EFFICACY OF AN AEROBIC AND A COMBINED AEROBIC RESISTANCE TRAINING INTERVENTION ON MIDDLE AGED TYPE 2 DIABETES MELLITUS PEOPLE OF MALAYSIA AND BANGLADESH – A COST EFFECTIVE APPROACH

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UNIVERSITI SAINS MALAYSIA

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by

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Faria Sultana
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LIST OF ABBREVIATIONS

µS	Microsecond
2 - h	2 hours
$	Dollars
€	Euro
ACSM	American College of Sports Medicine
ADA	American Diabetes Association
Ae	Aerobic Training
AIHW	Australian Institute of Health and Welfare
ANS	Autonomic Nervous System
BDT	Bangladeshi Taka
BISS	Bangladesh Institute of Sports Sciences
BIRDEM	Bangladesh Institute of Research & Rehabilitation in Diabetes, Endocrine and Metabolic Disorder
BMI	Body Mass Index
BG	Blood Glucose
BG – II	Bender-Gestalt II
BG Test	Bender-Gestalt Test
Bpm	Beats Per Minute
BRUMS	Brunel Mood Scale
CAN	Cardiovascular Autonomic Neuropathy
CI	Confidence Interval
CBA	Cost-Benefit Analysis

CEA	Cost-Effectiveness Analysis
CEP	Cost-Effectiveness Plane
CER	Cost Effectiveness Ratio
CMA	Cost-Minimisation Analysis
CMRR	Common Mode Rejection Ratio
CT	Circuit Training
CUA	Cost-Utility Analysis
CVD	Cardiovascular Disease
CONSORT	Consolidated Standards of Reporting Trials
DM	Diabetes Mellitus
DN	Diabetic Neuropathy
DSM -IV	Diagnostic and Statistical Manual of Mental Disorders - IV
EMG	Electromyography
EQ 5D	EuroQoL 5D
EQ 5D-5L	EuroQol 5D-5L
EQ-VAS	EuroQol Visual Analogue scale
FPG	Fasting Plasma Glucose
FU	Follow - Up
GDM	Gestational Diabetes Mellitus
H_O	Null Hypothesis
H_A	Alternative Hypothesis
HbA1c	Glycosylated Haemoglobin
HPLC	High Performance Liquid Chromatography

HPA	Hypothalamic-Pituitary-Adrenal
HRQoL	Health Related Quality of Life
HR	Heart Rate
HRmax	Heart Rate Maximum
HUSM	Hospital Universiti Sains Malaysia
Hz	Hertz
ICER	Incremental Cost-Effectiveness Ratio
IDF	International Diabetes Federation
Kg	Kilogram
kg/m^2	Kilogram Per Square Meter
KK	Klinik Kesihatan
MPF	Mean Power Frequency
MG	Megabyte
MHz	Megahertz
mm	Millimetre
MOH	Ministry of Health
MVC	Maximum Voluntary Contraction
MYR	Malaysian Ringgit
NA	Not Available
NDR	National Diabetes Registry
NICE	National Institute for Health and Clinical Excellence
NE	North-East
nm	Nanometre
NW	North-West

OGTT	Oral Glucose Tolerance Test
OPD	Outpatient department
PAN	Peripheral Autonomic Neuropathy
PEDro	Physiotherapy Evidence Database
pg	Page
PN	Peripheral Neuropathy
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QoL	Quality of Life
QALY	Quality Adjusted Life Years
RCT	Randomized Control Trial
RM	Repetition Maximum
RMS	Root Mean Square
RO	Research Objective
ROM	Range of Motion
RQ	Research Question
RT	Resistance Training
Sc	Skin Conductance
SD	Standard Deviation
secs	Seconds
SE	South-East
SW	South-West
SEMG	Surface Electromyography

SENIAM	Surface Electromyography for Non-invasive Assessment of Muscles
SF-36	Short-Form 36-Item
SF	Spontaneous Fluctuation
SNA	Sudomotor Nerve Activity
SPSS	Statistical Package for the Social Sciences
T2DM	Type 2 Diabetes Mellitus
USRDS	US Renal Data System
US	Unites States
USB	Universal Serial Bus
USD	US Dollars
USM	Universiti Sains Malaysia
VAS	Visual Analog Scale
WLAN	Wireless Local Area Network
WHO	World Health Organization
WHO QOL-BREF	World Health Organization Quality of Life
WP	Wilayah Persekutuan
ZCR	Zero Crossing Rate

TAHAP KEBERKESANAN INTERVENSI AEROBIK DAN GABUNGAN LATIHAN AEROBIK-HALANGAN DALAM KALANGAN PESAKIT DIABETES MELLITUS JENIS-2 DI MALAYSIA DAN BANGLADESH - PENDEKATAN KEBERKESANAN KOS

ABSTRAK

Kajian ini bertujuan untuk menilai keberkesanan perbandingan program gabungan senaman aerobik intensiti rendah ke sederhana dalam meningkatkan status kesihatan sedentary individu umur pertengahan (40-60 tahun) yang didiagnosa menghidap T2DM dan menilai keberkesanan kos terhadap intervensi latihan tersebut. Kajian dijalankan di Kelantan, Malaysia dan di Dhaka, Bangladesh. Seramai 75 individu yang menghidap T2DM di Kelantan, Malaysia dan 75 orang lagi yang menghidapi T2DM di Dhaka, Bangladesh telah dipilih dalam kajian ini. Mereka dinilai dan dipadankan berdasarkan tahap status sosioekonomi dan fisiologikal melalui ujian awal berdasarkan kriteria inklusi. Subjek telah dikategorikan secara rawak dan diasingkan kepada tiga kumpulan iaitu, Kumpulan Terkawal (Kumpulan A) dan dua kumpulan eksperimental. Kumpulan B (kumpulan senaman aerobik tertakluk kepada latihan aerobik rendah ke sederhana-diselia dengan aktiviti berjalan kaki pada intensiti 40-60% HRmax) dan Kumpulan C (kumpulan tertakluk kepada aktiviti yang diselia dengan berjalan kaki pada intensiti 40-60% HRmax dan senaman latihan rintangan). Setiap kumpulan terdiri daripada 25 subjek sama ada di Malaysia mahupun di Bangladesh. Selepas itu, penilaian pra intervensi dilakukan dengan *Euro-Qol 5D-5L (EQ 5D-5L)*, *Brunel Mood States (BRUMS)*, *Glycosylated haemoglobin (HbA1c)*, *Electromyography (EMG)*, *Bender-*

Gestalt II (BG- II) dan *Skin Conductance (Sc)*. Protokol latihan dijalankan selama 20-50 minit / hari; 3-4 hari / minggu; untuk tempoh 14 minggu. Pada akhir minggu ke-14, penilaian paska intervensi dijalankan mengikut protokol pra intervensi. Selepas itu, dengan selang 14 minggu tiada lagi senaman dijalankan, penilaian susulan dijalankan ke atas semua pembolehubah yang disebutkan sebelum ini untuk mengesahkan tahap kelestarian intervensi. Ujian *Wilcoxon signed-rank* mendapati bahawa subjek di Malaysia dan di Bangladesh dalam kumpulan B (p = .002; p = .000) dan kumpulan C (p = .001; p = .010) mempunyai peningkatan yang ketara dalam tahap mobiliti. Pengukuran ANOVA berulang dua hala / ANOVA Factorial bercampur mendapati bahawa kumpulan B (p = .000; p = .000) dan kumpulan C (p = .000; p = .000) berkesan dalam mengurangkan tahap *Glycosylated hemoglobin* (HbA1c); dan dalam meningkatkan status kesihatan keseluruhan subjek di kedua-dua negara. Intervensi latihan eerobik (p = .000; p = .009) dan gabungan (p = .008; p = .001) didapati amat berkesan dalam fasa mengurangkan keupayaan dan mengaktifkan otot peroneus brevis terhadap subjek di Malaysia dan di Bangladesh. Selain itu, hanya intervensi latihan gabungan (p = .001; p = .000) telah menunjukkan peningkatan dalam latensi tindak balas autonomi subjek T2DM di Malaysia dan di Bangladesh. Subjek bagi kumpulan C mempunyai peningkatan yang ketara (p = .000; p = .000) dalam Kemahiran Motor Visual di Malaysia dan di Bangladesh. Akhirnya, berdasarkan pada analisa keberkesanan kos, program gabungan senaman (kumpulan C) dilihat sebagai paling kos efektif antara program aerobik dan tiada senaman di Malaysia dan di Bangladesh.

EFFICACY OF AN AEROBIC AND A COMBINED AEROBIC RESISTANCE TRAINING INTERVENTION ON MIDDLE AGED TYPE 2 DIABETES MELLITUS PEOPLE OF MALAYSIA AND BANGLADESH – A COST EFFECTIVE APPROACH

ABSTRACT

This study compares the efficacy of a combined exercise training program over low - moderate level aerobic exercise training in improving the health status of sedentary middle–aged (40-60 years) individuals with T2DM and assess the cost effectiveness of those exercise interventions. This research was conducted in Kelantan, Malaysia and Dhaka, Bangladesh, based on 75 individuals with T2DM in Kelantan, Malaysia and 75 individuals with T2DM in Dhaka, Bangladesh. They were assessed and matched in the respective set-ups based on the extent of socio-economic and physiological status through preliminary testing according to inclusion criterions. Participants were randomly categorized into three groups – control group (Group A), and two experimental groups - Group B (Aerobic exercise group subjected to low-moderate aerobic exercise -supervised walking at 40-60% HRmax) and Group C (Combined exercise group subjected to supervised walking at 40-60% HRmax and resistance training exercises) comprising of 25 participants in each of the group in Malaysia as well as in Bangladesh. After that pre –intervention assessment was done with EuroQol 5D-5L (EQ 5D-5L), Brunel Mood States (BRUMS), Glycosylated haemoglobin (HbA1c), Electromyography (EMG), Bender-Gestalt II (BG- II) and Skin Conductance (Sc). Protocol for the exercise interventions was scheduled as approximately 20-50 minutes/day; 3-4 days/ week;

for 14 weeks. At the end of the 14th week, post intervention assessment was carried out following pre-intervention protocol. With an interval of 14 weeks of no exercise intervention, follow-up assessment was carried out on all the afore-mentioned variables to verify the extent of sustainability of the interventions. Wilcoxon signed-rank test revealed that both Malaysian and Bangladeshi participants in group B ($p = .002$; $p = .000$) and group C ($p = .001$; $p = .010$) had significant improvement in the level of mobility. Two-way repeated measure of ANOVA/Mixed Factorial ANOVA revealed that both group B ($p = .000$; $p = .000$) and group C ($p = .000$; $p = .000$) had significant reduction in the level of Glycosylated hemoglobin (HbA1c) and improvement in overall perceived health status in both the countries. Aerobic ($p = .000$; $p = .009$) and combined ($p = .008$; $p = .001$) exercise interventions were found as effective phase wise in reducing fatigability and activating peroneus brevis muscle in Malaysian and Bangladeshi participants. Whereas, only combined exercise intervention ($p = .001$; $p = .000$) has shown improvement in autonomic response latency in Malaysian and Bangladeshi T2DM participants. Group C participants had significant improvement ($p = .000$; $p = .000$) in Visual Motor Abilities in Malaysia and Bangladesh. Finally, based on the cost incurred and perceived health status, combined exercise program (group C) was observed to be the most cost-effective among aerobic and no exercise program both in Malaysia and Bangladesh.

CHAPTER 1

INTRODUCTION

1.1 Background and Scope of the Study

In last few decades, the world has seen radical changes in global lifestyles, owing to demographic transition, combined with urbanization and industrialization. Lifestyle-related diseases like diabetes; especially type 2 diabetes mellitus, in consequence, have emerged as major public health problem putting a humongous amount of health and economic burden on people worldwide. Therefore, it becomes essential to manage this epidemic in a holistic manner; where treatment interventions can lessen the health complications and minimize financial burden to improve the overall health status of diabetic individuals. Keeping those viewpoints in mind, the background and scope of this study have been discussed at length in the following sub-sections.

1.1.1 An Overview of Diabetes Mellitus (DM)

The growing prevalence of Diabetes Mellitus (DM) has led to an unprecedented epidemic of death and disability worldwide. DM, or solely diabetes, is a continuing disease that transpires when the pancreas is no longer able to make insulin, or when the body cannot make good use of the insulin it produces (Cho et al., 2015). Insulin is the name of a hormone which is produced by the pancreas, especifically, it is produced by the beta cells in the islets of Langerhans in the pancreas that helps to let glucose from the food we consume, pass from the blood stream into the cells in the body to produce energy (Aguiree et al., 2013). All the carbohydrate nourishments are broken down into glucose in the blood, and the hormone insulin helps glucose to enter the cells. Incapability to produce insulin or not being able to use it efficiently pushes towards having high blood glucose levels, generally termed as hyperglycaemia (Cho et al., 2015). Over the long-term, high glucose levels are associated with damage to the body and failure of various organs and tissues (Guariguata et al., 2014).

Generally, there are three types of DM (Cho et al., 2015). Firstly, type 1 diabetes used to be called juvenile-onset diabetes. It is usually caused by an auto-immune reaction where the body's defence system attacks the cells that produce insulin (Cho et al., 2015). Type 1 diabetes population generally are unable to produce insulin, or they are capable of producing an inadequate amount of insulin. This phenomenon is very common in children or young adults but can affect people of any age (Cho et al., 2015). In order to control the blood glucose levels, people with type 1 diabetes need to take insulin injections regularly (Aguiree et al., 2013). Secondly, type 2 diabetes mellitus (T2DM) is referred as non-insulin dependent diabetes or adult-onset diabetes, and it covers almost 90% cases of all kinds of diabetes (Cho et al., 2015). T2DM is categorised by relative insulin deficiency and insulin resistance, either or both of which might be existent at the time diabetes is diagnosed in a person (Aguiree et al., 2013). The diagnosis of T2DM can occur at any age. It can stay undetected for a long time and often the diagnosis is done only after people face any kind of complication or people do a routine blood or urine glucose check-up. Interestingly, obesity or overweight is often but not always associated with the occurrence of T2DM as it can cause insulin resistance and eventually proceed to a high level of blood glucose (Aguiree et al., 2013). Thirdly, Gestational diabetes mellitus (GDM) is a form of diabetes consisting of high blood glucose levels during pregnancy (Cho et al., 2015). It occurs in 1 in 25 pregnancies throughout the world and is related to complications to both mother and baby (Oostdam et al., 2012). Usually, GDM wanes after pregnancy, but women with GDM and their children are at a high risk of having T2DM later in life (Oostdam et al., 2012). Approximately half of women with a history of GDM go on to develop type 2 diabetes within 5 to 10 years after delivery (Oostdam et al., 2012). Apart from the aforementioned 3 types of DM, there do exist other specific types of diabetes which occur very seldom in individuals.

Commonly, DM is diagnosed based on World Health Organization (WHO) recommendations from 1999 expert committee meeting. WHO has made a feasible diagnostic classification for detecting diabetes by incorporating both fasting and 2 hours (2-h) after glucose load (75 g) criteria (Table 1.1).

Table 1.1: *Diagnostic criterion of diabetes mellitus and other categories of hyperglycaemia*

	Glucose concentration in venous plasma(mmol/L)
Diabetes Mellitus	Fasting ≥7.0 or 2- h post-glucose load ≥11.1 or HbA1c ≥ 6.5%
Impaired glucose tolerance	Fasting (if measured) < 7.0 and 2- h post-glucose load ≥7.8 and <11.1
Impaired fasting glucose	Fasting ≥6.1 and <7.0 and 2- h post-glucose load (if measured) <7.8

*Glucose load= 75 g glucose orally

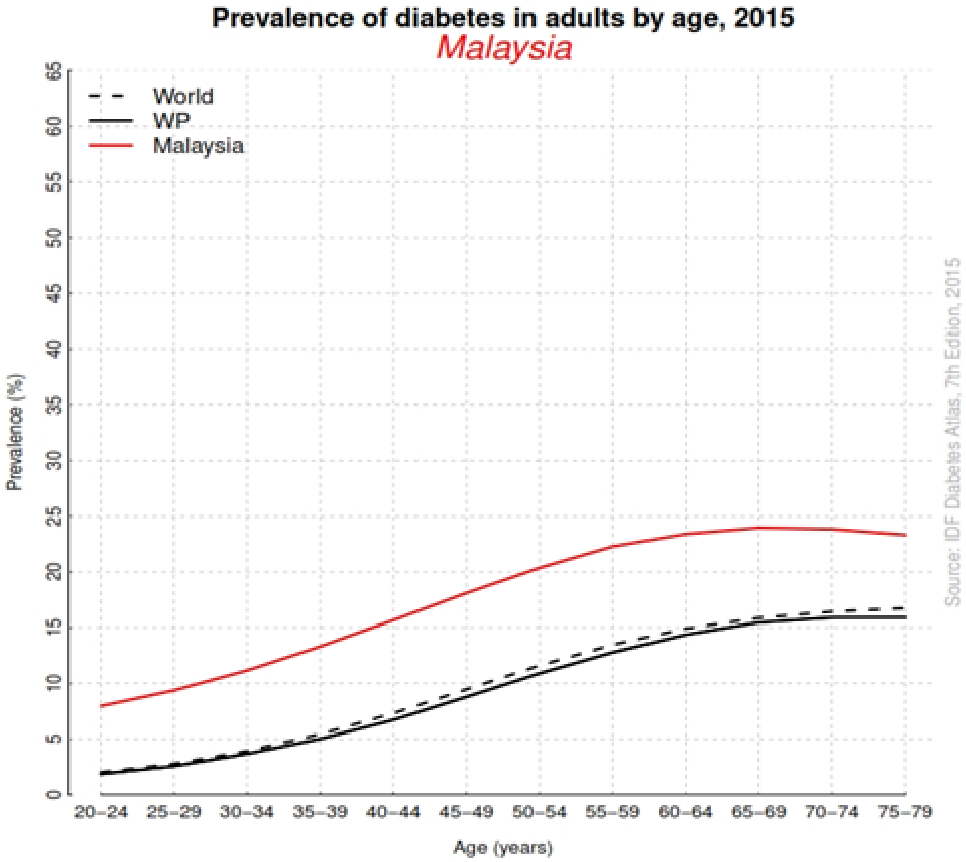
Source: World Health Organization Expert Committee. (2006).

1.1.2 Prevalence of Type 2 Diabetes Mellitus (T2DM)

In 2013, there were 387 million people with diabetes worldwide, and this is projected to increase to 592 million by the end of 2035 (Aguiree et al., 2013). In another study, it was stated that DM would see the greatest increase in the developing countries of Africa, Asia, and South America and among them 90% of diabetic individuals will be having T2DM (Stumvoll et al., 2005). Furthermore, in every country, the number of people with T2DM is increasing at an alarming rate. International Diabetes Federation (IDF) has also stated that 77% of people with T2DM resides in countries with high percentage of low- and middle-income population and 179 million people with diabetes are undiagnosed (Guariguata et al., 2014). Currently, it is estimated that almost 550 million people all over the world are also pre-diabetic, a state where blood glucose (BG) levels are above the normal range (based on table 1.1), hence greatly increasing their risk for T2DM (Aguiree et al., 2013). T2DM is a major source of premature mortality and morbidity related to cardiovascular disease (CVD), kidney disease (diabetic nephropathy), eye disease (diabetic retinopathy), and nerve disease (diabetic neuropathy) (Lloyd-Jones et al., 2009). More frighteningly, T2DM caused 4.9 million deaths in 2013, and it has caused at least USD 612 billion dollars in the expenditure on health in 2013 worldwide; which is equivalent to almost 11% of total spending on adults around the world (Aguiree et al., 2013). In the United States, diabetes is already the leading cause of blindness among working-age adults (Williamson et al., 2004), end-stage renal disease (US Renal Data System (USRDS), 2004), and nontraumatic loss of limb (Ulbrecht et al., 2004). It is also the fifth-leading cause of death globally (Hogan et al., 2003).

1.1.2(a) Prevalence of Type 2 Diabetes Mellitus (T2DM) in Malaysia

There were 3.3 million cases of T2DM in Malaysia and the prevalence in adults (20-79 years) is 16.6% in 2015 (Cho et al., 2015). The rate of prevalence of diabetes in Malaysia is much higher than the world prevalence and the trend shows that a growing population over the age of 50 makes up the largest proportion of diabetes prevalence in this country (Figure 1.1).



Source: IDF Diabetes Atlas, 7th edition, 2015;

Figure 1.1: Prevalence of Diabetes in Adults by Age in Malaysia, 2015

Table 1.2 displays the data of the National Diabetes Registry (NDR) regarding T2DM across different regions, age and ethnicity in Malaysia. According to NDR which was established to keep track of the target achievement and clinical outcomes of participants with diabetes managed at primary healthcare clinics (Klinik Kesihatan or KK) under the Ministry of Health (MOH), there were 657,839 participants registered in the NDR, of which 653,326 were diagnosed with T2DM, between 2009 to 2012. The number of registered T2DM individuals ranged from 106,101 in Selangor to 524 in Wilayah Persekutuan (WP) Labuan (Table 1.2). The Kelantan state also had a huge prevalence of registered T2DM individuals (27,002 persons) (Table

1.2). The mean age of T2DM participants in the NDR was 59.7 years old, 41.6% were men, and 58.4% were women (Table 1.2).

