ISRCTN15698435 https://doi.org/10.1186/ISRCTN15698435

A feasibility study for My Breathing Matters, an asthma self-management website

Submission date	Recruitment status	[_] Prospectively registered
23/10/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/03/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/05/2023	Respiratory	

Plain English summary of protocol

Background and study aims

The UK has one of the highest rates of asthma in the world. Nearly 6 in every 100 of the UK population have asthma, or 5.4 million people, most of whom are managed by GP surgeries. Hospital admission and death rates for asthma have dropped in the last decades of the last century, but these improvements have stalled since 2000. Early death from asthma was 1.5 times as high in the UK as in the rest of the EU in 2008, with around 1000 to 1200 deaths a year recorded since 2000. It is estimated that 9 out of 10 deaths could be prevented. Asthma is associated with high numbers of admissions and emergency department attendances, and it is estimated that 7 in 10 of these could have been prevented by appropriate early treatment and self-management. Poor control of asthma symptoms is common and the majority of asthma patients in the UK suffer potentially avoidable symptoms and reduction in their quality of life. Although the UK leads the world in providing guidelines for asthma management, these have been poorly implemented. People with asthma do not receive evidence-based treatment and management, particularly individual action plans, which are known to improve outcomes. Patient education and proactive self-management have been convincingly shown to improve clinical outcomes in asthma and have been recommended in guidelines for 20 years.

Increasingly widespread access to the internet and mobile phones means that healthcare Digital Interventions (DIs) are accessible to the majority of patients, and can be used to provide information and support at any time the patient needs it . DIs can empower patients by providing better access to personalised information, and support for active involvement in treatment and self-management. A large analysis of multiple research studies found a small but meaningful positive effect of DIs on health-related behaviours. Another review of research found evidence that computer-based health interventions for those with chronic health conditions significantly improved knowledge, health behaviours and clinical outcomes. DIs have the potential to make significant savings by automating routine aspects of patient education, monitoring and support, freeing up health professional resources for when patients most need them. These savings can play an essential part in meeting the NHS Quality, Innovation, Productivity and Prevention (QIPP) agenda to achieve increased efficiency gains despite the growing demand created by an expanding and ageing population.

The main aim of the My Breathing Matters trial is to assess the feasibility, acceptability,

effectiveness and cost-effectiveness of a DI in primary care for the self-management of asthma, in comparison to usual care (with provision of standard patient information materials produced by the charity Asthma UK).

Who can participate?
Adults who are receiving medication for asthma and whose asthma is affecting their life

What does the study involve?
People who are interesting in taking part in the study will complete the questionnaire and consent form provided and post it back to the research team in the freepost envelope provided. If they are eligible for the study, a research nurse will contact the participant to arrange an appointment to take part in the first part of the study. At this appointment the nurse will check the participant's asthma, and ask them to answer some questions about their breathing. If the participant is able to take part in the study, the nurse will put them in a group by chance (the same as flipping a coin).
One group will use the My Breathing Matters website at home. The other group will continue to receive usual care from their GP practice. Those who are in the group using the My Breathing Matters website can use the website as much or as little as they like. They will be given access to lifestyle modules, which aim to boost the ways that they can help their breathing. There will be the option to take part in a telephone interview later on in the study, to talk about experiences of My Breathing Matters. Participants can decide if want to do this when the investigators ask them, after they have tried My Breathing Matters.
For all groups, the study will last for 12 months. 3 months after joining the study all participants will be asked to answer some questions about their breathing (these will be questionnaires that will be posted to them, and they will be provided with a stamped, pre-addressed envelope to return them in). 12 months after joining the study, participants will have an appointment with a research nurse, to check their asthma.

What are the possible benefits and risks of participating?
The researchers cannot guarantee that taking part in this study will benefit patients. However, patients may find that the website has a positive impact on their breathing and general well-being, which has been shown in some previous studies. Patients will also receive a £10 gift voucher for taking part.
The investigators think there is very little risk of harm in taking part, and previous studies have found no negative events. My Breathing Matters is not meant to replace the care provided by GPs and patients should seek advice from GPs if they experience any problems. The main disadvantage is that the research will take up some of patients' time. They will need to attend two appointments (lasting 1 hour each) with a research nurse and complete some questionnaires sent to them in the post. Participants can use as much or as little of the website as they like.

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

When is the study starting and how long is it expected to run for?
November 2015 to December 2018

Who is funding the study?
NIHR (UK)

Who is the main contact?
1. Mrs Victoria Hayter (public contact), V.J.Hayter@soton.ac.uk
2. Dr Ben Ainsworth (scientific contact), mybreathingmatters@soton.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Victoria Hayter

ORCID ID
https://orcid.org/0000-0002-2157-2855

Contact details
University of Southampton
Highfield Campus
Southampton
United Kingdom
SO17 1BJ

Type(s)
Scientific

Contact name
Dr Ben Ainsworth

ORCID ID
https://orcid.org/0000-0002-5098-1092

Contact details
Centre for Applications of Health Psychology Academic Unit of Psychology (B44)
University of Southampton
Highfield
Southampton
United Kingdom
SO17 1BJ
+44 238 059 1950
mybreathingmatters@soton.ac.uk

Additional identifiers

Protocol serial number
32823

Study information

Scientific Title
'My Breathing Matters' - A feasibility study of a digital self-management programme designed to improve the quality of life of people with asthma.

Study objectives
The primary aim of the My Breathing Matters trial is to assess the feasibility, acceptability, effectiveness and cost-effectiveness of a DI in primary care for the self-management of asthma, in comparison to usual care (with provision of standard patient information materials produced by the charity Asthma UK).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central – Berkshire Research Ethics Committee, 16/01/2017, ref: 16/SC/0614

Primary study design
Interventional

Study design
Randomised; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Validation of investigation /therapeutic procedures

Study type(s)
Treatment

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

Interventions
My Breathing Matters is a digital intervention for the self-management of asthma, consisting of pharmacological support, (advice about asthma reviews and personal asthma action plans, information about medication and side effects) and non-pharmacological components (stress reduction, online versions of breathing retraining courses shown to be acceptable and feasible) and optional user-selected lifestyle modifications.

All interested patients will be screened by their Asthma Quality of Life Questionnaire score. All suitable patients will be invited to a baseline consultation with a research nurse at their local GP practice. The baseline appointment lasts approximately 30 minutes and includes consent, clinical and questionnaire measures. All eligible patients will be randomised at the baseline appointment to either usual care or the intervention arm of the study (randomised in a 1:1 ratio, stratified block randomisation by the average value of AQLQ scores in the BREATHE trial). All eligible patients receive standardised asthma advice – Asthma UK information leaflet.

Those patients randomised to the intervention arm will be given instructions for logging onto the intervention and have access to the online My Breathing Matters intervention for 12 months, and invited to take part in interviews to discuss their experiences using the intervention after 3 months. Those in the usual care group do not have access to My Breathing Matters (until they have completed their 12 month follow up appointment).

After 3 months all participants in both arms are asked to complete postal questionnaires, and then after 12 months all patients are invited to a second appointment with the research nurse to cover clinical and questionnaire measures.

Intervention Type
Other

Primary outcome(s)
Feasibility and acceptability of intervention and trial procedures, including:
1. Uptake assessed using data from recruitment and data collection procedures
2. Adherence assessed throughout the study using data from questionnaire response rates
3. Completion rates measured using data from questionnaire and interview response rates

Key secondary outcome(s)
Feasibility of measuring (and estimates of effect size to perform sample size calculations) in the following trial measures:
1. Asthma-specific quality of life assessed using the AQLQ questionnaire - short version at baseline, 3 months and 12 months
2. Asthma control assessed using the Asthma Control Questionnaire (ACQ) at baseline, 3 months and 12 months
3. Lung function assessed using standard tests (FEV1, FEV1/FVC, PEFR) at baseline, 3 months and 12 months
4. Quality of life and wellbeing assessed using the EQ5D and ICECAP-A questionnaires at baseline, 3 months and 12 months
5. Anxiety and depression assessed using the Hospital Anxiety and Depression Scale (HADS) at baseline, 3 months and 12 months
6. Patient enablement assessed using the Patient Enablement Instrument (PEI) at baseline, 3 months and 12 months
7. Patient burden (time and costs) measured using the Southampton Time & Costs Measure at 12 months
8. Health resource use (professional contacts, referrals, prescriptions) assessed using notes review at 12 months
9. Adherence to recommendations assessed using notes review at 12 months
10. Medication adherence using Medication Adherence Report Scale for Asthma (MARS-A) questionnaire at baseline, 3 months and 12 months

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Age 18 years and over
2. Physician diagnosed asthma in medical record
3. At least one anti-asthma medication prescription in the previous year (determined from the physician prescribing records)
4. Impaired asthma-related health status (Asthma Quality of Life Questionnaire score of <5.5)
5. Informed consent
6. Able to access the internet and understand written English

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
88

Key exclusion criteria
1. Asthma judged at the baseline assessment to be dangerously unstable and in need of urgent medical review (if unstable asthma is found, the patient will be referred back to usual primary care clinician for review)
2. Terminal disease or other condition which in the opinion of the family doctor makes them inappropriate to take part
3. Diagnosed with ‘difficult asthma’ as defined by BTS
4. Documented diagnosis of Chronic Obstructive Pulmonary Disease (COPD)
5. Household member already enrolled on the study

Date of first enrolment
15/03/2017

Date of final enrolment
11/08/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton Highfield Campus
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
We will record and store paper questionnaire data in line with University Policy. Premises are manned 24 hours a day by a dedicated security team, and data will be kept in a locked filing cabinet only accessible by dedicated members of the research team (in a building only accessible by university employees). The data will be held securely on computers or in locked filing cabinets as described above for as long as it is required for dissemination purposes. After this time it will be transferred to an off-site storage facility that has been inspected and is approved by the sponsor (University of Southampton). Participants agree to this when they complete the consent form.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/11/2019	12/12/2019	Yes	No
Funder report results	NIHR	31/12/2022	16/05/2023	No	No
HRA research summary			28/06/2023	No	No