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IMPlementing IMProved Asthma self-management as RouTine (IMP^{2}ART) in primary care: update to the study protocol for a cluster randomised controlled implementation trial

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update

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Abstract

Background

This paper updates the protocol for the IMPlementing IMProved Asthma self-management as RouTine (IMP^{2}ART) trial previously published in 2023. The update describes the rationale for some changes to outcome definitions and provides a link to the statistical analysis plan and health economic analysis plan prepared prior to commencing analysis.

Methods

IMP^{2}ART is a parallel group, cluster-randomised controlled hybrid II implementation trial which aims to determine whether facilitated delivery of the IMP^{2}ART strategy increases the provision of asthma action plans and reduces unscheduled care in the context of routine UK primary care. 144 general practices were randomly assigned to either the IMP^{2}ART implementation strategy or control group. Following a facilitation workshop, implementation group practices received a range of resources to help them prioritise supported self-management; control group practices continued with usual asthma care. We report the rationale for changing the definition of the primary implementation outcome (asthma action plan provision), and also some secondary outcomes affected by national level changes in guidelines and incentivised standards of asthma care. The primary clinical outcome remains a record of unscheduled care (yes/no) in the second year after randomisation assessed from routine data. All changes were made in discussion with the Independent Trial Steering Committee, the sponsor and with the agreement of the funder.

Trial registration:

ISRCTN15448074. Registered on 2 December 2019.

Introduction

Each year, asthma is responsible for substantial morbidity, mortality and use of healthcare resources[1]. Supported by an 'overwhelming' evidence-base[2, 3], UK and international guidelines recommend that people with asthma should be provided with self-management education, reinforced by a personalised action plan, and supported by regular review with a healthcare professional[4, 5]. Implementation in routine clinical practice, however, is challenging. A systematic review of the implementation of supported self-management concluded that whilst patient education, professional training and organisational support were all essential, they were rarely effective in isolation[6].

IMP^{2}ART (IMPlementing IMProved Asthma self-management as RouTine) is a UK-wide cluster randomised trial that is testing the impact of a whole systems implementation strategy that embeds

supported asthma self-management in primary care, compared with usual care. 144 general practices have been randomly assigned to either the IMP^{2}ART implementation strategy or the control group. Following a facilitation workshop, implementation group practices received patient, professional and organisational resources to support to help them prioritise and deliver supported self-management[7]; control group practices continued with usual asthma care. As described in the protocol, published in *Trials* in 2023[8], we assessed the impact of the IMP^{2}ART implementation strategy on unscheduled care (the primary clinical outcome), ownership of an action plan (primary implementation outcome), and a number of secondary outcomes derived from routine healthcare data. We included a health economic evaluation, and an in-depth process evaluation[9].

Why the protocol update is needed

We have not changed the aims and objectives, but a low response rate to the questionnaire intended to collect ownership of action plans forced a review of how we defined the primary implementation outcome. In addition, national contextual changes (the Quality and Outcomes Framework (QOF)[10] and changes to UK guidelines[5]) required us to reconsider the definitions we had used to derive some secondary outcomes from routine healthcare data. All changes were made in discussion with the Independent Trial Steering Committee, the sponsor and with the approval of the funder. For transparency, we here present the rationale for the changes made.

Definition of the primary implementation outcome

Our primary implementation outcome (asthma action plans) is a marker of supported self-management, and our protocol defined two complementary approaches for assessing this each of which had advantages and disadvantages:

- Ownership of an action plan reported in a Quality-Improvement Questionnaire (QI-Q) mailed to a random sample of 50 patients from a random sample of 32 practices at 12-months post-randomisation was defined as the primary implementation outcome in the original protocol[8]. This approach overcomes coding inconsistencies, and any potential influence of IMP^{2}ART on clinical coding practice. We required 640 responses for a sufficiently powered analysis (see sample size calculation[8]). However, only half the practices, already challenged by the aftermath of the COVID pandemic, sent out the automated mailing within the defined time window and only 223/950 (23%) responses were received. In addition, questionnaire responders were older and more likely to be female than the general asthma population. (See Table 1 for details).
- Having a code in the Electronic Health Record (EHR) of the provision/updating of an action plan in the previous 3-years assessed at 12-months post-randomisation was defined as a secondary implementation outcome in the original protocol. This approach uses data from all eligible patients from all participating practices, which aligns with the implementation research principle of delivering a service to all who are clinically eligible[11]. The recognised inconsistencies of clinical

coding should affect both groups equally at baseline. Our concern was that the links to recording provision/updating of an action plan in the IMP^{2}ART asthma review template [12] would influence coding differentially in the implementation group. The process evaluation, however, suggested that few practices used the IMP^{2}ART template as local NHS schemes incentivised use of other clinical templates.

Table 1
Rationale for changes to protocol and operationalising outcomes

Outcome	Original definition	Revised definition	Rationale
Primary clinical outcome	Proportion of clinically eligible patients with at least one episode of unscheduled care for asthma in the 2nd year post-randomisation	No change	
Primary implementation outcome	Proportion of people (≥ 5yrs of age) who respond 'Yes' to the question 'Has your asthma nurse or doctor provided you with an asthma 'action plan'?' in the QI-Q mailed at 12-m	Proportion of people with active asthma who have a record in their EHR of the provision/updating of an action plan in the previous 2 years assessed at 24m post-randomisation.	Poor response to QI-Q: 18/35 (51%) of practices mailed the QI-Q within the time window (T-3m to T + 6m). 223/950 (23%) responses received. Responders were older [60.6yrs (SD 17.5) vs 45.0yrs (SD 24.4)] and more likely to be female [61% vs 53%] than the general asthma population. The IMP^{2}ART template was rarely used: 76% of the practices did not use the template at all, others did not find it helpful.
Asthma symptom control	Three negative responses to the RCP3Qs as coded in the EHR [13].	Good asthma control as measured by the RCP3Qs, ACT, C-ACT or ACQ.	Changes to the QOF in 2021 (but applied post-pandemic) expected the use of validated questionnaires rather than screening with RCP3Qs[13].
Ratio of reliever to preventer prescriptions	Proportion prescribed SABA or ICS and ratio ICS/All asthma drugs. (Based on previous UK guidelines which recommended ICS (BTS/SIGN) or SABA	Definitions not changed, but limitation noted as UK guidelines changed to first line use of combination inhalers in November 2024[5]	Impact on the trial judged to be minimal as only 13 practices were still active in IMP^{2}ART when the UK guidelines changed. Only 6 had ≥3 months left in the trial.

Abbreviations: ACT (and C-ACT) Asthma Control Test (and Children's ACT), or ACQ: Asthma Control Questionnaire, BTS/SIGN: British Thoracic Society/Scottish Intercollegiate Guideline Network, EHR: Electronic Health Record, ICS: inhaled corticosteroids, m: month, NICE: National Institute Health and Care Excellence, QI-Q: Quality Improvement Questionnaire, QOF: Quality and Outcome Framework, RCP3Qs: Royal College of Physicians 3 Questions, SABA: short-acting beta agonists, SD: standard deviation, yrs: years.

Outcome	Original definition	Revised definition	Rationale
	(NICE) as first line treatment)		The effect would be similar in both groups.

Abbreviations: ACT (and C-ACT) Asthma Control Test (and Children's ACT), or ACQ: Asthma Control Questionnaire, BTS/SIGN: British Thoracic Society/Scottish Intercollegiate Guideline Network, EHR: Electronic Health Record, ICS: inhaled corticosteroids, m: month, NICE: National Institute Health and Care Excellence, QI-Q: Quality Improvement Questionnaire, QOF: Quality and Outcome Framework, RCP3Qs: Royal College of Physicians 3 Questions, SABA: short-acting beta agonists, SD: standard deviation, yrs: years.

We therefore opted to switch our primary implementation outcome to 'Having a record in the EHR of the provision/updating of an action plan in the previous 2-years assessed at 24m post-randomisation' and relegate the alternative approach 'Ownership of an action plan reported in the QI-Q' to a secondary outcome. Aligning the time window with the 2-year participation in the trial ensures that the full intervention effect is captured regardless of variation in the rate at which a practice adopted the implementation strategy.

We made no change to the primary clinical outcome. We made minor changes to the definitions of some secondary outcomes to reflect the changing context for delivery of asthma care in the UK. (See Summary Table 1).

Fidelity assessment from the process evaluation to inform pre-specified Complier-Average Causal Effect (CACE) analyses

We conceived fidelity to IMP^{2}ART as a complex spectrum of adoption/adaptation/attrition to the multi-component implementation strategy. Using process evaluation data, we have now quantified delivery and receipt of IMP^{2}ART components and agreed thresholds for fidelity which can be used as a composite to define the 'complier' population in the CACE analysis. (See Table 2).

Table 2
Measurable fidelity to core components for use in the CACE analysis

	Fidelity criterion		
Component*	Meeting the threshold for the fidelity criterion	Not meeting the threshold for the fidelity criterion	• Notes [Equation used to assess fidelity]
Facilitation[7] [Over-arching]	Workshop with at least one attendee present	No workshop	• 4 practices did not receive a workshop but still had some facilitation.
Audit and feedback[14] [Organisational]	Practice received ≥20 (out of 24) monthly reports within 3m of the pertinent month	Practice received < 20 monthly reports within 3m of the pertinent month	[Number of reports delivered within 3-months of the month to which they pertained/24]
Education module-1[15] [Professional (team)]	Practice completed ≥80% of Module 1	Practice did not complete ≥80% of Module 1	• Module-1 is team-based learning; log-in was at practice level. • 80% is widely used as a threshold for completion of e-learning modules.
Education module[15] [Professional (individual)]	At least one person in the practice completed ≥80% of Module 2	No-one in the practice completed ≥80% of Module 2	• Module-2 is designed for individual learning by the clinician(s) responsible for asthma care; log-in was at individual level. • 80% is widely used as a threshold for completion of e-learning modules.
Composite			
Overall engagement with IMP^{2}ART[7]	Practice met all four thresholds	Practice did not meet all four thresholds	• Can be used as dose-like variable in analysis: Practices meeting 1, 2, 3 or 4 thresholds
* Detailed information about the components of the implementation strategy is in the cited developmental papers			

Trial status

Trial data collection is now complete and the routine datasets are being prepared for analysis with code lists defined and included in the statistical and health economic analysis plans (v1.0 05/12/2025: https://doi.org/10.1186/ISRCTN15448074).

Declarations

Ethics approval and consent to participate: NHS Lothian (REC No: 19/EM/0279). R&D approvals were obtained from Scotland (Lothian Ref: 2020/0009; Lanarkshire R&D, Ref: L20011; Tayside, Ref: 2020PS01; Grampian, Ref: 2020GP001E; Dumfries, Ref: JC/LM/21/DGY/020; Highlands, Ref: HIGHLAND 1752; Fife, Ref: 21-024; Forth Valley Ref: FV1315; Arran and Ayrshire, Ref: R&D 2021AA025 and Greater Glasgow and Clyde, Ref: GN21RM217P.

Consent for publication: Not applicable.

Availability of data and materials: Due to the confidentiality of NHS routine data required for this trial, data cannot be made available.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: HP, SJCT, DF, JS, LS contributed to the design of the study. HP drafted the manuscript, and DF, TH, VH, MJ, CM, JS, LS, contributed to drafts of the manuscript. All authors read, commented on and approved the final manuscript.

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