ORIGINAL ARTICLE

Effectiveness of an integrated-Weight Management Programme (i-WMP) in Reducing Body Weight among Noncommunicable Disease Patients in Malaysian Government Primary Care Clinics: A Randomised Controlled Trial

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ABSTRACT

Introduction: Obesity is a global issue called as "globesity". Overweight and obesity may lead to many noncommunicable diseases (NCDs). Primary care is the first centre to monitor and follow-up the progress of NCD patients. Therefore, the objective of this study was to determine the effectiveness of an integrated-Weight Management Programme (i-WMP) to reduce body weight among NCD patients from two Government primary care clinics from Hulu Langat District. **Methods:** This study was single-blinded randomised controlled trial by design. There were 244 eligible patients were randomised into intervention (n = 122) or wait-list control group (n = 122). The i-WMP was developed based on the behaviour change wheel through the operationalization of behaviour change techniques. The duration of this intervention programme was four weeks. Data collected at week 0, week 4, and week 12. The software IBM SPSS was used to analyse the data. Generalized linear mixed model analysis with intention-to-treat principle was applied. **Results:** The retention rate was 74.2%. Findings showed that the i-WMP was significantly effective in reducing not only body weight as primary outcome but also secondary outcomes such as waist-to-height ratio, waist circumference, body mass index, and total sitting time. It also improved effectively other secondary outcomes such as participants' knowledge, attitude, and practice towards dietary and towards physical activity. However, no significant changes were reported for body fat percentage and total physical activity metabolic equivalent of task-minutes/week. **Conclusion:** Implications surrounding the implementation of i-WMP in the primary care clinics are recommended.
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Keywords: Obesity, Body weight, Randomised controlled trial, Weight management programme, Noncommunicable disease

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INTRODUCTION

BMI of 25 kg/m² and above is categorised as overweight, while BMI of 30 kg/m² and above is categorised as obese. In 2016, there were 1.9 billion (39%) adults worldwide were overweight or obese (1). Based on the National Health and Morbidity Survey 2019, the prevalence of overweight or obese among Malaysian adults (≥ 18 years old) was about 50% (2). Overweight and obesity are reportedly being the main leading causes of noncommunicable diseases (NCDs; e.g., cancer, type II diabetes mellitus, and cardiovascular disease) (1). Primary care was the "first pot of call" to screen and intervene overweight and obese NCD patients (3). According to a systematic review, behavioural intervention was able to reduce and maintain body weight (BW) effectively and safely (4, 5).

Behavioural intervention is defined as "the intervention that designed to affect the actions that individuals take with regards to their health" (6 p. 643). The goal of this type of intervention was to change the patient behaviour towards healthy eating and active living (6). The behaviour change techniques (BCTs) were then introduced into the behavioural intervention (henceforth referred to as behavioural weight management programme (BWMP). BWMP aimed to reduce BW from 0.5 to 1.0 kg per week through diet and physical activity recommendations (7).

In particular, behaviour change wheel (BCW) is a holistic theoretical framework to characterise and develop a behaviour intervention. The central of BCW comprised of a behavioural system that encompasses capability, opportunity, and motivation (COM-B system) detailing intervention functions and policy categories. The former includes restriction, coercion, education, incentivisation, environmental restructuring, modelling, persuasion, enablement, and training, whereas the later includes communication or marketing, legislation, environmental or social planning, guidelines, fiscal, service provision, and regulation (8, 9). COM-B has been applied in an obesity reduction intervention by National Institute for Health and Clinical Excellence (8).

Existing practices or most of the available weight management programmes were focused on knowledge and awareness ("know what" and "know why") related to diet and physical activity. Hence, a scientifically driven programme based on BCT that enhance on skills ("know how") of healthy eating and active living is vital and needed, with additional of self-weighing and self-monitoring (10–12). Based on the finding of a systematic review and meta-analysis, majority of behavioural weight management programme were effective (7). More and more studies were conducted on BCW or/ and BCT especially for intervention development (13–22). Evidence showed that programme with multi-components such as diet, physical activity, and behavioural techniques were more effective in BW reduction (7). Evidence suggests that a BW decrease of 1 kg could reduce 16% of risk in diabetes progression (23). This is important especially for NCD patients.

Based on the rationales explicated as above, the objective of this study was to determine the effectiveness of an integrated-Weight Management Programme (i-WMP) in a sample of NCD patients from two Malaysian primary care clinics from Hulu Langat District. The i-WMP was developed based on BCW through the operationalisation of BCTs. Three key ingredients namely dietary advice, physical activity, and behavioural intervention were integrated into i-WMP.

MATERIALS AND METHODS

Study design
This study is single-blinded randomised controlled trial by design. Participants were randomly allocated into either one of the groups, intervention or wait-list control group.

