# THE DEVELOPMENT OF PROBLEM SOLVING-BASED LIFESTYLE MODULE AND ITS EFFECTIVENESS ON DIABETES RISK SCORE, RANDOM CAPILLARY BLOOD GLUCOSE AND PERCEPTION IN PRACTISING HEALTHY LIFESTYLE AMONG DIABETES HIGH-RISK GROUP IN KELANTAN

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**2023**

# THE DEVELOPMENT OF PROBLEM SOLVING-BASED LIFESTYLE MODULE AND ITS EFFECTIVENESS ON DIABETES RISK SCORE, RANDOM CAPILLARY BLOOD GLUCOSE AND PERCEPTION IN PRACTISING HEALTHY LIFESTYLE AMONG DIABETES HIGH-RISK GROUP IN KELANTAN

**by**


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**Thesis submitted in fulfilment of the requirements**

**for the degree of**

**Doctor of Public Health (Epidemiology)**

## March 2023

# ACKNOWLEDGEMENT

In the name of ALLAH, the Most Merciful and Compassionate. Salutations to His Messenger Muhammad (peace be upon him), his family, and his companions. The research had numerous hurdles, including the COVID-19 pandemic, which made gathering data from the community difficult. Despite these challenges, Allah has enabled me to overcome them with His grace and blessings. I managed to complete the thesis writing for my Doctor of Public Health dissertation study project with the assistance and success bestowed by Allah.

First and foremost, my utmost gratitude to my supervisors. My main supervisor; Associate Professor Dr Nor Azwany Bt Yaacob, and my co-supervisors, Associate Professor Dr. Rohana Abdul Jalil; both are senior lecturer from the Department of Community Medicine; and Dr Nik Mohd Rizal bin Mohd Fakri from Department of Medical Education, School of Medical Sciences, Universiti Sains Malaysia. I will be eternally thankful to them for their expertise, compassion, and dedication in managing this project to its conclusion having faith in my ideas. I alwI always felt confident because I was coached by such a strong team. Their support was endless, regardless of time. Only Allah has the authority to reward your efforts.

I would like to express my appreciation to Pn Norhasliza binti Ariffin from Nutrition Unit, Kelantan State Health Department for her ideas and support in pursuing this research as well as her willingness to accommodate me in conducting the research. Not forgetting, the physiotherapist at Klinik Kesihatan Gunong, Pn Nor Hayati binti Zakaria, hopes you recover swiftly.

Many thanks are also conveyed to Dr. Hasni binti Yaacob and Dr. Hanif bin Ismail from Klinik Kesihatan Gunong and Dr. Nor Azah binti Mohamad Nawi and Dr. Ros

Suzayney binti Md Raji from Klinik Kesihatan Pengkalan Kubor for their full cooperation and major participation in the process of data collecting, moral support, and willingness to offer assistance at any time. My thanks, are also extended to their staffs who participated in the data collection.

I would like thanks all participants and health staffs involved in this study. I really appreciate their time and effort. My sincere gratitude goes to all who contributed in numerous ways. Without their willingness to share a little of their experience with us, this research would not have come to anything.

I would like to acknowledge everyone in the Department of Community Medicine for their endless encouragement and assistance during the course of my study.

And last but not least, I am indebted to my husband Wan Ahmad Ikmal and my two sons, Muslih and Mus'ab, for being, without fail, my rock and pillar of support. My heartfelt appreciation goes to my mother, my in-laws, and my siblings for raising me and supporting me through every happiness and sorrow, which have shaped who I am today. Without them, I never would have made it this far, therefore I dedicate this milestone to all of them. I am also grateful to my babysitter, who has taken good care of my boys while I focus on my studies.

جَزَاكَ ٱللَّهُ خَيْرًا

"May the Almighty recompense you with goodness."

***Al-Fatihah for my late father, Hj Mahmud bin Mohd Zain (1943 – 2004)***
***May Allah bless his soul…***

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# LIST OF SYMBOLS

| | |
|---|---|
| > | More than |
| < | Less than |
| ≥ | Equal or more than |
| α | Alpha |
| β | Beta |
| σ | Standard deviation |
| Z | Z-score |
| Δ | Precision |
| x | Multiplication |
| % | Percentage |
| n | Number of samples |
| r | Rho |
| η2 | Partial eta squared |
| f | Effect size |
| √ | Square root |

# LIST OF ABBREVIATIONS

| | |
|---|---|
| ADA | American Diabetes Association |
| BMI | body mass index |
| CBG | capillary blood glucose |
| CDC | Centers for Disease Control and Prevention |
| CHS | community health screening |
| CI | confidence interval |
| CVD | cardiovascular disease |
| CVI | Content Validity Index |
| df | degree of freedom |
| EnPHC | Enhanced Primary Healthcare |
| FINDRISC | Finnish Type 2 Diabetes Risk Assessment |
| FVI | Face Validity Index |
| HCP | healthcare provider |
| IDF | International Diabetes Federation |
| IFG | impaired fasting glucose |
| I-FVI | Item level Face Validity Index |
| IGT | impaired glucose tolerance |
| IPH | Institute of Public Health |
| ITT | Intention-to-treat |
| MOH | Ministry of Health |
| MOOC | massive open online course |
| MySTAR | MySelf Transformation and Reflection |
| NCD | Non-communicable disease |
| OBS | Open Broadcaster Software |
| PHC | primary health care |
| PP | Per protocol |
| RCT | randomised control trials |
| RM ANCOVA | repeated measure analysis of covariance |
| RM ANOVA | repeated measure analysis of variance |
| SBP | systolic blood pressure |
| S-CVI | Scale level Content Validity Index |
| SD | Standard deviation |
| S-FVI | Scale level Face Validity Index |
| SLIMS | adapted IDEAL model of problem solving |
| STOP | Saya (S) Tak (T) Okay (O) Prediabetes (P) |
| T2DM | type 2 diabetes mellitus |
| WHO | World Health Organization |

# LIST OF APPENDICES

# ABSTRAK


## PEMBANGUNAN MODUL GAYA HIDUP BERASASKAN PENYELESAIAN MASALAH DAN KEBERKESANANNYA TERHADAP SKOR RISIKO DIABETES, PARAS GLUKOSA KAPILARI RAWAK DAN PERSEPSI MENGAMALKAN GAYA HIDUP SIHAT DALAM KALANGAN KUMPULAN BERISIKO TINGGI DIABETES DI KELANTAN

**Latar belakang:** Kumpulan berisiko tinggi diabetes berada pada tahap peralihan sebelum menjadi penyakit diabetes mellitus jenis 2 (T2DM), namun keadaan ini masih boleh di elakkan. Pendidikan gaya hidup berstruktur dapat memperkasakan penjagaan kendiri dalam perubahan gaya hidup yang sesuai bagi mereka yang berisiko tinggi.

**Objektif:** Untuk membangunkan pendidikan gaya hidup berasaskan penyelesaian masalah dan menentukan keberkesanannya terhadap skor risiko diabetes FINDRISC, paras glukosa kapilari (CBG) dan persepsi amalan lima tugasan gaya hidup sihat dalam kalangan kumpulan berisiko tinggi diabetes di Kelantan. Kepuasan modul dinilai dalam kumpulan intervensi pada pasca intervensi.

**Kaedah:** Kajian ini dibahagikan kepada dua fasa. Fasa pertama ialah pembangunan modul dan fasa kedua ialah penyelidikan kuasi-eksperimen. Berdasarkan tinjauan literatur dan perbincangan pakar, modul pendidikan gaya hidup berasaskan penyelesaian masalah telah dibangunkan. Bahan yang dihasilkan termasuk penceritaan kuliah pendidikan, video penjagaan diri dan simulasi kaunseling. Seramai 12 pakar menilai Indeks Kesahan Kandungan (CVI) dan 20 ahli komuniti menilai Indeks Kesahan Muka (FVI). Kumpulan intervensi adalah komuniti Bachok,

manakala kumpulan kawalan adalah dari komuni Tumpat yang menerima pendidikan kesihatan sedia ada dari klinik mereka. Dalam kalangan 80 peserta berisiko tinggi diabetes, Skor Risiko Diabetes FINDRISC, CBG, dan keyakinan dalam melaksanakan tugas MySTAR dikumpulkan sebelum dan pasca 8-minggu intervensi. Skor risiko diabetes dibandingkan menggunakan RM ANOVA, manakala tugasan CBG dan MySTAR dibandingkan menggunakan RM ANCOVA antara kumpulan mengikut masa. Bagi setiap analisis, analisis niat-untuk-merawat (ITT) dan per-protokol (PP) telah dilakukan.

**Keputusan:** Modul gaya hidup berasaskan penyelesaian masalah telah dinamakan sebagai modul STOP&SLIMS, yang terdiri daripada 17 video naratif pendidikan, empat video penjagaan kendiri dan cabaran dua minggu pemakanan sihat dan gaya hidup aktif. Tiga subkomponen modul telah dibangunkan iaitu pengenalan prediabetes, pemakanan sihat dan gaya hidup aktif, menunjukkan CVI (masing-masing 90.4%, 88.1% dan 90.2%) dan FVI yang tinggi, antara 0.88 hingga 1.0. Daripada 80 peserta, 31 peserta kumpulan intervensi dan 33 peserta kumpulan kawalan telah menyelesaikan kajian. Selepas 8 minggu intervensi, tiada perbezaan signifikan antara kumpulan dalam Skor Risiko Diabetes FINDRISC. CBG rawak juga tidak mempunyai perberbezaan signifikan dalam ITT tetapi terdapat perbezaan signifikan dalam PP antara kumpulan. Berbanding kumpulan kawalan, kumpulan intervensi mempunyai skor keyakinan yang lebih tinggi terhadaap tugasan MySTAR dengan perbezaan min diselaraskan [95% Sela Keyakinan (CI)] iaitu melakukan 150 minit senaman berintensiti sederhana seminggu [15.25 (3.45, 27.05)] dan aktiviti fizikal yang kerap sekurang-kurangnya 3 kali seminggu [18.00 (8.14, 27.85)]. Sementara itu, pasca intervensi, terdapat perbezaan yang ketara antara kumpulan dalam purata skor persepsi mengamalkan "Suku Suku Separuh" [15.00 (1.82,

28.17)], mengelak pengambilan makanan dan minuman manis [19.15 (8.20, 30.09)], 150 minit senaman berintensiti sederhana seminggu [31.41 (18.44, 44.39)] dan aktiviti fizikal yang kerap sekurang-kurangnya 3 kali seminggu [28.44 (15.35, 41.53)]. Kumpulan intervensi juga mempunyai skor min kepuasan yang tinggi untuk modul ini iaitu antara 4.3 hingga 4.7.

**Kesimpulan:** Modul STOP&SLIMS berpotensi untuk diterapkan khususnya pada kumpulan berisiko tinggi diabetes untuk meningkatkan gaya hidup sihat mereka terutamanya dari aspek pemakanan sihat dan gaya hidup aktif.

**Kata Kunci:** pendidikan gaya hidup, penyelesaian masalah, penjagaan kendiri, diabetes berisiko tinggi, pencegahan diabetes

# ABSTRACT


## THE DEVELOPMENT OF PROBLEM SOLVING-BASED LIFESTYLE MODULE AND ITS EFFECTIVENESS ON DIABETES RISK SCORE, RANDOM CAPILLARY BLOOD GLUCOSE AND PERCEPTION IN PRACTISING HEALTHY LIFESTYLE AMONG DIABETES HIGH-RISK GROUP IN KELANTAN

**Background:** Diabetes high-risk groups are at intermediate stage in developing type 2 diabetes mellitus (T2DM) but are still reversible. A structured lifestyle education that empowers self-care in lifestyle modifications must be tailored to high-risk groups.

**Objectives:** To develop a problem-solving-based lifestyle education and determine its effect on diabetes risk score (FINDRISC), capillary blood glucose (CBG), and perception practising five healthy lifestyle tasks using MySTAR among diabetes high-risk population in Kelantan. Module satisfaction was assessed among the intervention group participants at post-intervention.

**Methods:** There are two phases of this study. Phase one is the development of the module and phase two is a quasi-experimental study. Based on the literature review and expert discussions, problem-solving based lifestyle education module was developed. Materials include narrated lectures, self-care and simulated counselling videos. Twelve experts evaluated the content validity index (CVI) and 20 community members assessed face validity index (FVI). The intervention group was from the community in Bachok, while the control group was in from Tumpat, who received usual health education from their clinic. The FINDRISC diabetes risk score, CBG and perceived confidence in practising MySTAR tasks were collected pre-and post-8 weeks intervention among 80 diabetes high-risk participants. Module satisfaction

questionnaire was given to the intervention group post-intervention. Diabetes risk score was compared using RM ANOVA, while CBG and MySTAR tasks were compared using RM ANCOVA between groups overtime. For each analysis, intention-to-treat (ITT) and per-protocol (PP) analysis were performed.

**Results:** The problem-solving-based lifestyle module was named STOP & SLIMS module, consisting of 17 narrative educational videos, four self-care videos, and two-weekly healthy eating and active lifestyle challenges. Three subcomponents of the module; introduction of prediabetes, healthy eating, and active lifestyle, showed high CVI (90.4%, 88.1%, and 90.2% respectively) and high FVI, ranging from 0.88 to 1.0. Out of 80 participants, 31 participants in the intervention group and 33 in the control group completed the study. There was no significant difference in FINDRISC diabetes risk score between the groups after 8 weeks of intervention. CBG was not significantly different in ITT but significant in PP analysis between the group. In the comparison of groups, the intervention group showed a significantly higher score of perceived confidence to practice MySTAR tasks with adjusted mean difference [95% Confidence Interval (CI)] by doing moderate-intensity exercise 150 minutes per week [15.25 (3.45, 27.05)] and regular physical activity at least three times per week [18.00 (8.14, 27.85)]. Meanwhile, at post-intervention, there were significant differences in mean scores of perceived practising "*Suku Suku Separuh*" [15.00 (1.82, 28.17)], avoid consume sweet food and beverages [19.15 (8.20, 30.09)], moderate-intensity exercise 150 minutes per week [31.41 (18.44, 44.39)] and regular physical activity at least three times per week [28.44 (15.35, 41.53)] between the groups. The intervention group also had high mean satisfaction score for the module ranging from 4.3 to 4.7.

**Conclusion:** The STOP & SLIMS module has the potential to be delivered, particularly to diabetes high-risk groups in order to improve their healthy lifestyle practising, particularly healthy eating and active lifestyle.

**Key words:** Lifestyle education, problem-solving, self-care, diabetes high-risk, diabetes prevention

# CHAPTER 1 :

# INTRODUCTION

The International Diabetes Federation, (IDF, 2022) reported a significant global diabetes landscape that continues to rise due to an ageing population, urbanisation, and epidemiological transition towards a sedentary lifestyle (Sun *et al.*, 2022). It can cause a variety of short-and long-term health issues as well as economic consequences. The cost will keep going up in the same direction as the increasing burden of diseases, requiring more comprehensive strategies to battle type 2 diabetes mellitus (T2DM) (Arena *et al.*, 2017; Shahid *et al.*, 2019; Moien *et al.*, 2020). There was no exception for Malaysia regarding the burden of T2DM and its metabolic risk factors [Institute for Public Health (IPH), 2020; Goh *et al.,* 2022]. Primary prevention is the only way to decrease or manage the public health burden of T2DM.

Chances of developing T2DM depend on the combination of risk factors which are non-modifiable such as age, ethnicity and family history of diabetes. However, modifiable risk factors such as physical activity and dietary habits can be changed to minimise the risk of developing T2DM. According to American Diabetes Association (ADA, 2018), diabetes high-risk groups are prediabetes, women with history of gestational diabetes or had history of delivered macrosomia baby (birth weight $\geq$ 4kg), overweight or obese, aged 45 years and above, ethnicity of Asian, African American, American Indian, or Alaska Native and have first degree family with diabetes. Debates on the identifiable threshold at which prevention efforts are to be implemented, based on fasting blood sugar and HbA1c, are ongoing with different cut-off points (Davidson & Kahn, 2016; Echouffo-Tcheugui & Selvin, 2021). Diabetes high-risk groups including prediabetes, often known as the intermediate

stage of developing T2DM, is typically asymptomatic. It is characterised by glucose levels higher than normal but below the diagnostic levels for T2DM (Mirasol *et al.*, 2017; Tuomilehto, 2019). The clinically confirmed prevalence of prediabetes in Malaysia was 11.62 % and this number may need to be considered because the studies were small (Akhtar *et al.*, 2022).

Meanwhile, Effah Leiylena (2017) found that 25% of adults who attended community health screening (CHS) in Kelantan fulfilled the epidemiological definition [random capillary blood glucose (CBG) of ≥6.6 mmol/L and <7.8 mmol/L] of prediabetes. Despite these disparities, these figures indicate that the number of people with prediabetes is one of the public health concerns. People with prediabetes and other diabetes high-risk groups must be assisted before they get diagnosed with confirmed T2DM and its associated complications, like heart disease and nerve damage (Huang *et al.*, 2014; Davidson *et al.*, 2021; Evans *et al.*, 2021).

Diabetes high-risk groups can be detected early at CHS and opportunistic screenings at the primary care level. It can be conducted using either non-invasive diabetic risk prediction or CBG, followed by confirmed clinically through a laboratory glucose test (Rowan *et al.*, 2014; Mafauzy *et al.*, 2020; Echouffo-Tcheugui & Selvin, 2021). Since Year 2008, Malaysia has carried out the health screening using the Health Status Screening Form, also known as *Borang Saringan Status Kesihatan* (BSSK), for adults (20-59 years old), teens (10-19 years old) and elderly (60 years and above). The above forms consist of screening:

1. History of medical / surgical / reproductive involving individuals and family
2. Dietary patterns and physical activity
3. Use of medicines or drugs
4. Mental health

5. Anthropometric measurements for nutritional status assessment

It aims to detect high-risk groups for non-communicable diseases (NCD) or diseases at an early stage, including T2DM, to reduce morbidity and mortality related to NCD [Ministry of Health Malaysia (MOH), 2015; Effah Leiylena, 2020]. It is associated with various risk factors such as, obesity, unhealthy diet, physical inactivity, family history of diseases, and socioeconomic status (Cosentino *et al.*, 2020; MOH, 2020). All adults must be screened for diabetes or prediabetes starting at the age of 45, regardless of diabetes risk, through blood investigation. If they are overweight or obese and have at least one other diabetes risk, screening must be commenced regardless of symptoms (ADA, 2018). The MOH adjusted this recommendation to screen all individuals aged 30 years and above regardless of their risk factors and those younger than 30 years with risk factors (Mafauzy *et al.*, 2020; MOH, 2020) because of the high prevalence among youth. In addition, multi-ethnic cohort studies found that at a lower body mass index (BMI), there was a significant link between obesity and T2DM among Asian (Nanditha *et al.*, 2016; Shen *et al.*, 2016). To reduce the implication of broad population screening, simple and straightforward risk assessment can be used to screen prediabetes besides blood glucose measurement using Finnish Type 2 Diabetes Risk Assessment Tool (FINDRISC) and cardiovascular risk screening (Mafauzy *et al.*, 2020; Echouffo-Tcheugui & Selvin, 2021). Lowering the age for screening and using a high-risk approach is more cost-effective in surveillance of diabetes high risk but it puts strain on the healthcare system (Feisul Idzwan *et al.*, 2014; Chandran *et al.*, 2021). At the same time, it still depends on the individuals' own decisions to perform a health screening and live a healthy lifestyle (Subramaniam *et al.*, 2016; Messina *et al.*, 2017). Therefore, a

similar targeted high-risk-based approach should be used in high or low-resource settings to prevent T2DM (Karachaliou *et al.*, 2020; Chandran *et al.*, 2021).

