

The Effect of Weight Loss Program on Overweight and Obese Females Based on Protection Motivation Theory: A Randomized Control Trial

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Abstract

Background: It is especially true that prevalence of overweight and obesity is increasing worldwide and it is probably because of changes in diet and physical behavior pattern.

Objectives: The current study aimed to test the effect of weight loss program on overweight and obese females based on protection motivation theory.

Methods: A randomized clinical trial (RCT) was implemented in the form of single blind. In total, 150 females with overweight and obesity were randomly divided into three groups including: 1, standard program group; 2, motivation interviewing (MI) group and; 3, motivation interviewing (MI) and intention intervention (II) condition (50 subjects in each group). They participated in a randomized clinical trial, also attended a private nutrition clinic in Gorgan city (Golestan province, North of Iran) for the first time. A researcher-made questionnaire and participant's sheets (including three days food recall and anthropometric traits) were used to collect data. Data were analyzed using SPSS (ver.11) and statistical tests including Kruskal-Wallis, One-way ANOVA, Friedman test, Tukey test, Paired T-test and linear regression model were employed.

Results: The mean age of females was 38.45 ± 9.49 years, most of them had academic degree 46.7% (n = 70), 78.7% (n = 118) were married and 60.7% (n = 91) were housewives. ANOVA repeated measure test showed that daily energy intake decreased two (P = 0.001) and six months (P = 0.001), weight (P = 0.007) and body mass index (BMI) (0.005) after intervention. Threat appraisal statistically differed six months after intervention (P = 0.001).

Conclusions: Motivational interviewing resulted in decreased daily energy intake, anthropometric characteristics as well as augmented scores of coping and threat appraisal.

Keywords: Motivational Interviewing, Weight Reduction Programs, Psychological Theory, Humans

1. Background

Obesity is particularly prevalent in Iranian females (1) and also causes one of the most common public health problems worldwide (2). It is well known that overweight and obesity are the risk factors for several diseases (3); in the Middle-east region, the burden of obesity and overweight falls disproportionately on females (4). Based on the world health organization (WHO) reports, about 300 million people are involved with obesity worldwide (5). Iranian Ministry of Health announced that 35 % of total mortality rate is caused by coronary heart disease (CHD) (1). Iran is also exposed to this public health problem and obesity prevalence is 22.3% (6). Females face greater risk of overweight and obesity than males (7, 8) and they might be involved in problems such as hypertension during pregnancy, diabetes, thromboembolism (6, 9-12), and

cervical, breast and colon cancers (13). According to the numerous studies, clinic-based interventions through face-to-face method in the form of weekly visits are well-known as a beneficial weight loss program (14, 15).

Motivation interviewing (MI) is known as a collaborative, individual based form to aspirate and fortify motivation for change (16). MI is immensely used in the health field with efficient results (17). The number of MI scientific publications has approximately doubled over the three years (18). MI is beneficially executed to a range of dietary change (19). Practical approaches rarely support professionals and clients to change (20). Treatment of health problems using traditional process is not sought (21); for instance, according to traditional treatment process, only 30% of hypertension patients are controlled (22) and only 25% of subjects, 18 months after intervention, had achieved

to lose weight (23). Although, some conflicts existed in the way that some surveys reported more efficacy in MI than traditional change behavior (24-26), some other studies on MI showed similar results in the two methods (19, 25, 27). Despite the creativity of the MI and the prevalence of overweight and obesity as a chronic problem, there are a few studies in Iran on lifestyle related health problems and MI attractiveness (21).

The protection motivation theory (PMT), developed by Rogers et al., demonstrates that people may be motivated to change behavior if associated with a threat (28). PMT includes six constructs in the form of two processes named coping and threat appraisal that their total score formed final motivation, which was considered as the current study aim. No surveys adequately noticed MI effectiveness on overweight and obesity based on PMT in Iran. Authors assume that since this theory is an eligible predictor of dietary (29) and physical activity (30), it seems likely to be an eligible predictor of persons with overweight and obesity. In addition, it is assumed that a person's intention presents a precursor to behavior that exists in several models including PMT; therefore, with regards to several studies (31, 32), II can elevate the chance of behavior modification.

2. Objectives

The current study aimed to examine whether the addition of MI, and MI and II to a standard education can promote females to weight loss program.

3. Methods

3.1. Study Design

A single-blind randomized clinical trial (RCT) study was conducted from September 2013 to July 2014 in Gorgan, Iran (registration No.: IRCT2014051817736N1). Females admitted to the nutrition clinic for the first time (eligible based on BMI range as overweight and obese) were selected by convenient sampling; then, to control selection bias, block random allocation with 25 blocks sized six persons for each block repeating twice the words of A, B and C were used. Blocks number selecting was conducted randomly by statistical package for the social science (SPSS) version 18, and afterward the subjects were randomly allocated into three groups: 1, MI group (50 subjects); 2, MI and II group (50 subjects) and control group (50 subjects). To blind participant's assignment, blocks size was not announced. All participants were selected from a private nutrition clinic and not referred from other clinics or health centers; they were personally admitted for the first time.

Each session included 7 to 10 participants. In MI with II group, females were not only provided with MI but they also received a weight loss program based on the defined schedule named intention implementation. Participants were finally followed-up two and six months after interventions in terms of PMT constructs anthropometrics characteristics and daily energy intakes.

3.2. Control Group

Nutritional education was delivered (in total, four sessions in two weeks, two sessions per week, and 45 to 60 minutes per session) regarding diet, daily energy intake and weight loss methods by a nutritionist and a health education specialist. At the end of the sessions, researchers provided answers if required. It should be noted that all participants received the same group-based education; moreover, subjects in all groups were given a nutritional brochure and pamphlet; developed based on Protection Motivation Theory constructs.

3.3. Experimental Groups

3.3.1. Motivational Interviewing Group

MI consisted of five sessions of approximately 45 to 60 minutes performed by a psychologist for 7 to 10 subjects each session, held in two weeks. Motivation interviewing sessions were developed considering the five session group motivation interviewing (33); although, the optional number of MI sessions did not recorded (16, 34).

3.3.2. Motivational Interviewing and Intention Implementation Group

This group received all intervention exactly like the two aforementioned groups, besides; they were provided a detailed timeline as follows:

Firstly, the subjects were told that if they pursue a definite diet schedule it is more likely to perform and commit to an accurate dietary program; secondly, participants were asked to write this sentence I will try to lose 1 kg weight, consume 3 to 4 and 4 to 5 portions of fruits and vegetables, respectively, and also reduce fatty foods as recommended by guidelines, in the next two weeks.

3.4. Participants

Inclusion criteria were as follow: 1, BMI 25 to 29.9 (overweight) and 30 to 35 (obese); 2, lack of diseases including cardiovascular, thyroid, diabetes and consuming drugs that may consequently interfere with appetite and weight; 3, inclined to participate in the study and; 4, being literate. Exclusion criteria were also as follow: 1, being pregnant; 2, diet disruptive diseases during the study; 3, inability to exercise and; 4, absence more than two sessions (control and

MI). Totally, 50 eligible participants (for each group) were included; furthermore, two subjects in the MI group were excluded due to absence of more than two sessions that were replaced by newly arrived subjects. Totally, 214 participants were excluded from the control (2), MI (6) and II (6) groups with six-month follow-up, respectively.

3.5. Sample Size

Based on a similar investigation (35) three participating groups each of 50 subjects were planned, (totally 150 females) and considering two units change in mean and standard deviation as 2.4 and 2.34, %90 test power, %95 confidence interval (CI) and also %25 attrition of samples.

Equation 1.

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 \times (S_1^2 + S_2^2)}{(y_1 - y_2)^2} \quad (1)$$

3.6. Measures

To conduct the study, three measures were used including interview by a psychologist and a health education specialist, a structured and researcher-made questionnaire based on PMT, participant's sheets (anthropometrics characteristics and three days dietary recalls). Anthropometrics characteristics were also recorded by nutritionist and, in brief, three days intake nutrition sheets were completed by the subjects.

3.7. Variables Definition

Overweight and obesity were categorized based on the general WHO criterion as $25 \leq \text{BMI} < 30$ for overweight and $\text{BMI} \geq 30$ for obesity (2). Subjects' educational levels were as follows: 1, elementary school; 2, middle school; 3, high school and; 4, academy. Marital status was also classified as single and married. Subjects' current jobs were classified into housewife, farmer, retired, unemployed and others.

3.8. Instrument

Participant sheets were used including anthropometric characteristics (consisted of BMI, weight, waist circumference and waist to hip ratio) and three days dietary recall (36, 37). A researcher-made questionnaire based on PMT was developed including eight parts: A, demographic characteristics; B, perceived self-efficacy (11 questions with 10 items scale which are given scores 1 - 10, ranged 11 to 110); C, intention (11 questions ranged 11 to 44); D, perceived susceptibility (9 questions ranged 9 to 36); E, perceived severity (4 questions ranged 4 to 16); F, perceived rewards (8 questions ranged 8 to 32); G, perceived response efficacy (8 questions ranged 8 to 32) and; H, perceived costs (12 questions ranged 12 to 48). Questions such as intention,

perceived susceptibility, perceived severity, perceived rewards, perceived response efficacy and, in brief, perceived costs all scored 1 to 4 based on four-point Likert scale including completely agree, agree, disagree and completely disagree. According to the searched studies, related questionnaire was not found; then, a researcher-made questionnaire was developed using literature review and considering face and content validity process recommended by Lawshe (38). To assess validity, face validity was surveyed by five specialists for 93 questions that six of them were deleted in this stage, and content validity was studied by ten specialists for the remained 87 items (according to Lawshe tabulation, 0.62 is acceptable for each item to remain in the questionnaire). In this phase, content validity rate (CVR) was investigated (with regards to items including necessary, necessary but non-essential, non-necessary) that six items were deleted, in the final stage, content validity index (CVI) was calculated (regarding simplicity, clarity and relevance) that no questions were deleted and all 81 items were finally considered (0.79 value is acceptable for each item). Internal homogeneity and Cronbach' alpha were applied to assess the reliability of the questionnaire and the values of these coefficients were also calculated for all structures. The alphas were ranked strongest and weakest as perceived self-efficacy (0.91), and perceived susceptibility (0.72). The obtained results were 0.87, 0.82, 0.85, 0.88 and 0.89 for perceived severity, perceived costs, intention, perceived response efficacy, perceived rewards, respectively.

3.9. Data Analysis

To describe mean and standard deviation of anthropometric and demographic characteristics, the descriptive methods were applied. Since all three groups were different at baseline in terms of constructs, then, the score of post-intervention was subtracted from baseline score for each construct and variables including knowledge, intention, perceived susceptibility, perceived severity, perceived costs, perceived rewards, perceived response efficacy and perceived self-efficacy and finally the scores were used to compare groups. Furthermore; Kolmogorov-Smirnov test showed that the distributions of scores were not normal; then, Kruskal-Wallis test was used to compare constructs of all groups. To test daily energy intake, nutritionist version 4 (N4) and ANOVA repeated measure were used. To compare anthropometrics characteristics, paired T-test was employed at baseline and two- and six-month follow-up. To predict construct effects on intention, after controlling other constructs, multiple linear regression model was used. Missing values of questions were replaced by the median. P-value < 0.05 was considered significant.

3.10. Ethical Issues

Informed consent letters were obtained from subjects. Subjects could voluntarily stop cooperation at each stage of the study. The current study was approved by the ethics committee of health education and promotion department of Isfahan University of Medical Sciences.

4. Results

4.1. Participants

One hundred-fifty females with overweight and obesity were recruited and randomly divided into three groups each of 50 in control, MI, and MI and II. The means of the groups and demographic traits are presented in [Table 1](#). Females mean age was 38.45 ± 9.49 years ranged from 19 to 67. The mean of BMI was 28.7 ± 2 at baseline. Most of the subjects had academic degree 46.7% ($n = 70$), 78.7% ($n = 118$) were married and 60.7% ($n = 91$) were housewives. Normality test showed that the three groups did not differ on daily energy intake, BMI and weight at the baseline. However, they were different in all PMT constructs and two anthropometrics characteristics including waist circumference and waist to hip ratio.

