kasih,

....
AMUTHA RAMADAS

APPENDIX B – 4

Borang Keizinan

Tajuk: Intervensi Diet di Kalangan Pesakit Diabetes Mellitus Jenis 2: e-Pendekatan (DIDeA)

NOTA: Borang keizinan ini akan kekal bersama para penyelidik dari Monash University bagi tujuan rekod.

Saya bersetuju untuk menyertai kajian seperti yang disebut di atas yang dijalankan oleh Monash University. Saya telah diberi penjelasan tentang kajian ini dan telah membaca Kenyataan Penjelasan yang akan saya simpan bagi tujuan rekod. I faham bahawa persetujuan untuk menyertai kajian bermakna:

Saya bersetuju untuk mengambil bahagian dalam kajian intervensi; ditemuramah untuk melengkapkan borang soal-selidik tentang maklumat sosio-demografi, diet dan gaya hidup saya; bersedia untuk maklumat susulan sepanjang tempoh kajian dan ketika penilaian.

Saya faham bahawa penyertaan saya adalah secara sukarela, iaitu saya boleh menarik diri daripada sebahagian atau seluruh projek, dan saya boleh menarik diri sebelum melengkapkan borang soal-selidik pada awal kajian tanpa sebarang penalti atau kesan negatif.

Saya faham bahawa sebarang data yang penyelidik gunakan daripada borang soal-selidik untuk tujuan laporan atau penerbitan tidak akan mengandungi nama atau ciri-ciri pengenalan diri.

Saya faham bahawa sebarang maklumat yang saya berikan adalah sulit dan tiada sebarang maklumat tentang individu-individu yang akan disebut dalam laporan projek ini atau diberikan kepada pihak lain.

Saya faham bahawa data daripada borang soal-selidik akan disimpan dengan selamat dan hanya dapat diakses oleh para penyelidik. Saya juga faham bahawa data akan dihapuskan selepas tempoh 5 tahun kecuali jika saya bersetuju data itu digunakan untuk kajian masa depan.

Nama : ....

Tandatangan : ....

Tarikh : ....

APPENDIX C – 1

Figure C - 1: The landing page of *my*DIDeA

APPENDIX C – 2

Figure C - 2: Homepage of *my*DIDeA

APPENDIX C – 3

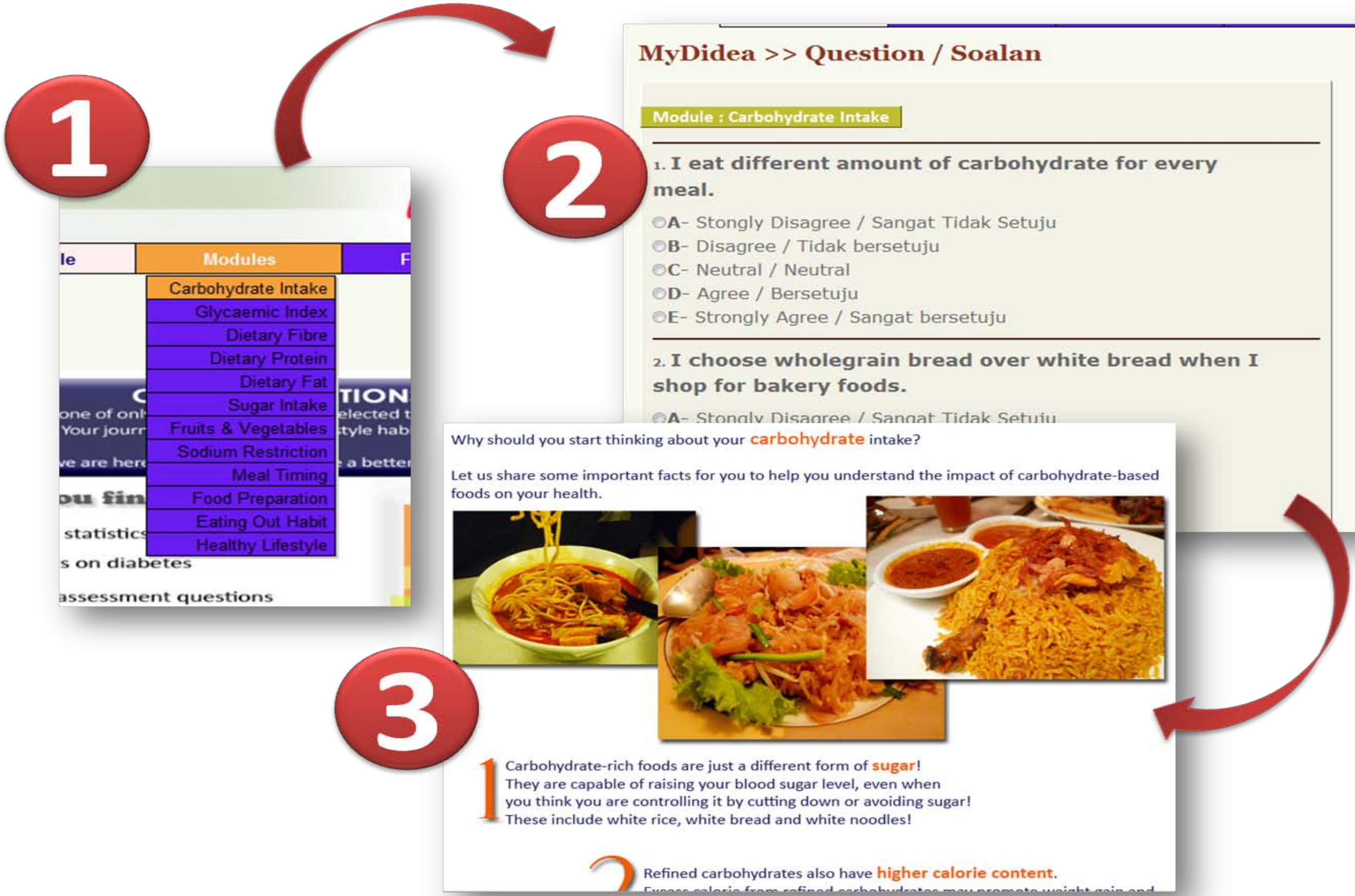

Figure C - 3: A sample lesson plan

APPENDIX C – 4

Figure C - 4: The side bar and a sample factsheet

APPENDIX C – 5

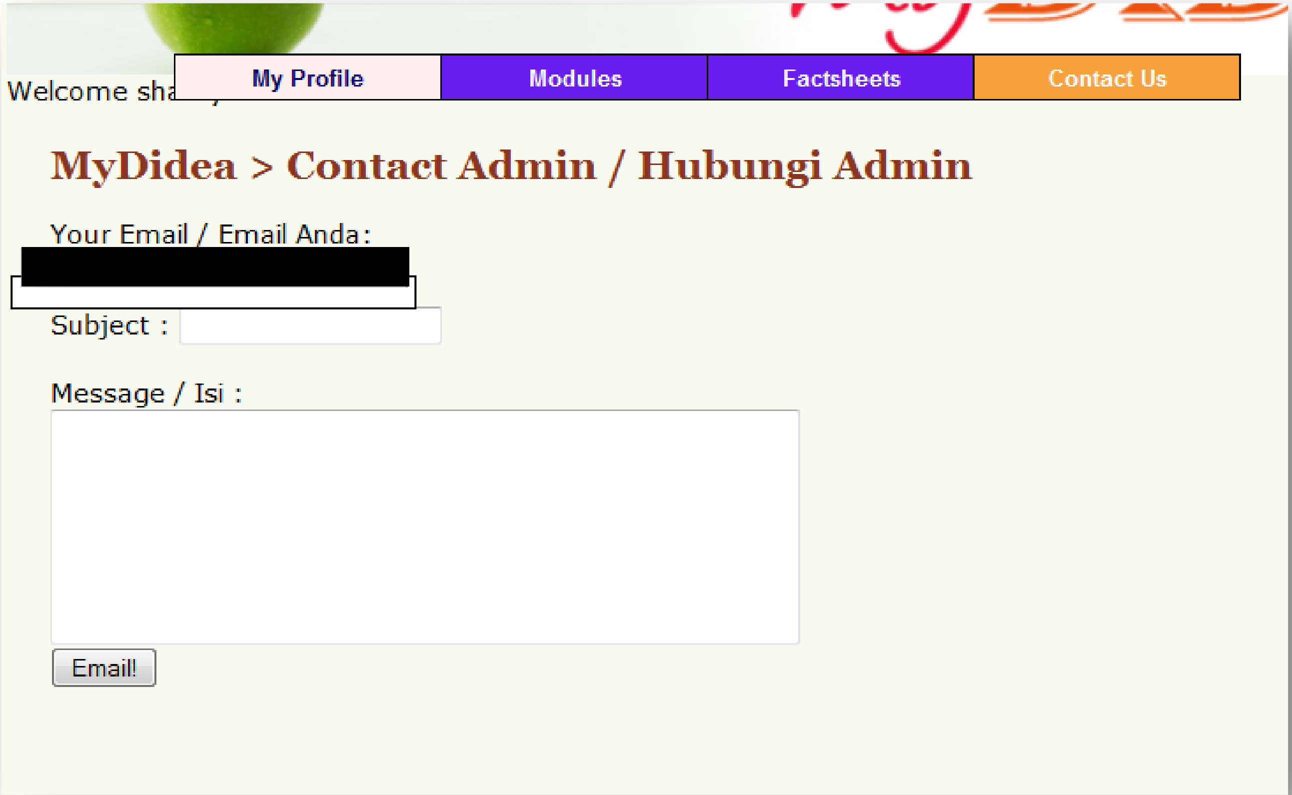

Figure C - 5: The contact box

APPENDIX D – 1

MONASH University | myDIDeA

Dietary Intervention among Patients with Type 2 Diabetes Mellitus: An e-Approach

Instructions on how to complete the questionnaire:

Where boxes and tables are provided, please put a tick (√) or a cross (**X**) against your response, unless it is indicated otherwise. Spaces are provided for you to write your views on the subject. Should you need more space to write, please feel free to attach additional sheets. All parts of the questionnaire should be completed.

There is no right or wrong answer to the questions in the survey. Please provide honest opinions and as much details as you can.

Only the Investigators of the project will have access to the data. All information you provide here will remain confidential.

Thank you for agreeing to take part in this study.

A. SOCIO-DEMOGRAPHIC INFORMATION

1. Name : ____
2. Year of birth : ____
3. Gender : ☐ (1) Male ☐ (2) Female
4. Ethnicity : ☐ (1) Malay ☐ (2) Chinese ☐ (3) Indian ☐ (4) Others: ____________
5. Education : ☐ (1) Primary ☐ (2) Lower secondary
   ☐ (3) Higher secondary ☐ (4) Tertiary
6. Occupation : ☐ (1) Student ☐ (2) Employed
   ☐ (3) Unemployed ☐ (4) Retired
7. Personal income (RM) per month : ____
8. E-mail add : ____
9. Contact no. : ____

B. MEDICAL CONDITION

10. When were you diagnosed as having type 2 diabetes mellitus? _____ /_____ (month & year)
11. Does any of your immediate family members suffering from diabetes? ☐ (1) Yes ☐ (0) No
12. Do you self-monitor your blood glucose level? ☐ (1) Yes ☐ (0) No (skip to #14)
13. What is the frequency of you testing your blood glucose level in a week? __________ times
14. Are you taking any pill(s) for diabetes (as prescribed by your doctor? ☐ (1) Yes ☐ (0) No (skip to #16)
15. Please specify the name(s) of the diabetes pills you are taking.

    ____
16. Are you taking any insulin injections? ☐ (1) Yes ☐ (0) No
17. Have you have or ever had the following: *(self-reported)*
    ☐ Diabetic coma ☐ Hypoglycaemia
    ☐ Heart disease ☐ Kidney disease
    ☐ Nerve disorder ☐ Foot ulcer
    ☐ High blood pressure
    ☐ High cholesterol
    ☐ Other complications : __________

C. ANTHROPOMETRY

Blood pressure: ________________ Resting heart rate: _____________

Measurement	I	II	Average
Weight (kg)			
Height (m)			
Waist circumference (cm)			
Body fat mass (kg)			
Percentage of body fat (%)			

D. SMOKING HABIT

18. Are you a smoker now? ☐ (1) Yes ☐ (0) No (skip to #21)
19. How long have you been smoking? ___________ months
20. On average, how many cigarettes do you smoke every day? ____________ stick(s)
21. Have you ever smoked before this? ☐ (1) Yes ☐ (0) No
22. Are you constantly exposed to cigarette smoke ☐ (1) Yes ☐ (0) No

E. ALCOHOL CONSUMPTION

23. Do you drink any form of alcohol now? ☐ (1) Yes ☐ (0) No
    (skip to #27)
24. How often do you drink alcohol?
    ☐ Everyday
    ☐ More than once a week
    ☐ Once a week
    ☐ 1 – 3 times a month
25. How long have you been drinking alcohol? ____________ months
26. On an average, how much alcohol do you normally take? ____________ glass(es)
27. Have you ever drunk alcohol before? ☐ (1) Yes ☐ (0) No

F. INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

The questions will ask you about the time you spent being physically active in the **last 7 days**.

*Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.*

28. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics or fast cycling?
    ________ days ☐ (0) none (skip to #30)

29. How much time did you usually spend doing vigorous physical activities on one of those days?
    ________ hours/mins ☐ (0) don't know/not sure

*Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.*

30. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.
    ________ days ☐ (0) none (skip to #32)

31. How much time did you usually spend doing moderate physical activities on one of those days?
    ________ hours/mins ☐ (0) don't know/not sure

*Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.*

32. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?
    ________ days ☐ (0) none (skip to #34)

33. How much time did you usually spend **walking** on one of those days?
    ________ hours/mins ☐ (0) don't know/not sure

*The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.*

34. During the last 7 days, how much time did you spend sitting on a weekday?
    ________ hours/mins ☐ (0) don't know/not sure

G. SEMI FOOD FREQUENCY QUESTIONNAIRE (SFFQ)

Please indicate the frequency of your food intake for the last 30 days:

Code	A. Cereals & products	times/day	times/week	times/month	never	serving size
Breads						
A1	White bread					
A2	Whole meal bread					
A3	Whole grain bread					
A4	Pitta bread / naan					
A5	Roti/bun, muffin					
Rice & rice-based products						
A6	White rice (normal)					
A7	Parboiled rice					
A8	Brown rice					
A9	Pulut rice					
A10	Fried rice / chicken rice / oily rice / briyani rice / nasi lemak					
A10	Fried meehoon / kueh teow					
A11	Meehoon soup / laksa					
A12	Tosai					
A13	Idli					
A14	Putu mayam					

A15	Rice porridge					
Wheat-based products						
A16	Fried mee					
A17	Mee soup / mee kari / mee bandung					
A18	Instant noodles					
A19	Pasta / Spaghetti					
A20	Capati					
A21	Roti canai					
Others						
A22	Cornflakes / sweet cereals					
A23	Oats / muesli					
Code	**B. Fruit & products**	**times/day**	**times/week**	**times/month**	**never**	**serving size**
Tropical fresh fruits						
B1	Watermelon					
B2	Papaya					
B3	Banana					
B4	Pineapple					
B5	Mango					
B6	Guava					
B7	Nangka / cempedak					
B8	Starfruit					
B9	Ciku					
Temperate fresh fruits						
B10	Apple					
B11	Orange					
B12	Grapes					
B13	Pear					
Others						
B14	Raisins / prune					
B15	Canned / preserved fruits					
B16	Fresh juice					
B17	Smoothie with milk/soya milk					
Code	**C. Vegetables & products**	**times/day**	**times/week**	**times/month**	**never**	**serving size**
Starchy Vegetables						
C1	Potato, French fries					
C2	Potato, boiled					
C3	Tubers (yam / sweet potato / taro / beet root)					
C4	Pumpkin					
C5	Sweet corn					
Non-starchy Vegetables						
C6	Green leafy vegetables (kangkung, spinach salad, tapioca shoots, ulam)					
C7	Cabbage (cauliflower, lettuce, broccoli)					

C8	Coloured vegetables (carrots, radish, tomato, brinjal, cucumber, bell pepper)					
C9	Leguminous vegetables (long beans, four-angled beans, French beans, lady's finger, asparagus)					
C10	Taugeh / sprouts					
Others						
C11	Vegetable soup					
C12	Fresh vegetable juice					
C13	Preserved vegetables / acar					
Code	**D. Dairy products & alternatives**	**times/day**	**times/week**	**times/month**	**never**	**serving size**
D1	Fresh milk / UHT					
D2	Milk, full cream, powdered					
D3	Milk, skim, powdered					
D4	Condensed / evaporated milk					
D5	Non-dairy creamer					
D6	Ice cream					
D7	Yogurt / dadih					
D8	Cheese					
D9	Soy milk					
D10	Beverages (Milo, Horlicks)					
Code	**E. Meat , fish and seafoods**	**times/day**	**times/week**	**times/month**	**never**	**serving size**
E1	Red meats (beef, pork, mutton)					
E2	White meats (chicken, duck, rabbit)					
E4	Fish (fresh and sea water)					
E5	Seafoods (prawn, sotong, clams)					
E6	Eggs (hen, duck, quill)					
Code	**F. Legumes & products**	**times/day**	**times/week**	**times/month**	**never**	**serving size**
F1	Dhal					
F2	Lentils					
F3	Chickpeas					
F4	Mungbean					
F5	Groundnuts					
F6	Other nuts (almonds, pistachio, cashew)					
F7	Baked beans with tomato sauce					
F8	Soy bean products (tauhu, tempe)					
Code	**G. Snack products**	**times/day**	**times/week**	**times/month**	**never**	**serving size**
G1	Chocolate					
G2	Dark chocolate					

G3	Crackers / biscuits / cookies					
G4	Potato chips					
G5	Soft drink / soda					
G6	Cakes / doughnuts / cupcakes / pastries					
G7	Local kuih (currypuff, pisang goreng etc)					
Code	**H. Miscellaneous**	**times/day**	**times/week**	**times/month**	**never**	**serving size**
H1	Sugar					
H2	Honey					
H3	Jam / kaya					
H4	Peanut butter					
H5	Butter / margarine					

H. SUPPLEMENTS INTAKE

35. In the past 30 days, did you consume any herbs / vitamin / mineral? ☐ (1) Yes ☐ (0) No (skip to J)

36. If yes, name the supplements and the frequency of its consumption in the table below:

Type	Frequency			
	Everyday	**> once/week**	**Once a week**	**1 – 3 times a month**
Multivitamin				
Vitamin B complex				
Vitamin C				
Calcium				
Iron				
Fish oil				
Evening primrose oil				
Chinese herbs/ginseng				
Others:				

APPENDIX D – 2

PROCESS EVALUATION

Please tick (√) response that describe you the best.