Ethical consideration
Ethic approval was obtained from Medical Research and Ethics Committee, Ministry of Health Malaysia [(10)KKM/NIHSEC/P17-756] and Ethics Committee for Research Involving Human Subjects Universiti Putra Malaysia [UPM/TNCPI/RMC/1.4.18.2 (MREC-JKEUPM)]. This study was retrospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12621001255875). The consent was obtained from each participant for this study.

Participants
In this study, the probability sampling techniques was used to select the study location. There was a total of 11 clinics in Hulu Langat District during the study period. Therefore, each number of "1" to "11" was written in each small piece of paper, then they were folded and mixed. One paper was randomly picked and opened, it showed "2" that meant for two clinics. Using the similar method by listing down the clinics from "1" to "11", two Malaysian primary care clinics were randomly selected from Hulu Langat District, Selangor, Malaysia.

The study was conducted from January 2018 until December 2018. NCD patients (BMI of 25 kg/m² and above) were referred by health care providers or self-referred for screening to check their eligibility in this study. Posters were put on the entrance and NCD counter in the government primary care clinic. In the waiting room, the patients were screened based on a screening list (with inclusion and exclusion criteria) by research assistants. The patients were given an information sheet and consent form to sign if they fulfilled the selection criteria and agreed to participate in this study. To this end, 861 NCD patients were checked for eligibility, 617 excluded, and 244 remained for randomisation.

Inclusion criteria
NCD patients with asthma, cardiovascular diseases, hypertension, diabetes mellitus, hyperlipidaemia, and/ or cancer, had body mass index (BMI) $\geq$ 25 kg/m², were 18 years old and above, had consented for their participation were included in the research.

Exclusion criteria
Patients who were physically impaired, having difficulty in understanding or speaking Malay, lactating mothers,

pregnant women or planning for pregnancy, attending any weight loss programme during the study recruitment or three months before the data collection, had other special conditions including cardiovascular disease that occurred recently, history of eating disorder, substances abuse, terminally ill, or severe psychiatric illnesses that diagnosed by health care providers were excluded from the research.

Sampling size

The present sample size took two groups comparison into consideration is shown as below (24, 25):

$$n = 2\sigma^2[z_{1-\alpha/2} + z_{1-\beta}]^2/(\mu 1 - \mu 2)^2$$

σ = estimated standard deviation (assumed to be equal for each group), 2; $\mu 1$ = estimated mean (larger); $\mu 2$ = estimated mean (smaller); the mean difference of BW ($\mu 1$ - $\mu 2$) = 1.0 kg; power = 80% (25).

Taking into the account of design effect and attrition rate, the final sample size was 244 (25, 26).

Randomisation and procedures

The sequentially numbered, opaque sealed envelopes were prepared beforehand by the third party for randomisation to preserve concealment. All recruited NCD patients were randomised into intervention or wait-list control groups by using the random permuted block with the block size of four and six. This was to obtain a balance number of participants between intervention and wait-list control groups, thereby minimizing the selection bias.

Participants were blinded to reduce the response bias throughout the study. Different schedules and venues were arranged to avoid contamination. The programme and data collection were collected by stages for them. Some participants would receive the programme earlier than others. The wait-list control group would receive the programme after the data collection. This effort has been done to avoid type II error.

Intervention versus wait-list control group

Both groups received the usual care related to their NCD follow-up, health screening, and dietary advice in the respective clinic. The guidelines of such usual care include clinical practice guidelines on the management of obesity (27), Overweight and Obesity Management Standard Operating Procedures (SOP) 2016 (28), Diet Management Pre-Diabetes and Diabetes Mellitus SOP (2016) (28), Diet Management Prehypertension and Hypertension SOP (2016) (28), Diet Management Hyperlipidaemia SOP (2016) (28).

Participants from the intervention group received i-WMP, whereas participants from the wait-list control group received the same intervention programme after the data collection.
The 4-week i-WMP was developed based on BCW

by researcher (STT) with a group of multi-disciplinary experts including family medicine specialist, public health physician, psychologist, dietician, psychiatrist, nutritionist, physiotherapist, and physician. i-WMP incorporated input from the focus group discussions. The programme has gone through content validity and face validity to enhance and finalize the content of module (29). BCW intervention functions such as education, modelling, persuasion, environmental restructuring, training, and enablement were applied to the programme, along with dietary advice, physical activity, and behavioural intervention (BCTs) (8). BCTs such as provision of information on consequences of behaviour in general, action planning, review of outcome goals, goal setting (behaviour and outcome), self-monitoring of behaviour/behaviour outcome, information about others' approval, barrier identification/problem solving, setting graded tasks, modelling, use of follow-up prompts, environment restructuring, use of prompts/cues, information on where and when to perform the behaviour, and behavioural contract agreement were also applied to i-WMP (25, 30).

In compliance with the Malaysian Dietary Guideline 2010, dietary and physical activity advice was given to participants from the intervention group (31). They were asked to eat healthily based on the Malaysian Healthy Plate (Quarter-Quarter-Half) and be physically active. Participants were encouraged to gradually increase their steps up to 10,000 steps per day, to eventually achieve at least 30 minutes of brisk walk five days a week. Participants also were reminded to weigh themselves on the next day morning (every Saturday for 12 weeks) immediate after woke up before any meal (habit formation). The reminder was sent once on every Friday night through WhatsApp or short message service. On every Saturday morning (from week 0 to week 12), they would reply to the reminder on their self-report BW. Such self-weighing and self-monitoring exercises were based on self-regulation (control theory) (5, 25, 30, 32-33). Besides equipped with the knowledge and skills, the participants also were given behaviour change toolkit (a healthy plate, pedometer, weighing scale, and booklet) to increase their capability, opportunity, and motivation (8).

This was a four-week group-based intervention programme conducted by the researcher (STT). There were three sessions. Both sessions 1 and 2 were conducted during the first visit (week 0), while Session 3 was conducted during the second visit (week 4). Session 1 and 2 lasted about 2.40 hours, whereas Session 3 lasted about 1.25 hours. All of the session was conducted face-to-face by the same researcher (STT) who was assisted by a research assistant. The programme was conducted in a group of six to 10 participants. The same participant would join the same group based on the scheduled appointment. The programme was conducted according to the standardized training module. The contents of

i-WMP are shown in Table I.

Measures
The baseline data such as socio-demographic profile; smoking and vaping; mental health status (depression and anxiety) were collected at week 0 (baseline).

Patient Health Questionnaire-9
The Patient Health Questionnaire-9 (PHQ-9) was used to detect depression for the past two weeks. This 9-item Malay version of PHQ-9 was found to be valid and reliable in a Malaysian government primary care clinic among women. The scores of the PHQ-9 range from 0 to 27, where the cut-off point was ≥ 10 (34). In this study, the Cronbach alpha value for the Malay version of PHQ-9 was 0.76.

The Generalized Anxiety Disorder-7
The Generalised Anxiety Disorder-7 (GAD-7) was used to detect anxiety for the past two weeks. The 7-item GAD-7 for Malay version was found to be reliable and valid in a Malaysian government primary care clinic among women. The scores range from 0 to 21 for GAD-7, where the cut-off point was ≥ 8 (35). In this study, the Cronbach alpha value for Malay version of the GAD-7 was 0.87.

Outcomes
Primary outcome of this study was BW. Meanwhile, the secondary outcomes including body fat percentage (BF%); waist circumference (WC); BMI; waist-to-height ratio (WHtR); knowledge, attitude, and practice (KAP) towards dietary and towards physical activity; total sitting time; total physical activity metabolic equivalent of task (MET)-minutes/week. These outcomes were taken at week 0, week 4, and week 12.

Anthropometric measurements
As per the International Standards for Anthropometric Assessment, anthropometric measurements that taken twice by the research assistant including height, BW, BF%, and WC. Such measurements were taken with minimal clothing, without accessories, shoes, socks, and empty pockets (36).

BW was measured to the nearest 0.1 kg by Omron KaradaScan Body Composition Monitor HBF-375 (Omron Healthcare Co., Ltd, Kyoto, Japan). Height was measured to the nearest 0.1 cm by using Seca 213 portable stadiometer (seca gmbh & co. kg, Hamburg, Germany). It only took once at baseline. Participants' WC was measured by Seca 201 ergonomic circumference measuring tape, nearest to 0.1 cm. Height was taken to calculate the BMI and WHtR. The Omron KaradaScan Body Composition Monitor HBF-375 was used to measure the BF%, nearest to 0.1%.

Knowledge, attitude, and practice questionnaire
The Malay version of KAP towards dietary and towards physical activity questionnaires were adapted from a previous study (37). With respect to dietary (30 items), Cronbach alpha coefficient values were 0.70 for K (10 items), 0.55 for A (10 items), and 0.85 for P (10 items) (37). In the case of physical activity (30 items), Cronbach alpha coefficient values were 0.68 for K (10 items), 0.86 for A (10 items), and 0.74 for P (10 items) (37). In this study, the Cronbach alpha coefficient value for KAP towards dietary and towards physical activity were ranging from 0.6 to 0.8. The scores range from 0 to 10 for K, 10 to 50 for A, and 10 to 40 for P.

International Physical Activity Questionnaire Short Form
The 7-item International Physical Activity Questionnaire Short Form (IPAQ-SF) was used to assess physical activity. Both the English and Malay versions of IPAQ-SF were found to demonstrate good concurrent validity (ρ = 0.995) (38). In particular, the IPAQ-SF assessed participants' several intensities of activities for the past seven days. The average MET scores were 8.0 METs for vigorous-intensity activities, 4.0 METs for moderate-intensity activities, and 3.3 METs for walking. A total physical activity MET-minutes/week could be calculated. Participants' total sitting time in one of the working days (in minutes) was measured by the last IPAQ-SF item (39).

The validated and pretested questionnaires were used in data collection. The permission was obtained from the respective authors for their questionnaires to be used in this study.

Data analyses
Data were analysed using IBM SPSS. First, descriptive statistics such as median (interquartile range) or mean (standard deviation) were used to present study outcomes. Second, inferential statistics such as chi square/fisher's exact test and independent samples t-test/Mann-Whitney U test were used to make statistical comparisons. For generalised linear mixed model (GLMM) analyses, the cluster effect and covariates were adjusted. In particular, to examine the effectiveness of i-WMP on study outcomes, respective baseline outcomes, gender, age, ethnicity, and total monthly household income were controlled as covariates in the GLMM model. All randomly allocated participants that received intended treatment were included in statistical analyses. The confidence interval (CI) was set at 95% and a level of significance of 0.05.

RESULTS

In this study, 244 NCD patients were randomly allocated to either intervention or wait-list control group. The Consolidated Standards of Reporting Trials (CONSORT) flow diagram of this study is shown in Figure 1(40). The retention rate was 74.2% in this study.

Based on the Table II, the mean age of participants from

Table I: Contents of integrated-Weight Management Programme

Topics (duration)	Intervention functions in BCW	Behaviour change technique in CALO-RE	Content
Session 1 (Week 0)			
Unit 1: **What is overweight and obesity?** (20 min) • The definition of overweight and obesity. • The risk factors of overweight and obesity, with the benefits of risk factors reduction. • The epidemiology and consequences of overweight and obesity, with the benefits of body weight reduction.	Education Persuasion	BCT1: Provide information on consequences of behaviour in general BCT3: Provide information about others' approval	Participants are given an introduction on overweight and obesity; the risk factors of overweight and obesity (energy balance), with the benefits of risk factors reduction (BCT1); the epidemiology and consequences of overweight and obesity, with the benefits of body weight reduction (BCT1 and BCT3). **Activity:** Participants are asked to write down their "WHY" (motivation) to lose weight (BCT1). **Study outcomes:** Anthropometric measurements and KAP
Unit 2: **How light am I today?** (10 min) • The self-weighing with its benefits.	Education Persuasion Training Environmental restructuring Modelling	BCT1: Provide information on consequences of behaviour in general BCT11: Prompt review of outcome goals BCT17: Prompt self-monitoring of behaviour outcome BCT20: Provide information on where and when to perform the behaviour BCT22: Model/ Demonstrate the behaviour BCT24: Environment restructuring BCT27: Use of follow-up prompts	Participant are introduced and taught on the benefit of self-weighing (BCT1). They are asked to weigh themselves by weekly for the same timing (BCT20). **Activity:** Each participant is given a weighing scale to place at the flat and stable location where they could remember to weigh themselves (BCT24). They are taught on how to weigh themselves on every Saturday morning before their first meal (BCT22). They are reminded to weigh themselves and record in a given booklet on the next morning (BCT17) by sending them a text message through WhatsApp or short message service (BCT27). Participants are taught to review their weight loss progress, which is advisable to reduce 0.5 kg of their weight per week (BCT11). **Study outcomes:** Anthropometric measurements and KAP
Unit 3: **What is my goal?** (10 min) • The goal setting and commitment.	Training	BCT6: Goal setting (outcome) BCT25: Agree behavioural contract	Participants are guided to set their goal, advisable to reduce 0.5 kg of their weight per week (BCT6). **Activity:** Participants are asked to sign on their own pledge and witnessed by another participant (BCT25). **Study outcomes:** Anthropometric measurements
Unit 4: **How to eat and drink healthily?** (30 min) • Quarter-Quarter-Half (Malaysian Healthy Plate) with its benefits. • Healthy food choices, food preparation, cooking choices, and eating out, with their benefits. • Limit in fat, oil, sugar, and salt intake, with their benefits. • The water intake with its benefits.	Education Persuasion Training Environmental restructuring Modelling	BCT1: Provide information on consequences of behaviour in general BCT16: Prompt self-monitoring of behaviour BCT20: Provide information on where and when to perform the behaviour BCT22: Model/ Demonstrate the behaviour BCT23: Teach to use prompts/ cues BCT24: Environment restructuring	Participants are taught on the concept of Quarter-Quarter-Half in the Malaysian Healthy Plate. It is beneficial in controlling their food portion and calories intake. This is also to promote the benefit of using healthy plate for three main meals in terms of variety (carbohydrate, protein, vegetables, and fruits), balance, and moderation of food intake (BCT1). Participants are taught on the healthy food choices, food preparation, cooking choices (steam, grill, bake, and boil), and eating out, with their benefits (BCT1). They are taught to limit fat, oil, sugar, and salt intake, with their benefits (BCT1). Participants are taught on the water intake and its benefits in reducing body weight (BCT1). **Activity:** Each of the participants is given a healthy plate to guide them on where, when, and how to apply Quarter-Quarter-Half in their daily meal (BCT20, BCT22, and BCT24). They are guided when to drink water and how much to drink per day by marking (quantity and time) on an empty mineral water (BCT23). Participants are asked to record their compliance on the Quarter-Quarter-Half concept and water intake in daily in a given booklet (BCT16). **Study outcomes:** Anthropometric measurements and KAP
Unit 5: **Walking and brisk walking!** (30 min) • The physical activity with its benefits. • The 10,000 steps per day with its benefits. • The brisk walk with its benefits. • Warm up and cold down.	Education Persuasion Training Environmental restructuring Modelling	BCT1: Provide information on consequences of behaviour in general BCT5: Goal setting (behaviour) BCT9: Set graded tasks BCT16: Prompt self-monitoring of behaviour BCT20: Provide information on where and when to perform the behaviour BCT22: Model/ Demonstrate the behaviour BCT24: Environment restructuring	Participants are taught on the various types of physical activity, especially 10,000 steps per day with its benefits (BCT1), including using staircase, walk to colleague's seat instead of inter-com for discussion to increase walking step (BCT20). They are taught on the benefits of moderate-intensity physical activity: brisk walk (BCT1). Participants are taught to warm up and cool down before exercise. **Activity:** They are taught on how to walk and brisk walk with the right technique (BCT22). Each of the participant is given a pedometer to count their daily steps (BCT24). They are encouraged to gradually increase their walking steps to 10,000 steps per day, ultimate goal is to perform brisk walk for 30 minutes per day, five days a week (BCT5 and BCT9). Participants are asked to record their walking step and physical activity in a given booklet (BCT16). **Study outcomes:** Anthropometric measurements, KAP, and IPAQ-SF
Unit 6: **Healthy eating and active moving daily plan!** (10 min) • The daily action plan.	Training	BCT7: Action planning	Participants are encouraged to follow a healthy eating and active moving plan for their daily routine (BCT7). **Study outcomes:** Anthropometric measurements, KAP, and IPAQ-SF