With regards to [Table 2](#), ANOVA repeated measure illustrated that daily energy intake decreased two and six months after intervention ($P = 0.001$). Greenhouse-Geisser assumption also demonstrated that intervention resulted in 16% decrease in the aforementioned variables. Tukey test found difference between control group and two intervention groups ($P = 0.001$); two intervention studies had similar results ($P = 0.533$).

According to [Table 3](#), ANOVA repeated measure test showed that weight ($P = 0.007$) and BMI ($P = 0.005$) were significantly different two and six months after intervention; moreover, Greenhouse-Geisser assumption demonstrated that intervention caused 7% of weight and BMI loss. Friedman test reported that waist circumference and waist to hip ratio also decreased meaningfully in two- ($P = 0.001$) and six-month ($P = 0.001$) follow-up. The median and IQR of circumference were 84 and 11 and waist to hip ratio were 81 and 0.07, respectively. Tukey test found differences between control and MI ($P < 0.038$) and II groups ($P < 0.004$). BMI was also different among the three groups, which Tukey test showed difference between control and MI group ($P < 0.003$).

The scores of coping appraisal (self-efficacy + perceived cost-response efficacy) and threat appraisal (perceived severity + perceived susceptibility-perceived rewards) increased in two- and six-month follow-up in all three groups; although they decreased in six months they were higher than the baseline. Paired t-test showed that

coping ($P = 0.683$) and threat ($P = 0.312$) appraisals did not differ two months after intervention, intervention did not reduce daily energy intake either ($P = 0.285$); of course, coping appraisal was not also different in six-month follow-up ($P = 0.075$); while, threat appraisal ($P = 0.001$) and intervention ($P = 0.001$) were statistically different six months after intervention.

[Table 4](#) shows all constructs of females PMT predicted intention when entered the model, separately; while, after adjustment, three of them were significantly predicted subject's intention including perceived self-efficacy ($P = 0.001$), perceived response efficacy ($P = 0.001$) and perceived rewards ($P = 0.022$).

5. Discussion

5.1. Effectiveness of MI Compared to that of Standard Education in Wight Loss

The current study aimed to assess the effect of MI and MI with II on weight loss and anthropometrics traits, and explore two appraisal processes of PMT and its prediction about females intention.

According to the current study findings, daily energy intake did not differ at the baseline across all three groups; while, it reduced more in the two intervention groups compared to that of the control group. However, subjects in the control condition also lost weight that it is not surprising because they were also provided by standard nutritional education. In the study by West *et al.*, subjects in both control and MI groups lost weight significantly, while females in MI group had lost notably more weight than the control subjects and MI had resulted in more stable outcomes compared to the standard program (39). In the study by Saffari *et al.*, using MI technique, presented more efficacy in MI group than the control on reduction of BMI, weight, total fat and increased consumption of fruits and vegetables (40). Of course, in the study by Saffari, contrary to the current study, subjects were not followed-up, while MI effectiveness was more in the current study six-month follow-up. Participants in the study by Graff Low *et al.* lost weight more significantly in MI condition after three months compared to the control group (41). All aforementioned studies are in accordance with the current study. Befort *et al.* failed to improve outcomes of a behavioral weight loss program (19), which was not similar to the current study findings, it might be likely caused by different types of MI, because in the current study all sessions were done in the form of group-based while in Befort's study MI session had two forms (in-person and by phone). In a meta-analysis by Burke *et al.*, MI was equivalent to other treatments and yielded moderate effects (25);