			Strongly disagree (1)	Disagree (2)	Neutral (3)	Agree (4)	Strongly agree (5)
Content satisfaction	**Performance expectancy**	*my*DIDeA helped me understand the benefits of self-managing my diet.					
		It motivated me to monitor my diet.					
		I found *my*DIDeA to be useful in the management of my diet.					
		*my*DIDeA gave me confidence that I could better manage my diet.					
	Effort expectancy	I found *my*DIDeA easy to use.					
		I found answering questions for each module frustrating.					
		The time interval between 2 modules (2 weeks) was too long.					
		There were too many modules in total.					
	Patient Centred factors	Recommendations given through *my*DIDeA were right on target for me.					
		I am inspired to do better with my diet and lifestyle management now.					
		*my*DIDeA was a reminder that my diet is important.					
		*my*DIDeA made me realise that Internet can help people to improve their health.					

Acceptability	**Attitude towards technology**	*my*DIDeA is a good idea to educate diabetic patients on diet.					
		I like using *my*DIDeA.					
	Anxiety	I felt apprehensive about using *my*DIDeA.					
		It scared me to think that I could give the wrong answer to the questions.					
	Self efficacy	I feel confident using *my*DIDeA.					
	Behavioural Intention	I intend to use *my*DIDeA if it becomes publicly available in the future.					
		I predict I would use *my*DIDeA in the future (if I have access).					
Usability	**Facilitating Conditions**	The guideline given at the homepage was sufficient for me to use *my*DIDeA.					
		Options to contact the nutritionist via *my*DIDeA provided me with good support to use the website.					
	User-friendliness	I liked the overall presentation of *my*DIDeA.					
		I was able to find my way around the website.					
		I liked the layout of each module.					
		I liked the personal login.					

APPENDIX D – 3

DIETARY KNOWLEDGE, ATTITUDE AND BEHAVIOUR QUESTIONNAIRE (DKAB-Q)

Knowledge

#	Question	True	False	Don't know
1.	1 cup of brown rice has more fibre than 1 cup of white rice.			
2.	Legumes and legume-based products have protein.			
3.	Excessive intake of carbohydrate-rich meals may cause weight gain.			
4.	Taking a daily nutrient supplement is the best assurance of getting enough vitamins and minerals.			
5.	Butter has more saturated fat than margarine.			
6.	Eating approximately at the same time every day is important to diabetic patients.			
7.	Low glycaemic index foods may help to keep the blood glucose under control.			
8.	Sugar does not provide any nutrients except calories.			
9.	Diet has little effect on the development of major diseases such as diabetes mellitus.			
10.	We should avoid eating the burnt edges of meat or fish.			
11.	Cleanliness of the restaurant could be compensated with lower price of the foods.			
12.	One teaspoon of salt is the maximum allowed level for a day.			

Attitude

No.	Statement	Strongly agree	Agree	Undecided	Disagree	Strongly Disagree
13.	I dislike milk and milk products.					
14.	It costs more to eat healthy foods.					
15.	It is not easy to eat healthy diet.					
16.	I find whole grains such as brown rice and whole grain bread tasteless and unappealing to me.					
17.	Food that doesn’t raise my blood sugar level fast taste as good as food that does.					

18.	I prefer not to peel my fruits.					
19.	I reuse cooking oil few times before discarding it.					
20.	I try hard not to add refined sugar to my drinks so that I don't have health complications later.					
21.	I will have constipation if I consume high fibre food.					
22.	My work schedule makes it very hard for me to have my lunch at the same time every day.					
23.	I enjoy eating raw vegetables such as lettuce, carrots, tomato and cucumber.					
24.	During the past 1 month, I have thought about changes I can make to decrease the amount of salt in my food.					

Behaviour

No.	Question	Yes	No	Don't know
25.	Are your meals synchronised with your medication time?			
26.	Do you add artificial flavouring such as MSG to your daily cooking?			
27.	Do you look out for breads made of whole wheat flour in bakeries?			
28.	Do you remove the skin from the chicken and trim all the fat from the meat that you cook and/or eat?			
29.	Do you marinate your meat/chicken with soy sauce?			
30.	Do you eat more than a match box size of meat most of the days?			
31.	Are you currently using sugar substitutes eg. Pall Sweet, Equal?			
32.	Do you usually make your own fruit juice out of fresh fruits at home?			
33.	Do you regularly self-monitor your blood sugar?			
34.	Do you compare carbohydrate content of food items you buy?			
35.	Did you take any sugary drinks when you last eat out?			
36.	Do you find it difficult to search for food that doesn't raise your blood sugar fast?			

APPENDIX D – 4

DIETARY STAGES OF CHANGE QUESTIONNAIRE (DSOC-Q)

Module	Statement	Strongly agree	Agree	Undecided	Disagree	Strongly Disagree
Carbohydrate	I eat different amount of carbohydrate for every meal.					
	I chose wholegrain bread over white bread the last time I shopped for food.					
	I eat a variety of whole grains, beans, fruits and vegetables daily.					
	I eat breakfast dishes made of white flour to more than 3 times a week. This includes muffin, buns, *thosai, idli, roti canai, laksa and bihun.*					
	I count my serving sizes whenever I eat carbohydrate-rich meals.					
Glycaemic Index	In most days of the week, I eat foods that do not increase my blood sugar level fast.					
	Sometimes I substitute rice meals or noodles with beans, vegetables and fruits.					
	I am adding as much beans, pulses and legumes as I can in my cooking.					
	I eat white rice or noodles for lunch or dinner most of the days.					
	I do not snack on foods like cakes, doughnuts and biscuits.					
Dietary fibre	I eat fruits and vegetables every day.					
	I prepare foods with legumes or dhals most of the days.					
	I have breakfast with oats, wholegrain bread or cereals every day.					
	I snack on whole wheat crackers or sesame seed crackers instead of biscuits or cookies.					
	I eat unsweetened dried fruits such as prunes and raisins.					

Module	Statement	Strongly agree	Agree	Undecided	Disagree	Strongly Disagree
Dietary protein	I eat at least one serving of fish or meat without fat (or soy products) at every meal.					
	I take soy milk and soy products at regular basis.					
	I drink low fat or skim milk (or unsweetened soy bean milk).					
	I have dairy products made of low-fat milk such as low-fat yogurt quite often.					
	I add tauhu, taugeh, beans, dhals or lentils to my cooking regularly.					
Dietary fat	I eat fried fast foods when I eat out.					
	Steamed or grilled meat and fish are not tasty.					
	I always choose low-fat versions of foods whenever they are available.					
	I limit or avoid eating snacks like chips and popcorns when I watch movies or doing leisure activities.					
	I market for oily fish such as salmon and mackerel.					
Sugar intake	I always check food labels for its sugar content.					
	I prefer the sweetness of natural foods instead of commercial sweeteners.					
	Cakes, muffins, buns and biscuits with sugar are taken in limited quantity.					
	I refrain from adding sugar to my drinks.					
	I do eat sugary desserts.					
Fruits and vegetables	I prepare my own fresh fruit juices.					
	I only eat tropical fruits likes papaya, mango and pineapple.					
	Most of the days, I eat 5 to 7 servings of fruits and vegetables.					
	I prepare or buy pre-cut fruits for snacking.					
	I always add more vegetables in my daily meals.					

Module	Statement	Strongly agree	Agree	Undecided	Disagree	Strongly Disagree
Sodium intake	I marinate my chicken and meat with soy sauces.					
	I generally avoid pickled vegetables and fruits.					
	I add a little bit more salt to my food at the table.					
	I tend to cook from canned and instant foods as they are easier to prepare.					
	I do not purchase processed foods such as sausages, nuggets and ready-to-eat frozen foods.					
Meal timing	I rush through my meals.					
	I eat around the same time every day.					
	I do not eat heavy meals after 8pm.					
	I make sure I have a healthy breakfast every morning.					
	I usually have a 4 to 5 hours gap in between each meal.					
Food preparation	I prefer fried chicken, fish and meat any time.					
	I do not eat the charred part of the meat after barbequing or grilling.					
	Cooking oils are not reused in my home.					
	I never deep-fried my vegetables.					
	I remove the skin of the chicken or fat from the meat before cooking.					
Eating out habit	I do not add any sauces or ketchup to my food when I eat out.					
	I do order carbonated drinks when I eat out.					
	I always ask for meals that are prepared with less sugar though it may not be mentioned in the menu.					
	I supersize my fast foods orders because it is more worth for my money.					
	I bring my own drinks when eating out.					

Module	Statement	Strongly agree	Agree	Undecided	Disagree	Strongly Disagree
Healthy living	Supplements are the only way for me to improve my vitamin and mineral intake.					
	I rarely exercise.					
	I do not smoke or drink.					
	I drink at least 6 glasses of water in a day.					
	I manage my time well, giving work, home and personal space equal importance.					

APPENDIX E

VALIDATION OF DIETARY KNOWLEDGE, ATTITUDE AND BEHAVIOUR QUESTIONNAIRE (DKAB-Q)

Table E-1: Cronbach's Alpha, Item-to-total Correlation and Intraclass Correlation Coefficient for DKAB-Q.

Domain	Item	Diabetic patients (n=30)			Healthy controls (n=30)			Total (N=60)		
		Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient *
Knowledge		0.72			0.70			0.65		
	1		0.27	0.83		0.21	0.80		0.23	0.81
	2		0.29	0.87		0.30	0.94		0.28	0.90
	3		0.36	0.89		0.23	0.80		0.27	0.57
	4		0.25	0.77		0.24	0.76		0.29	0.77
	5		0.25	0.78		0.18	0.87		0.26	0.83
	6		0.30	0.91		0.25	0.78		0.23	0.73
	7		0.19	0.77		0.38	0.73		0.26	0.70
	8		0.33	0.85		0.37	0.73		0.26	0.68
	9		0.28	0.71		0.26	0.73		0.25	0.53
	10		0.38	0.75		0.20	0.79		0.35	0.72
	11		0.30	0.79		0.21	0.68		0.19	0.45
	12		0.27	0.76		0.21	0.79		0.24	0.78

Table E-1: Cronbach's Alpha, Item-to-total Correlation and Intraclass Correlation Coefficient for DKAB-Q (continued).

Domain	Item	Diabetic patients (n=30)			Healthy controls (n=30)			Total (N=60)		
		Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*
Attitude		0.71			0.71			0.64		
	13		0.37	0.78		0.41	0.79		0.19	0.63
	14		0.25	0.82		0.14	0.75		0.24	0.70
	15		0.41	0.78		0.59	0.68		0.42	0.66
	16		0.29	0.81		0.56	0.60		0.36	0.81
	17		0.29	0.76		0.16	0.93		0.27	0.84
	18		0.39	0.74		0.29	0.71		0.30	0.76
	19		0.16	0.73		0.62	0.69		0.26	0.59
	20		0.30	0.73		0.24	0.70		0.26	0.69
	21		0.34	0.74		0.17	0.70		0.25	0.66
	22		0.25	0.73		0.41	0.69		0.29	0.60
	23		0.39	0.73		0.32	0.76		0.31	0.60
	24		0.36	0.78		0.15	0.67		0.23	0.69
Behaviour		0.73			0.68			0.64		
	25		0.29	0.84		0.41	0.84		0.34	0.89
	26		0.40	0.70		0.37	0.75		0.22	0.68
	27		0.28	0.92		0.35	0.72		0.32	0.81
	28		0.33	0.88		0.22	0.81		0.30	0.84
	29		0.15	0.71		0.38	0.63		0.35	0.50
	30		0.26	0.70		0.19	0.62		0.26	0.50
	31		0.33	0.88		0.27	0.81		0.26	0.84
	32		0.42	0.77		0.23	0.86		0.35	0.84
	33		0.32	0.80		0.28	0.71		0.29	0.82
	34		0.53	0.76		0.28	0.76		0.41	0.65
	35		0.31	0.72		0.17	0.60		0.23	0.72
	36		0.12	0.78		0.32	0.60		0.29	0.79
Average		**0.72**			**0.69**			**0.65**		

*significant at p<0.05

Table E-2: The difference in mean DKAB-Q scores within groups.

Domain	Diabetic patients (n=30)				Healthy individuals (n=30)			
	DKAB-Q1 score (Mean + SD)	**DKAB-Q2 score (Mean + SD)**	**95% CI**	***P***	**DKAB-Q1 score (Mean + SD)**	**DKAB-Q2 score (Mean + SD)**	**95% CI**	***P***
Knowledge	7.43 + 2.33	7.00 + 2.20	-0.03 – 0.90	0.208	7.40 + 1.61	6.73 + 1.60	0.29 – 1.07	0.01*
Attitude	38.73 + 5.88	39.20 + 5.30	-1.57 – 0.64	0.322	39.20 + 6.21	38.6 3 + 4.91	-0.53 – 1.66	0.586
Behaviour	7.30 + 2.00	7.27 + 1.76	-0.42 – 0.49	0.256	5.20 + 2.28	4.90 + 2.12	-0.21 – 0.80	0.477
TOTAL	**53.47 + 7.70**	**53.47 + 7.22**	**-1.24 – 1.24**	**0.939**	**51.80 + 7.86**	**50.27 + 6.76**	**0.33 – 2.74**	**0.03***

Notation: All data were normally distributed.
Paired t-test was used to compare DKAB-Q1 and DKAB-Q2 for each domain.
*significant at p<0.05

Table E-3: The difference in mean DKAB-Q scores between groups.

Domain	Score difference (Mean + SD)		95% CI	*P*
	Diabetic patients	**Healthy controls**		
Knowledge	0.83 + 1.02	0.93 + 0.87	-0.59 – 0.39	0.684
Attitude	1.87 + 2.32	2.03 + 2.14	-1.32 – 0.99	0.773
Behaviour	0.90 + 0.80	0.77 + 1.14	-0.38 – 0.64	0.601
TOTAL	**2.33 + 2.34**	**2.67 + 2.34**	**-1.54 – 0.88**	**0.583**

Notation: All data were normally distributed.
Independent *t*-test was used to compare the mean score difference between groups for each domain.

APPENDIX F

VALIDATION OF DIETARY STAGES OF CHANGE QUESTIONNAIRE (DSOC-Q)

Table F-1: Cronbach's Alpha, Item-to-total Correlation and Intraclass Correlation Coefficient for DSOC-Q.

