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An online study to change perceptions of asthma and asthma medication in adults

Submission date
05/11/2018

Recruitment status
No longer recruiting

Registration date
30/11/2018

Overall study status
Completed

Last Edited
08/04/2020

Condition category
Respiratory

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

Plain English Summary
Background and study aims
The United Kingdom has one of the highest number of people with asthma in Europe and although asthma cannot be cured, there are effective medicines available to control asthma. The most important treatment for controlling asthma is inhaled corticosteroids, also known as 'the preventer inhaler'. However, more than half of people with asthma report not taking their preventer inhaler regularly, which leads to poor asthma control with more frequent and severe asthma symptoms and an increased risk of hospital admission. It is therefore very important that people with asthma are supported to take their preventer inhaler more consistently as prescribed (called adherence). Research shows that patients' beliefs about treatment are fundamental in the decision process to take medication as prescribed, in particular doubts about personal need for the treatment and concerns about potential harm. Moreover the need for the preventer inhaler is often influenced by the experiences a patient has had with their asthma, e.g. only experiencing intermittent symptoms does not reinforce the need for regular treatment. Providing patients with a coherent 'story' that links their experience of having asthma with their asthma medication can prevent patients from developing misconceptions and misplaced concerns, and consequently improve adherence. This study will test whether a new intervention will increase the perceived need for treatment and reduce the concerns about potential harm of the treatment in patients. The intervention uses a simple, medically accurate explanation of asthma and asthma medication, in line with health psychology theory, that helps people to think of asthma and the preventer in a way that makes sense to them.

Who can participate?
People aged 18 and over with or without asthma

What does the study involve?
Participants are randomly allocated to receive either information developed based on health psychology theory (the intervention) or to standard NHS asthma information (the control). The intervention is either presented in a written format (matched to the NHS information) or as a video. This study is run in parallel in a group of people with asthma and a group without asthma. People without asthma are instructed to imagine they had just been diagnosed with asthma, which may allow the researchers to gain a better understanding of how the intervention might affect someone who has just been diagnosed with asthma. Both groups are recruited through

Amazon MechanicalTurk, an online participant panel paying small monetary rewards for study participation. Participants fill in a brief demographics questionnaire and if they report having asthma, a brief questionnaire about their asthma. After viewing the intervention, participants with and without asthma complete questionnaires measuring medication beliefs, side-effect expectations, adherence/behavioural intentions, effectiveness perceptions regarding the preventer, and general understanding of the information. After a period of two weeks, participants are invited to fill out the follow-up questionnaires (similar to the ones directly after the intervention).

What are the possible benefits and risks of participating?
The possible benefits to participants taking part are that they may increase their knowledge about asthma and asthma medication and they receive a small monetary reward for their participation (£2). Further, their input in this study will help to improve the way information is provided for people with asthma. There are no known risks to participants taking part in this study.

Where is the study run from?
UCL School of Pharmacy (UK)

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

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

Who is the main contact?
Caroline Katzer

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Reframing asthma and inhaled corticosteroids to modify treatment beliefs: an online randomised controlled trial

Study hypothesis
The aim of the present study is to test a theory-based intervention which reframes asthma and inhaled corticosteroids, to evaluate whether it has the potential to modify medication and illness beliefs in a cohort of people with asthma and a cohort of people who are asthma-naive (a proxy-group for newly diagnosed patients).

Main hypothesis: In both cohorts, lower concerns about the treatment and higher necessity for the treatment are expected within the intervention groups after receiving the intervention, compared to before the intervention and compared to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College London Research Ethics Committee, 31/07/2017, ref: 9293/003

Study design
Parallel-cohort repeated measures randomised controlled trial intervention study conducted online

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

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

Condition
Asthma (including people without asthma as a proxy group for newly diagnosed patients)

Interventions
Participants within each cohort were randomised using the computerised block randomisation function in Qualtrics online survey software. All participants received information about asthma and its treatment (in particular inhaled corticosteroids (ICS)). The control group was presented with standard care information about asthma and asthma medication, as presented on the National Health Service (NHS) webpage. Those in the intervention groups were presented with the Balance Model of asthma (BM-intervention). The Balance Model is a medically accurate description of asthma, but by using reframing it moves asthma away from the classical, medical description to a simpler and more positive explanation that is easy to understand for patients and creates a common-sense fit between medication and illness beliefs. As the channel through which an intervention is delivered may also impact its effectiveness, participants were randomised to either receive the BM-intervention in written format (matched NHS format) or as a four-minute video (same content as written format). Outcome data was collected immediately after the intervention and at two-week follow-up.

Intervention Type
Behavioural

Primary outcome measure
Participants' beliefs about inhaled corticosteroids are assessed using the Beliefs about Medicines Questionnaire Specific Asthma version (BMQ-S, Horne & Weinman 2002), a 11-item questionnaire used to measure beliefs about the personal need for ICS and the concerns about the potential adverse consequences of ICS. Measurements taken at baseline (asthma cohort only), immediately post-intervention and two-week follow-up.

Secondary outcome measures
1. Medication adherence/adherence intention: people in the asthma cohort fill out the 10-item version of the Medication Adherence Report Scale (MARS; Horne, Weinman, & Hankins, 1999) at baseline and 2-week follow-up, and an adherence intention measure immediately post-intervention. The cohort without asthma completes the adherence intention measure immediately post-intervention and at 2-week follow-up.
2. Whether the information provided by the intervention had been understood and found to be coherent, whether perceptions about potential side-effects were reduced, whether efficacy beliefs about ICS were increased and perceptions of self were positively altered. Measured using visual analogue scales immediately post-intervention and at 2-week follow-up.
3. Beliefs about asthma, measured using the Illness Perceptions Questionnaire brief version (B-IPQ; Moss-Morris et al., 2002) at baseline, immediately post-intervention and 2-week follow-up.

Overall study start date
01/03/2017

Overall study end date
31/03/2018

Eligibility

Participant inclusion criteria

1. At least 18 years old
2. Having been diagnosed with asthma for the asthma patient arm of the study

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
733

Total final enrolment
891

Participant exclusion criteria
Does not meet inclusion criteria

Recruitment start date
13/11/2017

Recruitment end date
13/03/2018

Locations

Countries of recruitment
Australia

Canada

Guernsey

Ireland

Malta

New Zealand

United Kingdom

United States of America

Study participating centre
Online study, recruitment of participants through Amazon MechanicalTurk
United Kingdom
N/A

Sponsor information

Organisation
University College London

Sponsor details
Gower Street
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WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care North Thames

Results and Publications

Publication and dissemination plan
The trialists intend to publish in a peer-reviewed journal and disseminate the findings at academic conferences.

Intention to publish date
01/01/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at the ERS International Congress	19/11/2018	08/04/2020	No	No