

Development and Validation of a Web-based Intervention to Act for Weight Loss for Adults with Type 2 Diabetes and Obesity (Chance2Act): an Intervention Mapping Approach

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Abstract

Background: Weight loss can improve metabolic parameters and potentially lead to remission in adults with type 2 diabetes (T2D). However, a large proportion of T2D patients are overweight or obese, with 59% to 79% unready for weight loss. There is a scarcity of stage-matched approaches for this population.

Objective: This study aimed to develop and validate a behavioural intervention module targeting T2D adults with obesity who are unready-to-act for weight loss, following the Intervention Mapping (IM) framework.

Methods: The intervention development was guided by the Intervention Mapping (IM) framework. Step 1 involved the creation of a Logic Model of the Problem to summarize the findings from the needs assessment. Step 2 focused on developing Matrices of Change Objectives, which outlined the preliminary content for the intervention. This content was refined in Step 3, into the final themes, scopes, and activities of the intervention. In Step 4, the content was validated using both Content Validity Index and Face Validity Index to determine the content's relevance clarity, simplicity and unambiguity of the intervention. Finally, the usability testing of the intervention website was done to ensure it met the recommended standards of website usability.

Results: In Step 1, the Logic Model identified barriers such as poor knowledge, low self-efficacy, and lack of social support. Twenty change objectives were formulated as the preliminary content during Step 2. These content was finalised into four modules with twenty activities in Step 3. In Step 4, the content was produced as the Chance2Act Intervention Manual, with I-CVI, S-CVI/Average, I-FVI, and S-FVI/Average all exceeding 0.9, indicating excellent validity. Usability testing yielded a system usability score of 69.5, surpassing the recommended threshold for website usability.

Conclusions: The Chance2Act Intervention was developed and validated, providing a tailored approach for behaviour change in T2D adults who are unready-to-act for weight loss. Future research is needed to evaluate its effectiveness and explore its integration into primary care to enhance weight management strategies for this high-risk group. Clinical Trial: U.S. Clinical Trial Register NCT05736536; <https://beta.clinicaltrials.gov/study/NCT05736536>

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Original Manuscript

Original Paper

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Conclusions: The Chance2Act Intervention was developed and validated, providing a tailored approach for behaviour change in T2D adults who are unready-to-act for weight loss. Future research is needed to evaluate its effectiveness and explore its integration into primary care to enhance weight management strategies for this high-risk group.

Trial Registration: U.S. Clinical Trial Register NCT05736536; <https://beta.clinicaltrials.gov/study/NCT05736536>

Keywords: Stages of change, weight loss, Transtheoretical model, diabetes, obesity managements, e-Health; overweight

Introduction

Background

Type 2 diabetes (T2D) is a chronic metabolic disorder characterized by persistent high blood glucose levels due to insufficient insulin production or insulin resistance [1]. Globally, 10.5% of the population had diabetes in 2021 [2], while in Malaysia, 15.6% of adults were diagnosed with diabetes in 2023 [3]. Obesity and T2D are closely linked public health issues in Malaysia, where 80 to 90% of T2D patients are overweight or obese [4]. Obesity contributes to T2D and can worsen the condition [5,6]. Weight loss can improve various health outcomes for individuals with T2D, including better glycaemic control, reduced risk of complications, and potential diabetes remission [7,8]. However, many individuals with T2D (59% to 79%) are not ready to engage in weight loss efforts [9,10].

Effective obesity management requires not only the recognition of the importance of behaviour change strategies [11,12], but also the development of detailed implementation plans, which are currently insufficient in existing guidelines. One promising approach is the implementation of stage-matched interventions, which have shown success in previous studies by aligning strategies with the individuals' stage of behaviour change [13,14]. This approach is explained by the Transtheoretical Model (TTM), which highlights that behaviour change is a dynamic process, progressing through five sequential stages, each requiring tailored interventions to facilitate transitions [15].

The TTM categorizes individuals into the stages of pre-contemplation, contemplation, preparation, action, and maintenance, each representing a specific point in the process of adopting healthier behaviours. Individuals in the pre-contemplation stage may not even be aware of the need for change, while those in contemplation are considering it but may remain hesitant. Those in the preparation stage are planning for change but are yet to be fully committed [15]. Lacking the drive for behavioural change, these individuals who are in the unready-to-act stage may not be interested in adopting traditional action-oriented weight loss interventions. To overcome this problem, an intervention targeting these patients needs to be rigorously developed and validated.

However, to date, the current approaches offered by the Ministry of Health (MOH) Malaysia often focus on obese individuals without other comorbidities, thereby overlooking the T2D patients who frequently visit the MOH facilities [16–18]. Additionally, the evidence on health interventions that focus on T2D patients with obesity who are in the stage of unready-to-act for weight loss was also observed to be scarce.

Study Objectives

This study aimed to develop and validate a behavioural intervention for adults with T2D with obesity who are unready-to-act for weight loss.

Methods

Study design

This study employed the Intervention Mapping (IM) framework, a systematic, theory-based approach, to develop an intervention tailored to individuals at the unready-to-act stages of behaviour change. This stepwise framework consisted of six steps [19]:

- i. Logic Model of the Problem
- ii. Matrices of Change Objectives
- iii. Intervention Design
- iv. Intervention Production
- v. Intervention Implementation Plan

vi. Evaluation Plan

The initial four steps of the framework formed the development and validation of the intervention. The IM framework advocates for the integration of behavioural theory in intervention development to specify potential behavioural outcomes [19]. In this study, the TTM was selected as the overarching theoretical model, with all four core constructs; Stages of Change, Self-Efficacy, Decisional Balance, and Processes of Change used to guide the intervention development [15]. The Stages of Change construct was employed to tailor the content of the intervention according to participants' readiness to change, while the Processes of Change construct served as the foundation for sequencing the intervention components. Additionally, Self-Efficacy and Decisional Balance were used to inform the content development.

The remaining two steps of the IM framework which involve the intervention's implementation plan and evaluation were not discussed in the current manuscript. The methodological steps which guided this study are illustrated in the schematic diagram presented in Figure 1.