Component	Item	Diabetic patients (n=40)			Healthy controls (n=40)			Total (N=80)		
		Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*
Carbohydrate		0.79			0.71			0.74		
	1		0.33	0.75		0.35	0.61		0.34	0.71
	2		0.20	0.83		0.25	0.87		0.25	0.89
	3		0.62	0.71		0.42	0.83		0.53	0.76
	4		0.28	0.82		0.36	0.57		0.25	0.75
	5		0.27	0.77		0.22	0.63		0.26	0.77
Glycaemic Index		0.78			0.70			0.74		
	6		0.27	0.69		0.24	0.86		0.27	0.81
	7		0.47	0.78		0.26	0.81		0.29	0.85
	8		0.29	0.77		0.04	0.81		0.23	0.78
	9		0.30	0.75		0.13	0.43		0.17	0.47
	10		0.34	0.76		0.47	0.68		0.32	0.72
Dietary fibre		0.78			0.71			0.73		
	11		0.31	0.78		0.41	0.87		0.34	0.85
	12		0.23	0.77		0.21	0.84		0.33	0.79
	13		0.30	0.79		0.40	0.80		0.34	0.79
	14		0.33	0.78		0.17	0.75		0.26	0.78
	15		0.35	0.85		0.12	0.80		0.25	0.83

Table F-1: Cronbach's Alpha, Item-to-total Correlation and Intraclass Correlation Coefficient for DSOC-Q (continued).

Component	Item	Diabetic patients (n=40)			Healthy controls (n=40)			Total (N=80)		
		Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*
Dietary protein		0.76			0.71			0.74		
	16		0.42	0.74		0.23	0.77		0.25	0.76
	17		0.27	0.86		0.38	0.83		0.31	0.86
	18		0.27	0.85		0.19	0.78		0.22	0.81
	19		0.23	0.78		0.34	0.77		0.27	0.77
	20		0.42	0.81		0.39	0.81		0.40	0.79
Dietary fat		0.78			0.71			0.74		
	21		0.23	0.83		0.46	0.73		0.33	0.81
	22		0.38	0.90		0.39	0.81		0.38	0.85
	23		0.34	0.78		0.28	0.77		0.24	0.86
	24		0.39	0.87		0.11	0.86		0.26	0.85
	25		0.37	0.83		0.18	0.66		0.25	0.80
Sugar intake		0.79			0.71			0.73		
	26		0.22	0.79		0.28	0.78		0.26	0.80
	27		0.29	0.78		0.17	0.40		0.24	0.65
	28		0.25	0.82		0.51	0.75		0.31	0.77
	29		0.20	0.71		0.18	0.82		0.27	0.86
	30		0.44	0.74		0.17	0.11		0.31	0.71
Fruits & vegetables		0.78			0.70			0.73		
	31		0.26	0.75		0.20	0.80		0.22	0.77
	32		0.45	0.74		0.21	0.87		0.27	0.79
	33		0.14	0.80		0.46	0.91		0.26	0.84
	34		0.24	0.87		0.42	0.87		0.30	0.87
	35		0.28	0.56		0.20	0.34		0.25	0.46
Salt intake		0.79			0.71			0.74		
	36		0.12	0.88		0.38	0.90		0.29	0.91
	37		0.26	0.87		0.22	0.85		0.24	0.86
	38		0.25	0.72		0.16	0.77		0.18	0.74
	39		0.32	0.73		0.13	0.88		0.20	0.80
	40		0.31	0.84		0.23	0.90		0.24	0.87

Table F-1: Cronbach's Alpha, Item-to-total Correlation and Intraclass Correlation Coefficient for DSOC-Q (continued).

Component	Item	Diabetic patients (n=40)			Healthy controls (n=40)			Total (N=80)		
		Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*	Cronbach's Alpha	Item-to-total correlation	Correlation Coefficient*
Meal timing		0.79			0.70			0.73		
	41		0.28	0.81		0.29	0.91		0.24	0.87
	42		0.26	0.85		0.51	0.81		0.33	0.83
	43		0.13	0.86		0.51	0.83		0.30	0.85
	44		0.49	0.85		0.21	0.87		0.34	0.86
	45		0.34	0.79		0.38	0.79		0.30	0.84
Food preparation		0.79			0.70			0.73		
	46		0.27	0.83		0.18	0.74		0.24	0.82
	47		0.26	0.82		0.36	0.67		0.27	0.76
	48		0.27	0.72		0.23	0.60		0.25	0.69
	49		0.36	0.86		0.37	0.51		0.36	0.73
	50		0.44	0.76		0.42	0.53		0.43	0.66
Eating out habit		0.80			0.71			0.73		
	51		0.32	0.85		0.23	0.84		0.30	0.84
	52		0.29	0.82		0.15	0.82		0.23	0.85
	53		0.29	0.85		0.18	0.94		0.22	0.90
	54		0.27	0.85		0.22	0.92		0.23	0.89
	55		0.25	0.86		0.28	0.90		0.25	0.87
Healthy living		0.79			0.71			0.75		
	56		0.34	0.86		0.36	0.87		0.33	0.87
	57		0.47	0.73		0.34	0.86		0.40	0.79
	58		0.35	0.75		0.25	0.63		0.28	0.62
	59		0.38	0.77		0.36	0.75		0.26	0.66
	60		0.36	0.77		0.32	0.84		0.32	0.80
Average		**0.79**			**0.71**			**0.74**		

*significant at $p<0.05$

Table F-2: The difference in mean DSOC-Q scores within groups.

Domain	Diabetic patients (n=40)				Healthy individuals (n=40)			
	DSOC-Q1 score (Mean + SD)	DSOC-Q2 score (Mean + SD)	95% CI	*P*	DSOC-Q1 score (Mean + SD)	DSOC-Q2 score (Mean + SD)	95% CI	*P*
Carbohydrate	16.28 + 2.83	16.28 + 2.91	-0.397 – 0.397	1.000	16.98 + 2.64	17.40 + 2.80	-0.942 – 0.092	0.104
GI	16.02 + 2.52	15.78 + 2.65	-0.256 – 0.756	0.323	16.88 + 3.07	17.7 + 3.56	-1.628 – -0.022	0.044*
Dietary fibre	14.50 + 2.59	14.52 + 2.88	-0.540 – 0.490	0.922	14.42 + 2.87	14.10 + 3.33	-0.283 – 0.933	0.286
Dietary protein	15.10 + 2.72	14.75 + 3.78	-0.263 – 0.963	0.255	15.45 + 3.46	15.95 + 4.00	-1.061 – 0.61	0.079
Dietary fat	16.20 + 2.31	16.02 + 2.42	-0.310 – 0.660	0.476	15.78 + 3.02	16.20 + 3.05	-0.921 – 0.071	0.091
Sugar	16.70 + 2.50	16.95 + 2.55	-0.718 – 0.218	0.287	17.65 + 2.85	18.05 + 3.11	-0.890 – 0.090	0.107
Fruits & vegetables	14.85 + 2.35	14.85 + 2.54	-0.416 – 0.416	1.000	15.82 + 3.63	16.02 + 3.45	-0.743 – 0.343	0.461
Salt	14.48 + 1.66	14.58 + 2.32	-0.545 – 0.345	0.652	12.38 + 2.79	12.40 + 3.37	-0.569 – 0.519	0.926
Meal timing	16.42 + 2.85	16.40 + 2.84	-0.441 – 0.491	0.914	17.22 + 2.84	17.62 + 3.02	- 0.879 – 0.079	0.099
Food preparation	18.76 + 2.30	19.08 + 2.11	-0.994 – 0.344	0.332	16.80 + 3.31	17.50 + 3.90	-1.328 - -0.072	0.030*
Eating out habit	15.32 + 1.73	15.22 + 1.69	-0.188 – 0.388	0.484	15.22 + 3.32	15.55 + 3.54	-0.791 – 0.141	0.166
Healthy eating	17.45 + 2.39	17.35 + 2.37	-0.416 – 0.616	1.697	17.00 + 3.14	17.50 + 3.15	-1.084 –0.084	0.091

Notation: All data were normally distributed.
Paired t-test was used to compare DSOC-Q1 and DSOC-Q2 for each domain.

*significant at p<0.05

Table F-2: The difference in mean DSOC-Q scores between groups.

Domain	Score difference (Mean ± SD)		95% CI	*P*
	Diabetic patients	Healthy controls		
Carbohydrate	0.00 ± 1.24	0.42 ± 1.62	-0.216 – 1.066	0.191
GI	-0.25 ± 1.58	0.82 ± 2.51	0.141 – 2.009	0.025*
Dietary fibre	0.02 ± 1.61	-0.32 ± 1.90	-1.134 – 0.434	0.377
Dietary protein	-0.35 ± 1.92	0.50 ± 1.75	0.032 – 1.668	0.042*
Dietary fat	-0.18 ± 1.52	0.42 ± 1.55	-0.083 – 1.283	0.084
Sugar	0.25 ± 1.46	0.40 ± 1.53	-0.517 – 0.817	0.556
Fruits & vegetables	0.00 ± 1.30	0.20 ± 1.70	-0.474 – 0.874	0.656
Salt	0.10 ± 1.39	0.02 ± 1.70	-0.767 – 0.617	0.830
Meal timing	-0.02 ± 1.46	0.40 ± 1.50	-0.233 – 1.083	0.203
Food preparation	0.32 ± 2.09	0.70 ± 1.96	-0.528 – 1.278	0.411
Eating out habit	-0.10 ± 0.90	0.32 ± 1.46	-0.116 – 0.966	0.121
Healthy eating	1.83 ± 0.29	1.61 ± 0.26	-0.167 – 1.367	0.123

Notation: All data were normally distributed.

Independent *t*-test was used to compare the mean score difference between groups for each domain.

*significant at $p<0.05$

APPENDIX G

GENERAL LINEAR MODEL

PRIMARY OUTCOME – DIETARY KNOWLEDGE, ATTITUDE AND BEHAVIOUR (DKAB)

Table G-1: The mean DKAB scores differences between study groups.

Score	Mean difference	Std error	95% Confidence Interval		*P*
			Lower bound	Upper bound	
DKAB	6.414	1.502	3.421	9.407	0.000***
Knowledge	0.949	0.364	0.224	1.674	0.011*
Attitude	5.035	1.277	2.491	7.580	0.000***
Behaviour	0.681	0.432	-0.179	1.541	0.119

Notation: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.
*significant at p<0.05
***significant at p<0.001

Table G-2: The pairwise comparisons of mean DKAB scores between study groups.

Score	Data collection point	*e*-Intervention (Mean + SD)	Control (Mean + SD)	Mean difference	Std error	95% Confidence Interval		*P*
						Lower bound	Upper bound	
DKAB	Baseline	34.15 + 5.23	33.69 + 5.50	0.420	1.168	-1.909	2.748	0.721
	Post-intervention	45.20 + 8.04	40.15 + 9.86	6.262	2.101	2.076	10.448	0.004**
	Follow-up	53.95 + 8.73	41.27 + 7.74	12.813	1.912	9.004	16.623	0.000***
Knowledge	Baseline	5.83 + 2.10	5.94 + 1.70	-0.242	0.450	-1.140	0.655	0.592
	Post-intervention	8.14 + 2.16	6.73 + 1.58	1.320	0.434	0.455	2.185	0.003**
	Follow-up	8.52 + 2.00	6.84 + 1.45	1.537	0.384	0.773	2.301	0.000***
Attitude	Baseline	23.67 + 4.10	23.03 + 4.31	1.003	0.948	-0.886	2.892	0.293
	Post-intervention	30.76 + 6.18	27.31 + 8.59	4.725	1.813	1.114	8.337	0.011*
	Follow-up	38.23 + 6.67	29.06 + 6.69	9.553	1.595	6.374	12.731	0.000***

Notation: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.
(c) No between groups comparisons were conducted for behaviour score as there was no significant relationship between study groups found.

*significant at p<0.05
**significant at p<0.01
***significant at p<0.001

Table G-3: The pairwise comparisons of mean DKAB scores at each data collection points.

Score	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference	Std error	95% Confidence Interval		*P*	Mean difference	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
DKAB	Baseline	Post-intervention	-11.660	0.916	-13.963	-9.357	0.000***	-6.400	1.269	-9.656	-3.144	0.000***
		Follow-up	-20.300	1.090	-23.040	-17.560	0.000***	-7.750	0.860	-9.957	-5.543	0.000***
	Post-intervention	Baseline	11.660	0.916	9.357	13.963	0.000***	6.400	1.269	3.144	9.656	0.000***
		Follow-up	-8.640	0.842	-10.757	-6.623	0.000***	-1.350	0.876	-3.597	0.897	0.407
	Follow-up	Baseline	20.300	1.090	17.560	23.040	0.000***	7.750	0.860	5.543	9.957	0.000***
		Post-intervention	8.640	0.842	6.523	10.757	0.000***	1.350	0.876	-0.897	3.597	0.407
Knowledge	Baseline	Post-intervention	-2.380	0.218	-2.927	-1.833	0.000***	-0.750	0.194	-1.248	-0.252	0.002**
		Follow-up	-2.720	0.258	-3.368	-2.072	0.000***	-0.950	0.221	-1.517	-0.383	0.001**
	Post-intervention	Baseline	2.380	0.218	1.833	2.927	0.000***	0.750	0.194	0.252	1.248	0.002**
		Follow-up	-0.340	0.173	-0.774	0.094	0.171	-0.200	0.193	-0.695	0.295	0.928
	Follow-up	Baseline	2.720	0.258	2.072	3.368	0.000***	0.950	0.221	0.383	1.517	0.001**
		Post-intervention	0.340	0.173	-0.094	0.774	0.171	0.200	0.193	-0.295	0.695	0.928

Table G-3: The pairwise comparisons of mean DKAB scores at each data collection points (continued).

Score	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Attitude	Baseline	Post-intervention	-7.460	0.721	-9.273	-5.647	0.000***	-4.425	1.111	-7.276	-1.574	0.002**
		Follow-up	-14.880	0.830	-16.966	-12.794	0.000***	-6.425	0.835	-8.567	-4.283	0.000***
	Post-intervention	Baseline	7.460	0.721	5.647	9.273	0.000***	4.425	1.111	1.574	7.276	0.002**
		Follow-up	-7.420	0.665	-9.091	-5.749	0.000***	-2.000	0.738	-3.894	-0.106	0.036*
	Follow-up	Baseline	14.880	0.830	12.794	16.966	0.000***	6.425	0.835	4.283	8.567	0.000***
		Post-intervention	7.420	0.665	5.749	9.091	0.000***	2.000	0.738	0.106	3.894	0.036*
Behaviour	Baseline	Post-intervention	-1.820	0.195	-2.310	-1.330	0.000***	-0.450	0.273	-1.150	0.250	0.334
		Follow-up	-2.700	0.216	-3.243	-2.157	0.000***	-0.375	0.284	-1.103	0.353	0.594
	Post-intervention	Baseline	1.820	0.195	1.330	2.310	0.000***	0.450	0.273	-0.250	1.150	0.334
		Follow-up	-0.880	0.172	-1.312	-0.448	0.000***	0.075	0.159	-0.333	0.483	1.000
	Follow-up	Baseline	2.700	0.216	2.157	3.243	0.000***	0.375	0.284	-0.353	1.103	0.594
		Post-intervention	-0.880	0.172	0.448	1.312	0.000***	-0.075	0.159	-0.483	0.333	1.000

Notation: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.

*significant at p<0.05
**significant at p<0.01
***significant at p<0.001

APPENDIX H

GENERAL LINEAR MODEL – SECONDARY OUTCOMES

Table H-1: The mean differences of secondary outcomes between study groups.

Secondary outcome	Mean difference	Std error	95% Confidence Interval		*P*
			Lower bound	Upper bound	
Dietary Stages of Change (DSOC) score	6.282	2.970	0.363	12.201	0.038*
Food groups					
Carbohydrate	0.102	0.334	-0.564	0.768	0.761
Fruits	0.346	0.180	-0.013	-0.704	0.059
Vegetables	-0.104	0.117	-0.338	0.129	0.377
Protein	0.135	0.181	-0.225	0.496	0.457
Miscellaneous	0.214	0.112	-0.09	0.437	0.059
Anthropometry measurement					
Weight (kg)	6.447	3.310	-0.148	13.042	0.055
Body Mass Index (kg/m^2)	1.656	1.062	-0.461	3.772	0.123
Waist circumference (cm)	4.867	2.762	-0.636	10.369	0.082
Body fat (%)	1.699	1.135	-0.563	3.962	0.139

Table H-1: The mean differences of secondary outcomes between study groups (continued).

Secondary outcome	Mean difference	Std error	95% Confidence Interval		*P*
			Lower bound	Upper bound	
Blood pressure and resting heart rate					
Systolic BP (mmHg)	0.456	2.690	-4.904	5.817	0.866
Diastolic BP (mmHg)	1.164	1.760	-2.344	4.672	0.511
Resting heart rate (beats/min)	-1.035	2.259	-5.537	3.466	0.648
Blood biomarker					
Fasting blood sugar (mmol/L)	0.322	0.576	-0.825	1.469	0.577
HbA1c (%)	0.154	0.446	-0.734	1.042	0.731
Triglyceride (mmol/L)	0.360	0.200	-0.038	0.758	0.076
Total cholesterol (mmol/L)	0.167	0.239	-0.308	0.643	0.485
HDL-C (mmol/L)	-0.006	0.045	-0.095	0.084	0.900
LDL-C (mmol/L)	0.045	0.197	-0.347	0.437	0.820

Notations: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.
*significant at p<0.05

Table H-2: The pairwise comparisons of mean Dietary Stages of Change (DSOC) scores between study groups.

Attitude score	*e*-Intervention (Mean + SD)	Control (Mean + SD)	Mean difference	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound	
Baseline	193.27 + 14.60	191.20 + 16.19	1.703	3.878	-6.026	9.432	0.662
Post-intervention	197.54 + 16.69	191.24 + 17.10	5.558	4.376	-3.163	14.279	0.208
Follow-up	199.65 + 18.21	191.50 + 15.06	8.918	3.899	1.147	16.690	0.025*

Notations: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.
**significant at p<0.05

Table H-3: The pairwise comparisons of mean Dietary Stages of Change (DSOC) scores at each data collection points.

Score	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
DSOC	Baseline	Post-intervention	-4.638	2.413	-10.715	1.440	0.189	1.024	2.619	-5.696	7.744	1.000
		Follow-up	-6.432	3.478	-15.191	2.328	0.220	2.311	3.202	-5.906	10.528	1.000
	Post-intervention	Baseline	4.638	2.413	-1.440	10.715	0.189	-1.024	2.619	-7.744	5.696	1.000
		Follow-up	-1.794	3.595	-10.847	7.259	1.000	1.287	3.224	-6.987	9.560	1.000
	Follow-up	Baseline	6.432	3.478	-2.328	15.191	0.220	-2.311	3.202	-10.528	5.906	1.000
		Post-intervention	1.794	3.595	-7.259	10.847	1.000	-1.287	3.224	-9.560	6.987	1.000

Note: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.

Table H-4: The pairwise comparisons of mean food servings at each data collection points.

Food group	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Carbohydrate	Baseline	Post-intervention	0.744	0.391	-0.238	1.726	0.195	0.880	0.501	-0.406	2.166	0.274
		Follow-up	0.127	0.453	-1.013	1.266	1.000	0.444	0.506	-0.855	1.744	1.000
	Post-intervention	Baseline	-0.744	0.391	-1.726	0.238	0.195	-0.880	0.501	-2.166	0.406	0.274
		Follow-up	-0.617	0.171	-1.048	-0.186	0.003**	-0.436	0.177	-0.890	0.018	0.063
	Follow-up	Baseline	-0.127	0.453	-1.266	1.013	1.000	-0.444	0.506	-1.744	0.855	1.000
		Post-intervention	0.617	0.171	0.186	1.048	0.003**	0.436	0.177	-0.018	0.890	0.063
Fruits	Baseline	Post-intervention	0.175	0.290	-0.553	0.903	1.000	0.503	0.203	-0.019	1.025	0.062
		Follow-up	0.301	0.242	-0.307	0.909	0.666	0.518	0.209	-0.018	1.054	0.061
	Post-intervention	Baseline	-0.175	0.290	-0.903	0.553	1.000	-0.503	0.203	-1.025	0.109	0.062
		Follow-up	0.126	0.132	-0.206	0.457	1.000	0.015	0.055	-0.125	0.155	1.000
	Follow-up	Baseline	-0.301	0.242	0.666	-0.909	0.307	-0.518	0.209	-1.054	0.018	0.061
		Post-intervention	-0.126	0.132	-0.457	0.206	1.000	-0.015	-0.155	0.125	0.055	1.000

Table H-4: The pairwise comparisons of mean food servings at each data collection points (continued).

Food group	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Vegetables	Baseline	Post-intervention	0.545	0.184	0.083	1.007	0.016*	0.780	0.170	0.344	1.216	0.000***
		Follow-up	0.640	0.159	0.240	1.041	0.001**	0.768	0.165	0.346	1.191	0.000***
	Post-intervention	Baseline	-0.545	0.184	-1.007	-0.083	0.016*	-0.780	0.170	-1.216	-0.344	0.000***
		Follow-up	0.095	0.064	-0.067	0.257	0.446	-0.012	0.026	-0.077	0.054	1.000
	Follow-up	Baseline	-0.640	0.159	-1.041	-0.240	0.001**	-0.768	0.165	-1.191	-0.346	0.000***
		Post-intervention	-0.095	0.064	-0.257	0.067	0.446	0.012	0.026	-0.054	0.077	1.000
Protein	Baseline	Post-intervention	0.646	0.217	0.100	1.191	0.016*	0.633	0.183	0.162	1.104	0.006**
		Follow-up	0.475	0.267	-0.197	1.147	0.253	0.462	0.188	-0.19	0.944	0.063
	Post-intervention	Baseline	-0.646	0.217	-1.191	-0.100	0.016*	-0.633	0.183	-1.104	-0.162	0.006**
		Follow-up	-0.171	0.151	0.793	-0.550	0.208	-0.171	0.095	-0.415	0.074	0.257
	Follow-up	Baseline	-0.475	0.267	-1.147	0.197	0.253	-0.462	0.188	-0.944	0.019	0.063
		Post-intervention	0.171	0.151	-0.208	0.550	0.793	0.171	0.095	-0.074	0.415	0.257

Table H-4: The pairwise comparisons of mean food servings at each data collection points (continued).

Food group	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Miscellaneous	Baseline	Post-intervention	0.232	0.146	-0.135	0.598	0.363	0.178	0.110	-0.104	0.459	0.353
		Follow-up	0.106	0.177	-0.340	0.552	1.000	0.092	0.116	-0.206	0.390	1.000
	Post-intervention	Baseline	-0.232	0.146	-0.598	0.135	0.363	-0.178	0.110	-0.459	0.104	0.353
		Follow-up	-0.126	0.088	-0.348	0.096	0.490	-0.086	0.038	-0.182	0.011	0.094
	Follow-up	Baseline	-0.106	0.177	-0.552	0.340	1.000	-0.092	0.116	-0.390	0.206	1.000
		Post-intervention	0.126	0.088	-0.096	0.348	0.490	0.086	0.038	-0.011	0.182	0.094

Notation: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.

*significant at p<0.05

**significant at p<0.01

***significant at p<0.001

Table H-5: The pairwise comparisons of mean anthropometry measurements at each data collection points.

Anthropometry measurement	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Weight (kg)	Baseline	Post-intervention	-0.803	0.554	-2.196	0.590	0.468	0.455	0.526	-0.895	1.804	1.000
		Follow-up	-0.645	0.573	-2.085	0.795	0.803	0.352	0.536	-1.023	1.727	1.000
	Post-intervention	Baseline	0.803	0.554	-0.590	2.196	0.468	-0.455	0.526	-1.804	0.895	1.000
		Follow-up	0.158	0.070	-0.019	0.335	0.094	-0.102	0.058	-0.251	0.046	0.268
	Follow-up	Baseline	0.645	0.573	0.803	-0.795	2.085	-0.352	0.536	-1.727	1.023	1.000
		Post-intervention	-0.158	0.070	-0.335	0.019	0.094	0.102	0.058	-0.046	0.251	0.268
Body Mass Index (kg/m^2)	Baseline	Post-intervention	-0.291	0.202	-0.799	0.216	0.474	0.183	0.207	-0.349	0.715	1.000
		Follow-up	-0.235	0.209	-0.760	0.290	0.803	0.211	0.211	-0.395	0.686	1.000
	Post-intervention	Baseline	0.291	0.202	-0.216	0.799	0.474	-0.183	0.207	-0.715	0.349	1.000
		Follow-up	0.056	0.026	-0.008	0.121	0.107	-0.037	0.021	-0.091	0.016	0.255
	Follow-up	Baseline	0.235	0.209	-0.290	0.760	0.803	-0.146	0.211	-0.686	0.395	1.000
		Post-intervention	-0.056	0.026	-0.121	0.008	0.107	0.037	0.021	-0.016	0.091	0.255

Table H-5: The pairwise comparisons of mean anthropometry measurements each data collection points (continued).

Physical measurement	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Waist circumference (cm)	Baseline	Post-intervention	-0.740	0.461	-1.900	0.420	0.353	0.514	0.307	-0.273	1.302	0.318
		Follow-up	-0.539	0.458	-1.690	0.611	0.739	0.394	0.301	-0.377	1.165	0.605
	Post-intervention	Baseline	0.740	0.461	-0.420	1.900	0.353	-0.514	0.307	-1.302	0.273	0.318
		Follow-up	0.200	0.102	-0.056	0.457	0.172	-0.120	0.067	-0.293	0.053	0.259
	Follow-up	Baseline	0.539	0.458	-0.611	1.690	0.739	-0.394	0.301	-1.165	0.377	0.605
		Post-intervention	-0.200	0.102	-0.457	0.056	0.172	0.120	0.067	-0.053	0.293	0.259
Body fat (%)	Baseline	Post-intervention	-0.291	0.202	-0.799	0.216	0.474	0.183	0.207	-0.349	0.715	1.000
		Follow-up	-0.235	0.209	-0.760	0.290	0.803	0.146	0.211	-0.395	0.686	1.000
	Post-intervention	Baseline	0.291	0.202	-0.216	0.799	0.474	-0.183	0.207	-0.715	0.349	1.000
		Follow-up	0.056	0.026	-0.008	0.121	0.107	-0.037	0.021	-0.091	0.016	0.255
	Follow-up	Baseline	0.235	0.209	-0.290	0.760	0.803	-0.146	0.211	-0.686	0.395	1.000
		Post-intervention	-0.056	0.026	-0.121	0.008	0.107	0.037	0.021	-0.016	0.091	0.255

Notation: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.

Table H-6: The pairwise comparisons of mean blood pressures and resting heart rate at each data collection points.

Blood biomarker and blood pressure	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Systolic blood pressure (mmHg)	Baseline	Post-intervention	0.780	2.466	-5.422	6.982	1.000	0.025	2.601	-6.648	6.698	1.000
		Follow-up	1.760	2.485	-4.488	8.008	1.000	-0.425	2.631	-7.176	6.326	1.000
	Post-intervention	Baseline	-0.780	2.466	-6.982	5.422	1.000	-0.025	2.601	-6.698	6.648	1.000
		Follow-up	0.980	0.370	0.050	1.910	0.036*	-0.450	0.338	-1.317	0.417	0.585
	Follow-up	Baseline	-1.760	2.485	-8.008	4.488	1.000	0.425	2.631	-6.326	7.176	1.000
		Post-intervention	-0.980	0.370	-1.910	-0.050	0.036*	0.450	0.338	-0.417	1.317	0.585
Diastolic blood pressure (mmHg)	Baseline	Post-intervention	-0.780	1.311	-4.076	2.516	1.000	1.875	1.293	-1.443	5.193	0.478
		Follow-up	-0.200	1.311	-2.516	4.076	1.000	0.925	1.421	-2.721	4.571	1.000
	Post-intervention	Baseline	0.780	1.311	-2.516	4.076	1.000	-1.875	1.293	-5.193	1.443	0.478
		Follow-up	0.580	0.278	-0.118	1.278	0.132	-0.950	0.376	-1.915	0.015	0.055
	Follow-up	Baseline	0.200	1.308	-3.090	3.490	1.000	-0.925	1.421	-4.571	2.721	1.000
		Post-intervention	-0.580	0.278	-1.278	0.118	0.132	0.950	0.376	-0.015	1.915	0.055

Table H-6: The pairwise comparisons of mean blood pressures and resting heart rate at each data collection points (continued).

Blood biomarker and blood pressure	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Resting heart rate (beats/min)	Baseline	Post-intervention	-2.052	1.489	-5.798	1.693	0.531	-0.925	1.688	-5.257	3.407	1.000
		Follow-up	-0.972	1.452	-4.623	2.679	1.000	-1.575	1.701	-5.940	2.789	1.000
	Post-intervention	Baseline	2.052	1.489	-1.693	5.798	0.531	0.925	1.688	-3.407	5.257	1.000
		Follow-up	1.080	0.420	0.025	2.135	0.043*	-0.650	0.280	-1.369	0.069	0.086
	Follow-up	Baseline	0.972	1.452	-2.679	4.623	1.000	1.575	1.701	-2.789	5.940	1.000
		Post-intervention	-1.080	0.420	-2.135	-0.025	0.043*	0.650	0.280	-0.069	1.369	0.086

Notation: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.
*significant at p<0.05

Table H-7: The pairwise comparisons of mean blood biomarkers at each data collection points.

Blood biomarker	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Fasting blood sugar (mmol/L)	Baseline	Post-intervention	0.729	0.484	-0.457	1.975	0.376	0.320	0.436	-0.798	1.439	1.000
		Follow-up	1.024	0.493	-0.214	2.263	0.135	0.175	0.393	-0.833	1.184	1.000
	Post-intervention	Baseline	-0.759	0.484	-1.975	0.457	0.376	-0.320	0.436	-1.439	0.798	1.000
		Follow-up	0.265	0.087	0.046	0.484	0.013*	-0.145	0.108	-0.423	0.132	0.574
	Follow-up	Baseline	-1.024	0.493	-0.214	2.263	0.135	-0.175	0.393	-1.184	0.833	1.000
		Post-intervention	-0.265	0.087	-0.484	-0.046	0.013*	0.145	0.108	-0.132	0.423	0.574
HbA1c (%)	Baseline	Post-intervention	0.436	0.206	-0.081	0.954	0.123	0.543	0.275	-0.164	1.249	0.179
		Follow-up	0.602	0.215	0.061	1.144	0.025*	0.500	0.266	-0.181	1.181	0.214
	Post-intervention	Baseline	-0.436	0.206	-0.954	0.081	0.123	-0.543	0.275	-1.249	0.164	0.179
		Follow-up	0.166	0.063	0.008	0.324	0.036*	-0.043	0.026	-0.108	0.023	0.330
	Follow-up	Baseline	-0.602	0.215	-1.144	-0.061	0.025*	-0.500	0.266	-1.181	0.181	0.214
		Post-intervention	-0.166	0.063	-0.324	-0.008	0.036*	0.043	0.026	-0.023	0.108	0.330

Table H-7: The pairwise comparisons of mean blood biomarkers at each data collection points (continued).

Blood biomarker	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
Triglyceride (mmol/L)	Baseline	Post-intervention	0.059	0.096	-0.183	0.302	1.000	0.130	0.091	-0.104	0.364	0.501
		Follow-up	0.097	0.094	-0.139	0.333	0.920	0.101	0.091	-0.133	0.335	0.839
	Post-intervention	Baseline	-0.059	0.096	-0.302	0.183	1.000	-0.130	0.091	-0.364	0.104	0.501
		Follow-up	0.038	0.016	-0.003	0.079	0.077	-0.029	0.010	-0.053	-0.005	0.016*
	Follow-up	Baseline	-0.097	0.094	-0.333	0.139	0.920	-0.101	0.091	-0.335	0.133	0.839
		Post-intervention	-0.038	0.016	-0.079	0.003	0.077	0.029	0.010	0.005	0.053	0.016*
Total cholesterol (mmol/L)	Baseline	Post-intervention	0.291	0.184	-0.172	0.754	0.368	0.045	0.195	-0.455	0.546	1.000
		Follow-up	0.356	0.179	-0.093	0.805	0.161	0.010	0.194	-0.487	0.507	1.000
	Post-intervention	Baseline	-0.291	0.184	-0.754	0.172	0.368	-0.045	0.195	-0.546	0.455	1.000
		Follow-up	0.065	0.025	0.002	0.128	0.043*	-0.035	0.021	-0.088	0.018	0.312
	Follow-up	Baseline	-0.356	0.179	-0.805	0.093	0.161	-0.010	0.194	-0.507	0.487	1.000
		Post-intervention	-0.065	0.025	-0.128	-.0002	0.043*	0.035	0.021	-0.018	0.088	0.312

Table H-7: The pairwise comparisons of mean blood biomarkers at each data collection points (continued).

Blood biomarker	Data collection (I)	Data collection (J)	*e*-Intervention					Control				
			Mean difference (I-J)	Std error	95% Confidence Interval		*P*	Mean difference (I-J)	Std error	95% Confidence Interval		*P*
					Lower bound	Upper bound				Lower bound	Upper bound	
High density lipoprotein (HDL) (mmol/L)	Baseline	Post-intervention	-0.013	0.028	-0.085	0.058	1.000	-0.001	0.018	-0.048	0.046	1.000
		Follow-up	-0.036	0.026	-0.100	0.029	0.529	0.007	0.020	-0.044	0.057	1.000
	Post-intervention	Baseline	0.013	0.028	-0.058	0.085	1.000	0.001	0.018	-0.046	0.048	1.000
		Follow-up	-0.022	0.020	-0.074	0.029	0.857	0.008	0.004	-0.001	0.017	0.106
	Follow-up	Baseline	0.036	0.026	-0.029	0.100	0.529	-0.007	0.020	-0.057	0.044	1.000
		Post-intervention	0.022	0.020	-0.029	0.074	0.857	-0.008	0.004	-0.017	0.001	0.106
Low density lipoprotein (LDL) (mmol/L)	Baseline	Post-intervention	0.289	0.143	-0.070	0.648	0.152	0.094	0.171	-0.346	0.534	1.000
		Follow-up	0.348	0.146	-0.019	0.715	0.068	0.073	0.169	-0.360	0.506	1.000
	Post-intervention	Baseline	-0.289	0.143	-0.648	0.070	0.152	-0.094	0.171	-0.534	0.346	1.000
		Follow-up	0.059	0.030	-0.015	0.134	0.030	-0.021	0.014	-0.055	0.014	0.429
	Follow-up	Baseline	-0.348	0.146	-0.715	0.019	0.068	-0.073	0.169	-0.506	0.360	1.000
		Post-intervention	-0.059	0.030	-0.134	0.015	0.161	0.021	0.014	-0.014	0.055	0.429

Notation: (a) Data were controlled for gender, age, education, smoking and drinking habit, total mets/week, duration of disease and type of treatment.
(b) Adjustment was done using Bonferroni.
*significant at $p<0.05$

APPENDIX I

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Review

Web-based interventions for the management of type 2 diabetes mellitus: A systematic review of recent evidence

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A B S T R A C T

Introduction: The Internet has emerged as a potentially effective medium for information exchange. The Internet's potential has been recognised and web-based education programmes have been steadily adopted in recent years in preventing and managing chronic diseases such as diabetes mellitus. This review provides a descriptive discussion of web-based behavioural interventions for the management of type 2 diabetes mellitus.
Method: Systematic literature searches were performed using MEDLINE, EMBASE, PUBMED, PsycINFO, Web of Science and Cochrane Library to retrieve articles published between 2000 and June 2010 which fulfilled all inclusion criteria. Methodological quality assessment and data synthesis were then performed.
Results: Twenty articles representing 13 different studies were reviewed. None of the studies were ranked as low in the methodological quality. Goal-setting, personalised coaching, interactive feedback and online peer support groups were some of the successful approaches which were applied in e-interventions to manage type 2 diabetes mellitus. Strong theoretical background, use of other technologies and longer duration of intervention were proven to be successful strategies as well.
Conclusion: The web-based interventions have demonstrated some level of favourable outcomes, provided they are further enhanced with proper e-research strategies.

Contents

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1. Introduction

Diabetes mellitus (DM) is a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both [1]. There are two common conditions of DM: type 1 and type 2. Type 2 diabetes mellitus (T2DM) is the most common form of diabetes and is characterized by disorders of insulin action and insulin secretion, either of which may be the predominant feature.

DM is an increasingly important medical and public health issue. The prevalence of diabetes in adults worldwide is estimated to rise from 171 million in the year 2000 to 366 million in the year 2030 [2]. The major part of this increase is expected to occur in developing countries, with the greatest absolute increase expected to be seen in India. Similarly, the number of diabetic patients in the United States is expected to rise from 17.7 million in the year 2000 to 30.3 million 30 years later, given the increasing incidence of obesity [3].

Being a progressive disease, T2DM is one of the chronic conditions, which favours a focus on behavioural intervention. Lifestyle intervention has been the forefront runner in the prevention and management of T2DM [4]. Besides, a wide range of interventions aimed at improving the provision of diabetes care and achieving better metabolic control for patients with diabetes have been implemented [5].

The Internet holds promise for a wide-scale promotion of behavioural change to facilitate the prevention and management of T2DM, besides being an important source of health information and thus may be an appropriate delivery medium for health behaviour change interventions. The Internet's potential has been recognised and web-based education programmes have been steadily adopted in recent years in preventing and managing chronic diseases [6–9]. Unlike face-to-face interventions, website-delivered interventions can potentially reach broad populations as it is available 24 h, and could be hosted by both government and non-governmental agencies.

This review provides a descriptive discussion of web-based behavioural interventions in patients with T2DM. For each intervention studied here, objective, targeted outcome, characteristics of the study, the major content of the intervention and most important findings were assessed.

2. Methodology

2.1. *Search strategy and data sources*

Systematic literature searches were performed using MEDLINE, EMBASE, PUBMED, PSYCINFO, Web of Science and Cochrane Library according to the PRISMA guidelines [10]. The completed checklist is available from the authors upon request. We retrieved articles written in English relating to Internet based interventions for self-monitoring/self-management, physical activity, dietary behaviours, or weight loss among adults for the management of T2DM (Table 1). As this review aims to evaluate the recent surge in web-based interventions, the searches were confined to articles pub-

Table 1 – Sample search using Embase database.[a]

No.	Query	Results[b]
#7	#6 AND ([adult]/lim OR [aged]/lim) AND [english]/lim AND [2000–2010]/py	40
#6	#1 AND #2 AND #3 AND #5	98
#5	#3 OR #4	86,098
#4	web	47,978
#3	'internet'/exp	51,555
#2	intervention	318,092
#1	'diabetes'/exp	407,820

[a] Comparable strategies used with other databases.
[b] As of 27 August 2010.

lished from 2000 to June 2010. The reference lists of retrieved articles from the searches were screened for additional articles. The search keywords were "diabetes" AND "intervention" AND ("internet OR web"). Only randomised controlled trials (RCTs) and quasi experimental studies were included in this review. No attempt was made to contact authors for additional information; and the review was limited to the peer-reviewed published articles.

2.2. *Selection of studies*

Several criteria were employed for the literature inclusion. To be eligible, articles had to meet the following inclusion criteria:

- articles published in scientific journals between 2000 and June 2010;
- articles published in English because of the limitation of resources for translation;
- exchange of information via the website between a health-care provider and an individual with T2DM;
- intervened on physical activity, nutrition, self-monitoring or weight loss;
- used randomised-controlled trial or quasi-experimental designs;
- outcome measures to include behaviour changes or biomarkers related to T2DM.

Conference proceedings, book chapter reviews and dissertations, and those studies which explored the technological aspect of Internet or web-based interventions were excluded. The reference lists of the selected articles were checked for additional eligible articles, using the same inclusion and exclusion criteria.

2.3. *Data extraction and data synthesis*

As this is a qualitative systematic review, the data extracted from the selected studies were not statistically combined and re-analysed. Instead, the studies were broken down and summarised systematically according to a previously suggested method [11]: objective (management of T2DM), targeted outcome (self-monitoring, weight-loss, dietary behaviour, physical activity or combined), characteristics of the study (type of study, behavioural theory used, sample size and the reach of the intervention), the major content of the intervention and its follow-up period, most important findings and finally the conclusion on the effectiveness of the web-based intervention in the management of T2DM.

2.4. *Methodological quality assessment*

A list of criteria which was based on Cochrane Collaboration Back Review [12] and adopted for an internet-based physical activity interventions review [13] was used to assess the methodological quality of the articles. Appendix A presents the suggested list of 13 criteria that was used to determine the quality of the e-interventions. Each fulfilled criterion marked one point for the methodological scoring. As there were no guidelines for cut-off points to rate the quality of the studies, the highest possible score of 13, was divided into tertiles: score > 9 (good), 5–8 (average) and 1–4 (low). Almost similar method was used in a previously reported systematic review [13].

3. Results

3.1. *Study selection and characteristics*

Fig. 1 shows the PRISMA flow chart of the article selection process. The search resulted in 145 articles and another 42 articles were found through cross-referencing. We assessed 70 full-text articles for eligibility after excluding 72 duplicates and 45 articles which did not address the topic. Fifty articles were excluded at the final stage of eligibility assessment and the remaining 20 articles were included in this review. However, these 20 articles represent only 13 intervention studies, as we found more than one article describing results from the same study at different data collection point. In that case, articles belonging to the same study will be discussed together throughout the review.

3.2. *Data extraction and synthesis*

Table 2 summarised the Internet-based interventions for the management of T2DM that were reviewed in this article, while Table 3 provides information on significant results obtained by these studies. All articles were published between 2000 and mid-2010, but the majority of the articles were published more recently (after 2005). Six studies were conducted in the United States, while four were carried out in South Korea. Two interventions were reported in Canada and one in Taiwan. The majority of the articles focused on self-monitoring while seven on physical activity and two were combined interventions.

3.3. *Methodological quality*

Table 4 describes the results of the assessment of methodological quality of the studies. We grouped the articles describing the same group before assessing the quality. Seven out of 13 studies met at least 9 of the 13 criteria [14–16,23,25–28,33] and categorised as studies with good methodological quality. The rest of the studies reported with average quality [17–22,24,29]. None was found to have poor methodological quality.

All reported studies gave explicit details on the eligibility criteria. Although almost all studies mentioned the

Table 2 – Summary of web-based RCTs and quasi-experimental reviewed.

Focus	Study	Study design	Theory/ Model	*n*	Participation rate	Study population	Intervention Providers	Intervention	Intervention/ follow-up period	Most important results	Conclusion[a]
Self-monitoring	Kwon et al. [14]; Cho et al. [15]	RCT	–	80	67%	Adults with T2DM; Outpatient clinic of a hospital; South Korea	Physicians	Internet-based glucose monitoring system (IBGMS) to upload FBG, medication, BP, weight and recorded changes in their lifestyle and questions in the memo box. Appropriate recommendations sent fortnightly.	12 weeks/ 30 months	The mean HbA1c ($6.9 \pm 0.9\%$, $p = 0.009$) and HbA1c fluctuation index (HFI) (0.47 ± 0.23, $p = 0.001$) were significantly lower in the intervention group.	+
Self-monitoring	McMahon et al. [16]	RCT	–	104	83%	Adults with poorly controlled diabetes; Medical centre; USA	Care manager, nurse, diabetes educator, physicians	Recommendations were provided based on blood pressure and blood glucose data uploaded by patients. The patients communicated with the care manager via the IM and telephone. The website also contained web-enabled diabetes educational modules and had links to other web-based diabetes resources.	12 months	Intervention group had lower HbA1c than education and usual care ($p < 0.05$). Persistent website users had greater improvement in HbA1c than usual care (-1.4%, $p < 0.05$).	+

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Table 2 (*Continued*)

Focus	Study	Study design	Theory/ Model	*n*	Participation rate	Study population	Intervention Providers	Intervention	Intervention/ follow-up period	Most important results	Conclusion[a]
Self-monitoring	Bond et al. [17–19]	RCT	–	62	–	Older adults >60 years with T2DM; Diabetes centre, Health System and local diabetes fairs; USA	Study nurse	Enter blood sugar readings, exercise programmes, weight changes, blood pressure, and medication data into the web. On-line library, advice and counselling from a nurse via e-mail, a personal electronic log of self-management activities, and weekly on-line problem-solving group discussions.	6 months	Significant reductions in HbA1c ($-0.62 \pm 0.13\%$, $p < 0.01$), weight (-4.5 ± 1.2 lb, $p < 0.001$) and cholesterol level (-11.4 ± 4.3, $p < 0.05$)and significant improvement in HDL (6.4 ± 2.1 mg/dL, $p < 0.05$)level, measures of depression, QOL, social support, and self-efficacy in the intervention group.	+
Self-monitoring	Lee et al. [20]	Quasi experimental	–	274	–	Adults with T2DM; Metabolism Centre of a teaching hospital; Taiwan	Patient educator, physicians	Integrating patients' medical care data into their education program components and presenting them on the Web. Included a set of predefined instructions and materials on knowledge and skills of managing DM.	6 months	Significant differences between intervention and control group in FBG (108.82 ± 45.52 mg/dL vs 125.99 ± 41.44 mg/dL, $p = 0.001$), HbA1c ($6.74 \pm 2.12\%$ vs $7.42 \pm 1.65\%$, $p = 0.001$), and TC (160.99 ± 29.047 vs 174.60 ± 40.597 mg/dL, $p = 0.012$).	+

Table 2 (*Continued*)

Focus	Study	Study design	Theory/ Model	*n*	Participation rate	Study population	Intervention Providers	Intervention	Intervention/ follow-up period	Most important results	Conclusion[a]
Self-monitoring	Kim and Song [21]; Kim and Kim [22]	Quasi experimental	–	34	–	Adults with T2DM; Endocrinology outpatient; South Korea	Endocrinologist, researchers	Access web using personal cellular phones or Internet services to input daily blood glucose levels. Weekly optimal recommendations were sent via cellular phone and the Internet.	12 months	Significant decrease in HbA1c −1.22 (3 months), −1.09 (6 months), −1.47 (9 months), and −1.49 (12 months).	+
Self-monitoring	Ralston et al. [23]	Pilot RCT	Wagner's Chronic Care Model	83	42%	Adults with T2DM; University teaching clinic; USA	Care manager	e-Medical records, secure e-mail with providers, feedback on blood glucose readings, an educational website, and an interactive online diary for entering information about exercise, diet, and medication.	12 months	HbA1c levels declined by 0.7% (95% CI 0.2–1.3) in intervention group.	+
Self-monitoring	Noh et al. [24]	RCT	–	40	–	Adults with T2DM; 5 hospitals; South Korea	Automatic response	eMOD (electronic Management of Diabetes) provides real-time information about diet, dining out, hypoglycaemia, sick-day, stress management and diabetes management. The web was accessible via computer and cellular phone.	6 months	Improvement in HbA1c by web-based intervention via computer and cellular phone.	+

Table 2 (*Continued*)

Focus	Study	Study design	Theory/Model	*n*	Participation rate	Study population	Intervention Providers	Intervention	Intervention/follow-up period	Most important results	Conclusion[a]
Physical activity	Fell et al. [25]; McKay et al. [26,27]; Glasgow et al. [28]	RCT	Self-efficacy theory/Social support theory	160	60%	Adults with T2DM; Primary care clinics; United States	Online coach, research staff	D-Net: Goal-setting and personalized feedback, identified and developed strategies to overcome barriers, on-line "personal coach," and peer group support areas.	8 weeks/10 months	There was an overall moderate improvement in physical activity levels. Participant website usage decreased over the time.	+ –
Physical activity	Kim et al. [29]	RCT	Transtheoretical Model	73	–	Adults with T2DM; Outpatient clinic at a university hospital; South Korea	Study nurse	Website, print material and usual care were compared. Pre-planned physical activity counselling strategies that were individually tailored. Remarks were specifically targeted to fit the stage of motivational readiness based on physical activity readiness questionnaires. The booklet included five modules representing different stages of behavioural change for physical activity. Each module included individually targeted and stage-appropriate strategies.	12 weeks	Web-based and printed material interven-tions, compared with usual care, were effective in increasing physical activity and decreasing FBG (-14.14 ± 14.21 mg/dL, $p < 0.01$) and HbA1c (-0.59 ± 0.61, $p < 0.01$). Post hoc analysis for change scores indicated significant differences between Web-based intervention and usual care and between printed material intervention and usual care.	+

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Table 2 (*Continued*)

Focus	Study	Study design	Theory/ Model	*n*	Participation rate	Study population	Intervention Providers	Intervention	Intervention/ follow-up period	Most important results	Conclusion[a]
Physical activity	Richardson et al. [30]	Pilot RCT	Health Belief Model	30	59%	Adults with T2DM; Advertisements and flyers; United States	Research staff	Enhanced pedometers were used to upload detailed, time-stamped step-count data to a website and receive automated step-count feedback, automatically calculated goals, and tailored motivational messages.	6 weeks	No significant difference between groups in the increase of bout steps. Those who received lifestyle goals were more satisfied with the intervention and wore the pedometer more often than did those who received structured goals.	+ –
Physical activity	Liebreich et al. [31]	Pilot RCT	Social Cognitive Theory	49	64%	Adults with T2DM; Advertisements, diabetes education classes, health care professional, previous research involvement; Canada	Study coordinator	Personalized weekly emails, an on-line logbook and message board.	12 weeks	Significant improvement in total duration vigorous and moderate of physical activity, and behavioural capacity in intervention group.	+

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Table 2 (*Continued*)

Focus	Study	Study design	Theory/ Model	*n*	Participation rate	Study population	Intervention Providers	Intervention	Intervention/ follow-up period	Most important results	Conclusion[a]
Physical activity and nutrition	Wolf et al. [32]	RCT	–	147	–	Adults with T2DM; Members of Southern Health System; United States	Dietician	Case management entailed individual and group education, support, and referral by registered dieticians.	12 months	Greater weight loss, reduced waist circumference, reduced HbA1c level (−0.19%, $p = 0.45$), less use of prescription medications and improved health-related quality of life in intervention group.	+
Diabetes risk factors	Holbrook et al. [33]	RCT	–	511	32%	Adults with T2DM; Health care providers; Canada	Researchers	Shared access by the primary care provider and the patient to a Web-based, colour-coded diabetes tracker, which provided sequential monitoring values for 13 diabetes risk factors, their respective targets and brief, prioritised messages of advice.	6 months	The clinical composite score also had significantly more variables and process composite score was significantly better for patients in the intervention group.	+

[a] Conclusion is either + (positive), − (negative) or + − (neutral) relative to the study's primary outcome or objective as highlighted by the respective authors in their results.

