A Customized Intervention Program Aiming at Improving Healthy Eating and Physical Activity among Preschool Children: Iran Healthy Start Study Protocol

Atieh Mehdizadeh, MD, PhD Candidate, Department of Nutrition, Mashhad University of Medical Science, Mashhad, Iran

Mohsen Nematy, MD, PGDip, PhD, Biochemistry and Nutrition, Endoscopic & Minimally Invasive Surgery, and Cancer Research Centers, Mashhad University of Medical Sciences, Mashhad, Iran

Majid Khadem-Rezaiyan, MD, Department of Community Medicine, Mashhad University of Medical Science, Mashhad, Iran

Majid Ghayour-Mobarhan, MD, MSc, PhD, Metabolic Syndrome Research Center, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

Mohammad Ali Sardar, PhD, Department of General Courses, Mashhad University of Medical Sciences, Mashhad, Iran

Anne Leis, PhD, Department of Community Health & Epidemiology, College of Medicine, University of Saskatchewan, Saskatoon, Canada

Louise Humbert, PhD, College of Kinesiology, University of Saskatchewan, Saskatoon, Canada

Mathieu Bélanger, PhD, Department of Family Medicine, Université de Sherbrooke, Moncton, Canada

Hassan Vatanparast*, MD, PhD, College of Pharmacy and Nutrition, University of Saskatchewan, Saskatoon, Canada

*Correspondence: vatan.h@usask.ca; Tel.: +1-306-966-6341; Fax: +1-306-966-6377
Abstract

Background: Prevention of childhood obesity is a key approach to the primary prevention of non-communicable diseases. Several models, based on population health approach and aligned with ecological models, are used to design childhood obesity prevention programs around the world.

Objectives: The purpose of this study is to determine the efficacy of “Iran Healthy Start (IHS)/Aghazi Salem, Koodake Irani” -the customized Iranian version of Canadian Healthy Start/Deport Santé health promotion program- which is now being developed in Mashhad University of Medical Sciences (Mashhad, Iran), and focuses on improving physical activity and healthy eating among preschool children.

Methods: The intervention will be evaluated by a pilot randomized controlled design. The components of intervention are including customized Decoda online resources for children, implementation guide for educators and managers, training and monitoring, communication and knowledge exchange, building partnership and parent engagement. Outcomes include changes in anthropometry, physical activity level, nutritional risk status and dietary intake and quality of life.

Discussion: Double burden of malnutrition in early years children is a major health concern in developing countries. This justifies the need for health promotion programs that specifically designed to target both over- and under-nutrition prevention. If the efficacy approved, Iran Healthy Start has the potential of a comprehensive health promotion program for young children whose life style behaviors can be improved toward a healthy future life in a nutrition transition setting.

Trial Registration: The study is registered in the Iranian Registry for Clinical Trials (IRCT) (ID: IRCT2016041927475N1-11/12/2016) and is accessible through the WHO database of clinical trial registries.

Keywords: childhood obesity; healthy eating; physical activity; parent; Healthy Start/Deport Santé; Iran; intervention
Background

Today, non-communicable diseases (NCDs) and obesity - as the main predisposing factor of NCDs - are the most common cause of mortality and morbidity, with a higher prevalence in low- and middle-income countries.[1] The World Health Organization (WHO) has introduced NCDs as the major challenge for development and emphasizes the need for urgent action to prevent and control NCDs.[2] Among the NCDs risk factors, obesity needs particular attention, since metabolic syndrome and diabetes are directly associated with obesity.[3, 4] Early childhood obesity is associated with a higher risk of developing NCDs at a younger age and premature death in adulthood,[5, 6] since adiposity tracks into adulthood.[7] Prevention of childhood obesity is a key approach to the primary prevention of non-communicable diseases.[3] Based on WHO report, in 2016, an estimated 42 million children under 5 years of age are overweight or obese, while around 70% of them live in Asia and Africa.[8] In Iran, according to the latest report of an Iranian national survey on May 2015 which was conducted in 30 provinces, prevalence of overweight, obesity and abdominal obesity among children and adolescents of 6-18 years old was 9.7%, 11.9% and 19.1% respectively.[9]

After the announcement of the WHO on February 2015, regarding the urgency of ending childhood obesity around the world, societies and governments took urgent and meaningful action to address this issue. Childhood obesity is a complex and multidimensional health problem and usually single and narrow target interventions do not reach to success. Evidences suggest that improving healthy eating and physical activity behaviors are the cornerstone for weight management strategies[10, 11], along with decreasing sedentary activities[12, 13] and maintaining healthy sleep patterns.[14, 15] Most recent intervention strategies have focused on modifying environment in a way that provides healthy options for children and increases opportunities for physical activity and healthy eating.

