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Using picture instructions to improve self-management of asthma

Submission date
27/11/2018

Recruitment status
No longer recruiting

Registration date
28/12/2018

Overall study status
Completed

Last Edited
27/09/2022

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
The burden of asthma remains a major public health issue in Malaysia, thus, steps to lighten the burden must be cost effective, multimodal and patient-centred. Asthma self-management improves asthma control, reduces attacks and hospitalisation, as well as improving quality of life. It has been shown that self-management education on asthma improves clinical outcomes and reduces healthcare costs. An asthma action plan is part of self-management education that enable individuals with asthma to adjust their own treatments according to changes in their condition. But, in Malaysia, less than 1 in 10 people with asthma have a written asthma management plan. Pictorial representations have been shown to improve recall of medical instructions in a clinical setting and pictograms have been shown to be an effective tool, enhancing consultations and facilitating understanding. Therefore, this study aims to find out whether a supported self-management intervention incorporating the pictorial asthma action plan is feasible for adult patients with asthma.

Who can participate?
Patients aged 18 years and over with asthma who attend the participating primary healthcare clinic.

What does this study involve?
Participants use a pictorial asthma action plan for their asthma self-management taught by a trained medical officer, in addition to the usual care. The trained medical officer is not part of the researcher team. After enrolment, participants receive four telephone calls by a researcher at 1, 3, 6 and 12 months. During each telephone call, participants are asked about their asthma control, unscheduled health care utilization, medications, hospitalization and number of routines follow-up appointments. All participants are asked these questions based on a standardized validated questionnaire. They are also asked about the use of the pictorial asthma action plan tool. The telephone call may take about 10 minutes.
After the 12-month follow-up, participants may be invited to take part in a focus group discussion. The researcher asks more questions about topics related to their experience in using the pictorial asthma action plan for asthma self-management. The discussion is recorded using an audio voice recorder. The interview takes about 60 minutes.

What are the possible benefits and risks of participating?
All participants will receive usual asthma care. There may or may not be any benefits to the participants. Information obtained from this study will help improve the management of other participants with the same disease or condition. Participants will be able to contribute significantly to the development of an intervention to improve asthma self-management. The researcher will also be able to contribute to the larger body of medical knowledge in the field of asthma self-management. There is no risk involved in this study as participants only need to answer questions, and the questions do not provoke any unpleasant feelings or any unnecessary concern. Also, the clinical assessments would not provoke any unnecessary discomfort.

Where is the study run from?
The enrolment of this study takes place at a primary healthcare clinic, Bandar Botanik Health Clinic in Klang, Selangor, Malaysia.

When is the study starting and how long is it expected to run for?
The enrolment of study participants will take place between July 2019 and August 2019 with follow-ups in September 2019, November 2019, March 2020 and September 2020.

Who is funding the study?
National Institute of Health Research, funding reference: GHR 16/136/109

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
Study protocol Version 1

Study information

Scientific Title
A pictorial asthma action plan to improve asthma control in adults with asthma: a pre- and post quasi-experimental study

Study objectives
A pictorial asthma action plan tool is feasible to be used by adults with asthma in primary care setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 10/06/2019, The Medical Research Ethics Committee, Ministry of Health, Malaysia, ref: NMRR-18-2683-43494
2. Approved 14/05/2019, University of Edinburgh Research Governance, ref: AC 19061

Sponsorship review will be carried out by the University of Edinburgh Academic and Clinical Central Office for Research and Development (ACCORD) who will advise as to whether additional UK ethics approvals should be sought.

Study design
Pre- and post-quasi-experimental study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma

Interventions
Current interventions as of 05/06/2019:

This study will be divided into two parts, which involves
1. the development of a pictorial asthma action plan, and
2. the assessment of acceptability, demand and practicability of a pictorial asthma action plan as an interventional tool to improve asthma control in adults with asthma.

The intervention will involve an existing self-management plan following GINA guidelines incorporating a pictorial asthma action plan tool. The pictorial asthma action plan tool will be adapted for the Malaysian context from the Charing Cross Hospital pictorial asthma action plan developed by Roberts et. al 2009. The participants will be taught on the use of a pictorial asthma action plan tool by the clinic medical officers (who are not part of the research team) on a one-to-one encounter at the clinic. The clinic medical officers will receive training from the research team on the correct use of the pictorial asthma action plan.

