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Can outcomes for children with asthma be improved by enhancing integrated care with technology?

Submission date
17/03/2023

Recruitment status
No longer recruiting

Registration date
28/03/2023

Overall study status
Ongoing

Last Edited
05/06/2025

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is the most common long-term condition among children, yet outcomes are often poor. The National Review of Asthma Deaths (NRAD) found deficits in care: 93% of children had received inadequate routine care. 4% of children were thought to have received a good standard of care. In 48% of deaths reviewed, there was room for improvement in clinical care and/or organisation of care; while in 46% of cases, care was well below expected standards. Health for children with asthma could be improved with care pathways that improve prevention, self-management, risk stratification, treatment, and monitoring. Effective technology could augment an integrated care pathway to provide a comprehensive package of care. To achieve good outcomes for asthma, the priority is to prevent attacks with inhaled corticosteroids (ICS) and to recognise and manage wheeze promptly and effectively. However, traditional asthma care is associated with unmet needs along each step of the pathway including poor adherence to ICS - as low as 30% in some populations, adverse outcomes, and poor outcomes at a national level. This project aims to improve outcomes among children with asthma by enhancing newly developed integrated care pathways with technology for improving symptom and treatment tracking. If successful, the combined technology-enhanced multidisciplinary integrated care pathway has the potential to transform outcomes for children with asthma.

Who can participate?
Children aged between ≥6 to <16 years who are registered with a GP in South London/North London and have an asthma Control Test score <20 and/or unscheduled healthcare use for asthma (primary or secondary care) within the last 6 months

What does the study involve?
Patients that are eligible for the trial will be randomised into one of two groups and will remain in the trial for 6months unless they withdraw (there will be a 12-months follow-up for children already recruited) Participants randomised to group 1 will be given two devices - a SMART sensor (inhaler top sensors for preventer inhalers which enables remote monitoring of medication use, adherence, control, symptoms and triggers) and a Wheezo device which detects the presence of wheeze. Participants randomised to group 2 will continue with standard asthma

care. The research team (via Health Touch) will ask all participants and parents/carers to complete various questions online at baseline, monthly and at 6-months follow-up (there will be a 12-month follow-up for children already recruited). Data will also be collected from health records. All data will be collected via a portal called Health Touch.

What are the possible benefits and risks of participating?
The research participants may experience direct benefits in terms of their asthma control by taking part in this research study. Participants in the control group will also provide a valuable contribution to the study, and if demonstrated to be effective, they may benefit from using these devices at a later date. This project has been checked by several people to minimise any potential risks. We do not anticipate any disadvantages to taking part in this study. The intervention devices (Wheezo and SMART/Propeller) are designed to improve asthma outcomes.

Where is the study run from?
This is a multicentre trial to be conducted predominantly in three London Boroughs (Lambeth, Southwark, and Tower Hamlets), through two Universities (KCL and QMUL) and associated NHS Trusts (Evelina London Children's Hospital/GSTT and Barts Health Trust).

When is the study starting and how long is it expected to run for?
November 2021 to November 2025

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

Who is the main contact?
Professor Ingrid Wolfe, OBE, BSc, MBBS, MSc, PhD, FRCPCH, FFPH
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
311701

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 54727, IRAS 311701

Study information

Scientific Title
Technology Enhanced integrated AsthMa care (TEAMCare): randomised control trial of technology to improve outcomes among children with asthma

Acronym
TEAMCare

Study objectives
H0 - Combining technology with standard integrated asthma care will show no benefits in improving outcomes for children with asthma.
H1 - Combining technology with standard integrated asthma care will help improve asthma outcomes for children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/02/2023, West of Scotland REC 1 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, Scotland; +44 (0)141 314 0212; WosRec1@ggc.scot.nhs.uk), ref: 22/WS/0178

Study design
Randomized interventional study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Childhood asthma

Interventions
Current interventions as of 05/06/2025:
1. Intervention (Device Arm): technologically enhanced normal care pathways: Remote wheeze monitoring, using Wheezo AND
remote treatment monitoring, using Propeller/Smart Respiratory (note: Propeller was discontinued from the UK market and was only used by participants randomised before 12/2024)
2. Control arm: normal care pathway

Location
This is a multicentre trial to be conducted predominantly in three London Boroughs (Lambeth, Southwark, and Tower Hamlets), through two Universities (KCL and QMUL) and associated NHS Trusts (Evelina London Children's Hospital/GSTT and Barts Health Trust), as part of services integrated between secondary and primary care. Further participant identification centre (PIC) sites will also be included.

Participant Recruitment and Randomisation

Children and young people (aged ≥ 6 to < 16 years) with poorly controlled asthma will be identified through several routes:
1) Eligible patients receiving or referred for integrated care will be invited to participate in the study.
2) Eligible patients identified in a TEAMCare specific Call-recall schedules (proactive identification via primary care records) will be directed to the research portal and invited to participate in the study.
3) Children who attend an Emergency Department or are admitted for non-elective care for asthma, and children attending outpatient clinics for asthma will be invited, with their parent /carer, to participate in the study. In addition to direct referrals from Emergency Department staff, Specialist asthma nurses based at Guy's and St Thomas's or Bart Health NHS Trusts will check the list of Emergency Department attendances on a weekly basis.

4) Eligible children identified at affiliated Participant Identification Centres (PIC) sites will be invited to take part in the study
All eligible children interested in the study will be sent a Participant Information Sheet. Participant information sheets will be translated as appropriate for the target populations. Those who would like to participate will be asked to give informed consent to participate in the evaluation and follow-up, for 1) access to health care records, 2) completing questionnaires at baseline and follow-up time points, and 3) participating in specific elements of nested studies, e. g. qualitative interviews and app and device data sharing. For children under 12 years of age the parent/carer will be asked to provide, on behalf of the child, informed consent. For adolescents between 12 and < 16 years of age, the parent will be asked to provide informed consent and the young person will be asked to provide assent to participate.

Stratification: Randomisation will be stratified to ensure balance across the trial arms at each site.

Recruitment plan assessment
We have reviewed the prevalence of children with asthma in our study site populations, and our current methods for reaching them. Across Southwark and Lambeth, we expect to identify ~10, 500 children with asthma (using call-recall via primary care records); of these, ~1400 children

would be expected to take up the service, based on previous experience. Across Tower Hamlets children will be invited through their integrated Asthma Service.
However, the current integrated asthma services do not have sufficient capacity to provide care for the large numbers of eligible children we would expect to recruit through proactive identification of unmet needs. We therefore will need to employ additional recruitment methods, described below.
4.5.2 Recruitment via TEAMCare specific call-recall schedules.
For the integrated service in Southwark and Lambeth, children are proactively identified, using primary care records. This process is carried out within General Practitioner (GP) practices or Federations using a CYPHP developed 'call-recall' tool, adapting a well-established public health system for contacting patients for vaccination and screening. We will adapt the integrated service's system for identifying children with asthma to target only those children within the TEAMCare trial age range. Children with asthma will be invited via text message to be part of the study and will be directed, via an embedded link, to the trials research portal rather than the current route which is via the integrated service portal. An ACT test or self-reported unscheduled care use will determine the child's eligibility.

Participant enrolment and follow-up
Following consent and randomisation, participants will be given a supported introduction to the technology (if applicable), including registration and onboarding to use the associated mobile Apps and web portals.

They will be asked to continue the use of the device and associated mobile App at home for 6 months. Additionally, all participants, regardless of group, will be asked to complete follow-up questionnaires administered online at baseline, monthly and at 6-months follow-up (there will be a 12-months follow-up for children already recruited). A sub-group of participants will be invited to participate in the nested qualitative research. Discussions throughout the trial will take place with commissioning bodies to ensure trial results provide appropriate information for commissioning purposes with a view to the continuation of the rollout of these technologies should their use prove beneficial.

Analysis methods

While participants and practitioners will be unblinded, data analysts will be blinded. The main planned comparisons is:

• Device arm vs. Control arm

Data and Information Governance
Data collection: With participant consent and data sharing agreements in place, data will be extracted from participant health care records during the follow-up period. Participants will be invited to complete questionnaires at baseline, monthly and at 6-months follow-up (there will be a 12-months follow-up for children already recruited), to assess the outcomes described above and a short monthly survey to give details of any unscheduled healthcare attendance.

Data handling: Data will be held securely in a trials database, in line with the sponsor's requirements, accessed through password protected computers. Study data will be anonymised with a unique study identification code. Participant identifiable data will be accessed only when necessary for study administration (e.g. monitoring, follow-up). Anonymised data sets will be used by the research team for analysis.

Previous Interventions:
Briefly, the intervention involves technologically enhanced integrated care pathways in the following groups:
1. Remote wheeze monitoring, using Wheezo, within the integrated care pathway
2. Remote treatment monitoring, using Propeller, within the integrated care pathway
3. Control: integrated care pathway

Location
This is a multicentre trial to be conducted in three London Boroughs (Lambeth, Southwark, and Tower Hamlets), through two Universities (KCL and QMUL) and associated NHS Trusts (Evelina London Children's Hospital/GSTT and Barts and The London), as services integrated between secondary and primary care. There are no site-specific requirements beyond the integrated care services that already exist or are in development.

Participant population
The trial will be conducted as part of the usual integrated care services for children with asthma. Patients with asthma are identified proactively as part of integrated care using population health management tools and methods for identification. These include primary care patient lists, secondary care patient lists, and schools. The trial will be conducted alongside the usual pathway of care which is integrated between primary and secondary care.

Participant Recruitment and Randomisation
Trial participants will be identified through two routes:
1. All eligible patients receiving or referred for integrated care will be invited to participate in the study and provided with information in formats for parent and child, to consider. Participant information sheets will be professionally translated as appropriate for the target populations
2. Children who attend an Emergency Department or are admitted for non-elective care for asthma, and children attending outpatient clinics will be invited, with their parent/carer, to participate in the study. In addition to direct referrals from Emergency Department staff, TEAMCare research nurses will check the list of Emergency Department attendances on a weekly basis.

Those who would like to participate after reading the patient information sheet will be asked to give informed consent to participate in the evaluation and follow-up, for a) access to health care records, b) completing questionnaires at baseline and follow-up time points, and c) participating in specific elements of nested studies, e.g. qualitative interviews and app and device data sharing. For children under 12 years of age, the parent/carer will be asked to provide, on behalf of the child, informed consent. For adolescents between 12 and 16 years of age, the parent will be asked to provide informed consent and the young person will be asked to provide assent to participate. Professional translators will be used as appropriate.

Stratification: Randomisation will be stratified to ensure balance across the trial arms at each site.

Recruitment plan assessment
We have reviewed the prevalence of children with asthma in our study site populations, and our current methods for reaching them. Across our two sites, we expect to invite ~10,500 children for an online asthma (biopsychosocial) health check during a six-month recruitment period, and ~1400 children to take up the service and be invited to participate in the study through this route. Therefore, over a 12-month period, and in combination with the other recruitment methods, (e.g. attendance at emergency departments) we are confident about recruiting our required sample.

Participant enrolment and follow-up
Following consent and randomisation to the three trial arms, participants in the two interventional study arms will be given a technology induction including a demonstration of the device and registration for the mobile App and web portal. They will be asked to continue the use of the device and associated mobile App at home for the following 12 months. Additionally, all participants, regardless of group, will be asked to complete follow-up questionnaires administered online at baseline, 6 and 12 months after enrolment as well as a short monthly questionnaire about unscheduled healthcare use. A sub-group of participants will be invited to participate in the nested qualitative research. Discussions throughout the trial will take place with commissioning bodies to ensure trial results provide appropriate information for commissioning purposes with a view to the continuation of the rollout of these technologies should their use prove beneficial.

Analysis methods

While participants and practitioners will be unblinded, data analysts will be blinded. The main planned comparisons are:
1. Wheezo trial arm versus Control
2) Propeller trial arm versus Control

Regression analyses will be used to estimate the effect size of intervention in each arm, compared with the control, with appropriate covariates including the trial site.

Data and Information Governance
Data collection: With participant consent and data sharing agreements in place, data will be extracted from participant health care records during the follow-up period. Participants will be invited to complete questionnaires at baseline, 6- months, and 12-month follow-up, to assess the secondary outcomes described above and a short monthly survey to give details of any unscheduled healthcare attendance.

Data handling: Data will be held securely in a trials database, in line with the sponsor's requirements, accessed through password-protected computers. Study data will be anonymised with a unique study identification code. Participant-identifiable data will be accessed only when necessary for study administration (e.g. monitoring, and follow-up). Anonymised data sets will be used by the research team for analysis

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Wheezo, Propeller to Wheezo, SMART Respiratory

Primary outcome(s)
Current primary outcome measure as of 05/06/2025:
Asthma symptom control measured using the asthma control test (ACT) scores among participants at baseline, 6 months, and 12* months.

* only for children recruited before 12/24

Previous primary outcome measure:
The proportion of participants requiring unscheduled health service use for asthma during the 12-month intervention period measured using parent/patient reporting in a monthly online questionnaire and by extracting data from primary and secondary care health records, where possible

Key secondary outcome(s))
Current secondary outcome measure as of 05/06/2025:
1. Rates of primary and secondary care health service use, and medicines use during the follow-up period, measured by extracting data from primary and secondary care health records during the 6 and 12*-month intervention period and via patient/parent reporting where appropriate
2. Health-related quality of life, measured using the Pediatric Quality of Life Inventory (PedsQL) at baseline, 6 and 12* months
3. Missed days of school and parental missed days of work, measured using the TEAMCare Healthcare Service Use Information Questionnaire (non-validated) completed monthly during the 6 and 12*-month intervention period
4. User experience of the Wheezo and Propeller technologies, measured by data extracted from qualitative interviews

* Only applicable for patients who were randomised before 12/2024

Previous secondary outcome measure:
1. Rates of primary and secondary care health service use, and medicines use during the follow-up period, measured by extracting data from primary and secondary care health records during the 12-month intervention period and via patient/parent reporting where appropriate
2. Children's health-related quality of life, measured using the Pediatric Quality of Life Inventory (PedsQL) and the Child Health Utility 9 Dimension (CHU-9D) at baseline, 6 months, and 12 months
3. Children's asthma symptoms, measured using the Asthma Control Test (ACT) at baseline, 6 months, and 12 months
4. Parental wellbeing, measured using the Warwick Edinburgh Mental Wellbeing Score (WEMWS) at baseline,6 and 12 months
5. Children's wellbeing and mental health, measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, 6 months, and 12 months
6. Missed days of school and parental missed days of work, measured using the TEAMCare Healthcare Service Use Information Questionnaire (non validated) completed monthly during the 12-month intervention period
7. User experience of the Wheezo and Propeller technologies, measured by data extracted from qualitative interviews

Completion date
30/11/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 05/06/2025:
1. Asthma Control Test score <20 within the last 6 months and/or unscheduled healthcare use for asthma (primary or secondary care) within the last 6 months
2. Age between ≥ 6 and < 16 years at enrolment

3. Able to provide informed consent/assent
4. A good command of English in order to use the device apps
5. Access to a smartphone
6. Access to an email address
7. Use of or ability to change to an inhaler compatible with Smart Respiratory smart sensors

Previous participant inclusion criteria:
1. Asthma Control Test score < 20 and/or unscheduled healthcare use for asthma (primary or secondary care) within the last 6 months
2. Age between 6 and 16 years at enrolment
3. Able to provide informed consent/assent
4. Access to a smartphone
5. Access to an email address
6. Use of or ability to change to an inhaler compatible with Propeller smart sensors

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
Current participant exclusion criteria as of 05/06/2025:
1. Participation in other asthma studies with a direct bearing on treatment
2. Patients who have 'opted out of the national data opt-out NHS service'

Previous participant exclusion criteria:
Participation in other asthma studies with a direct bearing on treatment

Date of first enrolment
01/04/2023

Date of final enrolment
31/05/2025

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
Guy's and St Thomas' NHS Foundation Trust

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	19/01/2023	27/03/2023	No	Yes
Participant information sheet	version 2.0	19/01/2023	27/03/2023	No	Yes
Participant information sheet	version 2.0	19/01/2023	27/03/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes