



Effect of a Balanced Low-Calorie Diet With or Without Nutrition Education on Weight Loss and Processes of Behavior Change Among Healthy Obese Women: A Randomized Clinical Trial

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Abstract

Background: The use of weight-loss dieting has always been overemphasized as the first modality to treat obesity. Success in weight loss is considered a major problem in obese individuals. The processes of behavior change have been used to facilitate intervention promoting change. Only a minority of studies have employed this construct for weight loss.

Objectives: The purpose of this study was to assess the effect of a balanced low-calorie diet with or without nutrition education on the weight loss and processes of change among obese women.

Methods: In a randomized clinical trial, 90 apparently healthy obese women age 18 - 50 with body mass index (BMI) of 30 - 40 kg/m² were recruited from the nutrition clinic in Ardabil, located in the northwest of Iran. Participants were assigned randomly to receive a balanced low-calorie diet with or without nutrition education. Participants completed a processes of change questionnaire at baseline and at three and six months after intervention. A generalized linear model repeated measures analysis of variances was used to assess the time effect as well as the interaction between the time and the group effect.

Results: Significant differences were found in the time effect for weight ($F = 12.64$, $df = 2$, $P < 0.001$), BMI ($F = 10.90$, $df = 2$, $P = 0.001$), and counterconditioning ($F = 22.82$, $df = 2$, $P < 0.001$), and helping relationships ($F = 5.47$, $df = 2$, $P = 0.006$), reinforcement management ($F = 3.65$, $df = 2$, $P = 0.03$), self-liberation ($F = 5.05$, $df = 2$, $P = 0.008$), stimulus control ($F = 12.12$, $df = 2$, $P < 0.001$), and substance abuse subscales ($F = 6.72$, $df = 2$, $P = 0.002$). Significant differences were shown in interaction time and group effect for weight ($F = 5.69$, $df = 2$, $P = 0.011$), BMI ($F = 4.91$, $df = 2$, $P = 0.018$) and counterconditioning ($F = 5.11$, $df = 2$, $P = 0.008$) and stimulus control ($F = 5.50$, $df = 2$, $P = 0.006$) subscales.

Conclusions: The findings support the use of nutrition education for more weight loss and improvement in the counter conditioning and stimulus control subscales among obese women attending the nutrition clinic. It seems that nutrition education should be considered important in effective weight-loss interventions.

Keywords: Low Calorie Diet, Nutrition Guidelines, Psychological Adaptation, Weight Loss

1. Background

Dieting to lose weight has become prevalent in the past few decades (1). However, success in weight loss is considered a major problem in obese individuals (2). Identification of effective interventions is an important component to curb obesity (3). For this purpose, an understanding of behavior-change strategies associated with weight loss is needed.

The processes of change are a common set of strategies and techniques for modifying a health behavior (4) and are considered important recommendations for the devel-

opment of interventions (5). These processes, including two subgroups of cognitive and behavioral processes, are activities and experiences that occur during the behavior-change process (6). The cognitive processes focus on the individual feeling and experiences, while the behavioral processes focus on the behavior and its reinforcement (7). Processes of change definitions are presented in Table 1 (8).

Today, there is an interest in understanding the change processes over time (9), but the most effective strategies for weight loss are unclear (3, 10).

Table 1. Processes of Change Definitions

Processes of Change	Definition
Cognitive Processes	
Consciousness Raising	Increasing knowledge about the problem and self
Dramatic Relief	Experiencing and expressing an emotional reaction to events occurring in the environment
Self Re-evaluation	Appraising the pros and cons associated with changing
Environmental Re-evaluation	Appraising how one's problem affects other people or the environment
Social Liberation	Is concerned with changes in the environment that provide the individual with alternatives
Behavioral Processes	
Self-Liberation	Choosing and committing to act, believing inability to change
Counterconditioning	Replacement alternatives for problem behaviors
Stimulus Control	Avoiding or countering stimuli that can cause problem behaviors
Helping Relationships	Building relationships with those who can support change of the problem
Reinforcement Management	Rewarding oneself or being rewarded by others for making changes
Interpersonal Systems Control	Avoiding tempting situations that lead to problem behavior
Substance Use	Use of medication to alter appetite or metabolism

2. Objectives

The purpose of this study was to address an understanding of behavior change strategies associated with weight loss by measuring changes in the processes of change during a balanced low-calorie diet with or without nutrition education.

