STUDY PROTOCOL

# The Effectiveness of Health Education and Motivational Messaging Intervention on Promoting Healthy Lifestyle Behaviours in Overweight and Obese Female University Students: A Randomised Controlled Trial Protocol

Hanan Alzarea[1,2], Geeta Appannah[1,3,4], Wan Ying Gan[1], Nurul Husna Mohd Shukri[1], Asmaa Ahmad[2]

[1] Department of Nutrition and Food Science, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 Serdang, Selangor, Malaysia
[2] Department of Nutrition and Food Science, Faculty of Home Economics, Northern Border University, Arar 73213, Saudi Arabia
[3] Division of Nutrition, Dietetics and Food Science, School of Health Sciences, IMU University, 57000 Bukit Jalil, Kuala Lumpur, Malaysia
[4] Centre for Transformative Nutrition and Health, Institute for Research, Development and Innovation (IRDI), IMU University, Bukit Jalil, Kuala Lumpur , Malaysia

**ABSTRACT**

**Introduction:** Obesity among female university students in Saudi Arabia has become a critical public health concern. This study assesses the effects of health education and motivational messaging on promoting healthy lifestyle behaviours among overweight and obese female students at Northern Border University. **Methods:** A cluster-randomised controlled trial, employing a multistage sampling method, will be conducted among 250 female students aged 18-24 years with a body mass index (BMI) ≥ 25 kg/m2. Colleges will be randomly assigned to a college-based intervention or a control group. The intervention, grounded in Social Cognitive Theory and the Health Belief Model, will include six weekly in-person health education sessions (90 minutes each), followed by motivational messaging via WhatsApp over six weeks. Data will be collected at baseline, post-intervention, and three-month follow-up, with an additional intervention group assessment three months post-follow-up to assess weight loss motivators. Primary outcomes will include BMI and waist circumference reductions and improvements in obesity-related knowledge, attitudes, and practices. Secondary outcomes will include enhanced dietary intake, increased physical activity, reduced disordered eating, and decreased sedentary behaviour. Data will be analysed using descriptive statistics and Generalised Estimation Equation analysis to evaluate the intervention's effects. **Discussion:** The study intends to generate evidence-based insights for sustainable and culturally tailored strategies and to promote healthier lifestyles to combat obesity.**Trial Registration:** This study is registered at ClinicalTrials.gov (NCT06150248).
*Malaysian Journal of Medicine and Health Sciences* (2026) 22(1): 1-7. doi:10.47836/mjmhs.v22.i1.1465

**Keywords:** Healthy lifestyle, Intervention, Nutrition, Obesity, Saudi Arabia, University students

**Corresponding Author:**
Geeta Appannah, PhD
Email: geeta@upm.edu.my
Tel: +603-97692471

## INTRODUCTION

Overweight and obesity represent significant public health challenges globally, with particularly concerning trends in Middle Eastern countries, including the Kingdom of Saudi Arabia (KSA). Recent World Health Organization (WHO) data indicate that the prevalence of overweight and obesity in Saudi Arabia has reached 68.2% and 33.7%, respectively (1). A nationwide survey revealed that approximately 25% of the Saudi population is obese, with women exhibiting higher prevalence rates than men (33.1% versus 23.9%) (2). These rates are particularly alarming among university students, who experience rapid lifestyle changes that often contribute to weight gain and associated health risks (3).

The high prevalence of obesity among Saudi female university students can be attributed to poor dietary patterns, irregular eating times, frequent snacking, and high consumption of processed foods (1). Cultural and environmental factors unique to Saudi Arabia, such as limited outdoor physical activity opportunities for women and traditional dietary practices, further compound this challenge. These issues affect immediate health, increase the risk of developing chronic conditions like cardiovascular disease and type 2 diabetes, and pose a significant economic burden on the healthcare system (4).

Evidence suggests holistic and multi-component interventions are more effective than single-strategy approaches in fostering sustainable behavioural changes. When combined with motivational support, health education has demonstrated promising results in

promoting healthy weight maintenance and reducing obesity rates (5). This integrated approach addresses cognitive and emotional aspects of behavioural change, unlike traditional interventions focusing solely on dietary or physical activity improvements. The effectiveness of the combined approach is particularly relevant in the Saudi Arabian context, where cultural sensitivity and social media engagement play determinant roles in health promotion. The Saudi Ministry of Health, aligned with Vision 2030, incorporates health education and motivational messaging to enhance public awareness via culturally tailored approaches (6). This study contributes to the UN Sustainable Development Goal 3, which seeks to ensure healthy lives and foster well-being for all ages. However, limited research on obesity among female university students in the KSA reveals the need for targeted interventions.

