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Does Baby Check improve parental recognition of the severity of their child's illness: a pilot study of the revised Baby Check Symptom Diary

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 09/10/2014	**Condition category** Neonatal Diseases	

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
N0220111014

Study information

Scientific Title

Study objectives
Can parents safely and routinely use Baby Check (a parent administered infant illness severity score) and that they will seek professional medical attention for their infant more appropriately than parents without Baby Check? These hypotheses will be examined specifically in relation, accuracy of diary use and appropriateness of visits to the GP and hospital admissions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Neonatal Diseases

Interventions
This pilot study is confined to the residents of the South and South West PCTs in Sheffield. The participating Health Visitors will recruit Primips at 36 weeks at their routine ante natal visit. They will be enrolled by the Health Visitor 1-14 days postnatally. The CONI office (in Sheffield) will randomise families and send the appropriate symptom diary (and thermometer if randomised to Baby Check arm) to the family home enabling the Health Visitor to familiarise the family with the use of the symptom diary (and Baby Check) at this first post natal visit.

GPs will be informed and sent appropriateness of consultation forms at the time of the infants' enrolment.
The symptom diaries will be kept by the parents for a period of 3 months during which we would

expect from routine health care there would be around six contacts with either the Health Visitor or the GP. Once completed the diaries will be returned to the CONI office for analysis prior to being returned to the parents or being destroyed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The proposed pilot study to be undertaken in Sheffield is to test whether parents can use and complete the revised diary; whether when used in conjunction with Baby Check it influences the use of medical services (GP and hospital); whether following consultation with the GP the parents are more empowered and the GP perceives the consultation to be appropriate.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2002

Completion date
30/09/2004

Eligibility

Key inclusion criteria
This pilot study is confined to the residents of the South and South West PCTs in Sheffield. The participating Health Visitors will recruit Primips at 36 weeks at their routine ante natal visit. They will be enrolled by the Health Visitor 1-14 days postnatally. For the pilot scheme only families with English as their first language will be recruited. We will recruit 120 families, randomised to 60 study infants and 60 controls.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
120 (60 study infants and 60 controls)

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment

01/06/2002

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Teaching Hospital
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Sheffield Childrens Hospital NHS Trust (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