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Promoting healthy eating habits in primary care nutrition counselling by the nutrition app 'SAlBi educa'

Submission date	Recruitment status	[_] Prospectively registered
21/01/2022	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
03/02/2022	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
30/05/2022	Other	

Plain English summary of protocol

Background and study aims
The WHO estimates that 38% of the Spanish adult population (45% men and 30% women) were overweight in 2016, and 16 % (16% men and 15% women) were obese. Interventions to decrease overweight are essential strategies to prevent obesity. New technologies have made possible the development of innovative tools such as a nutrition app to promote healthy eating habits. The aim of this study is to evaluate the short-term impact of the 'SAlBi educa' app to improve healthy eating habits in a sample of the adult population.

Who can participate?
The participants are adults aged 18 and over.

What does the study involve?
The study involves two groups, one control group and one intervention group. Both groups attend traditional group-based dietary counselling in the Health Care centres once a week for 4 weeks. Additionally, the intervention group use the app 'SalBi educa'. The facilitator is a nurse, or doctor, each trained to provide this coordinated programme of support.

What are the possible benefits and risks of participating?
Trial procedures are non-invasive and pose no significant risk to participants. If the app is effective the possible benefits would be better healthy eating habits, reducing bodyweight, increasing nutritional knowledge, among others.

Where is the study run from?
The University of Sevilla and four public Health Care Centres of Seville (Spain)

When is the study starting and how long is it expected to run for?
May 2017 to February 2020

Who is funding the study?
Fundación Progreso y Salud, Junta de Andalucía (Spain)

Who is the main contact?
Dr. Ana B. Cerezo, PhD
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PIN-0050-2018

Study information

Scientific Title
A randomised controlled trial testing the impact of SAlBi educa nutrition app on healthy eating habits

Acronym
SAlBi educa

Study objectives
The use of SAlBi educa nutrition app in primary care nutrition counseling will contribute to improving the user's healthy eating habits

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/07/2017, Andalusian Regional Government's Biomedical Research Ethics Committee (CEI de los Hospitales Universitarios Virgen Macarena - Virgen del Rocío de Sevilla, H. U. Virgen Macarena, Avda. Dr. Fedriani, 3, 41009, Sevilla, Spain; +34 955043127; portaldeetica.csalud@juntadeandalucia.es), ref: 1493-M1-17

Primary study design
Interventional

Study design
Prospective interventional randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Healthy eating habits

Interventions
Current interventions as of 04/04/2022:

Participants are encouraged to follow an intervention to improve healthy eating habits. They were randomly assigned to the control group and experimental group. (The online tool: https://www.randomizer.org/ was used)
- Group A (Control) Traditional nutritional education intervention.
- Group B (Experimental): Traditional nutrition education intervention and the nutrition app – SAlBi educa.
In both groups, four group educational activities were carried out; once a week for four weeks in the following order:
a) Healthy eating and Mediterranean diet
b) Food and nutrients, based on regular consumption portions
c) Physical activity
d) Reading and understanding the nutritional information labelling

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Previous interventions:

Participants are encouraged to follow an intervention to improve healthy eating habits. Four Health Care centres are randomly assigned to the control group (2 Centres) and experimental groups (2 Centres). (The online tool: https://www.randomizer.org/ was used)
- Group A (Control) Traditional nutritional education intervention.
- Group B (Experimental): Traditional nutrition education intervention and the nutrition app – SAlBi educa.
In both groups, four group educational activities were carried out; once a week during four weeks in the following order:
a) Healthy eating and Mediterranean Diet.
b) Food and nutrients, based on regular consumption portions.
c) Physical activity
d) Reading and understanding the nutritional information labelling.
The group assignation are blind for the participants.

Intervention Type
Behavioural

Primary outcome(s)

Data collected by SalBi educa app (experimental group) and by paper dietary record (control group) every week (during 4 weeks), including at least 3 days record per week:
1. Caloric intake: compared with energy requirement and determined by age, sex, height and physical activity, using the FAO equations.
2. Number of meals (5 meals per day)
3. Caloric distribution (25% breakfast, 10% mid-morning, 30% lunch, 10% afternoon snack, 25% dinner).
4. Intake of carbohydrates, of which sugars (45-60% of the daily energy for carbohydrates and less than 10% for sugars).
5. Fat intake (30-35% of the daily energy intake).
6. Protein intake (between 10-15% of the daily energy ingested).
7. Fiber intake (consumption of at least 25 g of fiber per day).
8. Fruit and vegetable consumption: consumption of at least 5 servings of fruit and vegetables per day were considered healthy.

Key secondary outcome(s)
Data are collected by validated questionnaires:
1. Sociodemographic items (age, sex, marital and economic status) at baseline.
2. Anthropometric measures (weight, size, waist, hip) at baseline, and every week for weight measurement.
3. Daily Food Record (for 3 days) at baseline, and every week.
4. General Nutrition Knowledge Questionnaire (GNNQ) at baseline and 4 weeks.
5. Questionnaire of Mediterranean Diet Adherence at baseline and 4 weeks.
6. International Physical Activity Questionnaire (IPAQ) at baseline and 4 weeks.
7. Food Frequency Questionnaire (FFQ) at baseline.

Completion date
27/02/2020

Eligibility

Key inclusion criteria
People >18 years old who attend the intensive nutrition counselling in Primary Care centres and volunteers who wish to participate in the study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
58

Key exclusion criteria
1. People whose physical or mental state made it impossible for them to complete the questionnaires and use the application.
2. People with a language other than Spanish that makes it impossible for them to use the application and to understand the questionnaires correctly.
3. People with Eating Disorders (anorexia nervosa or bulimia).
4. Polymedicated people (≥5 drugs for 6 months)
5. People who practice high-performance/professional sports
6. People who participate in other loss weight programmes
7. Pregnant and breastfeeding people.
8. People who do not have a smartphone on which to install and use the application.

Date of first enrolment
01/09/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Spain

Study participating centre
Centro de Salud Puerta Este Dr. Pedro Vallina
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Sevilla
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41020

Study participating centre
Centro de Salud Esperanza Macarena
C/María Auxiliadora, 4
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41003

Study participating centre
Centro de Salud Bellavista
Av. de Jerez, 67

Sevilla
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Study participating centre
Centro de Salud Los Bermejales
Av. de Jerez, s/n
Sevilla
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Sponsor information

Organisation
University of Seville

ROR
https://ror.org/03yxnpp24

Funder(s)

Funder type
Government

Funder Name
Proyectos Fundación Progreso y Salud, Consejería de Salud y Familia, Junta de Andalucía

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Study website	14/05/2022	30/05/2022	Yes	No

Study website	11/11/2025	11/11/2025	No	Yes