The proposed intervention is theoretically grounded in the Social Cognitive Theory (SCT) and the Health Belief Model (HBM), emphasising perceived benefits, self-efficacy, and social support to enhance health behaviour change (7). It comprises structured health education workshops on balanced nutrition, physical activity, diet, and behavioural strategies, complemented by sustained motivational messaging delivered via social media platforms. This design leverages modern digital solutions while respecting cultural sensitivities, making it scalable and accessible for widespread implementation.

Recent evidence shows that combined interventions improve adherence to physical activity and diet, reducing body weight and waist circumference (8). Digital platforms enhance sustainability and cost-effectiveness, fitting well into university health programmes and public campaigns (9). The primary objective of this study is to assess the effectiveness of a combined health education and motivational messaging intervention in promoting healthy lifestyle behaviours among overweight and obese undergraduate female students at Northern Border University through cluster-randomised controlled trials.

## METHODS

### Study Design

A two-arm, parallel, cluster-randomised controlled trial (CRCT) will be conducted from April to December 2025 to evaluate the impact of a combined health education and motivational messaging intervention on promoting a healthier lifestyle among overweight and obese female university students. Colleges will be randomly assigned to a college-based intervention group or a college control group, with each college serving as the allocation unit.

### Setting, Recruitment, and Participants

Participants will be recruited randomly from Northern Border University (NBU) in Arar, Saudi Arabia. using a multistage random sampling technique, ensuring qual representation of all target populations. The Arar Region has one university with four campuses (Arar, Rafha, Turayf, and Al-Uwayqilah) and 16 faculties, of which the Arar campus houses nine. Two geographically varied Arar-based faculties, with different student compositions and fields of study will be selected randomly (10). Recruitment will employ flyers, emails, and social media, followed by eligibility screening until the target sample meets the inclusion criteria. Eligible participants will be female students aged 18–24 years with a body mass index (BMI) ≥ 25 kg/m , capable of giving informed consent and completing the intervention. Exclusion criteria encompass non-enrolled or male students, pregnant/postpartum students, and those with severe medical conditions or on medications that might induce weight loss.

### Stages of a Cluster-randomised Controlled Trial (CRCT)

1. **Enrolment:** Two of the nine colleges will be randomly selected, and eligibility will be assessed, excluding those with medical conditions or availability issues. An information sheet will detail the study's purpose, procedures, and benefits, after which written informed consent will be obtained. Participants will be free to withdraw at any time.
2. **Randomisation:** Two colleges will be randomly assigned to the intervention group (IG) and control group (CG) via a computer-generated systematic sampling method. The principal investigator will generate random numbers to enhance accuracy and reduce bias. All students within each college will be assigned to the same group to prevent contamination. Colleges in the intervention group will receive structured health education plus motivational messaging. In contrast, the control group will receive the regular health education currently offered by student health units at the university. To minimize contamination between the intervention and control groups, the study employs several strategies: the groups are physically separated by being located on different college campuses or buildings with limited overlap in daily activities, and intervention sessions are scheduled at times that do not coincide with control group activities to reduce casual interactions. Participants receive clear instructions emphasizing the importance of not sharing intervention content with peers outside their group to maintain study integrity. The research team monitors potential cross-group communication through periodic surveys and informal check-ins, adjusting analyses if contamination is detected. Additionally, distinct facilitators are assigned to each group to prevent inadvertent sharing of materials or methods. These combined measures help preserve the internal validity of the study and ensure that outcomes accurately reflect the intervention's effects without contamination bias.

3. **Follow-up:** Participants who discontinue or are lost to follow-up will be tracked, and reasons for withdrawal will be noted.
4. **Analysis:** Each group will undergo a final analysis, with reasons for exclusion documented (Figure 1).

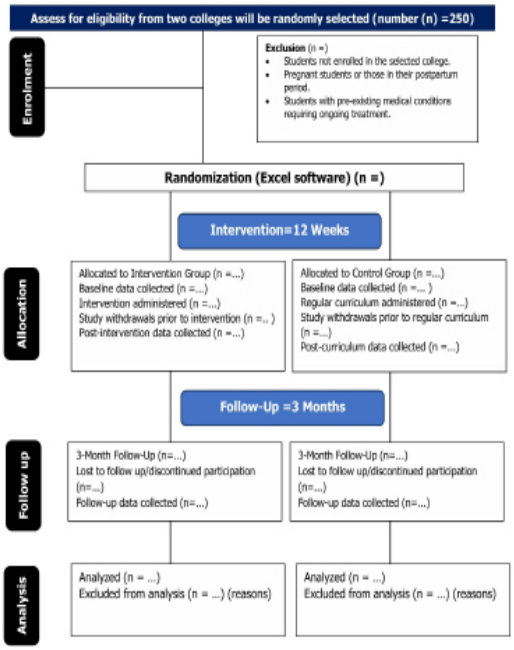


**Figure 1: Consolidated Standards of Reporting Trials (CONSORT) Diagram of the Clusters and Study Participants**

## Sample Size Calculation

The sample size for this study will be determined using a comparison of means for a cluster randomisation design using the following formula (11).

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2 / K)\,(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

According to previous literature, it is anticipated that the smallest effect size will be observed for waist circumference (12). Therefore, the sample size will be calculated based on the same article's mean values and standard deviations (SDs).

The sample size calculation using OpenEpi will require 116 participants (58 per group) based on a 95% confidence level and 80% power. Since this study employs a cluster randomisation design, the design effect (DE) is calculated considering the intracluster correlation coefficient (ICC = 0.01), m = 90 (sample per each cluster), and k = 2 (number of clusters or groups):
DE = 1+p(m-1) = DE = 1+0.01(58-1) = 1.57
Effective sample size (ESS) = DE*m*k = 1.57*58*2 = 183

After adjusting for an anticipated dropout rate of 30%, a sample size of 250 participants is required, necessitating the inclusion of two clusters of 125 participants each.

## Blinding

Due to the intervention design, it was impossible to blind the participants. Only the investigator will be aware of the group allocations, minimising participation bias and allowing a more credible assessment of the intervention's efficacy. All participants from the same college will be assigned to the same group and physically separated to minimise cross-contamination.

## Interventions

The intervention will be developed based on SCT, emphasising self-efficacy, goal setting, outcome expectations, and environmental influences (13). The HBM will also be incorporated to underscore obesity-related risks and preventive measures (14). The intervention will align with WHO guidelines for healthy diet and physical activity (Global Action Plan for Physical Activity 2018-2030 and the Global Strategy on Diet, Physical Activity and Health), endorsed by the Saudi Ministry of Health.

These theoretical frameworks are chosen to align with evidence-based practices in obesity prevention. Five experts, including consultants and specialists in nutrition, psychology, and health promotion research, will review and validate the content to ensure its relevance, clarity, and suitability. Focus group discussions and a pilot test will establish face validity and provide the intervention's feasibility among university students.

The 12-week intervention will be divided into two stages. The first stage will comprise six weekly 90-minute face-to-face sessions covering obesity awareness, nutrition concepts, Physical Activity guidelines, food labelling, healthy cooking, and meal planning. The second stage will involve sending two weekly WhatsApp messages, accompanied by culturally tailored health tips designed to promote and sustain healthy behaviours. These messages will reinforce positive lifestyle changes by leveraging social support mechanisms, relapse prevention strategies, and self-monitoring techniques. The intervention will harness established behaviour change techniques, including enhancing self-efficacy, encouraging goal setting, and providing social support to promote healthy lifestyles.

## Data Management

This research will involve collecting confidential personal data, necessitating robust data protection and confidentiality measures. Access control will be strictly maintained, ensuring only authorised personnel can access the data. Data security will be guaranteed through encryption, strong passwords, and multifactor authentication. Data cleaning will be conducted before analysis to improve data quality by identifying and correcting incomplete or defective data arising from inconsistencies or recording errors. The researcher will also perform cross-checking using paper tracking.

**Planned Data Analysis**

Data analysis will be conducted using the Statistical Package for Social Sciences (SPSS) version 29 (Chicago, IL, USA). All missing values and outliers will be checked before data analysis. Descriptive statistics, including means, medians, and standard deviations, will describe continuous variables, while frequencies and percentages will be used for categorical variables. The normality of continuous variables will be tested using the Kolmogorov-Smirnov and Skewness and Kurtosis tests (15).

Baseline homogeneity between groups for demographic and all dependent variables will be assessed using the independent t-test for continuous and normally distributed variables, the Mann-Whitney *U*-test for continuous and non-normally distributed variables, and the Chi-square test for categorical variables.

Generalised Estimation Equation (GEE) analysis will evaluate the intervention programme's effect on outcome variables between and within groups at three time points: baseline, post-intervention, and three-month follow-up. The analysis will include adjustments for clustering (15). The model will adjust for relevant covariates, including participants' education level, parents' education level, household income, number of siblings, household members, and age. Post hoc tests using the Bonferroni method will be conducted for pairwise comparisons.

**Ethical Considerations**

Ethical approval will be obtained from the Ethics Committee for Human Study of Universiti Putra Malaysia (JKEUPM-2023-458) and the Northern Border University in Saudi Arabia (HAP-09-A-043). Before distributing the questionnaire, written informed consent will be obtained from all participants. The study is registered with ClinicalTrials.gov (NCT06150248).

**Outcome Measures**

***Primary Outcomes***

The primary outcomes will be reduced BMI and WC and improved knowledge, attitudes, and practices regarding obesity.

**Secondary Outcomes**

The secondary outcomes will comprise improvements in Physical Activity levels, dietary intake, and dietary quality, as well as in managing disordered eating and sedentary behaviours.

**Research Instruments**

Participants in both groups will be assessed at multiple time points: at baseline before the intervention, immediately after the intervention, and at three-month follow-up. An additional follow-up will be conducted for the intervention group three months after the initial follow-up to assess motivators for weight loss , as illustrated in Figure 2. Data will be collected using a validated, pre-tested, self-administered questionnaire.

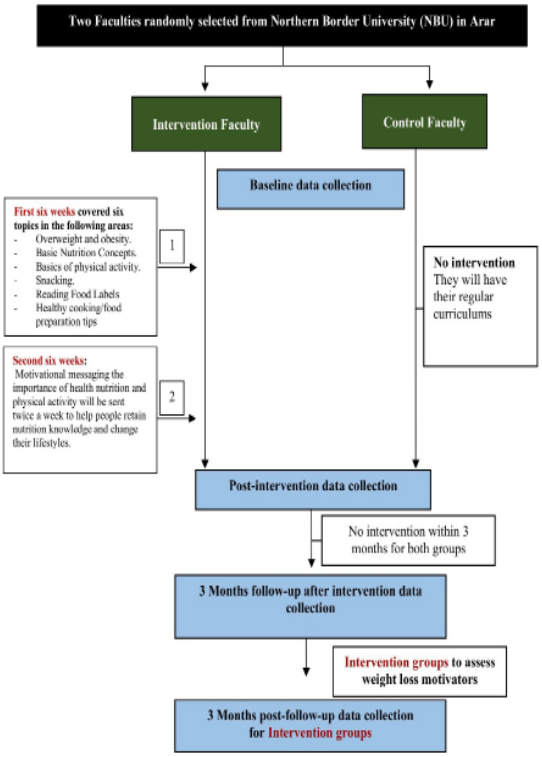


**Figure 2: Development and Session Outlines of the Health Education and Motivational Messaging Intervention Module**

**Sociodemographic Characteristics**

At the commencement, a sociodemographic questionnaire adapted from Khalaf et al. (16) will collect information on age, family income, parents' education, and family size.

**Anthropometry Measurements**

Body weight and height will be measured twice to the nearest 0.1 kg and 0.1 cm, respectively, using a validated digital scale, with participants wearing light clothing and no shoes. BMI will be calculated according to established standards: 25.0–29.9 kg/m2 classified as overweight and ≥30.0 kg/m2 as obese (17). WC will be measured at the midpoint between the iliac crest and lower rib margin to the nearest 0.1 cm. A WC >80 cm will indicate increased risk, and >88 cm implies significantly elevated risk (18).

**Knowledge, Attitudes, and Practices Related to Obesity**

An adopted version of the Knowledge, Attitudes, and Practices Questionnaire (KAPQ), developed by Alhawiti (20), will evaluate participants' obesity-related KAP. The instrument comprises three sections: knowledge (37 questions assessing the aetiology, health risks, and prevention strategies); attitudes (seven questions exploring perceptions about body shape, weight, and obesity management); and practices (three questions examining self-monitoring and weight-loss behaviours).

**Body Image**
The Stunkard Figure Rating Scale (19) uses nine female contour drawings to assess body image. Participants select the figures closest to their current and ideal sizes, with the discrepancy (current minus ideal) reflecting satisfaction.

**Physical Activity**
The Short Form (SF) International Physical Activity Questionnaire (IPAQ) will assess Physical Activity levels across various domains. The SF consists of seven questions measuring the frequency and duration of physical activities over the past seven days, covering vigorous, moderate, and sedentary activities (21, 22). This version is chosen for its brevity and suitability for the study population while providing a comprehensive Physical Activity profile.

**Dietary Intake**
The 24-hour Dietary Recall Questionnaire (24HR-DR) (24, 25) will determine dietary intake across two to three non-consecutive days, including one day on a weekend. Participants will receive a serving size guide via WhatsApp to accurately estimate portions. Responses will be entered into Nutritics Nutrition Analysis Software (v5.09, Dublin), which features a comprehensive Middle Eastern food database. The dietary records will calculate the average daily intake, total energy intake (kcal/day), and macronutrient distribution.

**Food Frequency**
Faleh's (23) 64-item Food Frequency Questionnaire (FFQ) will assess the quantity and serving size of food consumed over time, categorised into meats, cereals, dairy products, sweets, beverages, fruits, vegetables, fast foods, processed foods, fats, oils, baked foods, grains, nuts, seeds, legumes, pulses, sweets, and desserts. Participants will report how frequently they consumed each food during the past month across eight frequency categories.

**Disordered Eating Behaviour**
The Eating Attitudes Test-26 (EAT-26), developed by Garner and Garfinkel, will assess disordered eating behaviours and weight-related anxiety. Validated in diverse populations, including Saudi Arabian cohorts (26), it evaluates two dimensions: Eating Attitudes, which addresses cognitive and emotional responses to weight anxiety and food concerns, and Eating Behaviours, which focus on practices like dietary restriction, guilt post-consumption, and food-related anxiety.

**Sedentary Behaviour**
The Arabic Sedentary Behaviour Questionnaire (ASBQ), developed by Al-Hazzaa (28), measures a range of sedentary activities within a cultural context like sitting, screen time, and electronic device use within a cultural context. Comprising 13 items, it sums sedentary minutes across weekdays and weekends, weighting these to produce a weekly sedentary score (29).

**Motivators for Weight Loss**
The Motivators for Weight Loss Questionnaire, adapted from Alfadda (30), consists of 20 items assessing personal, social, and health-related aspects of weight loss motivation using a five-point Likert scale.

**Quality Control of the Questionnaire**

**Content Validity**
Four experts in health and nutrition will review the questionnaire to assess its alignment with the Saudi cultural context and suitability for measuring the intended outcomes. A specialised team will oversee the translation process (English to Arabic and back) to ensure accurate cultural and linguistic transfer. Anthropometric instruments will be calibrated to ensure accuracy and reliability.

**Face Validity**
Face validity will be tested on a random 10% sample of participants matching the study's demographics. Participants will review the questionnaire individually, providing feedback on its clarity, comprehension, and format.

**Reliability**
Reliability will be assessed via Cronbach's alpha, with values >0.7 considered acceptable. A pre-test will be conducted on a separate 10% sample from areas outside the central study locations.

**Ethics of Study**
Ethical approval will be obtained from the Ethics Committee for Human Study of Universiti Putra Malaysia (JKEUPM-2023-458) and the Northern Border University in Saudi Arabia (HAP-09-A-043). Before distributing the questionnaire, written informed consent will be obtained from all participants. The study is registered with ClinicalTrials.gov (NCT06150248).

## DISCUSSION

This study will generate evidence-based insights for sustainable intervention strategies to promote healthier lifestyles among young female students. The findings, scalable to NBU faculties and tertiary institutions across Saudi Arabia, may have broader implications for culturally tailored public health initiatives targeting obesity in Saudi Arabia and other regions.

To improve the rigor and applicability of future studies, several methodological enhancements should be considered. We recommend incorporating objective measures such as accelerometers to accurately capture physical activity levels, wearable devices to monitor sedentary time, and biomarkers or direct observation

methods to assess dietary intake when feasible. Utilizing these tools would significantly enhance the validity and reliability of the collected data by reducing self-report biases and measurement errors. This approach would provide a more comprehensive and precise understanding of the behaviours studied, ultimately strengthening the quality and applicability of research findings in the field. Moreover, future research should overcome the limitation of having only two clusters (colleges) by increasing the number of clusters. This would allow for a better representation of variability within clusters and improve statistical power. Using very few clusters can result in less reliable conclusions and potential bias, as standard errors may be underestimated and significance overstated. Additionally, researchers need to consider how the small number of clusters affects the generalizability of their findings, recognizing that results might not be applicable beyond the sampled clusters. By expanding the number of clusters and employing suitable inference techniques, the robustness and relevance of results in studies involving clustered data can be significantly enhanced.

**ACKNOWLEDGEMENT**

The authors acknowledge the assistance provided by the Saudi Arabian Culture Mission, the Northern Border University, the Ministry of Education, and the participants in this study.

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