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Mobile mindfulness for asthma

Submission date	Recruitment status	[X] Prospectively registered
03/04/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/08/2022	Respiratory	

Plain English summary of protocol

Background and study aims
Mindfulness is a type of meditation-based therapy that's been used to treat a range of health conditions, including anxiety and depression. Currently, few studies have explored how mindfulness can help long-term health conditions such as asthma. A previous study looked at how acceptable a traditional 'short-course' of mindfulness was to help patients with asthma. The patients in this study liked mindfulness and felt it helped how they felt about their asthma, but attendance was low, perhaps because of the commitment of attending a weekly group meeting. The researchers want to see if 'Headspace', a mindfulness-based 'online' programme (app and website), can help. The Headspace programme takes 30 days of 10-minute practices that can be done whenever it's convenient for the user. This feasibility study will mainly look at how many people want to take part in the study, how many go on to take part and how many complete the process, but will also look at how much mindfulness could help improve quality of life for people with asthma. The aim of this study is to look at whether using Headspace to people with asthma is feasible and effective at improving quality of life.

Who can participate?
Adults who have asthma and access to the internet.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given the opportunity to start using the Headspace app straight away to use for six months. Those in the second group continue as normal and are given the opportunity to try Headspace after the study ends. At the start of the study and then six week and three months later, participants in both groups complete a range of questionnaires to assess their wellbeing. In addition, the number of participants who took part and those who completed all assessments is recorded to see if a larger study would be possible.

What are the possible benefits and risks of participating?
It is possible that taking part in the study may benefit people in a number of different ways, mostly by improving how their breathing affects them and their quality of life. There is very little risk of harm in taking part, and previous studies have found no negative events. Some people have found that mindfulness can make them anxious, especially if they have been diagnosed with mental health problems but if participants have any questions they can contact the study team.

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

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

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
1. Dr Ben Ainsworth (scientific)
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
34048

Study information

Scientific Title
Investigating the feasibility of a mobile mindfulness-based digital intervention for patients with asthma

Study objectives
The aim of this study is to determine the feasibility and estimate effectiveness of Headspace, a digital mindfulness-based stress reduction app, in helping to improve quality of life for people with asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central- Hampshire B Research Ethics Committee, 17/03/2017, ref: 17/SC/0088

Primary study design
Interventional

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Respiratory disorders; UKCRC code/ Disease: Respiratory/ Chronic lower respiratory diseases

Interventions
All participants in the study will complete questionnaire measures about their asthma, quality of life and mindfulness. These will primarily be delivered online at baseline, 6 weeks (post baseline) and at 3 months.
Following consent, participants will randomly allocated to one of two groups. Randomisation will be electronically via the Life Guide web platform.

Intervention Group: This group will have the opportunity to use the Headspace app and website immediately for 6 months.

Control group: This group will continue as normal for the duration of the study and will have the opportunity to use the Headspace app and website 3 months after they have completed all of the questionnaires for the study.

All participants will be in the study for 3 months in total. All participants will be given access to the Headspace App at no cost during the study. Should they wish, participants in both groups will be able to request an additional 6 months of free access to Headspace at the end of the study.

A purposive sample of participants will also be invited to take part in a telephone interview at 6 weeks post intervention to elicit in depth discussions on the experiences of taking part and the acceptability of the intervention.

Intervention Type
Other

Primary outcome(s)
Feasibility outcomes:
1. Response rate is recorded as the number of participants who respond favourably to the Patient Invite Letter by 6 months
2. Recruitment rate is recorded as the number of eligible participants who consent to participate in the study by 6-9 months
3. Retention rate is recorded as the number of participants who consent to participate that remain in the study until the end of follow up at 3 months

Key secondary outcome(s)
1. Headspace usage will measured by data access granted by Headspace to allow the study team to monitor intervention usage- and whether this is associated with symptom improvement which will be measured by using validated quality of life questionnaires, primarily the Asthma Quality of Life Questionnaire (AQLQ) at baseline, 6 weeks and 3 months
2. Participant experience of taking part in the study and the acceptability of the intervention will be measured by qualitative analysis of telephone interviews on a purposive sample of participants from the intervention group up to 6 weeks post- intervention
3. Anxiety and asthma- specific quality of life will be measured using validated questionnaire measures at baseline, 6 weeks and 3 months with the primary questionnaire outcome measure being the Asthma Quality of Life Questionnaire (AQLQ)
4. Self- reported mindfulness will be measured using validated questionnaire measures below at baseline, 6 weeks and 3 months
5. Asthma-related quality of life is measured by the Asthma Quality of Life Questionnaire (AQLQ) at baseline, 6 weeks and 3 months
6. Asthma control is measured by the Asthma Control Questionnaire (ACQ) at baseline, 6 weeks and 3 months
7. Anxiety and depression is measured by the Hospital Anxiety and Depression Scale (HADS) at baseline, 6 weeks and 3 months
8. Enablement is measured by the Patient Enablement Instrument (PEI) at baseline, 6 weeks and 3 months
9. Mindfulness is measured by the Philadelphia Mindfulness Scale (PMS) at baseline, 6 weeks and 3 months

10. Medication adherence is measured by the Medication Adherence Report Scale for Asthma (MARS-A) at baseline, 6 weeks and 3 months
11. Acceptance and action is measured by the Acceptance and action questionnaire (AAQ-II) at baseline, 6 weeks and 3 months

Completion date
31/05/2018

Eligibility

Key inclusion criteria
1. Adult (18 years or over)
2. Have a confirmed diagnosis of asthma- between steps 2 and 4 of BTS Asthma Guidelines for symptom severity (mild to moderate)
3. Have access to the Internet- which can be either a computer or a mobile device

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
158

Key exclusion criteria
1. Under 18 years of age
2. Previously diagnosed major and unstable comorbid psychological disorders other than anxiety / depression (measured using the MINI neuropsychiatric interview questionnaire)
3. Current participation in another asthma intervention study
4. Have had acute exacerbation of asthma (needing a course of oral steroid or increased dose of maintenance steroid) within 28 days of the first intervention of the study

Date of first enrolment
01/06/2017

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton
Primary Care & Population Sciences (Faculty of Medicine)
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Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Ben Ainsworth (ben.ainsworth@southampton.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/08/2021	31/08/2021	Yes	No
Abstract results	results presented at the European Resopiratory Society (ERS) International Congress	09/11/2018	26/03/2019	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version 1.5	05/06/2017	11/08/2022	No	No