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Can a mindfulness app enhance well-being?

Submission date
02/08/2018

Recruitment status
No longer recruiting

Registration date
14/08/2018

Overall study status
Completed

Last Edited
06/09/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Technology is advancing at an alarming rate. The smartphone plays a key role in this advancement, and estimates suggest that 1.82 billion smartphones were in use globally at the end of 2013. The development of smartphone applications, or 'apps', has made it possible for smartphones to be used to improve public health, for example by using them to deliver programs aimed at increasing wellbeing.
One particular program that has shown promise as a means of increasing wellbeing is 'mindfulness training'. Mindfulness is the process of observing thoughts and feelings in the present moment, without judgement or reaction, and has its origins in Buddhist teachings dating back several thousand years. Mindfulness is traditionally taught via group-based, in-person programs. However, these can be costly, time-consuming, and difficult to access. Smartphone apps could provide a more cost-effective and accessible way of delivering mindfulness training to the general public, with early studies suggesting that online-based mindfulness programs can lead to a wide variety of benefits. However, few studies have tested whether mindfulness apps are also effective at delivering mindfulness training. Further, little is known about how long people have to use mindfulness apps for in order to experience certain benefits, and who is likely to benefit from using a mindfulness app the most.
This study aims to test whether healthy adults from the general population feel as though their sense of wellbeing has increased after using the mindfulness app ‘Headspace’ for a period of 30 days. Headspace is one of the world's most popular mindfulness apps, and has been downloaded more than 25 million times. It features daily guided mindfulness exercises, usually ranging from 10 to 20 minutes, taught by former Buddhist monk Andy Puddicombe. This study will help us to answer whether mindfulness apps such as Headspace are an effective way of teaching mindfulness training, and whether using Headspace can increase public well-being, for example by making people feel less stressed, or more satisfied with their lives.

Who can participate?
Any adult from the general population who has access to a smartphone

What does the study involve?
A group of participants will be given free access to Headspace and asked to complete questionnaires about their sense of well-being (how stressed they feel, how resilient they feel, and how satisfied with their life they feel), before and after using Headspace for 10 days and for 30 days. A second group of participants (the control group) will complete the same

questionnaires over the same time period, but without using Headspace. These participants will be on a waiting list, and will have free access to Headspace for 30 days at the end of the study, should they wish to use it. We will then compare scores between groups in order to deduce whether Headspace has improved peoples' sense of wellbeing.

What are the possible benefits and risks of participating?
The possible benefit of taking part in this study is that participants may experience an increase in well-being after engaging with Headspace, though there is no guarantee that this will be the case. There are no known risks to participants taking part in this study.

Where is the study run from?
London Metropolitan University, London

When is the study starting and how long is it expected to run for?
February 2016 to August 2016

Who is funding the study?
This study will form part of a Masters degree dissertation, and will therefore not receive any funding

Who is the main contact?
1. Dr. Marcos Economides,m_econ@outlook.com
2. Ms Louise Champion, loudibley@yahoo.co.uk

Contact information

Type(s)
Scientific

Contact name
Dr Marcos Economides

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HS001

Study information

Scientific Title
The efficacy of a brief app-based mindfulness intervention on psychosocial outcomes in healthy adults: a pilot randomised controlled trial

Study objectives
We hypothesized that relative to a wait-list control group, participants in the Headspace group would experience significant beneficial impact across all three outcome measures (perceived stress, satisfaction with life, and resilience), and that the extent of this benefit would be greater following 30 days of the intervention than 10 days.
We also hypothesized that users with higher self-rated task enjoyment (or lower self-rated task difficulty) would experience the largest positive change across all three outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Metropolitan University Ethics Committee, 14/04/2016, 13050652

Study design
Interventional online pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Psychosocial health (perceived stress, satisfaction with life, resilience) in healthy adults

Interventions
Participants will be randomised via a simple, computer-generated sequence into the intervention or the control group.
Participants in the intervention group will self-administer Foundation Series 1-3 of the commericially-available Headspace app. This results in 30 sessions in total, and participants will be encouraged to complete one 10-20 minute Headspace session per day.

Participants in the wait-list control group will be instructed that they will receive access to the Headspace intervention with a 30 day delay.

Intervention Type
Other

Primary outcome measure
The following were measured at the baseline, after 10 days and after 30 days:
1. Satisfaction with life, assessed using the Satisfaction With Life Scale (SWLS)
2. Perceived stress, assessed using the Perceived Stress Scale
3. Resilience, assessed using the Wagnild Resilience Scale

Secondary outcome measures
Three self-reported questions were included as secondary measures for the intervention group only and were assessed after 10 days and 30 days of the Headspace intervention:
1. The number of Headspace sessions completed
2. Perceived difficulty associated with completing the Headspace intervention
3. Perceived enjoyment associated with completing the Headspace intervention

Overall study start date
01/02/2016

Completion date
01/08/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Access to a smartphone

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Approximately 100

Total final enrolment
74

Key exclusion criteria

1. Engagement with mindfulness or meditation for more than 20 total minutes
2. Presence of psychological illness
3. History of psychological disorder or ongoing treatment for a psychological disorder
4. Score greater than 11 on the General Health Questionnaire 28 (GHQ-28) or a positive answer to questions 27 and 28 regarding suicidality

Date of first enrolment
18/04/2016

Date of final enrolment
02/05/2016

Locations

Countries of recruitment
England

United Kingdom

United States of America

Study participating centre
London Metropolitan University
School of Social Sciences
London
United Kingdom
N7 8DB

Sponsor information

Organisation
London Metropolitan University

Sponsor details
166-220 Holloway Rd
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N7 8DB

Sponsor type
University/education

Website
https://www.londonmet.ac.uk/

ROR
https://ror.org/00ae33288

Funder(s)

Funder type
Not defined

Funder Name
This study formed part of a Master's dissertation, and therefore received no funding

Results and Publications

Publication and dissemination plan
The researchers plan to submit the study for peer-reviewed publication at an appropriate academic journal.

Intention to publish date
15/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during the current study are intended to be published in raw anonymised form, as supplementary data to a peer-reviewed publication in an academic journal. The data will thus be freely available once the study is published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/12/2018		Yes	No
Dataset		31/12/2018	06/09/2023	No	No
Protocol (other)		31/12/2018	06/09/2023	No	No