UNIVERSITI PUTRA MALAYSIA

EFFICACY OF A PLATE MODEL ON GLYCAEMIC CONTROL AMONG INDIVIDUALS WITH TYPE 2 DIABETES MELLITUS

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EFFICACY OF A PLATE MODEL ON GLYCAEMIC CONTROL AMONG INDIVIDUALS WITH TYPE 2 DIABETES MELLITUS

By

TIEW KEE FONG

Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfilment of the Requirements for the Degree of Doctor of Philosophy

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This thesis is dedicated to
my parents, Mr. Tiew Choo Seng and Mrs. Koo Sew Lan
for their love, endless support and encouragement

Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfillment of the requirement for the degree of Doctor of Philosophy

EFFICACY OF A PLATE MODEL ON GLYCAEMIC CONTROL AMONG INDIVIDUALS WITH TYPE 2 DIABETES MELLITUS

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February 2015

Chair: Chan Yoke Mun, PhD
Faculty: Medicine and Health Sciences

Conventional meal planning method helps to improve glycaemic control in individuals with type 2 diabetes mellitus (T2DM) but it also be seen as too complicated and time consuming which results in poor compliance. *My Healthy Plate* (MHP) is a visual meal planning tool developed to help T2DM patients adhere to the Malaysian Dietary Guidelines, with an emphasis on the use of the plate model concept to represent a balanced diet with the proper portions of food groups that should be consumed at each meal. This quasi-experimental study aimed to determine the effects of MHP on diabetes control in people with T2DM. Subjects were 113 patients with poorly controlled T2DM recruited based on quota sampling, stratified by sex and ethnicity, from the Medical Outpatient Department of Hospital Serdang, Selangor. Subjects were allocated to intervention (n = 55) or control groups (n = 58) to receive either four-lesson MHP program or dietary and diabetes newsletters provided bi-monthly for two months, followed by three-monthly newsletters by mail and telephone call. A total of 84 subjects (intervention = 36, control = 48) completed the assessments at baseline, immediately one- and five-month after the intervention. Overall, none of the baseline characteristics, including socio-demographic, lifestyle habits, diabetes history, psychosocial factors, anthropometric measurements, dietary factors and glycaemic control, were found to be significantly different between intervention and control groups ($p > 0.05$). Using the 2 x 3 mixed-design ANOVA, the intervention group had greater improvement in total physical activity (interaction effect $F = 3.240$, $p = 0.042$), fat-related ($F = 3.402$, $p = 0.036$) and fruit and vegetable-related dietary behavior ($F = 5.580$, $p = 0.005$), vegetable intake ($F = 3.723$, $p = 0.030$), fruit and vegetable intake ($F = 5.208$, $p = 0.008$), total food group score ($F = 4.754$, $p = 0.010$) and serving score ($F = 5.741$, $p = 0.004$) and HbA1c ($F = 3.640$, $p = 0.029$) over time than the controls after adjustment for baseline measures. At five-month after intervention, there were significantly higher proportion of intervention subjects who moved to the higher stages of change ($\chi^2 = 14.534$, $p < 0.0001$). Besides, a significant intervention effect was found on perceived barriers to healthy eating (-1.85 points), fruit intake (+0.33 times/day), fruit and vegetable intake (+0.86 times/day), total food group score (+0.46 points) and serving score (+1.51 points) and HbA1c (-1.15%) but not for self-efficacy, physical activity and anthropometric measurements. Multivariate linear regression analysis found that ethnicity, personal income, type of medication, physical activity and perceived barriers were significantly predicted baseline glycaemic control while change in self-efficacy, change in fat-related dietary behavior, change in waist circumference, and treatment allocation significantly predicts change in glycaemic control after adjusted for confounding variables. All intervention subjects were overwhelmingly satisfied with the MHP Program with the majority reported that they understood the program well (91.9%), felt the program was helpful in achieving diet goals (91.9%) and managing diabetes (83.3%). In conclusion, MHP could be an alternative meal planning tool to promote diet quality and glycaemic control among individuals with T2DM.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