Lifestyle interventions are the cornerstones of T2DM prevention and had shown to be successful in reducing the risk of progression to T2DM in short- and long-term among high-risk groups, particularly prediabetes (Kerrison *et al.*, 2017; Glechner *et al.*, 2018; Shirinzadeh *et al.*, 2019). The recommended strategies for the prevention of T2DM are the identification of individuals at high risk of developing T2DM, assessment of risk levels by measuring plasma glucose levels, and initiation of lifestyle interventions with or without pharmacological therapy (Mirasol *et al.*, 2017; ADA, 2018; Bell *et al.*, 2020; Cosentino *et al.*, 2020). Experts in Malaysia also emphasised lifestyle intervention as the first line of management of prediabetes and diabetes (Mafauzy *et al.*, 2020). Only those with a very high risk of diabetes and failed lifestyle intervention will be considered for pharmacological therapy of metformin in addition to lifestyle modification (Stevens *et al.*, 2015; Sheng *et al.*, 2019). Previous studies showed that the promotion of increased physical activity, low-calorie diet, and behaviour change might help reduce weight and the incidence of T2DM either in clinical or community-based (Lindstrom *et al.*, 2003; Kosaka *et al.*, 2005; Ackermann *et al.*, 2011; Norliza *et al.*, 2016; Chen *et al.*, 2017; Qiu *et al.*, 2022). However, it needs the strong willingness of individuals and social support to maintain and achieve the recommended target (Razatul *et al.*, 2014; Subramaniam *et al.*, 2016; Messina *et al.*, 2017; Twohig *et al.*, 2019).

In 2013, The MOH launched *Komuniti Sihat Perkasa Negara* (KOSPEN), literally translated into ‘Healthy Communities, Strengthen the Nation’, a grassroots community programme. KOSPEN aimed to execute National NCD Screening Programs by providing adequate resources in collaboration with other non-health

agencies with specific appropriate funds for prevention and promotion programmes (Lim *et al.*, 2015; Feisul Idzwan *et al.*, 2020). However, those detected as high-risk during community screening were observed to have lack of continuity of clinical management. The screening uptake was not optimal and only 50% did a confirmation test in the nearest primary healthcare (PHC) (Effah Leiylena, 2020). Progressive physical restructuring and organisational evolution were crucial to the continuing improvement of access and equity and to minimize the non-communicable disease (NCD) burden (Fariza *et al.*, 2020). Therefore, in 2017, the MOH introduced Enhanced Primary Healthcare (EnPHC), a population-wide primary prevention program that integrates community outreach activities and the healthcare system (Integrated NCD Services at Primary Care) using the person-centered care approach. It focused on the prevention, early detection, and treatment of NCD through active community involvement, integration of chronic care bundle and appropriate referral (Sivasampu *et al.*, 2020). However, Mohammad Zabri *et al.* (2020) found that those who had regular NCDs follow-up in the clinic did not perceive doable practical skills to change their lifestyle and were lacking in shared decision-making between healthcare providers (HCP) and patients (Razatul *et al.*, 2014).

Integrating healthy behaviour changes and prediabetic education needs into their self-care may empower them to be responsible for their health (Subramaniam *et al.*, 2017). A self-efficacy enhancing education programme that consists of behavioural, cognitive, and social skills such as problem-solving skills is recommended to empower prediabetes by increasing their ability to control and adopt a healthy lifestyle. Problem solving is one of behaviour modification approaches using basic human thinking process used to manage life problems and emotional disorders (Schumann *et al.*, 2011). It provides simple, and cost-effective cognitive behaviour

change that improve patient adherence in practising healthy lifestyle to overcome the underlying social determinants of health (Fitzpatrick & Hill-Briggs, 2017). The Association of Diabetes Care and Education Specialists (ADCES) defines problem solving as learning to brainstorm, choose, apply, and evaluate solutions (ADCES, 2021). This programme may include healthy diet education, physical activity intervention, and behavioural modification. Subsequently, it may improve the ability of people to perform self-care and maintain healthy lifestyle behaviour change (Hill-Briggs *et al.*, 2007; Venditti *et al.*, 2014; Fitzpatrick & Hill-Briggs, 2017; Torabizadeh *et al.*, 2018). This approach is currently being looked at as part of lifestyle education.

### 1.1 Problem Statement

Diabetes is one of the fastest growing global health emergencies and is estimated to double by 2045 leading to a heavy burden on the healthcare system, particularly in low- to middle-income countries. This predisposed the development of complications such as heart disease and microvascular complications. The prevalence of diabetes high-risk groups mirrors the upward trend of diabetes and its metabolic risk factors (Huang *et al.*, 2014; Barbu *et al.*, 2021; Davidson *et al.*, 2021; Evans *et al.*, 2021). Fortunately, diabetes high-risk groups can revert to normoglycemic or low risk through lifestyle modification with or without treatment.

Emerging evidence has demonstrated that early T2DM identification and intensive lifestyle change programs for high-risk people with T2DM or people at the prediabetes stage have significant health benefits (Kerrison *et al.*, 2017; Glechner *et al.*, 2018; Sheng *et al.*, 2019; Shirinzadeh *et al.*, 2019). Currently, studies on CHS among diabetes high risk mainly focus on the reduction of weight, healthy eating and physical activity through behaviour change (Lindstrom *et al.*, 2003; Ackermann *et*

*al.*, 2011; Saito *et al.*, 2011; Schmiedel *et al.*, 2015; Norliza *et al.*, 2016; Böhme *et al.*, 2020).

People with high-risk of developing T2DM are mostly asymptomatic, however are told to have a higher risk for T2DM. Knowledge is not a barrier to practising a healthy lifestyle (Messina *et al.*, 2017). Detection of their risk during community screening should be followed by risk communication (Rowan *et al.*, 2014; Evans *et al.*, 2021). Changing one's lifestyle is difficult because each person has unique needs; hence, general health education may only apply to some. Furthermore, lifestyle modification must be maintained to achieve the best health benefits. Thus, individuals must be guided to change their lifestyles. However, there is currently no structured health education for diabetes high-risk groups to serve as guide and help identify the solution to their unhealthy lifestyle. Integration of behavioural theories in preventive health promotion is crucial in view of interrelated personal and environmental factors influence the individuals as well as their surroundings differently (Hill-Briggs *et al.*, 2021). Problem-solving is a simple and cost-effective cognitive behaviour modification (Schumann *et al.*, 2011). However, the role of problem-solving is not well understood because it is delivered informally (Yu *et al.*, 2021).

### 1.2 Justification of Study

The needs for self-care in those at risk differ from those in people with T2DM. The current clinical management approach focuses on disease management rather than those at risk, such as prediabetes. Tagging prediabetes intervention with the management of T2DM would not be effective and, at the same time, would overwhelm the existing challenges of managing T2DM. Increasing patient access to

effective lifestyle therapy is an excellent way to reduce the prevalence of T2DM. They must be encouraged to prevent the progression of pathology to T2DM.

To date, prediabetes is regularly detected by various CHS efforts. There is growing evidence of risk-based screening using non-invasive diabetes risk scores worldwide to detect individuals at high-risk of T2DM (Barry *et al.*, 2017; Echouffo-Tcheugui & Selvin, 2021; Evans *et al.*, 2021). They will be given further plans to assess their health status, including progression toT2DM. However, there needs to be a structured guide on lifestyle modification. For population-level lifestyle changes to work, people must make significant changes in their own lives and move toward primary prevention. Equipping them with problem-solving skills will help them identify how to modify their lifestyles to suit their needs. A structured module will also facilitate health care providers such as nurses in all healthcare settings and community health volunteers to give advice tailored to the individual's needs, motivate individuals to do self-care in lifestyle modification and delay the progression of T2DM especially with early detection of diabetes high-risk.

### 1.3 Research Question

Does problem-solving-based lifestyle education module able to improve diabetes risk?

### 1.4 Objectives

#### 1.4.1 General Objectives

To develop and assess the effectiveness of a problem solving-based lifestyle education module among the diabetes high-risk group in Kelantan.

### 1.4.2 Specific Objectives

Part 1:

1. To develop and validate problem solving-based lifestyle education module for the diabetes high-risk group.

Part 2:

2. To compare pre- and post-intervention on mean FINDRISC diabetes risk score between intervention and control groups among the diabetes high-risk group in Kelantan.
3. To compare pre- and post-intervention on mean random capillary blood glucose between intervention and control groups among the diabetes high-risk group in Kelantan.
4. To compare pre- and post-intervention on mean perception in practising lifestyle based on MySelf Transformation and Reflection (MySTAR) at pre- and post-intervention between intervention and control groups among the diabetes high-risk group in Kelantan.
5. To describe the satisfaction score of problem solving-based lifestyle module among intervention diabetes high-risk group participants.

## 1.5 Research Hypotheses

1. There is a significant mean difference of FINDRISC diabetes risk score between intervention and control groups among the diabetes high-risk group in Kelantan.
2. There is a significant mean differences of random capillary blood glucose between intervention and control groups among the diabetes high-risk group in Kelantan.
3. There is a significant mean difference of perception in practising lifestyle based on MySTAR score between intervention and control groups among diabetes high-risk group in Kelantan.

# CHAPTER 2 :

# LITERATURE REVIEW

## 2.1 The Burden of Diabetes

The T2DM epidemic is a significant public health challenge around the world. Diabetes, specifically T2DM, will continue to be one of the leading causes of morbidity and mortality (Arena *et al.*, 2017; Hostalek, 2019; Moien *et al.*, 2020). The IDF (2022) reported approximately 10.5% (573 million) of adults worldwide have T2DM in 2021 and it is projected to double by 2045 (Sun *et al.*, 2022). This led to crucial health concerns and a heavy burden on the healthcare system (Shahid *et al.*, 2019; Moien *et al.*, 2020). A systematic review reported pooled prevalence of T2DM in Malaysia from 15 studies was 14.39% (95% CI, 12.51%–16.38%) while pooled prevalence of prediabetes from 9 studies was 11.62% (95% CI, 7.17%– 16.97%). Indians showed the highest prevalence of T2DM (25.10%; 95% CI, 20.19%–30.35%) followed by Malays (15.25%; 95% CI, 11.59%–19.29%), Chinese (12.87%; 95% CI, 9.73%–16.37%) and Bumiputeras (8.62%; 95% CI, 5.41%–12.47%) (Akhtar *et al.*, 2022).

At least 63% of adult Malaysians aged 18 years have at least one NCD risk factors, such as overweight/obesity, high cholesterol, high blood pressure, or high blood sugar (IPH, 2020). A systematic review reported Malaysia having the higher prevalence rate of insulin resistance compared to Indonesia (Goh *et al.*, 2022). As half of Malaysian currently have abdominal obesity [52.6% (95% CI: 50.54, 54.58)] (IPH, 2020), there is an urgent need for increased awareness of the risk of developing T2DM and early screening (Chandran *et al.*, 2021).

## 2.2 Glucose Dysregulation

Myriads of interrelated factors such as genetic, environmental, and societal factors influence an individual life course (Hill *et al.*, 2013; Nanditha *et al.*, 2016; Arena *et al.*, 2017; Hostalek, 2019). Urbanization with bad dietary choices and the epidemiological change to a sedentary lifestyle (Feisul Idzwan *et al.*, 2020; Murray *et al.*, 2020; Evans *et al.*, 2021) leads to a positive energy balance, weight gain, and an accumulation of extra lipids in the body (Asif, 2014; Yip *et al.*, 2017). There are three mechanisms by which fat accumulation in the liver induces gluconeogenesis and causes insulin resistance in skeletal muscle. Persistent hyperinsulinemia and/or a fatty pancreas can result in pancreatic-cell dysfunction and decreased insulin production (Tabák *et al.*, 2012; Yip *et al.*, 2017).

There are different definitions of dysglycemia endorsed by different clinical organisations and guidelines. The most recommended cut-off point for blood glucose tests is using the World Health Organization (WHO) classification (Huang *et al.*, 2014; Mafauzy *et al.*, 2020). Debates on abnormal glucose metabolism classification are ongoing due to high variability within the individuals (Davidson & Kahn, 2016; Barry *et al.*, 2017; Hostalek, 2019). Nevertheless, any definition of prediabetes generally showed significant progression towards T2DM over time (Richter *et al.*, 2018) with no differences in clinical management (Vistisen *et al.*, 2019). The stage of glucose dysregulation can be classified as pre-prediabetes, prediabetes and T2DM (Echouffo-Tcheugui and Selvin, 2021).

**1. Pre-prediabetes**

A condition known as compensated hyperinsulinemia occurs when there is increased insulin production, but the fasting glucose level and glucose tolerance test remain normal. During fasting, glucose metabolism maintains blood glucose in a normal range of 4.3-5.5 mmol/L (Moacir, 2021). The earliest stage occurs at primordial levels until the first abnormal glucose tolerance test. Individuals with CBG less than 6.1 mmol/L can be considered healthy; if the value is higher, further confirmation is required via a standard glucose tolerance test (Tirimacco *et al.*, 2010; Susairaj *et al.*, 2019).

