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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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