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# Randomized clinical trial to assess the efficacy of an intervention to reduce the cardiovascular risk by improving the information given to patients

**Submission date**
30/01/2018

**Recruitment status**
No longer recruiting

**Registration date**
06/02/2018

**Overall study status**
Completed

**Last Edited**
17/06/2021

**Condition category**
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Cardiovascular disease is a term that describes conditions that affect the heart and the blood vessels. Patients at high risk of developed cardiovascular diseases need to be followed more frequently in order to monitor their blood pressure, blood cholesterol (fatty substance in the blood), and unhealthy habits, such as tobacco, not exercising, alcohol intake and diet. It is very important to reduce their cardiovascular risk through medication and non-medication programmes in order to reduce their risk, and reduce the probability of having cardiovascular events in the near future. The aim of this study is to see if a programme of providing information about cardiovascular risks can improve the risk of developing cardiovascular disease.

Who can participate?
Adults aged 40-69 who have a high risk of developing cardiovascular disease.

What does the study involve?
Participants are allocated to one of two groups. Those in the first group are visited by a research nurse every three months, and telephone calls every month, for one year. During the visits the nurse explains the concept of cardiovascular risk, and which are the best ways to reduce it, talking about tobacco, diet, complying to medication. Those in the second group receive a visit once at the beginning of the study to register health habits and to calculate cardiovascular risk. They are then followed by their GPs as per the usual standard of care. Participants are followed up after one year to measure their blood pressure and blood cholesterol levels.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in cardiovascular risk. There are no risks associated to participating in the trial.

Where is the study run from?
EAP Sardenya - IIB Sant Pau (Spain)

When is the study starting and how long is it expected to run for?
October 2016 to December 2019

Who is funding the study?
Generalitat de Catalunya (Catalan Health Department) (Spain)

Who is the main contact?
Dr Carlos Brotons (Public)

# Contact information

### Type(s)
Public

### Contact name
Dr Carlos Brotons

### ORCID ID
http://orcid.org/0000-0001-9388-6581

### Contact details
Sardenya Primary Health Care Center
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
SLT002/16/00313

# Study information

### Scientific Title
Multicentre, randomised, open clinical trial to assess the efficacy of an intervention to reduce the cardiovascular risk by improving the information given to patients at high cardiovascular risk

### Acronym
INFORISK study

### Study objectives

An intervention addressed to patients at high cardiovascular risk based on the information about cardiovascular risk can reduce cardiovascular risk and improve control of risk factors.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
IDIAP Ethics Committee, 09/05/2017, ref: ref: P17/093

## Study design
Multicentre randomised controlled open clinical 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 below to request a patient information sheet

## Health condition(s) or problem(s) studied
People at high cardiovascular risk

## Interventions
The intervention consists of explaining cardiovascular risk in a more comprehensive way including figures, in terms of absolute risk, relative risk and vascular age.

Randomization (1: 1 ratio) is done through an electronic system that assigns the subjects in each group (intervention or control).

Intervention arm: Cardiovascular risk estimation is explained by a research nurse in a more understandable manner, using not only absolute risk, but also relative risk as well as the vascular age, with different figures. Cardiovascular estimation is done using European SCORE as well as Regicor tool. The programme is mainly focused on changing unhealthy habits, such as tobacco, sedentarism, and diet. Compliance to medication is reinforced, and control of blood pressure and lipids are monitored, with adjustement of medication if needed. Patients are visited every three months, and two telephone calls are done between each visit to reinforce changes.

Control arm: Participants are visited once at the beginning in order to register healthy habits and risk factors, and cardiovascular risk is estimated. They are then follow by their GPs as usual care.

Participants are visited every three months to monitor changes in healthy habits, risk factors, and pharmacological treatment, and reinforce the concept of cardiovascular risk.

Patients from both arms are visited again at one year (last visit) to be assessed in terms of cardiovascular risk. Blood pressure and blood cholesterol is measured as the beginning and at the end of the study.

### Intervention Type
Behavioural

### Primary outcome measure
Cardiovascular risk is measured using the SCORE system as well as REGICOR tool at baseline and at one-year, at the end of the trial

### Secondary outcome measures
1. Physical exercise is measured using IPAQ (International Physical Activity questionnaire) at baseline and at the end of the trial
2. Diet is measured using Mediterranean Diet Score at baseline and the end of the trial
3. Tobacco measured using a specific questionnaire collecting information on number of cigarrtes at baseline and at the end of the trial
4. Blood lipids are measured using blood tests at baseline and at the end of the trial
5. Blood pressure is measured using a semi-automatic digital blood pressure monitor at baseline and at the end of the trial
6. Weight is measured using a digital weighing scale at baseline and at the end of the trial
7. BMI is measured using heght and weight (Kg/m2) at baseline and at the end of the trial

### Overall study start date
01/10/2016

### Completion date
31/12/2019

## Eligibility

### Key inclusion criteria
1. Both gender
2. 40- 69 years old
3. Fulfilling at least one of the following criteria
3.1. High cardiovascular risk (SCORE ≥5% and/or REGICOR ≥10%)
3.2. SCORE relative risk >= 4
3.3. Diabetes with proteinuria or a major risk factor (smoking, dyslipidaemia or hypertension)
4. Severe kidney chronic disease (GFR < 30 mL/min/1.73 m2)
5. Subclinical Atherosclerosis

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
628 patients in the intervention group and 628 in the control group

### Total final enrolment
464

### Key exclusion criteria
1. Patients with established cardiovascular disease
2. Life expectancy of less than 1 year
3. Mental disease limiting patient's self-care capability
4. Drug and/or alcohol abuse
5. Already enrolled in another clinical trial

### Date of first enrolment
01/10/2016

### Date of final enrolment
28/02/2018

## Locations

### Countries of recruitment
Spain

### Study participating centre
**EAP Sardenya - IIB Sant Pau**
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08025

## Sponsor information

### Organisation
Biomedical Research Institute Sant Pau

### Sponsor details
c/ Sant Antoni Maria Claret
167
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### Sponsor type
Research organisation

### Website
http://www.recercasantpau.cat/

### ROR
https://ror.org/059n1d175

## Funder(s)

### Funder type
Government

### Funder Name
Generalitat de Catalunya (Catalan Health Department)

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

### Intention to publish date
31/12/2020

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Carlos Brotons at cbrotons@eapsardenya.cat.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 31/03/2021 | 17/06/2021 | Yes | No |