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Managing cigarette cravings using the Physical over Smoking (PoS) App

Submission date
17/02/2015

Recruitment status
No longer recruiting

Registration date
25/02/2015

Overall study status
Completed

Last Edited
30/05/2017

Condition category
Mental and Behavioural Disorders

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

Plain English Summary
Background and study aims
Research evidence on smokers show that even relatively small doses of exercise can help to manage cigarette cravings and withdrawal symptoms. A smartphone application named Physical over Smoking (PoS) has been developed to support quitters to manage cigarette cravings by counter-suggesting short exercises, tailored to participants' information (gender, age etc) and current status (place, mood and social environment). The aim of this study is to test how well the PoS App works in a group of adult smokers who have recently quit smoking in comparison to a group of non users of the App.

Who can participate?
Adults with no other addictions or mental and physical problems who are addicted to cigarettes and want to quit smoking.

What does the study involve?
All participants receive a short quit smoking counselling program and then they are randomly allocated to one of two groups. One group uses the PoS App when experiencing cigarette cravings as an aid to overcome the urge. The other group do not receive any after quit support. Both groups are followed up for 6 months after quit day.

What are the possible benefits and risks of participating?
All participants benefit from the free counselling quit smoking program. There are no risks or any kind of harm involved.

Where is the study run from?
University of Jyvaskyla (Finland)

When is the study starting and how long is it expected to run for?
February 2014 to December 2015

Who is funding the study?
National Institute for Health and Welfare (Finland)

Who is the main contact?
Mary Chasandra

Contact information

Type(s)
Public

Contact name
Dr Mary Chasandra

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effectiveness of a smartphone application on long term abstinence, awareness, efficacy and power of control of cigarette cravings of adult smokers: a two-arm superiority randomised controlled trial

Study hypothesis
1. Users of the PoS App will have higher abstinence rates at follow up measures in comparison to the control group
2. Users of the PoS App will report higher efficacy on being aware of experiencing cravings compared to the control group
3. Users of the PoS App will report higher efficacy on managing cravings compared to the control group
4. Users of the PoS App will report higher power of control to manage cravings compared to the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Finland Health Care District's Ethics Committee (Keski-Suomen sairaanhoitopiirin eettinen toimikunta), 14/10/2014 (no ref number)

Study design
Two-arm intervention single-center parallel superiority pragmatic randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Use contact information to ask for the Participant Information Sheet (in Finnish or a translation in English)

Condition
Tobacco smoking

Interventions
Participants identified as eligible and agreed to participate will receive a quit smoking counselling program. The program will consist of 3 motivational interviewing 2 hours weekly sessions. After they set their quit smoking day they will be randomly assigned to the experimental group (after quit support by using the Physical over Smoking App for managing their cravings) or to the control group (no after quit support) and have a 4th meeting. All participants will be followed for 6 months after the 4th meeting.

Intervention Type
Mixed

Primary outcome measure
1. Self report of tobacco use at a. before quit day; b. 1 & 2 & 3 weeks after 4th meeting; c. 1 & 3 & 6 months after 4th meeting. Cotinine in saliva measured at 4th meeting
2. Self report of efficacy on being aware of experience cravings at a. before quit day; b. 1 & 2 & 3 weeks after 4th meeting; c. 1 & 3 & 6 months after 4th meeting
3. Self report of efficacy on managing cravings at a. before quit day; b. 1 & 2 & 3 weeks after quit; c. 1 & 3 & 6 months after quit
4. Self report of power of control to manage cravings at a. before quit day; b. 3 days after, c. 1 & 3 & 6 months after quit

Secondary outcome measures
1. Self-reported current physical activity behavior (IPAQ) a. before quit day; b. 3 & 6 months after 4th meeting. 3 days measurement of step counts (pedometer) at before quit day time point
2. Self-reported attitudes, intentions and perceived behavioural control of quit smoking at

before quit day time point
3. Self-reported attitudes, intentions and perceived behavioural control of craving management at a. before quit day; b. 4th meeting
4. Self-reported attitudes, intentions and perceived behavioural control of increase physical activity behavior at a. before quit day; b. 4th meeting
5. Self-reported Usability of the Physical over Smoking App from experimental group only at a. 1 week; b. 1 month, 3 months & 6 months after 4th meeting
6. Fidelity checks in both groups at a. 3 days after 4th meeting and b. 1 week; c. 1 month, 3 months & 6 months after 4th meeting

Overall study start date
01/02/2014

Overall study end date
31/12/2015

Eligibility

Participant inclusion criteria
Adult smokers

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50 participants in total (25 for experimental group and 25 for control group)

Participant exclusion criteria
1. Patients with additional addictions (alcohol, drugs, etc) according to NIDA screening tool
2. High scores of active psychological distress according to GHQ-12: if scores 20+ on a scale from 0 to 36.
3. Low scores on Tobacco Dependence Screener (TDS): less than 5 on a scale from 1 to 10
4. Low scores on Motivation to stop smoking scale: less than 3 on a scale from 1 to 7
5. Health risks by increasing physical activity according to the screening tool of PAR-Q

Recruitment start date
01/12/2014

Recruitment end date
01/05/2015

Locations

Countries of recruitment

Finland

Study participating centre
JYTE; Jyvaskyla Community Primary Health Care Center: Palokan terveysasema
Ritopohjantie 26
Jyvaskyla, Palokka
Finland
40270

Sponsor information

Organisation
University of Jyvaskyla

Sponsor details
Department of Sport Sciences
PO Box 35
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Sponsor type
University/education

Website
https://www.jyu.fi/sport/en

ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Welfare (TERVEYDEN JA HYVINVOINNIN LAITOS)

Results and Publications

Publication and dissemination plan
Protocol paper submitted for publication before the end of April 2015.
Main results of the intervention paper submitted for publication before February 2016.

Added 16/01/2017: The publication of the results paper is in progress.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mary Chasandra.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/10/2015		Yes	No
Basic results	results	17/01/2017	27/01/2017	No	No
Results article		26/05/2017		Yes	No