Cost-Effective Exercise Programs on Health-Status of Malaysian Diabetic Individuals - A Socio-Psychological Analysis

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Abstract
Lifestyle-related diseases like Type 2 Diabetes Mellitus (T2DM) induces humongous amount of global health and economic burden. This study purports to compare the efficacy of aerobic and combined exercise intervention programs evident amongst T2DM individuals in Kelantan, Malaysia to assess the cost-effectiveness of those exercise interventions.
75 middle-aged T2DM individuals from middle-income population of Kelantan, Malaysia were recruited as participants, and hence they were assessed with HbA1c for evaluation of stability in regulation of blood-glucose level; EuroQol 5D-5L questionnaire for evaluation of perceived health-status; Brunel Mood States (BRUMS) for assessment of changes in mood states and Bender-Gestalt II (BG- II) for evaluation of cognitive competence. After the baseline assessment, they were randomly categorized into 3 groups – control group, and two experimental groups, such as - aerobic exercise training and combined introduction of aerobic and strength-training exercises. Protocol for the exercise interventions was scheduled as 20-50 minutes/day; 3-4 days/ week; for 14 weeks. Thereafter to assess the effectiveness of the intervention programs, post-intervention analyses were carried out after 14 weeks. Finally, incremental cost effectiveness ratio (ICER) was calculated to determine the most cost - effective exercise program for the diabetic population.
Post-intervention analyses revealed significant improvement in the level of HbA1c; mobility and in overall perceived health status. Further to that, participants of the combined intervention Group had significant improvement in cognitive comprehension and working memory levels. Finally, cost effectiveness analysis showed that combined exercise program has been observed to be the most cost-effective program having the lowest ICER among aerobic and no exercise program in Malaysia.

Keywords: *Type 2 Diabetes Mellitus, Exercise regimes, EuroQol 5D-5L, Cognitive competence, Mood States, Cost Effectiveness Analysis*

1.Introduction
In last few decades, the world has seen radical changes in global lifestyles, owing to demographic transition, combined with urbanization and industrialization. Type 2 diabetes mellitus (T2DM) has emerged as major public health problem putting a humongous amount of health and economic burden on people worldwide. In 2013, there were 387 million people with diabetes, and this is projected to increase to 592 million by the end of 2035 (Aguiree et al., 2013). There were 3.3 million cases of diabetes in Malaysia and the prevalence in adults (20-79 years) was 16.6% in 2015 (Cho et al., 2015). Cost per person with diabetes in Malaysia was calculated to USD 565.8 in 2015 (Cho et al., 2015) which does put a lot of pressure on the economy of Malaysia.
Exercise along with diet and medication has been considered as one of the three keystones of

diabetes therapy (Boulé et al., 2001). Since decades, physical activity and exercises have been recommended by the American Diabetes Association (ADA) (Sigal et al., 2004) and American College of Sports Medicine (ACSM) for regulation of blood sugar level in the T2DM individuals (Albright et al., 2000). The low-cost, non-pharmacological nature of exercise further enhances its therapeutic appeal. Numerous studies have demonstrated the positive adaptations of aerobic exercise on glucose control (Vanninen et al., 1992; Walker et al., 1999) in people with T2DM. Various other recommendations from the ADA (Sigal et al., 2004) and the ACSM (Albright et al., 2000) emphasized upon combination of both resistance and aerobic exercise, for a complete rehabilitation program for T2DM individuals. However, the impacts of exercise intervention programs for T2DM individuals may differ based on the components and protocols used for the exercises on different population fragment (Sigal et al., 2007).

Recent enhancement in awareness to maintain cost of healthy living within budgets, has created the perfect climate in the health care sector, for Cost-effectiveness analysis (CEA). CEA is a method for evaluating the costs of health-intervention resources and health outcomes (Husereau et al., 2013). Several researches 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 perceived health status of this disease by the diabetic individuals as well because it implies enormous strains on the overall psyche of an individual. Having said that, there was no research done on the Malaysian population to assess and recommend alternatives to enhance the health status of middle aged T2DM population from self-perceived health status perspective and no CEA was also carried out to determine the cost effectiveness of intervention programs in Malaysia for T2DM individuals. Hence, the present study has been conducted to determine the cost-effective exercise programs and the effects of differential exercise interventions on the socio-psychological aspect of the middle-aged individuals (40-60 years) with T2DM in Kelantan, Malaysia.

