# Motivational Approach to Lifestyle Modification Intervention on Cardiometabolic Risk Profiles among Obese Adults: A Randomized Controlled Trial

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# ABSTRACT

# Introduction

Lifestyle modification intervention (LMI) is effective in promoting cardiometabolic risk (CMR) reduction. However, the current standard LMI for obese adults in Malaysia has only a periodic review. Hence, this study aims to determine the effect of LMI with a motivational approach on CMR profiles among obese adults.

# Methods

This is a randomized controlled trial with two groups; intervention group who received a 6month LMI with a motivational approach, and a control group who received a 6-month standard LMI. The T-test (independent and paired) are used to determine the significant differences in the CMR profile within and between the intervention and control group after six months.

# Results

The findings showed that the obese adults in the intervention group (n=40) had a significant reduction in the body mass index (p=0.002) and a significant rise in high-density lipoprotein level (p=0.021) after six months. Additionally, the intervention group also achieved a reduction in the low-density lipoprotein and high-sensitivity C-reactive protein level after six months. Contrariwise, the control group (n=39) had an unexpected rise in fasting blood glucose level (p=0.012), low-density lipoprotein and the high-sensitivity C-reactive protein after six months. Both the intervention and control group also had a significant reduction in the waist circumference measurement after six months (p<0.05).

# Conclusions

The LMI with the motivational approach is clinically more effective than the standard treatment to improve the CMR profile of obese adults after six months. Consequently, larger

trials with specific sub-groups of obese adults, such as those with pre-diabetes or prehypertension, are warranted.

#### Keywords

Lifestyle Modification Intervention; Cardio Metabolic Risk Profile; Obese

### BACKGROUND

The global prevalence of obesity in adults is alarmingly high[1]. The data from the country profiles compiled by the World Health Organization (WHO) showed that the prevalence of obesity was highest among Americans (26 %), followed by the adult population of the Eastern Mediterranean (24 %) and Europeans (23 %), and the prevalence of obesity was still less than 10% among adults in the Western Pacific region[2]. Even so, it is noticeable that the prevalence of obesity in countries of the Western Pacific region is increasing. In Malaysia, the prevalence of obesity has been rising over the years. The Malaysian National Health and Morbidity Survey (NHMS) report shows that the prevalence of obesity has increased from 27.2 % in 2011 to 30.6 % in 2015[3]. Other than that, the NHMS 2015 also reported that the prevalence of obesity among adults in Malaysia is higher than the global average[3].

Obesity is a public health concern because it increases cardiometabolic risk (CMR). Obesity can lead to insulin resistance[4]. Insulin resistance is a state in which a higher amount of insulin is required for it to perform its normal response, and this disturbs the regulation of blood glucose levels[5]. In particular, the high concentration of adipose tissues in obese adults increases the delivery of free fatty acids from the systemic circulation to the peripheral tissue, which in turn reduces glucose uptake, leading to hyperglycaemia (an increased systemic blood glucose level) and hyperinsulinemia (an increase in insulin secretion to neutralise the blood glucose level)[6]. After a while, the insulin resistance triggers various unfavourable pathways leading to the development of a cluster of risk factors that predispose to T2DM and CVD, which can be referred to as cardiometabolic risk (CMR)[7].

Across the world, lifestyle modification intervention (LMI) is the initial component of treatment for obesity[8] and increased CMR[9]. The objective of LMI is to induce body weight loss by decreasing calorie consumption through an energy- and fat-restricted diet, and increasing energy use through a moderate- to vigorous-intensity physical activity prescription[10]. Nevertheless, the main practical concern with LMI as the standard treatment for obese adults in Malaysia is the periodic review, where the second consultation is only after six months of the first, with no other consultation at all throughout the six-month period[11]. According to Atkinson et al, a long break between interventions or consultations may affect motivation to practise the lifestyle modification, as advised during the first consultation[12]. Motivation is an important aspect of promoting behavioural changes[13]. From a healthcare perspective, personal motivation for behavioural change can be promoted using the motivational interviewing technique[14–16]. In the same way, the motivational interviewing technique has been effective in promoting behavioural changes among obese adults[17]. Therefore, the aim of this study is to evaluate the effect of LMI with a

motivational approach, to increase obese adults' motivation for behavioural change, on the CMR profile of obese adults.

