

Application of the Theory of Planned Behavior for Weight Control in Women: A Randomized and Controlled Study Protocol

Abstract

Background: The prevalence of obesity, which has become a remarkable public health concern in a global extent, is increasing with each passing day. Different methods are available to treat obesity, but the most effective and reliable treatment approach is the implementation of lifestyle and behavioral changes.

Aim: This study aims to examine the effect of education and counseling given to women according to the theory of planned behavior (TPB) on weight management.

Methods: This study was conducted as a single-blind randomized controlled study consisting of experimental and control groups. A total of 78 overweight and obese women were included in the study. The participants were assigned to either of the groups by the block randomization method. A training program consisting of a total of six sessions was applied to the experimental group and counseling was provided for 6 months. The primary outcomes of the study are Healthy Lifestyle Behaviors Scale II sub-dimensions and total score average. The secondary outcomes are body mass index and waist/hip ratio. The participants and the statistician analyzing the data were single blinded. The data will be analyzed with SPSS 22.0 package program.

Conclusion: This study will present an evidence-based approach to induce behavioral changes in women who are at a risk for obesity. In addition, based on the outcomes of the research, the effect of the TPB in motivating individuals to practice weight control will be evaluated.

Keywords: Health behaviors, obesity, theory of planned behavior, women

Seda Göger¹, Ayşe Çevirme²

¹Department of Health Care Services, Vocational School of Health Services, Sakarya University, Sakarya, Türkiye

²Department of Nursing, Faculty of Health Sciences, Sakarya University, Sakarya, Türkiye

Introduction

Next to smoking, obesity is the leading cause of preventable deaths and it has been documented that it will emerge as the most important health problem in the world in the 21st century.¹ In 2016, 1.9 billion adults aged 18 years and above were reported to be overweight and more than 650 million adults were reported to be obese worldwide. The worldwide prevalence of obesity in adults is 13%, and this rate is 11% for men and 15% for women.² According to the report published by the Global Burden of Disease, Obesity Cooperation Group in 2015, the number of obese individuals in the world has exceeded 700 million. Furthermore, it has been emphasized that more than 600 million of them are adults.³ In the United States of America, which is one of the countries with the highest prevalence of obesity was more prevalent in women than in men.⁴ In Türkiye, according to the research conducted by the Turkish statistical institute, the obesity prevalence, which was 21.1% in 2019, descended to 20.2% in 2022.⁵

Many factors such as age, gender, genetics, hormones, physical activity, and nutrition affect the development of obesity. Situations such as pregnancy, breastfeeding, oral contraceptive use, and menopause, which are experienced by women during different life periods, increase their predisposition to obesity; furthermore, cultural factors can also contribute to obesity.^{6,7}

Although obesity is an easily diagnosed disease, it is difficult to treat. Different methods are available to treat obesity, but the most effective and reliable treatment approach is the implementation of lifestyle and behavioral changes.⁸ Theory-based interventions to instill behavioral changes in obesity management are effective.⁹ In this context,

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Corresponding author: Seda Göğer E-mail: sedagoger@sakarya.edu.tr

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Copyright@Author(s) - Available online at www.jer-nursing.org Content of this journal is licensed under a Creative Commons Attribution-NonCommercial 4.0 International License. the theory of planned behavior (TPB), which can explain the behavioral change care process in humans, is the most appropriate model in which individuals take responsibility for their own decisions in obesity management. It is also the most effective theory that can explain how attitudes affect behavior. With the perceived behavioral control factor, TPB helps overweight and obese individuals to properly diagnose the condition and assess their ability to improve their motivation to lose weight.¹⁰

TPB has been applied in studies in various fields such as education, psychology, business, public relations, and health. TPB can be used to explain human health behaviors, and although it can be used over a broad spectrum, review of the current literature shows that its use in the field of health is limited. In some studies in the literature, TPB has been employed in different fields such as sexual functions in menopausal women,¹¹ health of children born to couples with thalassemia,12 intention to quit smoking in adolescents,13 breastfeeding behavior,¹⁴ spousal violence,¹⁵ and organ donation.¹⁶ However, studies in which TPB is used for obesity management are limited, and there is no TPB-based health education program in the literature to alter the health behaviors of women at risk for obesity. In light of such information and taking into account that obesity is becoming more prevalent globally and is significantly affecting the quality of life of people, this study was planned to examine the effects of TPB-based education and counseling services on the health behaviors of overweight and obese women.