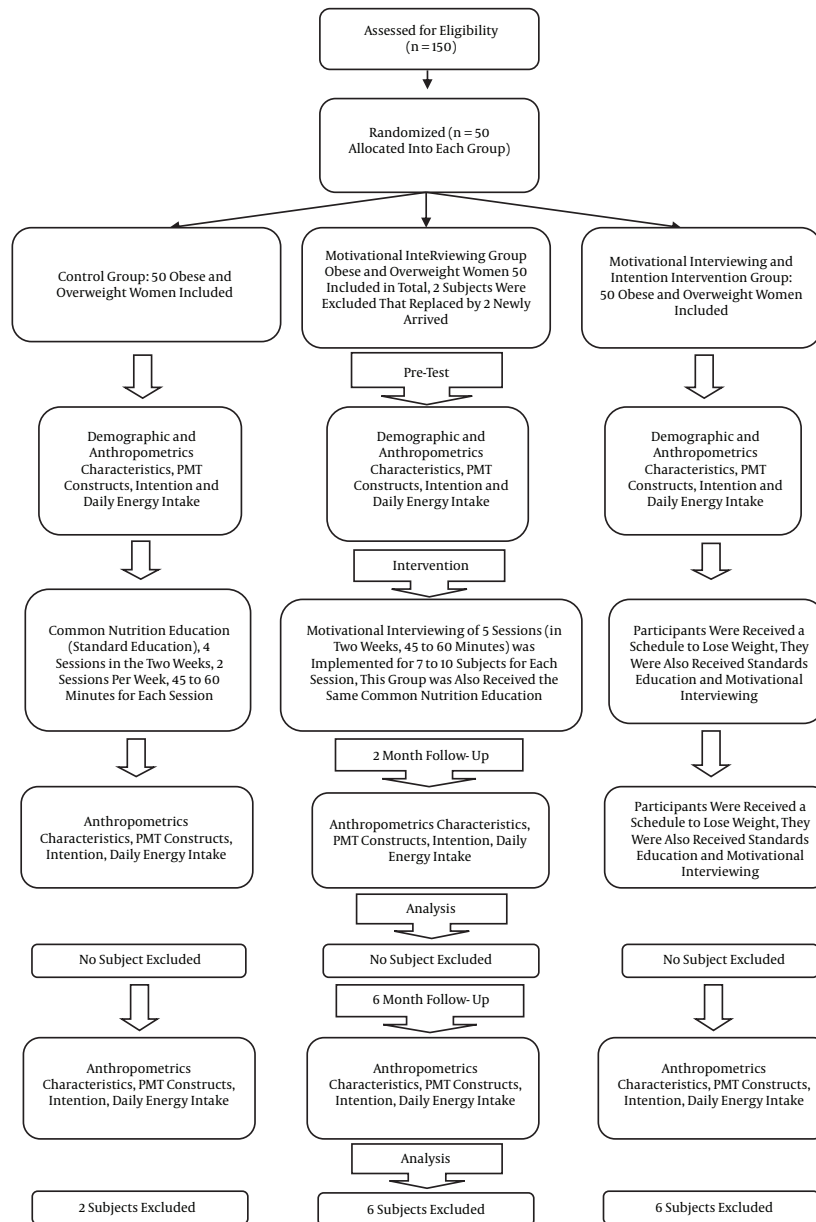


Figure 1. Flow Chart of Randomized Clinical Trial

it seems likely that scholars focused on assessing the extent to which MI can be beneficial with numerous subjects than in constructing definite designs. In most of these studies, intervention procedures were not clearly illustrated, standardized or used similar training techniques.

5.2. Effectiveness of MI Compared to II Concerning Anthropometric Characteristics

The current study delineated that MI and II did not differ and both of them lead to the same level of weight loss. The study by Prestwich et al. revealed that combining MI and II was more effective to decrease saturated fat than MI (32) which might be caused by new techniques applied in their study named reasons for II. Milne et al. showed that conducting MI with II resulted in more engagement