Previous interventions:

This study will be divided into two parts, which involves
1. the development of a brief pictorial asthma action plan, and
2. the assessment of acceptability, demand and practicability of a pictorial asthma action plan as an interventional tool to improve asthma control in adults with asthma.

The intervention will be conducted in an urban primary health care clinic in the district of Klang, Selangor, Malaysia. The recruitment process for eligible participants will commence in January 2019 to March 2019. An independent statistician from our Clinical Research Center will sequentially number the eligible participants and they will be allocated into two groups using a computer-generated blocked randomization of four with an allocation ratio of 1:1 to create the randomization schedule. The group allocation will be concealed from the other research team involved in the recruitment and those involved in the assessments of outcomes at baseline and at every assessment time points. An independent clinic staff not part of the research team or involved in the intervention will conduct the assignment of interventions after the baseline assessment. Blinding of the participants will not be possible owing to the nature of the intervention as the participants in the intervention group will know that they will receive the pictorial asthma action plan. Blinding of assessor is possible as the assessments will be conducted by the enumerators who will not know if the participants are in the intervention or the control group. We will record any events that result in loss of blinding in order to inform the process for a full trial.

The intervention will involve a pictorial asthma action plan tool. The participants in the intervention group will be taught how to use a brief pictorial asthma action plan tool at home by trained clinic medical officers in a one-to-one encounter at the clinic.

Participants in the control group will receive the usual asthma care during the study and act as a comparison group to the intervention group. The context of usual care in this study may be either with or without follow up care.

The treatment duration is one month and the total follow up duration is 11 months for both study arms.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 05/06/2019:
1. Asthma control as measured by GINA Asthma symptom control at baseline and 1-, 3-, 6- and -12 month post intervention.
2. Whether study participation leads to serious negative consequences for participants.
3. Any serious concerns about the acceptability and feasibility of the trial procedures that can be rectified prior to a full trial.
4. Whether follow up data is available from at least 60% of participants at 12 months post intervention.

Previous primary outcome measures:
1. Asthma control is measured using ACQ mean score at baseline and 1-, 3-, 6- and -12 month post intervention.
2. Whether trial participation leads to serious negative consequences for participants.
3. Any serious concerns about the acceptability and feasibility of the trial procedures that can be

rectified prior to a full trial.
4. Whether follow up data is available from at least 60% of participants at 12 months post intervention.

Key secondary outcome(s))
1. Unscheduled health care utilization will be measured using patient interview via telephone call and from the patient's medical notes at baseline and 1-, 3-, 6- and -12 month post intervention.
2. Number of courses of oral steroids used will be measured using patient interview via telephone call and from the patient's medical notes at baseline and 1-, 3-, 6- and -12 month post intervention.
3. Hospitalization will be measured using patient interview via telephone call and from the patient's medical notes at baseline and 1-, 3-, 6- and -12 month post intervention.
4. Frequency of reliever medication use will be measured using patient interview via telephone call and from the patient's medical notes at baseline and 1-, 3-, 6- and -12 month post intervention.
5. Frequency of controller medication use will be measured using patient interview via telephone call and from the patient's medical notes at baseline and 1-, 3-, 6- and -12 month post intervention.
6. Frequency of utilizing the brief pictorial asthma plan will be measured using patient interview via telephone call and from the patient's medical notes at baseline and 1-, 3-, 6- and -12 month post intervention.
7. Number of routine follow up appointments will be measured using patient interview via telephone call and from the patient's medical notes at baseline and 1-, 3-, 6- and -12 month post intervention.

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Known asthma diagnosed by a healthcare practitioner
2. Taking inhaled corticosteroids
3. Aged 18 years and older
4. Able to understand the Malay and English languages

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. Known colour-blindness.
2. Severe exacerbations requiring admission.
3. Known self-reported condition prohibiting participation such as cognitive impairment, and severe communication problems

Date of first enrolment
01/07/2019

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
Klinik Kesihatan Bandar Botanik Klang
Blok A, Jalan Langat, Bandar Botanic
Klang
Malaysia
41200

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research GHR 16/136/109

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 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?
Results article		20/09/2022	27/09/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes