

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/07/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/12/2024	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 plan 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.

Study website

<https://www.ed.ac.uk/usher/respire/research/non-communicable-diseases/current/paap>

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Efficacy

Participant information sheet

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/06/2022

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)

Patient, Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

180

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

Sponsor details

ACCORD
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh

Scotland
United Kingdom
EH16 4TJ
+44 (0)131 242 9100
cmvm.communications@ed.ac.uk

Sponsor type

University/education

Website

<https://www.ed.ac.uk/medicine-vet-medicine/institutes-centres-facilities-networks/institutes-and-centres/queens-medical-research>

ROR

<https://ror.org/01nrxf90>

Funder(s)

Funder type

Government

Funder Name

NIHR Global Health Research Unit on Respiratory Health (RESPIRE)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/05/2026

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