Journal of Midwifery & Reproductive Health

JMRH.mums.ac.ir

The Effect of Training Based on Extended Parallel Process Model on Weight of Women with High Body Mass Index: A Cluster Randomized Trial

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ARTICLE INFO

Article type:
Original article

Article History:
Received: 21-Dec-2021
Accepted: 24-Jun-2022

Key words:
Weight
Prenatal care
Obesity
Extended parallel Process Model
Body mass index

ABSTRACT

Background & aim: Changing lifestyle before pregnancy is necessary to avoid the consequences of obesity in pregnancy. This study was performed to investigate the effect of training based on extended parallel process model (EPPM) on the weight of women with high body mass index before pregnancy.

Methods: In this two-group cluster randomized trial, 60 eligible women participated. Experimental and control groups were randomly selected from two comprehensive healthcare centers in Mashhad, Iran. Data collection tools included a questionnaire based on the constructs of the extended parallel process model and Baecke Physical Activity Questionnaire. The experimental group received the national nutrition guidelines based on EPPM constructs including threat as well as efficacy and the control group received the same content in a routine way. Participants' weight was measured before, two and four weeks after the intervention.

Results: The two groups were homogeneous in terms of demographic and obstetric characteristics. The mean changes of construct of threat before, two and four weeks after the intervention in the experimental group compared to the control increased by 4.84 and 3.59 times, respectively, which was statistically significant ($P<0.05$). The mean changes of construct of efficacy before, two and four weeks after the intervention in the experimental group and also the mean weight loss four weeks after the intervention was not statistically significant.

Conclusion: Further studies are needed to confirm the effectiveness of this model for weight loss and its role in increasing the perceived efficacy of overweight women at the pre-pregnancy stage.

Please cite this paper as:
Mostajabi SZ, Jahani Shoorab N, Kordi M, Esmaily H. The Effect of Training Based on Extended Parallel Process Model on Weight of Women with High Body Mass Index: A Cluster Randomized Trial. Journal of Midwifery and Reproductive Health. 2020; 10(4): 3462-3471. DOI: 10.22038/jmrh.2022.62386.1761

Introduction

Obesity and overweight is a health challenge. The rate of obesity is increasing in urban and industrial communities. The prevalence of overweight and obesity in women aged 15-49 years in Zimbabwe in 2020 was reported to be 34.2% and 12.3%, respectively (1). In the United States, the prevalence of adult female obesity in 2014 was 40.4% (2). Monfared et al. in 2016 reported the prevalence of overweight and obesity in Rasht women aged 20-50 years as 24.8% and 2.9%, respectively (3).

According to body mass index, people with BMI≥25 are considered as overweight and with BMI≥30 as obese. Various hormonal, genetic and

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environmental factors play a role in obesity (2, 5). But the most important factor is lifestyle and nutritional habits that cause an imbalance between energy consumption and intake and accumulation of fat in the body (5).

Obesity and overweight before pregnancy are associated with maternal overweight during pregnancy, high fetal weight at birth, increased blood pressure and preeclampsia during pregnancy, urinary tract infection, gestational diabetes, and abnormal fetal position. The incidence of these complications exposes women to more labor induction with oxytocin, perineal ruptures, cesarean section, and anesthesia, increasing maternal mortality and morbidity along with perinatal mortality (5, 6). Obesity is a risk factor for venous thromboembolism in pregnancy and postpartum (7). Maternal obesity is also a risk factor for neonatal macrosomia, obesity and cardiovascular disease, and type 2 diabetes of child in future (5). Prenatal obesity is associated with 13% reduction in breastfeeding and 20% reduction of milk production (8). Increased breast tissue and areoles with decreased areas where milk is stored are the mechanical factors affecting the reduction of milk in obese women (9).

Therefore, weight fitness of women in prenatal period is a basic strategy to promote the health of future generations (10). Prenatal period is the golden age for assessing the risk factors that can threaten future pregnancy. Therefore, weight control of women before pregnancy is one of the important factors in prenatal counseling care (11). Despite providing prenatal care, a relatively high percentage of women at childbearing age have weight more than normal. Salem et al. (2016) reported the rate of overweight and obesity as 37.5% in Rafsanjan (12).

Lifestyle changes (physical activity, dietary pattern), diet therapy, medication therapy, and surgery are the main treatments for obesity and overweight, which are used alone or in combination according to the individual's physical condition, comorbidities and BMI (13, 14). Performing surgery is limited to its specific indications and is not very popular due to complications such as pain, swelling, long-term recovery and long-term hospitalization problems, as well as the general risks of surgery. On the other hand, weight loss with drug treatments has less efficacy due to the possibility of complications such as cramps and bloating, fecal incontinence and decreased levels of some vitamins, without lifestyle modification, has little effectiveness (15). Lifestyle modification by changing diet and activity to lose weight requires sufficient awareness and motivation (16).

Witte extended parallel process model (1992) is one of the most important theoretical guidelines for transmitting health messages and causing ability to change high-risk health behaviors with two constructs of threat and efficacy. The construct of threat in this model consists of two components of perceived sensitivity and intensity. The construct of efficacy consists of variables of perceived effectiveness and self-efficacy of individuals at risks. According to the extended parallel process model, the fear caused by perceived risk motivates people to seek coping strategies with threat (perceived threat) and if people believe that they are at high risk of exposure to health, they will be more excited to cope with threat (perceived severity) and after adopting and choosing coping strategies, they will evaluate their performance (perceived self-efficacy) and strategies for coping (perceived effectiveness) (17, 18). Meadows et al. in 2020 evaluated the role of this model in promoting skin cancer prevention behaviors in university students in the southeast (18). Alwall and colleagues in 2018 did not report the threat after parallel process model training in preventive behaviors and health work safety (19).

Due to the contradiction of studies in the field of efficacy of the extended parallel process model and the appropriateness of the subject under study with this model and also the lack of valid scientific information on the effect of this model in changing nutritional and activity behaviors in obese and overweight patients, the present study was performed to determine the effect of training based on the extended parallel process model on weight in women with high BMI in Mashhad health centers.

Materials and Methods

This two-group cluster randomized trial was conducted in 2015 on 60 women who referred to the center No. 3 in Mashhad for prenatal

counseling. Sampling was performed by multistage sampling. First, for sampling among five health centers in Mashhad, the center No. 3 was selected due to cooperation and having more prenatal care units, and among its thirteen affiliated urban health centers, two centers were randomly selected through lottery by the first author and assigned to the two groups of intervention and control, so that the names of the affiliated centers were put in the bag, the first name drawn by the researcher was considered as the intervention group (Siloo Center) and the second center as the control group (Imam Reza Center). The eligible women referred to these two centers from Nov 22, 2015 to March 19, 2016 through convenience sampling and included in the study after explaining the objectives and signing written consent.

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 (s_1^2 + s_2^2)}{(\overline{X_1} - \overline{X_2})^2} = 25$$

$1-\beta = 0.84$	=20%= Type II error rate β
$1-\frac{a}{2}$=1.96	=0.05= Type I error rate α
$\overline{X_1}$ =10.2	Mean knowledge score after training in the control group
$\overline{X_2} = 12.4$	Mean score of knowledge after training in the experimental group
$S1 = 3.18$	Standard deviation of knowledge score after training in the control group
$S2 = 2.3$	Standard deviation of knowledge score after training in the experimental group

To calculate the sample size, a pilot study was performed on 10 women. Then, the sample size was determined by the formula of comparing the means based on the mean of knowledge and weight, separately. The highest estimate of the sample size was based on the knowledge variable, so it was considered as a basis, and with 95% confidence and 80% power, the sample size was estimated at least 25 people for each group; which was increased to 30 people in each group considering possible loss of 20%.

A total of 64 eligible women entered the study from whom four were excluded from the study (one due to pregnancy, one due to incomplete filling out the checklists at the baseline of the study and two due to non-referral during follow-up). Finally, the study was performed on 60 patients (30 in the intervention group and 30 in the control group).