**2. Prediabetes**

This is a reversible phase when certain condition led to abnormal glucose tolerance test such as pregnancy, stress, and prolonged steroids intake. Elimination of the condition will reverse the abnormal level to normoglycemia (Echouffo-Tcheugui and Selvin, 2021). It is also an early phase of T2DM when majority are asymptomatic. The symptoms, if present, are mild and sometimes neglected; however, it can lead to consequences such as heart disease, stroke, renal disease, and nerve damage over time (Huang *et al.*, 2014; Barbu *et al.*, 2021; Davidson *et al.*, 2021; Evans *et al.*, 2021). This phase can be detected with oral glucose tolerance tests. Impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) diagnoses are typically associated with a very high risk of developing T2DM (Table 2.1). The presence of IFG indicates hepatic insulin resistance, whereas IGT indicates skeletal muscle insulin resistance (Yip *et al.*, 2017). Without appropriate care, around 70% of patients are expected to develop T2DM within ten years even sooner if both IGT and IFG are present (Ligthart *et al.*, 2016; van Herpt *et al.*, 2020). HbA1C was added as one of the diagnostic criteria for prediabetes and diabetes due to non-fasting and low-

intraindividual variability compared to glucose test in measuring chronic hyperglycaemia (Wan Nazaimoon *et al.*, 2013; Tuomilehto, 2019; Echouffo-Tcheugui & Selvin, 2021). However, debate on its accuracy is ongoing as HbA1C is known to be influenced by many factors such as ethnic variation and hemoglobinopathies and is not specific nor sensitive to screen T2DM. In addition, HbA1C is laboratory dependent, thus, is not suitable for activities in the community for earlier prediabetes risk mitigation (Echouffo-Tcheugui and Selvin, 2021). At community level, prediabetes can be detected with CBG test of ≥ 6.6 mmol and < 7.8 mmol/L with specificity of 65.5%, sensitivity of 64.7% and 0.72 of area under receiver operating curve (Somannavar *et al.*, 2009).

### 3. Overt Diabetes

The classic symptoms of T2DM appear in this phase and elevated venous glucose levels is diagnosed. The cut-off point of ≥7.8 mmol/L for random CBG is equivalent to the 2 hour post prandial (≥ 11.1 mmol/L) for diagnosis of T2DM (Somannavar *et al.*, 2009; Susairaj *et al.*, 2019), while Tirimacco *et al.* (2010) suggested of ≥7.0 mmol/L. Table 2.1 shows the cut-off point of the standard measurements.

Table 2.1: The measurements for diagnosis of abnormal glucose metabolism

| Phase | Capillary Blood Glucose (mmol/L) | Fasting Blood Glucose (mmol/L) | 2-hours Post Prandial (mmol/L) | HbA1C [b] (%) |
|---|---|---|---|---|
| **Normoglycemia** | < 6.1 | WHO: < 6.1[a]<br>ADA: < 5.6 | < 7.8 | |
| **Prediabetes** | 6.5-7.8 | WHO: 6.1-6.9[a]<br>ADA:5.6-6.9 | 7.8-11.1[a] | ADA: 5.7-6.4[a]<br>WHO: 6.1-6.9<br>NICE: 6.0-6.4 |
| **Diabetes** | ≥ 7.0 | ≥ 7.0 | ≥ 11.0 | MOH: ≥ 6.3 |

[a] Ministry of Health Malaysia (MOH, 2020)
[b] non-diabetic level by (Mafauzy *et al.*, 2020)
HbA1C: Glycated Haemoglobin
ADA: American Diabetic Association; WHO: World Health Organization.
NICE: National Instituteof Health and Care Excellence.

## 2.3 Risk Factors for Type 2 Diabetes

T2DM and other NCDs share similar root causes, of which more than 80% are attributed to environmental factors, mainly lifestyle (Hartley, 2014; Hill-Briggs *et al.*, 2021). The pathogenesis of T2DM is closely associated with increased body weight, obesity, sedentary lifestyle, and insulin resistance (Murray *et al.*, 2020). Exposure to these risk factors occurs throughout the lifespan of everyone and accumulates over an individual's lifetime (Ligthart *et al.*, 2016). There are two categories of T2DM risk factors which are non-modifiable and modifiable.

### 2.3.1 Non-modifiable Risk Factors

#### 2.3.1(a) Aging

The chances of developing T2DM increase with age. Aging populations increase the prevalence of NCDs, which negatively influence public health (Nanditha *et al.*, 2016; Shang *et al.*, 2019). According to a China Health and Retirement Longitudinal Study survey, more than half of middle-aged and elderly Chinese have prediabetes or diabetes. The T2DM prevalence is 14.4% among those aged 45–59 years old and increases with age. More than a quarter of respondents (26.5%) have T2DM among those aged 80 and older. Rapid urbanisation, excessive caloric intake, sedentary lifestyle, and low systemic inflammation from environmental toxins and smoking are believed to be the leading causes of diabetes in China (Zhao *et al.*, 2016). In addition, the human body gets less sensitive to insulin and shows insufficiency in insulin production as the human body ages (Yip *et al.*, 2017). In Malaysia, the peak dysglycemia among unknown diabetes was at 45-49 years old and its prevalence also increases with age. In addition, the level of physical inactivity gradually increased in adults from the age group of 55-59 years to 75 years and above (IPH, 2020) .

### 2.3.1(b) Sex

The lifetime risk of women with prediabetes developing diabetes is greater than that of men with the condition (van Herpt *et al.*, 2020). Various exposure occurs to either genetic or environmental factors, causing unequal distribution of disease between gender (Harreiter & Kautzky-Willer, 2018). Zhang *et al.* (2019) reported that the frequencies of illiteracy and obesity are higher among women than among men. Women are more likely to have elevated levels of total cholesterol, TG, and low-density lipoprotein cholesterol leading to insulin resistance. In contrast, men with lower BMI and young age are reported to be more prone to develop T2DM (van Herpt *et al.*, 2020). Furthermore, men with similar BMI and age of women have more trunk, visceral, and liver fat compared to women. This difference in fat distribution might be one of the underlying reasons for the difference in diabetes prevalence among the genders regarding T2DM (Yip *et al.*, 2017; Barbu *et al.*, 2021). National Health Morbidity Survey 2019 reported higher prevalence of overweight among men [35.1% (95%CI; 32.98, 37.33)] compared to women [29.3% (95%CI; 27.54, 31.12)] but higher prevalence of obesity among women [38.8% (95%CI; 36.60, 41.08)] compared to men [29.0% (95%CI; 26.85, 31.20)]. In addition, females were also found more inactive [28.2% (95% CI: 26.4, 30.2)] than males [22.1% (95% CI: 20.4, 24.0)] (IPH, 2020) .

### 2.3.1(c) Ethnic

The T2DM is documented to be more prevalent in African American, Hispanic, and Asian populations (Barbu *et al.*, 2021). In comparison to Caucasian, Asians are more likely to develop diabetes at a significantly young age (Gujral *et al.*, 2020). In Malaysia, Indians showed the highest prevalence of T2DM (25.10%; 95% CI,

20.19%–30.35%) followed by Malays (15.25%; 95% CI, 11.59%–19.29%), Chinese (12.87%; 95% CI, 9.73%–16.37%) and Bumiputeras (8.62%; 95% CI, 5.41%–12.47%) (Akhtar *et al.*, 2022). On the other hand, the highest prevalence of physical inactivity was observed among Chinese [32.5% (95% CI: 29.0, 36.3)] followed by Malays [25.7% (95% CI: 24.1, 27.4)], and Indians [25.0% (95% CI: 20.5, 30.2)] (IPH, 2020).

### 2.3.2 Modifiable Risk Factors

#### 2.3.2(a) Obesity

T2DM transpires due to various factors that cause insulin resistance and β-cell dysfunction. A meta-analysis review showed BMI and waist circumference measurement were useful in predicting T2DM (Ojo *et al.*, 2020), especially in lower risk population (Barbu *et al.*, 2021). Half of the people with T2DM are obese (BMI > 30 kg/m2), and 90% of diabetic patients are overweight (Radia Marium *et al.*, 2019). Nationwide studies in Malaysia and Iran reported similar findings (Norlaila *et al.*, 2011; Wan Nazaimoon *et al.*, 2013; Hasandokht *et al.*, 2020). In contrast with Bangladesh and India, the onset of prediabetes starts at an even lower BMI value (Anjana *et al.*, 2017; Bhowmik *et al.*, 2018). T2DM has been observed to occur at a significantly lower BMI in multi-ethnic cohort studies, especially in the Asian population (Shen *et al.*, 2016). Asian population is highly susceptible to T2DM due to different responses to nutrition and food, leading to lower insulin sensitivity (Wilson *et al.*, 2021). Studies in China, the U.S., and Finland state that the risk of T2DM can be lowered through modest weight loss (Gillett *et al.*, 2012).

### 2.3.2(b) Sedentary Lifestyle

A sedentary lifestyle has been proven to be one of the major causes of developing T2DM, as well as other NCDs (Hu *et al.*, 2020; Moghetti *et al.*, 2020). A systematic review found that standing and walking reduces postprandial glucose, insulin, and non-esterified fatty acid absorption in postmenopausal women compared to prolonged sitting (Moghetti *et al.*, 2020). Hyperinsulinemia occurs when reduced glucose uptake by skeletal muscle in sedentary individual. In Turkey, a low level of physical activity due to traditional and cultural attitudes might contribute to a higher rate of obesity and T2DM in women than men (Satman *et al.*, 2013). Anjana *et al.* (2015) found that age 40 to 79 and less physical activity were significant risk factors for prediabetes. In Japanese population, brisk walking is a protective factor against the onset of diabetes (Iwasaki *et al.*, 2021). In Malaysia, the nationwide population-based study showed reduction in prevalence of physical inactivity among the adult population aged ≥16 years from 35.7% in 2011, 33.5% in 2015 and 25.1% in 2019. The National Strategic Plan for Active Living (NASPAL) was initiated in 2017 to promote and educate Malaysians to be physically active and to reduce sedentary lifestyle (IPH, 2020) .

### 2.3.2(c) Smoking

Individuals who are chronic smokers have a higher risk of developing T2DM compared to non-smokers. This risk arises due to insulin insensitivity resulting from nicotine, one of the active chemicals in cigarettes. Smoking is found to have severely aggravated glucose tolerance and the insulin sensitivity index. Among individuals with normal BMI, studies have found that smokers have higher abdominal obesity, and the act of smoking is also linked to be the cause of detrimental changes in body composition. Both factors could lead to T2DM (Radia Marium *et al.*, 2019). Yun *et*

*al.* (2012) conducted a study in Korea found that people who smoked more than 20 cigarettes had 1.93 higher odds of abdominal obesity compared to people who had never smoked.

### 2.3.2(d) High Blood Pressure

There are overlap risk factors between T2DM and hypertension. It is complicated to understand whether T2DM causes hypertension or vice versa (Radia Marium *et al.*, 2019). The pathophysiological mechanism that explains the association is a high systolic blood pressure (SBP) which induces microvascular dysfunction and altered endothelial dysfunction (López-Jaramillo *et al.*, 2017). Evans *et al.* (2021) reported that the increase in 20mmHg of SBP and 10mmHg of diastolic blood pressure are associated with more than half higher risk than normal blood pressure to develop T2DM. However, it remains inconclusive (Barbu *et al.*, 2021).

## 2.4 Non-invasive Diabetes Screening

Diabetes screening should ideally be carried out in primary care clinics and community health program with follow-up consultation for those who are high-risk (Shirinzadeh *et al.*, 2019). A targeted high-risk-based approach should be used in high or low-resource settings to prevent T2DM (Weber *et al.*, 2021). Besides using CBG, non-invasive risk assessment questionnaire can be used to identify prediabetes, especially in rural areas (Anjana *et al.*, 2015).

The two commonly used questionnaire on diabetes risk assessment are ADA diabetes risk score and FINDRISC diabetes risk score. The ADA diabetes risk score is a screening tool to identify diabetes high-risk groups and to increase awareness on the need to change modifiable risk factors and promote healthy lifestyle. It consists of seven questions covering age, gender, history of gestational diabetes, family history

of diabetes, physical activity, and measurements of BMI (Ackermann *et al.*, 2011). It has 79.0% sensitivity, 67.0% of specificity with area under receiver operating curve (AUROC) of 0.83 (Nurul Fatihah *et al.*, 2022). The FINDRISC diabetes risk score consists of eight questions which are age, BMI, physical activity, vegetable and fruit consumption, used of anti-hypertensive and history of hyperglycaemia to determine diabetes risk. The FINDRISC score is a good predictor of developing T2DM within ten years (Rydén *et al.*, 2013) and correlates with central obesity (Meijnikman *et al.*, 2016).

The ADA diabetes risk score with the cut-off point of 5, despite having high sensitivity, has relatively lower specificity and positive predictive value (10%), which may not be cost-effective. While FINDRISC diabetes score of 11 had a lower sensitivity of 86.4% for diabetes screening but higher positive predictive value (12.0%). The use of FINDRISC diabetes risk score in a targeted community screening approach would greatly reduce the number of patients who need to be screened. Thus, population screening using the FINDRISC diabetes risk score is a more cost-effective and feasible approach in the Malaysian health system (Hooi *et al.*, 2020).

Asian populations get T2DM at a lower mean BMI than Caucasian (Gujral *et al.*, 2020). Therefore, the risk score must be evaluated using Asian cut-off point for BMI and waist circumference. However, studies have shown no statistical difference between FINDRISC and modified Asian FINDRISC (Ku & Kegels, 2013; Hooi *et al.*, 2020; Rifqi *et al.*, 2022).

## 2.5 Lifestyle Intervention for Diabetes High-Risk

Lifestyle modification through therapeutic lifestyle change programs has proven to be cost-effective in overcoming the underlying social determinants of health by improving lifestyle choices, risk factors and multiple biomarkers related to chronic disease (Kerrison *et al.*, 2017; Glechner *et al.*, 2018; Shirinzadeh *et al.*, 2019; Hill-Briggs *et al.*, 2021). For instance, the Centers for Disease Control and Prevention (CDC) established the National Diabetes Prevention Program, a lifestyle change program that focuses on assisting participants in making positive lifestyle changes, such as eating healthier and engaging in more physical activity to combat the increasing prevalence of prediabetes and T2DM (Ackermann *et al.*, 2011; Mudaliar *et al.*, 2016; Twohig *et al.*, 2019).

Lifestyle change and metformin able to reduce 20% relative risk reduction in developing T2DM (Sheng *et al.*, 2019). Study by Muhammad Zafar Iqbal *et al.* (2012) in Pakistan, found that the addition of metformin with lifestyle modification did not show any difference of conversion of IGT among diabetes high risk group after 18-month follow-up. On the other hand, Stevens *et al.* (2015) reported a network meta-analysis on the effectiveness of standard lifestyle intervention with additional pharmacotherapies in reducing the risk of progression to T2DM. Twenty-one studies found a reduced hazard progression to T2DM indicating that the addition of pharmacotherapies is able to reduce the risk of T2DM more than standard lifestyle advice. However, these studies had longer duration of intervention varying from a mean of 1.5 to 9.4 years.

The cost-effectiveness of long-term lifestyle intervention in preventing T2DM was reviewed (Glechner *et al.*, 2018). Sixteen RCTs involving 9796 participants revealed a sustained reduction in the occurrence of T2DM after one to three years of

intervention compared to the usual care. Early initiation of lifestyle intervention can reduce cost per quality-adjusted life-year and cost prevention of T2DM over the long term were mostly reported in clinical setting and high-income countries. Therefore, further studies are needed to assess the feasibility of lifestyle intervention in low-middle income countries like Malaysia and its effect on external motivation for long-term behavioural change.

A systematic review and meta-analysis by Shirinzadeh *et al.* (2019) investigated the effect of community-based lifestyle intervention program as a preventive strategy for T2DM in low- and middle-income countries. Six RCT studies were included, with a total of 2574 participants. The studies focused on lifestyle intervention without pharmacological treatment. These programs might have an impact on the rate of diabetes and positively affect anthropometric indices and glycaemic control in the at-risk population. However, the analysis involved small studies with heterogenous methodologies. They suggested for more research to be done to determine which community-based interventions and delivery methods can best prevent or reduce T2DM. Ackermann *et al.* (2011) conducted group-based lifestyle intervention in the community delivered by community volunteers reported to be able to maintain significant weight loss at 8-month maintenance phase. This study was adapted to design the Co-HELP module in Malaysia for a prediabetes community-based healthy lifestyle program. The end outcome are clinical outcomes of cardiometabolic risk factors and quality of life over a year follow up (Norliza *et al.*, 2016). However, both studies did not measure the individual's capability to perform and maintain healthy behaviour change.

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### 2.5.1 Components of Lifestyle Intervention

There are three lifestyle intervention components which are dietary, physical activity and behaviour modification approach (Fitzpatrick and Hill-Briggs, 2017). Lifestyle modifications, including exercise and diet, are associated with improved glycaemic control, which translates into a reduction in T2DM occurrence in individuals with prediabetes (Sénéchal *et al.*, 2014). For example, a Japanese study at an outpatient clinical setting with 6 months active intervention on dietary, fat intake, reduced alcohol intake, reduced snacks and increased physical activity showed significant reduction in BMI and plasma glucose after a 4-year follow up (Kosaka *et al.*, 2005). Most studies incorporate behaviour change as an essential component in lifestyle intervention and the intervention group showed more significant improvement in glycemia (Balk *et al.*, 2016) .

A systematic review by Kerrison *et al.* (2017) evaluated the effectiveness of lifestyle interventions worldwide for prediabetes. Nine randomised control trials (RCT) were included, with a total of 6030 participants. All the studies promoted a healthy diet and encouraged moderate physical activity to achieve 150 minutes of exercise per

week or 30 minutes per day. Improving prediabetes to normoglycemia with interventions ranging from 3 months to 5 years is challenging for long-term adherence in practising a healthy lifestyle. One of the studies was a study by Lindstrom *et al.* (2003) in Finland which used endurance and resistance training; it targeted 0.5-1.0 kg weight loss per week. It was conducted with a 3-year duration and 9 months active phase. The participants were encouraged to increase physical activity every visit by dietician and individualised diet recommendations by nutritionist.

### 2.5.1(a) Healthy Eating

As the economy grow rapidly and with trade becoming more global, there have been significant changes in food production. Whole grains are usually a big part of healthy eating plans for preventing and treating. Adults who are overweight or obese can lose weight by reducing their energy intake while maintaining healthy eating habits (Asif, 2014; Karatzi & Manios, 2021). A scooping review on dietary components and nutritional strategies to prevent T2DM found that people with a Mediterranean-style diet which consists of high fibre diet are less likely to get T2DM. However, further study to examine the role of different food choices and dietary habits for diabetes prevention are needed as diet habit are highly influenced by geographical and culture context (Ley *et al.*, 2014). A well-balanced diet with plenty of fruit and vegetables, combined with ample exercise, was supported by extensive studies as an effective strategy for slowing T2DM progression and complications (Yau *et al.*, 2020). A systematic review and meta-analysis by Uusitupa *et al.* (2019) of the available evidence for the prevention of T2DM have concluded that a Mediterranean diet can be recommended for long-term prevention. However, this may not be suitable for non-Mediterranean population with different food choices (Yau *et al.*, 2020).