Improving teenage self-management of asthma

Submission date Prospectively registered Recruitment status 22/07/2015 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 23/07/2015 Completed [X] Results [] Individual participant data **Last Edited** Condition category 20/05/2021 Respiratory

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Public

Contact name

Dr Simone Holley

Contact details

Southampton General Hospital
Mailpoint 803
Southampton University Hospital NHS Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 19303

Study information

Scientific Title

Improving teenage self-management of asthma: randomised controlled trial

Acronym

ITSMyAsthma RCT

Study objectives

The aim of this study is to assess the effectiveness of a teenage asthma toolkit, designed to support healthcare professionals to empower teenagers to self manage their asthma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

15/NW/0551

Study design

Randomised; Interventional; Design type: Screening, Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Topic: Children, Respiratory disorders; Subtopic: All Diagnoses, Respiratory (all Subtopics); Disease: Respiratory, All Diseases

Interventions

Clinic – HCPs (doctors and nurses) will use the self-efficacy questionnaire to identify where participants need additional support to improve their asthma self-management skills. The needs of individual patients will then be used to identify specific behavioural interventions. These interventions will be applied in clinic.

Intervention Type

Behavioural

Primary outcome measure

The primary outcome measure will be the asthma control test

Secondary outcome measures

N/A

Overall study start date

15/07/2015

Completion date

30/09/2017

Eligibility

Key inclusion criteria

- 1. Aged 12-18 years
- 2. Able to consent to participation in the study
- 3. Doctor diagnosed asthma
- 4. Prescription of a regular prophylactic medication for asthma (eg inhaled corticosteroid, montelukast)

Participant type(s)

Patient

Age group

Child

Lower age limit

12 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 350; UK Sample Size: 350

Key exclusion criteria

- 1. Lack of informed consent from them or their parent
- 2. Very poorly controlled asthma that, in the view of their paediatrician, requires a step up in preventer therapy
- 3. Significant other long term medical condition that has a day to day impact on their lives (should not usually include con-existing atopic diseases)

Date of first enrolment

15/07/2015

Date of final enrolment

31/05/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Southampton General Hospital

Mailpoint 803
Southampton University Hospital NHS Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation

Southampton University Hospitals NHS Trust & University of Southampton

Sponsor details

University Geriatric Medicine Level E Centre Block (807) Tremona Road Southampton England United Kingdom SO16 6YD

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/0485axj58

Funder(s)

Funder type

Charity

Funder Name

Asthma UK

Alternative Name(s)

Asthma UK, Asthma + Lung UK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results			20/05/2021	No	No
HRA research summary			28/06/2023	No	No