#### **METHODS**

#### Study design

This study was a parallel two-group RCT that compares the effect of two interventions, the standard LMI (control group) and the LMI with the motivational approach (intervention group). Both were initiated at the same time, and all the participants were evaluated after six months of the study intervention period. The blocked randomisation method was applied to randomise the participants into either the control or the intervention group. The inclusion criteria for the obese adult participants were an age between 19 and 60 years old with body mass index (BMI) values between 27.5 kg/m<sup>2</sup> and 39.9 kg/m<sup>2</sup>, the ability to speak and understand Malay or English language and written informed consent. On the other hand, any obese adults with self-reported co-morbidities - such as type 2 diabetes mellitus (T2DM) or thyroid disorders, pregnancy or lactation, or currently active involvement in another clinical trial, diet programme or fitness programme - are excluded from this study.

#### **Outcomes measurements**

The CMR profile involves eight outcome measures including waist circumference (WC), blood pressure (BP), fasting blood glucose (FBG), total cholesterol (TC), low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglyceride (TG), and high-sensitivity Creactive protein (hs-CRP) levels. In particular, the WC was taken on top of the iliac crest in a horizontal line nearest to 0.5 cm using Seca<sup>TM</sup> 201 (a retractable ergonomic circumference measuring tape). The BP was measured using an automatic BP monitor (Omron<sup>TM</sup> HEM-7322-E). During the measurement of the BP, the participant was instructed to sit in an upright position and a cuff of the correct size was applied to the arm, and the measurement was taken after five minutes of resting. For the FBG, TC, LDL, HDL, TG, and hs-CRP levels, a fasting blood specimen was obtained and sent to the pathology laboratory for analysis. Before the blood taking procedure, the participants were assessed for health conditions and in the event that the participants had experienced any inflammation-related conditions such as cuts, infections or allergic reactions in the past forty-eight hours (two days), the blood taking procedure was postponed to after seventy-two hours (three days) so that the test results would be unaffected by any health conditions. On the other hand, if the participants were free from any health conditions, the blood taking procedure proceeded.

#### Procedures

This study started off by screening the prospective participants and obtaining written informed consent. After that, the participants were randomised to either the control group or the intervention group. Upon randomisation, the baseline assessment was conducted and then the implementation process started. The participants in the control group were given the standard LMI which consists of one session of lifestyle advice using printed education materials, targeted at achieving an optimal CMR profile and body weight loss through a decrease in calories consumed and increased energy expended, alongside positive lifestyle behaviour (e.g. goal setting, stimulus control, self-monitoring, and stress management). On the other hand, the participants in the intervention group received the standard LMI with an additional element of the motivational approach. In particular, the motivational approach refers to the individual, monthly motivational interviewing session with the researcher. The activities involved in the monthly sessions include goal setting (short- and long-term), self-monitoring skills for lifestyle changes, stress management skills, identifying cues for behavioural change and tailored lifestyle advice. Accordingly, the data collected were entered into the SPSS for data analysis.

### **Study tools**

The education materials from various publications from the Division of Health Education, Malaysian Ministry of Health (MOH) - mainly on the topics of obesity, CVD and T2DM, recommended healthy dietary intake and the promotion of the physical activity - were used to guide the implementation of the LMI.

### Data analysis

Statistical analysis was done using SPSS Version 21. The descriptive data were presented as means (m) and standard deviation (sd). The statistical differences between the pre- and post-test values within groups were analysed using the paired-samples t-test. Additionally, the statistical significance of the differences between the intervention and control groups on the outcome measures after six months of the LMI was determined using an independent-samples t-test. All statistical tests were two-sided, with a type I error rate of 0.05. A p-value of <0.05 was considered statistically significant.

### RESULTS

A total of 98 participants (49 participants in each group) received the standard LMI (control group) and the standard LMI with a motivational approach (intervention group). Throughout the six months of the intervention delivery period, eight participants from each group were lost to follow-up, resulting in 41 participants in each group for analysis. Upon data analysis, two outliers were found in the control group, and one outlier was found in the intervention group. In the end, the final analysis reported a total of 79 participants, with 39 participants in the control group and 40 participants in the intervention group. The CONSORT participant flowchart is illustrated in Figure I.

**Figure I. The CONSORT Participants Flowchart** 



#### **Demographic characteristics**

The mean age of the participants was 33.2 years old (SD = 9.58). The majority of the participants were women (68%), married (58%), and non-smokers (88%). The educational status of the participants varied, with most of them Malaysian Certificate of Education (Sijil Pelajaran Malaysia - SPM) (20%) and degree holder (36%). In addition, the average income of the participants was Ringgit Malaysia (RM) 1900 per month. The demographic characteristics of the study participants are described in Table I.

Variables	All	Control	Intervention	<i>p</i> -value	
	N=98	<i>n</i> = 49	<i>n</i> = 49		
Age (years $\pm SD$ )	$33.21 \pm 9.58$	$34.76\pm10.39$	$31.67 \pm 8.51$	0.112 <sup>a</sup>	
Gender					
Men	31 (31.6 %)	14 (28.6 %)	17 (34.7 %)	0.515 <sup>b</sup>	
Women	67 (68.4 %)	35 (71.4 %)	32 (65.3 %)	0.313	
Marital status					
Single	37 (37.8 %)	18 (36.7 %)	19 (38.8 %)		
Married	57 (58.2 %)	28 (57.1 %)	29 (59.2 %)	0.593 <sup>b</sup>	
Divorced/Widowed	4 (4.1 %)	3 (6.1 %)	1 (2.0 %)		
Educational status					
Certificates	3 (3.1 %)	3 (6.1 %)	0 (0 %)		
SPM	20 (20.4 %)	12 (24.5 %)	8 (16.3 %)		
Matriculation	17 (17.3 %)	9 (18.4 %)	8 (16.3 %)		
Diploma	12 (12.2 %)	5 (10.2 %)	7 (14.3 %)	0.161 <sup>b</sup>	
Degree	35 (35.7 %)	16 (32.7 %)	19 (38.8 %)		
Master	9 (9.2 %)	2 (4.1 %)	7 (14.3 %)		
Doctor of philosophy	2 (2.0 %)	2 (4.1 %)	0 (0 %)		
Monthly income (RM $\pm$ SD)	$1909.00 \pm 2272.38$	$1840.82 \pm 2088.15$	$1977.18 \pm 2462.74$	0.768 <sup>a</sup>	
Smoking status					
Smoker	5 (5.1 %)	3 (6.1 %)	2 (4.1 %)		
Former smoker	7 (7.1 %)	4 (8.2 %)	3 (6.1 %)	0.823 <sup>b</sup>	
Never smokes	86 (87.8 %)	42 (85.7 %)	44 (89.8 %)		

Table I. Distribution of the study participants by demographic characteristics (n=98)

Note:

SPM Sijil Pelajaran Malaysia, RM Ringgit Malaysia, SD Standard deviation

<sup>a</sup> the *p*-value is determined using an independent sample t-test

<sup>b</sup> the *p*-value is determined using the chi-square test

#### **Cardiometabolic Risk Profile**

The results showed that there is a significant reduction of WC measurements in both the intervention and control groups, with a higher percentage of WC changes in the intervention group (-2.04 %, p=0.001) compared to the control group (-1.57 %, p=0.012) (see Table II). Additionally, the diastolic blood pressure was significantly reduced after six months among the obese adults in the intervention group (-3.20 %, p=0.015), while there were nonsignificant changes among the control group. Pertaining to the changes in the FBG level, the findings reported that there was a significant increase in the FBG level in the control group (4.23 %, p = 0.012) after six months. On the other hand, the FBG levels of the intervention group were stabilized throughout the six months of the study period. With regards to the lipid profile, the participants in the intervention group had reduced TC levels after six months (-0.36 %, p=0.884), while TC levels remained unchanged for the participants in the control group. In addition to that, the pre-post analysis indicates that the intervention group also had a reduced level of LDL after six months (-1.62 %, p=0.590), whereas the control group had a rise in the LDL level after six months (0.62 %, p=0.837). Meanwhile, the participants in the control group showed a significant reduction of TG level after six months (-17.5 %, p = 0.002). More importantly, the findings showed that there was a significant rise in the HDL level in the intervention group after six months (5.51 %, p=0.021). Furthermore, the hs-CRP

level of the participants in the intervention group was reduced after six months (-16.4%, p = 0.205), while it was increased among the participants in the control group (5.21%, p = 0.504).

In summary, the pre-post cardiometabolic risk profile changes reported that the participants in the intervention group had a significant rise in HDL level and greater reduction in the WC measurement, diastolic BP, TC, LDL and hs-CRP levels after six months compared to participants in the control group. In contrast, the participants in the control group had a significant reduction in TG level and a significant rise in FBG level after six months. Nevertheless, in the comparison between the post-intervention values of the CMR profiles between the intervention and the control group, no statistically significant difference was reported.