Table I: Contents of integrated-Weight Management Programme (CONT.)

Topics (duration)	Intervention functions in BCW	Behaviour change technique in CALO-RE	Content
Session 3 (Week 4)			
Unit 7: Did I achieve my goal? (10 min) • Goal review.	Training	BCT11: Prompt review of outcome goals	Participants are informed on their current weight to review if they have achieved their goals that set previously (BCT11). **Study outcomes:** Anthropometric measurements
Unit 8: Healthy snaking: fibre! (15 min) • The fibre intake with its benefits.	Education Persuasion Training Environmental restructuring Modelling	BCT1: Provide information on consequences of behaviour in general BCT20: Provide information on where and when to perform the behaviour BCT22: Model/ Demonstrate the behaviour BCT24: Environment restructuring	Participants are taught on the type and source of fibre with its benefits (BCT1). **Activity:** Participants were given tips on when and where to take healthy snacks, and what are the choices of healthy snacks (BCT20 and BCT22). They are advised to throw away or lock up their high calorie snacks, but replace with legume, whole grains (biscuit, bread), nuts, vegetable, and fruits to increase their fibre intake (BCT24). **Study outcomes:** Anthropometric measurements and KAP
Unit 9: 0 Challenge! (25 min) • The challenges and solutions.	Enablement	BCT8: Barrier identification/ problem solving	**Activity:** Participants are asked to list down their barriers and solutions to overcome the barriers. Participants are provided a list of challenges and solutions to overcome them (BCT8). The list was prepared beforehand based on the FGDs. **Study outcomes:** Anthropometric measurements, KAP, and IPAQ-SF
Unit 10: Healthy eating and active moving daily plan! (10 min) • The daily action plan.	Training	BCT7: Action planning	Participants are encouraged to follow a healthy eating and active moving plan for their daily routine (BCT7). **Study outcomes:** Anthropometric measurements, KAP, and IPAQ-SF