3. Methods

The target sample size of 60 subjects (30 in each group) was calculated for the study by considering type I error ($\alpha = 0.05$), type II error ($\beta = 0.1$), mean and standard deviation in a previous study (11), and the following equation:

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \times (\delta_1^2 + \delta_2^2)}{(\mu_1 - \mu_2)^2} \quad (1)$$

Given an anticipated dropout rate of 30%, the enrollment target was set for 90 subjects. In this randomized clinical trial, 90 volunteer obese women were recruited from a private nutrition clinic in Ardabil city in the north-west of Iran from September 2012 to February 2013. The participants were apparently healthy, nonpregnant, nonlactating, nonmenopausal, and nonreferral obese women from urban areas ages 18 - 50 with a body mass index (BMI) ranging from 30 to 40 kg/m². They had no participation in weight-loss programs, including formal or self-imposed diet and activity programs, in the previous six months. Exclusion criteria included pregnancy, menopause, use of dietary supplements, laxatives, and diuretics, and not using

the recommended diet during the interventions. Written information, including the aim of the study and security of personal information, was given to each participant. Written informed consent was obtained from the subjects. The protocol of the study was approved by the Ethics Committee of Tabriz University of Medical Sciences and was registered by the registration center for clinical trials in Iran with the registration code number IRCT201110181197N12.

The study flowchart is presented in Figure 1. A convenience sampling was used to choose study participants. They were randomly assigned to receive a balanced low-calorie diet with or without nutrition education, using even-odd numbers of admissions via a block randomization. The balanced low-calorie diet was an individualized diet with an energy deficit of 500 calories of daily average energy intake that was calculated from three-day food records (two weekdays and one weekend day) before any intervention for every person. In this study, daily energy intakes were calculated using the Nutritionist IV software version 3.5.2. The recommended macronutrient content of both groups was based on percent of ingested calories and was approximately 55% carbohydrate, 15% protein, and 30% fat.

Intervention consisted of a six-month balanced low-calorie diet. In the intervention group with nutrition education, six one-hour sessions were conducted over the initial three months. The interval between sessions was two weeks. These were led by a registered dietitian in an individual format and one-on-one counseling about the food guide pyramid, food exchange systems, importance of self-monitoring of caloric intake, behavioral strategies