Table 1. Means and Demographic Characteristics at the Baseline^a

Variables	Motivation Interviewing Group (n = 50)	Motivation-Intention Group (n = 50)	Control Group (n = 50)	P-Value
Age, Mean ± SD	37.9 ± 8.9	39.5 ± 10.3	37.9 ± 9.1	0.62
BMI, Mean ± SD	28.2 ± 2.23	29.01 ± 2.09	28.8 ± 1.59	0.12
Weight, Mean ± SD	74.2 ± 6.95	77.34 ± 6.89	75.9 ± 6.05	0.07
Height, Mean ± SD	162.1 ± 7.17	163.1 ± 5.54	162.2 ± 6.23	0.67
Waist circumference, Mean ± SD	80.36 ± 6.98	84.52 ± 9.84	89.02 ± 10.77	0.001
Waist to hip ratio, Mean ± SD	0.81 ± 0.045	0.80 ± 0.042	0.78 ± 0.049	0.004
Education				0.36
Elementary school	4 (8)	-	2 (4)	
Middle school	5 (10)	8 (16)	5 (10)	
High school	15 (30)	20 (40)	21 (42)	
Academic	26 (52)	22 (44)	22 (44)	
Job				0.73
Housewife	31 (62)	31 (62)	29 (58)	
Retired	2 (4)	4 (8)	2 (4)	
Unemployed	11 (22)	6 (12)	9 (18)	
Other	6 (12)	9 (18)	10 (20)	
Marital status				0.75
Single	11 (22)	9 (18)	12 (24)	
Married	39 (78)	41 (82)	38 (76)	

Abbreviation: BMI, body mass index.

^aValues are expressed as No. (%) unless otherwise indicated.**Table 2.** The Mean of Daily Energy Intake in Females at the Baseline, Two and Six-Month Follow-up

Variables	Group	Intervention	N	Mean	Std. Deviation	P-Value
Daily Energy Intake	Control	Baseline	50	2471	35.61	0.001
		Two-month follow-up	50	2218	2849	
		Six-month follow-up	48	2157	20.82	
	Motivational interviewing	Baseline	50	2427	46.14	
		Two-month follow-up	50	2115	2871	
		Six-month follow-up	44	1178	23.30	
	Motivational interviewing and implementation intention	Baseline	50	2466	38.63	
		Two-month follow-up	50	1992	26.44	
		Six-month follow-up	44	1661	18.60	

of the subjects in exercise behavior (42) that is not compatible with the current study findings that can be due to two different factors, because Milne studied exercise and conducted follow-up just for one month compared to six months and nutrition pattern in the current survey. In a meta-analysis implemented by Barnes et al. (43), 24 studies were included, 54.2% represented MI resulted in 5% loss

of initial body weight that is similar to the current study results with 7% of weight lost.

5.3. The Effect of Coping and Threat Appraisal on Daily Energy Intake

In the current study, threat appraisal just decreased daily energy intake that is not in accordance with that

Table 3. Anthropometrics Traits of Participants at Baseline, Two- and Six-Month Follow-up

Variables	Group	Intervention	N	Mean	Std. Deviation	P-Value
BMI, kg/m ²	Control	Baseline	50	28.90	1.59	0.953
		Two-month follow-up	50	28.50	2.56	
		Six-month follow-up	48	28.68	2.53	
	Motivational interviewing	Baseline	50	28.27	2.19	0.001
		Two-month follow-up	50	27.13	2.20	
		Six-month follow-up	44	26.53	2.17	
	Motivational interviewing and implementation intention	Baseline	50	29.15	2.04	0.001
		Two-month follow-up	50	28.19	2.53	
		Six-month follow-up	44	27.46	2.54	
Weight, kg	Control	Baseline	50	75.81	6.15	0.027
		Two-month follow-up	50	74.57	6.14	
		six-month follow-up	48	75.07	6.28	
	Motivational interviewing	Baseline	50	74.80	6.94	0.001
		Two-month follow-up	50	71.69	5.59	
		Six-month follow-up	44	70.10	5.60	
	Motivational interviewing and implementation intention	Baseline	50	77.68	6.76	0.001
		Two-month follow-up	50	74.94	5.95	
		Six-month follow-up	44	72.98	5.63	

Table 4. The Effectiveness of Coping and Threat Appraisals on Daily Energy Intake in Two- and Six-Month Follow-up