Note: BCW: behaviour change wheel; BCT: behaviour change technique; CALO-RE: 'Coventry, Aberdeen & London – Refined'; KAP: knowledge, attitude, and practice; IPAQ-SF: International Physical Activity Questionnaire short form; min: minutes
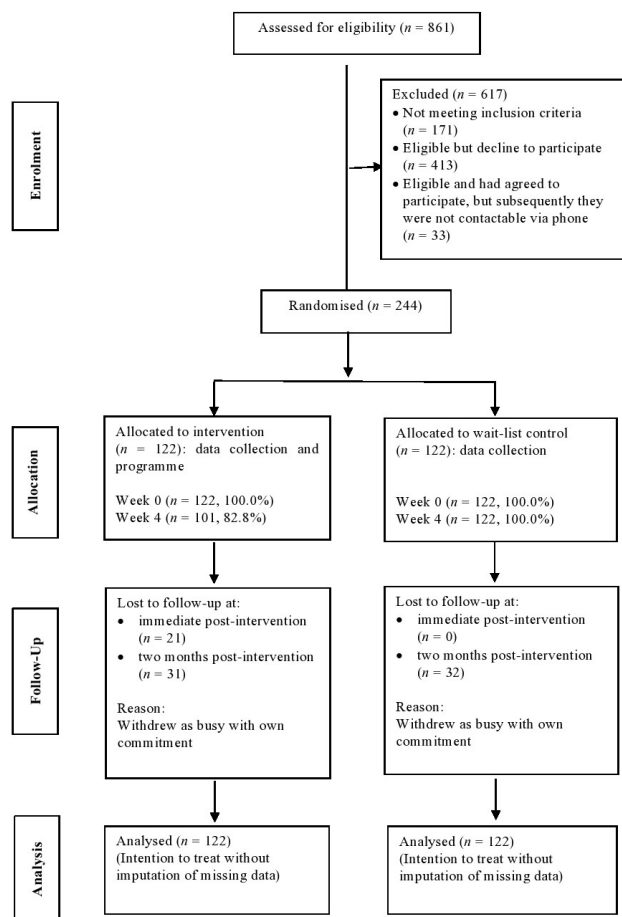

Figure 1: CONSORT flow diagram of this study. The Consolidated Standards of Reporting Trials (CONSORT) flow diagram shows the number of patients that have been screened, recruited, randomized, and analysed.

intervention group and wait-list control group were 51 and 49 years old, respectively. Most of the participants from both groups were predominantly women (58.2% - 59.0%); Malay (82.0% - 86.1%); Muslim (82.8% - 86.9%); married (78.7% - 84.4%); attended college or university (35.2% - 42.6%); no smoking and/or vaping (87.7% - 89.3%). The mean scores of depression and anxiety for participants in the intervention group were 4.43 and 2.40, respectively. Whilst, the mean scores of depression and anxiety for participants in the wait-list control group were 5.08 and 2.69, respectively. No statistical differences in terms of baseline data were found between intervention group and wait-list control groups.

Table III presents the GLMM findings concerning the effectiveness of i-WMP on study outcomes. i-WMP was found to be significantly effective in reducing BW, $F_{(2, 499)} = 16.020$, $p < 0.001$; BMI, $F_{(2, 499)} = 16.711$, $p < 0.001$; WC ($F_{(2, 499)} = 16.767$, $p < 0.001$; WHtR, $F_{(2, 499)} = 16.918$, $p < 0.001$; and total sitting time, $F_{(2, 499)} = 3.774$, $p = 0.024$. It also was effective in improving diet knowledge, $F_{(2, 499)} = 6.134$, $p = 0.002$; diet attitude, $F_{(2, 499)} = 10.201$, $p < 0.001$; diet practice, $F_{(2, 499)} = 43.080$, $p < 0.001$; physical activity knowledge, $F_{(2, 499)} = 34.527$, $p < 0.001$; physical activity attitude, $F_{(2, 499)} = 19.252$, $p < 0.001$; and physical activity practice $F_{(2, 499)} = 12.455$, $p < 0.001$. However, changes in BF% and total physical activity MET-minutes/week were not statistically significant.

DISCUSSION

The research objective of present research was to

Table II: Descriptive and inferential analyses of socio-demographic profile, smoking and/or vaping, and mental health status between intervention and wait-list control groups (N = 244)

