ISRCTN78556552 https://doi.org/10.1186/ISRCTN78556552

Living well with asthma: supporting self care

Submission date 16/04/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/06/2013	**Overall study status** Completed	
Last Edited 16/05/2016	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
People with asthma often put up with symptoms such as wheeze, shortness of breath or interrupted sleep without realising that adjusting their inhalers might help. Some studies have shown that people with asthma have fewer symptoms when they use online resources to learn about asthma and to receive feedback about their symptoms and medications. We have developed such a resource which will be available free of charge to people with asthma. Before it can be made widely available we need to find out how it works in practice, so we are trying it out in this study. We want to find out how the website is used so we can learn ways to improve it.

Who can participate?
Adults over the age of 16, with a diagnosis of asthma and an ACQ (Asthma Control Questionnaire) score greater than or equal to 1, can participate.

What does the study involve?
We will randomly allocate people into one of two groups: one group will get to use the website for 12 weeks and the other group will manage their asthma as normal. There will be a follow-up, 12 weeks after the first visit, covering similar areas as the first visit and to check lung function. Those who didnt have a login for the website will be given one then for 12 weeks. We also want to interview some people for their feed about using the website. This interview will take less than 60 minutes and is optional.

What are the possible benefits and risks of participating?
The benefits are that the participants will learn about their condition and may gain better control of their asthma, resulting in fewer symptoms. As long as participants continue to seek advice from their doctor or nurse as usual, we do not see any risks to any individuals taking part in this study.

Where is the study run from?
This study has been set up and will be run by the University of Glasgow, sponsored by NHS Greater Glasgow and Clyde.

When is study starting and how long is it expected to run for?
The study starts in June 2013 and will run until November 2014. The study will be recruiting participants for 6 months and the participants will be in the study for a maximum of 5 months (3 months using the online resource and 2 months to participate in a qualitative interview).

Who is funding the study?
This project is funded by the Chief Scientist Office, Scottish Government (reference CAF/11/08).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RAISINV2.0

Study information

Scientific Title
A pilot Randomised controlled trial (RCT) of Asthma Internet Self management INtervention

Acronym
RAISIN

Study objectives
Current hypothesis as of 13/02/2014:
This pilot RCT aims to establish:
1. Recruitment and retention rates
2. Provide estimates of efficacy across a range of outcomes in order to estimate effect sizes for future full scale evaluations
3. Usability of this online resource

We hypothesise that this online resource, which has been designed with end user involvement and aims to improve adherence to therapy using multiple strategies, will result in improved symptom control and asthma quality of life.

Previous hypothesis:
This pilot RCT aims to establish:
1. Recruitment and retention rates
2. Feasibility of selected outcome measures (clinical and process)
3. Usability of this online resource. This pilot study does not aim to show changes in outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee, 19/03/2013, WOS/13/0004

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Asthma self management

Interventions
Participants are randomised to two groups:
1. One group receives an internet-based resource which aims to promote adherence to asthma treatments by challenging negative beliefs, promoting activation, recognising barriers, using

goalsetting, and providing information, leading to improvements in symptoms control and quality of life.
2. Other group manages asthma as usual.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 13/02/2014:
1. Recruitment and retention rates at 12 weeks from baseline
2. Web use over 12 weeks (via automatically collected counts of access to website) plus perceived barriers and facilitators to sustained use of resource (via qualitative evaluation)
3. Changes at 12 weeks from baseline for:
3.1. Asthma Control Questionnaire (ACQ)
3.2. Asthma Quality of Life Questionnaire (AQLQ)

Previous primary outcome measures:
1. Recruitment and retention rates at 12 weeks from baseline
2. Web use over 12 weeks (via automatically collected counts of access to website) plus perceived barriers and facilitators to sustained use of resource (via qualitative evaluation)

Secondary outcome measures
Current secondary outcome measures as of 13/02/2014:
1. Changes at 12 weeks from baseline for
1.1. EQ-5D3
1.2. Patient Activation Measure (PAM)
1.3. Morisky Medication Adherence Scale (MMAS)
1.4. Lung function (via pre bronchodilator spirometry)
1.5. Airway inflammation (via fractional exhaled nitric oxide)
2. Problematic Experiences of Therapy Scale (PETS) in those in intervention group at follow up visit only (at 12 weeks)
3. Self-reported health care utilisation
4. Self-reported medication utilisation
5. Adverse events

Previous secondary outcome measures:
1. Changes at 12 weeks from baseline for:
1.1. Asthma Control Questionnaire (ACQ)
1.2. Asthma Quality of Life Questionnaire (AQLQ)
1.3. EQ-5D3
1.4. Patient Activation Measure (PAM)
1.5. Morisky Medication Adherence Scale (MMAS)
1.6. Lung function (via pre bronchodilator spirometry)
1.7. Airway inflammation (via fractional exhaled nitric oxide)
2. Problematic Experiences of Therapy Scale (PETS) in those in intervention group at follow up visit only (at 12 weeks)

3. Self-reported health care utilisation
4. Self-reported medication utilisation
5. Adverse events

Overall study start date
01/06/2013

Completion date
31/10/2014

Eligibility

Key inclusion criteria
1. Written informed consent
2. Age 16 years or older
3. Diagnosis of asthma by a health professional and duration of asthma symptoms for more than 1 year
4. Juniper ACQ score ≥ 1
5. Ability to access the internet

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Unstable asthma
2. Presence of active lung disease other than asthma
3. Mental impairment/language difficulties making informed consent impossible
4. Terminal illness
5. Cognitive impairment

Date of first enrolment
23/09/2013

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
1 Horselethill Road
Glasgow
United Kingdom
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Sponsor information

Organisation
NHS Greater Glasgow & Clyde (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Goverment (UK), Ref: CAF/11/08

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/05/2014		Yes	No
Results article	results	12/05/2016		Yes	No