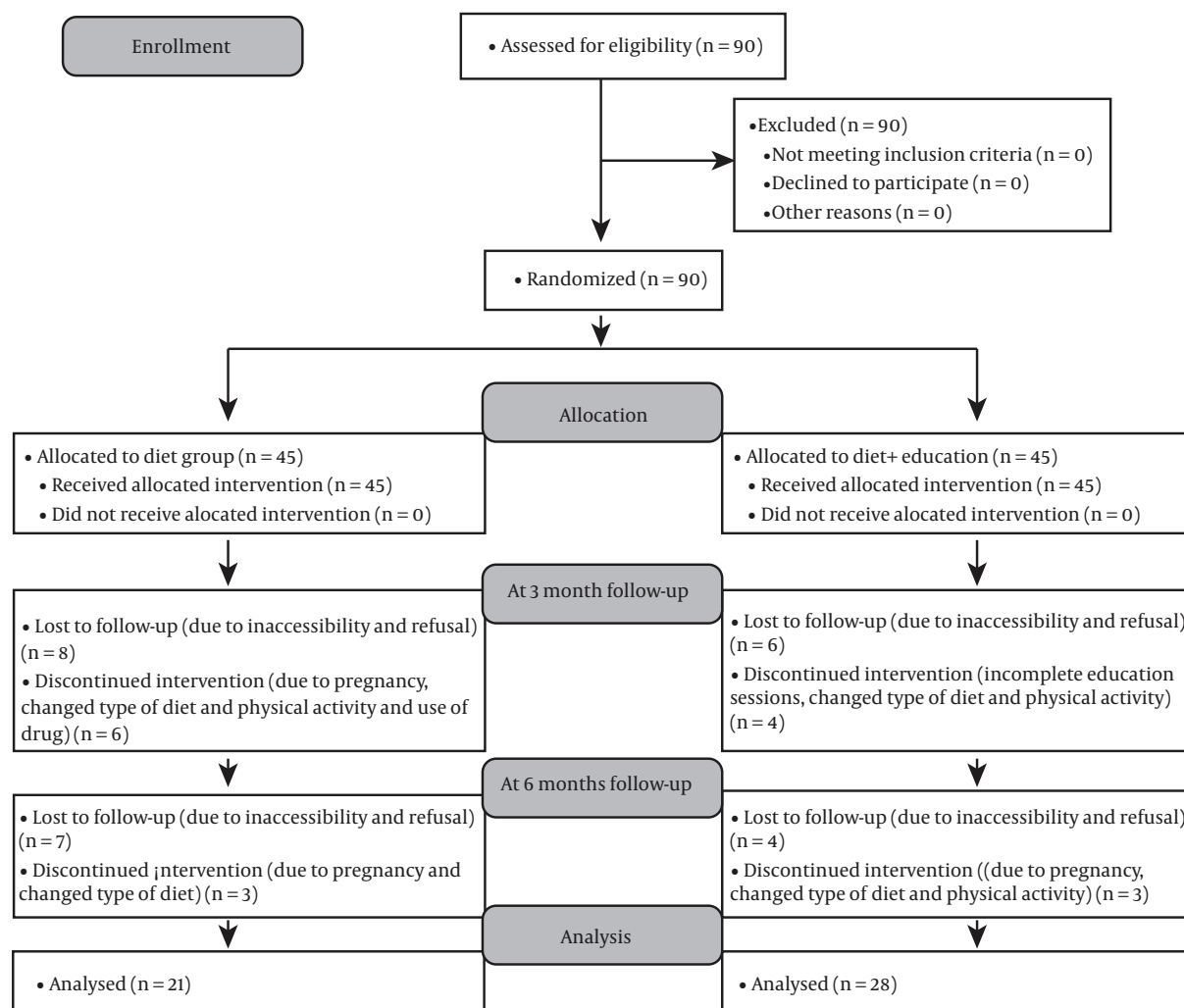


Figure 1. Study Flowchart for Enrollment, Randomization, Allocation, and Follow-up

for caloric adherence, reading food labels, serving sizes and portion control, goal setting for weight loss, and stimulus control.

Participants' weight and height were measured in light clothing and without shoes using a calibrated scale (SECA model 224, SECA Corp., Hamburg, Germany). The BMI was calculated as weight (kg) divided by squared height (m²) of each participant. The processes of change have been indicated to be a valid model when applied to weight management (12). In this study, the processes of change for weight loss were measured using a five-point Likert scale (1 = never to 5 = always) of frequency of process use. This questionnaire contained 48 items. There were four items assessing each of the 12 subscales (13). Participants' scores on each subscale were calculated by averaging

scores within each subscale.

In our study initially, the original questionnaires were translated from English into Persian; then the content validity of translated questionnaires was evaluated by a bilingual expert who read and spoke both the Persian and English languages. Based on the expert's views, sentences assessed as weakly worded, unclear, or not appropriate were rewritten by the researchers. The back translation technique was used in order to attain a culturally equivalent instrument. The equivalence of Persian and English versions was ensured during the process of back translation. Later, a pilot study was carried out to evaluate test-retest reliability and internal consistency of the translated, modified questionnaires. In this pilot study, 10 participants with the same inclusion criteria completed questionnaires twice,

once at baseline and again approximately 10 days later. The test-retest reliability of the subscales and internal consistency are presented in Table 2. Test-retest reliability was considered to be good if the intraclass correlation coefficient ICC was greater than 0.75, moderate if between 0.50 and 0.75, and poor if less than 0.50 (14). Based on the results, the questionnaire had shown the reliability and internal consistency. Therefore, it can be applied for measurement of processes of change.

Data collection was performed at three and six months after dietary intervention. All statistical analyses were performed using the Statistical Package for Social Science (SPSS version 13.0, SPSS Inc., Chicago, IL, 2005). Data was checked for normality with the Kolmogorov-Smirnov test. All variables had normal distribution. Independent two-tailed t tests were performed to compare group differences at baseline. A generalized linear model (GLM) repeated measures analysis of variances was used to assess the trend of change between baseline, three months and six months for the time effect, as well as the interaction between the time and the group effect. The significance level was set at $P < 0.05$.

