

Effects of Nutrition Education Supported by Mobile Application on Weight Loss and Quality of Life: A Randomized Controlled Trial

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Research

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Abstract

Background Obesity is a growing health problem which affects people from all age groups all over the world. Obese people do not feel motivated enough to change their lifestyle behaviors. Mobile applications can be used to motivate people.

Objective To evaluate effect of nutrition education supported by MOtiVE mobile application on weight loss and quality of life (QoL).

Methods In this randomized-controlled study, 79 overweight/obese adult patients who presented to University Hospital Outpatient Clinic between March-September 2018 to consult a dietitian were included. All the participants were provided a weight-loss diet program by the dietitian. Then, participants were randomized to experimental and control groups. During the first interview, all participants completed the questionnaire and anthropometric measurements were done. BMI, the scores obtained from different Quality of Life scales and Healthy Eating Index (HEI) were the dependent variables. The participants in the experimental group were provided with daily messages for 3 months via MOtiVE mobile application designed solely for this study. All the participants were asked to present three months later for a follow-up appointment. Using SPSS 25.0, change in BMI, QoL scores and other variables within both groups was assessed via Wilcoxon signed-rank test and McNemar chi-square test. $p < 0.05$ was considered statistically significant.

Results Although 39 cases and 40 controls took the first test, 20 cases and 18 controls participants completed the study. The mean BMI decreased significantly in both groups being more predominant in cases as from $33.8 \pm 6.0 \text{ kg/m}^2$ to $32.8 \pm 5.8 \text{ kg/m}^2$ ($p = 0.001$) in cases and from $33.3 \pm 5.0 \text{ kg/m}^2$ to $32.2 \pm 4.7 \text{ kg/m}^2$ ($p = 0.006$) in controls. Moreover, waist circumference decreased ($p = 0.029$), self-esteem ($p = 0.035$) and healthy eating scores ($p = 0.007$) increased only in cases significantly.

Conclusions Nutrition education supported by MOtiVE mobile application improved anthropometric measurements, self-esteem, quality of life and healthy eating habits of the overweight/obese participants. Free mobile applications can be used in increasing motivation to adopt new behaviors in order to tackle obesity.

Trial Registration: ClinicalTrials.gov NCT04026971

Background

Obesity is a multifactorial and chronic disease characterized by excessive accumulation of fat in the body resulting from the interaction between genetic and environmental factors. According to World Health Organisation in 2016, more than 1.9 billion adults were overweight and over 650 million were obese(1). In weight loss programs, the most important factor is lifestyle changes. Internet-based programs are potential supporters for individuals participating in weight loss programs because the Internet is easy to access. Studies conducted on this issue have shown that such programs, although

short-term, lead to positive changes in diet, physical activity level, glycemic control, anthropometric measurements and biochemical parameters(2-5). In several studies, low self-esteem and poor body image were determined to be associated with obesity(6, 7). Providing motivational support to achieve lifestyle changes can play a significant role in maintaining weight loss by increasing self-esteem. The main purpose of the present study was to compare the effect of standard education on weight loss, quality of life (QoL) and healthy eating behavior with that of nutrition education supported by mobile application. It was assumed that the mobile applications would increase people's motivation for and adaptation to diet.

Methods

Trial Design

The present study were conducted with patients who presented to the ____ University Hospital Endocrine&Metabolic Diseases Outpatient Clinic between March-September 2018 to consult a dietitian and to receive routine nutrition therapy, aged between 18-64 years and Body Mass Index (BMI) ≥ 25 . The participants were first given the standard nutrition training by the dietitian in the outpatient clinic, and then person-specific diet program. After this, the patients who gave their consent to participate in the study were randomly assigned to the case and control groups. Then, anthropometric measurements of all the participants were performed and the data collection forms were filled in. The "MOtiVE" mobile application for smart phones designed specifically for this study was installed on the smart phones of the cases, and text, visual or video messages were sent to them via this application for three months. The participants in the control group underwent the routine procedure. In line with the routine practice of the outpatient clinic, all the participants were told to present three months later for control appointments. At the end of December 2018, at the end of the three-month follow-up period, the data collection process ended. In a systematic review conducted by Aguilar-Martinez et al, showed that most of the trials last for 2-4 months(8).

Participants and Recruitment Of the patients, those who did not have a smart phone with internet connection, underwent bariatric surgery, took medication or practice a special diet for thyroid problems, diabetes, celiac, gout and kidney diseases and whose body fat analysis was not fulfilled due to the presence of a pacemaker, prosthesis etc. were not included in the study.

According to the results of a study conducted by Allen et al, 25 participants in each group was enough to reach 80% power(9). In a meta-analysis conducted by Mateo, revealed that many studies had 40-45 participants in each group, some of them being less(4). When we consider 80% power with a %5 error and medium effect size ($d:0.5$) we had to have 51 participants in each group calculated via G-power. When we evaluate admissions to the outpatient clinic, we saw that each week we can have 4 or 5 new participants. Thus, considering this data, we decided to take 40 participants in each group. The flowchart of the study is given in Figure 1.

In the present study, randomization was carried out in the following block allocation sequence: AABB, ABAB, BABA, BBAA, ABBA, BAAB.

Change in the BMI and other anthropometric indices and the scores obtained from the Weight Efficacy Lifestyle (WEL) test, Quality of Life Scale SF-36 (QoLSSF-36), Rosenberg Self-Esteem Scale (RSES), Obesity and Weight-Loss Quality of Life Instrument (OWLQoL), Healthy Lifestyle Behavior-II Scale (HLSB-II) and Healthy Eating Index (HEI) were the dependent variables.

Measurements:

Anthropometric measurements

The body height was measured with a stadiometer whereas the body weight, body fat percentage and BMI were measured with the Tanita BC-418 Segmental Body Composition Analyzer. Waist circumference was measured with a non-elastic standard measuring tape, with the individual wearing light clothes, standing still, in an upright position and with arms open sideward. WC was measured from the midpoint between the distal border of the lowest rib and the superior border of the iliac crest(10). Neck circumference was measured by placing the inelastic measuring tape around the neck from the point just below the laryngeal prominence.

QLSSF-36: The scale consists of social functioning, physical functioning, role limitations due to physical problems, mental health, role limitations due to emotional problems, energy/vitality, and perception of general health and pain subscales. The higher the score is the better the quality of life is(11, 12).

WEL Test: It was consisted of 20 questions about negative feelings, food accessibility, social pressure, physical disturbance and positive activity. The higher the score is the better the weight efficacy lifestyle is(13, 14).

HEI: It was developed by the United States Department of Agriculture to investigate the quality of diet in Americans(15). The new HEI-2015, which was published in 2018, consists of 13 components related to diet. The increase in scores indicates a positive development(16). Nutritional values for individuals based on their 24-hour food consumption records were calculated using the _____ (_____ dietary data system) and measurements were calculated based on Dietary Guidelines for _____, 2015(17).

RSES: The first 10 items of the scale are used to measure self-esteem. Self-esteem increases as the score obtained from the RSES decreases(18, 19).

HLSB-II: The scale includes health responsibility, exercise, nutrition, self-actualization, interpersonal support, and stress management subscales(20, 21).

OWLQOL: The higher the score obtained from the scale is, the higher the quality of life of the person is(22, 23).

All of the scales were validated in _____ and found to be reliable to use in _____.

MOtiVE Application for Mobile Phones: The program was developed by the researchers with taking technical support from a software engineer, specifically for this study and it is compatible with both Android and IOS. The messages were sent to the participants in the case group once a day for three months. Messages sent to the phone screen every morning at 9:00 AM were either text, visual or video messages. The visual messages designed to draw the attention of the reader included both a text and an illustration (Figure 2).

By sending text messages like "*Sunday is the only day when most of us do not work. You will be more comfortable during the weekdays if you do your shopping and prepare meals on the weekend. Prepare your meatballs this Sunday and freeze them....*", practical solutions were offered to the participants. By sending text messages like "*Lifestyle changes improve your quality of life and enable you to lead a better quality of life. Improve your quality of life with diet and regular exercise. Thus, do not give up...*" the participants were motivated.

Video messages were uploaded to YouTube and a link address (e.g. What is an antioxidant? <https://www.youtube.com/watch?v=TlaQq1CbNBM>) was sent to the cases, which enabled them to access. The videos were also subtitled so that the watcher could get the message in noisy environments. The registration screen of the MOtiVE, home screen layout, samples of messages sent for 90 days are given in Additional files.

One of the features of the MOtiVE is to calculate for how many days the participant was following the program and to send the message specific to that day to the person's phone. Thanks to this feature of the MOtiVE, it was possible to send a message like "*Congratulations, you have been on a diet for a full month...*" to the person who participated in the program for a month. So the program was made person-specific. Another feature of the MOtiVE is that only one-way communication was possible in order to avoid bias. The application enabled only the researchers to send messages to the participants but did not allow the participants to communicate with the researchers. In this way, standardization was established between the participants in terms of determining their knowledge and interest. Another feature of the MOtiVE is to report whether the participants see the message of that day, which enabled the researchers to find out whether the participant has read the messages.

Statistical Analysis

In the analysis of the study data, IBM SPSS Statistics (version 25; IBM, New York, NY, USA) was used. Continuous variables were presented with mean±standard deviation. At the baseline, the homogenously randomization of the participants to the case and control groups was investigated using the independent samples t-test (Mann Whitney-U test if parametric condition could not be met) and chi-square tests. The efficacy of the intervention was assessed using Wilcoxon signed rank test separately in the case and control groups. p<0.05 considered significant.

Ethical issues

Study was conducted in accordance with the Declaration of Helsinki and ethical approval was obtained from _____ University Medical Research Ethics Committee (no:17-7.1/14, 08.08.2017) and the written consent was obtained from the patients. The study was recorded in clinical trials (no: ClinicalTrials.gov NCT04026971).

Results

The number of the patients who took the first test was 79 (cases:39, controls:40). The number of individuals who took the final test was 38 (cases:20, controls:18). According to the feedback provided by MOTiVE, all participants read all the messages.

Of the participants, 90% in the case group and 83.4% in the control group were women. There was no significant age difference between cases and controls (34.7 ± 14.0 years vs. 38.7 ± 13.5 years; $p=0.349$). The analysis performed to test whether the participants who took the final test had been homogenously randomized to the case and control groups at the baseline revealed that there were no significant differences between the groups in terms of their sociodemographic characteristics, anthropometric measurements, or the scores they obtained from the RSES, OWLQOL, HLSB-II scale, WEL test and HEI and their sub-dimensions except for the nutrition subscale of the HLSB-II scale. The participants in the control group obtained significantly higher scores from the nutrition subscale of the HLSB-II scale (Case group: 20.9 ± 3.6 , Control group: 23.6 ± 4.2 , $p=0.043$). Therefore, it can be said that the participants were homogenously distributed to the case and control groups.

Anthropometric Measurements:

Although weight, BMI and neck circumference measurements of the participants significantly decreased in both groups at the end of the 3 months, these differences were more dominant in the cases. Waist circumference decreased significantly only in the cases. The changes in the anthropometric measurements of the participants at the end of the three-month follow-up were given in Table 1.

Table 1
Comparison of Anthropometric Measurements

Measurements	Groups	n		Mean	SD	Median	Min.	Max.	p*
Weight, kg	Case	20	First test	91.4	18.0	89.3	67.7	129.0	0.001
			Final test	88.5	17.1	87.2	66.3	120.9	
	Control	18	First test	89.4	17.9	86.2	67.1	128.9	0.006
			Final test	86.4	16.9	83.7	61.8	125.4	
BMI, kg/m ²	Case	20	First test	33.8	6.0	33.2	25.7	45.7	0.001
			Final test	32.8	5.8	31.9	23.8	43.0	
	Control	18	First test	33.3	5.0	32.6	26.0	41.6	0.006
			Final test	32.2	4.7	32.5	23.8	40.4	
Body Fat Percentage, %	Case	20	First test	39.5	5.2	26.6	46.7	40.3	0.489
			Final test	39.3	6.0	24.9	47.7	39.5	
	Control	18	First test	39.1	4.6	30.5	48.3	38.3	0.556
			Final test	38.7	4.9	29.3	46.0	39.1	
Waist circumference cm	Case	20	First test	108.2	15.1	86.0	141.0	109.5	0.029
			Final test	106.1	15.1	82.0	135.5	107.0	
	Control	18	First test	108.3	12.7	87.0	130.0	108.5	0.060
			Final test	105.5	12.4	86.0	126.0	105.0	
Neck circumference (cm)	Case	20	First test	37.3	3.5	33.0	45.0	36.2	0.001

Measurements	Groups	n		Mean	SD	Median	Min.	Max.	p*
Control	18		Final test	36.4	3.3	33.0	44.5	35.7	
			First test	38.3	4.1	32.5	48.0	38.0	0.028
			Final test	37.5	4.3	32.0	48.0	36.5	

Scales: RSES scores significantly decreased in the cases which showed increase in self-esteem. There were not significant changes in WEL test scores of the participants in both groups. HLSB-II scale scores significantly increased only in the cases. As for the subscales of the HLSB-II scale, there were significant increases in the nutrition and stress management subscale scores in the cases. Except for the mental health subscale in the cases, the participants neither in the cases nor controls obtained significantly different mean scores from the QLSSF-36 and its subscales. While the mean HEI scores of the controls did not change significantly at the end of the three months, those of the cases increased significantly. The comparison of all the data collection tools used in the present study is presented in Table 2.

Table 2
Comparison of all the data collection tools used in the present study

Scales	Groups	n		Mean	SD	Median	Min.	Max.	p*
RSES	Case	20	First test	1.1	0.7	1.0	0.25	2.9	0.035
			Final test	0.7	0.5	0.6	0.25	2.0	
	Control	18	First test	0.9	0.5	0.8	0.25	2.3	0.723
			Final test	0.9	0.6	0.7	0	2.3	
OWLQOL	Case	20	First test	55.2	16.6	58.0	28.0	87.0	0.064
			Final test	45.3	21.5	38.5	20.0	95.0	
	Control	18	First test	51.3	21.0	50.0	11.0	95.0	0.331
			Final test	49.7	22.4	52.5	2.0	93.0	
HLSB-II	Case	20	First test	131.0	15.4	126.5	11.0	173.0	0.021
			Final test	141.0	19.5	144.0	111.0	188.0	
	Control	18	First test	135.0	20.2	135.0	99.0	177.0	0.981
			Final test	135.0	19.3	129.5	109.0	167.0	
WEL Test	Case	20	First test	51.0	13.7	48.0	24.0	89.0	0.256
			Final test	47.7	16.9	46.5	20.0	91.0	
	Control	18	First test	47.2	16.8	48	20.0	83.0	0.177
			Final test	42.0	12.7	39.0	26.0	70.0	
QLSSF-36 Physical Function	Case	20	First test	74.7	24.6	77.5	25.0	100.0	0.138

Scales	Groups	n		Mean	SD	Median	Min.	Max.	p*		
QLSSF-36 Role Limitations Due to Physical Problems	Case	Final test	80.5	18.5	90.0	45.0	100.0				
			Control	18	First test	67.2	30.0	70.0	0	100.0	0.506
		Final test	72.5	31.9	82.5	0	100.0				
			Control	18	First test	56.9	43.5	75.0	0	100.0	0.363
		Case	Final test	68.7	45.0	100.0	0	100.0			
			Final test	68.0	40.9	100.0	0	100.0			
			Control	18	First test	55.5	47.1	66.6	0	100.0	0.181
			First test	56.6	42.0	66.6	0	100.0			
QLSSF-36 Role Limitations Due to Emotional Problems	Case	Final test	51.0	15.4	50.0	20.0	75.0				
			Control	18	First test	58.2	16.1	60.0	25.0	85.0	0.203
		First test	50.2	20.8	52.5	10.0	80.0				
			Final test	53.6	19.5	55.0	0	95.0			
		Control	First test	57.6	16.6	60.0	16.0	80.0			
			Final test	67.4	12.3	70.0	32.0	80.0			
			First test	57.1	21.7	54.0	8.0	96.0			
			Final test						0.048	0.583	

Scales	Groups	n		Mean	SD	Median	Min.	Max.	p*
			Final test	58.0	19.3	56.0	4.0	100.0	
QLSSF-36 Social Function	Case	20	First test	69.3	25.1	62.5	25.0	100.0	0.526
			Final test	75.6	26.4	87.5	25.0	100.0	
	Control	18	First test	60.4	30.6	62.5	0	100.0	0.104
			Final test	75.0	21.8	75.0	37.5	100.0	
QLSSF-36 Pain	Case	20	First test	68.7	25.6	67.5	10.0	100.0	0.811
			Final test	70.3	25.3	77.5	32.5	100.0	
	Control	18	First test	69.3	28.9	67.5	10.0	100.0	0.218
			Final test	75.5	22.8	85.0	22.5	100.0	
QLSSF-36 Perception of General Health	Case	20	First test	51.0	21.2	50.0	15.0	90.0	0.982
			Final test	53.2	19.4	57.5	10.0	80.0	
	Control	18	First test	48.6	18.2	47.5	20.0	80.0	0.206
			Final test	53.8	20.4	55.0	5.0	85.0	
HLSB-II Health Responsibility	Case	20	First test	21.7	4.7	21.0	12.0	31.0	0.294
			Final test	23.0	5.2	23.0	16.0	33.0	
	Control	18	First test	22.8	5.4	23.0	11.0	33.0	0.896
			Final test	22.8	5.3	22.0	14.0	33.0	
HLSB-II Exercise	Case	20	First test	15.7	4.2	15.5	8.0	24.0	0.245

Scales	Groups	n		Mean	SD	Median	Min.	Max.	p*
HLSB-II Nutrition	Case	20	Final test	17.0	5.6	17.5	8.0	29.0	
			First test	14.8	5.4	14.0	8.0	25.0	0.325
	Control	18	Final test	16.1	4.6	16.5	9.0	24.0	
			First test	20.9	3.6	21.0	15.0	31.0	0.001
HLSB-II Self-actualization	Case	20	Final test	25.0	4.2	25.5	17.0	36.0	
			First test	23.6	4.2	23.5	18.0	33.0	0.950
	Control	18	Final test	23.9	4.1	23.0	18.0	32.0	
			First test	26.7	2.9	26.5	21.0	33.0	0.124
HLSB-II Interpersonal Support	Case	20	Final test	27.7	3.1	28.0	20.0	34.0	
			First test	26.8	3.8	26.0	21.0	34.0	0.457
	Control	18	Final test	26.6	4.2	26.0	19.0	34.0	
			First test	26.9	3.5	27.5	21.0	33.0	0.323
HLSB-II Stress Management	Case	20	Final test	27.5	4.1	29.0	21.0	35.0	
			First test	27.7	4.1	28.0	21.0	36.0	0.175
	Control	18	Final test	26.3	4.6	24.5	18.0	35.0	
			First test	18.9	2.9	18.5	15.0	25.0	0.036
	Control	18	Final test	20.7	3.2	21.0	14.0	28.0	
			First test	19.0	3.3	19.5	13.0	26.0	0.876

Scales	Groups	n		Mean	SD	Median	Min.	Max.	p*
			Final test	19.1	3.1	18.0	14.0	26.0	
HEI Score	Case	20	First test	49.2	9.8	52.0	30.0	65.0	0.007
			Final test	56.1	11.4	56.5	34.0	72.0	
	Control	18	First test	53.7	8.2	54.0	43.0	68.5	0.486
			Final test	55.7	10.3	55.7	37.0	72.5	

Discussion

The use of internet-based applications to develop a healthy lifestyle is increasing. However, most of these programs have not been evaluated with appropriate and standardized methods and have different exposure times. Saffron Naimark et al. investigated the effect of an internet-based application on improving healthy lifestyle in a randomized controlled trial. They collected data on nutrition knowledge, diet quality and physical activity periods using online data collection forms. The cases used the Internet-based application designed based on healthy lifestyle recommendations of the US Department of Agriculture and the Israeli Ministry of Health for 14 weeks. Of the 99 participants 86% of them (n=85, 56 in case group, 29 in control group) completed the study. Besides significant weight loss ($p=0.03$), knowledge score, diet quality score, and success score indicating success in maintaining a healthy life increased significantly in the cases. There was a significant correlation between the frequency of using the application and high success score ($p<0.01$)(24). Similarly in their randomized controlled study aimed at weight loss, Kevin Patrick et al. sent SMSs and/or multimedia messages to the participants in the case group 2-5 times a day for 16 weeks. At the end of the 16th week the weight loss in the cases was significantly higher ($p=0.02$). It was concluded that SMSs and multimedia messages could promote behaviors supporting weight loss in obese adults(25). In present study, all participants took nutritional training first with their personal diets and then randomized to cases and controls. That could be the reason for controls to lose weight significantly as well as cases, cases being more predominant. Besides weight loss, present study showed significant improvements regarding self-esteem; healthy lifestyle behaviors, quality of life and healthy eating habits were observed only cases. Therefore, in line with Kevin Patrick et al.'s study, mobile applications can improve behaviors that support weight loss.

In a meta-analysis including 14 randomized controlled trials to investigate whether internet-based interventions were effective in empowering patients concluded that these interventions yield to positive improvements. On the other hand, in 3 studies using general self-efficacy scales and in 1 study using the RSES conducted to assess self-esteem, no changes were observed. The comparison of face-to-face

interviews and internet-based interventions demonstrated that no significant differences were observed in self-esteem(26). In the present study, cases received messages addition to the routine nutritional therapy. Unlike the meta-analysis, a significant decrease in RSES scores thus, a significant increase in self-esteem was observed in cases in the present study. However, according to the analysis of the self-efficacy scores obtained from the WEL test, we also could not show significant changes in both groups. It is thought that internet-based interventions can be used to improve self-esteem, lifestyle behaviors and quality of life of patients but not self-efficacy.

Although the use of a mobile application led to changes in health behaviors, the mechanisms by which these applications facilitate behavior change are generally not known. Joshua H West et al. conducted a cross-sectional study including 217 participants. The participants gave their feedback about their diet and nutrition applications in the last 6 months and most of the participants agreed that the application increased their dietary motivation, improved their self-efficacy, and increased their willingness to set dietary goals and to reach the target. Therefore, it was concluded that diet and nutrition-related practices focusing on the improvement of motivation, willingness, self-efficacy, attitude, knowledge and goal setting might be particularly useful(27). Jacobs et al demonstrated the importance of adherence to intervention on weight loss in a large sample using a smartphone application *Noom* tracking individual self-monitoring and showed that after three months, significant reduction in BMI was accomplished. They concluded that smart phone application use can induce weight loss associated with adherence(28). The present study was also aimed at improving healthy lifestyle behaviors via inducing motivation. At the end of the present study, there was a significant improvement in the mean scores BMI as well as from the overall HLSB-II scale and only its nutrition and stress management subscales.

Limitations and Strengths

The mobile application MOtiVE and its unique features solely designed for this study can be considered as the main strength to this study. Personnel feedback about messages, personnel timing and sending messages according to enrollment time makes this program tailored to participant. Moreover, one-way communication ensured standardization about knowledge and motivation. The main limitation of this study was losses during follow-up period. Nearly half of the participants didn't complete the study. In cases, even though they follow the messages, some of them refused to come for post-test and final measurements. This may be due to conducting this study in a university hospital where control appointments could only be given for three months later. This showed us that people need stronger motivations to continue follow-ups.

Conclusions

In conclusion, it is thought that provision of mobile application based nutrition education to overweight and obese individuals in addition to the routine nutritional therapy may lead to improvements in anthropometric measurements, self-esteem, healthy lifestyle behaviors, quality of life and healthy eating habits of the participants, and it might help to achieve the targeted weight loss. As the number of dietary

and nutritional practices continues to increase, to ensure healthy lifestyle behavior changes, application developers together with health professional should consider integrating the appropriate theoretical structures into the newly developed mobile applications. Because these types of mobile applications are easily accessible, such applications should be created and made available to the public free of charge in the protection of public health, and prevention and reduction of obesity.

List Of Abbreviations:

Quality of Life (QoL)

Body Mass Index (BMI)

Weight Efficacy Lifestyle (WEL) test,

Quality of Life Scale SF-36 (QoLSSF-36),

Rosenberg Self-Esteem Scale (RSES),

Obesity and Weight-Loss Quality of Life Instrument (OWLQoL),

Healthy Lifestyle Behavior-II Scale (HLSB-II)

Healthy Eating Index (HEI)

Declarations

CRediT authorship contribution statement

All the authors declare that, according to CRediT (Contributor Roles Taxonomy), they had substantial contributions to the conception or design of the work as;

DP: Conceptualization, Methodology, Software, Investigation, Formal analysis, Writing-original draft, reviewing and editing, Supervision, Funding acquisition

SS: Conceptualization, Methodology, Investigation, Writing- reviewing and editing, Supervision.

RM: Conceptualization, Methodology, Software, Formal analysis, Writing-original draft, reviewing and editing, Supervision, Funding acquisition

All the authors declare that they approved the final version to be published.

Ethical issues

Study was conducted in accordance with the Declaration of Helsinki and ethical approval was obtained from _____ University Medical Research Ethics Committee (no:17-7.1/14, 08.08.2017) and the written

consent was obtained from the patients. The study was recorded in clinical trials (no: ClinicalTrials.gov NCT04026971).

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Conflicts of Interest: None

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Figures

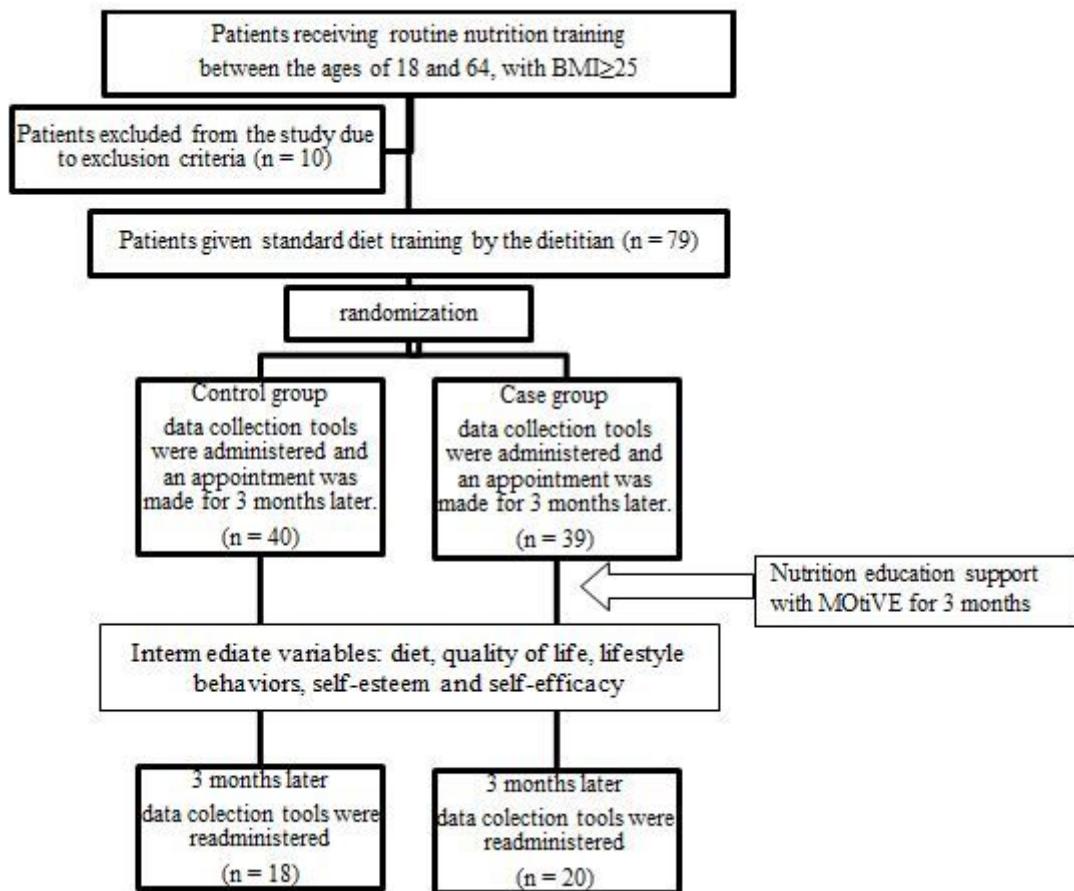


Figure 1

The flowchart of the study

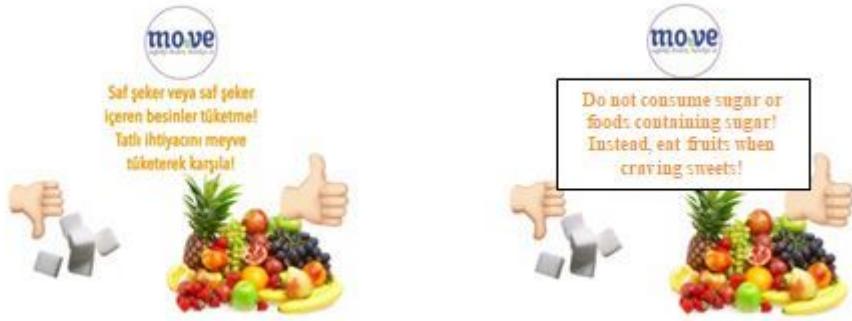


Figure 2

Visual Message Example

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