Non-CTIMP Study Protocol

Effectiveness of Pictorial Asthma Action Plan in Public Primary Care Clinics: A Randomised Controlled Study

Sponsor	The University of Edinburgh ACCORD The Queen's Medical Research Institute 47 Little France Crescent Edinburgh EH16 4TJ
Protocol authors	1. Associate Professor Dr. Ai Theng Cheong 2. Professor Dr. Sazlina Shariff Ghazali 3. Dr. Hani Syahida Salim 4. Dr. Fadzilah Mohamad 5. Dr. Poh Ying Lim 6. Professor Dr. Ping Yein Lee 7. Associate Professor Dr. Norita Hussein 8. Professor Dr. Nik Sherina Hanafi 9. Dr. Siti Nurkamilla Ramdzan 10. Dr. Rizawati Ramli 11. Dr. Tan Siow Foon 12. Dr, Norasnita binti Nordin 13. Dr Fazlina Binti Mohamed Yusoff 14. Dr Zuzana Aman 15. Dr Wong Chee Kuan 16. Professor Dr. Ee Ming Khoo 17. Professor Dr. Hilary Pinnock
Funder	**NIHR Global Health Research Unit on Respiratory Health (RESPIRE)**
Funding Reference Number	**NIHR132826**
Chief Investigator	**Professor Harry Campbell**
Sponsor number	AC**22169**
Ethics Number	**Insert Ethics number before finalisation (include both the local country ethics number and the UoE/UK-based ethics number where applicable)**
Project registration	**This study protocol will be registered with ISRCTN.**
Version Number and Date	**Version 2.0 dated 27.2.2023**

CONTENTS

LIST OF ABBREVIATIONS

ACCORD	Academic and Clinical Central Office for Research & Development
CI	Chief Investigator
CRF	Case Report Form
FGD	Focus Group Discussion
FMS	Family Medicine Specialist
GCP	Good Clinical Practice
GINA	Global Initiative for Asthma
HCP	Health Care Provider
ICH	International Conference on Harmonisation
ICS	Inhaled corticosteroids
IDI	In Depth Interviews
LABA	Long acting beta2-agonist
PAAP	Pictorial Asthma Action Plan
PI	Principal Investigator
SABA	Short acting beta2-agonist
SMART	Single maintenance and reliever therapy
tAAP	Text-based Asthma Action Plan

1 INTRODUCTION

1.1 BACKGROUND

Asthma affected an estimated 262 million people in 2019 and caused 455 000 deaths (GBD 2019 Diseases and Injuries Collaborators, 2020; World Health Organization, 2022). It is a public health issue that affects 100 million people in Southeast Asia (To et al., 2012). Most asthma-related deaths occur in low- and middle-income countries (To et al., 2012). A study conducted in Asia reported that asthma control is poor in majority of patients and that their perceptions of control did not correlate with standard-defined asthma control (Price et al., 2015). Asthma also affects multiple aspects of the

patients' life including work days' loss, limitation in sleeping, normal physical activities and chores (Institute for Public Health, 2008). The aim of this project is to determine the effectiveness of supported self-management incorporating the pictorial asthma action plan for adult patients with asthma in clinical practice in public primary care clinics in the Klang District, Selangor State, Malaysia.

1.2 RATIONALE FOR STUDY

In Malaysia, the prevalence of asthma among adults is estimated at 4.2% with asthma related deaths at 1.2% in 2006 (Institute for Public Health, 2008). The Third National Health and Morbidity Survey (2006) reported 20.0% of adult asthma patients visited emergency department for acute exacerbations and of these 10.0% were admitted (Institute for Public Health, 2008). In addition, among the adult asthma patients, 68.0% visited their doctors for asthma attacks, 27.3% reported having a min of 6 (4-8) work–days loss and 69% did not have regular long term follow up (Institute for Public Health, 2008). This was in congruent with other local studies that found only about a third of patients with asthma had regular follow up care and controller medications were underutilized and oral short acting beta agonist use was common (Chin et al., 2017; Lee & Khoo, 2003; Zainudin et al., 2005). The burden of asthma remained a major public health issue in Malaysia, thus, steps need to be taken to reduce the burden, which must be cost effective, multimodal and patient-centred.

Asthma is a neglected disease; it is not yet considered a public health priority (Cheong et al., 2021). Globally it is estimated to be one of the expensive diseases. Despite having effective treatment, control of asthma is still suboptimal. It is reported that asthma requires high utilization of public health care resources, mainly because of huge number of hospitalisation and emergency visits due to poor self-management of asthma. This leads to major expenditures on direct and indirect costs (Bahadori et al., 2009). Similary a Malaysia hospital reported the high cost of asthma management was due to hospitalisation and medication.(Yong & Shafie, 2018). In addition, health care strategies to improve asthma control are limited due to disparities in country financial allocations for asthma compared to other non-communicable diseases.

Asthma self-management is recommended in all major national/international asthma guidelines (Global Initiative for Asthma, 2019). It has been shown to improve clinical outcomes and reduce health costs (Gibson et al., 2002; Pinnock et al., 2017). Self-management delivered in routine care often focuses on the didactic transfer of information and skills with little effort to take into account patients' preferences or views about self-managing asthma (Gibson et al., 2002; Ring et al., 2011). In Malaysia, asthma self-management is poorly studied. A local study among patients with asthma attending an emergency department in Kuala Lumpur in 2001 showed poor uptake of education on the nature of asthma and self-management skills (Lee & Khoo, 2003). About half (53%) of these patients could not recognize features of worsening asthma and only nine percent were taught on actions to take (Lee & Khoo, 2004). Recent preliminary studies on perception of asthma and its treatment among school children and their caregivers in Malaysia reported social-cultural beliefs play a major role in influencing patient's self-care practice (Ramdzan et al., 2017). Despite guidelines and literature have highlighted the importance of tailoring self-management to local context

in diverse communities during its implementation (Pinnock et al., 2017), most major studies on asthma self-management (on which guideline recommendations are based) were conducted in Western populations, limiting their applicability to our local context. A culturally tailored asthma self-management intervention could potentially reduce the burden of asthma in Malaysia.

Asthma action plan is an integral part of self-management education. It enables patients with asthma adjust their own treatments according to changes in their disease (Global Initiative for Asthma, 2022; Ignacio-García et al., 2002). A meta-analysis comparing written asthma action plans delivered in the context of supported self-management to standard treatments showed a 40% reduction in asthma-related presentation to hospitals and a 20% reduction in emergency visits among patients with written asthma action plan (Gibson et al., 2002). However, written asthma action plans favour those with satisfactory health literacy. It has been shown that limited health literacy level is linked with poor asthma control (Mancuso & Rincon, 2006). An asthma action plan that illustrates the written action plan in pictorial format has been studied to help patients understand their disease and management better. It has been shown to be an effective tool in enhancing asthma consultations and improving recall of medical instructions in clinical settings (Houts et al., 1998, 2006).

