

Children's Health in Asthma: Research to Improve Status through Modifying Accommodation

Submission date 09/03/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 14/02/2012	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym

CHARISMA

Study objectives

The aim of the study is to evaluate the effectiveness and cost-effectiveness of improving ventilation in heating in the homes of children with moderate or severe asthma who live within Wrexham.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North East Wales Local Research Committee approved of the trial on the 30th July 2003.

Study design

Pragmatic randomised controlled trial with delayed-implementation controls.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Moderate or severe asthma in children

Interventions

Pragmatic randomised controlled trial with delayed-implementation controls: analysis by intention to treat. Patients are identified from GP records. Remote randomisation is stratified by GP practice, whether central heating needs improving, child's age and gender, type of housing, and household smoking status.

A package of housing improvements designed to provide adequate ventilation and temperatures and to reduce mould spores:

1. If the recruited child has one or more siblings who suffer from asthma and sleep in a different

room, the housing department install a whole-house ventilation system. Otherwise they install a single-room ventilation unit

2. Improvements to bring central heating to a defined standard, if required

The control group are offered the same installation package 12 months later, after the final follow-up questionnaire has been returned.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Parental assessment of the child's asthma-specific quality of life (PedQL asthma module) four and twelve months after randomisation. Baseline PedQL will be used as a covariate.

Secondary outcome measures

1. General health-related quality of life (PedQL core module), school attendance and the use of health care including medication
2. An economic analysis will compare costs

Overall study start date

01/09/2003

Completion date

01/05/2007

Eligibility

Key inclusion criteria

1. Children aged 5 - 15 at recruitment
2. Living in Wrexham County Borough Council
3. On list of participating general practice
4. Taking inhaled steroids for asthma (three or more prescriptions over a 12 month period)
5. Written consent from parent or guardian to take part, complete questionnaires, and allow access to child's medical records

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

15 Years

Sex

Not Specified

Target number of participants

200

Key exclusion criteria

1. Cystic fibrosis
2. Likely to move of the Wrexham County Borough Council area within 12 months
3. Ventilation system already installed and central heating already aequate at pre-randomisation base line

Where a household contains two or more eligible children, one participant is chosen at random as the index case for whom outcomes are assessed.

Date of first enrolment

01/09/2003

Date of final enrolment

01/05/2007

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre

University of Wales Bangor

Bangor

United Kingdom

LL57 2AS

Sponsor information**Organisation**

University of Wales Bangor (UK)

Sponsor details

IMSCaR

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Normal Site

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Sponsor type
University/education

Website
<http://www.bangor.ac.uk/home/2006/index.php.en?&width=1024&height=768>

ROR
<https://ror.org/006jb1a24>

Funder(s)

Funder type
Government

Funder Name
North Wales Research Committee (UK)

Funder Name
Npower-Health Through Wales (UK)

Funder Name
Wrexham County Borough Council (UK)

Funder Name
Wrexham Local Health Alliance (UK)

Funder Name
Local Health Board, National Public Health Service for Wales (UK)

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?
Results article	cost-effectiveness results	01/11/2011		Yes	No
Results article	results	01/11/2011		Yes	No