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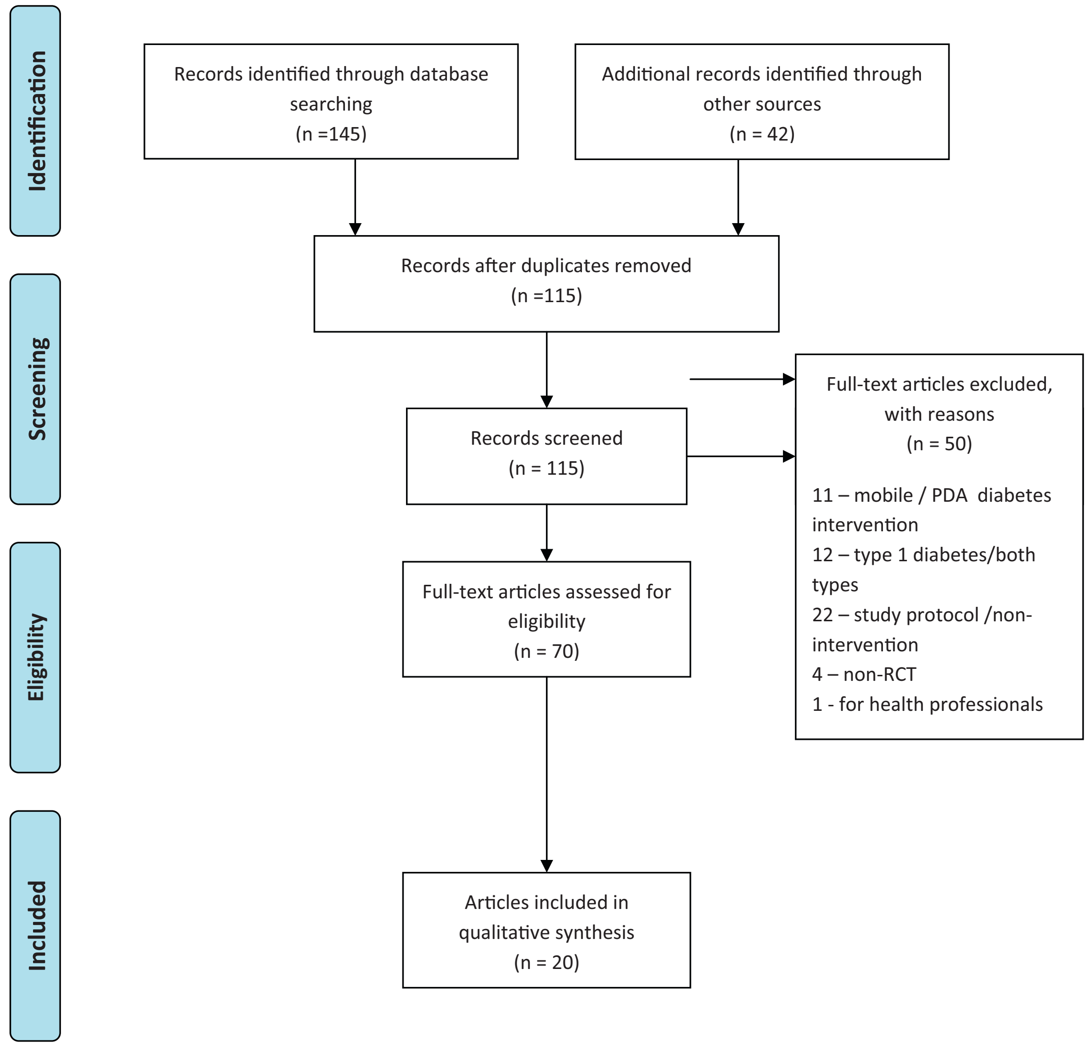

Fig. 1 – PRISMA flow chart shows the articles selection process.

Table 3 – Primary outcomes measured, and the number of studies with a statistically significant results.

Focus	Specific primary measure	Number of studies with significant results/Number of studies assessing it	Reference
Self-monitoring	HbA1c	7/7	[14–24]
	FBG	2/2	[20–22]
	Cholesterol	3/3	[17–22]
	Weight	1/1	[17–19]
	Measures of depression	1/1	[17–19]
	QOL	1/1	[17–19]
	Social support	1/1	[17–19]
	Self efficacy	1/1	[17–19]
Physical activity	Physical activity level	2/3	[25–28,29,31]
	Bout steps	0/1	[30]
	HbA1c	1/1	[29]
	FBG	1/1	[29]
Physical activity and nutrition	Weight	1/1	[32]
	Waist circumference	1/1	[32]
	HbA1c	1/1	[32]
	QOL	1/1	[32]
Diabetes risk factors	Clinical composite score	1/1	[33]

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Table 4 – Methodological quality of the interventions.

Criteria	Kwon et al. [14]; Cho et al. [15]	Mc Mahon et al. [16]	Bond et al. [17–19]	Lee et al. [20]	Ralston et al. [23]	Noh et al. [24]	Kim and Song [21]; Kim and Kim [22]	Fell et al. [25]; McKay et al. [26,27]; Glasgow et al. [28]	Richardson et al. [30]	Kim and Kang [29]	Liebreich et al. [31]	Wolf et al. [32]	Holbrook et al. [33]
Eligibility criteria	√	√	√	√	√	√	√	√	√	√	√	√	√
Method of randomization	√	√	√	√	√	×	√	√	√	×	√	√	√
Randomization by independent person	Not clear	√	Not clear	×	√	Not clear	Not clear	Not clear	√	×	Not clear	×	√
Similar baseline data	√	√	√	√	√	√	√	√	√	√	√	√	√
Description of intervention	√	√	√	√	√	√	√	√	√	√	√	√	√
Compliance to intervention	×	√	×	√	×	×	×	√	×	×	√	×	×
Blinding of outcome assessor	Not clear	Not clear	Not clear	Not clear	×	×	Not clear	Not clear	Not clear	Not clear	Not clear	Not clear	√
Description of drop outs	√	√	×	×	√	√	×	√	×	×	√	√	√
Outcome assessment ≥ 6 months after randomization	√	√	×	×	√	√	√	√	√	×	×	√	√
Timing of assessments	√	√	√	√	√	√	√	√	√	√	√	√	√
Sample size calculation	√	√	√	×	√	×	×	×	×	√	×	×	√
Intention-to-treat analysis	×	√	×	×	√	×	×	×	×	×	√	√	√
Point estimates and measures of variability	√	√	√	√	√	√	√	√	√	√	√	√	√
Total fulfilled criteria	9	12	7	7	11	7	7	9	8	6	9	9	12

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randomization process, majority did not elaborate if the randomization was conducted by an independent person or system. Baseline data were reported to be statistically similar between groups and the interventions were described well in all the studies. However, none of the studies gave information on the blinding of outcome assessor.

The description on compliance of the intervention here was defined as the reporting of the number of log-ins. Only four studies reported data on website log-ins of the participants [16,20,28,31]. Description of the drop-outs, timing of the assessments and other statistical measures were reported in some studies but not all.

4. Discussion

4.1. Characteristics of the studies

4.1.1. Self-monitoring

Self-management or self-monitoring is a well-researched segment in the management of this disease. Despite the fact that they were not designed based on behavioural theories, self-management e-interventions [14–24] have all shown to be successful. These studies had almost similar self-monitoring method in the intervention, where the participants were required to log in to enter their blood glucose readings daily or weekly. Patients then receive their recommendations provided by medical professionals after the uploaded information was assessed. Reduced glycosylated haemoglobin (HbA1c) was reported in the intervention group in six of the studies [14–19,21–24] while Lee et al. [20] reported decrease in HbA1c and FBG.

In the first reported study, the Internet-Based Glucose Monitoring System (IBGMS) was utilised for a 3-month RCT [14], which was then followed-up for 30 months [15]. The instructors logged in daily to assess participants' FBG, medication, BP, weight and changes in their lifestyle, and sent appropriate recommendations to each patient in the intervention group every fortnight. To date, this remains the study with the longest follow-up. Patients with poor glycaemic control were specifically targeted by MyCare Team [16]. Despite being a successful e-intervention, there was no reported follow-up of this RCT. RCTs and quasi-experiments in obese, older or general patients with T2DM have all ended in a positive note [17–20,22–24].

The success of these e-interventions are determined by many factors such as frequent contact between the intervention participants and the physician; weekly therapeutic changes; training on the website usage; interactive and individualised approach; online group discussion and integration of medical data [14–16,20,23]. All e-interventions focusing on self-monitoring were conducted for a period of 6–12 months. The core of the program and intervention approach were the other crucial factors in determining the success of a self-monitoring intervention. This may suggest that web-based self-monitoring interventions have more impact on the blood glucose control but the sustainability of positive findings of these studies is questionable as only one intervention had follow-up.

4.1.2. Physical activity

The number of internet-based behavioural interventions targeting physical activity/exercise is rather limited. To date, only two RCTs and two pilot RCTs have been published [27–31].

D-Net was one of the major behavioural intervention studies which aimed at increasing physical activity level of the participants [25–28]. The response to the recruitment was greater in younger and newly diagnosed patients [25] than in older patients and those who had diabetes for many years. However, there was only moderate improvement in physical activity levels (min/day) at post-intervention [27] and post-follow-up [28]. A short pilot physical activity intervention [30] which utilised a pedometer did not find any significant difference after the intervention, despite the frequency of pedometer use and increased satisfaction level of those who received lifestyle intervention. In contrary, the use of Internet as the medium of information delivery in Korea was found to promote physical activity and has resulted in a better glucose control [29]. A pilot RCT conducted in Canada [31] offered personalized weekly emails, an on-line logbook and message board to the patients and it showed improvement in total vigorous and moderate minutes of physical activity, and behavioural capacity.

Website-based physical activity interventions, just like any other behavioural interventions have the problem of sustainability. For example, the participant website usage of D-Net was found to decrease over the time, despite the additions of self-management and peer-support components [28].

4.1.3. Combined interventions

There were two combined interventions reported on a lifestyle intervention in the management of T2DM [32,33]. Wolf and co-authors [32] reported a low cost lifestyle intervention which combined physical activity and dietary behaviour has resulted in the improvement of anthropometrical measurements, HbA1c and health-related quality of life when compared with the group which received the usual care for patients with T2DM. The study, however, did not incorporate any behavioural theory into the intervention program. Holbrook and co-workers [33], on the other hand, focused their intervention on various factors associated with diabetes and successfully improved the clinical and process composite score.

Although multifaceted intervention seems to be effective and has been reported to be helpful [34], there is always a limitation where researchers cannot always identify the component that contributed to the effectiveness of the intervention. Besides, poor implementation of complex intervention may undermine the power and the validity of the entire study. This may be one reason why there is a lack of combined interventions in preventing or managing T2DM.

4.2. Use of behavioural theories

The number of studies applying a behavioural theory in their intervention was rather limited. Intervention studies which focused on self-monitoring of blood glucose did not report any specific theory or model in their design of intervention, website or recommendations except for Ralston et al. [23] who used Wagner's Chronic Care Model. The use

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of behavioural theories to support the physical activity e-interventions among T2DM patients was found to be fruitful. Interventions guided by Self-efficacy Theory and Social Support Theory [25–28], Health Belief Model [30], Transtheoretical Model [29] and Social Cognitive Theory [31] were all found to produce positive results.

So far, the evidence is not sufficient for any recommendation on the most suitable theory or model for future interventions. The decision on the most relevant theory, therefore, should be made based on the objective of the e-intervention and the factor to be intervened.

4.3. *Intervention providers*

The interventions were mainly provided by the researchers or research staff members appointed for the study [21–23,27,30,31]. Physicians [14,20], study nurse [18,19], dietician [32] and endocrinologist [21,22] were also engaged in providing intervention to the patients. MyCare Team intervention had a larger group of healthcare personnel involved in the delivery of the intervention programme [16], while a latest intervention by Noh et al. [24] relayed totally on the system to deliver automatic responses to the patients when they logged in their blood data.

4.4. *Usage of other technology for reinforcement of the intervention*

E-mail and short messaging service (SMS) technologies that were commonly used together with the websites to reinforce the intervention. E-mails were used as a component of the intervention, with the researchers sending weekly recommendations or as communication method between providers and patients [18,23,31]. Richardson et al. [30] on the other hand, only used the e-mail component to contact the participants before and after the intervention program.

SMS were used by the researchers to send warning message to the participants if they did not log into the website for a stipulated time [16,29]. Some studies also used SMS as a part of the intervention program by requesting the participants to send their blood sugar readings to the website via SMS [21,22] or by sending recommendations and feedback to the participants [20]. Noh et al. [24] made their intervention web to be accessible both by cellular phone and computer-based Internet.

Sending automated e-mails whenever the website is updated and warning e-mails or SMS whenever the participant did not log in for a stipulated time is encouraged for more frequent engagement to the website throughout the intervention. In summary, the use of other technologies was found to be an excellent method of reinforcing web-based interventions.

4.5. *Optimal duration of intervention and follow-up period*

The duration of the intervention ranged between 12 and 52 weeks, with an average of 27.2 ± 18.3 weeks. Seven self-monitoring e-intervention on the management of T2DM ranged between 12 and 52 weeks, with an average of 34.3 ± 17.1 weeks. Only one study reported a follow-up of 30 months. The physical activity based e-interventions were conducted with an average of 9.5 ± 3.0 weeks with only the D-Net study reporting a 10-months follow-up [28]. Only relatively longer studies (12 weeks) reported positive findings [29,31]. Combined interventions also were successful after duration of 6 and 12 months [32].

The findings suggest that behavioural intervention require a longer duration to yield positive results as compared to self-monitoring e-interventions. Although the interventions are feasible short-term, a longer follow-up is essential to investigate the sustainability of the web-based interventions.

4.6. *Outcome measures*

Blood biomarkers – HbA1c, FBG, 2HPPT and/or total cholesterol remained the most commonly reported outcome measures of web-based interventions in the management of T2DM. The majority to the self-monitoring interventions reported solely the blood biomarkers [14–16,20–24]. Bond and co-authors [18] reported the blood biomarkers, body weight and psychosocial well-being as their primary outcome measures.

Besides blood biomarkers, there were few other outcome measures reported by these interventions. The D-Net study [27,28] and Liebreich et al. [31] measured the level of physical activity, while another pilot RCT on Internet-mediated walking [30] measured the bouts of steps. Blood biomarkers and anthropometrical measurements were also used as outcome measures for a lifestyle e-intervention [32]. Holbrook et al. [33] reported a composite score of clinical and process scores.

Majority of the studies included the blood biomarkers especially HbA1c as their primary outcome measure. However, some studies incorporated other outcome measures such as scoring, dietary or physical activity data corresponding to their objectives.

4.7. *The 'reach' of the interventions*

In this review, the 'reach' of the web-based interventions is determined by the participation rate and recruitment setting. Participation rate is calculated by dividing the number of study participants by the number of the target population who were contacted and eligible to participate, and converted to percentage [35].

Only 8 out of 13 studies (62%) reported either the participation rate or details needed to calculate the participation rate. The percentages are presented in Table 2. The participation rate varied between 32% and 83%, with a mean of 58%.

