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A Nutrition Education Intervention Trial for Adolescent Girls in Isfahan: Study Design and Protocol

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Abstract

Background

Nutrition behaviors of adolescent girls is of serious health concerns. Although nutrition education interventions in Iran have met with some success, most of them could not promote nutrition behavioral changes. The aim of our study is to determine a school-based nutrition education intervention to improve adolescents' nutrition behaviors and behavioral mediators based on the social cognitive theory (SCT).

Materials and Methods

This study is a single-blind randomized controlled trial. Eligible participants will be all student girls in grade 6 and 7, their parents and teachers in Isfahan governmental schools. This multi component school-based intervention include adolescents' nutrition education package, parents' nutrition massages, participatory homework, parents and teachers nutrition education package, supportive group, and collaboration with decision makers. Changing in nutrition behaviors including breakfast, fruit and vegetable, snack and fast food consumption will be examined**,** as primary outcome. Secondary outcome will be behavioral mediators such as knowledge, self-efficacy, intention, situation, self-regulation, social support, outcome expectations and expectancies, in adolescent girls. The outcomes will be assessed at baseline, and after 3 and 6-month follow-up.

Discussion

This study evaluates a school-based, guided SCT intervention, designed to improve healthy dietary behaviors, nutrition knowledge of adolescent girls. Few behavioral interventions have targeted this high-risk population in Iran. The intervention seems to be promising and has the potential to bridge the gap of the limited program outcomes of nutrition education in Iranian adolescents.

Key Words: Adolescent, Dietary habits, Education, Iran, Research design, Students.

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1- INTRODUCTION

However studies worldwide have shown that poor nutrition behaviors are common in adolescents than other age groups (1-3). Poor nutrition behaviors can be the reason of health-related problems in adolescents like obesity (4), and future generation's health problems like non-communicable diseases (5), that can impose serious financial burden for society (6). Nutrition behaviors of Iranian adolescents are not desirable for this age (7). Breakfast skipping (8-11), low fruit and vegetables consumption are common behaviors (12-14), while consumption of fast foods (15) and unhealthy snacks are higher than the acceptable values (10, 12, 16). Unhealthy nutrition behaviors of Iranian adolescent girls is of serious health concerns (17). Adolescent girls become more sensitive to their body size and attempt to control their weight through unhealthy nutrition behaviors (18). Also healthy nutrition during adolescence period enable girls to achieve better health status during childbearing years in future (19). Nutrition behaviors are complex and influenced by multiple factors across different levels (20).

Nutrition education interventions combine educational Strategies and environmental supports to facilitate voluntary adoption of healthy nutrition behaviors and can delivered through individual, community, and policy levels (21). Studies documented that nutrition education interventions guided by behavioral theories are more effective in changing behavior than non-theoretical approaches (21, 22). Social Cognitive Theory (SCT) (23) is the most commonly used theory in interventions to promote healthy nutrition among adolescents (24), and often used in the development of curriculums for schools and after-school education programs since in school environment, adolescents are given an opportunity to develop socially and cognitively (25). The main factors determining behavior in the theory included knowledge of the risks or benefits of behavior, self-efficacy, outcome expectations and expectancies, acceptance of facilitators and impediments that are considered as environmental factors. Behavioral intention (26) and self-regulation are another concept in the theory that can be a strong predictor of nutrition behaviors (27, 28).

Although nutrition education interventions in Iran have met with some success, most of them do not promote behavioral changes (29) and the impact of the interventions especially in adolescents is relatively low (13). This may be due to lake of focusing on behavioral change theories in intervention planning (30), and neglecting some determinants like supportive policies and change in environment (31). Our primary objective in this study is to determine a school-based nutrition education intervention to improve healthy dietary behaviors, nutrition knowledge of adolescent girls (breakfast, fruit and vegetable, snack and fast food consumption). We hypothesized that theory-based nutrition education intervention can improve nutrition behaviors in adolescents. To our knowledge few of the interventions that used this theory have measured changes in behavioral constructs of the theory, so our secondary objective is to examine the change in scores of SCT components. This paper provide the study design and protocol of our intervention.

2- MATERIALS AND METHODS

2-1. Study design

A single-blind randomized controlled trial will be conducted to examine the effects of school-based nutrition education intervention on nutrition behaviors in adolescent girls in Isfahan, Iran. The study design, implementation, and reporting are conformed to the Consolidated Standards of Reporting Trials (CONSORT) (32).