At present in Malaysia, a non-pictorial written asthma action plan is used in clinical practice. A study conducted at public primary care clinics had reported that about 60% of patients with asthma had limited health literacy (Salim et al., 2018). Pictorial asthma action plan (PAAP) has the potential to overcome the inequity of text-based asthma action plan (tAAP) and benefit all patients regardless of their health literacy. We conducted a pre-post feasibility study of PAAP among patients with asthma in a public primary care clinic and found that those who were given PAAP were more likely to have better asthma control compared with baseline (Sazlina et al., 2022). In addition, the health care providers (HCPs) and patients preferred the pictorial plan over the written plan. The facilitators to using the pictorial plan included simplicity, usefulness, user friendliness and that the pictures were easy to understand (Sazlina et al., 2022). HCPs felt it was easy for HCPs at all levels to deliver the pictorial plan and this would reduce their workload (Sazlina et al., 2022). Findings of this feasibility study have been presented to the officers from the Ministry of Health included Family Health Development Division, Ministry of Health Malaysia, Klang Health District Office and the patients. Positive feedback was received. A full scale randomised controlled trial is thus needed to evaluate the effectiveness of PAAP.

2 STUDY OBJECTIVES

2.1 OBJECTIVES

This study aims to assess the effectiveness of a pictorial asthma action plan (PAAP) for adult patients with asthma in public primary care clinics in the Klang District, Selangor State, Malaysia.

2.1.1 Primary Objective

1. To determine the effectiveness of the PAAP among adult with asthma in public primary care clinics, at 3-, 6- and 12-month compared to baseline and compared to control group.

2.1.2 Secondary Objectives

1. To determine the effectiveness of the PAAP in improving medication use (reduced numbers of reliever use, adherence to inhaled corticosteroids (ICS) use), at 3-, 6- and 12-month compared to baseline and compared to control group.
2. To assess the effectiveness of the PAAP in improving clinical outcomes (reducing acute exacerbations, emergency visits, hospitalization) and days lost from work, at 3-, 6- and 12-month compared to baseline and compared to control group.
3. To assess the acceptability of the PAAP in clinical setting at 12- month.

2.2 ENDPOINTS

2.2.1 Primary Endpoint

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

2.2.2 Secondary Endpoints

The secondary endpoints will be assessed at 3-, 6- and 12-months are as follows:

- Number of times reliever medication (inhaled or oral bronchodilators) is used in the past one month.
- Adherence to controller medication in the past one month.
- 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 one month.
- Frequency of asthma-related emergency visits (to a health clinic and/or hospital emergency department) in the past one month.
- Frequency of asthma-related admissions in the past one month.
- Numbers of days lost from work for asthma treatment (defined as number of days of medical leave taken by an employee, or unable to work if self-employed) in the past one month.
- Number of times the participants reported using their pictorial asthma action plan in the previous month.

3 STUDY DESIGN

This is a randomised controlled trial comparing 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 one year. The PAAP will be delivered as part of self-management education. Patients will be followed up at 3-, 6- and 12- month. This study will be conducted in accordance with the extension of the Consolidated Standards of Reporting Trials (CONSORT) Statements on reporting non-pharmacological randomised trials (Boutron et. al., 2017). The trial protocol will be registered. The flow of study participants is shown in Figure 1.

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-month of the study.

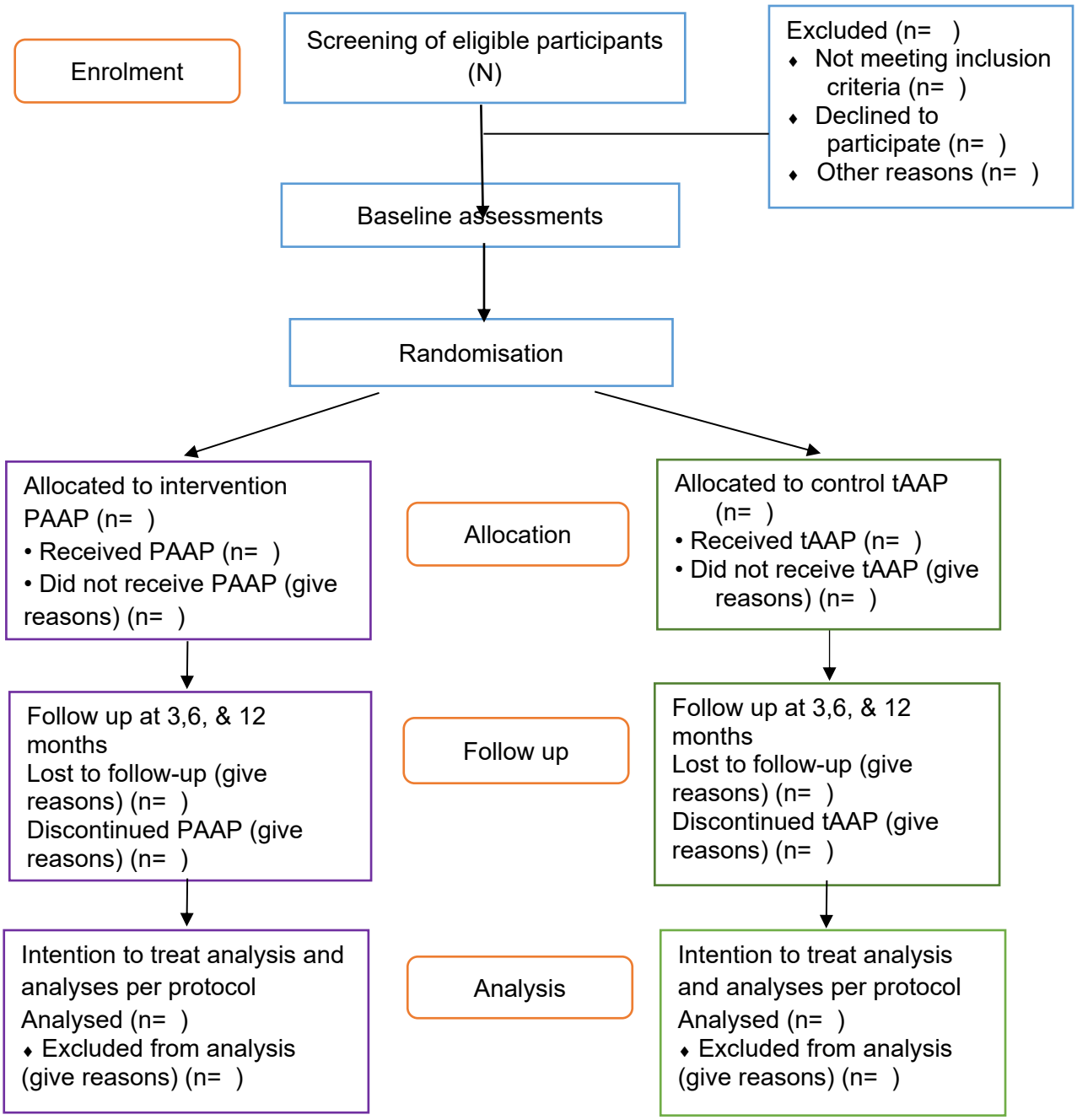

Figure 1. Flow of study participants

4 STUDY POPULATION

Study population will be patients with asthma and health care providers from public primary care clinics in Klang District, Selangor. A total of 180 participants who have physician-diagnosed asthma and are prescribed inhaled corticosteroids will be participating in this study.

4.1 STUDY LOCATION

We will collect data from public primary care clinics in Klang District, Selangor. Selangor was chosen because it had been shown to have the highest prevalence of adults with asthma (22%) in Malaysia in 2006 (Institute for Public Health, 2008). In addition, adults with asthma in urban area had been found to have higher asthma prevalence compared with the rural area (61.6% vs 38.4%, respectively) (Institute for Public Health (IPH), 2008).

All these clinics are led by at least one family medicine specialist, and the clinic team consists of medical officers, pharmacists, registered nurses and assistant medical officers.

A site feasibility assessment will be conducted by the principal investigators to identify clinics which have at least 50 patients with asthma under follow up (Appendix 6). Researchers will then approach the officer in charge of the clinic and invite them to participate in the study. The proportion and number of participants that will be recruited from each clinic will be based on its asthma workload.

4.2 SAMPLE SIZE

Sample size is calculated based on the two-proportion formula (Lwanga et al., 1991), using estimates from our feasibility study in which the percentage of well controlled asthma at baseline and 6 months were 34.3% and 64.4% respectively (Sazlina et al., 2022), with a power of 80%, 5% risk error, 30% attrition rate, and a design effect of 1.5, the sample size needed is 90 per arm.

For the sample size of qualitative component, we will purposively recruit 20 patients and 20 HCPs from the intervention group. Recruitment will continue until data saturation.

4.3 INCLUSION CRITERIA

Detailed participant inclusion criteria for patients:

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.

4.4 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.

4.5 JUSTIFICATION FOR INCLUSION OF VULNERABLE POPULATIONS

No inclusion of vulnerable populations in this study.

4.6 CO-ENROLMENT

Co-enrolment is not encouraged as the participants need to commit for 12 months for this study, which may burden them if they co-enrol in other studies.

5 PARTICIPANT SELECTION AND ENROLMENT

5.1 IDENTIFYING PARTICIPANTS

Researchers will arrange with the site investigators who are part research team and also part of the clinical team caring for patients with asthma to access the list of patients with asthma who require follow-up at the clinics.Potential participants (patients) will be recruited from the clinics that agree to participate in this study. Patient list with asthma coming for follow up will be screened for eligibility.

Research assistants (RAs) who are not involved in the allocation process will enrol participants after screening for eligibility. They will contact eligible participants for agreement to participate. Participants who agreed to participate will be enrolled during their follow up visit with the health care providers. The RA will explain the study protocol and written informed consent will be obtained from each participant before baseline assessment at enrolment.

Before enrolment, potential participants will need to agree to the following requirements:

- A 12-month commitment to the project,
- Agree to be contacted via telephone calls at each follow up study time points by the research team, and
- Allow access to personal and medical data from their medical record

For the identification of health care providers (HCPs), contacts information of HCPs who are involved in the management of patients with asthma were obtained from the officer in charge of the primary care clinics with the permission from the HCPs, respectively. Potential participants will be approached and invited to participate in the study via telephone call, text messages or email. The purpose of the study will be explained to the participants during the initial approach via telephone call, text

messages or email. A participant information sheet will be sent to the participants to facilitate their understanding of the study. For those who are interested to participate in the study, appointment will be arranged for a focus group discussion or one to one interview.

RANDOMISATION, ALLOCATION AND BLINDING PROCESSES

Randomisation is done at individual level at each clinic rather than at 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 control and intervention group will be documented in a master list (allocation sequence). The researcher will prepare a sealed opaque envelope with numbering tAAP (control) or PAAP (intervention) according to the allocation sequence. The allocation sequence will be concealed from other research team members involved in participants recruitment and in the assessment of outcomes at baseline and at every assessment time points.

The RA will sequentially number the participants who have been successfully enrolled. The research assistants will deliver the sealed envelope that its number is matched with the sequential numbering of the participant after 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 group 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. The flow of study participants has been shown in Figure 1. Training will be formally delegated by the PI using a Training Log (Appendix 7) and the Delegation Log will be used to document the delegated study responsibilities (Appendix 8),

The participants will be reimbursed for the time spent for the study. Each participant will be reimbursed total of RM100 (GBP20) for participating in the assessments at four different time points (0, 3, 6, 12 month). Participants will be paid RM25 (GBP5) after data collection during each time point.

Patients and health care providers who participate in the focus group discussion or in-depth interview for qualitative feedback will be reimbursed RM50 (10 GBP) and RM100 (20 GBP) respectively. The higher rate is being given to HCP to take into consideration the length of time spent by the professional group. These rates had been used and widely accepted by previous research in Malaysia and the previous feasibility study of this project.

5.2 CONSENTING PARTICIPANTS

Participants are given 2 weeks to decide if they would like to participate in this study. The trained research assistant will enrol eligible participants upon their agreement and written informed consent obtained.

5.2.1 Withdrawal of Study Participants

Participants are free to withdraw from the study at any point or a participant can be withdrawn by the Principal Investigator. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant's case report form, if possible. The participant will have the option of withdrawal from:

(i) all aspects of the trial but continued use of data (and samples) collected up to that point.
(ii) all aspects of the trial with deletion of all previously collected data (and samples).

To safeguard rights, the minimum personally-identifiable data possible will be collected.

6 STUDY ASSESSMENTS

INTERVENTION

The intervention consisted of a pictorial asthma action plan (see Appendix 4) incorporated within an existing self-management education and support, and is described in Table 1 using the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014). The PAAP has been found to be feasible for used at primary care clinic in Malaysia from our earlier feasibility study (Sazlina et al., 2022).

Table 1. TIDieR Checklist

TIDieR item	Description
Title	Effectiveness of pictorial asthma action plan in public primary care clinics
Why	This study will address components of the COM-B Behaviour Change Wheel to improve asthma control by supporting self-management behaviour including the use of a pictorial asthma action plan personalised to the patient's capability, motivation and opportunity. • Capability: Psychological and physical capacity to use the plan will be considered and the self-management support personalised accordingly • Opportunity: Use of a pictorial action plan provide opportunity for participants with limited health literacy to understand and use the action plan • Motivation: Supported self-management strategies will be provided to enhance motivation

