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The efficacy of behavioural intervention to increase physical activity among Jordanian patients with coronary heart disease

Submission date
04/01/2012

Recruitment status
No longer recruiting

Registration date
21/03/2012

Overall study status
Completed

Last Edited
18/02/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Physical activity is an important healthy behaviour for prevention and treatment of coronary heart disease. Therefore, it is consistently recommended by international cardiac rehabilitation guidelines as a main component of cardiac rehabilitation programs and secondary prevention programmes. However, there are no available structured physical activity programs in Jordan and the Jordanian patients with coronary heart disease have low physical activity level. Importantly, behavioural interventions such as goal setting, feedback and self monitoring have shown efficacy in increasing the level of physical activity among coronary heart diseases patients who are not attending physical activity programs in western societies. It is beneficial to deliver behavioural intervention in effective way by motivating the patients to increase their level of physical activity through individualised consultation. The main aim of this study is to examine the effect of behavioural change intervention on the level of physical activity among Jordanian patients with coronary heart disease. The other aims are to assess the outcome of the behavioural intervention on blood pressure, body mass index, self efficacy and health related quality of life. In addition, individual characteristics such as gender, age and health status will also be investigated in terms of their relationships with level of physical activity.

Who can participate?
The participants will include current out patients aged between 18 and 70 years, who are clinically diagnosed of coronary heart disease, who attend the cardiac clinics for follow up and are able to perform physical activity. The participants should also have understanding of Arabic language and have access to a mobile telephone. The patients who have unstable major health problems that prevent them from participation in physical activity, such as low blood pressure (hypotension), joint diseases and major heart problems will not be recruited in the study.

What does the study involve?
The first group will be the intervention group who will receive the consultation programme in addition to standard care, and the second group is the control group who will receive just standard advice about physical activity provided by their physicians. The intervention consists of providing patients with behavioural change strategies (goal-setting, self-monitoring and feed-

back) towards being physically active. The intervention will be delivered over six months and it will consist of one face-to-face individualised consultation, six telephone call based consultations and 18 reminder mobile text messages. The intervention aims to educate and motivate patients to include 30 minutes of moderate physical activity such as brisk walking into their daily routine on at least five days per week. Goal setting consists of teaching patients to set goals including short-term ones (one month), for example 'I will do brisk walking five times weekly for 30 minutes', and long term (six months), for example 'I will go to work by walking instead of going by car for the next 6 months'. Self- monitoring includes encouraging the patients to document their performance of physical activity in a diary book, including the type and amount of it or simply put marks for the days of the week on which it is done. Feedback includes reviewing the set goals and diary notes by the researcher through the telephone consultations. In addition, at the end of the study the researcher will ask the participants about their opinions and experiences regarding the intervention components and methods of delivery.

What are the possible benefits and risks of participating?
The intervention group will perform physical activity and get many physiological and psychological benefits. They may include decreased blood pressure, body weight and body lipids and improved quality of life. The physical activities that will be prescribed to the patients have no risk. However, the risks are minimal since the level of physical activity is moderate and that which would be routinely recommended to patients with coronary heart disease as part of standard care. To decrease the risk the researcher will contact the clinic doctors of all patients who consent to take part and ask them to confirm that their patient is able to participate in moderate physical activity.

Where is the study run from?
Jordan University Hospital and King Abdullah University Hospital

When is study starting and how long is it expected to run for?
The recruitment started in February 2012 and will continue until April 2012

Who is funding the study?
University of Nottingham, UK

Who is the main contact?
Eman Alsaleh
ntxea2@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Eman Alsaleh

Contact details
2 Woodlane Gardens
Nottingham
United Kingdom

NG3 3BF
+44 (0)7413522660
ntxea2@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Consultation-based behavioural intervention to increase physical activity among Jordanian patients with coronary heart disease: a multicentre randomised controlled trial

Study objectives
There is a need to provide an intervention that aims to motivate Jordanian patients with coronary heart disease to adopt physical activity in their daily life. The primary aim is to examine the effect of behavioural change intervention delivered by consultation on the level of physical activity among Jordanian patients with coronary heart disease. Self efficacy and social cognitive theory will guide the study via mediators of health behaviours including knowledge, benefits and barriers to physical activity and self efficacy to improve patients' level of physical activity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. King Abdullah University Hospital, 13/10/2011, ref: 12/39/2011
2. Jordan University Hospital - approval pending

Study design
Multicentre 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
Not available in web format, please contact Eman alsaleh at ntxea2@nottingham.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary heart disease

Interventions
The intervention aims to educate and motivate patients to integrate 30 minutes of moderate physical activity into their daily routine on at least five days per week as recommended by international guidelines. The intervention consists of individually tailored face-to-face and telephone consultations to develop physical activity goals and 18 motivational text messages to attain these goals. Consultation will be individually tailored to the current physical activity level and needs of every patient determined from self-reported physical activity questionnaire and patients' reports of their needs and barriers in performing physical activity. Intervention will also focus on improving mediators of health behaviours which include providing information about physical activity, increasing perceived benefits of physical activity and self-efficacy(confidence) and decreasing perceived barriers to physical activity. Qualitative semi-structured interviews will be conducted with 15 patients from the intervention group at the end of the intervention to evaluate the patients' perceptions of the benefits and barriers to physical activity and their perceptions of the consultation program including aspects of the intervention which were most or least useful and/or motivating.

Control group who will receive just standard advice about physical activity provided by their physicians.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Physical activity level (duration, frequency, and intensity) measured pre and post intervention

Secondary outcome measures
1. Self -efficacy
2. Health-Related Quality of Life
3. Blood pressure
4. Body mass index

Measured pre and post intervention

Overall study start date
01/02/2012

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Patients who have a clinically documented diagnosis of coronary heart disease (including angina, myocardial infarction, coronary angioplasty or post heart surgery)
2. Patients who are clinically stable and able to perform physical activity (PA) (confirmed by their hospital doctor)
3. Adults aged between 18 and 70 years
4. Patients who can understand and write Arabic
5. Patients who have access to a mobile telephone and text essays

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
156

Total final enrolment
156

Key exclusion criteria
Patients who have no co-morbidity or unstable major health problems that prevent them from participating in moderate physical activity (as confirmed by their hospital doctor)

Date of first enrolment
01/02/2012

Date of final enrolment
01/04/2012

Locations

Countries of recruitment
England

Jordan

United Kingdom

Study participating centre

2 Woodlane Gardens
Nottingham
United Kingdom
NG3 3BF

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
c/o Dr Holly Blake
School of Nursing, Midwifery & Physiotherapy
Faculty of Medicine and Health Sciences
Queen's Medical Centre
Nottingham
England
United Kingdom
NG7 2HA

Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/12/2012		Yes	No
Results article	results	26/07/2016	18/02/2021	Yes	No