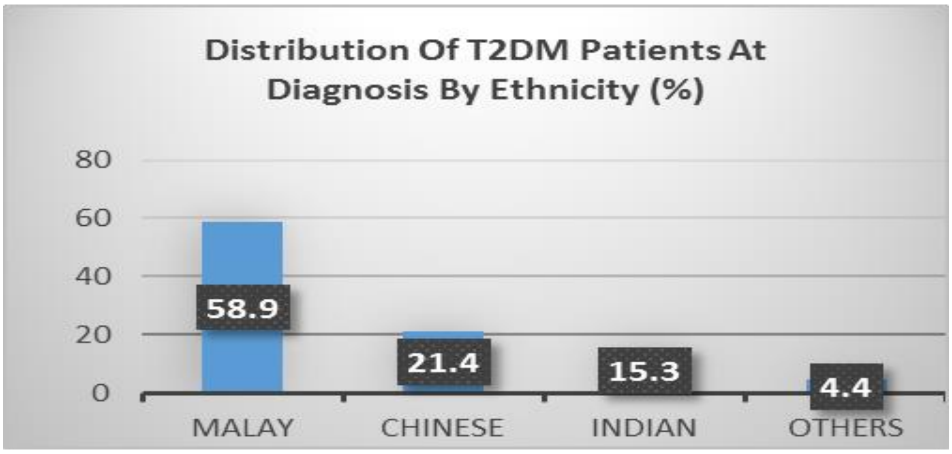
Table 1.2: *Characteristic of T2DM patients in Malaysia*

State	No. of patients, n(%)	Male, n(%)	Mean age (95% CI)	Ethnicity, n(%)				
				Malay	Chinese	Indian	Other Malaysian	Foreigner/ Unknown
Johor	92,750(14.2)	38,386(41.4)	59.8 (59.7-59.9)	58,306(62.9)	22,724(24.5)	11,219(12.1)	397(0.4)	104(0.1)
Kedah	42,344(6.5)	16,482(38.9)	59.1 (59.0-59.2)	31,515(74.4)	5,059(11.9)	5,274(12.5)	453(1.1)	43(0.1)
Kelantan	27,002(4.1)	9,692(35.9)	59.3 (59.2-59.4)	25,497(94.4)	1,066(3.9)	145(0.5)	278(1.0)	16(0.1)
Melaka	42,974(6.6)	18,640(43.4)	61.0 (60.9-61.1)	28479(66.3)	9,883(23.0)	4,264(9.9)	292(0.7)	56(0.1)
Negeri Sembilan	57,869(8.9)	25,288(43.7)	60.4 (60.3-60.5)	33,317(57.6)	10,810(18.7)	13,347(23.1)	314(0.5)	81(0.1)
Pahang	38,119(5.8)	15,972(41.9)	58.9 (58.8-59.1)	29,700(77.9)	5,450(14.3)	2,664(7)	201(0.5)	104(0.3)
Perak	74,492(11.4)	31,604(42.4)	61.1 (61.1-61.2)	38,867(52.2)	18,869(25.3)	16,113(21.6)	588(0.8)	55(0.1)
Perlis	13,388(2.1)	5,311(39.7)	58.9 (58.7-59.1)	11,521(86.1)	1,217(9.1)	326(2.4)	314(2.3)	10(0.1)
Pulau Pinang	40,439(6.2)	17,271(42.7)	60.6 (60.5-60.7)	17,758(43.9)	14,534(35.9)	7,876(19.5)	210(0.5)	61(0.2)
Sabah	11,302(1.7)	4,933(43.6)	58.8 (58.6-59.0)	560(5.0)	3,594(31.8)	104(0.9)	6,888(60.9)	156(1.4)
Sarawak	43,333(6.6)	17,046(39.3)	59.3 (59.2-59.4)	12,030(27.8)	14,850(34.3)	254(0.6)	16,088(37.1)	111(0.3)
Selangor	106,101(16.2)	45,019(42.4)	58.5 (58.4-58.6)	55,245(52.1)	19,664(18.5)	29,603(27.9)	1067(1.0)	522(0.5)
Terengganu	22,272(3.4)	8,275(37.2)	58.3 (58.2-58.5)	21,786(97.8)	427(1.9)	21(0.1)	23(0.1)	15(0.1)
WP Kuala Lumpur	37,713(5.8)	16,261(43.1)	60.5 (60.4-60.7)	17,258(45.8)	11,587(30.7)	8,448(22.4)	317(0.8)	103(0.3)
WP Labuan	524(0.1)	202(38.5)	55.8 (54.8-56.8)	363(69.3)	72(13.7)	4(0.8)	77(14.7)	8(1.5)
WP Putrajaya	2,704(0.4)	1,408(52.1)	54.5 (54.1-54.9)	2,494(92.2)	62(2.3)	128(4.7)	12(0.4)	8(0.3)
Total patients, n (%)	**653,326(100)**	**271,790 (41.6)**	**59.7 (59.7-59.7)**	**384,696(58.9)**	**139,868(21.4)**	**99,790(15.3)**	**27,519(4.2)**	**1,453(0.2)**

Source: (NDR, Volume 1, 2009 – 2012)

In terms of ethnicity, 58.9% were Malay, 21.4% were Chinese, and 15.3% were Indian (Table 1.3) among the total diabetic population in Malaysia.

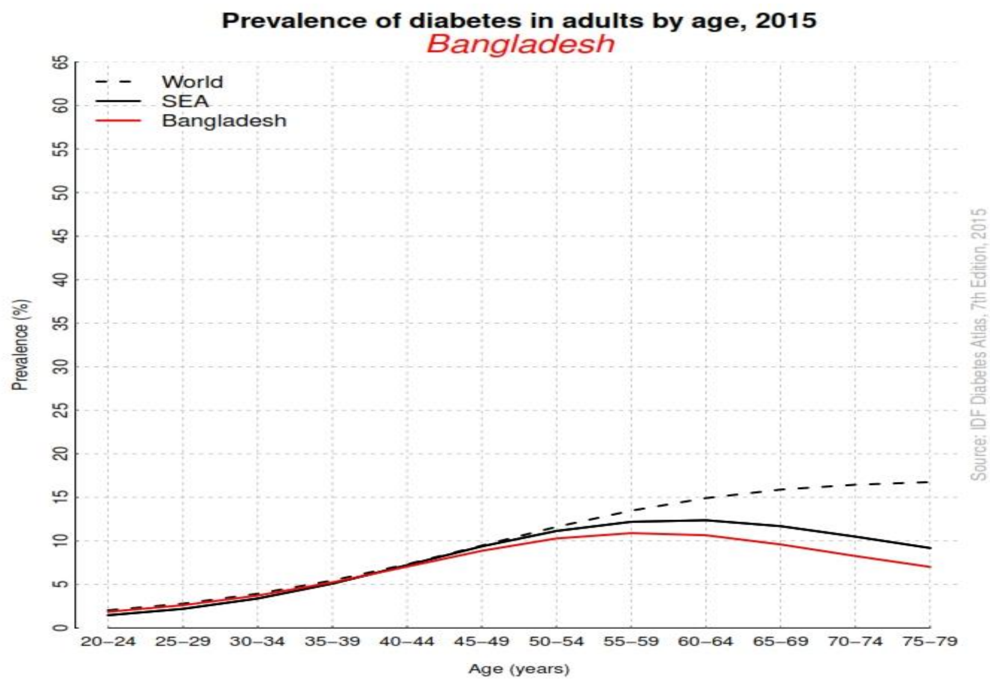
Table 1.3: *Distribution of T2DM population at Diagnosis by Ethnicity*



Source: (NDR, Volume 1, 2009 – 2012)

1.1.2(b) Prevalence of Type 2 Diabetes Mellitus (T2DM) in Bangladesh

Similarly, the prevalence of T2DM in Bangladesh increased considerably from 4% in 1990 to 10% in 2011 and is expected to reach 13% by 2030 (Saquib et al., 2012). It has become a major public health issue in this country, affecting one in ten adults and the highest age adjusted prevalence of this disease was observed in the south-eastern part of the country (Chittagong, 12.4%, and Barisal,11.6%), followed by central part (Dhaka, 10.2%), middle-western part (Rajshahi, 10.2%), eastern part (Sylhet, 10.0%), north-western part (Rangpur, 8.0%), and western part (Khulna, 6.4%) (Akhter et al., 2014). It has been shown that residents in the south-eastern part of Bangladesh have two times more probability to be diabetic compared with those living in western parts (Hussain et al., 2006). According to IDF, people aged between 45-60 years leads to the highest portion of the diabetic scenario in Bangladesh. Meanwhile, globally, a growing population over the age of 60 makes up the largest proportion of diabetes prevalence (Figure 1.2).



Source: IDF Diabetes Atlas, 7th edition, 2015

Figure 1.2: Prevalence of Diabetes in Adults by Age in Bangladesh, 2015

In a study by Saquib et al. (2013), it has been observed that in Bangladesh, within the age-range of 30 to 40 years, approximately 15% and 31% participants respectively had T2DM and metabolic syndrome. Both of these figures, however postulates that onset of T2DM occurs at younger age in Bangladesh in recent times compared to the past (Saquib et al., 2013). Nearly 17% of participants who thought they did not have T2DM was diagnosed with this disease, and the majority of the newly diagnosed cases were younger than 50 (Saquib et al., 2013). Nevertheless, the prevalence of T2DM in Bangladesh still is at a higher extent among middle aged people, aged between 45 to 60 years (Cho et al., 2015). These results stress the need to encourage the middle aged population of Bangladeshi society to seek annual health check-ups, specifically if they are smoking, overweight, or have a family history of T2DM. Also, cardiovascular disease was evident in more than half of the cases diagnosed with metabolic syndrome and T2DM (Saquib et al., 2013).

1.1.3 Cost of Type 2 Diabetes Mellitus (T2DM)

T2DM considerably adds to the prevalling crises associated with preventable diseases and leads to economic losses that arise from high health-care cost and loss of productivity (Ghaffar et al., 2004). Generally, there would be two types of costs to be considered while measuring the costs of a disease like T2DM (Phillips & Thompson, 2003). First, there exists a direct cost which refers to the immediate costs a person has to bear in terms of the money needed to buy medical services, drugs and other supplies to get better or keep the condition under control. It can also be considered the financial costs borne by national healthcare systems. On the other side, the second type of cost is indirect cost which refers to the costs of productivity losses due to taking time off from work for sickness or attendance for health care; inability to work because of disability (e.g. impairment of vision); premature retirement because of disability; premature mortality because of the acute or chronic complications and others (Ghaffar et al., 2004).

In the United States alone, the direct medical cost of diabetes amounts to US$92 billion annually, with indirect costs adding another US$40 billion (Hogan et al., 2003). In Italy, the cost of T2DM was estimated at US$58 billion, amounting to >6% of total private and public healthcare expenditure (Lucioni et al., 2003). T2DM also causes a substantial economic burden in lower-income economies. For example, in the Caribbean and Latin America, the total annual cost associated with diabetes may be around US$65 billion (Barcelo et al., 2003). In developing countries, a large number of people are living on or beneath the poverty line and face problems in accessing health care services. Along with that, these countries also face lack of national welfare schemes and provision of health insurance for the poor population. The underprivileged people cannot afford to pay for healthcare services. Hence, they are diagnosed late with diabetes, resulting in acute and chronic complications (Caro et al., 2002). Once considered to be a disease of wealthy nations, T2DM now constitutes a truly global affliction. IDF anticipates that the worldwide incidence of diabetes among those aged 20 to 79 years will increase by around 70% in the next 20 years (Aguiree et al., 2013). The increase will affect all global regions, with projected increases ranging from 21% in Europe to 11% in Africa (Aguiree et al., 2013). Regarding South East Asia, it will see an additional 40 million cases of T2DM by 2025 (Aguiree et al., 2013).

In addition to that, cost per person with diabetes in Malaysia was calculated to be US$ 565.8 in 2015 (Cho et al., 2015) which does put a lot of pressure on the economy of Malaysia. Likewise, the prevalence of T2DM and its adverse health effects have risen more rapidly in South Asia (Ghaffar et al., 2004) and in Bangladesh, the cost per person with diabetes was US$ 42 in 2015 (Cho et al., 2015), which does lead the country into to a huge economic burden.

1.1.4 Measurement of Health Status of Type 2 Diabetes Mellitus (T2DM) Population

T2DM requires constant medical care, patient self-care and education to prevent various complications and to reduce the risk of long-term diseases to maintain a healthy life-style (Lloyd-Jones et al., 2009). According to Australian Institute of Health and Welfare (AIHW), health status is an inclusive concept which is verified by more than the existence or absence of any kind of disease. It is often summarised by self-assessed health status or life expectancy or/and in a broader sense also include physiological and psychological measurements. Over the last few decades, extensive effort has been given in developing health-status measurement tools to analyse various results in public-health and clinical research (Hammond et al., 1992). In the context of any sort of diabetes research, traditional physiological and pathological measurement, such as measuring Glycosylated Haemoglobin (HbA1c), has been used and recommended by experts all around the world (Castaneda et al., 2002; Sigal et al., 2007; Bweir et al., 2009). More significantly, measurement of HbA1c is essential to have a more proper and accurate status of the blood glucose level of the diabetic patients, which basically quantify average glycaemia over several weeks and months, thereby complimenting everyday testing by the patients themselves (Sigal et al., 2005). Apart from that, health and wellness evaluative index, such as EuroQol 5D-5L (EQ

5D-5L) (Tin et al., 2015; Falconer et al., 2010), and others were extensively utilised to measure the health status of the T2DM population. There were also a small number of researches done, including psychological measurement like Bender-Gestalt (BG) Test (Ornoy et al.,1999), physiological measurement like assessing muscle fatigability by Electromyography (EMG) (Abboud et al., 2000, Kwon et al., 2003), and psychophysiological measurement like autonomic manifestations of emotionality assessed by skin conductance apparatus (Mohanraj and Narayanan, 2016), to complement the findings from traditional measurements in evaluating health status of different sorts of diabetic population.

1.1.5 Importance of Exercises in Managing Type 2 Diabetes Mellitus (T2DM)

In the purview of diabetes care, it is crucial to maintain HbA1c and equally important to manage other risk factors, including obesity, hypertension and dyslipidaemia. For this reason, it is a must to manage this disease with effective and efficient interventions. Meanwhile, exercise along with diet and medication has been considered as one of the three keystones of diabetes therapy (Boulé et al., 2001). Since decades the American Diabetes Association (ADA) (Sigal et al., 2005) and American College of Sports Medicine (ACSM) (American College of Sports Medicine Position Stand, 2000), have recommended regularised physical activity and exercises for regulation of blood sugar level among individuals suffering from T2DM. Moreover, regular exercise is recommended for people with T2DM since it might have beneficial impacts on metabolic risks factors for the development of diabetic complications (ADA, 2002). The low-cost, non-pharmacological nature of exercise further enhances its therapeutic appeal. The metabolic effects on glucose uptake and the structural remodelling of skeletal muscle are the major reasons of the improved glucose homeostasis, even in individuals with insulin resistance diseases (Sigal et al., 2013).

Concerning the type of exercise, many studies have demonstrated the positive adaptations of aerobic exercise on glucose control (Ronnemaa et al., 1986; Wing et al., 1988; Vanninen et al.,1992; Walker et al., 1999), glucose tolerance (Lampman et al., 1987; Segal et al., 1991; Tessier et al., 2000) and insulin sensitivity (Segal et al., 1991; Mourier et al., 1997) in people with T2DM. Generally, aerobic exercise refers to physical activities like walking, bicycling or jogging that includes constant and cadenced developments of big muscle groups, continuing for not less than 10 minutes at a time (Sigal et al., 2013). Moderate to high levels of aerobic exercise and advanced levels of cardiorespiratory fitness are related to considerable reductions in mortality and morbidity in both men and women and in both type 1 and type 2 diabetes (Sigal et al., 2013). Large cohort studies have demonstrated that, in people with T2DM, regular physical activity (Gregg et al., 2003; Hu et al., 2005) and/or moderate to high cardiorespiratory fitness are associated with reductions in cardiovascular complications and also reduces overall mortality rate over 15 to 20 years of follow-up (Church et al., 2005). Further benefits of aerobic exercise consist of improved cardiorespiratory fitness in both type 1 and type 2 diabetes (Nielsen et al., 2006) and slowing of the development of peripheral neuropathy (Balducci et al., 2006). Furthermore, several clinical trials evaluating aerobic exercise interventions in people with T2DM have demonstrated a beneficial effect of aerobic exercise on reducing the level of HbA1c (Piette et al., 2011; Engel and Linder, 2006; Goldhaber-Fiebert et al., 2003; Tessier et al., 2000) and enhancing quality of life (Kell et al., 2001; Singh et al., 1997). Similarly, the ADA recommends that individuals with T2DM could perform moderate-intensity aerobic exercise at least for 150 minutes and/or vigorous aerobic exercise at least for 90 minutes per week (Sigal et al., 2005). The point to be noted here is, even though this kind of lifestyle modification could have a significant effect on the metabolic and cardiovascular health of T2DM population, it is often challenging for people who have been habitually inactive to follow these guidelines.

In recent times resistance training also has gained popularity in exercise programs with people with T2DM due to its benefits in physical fitness and metabolic adaptations (Eriksson et al. 1998; Honkola et al. 1997; Dunstan et al. 1998). Resistance training exercise refers to a physical movement which helps to enhance the strength of muscles and/or endurance by involving brief activities with weights, resistance bands, weight-machines or his/her own body weight, such as push-ups (Sigal et al., 2013). Moreover, resistance training has recently been recognized as a useful therapeutic tool for the treatment of a number of other chronic diseases as well (Kongsgaard et al., 2004; Schmitz et al., 2005; Segal et al., 2003; Hare et al., 1999) and has been demonstrated to be safe and efficacious for the elderly (Singh et al., 1997) and obese (Cuff et al., 2003). Like aerobic exercise, resistance training has been reported to enhance insulin sensitivity (Eriksson et al., 1998; Poehlman et al., 2000), daily energy expenditure (Ades et al., 2005), and quality of life (Kell et al., 2001; Singh et al., 1997). Furthermore, resistance training has the potential for increasing muscle strength (Hunter et al., 2004; Hare et al., 1999), lean muscle mass (Ryan et al., 2001) and bone mineral density (Engelke et al., 2006), which could enhance functional status and glycemic control and assist in the prevention of sarcopenia and osteoporosis (Sigal et al., 2013). However, resistance training exercises are usually reliant on equipment, proper knowledge of exercise techniques and also involves some initial instructions

(Sigal et al., 2013). Nevertheless, to make resistance training a realistic form of exercise for T2DM population, in-depth studies are required to find out sustainable, economically reasonable and practical ways to safely implement resistance training at a mass level.

Various statements from the ADA (Sigal et al., 2004) and the ACSM (2000) recommended that a complete rehabilitation program for individuals with diabetes should combine both resistance and aerobic exercise. Moreover, it has been observed that the effects of combined exercise (aerobic and resistance training) on fitness are bi-dimensional: as aerobic exercise upsurges cardiorespiratory fitness, resistance training improves the strength of muscle and endurance (Sigal et al., 2007). Indeed, specific adaptations in skeletal muscle (Zierath, 2002) seem to be beneficial to individuals with type 2 diabetes, since the active muscle tissue reveals a higher metabolic rate in glucose metabolism (Baron et al., 1988). A well-controlled study observed that a combined strength and aerobic training program for people with T2DM had improved body composition, glucose control, cardiovascular fitness and muscular strength after 8 weeks of training (Maiorana et al. 2002). Similarly, another study by Sigal et al. (2007) demonstrated that the effects of aerobic training and resistance training on HbA1c were approximately equal, and the effects of combined exercise training were twice as beneficial as those of aerobic exercise training. Researchers have also highlighted the point that the combined aerobic and resistance exercise program is expected to be more sustainable because 90 minutes of only one type of exercise can be uninteresting for many people (Sigal et al., 2007). The impacts of training programs that combine both resistance and aerobic exercises for T2DM individuals may differ based on the components and protocols used for the exercises on different population fragments (Sigal et al., 2007).

1.1.6 Importance of Cost-Effectiveness Analysis (CEA)

Recent enhancement in awareness to maintain cost of healthy living within budgets, has created the perfect climate in the health care sector, for CEA. Cost-effectiveness analysis is a method for evaluating the costs of health-intervention resources and health outcomes (Husereau et al., 2013). The term cost-effectiveness has turned into being synonymous with evaluation of health economics and has been used to illustrate the magnitude to which interventions satisfy to what can be considered to denote value for money. Strictly speaking, CEA is just one of the techniques of economic evaluation, where the choice of technique rest on the nature of the benefits specified. In a study by Phillips & Thompson (2003), it was mentioned that CEA has been defined by the National Institute for Health and Clinical Excellence (NICE) in the year 2003 as a study of economics which has been designed to measure consequences of various interventions by a single outcome, typically in ‘natural’ units (e.g., life-years gained, heart attacks avoided, deaths avoided, or cases identified). The alternative interventions are being compared in terms of cost per unit of effectiveness (Phillips & Thompson, 2003).

Apart from CEA, there are mainly three other main approaches that are currently in use for economic evaluation of health care (Palmer et al., 1999). Those are - the Cost-Minimisation Analysis or CMA (used when the results of the techniques/interventions being compared are the same); Cost-Utility Analysis or CUA (used when consequence of interventions vary, e.g. quality of life scales); and Cost-

Benefit Analysis or CBA (used when a monetary value is being attached to services received) (Palmer et al., 1999).

Costs are seen in different ways from different point of views. In economics, the idea of cost is built on the value which can be gained from exhausting resources somewhere else – stated as the opportunity cost. Therefore it means, the resources which are used in a programme can not be used in another programme and, therefore, the profits that could have been received have been forgone (Phillips & Thompson, 2003). It is common, in practice, to take the price paid as the opportunity cost, and to embrace a practical method to costing and use market prices wherever possible. In cost-effectiveness analysis it is conventional to distinguish between the direct costs (e.g. Medical costs - drugs, staff time, equipment, Patient costs – transport, out-of pocket expenses) and indirect or productivity costs (e.g. production losses, other uses of time) associated with the intervention, as well as what are termed intangibles (e.g. pain, suffering, adverse effects), which, even though can be challenging to quantify, are often consequences of the intervention and should be incorporated in the cost profile (Phillips & Thompson, 2003).

However, it is crucial to specify which costs are incorporated in a cost-effectiveness analysis and which are not, to make sure that the findings are not subject to misinterpretation. The central function of CEA is to illustrate the comparative value of alternative interventions for the betterment of health status. CEA analysis can provide information that can help decision makers and individuals in a variety of settings to weigh alternatives and decide which best serve their programmatic needs (Husereau et al., 2013). The cost effectiveness ratio (CER), i.e. the cost per unit of output or effect, is the most popular measure of an activity's cost- effectiveness, with the implication that the lower the CER, the better is the activity (Husereau et al., 2013). Using cost-effectiveness analysis with independent programmes requires that cost-effectiveness ratios (CERs) are calculated for each programme and placed in rank order.

The possibility is that choices need to be made between different treatment regimens for the same condition, different dosages or treatment, different exercise regimes versus usual care – that is, mutually exclusive interventions. The key question here would pertain to the additional benefits to be gained from the new therapeutic or exercise intervention and how much greater would be the cost of that? In order to answer such a question, incremental cost-effectiveness ratios (ICERs) are used. The incremental cost effectiveness ratio can be better understood with an example. For instance, an activity (a health care intervention or treatment), termed as *"a"* and its best alternative activity (any other intervention or treatment) termed as *"b"* can be considered for treating a disease. These two activities bear certain costs which can be denoted as "C*a*" (Costs of activity "*a*") and "C*b*" (Costs of activity "*b*"). Along with costs, these activities also pertain to some specific effects on the disease. So, effects of the activities can be denoted as 'E*a*" (Effects of activity "*a*") and "E*b*" (Effects of activity "*b*"). Now the ICER for activity *"b"* would be:

$$ICER = (Cb – Ca) / (Eb – Ea) = \Delta C/\Delta E$$

The numerator of the ICER is called the incremental cost, and the denominator is the incremental effect (Phillips & Thompson, 2003). A useful way of showing the decision rules that apply to the ICER is the cost-effectiveness plane. This plane shows the costs and effects of an activity compared to the other alternatives (Phillips &

Thompson, 2003). Data of costs and effects are usually simulated repeatedly (generally 1,000 times) to generate a vector of ICERs, which are then plotted on the cost-effectiveness plane and from which the cost-effectiveness acceptability curve is derived. This indicates the likelihood that the ICER lies below a defined threshold (ceiling), which signifies a standard, against which the evaluation of the intervention is done, to evaluate whether that could be considered as cost-effective or not. There are understandably a number of issues that frame the use of such explicit approaches to notifying what therapies are made available, many of which are argumentative and controversial.

In the present scenario, very few researchers have adopted CEA to inform decisions maker about health services in developing countries although T2DM in developing countries have certainly emerged as a major public health problem. Besides, in the case of developing countries like Malaysia and Bangladesh, complications from diabetes can be devastating (Tuomilehto et al., 2001; Sevick et al., 2000; Diabetes Prevention Program Research Group, 2012). Moreover, it has been seen that the incremental costs of an individual with T2DM arise not only when the diagnosis is done but at least 8 years earlier (Stumvoll et al., 2005).

Hence, the medical and socioeconomic burden of this disease imposes enormous strains on health care systems. As a result, it is a must for diabetic individuals to maintain their glycaemic level and levels of other co-morbidities to sustain healthy and stress-free lives. In achieving this goal of enhancing the health status of these individuals, there exists a need to have opportunities and alternatives that can be beneficial for them from the perspectives of both health and cost. If any alternative provides them with a way to improve their health conditions by reducing the cost burden of the disease, then it denotes that diabetic individuals have an option to tackle this epidemic in a cost-effective way. This situation has really ignited the scope of producing more cost-efficient interventions for the type 2 diabetic population and enriches global health economics literature to reduce the burden of the cost of T2DM on individuals and societies. Therefore, in depth researches on cost-effective interventions are becoming essential for health care management and programs for individuals and societies to manage the burden of T2DM.

1.2 Rationale of the Study

Several studies were previously conducted to evaluate and assess different aspects of T2DM, mainly based on biological indices specifically for developed regions of the world. It is imperative to assess the socioeconomic burden of this disease as well because it implies enormous strains on the healthcare system of a country, especially of a developing country. Having said that, there was no research done on the Malaysian and Bangladeshi population to assess and recommend alternatives to enhance the quality of lives of the middle aged T2DM population both from health and economic perspectives. Therefore, it becomes necessary to assess different alternatives which can be beneficial for the T2DM population from both health and economic perspectives for these two developing countries. Hence, the present study has been conducted to assess the cost effectiveness of the exercise interventions along with the effects of differential exercise interventions on the quality of life of the middle-aged individuals with T2DM in Kelantan, Malaysia and Dhaka, Bangladesh. Moreover, this study has also assessed the cost effectiveness of the aerobic and combined exercise training programs to help the health care authorities to strategize an authentic, economical yet less time-consuming package of exercise intervention techniques, intended for reduction in metabolic distress and life-threatening crises towards realistic management of economic resources for T2DM population of Kelantan, Malaysia and Dhaka, Bangladesh. In addition to that, this research tries to offer a scope to design specific and tailored aerobic and combined exercise (aerobic and resistance exercises) protocol for the T2DM population living in these two countries based on the findings of the research.

1.3 Problem statement

Whether training of differential exercise interventions have beneficial impacts on health-status in Malaysian & Bangladeshi middle-aged T2DM individuals and which differential exercise intervention program is cost-effective for Malaysian & Bangladeshi middle aged T2DM individuals?

Hence, based on the problem statement, the conceptual framework followed in this research is displayed in figure 1.3

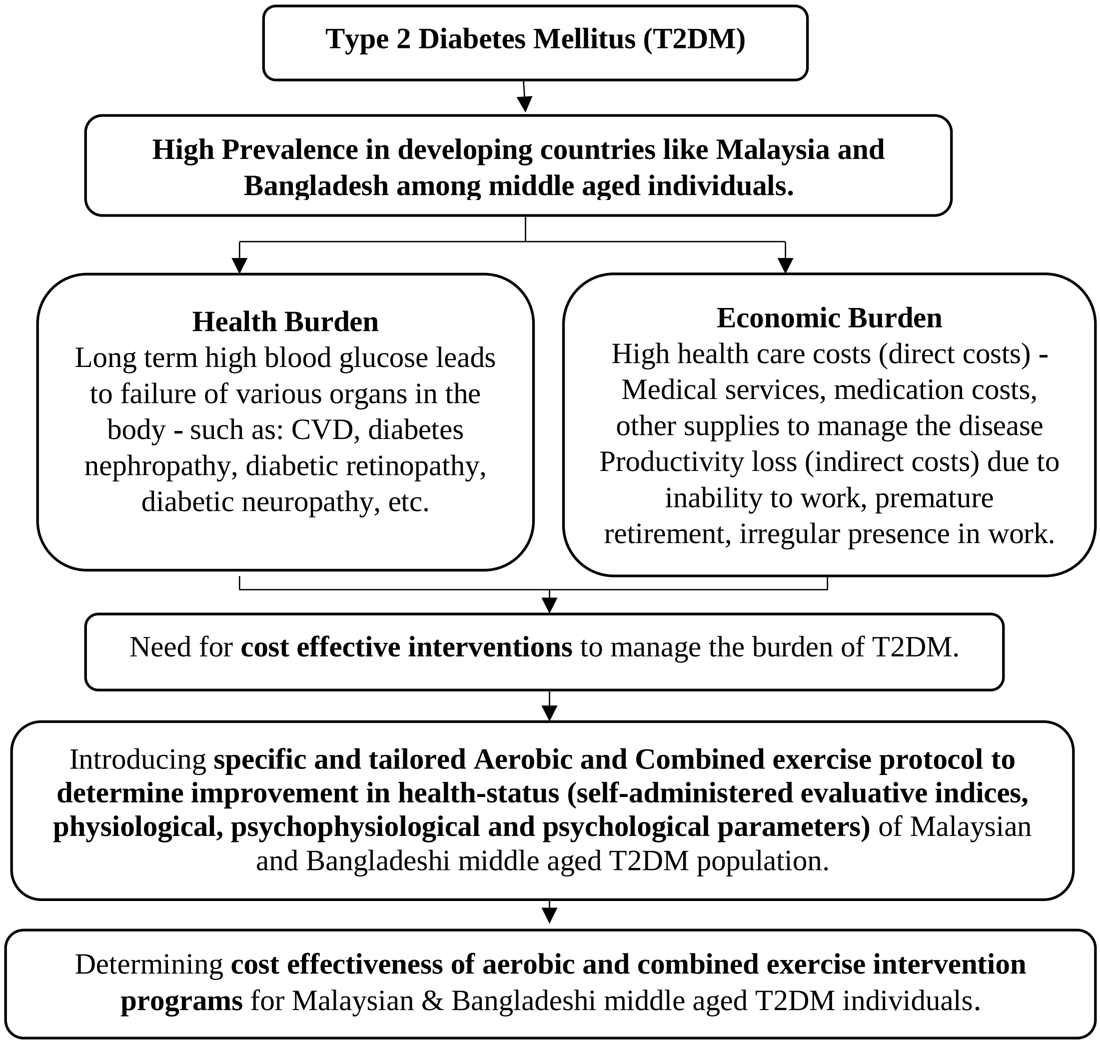


Figure 1.3: Conceptual Framework

1.4 Objectives

General Objective

To assess the effectiveness of aerobic and combined (aerobic and resistance) exercise intervention training on improvement in health status in Malaysian and Bangladeshi middle aged T2DM individuals and to determine the cost effectiveness of these differential exercise intervention programs.

Specific Objectives

1. To investigate the effect of aerobic exercise intervention training on improvement in health and wellness status of Malaysian and Bangladeshi middle aged T2DM individuals (RO1).
2. To investigate the effect of combined exercise (aerobic and resistance exercises) intervention training on improvement in health and wellness status of Malaysian and Bangladeshi middle aged T2DM individuals (RO2).
3. To identify the effectiveness of aerobic exercise and combined exercise (aerobic and resistance exercises) intervention training on improvement in health and wellness status of Malaysian and Bangladeshi middle aged T2DM individuals (RO3).
4. To determine the cost effectiveness of aerobic and combined exercise (aerobic and resistance exercises) intervention programs for Malaysian and Bangladeshi middle aged T2DM individuals (RO4).

1.5 Research Questions

1. Is there any significant difference in health and wellness status measured by health and wellness status evaluative indices (EuroQol 5D-5L [EQ 5D-5L] and Brunel Mood Scale [BRUMS]) of Malaysian & Bangladeshi middle aged T2DM individuals within control, aerobic exercise and combined exercise group based on time (Time Effect); regardless of time (Intervention Effect) and group with regard to time (Interaction Effect)?

2. Is there any significant difference in health and wellness status evaluated by physiological parameters (Glycosylated Haemoglobin [HbA1c] and Electromyography [EMG]) of Malaysian & Bangladeshi middle aged T2DM individuals within control, aerobic exercise and combined exercise group based on time (Time Effect); regardless of time (Intervention Effect) and group with regard to time (Interaction Effect)?
3. Is there any significant difference in health and wellness status assessed by psychological parameter (Bender-Gestalt II [BG – II]) of Malaysian & Bangladeshi middle aged T2DM individuals within control, aerobic exercise and combined exercise group based on time (Time Effect); regardless of time (Intervention Effect) and group with regard to time (Interaction Effect)?
4. Is there any significant difference in health and wellness status evaluated by psychophysiological parameter (Skin Conductance [Sc]) of Malaysian & Bangladeshi middle aged T2DM individuals within control, aerobic exercise and combined exercise group based on time (Time Effect); regardless of time (Intervention Effect) and group with regard to time (Interaction Effect)?
5. Whether aerobic exercise or/and combined exercise intervention program/s is/are cost effective or not for Malaysian & Bangladeshi middle aged T2DM individuals?

1.6 Research Hypotheses

The following hypotheses were articulated to attain the aforementioned objectives.

1.6.1 Null Hypothesis (H_O):

1. Aerobic exercise has no effect on improvement in health and wellness status of Malaysian & Bangladeshi middle aged T2DM individuals.
2. Combined exercise (aerobic and resistance exercises) has no effect on improvement in health and wellness status of Malaysian & Bangladeshi middle aged T2DM individuals.
3. No difference between the effects of aerobic exercise and combined exercise (aerobic and resistance exercises) intervention training on improvement in health and wellness status of Malaysian & Bangladeshi middle aged T2DM individuals.
4. Aerobic and/or combined exercise (aerobic and resistance exercises) intervention program is not cost effective for Malaysian & Bangladeshi middle aged T2DM individuals.

1.6.2 Alternative Hypothesis (H_A):

1. Aerobic exercise has effect on improvement in health and wellness status of Malaysian & Bangladeshi middle aged T2DM individuals.
2. Combined exercise (aerobic and resistance exercises) has effect on improvement in health and wellness status of Malaysian & Bangladeshi middle aged T2DM individuals.
3. Difference between the effects of aerobic exercise and combined exercise (aerobic and resistance exercises) intervention training on improvement in health and wellness status of Malaysian & Bangladeshi middle aged T2DM individuals.