TIDieR item	Description
What	Pictorial asthma action plan was developed earlier during our feasibility study and the process of development is as follows: We adapted the format of pictorial asthma action plan from published studies and aligned it with the recommendation of actions from the (text) action plan of the Malaysian Management of Asthma in Adults guidelines(Malaysian Health Technology Assessment Section (MaHTAS), 2017). Adaptation was an iterative process that involved an advisory group that comprised two doctors from the clinic, and four patient and public colleagues with asthma (who had differing experience of using text-based asthma action plans) and two relatives of patients with asthma. • The pictorial asthma action plan illustrates different levels of asthma control with pictures depicting asthma symptoms and zoned actions (green, yellow and red zone) needed such as adjust the dose of reliever, use prednisolone or seek medical attention. The characters in the pictures are used following feedback from patient and public representing the range of ethnic groups in Malaysia. The action plan was developed in English language and translated to Malay language, using the forward and backward translation processes. • The pictorial action plan in both languages had undergone content validity checks by nine panellists comprising five health care providers involved in the management of asthma in primary care facilities and four patients with asthma who had used a text-based asthma action plan. They commented on the 1) accuracy (the pictures conveyed the intended meaning); 2) clarity (the pictures were understood and provided clear information about the zone of asthma care); 3) style (font and picture size were appropriate); and 4) relevance (the pictures were relevant to the local social context). • For this study, we will adapt the earlier PAAP and update it according to latest GINA guidelines and Malaysia asthma clinical practice guideline (Global Initiative for Asthma, 2022; Malaysian Health Technology Assessment Section (MaHTAS), 2017). Two pathways have been practiced in the clinics and will be used in this study: 1. The use of combination budesonide and formoterol as preventer and reliever (SMART asthma action plan) and 2. The use of inhaled corticosteroid as preventer and short-acting beta-agonist as reliever (Alternative asthma action plan) (Refer appendix 4). The updated version will undergo content validity check by an expert panel that consists of health care providers involved in the management of asthma and patients with asthma.

TIDieR item	Description
Who provide	The action plan will be provided by the clinic's doctors or pharmacists tailor to the treatment of patients. • The research team will conduct a 2-hour group training for the clinic's health care providers (medical officers, pharmacists and nurses) during a scheduled Continuous Professional Development (CPD) session which aims to maintain staff skills. The training will emphasise on communication skills and include interactive lectures, role-plays using simulated patient consultations and group discussion to familiarise the staff with the pictorial action plan.
How	The action plan will be personalised for each participant and will be provided one-to-one by the clinic's doctors or pharmacists.
Where	The action plan will be provided at the asthma clinic run routinely at the public primary care clinic.
When and How much	The intervention (provision of the pictorial action plan) will be provided after the baseline assessment They will be taught how to use the action plan by the doctors or pharmacists at the first visit.
Tailoring	The action plan will be personalised for each participant such as the type of controller medication and medication dosage. The doctors who provide the action plan will circle a picture of the relevant controller medication and write down the dosage to be taken by the participant.
Fidelity assessment	During the first clinic visit the research team will check whether all participants have received an asthma action plan (PAAP or tAAP) that is completed with relevant information. Relevance will be judged independently by two primary care doctors who will discuss any disagreements to reach a consensus.

6.1 STUDY ASSESSMENTS

Assessment of eligible criteria will be carried out at the screening stage.

All study outcomes (primary and secondary outcomes) will be measured at baseline and at 3-, 6- and 12-months post intervention.

Primary outcome
Asthma control will be measured using the validated Global Initiative for Asthma (GINA) Asthma Symptoms Control.

Secondary outcomes

The secondary outcomes measured in this study all related to the previous one-month:

- Number of times reliever medication (inhaled or oral bronchodilators) was used in the past one month.
- Adherence to controller medication in the past one month.
- 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 one month.
- Frequency of asthma-related emergency visits (to a health clinic and/or hospital emergency department) in the past one month.
- Frequency of asthma-related admissions in the past one month.
- Numbers of days lost from work for asthma treatment (defined as number of days of medical leave taken by an employee, or unable to work if self-employed) in the past one month.
- Number of times the participants reported using their pictorial asthma action plan in the previous month.

Table 2: Study assessment

Assessment	Screening	Day 1 baseline	3-month	6-month	12-month
Assessment of Eligibility Criteria, contact details	☒				
Written informed consent	☒				
Demographic data		☒			
Asthma control		☒	☒	☒	☒
Number of times reliever medication was used in the past one month.		☒	☒	☒	☒
Adherence to controller medication in the past one month.		☒	☒	☒	☒
Frequency of acute exacerbations in the past one month.		☒	☒	☒	☒
Frequency of asthma-related emergency visits in the past one month.		☒	☒	☒	☒
Frequency of asthma-related admissions in the past one month.		☒	☒	☒	☒
Numbers of days lost from work for asthma treatment in the past one month.		☒	☒	☒	☒
Number of times the participants reported using their pictorial asthma action plan in the previous month			☒	☒	☒
Acceptability for the use of PAAP (qualitative)					☒

In-depth-Interviews (IDIs)/Focus group discussion (Appendix 2)

At the end of the 12-month of the study, focus group discussions will be conducted to explore the acceptability of the pictorial asthma action plan (PAAP) and the barriers and motivation to using the PAAP. In circumstances where the participants have difficulty joining the focus group, IDIs will be carried out. We will purposively recruit 20 participants from the intervention group and the health care providers who are involved. The research team will choose the participants from the intervention group based on their characteristics such as asthma control, frequency use of asthma action plan and motivation to use asthma action plan. The healthcare providers chosen will be based on their characteristics such as years of practice, occupation, experience of using asthma action plan/pictorial asthma action plan with patients. Participants with different characteristic will be invited to provide wide range of opinion.

Recruitment will continue until data saturation. All interview sessions will be moderated by the research team who are experienced in conducting qualitative research. The interviews are expired to last 1 to 1.5 hours. All interviews will be audio recorded and transcribed verbatim. All audio-recordings were transcribed verbatim in the original languages (Malay, English or a mix of Malay and English) to preserve semantics as much as possible and these served as source data for the analysis. The transcripts will be checked for accuracy before analysis is carried out. English language will be used for coding and analysis. The data will be thematically analysed. Quotes used in papers and reports will be translated into English.

Questionnaire (Appendix 1)

The questionnaire will be used to capture patients' baseline information (sociodemographic, health literacy, medical and health information) and demographic characteristics of HCPs.

The questionnaire will have 4 sections for patients' baseline information:

Section A: Socio-demographic and socio-economic information including age, gender, ethnicity, highest education level, occupation, marital status, and household incomes.

Section B: Medical and health care information including duration of asthma, family history of asthma, triggers and allergies, frequency of attacks, use of health care resources, medications, vaccinations, current and history of alternative treatment use, smoking status, co-morbid conditions, previous asthma education and ownership/use of an asthma action plan, use of an asthma diary.

Section C: Asthma control assessment using the GINA Asthma Symptom Control.

Asthma control will be measured using the validated Global Initiative for Asthma (GINA) Asthma Symptoms Control(ref). This questionnaire comprises of four questions that measure the adequacy of asthma treatment in the past four weeks. The questions focus on day and night-time symptoms, use of reliever, and limitation of activity due to asthma. The option for each response is either a "Yes" or a "No". If participant's

responses to all questions are “No”, he is deemed to be well-controlled; If there is a “Yes” to any response to the questions, the participant’s asthma is deemed to be not controlled.

Section D: Health literacy will be measured using the validated 18 item Health Literacy Survey-Malaysian-Q18 (HLS-M-Q18) which assesses one’s ability to access, understand, appraise, and use health information in the context of health care, disease prevention, and health promotion (Mohamad et al., 2020). The HLS-M-Q18 has been adapted from the European Health Literacy Survey Questionnaire (HLS-E-Q47) for the use in the Malaysia National Health Morbidity Survey in 2019 and shown to be valid and reliable for use in Malaysia (Mohamad et al., 2020). It is rated on a 4-Likert scale, ranging from 1=very difficult to 4=very easy. According to the instructions of the HLS-M-Q18, an index of health literacy score was constructed using the mean-based scores of the 18 items. These are transformed into a unified metric ranging from 0 to 50 using the formula = (*mean* – 1)* (50/3)(Jaafar et al., 2021). The index scores are grouped into two categories: limited and adequate health literacy. An index score of ≤33 indicates limited health literacy(Jaafar et al., 2021).

Information on health care visits (emergency visits at the clinic or hospital for asthma attacks) will be verified by clinic doctors from the participants’ medical records. In case of discrepancies, the information will be checked with the patients, as patients in Malaysia might seek care from other health providers, and the medical record may not be complete.

For the demographic characteristics of HCPs, the information captured include age, gender, ethnicity, duration of practice, occupation and experience if using asthma action plan with patients.

6.2 LONG TERM FOLLOW UP ASSESSMENTS

Trained RAs will contact all participants at 3-, 6- and 12-month post intervention via telephone calls. They will collect the data using a case report form. The case report form consists of questions to assess primary and secondary outcome measures. This includes GINA asthma symptom control questionnaire, number of times reliever medication is used, adherence to controller medication, frequency of acute exacerbations, emergency visits, hospitalisation, days lost from work and use of PAAP in past month. Data will be verified from participants’ clinic records, if available.

Results of patients’ status of asthma control will be informed by the site investigators of research team (primary care physician from the respective clinics) to the participants after each assessment at 3, 6 and 12 months.

6.3 STORAGE AND ANALYSIS OF SAMPLES

Not applicable. There are no biological samples involved in this study.

6.4 TRANSCRIPTION AND TRANSLATION

6.4.1 Transcription Services

The audio recordings will be sent for transcription services by experienced transcribers (freelancers) and the non-disclosure agreement (NDA) will be carried out between Universiti Putra Malaysia (UPM) and the delegated transcriber (Appendix 9).

6.4.2 Translation Services

Quotes that use in the reports or manuscripts will be translated to English by researchers who are bilingual (proficient in both Malay and English) as the researchers will understand the context most.

7 DATA COLLECTION

7.1 Source Data Documentation

Source documents include the baseline questionnaire and case report forms for data collection at 3-, 6- and 12-month follow-up, and interview transcripts notes. Questionnaire and topic guide are shown in Appendix 1 and Appendix 2.

7.2 Case Report Forms

Data collection will be carried out at 3-, 6- and 12-month post intervention by a trained RA who is not involved in patients' recruitment and baseline assessments (Appendix 1). Data to be collected include assessment of primary and secondary outcomes as stated earlier. Some information on health centre visits (such as unscheduled visits to the health clinic or hospital emergency department for asthma attacks and number of routine follow up to the health clinic) will be verified from the participants' medical records.

8 DATA MANAGEMENT

8.1.1 Personal Data

The following personal data will be collected as part of the research:

Patients:

- Name and identity card number in the consent form
- Name and telephone number for follow up assessment and interviews
- Age, gender, ethnicity, marital status, educational level, occupation, personal and household income, health literacy, medical profile, asthma control and audio recordings in interviews

Health care providers:

- Name and identity card number in consent form (in accordance to the guidelines of the Malaysia Medical Research Ethics Committee)
- Name and telephone number for arrangement of IDI/FGD session
- Age, gender, ethnicity, years of practice, occupation, experience of using asthma action plan/pictorial asthma action plan with patients, audio recordings for participation in interviews/focus group discussion

Personal data collected from paper copies (e.g. consent forms) will be stored at a locked and keyed cabinet in Universiti Putra Malaysia with access only to the principal investigator and co-researchers. The key will be kept by the principal investigator in a locked drawer.

The data collected from participants from the interviews will be uploaded to a password protected Microsoft word in order to conduct the analysis. Only the principal investigator and co-researchers will have access to this data. For qualitative study, once the transcripts have been completed and checked by the researchers for accuracy, the audio recordings will be erased. To de-identify the transcripts, a code will be applied.

All of the personal data including identifying information will be stored in a secure data-storing facility and secure servers at (Department of Family Medicine, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia) for 5 years following the end of the study.

All data will be stored for 5 years. After 5 years, all paper records will be shredded and disposed of securely and electronic records will be permanently erased.

Participant personal identifiable data will not be transferred outside of Malaysia.

8.1.2 Data Information Flow

The flow of collection, use and deletion of personal data is as follows (figure 2):

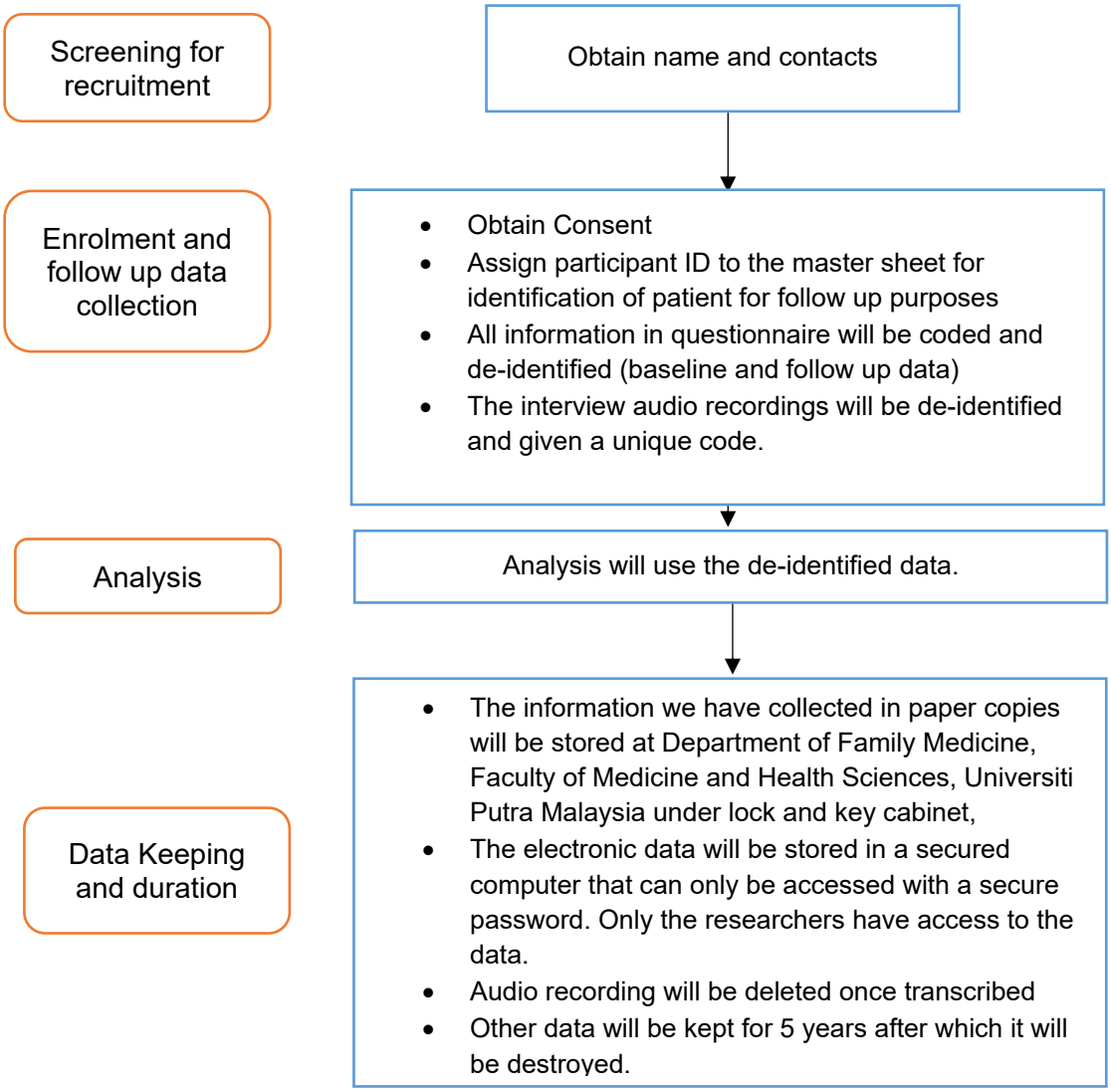

Figure 2: Data information flow

8.1.3 Transfer of Data

The data collection will be held in Malaysia and manage locally at Universiti Putra Malaysia. At the end of the study, the de-identified data will be transferred to a data repository (DataVault or DataShare) at the University of Edinburgh via DataSync. This will be performed via local upload to a password-protected Datasync folder, accessed via a web browser, for retrieval and download at UoE.
The archived data might be used for possible secondary analysis for the future.

8.1.4 Data Controller

The Data Controllers for this study are the University of Edinburgh and Universiti Putra Malaysia (UPM). UPM is also the data processor for this study.

8.1.5 Data Breaches

Any data breaches will be reported to the University of Edinburgh Data Protection Officer who will onward report to the relevant authority according to the appropriate timelines if required. The notification of data breaches will also be notified to the Malaysia Ministry of Health Medical Research Ethic Committee of and the Universiti Putra Malaysia Research Management Centre.

9 STATISTICS AND DATA ANALYSIS

9.1 SAMPLE SIZE CALCULATION

Sample size is calculated based on the two-proportion formula (Lwanga et al., 1991), using estimates from our feasibility study in which the percentage of well controlled asthma at baseline and 6 months were 34.3% and 64.4% respectively (Sazlina et al., 2022), with a power of 80%, 5% risk error, 30% attrition rate, and a design effect of 1.5, the sample size needed is 90 per arm.

For the sample size of qualitative component, we will purposively recruit 20 patients and 20 HCPs from the intervention group. Recruitment will continue until data saturation.

9.2 PROPOSED ANALYSES

Descriptive analysis will be done for the demographic characteristics of the participants, GINA asthma symptom control, clinical history and baseline variables will be reported using means and standard deviations (SD) or median and inter-quartile range (IQR) for continuous variables (depending on data distribution), and as frequencies and percentages for categorical data. Normality test such as histogram with normal curve will be used to check for normality. Missing data pattern will be checked and imputation method such as last observation carried forward will be applied. Intention to treat analysis and per-protocol analysis will be performed and compared.

Baseline data between intervention and control group will be compared, using Chi-square or fisher exact test for categorical variables and independent t-test or One-way ANOVA for normally distributed data whereas Mann Whitney test or Kruskal Wallis test will be used for data that are not normally distributed.

The primary outcome, asthma control, will be categorised into well controlled and not controlled (include partly controlled and uncontrolled). Generalised Estimating

Equation analysis will be conducted to determine the effectiveness of the intervention on asthma control and secondary outcomes over the four assessment time points, within and between both groups. Akaike information criterion (AIC) and Bayesian information criterion (BIC) will be checked to ensure the best fit model. The estimates will be reported with 95% confidence intervals. Statistical analysis will be done using SPSS version 27.0.

The acceptability will be reported descriptively and narratively from qualitative analysis. The analysis of the interviews data is an iterative process. Interviews will be transcribed verbatim. The transcripts will be checked for accuracy before analysis is carried out. English language will be used for coding and analysis. The data will be thematically analysed (Braun & Clarke, 2006).

10 ADVERSE EVENTS

Asthma action plan as part of self-management support is an evidence-based intervention which is known to improve outcomes (Pinnock, 2017). Provision of action plans is a recommendation in guidelines. However, if any participant expresses concern about the severity of their asthma, they will be advised to consult their attending doctor for further assessment. No adverse events will be reported to the sponsor for this study.

11 OVERSIGHT ARRANGEMENTS

11.1 INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, ethics committees review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

11.2 STUDY MONITORING AND AUDIT

The Sponsor will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Principal Investigator research sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

11.3 STEERING COMMITTEE/DATA MONITORING COMMITTEE

There is no independent steering committee/data monitoring committee. The research team will do the data monitoring.

12 GOOD CLINICAL PRACTICE

12.1 ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP) in additional to the principles of the ethics committee(s)/Institutional Review Boards (IRBs) who have reviewed and approved this study.

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

This study will receive approval from the University of Edinburgh's Medical School Ethics Committee (EMREC) in addition to the Malaysia Ministry of Health Medical Research Ethics Committee.

12.2 PRINCIPAL INVESTIGATOR RESPONSIBILITIES

The Principal Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Principal Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

12.2.1 Informed Consent

The Principal Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the participant will be performed by the Principal Investigator or qualified delegated person, and must cover all the elements specified in the Participant Information Sheet and Consent Form. There will be an English and Malay version of the Participant Information Sheet and Consent Form. For those who might not adeqately understand English or Malay or illiterate, the relative of participants or other healthcare staff will act as translator. The instructions will be given to the translator to translate the Participant Information and Informed Consent Forms as

directly as possible and not paraphrase or adapt what is said. A witness (another person either healthcare provider or other patient/relative who understand English/Malay) need to make sure that the information is conveyed correctly and understandable by the paticipants. (The professional interpretation and translation service is a better option but not available in the local setting.)

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the sponsor.

The Principal Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy filed in the Principal Investigator Site File (ISF) and participant's medical notes (if applicable).

12.2.2 Study Site Staff

The Principal Investigator must be familiar with the protocol and the study requirements. It is the Principal Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

12.2.3 Data Recording

The Principal Investigator is responsible for the quality of the data recorded in the Case Report Form (CRF) at each Principal Investigator Site.

12.2.4 Principal Investigator Documentation

The Principal Investigator will ensure that the required documentation is available in local Investigator Site files ISFs.

12.2.5 GCP Training

For non-CTIMP (i.e. non-drug) studies all researchers are encouraged to undertake GCP training in order to understand the principles of GCP. However, this is not a mandatory requirement unless deemed so by the sponsor. GCP training status for all investigators should be indicated in their respective CVs.