In developing countries such as Iran, nutrition transition is occurring side-by-side with epidemiologic transition. A history of low birth weight or stunting which still exists in developing countries is a risk factor for later overweight and obesity in children and consequent cardiovascular or diabetes.[16] According to the data released from WHO, UNICEF and World Bank Group in 2016, Middle East and North Africa which mainly include higher-middle income countries have the highest prevalence of overweight and obesity (10.7%) after Eastern Europe and Central Asia (12.8%) among global regions, while the prevalence of co-existing stunting is 15.3% among Middle Eastern and North African
The presence of both overweight and underweight in a population or even in families is recognized as “double burden of malnutrition” and highlights the importance of nutrition in early life and its close relation with later-life health conditions. In such a situation, a question rises that: “How can an obesity prevention program be conducted, where the problem of overweight and underweight simultaneously exists among children?”

Several childhood obesity prevention programs using different models based on population health approach, and aligned with ecological models, have been designed and conducted around the world with different scientific rationale. Interventions that adhere to principles of the population health approach are designed based on the fact that in a comprehensive population health approach, all levels of impact such as the intrapersonal (psychological and biological), interpersonal (psychological and social), institutional, community (resources and facilities) and governmental policy should be included and stimulated in order to promote the achievements. Healthy Start/Depart Santé (HSDS) is a health promotion program, designed as a population health intervention aiming at promoting physical activity and healthy eating among both Anglophone and Francophone preschoolers in early daycare or preschools in Canada. HSDS is composed of six interlinked components: 1) evidence-based resource, “Literacy, Education, Activity, Play (LEAP)” from the Decoda literacy online resources; 2) HSDS implementation guide; 3) training and monitoring; 4) intersectoral partnership; 5) additional resources; 6) communication, knowledge Development and exchange.

To address the challenge of childhood obesity and double burden of malnutrition in a developing country, we decided to calibrate and customize HSDS as a health promotion initiative which is now successfully running in two provinces in Canada. “Iran Healthy Start (IHS)/Aghazi Salem, Koodake Irani” is the customized Iranian version of Canadian HSDS health promotion program, which is now being developed in Mashhad University of Medical Sciences, and focuses on improving physical activity and healthy eating among preschool children. The principles of IHS is adapted from the original Canadian HSDS, considering unique conditions that exist in Iranian culture, preschool education bylaws, curriculum and environment.

From our point of view, some characteristics of HSDS makes it more relevant to what we need. The key characteristic of HSDS is that it is based on evidence-based ecological framework and adheres to the population health approach. Further, introduces strategies...
for all levels of influence. Another advantage of this program is its multi-culture nature, which makes the program more relevant at international stage and makes the customization easier, although it requires fundamental modifications to be feasible for Iranian preschool children. HSDS targets all children, regardless of their weight or risk of obesity, which is primary prevention initiative (health promotion) in public health approach. This level of prevention includes very basic and fundamental activities that are directed at reducing the risk of exposure to a risk factor in an individual or the population.[27]

Study Objectives:

1. To customize and implement the health promotion program (Iran Healthy Start), aligned with preschool bylaws in Iran;

2. To determine whether Iran Healthy Start program can:
   - Increase physical activity level and attraction to physical activity among preschoolers,
   - Reduce sedentary behaviors at home among preschoolers,
   - Improve anthropometric parameters in preschoolers toward healthy weights,
   - Improve quality of life in preschoolers,
   - Improve eating habits and nutrition risk among preschoolers;

3. To evaluate the feasibility, attrition rate, as well as facilitators and barriers for implementing this program in Iranian preschools;

4. To Calibrate measurement tools: validating Persian translation of Nutrition Screening Tool for Every Preschooler (NutriSTEP®) and Children Attraction toward Physical Activity (CAPA).

Methods

This section is addressed based on the SPIRIT guideline for clinical trials protocol.[28] In a multi-sectoral approach, the key stakeholders including Departments of Nutrition, Chancellor for Health and Chancellor for Research in Mashhad University of Medical Sciences, Provincial Education Department and Nutrition Affairs Department of the Iranian Ministry of Health and Medical Education are involved in “Iran Healthy Start” program. IHS is supported
and funded by Mashhad University of Medical Sciences. A memorandum of understanding was signed between Mashhad University of Medical Sciences and HSDS lead organization (Saskatchewan Network for Health Services in French-RSFS) in Canada.

1. Providing the Intervention Material

Prior to the evaluation, we need to provide the material and equipment for children and educators, as well as materials for engaging parents. This step requires active involvement of the expert panel for development and customization of the educational content and assistants for providing the toolkit and supplementary materials for implementation.

1.1. Development of the intervention components, materials and customization process

Considering some basic differences between Iranian and Canadian education environment and principles, the following criteria was determined for development and customization of the intervention components and content: 1) Iranian preschool education bylaws; 2) current nutrition and physical activity guidelines for preschoolers; 3) physical area or environment in most preschools in Iran; 4) Iranian common plays, lyrics or songs and paly tools among preschool children; 5) Iranian culture (menu, common foods, eating culture); 6) known foods preferred by Iranian children of this age; 7) commonly available and cost of foods. For this purpose, an expert panel including nutritionist, physical activity expert, epidemiologist, representative of Provincial Education Department, graphist, psychologist, and an expert in children plays and lyrics gathered in eight, two-hour meetings to reach a consensus. Accepted modifications for each component or material or activity unit were registered by the secretory.

There are several main differences between preschool education system in Iran and Canada, which cause the differences in Healthy Start program components in two countries. Instead of “Additional Resources” in HSDS, we included “Parent Engagement”. This component is the main difference and better to say the main strength of IHS protocol. We engaged parents, because based on recent evidences, parents play a very crucial role in children weight-control management. This role is comparable or even more important than children themselves.[29, 30] Therefore, we organized the Iran Healthy Start program in six components: 1) customized Literacy, Education, Activity, Play (LEAP): illustrated handbook containing physical activity and nutrition cards accompanied with Healthy-kid Toolkit; 2) IHS implementation guide; 3)
parent engagement 4) training and monitoring; 5) communication and knowledge exchange; 6) building partnership. Details of IHS components and customization criteria are explained in the Method section.

1.2. The intervention

Iran Healthy Start program has six components (Table-1):

1) **Customized LEAP:** Two illustrated handbooks:
   - Physical activity: containing 20 activity units along with complementary chapter containing information for educators. (ISBN:2-25-7457-600-978)

The activity units were translated and customized based on criteria discussed during "customization" process. This handbook is accompanied with "Healthy-kid Toolkit”, which contains utilities and materials for LEAP activity units.

2) **IHS Implementation Guide:** Handbook for managers and educators containing modified self-assessment tool as well as principles of the program, action planning, policies and practices, details of implementation, log pages and report pages for both educators and managers. It also contains a suggested healthy weekly menu for serving snack or hot meal for children at preschool.

3) **Training and Monitoring:** Compromises on-site training workshop followed by a supplementary booster session during implementation (3-4 hours), as well as ongoing support through mobile and virtual contacts (telegram) and weekly visits. The initial workshop introduces the program, objectives, customized LEAP activity units, IHS Toolkit and resources. Educators and managers of intervention centers are invited to become a member of Iran Healthy Start telegram channel, which is the most popular virtual social network among Iranians. Implementation is monitored by weekly visits and daily logs and checking videos and photos while children do the activities every day.

4) **Building Partnership:** Attracting participation of key stakeholders and policy makers:
   - Ministry of Health and Medical Education: Nutrition Affairs Department of the Ministry was informed about the details of the project from the inception of the project. The results of the pilot study will be reported to the aforementioned Department for further steps toward national implementation of the program.
Provincial broadcasting (radio and TV): A TV show and radio talks related to childhood obesity, physical activity in children, healthy nutrition, parenting and many other related topics were recorded to introduce the program and report the future outcomes.

