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Nutrition and healthy lifestyle program

Submission date	Recruitment status	[X] Prospectively registered
30/05/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/06/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2017	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to assess the effectiveness of a nutrition and healthy lifestyle program that aims to educate children and their families about the importance of healthy eating, healthy living, and exercise.

Who can participate?
Children aged 7-12 with body mass index greater than 85% percentile (defined as overweight) and their families

What does the study involve?
Participants attend monthly group sessions and monthly individual sessions for the first six months. After the first 6 months, participants attend booster sessions at 6-month intervals and ongoing individual sessions as needed. Assessments are carried out before, during, and at the end of the two-year study, and involve completing questionnaires, providing blood samples, and height/weight/waist/blood pressure measurements.

What are the possible benefits and risks of participating?
In addition to direct physical benefits (i.e. healthier lifestyle habits), participants will benefit from learning about their own emotional needs, and having support for mental health difficulties. Participation in the current study may also prompt participants to become more knowledgeable about important issues related to physical wellbeing, such as exercise, eating healthily, and the importance of addressing mental health problems and family functioning in the recovery from pediatric obesity. There are few, if any, safe, cost-effective community-based intervention programs for childhood obesity. This study will enable the development of such an intervention. Emotional risks in participating in the intervention may include feeling uncomfortable, anxious or upset. However, a licenced clinical practitioner will be present at all times during the intervention. Patients will be informed that a licensed mental health practitioner will also be available at any time after the intervention. Participants will be reminded and ensured that they may refrain from completing clinical tests or a question or questionnaire without consequence, should they feel any discomfort about these.

Where is the study run from?
Kindercare Pediatrics (Canada)

When is the study starting and how long is it expected to run for?
July 2016 to September 2016

Who is funding the study?
Kindercare Pediatrics (Canada)

Who is the main contact?
Dr Daniel Flanders

Contact information

Type(s)
Scientific

Contact name
Dr Daniel Flanders

Contact details
491 Eglinton Ave W
Toronto
Canada
M5N 1A8

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0001

Study information

Scientific Title
A pilot outpatient community-based pediatric obesity treatment program

Study objectives
The study aims to determine whether a multi-disciplinary intervention to treat childhood obesity has a beneficial effect.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Toronto Academic Health Sciences Network (TAHSN), Canada, approval pending, expected 01/07/2016

Study design
Single-center interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Quality of life

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
Childhood obesity

Interventions
Participants will be attending monthly group sessions and monthly individual sessions for the first six months. After the first 6 months, participants will attend booster sessions on a 6-month interval and ongoing individual sessions as clinically indicated.

Physical Interventions for Parents and Kids:
1. Mindful eating: understanding hunger and fullness (month 1)
2. Education on frequency of eating different foods (month 1)
3. Education on food groups (proteins, fats, carbohydrates, fiber) (month 1, 2)
4. Education on meal planning and label reading for kids (month 2)
5. Physical activity (month 3)
6. Grocery store tour for kids and adults (month 4)

Mental Health Interventions for Kids:
1. Motivational Interviewing (month 1)
2. Psychoeducation in Peer Support (month 1)
3. Psychoeducation in Coping with emotion and emotional self-efficacy (month 1)
4. Psychoeducation in Tolerating Distress (month 1)
5. Continuation of these interventions through months 3 - 6

Mental Health Interventions for parents:
1. Psychoeducation in empowerment and parental self-efficacy (month 1)
2. Education on identifying mental health issues (month 1)
3. Psychoeducation on coaching children's emotions (month 2)
4. Continuation of these interventions through months 3-6

Booster sessions: at 12 months, 18 months and 24 months
1. Meetings between families and clinicians to check in with progress, identify problems, and recommend intervention applications going forward

Intervention Type
Behavioural

Primary outcome measure
1. Mental Health measures: All mental health measures will be administered once every month for the first six months of the study, then at 12 months, 18 months, and 24 months (study's completion). These measures include:
1.1. Dutch Eating Behaviour Questionnaire
1.2. Peds QL Quality of Life Questionnaire (administered to the parent and child)
1.3. Parenting Stress Index (Short)

2. Physiological measures:
2.1. Blood work (every 6 months; testing for cholesterol, glucose, inflammation, insulin, iron)
2.2. Height/weight/waist circumference (monthly)
2.3. Blood pressure (monthly)

Secondary outcome measures
No secondary outcomes

Overall study start date
01/09/2016

Completion date
01/09/2018

Eligibility

Key inclusion criteria
Ages 7-12 with body mass index greater than 85% percentile

Participant type(s)
Other

Age group
Child

Lower age limit
7 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
12 children and their families

Key exclusion criteria

1. Children under the age of 7 years
2. Youth over the age of 12 years
3. Have body mass index under the 85th percentile

Date of first enrolment
02/07/2016

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Canada

Study participating centre
Kindercare Pediatrics
491 Eglinton Avenue West
Toronto
Canada
M5N 1A8

Sponsor information

Organisation
Kindercare Pediatrics (Canada)

Sponsor details
491 Eglinton Avenue #301
Toronto
Canada
M5N 1A8

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h1ytk17

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Kindercare Pediatrics (Canada)

Results and Publications

Publication and dissemination plan
We are planning on disseminating results to the Canadian Pediatric Society, the Canadian Obesity Network and their annual Conference, and the Ontario Pediatric and Bariatric Network. Other details are to be confirmed at a later date.

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available