Inclusion criteria were: childbearing age, minimum BMI 25, minimum literacy of reading and writing, no chronic diseases, no infertility and abortion. Exclusion criteria were pregnancy, not following the instructions or using anti-obese medications or drug affected appetite during the study period. Data collection tools were: demographic and obstetrics information questionnaire (including 13 questions about demographic information, number of pregnancies, number of children, tendency for pregnancy and satisfaction from current weight), researcher-made questionnaire based on extended parallel process model constructs, BPAQ, Stunkard Figure Rating Scale (FRS), and nutrition follow-up checklist. The content validity of the demographic and obstetrics questionnaire was confirmed by ten faculty members that was reliable due to its clear questions.

The questionnaire based on the constructs of the parallel process model was developed with 36 questions in relation to the two constructs. The construct of threat was the sum of the scores in two sections of perceived severity and sensitivity. Each section was scored with 12 questions on a five-point Likert scale and the score range was 0-24 (Strongly agree with score 2, agree with score 1.5, no opinion with score 1, disagree with score 0.5 and strongly disagree with score zero). The construct of efficacy was designed with a sum of perceived effectiveness and self-efficacy scores with 6 questions in each section and on a five-point Likert scale and was in the range of 0-24 (Strongly agree with score 4, agree with score 3, no opinion with score 2, disagree with score 1 and strongly disagree with score zero). The difference in efficacy scores from threat was calculated as a risk or fear control score, as in the study of Apanovitch (20). A positive or zero score (scores ranged 0 to +48) means that the person is in the risk control stage, and if the calculated number is negative, it means that the person is in the fear control stage (score ranged -1 to -48). The validity of this tool was determined by content validity and

its reliability was determined by Cronbach's alpha coefficient (alpha coefficient of perceived sensitivity 0.87, perceived intensity 0.81, perceived efficacy 0.90 and perceived self-efficacy 0.84).

Baecke Physical Activity Questionnaire (BPAQ) consisted of 16 questions that measure a person's physical activity with a five-point Likert scale[1]. The physical activity score of ≤2.40 means that the person is in the inactive group and a score of > 2.40 indicates that the person is in the active group. The validity of this questionnaire in Iran has also been confirmed by Etemad et al. (2012) (21). The reliability of this tool was calculated with Cronbach's alpha coefficient of 0.75.

Stunkard Figure Rating Scale (FRS indicated a person's mental perception of body shape in nine states. On this scale, Figure 1 shows the thinnest and Figure 9 shows the fattest person. It is a standard tool and its validity in Iran has been confirmed through simultaneous validity (22). The reliability of this tool in this study was calculated through Cronbach's alpha correlation coefficient of 0.75.

The Nutrition and Activity Follow-up Checklist also included 25 nutrition and physical activity guidelines in the latest edition of the Ministry of Health Integrated Care Booklet for prenatal counselling of women with high BMI. Its validity was confirmed by content validity and its reliability by Cronbach's alpha coefficient of 0.75.

[1] To calculate the total physical activity score, it was necessary to calculate the scores of the three sections of work index, exercise index and leisure. The worrk index was obtained by dividing the total scores obtained from eight questions from one to eight by eight. The exercise index was the sum of the scores obtained from four questions (9-12), which is divided by four. The leisure index was calculated by dividing the total scores obtained from four questions (16-13) by four. In this scale, the scoring of question 9 is that if the person negatively answers the question of the first part, the score is one and if positively answers, it is scored by the following formula: score 2 to 0.01 - <4, score 3 to 4 - <8, score 4 to 8 - <12 and score 5 to ≥12.

In the first session, all questionnaires were completed by both groups. For the experimental group, using the national nutrition guideline, two training sessions based on the model were held (the first author) for 45 to 60 minutes at two-day intervals. In the first session, according to the construct of threat, the prevalence of obesity and its prevalence in the society, especially women, the complications of obesity in the mother and fetus were expressed. The second training session focused on how to determine the nutritional share and recommendations of the prenatal nutrition care department based on the national nutrition guideline to change the diet and increase physical activity (according to the efficacy construct).

Training sessions were held using lectures and PowerPoint presentation (with emphasis on slides related to the complications of maternal obesity) and questions and answers. Finally, to increase women's perceived self-efficacy, they were given a checklist of nutrition and physical activity along with an explanation of how to complete it daily at home. They were asked to come to the next appointment (2 and 4 weeks later) with the completed checklists. Phone calls were made every three days to remind them to complete the form.

The control group, after receiving routine care and training by the staff, was given two checklists of nutrition and physical activity similar to the experimental group, and they were also asked to come to the next appointment with the completed checklists.

In this study, a German seca scale with an accuracy of 100 grams, which has scientific validity, was used for weighing. All weighings were performed by the researcher and women were weighed with minimal clothes without shoes.

Data were analyzed using SPSS statistics software (version 16). After performing Shapiro test, the normality of quantitative variables in the groups was checked. Accordingly, the homogeneity of the two groups was assessed in order to determine the intervening variables using independent t-test or Mann-Whitney test, and for qualitative variables, Chi-square test was used. Then, analysis of variance with repeated measures was performed after

considering the Sphericity test and homogeneity of variances and considering the variable of response before the intervention as covariate. Due to the lack of interaction effect between the group and the time, interaction effect was not considered in the models. In all tests, P<0.05 was considered statistically significant. This reseach was approved by the regional ethics committee of Mashhad University of Medical Sciences with the ethic code IR.MUMS.REC.1394.543

Results

The mean age of the subjects in the experimental group was 31.37±4.5 years and in the control group was 30±4.9 years. The majority of subjects had a diploma education and were consistent in terms of demographic and fertility characteristics and BMI (P>0.05). About 46.6% (n=28) of participants considered their weight less than reality and there was no significant difference between the two groups in this regard and the majority in both groups were dissatisfied with their weight (Table 1).

Table 1. Frequency of some demographic and fertility characteristics of the participants in the two groups

Variables	Experimental group (n=30) N (%)	Control group (n=30) N (%)	Test result
BMI			
25-29.9	16(53.3)	15(50.0)	Chi-square
30-34.9	14(46.7)	14(44.7)	X2=12.4
35-40	0(0.0)	1(3.3)	df=6,P>0/05
Body image			
Correct perception of equal as reality	17(59.7)	12(40)	
False perception of less than reality	13(43.3)	15(50)	Chi-square P=0.12
False perception of more than reality	0(0)	3(10)	
Satisfaction of weight			
No satisfied	5(16.7)	12(40)	
Low satisfied	20(66.7)	12(40)	Mann-Whitney Z=-1.1 P=0.25
No difference	4(13.3)	3(10)	
Relatively satisfied	1(3.3)	3(10)	

All women (100%) in the experimental group and 26 (86.7%) in the control group tended to lose weight. The results of Chi-square test showed no significant difference between the two groups in terms of tendency to lose weight (P=0.11). Also, the results of independent t-test showed that there was no statistically significant difference between the two groups in terms of mean score of threat construct and the two groups were homogeneous in terms of this variable at the beginning of the study (P=0.66). But, Mann-Whitney test showed that threat score changes before and two weeks later (P=0.001) and before and four weeks after the intervention (P=0.01) was significant in the experimental group compared to the control. The results of independent t-test showed that before the intervention, the two groups were homogeneous in terms of mean efficacy score (P=0.51). According to the results of independent t-test, the difference in mean efficacy score before and two weeks later (P=0.55) in the experimental group was not significantly different from the control group; also the efficacy changes before and four weeks later (P=0.73) in the experimental group was not significantly different from the control group.

Also, the mean weight loss after one month was 860 g in the experimental group (540 g in the first two weeks of the intervention and 320 g in the next two weeks) and 490 g in the control group (400 g in the first two weeks and 90 g in the next two weeks). However, this

difference was not statistically significant, but there was a statistically significant difference between the mean weight before and after the intervention in both groups (Table 2).

