

UNIVERSITI TEKNOLOGI MARA

**DEVELOPMENT, VALIDATION,
AND EVALUATION OF A WEB-
BASED BEHAVIOUR
INTERVENTION (CHANCE2ACT)
TO ACT FOR WEIGHT LOSS FOR
ADULTS WITH TYPE 2 DIABETES
MELLITUS AND BODY MASS
INDEX OF $\geq 23\text{kg/m}^2$**

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ABSTRACT

Background: In adults with type 2 diabetes (T2D), weight loss has been shown to improve haemoglobin A1C, blood pressure, triglyceride levels, health-related quality of life, and reduce the need for medications. Although the majority of patients with T2D are either overweight or obese, many are not ready to act for weight loss. This study aimed to develop, validate, and evaluate a behavioural change intervention for adults with T2D and obesity who are not ready to act for weight loss.

Methodology: The development of the health intervention was guided by the Intervention Mapping (IM) framework, which comprises six steps. Content development was conducted in the initial three steps of the 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 (I-CVI) and Scale Content Validity Index/Average (S-CVI/Ave) to ensure content relevance, and Face Validity Index (I-FVI) and Scale Face Validity Index/Average (S-FVI/Ave) to confirm the clarity, simplicity and unambiguity of the intervention. Additionally, the usability testing of the intervention website was done to ensure it met the recommended standards of website usability. Phase 2, which encompassed the remaining two steps of the IM framework. The pilot study was conducted as a non-randomized controlled trial in Beserah Health Clinic (Intervention) and Paya Besar Health Clinic (control) in Kuantan, Pahang. The study employed an unblinded, parallel assignment design, with a 1:1 allocation ratio.

Results: During Phase 1, the content was successfully developed into the Manual of the Chance2Act Intervention. The validation study showed good content validity (I-CVI and S-CVI/Ave = 1.00) and high face validity (I-FVI and S-FVI/Ave > 0.9) across all criteria. After being transformed into a website, the usability testing yielded a System Usability Score (SUS) of 69.5, exceeding the recommended threshold. Phase 2 results indicated significant within-group improvements in the intervention group, particularly in the progression across stages of change after two months (P -value = 0.02) and self-efficacy for a healthy diet in availability subscale at one and two months, with a P -value of 0.002 and 0.03, respectively.

Discussion: The meticulous development of the intervention, guided by the Intervention Mapping (IM) framework, ensured a systematic approach to addressing the health issue. This structured methodology is reflected in the validation results, which demonstrated high content and face validity for the intervention components. However, the SUS score has just met the minimum threshold, which highlighted usability issues and observed challenges with maintaining intervention fidelity. Phase 2 results were inconclusive due to several limitations particularly the time constraint which restricted the ability to assess the intervention's effects fully.

Conclusion: This research has successfully achieved its initial objectives. However, its effect to promote behaviour change cannot be demonstrated due to the study's limitations including the challenges to maintain the intervention protocol fidelity and short study duration. Further studies are recommended to refine the intervention development, enhance the website usability and its implementation strategies to accelerate the readiness to act for weight loss within this population.

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CHAPTER ONE

INTRODUCTION

1.1 Preamble

This chapter offers an overview of the study's background, addressing topics on diabetes and obesity. Section 1.2 introduces the definition and epidemiology of type 2 diabetes (T2D). Section 1.3 defines obesity and describes its epidemiology. Section 1.4 connects the role of obesity to the natural history of T2D. In section 1.5, the benefits of weight loss for patients with T2D are explained. Section 1.6 explains the role of behavioural modification for weight loss, highlighting its importance in weight management. Section 1.7 explores the opportunities for improvement of obesity care for patients with T2D.

Subsequently, we will go into the problem statement (section 1.8), outlining the key issues and challenges that the study aims to address. The discussion is followed by the formulation of research questions (section 1.9), hypotheses (section 1.10), and objectives that guide the study (section 1.11). Lastly, the study's significance is elaborated, explaining how this study contributes to the existing body of knowledge and its potential impact on the body of knowledge, clinical, and public health practices (section 1.12).

1.2 Definitions and Epidemiology of Type 2 Diabetes

1.2.1 Definition and Characteristics of Type 2 Diabetes

Diabetes is a chronic metabolic disorder with multiple causes, characterised by persistent high blood glucose levels that occurs either when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. Insulin is an important hormone that regulates blood glucose (World Health Organization, 2023). Diagnosis of diabetes can be made using blood tests, including fasting or random plasma glucose, oral glucose tolerance test, and haemoglobin A1c (Ministry of Health Malaysia, 2019a).