KEBERKESANAN MODEL PINGGAN DALAM KAWALAN GLISEMIK DI KALANGAN INDIVIDU YANG MENGHIDAP PENYAKIT DIABETES MELLITUS JENIS 2

Oleh

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Kaedah perancangan makanan tradisional membantu individu yang menghidap penyakit diabetes mellitus jenis 2 (*type 2 diabetes mellitus*, T2DM) meningkatkan kawalan glisemik tetapi ia juga dilihat sebagai cara yang terlalu rumit dan memakan masa serta mengakibatkan pematuhan yang kurang memuaskan. Pinggan Sihat Saya (PPS) adalah kaedah perancangan makanan secara penglihatan bagi membantu pesakit T2DM mematuhi Garis Panduan Pemakanan Malaysia, dengan menekankan penggunaan konsep model pinggan untuk mewakili diet yang seimbang dengan porsi kumpulan makanan yang sesuai diambil untuk setiap hidangan. Kajian kuasi-eksperimen ini bertujuan untuk menentukan kesan PSS dalam pengawalan penyakit diabetik di kalangan individu T2DM. Subjek kajian ini adalah 113 pesakit T2DM dengan kawalan sub-optimal yang diambil dari Jabatan Pesakit Luar Perubatan Hospital Serdang, Selangor berdasarkan persampelan kuota dan berstrata mengikut jantina dan etnik. Subjek diagihkan kepada kumpulan intervensi (n = 55) atau kawalan (n = 58) untuk penerimaan empat pengajaran dari program PSS atau risalah pemakanan dan diabetik yang diberikan setiap dua minggu selama dua bulan, diikuti dengan risalah melalui pos dan panggilan telefon secara bulanan selama tiga bulan. Seramai 84 subjek (intervensi = 36, kawalan = 48) melengkapkan penilaian pada pra-intervensi, satu- dan lima-bulan pos-intervensi. Secara keseluruhan, tiada perbezaan yang signifikan antara kumpulan intervensi dan kawalan atas ciri-ciri pra-intervensi, termasuk sosio-demografik, gaya hidup, sejarah diabetik, faktor-faktor psikososial, ukuran antropometri, faktor-faktor pemakanan dan kawalan glisemik (p > 0.05). Ujian ANOVA 2 x 3 rekabentuk campuran menunjukkan kumpulan intervensi mempunyai peningkatan yang lebih besar mengikut masa dalam jumlah aktiviti fizikal (kesan interaksi F = 3.240, p = 0.045), tingkahlaku pemakanan yang berkaitan dengan lemak (F = 3.402, p = 0.036) dan buah-buahan dan sayur-sayuran (F = 5.580, p = 0.005), pengambilan sayur-sayuran (F = 3.723, p = 0.030), pengambilan buah-buahan dan sayur-sayuran (F = 5.208, p = 0.008), jumlah skor kumpulan makanan (F = 4.754, p = 0.010) dan skor sajian (F = 5.741, p = 0.004), serta paras HbA1c (F = 3.640, p = 0.029) berbanding dengan kumpulan kawalan selepas diselaraskan dengan ukuran pra-intervensi. Pada lima bulan pos-intervensi, lebih ramai subjek intervensi memaju ke akhir peringkat perubahan (G^2 = 14.534, p < 0.0001). Selain itu, kesan intervensi yang signifikan dijumpai pada tanggapan halangan terhadap pemakanan sihat (-1.85 mata), pengambilan buah-buahan (+0.33 kali/hari), pengambilan buah-buahan dan sayur-sayuran (+0.86 kali/hari), jumlah skor kumpulan makanan (+0.46 mata), skor sajian

(+1.51 mata), serta paras HbA1c (-1.15%) tetapi bukan pada keyakinan diri, aktiviti fizikal dan ukuran antropometri. Analisis variasi linear berganda mendapati etnik, pendapatan peribadi, jenis rawatan, aktiviti fizikal dan tanggapan halangan merupakan penentu-penentu yang signifikan kepada kawalan glisemik pada pra-intervensi manakala perubahan keyakinan diri, perubahan tingkahlaku pemakanan berkaitan dengan lemak, perubahan lilitan pinggang dan peruntukan kumpulan intervensi merupakan penentu-penentu yang signifikan kepada perubahan kawalan glisemik setelah diselaraskan dengan pembolehubah pembauran. Semua subjek intervensi berpuas hati dengan program PSS dengan majoriti melaporkan bahawa mereka memahami program ini dengan baik (91.9%), berpendapat bahawa program ini membantu mereka dalam pengurusan diet (91.9%) dan diabetik (83.3%). Kesimpulannya, PSS boleh dijadikan sebagai kaedah perancangan makanan alternatif dalam menggalakkan kualiti makanan dan kawalan glisemik di kalangan individu T2DM.

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I certify that a Thesis Examination Committee has met on 6 February 2015 to conduct WKH ILQDO H[DPLQDWLRQ RI 7LHZ .HH)RQJ RQ KHU WKHVLV HQWLWOHG ³Efficacy of a Web-based Model on Glycaemic Control DPRQJ ,QGLYLGXDOV ZLWK 7\SH 'LDEHWHV 0HOOLWXV´ LQ accordance with the Universities and University Colleges Act 1971 and the Constitution of the Universiti Putra Malaysia [P.U.(A) 106] 15 March 1998. The Committee recommends that the student be awarded the Doctor of Philosophy.

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TABLE OF CONTENTS

		Page
ABSTRACT		i
ABSTRAK		iii
ACKNOWLEDGEMENTS		v
APPROVAL		vi
DECLARATION		viii
LIST OF TABLES		xiii
LIST OF FIGURES		xvii
LIST OF ABBREVIATIONS		xix
CHAPTER		
1	**INTRODUCTION**	1
	Background	1
	Statement of problem	2
	Significance of the study	3
	Conceptual framework	5
	Objectives of the study	6
	General objective	6
	Specific objectives	6
	Null Hypotheses	7
	Operational Definition	7
2	**LITERATURE REVIEW**	10
	The overview of diabetes mellitus	10
	Glycaemic control	11
	Factors associated with glycaemic control	14
	Lifestyle behaviors	14
	Dietary factors	18
	Anthropometric measures	24
	Dietary modification on diabetes management	26
	Issues in dietary modification	27
	Plate Model in dietary modification	29
	Rationale of using Plate Model in dietary modification	32
	Theories and models for intervention development	33
	Stages of Change	33
	Health Belief Model	38
	Perceived barriers	39
	Self-efficacy	40
3	**METHODOLOGY**	42
	General study design	42
	Study location	42
	Sample size calculation	42
	Screening of subjects	44
	Inclusion criteria	44
	Exclusion criteria	44
	Recruitment of subjects	45
	Sampling	45

	Data collection	46
	Instruments	47
	A) Socio-demographic and lifestyle characteristics	47
	B) Diabetes history	47
	C) Anthropometric measurements	47
	D) Biochemical parameters	48
	E) Assessment on physical activity	49
	F) Assessment on psychosocial domain	49
	G) Assessment on dietary behavior and intake	52
	H) Program evaluation	54
	Intervention components	55
	Educational materials	55
	Pilot study	64
	Statistical analyses	67
4	**RESULTS**	68
	Recruitment and retention of subjects	68
	Adherence to the intervention program	69
	Baseline characteristics of subjects	69
	Socio-demographic characteristics	69
	Lifestyle habits	70
	Diabetes history	72
	Psychosocial factors	72
	Anthropometric measurements	75
	Dietary assessment	75
	Diabetes control	81
	Factors associated with glycaemic control	82
	Summary of baseline results	85
	Comparison of baseline characteristics between groups	85
	Outcomes of the intervention	87
	Changes in psychosocial factors	87
	Changes in physical activity	91
	Changes in anthropometric measurements	94
	Changes in dietary assessment	96
	Changes in glycaemic control	110
	Factors predicting changes in glycaemic control	116
	Summary of the null hypotheses testing	118
	Program evaluation	119
	Compliance of plate model	119
	Subjects’ feedback	119
	Subjects’ input regarding the program	120
5	**DISCUSSION**	121
	Study design and recruitment of subjects	121
	Baseline results	123
	Socio-demographic characteristics	123
	Diabetes profile	123
	Lifestyle habits	124
	Psychosocial factors	125
	Anthropometric measurements	127
	Dietary assessment	127

The effects of the intervention 130
Changes in psychosocial factors 130
Changes in physical activity 131
Changes in anthropometric measurements 132
Changes in dietary assessment 132
Changes in glycaemic control 136
Factors associated with glycaemic control and its changes 137
Predictors of glycaemic control 137
Predictors of glycaemic control change 141
Feasibility of *My Healthy Plate* Program 146

6 CONCLUSIONS 148
Summary and conclusions 148
Limitations 149
Recommendation for future research 150

BIBLIOGRAPHY 152
APPENDICES 188
BIODATA OF STUDENT 246
LIST OF PUBLICATIONS 247

LIST OF TABLES

Table		Page
1.1	Operational definition of terms	7
2.1	Meal planning approaches	28
2.2	Comparison of the plate model with other newer methods of dietary modification in type 2 diabetes mellitus	34
2.3	Characteristics of people through a series of change processes	36
2.4	General guidelines for applying stages and processes of change	37
2.5	Potential change strategies based on the Health Belief Model	39
3.1	Measurements conducted in subjects	43
3.2	Body mass index classification	48
3.3	Waist-circumference classification	48
3.4	Targets for type 2 diabetes mellitus	49
3.5	Physical activity classification	50
3.6	The statement of willingness to change	50
3.7	Questionnaire items measuring perceived barriers to healthy eating	51
3.8	Question items measuring self-efficacy to healthy eating	51
3.9	Questionnaire items measuring fat-, fruit and vegetable-related dietary behavior	52
3.10	Questions from the BRFSS fruit and vegetable module	53
3.11	Number of servings according to food groups recommended by Malaysian Dietary Guidelines	54
3.12	Hand Jive Method as a guide to portion control	58
3.13	*My Healthy Plate*: carbohydrate-containing foods are exchangeable	61
3.14	Strategies applied in the MHP program's module based on the Health Belief Model	62
3.15	Module's lesson plans for running *My Healthy Plate Program*	63

3.16	Baseline characteristics between respondents and non-respondents	65
3.17	Changes in outcome measurements among pilot subjects	65
3.18	Subjects' satisfaction and feedback in the MHP program (*n* = 10)	66
3.19	Subjects' input regarding the *My Healthy Plate Program*	66
4.1	Adherence to the intervention program (*n* = 55)	69
4.2	Socio-demographic characteristics of subjects (*n* = 113)	70
4.3	Distribution of subjects according to lifestyle habits (*n* = 113)	71
4.4	Distribution of subjects according to diabetes history (*n* = 113)	72
4.5	Distribution of subjects according to perceived barriers to healthy eating (*n* = 113)	73
4.6	Distribution of subjects according to subscale and individual item of perceived barriers to healthy eating (*n* = 113)	74
4.7	Distribution of subjects according to self-efficacy score (*n* = 113)	74
4.8	Distribution of subjects according to individual item of self-efficacy to healthy eating and diabetes management (*n* = 113)	75
4.9	Distribution of subjects according to anthropometric measurements (*n* = 113)	76
4.10	Mean subscale and individual item score for fat-related dietary behavior (*n* = 113)	77
4.11	Mean individual item score for fruit and vegetable-related dietary behavior (*n* = 113)	78
4.12	Distribution of subjects according to consumption pattern of fruits and vegetables (*n* = 113)	79
4.13	Distribution of subjects according to dietary diversity score (*n* = 113)	80
4.14	Distribution of subjects according to recommended glycaemic, lipids, and blood pressure control for individuals with diabetes (*n* = 113)	81
4.15	Association between glycaemic control and characteristics of socio-demographic, diabetes history, lifestyle habits, psychosocial factors, anthropometric measures and dietary factors in simple and multiple regression models (*n* = 113)	83
4.16	Baseline characteristics of intervention and control groups (*n* = 84)	86

4.17 Distribution of subjects between the intervention and control groups by stages of change across three different time points 88

4.18 Comparison of changes of mean (SD) scores for subscales and total perceived barriers within and between the intervention (*n* = 36) and control groups (*n* = 48) across three different time points 89

4.19 Interaction effects on subjects' perceived barriers to healthy eating (*n* = 84) 90

4.20 Comparison of changes of mean (SD) scores for total self-efficacy within and between the intervention (*n* = 36) and control groups (*n* = 48) across three different time points 92

4.21 Interaction effects on subjects' total self-efficacy to healthy eating and diabetes management (*n* = 84) 92

4.22 Comparison of changes of total physical activity[a] within and between the intervention (*n* = 36) and control groups (*n* = 48) across three different time points 93

4.23 Interaction effects on subjects' physical activity [a] (*n* = 84) 93

4.24 Changes in anthropometric measurements within and between the intervention (*n* = 36) and control groups (*n* = 48) 95

4.25 Interaction effects on subjects' anthropometric measurements (*n* = 84) 95

4.26 Comparison of changes in fat-, fruit and vegetable-related dietary behavior within and between the intervention (*n* = 36) and control groups (*n* = 48) across three different time points 97

