

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

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

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

Blenheim House

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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?
Results article	results	01/02/2010		Yes	No