Variables	Frequency (n) and percentage (%)		Test statistics	p-value
	Intervention (n = 122)	Wait-list control (n = 122)		
Age (years)				
Mean (SD)	50.50 (9.91)	49.45 (10.70)	t = 0.795	0.428
Gender				
Men	50 (41.0)	51 (41.8)	χ^2 = 0.017	0.897
Women	72 (59.0)	71 (58.2)		
Ethnicity				
Malay	105 (86.1)	100 (82.0)	2.108†	0.570†
Chinese	5 (4.1)	8 (6.6)		
Indian	11 (9.0)	14 (11.5)		
Others	1 (0.8)	0 (0.0)		
Religion				
Muslim	106 (86.9)	101 (82.8)	2.386†	0.507†
Buddhist	3 (2.5)	6 (4.9)		
Hindu	8 (6.6)	12 (9.8)		
Christian	5 (4.1)	3 (2.5)		
Marital status				
Single	7 (5.7)	16 (13.1)	7.602†	0.080†
Married	103 (84.4)	96 (78.7)		
Widowed	6 (4.9)	9 (7.4)		
Divorced	4 (3.3)	1 (0.8)		
Separated	2 (1.6)	0 (0.0)		
Formal education level				
Primary	4 (3.3)	8 (6.6)	2.700†	0.621†
Lower secondary	24 (19.7)	29 (23.8)		
Upper secondary	39 (32.0)	39 (32.0)		
Pre-university	3 (2.5)	3 (2.5)		
College or university	52 (42.6)	43 (35.2)		
Working status				
Government or semi government	20 (16.4)	24 (19.7)	χ^2 = 2.586	0.629
Private	32 (26.2)	26 (21.3)		
Self-employed	26 (21.3)	26 (21.3)		
Unemployed	22 (18.0)	29 (23.8)		
Retired	22 (18.0)	17 (13.9)		
Total monthly household income (RM)				
Median (IQR)	4,000.00 (3,000.00)	4,000.00 (4,537.50)	4,018.000^	0.104^
Smoking and/or vaping				
Yes	15 (12.3)	13 (10.7)	χ^2 = 0.161	0.688
No	107 (87.7)	109 (89.3)		
Depression				
Mean (SD)	4.43 (3.52)	5.08 (4.28)	t = -1.291	0.198
Anxiety				
Mean (SD)	2.40 (3.10)	2.69 (3.56)	t = -0.672	0.502

Note: For total monthly household income, the number of participants for intervention and wait-list control groups were 101 and 92, respectively.
*$p < 0.05$ significant   **$p < 0.001$ significant   †Fisher's exact test
^Mann-Whitney U test   SD: standard deviation   IQR: interquartile range

determine the effectiveness of i-WMP among participants from intervention and wait-list control groups over three-time points (week 0, week 4, and week 12) in terms of mean change in outcomes.

In the present study, social demographic profiles (age, gender, and ethnicity) were compatible with those who attended Malaysian government primary care clinics

Table III: Effectiveness of integrated-Weight Management Programme on study outcomes

Variables	F	df1	df2	p-value
Body weight (kg)				
Time	4.636	2	499	0.010*
Group	61.088	1	499	<0.001**
Time x Group	16.020	2	499	<0.001**
Body mass index (kg/m²)				
Time	4.872	2	499	0.008*
Group	65.764	1	499	<0.001**
Time x Group	16.711	2	499	<0.001**
Waist circumference (cm)				
Time	3.640	2	499	0.027*
Group	73.504	1	499	<0.001**
Time x Group	16.767	2	499	<0.001**
Waist-to-height ratio				
Time	3.647	2	499	0.027*
Group	75.164	1	499	<0.001**
Time x Group	16.918	2	499	<0.001**
Body fat percentage (%)				
Time	0.730	2	499	0.482
Group	1.039	1	499	0.309
Time x Group	0.344	2	499	0.709
Diet knowledge				
Time	34.328	2	499	<0.001**
Group	23.031	1	499	<0.001**
Time x Group	6.134	2	499	0.002*
Diet attitude				
Time	8.070	2	499	<0.001**
Group	32.601	1	499	<0.001**
Time x Group	10.201	2	499	<0.001**
Diet practice				
Time	91.527	2	499	<0.001**
Group	116.225	1	499	<0.001**
Time x Group	43.080	2	499	<0.001**
Physical activity knowledge				
Time	60.746	2	499	<0.001**
Group	131.039	1	499	<0.001**
Time x Group	34.527	2	499	<0.001**
Physical activity attitude				
Time	11.572	2	499	<0.001**
Group	59.284	1	499	<0.001**
Time x Group	19.252	2	499	<0.001**
Physical activity practice				
Time	33.324	2	499	<0.001**
Group	38.397	1	499	<0.001**
Time x Group	12.455	2	499	<0.001**
Total physical activity MET-minutes/week				
Time	10.300	2	499	<0.001**
Group	0.227	1	499	0.634
Time x Group	0.477	2	499	0.621
Total sitting time (minutes)				
Time	2.112	2	499	0.122
Group	1.606	1	499	0.206
Time x Group	3.774	2	499	0.024*

Note: Controlling covariates for baseline of respective outcome variable, gender, age, ethnicity, and total monthly household income
*$p < 0.05$ significant
**$p < 0.001$ significant

(41). Baseline data between two groups had been balanced up through the process of randomisation.

