

The children's health and activity modification program (C.H.A.M.P.): a community-based lifestyle program for children with obesity and their families

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Registration date 27/03/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/12/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The increase of childhood obesity is a global public health concern. The Children's Health and Activity Modification Program (C.H.A.M.P.), a 4-week camp-based program, was developed for children with obesity and their families using a multidisciplinary approach. The primary objective of the study was to test the reach, effectiveness, adoption, implementation and maintenance of the program. Secondary objectives were to improve: (a) physical activity behaviour among children both during and following the program; (b) physiological outcomes (e.g., standardized body mass index [z-BMI], body fat percentage, muscle percentage, fitness), and (c) psychological outcomes (e.g., task and barrier physical activity-related self-efficacy, health-related quality of life [QOL], etc.). Perceptions of the program from both children and caregivers were also assessed.

Who can participate?

Children aged between 8 and 14 years with a BMI greater than or equal to the 95th percentile for his/her age and gender. At least one caregiver from each family also participated in the family-based component of the study.

What does the study involve?

C.H.A.M.P. was a 4-week lifestyle intervention that was delivered to two groups of children and caregivers over the course of two years. All children attended the program on weekdays (i.e., Monday to Friday) from 9am-4pm for four consecutive weeks during the month of August, and caregivers attended weekly group-based educational sessions on four Saturdays from 10am-2pm. C.H.A.M.P. consisted of several group-based activities for the children including daily: (a) sport, fitness, strengthening, and/or games-based physical activity sessions; (b) behaviour modification counselling; and (c) dietary counselling. Weekly educational sessions for parents and caregivers targeted behaviour modification strategies, physical activity, and nutrition in the home environment among other topics. Post program group support was offered to both children and caregivers (combined) in the form of "booster sessions" held once every two

months for one year following the program. Each family paid a fee of \$200.00 (CAD) for participating.

What are the possible benefits and risks of participating?

Following completion of the study, a range of benefits were noted by and observed for children and caregivers as a result of participation in the program. These included a significant increase in physical activity, improvements in cardiovascular health, glucose metabolism and blood lipid levels, decrease in weight, increase in muscle and a general increase in quality of life. No-one suffered any adverse side effects to participating in the program. Before the study started, a number of potential risks for children were identified (and shared with families) including: physical discomfort and injuries associated with greater levels of physical activity; exposure to small amounts of radiation from the DXA scan used to assess body composition; varying degrees of discomfort and/or physical reactions (e.g., rashes) associated with some of the research-based assessments including vessel wall imaging, heart rate, and blood pressure measurements; and feelings of distress or discomfort due to discussions around body weight.

Where is the study run from?

C.H.A.M.P. took place at The University of Western Ontario in London, Ontario, Canada. However, various community settings (i.e., Canadian Centre for Activity and Aging, a local YMCA, and a nearby school field) were also used for specific activities.

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

January 2008 to September 2014

Who is funding the study?

The Lawson Foundation (Diabetes Funding Opportunity) in London, Ontario (Canada)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

GRT 2008-016 (The Lawson Foundation); Award ID: R4171A01 (The University of Western Ontario); ROLA #0000005584 (The University of Western Ontario); 161975 (Canadian Institutes of Health Research; Competition 2006-06CCT)

Study information

Scientific Title

The Children's Health and Activity Modification Program (C.H.A.M.P.): a family-based lifestyle intervention for children with obesity and at risk for type II diabetes

Acronym

C.H.A.M.P.

Study objectives

The purpose of the project was to develop, implement, and assess the effectiveness of a community- and group-based lifestyle intervention program for children with obesity and their families. A 4-week intervention (day-camp) was offered to two cohorts of children during the month of August in 2008 and 2009 and included physical activity, dietary, and behaviour modification components. Weekend educational sessions related to physical activity, dietary, and behaviour modification counseling were also held for caregivers, and follow-up support was offered to families in the form of 2-hour group-based "booster sessions" scheduled once every two months for one year following the formal intervention.

The primary objective of the study was to assess the feasibility of C.H.A.M.P. using the RE-AIM framework; that is, to evaluate the reach, effectiveness, adoption, implementation and maintenance of the program.

Secondary objectives were to improve and/or facilitate:

1. Physical activity behaviour among children both during and following the intervention;
2. Physiological outcomes (e.g., standardized body mass index [z-BMI], body fat percentage, muscle percentage, fitness),
3. Psychological outcomes (e.g., task and barrier physical activity-related self-efficacy, health-related quality of life [QOL], etc.).

It was hypothesized that this 2-year pilot project would provide important information related to the preliminary effectiveness of the intervention in relation to a range of outcomes, as well as recruitment and logistical issues associated with the implementation of a research-based program for children with obesity. With regard to specific (secondary) outcomes, it was hypothesized that C.H.A.M.P. would be associated with improvements in children's physical activity behaviours, as well as in the physiological and psychological outcomes of interest.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB), 10/07/2008, ref: 15158

Study design

Single-centre single-cohort interventional feasibility study held over the course of two years

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

C.H.A.M.P. was a community- and family-based lifestyle (feasibility) intervention that targeted children with obesity and their caregivers.

Interventions

C.H.A.M.P. was a feasibility study and we were interested in assessing various dimensions of the program (including its reach, efficacy/effectiveness, adoption, implementation, and maintenance). There was no control group; rather, children served as their own controls in that pre- and post-intervention assessments (as well as 3, 6, and 12 month follow-up assessments) were conducted to evaluate many of the variables of interest. Families were recruited through advertisements placed in the media (i.e., local newspapers, radio), posters displayed in the community (e.g., libraries, community centers, hospitals, and family medical clinics), physician referrals, and word-of-mouth. The length of recruitment was approximately 3 weeks (Year 1) and 3 months (Year 2) in duration. The following represents an overview of the program (treatment) components, as outlined (with the most detail) in our study protocol.

CHILDREN'S COMPONENT

Two cohorts of children attended camp for the month of August in 2008 (Year 1) and 2009 (Year 2) on weekdays from 9am until 4pm. During the 4-week program, children engaged in a variety of group-based physical and educational activities. Children usually completed one of each of the following sessions on a daily basis: education (e.g., related to physical activity, nutrition, anti-bullying, etc.), aerobic activity (e.g., dance, yoga, etc.), water-based activity (e.g., water polo, synchronized swimming, etc.), circuit-based or resistance training exercise (e.g., Thera-Band® exercise training, machine-based circuits, etc.), and games or sports (e.g., basketball, floor hockey, dodgeball, etc.). Physical activities, education sessions, and team building activities centered on a given 'theme' of the week; themes included Sports Week, Healthy Eating Week, Olympics Week, and Adventure Week. Thirty minutes was allocated for lunch each day, and food was not provided during the program. Guest speakers for the education and physical activity sessions for the children included the Principal Investigator, a Special Constable from the Campus Community Police, varsity and professional athletes and coaches, a Public Health Dietitian, and a Certified Co-Active Life Coach. The last day of each week consisted of an activity-based field trip (e.g., indoor rock climbing) and a movie, and a C.H.A.M.P. Talent Show took place on the last day of the 4-week intervention. The child-based portion of the intervention took place at the Canadian Centre for Activity and Aging in London, Ontario (Year 1), and at a local YMCA where children used the exercise equipment, swimming pool, gymnasium, and an interactive computer technology/exercise centre for children and youth (Years 1 and 2).

FAMILY COMPONENT

Parents and caregivers attended weekly group-based educational sessions on four consecutive Saturdays in August of 2008 (Year 1) and 2009 (Year 2) from 10am until 2pm. Sessions focused on nutrition education (e.g., an in-store supermarket tour and discussions related to portion sizes, label reading, and menu planning, delivered by a Registered Dietitian), healthy parenting (e.g., group discussions around effective parenting skills and issues such as self-esteem and coping with food-related issues, facilitated by a family therapist), diabetes education (e.g., a virtual anatomy "tour" of the human body and complications associated with diabetes, led by an exercise physiologist), anti-bullying (led by a parent support and advocacy organization that targets bullying in schools), family goal setting (e.g., a family goal setting workshop led by the Principal Investigator), and life coaching (e.g., discussions focused on the creation of a positive

and self-esteem-enhancing family environment, led by a Certified Co-Active Life Coach). Although the children did not attend the family-based education sessions, parents and guardians were encouraged to bring their children (including siblings) to participate in supervised and structured physical activities led by the camp counsellors. Thirty minutes per group-based caregiver session were allotted for “family picnic time”, and a pot-luck lunch took place following the last session. All caregiver sessions took place at The University of Western Ontario, and parking was free for all participants.

PROGRAM STAFF AND VOLUNTEERS

Several camp counsellors (6 in Year 1, 10 in Year 2) and program volunteers (7 in Year 1, 9 in Year 2) were involved in the implementation of the intervention. All staff and volunteers were screened and completed a two-phased interview process; once hired, counselors were required to complete a police background check, CPR/First Aid training, and a one-week training program led by the Principal Investigator and Project Coordinator. All counselors were certified school teachers, university students, and/or employees at the program delivery settings (i.e., The University of Western Ontario, Canadian Centre for Activity and Aging, or the YMCA). Volunteers were university (graduate and undergraduate) students.

PROGRAM COST

The fee for the 4-week intervention (plus all post-program support sessions) was \$200.00 (CDN). In addition to including all program activities, the fee contributed toward the cost of bussing from Monday to Friday and a one-month family membership at the YMCA. Parents were expected to provide lunches and snacks for their children because education related to the preparation of healthy meals (including lunches and snacks) was an important part of the program curriculum.

FOLLOW-UP SUPPORT

“C.H.A.M.P. Booster Sessions” were group-based support sessions held for participants (caregivers and children) at various locations (The University of Western Ontario, YMCA, other community-based facilities) once every two months for one year following the formal 4-week intervention. These follow-up sessions were designed to:

1. Provide an opportunity for the maintenance of social contact among children and family members following completion of the formal program
2. Re-iterate, emphasize, and provide new information and resources pertaining to behavior modification strategies, physical activity and healthy food choices.

Sessions included activity-based (i.e., curling, dance, aerobic activity) classes, a healthy cooking demonstration with a public health dietitian, a follow-up session with a psychotherapist, and group discussions related to strategies for overcoming barriers to making healthy food choices and engaging in regular physical activity. The booster sessions also served as a means of disseminating research-based results related to the program and specific outcomes of interest. Additional means of follow-up support for families included bi-monthly C.H.A.M.P. newsletters in addition to telephone calls and e-mails.

Intervention Type

Behavioural

Primary outcome(s)

To answer our primary research question—that is, whether C.H.A.M.P. represented a feasible treatment option for children with obesity and their caregivers—data were collected in relation to the RE-AIM Framework, an evaluation tool for community-based health interventions. The following represents an overview of the RE-AIM dimensions, the methods used to measure each

outcome in our study, and the time points at which each outcome was measured.

1. REACH: Participant demographics were compared to census demographics in London, Canada, to assess representativeness, and records of inquiries about the program were used to analyze the participation rate as well as the most effective recruitment methods.

2. EFFECTIVENESS AND INDIVIDUAL-LEVEL MAINTENANCE: Effectiveness data were reported as part of RE-AIM and within the context of the feasibility study given that C.H.A.M.P. was offered in a 'real world' setting. In addition, whereas the short-term impact of the intervention (i.e., pre-post data) represented the effectiveness dimension of RE-AIM in the current project, the longer-term data (i.e., 3, 6, and/or 12 month) represented the individual-level maintenance element of RE-AIM in our study. Individual-level maintenance was also assessed using participant attrition. Measurements on specific outcomes (representing the secondary objectives, outlined below) were collected at baseline, post-intervention (i.e., approximately one week following the 4-week intervention), 3-month (in some cases), 6-month, and 12-month follow-up assessments. The impact of the intervention on these outcomes were assessed via a series of repeated measures ANOVAs to examine changes across time and post-hoc analyses were conducted to determine whether there were statistical differences in the variables of interest (physical activity behaviour, physiological outcomes, and psychological outcomes). Effect size values (η^2) were also calculated

3. ADOPTION: As outlined by Burke et al. (under review), adoption of C.H.A.M.P. was addressed by: (a) describing the delivery settings, the use of these settings over the 2-year period, and their potential for translating the research program into practice; and (b) calculating and reporting on the number of individuals and/or community organizations in the community that were involved in the implementation of the program.

4. IMPLEMENTATION: Again, as outlined by Burke and colleagues (under review), four steps were completed to analyze and explore the implementation of C.H.A.M.P.: 4.1. The original C.H.A.M.P. schedules (i.e., for both the child and caregiver sessions), in addition to revisions and notes made by research staff and program counselors, were analyzed to determine the percentage of the planned intervention that was actually implemented

4.2. At the end of each week/family session, the children and parents completed fidelity checks (i.e., small quizzes pertaining to the information provided during the educational sessions) to evaluate the degree to which the material being disseminated was retained.

4.3. A comparison between the original budgeted costs and the actual costs of running the program was calculated; and (d) Attendance was monitored using researcher records for the child and caregiver portions of the program.

5. SETTING-LEVEL MAINTENANCE: In the present study, we calculated the percentage of community organizations (who participated in the first year of the intervention) that were asked and agreed to participate in the second year of the program as an indicator of setting-level maintenance.

Key secondary outcome(s)

Numerous variables of interest were considered to be secondary outcomes in the C.H.A.M.P. project. The following provides an overview of these outcomes, along with information about the method used to measure the outcome and the time points at which they were measured:

1. PHYSICAL ACTIVITY (CHILDREN):

1.1. As outlined in Burke, Vanderloo, Gaston, Pearson, and Tucker (in press), self-reported physical activity was assessed at five time points (i.e., baseline, 1-week post-intervention, 3-, 6-, and 12-months post-intervention) using the Physical Activity Questionnaire for Older Children (PAQ-C). The PAQ-C is a commonly used 7-day recall tool. The PAQ-C is comprised of nine items which assess the frequency and intensity of spare time exercise, school-based exercise, and participation in sports after school, in the evenings, and on weekends, as well as perceived general activity level. Each item is scored on a 5-point Likert-type scale (i.e., 1 = no activity and 5

= the highest level of activity), whereby higher values are reflective of greater levels of physical activity. Because the PAQ-C is intended to be used during the school year and the present study included two assessments that took place during summer months (i.e., baseline and 12-months post-intervention), only the four items which referred to home-based physical activity were used in subsequent analyses.

1.2. Objective physical activity was assessed using the Actical® (MiniMitter, Oregon), which is a small durable (approximately 2.8 x 2.7 x 1.0cm³), lightweight (17g), and water resistant omnidirectional accelerometer easily worn on the child's hip. The Actical® sensors were programmed with the participant's personal information (e.g., age, weight, and height) to provide an estimate of activity-related energy expenditure. Children were asked to wear the accelerometer during waking hours for one week (7-day) periods at weeks 1 and 4 of the 4-week program, at 3, 6, and 12 months post-intervention (if possible).

2. PHYSIOLOGICAL MEASURES (CHILDREN):

2.1. Body composition was measured using a Dual Energy X-Ray Absorptiometry (DXA) scanner (GE Lunar), located in the Exercise and Health Psychology Laboratory at The University of Western Ontario. Body composition was measured at the baseline, post-intervention, 6 month, and 12 month follow-up assessments. The DXA machine differentiates between absolute and relative amounts of fat mass, muscle mass, and bone mass. It is considered to be an accurate criterion reference for quantifying fat and muscle mass in children. To determine standardized body mass index (BMI-z) scores for the children, weight was also measured on the DXA, while height was measured using a standard height and weight scale. Standardized BMI was calculated using the LMS method with an online calculator from the Children's Hospital of Philadelphia (The Children's Hospital of Philadelphia, 2008). Finally, using the umbilicus as the vertical landmark, waist circumference was measured by the C.H.A.M.P. paediatrician using a standard measuring tape, as another means of evaluating body composition.

2.2. Fasting blood sample measurements yielded values for total cholesterol, high density lipoprotein cholesterol (HDL-c), low density lipoprotein cholesterol (LDL-c), triglycerides, insulin, serum glucose, and HOMA-IR. Children had blood work drawn to determine metabolic status at baseline, week 4, and at 6 and 12 month follow-ups. Blood samples were taken by nurses specializing in paediatrics at the Paediatric Medical Day Unit (PMDU) located at the Children's Hospital of Western Ontario. The PMDU had a comfortable waiting room with toys, games, and books for children. A nearby Child Life Room was staffed with Child Life Specialists who integrated emotional support into play in order to minimize any stress that might have been associated with the procedures/hospital experience.

2.3. Vessel wall imaging (VWI) was conducted on all children to monitor plaque formation, vessel elasticity, and capillary function, thus providing an estimate of cardiovascular health. A small probe that emits ultrasound waves was held against the child's skin to obtain images of the heart, brachial artery (inner side of elbow), and carotid artery (neck). This probe was utilized to record blood flow through the brachial and carotid artery. An additional ultrasound probe was placed in the suprasternal notch (lower part of neck, between the collar bones) to record the flow of blood as it leaves the heart. Assessments were taken at baseline, post-intervention, and at 6 and 12 month follow-up time points.

2.4. Blood pressure was taken via a cuff that was placed around the participant's upper arm and inflated periodically in the same manner as blood pressure measurements taken by a physician at baseline, post-intervention, and 6 and 12 months post-intervention.

2.5. Children's resting heart rate, exercise heart rates, and distance run/walked (in metres) were measured by the Cooper 12-minute walk/run test. The Cooper test is a field-based, self-paced 12-minute walk or run test. This particular assessment is a self-paced test, thus it allowed the children to choose a pace with which they felt most comfortable. It also has minimal opportunity for embarrassment as participants finish at the same time and location (i.e., rather than a race whereby one child might be an obvious 'winner'). Children completed the Cooper 12 minute walk/run fitness test on the first and last days of camp, and at the 6 and 12 month follow-up time

points. Children were read instructions as to how to complete the test, and were instructed to choose a fast walking or jogging pace that they could maintain for 12 minutes. The length of the track was 25 meters, marked with a pylon every 5 meters for accurate recording of distance. Children were equipped with a Polar heart rate monitor comprised of two electrodes that were placed above the diaphragm. These electrodes transmitted the heart rate signal to a watch worn on the wrist. Resting heart rate was recorded prior to the test, while the children were seated. Exercise heart rates were recorded at 3-, 6-, 9- and 12-minute time points. Distance run/walked during the test was also used as a measure of fitness status, and was determined by counting the number of laps each child completed.

3. PSYCHOLOGICAL MEASURES (CHILDREN):

3.1. As outlined in Burke, Vanderloo, Gaston, Pearson, and Tucker (in press), physical activity-related task and barrier self-efficacy were assessed at baseline, 1-week post-intervention (i.e., 5 weeks), and at 3, 6, and 12 months post-intervention. An adapted version of the Self-Efficacy Scale was used to assess task self-efficacy; children were asked to identify how confident they were in their ability to complete regular physical activity for increasing amounts of time (10, 30, and 60 minutes) at three intensities (light, moderate, and hard). A color-coded scale with response options ranging from 0% (no confidence at all) to 100% (completely confident) was used, and verbal, written, and pictorial examples of mild, moderate, and hard physical activities were provided. Higher scores reflected greater efficacy to engage in physical activity for increasing durations and intensities. Barrier self-efficacy was assessed using a modified version of the Barrier Efficacy Scale. Again, using a color-coded scale ranging from 0% (no confidence at all) to 100% (completely confident), children evaluated their confidence in their ability to perform physical activity, for 60 minutes per day on most days, in the presence of six common barriers (e.g., "If I have a lot of activities to do with my friends and/or family", "If I am tired") presented verbally, in text, and via illustrations.

3.2. The Pediatric Quality of Life Inventory 4.0 (PEDS-QL 4.0), a reliable and valid measure of health-related quality of life (QOL) for children ages 8 to 12, was administered to children at baseline, 1-week post-intervention (i.e., 5 weeks), and at 3, 6, and 12 months post-intervention. The questionnaire included one document that was completed by the child and one proxy report that one parent/guardian completed based on his or her perceptions of the child's QOL. Both the child and parent proxy questionnaires consisted of the following subscales: 1) physical (n = 8 items); 2) emotional (n = 5 items); 3) social (n = 5 items); 4) and school (n = 5 items) functioning. Because C.H.A.M.P. took place when children were not in school, the school subscale was not included in subsequent analyses.

3.3. A short questionnaire containing questions pertaining to the Theory of Planned Behavior constructs was also administered to children. Specifically, items related to children's attitudes towards physical activity, subjective norms, perceived behavioural control, and intention were asked using a paper-and pencil survey completed by children at baseline, post-intervention, and 3, 6, and 12 months post-intervention.

3.4. Cohesion (i.e., perceptions of belonging and friendships) was assessed 2 weeks into the program (to allow cohesion to develop), the end of the 4-week program, and three months after the camp experience. The 18 item questionnaire was developed for the program and contained a five-point response scale (1 = highest, 5 = lowest).

4. PERCEPTIONS OF THE PROGRAM (CHILDREN AND CAREGIVERS):

4.1. Within one month following the intervention, focus groups were conducted with children and caregivers related to the impact of the intervention. Each session was audio-recorded and transcribed verbatim, and inductive content analysis was conducted using guidelines. Member checking took place and strategies were used to ensure data trustworthiness (i.e., credibility, dependability, confirmability, and transferability).

Completion date

30/09/2014

Eligibility

Key inclusion criteria

Children were eligible to participate in the study if they:

1. Were male or female and between the ages of 8 and 14 years
2. Had a body mass index (BMI) > 95th percentile for age and gender
3. Had written clearance to engage in physical activity prior to beginning the program (eligible children underwent a general medical assessment conducted by a paediatrician at the Children's Hospital of Western Ontario)

Caregivers were eligible to participate in the study if they had a child who met the above criteria.

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

40

Key exclusion criteria

Children were excluded from the study if they:

1. Were not between the ages of 8 and 14
2. Had a body mass index (BMI) that was not > 95th percentile for their age and gender
3. Possessed any contraindications for physical activity

Caregivers were not eligible to participate in the study if their child was excluded for any of the above mentioned reasons.

Date of first enrolment

11/07/2008

Date of final enrolment

31/07/2009

Locations

Countries of recruitment

Canada

Study participating centre

The University of Western Ontario
1151 Richmond St
London
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Sponsor information

Organisation

The University of Western Ontario

Organisation

The Lawson Foundation

Funder(s)

Funder type

Charity

Funder Name

The Lawson Foundation

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2012		Yes	No
Results article		17/12/2012		Yes	No
Results article		27/03/2015		Yes	No
Results article	Burke, S. M., Shapiro, S., Petrella, R. J., Irwin, J. D., Jackman, M., Pearson, E. S., Prapavessis, H., & Shoemaker, J. K. Using the RE-AIM framework to evaluate a community-based summer camp for children with obesity: A prospective feasibility study. BMC Obesity.	14/05/2015		Yes	No
Abstract results		01/12/2011		No	No
Other publications		31/07/2009		Yes	No