Step 1: Construction of the Logic Model of the Problem

In Step 1, an Intervention Development Committee (IDC) was established prior to conducting the needs assessment. The IDC serves as the steering committee in ensuring the relevance and validity of the intervention. The committee members consisted of five professionals, including:

- i. The principal investigator
- ii. An associate professor and public health physician in epidemiology
- iii. A lecturer in social behaviour and health promotion
- iv. A family medicine consultant
- v. A dietician in primary care.

The members of the IDC were selected for their expertise relevant to the study's focus and its primary care setting, where most T2D patients seek care. The principal investigator was a public health doctorate candidate with years of experience in coordinating the non-communicable disease program at the district level. The public health physician has extensive experience in public health intervention planning at the Ministry of Health headquarters and serves as a module coordinator for the Public Health Intervention Module at the university. The lecturer in social behaviour and health promotion holds a Doctor of Philosophy in behaviour change theory related to non-communicable diseases. The family medicine consultant and dietitian have substantial field experience in primary care, particularly with T2D patients. The committee members have conducted regular face-to-face and online meetings to fulfil the responsibilities of the committee. The responsibilities of the committee include:

- i. To plan and complete a needs assessment and to provide overall direction for the development of the intervention
- ii. To review and approve the outcomes and objectives, and choose the underlying behavioural change model for the intervention
- iii. Selecting the content of the intervention by creating the matrix of change objectives
- iv. Critically reviewing the prefinal version of the health intervention before validation by panel of experts.

By fulfilling these responsibilities, the IDC ensures that the intervention is well developed and can be effectively implemented to achieve its intended health outcomes.

The need assessment comprised of four elements which include literature reviews of the problem of unready-to-act for weight loss and existing health intervention for adults with T2D with obesity, previous work conducted by our group, informal interviews with the primary care providers, and

informal interviews with the adults who have T2D adults and obesity. A Logic Model of the Problem was then constructed to help the IDC restructure findings obtained from the needs assessment, organising them into factors and determinants that affect the problem which is the unreadiness to act for weight loss among adults with T2D and obesity.

Step 2: Intervention Outcomes and Objectives: Matrices of Change Objectives

Change objectives are parameters outlining what the target population must achieve to reach the desired behavioural outcomes, which laid as the foundation for the preliminary collection of the intervention content [19]. In Step 2, we developed a matrices of change objectives for the behavioural intervention based on the performance objectives and determinants for change.

Step 3: Intervention Design

In Step 3, the IDC worked from the matrices of change objectives (established in Step 2), to begin conceptualizing the content and designing the intervention. The plan for this step included selecting the foundational model for behaviour change, finalising intervention themes, components, scope and objectives, and practical applications. The practical application consisted of activities and delivery method which was validated in the next step.

Step 4: Intervention Production

The production of the intervention involved three key components; drafting and formatting the layout, conducting the validation study, website development and usability testing. The IDC finalized the themes and components of the intervention through a series of online and face-to-face meetings. Each module's scope was then outlined, specifying the objectives and activities to be covered, ensuring the content was comprehensive enough to address key behavioural aspects while remaining feasible within the available time and resources. The health intervention materials were created in Malay Language using CanvaPro (Canva Pty Ltd) and underwent critical review by the IDC prior to proceeding to the validation study.

The content's validation was evaluated based on the intervention's manual, which serves as the primary reference for the intervention's implementation. For the validation of the intervention module, six panels of experts from relevant fields related to obesity and diabetes management were appointed to evaluate the newly developed health intervention module. The expert panels involved in the content validation were:

- i. An epidemiologist in non-communicable disease
- ii. A family medicine consultant
- iii. A sport medicine consultant
- iv. A health promotion officer
- v. A medical officer in charge of diabetes program in health clinic
- vi. A dietician in primary care.

The panels of experts were selected based on their background expertise related to the study. The experts reviewed the intervention manual and rated the items according to the content relevant to the module objectives and theoretical construct of the Process of Change. Face-to-face meetings with the panel of experts were conducted to give an overview of the interventions. Written consent was obtained from each panel of experts to contribute to the study. Then, each of them was given a Content Validity Index (CVI) form to rate the contents' relevance using a 4-point Likert scale for each activity in the module. All experts are encouraged to leave written opinions and recommendations about the health education module.

The face validation was conducted among fifteen T2D patients to evaluate the interventions' clarity,

simplicity, and unambiguity. These patients were selected during their visit in the clinic. They were explained briefly on the health interventions to give an overview of the content. Written consents were obtained prior to their involvement in the validation study. The FVI evaluation form also used the Likert scale of 1 to 4 according to the content's clarity, simplicity, and unambiguity.

After the content has been validated, the final version of the Chance2Act Intervention Manual was sent to an appointed website developer and ready to be transformed into a website. Multiple discussions have been conducted to guarantee that the development of the website adheres to the predefined specifications detailed in the manual. Following the completion of the website development, a usability study was conducted, serving as a quantitative pilot test to evaluate the website's functionality and user experience. The usability of the website was assessed by using a validated Malay version of the System Usability Scale (SUS) which has been shown valid and reliable in assessing the usability of digital interfaces. Reliability testing showed a Cronbach alpha value of 0.85 (95% CI 0.79 – 0.91) [20]. The list of items evaluated in the SUS is illustrated in Table 1.

Table 1 The criteria used for System Usability Scale

Item no.	SUS Item	Strongly disagree			Strongly agree	
		1	2	3	4	5
1	I think that I would like to use this website frequently.	1	2	3	4	5
2	I found the website unnecessarily complex.	1	2	3	4	5
3	I thought the website was easy to use.	1	2	3	4	5
4	I think that I would need the support of a technical person to use this website.	1	2	3	4	5
5	I found the various functions in this website were well integrated.	1	2	3	4	5
6	I thought there was too much inconsistency in this website.	1	2	3	4	5
7	I would imagine that most people would learn to use this website very quickly.	1	2	3	4	5
8	I found the website very cumbersome to use.	1	2	3	4	5
9	I felt very confident using the website.	1	2	3	4	5
10	I needed to learn a lot of things before I could get going with this website.	1	2	3	4	5

Steps 5 and 6: Intervention Implementation and Evaluation Plan

These steps involve planning the implementation and evaluation of the intervention. We selected a non-randomised controlled trial as the most appropriate method to evaluate the intervention. As the implementation and evaluation are beyond the scope of this paper, methods and results will be published in full elsewhere.

Data Management and Analysis

The rating scores for both CVI and FVI were entered in Microsoft Excel 365 for tabulation and data analysis. The content validity index was used to indicate the agreement among the panels on the items (I-CVI) and an average of each scale (S-CVI) of the content. The score given by the panel of experts to rate content's relevance was used to calculate CVI. The score used the Likert scale of 1 – 4 (not relevant = 1, somewhat relevant = 2, relevant = 3, very relevant = 4). Ratings 1 and 2 reflect content that requires correction, while ratings 3 and 4 indicate valid content. The I-CVI was

calculated by the number of experts providing a score of 3 or 4 divided by the total number of experts. Values can range from 0 to 1. The calculated I-CVI of 0.83 or more indicates that the items are acceptable [21]. The S-CVI/Average was calculated based on the sum of I-CVI scores of all items divided by the total number of items (average of the I-CVI scores for all items across all experts).

The face validity was assessed by the content's clarity, simplicity, and unambiguity of all activities in each module through responses by the panel of raters. They rated the clarity, simplicity, and unambiguity for each criterion according to a four-interval scale (1 = not clear, not simple, or very ambiguous; 2 = somewhat clear, somewhat simple, or somewhat ambiguous; 3 = clear, simple, or unambiguous, 4 = very clear, very simple or very unambiguous). Similar to content relevance, ratings 1 and 2 reflect content that requires correction, whereas ratings 3 and 4 indicate valid content. There are two forms of face validity index which are item-level FVI (I-FVI) and scale-level FVI (S-FVI). The I-FVI was calculated by dividing the number of items rated as 3 or 4 by the number of raters. S-FVI/Average was calculated by averaging the I-FVI scores for all items across all raters. Values can range from 0 to 1. The calculated FVI of at least 0.80 was considered as acceptable [22]. The System Usability Scale consists of 10-item questionnaire. Items that are odd (1, 3, 5, 7, 9) generate a positive response, but items that are even (2, 4, 6, 8, 10), generate a negative response. Several calculation steps are required to generate the score:

- i. **Step 1:** Convert the user ratings from the 10 items into points.
 - a. For odd numbered items 1, 3, 5, 7, 9 are calculated by using this formula:
$$[\text{User Rating}] - 1 = \text{points}$$
 - b. For even numbered items 2, 4, 6, 8, 10 are calculated by using this formula:
$$5 - [\text{User Rating}] = \text{points}$$
- ii. **Step 2:** Total up the points from the 10 items to generate a user's total points
- iii. **Step 3:** Multiply the user's total points X 2.5* to get an individual user's score which will convert the scale to be out of 100.
- iv. **Step 4:** Repeat steps 1-3 for all users, and then average all user's Scores together to get a SUS score.

A score above 68 is considered above average, and scores above 80 are indicative of excellent usability [23]. A minimum of 5 responses is enough to evaluate the usability of the website [24]. After the completion of usability testing, the intervention was ready to be evaluated in the next phase, the intervention evaluation.

Results

Step 1: Logic Model of the Problem

The findings from the four elements of the needs assessment were analysed by the IDC to develop the Logic Model of the Problem. The main problem identified was the large proportion of adults with T2D and obesity who are not ready to act for weight loss. The assessment recognised a range of personal, behavioural, and environmental factors that contribute to the unreadiness for behavioural change observed in this population. The logic model of the problem, illustrated in Figure 2, mapped these interrelated determinants and their impact on health outcomes, which act as factors influencing the unreadiness to act for weight loss.

Personal determinants, such as uncertainty about obesity levels, lack of awareness of the combined impact of obesity and T2D, previous failures in weight loss, and inadequate family support, were identified as critical barriers. These factors directly influenced behavioural determinants, resulting in resistance to behavioural change, low confidence in managing diet and physical activity, and a lack of coping strategies for maintaining long-term behaviour change.

Environmental factors further compounded these challenges, with issues such as insufficient social

support, unhealthy workplace environments, and gaps in healthcare services exacerbating barriers to weight loss. Without intervention, this reluctance to act could lead to continued weight gain and an increased risk of diabetes-related complications. In response, the IDC proposed the "Chance2Act" intervention, aimed to accelerate the progress of motivational readiness for weight loss among T2D adults. This title was chosen to reflect the main outcome of the intervention, as it provides the chance for participants to learn on how to start taking action for weight loss.

Step 2: The Matrices of Change Objectives

Performance Objectives.

In Step 2, the findings from Step 1 were used to specify what would need to be changed for people to be ready for weight loss. The IDC formulated six performance objectives to ensure participants can achieve the intervention goal (refer to Table 2).

Table 2 The Matrices of Change Objectives (Step 2) formulated based on the identified Performance Objectives and Determinants

Performance objectives (PO)	Personal determinants			External determinant
	Knowledge and awareness	Self-efficacy	Decisional balance	Family support
PO.1. Learn about obesity and its link with diabetes	Know about obesity and the associated health risks	N/A	N/A	N/A
PO.2. Identify personal barriers for weight loss	- Recognize personal and environmental barriers. - Identify risks of relapse.	Solutions to develop confidence for weight loss.	Acknowledge the perceived disadvantages as barriers for weight loss.	N/A
PO.3 Develop a positive perception of weight loss	- Learn about the health benefits and improved quality of life associated with weight loss. - Identify individual's motivational drive for weight loss.	Be confident to manage the perceived disadvantages as 'manageable sacrifices' for gaining long-term benefits.	- Belief that the advantages of weight loss significantly outweigh the disadvantages. - Increasing rewards for the positive behaviour change achieved	N/A
PO.4 Willingness to change	- Know to set the realistic goals of weight loss. - Learn basic dietary and physical activity changes to achieve weight loss.	Express confidence to change weight loss.	Belief that there will be benefits in making necessary behavioural changes to their lifestyle.	N/A
PO.5 Monitor lifestyle changes	Acknowledge the habitual character of eating unhealthy food and sedentary lifestyle	Express confidence in the ability to correctly monitor one's dietary intake and physical activity	Feel positive about monitoring food intake and physical activity	N/A

Performance objectives (PO)	Personal determinants			External determinant
	Knowledge and awareness	Self-efficacy	Decisional balance	Family support
PO.6 Strengthen family involvement in weight loss	Learn the role of family support for weight loss.	Build confidence in the ability to seek and utilize family support.	N/A	Educate on how family can play a supportive role in weight loss.

Determinants.

The IDC listed several determinants, which were then refined according to the literature review and the TTM. There were two categories of determinants: personal determinants and external determinants. The personal determinants were knowledge and awareness, self-efficacy, and decisional balance. The external determinant was social support from family. Following this, matrices of change objectives were constructed.

Change Objectives.

The performance objectives together with determinants guided the construction of the twenty change objectives which serve as the preliminary collection of the intervention content. Overall, twenty change objectives served as a blueprint for developing the content of intervention modules. These change objectives were further refined by the IDC to form the final content in Step 3.

Step 3 and 4: Intervention Design and Intervention Production

Table 3 presents a summary of the intervention modules, scopes, activities, and the underpinning theoretical foundation. The intervention's content was organized into four modules, each designed to address various components of behaviour change related to obesity and T2D management. The modules comprise a total of seven submodules, with each module containing one to two submodules that are scheduled for delivery over one to two weeks. The intervention includes 20 activities distributed across the modules.

The intervention approach was divided into three key components: educational content, participant engagement, and behavioural support. The educational content formed the foundation which includes (1) health facts (2) five infographics on weight loss for patients with T2D (3) health comics illustrating twelve common barriers to weight loss (4) five animation videos explaining the relationship between obesity and diabetes, balancing decision for weight loss, and strategies for overcoming challenges, and (5) a motivational video highlighted a patient's success story. Participant engagement was fostered through feedback mechanisms, where participants identified personal barriers and received tailored recommendations, along with health quizzes to assess their understanding of weight loss concepts. The behavioural support component included a behavioural change contract for realistic goal setting, family involvement through education and support, and examples of family-based dietary plans to aid in achieving weight loss goals.

The results of this step were compiled into **The Manual of the Chance2Act Intervention**. This manual, consisting of five chapters and 111 pages, included an introductory chapter outlining the intervention and participant recruitment guidelines, with the core content spanning Chapters 2 to 5.

Table 3 The framework of the Chance2Act intervention

Module and Topic	Module objectives	Content/activities	Theoretical foundation
1 Obesity risk awareness (ORA)	- To improve awareness on the level of obesity among the participant s. - To provide knowledge on the risks of obesity on health and psychosoci al contexts. - To provide insights on the common barriers of weight loss.	- Participants read text, calculate body mass index and assess their knowledge on their own obesity status. - Participants read a segment “Do you know? Body weight perception.” - Participants watch animation Video 1: Obesity, Diabetes and You! - Participants answer quiz: <i>Obesity and health risks</i> - Participants read text and comic on the barriers of weight loss. - Participants give feedback on their barrier for weight loss.	- Self-efficacy - Decisional balance - Process of change: - Consciousness raising - Dramatic relief - Self-re-evaluation - Environmental re-evaluation
2 Weight loss motivation (WLM)	- To give solutions to overcome barriers of weight loss. - To boost participant s’ motivation by identifying their motivation al drive to lose weight.	- Participants receive tailored solution to overcome barriers for weight loss. - Participants watch videos based on the stages of change: - Precontemplati on: Video 2: Obesity threaten your life! - Contemplation: Video 3 The benefits behind the sacrifice - Participants read text and infographics “5 Reasons Why You	- Decisional balance - Process of change - Self re-evaluation - Environmental re-evaluation - Self-liberation - Helping relationship

Module and Topic	Module objectives	Content/activities	Theoretical foundation
	3. To increase social support received from family members to lose weight.	<i>Must Lose Weight</i> 4. Participants sign behaviour contract for losing weight 5. Participants read infographic on the forms of family support for weight loss 6. Participants list the family support they need and share with their family members	
3 Achieving a healthy weight loss (HWL)	1. To give knowledge on dietary changes and physical activity to achieve weight loss 2. To guide on weekly meal and physical activity planning for participants and family members	1. Participants read infographics on dietary changes for weight loss. 2. Participants read a segment “Do you know? Calorie requirement and obesity” 3. Participants read infographics on dietary changes in family context. 4. Participants read infographics “Do you know? Physical activity and pulse rate” 5. Participants read and download “Obesity-Free Family Plan”	1. Process of change a. Helping relationship b. Counterconditioning
4 Maintaining a healthy weight loss journey (WLJ)	1. To evaluate and track the progress of behavioural changes done for weight loss 2. To give	1. Participants read and download “My weekly Weight Loss Checklist” 2. Participants watch videos: a. Video 4: The challenging weight loss journey b. Video 5: Cope	1. Self-efficacy 2. Process of change a. Reinforcement management b. Stimulus control c. Social liberation

Module and Topic	Module objectives	Content/activities	Theoretical foundation
	awareness on the challenges during weight loss and the coping mechanism	3. Video 6: Let's succeed with me!	
	3. To give information on the supportive services related with obesity provided at primary health care		

Validation study.

Table 4 presents the results of the validation study. The I-CVI and S-CVI (Average) were both scored 1.00, indicating unanimous agreement among the expert panel on the relevance of each item and the overall module. Following the experts' recommendations, minor revisions were made to the health education module, including sentence restructuring and the replacement of some graphics. A second round of panel review was not done as both the I-CVI and S-CVI (Average) demonstrated an excellent consensus.

Subsequently, fifteen T2D patients were involved during the face validation process. Their ages were between 31 to 65, with seven females and eight males, thirteen were Malay and two were Chinese. All three criteria on the content clarity, simplicity, and unambiguity aspects achieve a level of agreement higher than 0.8, indicating a high degree of agreement among the evaluators for each item and exceeding the required cut-off point. Most of the panel of raters gave positive feedback. Most of the content appeared attractive, and the graphics used were visually appealing and engaging to most respondents. The text, infographics, and animation videos used in the intervention were easy to understand, informative, and straightforward. The medical terms used in the intervention, such as "insulin," "insulin resistance," and "diabetes remission," were considered acceptable by the panel of raters since the terms were followed by an explanation to ensure understanding.

