

# Pakistani women: ambassadors of healthy eating

<b>Submission date</b> 25/06/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/06/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/01/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Dietary and lifestyle changes along with the cultural and linguistic barriers convert immigrant women of Pakistani origin into a risk population for developing metabolic syndrome (MetS) and cardiovascular diseases (CVD). Currently, they are among one of Catalonia's most affected groups by obesity and cardiovascular disease, and due to cultural and linguistic barriers, their participation in general health promotion programs is limited. To address this situation, researchers have designed the first culturally and linguistically appropriate food education program called PakCat Program to improve their eating habits and to empower them to become ambassadors of healthy eating habits in their community. The aim of this study is to evaluate the effectiveness of a culturally and linguistically appropriate food education program that will allow the participants to become ambassadors of healthy eating habits for their community.

### Who can participate?

Adult (aged over 18 years) immigrant women of Pakistani origin living in Badalona and Santa Coloma de Gramenet

### What does the study involve?

Participants will answer a survey in Urdu which will collect information related to sociodemographic, health and life quality, anthropometric, and dietary aspects. Some of them will also participate in a focus group discussion to deepen the information related to these variables. Participants from Casa Asia will receive 10 educational sessions about healthy eating while from the Fundació Ateneu Sant Roc will participate in three general health education sessions. After finishing the sessions, participants will answer again the initial survey and some of them will participate in focus group discussions.

### What are the possible benefits and risks of participating?

Participants from both groups will acquire knowledge and skills to follow a healthy diet. Participation in the study does not entail any risk.

### Where is the study run from?

University of Barcelona (Spain)

When is the study starting and how long is it expected to run for?  
November 2020 to December 2022

Who is funding the study?

1. Hospital Universitari Germans Trias i Pujol (Germans Trias i Pujol University Hospital) (Spain)
2. University of Vic - Central University of Catalonia (UVIC-UCC) (Spain)

Who is the main contact?

Saba Mohamed Bibi, sanwaran8@alumnes.ub.edu

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Miss Saba Mohamed Bibi

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Pakistani women: promoting agents of healthy eating habits in Catalonia

### Acronym

### **Study objectives**

The participation of migrant women of Pakistani origin in a culturally and linguistically adapted food education program based on the stages of change model will improve their nutritional status, eating habits, and nutrition knowledge and skills, and empower them to become promoters of healthy eating habits for their community.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 28/06/2021, The Bioethics Committee of the University of Barcelona (CBUB) (C/Baldiri i Reixac 2 2a planta, Despacho 230, Barcelona, 08026, Spain; (+34) 93 403 54 63; cbub@ub.edu), ref: N/A

### **Study design**

Multicentre interventional community-based participatory research (CBPR) mixed-method randomized control trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

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

Community

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

Prevention, Quality of life

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Nutrition education program for the general population

### **Interventions**

The study is conducted in the province of Barcelona, specifically in Badalona and Santa Coloma de Gramenet, two neighboring and densely populated municipalities by people of Pakistani origin. The Fundació Ateneu Santa Roc (Badalona) and Casa Àsia (Santa Coloma de Gramenet) are the collaborative institutions of the study. These institutions annually attend between 50 to 60 Pakistani adult women. The intervention is started with the dissemination and recruitment phase in which the researchers have organized different introductory seminars for both the personnel and the participants of collaborative institutions to explain in depth all the characteristics of the project. Through their collaborative efforts, the dissemination and recruitment phase is completed with a sample of 137 women (70 from Casa Àsia and 67 from Fundació Ateneu Sant Roc) who have agreed to participate in the study by signing the written informed consent form. The researchers will conduct a pilot study with six Pakistani women

residing in Catalonia who are not participating in the study to evaluate the efficacy of the designed material for data collection and nutrition education sessions. Hereafter, the researchers will start the data collection phase which will be performed through a mixed-method approach involving combining both quantitative and qualitative methods. From the quantitative perspective, participants will be assisted by a multilingual nutritionist in answering an individual survey translated into Urdu. The survey includes information about the sociodemographic, health and life quality, anthropometric, and dietary aspects of participants. To delve deeply into these variables and to collaboratively design the intervention tailored to the sample's specific needs, the researchers will conduct six focus group discussions, three in both municipalities, each with six participants (n = 36).

In the phase of implementation of the food education intervention, to prevent the contamination of information the participants from one municipality will randomly become the control group and from the other, the intervention group. After the randomization procedure, the researchers will create six subgroups of women (12-15 women) for the intervention group and five subgroups for the control group to conduct the educative sessions in small groups. The intervention group will participate in 10 educative sessions based on the Transtheoretical model for 10 weeks, while the control group will attend three general sessions on healthy eating. Each weekly session will have a duration of 90 minutes. A multilingual nutritionist will carry out the sessions in Urdu and Punjabi at different community spaces. The material will be elaborated in Urdu, Catalan, Spanish, and English languages.

During the study's implementation, a process evaluation will be performed to determine participation and assistance. At the end of the nutrition education sessions, the evaluation will be initiated, in which the researchers will recollect the same variables that were gathered during the baseline data collection so the survey will be repeated and they will reconduct six focus groups (three with the intervention group and three with the control group) to comprehend in depth the changes in the study variables.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Each primary outcome was measured at the baseline and evaluation phase. The evaluation phase began after the completion of nutrition education sessions that lasted 10 weeks:

1. Sociodemographic data (identified through the survey)
2. Nutritional status (analyzed by anthropometric measurements (weight, height, and waist))
3. Nutrition knowledge (identified through an ad hoc questionnaire of 15 true/false questions included in the survey and the focus group discussions)
4. Nutrition skills (studied through an ad hoc questionnaire of 13 multiple-choice questions about nutritional skills included in the survey and the focus group discussion)
5. Dietary pattern (studied through an 18-item Food Frequency Questionnaire (FFQ) included in the survey and the focus group discussion)

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

19/11/2020

### **Completion date**

23/12/2022

## Eligibility

### Key inclusion criteria

1. Adult age (>18 years)
2. Immigrant women of Pakistani origin
3. Residence in Badalona or Santa Coloma de Gramenet
4. Voluntarily accepting to participate in the study

### Participant type(s)

Healthy volunteer

### Age group

Adult

### Lower age limit

18 Years

### Sex

Female

### Target number of participants

141

### Total final enrolment

137

### Key exclusion criteria

1. Diagnosis of cognitive impairment or any physical illness that could prevent participation in the study
2. Disagreement with the ethical conditions of the study

### Date of first enrolment

30/06/2021

### Date of final enrolment

20/12/2021

## Locations

### Countries of recruitment

Spain

### Study participating centre

Fundació Ateneu Sant Roc

C. de Cáceres, 34-36

Badalona, Barcelona

Spain  
08918

### **Study participating centre**

#### **Casa Àsia**

Capella dels Infants Orfes, Carrer d'Elisabets, 24  
Ciutat Vella, Barcelona  
Spain  
08001

## **Sponsor information**

### **Organisation**

University of Barcelona

### **Sponsor details**

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### **Sponsor type**

University/education

### **Website**

<http://www.ub.edu/web/ub/en/>

### **ROR**

<https://ror.org/021018s57>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

Hospital Universitari Germans Trias i Pujol (Germans Trias i Pujol University Hospital)

**Funder Name**  
University of Vic - Central University of Catalonia (UVIC-UCC)

## Results and Publications

**Publication and dissemination plan**  
Planned publication in a peer-reviewed journal

**Intention to publish date**  
30/08/2024

**Individual participant data (IPD) sharing plan**  
The datasets generated and/or analyzed during the current study will be available upon request from Saba Mohamed Bibi (sanwaran8@alumnes.ub.edu)

We can share the data collection instruments, the transcriptions of focus group discussions, the educational material elaborated for the nutrition education sessions, and the final results of our study.

The results will be available in approximately 3 months. The rest of the information can be sent upon request.

We obtained written informed consent translated into Urdu from every participant.

We assigned a code to every participant. We did not use any information that could reveal their identity.

Each participant received an information sheet translated into Urdu that included detailed information related to the project specifying what their participation would entail including the study procedures, duration, potential risks, and benefits. They were also informed of their right to take legal action against any unethical act carried out during the study.

Our study adhered to ethical standards at every step, ensuring that all procedures were conducted following approved ethical guidelines and protocols.

**IPD sharing plan summary**  
Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	Perceived barriers and facilitators to healthy eating	24/12/2023	26/06/2024	Yes	No
<a href="#">Other publications</a>	The designed material	08/12/2022	26/06/2024	Yes	No
<a href="#">Protocol article</a>		20/08/2022	26/06/2024	Yes	No
<a href="#">Results article</a>		14/01/2025	21/01/2025	Yes	No