

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

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

acerezo@us.es

**Study website**

<https://institucional.us.es/salbieduca/>

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

GP practice

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet.

### **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 measure

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.

## Secondary outcome measures

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.

## Overall study start date

24/05/2017

## 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

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

58

## 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 ( $\geq 5$  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

Spain

41020

**Study participating centre****Centro de Salud Esperanza Macarena**

C/María Auxiliadora, 4

Sevilla

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**Study participating centre****Centro de Salud Bellavista**

Av. de Jerez, 67

Sevilla

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**Study participating centre****Centro de Salud Los Bermejales**

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**Sponsor information****Organisation**

University of Seville

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<https://www.us.es/>

**ROR**

<https://ror.org/03yxnp24>

## Funder(s)

**Funder type**

Government

**Funder Name**

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

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/03/2022

**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?
<a href="#">Results article</a>		14/05/2022	30/05/2022	Yes	No