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C.H.A.M.P. Families: Feasibility of educating parents to treat obesity in their children

Submission date
23/04/2018

Recruitment status
No longer recruiting

Registration date
24/04/2018

Overall study status
Completed

Last Edited
15/03/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Childhood overweight/obesity is a serious global public health concern. Evidence suggests that the treatment of childhood obesity requires modifying the lifestyle of the entire family. It is important to involve parents to make changes to impact obesity in their children. The purpose of the study was to investigate whether a new parent-focused intervention targeting obesity in children is effective, and whether it is practical to use in the community. The intervention, called "C.H.A.M.P. Families", is an extension of our team's previous Children's Health and Activity Modification Program ("C.H.A.M.P."). "C.H.A.M.P. Families" consisted of a 13-week group-based educational intervention for parents of children with overweight/obesity.

Who can participate?
Parents of children aged 6-14 with overweight and obesity in London, Ontario, Canada. Parents were recruited by strategic community advertising, social media, physician referrals, and radio advertisements.

What does the study involve?
Parents of children with overweight/obesity participated in eight 90-minute educational sessions held at a local YMCA over the course of 13 weeks. The parent-focused sessions were designed to address numerous health- and obesity-related topics including physical activity, nutrition, sleep, screen time, sedentary behaviour and screen time, media literacy, and other social/environmental factors (e.g. marketing of unhealthy foods and beverages to children). Goal setting, motivational interviewing, and evidence-based group dynamics strategies were also used to promote lasting behaviour change. At the end of each session, parents were provided with resources, materials, and assigned 'homework' to encourage and support home-based discussions about the weekly topics with children and family goal setting. Finally, 'booster sessions' were held for families (parents, child, and siblings) at 3 and 6 months after the end of the educational sessions. These group-based family sessions include health-related presentations/interactive family activities, social support, and group discussions related to healthy behaviours and choices in the home environment. The C.H.A.M.P. Families program was offered at no cost to participants. Parking was free, and YMCA child minding and drop-in

children's programming were also available free of charge. Data were collected at four timepoints: baseline (≤4 weeks pre-intervention), mid-intervention (Week 6), post-intervention (≤2 weeks post-intervention), and at a 6-month follow-up (June 2018).

What are the possible benefits and risks of participating?
Prior to the start of the study, potential risks for children and parents (e.g. feelings of distress or upset as a result of speaking with other families and learning more about the potential risks of childhood obesity) were identified and shared with participating families. No adverse events related to parents' or children's involvement in the program occurred during the study. Potential benefits of the study include improved physical and psychosocial health for both parents and children, increased knowledge related to healthy living, and increased family communication, satisfaction, and cohesion. It is also possible that study participants did not receive any benefits from participation in the study.

Where is the study run from?
C.H.A.M.P. Families was a single-centre study developed and conducted by researchers from The University of Western Ontario in London, Ontario, Canada. The formal 13-week intervention took place at the YMCA of London – Centre Branch in London, Ontario, Canada.

When is the study starting and how long is it expected to run for?
Recruitment started in May 2017 and the 13-week intervention took place from September 2017 to December 2017. Booster session #1 was held in March 2018 and booster session #2 in June 2018.

Who is funding the study?
This project was supported by the Ontario Ministry of Research and Innovation and the Canadian Institutes of Health Research (CIHR).

Who is the main contact?
Principal Investigator: Shauna Burke, PhD (sburke9@uwo.ca)
Project Coordinator/PhD Student: Kristen Reilly, MPH (kreill2@uwo.ca)

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Additional identifiers

Protocol serial number
Ontario Ministry of Research and Innovation Early Researcher Award (Western University Award ID: R4171A13); Canadian Institutes of Health Research (CIHR) Doctoral Research Award (Competition: 201410MDR, CIHR ID: 336994, Western University Award ID: R4171A15).

Study information

Scientific Title
“C.H.A.M.P. Families”: The implementation and evaluation of a parent-focused pilot intervention targeting childhood overweight and obesity

Acronym
C.H.A.M.P. Families

Study objectives
The purpose of this study is to implement and evaluate the feasibility of a 13-week parent-focused pilot intervention targeting childhood overweight and obesity. Secondary objectives are to evaluate the effectiveness of the intervention in relation to several important child and family outcomes, including children’s health-related quality of life, children’s general health and wellbeing, children’s physical activity (PA) levels and sedentary time, body mass index for both parents and children, parent-reported family cohesion, communication, and satisfaction, parental self-efficacy related to supporting children’s healthy eating and physical activity behaviours, and children’s and parents’ overall perceptions of the program and its potential impact on their family’s health and wellbeing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) at the Full Board review level, 15/03/2017, 108826

Study design
Single-centre non-blinded study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Educational intervention targeting parents of children with overweight and obesity.