Groups	Pre-test	Post-test	$m_d \pm SE_d$	% changes <sup>a</sup>	p-value		
Waist circumference							
Control (n=39)	96.03±1.44	94.46±1.44	-1.51±0.58	-1.57	0.012*		
Intervention $(n-40)$	96.06±1.01	94.10±1.03	-1.96±0.56	-2.04	0.001*		
Systalic hold pressure							
Control							
(n=39)	117.54±2.22	116.44±2.28	$-1.10\pm1.30$	-0.94	0.400		
Intervention	110 (2) 1 00	110.05 1.50	0.22 1.47	0.27	0.826		
(n=40)	118.03±1.88	118.95±1.59	0.33±1.47				
Diastolic blood pre	essure						
Control	73 74+1 87	72 54+1 01	1 21+1 44	2 14	0.408		
(n=39)	/5./4_1.0/	72.34±1.91	-1.21±1.44	-2.14	0.408		
Intervention	76 38+1 58	73 78+1 50	-2.60+1.03	-3 20	0.015*		
(n=40)	/0.00_1.00	75.76_1.50	2.00_1.00	5.20	0.012		
Fasting blood gluc	ose						
Control	4.73±0.08	4.93±0.07	0.20±0.08	4.23	0.012*		
(n=39)			0.2020100				
Intervention	4.63±0.08	4.68±0.10	$0.06 \pm 0.08$	1.08	0.460		
(n=40)							
Total cholesterol							
Control	5.20±0.16	5.20±0.16	0.0±0.09	0	0.977		
(n=39)							
(n-40)	5.59±0.13	5.57±0.13	-0.02±0.12	-0.36	0.884		
(II-40)	rotain						
Control	lotein						
(n-39)	3.28±0.15	3.30±0.15	$0.02 \pm 0.09$	0.61	0.827		
(n=37) Intervention							
(n=40)	3.70±0.12	3.64±0.11	$-0.06\pm0.11$	-1.62	0.590		
High-density lipop	rotein						
Control							
(n=39)	$1.38\pm0.04$	$1.43 \pm 0.05$	$0.05 \pm 0.03$	3.62	0.063		
Intervention	1 07 0 04	1 24 0 04	0.00.002	<b>5 5</b> 1	0.0214		
(n=40)	$1.27\pm0.04$	$1.34\pm0.04$	0.08±0.03	5.51	0.021*		
Triglyceride							
Control	1 26 0 10	1.04+0.08	0.22+0.41	17 16	0.007*		
(n=39)	1.20±0.10	1.04±0.08	-0.22±0.41	-17.40	0.002*		
Intervention	1 38+0 13	1 27+0 14	-0 10+0 71	-7 97	0 367		
(n=40)	1.56±0.15	1.27±0.14	-0.10±0.71	-1.91	0.307		
High-sensitivity C-reactive Protein							
Control	5.37+0.93	5.65+0.96	$0.28\pm0.42$	5.21%	0.504		
(n=39)		2.00_0.00					
Intervention	6.94±1.09	$5.80 \pm 0.92$	-1.14±0.88	-16.43%	0.205		
(n=40)							

Table II. The pre- and post-intervention	changes to	cardiometabolic	risk profiles a	among
obese adults (n=79)				

Values are presented in mean  $\pm$  standard error of mean,  $m_d$  mean difference, SE<sub>d</sub> Standard error of difference

<sup>a</sup> % change = [(Post-test – Pre-test)/Pre-test] x 100 %

\* Values are significantly different from the baseline (Pre-test)

#### DISCUSSION

The findings of this study showed that the WC measurements were significantly reduced in both groups after six months when compared to the baseline measurement (p < 0.05). The findings indicate that LMI in either the current approach or the motivational approach is effective in reducing WC measurements among obese adults. The findings of the current study are comparable with two other similar Malaysian-based studies that found a minimum of three months' LMI was sufficient to reduce the WC of obese adults[18,19]. Besides that, this study measures the effect of the intervention on BP level among study participants because it is known that obesity can lead to reduced elasticity and increased arterial stiffness, which leads to elevation of BP. In this study, the intervention had resulted in a significant reduction of diastolic BP after six months. With consideration of the impact of long-term obesity on BP level, the intervention had further potential to maintain the BP level at an optimal level, compared to the standard LMI. According to Labarthe, maintaining a BP at a normal level is essential to ensure sufficient perfusion of the body tissues[20]. On the other hand, an elevated BP level may cause endothelial dysfunction that stimulates inflammation and also stimulates deposition of atherogenic particles in the vessel wall[21]. In a nutshell, obesity is associated with elevated BP level, but the LMI with the motivational approach may be clinically more beneficial to prevent or delay the pathogenesis of hypertension in adults with obesity.

In addition, the findings revealed that the LMI with motivational approach had stabilized the FBG level among the obese adults in the intervention group, while the FBG level was significantly increased among the obese adults in the control group. The findings of the current study are consistent with the findings of Jamal et al., in which the participants in the control group that received the standard LMI had a higher post-intervention FBG level compared to the baseline[19]. The circumstances are mainly because, in general, obesity leads to an increased FBG level through the insulin resistance state. In obese adults, the excessive adipose tissue releases pro-inflammatory cytokines, causing chronic low-grade inflammation, and disturbs the normal insulin signalling pathways, thus leading to the development of insulin resistance[22]. It is somewhat worrying that the findings could be related to the increasing incidence of T2DM in Malaysia[23]. Therefore, based on these results, the LMI with motivational approach was more clinically beneficial in preventing the pathogenesis of insulin resistance in obese adults - and in the long term preventing the incidence of T2DM in Obese adults - and in the long term preventing the incidence of T2DM in Obese adults - than the standard LMI.

Additionally, the changes in the hs-CRP level were not significant after six months between the intervention and control group. Nonetheless, from the pre- and post-intervention values, the findings reported that the intervention had resulted in a reduction of the hs-CRP level, while the control group had an increased level of hs-CRP after six months. The reduction in hs-CRP level among the participants in the intervention group may be attributed to the significant increment of the HDL level after six months. HDL has been known for its cardioprotective effect through its role in reversing the cholesterol transport process that helps to remove excess cholesterol and prevent atherosclerosis[24,25]. In accordance with Ali, Wonnerth, Huber and Wojta, 1 mg/dL increase in the HDL level results in a 2% to 3% reduction in the CVD risk[26]. In relation to this current study, participants in the intervention group achieved an 8% increase in the HDL level after six months, thus implying that the intervention could be more valuable than the standard LMI to promote a reduction in inflammation and subsequently improve the CMR profile.

#### **Study limitations**

The present study had some strengths, one of which was its relatively homogenous group of Malay obese adults living in suburban areas of Malaysia, which reduced the potential for confounding or modifying effects other than the intervention given. Also, the use of an objective measure of the outcomes added to the reliability of this study. The objective outcome measure contributes to the internal validity of comparative observational effectiveness research studies[27]. However, this study also had several limitations. The first limitation is a weak response rate from Chinese and Indian ethnic groups. In the end, only Malays were recruited and as a consequence limited the generalisability of the findings of this study. Another limitation is the time constraint. Initially, the expected total sample size for this study was 123 participants, but due to the time constraints, this study achieved 81.3 % of the anticipated target sample size. The relatively small sample size of this study might influence the non-significant findings of this study, as Friedman et al. mentioned that the sample size played a role in giving the trial power to test the hypothesis[28].

#### CONCLUSIONS

In conclusion, the findings of this study suggest that the LMI with motivational approach resulted in more clinically significant CMR profile improvement when compared to the standard LMI. In addition, the intervention also produced a clinically important impact to stabilise the FBG level, significantly increasing the HDL level while reducing the hs-CRP level among the obese adults after the six month study period. Hence, this study suggests that the addition of the motivational approach to the standard LMI for obese adults may produce better clinical health outcomes in the effort to promote a healthy lifestyle and CMR reduction among obese adults. In future, a more extensive sample size is needed to reduce the variability (spread) of the data and to determine the effect of the intervention among the sub-population of obese adults such as those with pre-diabetes or pre-hypertension state.

#### **Declarations**

#### **Authors' contributions**

All authors contributed equally to this work.

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### Ethics approval and consent to participate

Ethical approval was obtained from the Institutional Review Board (IRB) and all participants provided written informed consent to participate in this study.

## **Consent for publication**

Not applicable.

## Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

### **Competing interests**

The authors declare that they have no competing interests.

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