Methods

The aim of this study was to examine the effects of education and counseling given to women according to TPB on weight management

Study Design

This research was designed as a randomized, controlled, single-blind, and parallel group experimental study. Standard Protocol Items: Recommendations for interventional trials Statement 2013 checklist¹⁷ and the consolidated standards of reporting trials flowchart were used in this protocol.

Research Hypotheses

H1: There is a difference in the anthropometric body measurements before and after the education and counseling intervention given to women according to TPB.

H2: There is a difference in the physical activity levels before and after the education and counseling intervention given to women according to TPB.

H3: There is a difference in the Healthy Lifestyle Behaviors before and after the education and counseling intervention given to women according to TPB.

Study Population

At the time of planning the study, there were 53 family health centers (FHC) in Sakarya city center. To enhance the generalizability of the study findings to the population, three FHCs were selected from each of the central districts by simple random sampling. The sample size calculated while determining the number of women from the FHCs to be included in the study was proportioned to the number of women in the 18–49 age group in the selected FHCs; accordingly, the number of women from each FHC to participate in the study was determined.

Inclusion Criteria

- 1. Volunteering to participate in the study
- 2. To be registered with the obesity unit of Sakarya Serdivan Wellness Center or Serdivan FHC
- 3. Being a woman in the age group of 18–49 years (women in this age group were chosen for the sampling because they show similarities with each other in terms of hormonal activities)
- 4. Having a body mass index (BMI) of 25.0–30.0 kg/m² (overweight) or >30.0 kg/m² (obese)
- 5. Not going through menopause
- 6. Not having diabetes, thyroid disease, polycystic ovarian disease, a metabolic disease, Cushing's syndrome, a disease that prevents physical activity and hypertension
- 7. Not using hormonal contraceptive pills
- 8. Not being pregnant or breastfeeding
- 9. Owning and using a smartphone
 - 10. Having a mail account in Google and being able to use it.

Exclusion Criteria

- 1. Not volunteering to participate in the study
- 2. Having communication problems
- Not giving consent at any stage of the study and who quit the study.

Randomization and Blinding

General information about the study was given to the women before randomization, and their consent was obtained for participation in the study. Furthermore, initial measurements (pre-tests) were performed on the participants before dividing them into experimental and control groups. A total of 161 women were included in the evaluation, 62 of whom were excluded because they did not meet the inclusion criteria and 21 because they refused to participate in the study. Experimental and control groups randomization is show in Figure 1.

The participants were randomly assigned to groups to avoid selection bias. The experimental and control groups were blinded to randomization and will not know which group; they are in until the trial is complete. After the data are collected, the analysis was done by an independent and blinded statistician.

Block randomization method was applied to divide the participants into groups of equal sample size. For this, six combinations were created in blocks of four consisting of two letters. After the blocks were created, the participants were randomly assigned to the experimental and control groups using the computerized simple randomization method.

Sample Size and Power Analysis

GPower 3.1 program was used to determine the number of women to be included in the experimental and control groups. The aim of the study was to evaluate the differences between the groups in terms of the mean score of International Physical Activity and Healthy Lifestyle Behaviors Scale. In cases where it was not known how many units of difference between the groups was significant, the effect width value of 0.70 was used. The effect width value of 0.20 gives the results under a very high constraint, 0.50 gives the results under a moderate constraint, and 0.80 gives the results under the maximum acceptance constraint. The total number of participants was found to be 68 (34 women in each group) when the effect width was 0.70 at



5% margin of error and 81.17% power level.¹⁸ It was thought that some participants may drop out during the study. In this context, the dropout rate was calculated to be 12.5% based on the study of Orhan.¹⁹ As a result, 78 women were planned to be included.

Intervention

The data were collected by the researcher at the FHCs where the participants were registered. The body weight of the participants was measured by a digital scale with a sensitivity of 0.1 kg at the sports center, and the waist and hip circumference was measured by a researcher with a tape measure of 1.5 m in length. During the measurements, women were told to remove clothes such as jackets and shoes.

For the research, obesity training consisting of a total of five sessions structured according to TPB was scheduled for the experimental group, and a standard obesity training consisting of a single session was scheduled for the control group. Moreover, a training booklet and a brochure were prepared to be given to women after the training. To test the suitability of these materials to be used for the study, opinions were obtained from eight experts, seven of whom were in the field of public health nursing, and one in the field of physical therapy and rehabilitation. "Training Booklet Evaluation Form" was used while getting an expert opinion. This form was developed by Vural and Temel. In form; a total of 16 features are included in the study, including the fictional features of the booklet (four features), features related to Turkish expression (five features), features related to print quality (three features).²⁰

The training was imparted to the experimental and control groups that were applied online in groups of 5–6 people through the Google Meet program by the researcher. While determining the number of the group to be trained, a study conducted in Türkiye in which spousal

violence education was given according to the TPB was taken as a basis.¹⁵ The training to be given to the experimental group is structured according to the planned behavior theory. This theory consists of three sub-components. "Attitude Toward Behavior" refers to the individual's evaluation of any behavior as positive or negative, "Subjective Norm" refers to the social pressure felt by the individual in order to perform the behavior, "Perceived Behavioral Control" refers to the thought of whether the person has full control over his/ her behavior, and the perception of competence. While preparing the theory-based training, the subject of the sessions was determined in line with these three components. According to this; the definition of obesity, its causes, risk factors, and the associated health problems were explained in the first session of the training. In the second session, women's positive and negative attitudes, previous experiences, current behaviors, and misconceptions about weight control were examined. In the third session, the effects of culture on obesity were explained, and the existing social support and social pressure on women were determined. In the fourth session, positive health behaviors that need to be developed in the fight against obesity will be explained, and the obstacles or conveniences that women perceive in developing these behaviors were discussed. In addition, the concept of self-efficacy was explained to create awareness of individual abilities in weight control; besides, a video screening will be done for this purpose. In the fifth session, existing obesity prevention programs and services provided were explained. In the last session, possible solutions were presented, and questions were answered. Each session was last for approximately 30 min. Lecture, questionanswer, and discussion methods were used during the training. The materials were used during the training include a PowerPoint presentation, video show, and training booklet (Table 1). Women were asked to document their weight loss goals after each session.

After the training given to both groups, the women will be followed up by phone for 6 months. The women in the experimental group will be

Table 1. Seminar for the experimental group					
Seminars	Topics	Training method/materials			
Session 1	Information about obesity	Lecture, question-answer/ PowerPoint presentation, training booklet			
Session 2	The importance of attitudes in weight loss and developing positive health behavior	Lecture, question-answer, discussion/PowerPoint presentation, and training booklet			
Session 3	The effects of culture on obesity	Lecture, question-answer, discussion/PowerPoint presentation, training booklet, and video			
Session 4	The importance of perceptions and self-sufficiency in weight loss and developing positive health behavior	Lecture, question-answer, discussion/PowerPoint presentation, and training booklet			
Session 5	Obesity prevention programs and services	Lecture, question-answer/ PowerPoint presentation, training booklet, video			
Session 6	Providing solution suggestions for the obstacles perceived by women, answering questions	Question-answer, discussion/-			

given counseling services by the researchers, and their status will be evaluated every month. The women in the control group will be provided with the contact information of the researcher, and they will be reminded to contact the researcher in case of queries. The final measurements will be collected face to face by the researcher by calling the FHC where the participants are registered or by making a home visit. The timeline for the research is shown in Table 2.

Outcome Measures

Primary Outcome Measures

Healthy Lifestyle Behaviors-II Scale

Healthy Lifestyle Behaviors-II Scale was developed by Walker and Hill-Polerecky²¹ (1996) based on Pender's health promotion model. The scale aims to measure the health promotion behaviors of individuals. The scale was adapted to the Turkish population by Bahar et al.²² in 2008, and the validity and reliability study was conducted. Cronbach's alpha (α) value, which shows the internal consistency of the scale, was found to be 0.92. The scale consists of 52 items and six sub-dimensions, namely, spiritual development, interpersonal relationships, nutrition, physical activity, health responsibility, and stress management. It is a four-point Likert-type scale (1: "never," 2: "sometimes," 3: "often," and 4: "regularly"). The lowest score that can be obtained is 52, and the highest score is 208. While each

Table 2. Details and timing of data collection						
	Measurement times					
	Experimental Group		Control Group			
	Pre-test	Post-test	Pre-test	Post-test		
Measure	1 st week	24 week	1 st week	24 week		
Information form	×		×			
Anthropometric measurements	×	×	×	×		
International physical activity questionnaire	×	×	×	×		
Healthy lifestyle behaviors scale II	×	×	×	×		

sub-dimension can be evaluated individually, the total scale score can also be calculated. High scores indicate that the individual practices the specified health behaviors at a high level.

International Physical Activity Questionnaire Short Form

This questionnaire is not focused on a single culture or language. There are many types of physical activities performed by people all over the world. In the questionnaire, the intensity (mild, moderate, and severe) of physical activity is taken into account to accommodate different types of physical activities. The metabolic equivalents of task (MET) levels of physical activities to be used at the appropriate intensity have been published by Ainsworth et al.23 The guestionnaire has a 7-question short form and a 27-question long form. The short form provides information about sitting, walking, and the time spent in moderately intense and vigorous activities. Vigorous physical activities have a value of 8.0 MET, moderate activities have a value of 4.0 MET, and walking has a value of 3.3 MET. The minute and frequency (day) values of the relevant activities are multiplied by the MET values. The total physical activity value is obtained by summing the multiplication values obtained at the last stage. Accordingly, the physical activity levels of individuals are classified as physically inactive (<600 MET-min/week), low physical activity (600-3000 METmin/week), and adequate physical activity (health benefits) (>3000 MET-min/week).24

Secondary Outcome Measures

Body Mass Index

BMI is used to predict body weight according to height and does not provide information about body fat distribution.

Waist/Hip Ratio

This measurement provides information about body fat distribution.

Data Analysis

The data obtained from the research will be transferred to a computer environment and evaluated through IBM SPSS Statistics 21 package program (IBM Corp Armonk, NY, USA, Released 2012). Chi-square analysis will be used to compare the sociodemographic characteristics of the experimental and control groups. Experimental and control group data will be checked for conformity to normal distribution. Dependent samples t-test/Wilcoxon test will be used for intragroup comparisons and independent samples t-test/Mann-Whitney U-test will be used for intergroup comparisons. To determine the relationship between the variables, Pearson correlation analysis will be applied in case of normal distribution and Spearman correlation analysis will be applied in case of non-normal distribution. After the completion of the study, an intention-to-treat analysis will be conducted to prevent drop-out bias in case the participants drop out from the study.

Ethical Considerations

This research was conducted in accordance with the principles of Good Clinical Practices and the Declaration of Helsinki. Ethical approval was obtained from Sakarya University Non-Pharmaceutical Clinical Practices (Approval No: 273 Decision Date: 16.12.2020). The study was registered on 25 June 2021 on ClinicalTrials.gov with the Identifier, NCT05027750. Institutional permission was obtained from the FHCs where the study will be conducted. In addition, all participants were informed about the study, and their written and verbal consent was obtained.

Discussion

Improving women's health is an indispensable element of a healthy society.²⁵ This study will provide a holistic perspective within a conceptual framework for women who constitute a group at risk in terms of obesity. It is thought that this theory-based intervention will make an important contribution to the protection and improvement of women's health. Morever, use of TPB in this study will allow the provision of training and counseling services with an evidence-based approach and thus increase the motivation of women to lose weight.

In a study on the subject in the literature, a decrease was observed in the body mass index of the participants 6 weeks after the training intervention given to obese adolescents according to the TPB.¹⁰ In another study, it was determined that while the physical activity levels of the intervention group trained using the planned behavior theory increased, their body mass indexes decreased. No statistically significant difference was observed in the control group that did not receive any educational intervention.²⁶

In the fight against obesity, regular physical activity together with adequate and balanced nutrition is of great importance.²⁷ However, in addition to these health behaviors, factors such as successful stress management, health responsibility, good interpersonal relationships, and spiritual development are also effective in weight management.²⁸ Although there are some studies in the literature showing that interventions based on TPB increase the level of physical activity,^{29,30} there are no studies investigating the effect on other health behaviors. Therefore, the aim of this study is to evaluate the effect of training and counseling based on TPB on health behaviors such as nutrition, exercise, stress management, interpersonal relationships, and spiritual development. Thus, it is thought that the results to be obtained at the end of this study will guide future evidence-based research to instill a behavioral change in obesity management.

Limitations of the Study

The first limitation of the study is that the research is conducted in one particular region, which limits the generalizability of results. The other limitation of the study is that it will focus only on women. The last limitation of the study is that the investigator could not be blinded.

Conclusion

In line with the hypotheses of the current study, it is expected that the education and counseling intervention based on the theory of planned behavior will lead to positive changes in anthropometric measurements, physical activity levels, and healthy lifestyle behaviors of women who constitute a risk group for obesity. Therefore, it can be suggested that nurses should use evidence-based interventions by using their educator and consultant roles to prevent the sedentary lifestyle that increases with age in society and to improve health.

Ethics Committee Approval: Ethical approval was obtained from Sakarya University Non-Pharmaceutical Clinical Practices (Approval Number: 273 Decision Date: 16.12.2020). This study was registered on 25 June 2021 on ClinicalTrials. gov with the Identifier, NCT05027750.

Informed Consent: Written and verbal consent was obtained from the women who participated in the study.

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