Table 4 The Summary of the Content Validity Index and Face Validity Index of the Chance2Act Intervention

Criteria	Module	Total number of items	Number of items retained	Index per Item (I-CVI or I-FVI)	Average Scale Index (S-CVI/Ave or S-FVI/Ave)
CVI: Relevance	1	5	5	1.00	1.00
	2	9	9	1.00	
	3	6	6	1.00	
	4	4	4	1.00	
FVI: Clarity	1	5	5	1.00	1.00
	2	9	9	1.00	
	3	6	6	1.00	
	4	4	4	1.00	
FVI: Simplicity	1	5	5	0.93 - 1.00	0.99
	2	9	9	1.00	
	3	6	6	1.00	
	4	4	4	1.00	
FVI Unambiguity	1	5	5	1.00	1.00
	2	9	9	1.00	
	3	6	6	1.00	
	4	4	4	1.00	

Note:

I-CVI = Content validity index of the individual item

S-CVI = Content validity of the overall scale

S-CVI/Ave = Average of the I-CVI for all items

I-FVI = Face validity index of the individual item in the intervention

S-FVI = Face validity for the overall scale of the intervention

S-FVI/Ave = Average of the I-FVI for all items in the intervention

Website Development and Usability Testing

The Chance2Act intervention manual was submitted to a website developer for digital adaptation. The development process spanned approximately three months. The finalized website was made accessible via www.chance2act.com, with participants provided with a username and password for entry. Figure 3 showed the homepage of the Chance2Act Website through various electronic devices. Following development, usability testing was conducted using the System Usability Scale (SUS) among five participants aged 44–49 years, comprising three females and two males, all Malay and married. The overall SUS score was 69.5 (Table 5), reflecting acceptable usability, though feedback highlighted unnecessary complexity as a key area for improvement. Due to budgetary constraints, only minor modifications were implemented, including image compression to improve page loading speed, while maintaining adherence to the validated intervention protocol. The final version of the Chance2Act website was subsequently prepared for Phase 2, which focused on evaluating intervention effectiveness.

Table 5 System Usability Scale for the Chance2Act website

User	Item [†]										Total score ^a	Problems encountered	Suggestion
	1	2	3	4	5	6	7	8	9	10			
1	2	2	3	2	3	3	3	3	3	2	65	If the internet connection is	None

												poor, the page loading will be longer	
2	3	1	3	2	3	4	3	4	4	4	77.5	None	None
3	3	1	3	0	4	0	4	4	4	3	65	No problems in using this website. Very helpful for to know more about obesity	To convert into mobile application
4	3	3	3	3	3	4	2	3	2	3	72.5	None	None
5	2	2	4	4	3	2	3	1	3	3	67.5	None	None
Each item	13	9	16	11	16	13	15	15	16	15			
Mean score ^β											69.5		

[†]Converted score from the initial user rating

^αThe total score was calculated by summing the converted scores of each item and multiplying by 2.5, resulting in a score out of 100.

^βMean score is calculated by averaging the total score from all participants.

Discussion

Principle Results

Prior studies have demonstrated the effectiveness of IM in enhancing health interventions, with improved participant engagement and outcomes [25,26]. This study employed the formation of a multidisciplinary IDC, which included experts in public health, health promotion, and primary care. This collaboration ensured that the intervention was informed by a wide range of expertise, from theoretical foundations to practical considerations in clinical application. The role of such committees in health intervention design is well-documented, with benefits including enhanced accountability and interdisciplinary insight [27,28]. In contrast, some studies that employed the IM framework did not involve steering committees, potentially missing the depth of continuous expert input throughout the development process [29,30].

This intervention was grounded in the TTM, which categorized individuals based on their readiness to change. By targeting those in the earlier stages of readiness, the intervention provides tailored strategies to build motivation that support readiness for weight loss. Evidence supports the use of TTM, with studies showing improvements in behaviour change when multiple TTM constructs are employed, particularly in promoting physical activity, a key component of weight loss [31]. However, TTM's focus on individual behaviour can overlook broader socioeconomic and environmental factors that also influence weight loss [32]. Future improvement of this intervention may benefit from incorporating a more comprehensive approach that addresses these contextual factors.

The validation phase of the study, which was carried out in Step 4, employed the Content Validity Index (CVI) and Face Validity Index (FVI) to evaluate the relevance and clarity of the intervention content. High CVI scores indicated strong expert consensus on the relevance of the content with the behavioural objectives. Similarly, the FVI scores suggested that participants found the intervention are simple, clear and unambiguous to their experiences with T2D and obesity. These results emphasize the importance of participant engagement in the development process to ensure that interventions are relevant and user-centered [33]. While some minor refinements were suggested during validation, they did not alter the core content but rather enhanced the clarity and relevance of

the materials.

The System Usability Scale (SUS) score of 69.5 has met the minimum threshold for usability; however, unnecessary complexity was identified as a major limitation. This issue was caused by the absence of a personalized account feature, which necessitated repeated username and password entry, potentially causing frustration and reducing engagement. Resource constraints prevented the integration of individualized accounts and interactive features, with Google Forms used for quizzes and progress tracking as a cost-effective alternative. To enhance usability and participant engagement in future iterations, the incorporation of personalized accounts is recommended, as this would ease access, allow tailored content delivery, and improve monitoring of individual progress.

Strengths

The strengths of this study lie in its innovative approach to target T2D patients with obesity who are not ready to act for weight loss. To the best of our knowledge, this is the first intervention in Malaysia specifically designed for this group, addressing the barriers they face in adopting weight loss behaviours. Treating obesity in this population is crucial as weight loss has been shown to improve metabolic outcomes and reduce the burden of diabetes [34]. The intervention's focus on family support, incorporated into five of the twenty total activities, was another strength, although direct family participation was not monitored due to resource limitations.

