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A web-based physical activity (PA) intervention for adults not reaching Canada's recommendations

Submission date
04/07/2014

Recruitment status
No longer recruiting

Registration date
24/07/2014

Overall study status
Completed

Last Edited
27/11/2015

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Informing people of their risk of heart disease, along with counselling on what lifestyle choices should be adopted, is the first step towards preventing someone from developing the disease. Most Canadian physicians perform risk assessments on their patients as they are well aware of the importance of promoting regular physical activity. Despite this, 85% of adults in Canada do not meet Canadas physical activity guidelines (which state that adults aged 18-64 should do at least 150 minutes of moderate to vigorous physical activity every week in bouts of 10 minutes or more). This highlights a need to prioritise counselling on physical activity, but time constraints may stop physicians from being able to do this for all their patients adequately. eHealth technology is an innovative way for helping patients to self-manage their heart disease health factors. It follows the same principles of face-to-face counselling by asking people about their health behaviour, their motivation and factors determining motivation and behaviour. The feedback given to a person is based on the answers given and highly tailored to meet each persons individual needs. The aim of this study is to test the feasibility and efficacy of a web-based programme (the intervention) targeting physical activity in patients not reaching Canadas physical activity guidelines.

Who can participate?
Participants aged between 35 and 70 years of age that took part in the Quebec City Prospective Urban Rural Epidemiology (PURE) study (a study looking at health among the local population)

What does the study involve?
Each participant is randomly allocated into one of two groups. The experimental group take part in a web-based physical activity program. Each session takes about 10-15 minutes each and participants are asked to do 8 sessions over the course of 16 minutes. The control group receive their usual standard of care. Both groups complete questionnaires before and after the experimental group have completed the physical activity programme. The programme will be offered to the control group once the study is complete.

What are the possible benefits and risks of participating?
The potential benefits for participants with this research project are:
1. Personalized advice regarding their own physical activity.
2. Knowledge that they have contributed to the advancement of knowledge in the field of promotion of physical activity on the Internet.
This research project has no known physical or psychological risks.

Where is the study run from?
1. Université du Québec à Trois-Rivières (Canada)
2. lInstitut universitaire de cardiologie et de pneumologie de Québec (Canada)

When is study starting and how long is it expected to run for?
April 2014 to September 2014

Who is funding the study?
The Canadian Institutes of Health Research (CIHR) (Canada)

Who is the main contact?
Professor François Boudreau
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Study website
http://www.purecybersante.ca/

Contact information

Type(s)
Scientific

Contact name
Prof Francois Boudreau

Contact details
Université du Québec à Trois-Rivières
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
292463 (Canadian Institutes of Health Research)

Study information

Scientific Title
Feasibility and efficacy of a computer-tailoring (CT) physical activity intervention to promote self management of cardiovascular disease (CVD) risk factors: a pilot randomized controlled trial

Acronym
PURE-Cybersanté-Activité Physique

Study objectives
To examine the feasibility of adapted Web-based CT intervention. The specific research question is:
Research Question 1. Do intervention initiation and intervention completion regarding PA differ in relation to socioeconomic status and gender?
To determine the efficacy of adapted Web-based CT intervention after three months. The specific research questions are:
RQ 2.1 - What is the efficacy of CT intervention on PA?
RQ-2.2 - Is the intervention equally effective for subgroups differing in socioeconomic status and gender?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The ethics board of Université du Québec à Trois-Rivières; 16/07/2013; ref: CER-13-192-06.32
2. The ethics board of Institut universitaire de cardiologie et de pneumologie de Québec; 05/11/2013; ref: 21002

Study design
RCT. A design with baseline measurement (time 1) and follow-up measurement at three months.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Cardiovascular diseases

Interventions
Participants will be divided to 2 groups:
1. An experimental group (CT intervention): The intervention group will be invited to participate in eight 10-15 minute Web sessions distributed over a 16-week period
2. A control group (usual care): Will complete a pretest and a post-test. The intervention will be offered to the control group afterwards.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Leisure-time physical activity. The Godin Leisure-Time Physical Activity Questionnaire will be used : a validated French version will assess in both groups the average frequency of light, moderate, and vigorous exercise during free time in a typical week at baseline and 3-month follow-up. Also, forty participants in both groups will receive a blinded pedometer that has been validated. These participants will be instructed about how to wear pedometer correctly and physical activity behaviour will be measured during 7 consecutive days from morning to bedtime at 3-month follow-up.

Secondary outcome measures
N/A

Overall study start date
28/05/2014

Completion date
07/09/2014

Eligibility

Key inclusion criteria
Participants-inclusion criteria
1. Not meeting Canadas physical activity guidelines of 150 minutes of moderate-vigorous physical activity a week
2. To be between 40 and 75 years of age
3. Have internet access.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

250

Key exclusion criteria
Participants-exclusion criteria:
1. A documented history of CVD at the time of the study
2. Poor mental function, drug or substance (e.g., alcohol) abuse, unstable psychiatric illness at the time of the study
3. Physical disability or other limitations reducing the ability to walk

Date of first enrolment
28/05/2014

Date of final enrolment
07/09/2014

Locations

Countries of recruitment
Canada

Study participating centre
Université du Québec à Trois-Rivières
Trois-Rivières (Québec)
Canada
G9A 5H7

Sponsor information

Organisation
Canadian Institutes of Health Research (Canada)

Sponsor details
160 Elgin Street, 9th Floor
Address Locator 4809A
Ottawa
Canada
K1A 0W9

Sponsor type
Government

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (Canada) (e-Health Innovations Catalyst Grant-2012)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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?
Results article	results	09/10/2015		Yes	No