A feasibility study of WATCH IT: a community intervention to reduce morbidity in obese children

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/07/2007		Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/08/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
04/10/2017	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.watch-it.org.uk

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

078174/Z/05/Z

Study information

Scientific Title

A feasibility study of WATCH IT: a community intervention to reduce morbidity in obese children - a randomised controlled trial

Acronym

WATCH IT

Study objectives

This is a phase II trial which aims to assess the feasibility of conducting a definitive multicentre randomised controlled trial of the WATCH IT community programme for obese children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from Leeds West Ethics Research Committee on the 3rd May 2006 (ref: O6 /Q1205/14).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Childhood obesity

Interventions

The intervention is a community based programme to tackle obesity through one-to-one and group sessions. The control group is a 12 month wait list control.

Intervention Type

Other

Phase

Phase II

Primary outcome measure

The primary outcome is adiposity at 12 months. This will be assessed using % body fat by Dual Energy X-ray Absorptiometry (DEXA) scan, which will also provide more detailed outcomes relating to body fat: namely total and % fat mass, and total and % lean tissue, given as overall measures and broken down by region (abdomen, trunk, legs, arms).

Secondary outcome measures

Secondary outcomes of adiposity will be obtained from bioimpedance, BMI SD score and waist circumference at 6 and 12 months. Other secondary outcomes relate to feasibility (e.g. recruitment rate, attrition, acceptability etc.) plus, biomedical markers of morbidity, lifestyle, psychologial measures and physical fitness.

Overall study start date

01/10/2006

Completion date

01/07/2008

Eligibility

Key inclusion criteria

Young people aged 8 - 15 years with a BMI (Body Mass Index) above the 98th centile are eligible provided they and their principal carer have fluent English.

Participant type(s)

Patient

Age group

Child

Lower age limit

8 Years

Upper age limit

15 Years

Sex

Not Specified

Target number of participants

70

Key exclusion criteria

- 1. Siblings of enrolled participants
- 2. Learning difficulties to a degree that precludes grasping the cognitivve component of the programme
- 3. Recent initiation of obesity reduction medication (for example, orlisat, metformin and sibutramine)
- 4. Young people with a medical cause for obesity or a psychiatric morbidity

Date of first enrolment

01/10/2006

Date of final enrolment

01/07/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Belmont House Paediatrics (Leeds Primary Care Trust)

3-5 Belmont House Leeds United Kingdom LS2 9DE

Sponsor information

Organisation

University of Leeds (UK)

Sponsor details

Woodhouse Lane Leeds England United Kingdom LS2 9JT

Sponsor type

University/education

Website

http://www.leeds.ac.uk/

ROR

https://ror.org/024mrxd33

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 078174)

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	pilot study results	01/09/2006		Yes	No
Results article	RCT results	01/12/2011		Yes	No