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Study evaluating how using visual aids, such as pictures, in asthma action plans can benefit patients in public primary care clinics

Submission date
29/06/2023

Recruitment status
No longer recruiting

Registration date
05/07/2023

Overall study status
Completed

Last Edited
24/02/2026

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The use of an asthma action plan improves asthma self-management and enables patients with asthma to adjust their own treatments according to changes in their disease.
The purpose of this study is to determine the effectiveness of a pictorial asthma action plan to improve asthma control in adults with asthma.

Who can participate?
Patients who have asthma diagnosed by a doctor and are given inhaled corticosteroids will be participating in this study.

What does the study involve?
This study is carried out in four government primary care clinics in Klang District, Selangor, Malaysia. A total of 180 participants, who have asthma diagnosed by a doctor and are given inhaled corticosteroids will be participating in this study. The whole study will last about 18 months. Participants need to participate in four sessions over a period of 12 months. The first session will be in the clinic where participants have their asthma follow-up appointment, and the subsequent three encounters will be through telephone calls.
At baseline, participants are required to answer a questionnaire about their personal and medical information, and health literacy assessment. After answering the questionnaire, participants will receive a sealed envelope with an asthma action plan inside. It would be either a pictorial asthma action plan or a text-based asthma action plan. Participants are not allowed to choose the type of asthma action plan. The research assistant would not know which type of asthma action plan will be in the sealed envelope that will be given to participants. Participants will bring this envelope to the doctor/pharmacist for consultation. Participants will use the asthma action plan that will be given to them for their asthma self-management, in addition to the usual care. Participants will receive three telephone calls from a researcher/research assistant at 3, 6 and 12 months. During each telephone call, participants will be asked about their asthma control, unscheduled health care visits, about their medications use, and hospitalization. They will also be asked about the use of asthma action plan tool. The asthma control status will be informed to participants by the research team after each assessment.

After the 12-month follow-up, 20 participants who have used the pictorial asthma action plan and the health care providers involved in delivery of the asthma action plam may be invited to take part in a focus group discussion or one to one interview. The research team will choose the participants based on their characteristics such as asthma control, frequency use of asthma action plan and motivation to use asthma action plan. Participants with different characteristics will be invited to allow for contrasting opinions.

What are the possible benefits and risks of participating?
The asthma action plan might help participants to self-manage their asthma and have better asthma control. The results of this study might help to improve the healthcare of asthma patients in the future. There is no risk involved in answering the questionnaires.

Where is the study run from?
This study is carried out in four government primary care clinics in Klang District, Selangor, Malaysia.

When is the study starting and how long is it expected to run for?
June 2022 to December 2025

Who is funding the study?
NIHR Global Health Research Unit on Respiratory Health (RESPIRE), University of Edinburgh, United Kingdom.

Who is the main contact?
Dr Ai Theng Cheong, cheaitheng@upm.edu.my.

Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
Effectiveness of pictorial asthma action plan in public primary care clinics: A randomized controlled study

Acronym
PAAP

Study objectives
1. There is a significant difference in asthma control rate at 3, 6 and 12 months compared to baseline within and between the control and intervention group.
2. There is a significant difference in medication use (reduced numbers of reliever use, adherence to inhaled corticosteroids (ICS) use), at 3, 6 and 12 months compared to baseline within and between the control and intervention groups.
3. There is a significant difference in clinical outcomes (reducing acute exacerbations, emergency visits, and hospitalization) and days lost from work, at 3, 6 and 12 months compared to baseline within and between the control and intervention groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 16/03/2023, Edinburgh Medical School Research Ethics Committee (EMREC) (The University of Edinburgh ACCORD ,The Queen's Medical Research Institute, 47 Little France Crescent, Edinburgh, EH16 4TJ, United Kingdom; +44 1312423330; emrec@ed.ac.uk), ref: EMREC-RESPIRE-23-02

2. approved 12/07/2023, Ministry of Health Medical Research Ethics Committee (MREC) (National Institutes of Health, Ministry of Health Malaysia, Block A, Kompleks Institue Kesihatan Negara (NIH), No 1 Jalan Setia Murni U13/52, Seksyen U13 Bandar Setia Alam,, Shah Alam, 40170, Malaysia; +6(03)-3362 8888; mrecsec@moh.gov.my), ref: NMRR ID-23-01805-2FB

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Self-management in patients with bronchial asthma

Interventions
This randomised controlled trial compares the use of a pictorial asthma action plan (PAAP) vs a text-based asthma action plan (tAAP) among adult patients with asthma in public primary care clinics in Klang District, Selangor over 1 year. The PAAP will be delivered as part of self-management education. Patients will be followed up at 3, 6 and 12 months.

A qualitative approach will be used to explore the acceptability of the pictorial asthma action plan (PAAP) and the barriers and motivation to using the PAAP for patients and health care providers at the 12 months of the study.

Randomisation is done at the individual level at each clinic rather than at the clinic level to reduce possible bias due to variability of clinic profile and asthma care in both groups as the management and resources of the clinics are not homogenous.

One research team member will generate the allocation sequence using the computer random number generator based on the frame of consented participants using simple randomisation with an allocation ratio of 1:1. The number generated for the control and intervention group will be documented in a master list (allocation sequence). The researcher will prepare a sealed opaque envelope with the numbering tAAP (control) or PAAP (intervention) according to the allocation sequence. The allocation sequence will be concealed from other research team members involved in participant recruitment and in the assessment of outcomes at baseline and at every assessment timepoints.

The RA will sequentially number the participants who have been successfully enrolled. The research assistants will deliver the sealed envelope and its number is matched with the sequential numbering of the participant after the baseline assessment. The participants will be informed there are two arms to this study. They will bring their sealed envelope for their consultation. The doctors/pharmacist will open the envelope and counsel the participant according to the arm (tAAP or PAAP) they are allocated.

It is not possible to blind the participants due to the nature of the intervention as the participants will know they receive the pictorial or the text-based asthma action plan. However, the assessor, a trained RA will be blinded.

As the intervention and control groups are from the same clinic, measures will be in place to minimise cross-contamination whenever it is necessary. Participants from different allocated groups will be arranged to attend the clinic for their subsequent scheduled follow-up visits on different clinic days.

In addition, during the training of the health care providers, they will be instructed to share the allocated intervention only with the assigned participants. The intervention will be delivered over a 12-month duration.

Intervention Type
Behavioural

Primary outcome(s)
Asthma control measured using the validated Global Initiative for Asthma (GINA) Asthma Symptoms Control at 3, 6 and 12 months

Key secondary outcome(s))
Assessed at 3, 6 and 12 months:
1. Number of times reliever medication (inhaled or oral bronchodilators) is used in the past month
2. Adherence to controller medication in the past month
3. Frequency of acute exacerbations (defined as episodes characterised by acute or subacute onset of progressively worsening symptoms, such as shortness of breath, cough, wheezing or

chest tightness, which are worse than the patient's usual status and require a change in treatment) in the past month
4. Frequency of asthma-related emergency visits (to a health clinic and/or hospital emergency department) in the past month
5. Frequency of asthma-related admissions in the past month
6. Number of days lost from work for asthma treatment (defined as the number of days of medical leave taken by an employee, or unable to work if self-employed) in the past month
7. Number of times the participants reported using their pictorial asthma action plan in the previous month

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Aged 18 years or older under follow up care.
2. Asthma diagnosed by a health care practitioner.
3. Prescribed with daily inhaled corticosteroids (ICS) for poor asthma control in the last year (according to Global Initiative for Asthma (GINA) Asthma Symptoms Control (2022) step 2 management for asthma control), in addition to as needed inhaled short-acting beta2-agonist (SABA); or as needed low dose ICS-formoterol for those on SMART therapy (Global Initiative for Asthma, 2022)
4. Willing and able to provide written informed consent.
5. Able to understand Malay (national language of Malaysia) or English.

Detailed participant inclusion criteria for health care providers:
1. Health care providers who are involved in the management of asthma in the clinics
2. Willing and able to provide written informed consent.

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Detailed participant exclusion criteria for patients:
1. Less than 18 years of age
2. Unwilling or unable to provide written informed consent.
3. Co-morbid conditions prohibiting participation such as diagnosed cognitive impairment.
4. Diagnosed with other chronic respiratory disease (e.g. chronic obstructive pulmonary disease).
5. People whose family member living in the same household is a participant of this study.

Detailed participant exclusion criteria for health care providers:
1.Health care providers who are on long leave (more than 1 month) during the period of data collection, for example, those on subspecialty attachment leave or maternity leave.
2. Unwilling to provide written informed consent.

Date of first enrolment
15/08/2023

Date of final enrolment
15/02/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
Meru Health Clinic
Jalan Kenangan Meru
Pekan Meru
Klang
Malaysia
42200

Study participating centre
Kapar Health Clinic
Jalan Perbandaran
Taman Kapar
Kapar
Malaysia
42200

Study participating centre
Port Klang Health Clinic
Persiaran Raja Muda Musa
Kawasan 13
Pelabuhan Klang

Malaysia
42000

Study participating centre
Klang Health Clinic (Anika)
12 Jalan Pegawai
off Jalan Tengku Kelana
Klang
Malaysia
41000

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
NIHR Global Health Research Unit on Respiratory Health (RESPIRE)

Results and Publications

Individual participant data (IPD) sharing plan
The deidentified data will be stored in a data repository (DataShare) at the University of Edinburgh at the end of the study.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	27/02/2023	24/02/2026	No	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes