

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

Submission date 21/01/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/05/2022	Condition category Other	<input type="checkbox"/> Individual participant data

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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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

Study design

Prospective interventional randomized controlled trial

Primary study design

Interventional

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

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 assignment 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

C/Cueva de la Pileta, s/n

Sevilla

Spain

41020

Study participating centre

Centro de Salud Esperanza Macarena

C/María Auxiliadora, 4

Sevilla

Spain

41003

Study participating centre

Centro de Salud Bellavista

Av. de Jerez, 67
Sevilla
Spain
41013

Study participating centre

Centro de Salud Los Bermejales

Av. de Jerez, s/n
Sevilla
Spain
41013

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?
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Results article		14/05/2022	30/05/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes