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Evaluating the effectiveness of "Agoraphobia Free": A novel mobile application for treating Agoraphobia

Submission date
05/02/2016

Recruitment status
No longer recruiting

Registration date
10/02/2016

Overall study status
Completed

Last Edited
28/11/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Agoraphobia is a type of anxiety disorder where a person fears being in situations and places where they feel trapped or in danger, often because of openness or crowdedness. Although many believe it is just a fear of open or public places, it is much more complex and usually involves a range of different fears. In general, it can render people unable to function and the condition traps sufferers in a vicious cycle, preventing them from leaving home to seek the support or to attend treatment that might end the condition. Depending on how severe the condition is treatment may require one-to-one therapy in a patient's home and for the person to be escorted around the surrounding area, but this is often expensive and time-consuming. "Agoraphobia Free" is a new therapeutic app which aims to break this cycle by putting the two components of traditional treatment, namely education and exposure therapy (gradually exposing someone to their fear until it no longer scares them), in the hands of the users themselves via their phones or tablets. This study aims to look at the effectiveness of using the app for six weeks on the severity of symptoms in self-reported agoraphobia sufferers.

Who can participate?
Adults who suffer from agoraphobia.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given access to the “Agoraphobia Free” app, which is designed specifically to help people with agoraphobia, for a total of 12 weeks. The app features game play to make therapy sessions as engaging as possible, exposing users to virtual environments likely to trigger their fears. They are also taught ways of dealing with their fears within the app so that they are no longer as frightening. Those in the second group are given access to a more generalized app called “Stress Free”, which is designed to help people with anxiety in general, for a total of 12 weeks. This app involves teaching the user techniques such as calm breathing, relaxation and meditation, designed to lower anxiety levels. At the start of the study and then again after six and 12 weeks, participants in both groups complete a number of questionnaires in order to assess the severity of their agoraphobia symptoms.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their feelings of anxiety as well as increased knowledge about their condition. There are no notable risks of taking part in the study.

Where is the study run from?
University of Roehampton (UK)

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

Who is funding the study?
Nominet Trust (UK)

Who is the main contact?
Dr Elias Tsakanikos

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Clinical effectiveness of a mobile phone application to treat agoraphobia with and without panic disorder (PD) in a community-based sample

Acronym
Evaluation of Agoraphobia Free

Study objectives
The aim of this study is to examine whether the agoraphobia-specific mobile intervention ("agoraphobia-free") is more effective than the generic, control intervention ("stress free").

Ethics approval required
Old ethics approval format

Ethics approval(s)
Roehampton University Ethics Committee, 21/05/2014, ref: PSYC 14/ 117

Study design
Web-based assessor-blind randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

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
Agoraphobia/Agoraphobic anxiety

Interventions
Adults that self-identified with agoraphobia were randomised to the two treatment arms. Block randomisation was applied to ensure equal numbers of participants in each group (ratio 1:1).

Group 1: Participants are given access to the “Agoraphobia Free” app developed by Health e-Living Partnership Ltd. (HeLP) for iOS and Android. The app involves an interactive game-based intervention utilising cognitive-behavioural techniques that target agoraphobia.

Group 2: Participants are given access to a generic stress-reduction application (“Stress Free”), which does not specifically address agoraphobic symptoms. The app aims to help to lower anxiety levels through techniques such as calm breathing, differential deep muscle relaxation, self-hypnosis and meditation

Participants in both groups are given access to the application for a total of 12 weeks, and complete self-reported assessments at baseline, midpoint (6 weeks) and endpoint (12 weeks) of the trial.

Intervention Type
Device

Primary outcome measure
Severity of agoraphobic and panic symptoms are measured using the Panic and Agoraphobia Scale at baseline, 6 and 12 weeks.

Secondary outcome measures
1. Degree of subjective distress experienced because of agoraphobia is measured by using a single item ("How much distress have you experienced because of agoraphobia in the past week?"), which is rated from 1 ("No distress") to 5 ("Extreme distress") at baseline, 6 and 12 weeks
2. Completion of the intervention is measured as 1 (completion of the tasks) or 0 (non-completion of the tasks) at 6 and 12 weeks
3. Engagement with the apps is measured using app usage data (i.e. total number of times that users engaged with the app) at 6 and 12 weeks

Overall study start date
24/09/2014

Completion date
23/04/2015

Eligibility

Key inclusion criteria
1. Aged 18 or above
2. Identify themselves as suffering from agoraphobia
3. Willing and able to provide informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
170

Key exclusion criteria

1. Inability to give informed consent due to significant cognitive or intellectual impairment
2. No adequate understanding of English as a first language
3. Not having a mobile device than can run the application as designed
4. Any significant disease or disorder which, in the opinion of the Investigators, may either put the person at risk because of participation in the trial.

Date of first enrolment
22/09/2014

Date of final enrolment
28/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Roehampton
Whitelands College
Holybourne Avenue
London
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SW15 4JD

Sponsor information

Organisation
University of Roehampton

Sponsor details
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Sponsor type
University/education

ROR

https://ror.org/043071f54

Funder(s)

Funder type
Charity

Funder Name
Nominet Trust

Results and Publications

Publication and dissemination plan
Planned publication of study results.

Intention to publish date
31/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	24/11/2017		Yes	No