

Specialist health visitor intervention for failure to thrive

Submission date

23/01/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

17/09/2009

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Mary Rudolf

Contact details

Community Paediatrics
Leeds Community and Mental Health Trust
Belmont House
3-5 Belmont Grove
Leeds
United Kingdom
LS2 9NP
+44 0113 392 6352
mary.rudolf@leedsth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

To determine whether home intervention by a specialist health visitor affects the outcome of children with failure to thrive

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)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Other nutritional, metabolic and endocrine disease

Interventions

Conventional care vs conventional care plus specialist home visiting for 12 months

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Growth
2. Eating difficulties

3. Diet
4. Health service utilization including hospital admission
5. Maternal mental health

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/1994

Completion date

28/02/1997

Eligibility

Key inclusion criteria

Children referred to a failure to thrive clinic - aged 4-30 months and weight below third centile, or deceleration in weight gain over two centile channels

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

42 (added 17/09/09)

Key exclusion criteria

1. Chronic illness affecting growth
2. Parents non-english speakers

Date of first enrolment

01/04/1994

Date of final enrolment

28/02/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Community Paediatrics
Leeds
United Kingdom
LS2 9NP

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/1999		Yes	No