Figure.1 provides an overview of the study design. The study follows a pretest/posttest intervention design in government elementary schools in Isfahan. The study was approved by the Ethics Committee of the Isfahan University of Medical Sciences (ID number: 394335) and registered in Iranian Registry of Clinical Trials (IRCT201607052857N2).

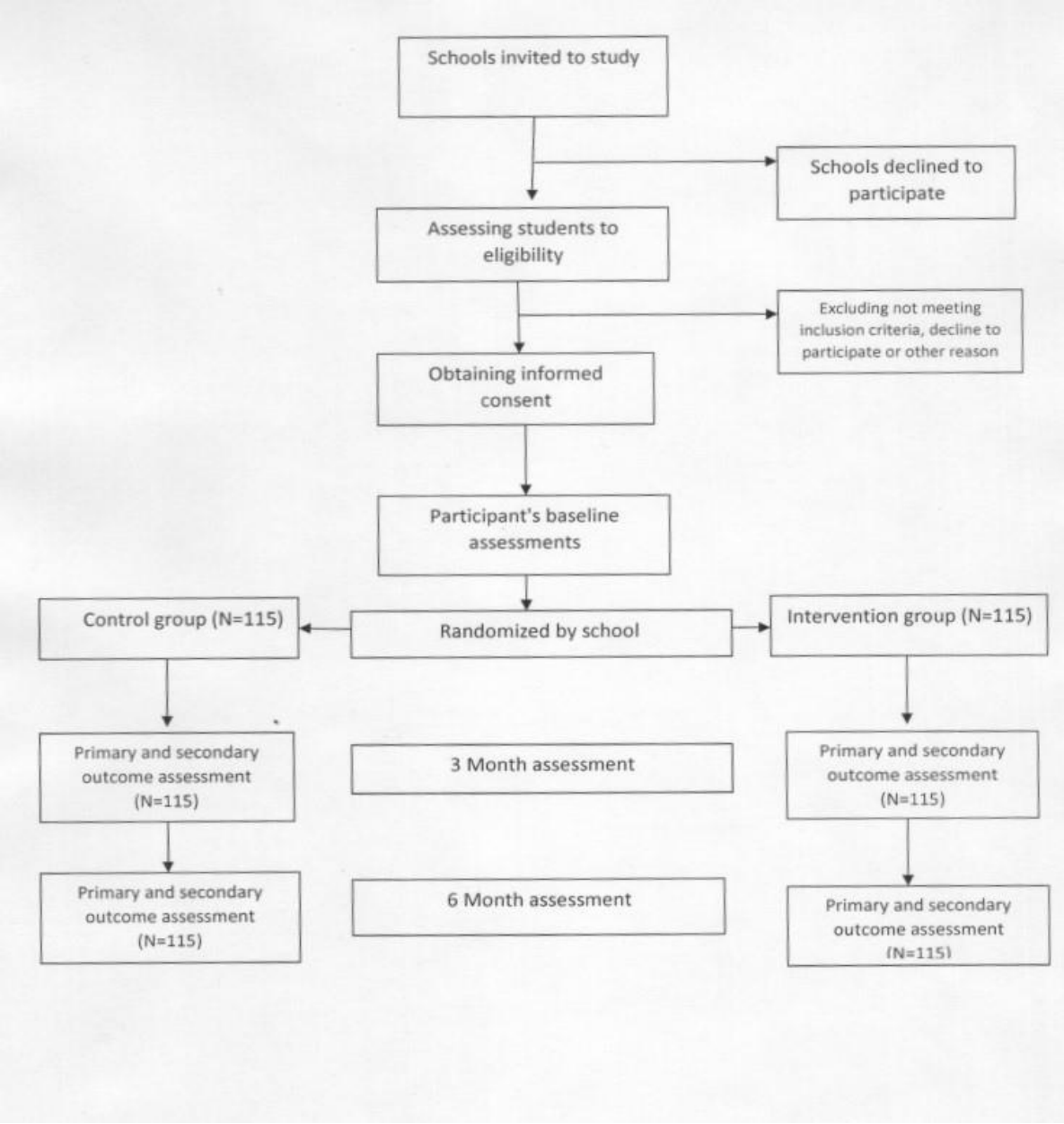

Fig1: Consort diagram

2-2. Participants

Eligible participants are all student girls in grades 6 and 7 in government elementary schools, their parents and, their teachers. Inclusion criteria are: adolescents living in Isfahan, having no allergy or chronic diseases, interfering with the intervention. Students or teachers that leave the school during the study and students, parents, or

teachers who do not participate in one educational session or answer more than 10% of questions will be subsequently excluded from the study.

2-3. Sample size

Sample size was estimated for change in nutrition behaviors and behavioral mediators, using the formula:

$$n= (Z_1 + Z_2)^2 (2S^2) / d^2$$

Where, $\mathbf{Z_1}$ = Z value corresponding to type I (significance level) = 1.96;
$\mathbf{Z_2}$ = Z value corresponding to type II errors=0.84;
S = estimate of standard deviation of the sample and
d = distance from mean to one side of the range that considered 0.4 s.

Because of the two-stage follow up of the study and characteristics of study population, considering 10% potential dropout at three and six months, the study aimed to recruit 230 participants from schools. Therefore, 115 students will be required in each of the two groups.

2-4. Blinding and Randomization

Two schools will be drawn from urban elementary schools through convenience sampling method. One education district will randomly select from five education districts in Isfahan, to facilitate logistical convenience in delivery.

All Elementary schools that exist in this region, will be invited to study. Schools that consent to take part in our study will match-pair based on their size and socioeconomic status. All eligible participants will be requested to complete the informed consent form. Recruitment and baseline assessments will be conducted prior to randomization, then randomly, one school will be allocated to intervention and one to the control group. Baseline and post-test assessments will be conducted by a research team member blinded to group allocation. Schools will remain in their allocated group during the study. However, trial participants may know if they are in the intervention or control group due to nature of interventions.

2-5. Intervention

For a better understanding of population needs and planning intervention, three sources of data and three methods are applied. The first was a comprehensive review that used a social-ecological approach (33) to describe nutrition behavior determinants in adolescent girls (**Figure.2**).

This survey provided an explanation of the problem and its symptoms among adolescent girls. The second study was a qualitative study to identify adolescents' healthy eating obstacles. Semi-structured focus group interviews with adolescents were selected as the means of data collection, to enable valuable insights. The results of focus group discussions guided the intervention activities. The third study was observing the school buffets.

A list from all foods in school buffets were compared to permissible foods that described gaps between standards and real access to healthy foods at schools. Strength and weakness of current programs on adolescents' nutrition in Isfahan, were explored by a panel of stakeholders of Isfahan schools and researchers. To have an effective program to improve adolescents' nutrition behaviors, stakeholders should be engaged in process (34), so stakeholders were took part in intervention planning process through meeting panels in this study. SCT principles are the guidelines for the educational intervention design used in this study (35). All the sessions and workshops will be held in the school by a team member of study who have MSc degree and are professional in adolescent health.

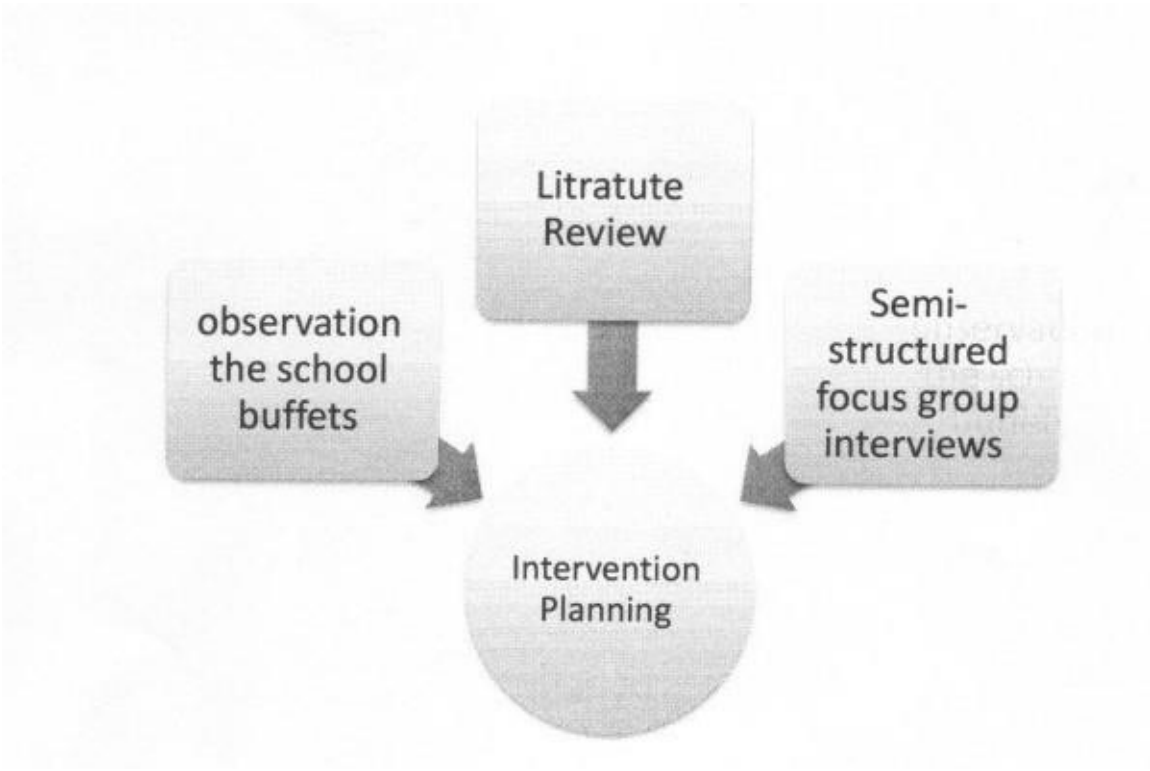

Fig.2: Sources of data for planning

2-5-1. Adolescents' nutrition education package

The nutrition education package contains eight (lasting, 60 min) weekly sessions for the students, so they will receive an in-class nutrition curriculum over a 2-month period. Adolescent nutrition package content is based on food-based dietary guidelines for Iran and Iranian food pyramid (36), approved by School Health Committee of Isfahan University of Medical Sciences.

Knowledge content includes information of nutritional recommendations proportional to age and gender, will be presented through group discussion and lectures. Self-efficacy is created from four resources, performance accomplishments, vicarious experience, verbal persuasion and emotional arousal (26). To strengthen self-efficacy, strategies of increasing motivation through appropriate model (Lectures by successful teenage about change their nutrition behavior), verbal persuasion by trainer, skill of doing an activity and the Strategies to overcome impediments of healthy nutrition behaviors will be used (21). Breaking intended goal to the operational steps (37), is another strategy to increase self-efficacy in this study; for example, students will be requested to create their breakfast menu in small groups. Bandura cites six ways to obtain self-regulation comprises self-monitoring, goal setting, feedback, self-rewarding, self-instructions and considering social support (38). The guided goal setting, is more effective for adolescents (39), this type of strategy will be used in accordance with proposed stages by Contento (21). This activity is also effective in enhancing self-efficacy.

The proper behavioral purpose is selected by trainer monitoring and activities which are considered to achieve this goal are determined by students. The students sets a contract to reach the goals. If a teenager fails to reach its designated activities at the last session, it is endeavored to improve self-regulation through problem-solving activity. Verbal feedback and social support also will be implemented to influence self-regulation.

Content of positive outcomes and their values is different depending on desired behavior and target group (21). Positive outcomes in this study are important short-term outcomes for adolescent girls (e.g. concentration) and long-term consequences (e.g. prevention of obesity), which has been transferred about the desired behavior in the form of a group discussion among adolescents; for example, can it be expected to focus more on lessons when eating breakfast? They should also discuss its significance in the group and say whether it is important or not to achieve this outcome and why do they care?

Students will be physically involved in preparing and tasting simple healthy foods. The purpose of these activities is to stimulate student's knowledge of interest in, and preference for simple healthy foods. In each group the students will be asked to discuss their feelings about goal behavior that can assist them understand emotions, so they can make changes according to their feelings in improving health (21). The students will also participate in two competitions to prepare healthy meals and snacks at school. Awards will be considered for winners.

2-5-2. Parents' nutrition massages

Parents are part of students' external environment, and individual approaches to behavioral change can be completed with parental involvement (40). So we designed massages to increase parental information and social support of adolescents' healthy nutrition. Ten massages will be sent by telegram application to each parent. These massages include contents related to parents' role in healthy nutrition behaviors of adolescents, nutrition concepts that students learn in the classroom, simple recipes from the cooking demonstrations and activities that parents can do for supporting healthy nutrition at home.

2-5-3. Participatory homework

Home activities that require parents' participation can increase parental support for education program (21). Adolescents should discuss with their parents on the subject of each class session and write a paragraph in brief. Also, adolescent goal-setting activity will be monitored by parents at home.

2-5-4. Parents and teachers nutrition education package

This package will be delivered through two workshops to parents and teachers, separately. The parents and teachers will complete two sessions (each 2-hour) of nutrition education workshops each month by attending school-approved courses. It provides a background to adolescents' nutrition behaviors and the role of parents and teachers in supporting students as regards healthy eating at home and school. These sessions are designed to increase the knowledge and support of parents and teachers.

2-5-5. Supportive group

Developing new social network to make supportive changes is a key element to increase nutrition education effectiveness (41). Parents and teachers will make a supportive group to create supportive environment at school. They will visit school buffet accidentally, monitor food supply in the buffet and give feedbacks to decision makers.

2-5-6. Collaboration with decision makers

Despite the school buffet rules in Iran, there is no well-organized monitoring of school buffets (10). Collaboration consists of structural relationships and can make changes in resources (21). The research team will meet school nutrition program directors in Isfahan monthly to discuss strategies for increasing purchase of healthy foods in school buffet.

2-6. Control group

The control group will continue to receive standard government routine health education by health teachers.

2-7. Outcome measures

Outcome assessments will be conducted prior to randomization (at baseline) and will be followed at 3 and 6 months post baseline. The questionnaire for outcome measures in our study has 60 questions and is divided into three main sections; **1**- demographic characteristics with 8 questions (including students' age, parents' age, education and socioeconomic status of family); **2**- adolescents' nutrition behaviors (primary outcomes) including 7 questions, and **3**- social cognitive constructs of nutrition behaviors (secondary outcomes) with 45 questions. The validity of our questionnaire's content is affirmed by a panel of experts on the subject and five adolescents in the society. After collecting opinions, content validity is calculated, and modifications are made. Item analysis and reliability regarding repeatability of measures will be assessed in a pilot study on 20 adolescents. Intra-class correlation coefficient and Cronbach alpha values are calculated in test-retest. The acceptable range > 0.7 for both calculations was considered.

2-7-1. Primary outcomes

Adolescents' nutrition behaviors will be assessed by questions based on dietary part of validated Persian version of Global School-based Student Health Survey (GSHS questionnaire) (42) and Youth Risk Behavior Surveillance System (YRBSS) questionnaire (43). The frequency of adolescents eating breakfast and fast food during the previous week range from 0 to 7 days per week on a Likert-type scale. Snack, fruit and vegetable, consumption during the previous week, has a 7-point Likert scale ranging from (1 = I did not eat during the past 7 days to 7 = 4 or more times per day during the past 7 days). Fruit and vegetable serving consumption during yesterday will be assessed in separate questions, on a scale of 1 to 6, (1 = none and 5 = 4 or more servings). A table based on Iranian food pyramid (36) will be used as a guideline.

2-7-2. Secondary outcomes

Secondary outcomes will be measured by questions in Persian according to an Australian adolescent healthy eating behaviors' questionnaire based on constructs of Bandura's SCT, developed by Dewar et al., 2012 (44). The original questionnaire is tested for reliability and relative validity regarding Iranian adolescent girls (45). We added a number of questions to measure our target behaviors. This section has seven parts including knowledge, self-efficacy, intention, situation (perceived support), self-regulation, social support and outcome expectation and expectancies.

2-7-3. Knowledge

Adolescents knowledge of nutrition behaviors deals with the extent of their knowledge of the importance and effects of healthy nutrition behavior on the status of concentration, weight, blood pressure, cancer, skin and hair health. Answers of 8 questions will be evaluated in form of true and false format, the correct answer is awarded one score and the wrong one given a score of zero (scoring between 0 and 8). For example: can fruit and vegetable consumption be effective for your skin/hair beauty?

2-7-4. Self-efficacy

Self-efficacy in this study is represented to evaluate a person's confidence to do healthy nutritional behavior and will be evaluated by 6 items. These questions assess self-efficacy in three areas of food selection, skills to prepare healthy foods and ability to consume healthy food in difficult conditions. Responses will be assessed with 6-point Likert scale from strongly disagree to strongly agree, answers are assigned a score from 1 to 6. Total score will be considered as self-efficacy of adolescents in healthy nutrition behaviors (scoring between 6 and 36). Item example: I find it difficult to choose a healthy food instead of fast foods when I go out with friends.

2-7-5. Intention

Total score of four questions represents the intention of the person in the next three months for the consumption of fruits, vegetables, breakfast, healthy snacks instead of unhealthy ones and home-made food instead of fast food. Answers are assessed with 4-point Likert scale. These choices ranges from not at all true of me to very true of me, and responses are given a point from 1 to 4. For example: do you intend to eat breakfast every mornings? (Score ranges from 4 and 16).

2-7-6. Situation (perceived support)

Mental expression of adolescent is about support of healthy nutrition behavior at home and school is considered as situation, girls will be asked to show the rate of their agreement or disagreement with the support that has been created by their parents and teachers. Responses of 4 items will be evaluated in form of 6-point Likert ranging from strongly agree to strongly disagree. Answers are given a score from 1 to 6. (Score ranges from 4 and 24). Item example: At school, fruit (fresh, dried or canned) is always available to eat.

2-7-7. Self-regulation

This score measures the frequency of which girls use self-regulation activities in the last three months to encourage themselves to do appropriate nutritional behaviors. Seven questions measure self-regulation in three areas of planning to do behavior, trying new combinations of healthy food and self-assessment. Answers are assessed using 4-point Likert ranging from I never did to I have always done. A point from 1 to 4 is considered for answer of each question (scoring between 7 and 28). For example: Did you plan your breakfast menu and prepare things to save your time at the morning?

2-7-8. Social support

Social support scale rates, adolescents' parents and teachers' support of healthy nutrition behaviors in the last three months. This support is in the form of access to healthy food at home and school and encouragement of parents and teachers to eat healthy food. Answers of 8 questions are assessed with four-point Likert scale from never to always. Points are considered from 1 to 4 respectively (Score varies from 8 to 32); for example: how often do your parents prepare a healthy snack at home during a day?

2-7-9. Outcome expectations and expectancies

The outcome expectations to the person's beliefs about the physical and cognitive benefits of healthy nutrition behavior including lack of serious diseases, increasing concentration, balanced weight and provision of growth needs are examined with four questions. Answering the questions is evaluated with the 6-point Likert scale from strongly disagree to strongly agree. For example: consuming fruit and vegetable can help me to control my weight. Outcome expectancies which values an individual for each of the listed beliefs are also assessed with four questions that their responses are evaluated with 4-point Likert scale from not at all

important to very important. For example: How important is controlling your weight to you? Adolescents' total scores will be calculated by summing the scores of outcome expectations and expectancies raging from8 to 40.

2-8. Statistical analysis

Quantitative variables will be described by mean ± standard deviation (SD) and qualitative variables will be describe frequency (%) and median (interquartile range [IQR]). The distributions of all variables will be obtained. The comparison between intervention and control at baseline will be used t-tests for continuous variables and Chi-square tests for categorical variables. For the variables are not normally distributed, non-parametric tests such as Mann–Whitney U will be used. The significant covariates at baseline will be used in further analyses. All the estimates will be presented along with corresponding %95 confidence interval (CI). Analysis of covariance (ANCONA) will be used to compare groups for each of change scores, controlling for baseline data and independent variables. ANCOVA will be applied for 3 and 6 months post-test, separately. In addition, repeated measure analysis will be utilized to compare groups controlling for time as well as other covariates. Friedman test will be used if the variables are not normally distributed. All statistical analyses will be conducted using SPSS version 20. P value less than 0.05 were considered statistically significant.

3- DISCUSSION

There is an urgent need to identify effective interventions for improving nutrition behaviors in adolescents. Few behavioral interventions have targeted this high-risk population in Iran. Our article presents a study design with a SCT-based intervention, the intervention has a strong theoretical foundation and incorporates a number of novel strategies to increase healthy nutrition in girls. To strengthen intervention, we used multiple resources that integrates quantitative and qualitative method for program planning, so the result of this study will provide useful insight into the role that a SCT-based intervention program could play in improving nutrition behaviors of adolescents.

Unique to this study is its measurement of behavioral mediators. Study data will contribute to a better understanding of the impact of a theory-based intervention on behavioral and psychosocial outcomes among adolescent girls. The intervention has the potential to bridge the gap of the limited program outcomes of nutrition education in Iranian adolescents. If successful, the findings of this trial may assist with the development of a theoretical model for nutrition intervention in schools.

4- CONFLICT OF INTEREST

5- ACKNOWLEDGMENT

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