4.27 Correlation between changes in fat-related and changes in fruit and vegetable-related dietary behavior (*n* = 84) 98

4.28 Interaction effects on subjects' dietary habit (*n* = 84) 99

4.29 Comparison of changes in fruit and vegetable intake within and between the intervention (*n* = 36) and control groups (*n* = 48) across three different time points 100

4.30 Interaction effects on subjects' fruit, vegetable and combined fruit and vegetable intake (*n* = 84) 101

4.31 Adequacy of fruit and vegetable intake in the intervention and control groups across three time points 101

4.32 Comparison of changes in dietary diversity score within and between the intervention (*n* = 36) and control groups (*n* = 48) across three different time points 103

4.33	Interaction effects on subjects' dietary diversity score (*n* = 84)	104
4.34	Comparison of changes in specific serving score within and between the intervention (*n* = 36) and control groups (*n* = 48) across three different time points	105
4.35	Interaction effects on subjects' specific serving score (*n* = 84)	106
4.36	Comparison of changes in glycaemic control within and between the intervention and control groups across three different time points by categories	111
4.37	Interaction effects on subjects' glycaemic control (*n* = 68)	116
4.38	Factors predicting change in glycaemic control (*n* = 84)	117
4.39	The frequency of meals taking and plate method used by intervention subjects at post-intervention 1 and post-intervention 2 (*n* = 36)	119
4.40	Subjects' feedback on the *My Healthy Plate Program* (*n* = 36)	120
4.41	Subjects' input regarding the *My Healthy Plate Program* (*n* = 36)	120

LIST OF FIGURES

Figure		Page
1.1	Conceptual framework	5
2.1	Disorder of glycaemia: etiologic types and stages	10
2.2	Various nutrition guides using plate model concept: (1) Idaho Plate Method; (2) Healthy Diabetes Plate; (3) MyPlate; (4) The New American Plate	31
3.1	General flow of study	43
3.2	Work flow of research activities	46
3.3	Flow of the development of a Malaysian-based plate model, *My Healthy Plate* and its educational materials.	56
3.4	From pyramid to plate: *My Healthy Plate* for meal planning	57
3.5	Allocation of the recommended portion sizes onto *My Healthy Plate*	57
3.6	Visualizing *My Healthy Plate* on meal planning for different needs	60
3.7	Skill exercise: food replicas were given for subjects to experience real life visual meal planning	64
4.1	Recruitment and retention of subjects throughout the study	68
4.2	Stages of change for diabetes management among subjects (n = 113)	73
4.3	Fat-related dietary behaviors score among subjects (n = 113)	78
4.4	Fruit and vegetable-related dietary score among subjects (n = 113)	78
4.5	Percentage change of subjects within the intervention and control groups by stages of change from baseline to post-intervention 2	88
4.6	Comparison of change in total physical activity between treatment groups across three time points	91
4.7	Distribution of subjects in the intervention and control groups based on ADA (2014b) recommended physical activity level across three different time points	94
4.8	Comparison of change in body mass index between treatment groups across three time points	96

4.9	Comparison of change in waist circumference between treatment groups across three time points	96
4.10	Comparison of change in total food group score between treatment groups across three time points	104
4.11	Comparison of change in total serving score between treatment groups across three time points	104
4.12	Distribution of subjects in the intervention and control groups based on recommended number of servings for grain across three different time points	107
4.13	Distribution of subjects in the intervention and control groups based on recommended number of servings for vegetable across three different time points	108
4.14	Distribution of subjects in the intervention and control groups based on recommended number of servings for meat across three different time points	108
4.15	Distribution of subjects in the intervention and control groups based on recommended number of servings for fruit across three different time points	109
4.16	Distribution of subjects in the intervention and control groups based on recommended number of servings for milk across three different time points	109

LIST OF ABBREVIATIONS

ADA	American Diabetes Association
AACE	American Association of Clinical Endocrinologists
BMI	Body mass index
CDA	Canadian Diabetes Association
CGP	Clinical Practice Guidelines
CHD	Coronary heart disease
CI	Confidence interval
CVD	Cardiovascular disease
DCCT	Diabetes Control Complications Trial
DDS	Dietary Diversity Score
EDIC	Epidemiology of Diabetes Interventions and Complications
FGS	Food Group Score
FPG	Fasting plasma glucose
FRDB	Fat-related dietary behavior
FVRDB	Fruit and vegetable-related dietary behavior
GDM	Gestational diabetes mellitus
GI	Glycaemic index
HBM	Health Belief Model
HDL-C	High-density lipoprotein cholesterol
IDF	International Diabetes Federation
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
LDL-C	Low-density lipoprotein cholesterol
MAR	Mean adequacy ratio

MI	Myocardial Infarction
MOH	Ministry of Health Malaysia
NHANES	National Health and Nutrition Examination Survey
RCT	Randomized controlled trial
SMBG	Self-monitory Blood Glucose
SS	Serving Score
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TTM	Transtheoretical model
UKPDS	UK Prospective Diabetes Study
USDA	United States Department of Agriculture
WC	Waist circumference
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

Background

Diabetes mellitus is a group of metabolic diseases primarily defined by hyperglycaemia, which has been resulted from the defects in insulin secretion, insulin action, or both (American Diabetes Association [ADA], 2014a). The chronic hyperglycaemia of diabetes is associated with long-term microvascular damage and macrovascular complications (ADA, 2014a; World Health Organization [WHO] & International Diabetes Federation [IDF], 2006) include retinopathy with potential loss of vision; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers, amputations, and Charcot joints; autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction; and macrovascular disease leading to atherosclerotic cardiovascular, peripheral arterial, and cerebrovascular disease (ADA, 2014a). Diabetes and its related complications are associated with reduced life expectancy, increased incidence of morbidity and mortality as well as diminished quality of life (WHO & IDF, 2006).

