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An educational intervention to promote health-related quality of life after an acute coronary syndrome

Submission date 19/07/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 08/08/2018	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/04/2019	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute coronary syndrome is a major health problem in Portugal and a leading cause of morbidity. Health-related quality of life (HRQoL) improvement is a major outcome to achieve after this event. Appropriate medication adherence and lifestyle modification can reduce risk factors like smoking, high blood pressure, high lipid profile and low levels of physical activity. Educational interventions have shown to be effective in these outcomes. The aims of the study are to assess the self-perception of HRQoL and to compare behavioral profiles (in areas of weight management, blood pressure and lipid profile; lifestyle changes, nutrition and physical activity; and medication adherence), number of rehospitalizations and self-perception of HRQoL before and after the intervention of the study group participants with those of the control group.

Acute coronary syndrome (ACS) is one of the leading causes of morbidity and mortality worldwide, as well as in Portugal. ACS is a term used to describe a range of conditions associated with sudden, reduced blood flow to the heart. It can be classified as either unstable angina, or 2 types of heart attack (either NSTEMI or STEMI, depending on how the coronary arteries are blocked). ACS is classed as a medical emergency and requires fast diagnosis and care. Treatment is designed to improve blood flow, treat complications and prevent future problems. ACS can result in reduced function for the patient, which can impact their quality of life.
The most common risk factors for ACS include age, high blood pressure, high blood cholesterol, smoking, lack of physical activity, being overweight or obese, unhealthy diets and diabetes. Adhering to medication and modifying lifestyles can reduce these risk factors.
Educational interventions have been shown to be useful in improving quality of life following ACS and in reducing risk factors. This study aims to assess the effects of an educational intervention on quality of life, lifestyle, adherence to medication and number of re-hospitalisations after ACS.

Who can participate?
People aged 21 or older who have been admitted to a coronary unit after a heart attack and can communicate in Portuguese

What does the study involve?
Participants will be asked to complete several questionnaires relating to health, behaviour and quality of life. They will be randomly allocated to intervention or control groups. The control group will receive the usual discharge planning and the intervention group will receive a new educational intervention, involving 3 sessions providing information and education. Both groups will receive the same care and advice normally given to patients who are discharged from this coronary unit. Participants will be followed up three times: ten days, one and three months after the baseline data collection.

What are the possible benefits and risks of participating?
Some participants may find it beneficial to talk about their experiences of lifestyle change such as smoking cessation, healthier diet and increased physical activity. This research will help the coronary unit at Hospital de Santa Cruz to improve hospital-home transition with a structured educational intervention, which could be of benefit for patients in the future. There are no known risks to participants taking part in this study.

Where is the study run from?
Hospital de Santa Cruz (Portugal)

When is the study starting and how long is it expected to run for?
February 2014 to July 2019

Who is funding the study?
Fundação para a Ciência e Tecnologia (Portugal)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
None

Study information

Scientific Title
The effectiveness of an educational intervention using Social Cognitive Theory versus standard care initiated during hospitalization at a coronary unit, in promoting health-related quality of life of adult and elderly patients with acute coronary syndrome: A feasibility randomized controlled trial

Study objectives
An educational intervention initiated during hospitalization of adult and elderly patients with acute coronary syndrome at a coronary unit promotes behavioral changes, namely regarding body weight, blood pressure and lipid profile management; lifestyle, nutritional, smoking and physical activity changes; and adherence to therapy.
An educational intervention initiated during hospitalization of adult patients with acute coronary syndrome at a coronary unit contributes to reducing the number of re-hospitalizations.
An educational intervention initiated during hospitalization of adult patients with acute coronary syndrome at a coronary unit improves HRQOL self-perception.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee for Health (Comissão de Ética para a Saúde: CES) of the Hospital Center of Western Lisbon (Centro Hospitalar de Lisboa Ocidental: CHLO), 14/10/2014, 99/CES-2014

Study design
Interventional single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

