ISRCTN15448074 https://doi.org/10.1186/ISRCTN15448074

Implementing improved asthma self-management as routine

Submission date 02/12/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/12/2019	**Overall study status** Ongoing	
Last Edited 11/03/2024	**Condition category** 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 September 2025

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Prof. Hilary Pinnock
hilary.pinnock@ed.ac.uk

Study website
https://www.aukcar.ac.uk/what-we-do/our-research/imp2art

Contact information

Type(s)
Scientific

Contact name
Dr Vicky Hammersley

Contact details
Usher Institute of Population Health Sciences and Informatics
Doorway 3, Medical School, Teviot Place
Edinburgh
United Kingdom
EH8 9AG
+44 (0)131 650 3044
Vicky.Hammersley@ed.ac.uk

Type(s)
Scientific

Contact name
Prof Hilary Pinnock

ORCID ID

http://orcid.org/0000-0002-5976-8386

Contact details
Asthma UK Centre for Applied Research
Usher Institute
Doorway 3
Medical School
Teviot Place
Edinburgh
United Kingdom
EH8 9AG
+44 (0)131 650 9474
hilary.pinnock@ed.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
256672

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS: 43924; IRAS: 256672

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

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional files

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 measure
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

Secondary outcome measures
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

Overall study start date
01/10/2018

Completion date
30/09/2025

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 144; UK Sample Size: 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
England

Scotland

United Kingdom

Study participating centre

University of Edinburgh
Usher Institute of Population Health
Sciences and Informatics
Doorway 3, Medical School
Teviot Place
Edinburgh
United Kingdom
EH8 9AG

Study participating centre
Queen Mary University London
Department name Centre for Primary Care and Public Health
Blizard Institute Yvonne Carter Building 58
Turner Street
London
United Kingdom
E1 2AB

Study participating centre
University of Sheffield
Medical Statistics Group
SCHARR Regent Court
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
University of Edinburgh

Sponsor details
c/o Mr Chris Coner
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ
+44 (0)1312423326
resgov@accord.scot

Sponsor type
University/education

Organisation
NHS Lothian

Sponsor details
c/o Kenneth Scott
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4TJ
+44 (0)131 242 3325
accord@nhslothian.scot.nhs.uk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
1. The protocol has not been published yet but will be published in 2020
2. Peer-reviewed scientific journals
3. Internal report
4. Conference presentation
5. Publication on website
6. The researchers will use the infrastructure of the Asthma UK Centre for Applied Research to support innovative approaches to dissemination (e.g. via social media, Science Festivals).
7. A final report will be submitted to the funder. The NIHR will publish this report.

Intention to publish date
31/01/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the researchers not having patient consent to share. They can't request consent for access from the patients because they are using routine data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		20/05/2019	05/12/2019	No	Yes
Protocol article	protocol	03/04/2023	18/05/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		13/11/2023	14/11/2023	Yes	No