After participating i-WMP, participants' knowledge towards dietary and towards physical activity (capability) increased significantly (p < 0.05) as compared to the wait-list control group. By knowing the importance and benefits of healthy eating and active living, their attitude towards dietary and towards physical activity improved significantly (ps < 0.001). Similarly, a cluster RCT successfully increase Vietnamese Americans' knowledge on the recommendation of fruits and vegetables intake and physical activity (ps < 0.001) (42).

It appears that higher nutrition knowledge was positively associated with increased fruits and vegetables intake (43). This finding helps explain why participants' practice towards dietary and towards physical activity increased significantly (ps < 0.001) among the intervention group as compared to the wait-list control group. The total sitting time also reduced statistically significant in the intervention group as compared to the wait-list control groups (p = 0.024). These behavioural practices were translated to decreases in BW, BMI, WC, and WHtR (ps < 0.001). What is worth mentioning is that in the present study there was a BW decrease of 1.48 kg (1.71%) among participants in intervention group (results were not presented here). Consistent with existing self-weighing-based intervention trial, participants from intervention group (self-weighing) significantly lost more weight than participants from control group did. This habit-formation theory-based intervention conducted in England primary care practices found that treatment group reduce more weight than usual care group (mean difference: -0.87 kg, 95% CI: -1.47 to -0.27, p = 0.004) (3).

An 8 weeks self-regulation weight loss trial recruited 100 adult patients (≥ 18 years old; BMI ≥ 30 kg/m^2) from four Oxfordshire primary care practices. The results from this RCT revealed that participants in intervention group lose more weight than control group, with adjusted mean difference of -3.20 kg (95% CI: -4.49 to -1.92). This is a guided self-regulation trial that significantly reduce BW as compared to unguided one (44). Self-monitoring could facilitate self-analysis (32). Isolated intervention (self-weighing) could have significant effect if the participants know how to practice healthy lifestyle (25).

However, the BF% reduction did not reach statistical significance. This finding did not lend support to a non-randomised interventional pilot study where a significant BF% reduction was observed (p = 0.010). It was a 6-month obesity health intervention programme with two weekly physical activity sessions (unsupervised) and a monthly health education session (45). This could be due to the intensity of exercises and the duration of intervention programme. Body fat reduction would require more intensive exercises and longer programme duration (45). Hence, i-WMP was found to reduce participants' total

sitting time (p = 0.024) but not total physical activity MET-minutes/week (p = 0.621). This could be due to time limitation, lacking of self-motivation, and no partner to exercise together (46).

The present study was RCT by design that serves as a gold standard for programme evaluation. Based on the previous reviews, not many RCTs concerning weight management programme were conducted in Malaysia (47, 48). i-WMP is BCW theoretical framework driven and encompasses three key ingredients: dietary advice, physical activity, and behavioural intervention (BCTs). The development of i-WMP involved experts from multi-disciplines to ensure good content validity. Moreover, feedback from focus group discussions involving overweight or obese NCD patients and health care providers were incorporated into the programme. Besides that, i-WMP was evaluated by using a robust analysis named GLMM. i-WMP represents a promising weight management programme that could be launched in local primary care clinics in an attempt to promote healthy lifestyle.

A few study limitations of the present study should be noted. First, no data on dietary record and biochemical indicators were obtained in order to reduce the patients' burden. Second, data were collected using self-administered questionnaires, raising the issue of measurement bias. Third, only NCD patients were recruited. Moreover, they were either referred by health care providers or self-referred. Hence, the generalisability of the present findings is limited.

Even though habit formation took averagely 66 days to achieve asymptote of automaticity (49), the duration of i-WMP was proposed to extend to six-month, 12-month, and 24-month. The longer duration of study may improve the BF% and total physical activity MET-minutes/week significantly.

This intervention could be practical to launch in the primary care clinics since the nutritionist or dietician is promoting healthy lifestyle there. The additional behaviour components could enhance the weight management programme in this setting (50). With the assistance of nurses, the nutritionist or dietician could be the most suitable personnel to conduct this i-WMP in the Malaysian government primary care clinics.

CONCLUSION

i-WMP was effective not only in reducing BW, BMI, WC, WHtR, and total sitting time, but also in improving KAP towards dietary and towards physical activity. These significant changes could be due to the use of BCTs such as action planning and self-monitoring behaviour. As i-WMP was driven by COM-B, it could elicit participants' motivation, capability, and opportunity to pursue a behavioural change towards a healthy

and active lifestyle. Based on the present findings, i-WMP could be recommended for implementation in Malaysian government primary care clinics by the health care providers.

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