

PROTOCOL

Promotion of food security in adolescents using new technologies:

An intervention program

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1. Investigator Signature

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2. Title page

Title	Promotion of food security in adolescents using new technologies: An intervention program
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3. Synopsis

The first United Nation's Millennium Development Goal is to eradicate extreme poverty and hunger. Following this objective, the European Union has been developing programs and funding research projects to assess and fight against food insecurity. WHO's European Food and Nutrition Action Plan (2015-2020) aims to reduce inequalities targeting vulnerable populations. In Portugal, the aim of the National Health Plan is to maximize health gains and to improve health in all individuals, reducing inequalities. Because of increasing autonomy that characterizes this life stage sometimes negatively influencing their eating patterns, sedentary life styles, and decreased financial resources of the families, adolescents are more likely to suffer from food insecurity. Furthermore, eating disorders are more likely to occur during adolescence and the literature has shown that both developmental tasks inherent to adolescence and pubertal changes, namely body changes, play here a key role.

Food insecurity, defined as limited or uncertain food accessibility, availability and quality, due to lack of resources, is a worldwide problem. The lack of valid epidemiological information to support decision-making constitutes a major public health challenge in Portugal. Moreover, there is a lack of management programs for adolescents targeting nutrition and well-being in order to optimize health status and reduce future co-morbidities.

Taking into account the principles above, we will conduct a longitudinal study with a mixed design, including 300 adolescents aged 12-14 years from two public schools. The intervention length is 6 months: (i) evaluation at baseline; (ii) 3 months of direct intervention; (iii) evaluation at month 3; (iv) follow-up at month 6. The intervention will include psycho-educative sessions directed to the adolescents and their parents. Furthermore, adolescents will have an access to the electronic platform and the

app developed by our team on purpose for this project, aiming to improve food security, psychological well-being, and prevent disordered eating among adolescents. The clinical endpoints will be: nutritional and physical status, well-being, and attitudes regarding eating.

Our consortium comprises a group of leading experts in different fields. The knowledge and expertise exchange among partners will assure goal attainment. We will be able to accomplish the schedule and answer to the relevant research questions addressed in the project. Our project will develop a set of psycho-educative sessions, an e-platform and an app for adolescents with the purpose of changing behaviors when needed and improve health.

4. Background and rationale

Nutrition status is a key indicator of poverty, hunger, poor health, inadequate education and social condition (1). The first United Nations' Millennium Development Goal is to eradicate extreme poverty and hunger. According to the European Parliament, the estimated losses linked to health inequalities had cost around 1.4% of GDP within the European Union in 2011 (2-4). Following this objective, the European Union has been developing programs and funding research projects to assess and fight against food insecurity. The new WHO's European Food and Nutrition Action Plan (2015-2020) established the reduction of inequalities in access to healthy food as a priority goal for food and nutrition policies in the European context (5). In Portugal, the aim of the National Health Plan (6) is to maximize health gains by involving all social partners at national, regional and local levels in the promotion of healthy policies and to improve health in all individuals, reducing inequalities. Moreover, the Portuguese Program for the Promotion of Healthy Eating (PNPAS), also considers the reduction of inequalities in diet as a one of its main challenges (7).

Food insecurity concept includes uncertainty or worry about food, inadequate quality of food, inadequate quantity of food, food acquired through socially unacceptable means, and lack of consistent access to adequate food (8). Rates of food insecurity have been rising worldwide (8). In fact, while the United States is one of the wealthiest nations in the world with a rich and abundant supply of food and resources, 14.3% of U.S. households were food insecure at some point in time during 2013 (9).

A study in Portuguese primary care centers attendees in 2012 showed that 49.0% were food insecure (10). Research has shown that young children are often protected from hunger even in households that have very low food security; however, adolescents may be more vulnerable (11). In adolescence, food insecurity showed to be associated

with poor well-being and psychosocial functioning (12), risk of suicidal behaviors (13) and overweight status (14, 15). Because of decreased financial resources of the families, increasing sedentary life styles and poor eating habits, adolescents are more likely to experiment adverse health conditions. Eating disorders (e.g., anorexia, binge eating, and eating disorders without other specification) and obesity are more likely to occur during adolescence (16). Portugal has one of the highest overweight prevalence rates in Europe (17). Several studies have pointed a paradoxical association between household food insecurity and overweight status in children (14, 15).

In the project *E-therapeutic intervention program for obese adolescents and their family*, funded by the Foundation for Science and Technology (PTDC / DTP-PIC / 0769/2012) and coordinated by Professor Helena Fonseca, an e-platform was developed aimed to support and to manage adolescent obesity (Next.Step). The preliminary results showed that the platform is effective in promoting healthy behaviors, suggesting the relevance of technological tools as catalysts of behavioral change in Portuguese adolescents. So, based on our previous knowledge on e-intervention tools for adolescents, we intend to design a new platform and an app to promote healthy life styles, and promote food security as well as prevent disordered eating including obesity among adolescents.

Research on the association between food insecurity and well being in adolescence is scarce. Little is known about the effectiveness of interventions to reduce food security by promoting healthy life styles and psychological well-being and preventing disordered eating. Based on the literature search, we hypothesized that: (i) At 3 and 6 months adolescents will show lower indicators of food insecurity compared to the indicators of food insecurity at baseline; (ii) psychological well-being variables mediate the relationship between food insecurity and disordered eating.

5. Objective and endpoints

5.1. General objectives

- To improve food security, psychological well-being and eating attitudes among adolescents.
- To test the effectiveness and the determinants associated with the success of the intervention (short and long-term).

5.2. Primary objectives

- To improve nutritional status and eating habits in this adolescent population.
- To study the evolution of the variable “Food insecurity” (T0-T1-T2) in this population.

5.3. Secondary objectives

To improve several clinical endpoints, such as:

- Psychological well-being
- Physical activity habits

5.4. Primary endpoints

- Changes in indicators of nutritional habits (preference towards healthy foods, perceived benefits of healthy eating, fast food intake, family meal frequency, having breakfast on a regular basis; attitudes regarding eating) among these adolescents at 3 and 6 months.
- Changes in food insecurity in households (based on the Food Insecurity Questionnaire) at 3 and 6 months;

5.5. Secondary endpoints

- Changes in indicators of nutritional status (BMI, waist circumference and fat mass) among this adolescent population at 3 and 6 months.
- Changes in the psychological well-being, physical activity and body image at 3 and 6 months.

6. Project design

We will perform an interventional study on food security, psychological well-being and healthy eating using a sample of Portuguese adolescents. An e-platform, an app and specific psycho-educative sessions will be developed to support this study.

About 300 community adolescents from two schools will be invited to participate in a study. The intervention length is 6 months: (i) three months of direct intervention; (ii) evaluation at baseline, month 3, and follow-up at month 6.

(i) Evaluation at baseline (T0)

- Application of validated questionnaires;
- Collection of anthropometric measures;
- Introduction to the use of the platform and the app;
- One psycho-educative session on healthy life styles for adolescents and another for parents.

(ii) Evaluation at 3-months (T1)

- Application of validated questionnaires;
- Collection of anthropometric measures;
- One psycho-educative session for adolescents and another for parents. The psycho-educative sessions will focus on the discussion of the strategies to improve health lifestyles which have meanwhile been developed in the platform and the app some of them by the adolescents themselves.

(iii) Evaluation at 6-months (T2)

- Application of validated questionnaires; collection of anthropometric measures.

The interactive e-platform and app will allow for the delivery and collection of information; discussion of nutritional and physical activities; share of solutions and strategies; favor cohesion among adolescents; promotion of behavior change. Psycho-

educative sessions will play an important role for discussing potential strategies to promote change.

The same validated questionnaires will be applied at T0, T1 and T2. Our team will apply robust statistical methods. The trial will follow the principles of best clinical practices, all adolescents and their parents will sign an informed consent and all procedures will be submitted to an Ethics Committee and to *Ministério da Educação – Monitorização dos inquéritos em meio escolar*.

Our aim is to assess the short and long-term change in clinical endpoints. This study has a high likelihood of success attending to the vast expertise of the team members involved in handling large studies, psychosocial variables assessment, interventions with adolescents, development of psycho-educative sessions, and management of group dynamics.

To accomplish our aims, this project comprises the following tasks:

Task 1 – Development and design of the interactive platform and the app;

Task 2 – Development of the psycho-educative sessions for adolescents and parents;

Task 3 – Perform the longitudinal study with a mixed design;

Task 4 – Evaluation of the impact of the intervention and development of the final report; production of scientific papers and dissemination of the results.

7. Study population

7.1. Overview

This study will include adolescents aged between 12 and 13 years who are attending school. This age range has been consistently identified as a critical period for prevention because it is a crucial period of adolescents' physical and cognitive development. The characteristics of this developmental period (e.g. the emergence of formal thought, body changes and evolving social relationships) will be key ingredients to potentiate the discussion and the integration of healthy lifestyle messages.

7.2. Inclusion criteria

To be eligible for this randomized controlled study, adolescents must fulfill the following inclusion criteria: age between 12 and 13 years; capable of computer use.

7.3. Exclusion criteria

The participants who meet any of the exclusion criteria listed below must be excluded from participating in the trial: psychiatric diagnosis; severe cognitive impairment; hearing/visual loss.

8. Project tasks and assessments

The current project is composed by four tasks:

Task 1 – Development and design of the interactive platform and the app;

Task 2 – Development of the psycho-educative sessions for adolescents and parents;

Task 3 – Perform the longitudinal study with a mixed design;

Task 4 – Evaluation of the impact of the intervention and development of the final report; production of scientific papers and dissemination of the results.

8.1. Task 1: Development and design of the platform and the app

Task 1 will includes the development of the interactive platform and the app to support the intervention (Task 3).

New health ICT is broadly defined as the use of information and communication technology in health care to support the delivery of patient or population care or to support patient self-management. Health ICT can support patient care related activities and has been demonstrated to improve health care quality. ICT have a key role on improving the well-known “4 P”: personalized, participatory, preventive and predictive medicine.

In task 1, our team will develop a platform and an app to provide (and collect) developmental adequate information on nutrition and exercise, stimulate the discussion among adolescents on the promotion of healthy lifestyles, enhance the problem-resolution skills and share strategies. It further intends to enhance cohesion among adolescents and promote the change of health behaviors. We will develop a storytelling video to support the introduction to the platform, the app and the contents presented.

ICT support will be used in two different ways:

(a) Interaction within the platform and the app

In order to attain our aims, our team will develop an e-platform and an app which will comprise:

- Presentation of strategies for promoting food security, healthy lifestyles and preventing disordered eating. We will motivate the adolescents to comment the suggested strategies and propose new ones.
- Nutritional and physical activities.
- Culinary tips with healthy and low cost meals.

(b) Preparation of the psycho-educative sessions

Psycho-educative sessions at T1 will be prepared taking into account the contents shared in platform (see 8.2.).

8.2. Task 2: Development of the psycho-educative sessions for adolescents and their parents

In task 2, we will develop the separate psycho-educative sessions for adolescents and parents. Psycho-educative sessions at T0 for parents and adolescents will be based on previous clinical experiences of the team. We will develop group dynamics in order to be able to discuss the strategies for promoting healthy lifestyles and the well-being in adolescence. We will deliver leaflets with culinary tips including healthy and low cost meals.

Psycho-educative sessions at T1 for adolescents and parents will be prepared taking into account the contents shared in the platform and in the app. We will propose inhere an awards activity. Adolescents will be invited to rate the strategies presented in the e-platform and the app.

8.3. Task 3: Perform the study

In Task 3, we will conduct a longitudinal study with a mixed design. The intervention will last 3 months. Adolescents will be followed over 6 months.

Baseline, 3-month and 6-month evaluations will be conducted to collect anthropometric data (BMI, waist circumference and fat mass) and to apply validated questionnaires to adolescents and parents. In order to evaluate the economic determinant of food security, parents will answer to the food security questionnaire. Adolescents will answer to:

- Socio-demographic questionnaire;
- Physical and eating health questionnaire, adapted from Health Behaviour in School-aged Children (2010) and from Project Eat (18) (to evaluate the contextual determinants of food security);
- Nutrition questionnaire (NUT-Q, Raich et al., 2008);
- Eating Attitudes Test-26 (EAT-26; Garner & Garfinkel, 1979);
- Contour Drawing Rating Scale (CDRS; Thompson & Gray, 1995);
- EADS-21 (Lovibond & Lovibond; validated by Pais-Ribeiro, Honrado, & Leal 2004)
- Adolescent anthropometric data (weight, height, BMI, waist circumference and fat mass).

In each classroom, an identification of the group leader will take place with the purpose of facilitating adherence.

In both, platform and app, adolescents can choose to use a nick name to protect their identity. The adolescents will be presented to life situations and simulated cases and will be stimulated to present specific strategies directed to the promotion of food

security and healthy lifestyles based on the cases presented. Adolescents will be motivated to comment the suggested strategies among them.

Culinary tips including healthy and low cost meals and physical activity tips will also be included. Adolescents will be stimulated to experiment these contents and comment on them.

8.4. Task 6: Evaluation of the impact of the intervention and development of the final report, production of scientific papers and dissemination of the results

This task is dedicated to the organization and systematization of all collected information and results, aiming at the evaluation of the impact of the intervention and at its dissemination for the scientific community. The program effectiveness evaluation will result in a final report on strategies for the prevention of food insecurity and disordered eating, and for the promotion of well-being in adolescence.

We plan to deliver four manuscripts to be submitted to peer review journals (ISI indexed).

- (a) Study 1. The data collected in T0 will be used for the first manuscript. The manuscript will be a quantitative and transversal study. We will identify: adolescents with food insecurity; and variables associated with food insecurity. We schedule its submission in November 2016.
- (b) Study 2. The data collected in T0 will be used for the second manuscript. The manuscript will be a quantitative and transversal study and will focus on the relationships between food insecurity, well-being and disordered eating. Specifically, we aim to test whether well-being is a mediator variable

between food insecurity and disordered eating; and whether sex is a moderator variable. We schedule its submission in December 2016.

- (c) Study 3. The data collected in T0 will be further used in the third manuscript. This manuscript will be a quantitative and transversal study and will focus on the impact of adolescents' family SES in food security, well-being and disordered eating. We schedule its submission in December 2016.
- (d) Study 4. In the fourth manuscript, we will use the data collected on-line (suggestions and reflections) during the 3-month intervention. The manuscript will be a qualitative study and will focus on the strategies pointed by the adolescents to motivate other adolescents to prevent food insecurity. We schedule its submission in March 2017.
- (e) Study 5. The data collected in T0, T1 and T2 will be used in the fourth manuscript. This manuscript will be a quantitative and longitudinal study and will evaluate the intervention impact on several indicators (e.g., physical and nutritional status, eating attitudes, body image and anthropometric data) across time. Specifically, we aim to study the impact of the intervention on the adolescents who were identified as food insecure in study 1. We schedule its submission in April 2017.

9. Potential risks and benefits

Risks for the participation in this study are not expected, either for parents as for children.

Additionally, the participation in this study might have some benefits for its participants. This study will provide relevant information on healthy eating and physical activity. Thus, it might contribute for a healthy life-style of the participants.

10. Project schedule

This project will start in June 2015, although some of the materials have already started to be developed. Baseline evaluation is planned for September 2015. The planned data for completion the follow-up evaluation is March 2016.

11. Statistical and analytical plan

11.1. Sample size

We expect to include 300 adolescents in the study (6 classes from each school).

11.2. Statistical methods

Quantitative analysis will be performed with SPSS and AMOS. In the quantitative analysis, continuous variables will be reported as mean and standard deviation. Qualitative analysis will be performed with NVivo program.

In Study 1, we will perform clusters analysis in order to identify adolescents with food insecurity. In Study 2, we will perform structural equations modeling in order to analyze whether well-being is a mediator variable between food insecurity and disordered eating, and whether sex is a moderator variable. Multilevel analysis will be performed in Study 3. In Study 4, in order to analyze the qualitative data we will conduct Thematic Analysis (NVIVO program). Finally, in Study 5, we will conduct repeated-measures factorial ANOVASs for each variable; the analyses will be complemented with multiple comparisons using Bonferroni adjustment at $p < .05$.

12. Ethical conduct

12.1. Independent Ethics Committee or Institutional Review Board

Prior to initiation of the project at any site, the project, including the protocol, informed consent, and other project documents must be approved by an appropriate IRB/IEC. The IRB/IEC must be constituted according to applicable regulatory requirements.

In the event that the IRB/IEC requires changes in the protocol, the sponsor shall be advised and must approve the changes prior to implementation. The investigator shall not modify the project described in the protocol once finalized and after approval by the IRB/IEC without the prior written approval of sponsor.

12.2. Subject information and consent

The details of the protocol must be provided in written format and discussed with both parents and adolescents. Parental written informed consent must be obtained as well as adolescent's written assent before any project-related procedure is performed. In obtaining informed consent, the information must be provided in language and terms understandable to the subject. The subject, or the subject's legal representative, must give their written consent to participate in the interventional study. The signed and dated consent form itself must be retained by the investigator as part of the project records. A copy of the signed and dated consent form must be given to the subject. The consent form must include all of the required elements of informed consent in accordance with ICH Guidelines E6 and local laws.

The consent form must be approved by the appropriate IRB/IEC and sponsor before trial initiation at a project site. Any subsequent changes to the approved informed

consent form must be reviewed and approved by the appropriate IRB/IEC and sponsor before implementation.

12.3 Protection and confidentiality of participants' data

The confidentiality of participants' data will be ensured. Identification numbers will be used for logistic reasons, although they will be saved independent of other data. These data will be not divulgated by other institutions without involvement in the project.

All the participants' data will be encrypt to preserve the anonymity of each individual, according to the obligations described in the Law dispatch 20510/2008, of July 24th. In the transference of the clinical data to a database from the SPR, the data encryption process will enable the guarantee of the confidentiality and anonymity of each individual. It will be available a code number to decode the subjects' identity. This code number will be just available for the principal investigator, in a different place of the other data. The computer where the data will be centralized will be available in the SPR, with restrict access (with an username and password) for the principal investigator, or other person designated for that propose.

13. Participants' insurance

Not applicable.

14. Publications and other rights

14.1 Rights to publish by investigator

The investigator has the right to publish or publicly present the results of the project in accordance with this Section 12.1 of the protocol.

The investigator agrees not to publish or publicly present any interim results of the project without the prior written consent of the sponsor. The investigator further agrees to provide to the sponsor 45 days prior to submission for publication or presentation, review copies of abstracts or manuscripts for publication (including, without limitation, slides and texts of oral or other public presentations and texts of any transmission through any electronic media, e.g., any computer access system such as the Internet, World Wide Web, etc) that report any results of the project. The sponsor shall have the right to review and comment with respect to publications, abstracts, slides, and manuscripts and the right to review and comment on the data analysis and presentation. If the parties disagree concerning the appropriateness of the data analysis and presentation, and/or confidentiality of the sponsor's confidential information, investigator agrees to meet with the sponsor's representatives at the project site or as otherwise agreed, prior to submission for publication, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement.

14.2 Use of proprietary or confidential information in a Publication

No publication or manuscript shall contain any trade secret information of the sponsor or any proprietary or confidential information of the sponsor and shall be confined to new discoveries and interpretations of scientific fact. If the sponsor believes there is patentable subject matter contained in any publication or manuscript submitted

for review, the sponsor shall promptly identify such subject matter to investigator. If sponsor requests and at sponsor's expense, investigator shall use its best efforts to assist sponsor to file a patent application covering such subject matter with the USA Patent and Trademark Office or through the Patent Cooperation Treaty prior to any publication.

14.3 Use of project information in a publication

Investigator is granted the right subject to the provisions of this protocol to use the results of all work provided by investigator under this protocol, including but not limited to, the results of tests and any raw data and statistical data generated for investigator's own teaching, research, and publication purposes only. Investigator/Institution agrees, on behalf of itself and its employees, officers, trustees, and agents, not to cause said results to be knowingly used for any commercial purpose whatsoever except as authorized by the sponsor in writing.

14.4 Authorships of publications

Authors of publications must meet the International Committee of Medical Journal Editors (ICMJE) guidelines for authorship and must satisfy the 3 criteria that follow:

- a) Authors must make substantial contributions to the conception and design of the project, acquisition of data, or analysis of data and interpretation of results;
- b) Authors must draft the publication or, during draft review, provide contributions (data analysis, interpretation, or other important intellectual content) leading to significant revision of the manuscript with agreement by the other authors;

c) Authors must provide written approval of the final draft version of the publication prior to submission.

All contributors who do not meet the 3 criteria for authorship should be listed in an acknowledgments section within the publication, if allowed by the journal, per the ICMJE guidelines for acknowledgment.

15 Investigators and project administrative structure

15.1 Sponsor

The sponsor of this project is indicated in Section 1, Investigator Signature Page and Section 2, Title Page. The sponsor is Sociedade Portuguesa de Reumatologia and Helena Fonseca is the principal investigator.

15.2 Investigators

15.2.1 Selecting Investigators

Only investigators qualified who have the knowledge, skills and experience to successfully achieve the project's goals are selected.

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