2.Methodology

2.1 Participants

For this study, based on the standardised inclusion and exclusion criteria, 75 participants were invited from the Diabetic clinic (outpatient), Hospital Universiti Sains Malaysia (HUSM) and from the community centre of Gunong (Kawasan Rukun Tatangga, Gunong, Bachok, Kelantan). Ethical approval for this study was obtained from the Human Research Ethics Committee of Universiti Sains Malaysia (USM/JEPem/15060229).

After the baseline assessment, participants were randomly categorized (following concealed allocation) into three different groups, namely Group A: Control group (N = 25, received no intervention); Group B: Experimental Group I (N = 25, received aerobic exercise training i.e. walking) and Group C: Experimental Group II (N = 25, received combined exercise, i.e. aerobic exercise training and resistance/strengthening exercise training).

2.2Assessment Protocol

Glycosylated haemoglobin was evaluated by analysis of HbA1c. EQ-5D-5L questionnaire created by the EuroQol (2005) group, was used to assess mobility, anxiety/depression, usual activities, self-care and pain/discomfort. Brunel Mood Scale (BRUMS) (Terry et al., 1999) was used to measure alterations in mood-states followed by physical activity (Lane and Terry, 2000; Terry et al., 1998 and 2003). Bender-Gestalt II test was employed for optimal diagnosis of the cognitive competence, pertaining to comprehension ability, working memory (Cipolotti and Warrington, 1995) of the T2DM participants (Stewart and Liolitsa, 1999; Ott et al., 1999).

2.3 Intervention Technique

In this research two different exercise interventions were introduced following standardised protocol. These two-exercise interventions were:

Aerobic Exercise Training (supervised walking followed by stretching exercises).

Combined Exercise Training (supervised walking and strengthening exercises were incorporated to target strength gain in the major muscle groups).

The intervention sessions were outlined based on the Joint Position Statement prepared by the ACSM and ADA (Colberg et al., 2010). Protocol for the exercise interventions was scheduled as 20-50 minutes/day; 3-4 days/ week for 14 weeks. All the intervention sessions were supervised by qualified exercise trainers, and to prevent methodological bias, the participants, researcher and the trainers for the study were blinded.

2.4 Data Analysis

In this study analyses of mean differences were carried out following Wilcoxon signed-rank test and Two-way repeated measures of ANOVA/ Mixed factorial ANOVA. The significance level for all the analysis was set at $p < .05$. The cost-effective analysis perspective adopted in this research was mainly the provider's perspective which referred to the direct costs of setting up and running a programme. All the costs were expressed in the Malaysian currency (Malaysian Ringgit – MYR). The unit of health was measured based on change in health status resulting from the differential exercise interventions by the direct elicitation method of Visual Analogue Scale (VAS) of EuroQol-5D-5L(EQ-5D-5L). Simple accounting of costs over a short period of time was considered, hence no consideration for asset depreciation was required. Besides, the health outcome (EQ-VAS) was taken from randomized controlled trial, so no synthesis of diverse epidemiologic and clinical studies required to be modelled.

3. Results

Statistical analyses were carried out based on findings from Wilcoxon Matched Pairs Signed Ranks Test (in case of analysis of EuroQoL-5D) and Two - way repeated measure of ANOVA. Participants from Kelantan, Malaysia basically represented the middle-income range with a mean monthly income of MYR 3407.81. Comparative efficacy of the intervention programs is detailed hereafter. Table 1 clarifies significant improvement in HbA1c values in both the aerobic and combined intervention groups, which was evident out of the differences observed between control and combined group (p =.000) and between control and aerobic group (p =.000).

Table 1: Pairwise Comparisons for HbA1c values across different groups based on phases

Phases	Groups	MD (95% CI)	*p*-value
Pre	Control - Aerobic	-.35 (-1.42,.72)	1.00
	Control - Combined	.02 (-1.05,1.08)	1.00
	Aerobic – Combined	.37 (-70,1.43)	1.00
Post	Control - Aerobic	4.26 (3.26, 5.26)	.000**
	Control - Combined	4.86 (3.88,5.87)	.000**
	Aerobic – Combined	0.72 (-1.73, .29)	.258

*p<.05; **p<.001

The following table (Table 2) displays that after 14 weeks of aerobic exercise (supervised walking) intervention, significant improvement in state of mobility (p = .001) and pain or discomfort (p = .011) was observed. In case of the participants of the combined exercise (supervised walking combined with resistance exercises) group, post-intervention improvement in perceived sense of mobility (p = .001) was evident.

