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The effects of parenting intervention on quality of life and parental confidence in management of young asthmatic children

Submission date 21/10/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/10/2010	**Overall study status** Completed	
Last Edited 18/04/2017	**Condition category** Respiratory	

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
8624

Study information

Scientific Title
The effects of parenting intervention on quality of life and parental confidence in management of young asthmatic children

Study objectives
The study will be a randomised controlled trial comparing care as usual versus care as usual supplemented by group-delivered Triple P parenting seminars and telephone support in parents /carers of 2 - 7 year old asthmatic children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved, ref: 09/H1017/115

Study design
Single-centre randomised interventional treatment pilot/feasibility study

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Respiratory; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

Interventions
Triple P parenting seminars and telephone support.

Follow-up length: 9 months
Study entry: registration only

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Paediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ), measured at 3 and 9 months

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2010

Completion date
09/01/2012

Eligibility

Key inclusion criteria
1. Parents of children with frequent episodic or chronic persistent asthma who are taking regular preventive medication
2. Parents must have an asthmatic child aged 2 - 7 years, either sex
3. Diagnosis of asthma in children, based on:
3.1. An observation of recurrent episodes of wheeze (preferably witnessed by a medical observer)
3.2. A clinical response to a bronchodilator medication (eg. Salbutamol)
3.3. An absence of other rarer lung conditions (e.g., cystic fibrosis, chronic neonatal lung disease) which may account for these symptoms

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
7 Years

Sex
Both

Target number of participants
Planned sample size: 180

Key exclusion criteria
1. The child has a significant disability
2. The parents are currently seeing a professional for the child's behaviour difficulties, are currently receiving psychological help or counselling, or have significant learning difficulties. For

the purposes of the study, in order to participate in the seminars, parents will be excluded if they don't understand English.

Date of first enrolment
01/06/2010

Date of final enrolment
09/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Manchester Royal Infirmary
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester and Manchester Children's University Hospital (CMMCUH) NHS Trust (UK)

Sponsor details
Manchester Royal Infirmary
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

Website
http://www.cmft.nhs.uk

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) Research for Patient Benefit (RfPB) programme

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