Principal investigator and some co-investigators in this study are GCP trained.

12.3 Data Protection Training

All University of Edinburgh employed researchers, students and study staff will complete the Data Protection Training through Learn.

12.4 Information Security Training

All University of Edinburgh employed researchers, students and study staff will complete the Information Security Essentials modules through Learn and will have read the minimum and required reading setting out ground rules to be complied with.

12.4.1 Confidentiality

All laboratory specimens, evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Principal Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

12.4.2 Data Protection

All Principal Investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the European Union General Data Protection Regulation, the Data Protection Act 2018 in the UK and any relevant Data Protection laws in the country where the study is being conducted (Malaysia Personal Data Protection Act 2010) with regard to the collection, storage, processing and disclosure of personal information.

Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data and be of a form where individuals are not identified and re-identification is not likely to take place.

STUDY CONDUCT RESPONSIBILITIES

12.5 PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator.

Amendments will be submitted to the sponsor for review and authorisation before being submitted in writing to the appropriate ethics committees/IRBs, for approval prior to participants being enrolled into an amended protocol.

12.6 MANAGEMENT OF PROTOCOL NON COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsor and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the appropriate ethics committees/IRBs for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsor every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to the sponsor at: QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

12.7 SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the sponsor (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the sponsor to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

12.8 STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 5 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

12.9 END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators or the sponsor has the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the appropriate ethics committees/IRBs and sponsor within 90 days, (or within the specific timelines specified by the individual ethics committees/IRBs). If the study is terminated prematurely, the end of study will be reported to the relevant ethics committees/IRBs and sponsor within 15 days. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved.

End of study notification will be reported to the sponsor via email to researchgovernance@ed.ac.uk and to the relevant ethics committees who approved the study.

A summary report of the study will be provided to the appropriate ethics committee(s)/IRBs within 1 year of the end of the study (or within the specific timelines specified by the individual ethics committees/IRBs).

12.10 CONTINUATION OF TREATMENT FOLLOWING THE END OF STUDY

The patients will continue to use the asthma action plan at the end of the study from their respective health clinics.

12.11 INSURANCE AND INDEMNITY

The sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the sponsor responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The sponsor requires individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites out with the United Kingdom will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

13 STAKEHOLDER ENGAGEMENT

We will involve lay representatives, health care providers and key administrators in the development of the study protocol to ensure the stakeholders' opinions are taken into account to ensure success of the study. They will review the protocol and all patient-related materials (including questionnaires, participant information sheets and consent form) to assess appropriate terminology. This process will be carried out before

recruitment begins and amendment may be needed for revised materials In addition, they will facilitate the design of the pictorial action plan that will be designed in accordance to the latest Global Initiative for Asthma guidelines. The results will be shared with the stakeholders for their feedback at the end of the data analysis.

14 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

14.1 AUTHORSHIP POLICY

Any publication or other dissemination of the Results (or any part of them) by any of the Parties shall not occur until Edinburgh has published the Results of the Project in the primary publication (the "Primary Publication"). Authorship of the Primary Publication shall be in accordance with normal academic practice. Notwithstanding the Confidentiality clause above, each Party shall be entitled to publish articles directly arising from its solely owned Results. Prior to the publication of articles directly arising from the work of more than one Party on the Project, each Party shall endeavour to circulate proposed publications at least 30 days in advance of submission for publication. All publications shall acknowledge the funding made available for the Project by the NIHR as required by the NIHR Award Terms. Each Party retains the right to request (such request not to be unreasonably refused) the delay of a publication in order to seek Intellectual Property protection for Results generated in the course of the Project if publication would reasonably prejudice such protection. Such delay shall not exceed 3 months, unless mutually agreed between the relevant Parties. Notification of the requirement for delay in submission for publication must be received by the publishing Party within 30 days after the receipt of the material by the other Party/Parties, failing which the publishing Party shall be free to assume that the other Party/Parties has no objection to the proposed publication. These provisions clause shall survive termination or expiry of this Agreement for the period of 1 year.

Other information: Appendices 6-9 are study management documents, not patient-facing materials, and are therefore submitted for information only

15 REFERENCES

Bahadori, K., Doyle-Waters, M. M., Marra, C., Lynd, L., Alasaly, K., Swiston, J., & FitzGerald, J. M. (2009). Economic burden of asthma: A systematic review. *BMC Pulmonary Medicine*, *9*, 24. https://doi.org/10.1186/1471-2466-9-24

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Cheong, A. T., Lee, P. Y., Shariff-Ghazali, S., Salim, H., Hussein, N., Ramli, R., Pinnock, H., Liew, S. M., Hanafi, N. S., Abu Bakar, A. I., Mohd Ahad, A., Pang, Y. K., Chinna, K., & Khoo, E. M. (2021). Implementing asthma management guidelines in public primary care clinics in Malaysia. *NPJ Primary Care Respiratory Medicine*, *31*(1), 47. https://doi.org/10.1038/s41533-021-00257-5

Chin, M. C., Sivasampu, S., & Khoo, E. M. (2017). Prescription of oral short-acting beta 2-agonist for asthma in non-resource poor settings: A national study in Malaysia. *PLOS ONE*, *12*(6), e0180443. https://doi.org/10.1371/journal.pone.0180443

GBD 2019 Diseases and Injuries Collaborators. (2020). Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: A systematic analysis for the Global Burden of Disease Study 2019. *Lancet (London, England)*, *396*(10258), 1204–1222. https://doi.org/10.1016/S0140-6736(20)30925-9

Gibson, P. G., Powell, H., Wilson, A., Abramson, M. J., Haywood, P., Bauman, A., Hensley, M. J., Walters, E. H., & Roberts, J. J. (2002). Self-management education and regular practitioner review for adults with asthma. In *Cochrane Database of Systematic Reviews*. John Wiley & Sons, Ltd. https://doi.org/10.1002/14651858.CD001117

Global Initiative for Asthma. (2019). *Global Strategy for Asthma Management and Prevention (2019 Update)*. Global Initiative for Asthma - GINA. https://ginasthma.org/

Global Initiative for Asthma. (2022). *Global Strategy for Asthma Management and Prevention, 2022*. Global Initiative for Asthma - GINA. https://ginasthma.org/gina-reports/

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Altman, D. G., Barbour, V., Macdonald, H., Johnston, M., Lamb, S. E., Dixon-Woods, M., McCulloch, P., Wyatt, J. C., Chan, A.-W., & Michie, S. (2014). Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ*, *348*, g1687. https://doi.org/10.1136/bmj.g1687

Houts, P. S., Bachrach, R., Witmer, J. T., Tringali, C. A., Bucher, J. A., & Localio, R. A. (1998). Using pictographs to enhance recall of spoken medical instructions. *Patient*

Education and Counseling, *35*(2), 83–88. https://doi.org/10.1016/S0738-3991(98)00065-2

Houts, P. S., Doak, C. C., Doak, L. G., & Loscalzo, M. J. (2006). The role of pictures in improving health communication: A review of research on attention, comprehension, recall, and adherence. *Patient Education and Counseling*, *61*(2), 173–190. https://doi.org/10.1016/j.pec.2005.05.004

Ignacio-García, J.-M., Pinto-Tenorio, M., Chocrón-Giraldez, M. J., Cabello-Rueda, F., Gil, A. I. L.-C., Ignacio-García, J.-M., & Ramón-Garrido, E. de. (2002). Benefits at 3 yrs of an asthma education programme coupled with regular reinforcement. *European Respiratory Journal*, *20*(5), 1095–1101. https://doi.org/10.1183/09031936.02.00016102

Institute for Public Health. (2008). *The Third National Health and Morbidity Survey (NMHS III) 2006, Asthma*. Ministry of Health, Malaysia.

