ISRCTN13895659 https://doi.org/10.1186/ISRCTN13895659

Headspace as a guided self-help mindfulness course for depression

Submission date
31/07/2017

Recruitment status
No longer recruiting

Registration date
01/09/2017

Overall study status
Completed

Last Edited
11/10/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression has serious personal and economic consequences. Improving Access to Psychological Therapies (IAPT) is an NHS initiative that aims to improve access to psychological therapies for people experiencing depression and anxiety. People experiencing depression are typically offered cognitive behavioural therapy self-help (CBT-SH) supported by a Psychological Wellbeing Practitioner (PWP). However, completion rates and outcomes for IAPT CBT-SH treatment are disappointing; only around 40% of referrals complete treatment, but 58% of people who complete treatment remain depressed. Mindfulness has been found to be useful to helping depression. It could be helpful as a self-help online as it is low cost and some people may not want to attend group sessions Headspace is a smartphone and online application delivering simple daily activities based on mindfulness practice. It teaches beginners the basic concepts of mindfulness through simple, empirically-supported guided meditations. The aim of this study is to investigate an alternative treatment to CBT-SH in IAPT, specifically, an online/smartphone app mindfulness-based self-help programme.

Who can participate?
Adults aged 18 who have mild or moderate clinical depression.

What does the study involve?
Participants are received 30 sessions of the Headspace programme over eight weeks. This is done for ten minutes per day using a smartphone application. Participants are offered six sessions with a PWP to provide encouragement. The programme will be examined for recruitment, retention, acceptability, and preliminary indicators of potential effectiveness. If Headspace is found to be feasible, this will inform the design of further studies, which may eventually inform decision making about the provision of Headspace in IAPT to benefit patients experiencing moderate depression.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in depression symptoms. There are risks of participants becoming more aware of negative thoughts and feelings through the programme as their become more aware of current and past experiences. The PWP will encourage participants to make a choice about to they respond. Participants will have a regular opportunity to talk with

the PWP about their experiences of their allocated intervention and the PWP will be supervised by the study lead who is a clinical psychologist with many years of experience in working in mental health care settings. In the event of a participant experiencing a high degree of distress the research team would follow good practice and ensure that the participant is referred on to an appropriate source of support.

Where is the study run from?
1. Croydon IAPT (UK)
2. Brighton and Hove Wellbeing Service (UK)

When is the study starting and how long is it expected to run for?
September 2017 to August 2018

Who is funding the study?
Headspace Meditation Limited (UK)

Who is the main contact?
Dr Clara Strauss
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35113

Study information

Scientific Title
Headspace as a PWP-guided online self-help mindfulness intervention for depressive symptoms in IAPT: A feasibility study

Study objectives
This is a feasibility study, which aims to address the following questions:

1) Recruitment: Can we recruit?
a. How many people are offered the study over the nine-month recruitment period (i.e., people who meet inclusion criteria and are given opportunity to take part)?
b. Of (1a), how many people consent to take part in the study? What is this as a percentage of people offered the study (1a)?
c. What are the reasons for people declining to take part in the study?
d. What is the demographic profile of people consenting/declining to take part (gender, age, ethnicity)?

2) Retention: Can we retain people to the intervention?
a. How many people complete the intervention (defined as listening to the guided mindfulness practices on at least 24 sessions of the 30 sessions within 8 weeks)? What is this as a percentage of those consented to take part?
b. What are reasons for dropping out of the intervention?
c. How many telephone support sessions with a psychological wellbeing practitioner (PWP) are attended on average out of the 6 sessions offered?
d. How many people attend at least 3 PWP sessions? What is this as a percentage of those consenting?

3) Acceptability: Is the intervention acceptable?
a. How do participants experience the intervention? What aspects of the intervention do participants find helpful and engaging? What aspects of the intervention do participants find unhelpful or act as barriers to engagement? What are short-term and lasting positive and negative effects of practising mindfulness using Headspace?
b. How do PWPs experience the intervention? What aspects of the intervention do PWPs find helpful and engaging? What aspects of the intervention do PWPs find unhelpful or act as barriers to engagement?
c. How do IAPT service leads/managers experience the intervention? What do IAPT service leads /managers see as the barriers and enablers to implementing the intervention in the service more fully?

4) Effectiveness: What are preliminary indictors of effectiveness?
a. What are the pre-post effect sizes on the primary outcome measure of depression symptom severity (PHQ-9)? How do these effect sizes compare to pre-post outcomes in trials of comparable interventions for depression (i.e. guided CBT-SH)?
b. What are the pre-post effect sizes on secondary outcomes measures? How do these effect sizes compare to pre-post outcomes in trials of comparable interventions for depression (i.e. guided CBT-SH)?
c. What are the pre-post effect sizes on measures of proposed mechanisms? How do these effect sizes compare to pre-post outcomes in trials of comparable interventions for depression (i.e. guided CBT-SH)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey Borders Research Ethics Committee, 06/07/2017, ref: 17/LO/1032

Study design
Non-randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

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
Specialty: Mental Health, Primary sub-specialty: Depression; UKCRC code/ Disease: Mental Health/ Mood [affective] disorders

Interventions
This is a feasibility study examining recruitment, retention, acceptability, and preliminary indicators of effectiveness to/of Headspace as a PWP-guided self-help intervention for depressive symptoms in IAPT.

Intervention
Participants are offered the 30-session foundation course of the Headspace programme (www.headspace.com) and asked to engage with this over eight weeks. Headspace is a smartphone and online application delivering simple daily activities based on mindfulness practice. It teaches beginners the basic concepts of mindfulness through simple, empirically-supported guided meditations. The 30-session course invites participants to spend at least 10 minutes per day over 8 weeks practising guided meditations. If participants complete all 30 sessions before the end of 8 weeks, and before their final support session with the mental health practitioner, they are instructed to repeat any sessions from the foundation course or select one of the other packs from Headspace that seems most helpful to them. As is routine at Step 2 in IAPT, participants are also be offered six PWP sessions, delivered by telephone or in person, to answer questions and provide encouragement. This intervention procedure therefore mirrors the usual way in which interventions are offered at Step 2 in IAPT; offering a self-help workbook alongside a limited number of PWP support sessions.

The purpose of using outcome measures in feasibility studies is to investigate and evaluate a number of processes related to the intervention (intervention recruitment, retention, acceptability and preliminary indicators of effectiveness), rather than outcomes related to the effectiveness of the intervention. As such, feasibility studies need not include a primary outcome measure.

Qualitative data regarding participants' experience of the interventions (e.g., helpful and unhelpful aspects of the intervention) will be collected through telephone interviews conducted after the end of the intervention by the RA with the first 10 participants opting in to this optional part of the study. The topic guide for the post-intervention telephone interviews will be based on the Change Interview (Elliott et al., 2001). The change interview is a semi-structured questionnaire designed to ask participants about any changes that occurred in their lives since starting the intervention and their attributions of these changes. Change can be attributed to the intervention or to external factors. Participants are also asked to comment on those aspects of the intervention that facilitated change, and those that may have hindered it. Each interview will take approximately 30-45 minutes, will take place over the phone, and will be audio recorded to aid transcription and data analysis.

Intervention Type
Other

Primary outcome measure
The purpose of using outcome measures in feasibility studies is to investigate and evaluate a number of processes related to the intervention (intervention recruitment, retention, acceptability and preliminary indicators of effectiveness), rather than outcomes related to the effectiveness of the intervention. As such, feasibility studies need not include a primary outcome measure.

Outcomes will be reported as follows:

1. Number of people meeting inclusion criteria in the participating IAPT services and offered the study.
2. Of 1), the number of people consenting to take part in the study
3. Reasons for not agreeing to take part in the study (recorded by practitioners conducting initial assessments)
4. Demographics (gender, age, ethnicity) of people who decline to take part in the study. This information is asked as part of the routine initial assessment and will be recorded by practitioners conducing initial assessments and fed back to the research team.
5. Number of people completing the intervention (defined as listening to the guided mindfulness practices on at least 24 out of 30 sessions within 8 weeks, i.e., 80% of sessions completed). Usage data is collected automatically by the Headspace app.
6. Number of people attending at least 3 PWP sessions
7. Reasons for dropping out of the intervention (recorded by participants when completing post-intervention measures or by practitioners at the IAPT service)
8. Helpful and/or engaging aspects of the intervention (participants' views). This will be recorded by participants when completing post-intervention measures (using open text boxes) and through qualitative telephone interviews with 10 participants conducted after the study by the RA (details below).
9. Helpful and/or engaging aspects of the intervention (PWP views). This will be recorded after the study by inviting PWPs to complete an anonymous online questionnaire (using open text boxes).

10. Unhelpful aspects of the intervention and/or barriers to engagement (participants' views). This will be recorded by participants when completing post-intervention measures (using open text boxes) and through telephone interviews conducted after the study by the RA with 10 participants (details below).
11. Unhelpful aspects of the intervention and/or barriers to engagement (PWP views). This will be recorded after the study by inviting PWPs to complete an anonymous online questionnaire (using open text boxes)
12. Barriers and enablers to IAPT implementation (IAPT service lead/manager views). This will be recorded after the study by inviting IAPT service lead/manager to complete an anonymous online questionnaire (using open text boxes)
13. Pre-intervention to post-intervention Cohen's d effect sizes and 95% confidence interventions on the primary effectiveness outcome (PHQ-9), secondary outcomes (GAD-7, SWEMWBS), and proposed mechanisms (FFMQ-15, SCS-SF, PSWQ, RRS). Details of these self-report measures are given below
14. Participant demographics (gender, age, ethnicity, marital status, level of education, previous experience of mindfulness) will be recorded at pre-intervention in order to describe the sample of participants

Self-report measures (administered twice unless otherwise noted: at pre-intervention and post-intervention):
1. Depression symptom severity (PHQ-9; Kroenke & Spitzer, 2002): the PHQ-9 is a 9-item self-report measure of depression symptom severity used in all IAPT services. Items are rated on a four-point scale from 0 to 3. Scores under 10 are considered sub-clinical, 10-14 moderate, 15-19 moderately severe, and 20 or over severe. As well as being administered at baseline and post-intervention, this scale will be administered at each PWP session
2. Anxiety severity (GAD-7; Spitzer et al., 2006): the GAD-7 is a 7-item measure of the severity of generalised anxiety disorder. Items are rated on a four-point Likert scale from 0 to 3. Scores between 5-9 are considered to indicate mild anxiety, 10-14 moderate anxiety, and 15 and over severe anxiety. As well as being administered at baseline and post-intervention, this scale will be administered at each PWP session
3. Wellbeing: this will be measured using the Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS; Stewart-Brown et al., 2009)
4. Mindfulness: this will be measured using the 15-item Five Facet Mindfulness Questionnaire (FFMQ-15; Baer et al., 2008)
5. Self-compassion: this will be measured using the 12-item short form of the Self-Compassion Scale (SCS-SF; Raes et al., 2011)
6. Worry: This will be measured using the 16-item Penn State Worry Questionnaire (Meyer et al., 1990)
7. Rumination: This will be measured using the 10-item Ruminative Responses Scale (Treynor et al., 2003)
8. System Usability Scale (Brooke, 1996): This 10-item measure (adapted to refer to Headspace) will be administered at post-intervention only to assess the usability of Headspace
9. PWP Rating Scale: This 4-item scale, adapted from the Session Rating Scale (Duncan et al., 2003), will be administered at post-intervention only to assess participants' experience of the PWP-lead support sessions
10. Intervention Expectation Form: This 6-item measure will be administered at baseline only to assess participants' expectations of Headspace
11. Lasting Effects Questionnaire: This questionnaire, adapted from Crawford et al. (2016), will be administered at post-intervention only to assess any negative effects resulting from using Headspace

12. Work and Social Adjustment Scale (Mundt et al., 2002): This 5-item self-report scale measures functional impairment attributable to an identified problem. This scale will not be recorded at baseline and post-intervention; it will be administered at each PWP session only

Secondary outcome measures
No secondary outcome measures.

Overall study start date
01/09/2017

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Adults aged 18+ years
2. Current service users at the participating services
3. Score 10-19 on the PHQ-9 (indicating mild or moderate clinical depression) at assessment in the service
4. Regular personal access to a smartphone, computer, or tablet with internet access to use Headspace
5. Sufficient literacy skills to read and understand self-help materials

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
1. Currently receiving a psychological intervention
2. Rated as medium or high risk to self or others on the service risk assessment tool, including risk of self-harm behaviours
3. Substance use associated with significant impairment
4. Meet diagnostic criteria based on the Mini International Neuropsychiatric Interview (MINI version 6.0.0, Sheehan et al, 2010) for a psychotic disorder, post-traumatic stress disorder, or obsessive-compulsive disorder

Date of first enrolment
11/09/2017

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Croydon IAPT
Wickham Park House
Bethlem Royal Hospital
Monks Orchard Road
Kent
Beckenham
United Kingdom
BR3 3BX

Study participating centre
Brighton and Hove Wellbeing Service
5th Floor
177 Preston Road
Brighton
United Kingdom
BN1 6AG

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

Sponsor details
Assessment and Treatment Centre
Chapel Street
Chichester
Worthing
England
United Kingdom
PO19 1BX

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Industry

Funder Name
Headspace Meditation Limited

Results and Publications

Publication and dissemination plan
Findings will be written up for submission for open-access publication in academic journals, including:

1. The trial protocol
2. A paper reporting on main findings in relation to the feasibility questions (recruitment, retention and acceptability)

Findings will be disseminated to participants and service user organisations.
Findings will be presented at service user events and at local, national and international conferences.

Intention to publish date
30/06/2019

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Clara Strauss (clara.strauss@nhs.net) following publication of the main trial findings. Data will be shared with other research teams for the purpose of contributing to systematic reviews and meta-analyses. Participant consent has been sought for this. Shared data will be fully anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		01/09/2021	11/10/2023	Yes	No