Although there is no cure for diabetes, it can be prevented and controlled (National Institutes of Health (NIH), 2008). The recent updated position statement of the ADA reveals that diabetes requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of long-term complications (ADA, 2014b). Nutrition therapy is an integral component of overall diabetes management and self-management education (Evert et al., 2014). Although nutrition and physical activity interventions alone are generally not adequately effective in managing diabetes over time for many individuals with diabetes as the progressive nature of the disease, nutrition therapy continues to be an important component of the overall treatment plan after pharmacotherapy is initiated (Inzucchi et al., 2012). Without a proper dietary habit, effective management of diabetes is hard to be achieved even with medication (Ministry of Health Malaysia [MOH], 2004).

The effectiveness of overall diabetes treatment plan is determined based on glycaemic control via patient self-monitoring of blood glucose or HbA1c (ADA 2014b). HbA1c or glycated haemoglobin is a naturally occurring, non-enzymatic product from exposure of haemoglobin to glucose, which reflects the average glucose concentration over an average of 120 days life span of a normal red blood cell (Lippi & Targher, 2010). It is the gold standard for the evaluation of glycaemic control in individuals with diabetes and has strong predictive value for diabetes-related chronic complications including retinopathy, neuropathy, nephropathy and cardiovascular disease (Lippi & Targher, 2010). Achieving good glycaemic control is particularly important for individuals with diabetes as it decreases the risk for microvascular and macrovascular complications (ADA, 2014b). The targeted glycaemic control for most individuals with diabetes is recommended to be below or around 7% (ADA, 2014b; Canadian Diabetes Association [CDA] Clinical Practice Guidelines [CPG] Expert Committee, 2013c; IDF, 2012) or below 6.5% (MOH, 2009).

The primary goal of nutrition therapy for individuals with diabetes is to promote and support healthful eating patterns with emphasizing a variety of nutrient dense foods in appropriate portion sizes, in order to improve overall health and attain targeted glycaemic control of HbA1c <7% (Evert et al., 2014). A simple diabetes meal planning approach is recommended as a strategy of nutrition therapy for effective diabetes management (Evert et al., 2014). As a simple method of dietary education, Plate Model was developed and used successfully since 1987 (Nydahl, Gustafsson, Eliasson, & Karlstrom, 1993) and has recently replaced the United States Department of Agricultureôs (USDA) iconic Pyramid, representing a new paradigm of nutrition guides (R. C. Post, Haven, & Maniscalco, 2012).

Statement of Problem

Glycaemia and diabetes are a rising global hazard, with the number of people with diabetes has increased by 1.3 fold over nearly three decades (Danaei et al., 2011). International Diabetes Federationôs (2013) most recent estimates indicate that the number of people with diabetes is set to rise by another 55% to achieve 592 million over the next two decades. In 2013, the disease caused a provoking 5.1 million deaths worldwide by which a person dies from the disease for every six seconds (IDF, 2013). Back to 2006, WHO (2006) had warned that without urgent action, the death related to diabetes will continue to rise by more than 50% in the next ten years. The global mortality and burden of disease related to diabetes is also projected rise drastically, with the rankings for leading causes of death is projected to move from 11th in 2002 to 7th in 2030 and the rankings for causes of burden of disease is projected to move from 20th to 11th (Mathers & Loncar, 2006). Approximately USD 548 billion dollars or 11% of the total spent worldwide was associated with diabetes-related health expenditure in 2013, and by 2035, this number is projected to exceed USD 627 billion (IDF, 2013).

While the prevalence of diabetes worldwide is projected to increase from 8.3% in 2013 to 8.8% in 2035, the regional prevalence of diabetes in the Western Pacific is projected to increase higher from 8.6% in 2013 to 11.1% in 2035 (IDF, 2013). Among 80 most populated countries in the world, Malaysia appears to have the highest prevalence of diabetes in the Western Pacific region (Whiting, Guariguata Weil, & Shaw, 2011), with a prevalence of diabetes in Malaysia recorded 11.6% in 2006 (MOH, 2008) and 15.2% in 2011 (MOH, 2011), much faster growth than the IDF projection (Whiting et al., 2011). It is ranked in the top 10 total burden of disease in Malaysia with a huge burden accounted by non-fatal disability (Faudzi et al., 2004). The disease will remain a major cause of mortality and morbidity worldwide as the world population continues to grow, aging, urbanizing, and increasing the prevalence of obesity and physical inactivity (Wild, Roglic, Green, Sicree, & King, 2004).

Type 2 diabetes mellitus (T2DM), which accounts for 90 ï 95% of those with diabetes, encompasses most obese individuals (ADA, 2014a). Type 2 diabetes mellitus frequently coexists with a constellation of risk factors for cardiovascular disease (CVD) and metabolic syndrome, which in turn, putting those with T2DM at higher risk for diabetes-related complications (ADA, 2014a; Air & Kissela, 2007). Among people with diabetes, older age (50 years and above) and fewer years of education (primary education or lower) are found to have a higher prevalence (MOH, 2008). Individuals with diabetes, particularly those with older age and fewer years of education, are associated with lower diabetes-related numeracy skills, including misinterpreting glucose meter readings and miscalculating carbohydrate intake and medication dosages, which, are subsequently associated with poorer glycaemic control (Cavanaugh et al., 2008).

