

# Implementing improved asthma self-management as routine

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
02/12/2019	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input checked="" type="checkbox"/> Statistical analysis plan
05/12/2019	Ongoing	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
13/01/2026	Respiratory	

## Plain English summary of protocol

### Background and study aims

Although it is known that supported self-management helps people live with their asthma it isn't widely provided: fewer than 1 in 4 people who replied to an Asthma UK web survey owned an asthma action plan. There are many reasons why self-management is not more widely used. These include a lack of resources available for patients, healthcare professionals not possessing the right skills, and the way that asthma management is organised in the health service. The IMP2ART programme of work has developed a new approach to target all three areas. Examples of resources include new patient resources, training for general practice staff, and organisational support (audit and monthly feedback and new patient-centred asthma review templates). The aim of this study is to test the IMP2ART approach in a UK-wide trial involving 144 general practices.

### Who can participate?

General practices in England or Scotland using either Emis, SystmOne, Vision or Microtest with a list of at least 6,000 patients. Practices must agree to a service level agreement (SLA) with Optimum Patient Care (OPC). Under the SLA, OPC will extract anonymised routine data on asthma patients and provide the practice with tailored reports on their asthma management. Data can only be de-anonymised for individual patients by their own practice.

### What does the study involve?

Practices are randomly allocated to either the IMP2ART intervention or to the control group. IMP2ART practices are provided with tailored resources which emphasise the importance of supported self-management. These resources will be targeted at:

Patients (e.g. a range of asthma action plans)

Professionals (online education package to develop skills in delivering asthma care)

Practice (IMP2ART-customised audit and feedback reports and review templates)

Facilitators help practices with the implementation of the strategy which is designed to fit into existing asthma reviews so it should not be a significant burden on staff time – and may even reduce unscheduled asthma appointments.

Control practices continue with usual care (they are able to access the training and resources at the end of the trial).

**What are the possible benefits and risks of participating?**

If successful the IMP2ART strategy will be immediately ready for roll-out to benefit people with asthma and the NHS. Practices allocated to the implementation strategy will be required to set time aside for completion of educational modules, review of audit and feedback reports, and setting up of computer templates. The researchers will support these by providing facilitator visits to guide practices through adoption and adaptation of the strategy to best suit the practice routines. The sub-group of patients recruited to the health economic study may find it time-consuming or difficult to complete the questionnaire. The researchers have minimised the burden of these by ensuring that the questionnaires have been piloted with their patient advisory group and only including questions that are essential for collecting trial outcomes.

**Where is the study run from?**

University of Edinburgh (UK)

**When is the study starting and how long is it expected to run for?**

October 2018 to March 2026

**Who is funding the study?**

National Institute for Health Research (UK)

**Who is the main contact?**

Prof. Hilary Pinnock

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## Contact information

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
256672

**ClinicalTrials.gov (NCT)**  
Nil known

**Central Portfolio Management System (CPMS)**  
43924

## Study information

**Scientific Title**  
IMP2ART Cluster Randomised Trial (PG4/5)

**Acronym**  
IMP2ART (PG4/5)

### Study objectives

Although supported self-management helps people live with their asthma it isn't widely provided: fewer than 1 in 4 people who replied to an Asthma UK web survey owned an asthma action plan. There are many reasons why self-management is not more widely used. These include:

1. Lack of resources available for patients
2. Healthcare professionals not possessing the right skills
3. The way that asthma management is organised in the health service

The IMP2ART programme of work has developed a new approach to target all three areas.

Examples of resources include:

1. New patient resources
2. Training for general practice staff
3. Organisational support (audit and monthly feedback and new patient-centred asthma review templates)

This study will now test the IMP2ART approach in a UK-wide trial involving 144 general practices.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 08/11/2019, East Midlands – Derby Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)207 104 8310; Email: NRESCommittee. EastMidlands-Derby@nhs.net), REC ref: 19/EM/0279

**Study design**

Randomized; Both; Design type: Process of Care, Education or Self-Management, Not Specified

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Asthma

**Interventions**

Practices will be assigned by chance to receive either the IMP2ART approach or continue with their usual asthma care. A facilitator will visit IMP2ART practices over a year, offer the IMP2ART resources, and discuss with them the best strategies for providing supporting self-management in their practice.

The researchers will measure the success of their intervention by comparing in the two groups:

1. Unscheduled consultations for asthma attacks recorded in anonymised electronic health records from the practice.
2. The number of action plans completed by sending a quality improvement questionnaire to a random sample of people with asthma. This questionnaire will also ask about asthma control and confidence in their care
3. Cost-effectiveness from anonymised routine data and a cost questionnaire sent to a random sample of people with asthma. Interviews with, and observation of, practice staff will help us understand how and why the IMP2ART approach worked or didn't.

If successful this strategy will be immediately ready for roll-out to benefit people with asthma and the NHS.

**Intervention Type**

Other

**Primary outcome(s)**

Primary health outcome: the proportion of clinically eligible patients with at least one episode of unscheduled care for asthma in the second year after randomization, measured using routine coded data at 24 months

Implementation outcome: the proportion of patients with an action plan, measured by questionnaire at 12 months post practice randomisation

**Key secondary outcome(s)**

1. Asthma symptom control, asthma attacks, 'GINA' control, asthma management and prescribing outcomes measured using routine coded data at baseline, 12 and 24 months.
2. Confidence in asthma, and health status & resource use measured using questionnaires at baseline, 12 and 24 months

#### Completion date

31/03/2026

## Eligibility

### Key inclusion criteria

#### Computer systems:

To facilitate data extraction, audit and feedback processes, and use of a review template, practices must use one of the four common EHR systems (Emis, SystmOne, Vision, or Microtest) – these systems cover 99% UK general practices. Practices will need to engage with OPC through a service level agreement (see section 3.3) to enable data extraction.

#### Outlier coding conventions:

The developmental work in PG1 revealed that a few practices use coding conventions that mean that the researchers will not be able to identify accurately the primary health outcome. Baseline data extraction will be undertaken before randomisation and these outlier practices excluded.

#### Practice list size:

The researchers require a minimum of 200 eligible patients/practice. The prevalence of 'active asthma' is 6%. Allowing for exclusion of children aged <5 years; people with co-morbid chronic obstructive pulmonary disease (COPD); a few patients excluded for clinical reasons; and natural turnover in the 'active asthma' list over 2 years, a practice with a list of 6,000 patients (estimated 360 patients on the asthma register) is likely to be the smallest practice with sufficient patients to be sure of having 200 eligible patients for analysis.

#### Practice diversity:

The researchers will monitor recruitment to ensure that participating practices represent a broad range of urban/rural location, high/low deprivation, small/large practices.

#### Federations and the risk of contamination:

A specific problem that may arise is 'federations' and 'networks' in which several practices work together. The decision about their inclusion/randomisation as one practice, or whether more than one of the partner practices within a federation can be involved and randomised as independent practices will depend upon how closely their day-to-day management is integrated (e.g. shared personnel, single management structure). The researchers will set up a sub-committee to discuss each case with the key criterion for inclusion being to avoid contamination of control practices. The committee will be chaired by Taylor (co-PI) with members Eldridge, Holmes and Neal representing methodological expertise as well as relevant background experience of models of primary care.

#### Co-enrolment:

The researchers will exclude practices already undertaking research or involved with an initiative that might affect the study outcomes. If there is any doubt, this will be adjudicated by the sub-committee who will consider each individual case.

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

144

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

06/01/2020

**Date of final enrolment**

30/06/2022

## Locations

**Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre****University of Edinburgh**

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## Sponsor information

**Organisation**

University of Edinburgh

**Organisation**

NHS Lothian

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1016-20008

## Results and Publications

### Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		13/11/2023	14/11/2023	Yes	No
<a href="#">Protocol article</a>		03/04/2023	18/05/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other files</a>	Health economic analysis plan version 1.3	16/12/2025	13/01/2026	No	No
<a href="#">Participant information sheet</a>		20/05/2019	05/12/2019	No	Yes
<a href="#">Statistical Analysis Plan</a>	version 1.0	13/12/2025	30/12/2025	No	No
<a href="#">Study website</a>		11/11/2025	11/11/2025	No	Yes