Limitations

Despite its strengths, the study has several limitations. First, the relatively small sample size of target consumers involved in the needs assessment may limit the generalizability of the findings from their perspective. Although the IM framework recommends including consumers in the steering committee, this was not feasible due to time constraints in completing the study. Additionally, we were unable to conduct qualitative or mixed-method studies for the needs assessment, as suggested by the IM framework, due to limited time and resources. Future research should incorporate these methodologies, as well as consumer involvement in the steering committee, to enhance the intervention's development. Furthermore, exploring the intervention's effects on behaviour change among T2D patients with obesity in real-world settings is essential to evaluate its long-term impact.

Conclusions

In conclusion, the Chance2Act intervention was specifically developed for adults with T2D and obesity who are unready-to-act for weight loss. The intervention provides a stage-matched approach tailored for this population, offering potential for integration into current T2D management practices. This study successfully developed and validated an obesity intervention, achieving a high degree of consensus among experts and raters, which underscores the credibility of its content. By addressing the complex relationship between obesity and T2D, our study helps to bridge a critical gap in existing interventions. Ultimately, we hope this intervention can positively impact patients' metabolic control and overall disease outcomes.

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Data Availability

Data sharing is not applicable to this article as no data sets were generated or analyzed during this study. In the next stage of our study, where data will be generated and analyzed, a detailed data

availability statement will be included. Access to this data will be restricted to protect the confidentiality of the study participants and to comply with the ethical board requirements. Requests for access to the data should be directed to the corresponding author, who will then seek necessary permissions from the Director General of Health Malaysia.

Conflict of interests

None declared.

Abbreviations

CVI: Content Validity Index

FVI: Face Validity Index

HWL: Achieving a Healthy Weight Loss

I-CVI: Content validity index of the individual item

IDC: Intervention Development Committee

I-FVI = Face validity index of the individual item in the intervention

IM: Intervention Mapping

MOH: Ministry of Health

ORA: Obesity Risk Awareness

S-CVI/Ave: Average of the I-CVI for all items

S-CVI: Content validity of the overall scale

S-FVI/Ave = Average of the I-FVI for all items in the intervention

S-FVI: Face validity for the overall scale of the intervention

T2D: Type 2 diabetes

TTM: Transtheoretical Model

UiTM: Universiti Teknologi MARA

WLJ: Maintaining a Healthy Weight Loss Journey

WLM: Weight Loss Motivation

References

1. World Health Organization. Diabetes. 2023. Accessed June 5, 2024. <https://www.who.int/news-room/fact-sheets/detail/diabetes>
2. International Diabetes Atlas. *IDF Diabetes Atlas 2021*. Vol 102. 10th Editi. (Boyko EJ, Magliano DJ, Karuranga S, et al., eds.); 2021. doi:10.1016/j.diabetes.2013.10.013
3. Institute of Public Health Malaysia. *National Health & Morbidity Survey 2023 Non-Communicable Diseases and Healthcare Demand Key Findings*; 2024. www.iku.gov.my/nhms%0AUse
4. Chandran A, Abdullah MN, Abdul F. *Ministry of Health Malaysia 2020. National Diabetes Registry Report 2013-2019*. Vol 1.; 2020. <https://www.moh.gov.my/index.php/pages/view/1905?mid=649>
5. Ruze R, Liu T, Zou X, et al. Obesity and type 2 diabetes mellitus: connections in epidemiology, pathogenesis, and treatments. *Front Endocrinol (Lausanne)*. 2023;14(April):1-23. doi:10.3389/fendo.2023.1161521
6. Sulu C, Yumuk VD. Treat Obesity to Treat Type 2 Diabetes Mellitus. *Diabetes Therapy*. 2024;15(3):611-622. doi:10.1007/s13300-024-01536-3
7. Dambha-Miller H, Hounkpatin H, Stuart B, Farmer A. Association between weight change and remission of type 2 diabetes: a retrospective cohort study in primary care. *Practical Diabetes*. 2021;38(5):8-14a. doi:10.1002/pdi.2355
8. Gao S, Zhang H, Long C, Xing Z. Association Between Obesity and Microvascular Diseases in Patients With Type 2 Diabetes Mellitus. *Front Endocrinol (Lausanne)*. 2021;12(October):1-9. doi:10.3389/fendo.2021.719515
9. Holmen H, Wahl A, Torbjørnsen A, Jenum AK, Småstuen MC, Ribu L. Stages of change for physical

