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Effectiveness of personalized written asthma action plans in the management of children with partly controlled asthma in Trinidad: A randomized controlled trial.

Submission date 25/10/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/11/2010	**Overall study status** Completed	
Last Edited 26/03/2014	**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
N/A

Study information

Scientific Title
Effectiveness of personalized written asthma action plans in the management of children with partly controlled asthma in Trinidad: A randomized controlled trial.

Study objectives
Current study hypothesis as of 20/05/2013:
In a primary care setting among children with partly controlled asthma, the use of written asthma action plans reduces revisits for acute asthma care.

Previous study hypothesis until 20/05/2013:
In a primary care setting among children with recurrent admissions to the Emergency room for asthma, the use of written action plans (WAPs) reduces revisits for acute asthma care.

Please note that as of 20/05/2013, the following changes were made to the trial record:
1. The public title was previously "Reducing emergency room visits in children with asthma: a randomised controlled trial"
2. The scientific title was previously "Efficacy of personalised written asthma action plans in the reduction of emergency room revisits in children with recurrent admissions for asthma: a randomised controlled trial"

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of the West Indies, Faculty of Medical Sciences Ethics Committee approved on the 30th November 2009

Study design
Interventional randomised double blind single centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Asthma

Interventions
Current interventions as of 20/05/2013:
Personalised written asthma action plan versus routine care. Total duration of treatment is 6 months with monthly follow up of both arms for 1 year.

Previous interventions until 20/05/2013:
Personalised written asthma action plan versus routine care. Total duration of treatment is 6 months with monthly follow up of both arms for 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of emergency room revisits, measured monthly

Secondary outcome measures
1. Number of unscheduled doctor visits, measured monthly
2. Number of school days missed, measured weekly
3. Number of night-time awakenings with symptoms, measured weekly
4. Mean change in peak expiratory flow rates, measured weekly

Overall study start date
01/02/2010

Completion date
30/04/2011

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/05/2013:
1. Children with partly controlled asthma with a history of presenting to the Emergency Room (ER) or Paediatric clinic for acute treatment of bronchospasm in the preceding six months
2. Ability of the child and/or parent to follow written directions.

Previous inclusion criteria until 20/05/2013:
1. Children with more than one admission to the ER for acute asthma care in the preceding six months
2. Children and/or the parents able to follow written directions
3. Children aged 1 - 16 years, either sex

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
100

Key exclusion criteria
Current exclusion criteria as of 20/05/2013:
1. Uncontrolled asthmatics
2. Inability of child and/or parent to follow written directions
3. Presence of co-morbid respiratory illness
4. Children or parents already in possession of written/verbal plans or other asthma education material
5. Children who sought care outside of the Chaguanas paediatric outpatient clinic or Emergency Room department and
6. Previous enrolment in an asthma educational programme/study.

Previous exclusion criteria until 20/05/2013:
1. Uncontrolled asthmatics
2. Inability of the child and/or parent to follow written directions
3. Presence of co-morbid respiratory illness
4. Previous enrolment in an asthma educational program/study

Date of first enrolment
01/02/2010

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
Trinidad and Tobago

Study participating centre
17 Hillside Terrace
Tunapuna
Trinidad and Tobago
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Sponsor information

Organisation
University of the West Indies (Trinidad and Tobago)

Sponsor details
Department of Paraclinical Sciences
Public Health and Primary Care Unit
Faculty of Medical Sciences
St. Augustine
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Sponsor type
University/education

Website
http://sta.uwi.edu/

ROR
https://ror.org/003kgv736

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Trinidad and Tobago)

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	results	01/02/2014		Yes	No