

# 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?
<a href="#">Results article</a>	results	01/06/1999		Yes	No