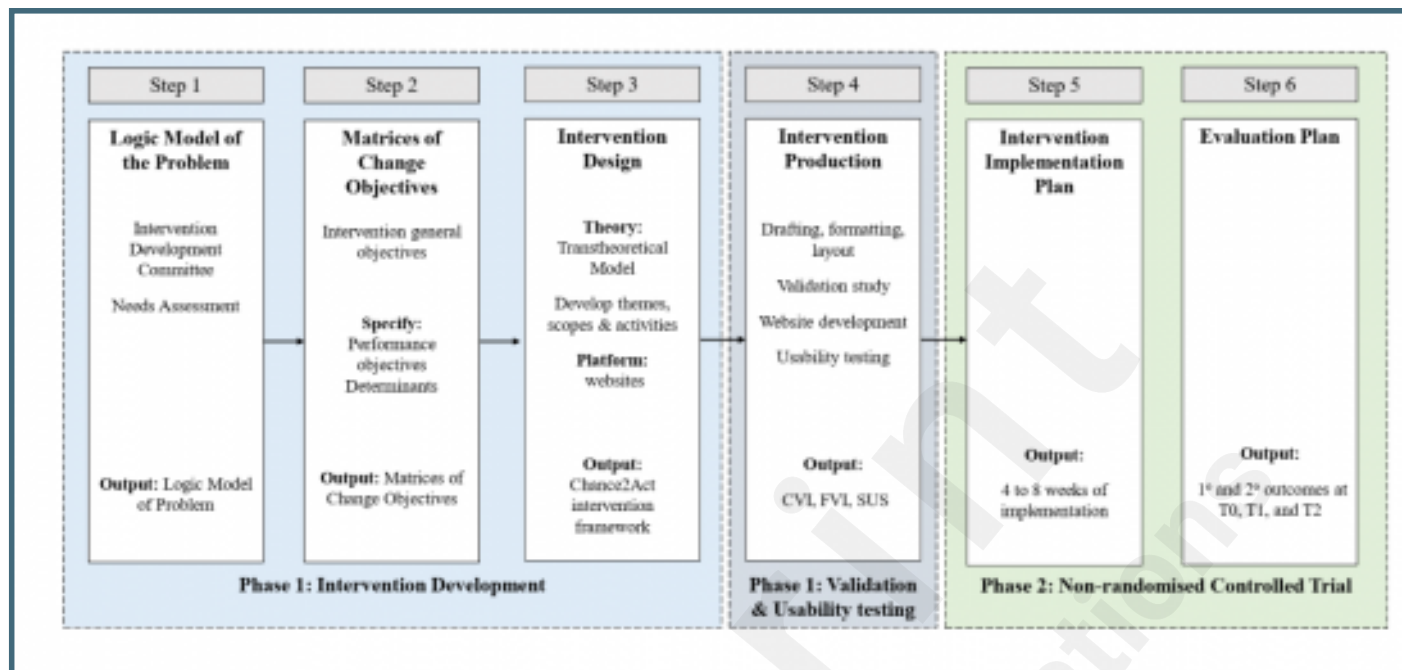
- activity and dietary habits in persons with type 2 diabetes included in a mobile health intervention: The Norwegian study in RENEWING HEALTH. *BMJ Open Diabetes Res Care*. 2016;4(1). doi:10.1136/bmjdr-2016-000193
10. Jalilian H, Pezeshki MZ, Janati A, Najafipour F, Sarbakhsh P, Zarnaq RK. Readiness for weight change and its association with diet knowledge and skills, diet decision making and diet and exercise barriers in patients with type 2 diabetes. *Diabetes and Metabolic Syndrome: Clinical Research and Reviews*. 2019;13(5):2889-2895. doi:10.1016/j.dsx.2019.07.052
 11. *CPG Management of Type 2 Diabetes Mellitus (6th Edition)*. 6th ed. Ministry of Health Malaysia; 2019.
 12. Ministry of Health Malaysia. *Clinical Practice Guidelines Management of Obesity*. 2nd ed. Medical Health Technology Assessment Section (MaHTAS) Ministry of Health Malaysia; 2023. doi:10.1080/j.1039-8562.2004.02077.x
 13. De Freitas PP, De Menezes MC, Dos Santos LC, Pimenta AM, Ferreira AVM, Lopes ACS. The transtheoretical model is an effective weight management intervention: A randomized controlled trial. *BMC Public Health*. 2020;20(1):1-12. doi:10.1186/s12889-020-08796-1
 14. Karintrakul S, Angkatavanich J. A randomized controlled trial of an individualized nutrition counseling program matched with a transtheoretical model for overweight and obese females in Thailand. *Nutr Res Pract*. 2017;11(4):319-326. doi:10.4162/nrp.2017.11.4.319
 15. Prochaska JO, Redding CA, Evers KE. *Health Behaviour and Health Education: Theory, Research and Practice*. 4th Editio. (Glanz K, Rimer B k., Viswanath K, eds.). Jossey-Bass A Wiley Imprint; 2002.
 16. Bahagian Pendidikan Kesihatan Kementerian Kesihatan Malaysia. Modul 1: Garis panduan pelaksanaan I Fit and Eat Right. In: 1st Editio. Bahagian Pendidikan Kesihatan Kementerian Kesihatan Malaysia; 2018.
 17. Mohd Zaki NA, Appannah G, Mohamad Nor NS, et al. Impact of community lifestyle intervention on anthropometric parameters and body composition among overweight and obese women: findings from the MyBFF@home study. *BMC Womens Health*. 2018;18(S1):110. doi:10.1186/s12905-018-0595-z
 18. Mustapha FI, Hussin SF, Ramly R. KOSPEN : From the Community , for the Community , by the Community. 2020;(5):20-23.
 19. Fernandez ME, Ruiter RAC, Markham CM, Kok G. Intervention Mapping : Theory- and Evidence-Based Health Promotion Program Planning : Perspective and Examples. 2019;7(August). doi:10.3389/fpubh.2019.00209
 20. Mohamad Marzuki MF, Yaacob NA, Yaacob NM. Translation, cross-cultural adaptation, and validation of the Malay version of the system usability scale questionnaire for the assessment of mobile apps. *JMIR Hum Factors*. 2018;5(2):1-7. doi:10.2196/10308
 21. Yusoff MSB. ABC of Content Validation and Content Validity Index Calculation. *Education in Medicine Journal*. 2019;11(2):49-54. doi:10.21315/eimj2019.11.2.6
 22. Yusoff MSB. ABC of Response Process Validation and Face Validity Index Calculation. *Education in Medicine Journal*. 2019;11(3):55-61. doi:10.21315/eimj2019.11.3.6
 23. Saad M, Zia A, Raza M, Kundi M, Haleem M. A Comprehensive Analysis of Healthcare Websites Usability Features, Testing Techniques and Issues. *IEEE Access*. 2022;10(September):97701-97718. doi:10.1109/ACCESS.2022.3193378
 24. Hinchliffe A, Kerry Mummery W. Applying usability testing techniques to improve a health promotion website. *Health Promotion Journal of Australia*. 2008;19(1):29-35. doi:10.1071/HE08029
 25. Garba RM, Gadanya MA. The role of intervention mapping in designing disease prevention interventions: A systematic review of the literature. *PLoS One*. 2017;12(3):1-17. doi:10.1371/journal.pone.0174438
 26. Halliday JA, Speight J, Russell-Green S, et al. Developing a novel diabetes distress e-learning program for diabetes educators: An intervention mapping approach. *Transl Behav Med*.

