Coaching and education for parents with overweight/obesity and their children

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/07/2018		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
24/09/2018	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
16/09/2021	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Background and study aims

In 2016, more than 1.9 billion adults and over 340 million children and adolescents aged 5-19 were overweight/obese globally. Overweight and obesity are defined as as abnormal or excessive fat accumulation that may result in physical, social, emotional, and mental health complications. The involvement of parents and children in interventions such as health education coaching and programs may help to reduce obesity and promote long-term healthy weights among members of the family. Children's parents, home and family environments are some of the strongest influences on their health behaviours, which means that one of the best ways to encourage positive health behaviour is to target parents and children whilst children are still young.

The aim of this study is to look at how a 3 month health education and coaching program can affect changes in physical activity and nutrition in overweight/obese parents, along with changes in parental motivation to engage in healthy behaviours.

Who can participate?

Overweight/obese parents with children between the ages of 2.5-10 years old (of any weight) who live in Middlesex County and live together for at least 5 days of the week

What does the study involve?

Pairs of parents and children will be randomly assigned into either the intervention or control group. Both groups will receive 6 online health education sessions. The intervention group will also receive 9 20 minute telephone-based coaching sessions. Participants will be assessed on their physical activity, nutrition, self-esteem and their perceptions of the program's efficacy.

What are the possible benefits and risks of participating?

The potential benefits from this program include information and/or coaching provided to participants, along with the long-term health behaviour changes within the family that this program aims to promote. There are no known risks for participating in this study. Although it is not anticipated, it is possible that some individuals may feel sensitive speaking about their personal experiences. If parent-participants feel they would like to share their feelings with individuals outside of the study environment, they are being advised to seek resources available in London and area (e.g. London Middlesex Counselling and Addiction Services).

Where is the study run from? Western University in London, Ontario, Canada. Some follow-up measurements occur at participants' homes, if they choose.

When is the study starting and how long is it expected to run for? June 2017 to June 2019

Who is funding the study? Institute of Coaching (USA)

Who is the main contact? Dr. Jennifer D. Irwin jenirwin@uwo.ca

Contact information

Type(s)

Scientific

Contact name

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Coaching and/or education intervention for parents with overweight/obesity and their children: a randomised controlled trial

Study objectives

Primary research question: What is the impact of 3 months of coaching plus health education compared to health education only on:

- 1. The physical activity (PA) levels of children (ages 2.5-10) and their parents with overweight (i. e., BMI of $> 25 \text{ kg/m}^2$)?
- 2. The dietary intake of children and their parents with overweight?
- 3. Parental motivation to engage in healthy behaviours?

Secondary research question: What is the impact of coaching plus health education compared to health education only on parental:

- 1. Body Mass Index (BMI)?
- 2. Overall perception of health?
- 3. Psychosocial variables (i.e., social support, self-esteem, and self-efficacy)?
- 4. Perceptions of the intervention's impact on themselves, their child, and their family?

We hypothesise that immediately following, and at 6 months post-intervention, the coaching plus education group will report higher levels of parent-child physical activity, greater improvements in parent-child dietary intake choices, greater parental psychosocial benefits, and greater improvements in parents' BMI values, compared to those who receive education only. We predict that parents from higher SES (socioeconomic status) backgrounds will be more favourably impacted than those from lower SES backgrounds, as researchers have found greater difficulties associated with affecting behaviour change within lower SES environments (Peters, Parletta, Lynch, & Campbell, 2014).

It is also hypothesized that male parents and children will report higher PA levels, while female parents and children will report greater dietary intake improvements, and their psychosocial health will be most positively impacted, given that previous research has found young males tend to be more active than their female counterparts, and obesity affects psychosocial health of women more negatively than men (Walker & Hill, 2009).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Western University Non-Medical Research Ethics Board (NMREB) at the Delegated Board review level, 02/06/2017, 109219

Study design

Interventional single-centre randomised controlled pilot study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Overweight/obese parents and their children (ages 2.5-10 years) of any weight.

Interventions

50 parent-child pairs will be randomly assigned, using a 1:1 ratio, to either the intervention group or control group. A computerized program will be used to determine participant assignment. As participants become eligible, they will be assigned to the next available slot, which will indicate which group they are assigned to. For instance, when using the website http://www.graphpad.com/quickcalcs/randomize1/ to randomly assign participants, it asked for the number of subjects in the study and how many groups they need to be randomly assigned to, and from this, it generated random assignment for that amount of subjects (e.g. Participant 1 = Group A, Participant 2 = Group B, Participant 3 = Group B, etc). For the purposes of this research, Group A will be the intervention group and Group B will be the control group. Group A will receive 9 20-minute telephone-based coaching sessions for parents, plus 6 online education sessions. They will create a schedule with their coach to receive these sessions, with 3 per month for 3 months. The agenda of the sessions will be of the participant's choosing. The 6 online health education sessions will consist of 3 sessions focused on physical activity and 3 sessions focused on healthy eating, all of which are created by the research team. These will be open to participants upon entry to the study, and parents will be asked to engage in their next lesson approximately 7-10 days after their previous one. The uptake of each lesson will be tracked by participant login and duration, and by a "What is the most important lesson I took from this session" question that they will be asked to complete and submit at the end of each module.

Group B will receive the same 6 online education sessions received by the intervention group. Assessments will be conducted at baseline, 6 weeks into the intervention, post-intervention (3 months), and 6 months post-intervention.

Intervention Type

Behavioural

Primary outcome measure

The following will be assessed at the baseline, 6 weeks into the intervention, post-intervention (3 months) and 6 months post-intervention:

- 1. Physical activity, assessed using:
- 1.1. 7 day pedometer-determined step count of parent and child (participants will be sent a log to track the end-of-day step count for each day the pedometer is worn, to be filled out for themselves and their child)
- 1.2. International Physical Activity Questionnaire (IPAQ)

- 2. Dietary intake, assessed via 24 hour food recall of parent and child with a 24 Multi-Pass Recall for parent and child
- 3. Parent perspectives on changes in their and their child's physical activity and nutrition behaviours, assessed via in-person interview
- 4. Parent motivation to engage in healthy behaviours, assessed using the Treatment Self-Regulation Questionnaire (TSRQ)

Adult participants will be asked to provide information about their demographics at the baseline.

Secondary outcome measures

The following will be assessed at the baseline, 6 weeks into the intervention, post-intervention (3 months) and 6 months post-intervention and completed only by the parent:

- 1. BMI, assessed by dividing weight in kilograms by height in meters squared (kg/m^2)
- 2. Social support, assessed using the Multi-dimensional Scale of Perceived Social Support
- 3. Changes in self-esteem and self-efficacy, assessed using the following:
- 3.1. Rosenberg Self-Esteem Scale
- 3.2. Weight Efficacy Lifestyle Questionnaire
- 3.3. Self-Efficacy for Overcoming Barriers
- 3.4. Eating Self-Efficacy Scale
- 3.5. Generalized Self-Efficacy Scale
- 3.6. Short Form-36
- 4. Parents' perceptions of the program's impact on themselves and their families, assessed via inperson interview

Overall study start date

02/06/2017

Completion date

31/07/2019

Eligibility

Key inclusion criteria

- 1. Parents or guardians
- 2. BMI of $> 25 \text{ kg/m}^2$
- 3. Live with their child for at least 5 days of the week
- 4. Have a child aged 2.5-10 years
- 5. Speak English
- 6. Comfortable using a computer for data collection
- 7. Live in Middlesex County

If there are two parents and two children in a family who meet our inclusion criteria, they will be permitted to participate as two separate dyads.

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

The sample size for this study is 50 parent-child pairs. Each parent-child pair will be randomly assigned to either the control or intervention group, using a 1:1 ratio, resulting in 25 pairs in each group.

Total final enrolment

100

Key exclusion criteria

N/A

Date of first enrolment

01/09/2017

Date of final enrolment

15/11/2018

Locations

Countries of recruitment

Canada

Study participating centre

Western University

Arthur & Sonia Labatt Health Sciences Building

1151 Richmond St

London

Canada

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Sponsor information

Organisation

The Office of Human Research Ethics

Sponsor details

Room 5150, Support Services Western University London, Ontario London Canada N6G 1G9 519-661-3036 ethics@uwo.ca

Sponsor type

University/education

ROR

https://ror.org/00dpysh46

Funder(s)

Funder type

Not defined

Funder Name

Institute of Coaching

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 22/07/2020:

A protocol paper outlining the development and implementation of this study is currently underway and will be submitted for publication in Fall 2018. Study results will be submitted to academic journals for publication from 2019-2020.

Qualitative findings regarding coach and participant experiences in this program will be published in August 2020.

Previous publication and dissemination plan:

A protocol paper outlining the development and implementation of this study is currently underway, and will be submitted for publication in Fall 2018. Study results will be submitted to academic journals for publication from 2019-2020.

Intention to publish date

02/06/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/03/2019		Yes	No
Other publications	Clients' and Coaches' Perspectives	03/08/2020	16/09/2021	Yes	No

Results article results 18/09/2020 16/09/2021 Yes No