Provincial Education Department: Aiming at incorporating this program or any of its components into the current preschool education bylaws, several meetings were arranged with heads-in-charge.

5) **Parent Engagement:** This is the main distinction between HSDS and IHS and includes:
   - Routine monthly meetings between parents and IHS team nutritionist

A 107-page book which is written for parents and contains five main chapters: 1) childhood obesity, the epidemic health problem, 2) importance of healthy nutrition and physical activity for children, 3) the role of parents in children weight management, 4) parental challenges and worryment, 5) specific nutrition and activity considerations for a preschool child. Parents are asked to read each chapter during one month. In monthly meetings, the content of each chapter is again explained and discussed for parents. These parent-nutritionist meetings are interactive and parents are allowed to ask their questions or share their comments or experiences regarding children’s nutrition and activity issues. This book is written by the two team members MN (Associate Professor in Nutrition) and AM (MD, PhD Candidate). Before releasing this resource, three collaborating mothers were selected to read the book and share their comments regarding fluency, practicality and usefulness of content as well as suggestions for adding topics or other required data.

6) **Communication and Knowledge Exchange:** The purpose of this component is maintained by a comprehensive website ([www.IranHealthyStart.com](http://www.IranHealthyStart.com)) containing details of the program, pages for managers, educators, parents and children as well as social media tools and reports of the study findings for the stakeholders. This component is expected to increase the sustainability of the intervention and dissemination of health promotion findings.

A brief introduction of components and comparison between Canada Healthy Start/Depart Santé and Iran Healthy Start programs are shown in Table 1.
<table>
<thead>
<tr>
<th>Program Components</th>
<th>Implementation Items</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HSDS, Canada [25]</strong></td>
<td><strong>Dur. of Intervention:</strong> 2-5 children Age: 2-5 months</td>
</tr>
<tr>
<td>1) LEAP</td>
<td>Illustrated handbook containing HOP (healthy opportunities for preschoolers) and Food Flair</td>
</tr>
<tr>
<td>2) HSDS Implementation Guide</td>
<td>Handbook for directors and educators</td>
</tr>
<tr>
<td>3) Training and Monitoring</td>
<td>On-site training session which includes monitoring of HSDS in the center, as well as a supplementary training session (1-2 hours)</td>
</tr>
<tr>
<td>4) Partnership</td>
<td>Partnerships and linkages with key stakeholders, decision and policy makers, etc.</td>
</tr>
<tr>
<td>5) Additional Resources</td>
<td>Supplementary resources from the government</td>
</tr>
<tr>
<td>6) Communication, Knowledge Development and Exchange</td>
<td>Hands-on material, website, social media tools, dissemination of evaluation findings and communications through main stream media releases</td>
</tr>
<tr>
<td><strong>HIS, Iran</strong></td>
<td><strong>Dur. of Intervention:</strong> 4-6 children Age: 11 months</td>
</tr>
<tr>
<td>1) Customized LEAP</td>
<td>Illustrated handbook containing customized LEAP based on Iranian preschool education bylaws, current nutrition and physical activity guidelines for preschoolers, physical area or environment in most preschools in Iran, Iranian common plays and lyrics or songs among preschool children, Iranian common playing tools and materials, Iranian culture (menu, common foods, eating culture), known foods preferred by Iranian children of this age and commonly available and cost of foods</td>
</tr>
<tr>
<td>2) IHS Implementation Guide</td>
<td>Translated handbook for directors and educators</td>
</tr>
<tr>
<td>3) Training and Monitoring</td>
<td>On-site training workshop and a supplementary booster session. Implementation is monitored by weekly visits and daily logs and sending videos and photos while children do the activities</td>
</tr>
</tbody>
</table>
| 4) Building Partnership | Attracting participation of:  
  - Ministry of Health by reporting results of the pilot study and proposing the national governmental program  
  - Iran broadcasting (radio and TV) to introduce the program and report the outcomes  
  - Provincial Education Department for incorporating the designed material into the preschool education bylaws |
| 5) Parent Engagement | A 107-page book provided for parents, containing five main chapters to be discussed in each gathering session of parents and IHS team nutritionist (routinely every month) |
| 6) Communication and Knowledge Exchange | Website, social media tools, reports of the study findings for the stakeholders |

Table 1. Brief introduction and comparing the components of Healthy Start/Depart Santé and Iran Healthy Start programs
2. Development of Evaluation Plan and Designing the Pilot Study

2.1. Obtaining required approval and licenses

Conducting any kind of educational interventions in preschools and schools in Iran needs a valid license from Provincial Education Department. This license was obtained on 10/8/2016. Mashhad University of Medical Sciences (MUMS), chancellor for research provided the financial support. The study is approved by Ethics Committee of Mashhad University of Medical Sciences (code:IR.MUMS.fm.REC.1395.208-9/25/2016) and registered in Iranian Registry for Clinical Trials (IRCT) (ID:IRCT2016041927475N1-11/12/2016) and is accessible through the WHO database of clinical trial registries. A comprehensive memorandum of understanding (MOU) was entered between Chancellor for Health, Mashhad University of Medical Sciences and Saskatchewan Network for Health Services in French-RSFS (April 2017).

2.2. Development of the evaluation plan

2.2.1. Study design

Evaluation of the Iran Healthy Start program is designed as a pilot randomized controlled trial. For the purpose of recruitment, officially registered preschools in the Provincial Education Department database are stratified according to the socioeconomic status of people living in that area. Three levels of high, middle and low socioeconomic areas are defined, according to the categorization of Provincial Education Department. Two preschools are randomly selected from each socioeconomic level (total of six centers) and then allocated into intervention and control groups (Figure 1). Three centers in intervention group (each center belongs to different socioeconomic level) and three centers in control group are defined. The selected centers are contacted in person and provided with comprehensive information. After confirmation of managers, two classes are randomly selected for enrollment (six classes in intervention and six classes in control groups). Then parents of eligible children are invited in a meeting in preschool and informed consent is obtained after a brief introduction on the whole program and the role of parents (for parents of intervention group) and informing parents for data collection and cooperation in filling questionnaires (for parents of control group). Components of intervention program for managers, educators, children and parents are conducted in intervention classes and control classes receive the conventional preschool education program. Aiming to acknowledge the cooperation of control preschools, wait-list approach is suggested to the managers to receive the intervention
in the next educational year as well as a comprehensive report for growth, nutrition and physical activity status of each child, which is given after the intervention is completed.

The intervention lasts for six months. Duration of an educational year in preschools in Iran is the same as schools and lasts for 8 months (October to May). From March 21st, there is around two weeks New Year (Norouz) holidays. The intervention will be completed before Norouz holidays. Required data is collected at baseline and after completion of the intervention period.

### Table: Study Design

<table>
<thead>
<tr>
<th>Group</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Control</strong></td>
<td>Random selection of two classes in each center: 6 classes from 3 preschools, n (children) = 148</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>Random selection of two classes in each center: 6 classes from 3 preschools, n (children) = 152</td>
</tr>
</tbody>
</table>

**Control Group**
- Child not included for no consent or any other reason
- Baseline data collection
- Control group continue the conventional preschool program
- Included based on inclusion criteria
- Remained for analysis

**Intervention Group**
- Child not included for no consent or any other reason
- Baseline data collection
- Intervention group receive 6 months IHS program besides the conventional preschool program
- Included based on inclusion criteria
- Remained for analysis

---

Mashhad is a large city in Northeast of Iran and has seven areas, based on classification of Provincial Education Department. Preschools in Mashhad are non-profit and are under supervision of Provincial Education Department. Most
of preschools in Mashhad start at 7:30 am and close at 2 pm. This is the official time, but most children, even those whose parents are employed, come at 8:30-9 and leave the preschool at 12-12:30. Preschool service taxis also follow this time (8:30-12:30). Therefore, children spend around four hours at preschools.

Looking at the preschool bylaws in Iran, there is not a systematic rule or program or guideline targeting optimal nutrition or structured physical activity for preschool children. Except for some preschools in the capital city (Tehran), almost all preschools are part time and do not serve lunch for children. Breakfast and snack is routinely up to the parents, but in some preschools, especially in higher socioeconomic areas, a hot meal is served as breakfast or snack, but not lunch. Regarding the physical environment, usually there are 20 to 30 children in a preschool class and the area of classes is usually around 12-15 squared meters and there is a small yard where around 10-15 children can safely play. Except for rural preschools, most of urban centers do not have enough space for children to even play or have moderate to vigorous physical activities. It is mandatory for preschool educators to teach training books in two volumes for preschool children during the educational year, which are developed by the Provincial Education Department and are aligned with the conventional educational objectives in the preschool bylaws, which are briefly titled as: 1) Training physical and movement skills, 2) Training emotional attitude and behaviors, 3) Training intellectual skills, 4) Training moral and social behaviors, 5) Developing fondness for learning the Holly book (Quran), 6) Training art and beautyism 7) Increasing religious tendency, 8) Training national identity, 9) Training language skills, 10) Promoting health and safety level, 11) Familiarity with the nature and conserving the environment. However, there are not any developed and designed activity units focusing on healthy nutrition and structured physical activity in the bylaws.

2.2.3. Participants and Data Collection

In the Iranian preschool bylaws, preschool is not a mandatory level and all children aged 4-6 years can be registered either in preschool-1 (age 4-5) or preschool-2 (age 5-6). All 4-6 years old children of the selected classes of each center are included in the study after a valid consent from their parents or legal guardian, while those with known chronic disease such as cardiovascular, respiratory, endocrine or musculoskeletal problems -after physician inquiry- as well as those who need to adhere to a specific diet, such as gluten-free or phenylalanine-free diets are excluded.
Data reflecting the nutrition status, diet quality, physical activity and sedentary behaviors, quality of life and anthropometry of children as well as general sociodemographic status of participants and their families are collected at baseline and after the intervention is completed. (Table-2) Data collection is performed by a team of four nutritionists who are given a comprehensive training to standardize data collection. They learned how to consistently do the anthropometric measurements, fill the required questionnaires and train the use of pedometers and filling the parent-report questionnaires to parents. Data entry is done by one person for consistency (PhD student). Each preschool takes about 7-10 days to collect all required data. Since parents’ cooperation is very important in data collection, aiming to acknowledge their cooperation especially in control preschools, a gift for children and a free nutrition consultation for children and their parents as well as a comprehensive report for child growth, nutrition and activity status are dedicated.

Since this is a pilot study and we cannot estimate the attrition rate, there is no need to define sample size, but sample characteristics represents the population of preschool children in Mashhad.

### Table-2. Overview of the study process

<table>
<thead>
<tr>
<th>Intervention</th>
<th>-Introduction to managers</th>
<th>-Introduction to parents</th>
<th>-LEAP activity units every day</th>
<th>-Providing ongoing support for educators</th>
<th>-Booster session for educators at month-3</th>
<th>-Resources and monthly sessions for parents</th>
<th>-Filling daily logs, weekly reports and comments (increasing intervention efficacy)</th>
<th>-Post-intervention data collection</th>
<th>-Feedback from staff and parents</th>
</tr>
</thead>
<tbody>
<tr>
<td>m*</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Control</td>
<td>-Baseline data collection</td>
<td>Conventional programs in preschools</td>
<td>Final data collection</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Table-3. List of variables, tools and data collection points

<table>
<thead>
<tr>
<th>Variable</th>
<th>Assessment Tool</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sociodemographic data</td>
<td>Questionnaire</td>
<td>Baseline</td>
</tr>
</tbody>
</table>

2.3. **Variables of interest**

Several variables are considered to assess the defined objectives, which are formerly specified. Following are the main outcome measures which are administered among both intervention and control participants. (Table-3)
2.3.1. Sociodemographic information

This questionnaire provides demographic data such as parents’ status, age, education level, job, family income as well as some known childhood obesity associated variables such as parental reported weight and height, duration of child exclusive and non-exclusive breastfeeding, age of solid food introduction, age of starting kindergarten, eating in front of screen, physical and sedentary behaviors and some general parenting habits such as child force feeding, use of food as reward or punishment, parents role model or presence at meal time and parental controlling approach.

2.3.2. Nutritional assessment

Diet Quality: Children’s food intake is assessed by 24-hour recall for each child, which is filled for three days (two regular and one holiday) with 14 days interval, at baseline and after the intervention. Since parents provide children’s mid-day snack themselves and educators are obligated to provide daily reports for parents about the amount of snack their child has eaten, parents are the best source for receiving the data of children’s food intake. Youth Healthy Eating Index (YHEI) was used for analysis of diet quality out of food recalls.[31, 32] YHEI focuses on total fat, sodium and saturated fat in children’s diet by examining food choices rather than direct calculation of nutrient intake. Furthermore, YHEI focuses on trans fatty acids, added sugar and low fiber in children’s diet, unlike conventional Healthy Eating Index (HEI).[31]
378Nutrition risk: The Nutrition Screening Tool for Every Preschooler (NutriSTEP®)[33, 34] has been first designed and validated in Canada in different languages for assessing eating habits and nutrition problems in 3-5 years old children. License was obtained from developers of NutriSTEP® questionnaires. The Persian version of NutriSTEP® was used after translation and cross-cultural adaptation.[35] NutriSTEP® scoring system categorizes children into low, medium and high risk in terms of nutritional status. It covers four main domains related to children’s food intake: 1) food and fruit intake, 2) physical growth and development, 3) factors affecting food intake and eating behavior, 4) physical activity and sedentary behavior.

387Anthropometry: Weight, height, mid arm circumference, waist circumference are obtained from all participants, at baseline and after completion of the intervention, according to the standardized protocol.[36] Weight is measured by Beurer BG13 Digital Scale, Germany with measuring rod of 0.1 kg and height by SECA 206 stadiometer, Germany with measuring rod of 0.1 cm. Waist and arm circumference is measured to the nearest 0.1 cm. Body mass index (BMI), BMI percentile and BMI z-score are calculated by AnthroPlus software, version 1.0.4, Geneva, WHO, 2009.[37]

2.3.3. Physical activity assessment

394Physical activity level is assessed using subjective and objective instruments.

396Children Attitude toward Physical Activity (CAPA): This index is assessed through a 25-item, Likert scale validated questionnaire which is answered by children by the assistance of the interviewer (educators) and scores child’s attitude and degree of attraction toward physical activity.[38, 39] CAPA original questionnaire was translated to Persian and culturally adapted, based on the current guidelines for translation and cross-cultural adaptation of questionnaires.[35] The Persian version of the CAPA questionnaire has excellent internal consistency among Iranian preschool children after omitting four questions (Cronbach's alpha=0.93).

404Physical activity Level (Subjective): The level of physical activity at home is assessed by a validated parent-report questionnaire,[40] after translation into Persian and cross-cultural adaptation.[35]
Physical activity Level (Objective): Pedometers are used for this purpose. Cost, memory capacity and use burden for children (weight, size, probability of child manipulation and falling) as well as accuracy and validity are considered for selection of pedometers, based on McClain, et al. suggestion.[41] For this purpose, we use Omron HJ320 Triaxis pedometer at baseline and after the intervention. Further to its reasonable price, Omron HJ320 has several advantages to be used in children. It locates on child’s waist, which is the body axis and gives a better estimation of physical activity level. Further, it has a-seven-day memory and records the number of steps during seven consecutive days. It is very light (45 gr) and easy to both set and use and impossible for child’s manipulation. All pedometers are set based on children’s average length of steps.

2.3.4. Quality of Life

Quality of life measures are increasingly being used as an index of population health status after the constitution of WHO on definition of “Health” that is a state of complete physical, mental (including emotional and cognitive), and social well-being.[42]

Pediatric Quality of Life Inventory™ questionnaire (PedsQL™4.0), for children (ages 5-7) is used for this purpose.[43, 44] PedsQL™4.0 has a previously validated Persian version,[45] and contains 23 items encompassing four fields of children function: physical, emotional, social and school, which is answered in a 5-point Likert scale.