Table 2. Mean weight of subjects before, two and four weeks after the intervention in the experimental and control groups

Variable	Experimental group (N=30) Mean±SD	Control group (N=30) Mean±SD	Independent t-test results
Weight (kg)			
Before intervention	74.06 ± 8.7	72.76 ± 10.36	P= 0.43 t=0.52
Two weeks after intervention	73.51 ± 8.49	72.36 ± 10.24	P= 0.63 t=0.47
Four weeks after intervention	73.19± 8.02	72.27 ± 10.55	P= 0.70 t=0.38
Weight mean difference before and two weeks after intervention	-0.54±0.97	-0.40 ± 0.93	P= 0.55 t=-0.59
Weight mean difference before and four weeks after intervention	- 0.86±1.38	-0.49 ±1.32	P= 0.29 t=-1.04
Paired t-test result Before with two weeks later	P= 0.005 t=3.05	P= 0.026 t=2.34	
Paired t-test result Before with four weeks later	P= 0.002 t=3.40	P= 0.051 t=2.04	

Table 3. Comparison of weight changes, threat and efficacy constructs of subjects two and four weeks after the intervention in the experimental and control groups based on the results of repeated measures analysis of variance and controlling the values before the intervention

Variable	Mean changes (Model coefficient)	Standard error	T	P-value
Weight changes				
Two weeks after intervention				
Experimental group	-0.11	0.24	-0.48	0.62
Control group a	-	-	-	-
Four weeks after intervention				
Experimental group	-0.32	0.34	-0.94	0.34
Control group a	-	-	-	-
Two weeks after intervention				
Threat construct **changes**				
Experimental group	4.84	1.58	3.05	0.003
Control group a	-	-	-	-
Four weeks after intervention				
Experimental group	3.59	1.56	2.29	0.02
Control group a	-	-	-	-
Two weeks after intervention				
Efficacy changes				
Experimental group	2.10	1.31	1.60	0.11
Control group a	-	-	-	-
Four weeks after intervention				
Experimental group	0.67	1.21	0.55	0.58
Control group a	-	-	-	-

[a] The control group is considered as the basis

The results of repeated measure analysis and controlling the values before the intervention showed that the mean changes of threat construct before and two weeks after the intervention increased by 4.84 units in the experimental group compared to the control

group and also before and four weeks after the intervention increased by 3.59 units in the experimental group compared to the control group which was statistically significant.

Also, the mean changes of efficacy construct before and two weeks after the intervention increased by 2.10 units in the experimental group compared to the control group and also before and four weeks after the intervention increased by 0.67 units in the experimental group compared to the control group, the changes were statistically significant (Table 3).

Table 3 showed that the changes in mean weight before and two weeks after the intervention in the experimental group decreased by 0.11 units more than the control group. Also, changes in mean weight before and four weeks after the intervention in the experimental group decreased by 0.32 units more than the control group. However, these changes were not statistically significant.

Also, the results of repeated measures analysis of variance showed that the group variable had a significant effect on the total physical activity in the post-test, so that the mean of total physical activity was significantly different in the experimental group compared to the control group.

(Group effect, P=0.04, interaction effect, P=0.75, time effect, P=0.25)

Discussion

The present study is the first study which investigated the effect of extended parallel process model on prenatal weight of women with high BMI. The results showed that women with high BMI have more perceived threat of overweight for future pregnancy than the group which received recommended care without using the extended parallel process model. Regarding the effect of model efficacy on weight loss, although these differences were not statistically significant, but weight loss during one month in the experimental group was almost twice as much as the control group (860 vs. 490 g).

In the study of Peyman et al. (2012), the effect of self-efficacy-based training in promoting nutritional behaviors and weight control was investigated on 78 obese and overweight girls aged 12-16 years in Hamedan, through four-session face-to-face training and 12 weeks of follow-up. There was no significant change in weight and BMI in the experimental group compared to the control group (24). Their result is consistent with the results of the present study. But the lifestyle change training program conducted by Jordan et al. (2006) on 114 white Hispanic and American women resulted in weight loss of 2.7 kg in the experimental group after two months of practical nutrition classes and lectures. While the control group gained weight (24). Practical intervention training and the difference in the duration of the intervention are the possible causes of difference between the Jordan's study and the present study. In addition, other factors such as the interest of caregivers and patients is proposed in the effectiveness of weight loss training (3,25). Therefore, mothers' interest in having a normal delivery and a healthy child, in the present study, mothers in the control group also had sufficient motivation to change their lifestyle. Therefore, receiving the usual training of health care providers could be effective in changing their nutritional and activity patterns. In the present study, 100% of the intervention group and more than 80% of the control group expressed their desire to lose weight. Therefore, both groups of participants lost weight after receiving training in health centers, and despite more weight loss in the experimental group, weight changes were not significant between the two groups. Expressing the threats of obesity in the group of training based on extended parallel process model can justify more weight loss of the experimental group, but it is necessary to assess the effect of longer implementation of the training program of the parallel parallel process by strengthening the perceived efficacy of overweight and obesity risks on weight changes in overweight and obese women in order to conclude on the effectiveness of this model in achieving a reasonable weight loss process in accordance with the American Diabetes Association (one to two pounds per week) (26).

