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

Submission date	Recruitment status	[_] Prospectively registered
09/03/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2012	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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.

Primary study design
Interventional

Study design
Pragmatic randomised controlled trial with delayed-implementation controls.

Study type(s)
Treatment

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, childs 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(s)
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.

Key secondary outcome(s)

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

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. Ttaking 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 childs medical records

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
15 Years

Sex
Not Specified

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)

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

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