Interventions
Eight 90-minute group-based education sessions were delivered to parents of children with overweight/obesity over the course of 13 weeks (September 18 to December 11, 2017). The program also included two 2-hour family-focused 'booster sessions' for parents and children; one of which was offered 3-months post-intervention (March 2018) and one of which will be offered 6-months post-intervention (June 2018). The formal 13-week intervention took place at a local YMCA facility and covered a broad range of topics related to child and family health, including:
1. Child growth and development
2. Family goal setting
3. Healthy eating and nutrition (e.g. family meals, food skills and literacy, meal planning, grocery shopping, etc)
4. Physical activity (e.g. family-friendly exercises, 24 hour movement guidelines, etc)
5. Sleep and sedentary behaviour (e.g. sleep hygiene, screen time, media literacy, etc)
6. Mental health and wellbeing (e.g. bullying, weight stigma, resilience, etc)
7. Parenting and family dynamics (family cohesion, positive communication, role modeling, etc)
8. Policy issues (e.g. health advocacy, the marketing of unhealthy foods and beverages to children, etc)
9. Community resources.

All program sessions were developed by researchers using Social Cognitive Theory constructs (Bandura, 1977; 2004) as a guide, as well as evidence-based strategies grounded in motivational interviewing (Miller & Rollick, 1991) and group dynamics (Carron & Burke, 2005; Forsyth, 2014; Martin et al., 2009). A number of health professionals, experts, and members from community organizations (e.g. Canadian Obesity Network, Heart and Stroke Foundation, Growing Chefs! Ontario, Middlesex-London Health Unit) were featured as guest speakers and delivered relevant content to parents at various sessions throughout the intervention.
At the end of each session, parents were provided with evidence-based resources, and were assigned take home activities to encourage, support, and reinforce the concepts discussed in the group setting for at-home use/implementation with children. A portion of some take-home activities were adapted, with permission, from resources used in an evidence-based obesity prevention program for parents of children aged 2-5 years in the United States (i.e. "Homestyles"; Byrd-Bredbenner et al., 2017).
In completing the 'homework' activities, parents were asked to engage in weekly discussions about the program topics with children in the home environment and at-home family goal setting related to a specific topic. Parents were encouraged to record all family goals on worksheets, to track their family's weekly progress, and to share their family experiences with the parent group at each subsequent intervention session.
The C.H.A.M.P. Families program was offered at no cost to participants. Parking was free, and complimentary YMCA child minding and drop-in children's programming (i.e. an existing YMCA program called "Active and Creative Kids") was available for all children (including siblings) of parent participants. As mentioned previously, one C.H.A.M.P. Families 'booster session' was offered at 3 months post-intervention), and another, final session will be offered at 6-months post-intervention; these hands-on, activity-based sessions were developed to involve both parents and children, members of the research team, graduate students, health professionals and/or community organizations, and to include the provision of evidence-based resources and

information, social support, and group-based discussions and activities related to child and family health and well-being in the home environment.
Data were collected at four timepoints: baseline (≤ 4 weeks pre-intervention), mid-intervention (Week 6), post-intervention (≤2 weeks post- intervention), and at a 6-month follow-up (June 2018).

Intervention Type
Behavioural

Primary outcome(s)
Feasibility of the pilot intervention using the RE-AIM Framework.
The RE-AIM Framework, a planning and evaluation tool for community-based health interventions (Estabrooks & Glasgow, 2006; Glasgow, Vogt, & Boles, 1999) will be used to determine the feasibility of the C.H.A.M.P. Families pilot intervention via an in-depth examination of five broad dimensions:
1. Reach: Family (parent and child) demographics will be compared to census demographics in London, Ontario, Canada to determine the reach of C.H.A.M.P. Families. In addition, records of participant and/or non-participant inquiries into the program will be used to analyze: (a) participate rate; (b) reasons for participating; (c) reasons for declining to participate; and (d) the most effective recruitment methods.
2. Effectiveness: In the present study, effectiveness will be measured via the short-term (i.e. baseline to mid- and/or post-intervention) measurements of the secondary outcomes described below (i.e. child outcomes: BMI-z, physical activity levels and sedentary time, parent- and self-reported health-related quality of life, overall perceptions of the program; parent outcomes: BMI, family cohesion, satisfaction, and communication, parental self-efficacy for engaging children in healthy behaviours, overall perceptions of the program). Short-term attrition will be explored, and reasons for drop out will be reported. Qualitative data were collected via focus groups held during the last session of the program with both parents and children (separately) to explore the effectiveness of the program via participants' experiences and perceptions of the intervention; these data will also be analyzed and reported.
3. Adoption (staff and setting levels): Data pertaining to and detailed descriptions of (e.g. roles, credentials, demographic information, and/or representativeness where applicable) delivery settings (YMCA, community organizations) and intervention agents (researchers, setting staff, guest speakers) who were invited to participate and/or delivered aspects of the program will be provided.
4. Implementation: Records detailing anticipated and actual planned intervention activities and components were kept and will be used to determine whether the C.H.A.M.P. Families program was delivered as it was intended (i.e. fidelity to study protocol). Adaptations to the intervention protocol (e.g., changes to assessment tools, measures, information sessions, and/or homework /resources) will also be reported. Additionally, completion of participant worksheets and goal setting logs (i.e. the at-home activities) will be assessed and reported. All costs associated with the development, implementation, and delivery of the program will also be reported (including in-kind contributions).
5. Maintenance (individual and setting levels): Individual-level maintenance will be assessed using the same secondary outcomes outlined in the effectiveness dimension of RE-AIM, but will be evaluated at 6 months post-intervention (Dzewaltowski et al., 2004; Glasgow et al., 1999). Long-term attrition will be measured via participant drop-out between post-intervention (i.e. Week 13) and 6-month follow-up (i.e. June 2018). The use of qualitative data obtained through focus groups with parents and children will be used to further contextualize differences between families that completed and those who did not complete follow-up assessments. Setting-level maintenance will be assessed using a follow-up mixed-methods questionnaire

delivered to participating staff and organizations (e.g. YMCA, Heart and Stroke Foundation, etc.) at approximately 6 months post-intervention to assess their perceptions of the program and to determine their level of interest and potential participation in future interventions.

Key secondary outcome(s))

As noted above, there were several secondary outcomes assessed in the C.H.A.M.P. Families research project, which represent the "Effectiveness" and "Maintenance-Individual" dimensions of RE-AIM discussed above. Data collection took place in the home of each participant to ensure the privacy and comfort of participants during the four measurement timepoints: baseline (≤4 weeks pre-intervention), mid-intervention (Week 6), post-intervention (≤2 weeks post intervention), and 6-month follow-up (June 2018). All of the secondary outcomes were assessed during each home visit, with the exception of the focus groups, which took place at the YMCA during the last group-based session of the intervention (Week 13). The following provides an overview of the secondary outcomes.

Child outcomes:
1. Children's Health-Related Quality of Life assessed using the Pediatric Quality of Life Inventory 4.0 (PEDS-QL 4.0; Varni, Seid, & Rode, 1999). This valid and reliable measure includes a self-report component (n = 23 items) completed by the child as well as a proxy report component (n = 23 items) completed by the parent/guardian based on his or her perceptions of the child's health-related quality of life (Varni, Seid, & Kurtin, 2001).
2. Children's General Health and Wellbeing assessed via parent reports using The Child Health Questionnaire – Parent Form 50 (Landgraf et al., 1998), a valid and reliable survey designed to measure the quality of life of children aged 5-18 years (HealthActCHQ Inc., 2016).
3. Children's Physical Activity and Sedentary Time measured objectively using Actical™ accelerometers (MiniMitter, Bend, Oregon). These small, lightweight devices collect information on the frequency, duration, and intensity of activity (i.e. sedentary, light, moderate, vigorous), and have been shown to be a valid and reliable predictor of physical activity in children (Evenson et al., 2008; Puyau et al., 2004). Children were asked to wear the device during waking hours (i.e. from wake time to bed time) for 7 consecutive days at each of the four assessment points. Children were instructed to wear the device on their right hip (secured on an adjustable elastic and Velcro belt), and to keep a daily log of the times the device was put on and taken off (as well as reasons for removing the device throughout the day if applicable). Parents were also provided with information regarding the wear-time logs and use and placement of the devices.
4. Children's Standardized Body Mass Index (BMI-z) calculated using researcher assessed height and weight, sex, date of birth, and date of measurement. Height (nearest 0.1 cm) and weight (nearest 0.1 kg) were measured on a firm, flat surface using a Seca 214 portable stadiometer and digital glass bathroom scale. Participants were instructed to remove shoes and heavy clothing while measurements were conducted. Calculations were performed using an online tool called "BMI Percentile Calculator for Child and Teen" developed by The Centers for Disease Control and Prevention (CDC; https://nccd.cdc.gov/dnpabmi/Calculator.aspx).
5. Children's Perceptions of the Program and Perceived Impact on Family Health and Wellbeing. The purpose of the single 60-minute focus group held for children (n = 7) on the last day of the formal intervention (Week 13) was to explore their experiences in the study (e.g. data collection, researcher home visits, parental involvement, etc.), as well as their perceptions of the program's impact on their family's communication, cohesion, and/or health behaviours.

Parent outcomes:
6. Parental Body Mass Index (BMI). Researcher-assessed weight and height was used to calculate parents' BMI. Height (nearest 0.1 cm) and weight (nearest 0.1 kg) were measured on a firm, flat surface using a Seca 214 portable stadiometer and digital glass bathroom scale. Participants were instructed to remove shoes and heavy clothing while measurements were conducted. An

online tool ("Adult BMI Calculator") developed by the CDC was used to perform these calculations (https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html).
7. Parent-Reported Family Cohesion, Communication, and Satisfaction measured via the FACES IV Package (Olson, 2011). This package is a valid and reliable tool consisting of six Family Cohesion scales (n = 42 items), one Family Communication scale (n = 10 items), and one Family Satisfaction scale (n = 10 items). This package of instruments is reliable and valid for both parents and children aged 12 years or older, although in the current study, only parents completed these scales.
8. Parental Self-Efficacy for Supporting Children's Health Behaviours assessed using the Parental Self-Efficacy Questionnaire, a valid and reliable 34-item questionnaire that assesses parental self-efficacy related to supporting children's healthy dietary and physical activity behaviours (Decker, 2012). Four additional scales (n = 4 items each) were administered to parents, measuring parental self-efficacy for:
8.1. helping their child get at least 60 minutes of moderate intensity physical activity per day
8.2. helping their child consume five servings of fruits and vegetables per day
8.3. limiting sugary drinks to once a week
8.4. limiting consumption of fruit juice to 6 ounces per day
These scales have been found to be valid and reliable for parents of children aged 4 to 10 (Wright et al., 2014).
9. Parents' Perceptions of the Program and Perceived Impact on Family Health and Wellbeing. Two 60-minute focus groups were held for parents (n = 6 in each group) during the last session of the program (Week 13) to explore their experiences and perspectives of the program, as well as perceptions of its impact on family health, health behaviours, communication, cohesion, and general satisfaction/wellbeing. Objectives of the focus groups for parents were to identify: which program components were perceived as impactful and useful; which aspects of the program could be improved in the future; the barriers and facilitators parents perceived in relation to implementing healthy behaviour changes in their homes; and the program's potential impact on parenting as well as family cohesion, communication, and satisfaction.

Completion date
15/03/2019

Eligibility

Key inclusion criteria
1. Parent of a child aged 6-14 years with BMI ≥85th percentile for age and sex (calculated using the CDC BMI Percentile Calculator for Child and Teens; https://nccd.cdc.gov/dnpabmi/Calculator.aspx)
2. At least one parent agreed to take part in the study
3. Both the child and his/her parent(s) were able to speak, read, and understand English

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
11

Key exclusion criteria
1. Child did not have a BMI ≥85th percentile for age and sex
2. Parents and children did not provide consent and assent, respectively
3. Parents and children were unable to read, speak, or understand English
4. Child had a medical condition or used medication(s) that could limit study participation

Date of first enrolment
01/05/2017

Date of final enrolment
11/09/2017

Locations

Countries of recruitment
Canada

Study participating centre
Western University
1151 Richmond Street
London
Canada
N6A 3K7

Sponsor information

Organisation
The Office of Human Research Ethics

ROR
https://ror.org/00dpysh46

Funder(s)

Funder type
Not defined

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Ministry of Research, Innovation and Science

Alternative Name(s)
Ministère de la Recherche, de l'Innovation et des Sciences, Ministry of Research, Innovation & Science, MRIS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Canada

Funder Name
Western University

Alternative Name(s)
University of Western Ontario, UWO

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location

Canada

Results and Publications

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

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results (participants' perceptions)	19/06/2019	07/11/2019	Yes	No
Results article		13/03/2023	15/03/2023	Yes	No
Protocol article	protocol	14/12/2018		Yes	No