ISRCTN95431788 https://doi.org/10.1186/ISRCTN95431788

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

Submission date	Recruitment status	[_] Prospectively registered
20/07/2007	No longer recruiting	[_] 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
Prof Mary Rudolf

Contact details
3-5 Belmont House
Belmont Grove
Leeds
United Kingdom
LS2 9DE
+44 (0)113 392 6352
mary.rudolf@leedsth.nhs.uk

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, psycholoigal 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