See additional files

Health condition(s) or problem(s) studied
Acute coronary syndrome

Interventions
Participants will be randomised into either the intervention or the control group using web-based block randomisation (20 blocks of 6 participants).
At the baseline, participants in both groups will be assessed on quality of life and clinical parameters including weight, BMI, abdominal perimeter, blood pressure, cholesterol, LDLs and blood glucose levels.
Participants in the intervention group will receive the educational intervention, with the first session provided after clinical stabilisation and before hospital discharge. This will involve one hour of lecturing and a booklet to take home. The lectures and booklet will provide information on what patients need to know about their heart condition, symptoms they should be able to recognise and manage, risk factors and ways to reduce them, lifestyle changes (smoking, diet, physical activity and stressful events), medication plan and adherence, and emotional and social issues they need to discuss. The intervention will emphasise that coronary health is a family affair. The booklet is individualised and contains spaces where the participants can take their own notes and annotate with further topics to include in the next session. The second session will be 10 days after discharge, and will be a telephone contact to clarify doubts and reinforce teaching in areas the participant identifies as lacunar. The third session will occur one month after discharge, either in the clinic or the patient's home, along with an intermediate assessment of the same clinical parameters obtained at the baseline. This session will involve monitoring the participants' lifestyle and introducing the possibility of returning the work, along with how one can maintain a good level of activity and a healthy diet.
Participants in the control group will receive the unit's usual discharge preparation and no educational intervention.
The participants in both groups will receive a calendar to register daily activity, number of smoked cigarettes, forgotten medicine and any complications that may occur.
There will also be a final follow-up 3 months after discharge for both groups, where the same measurements completed at the baseline will be taken, along with information from the calendar completed by both groups.

Intervention Type
Behavioural

Primary outcome measure
The following will be assessed before (baseline), 1 month and 3 months after the educational intervention:
1. Health-related quality of life, assessed using the EQ-5D and MacNew Quality of Life Questionnaire
2. Demographic and clinical data:
2.1. Demographic data assessed using a questionnaire including age, gender, ethnicity, level of education, marital status, professional activity, family household, daily physical activity and smoking habits
2.2. Clinical data, assessed by the health professional during data collection or from patients' medical records, based on the European Guidelines on cardiovascular disease prevention in clinical practice. This data includes weight, BMI, abdominal perimeter, blood pressure, cholesterol, LDLs and blood glucose levels. Questions about this will also be included in the questionnaire for participant information.

Secondary outcome measures
The following are assessed through statistical analysis of data from the demographic and clinical questionnaires at the baseline and after 3 months:
1. Body weight
2. Blood pressure
3. Lipid profile management
4. Lifestyle - changes in the following:
4.1. Nutrition
4.2. Smoking
4.3. Physical activity

The following are assessed using data from the calendar completed by the participants over the 3 month study period:
5. Adherence to therapy
6. Number of re-hospitalisations

Overall study start date
03/02/2014

Completion date
01/07/2019

Eligibility

Key inclusion criteria
1. Aged 21 years or old
2. Hospitalised due to acute coronary syndrome
3. Able to read and write in Portuguese
4. No diagnosed cognitive condition
5. Able to provide informed consent

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
120 for feasibility

Key exclusion criteria
1. Submitted for cardiac surgery and/or with other major comorbidities
2. Haemodynamic instability

Date of first enrolment
15/09/2018

Date of final enrolment
30/03/2019

Locations

Countries of recruitment
Portugal

Study participating centre
CHLO: Hospital de Santa Cruz
Av. Prof. Dr. Reinaldo dos Santos 27-29
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Sponsor information

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Sponsor type
University/education

Website
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ui&de: Nursing Research & Development Unit

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Sponsor type
Research organisation

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http://www.uide.pt/linhas-de-investigacao/develop-and-evaluate-complex-interventions/

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Sponsor type
University/education

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Sponsor type
Not defined

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ROR
https://ror.org/01c27hj86

Funder(s)

Funder type
Not defined

Funder Name
Fundação para a Ciência e a Tecnologia. FCT is the Portuguese national funding agency for science, research and technology

Results and Publications

Publication and dissemination plan
Protocol article in preparation

Intention to publish date
30/01/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		30/07/2018	02/04/2019	No	Yes