ISRCTN58144540 https://doi.org/10.1186/ISRCTN58144540

Increasing physical activity in obese children

Submission date 01/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/09/2005	**Overall study status** Completed	
Last Edited 11/12/2007	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-53574

Study information

Scientific Title

Study objectives
Compared to children with free access to targeted sedentary behaviors, children with contingent access to sedentary behavior will exhibit greater increases in physical activity, larger reductions in sedentary behaviors, and more favorable changes in fitness, body composition, diet, and motivation to be physically active.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Children's Hospital of Eastern Ontario (CHEO) Research Ethics Board on the 11th June 2001.

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

Health condition(s) or problem(s) studied
Obesity

Interventions
Intervention: Contingent Group -
The experimental (contingent) group is designed to increase child physical activity levels and decrease time spent in targeted sedentary behaviors by making access to sedentary activity contingent on physical activity. After data from activity monitors are downloaded, participants in the experimental contingent group will be told how much time they earned in each of the following two weeks for TV/VCR viewing and video games played via TV (e.g. Nintendo etc.). Parents will be taught how to program the TV allowance, which is an electronic device that records and helps budget TV/VCR viewing and video game playing. We acknowledge that targeted children may watch TV with parents or friends outside the house, or play computer games on a PC computer, and this will be measured by the concomitant use of self-report measures of sedentary activity. It is important to note that these potential sources of contamination also existed in previous clinical research that reduced access to TV viewing in obese children, and marked increases in physical activity were still obtained. Parents will be

asked to implement the contingencies for two weeks beyond 12-week post-treatment to encourage physical activity between weeks 10 and 12, and this fading of contingency management may provide an opportunity for parents to implement their own contingencies.

Control: Non-Contingent group -
Participants in the non-contingent control group will also visit the laboratory bi-weekly to have their physical activity monitors downloaded. They will also be given a TV allowance for monitoring purposes (and to control for this device in the home), but parents will be explicitly told that children should have free access to targeted sedentary activities independent of physical activity. The control group is designed to control for contact with investigators, feedback on physical activity levels, passage of time, the effects of wearing the activity monitors, and the presence of the TV allowance in the home.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Physical activity, measured by pedometer counts.

Secondary outcome measures
1. Time in sedentary behaviour
2. Aerobic fitness (peak maximal oxygen consumption)
3. Body Mass Index (BMI)
4. Percent body fat (bioelectrical impedance and skinfold measurement)
5. Food intake and macronutrient composition
6. Motivation to be physically active (self-report)

Overall study start date
01/09/2002

Completion date
30/06/2004

Eligibility

Key inclusion criteria
1. 8 - 12 year old children, either sex, who are overweight or obese defined as a Body Mass Index (BMI) above the 85th BMI percentile for age and sex (CDC, 2002)
2. Engaging in 15 hours of targeted sedentary behaviour per week, including TV/VCR/DVD use and video game playing
3. Engaging in less than 30 minutes of moderate to vigorous physical activity
4. No conditions that would limit physical activity
5. Agreement that the child or parent would not participate in any other exercise or weight control program during the course of the study
6. No regular participation in swimming or strength training because these activities cannot be measured properly by accelerometry

7. Willingness of the parents to enforce or maintain the contingencies or lack of as reflected by their assigned study group
8. Parent providing signed informed consent, and child providing signed informed assent

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
Children with developmental disabilities, who are often obese, will be excluded from participating in this initial trial in order to reduce the heterogeneity of the sample.

Date of first enrolment
01/09/2002

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
Canada

Study participating centre
Children's Hospital of Eastern Ontario
Ottawa, Ontario
Canada
K1H 8L1

Sponsor information

Organisation
Children's Hospital of Eastern Ontario (Canada)

Sponsor details
401 Smyth Road
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Sponsor type
Not defined

Website
http://www.cheo.on.ca/english/hub.shtml

ROR
https://ror.org/05nsbhw27

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-53574)

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