- 2021;11(6):1264-1273. doi:10.1093/tbm/ibaa144
27. Lightfoot CJ, Wilkinson TJ, Hadjiconstantinou M, et al. The Codevelopment of “My Kidneys & Me”: A Digital Self-management Program for People With Chronic Kidney Disease. *J Med Internet Res*. 2022;24(11). doi:10.2196/39657
 28. Passero L, Srinivasan S, Grewe ME, et al. Development and initial testing of a multi-stakeholder intervention for Lynch syndrome cascade screening: an intervention mapping approach. *BMC Health Serv Res*. 2022;22(1):1-11. doi:10.1186/s12913-022-08732-6
 29. Bang KS, Kim S, Lee G, Choi S, Shin DA, Kim M. The development of a health promotion program for unmarried mothers living in residential facilities using urban forests: An intervention mapping approach based on the transtheoretical model. *Int J Environ Res Public Health*. 2021;18(16). doi:10.3390/ijerph18168684
 30. Kim SS, Gil M, Kim D. Development of an Online-Coaching Blended Couple-Oriented Intervention for Preventing Depression in Middle Adulthood: An Intervention Mapping Study. *Front Public Health*. 2022;10(June). doi:10.3389/fpubh.2022.882576
 31. Jiménez-Zazo F, Romero-Blanco C, Castro-Lemus N, Dorado-Suárez A, Aznar S. Transtheoretical model for physical activity in older adults: Systematic review. *Int J Environ Res Public Health*. 2020;17(24):1-14. doi:10.3390/ijerph17249262
 32. Suhaimi T, Wafa SWWSST, Rasdi HFM, Talib RA. Models and theories to support health promotion programmes for overweight and obese adults: A scoping review. *Malays J Nutr*. 2022;28(3):335-355. doi:10.31246/mjn-2021-0126
 33. Almanasreh E, Moles R, Chen TF. Evaluation of methods used for estimating content validity. *Research in Social and Administrative Pharmacy*. 2019;15(2):214-221. doi:10.1016/j.sapharm.2018.03.066
 34. Lingvay I, Sumithran P, Cohen R V, le Roux CW. Obesity management as a primary treatment goal for type 2 diabetes: time to reframe the conversation. *The Lancet*. 2022;399(10322):394-405. doi:10.1016/S0140-6736(21)01919-X

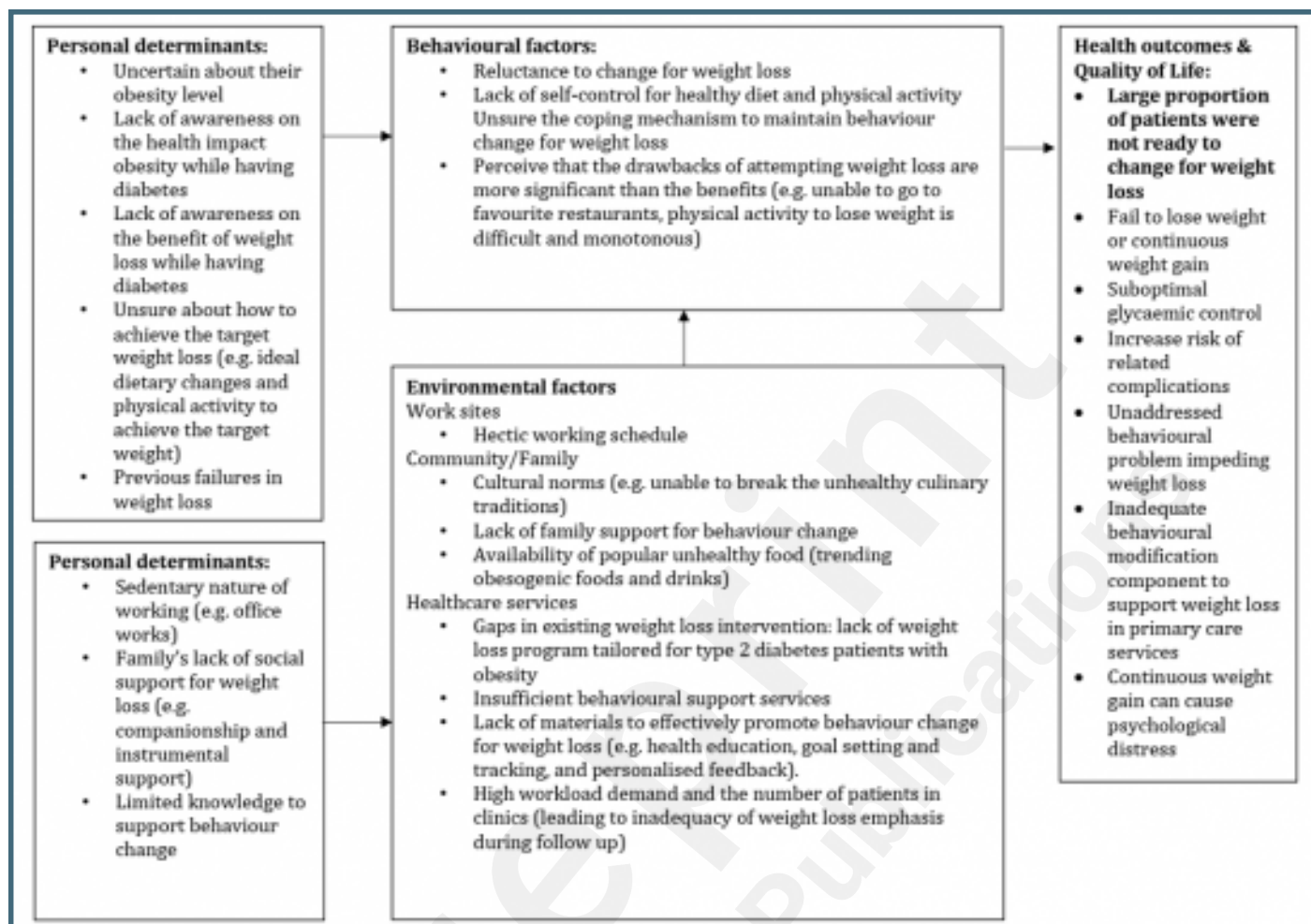
Supplementary Files

Figures

The Intervention Mapping framework used as the theoretical foundation in the development of the Chance2Act Intervention.



Logic model of the problem summarizing the findings from the needs assessment.



The homepage of the Chance2Act website.