Institute for Public Health (IPH). (2008). *The National Health and Morbidity Survey (NHMS III) 2006*. Ministry of Health, Malaysia.

Jaafar, N., Perialathan, K., Krishnan, M., Juatan, N., Ahmad, M., Mien, T. Y. S., Salleh, K. Z., Isa, A., Mohamed, S. S., Hanit, N. H. A., Hasani, W. S. R., Mohamad, E. M. W., & Johari, M. Z. (2021). Malaysian Health Literacy: Scorecard Performance from a National Survey. *International Journal of Environmental Research and Public Health*, *18*(11), 5813. https://doi.org/10.3390/ijerph18115813

Lee, P. Y., & Khoo, E. M. (2003). Asthma Control and Prior Medical Care of Patients Presenting With Acute Asthma at the Emergency Department. *Medical Journal of Malaysia*, *58*(4), 482–489.

Lee, P. Y., & Khoo, E. M. (2004). How well were asthmatic patients educated about their asthma? A study at the emergency department. *Asia-Pacific Journal of Public Health*, *16*(1), 45–49. https://doi.org/10.1177/101053950401600108

Lwanga, S. K., Lemeshow, S., & World Health Organisation. (1991). *Sample size determination in health studies: A practical manual / S. K. Lwanga and S. Lemeshow.* World Health Organisation. https://apps.who.int/iris/handle/10665/40062

Malaysian Health Technology Assessment Section (MaHTAS). (2017). *Clinical Practice Guideline: Management of Asthma in Adults*. Malaysian Health Technology Assessment Section, Medical Development Division, Ministry of Health Malaysia. https://www.moh.gov.my/moh/resources/Penerbitan/CPG/Respiratory/CPG%20Management%20of%20Asthma%20in%20Adults.pdf

Mancuso, C. A., & Rincon, M. (2006). Impact of Health Literacy on Longitudinal Asthma Outcomes. *Journal of General Internal Medicine*, *21*(8), 813–817. https://doi.org/10.1111/j.1525-1497.2006.00528.x

Mohamad, E. M. W., Kaundan, M. K., Hamzah, M. R., Azlan, A. A., Ayub, S. H., Tham, J. S., & Ahmad, A. L. (2020). Establishing the HLS-M-Q18 short version of the European health literacy survey questionnaire for the Malaysian context. *BMC Public Health*, *20*, 580. https://doi.org/10.1186/s12889-020-08704-7

Pinnock, H., Parke, H. L., Panagioti, M., Daines, L., Pearce, G., Epiphaniou, E., Bower, P., Sheikh, A., Griffiths, C. J., Taylor, S. J. C., & Groups, for the P. and R. (2017). Systematic meta-review of supported self-management for asthma: A health care perspective. *BMC Medicine*, *15*(1), 64. https://doi.org/10.1186/s12916-017-0823-7

Price, D., David-Wang, A., Cho, S.-H., Ho, J. C.-M., Jeong, J.-W., Liam, C.-K., Lin, J., Muttalif, A. R., Perng, D.-W., Tan, T.-L., Yunus, F., & Neira, G. (2015). Time for a new language for asthma control: Results from REALISE Asia. *Journal of Asthma and Allergy*, *8*, 93–103. https://doi.org/10.2147/JAA.S82633

Ramdzan, S., Lee, P., Cheong, A., Khoo, E., Hanafi, N., & HS, S. (2017). *Knowledge and perception of asthma and asthma treatment among Chinese school children with asthma in Malaysia.* 1st International Primary Care Respiratory Group South Asian Scientific Conference Sri Lanka.

Ring, N., Jepson, R., Hoskins, G., Wilson, C., Pinnock, H., Sheikh, A., & Wyke, S. (2011). Understanding what helps or hinders asthma action plan use: A systematic review and synthesis of the qualitative literature. *Patient Education and Counseling*, *85*(2), e131–e143. https://doi.org/10.1016/j.pec.2011.01.025

Salim, H. S., Lee, P. Y., Sazlina, S. G., Cheong, A. T., Pinnock, H., & Harrun, N. H. (2018). The prevalence of limited health literacy and its associations among adult asthma patients in primary care settings: A preliminary finding of a RESPIRE project. *9th International Primary Care Respiratory Group World Conference, Porto, Portugal*.

Sazlina, S. G., Lee, P. Y., Cheong, A. T., Hussein, N., Pinnock, H., Salim, H., Liew, S. M., Hanafi, N. S., Abu Bakar, A. I., Ng, C.-W., Ramli, R., Mohd Ahad, A., Ho, B. K., Mohamed Isa, S., Parker, R. A., Stoddart, A., Pang, Y. K., Chinna, K., Sheikh, A., … RESPIRE collaboration. (2022). Feasibility of supported self-management with a pictorial action plan to improve asthma control. *NPJ Primary Care Respiratory Medicine*, *32*(1), 34. https://doi.org/10.1038/s41533-022-00294-8

To, T., Stanojevic, S., Moores, G., Gershon, A. S., Bateman, E. D., Cruz, A. A., & Boulet, L.-P. (2012). Global asthma prevalence in adults: Findings from the cross-sectional world health survey. *BMC Public Health*, *12*, 204. https://doi.org/10.1186/1471-2458-12-204

World Health Organization. (2022). *Asthma*. https://www.who.int/news-room/fact-sheets/detail/asthma

Yong, Y. V., & Shafie, A. A. (2018). How Much Does Management of an Asthma-Related Event Cost in a Malaysian Suburban Hospital? *Value in Health Regional Issues*, *15*, 6–11. https://doi.org/10.1016/j.vhri.2017.05.001

Zainudin, B. M. Z., Kai Wei Lai, C., Soriano, J. B., Jia-Horng, W., De Guia, T. S., & Asthma Insights and Reality in Asia-Pacific (AIRIAP) Steering Committee. (2005). Asthma control in adults in Asia-Pacific. *Respirology*, *10*(5), 579–586. https://doi.org/10.1111/j.1440-1843.2005.00753.x


UPM
UNIVERSITI PUTRA MALAYSIA


UNIVERSITY
OF MALAYA


THE UNIVERSITY OF EDINBURGH


RESPIRE


FUNDED BY
NIHR
National Institute
for Health and
Care Research


UKaid
from the British people