Table 2: A comparison of pre-and post-exercise intervention effect on self-reported descriptions of health problems using five dimensional EuroQoL-5D health state scores GroupWise (Wilcoxon Matched Pairs Signed Ranks Test)

EQ-5D Individual Dimensions	Pre-Intervention *N*	Post intervention *n*	*P* value (Pre-Post)
CONTROL GROUP			
Mobility	25	24	.741
Self-care	25	24	.101
Pain/discomfort	25	24	1.00
Activity	25	24	.667
Anxiety/depression	25	24	.301
AEROBIC EXERCISE GROUP			
Mobility	25	22	.001**
Self-care	25	22	.100
Pain/discomfort	25	22	.011**
Activity	25	22	.292
Anxiety/depression	25	22	.101
COMBINED EXERCISE GROUP			
Mobility	25	24	.001**
Self-care	25	24	.100
Pain/discomfort	25	24	1.00
Activity	25	24	.661
Anxiety/depression	25	24	.567

*p<.05; **p<.001

Table 3: Pairwise Comparisons for EQ-VAS Score across different groups based on phases

Phases	Groups	MD (95% CI)	*p*-value
Pre	Control - Aerobic	9.00 (-1.88,19.88)	.138
	Control - Combined	-3.25(-14.13,7.63)	1.000
	Aerobic – Combined	-12.25(-23.13, -1.38)	.062
Post	Control - Aerobic	-1.70(-7.67,4.27)	1.000
	Control - Combined	-10.00 (-15.97, -4.03)	.000**
	Aerobic – Combined	-8.30 (-14.27, -2.33)	.003**

*p<.05; **p<.001

Table 3 depicts significant improvement in the health status revealed through the outcomes of the EQ-VAS Score followed by the combined intervention, which was evident out of the differences observed between control and combined group (p =.000) and between aerobic and combined group (p =.003).

Table 4: *Pairwise Comparisons for Comprehension score and Working Memory score across different groups based on phases*

	Phases	Groups	MD (95% CI)	*p*-value
Comprehension score	Pre	Control – Aerobic	-.50(-1.14,.14)	.182
		Control – Combined	-.55(-1.19,.09)	.119
		Aerobic – Combined	-.05(-.69,.59)	1.00
	Post	Control – Aerobic	1.90(1.20,2.60)	.000**
		Control – Combined	.70(.00,1.40)	.050
		Aerobic – Combined	-1.20(-1.90, -.50)	.000**
Working Memory score	Pre	Control – Aerobic	-.40 (-1.17,.37)	.617
		Control – Combined	-.70(-1.47,.07)	.087
		Aerobic – Combined	-.30(-1.07,.47)	1.00
	Post	Control – Aerobic	-.95 (-1.73, -.18)	.011
		Control – Combined	-1.15 (-1.93, -.38)	.002**
		Aerobic – Combined	-.20 (-.98,.58)	1.00

*p<.05; **p<.001

Table 4 reveals significant improvement in cognitive comprehension amongst participants of combined intervention and control group, which was evident out of the comparative improvements observed in the participants of control group (p =.000), and in the combined group (p =.000). In case of Working Memory however, improvement was only evident followed by the combined intervention (p =.002).

Table 5: *Ranking of Incremental Cost Effectiveness Ratio (ICER) (lowest to highest value)*

Intervention	Net Cost (MYR)	Incremental Cost (∆Cost)	EQ-VAS Score (Health Status –HS)	Incremental EQ-VAS Score (Health status– ∆HS)	ICER (∆Cost /∆HS) (MYR)
1.Control (no exercise) (Group A)	1205.98	n/a	80	n/a	-
2. Combined Exercise program (Group C)	3567.16	75.00	90	8.3	9.04
3. Aerobic Exercise program (Group B)	3492.16	2286.18	81.7	1.7	1344.82

Table 5 shows the ranking of the different exercise intervention programs based on the Incremental Cost Effectiveness Ratio (ICER) values from lowest to highest. The exercise intervention program which incurred lowest ICER value was ranked first in the table and followed accordingly. Here, combined exercise intervention program had the lowest ICER of positive MYR 9.04/Health Status with highest cost and most effective health status. After that the ICER value of aerobic exercise intervention program was MYR 1344.82/Health Status

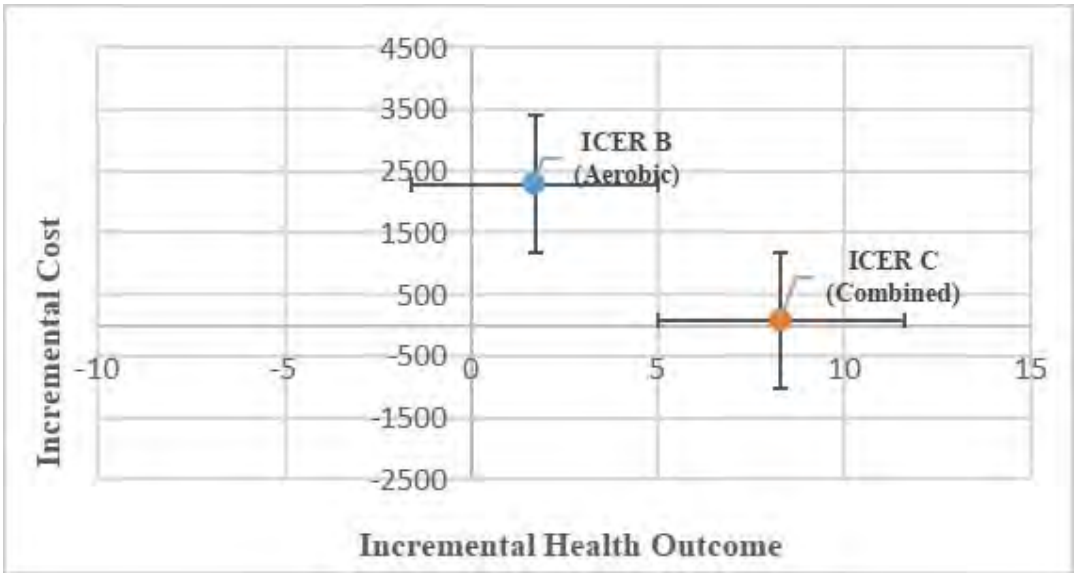
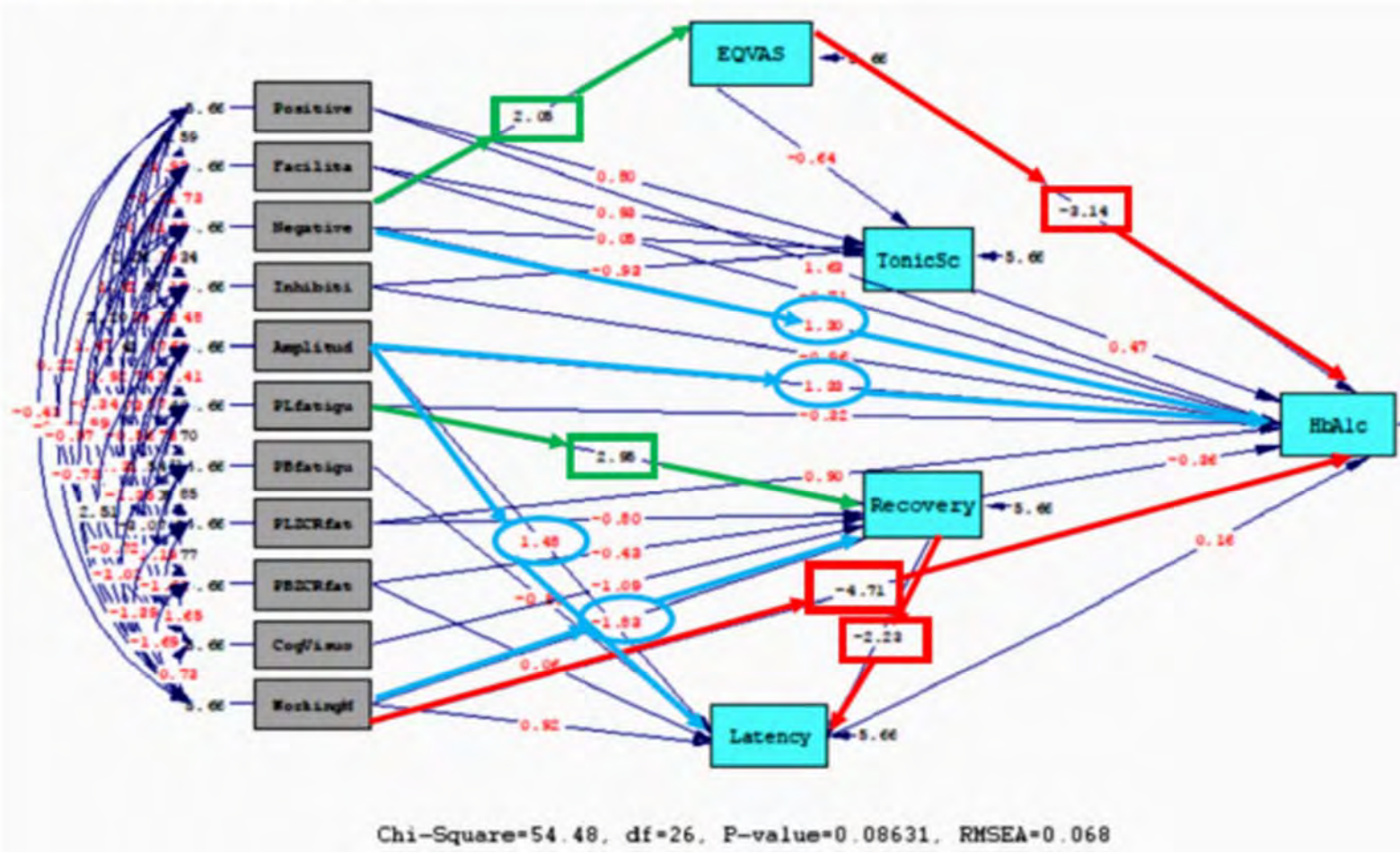


Figure 1: *Cost-Effectiveness Plane (CEP) with mean ICER values for aerobic exercise and combined exercise program in Malaysia*

The above figure demonstrates the mean Incremental Cost Effectiveness Ratio (ICER) values for aerobic exercise intervention program (ICER B) and combined exercise intervention program (ICER C). Mean of ICER B and the mean of ICER C both fell in the north-east quadrant of CE plane stating that both the intervention programs were more effective and costlier compared to no exercise group. In addition, the mean ICER C positioned itself much lower than the mean ICER B in the north-east quadrant of CE plane. Thus, it shows that the combined exercise is more effective and less costly compared to aerobic exercise program.

5.Discussion



Participants in the aerobic and combined exercise groups had improvements in the perceived level of mobility, as majority of the T2DM individuals reported to 'no problem' in mobility. Reason behind the evident perceived improvement in mobility could be attributed to the exercise interventions introduced to them. This evidence of beneficial impacts of exercise have been supported by Aoki and colleagues (1993) who acknowledged, individuals with T2DM may experience limited joint mobility due to glycation of joint structures, and hence flexibility training such as stretching activities are extremely essential for maintenance of full range of motion (ROM) of joints. Apart from that, both the exercise regimes perhaps escalated the range of movement at the joints, and consequently more synovial fluid was released into the joints, which perhaps finally improved the level of mobility of the T2DM individuals (Powers, 2014).

Figure 2: *Structural Model on Diabetes and Life Style Modifications*

Further to that, effectiveness of combined exercise intervention was also supported by Herriott et al., (2004), who emphasized on improvement in the level of flexibility. Apart from the observed improvements in mobility, perceived improvement in the levels of self-care, usual activities, pain in aerobic and combined exercise group were also evident, which were supported by the findings of the study done by Myers et al., in 2013.

Findings of beneficial impact of combined training on cognitive comprehension score revealed higher-order cognitive comprehension, in the form of visual motor integration (Stewart and Liolitsa, 1999 and Ott et al., 1999), and configurational ability (Cipolotti and Warrington, 1995),

which was evident amongst participants in Malaysia. Combined exercise participants were required to engage in both aerobic as well as resistance training, which perhaps improved level of mobility (Alosco et al., 2012) and visual-motor engagement and integration (Cipolotti and Warrington, 1995) in those T2DM individuals. Combined exercise was also evident as effective in improving working memory score of the participants, which Cipolotti and Warrington, (1995) postulated, as improvement in elaborative encoding and probable development in the own encoding strategy of those T2DM individuals, in enhancing their level of working memory (Klein and Waxman, 2003 and Enhamre et al., 2012). The structural model (Figure 2) however clarified the significance of improvement in working memory (denoted by red line) and in perceived health-status (denoted by green line) in reducing level of HbA1c. Apart from those direct influences, mediating contribution of mood changes and autonomic indices of emotionality were also evident, which implied that the T2DM participants who had higher negative mood-states, reported to have better health status, and also higher working memory which finally contributed behind improvement in glycaemic regulation (HbA1c).

Now, the most interesting part in the CEA was the point estimate showed that incremental cost per health status for combined group compared to aerobic exercise group had positioned in a place in the cost effectiveness plane where it clearly indicates that combined exercise program is more effective and less costly than aerobic exercise program. This has happened because the incremental health status score for combined group was higher than aerobic group. As a result, the higher cost of combined exercise program was soaked up by the higher rate of improvement in health status over the time. Hence, in this set up, combined exercise program was the most cost effective compared to other alternative. This outcome was supported by another study done to measure the cost effectiveness of exercise interventions in T2DM population in Canada (Coyle et al., 2012).

6.Conclusions

This research revealed efficacy of both aerobic and combined exercise intervention in improving overall health status of T2DM individuals from a socio-psychological perspective. Combined exercise program was evident as the most cost effective and best effective intervention program.

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