2.3.5. Qualitative interview with parents, educators and managers

We ask educators to write their comments about feasibility, attraction, useful hints and suggestions for increasing children’s and parents’ motivation to actively participate in the program, read the resource and attend the training sessions during the intervention. After the intervention is completed, we have in-person interview with managers, educators and a number of parents to figure out some qualitative data regarding the feasibility of the program in Iran preschools education environment as well as strengths and limitations of the program in components, materials and implementation aspects. Parents of intervention group are stratified to four stratum, based on the amount of the book they were supposed to read during six months: 1) less than 25% of book, 2) 25-50% of book, 3) 50-75% of book, 4) more than 75%. Then 10 parents are randomly selected from each strata and are contacted through phone call and qualitative data regarding fluency, practicality, usefulness, comprehensiveness and the potential barriers causing lack of parental cooperation are collected.
2.4. Data analysis

Descriptive analysis (frequency, percentage, mean, standard deviation) will be used to characterize and compare basic characteristics of participants in intervention and control groups. Outcomes related to nutrition and physical activity will be compared between intervention and control groups to seek for any possible improvements following the intervention. Considering the number of intervention (152) and control (148) participants, which anticipates a normal distribution, Independent sample t-test, and chi-square tests will be used for between group comparisons while Paired sample t-test and MacNemar tests will be used for analyzing within group changes. Any possible covariates will be controlled with ANCOVA test. All tests are two tailed and a significance level of <0.05 will be considered statistically significant. Data analysis will be done by IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp..

3. Implementation

3.1. Training the educators

Aiming at empowering the educators and integration of implementation among intervention centers, a workshop at baseline and a booster session at the middle of the intervention period is conducted. Details of LEAP activities, activity demonstrations, role of educators, collaboration with parents and other related implementation hints are presented and discussed.

3.2. Process Evaluation and Monitoring

RE-AIM framework is used to assess the implementation process.[46] Educators are asked to fill logs every day containing the code of activity unit, the time spent on each unit and feedback of children learning. Photos or videos of LEAP activities are received by the implementation team every day through virtual contacts (telegram channel). A team member has on-site weekly visits to ensure the standard implementation of the whole program and the activities.

Discussion

Developing societies need to have a health promotion program that can overcome the double burden of malnutrition. This requires both over- and under-nutrition prevention strategies to be combined and integrated into education and health systems. Iran Healthy Start has the
potential of a comprehensive health promotion program for young children whose life style behaviors can be modeled and improved toward a healthy future life. Iran Healthy Start is developed and customized considering several criteria. The results of this evaluation study might be a scientific foundation for future policies and plans. During the study, we try to have a look at feasibility and potential implementation problems and barriers in our country. The main obesity prevention program which is now conducting in some province of Iran is “Ending Childhood Obesity (IRAN-ECHO)”. This program is designed and implemented in the framework of the WHO-ECHO program.[47] IRAN-ECHO targets only overweight and obese children of school age. Thus, there is a lack of health promotion program in Iran that targets all children at younger age where health-related behaviors are more modifiable.

The current study has several strengths. First is the RCT nature of the study and the stratification which is based on socioeconomic level of families as an important independent variable influencing the risk of malnutrition among children. Another strength refers to strategies and plans that attracts active involvement of other stakeholders such as parents, preschool educators and managers and policy makers.

Some limitations need to be discussed. One refers to large number of students in each class and limited space; therefore, we had to modify the physical activity units to those that can be done at class and do not need too much space. Another limitation is that it is not possible to give a menu for snack or breakfast, neither to families nor to the preschool managers. The former relates to the fact that we have children from economically disadvantaged families who are unable to provide the healthy snack or breakfast menu every day and the latter refers to the fact that serving breakfast and snack is not a routine daily program of all preschools in Mashhad. Therefore, we decided to focus on that meal and advise the required modifications. Another limitation refers to the fact that we cannot include a follow-up period to evaluate the sustainability and longer-term effects of the program. The reason is that children of preschool level-2 usually leave the preschool at the end of the education year and it is not feasible to track them in other centers.

As a future plan, this evaluation study will guide for development and improvement of Iran Healthy Start intervention to be qualified as a comprehensive health promotion program and conducted in the whole country, aiming at prevention of overweight and obesity among preschool children.
Acknowledgments

Authors appreciate the Chancellor for Research, Mashhad University of Medical Sciences for their financial support and the kind cooperation of Provincial Education Department. We would like to also thank Ms. Gabrielle Lepage-Lavoie, Program Manager, Départ Santé / Healthy Start, Réseau Santé en Français de la Saskatchewan, Saskatoon, Canada for her help and support.

References