Study Time	Model	Unadjusted Coefficient		Adjusted Coefficient β	t	P-Value
		β	Standardd-Error			
Two-month follow-up, the mean difference of two-month follow-up and baseline	Constant	-131.709	82.839		-1.590	0.114
	Coping appraisal	-0.818	2.001	-0.58	-.0409	0.683
	Threat appraisal	-1.911	1.884	-0.086	-1.014	0.312
	Intervention	-70.211	65.480	-0.154	-1.072	0.285
Six-month follow-up, the mean difference of six-month follow-up and baseline	Constant	-65.551	88.122		-0.744	0.458
	Coping appraisal	2.437	1.357	0.181	1.795	0.075
	Threat appraisal	-8.618	2.519	-0.299	-3.421	0.001
	Intervention	-234.236	46.829	-0.452	-5.002	0.001

of meta-analysis by Milne et al. that showed coping appraisal affected the attitude or behavior more strongly than threat appraisal (29). In a cross-sectional study by Baghianimoghaddam et al., both appraisals predicted protection motivation and threat appraisal was stronger (44); which was similar to the results of the current investigation. In a meta-analytic review conducted by Miler et al. threat appraisal was highly augmented after intervention (45). According to the current study results, threat appraisal just resulted in decreased energy intake per day af-

ter six months that may likely posit the long term effect of MI. It should be noted that MI and II in the current study increased all scores of PMT constructs two and six months after intervention.

5.4. Predicting Intention Based on PMT Constructs

At first, all PMT constructs were transferred to the regression model, using backward regression model, separately. All constructs had a significant relationship with intention, secondly; using adjusting model, three constructs

Table 5. Predicting Intention of Females Based on Protection Motivation Theory Constructs Using Adjusted and Unadjusted Regression Model

Construct	Unadjusted		Adjusted	
	β	P-Value	β	P-Value
Perceived Cost	-0.17	0.036	-0.073	0.167
Perceived Response efficacy	0.88	0.001	0.283	0.001
Perceived Self-efficacy	0.70	0.001	0.653	0.001
Perceived Rewards	-0.26	0.001	-0.124	0.022
Perceived Susceptibility	0.27	0.001	0.033	0.557
Perceived Severity	0.41	0.001	0.094	0.106

were ranked based on strongest to the weakest including self-efficacy ($\beta = 0.65$), perceived response efficacy ($\beta = 0.28$) and perceived reward ($\beta = -0.12$). The study by Park, investigating functional food consumption behavior, showed that self-efficacy and perceived response efficacy were significant predictors of intention (46) that was similar to the current study findings; in addition, severity and vulnerability were not significant predictors of intention; confirming the current study results, while differing from those of other studies (47-49). The non-significant relationship of other PMT constructs with intention may be caused by the variety of subjects. For instance, females are significantly persuaded by subjective norms (family or friends) in the current study, and then it is not surprising that rewards are significant. Furthermore, the mean age of the current study subjects was 38.45 years who may have lower tendency to care about their health due to fewer health problems, then low effects of severity and susceptibility can be predictable.

5.5. The Weak and Strong Points of Study

The current study mainly investigated adults, but it seems more necessary to study overweight and obesity in children and teenagers due to the vital role of health problem prevention at this age; moreover, only females were studied that might limit the findings generalizability beyond this participants. In addition, the current study strong points can be named as follows: 1, there are a few studies to change behavior using motivational interviewing; 2, the investigation was randomized clinical trial; 3, samples were followed-up for six months; and 4, adequate sample size was estimated, as well.

MI increased scores of coping and threat appraisals of PMT, decreased daily energy intake, and consequently weight, BMI, waist circumference and waist to hip ratio. However, unlike other studies, combined MI and II showed no different results; therefore more studies are recommended.

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Footnotes

Authors' Contribution: Study concept and design, Firoozeh Mostafavi and Kamal Mirkarimi; acquisition of data, Rahman Berdi Ozouni-Davaji; analysis and interpretation of data: Mohammad Ali Vakili and Kamal Mirkarimi; drafting of the manuscript, Firoozeh Mostafavi and Kamal Mirkarimi; critical revision of the manuscript for important intellectual content, Firoozeh Mostafavi; statistical analysis, Mohammad Ali Vakili; administrative, technical, and material support, Eshghinia; study supervision, Samira Eshghinia and Firoozeh Mostafavi

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