Achieving good glycaemic control is particularly important for individuals with diabetes to reduce the occurrence of diabetes-related complications (The International Expert Committee, 2009). However, according to the American Association of Clinical Endocrinologists (AACE, 2003-2004), in spite of advances in diabetes care and numerous practical tools available, millions of Americans with T2DM fail to control their blood sugar levels. There are two out of three people fail to meet the good glycaemic control of HbA1c level Ò6.5% (AACE, 2003-2004). Nutrition therapy has been shown to improve glycaemic control with improvements of HbA1c ranging from 0.9 to 1.9% (Morris & Wylie-Rosett, 2010). It is crucial for preventing diabetes, managing existing diabetes, and preventing the development of diabetes complications (ADA, 2008). However, diet is the most challenging part of diabetes management for many individuals with diabetes (Evert et al., 2014).

Conventional meal planning methods such as food exchange system and carbohydrate counting help people with T2DM to attain better glycaemic control, but these methods may not be practical in day-to-day diabetes management. Such methods have frequently been rated as too complicated and time consuming (Rizor & Richards, 2000). Studies have shown that food exchange system and carbohydrate counting are complex and, hence, difficult to teach and understand as certain level of nutritional knowledge and math skill are required to master the skills (Gillespie, Kulkarni, & Daly, 1998; Wheeler et al., 1996).

In addition, studies also found that despite patients could follow the conventional meal plan closely in the very beginning by measuring food and counting carbohydrate, its complexity and time consuming features may lead to poor adherence in the later stage (Rizor & Richards, 2000). Such methods are considered by many as too difficult to follow and are therefore inappropriate for most patients, especially for elderly and those with lower educational level (Nydahl et al., 1993). Moreover, Malaysia with its multi-ethnic, multi-cultural and multilingual features that having different kind of cuisines and festive foods could pose a high degree of challenge to healthcare providers in providing care. Thus, it is a need to investigate a tool that is relatively simple, practical, effective and able to beat with the language and cultural barriers. Plate model is known with its simplicity, practicability, flexibility, and language independent features that has been used successfully in the Western countries over nearly three decades, yet, till date, the role of proving nutrition education intervention using plate model approach has not been evaluated in the Malaysian context.

Significance of the Study

Diabetes and its complications are a major cause of mortality and morbidity in Malaysia. It is a huge and growing problem, and the costs to society are high and escalating (IDF, 2013). Therefore, strategies in preventing diabetes, managing existing diabetes and delaying diabetes-related complications, especially through non-pharmacological interventions are urgently needed. Nutrition therapy is one of the most important non-pharmacological interventions for both individuals with newly diagnosed or existing T2DM. It is found to be successfully improved patientsô overall glycaemic control (Morris & Wylie-Rosett, 2010). Better glycaemic control is shown to reduce risk for any endpoint or death related to diabetes, myocardial infarction and microvascular complications (Stratton et al., 2000) and the risk reduction effects are persisted for up to 10 years, despite glycaemia may not be optimally controlled after one year of follow-up (Holman, Paul, Bethel, Matthews, & Neil, 2008). Therefore, the present study, which aimed to improve glycaemic control possibly decreases the diabetes-related health care cost and improves patientsô health outcomes and quality of life.

The recent updated position statement of the ADA has highlighted the importance of providing the individuals with diabetes with practical tools for day-to-day meal planning rather than focusing on individual macronutrients, micronutrients, or single foods (Evert et al., 2014). Studies have found that patients with diabetes are more likely to commit to healthful dietary changes when the meal plan is simpler and more visual (Rizor & Richards, 2000). Indeed, people with diabetes face many challenges, it is worthwhile to offer a plan that can simplify food selection and insulin dosing (Brown, Lackey, Miller, & Priest, 2001). Thus, a simple diabetes meal planning approach is recommended as a strategy of nutrition therapy for effective diabetes management (Evert et al., 2014). Moreover, a simple teaching tool that can help people to quickly and visually identify the healthy meal plans can actually facilitate the teaching processes which is extremely useful in busy hospitals and clinical settings (Rizor & Richards, 2000; Smith, Minor, Tillman, deShazo, & Replogle, 2012).

In addition, studies have shown that the general Malaysian adult population failed to adhere to the national dietary guidelines (Norimah et al., 2008). Following the national dietary guidelines closely are associated with better diet quality and glycaemic control (Kant & Graubard, 2005). However, studies regarding the adherence of national dietary guidelines for patients with diabetes in Malaysia are scarce. Thus, it is of significance to carry out the present study to find out the adherence rate and the subsequent diet quality and glycaemic control of people with poorly controlled T2DM.

Understanding the information regarding diet-disease links can be complex and challenging for these vulnerable subjects and, hence, limit their ability to implement the nutritional and health-related knowledge in the daily lives (Parmenter, Waller, & Wardle, 2000). As higher prevalence of T2DM was documented amongst lower educated subjects, there is an urgent need to promote nutritional awareness with messages that are tailor-made for this group. In this context, plate model might serve as one of the options as many new users perceived it as simple, visually appealing, and could be personalized to fit their diet (Quinlan, Lee, Mangroo, & Vierow, 2012).

Thus, this study provided an important opportunity to advance the understanding of the potential usage of the plate model in the Malaysian context. Using visual meal planning method, which is language independent, may also be beneficial for our multi-ethnic, multi-cultural and multilingual featuresô country. In addition, provision of baseline information on factors associated with glycaemic control as well as factors associated with change in glycaemic control among individuals with poorly controlled T2DM may help future researchers and health care providers to target and tailor intervention program for better diabetes management and prevention through similar or different approaches.

Conceptual Framework

Figure 1.1 shows the conceptual framework of the present study. This study intended to investigate the extent to which a simple and visual meal planning method, the plate model, could improve the overall diabetes management among individuals with poorly controlled T2DM in the Malaysian context. Health Belief Model (HBM) was used as a theoretical framework to guide the nutrition educational program and to improve intervention efficacy. According to the HBM, health behaviors are determined by the interaction of health beliefs and willingness to take action (Bauer & Sokolik, 2002). Therefore, the focus of the intervention was to create awareness among subjects and to help them develop an accurate perception of their own risk. Healthy eating is important in preventing diabetes-related complications and subjects were reassured that healthy eating is achievable by using plate model.

The effectiveness of the intervention was examined through the changes in psychosocial factors (stages of change, perceived barriers and self-efficacy), dietary behaviors (fat-, fruit and vegetable-related diet habits, fruit and vegetables intake, and dietary diversity score), anthropometric measurements (body mass index, waist

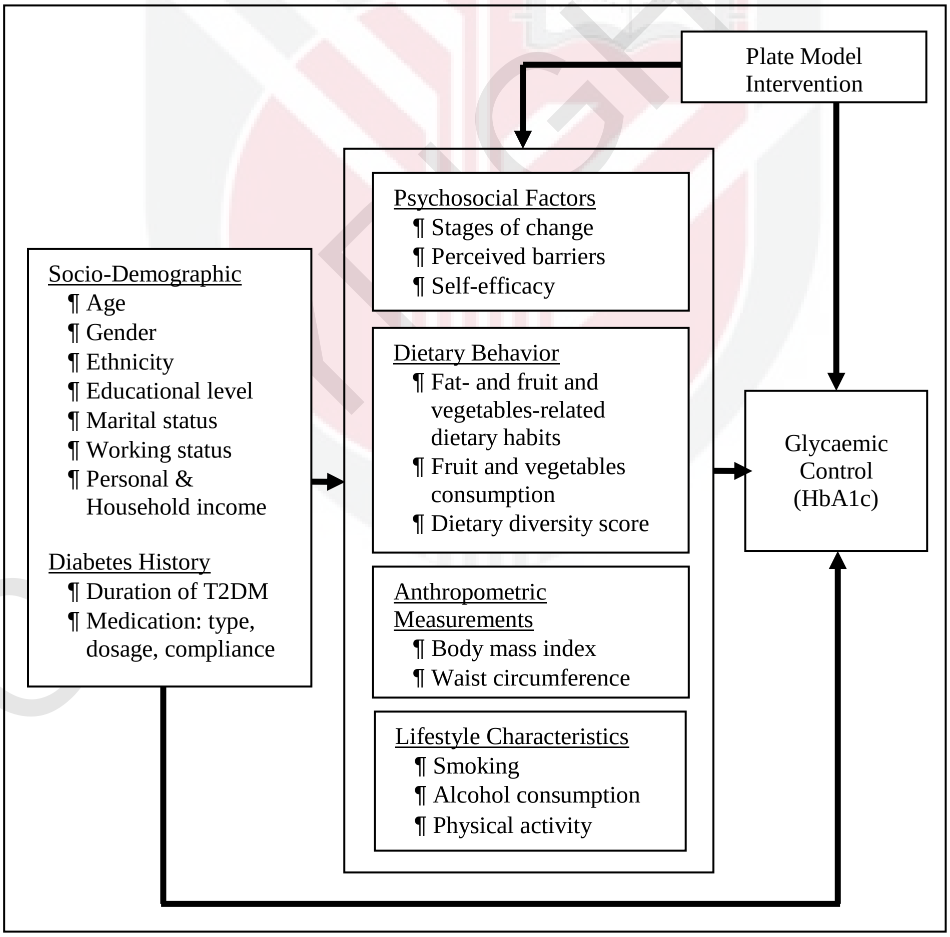

Figure 1.1: Conceptual framework

circumference), lifestyle characteristics (smoking, alcohol consumption and physical activity), and glycaemic control (HbA1c) before and after the intervention and within- and between- the treatment groups.

In addition, the present study also aimed to examine the contribution of baseline characteristics, including socio-demographic, diabetes history, psychosocial factors, dietary behavior, anthropometric measurements and lifestyle characteristics towards baseline glycaemic control. Besides, the contribution of baseline characteristics and change in psychosocial factors, dietary behavior, anthropometric measurements and lifestyle characteristics as well as intervention treatment allocation towards the change in glycaemic control over the intervention period among individuals with poorly controlled T2DM were also examined.

Objectives of the Study

General Objective

To determine the efficacy of a plate model on glycaemic control measured as HbA1c among individuals with poorly controlled T2DM.

Specific objectives

1. To determine the following variables of subjects at baseline:
    a. Socio-demographic background (age, gender, ethnicity, educational level, marital status, working status, personal and household income)
    b. Diabetes history (duration of T2DM, type and compliance on medications)
    c. Psychosocial factors (stages of change, perceived barriers, self-efficacy)
    d. Lifestyle characteristics (smoking, alcohol consumption, physical activity)
    e. Dietary behavior (fat-related dietary habits, fruit and vegetables-related dietary habit, fruit and vegetable consumption, dietary diversity score)
    f. Anthropometric measurements (body mass index, waist circumference)
    g. Glycaemic control (HbA1c)

2. To compare the mean difference in the changes of the following variables within- and between intervention and control groups at baseline, immediately 1 month (post-intervention 1) and 5 months (post-intervention 2) after intervention:
    a. Psychosocial factors
    b. Physical activity
    c. Dietary behavior
    d. Anthropometric measurements
    e. Glycaemic control

3. To examine the contribution of socio-demographic, diabetes history, psychosocial factors, lifestyle characteristics, dietary behavior and anthropometric measurements towards glycaemic control among individuals with poorly controlled T2DM.

4. To examine the contribution of baseline characteristics and change in psychosocial factors, physical activity, dietary behavior and anthropometric measurements and treatment allocation towards change in glycaemic control among individuals with poorly controlled T2DM.

Null Hypotheses

1. There is no significant difference in the changes of the following variables within- and between intervention and control groups at baseline, post-intervention 1 and post-intervention 2:
   a. Psychosocial factors
   b. Physical activity
   c. Dietary behavior
   d. Anthropometric measurements
   e. Glycaemic control

2. There is no significant contribution of socio-demographic, diabetes history, psychosocial factors, lifestyle characteristics, dietary behavior and anthropometric measurements towards glycaemic control among individuals with poorly controlled T2DM.

3. There is no significant contribution of baseline characteristics and change in psychosocial factors, physical activity, dietary behavior and anthropometric measurements and treatment allocation towards change in glycaemic control among individuals with poorly controlled T2DM.

Operational Definition

Table 1.1 shows the operational definition of terms for the variables used in this study.

Table 1.1: Operational definition of terms

Terms	Operational definition
Anthropometric measurements	External measurements of the body, such as height, weight, limb circumference, and skinfold thickness. [1]
Carbohydrate counting	It is a meal planning approach used with clients who have diabetes that focuses on the total amount of carbohydrate eaten at meals and snacks. [2]
Diabetes mellitus	A disease caused by either insufficient insulin production or decreased sensitivity of cells to insulin. It results in elevated blood glucose levels. [1]
Exchange lists	A structured system based on grouping foods with similar distributions of carbohydrate, protein, and fat so that foods within a group could be exchanged. [2]
Glycosylated haemoglobin	A blood test that reflects the blood glucose concentration over the life span of red blood cells (~120 days), expressed as a percentage of total haemoglobin with glucose attached; may also be called glycated haemoglobin or glycohaemoglobin. [3]
Haemoglobin	An iron-containing protein in red blood cells that binds oxygen and transports it through the bloodstream to cells. [1]
Haemoglobin A1c, HbA1c, A1c	Is a measurement of the glycosylation of the ñcò fraction and is the recommended assay method. An HbA1c of 6.0% reflects an average plasma glucose level of ~120 mg/dl or 6.7 mmol/l. In general, each 1% increase in HbA1c is a reflection of an increase in average glucose levels of ~30 mg/dl or 1.7 mmol/l. [3]

Table 1.1: (*Continued*)

Terms	Operational definition
Hyperglycaemia	An excessive amount of glucose in the blood (generally Ó180 mg/dl or 10.0 mmol/l) caused by too little insulin, insulin resistance, or increased food intake; symptoms include frequent urination, increased thirst, weight loss, and often tiredness or fatigue. [3]
Hypoglycaemia	Low blood glucose level (usually Ò 70 mg/dl or 3.9 mmol/l), which can be caused by the administration of excessive insulin or insulin secretagogues, too little food, delayed or missed meals or snacks, increased amount of exercise or other physical activity, or alcohol intake without food. [3]
Insulin	A hormone released from the ϐ-cells of the pancreas that enables cells to metabolize and store glucose and other fuels. [3]
Insulin resistance	An impaired biologic response (sensitivity) to other exogenous or endogenous insulin. [3]
Impaired fasting glucose, IFG	It is defined as high blood glucose levels after a period of fasting. [4]
Impaired glucose tolerance, IGT	It is defined as high blood glucose levels after eating. [4]
Macrovascular diseases	Diseases of the large blood vessels, including coronary artery disease, cardiovascular disease, and peripheral vascular disease.[3]
Medical nutrition therapy, MNT	The use of specific nutritional interventions to treat an illness, injury, or condition.[3]
Metabolic syndrome	A cluster of metabolic disorders characterized by central obesity and insulin resistance with increased risk for cardiovascular disease and type 2 diabetes; associated risk factors include dyslipidemia (elevated triglycerides, low high-density lipoprotein (HDL) cholesterol, and high low-density lipoprotein (LDL) cholesterol), hypertension, prothrombotic factors and impaired glucose tolerance. [3]
Metabolic equivalents, METs	The measure of caloric expenditure by the amount of oxygen consumed per minute per kilogram of body weight; 1 MET = ~3.5 ml oxygen consumed per kilogram of body weight per minutes in adults. [3]
Microvascular disease	Diseases of the small blood vessels, including retinopathy and nephropathy.[3]
Myocardial infarction, MI	Ischemia in the coronary arteries resulting in necrosis, tissue damage, and sometimes sudden death. [3]
Nephropathy	Known as kidney disease. The disease is caused by damage to small blood vessels, which can cause the kidneys to be less efficient, or to fail altogether. Maintaining near-normal levels of blood glucose and blood pressure can greatly reduce the risk of nephropathy. [4]
Nutrient density	A measure of the nutrients provided by a food relative to the energy it contains. [1]

Table 1.1: (*Continued*)

Terms	Operational definition
Plate model	It is a meal planning approach works by visualizing how much space each of the major food groups should occupy on oneôs plate. [5]
Retinopathy	Known as eye disease, which can damage vision or provoke blindness. Persistently high levels of blood glucose, together with high blood pressure and high cholesterol, are the main causes of retinopathy. [4]
Risk factors	Characteristics found in healthy individuals that increase the likelihood of a person developing a disease. [1]
Type 1 diabetes mellitus, T1DM	A form of diabetes that is caused by autoimmune destruction of insulin-producing cells in the pancreas, usually leading to absolute insulin deficiency; previously known as insulin-dependent diabetes mellitus or juvenile-onset diabetes. [1]
Type 2 diabetes mellitus, T2DM	A form of diabetes that is characterized by insulin resistance and usually relative (rather than absolute) insulin deficiency; previously known as non-insulin-dependent diabetes mellitus or adult-onset diabetes. [1]
Theory	An explanation based on scientific study and reasoning. [1]

Sources: [1](Smolin & Grosvenor, 2003); [2](Gillespie et al., 1998); [3](Mahan & Escott-Stump, 2004); [4](IDF, 2013); [5](Brown et al., 2001).

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