ISRCTN78356215 https://doi.org/10.1186/ISRCTN78356215

Flowy randomized controlled pilot trial

Submission date
26/01/2015

Recruitment status
No longer recruiting

Registration date
30/03/2015

Overall study status
Completed

Last Edited
20/03/2020

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
On the basis of a well established and proven theory for controlled respiration as a behavioural intervention for common mental health disorders (CMHD) and evidence that gamification can improve health outcomes through increasing patients' engagement, we have developed an mHealth game called Flowy, which is the first mHealth app to operationalize breathing retraining exercises for gameplay. We have designed Flowy to bridge intervention accessibility gaps, reduce the economic burden of chronic mental illness, endorse personalized patient-centered care, and engage users to understand and manage their own condition in a fun and meaningful way. We have engaged service users with CMHDs, their families and their care providers in Flowy's design, development and pilot evaluation. The study aims are to assess the acceptability of Flowy as a mobile health game that digitally delivers breathing retraining exercises for anxiety, panic and hyperventilation symptom management in people with moderate anxiety; the effectiveness in reducing symptom severity alongside improving quality of life; and both the user engagement and usability.

Who can participate?
Adults with anxiety disorders

What does the study involve?
Patients were randomly allocated to one of two groups. The intervention group played Flowy for 1 month and the control group patients were placed on a waiting list for 1 month and then given a code to download Flowy.

What are the possible benefits and risks of participating?
The possible benefits include an improvement in the patient's condition and the development of a new management tool for similar conditions. There are no known risks associated with breathing retraining exercises.

Where is the study run from?
Wolfson Institute for Preventive Medicine (UK) and Playlab London (UK)

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

Who is funding the study?
Playlab London (UK)

Who is the main contact?
Ms Quynh Pham

Study website
https://www.flowygame.com/survey

Contact information

Type(s)
Public

Contact name
Ms Quynh Pham

ORCID ID
http://orcid.org/0000-0002-0540-4181

Contact details
Playlab London
71b St John Street
London
United Kingdom
EC1M 4NJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Feasibility and efficacy of an mHealth game for managing anxiety: Flowy randomized controlled pilot trial and design evaluation

Study objectives
A breathing retraining game Flowy will be an acceptable, clinically effective, engaging and useful anxiety management intervention:
1. Determine the feasibility of Flowy as an anxiety management intervention
2. Validate the clinical efficacy of Flowy to measurably reduce clinical symptoms

Ethics approval required
Old ethics approval format

Ethics approval(s)
Queen Mary Research Ethics Committee (Panel B), 19/03/2014, QMREC2014/20

Study design
Interventional randomized controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
https://www.flowygame/survey

Health condition(s) or problem(s) studied
Anxiety disorders

Interventions
1. Intervention group: Flowy is an mHealth game that engages users in a series of mini games where they use breathing retraining exercises and perform diaphragmatic breathing to alleviate anxiety. These mini games range from sailing a boat down a river to flying balloons in the sky. Users touch the screen with their finger as they inhale and remove their finger from the screen as they exhale to control the gaming mechanics. A breathing indicator visually represents a full breath; users see a circle expanding as they inhale and contracting as they exhale. This indicator provides a visual guideline of a breathing retraining exercise, and also simplifies the cognitive assessment of what constitutes a full diaphragmatic breath. The goal of each mini game is to correctly follow the breathing indicator while advancing in the game narrative; users win by breathing correctly and staying calm. No usage guidelines were enforced to allow for assessment of naturalistic use patterns determined by the patient. Flowy also includes an in-game interactive tutorial on how to properly perform diaphragmatic breathing, as guided by the National Health Service Improving Access to Psychological Therapies protocol alongside evidence-based research protocol from literature.
2. Control group: participants were placed on a waiting list for 4 weeks. To prevent high attrition rates, participants received a weekly newsletter with curated content on breathing retraining exercises, Flowy game development, mindfulness meditation and similar content relevant to Flowy. Additionally, they received reminder emails through an online marketing tool MailChimp to complete study assessments. After 4 weeks, participants received a free code to download Flowy.

Intervention Type
Behavioural

Primary outcome measure
Acceptability of Flowy as an anxiety management intervention, assessed with recruitment and response rates throughout the study

Secondary outcome measures
1. Whether Flowy engaged participants sufficiently to make them proactively use the application, assessed by frequency and duration of use based on log data throughout the study
2. A significant reduction in anxiety, panic and hyperventilation symptoms and improvement in quality of life reported by participants in the intervention group from baseline to week 4, measured at eligibility prescreen, baseline, week 2 and week 4
3. A significant reduction in anxiety, panic and hyperventilation symptoms and improvement in quality of life reported by participants in the intervention group compared with the control group from baseline to week 4, measured at eligibility prescreen, baseline, week 2 and week 4
4. Participant perception of Flowy as a useful intervention, measured with a 21-question questionnaire that assesses intervention usability and utility at week 4
5. Assessment of the outcome measure scores in pilot study participants to establish parameters of measurable change in anxiety, hyperventilation and panic attack symptoms for a subsequent full-powered and full-scale randomized controlled trial
6. Study design evaluation to inform sample size calculation and methodology of a subsequent full-powered and full-scale randomized controlled trial

Anxiety symptoms were assessed with three questionnaires: Generalized Anxiety Disorder-7 (GAD-7) item scale, Overall Anxiety Severity and Impairment Scale (OASIS) and Anxiety Sensitivity Index-3 (ASI-3).

Panic symptoms were assessed with the Panic Disorder Severity Scale-Self Report (PDSS-SR).

Hyperventilation symptoms were assessed with the Nijmegen Questionnaire.

Quality of life, enjoyment and satisfaction were assessed with the Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form.

Overall study start date
18/02/2014

Completion date
11/07/2014

Eligibility

Key inclusion criteria
1. Age at least 18 years old
2. Screen GAD-7 score ≥6
3. Screen OASIS score ≥8
4. Screen ASI-3 score ≥16
5. Comorbid disorders including major depression, dysthymia, panic disorder, agoraphobia, social anxiety disorder, generalized anxiety disorder, simple phobia, obsessive compulsive disorder, and somatization disorder with moderate symptoms of anxiety
6. Concurrent use of antidepressants, anxiolytics, hypnotics, and herbal products with psychoactive substances acceptable provided there is no change in medication type and dose

after randomization
7. Provision of written informed consent
8. Able to comply with the study protocol (e.g., able to download Flowy onto mobile device or able to complete assessments)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Lack of mobile device or incompatible operating system (Android and iOS compatibility required)
2. Lack of access to Internet
3. Any co-existing medical conditions that could alter the clinical presentation of hyperventilation such as chronic severe asthma or chronic obstructive pulmonary disease
4. Lifetime history of bipolar disorder or psychosis
5. Presence of any Diagnostic and Statistical Manual of Mental Disorders (DSM) IV Axis I disorder, excluding those listed in the inclusion criteria, that are likely to interfere with the patient's ability to participate in the study, as judged by the investigator
6. Presence of any DSM-IV Axis II disorder that are likely to interfere with the patient's ability to participate in the study, as judged by the investigator
7. Participants who are acutely suicidal to the degree that precautions against suicide are needed or have a history of suicide attempt in the past 5 years

Date of first enrolment
11/04/2014

Date of final enrolment
15/05/2014

Locations

Countries of recruitment
Argentina

Brazil

Canada

Cyprus

England

Germany

Israel

Italy

Malaysia

United Kingdom

United States of America

Study participating centre
Playlab London
71b St John Street
London
United Kingdom
EC1M 4NJ

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Queens' Building
Queen Mary University of London
Mile End Road
London
England
United Kingdom
E1 4NS
+4402078827915
h.covill@qmul.ac.uk

Sponsor type
University/education

Website
http://www.arcs.qmul.ac.uk/research-degrees/research-degree-students/ethics/94438.html

ROR

https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
Playlab London

Results and Publications

Publication and dissemination plan
We aim to publish our findings in the Journal of Medical Internet Research (impact factor: 4.7)

Intention to publish date
23/02/2015

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	01/02/2016		Yes	No