The studies were focused either on adults T2DM [20,23–25,29–33], obese adults with T2DM [21,22] or older adults with T2DM [17–19]. McMahon and colleagues [16] conducted the trial on adults with poorly controlled diabetes. Hospital setting remains to be the most common ground to recruit subjects [14,16,22–25,29], though some studies have recruited subjects via health system or health care providers [17–19,33] advertisements in mass media, distribution of flyers [30] and mixed mediums [31].

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4.8. Limitations of the interventions

The limitations of these interventions include the restriction to Internet access [29], which may decrease website usage over time [27] and non-responses [26]. Distribution of weekly newsletter via the e-mail ensured the number of log-in remained high throughout the study. However, other telecommunication methods such as SMS have also been used together with websites to re-emphasize the intervention [21,22,29] and this has proven to be successful.

4.9. Relevant findings from other reviews and meta-analysis

Diabetes self-management education is defined as the process of providing the person with diabetes with the knowledge and skills needed to perform self-care, manage crises, and make lifestyle changes required to successfully manage this disease [36]. Appropriate self-management behaviour is one of the key determinants of successful blood glucose control. Self-management behaviour was one of the most commonly intervened factors, besides lifestyle habits in e-interventions among patients with T2DM. Recent systematic reviews and meta-analysis reported on non web-based self-monitoring interventions have not reached a consensus [37–40] though there was some evidence in favour of self-monitoring.

A review of 11 group-based self-management studies published in Cochrane suggested improvements in FBG, HbA1c and diabetes knowledge, besides reducing systolic blood pressure, body weight and the requirement for medication [41]. Larger effect size has been noted in diabetes self-management interventions that targeted improvement in knowledge (ES = 1.29) compared to metabolic control (ES = 0.510) or behaviour (ES = 0.36) [42]. There were differences in outcomes observed for number of sessions, duration of intervention and provision of booster sessions.

Heinrich et al. [43] found diabetes self-management interventions with education component to be effective for diet, self-monitoring of blood glucose, knowledge and diabetes specific quality of life (QoL). Dietary behaviour was relatively easy to change with self-management interventions, though the findings were inconclusive for exercise and clinical outcomes. Smaller studies with compact sessions of self-care management teamed with an educational approach have been shown to improve glycaemic control [44]. However, coordinated efforts of interventions, using specific delivery techniques, teaching methods, and content, given at a specific "dose" [45] and culturally appropriate diabetes health education [46] may give a better impact on the glycaemic control.

There were fewer reviews on technology-driven trials on self-management of diabetes. A review on computer-assisted interventions reported six interventions with moderate to large significant declines in HbA1c levels compared with controls [47]. There were also improvements in health care utilization, behaviours, attitudes, knowledge, and skills. Graziano and Gross [48] reviewed eight isolated telephone interventions on glycaemic control and found no concrete evidence. However, a meta-analysis published the following year, showed intensive telephone follow-up may have better effects on glycaemic control (−0.84%, 95% CI −1.67 to 0.0).

There were no quality data that support the efficacy of dietary treatment of type 2 diabetes [49]. Nevertheless, the adoption of exercise appears to improve HbA1c at six and twelve months in people with T2DM, though the authors have warned the risk of bias in these interventions. Exercise training was found to reduce HbA1c of diabetic patients, but without significant change in their body mass [50]. Specifically, resistance training has been suggested to be an effective intervention for glycaemic control [51,52]. Compared to not exercising, progressive resistance exercise led to small but significant absolute reductions in HbA1c of 0.3% (−0.25, 95% CI −0.47 to −0.03) [51]. Fewer studies have investigated combined resistance and aerobic training, but existing evidences appeared to result in additional change in HbA1c [52].

A previously reported systematic review on Internet-based physical activity interventions suggested that added values such as increased contact with the facilitator, tailored information and use of behavioural theories would improve effectiveness of these interventions [13]. This is an important aspect which needs to be focused in future studies, as declining usage could well affect the final outcome of the e-interventions.

Combined interventions usually include diet, physical activity and/or self-monitoring of blood glucose of the patients. Huisman et al. [53] and Norris et al. [54] reported meta-analysis on weight loss trials for diabetics using these combined intervention methods. Interventions with high self-regulation had better effects on both weight and HbA1c outcomes [53]. The authors also suggested that goal setting and inclusion of a partner or relative had better effect on weight reduction and emotion regulation had better effect on HbA1c. Although small pooled weight loss of 1.7 kg was found, multi-component interventions including very low calorie diets or low calorie diets may hold promise for achieving weight loss in adults with type 2 diabetes [54].

5. Limitations of the review

There are several limitations which should be considered while interpreting the results presented in this review. There is a possibility of publication bias as only published studies using the English language were considered. The review only took the recent peer-reviewed publications into consideration. Searches were carefully conducted using major databases and cross-referencing method, yet there is a chance for some publications not to be included in the search due to the inclusion criteria.

6. Conclusions and recommendation

The evolution of e-interventions seems to be inevitable at this era. Rapid development of the technology has led to the progression from generation of printed modules from computer and CD-ROMs to 'live' interaction of patients with the system and/or researchers via the Internet. Goal-setting, personalised coaching, interactive feedback and online peer support groups were some of the successful approaches which were applied in e-interventions to manage T2DM. Generally, the

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self-monitoring e-interventions yielded better results than the behavioural e-interventions, although this could also be due to higher number of self-management e-interventions that was reported. The availability of a care manager in form of clinical researcher, physician and/or nurse appears to strengthen the intervention program and increase the compliance. The use of other technology such as the mobile phones was also found to be an important aspect of successful interventions. Therefore, web-based intervention programmes have potential to reach and educate diabetic patients and further exploration in this area is warranted.

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Author contributions

Amutha Ramadas contributed to the literature search, concept and review design, and review write-up; Quek Kia Fatt and Carina KY Chan provided feedback on the review drafts and revised the review; Brian Oldenburg provided feedback on the review drafts and methodological quality, and revised the review.

Competing interest

None of the authors has any conflict of interest in the manuscript.

Summary points

What was already known?

- Behavioural and self-monitoring interventions could assist type 2 diabetes mellitus prevention and management effort.
- Websites are feasible medium for the delivery of behaviour interventions.

What this study adds?

- Constant tracking progress of participants, setting personalised goals, strong theoretical background, self-monitoring, providing social and peer support are important to determine the success of a web-based intervention.
- The use of other technology such as the mobile phones has been proven to improve compliance with the e-interventions.

Appendix A. Criteria of Methodological Quality

1. Were the eligibility criteria specified?
2. Was the method of randomization described?
3. Was the random allocation concealed? (ie, Was the assignment generated by an independent person not responsible for determining the eligibility of the patients?)
4. Were the groups similar at baseline regarding important prognostic indicators?
5. Were both the index and the control interventions explicitly described?
6. Was the compliance or adherence with the interventions described?
7. Was the outcome assessor blinded to the interventions?
8. Was the dropout rate described and were the characteristics of the dropouts compared with the completers of the study?
9. Was a long-term follow-up measurement performed (outcomes measured $\geq$ 6 months after randomization)?
10. Was the timing of the outcome measurements in both groups comparable?
11. Was the sample size for each group described by means of a power calculation?
12. Did the analysis include an intention-to-treat analysis?
13. Were point estimates and measures of variability presented for the primary outcome measures?

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STUDY PROTOCOL Open Access

Randomised-controlled trial of a web-based dietary intervention for patients with type 2 diabetes mellitus: Study protocol of *my*DIDeA

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Abstract

Background: The potential of web-based interventions in dietary behaviour modification of the diabetics has not been fully explored. We describe the protocol of a 12-month match-design randomised controlled trial of a web-based dietary intervention for type 2 diabetic patients with primary aim to evaluate the effect of the intervention on their dietary knowledge, attitude and behaviour (KAB). The secondary objective of this study is to improve the participants' dietary practices, physical measurements and biomarkers.

Methods/Design: A minimum total sample of 82 Type 2 diabetics will be randomised, either to the control group, who will receive the standard diabetes care or the e-intervention group, who will participate in a 6-month web-based dietary intervention in addition to the standard care. The dietary recommendations are based on existing guidelines, but personalised according to the patients' Stages of Change (SOC). The participants will be followed up for 6 months post-intervention with data collection scheduled at baseline, 6-month and 12-month.

Discussion: We are aiming for a net improvement in the KAB score in participants of the e-intervention group, besides investigating the impact of the e-intervention on the dietary practices, physical measurements and blood biomarkers of those patients. The successful outcome of this study can be a precursor for policy makers to initiate more rigorous promotion of such web-based programmes in the country.

Trial registration: Clinicaltrials.gov NCT01246687

Background

Diabetes is a growing concern in Malaysia and in the world. The prevalence of diabetes in adults worldwide was estimated to rise 366 million in the year 2030 from 171 million in 2000 [1]. The prevalence of Type 2 Diabetes Mellitus (T2DM) in Malaysians above 30 years old was reported to be between 11% and 14% in 2006, and it is estimated to rise further [2]. T2DM accounts for a huge burden of morbidity and mortality through micro and macrovascular complications [3,4]. This has lead to an increasing demand on dietary and lifestyle modifications to delay the disease progression.

Web-based interventions have been successfully implemented in improving self-management of diabetes [5-8], physical activity [9,10] and weight management [11,12] in adults with T2DM. A web-based nutrition education for diabetes prevention study among young adults has shown significant reduction in dietary fat intake [13]. To date there is no published study focused solely on dietary behaviour change in adults with T2DM via a website-based system. Nevertheless, dietary modification has been incorporated as a component of multifactorial behavioural interventions in diabetes prevention and management [11,12,14].

The success of a web-based intervention relies heavily on the website log-in rates, usability, and personalisation. Content development in simplified local language improves the usability of the website [15], while regular reinforcement using reminder services such as e-mails and SMS increases the log-in rates [16]. The use of behavioural theories could assist the personalisation of web-based interventions. Transtheoretical Model (TTM) [17] is one of such behavioural model that has been recently used in web-based interventions, especially

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those focusing on improving dietary and lifestyle behaviours [10,18].

The study protocol for a randomised controlled trial (RCT) of a web-based dietary intervention for patients with T2DM in Malaysia is presented here. We hypothesised that the e-intervention group will show a greater improvement in dietary KAB than the control group. Secondly, we hypothesised that the web-based intervention to results in a better dietary practices, anthropometric measurements and blood biomarkers in the e-intervention group than the controls.

Methods/Design

Study design

This is a two-armed matched-design randomized controlled trial (RCT) scheduled for 12 months (Figure 1). The study is designed according to the recommendations of the CONSORT statement for randomised trials of non-pharmacologic treatment [19].

The conceptual framework of the study is presented in Figure 2. Twelve dietary modules in the intervention package is personalised according to the patients' Stages of Change (SOC), and is expected to improve their dietary KAB and assist them to progress in their respective SOC. The improvements in KAB and progress in SOC are expected to be reflected in the patients' dietary practices. Adoption of healthy dietary practices then is expected to be reflected on the anthropometric measurements and biomarkers.

Study aims

The primary aim of our study is to evaluate the effect of a six month dietary e-intervention on dietary knowledge, attitude and behaviour (KAB) in patients with T2DM.

The secondary aim is to determine the impact of the intervention on dietary practices (nutrient intake, dietary GI, food frequency score, supplements intake, cooking method and eating out habit), physical measurements (height, weight, body mass index, waist circumference, body fat percentage and blood pressure) and blood biomarkers (fasting blood glucose (FBG), glycosylated haemoglobin (HbA1c) and lipid profile).

Ethics approval

The study has received ethics approval from Malaysian Ethics Research (NMRR-09-303-3416) and Monash University Human Research Ethics Committee (CF09/1583 - 2009000877).

Study sample

Sample size and power calculation

The sample size calculation is based on a difference in fat and fibre-related behaviour score as reported by a previous computer assisted dietary intervention study in type 2 diabetics [20]. Using a reduction in the mean behaviour score from 1.93 ± 0.5 (baseline) to 1.69 ± 0.4 (post intervention), the GPower software [21] calculated that 31 patients are needed in each group to detect this difference with a two-sided alpha of 0.05, a power of 80%. Based on 30% attrition rate for one year, a minimum of 41 participants are required in each group.

Recruitment process

The eligibility screening, recruitment of study participants and data collections are conducted in the outpatient medical clinic of three urban hospitals in Malaysia. Diabetic nurses provide assistance in identifying potential study participants according to the eligibility criteria (Table 1). If the patients are found have potential to participate in the study, they complete the baseline questionnaire after giving a written informed consent. They are, however, excluded if the baseline dietary KAB score was more than 50%.

Randomisation and treatment allocation

Eligible diabetic patients who have consented to participate are matched for age, sex and ethnicity, and randomised to either e-intervention or control group.

Control group

This group receives the usual standard treatment (diabetic control and management) given to patients with T2DM. Although the controls have access to the Internet, they receive neither website log-in information, nor any reinforcement via e-mail or SMS.

e-Intervention group

This group receives an intensive dietary intervention through the study website, personalised according to the participants' SOC, in addition to the usual standard treatment at the outpatient clinics.

Intervention programme

Dietary module

Twelve dietary lesson plans are developed for the intervention based on the Nutrition Recommendations and Interventions for Diabetes by American Diabetes Association [22], Malaysian Clinical Practice Guidelines for Type 2 Diabetes Mellitus [23] and Malaysian Medical Nutrition Therapy Guidelines for Type 2 Diabetes [24]. The intervention's structure and materials are developed using TTM's Stages of Change construct [17] (Table 2). The content of each lesson plan is studied for its relevance to the local community and fine-tuned to suit local context.

Website design

Suitable features to be highlighted in the website are discussed by a research panel comprising of nutritionist, behavioural psychologists, endocrinologist, public health expert, and a web master. Figure 3 outlines the structure

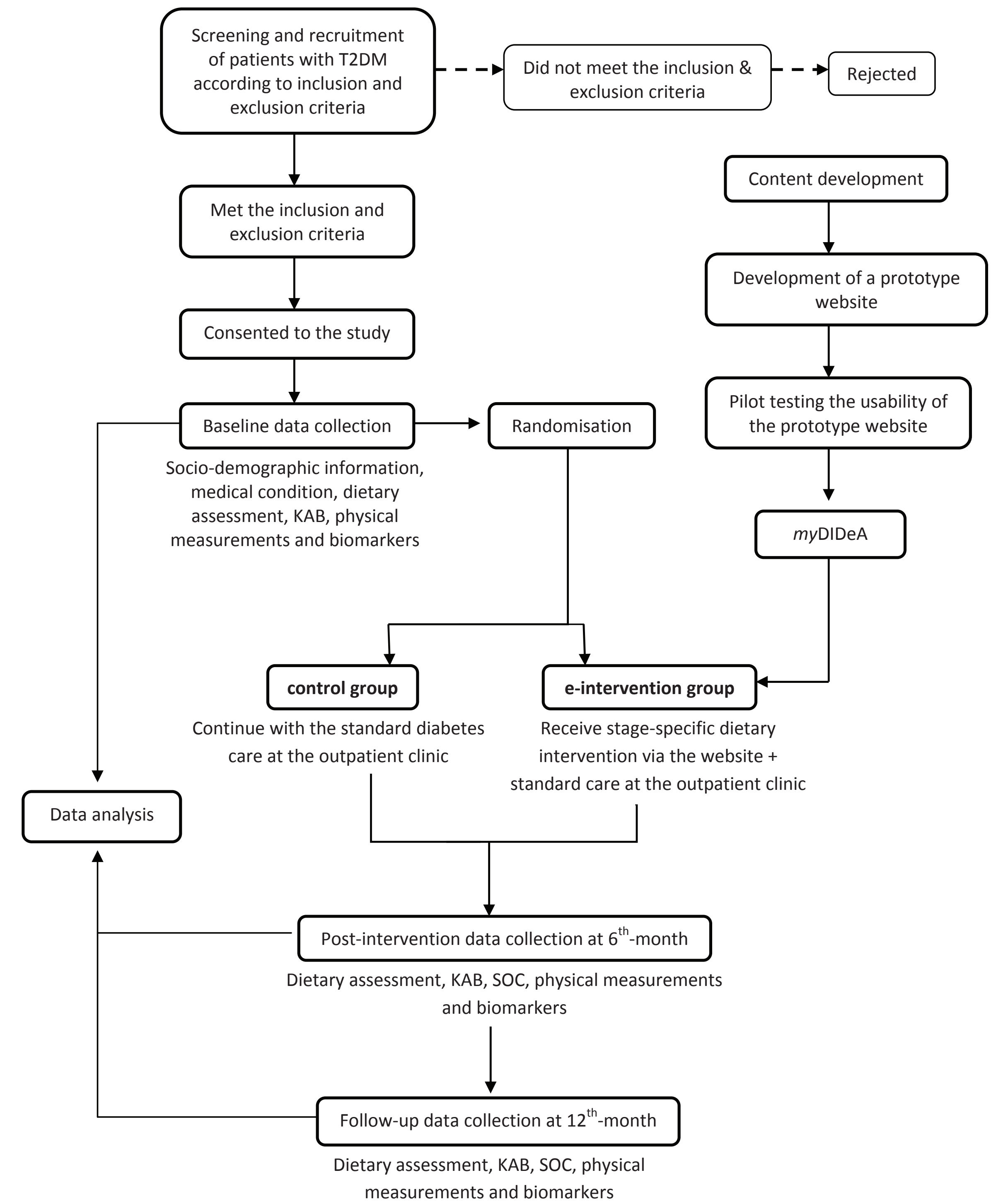

Figure 1 Flow chart of the proposed study.

of the study website, *my*DIDeA *(Dietary Intervention for Type 2 Diabetes Patients: An e-Approach)*.

*my*DIDeA will be tailored according to the participants' SOC. Each lesson plan has five Likert scale items (strongly agree = 5 to strongly disagree = 1) and participants are assigned to recommendations based on the score obtained. The recommendations are aimed to address the barriers and motivate the participants according to the lesson plan and stage. Relevant photographs and illustrations are added to enhance the understandability of the lesson

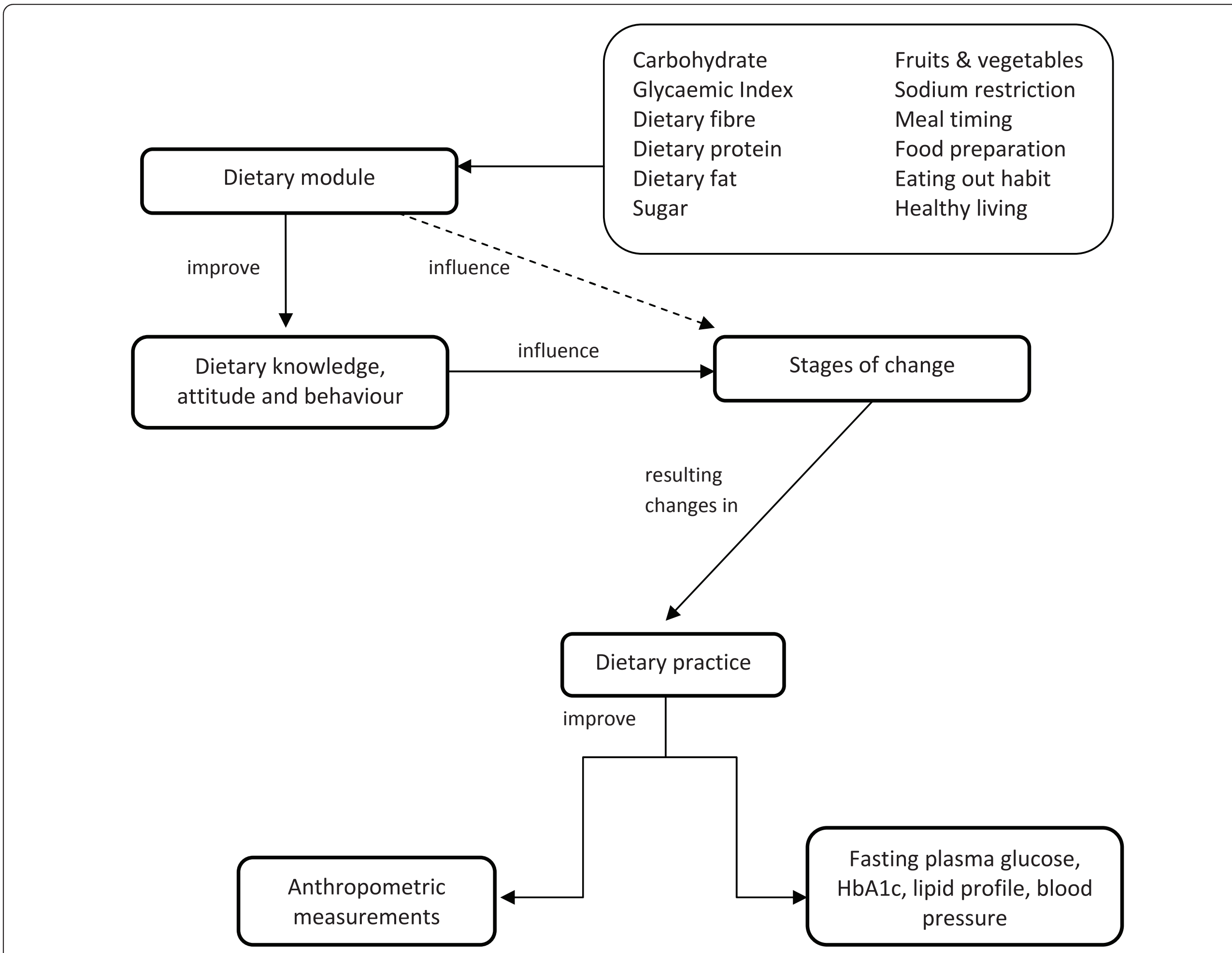

Figure 2 Conceptual framework.

Table 1 Eligibility criteria

Inclusion	Exclusion
Mentally sound men and women who are ≥ 18 years old.	Pregnant, lactating or intend to become pregnant during the study period.
Literate with a fair command of English and/or Malay languages.	Diagnosed with Type 1 Diabetes Mellitus (T1DM) or Gestational Diabetes Mellitus (GDM)
Have access to the Internet at home, work or public place.	Weighing more than 150% of the desired weight for height.
Willing to access the study website at least once every fortnight.	Any pre-existing condition compromising the quality of life or ability to participate according to protocol.
Have been confirmed of having HbA1c of ≥7.0%.	Have severe complications (chronic heart disease, cerebrovascular disease, diagnosed HIV/AIDS, cancer, emphysema, chronic liver or kidney disease) that would affect the subjects' ability to follow the tailored advice.
	Enrolled in other clinical studies.
	Having dietary KAB score more than 50% at baseline.

plans. Factsheets and statistics on diabetes, links to existing diabetes resources and an example of ideal health profile also are included.

The participants are briefed on *my*DIDeA, and are provided with unique username and password via e-mail or SMS after the randomisation. Log-in reminders are sent to their e-mail each time *my*DIDeA is updated with new lesson plan. The participants are also encouraged to send their queries to the study nutritionist via the website.

Outcome assessments

All assessments (Table 3) are conducted at the clinical settings by trained enumerators.

Primary outcomes

The primary outcome is assessed using a validated interviewer-administered dietary KAB questionnaire in English and Bahasa Malaysia.

Secondary outcomes

A semi-food frequency questionnaire (SFFQ) is used to record the subjects' dietary intake, while two days 24-

Table 2 Five Stages of Change, its characteristics and relevant strategies (Kendra C 2010)

Stage	Characteristics	Strategies
Pre-contemplation	• Not intending to change in the next 6 months. •In denial or ignorant of the problem.	•Encourage the patient to self-analyse and rethink his/her behaviour. •Explain the risks of current behaviour.
Contemplation	•Intending to change in the next 6 months. •Having conflicting emotion.	•Weigh the pros and cons of changing behaviour. •Address barriers and encourage confidence.
Preparation	•Planning to change in the next 30 days and have made a previous attempt to improve. •Experimenting and collecting information about change.	•Prepare an action plan or goal. •Motivate the patient to change.
Action	•Taking actions towards achieving the goal for at least the last 6 months.	•Encourage the patient to seek social support and motivate him/her to sustain the behaviour. •Reward for the success.
Maintenance	•New behaviour is sustained for at least 6 months.	•Strategies to cope with temptation. •Reward for the success.

hour dietary recall is used to analyse the nutrient intake [25]. Besides SFFQ and 24-hour dietary recall, consumption of supplements, cooking techniques and eating out habit for the past one month are also recorded. Anthropometric measurements (body mass index, waist circumference and percentage of body fat) and blood pressure are taken during the interview sessions. The results of participants' blood biomarkers are obtained from their medical record.

Process evaluation

Adherence to the intervention is assessed by the number of log-ins and duration spent in the website. Besides, the participants' satisfaction of the intervention is assessed by self-administered questionnaire at post-intervention.

Other measurements

The socio-demographic characteristics, medical history, and smoking and drinking habits are recorded in a structured questionnaire. International Physical Activity Questionnaire (IPAQ) is used to determine the level of physical activity of the participants [26].

Blinding

It is not possible to blind study nutritionist, webmaster and the participants. The enumerators trained to collect the data, however, are blinded during the data collection.

Statistical analysis

Axxya Systems Nutritionist Pro™ Diet Analysis is used to analyze the nutrient intakes and all statistical analyses are performed with IBM® SPSS® Statistics 17.0. Independent t-test or equivalent is used to determine differences between the study groups for continuous variables, while χ^2 or equivalent is used to determine the association between categorical variables. As this is a prospective RCT involving repeated measures, the ANOVA repeated measures model is applied to observe significant differences within the study groups. The evaluation of the intervention is based on an intention-to-treat analysis, with the p value 0.05 was taken as the level of significance.

Discussion

This is a 12 months web-based dietary intervention RCT for patients with uncontrolled T2DM with the aim to improve diabetes-related dietary KAB. We are employing existing guidelines in the development of the intervention package that will be modified to suit local context. TTM's SOC construct will be incorporated in the development of the study website, *my*DIDeA. We are aiming for a net improvement in the KAB score in participants of the e-intervention group, besides investigating the impact of the e-intervention on the dietary practices, physical measurements and blood biomarkers of those patients.

We hope to capture the 'teachable moment' to promote dietary behaviour change in diabetics with uncontrolled HbA1c (≥7.0%) and lower level of diabetes-specific dietary KAB (≤50% of total score). We are anticipating an increase in dietary KAB at the end of the trial, which may contribute to a better blood glucose control and ultimately prevent complication due to diabetes.

Besides offering a theory and evidence based education program, this trial will be utilising bilingual educational materials that have been modified to suit the local content. Culturally sensitive dietary intervention [27] and web content [15] leave greater impact, giving this trial an edge in helping the patients to improve their dietary KAB and achieve better glycaemic control.

This trial is capable of generating a personalised dietary intervention program for a large group of patients. At the same time, the intervention program could be accessed 24 hours using any device connected to the Internet. This will empower the patients to have total control of the intervention materials.

We will be conducting this RCT in urban hospitals, which means the respondents may be of a higher socioeconomic background than average Malaysians. This may

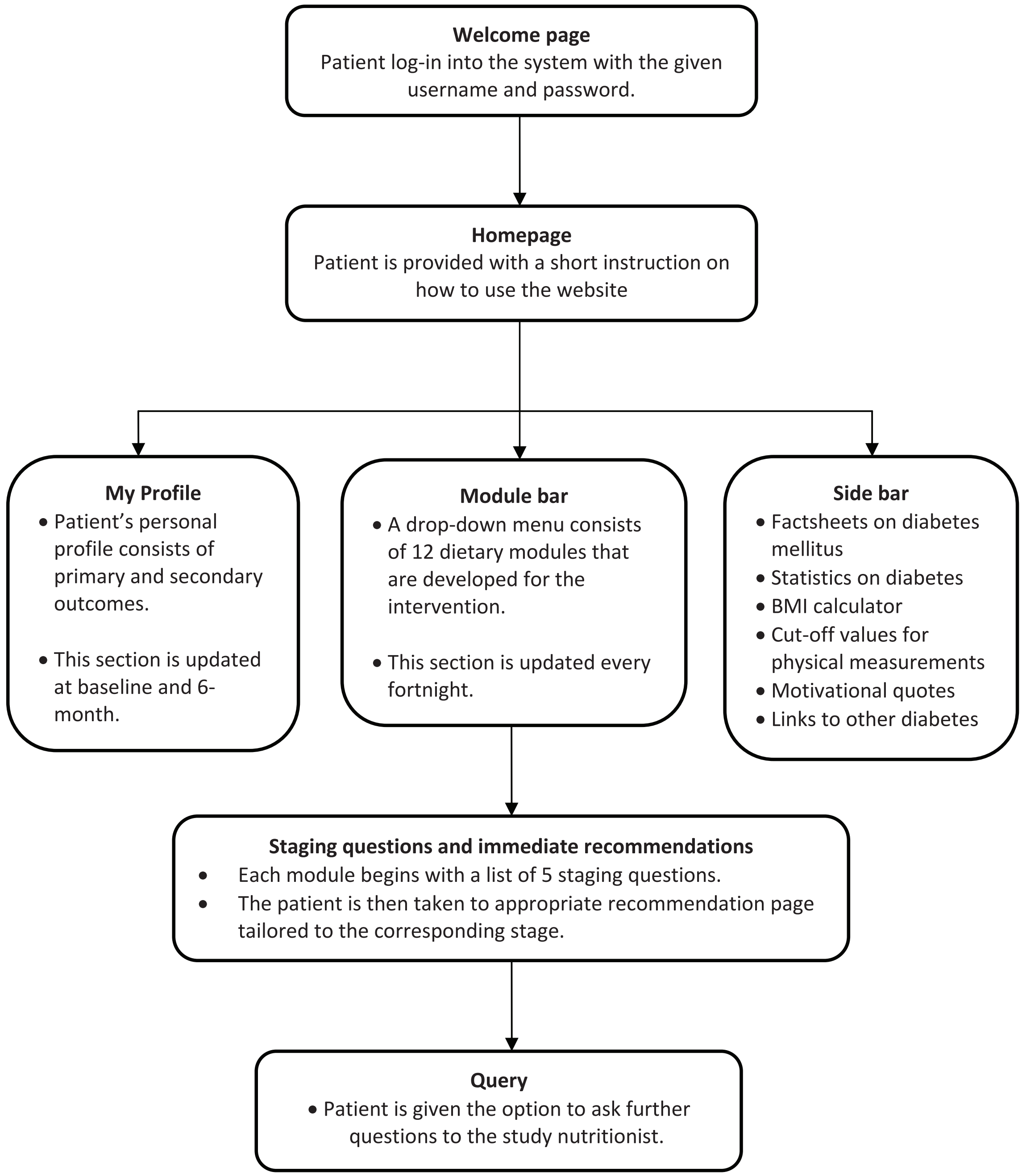

Figure 3 The website structure.

not be representative of the entire population as uptake of internet is different in the urban as compared to the rural. However, we are expecting for a better response to a web-based program in the urban area and it will be interesting to investigate responses from those with higher socio-economic status to an interactive website. This trial can be a model that is first implemented at the urban area for us to evaluate its success. If successful, it can be a precursor for policy makers to initiate more rigorous promotion of such web-based programs to other parts of the country.

Like all web-based interventions, this trial's reach also depends on the participants' responsiveness. Besides personalisation according to SOC, culture and language, the success of this intervention relies on the log-in rates and usability of *my*DIDeA. In order to maximise the participation of the trial patients, we will be regularly reinforcing them to log-in via e-mail and SMS.

Table 3 Assesments that will be carried out in the study

Outcome	Measure	Instrument
Primary	Nutrition KAB related to T2DM	Dietary Knowledge, Attitude and Behaviour Questionnaire*
Secondary	Dietary practices	Semi-Food Frequency Questionnaire* 24-hour dietary recall Supplement intake Cooking method Eating out habit
	Height	Body meter
	Weight and body composition	Four-point digital weighing scale
	Waist circumference	Non-elastic measuring tape
	Systolic and diastolic blood pressure	Automatic blood pressure monitor
	FBS, HbA1c and lipid profile	Medical record
Others/ Covariates	Socio-demographic characteristics	Pretested questionnaire
	Medical history	
	Physical activity	International Physical Activity Questionnaire
	Stages of change	Stages of Change Questionnaire*

*validated instrument.

Although qualitative assessments such as in-depth interview or focus group discussion were not part of this RCT, the outcome evaluation is supplemented by a detailed process evaluation. The process evaluation is measuring program reach, dose delivered, dose received, fidelity and implementation as well as the participants'' satisfaction with the program and acceptability. Collectively, these measures will enable us to draw conclusions about potential program enhancers and barriers if the program were to be delivered in other settings and contexts.

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Authors' contributions
AR developed the study framework and will be involved in data collection and in the development and implementation of the intervention. QKF gave feedback on the research design and will be giving his expertise in data analysis and interpretation of the study results. CKYC and BO gave feedback on the study protocol and to provide expertise in the development of the intervention package. ZH is to provide expertise in selection of the study sample. All authors read and contributed to the final manuscript.

Competing interests
The authors declare that they have no competing interests.

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