4. Results

Descriptive characteristics of the participants are presented in Table 3. No significant differences were found in these variables between two groups at baseline. Dropout was 26.5% at three months (31.1% in the diet group vs. 22.2% in the diet + education group) and 45.5% at six months (53.3% in the diet group vs. 37.7% in the diet + education group). Overall, 66 of the participants (31 in the diet group vs. 35 in diet + education group) and 49 of the participants (21 in the diet group vs. 28 in diet + education group) were reassessed at three and six months after intervention, respectively. Individuals who reassessed did not significantly differ from those individuals who did not reassess on weight, BMI, or processes of change subscales at baseline.

Changes in weight, BMI, and the processes of change subscales for who completed the six-month intervention are shown in Table 4. A significant decrease in weight and BMI and substance abuse subscale score and an increase in counterconditioning, stimulus control, reinforcement management, helping relationships, and self-liberation subscales scores were observed in the entire study population at the end of the intervention (Table 4 : the time effect). Significant differences were found in the trend of change in weight, BMI, and counterconditioning and stimulus control subscales between the groups (Table 4 : the time \times group effect), which suggests that the effect of in-

terventions on these variables was not the same for the two groups.

5. Discussion

The present study showed changes in weight, body mass index, and the processes of change during a balanced low-calorie diet with or without nutrition education among obese women attending the nutrition clinic.

Our six-month interventions resulted in a significant reduction in weight and BMI in both of the groups. The effect of interventions on these variables was not the same for the two groups, and more reduction in weight and BMI was observed in the diet + education group after six months. A poor outcome is associated significantly with unsatisfactory early weight loss and poor program attendance (15). Therefore, it can be expected that more weight loss in the diet + education intervention may be associated with long-term outcomes.

Once a decision is made to lose weight, multiple processes can be applied to help facilitate successful change. The processes of change attempt to explain this movement (9). Therefore, the results of this study can be a useful tool to help persons to achieve weight loss. The mean counterconditioning, interpersonal control systems, stimulus control, and substance abuse subscale scores were lower than other processes at baseline. All of the above processes are the behavioral processes (16). Not participating in any program of weight loss as a criterion for inclusion in this study may result in a lower mean substance abuse subscale score. However, the observed results were in line with findings of Suris et al. among the Mexican-American women who were enrolled in a behavioral weight-loss program (17).

Changes in behavioral processes, including counterconditioning, helping relationships, reinforcement management, and stimulus control subscales, were observed over time in study subjects. The participants were reported to be more likely to use behavioral processes in the action stage (16). In Palmeira and colleagues' study, an increase in behavioral-processes change was associated with weight loss (18). Assessing the processes of change in a work-site weight-control program showed increases in stimulus control, counterconditioning, contingency management, interpersonal control systems, and social liberation subscales (19). In a study by Chung et al., individuals used counterconditioning, stimulus control, and self-liberation as the primary behavioral processes for increasing fruit and vegetable intake (20). Although participants differed in their use of processes based on culture (21) and factors influencing the process of change need to be considered

Table 2. Test-Retest Reliability of the Processes of Change Subscales

Subscale	Test ^a	Re-Test ^a	ICC (95% CI)	Cronbach's α
Consciousness Raising	3.30 \pm 1.22	3.64 \pm 1.40	0.93 (0.83 - 0.98)	.93
Counterconditioning	2.37 \pm 0.60	2.47 \pm 0.59	0.53 (0.29 - 0.85)	.58
Dramatic Relief	3.65 \pm 0.83	3.72 \pm 1.15	0.86 (0.67 - 0.96)	.88
Environmental Re-evaluation	2.52 \pm 0.80	2.58 \pm 0.79	0.64 (0.24 - 0.90)	.72
Helping Relationships	3.27 \pm 0.94	3.77 \pm 0.87	0.78 (0.46 - 0.95)	.79
Interpersonal Control Systems	2.53 \pm 0.77	3.41 \pm 1.06	0.80 (0.52 - 0.95)	.82
Reinforcement Management	3.27 \pm 0.87	3.55 \pm 0.86	0.63 (0.15 - 0.92)	.65
Self-Liberation	3.87 \pm 0.96	4.39 \pm 0.74	0.65 (0.14 - 0.91)	.64
Self Re-evaluation	3.70 \pm 1.00	3.75 \pm 0.96	0.70 (0.34 - 0.92)	.75
Social Liberation	3.25 \pm 0.79	3.43 \pm 1.05	0.65 (0.26 - 0.91)	.77
Stimulus Control	1.90 \pm 0.78	3.13 \pm 1.03	0.71 (0.34 - 0.92)	.74
Substance Abuse	1.60 \pm 1.31	1.14 \pm 0.33	0.90 (0.77 - 0.97)	.91

^aData are presented as mean \pm SD.

Table 3. Descriptive Characteristics of Studied Obese Women by Intervention Group at Baseline^a

Variable	Diet Group	Diet + Education Group	P Value ^b
Age, y	28.40 \pm 7.98	27.02 \pm 6.37	0.37
Weight, kg	85.37 \pm 11.44	84.72 \pm 12.11	0.79
BMI, kg/m ²	32.28 \pm 2.90	33.22 \pm 3.16	0.92
Energy intake, kcal/d	2715.13 \pm 1097.88	2806.98 \pm 763.89	0.68
Recommended energy, kcal/d	2247.80 \pm 219.02	2262.22 \pm 235.28	0.67

^aData are presented as mean \pm SD and N = 45.

^bIndependent t tests.

(22), these relationships suggest that modifying the processes of change can be expected in any effective intervention.

The results of this study demonstrated that nutrition education can be more effective in increasing counterconditioning and stimulus-control processes among obese women attending the nutrition clinic. It is noted that people rely more on the behavioral processes of counterconditioning and stimulus control for progressing toward termination of behavior change (23), and behavioral changes are stabilized and relapse avoided with these subscales (24). These change processes could be considered problem-focused coping strategies (25). Therefore, the participants in the diet + education group may be more successful at weight-loss maintenance.

Counterconditioning typically is achieved by substituting alternatives for the problem behavior. This process was reported as one of the most effective strategies to change health behaviors (26). On the other hand, stimulus control encourages individuals to identify specific sit-

uations or stimuli that promote negative eating behaviors so that persons can avoid or limit exposure to them (27). This process was used in all weight-loss interventions (28). Teaching about stimulus control is best applied to people in the action stage (29), and it has been correlated with the action score (30). The incorporation of stimulus control led to increased weight loss and improved maintenance in weight-loss interventions (31). Systematic review of intervention components associated with increased effectiveness of dietary interventions has suggested the need for greater consideration of stimulus control (32).

The generalizability of the study is limited because data was collected on healthy obese women attending the nutrition clinic. The attrition rate, as a common problem for weight-loss interventions, may have restricted the ability to find stronger results.

In conclusion, the findings of the present study may have several important implications. It was the first study to translate the processes of change questionnaire for weight loss to the Persian language for use in Iran. The use

Table 4. Changes in Weight, Body Mass Index, and Processes of Change Subscales Over 6 Months^a

Variable	Baseline ^b	3 Months ^b	6 Months ^b	Time Effect, F (df) P Value ^c	Time × Group Effect, F (df) P Value ^d
Weight, kg					
Diet Group	85.37 ± 11.44	79.57 ± 11.17	75.50 ± 7.77	12.64 (2)	5.69 (2)
Diet+ Education Group	84.72 ± 12.11	78.34 ± 11.62	72.90 ± 13.16	< 0.001	0.011
Body Mass Index, kg/m²					
Diet Group	33.28 ± 2.90	31.49 ± 2.15	30.21 ± 2.03	10.90 (2)	4.91 (2)
Diet+ Education Group	33.22 ± 3.16	30.90 ± 3.33	28.54 ± 3.28	0.001	0.018
Dramatic Relief					
Diet Group	4.24 ± 0.70	4.29 ± 0.69	4.33 ± 0.68	0.13 (2)	0.296 (2)
Diet+ Education Group	4.35 ± 0.71	4.80 ± 2.79	4.29 ± 1.05	0.871	0.744
Environmental Re-evaluation					
Diet Group	3.30 ± 0.75	3.32 ± 0.88	3.13 ± 0.78	0.70 (2)	0.90 (2)
Diet+ Education Group	3.16 ± 0.89	3.22 ± 0.75	3.80 ± 2.49	0.498	0.408
Self Re-evaluation					
Diet Group	4.00 ± 0.56	4.02 ± 0.62	3.80 ± 0.61	0.56 (2)	0.85 (2)
Diet+ Education Group	4.11 ± 0.71	3.98 ± 0.59	3.86 ± 0.65	0.574	0.430
Social Liberation					
Diet Group	3.64 ± 0.72	3.60 ± 0.88	3.46 ± 0.89	2.80 (2)	0.75 (2)
Diet+ Education Group	3.36 ± 0.83	3.58 ± 0.86	3.58 ± 0.83	0.066	0.928
Counter-conditioning					
Diet Group	2.78 ± 0.72	3.02 ± 0.67	3.00 ± 0.70	22.82 (2)	5.11 (2)
Diet+ Education Group	2.64 ± 0.82	3.07 ± 1.09	3.57 ± 1.00	< 0.001	0.008
Helping Relationships					
Diet Group	2.82 ± 1.13	3.09 ± 1.13	3.06 ± 1.25	5.47 (2)	0.29 (2)
Diet+ Education Group	3.25 ± 1.20	3.47 ± 1.18	3.56 ± 1.11	0.006	0.744
Interpersonal Control Systems					
Diet Group	3.00 ± 0.91	3.53 ± 1.58	3.16 ± 0.83	2.44 (2)	0.15 (2)
Diet+ Education Group	2.86 ± 1.00	3.14 ± 0.97	3.31 ± 1.02	0.093	0.863
Reinforcement Management					
Diet Group	3.59 ± 0.96	3.69 ± 1.08	3.64 ± 1.16	3.65 (2)	0.29 (2)
Diet+ Education Group	3.44 ± 0.99	3.68 ± 1.06	3.99 ± 0.90	0.03	0.745
Self-Liberation					
Diet group	4.29 ± 0.56	4.43 ± 0.49	4.46 ± 0.51	5.05 (2)	0.95 (2)
Diet+ Education Group	4.19 ± 0.78	4.39 ± 0.61	4.38 ± 0.65	0.008	0.889
Stimulus Control					
Diet group	2.43 ± 0.94	2.57 ± 1.02	2.67 ± 1.06	12.12 (2)	5.50 (2)
Diet+ Education Group	2.02 ± 0.94	2.62 ± 1.10	3.10 ± 1.04	< 0.001	0.006
Substance Abuse					
Diet group	1.61 ± 0.81	1.52 ± 0.81	1.33 ± 0.60	6.72 (2)	0.09 (2)
Diet+ Education Group	1.51 ± 0.94	1.20 ± 0.78	1.12 ± 0.58	0.002	0.917

^aFor diet group (n = 21) and diet+ education group (n = 28).^bData are presented as mean ± SD.^cThe time effect represents the results of the GLM repeated measures analysis of the changes over time of each variable in the entire study population.^dThe time × group effect represents the results of the GLM repeated measures analysis of the interaction between the time and the group effect.

of nutrition education was associated with more weight loss and improvement in the counterconditioning and stimulus control subscales among obese women attending the nutrition clinic. These results lay a foundation for future research. A replication with a larger and more diverse sample might help to extend the applicability of the findings and provide more detailed information. Additional research also is needed to explore the relationship between processes of change and longer term weight-loss maintenance in this population.

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Footnotes

Authors' Contribution: Reza Mahdavi and Fatemeh Ghannadiasl participated in the design of the study and in writing the protocol. Fatemeh Ghannadiasl conducted data collection. Reza Mahdavi, Fatemeh Ghannadiasl, and Mohammad Asghari Jafarabadi conducted the statistical analyses and wrote the initial draft of the manuscript. All authors contributed to and approved the final manuscript
Clinical Trial Registration Code: This study was registered by the registration center for clinical trials in Iran with the registration code number IRCT20110181197N12.

Conflict of Interests: It was not declared by the authors.

Ethical Approval: The protocol of the study was approved by the Ethics Committee of Tabriz University of Medical Sciences.

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Informed Consent: Written informed consent was obtained from the subjects.

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