According to the finding of the present study, education based on the extended parallel process model increased the perceived threat in overweight women before pregnancy. Showing images of possible complications of mother and fetus following maternal obesity by PowerPoint

and motivating fear in them seems to increase the perceived sensitivity and severity in overweight mothers before pregnancy and as a result increased perceived threat. So that, perceived threat before and after the intervention was significantly increased in the experimental group compared to the control group. The highest perceived threat was reported at the beginning of the program, i.e the first two weeks after training. Shi et al. (2016) reported that increased perceived threat will lead to increase in melanoma preventive behaviors if threatening messages be repeated at least three times (27).

However, the results of the present study showed that the women's effeciency of the risks of overweight before pregnancy didn't change in two and four weeks after the intervention in the experimental group compared to the control group. The results of the study by Peyman et al. (2012) on the effect of self-efficacy-based education in promoting nutritional behaviors and weight control on 78 obese and overweight girls aged 12-16 years (23) are not consistent with the results of this study. So that, after performing four sessions of educational intervention for adolescent girls in Hamedan, self-efficacy increased in the experimental group compared to the control group. The reasons for the inconsistency of this study with the present study can be more sessions and the presence of the mother in educational sessions to make changes in the nutritional behavioral behaviors of the family. Self-efficacy is the main and important precondition for behavior change, including health behaviors, but in the early stages with (self-conviction) and with the belief that (I think), (I can) does not grow and develop, but forms as a result of enduring challenges, especially doing works, consecutive and consistent support and the pursuit of realistic plans (28).

It seems that the participants in the present study, after being in the real situation and practically monitoring their diet and activities, found that their ability to change their lifestyle is less than they expected, and perhaps the presence of a sponsor, especially the spouse in these sessions, in terms of cooperation, could facilitate the change in women's diet and lifestyle, which should be paid more attention in other nutritional studies. More practical strategies in obesity management are recommended in future studies to improve participanta self-efficacy.

One of the findings of this study was incorrect body image in almost half of the participants so that they considered their weight less than reality (43.3% of the experimental group and 50% of the control group). In the study of Okeh et al. in 2015, only 29.7% of obese women described their weight as real, and 73.7% of overweight patients didn't have a correct perception of their weight and thought their weight as normal. Incorrect perception of weight and body shape can cause women to neglect their condition and health, because the person has no reason to lose weight (29).

One of the strengths of the present study was that the questionnaire based on parallel process model was designed for the first time. One of the limitations of this study was the accuracy of the statements and reports of the subjects about the amount of physical activity and observance of the points inside the nutrition checklist that was beyond the researcher's control.

Training based on extended parallel process model can be used to increase women's sensitivity to nutritional style before pregnancy. It is recommended to perform longer and more practical studies to investigate the effect of this model on individual efficacy in controlling weight.

Conclusion

The results of the present study showed that training based on extended parallel process model increase the perceived threat of overweight risks before pregnancy in women with high BMI. However, increasing the perceived threat will not be effective in achieving the appropriate weight if the perceived efficacy of the person is not increased.

Acknowledgements

This article is part of the master thesis of the first author (code: 940697), which has been done with the financial support of the Vice Chancellor for Research of Mashhad University of Medical Sciences with the RCT registration number of IRCT2015122325668N1. We would like to thank the managers and staff of Health

Center No. 3 in Mashhad who cooperated with the researcher for sampling.

Conflicts of interest

Authors declared no conflicts of interest.

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