

# Improving health outcomes in obese children: a randomised controlled trial of the MEND programme

<b>Submission date</b> 13/09/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 06/10/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/04/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

[http://www.mendprogramme.org/the\\_research/](http://www.mendprogramme.org/the_research/)

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N&AHP/02/RDA/033

## **Study information**

**Scientific Title**

**Acronym**

MEND (Mind, Exercise, Nutrition and Diet)

**Study objectives**

Current hypothesis as of 28/06/2007:

We propose a randomised controlled trial in obese 8 - 12 year old children to test the hypothesis that an intensive family-based programme of nutrition education, exercise and behavioural modification, followed by free access to leisure facilities will improve body composition, cardiovascular fitness and self-esteem in obese school-aged children compared to a waiting list control group. The trial will be conservatively powered, with outcomes relevant to public health and the NHS Plan and could provide the first proven childhood obesity intervention programme in the UK.

Previous hypothesis:

We propose a randomised controlled trial in obese 8 - 11 year old children to test the hypothesis that an intensive family-based programme of nutrition education, exercise and behavioural modification, followed by free access to leisure facilities will improve body composition, cardiovascular fitness and self-esteem in obese school-aged children compared to a waiting list control group. The trial will be conservatively powered, with outcomes relevant to public health and the NHS Plan and could provide the first proven childhood obesity intervention programme in the UK.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

MREC approval gained.

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****Health condition(s) or problem(s) studied**

Childhood Obesity

**Interventions**

Please note that this trial has concluded; the official end date of this trial was 13th January 2007. The previous end date for this trial was 30/04/2008.

**Interventions:**

Childhood obesity treatment programme combining nutrition education, behavioural modification and physical activity.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Waist circumference

**Secondary outcome measures**

Body composition, weight, height, Body Mass Index (BMI), self- esteem, family functioning, child mental health, cardiovascular fitness and dietary intake and composition.

**Overall study start date**

01/04/2005

**Completion date**

13/01/2007

**Eligibility****Key inclusion criteria**

Current inclusion criteria as of 28/06/2007:  
Obese 8 - 12 year old children and their families.

**Previous inclusion criteria:**

Obese 8 - 11 year old children and their families.

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

8 Years

**Upper age limit**

12 Years

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/04/2005

**Date of final enrolment**

13/01/2007

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

MRC Childhood Nutrition Research Centre

London

United Kingdom

WC1N 1EH

**Sponsor information****Organisation**

UK Department of Health

**Sponsor details**

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**Sponsor type**

Government

**ROR**

<https://ror.org/03sbpja79>

## Funder(s)

**Funder type**

Government

**Funder Name**

Department of Health (UK) (ref: N&AHP/02/RDA/033)

**Funder Name**

Sainsbury's Supermarkets Ltd (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	01/02/2010		Yes	No