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Family-based, Healthy Living Intervention for Children with Overweight and Obesity and their Families: Protocol for a Randomized Controlled Trial

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ABSTRACT

Introduction: Family-based behavioral weight management interventions are efficacious and widely used to address childhood obesity. Curriculum and strategies vary extensively and scale-up often depends on ensuring that the intervention fits the adoption context. We aim to evaluate the impact and implementation of a "made in British Columbia" (BC) family-based early intervention program (EIP) for 8 – 12 year olds with overweight and obesity and their families.
Methods and analysis: A randomized waitlist-controlled trial will assess a 10-week interactive, family-based lifestyle intervention followed by four maintenance sessions, in BC, Canada, from October 2018 to March 2019. We aim to enroll 105 families. The intervention includes at least 26 contact hours between participants and program providers, including interactive activities and educational materials through weekly 90-minute group sessions, an online family portal, and self-directed family activities. Curricular content includes information and activities related to healthy eating, physical activity, positive mental health, parenting practices, and sleep hygiene. The waitlist control group will receive a modified program with the same 10-weekly sessions in the family portal, and four group sessions. Families participate in data collection at baseline, post-intervention (week 10), and follow-up (week 18). Parents will complete behavioral questionnaires. Children will participate in a 'health fair style' measurement session. The primary outcome is to asses changes in child BMI. Secondary outcomes include changes in child and parent physical activity behaviour and skills, healthy eating behaviour, and mental health. Process evaluation will address reach, implementation, and maintenance using recruitment tracking forms, parent questionnaire, program attendance tracking forms, leader feedback surveys, parents and children satisfaction surveys and post-program interviews with facilitators, stakeholders, and parents. Intention-to-treat analyses will be conducted. Process evaluation will be analyzed thematically. **Ethics and dissemination:** Study procedures were designed to address research and community needs and will follow ethical standards. NCT03643341, v2, 10/04/2018

Key words: Family-based, Behavioural weight-management, Childhood obesity

ARTICLE SUMMARY

Strengths and limitations of this study

- The randomized wait-list control design is a strong and ethical design
- Intervention informed by best available evidence and community stakeholders
- Innovative components include positive mental health
- Participant enrollment and drop-out are challenges that can increase selection and attrition bias, respectively

INTRODUCTION

Obesity is one of the most common pediatric health problems[1] and has been linked to multiple physiological and psychosocial problems throughout childhood, with many of these

comorbidities tracking into adulthood[2]. Family-based behavioral weight management interventions are a main approach for achieving weight control in children and adolescents[3]. Encouraging the whole family to make behavioral changes decreases the focus being placed solely on children's dietary and activity behaviors[4] and also focuses on providing a supportive environment for making lifestyle modifications in the home setting.

In order to achieve public health goals, knowledge translation, uptake and sustained implementation within and across jurisdictions are essential. However, these processes are often influenced by community and organizational factors, implementation processes, innovation and user characteristics[5–8]. A recent expert review of factors influencing implementation of PA interventions for youth identified the importance of processes like engaging leaders, staff and champions, conducting needs assessments and planning for sustainability as well as evaluating[7]. Key characteristics of innovations included its adaptability[7]. Compatibility/fit and flexibility have been identified previously as important to adoption and implementation[5,6,9,10].

Thus, the proposed research provides the opportunity to examine the efficacy of an evidence-based model that was developed to enhance implementation using an extensive needs assessment and stakeholder engagement process with over 300 stakeholders across the province who provided input based on their current clinical and professional practice and experience, and the experience and feedback from the implementation of previous family-based lifestyle interventions in British Columbia (BC). Stakeholder's input emphasized the importance of: compatibility with existing resources, flexibility to adapt for different communities, a focus on healthy lifestyles rather than weight, one face-to-face contact per week to reduce family and community burden and enhance relative advantage. Additionally, published family-based weight-management interventions have typically focused on healthy eating and PA; however, sleep, stress and screen time are emerging significant influences on a child's overall physical and mental health[11]. Therefore, the Family Healthy Living Early Intervention Program (EIP) curriculum targets healthy lifestyle with an additional focus on mental health, sleep hygiene, and screen time.

The purpose of the proposed trial is to examine the efficacy of the experimental intervention vs wait-list control group on health and behaviour outcomes over a 10-week period. The primary outcome is to asses changes in child BMI. Secondary outcomes include changes in child fundamental movement skills; physical activity (PA) engagement, predilection, adequacy, intrinsic motivation, competence, confidence; sedentary habits and screen time, confidence, and family support; self-esteem, gratitude, self-compassion, and sleep. Also changes in dietary behaviors, healthy eating outcome expectation, motivation, self-efficacy, and perceived cooking skills will be assessed. Parent outcomes assessed include PA support, habit, and identity; changes in parent feeding practices, structure of the home food environment, parents' personal dietary behaviors, food preparation self-efficacy, habit and identity.

The purpose of this paper is to describe the design and evaluation of the EIP. Our primary hypothesis is that children participating in the EIP will maintain or reduce their BMI after 10 weeks, compared to those in the waitlist control group. Our secondary hypotheses are that EIP participants (parents and children) will make more positive lifestyle changes in PA and healthy eating, as well as parenting practices and mental health, after 10 weeks, relative to the waitlist participants. We also hypothesize that the EIP will reach a broad demographic, and families and staff will be satisfied with the EIP.

METHODS AND ANALYSIS

The SPIRIT reporting guidelines was used to report the study protocol[12].

Study Design

A randomized waitlist-controlled trial will assess the 10-week interactive family-based lifestyle intervention followed by 4 maintenance sessions (Figure 1), in BC, Canada, from October 2018 to March 2019. The intervention includes at least 26 contact hours between participants and program providers, including interactive activities and educational materials

through weekly 90-minute group sessions, an online family portal, and self-directed family activities.

We will aim to enroll 105 parent-child dyads. The sample size estimation was based on the meta-analysis[13] that evaluated the efficacy of randomized controlled trials of family-based intervention to reduce BMI. A significant mean effect size of −0.62 (SD = 0.10) was found for the family-behavioral treatments (95% CI = −0.80 to −0.44). In order to replicate this outcome following 2:1 randomization, and anticipating 20% drop out, the estimated sample for the intervention group is n=70 and the waitlist control group is n=35 (using a two-parallel group design, type 1 error=5% and power=80%). A simple, unstratified, randomization using computer-generated random numbers will be blocked within each of our recruitment sites in the province of British Columbia, Canada (Burnaby, Campbell River, Chilliwack, Kelowna, North Cowichan, Prince George, Surrey Guildford, Surrey Tong Louie, Vancouver Langara, and Westshore Greater Victoria). An allocation of 2:1 in favor of the intervention group will be used because it will be unethical to assign participants to an inferior intervention. Blinding families is not possible as intervention and waitlist program start dates are different. However, investigators will be blinded according to CONSORT standards. Knowledge of treatment allocation will be restricted to a research associate who was not part of the investigation team. Participants were instructed to not discuss details of their treatment with others outside the study. All participants' identifiers will be removed during data analyses.

<Figure 1>: EIP Intervention Description.

Inclusion/Exclusion Criteria

Participants will be children aged 8 to 12 years old, with a BMI ≥85th percentile for age and sex[14], accompanied by a parent, family member, or legal guardian. At least one member of the family will have to be able to speak and read English, and families will have to agree to attend

group meetings over 10 weeks. Families will be excluded if medical clearance was needed and not obtained, and if the child has a BMI <85th percentile.

Waitlist Control Group

An ethical imperative for any study of a family-based obesity early intervention program is to ensure that the control arm receives essential information about preventive guidelines for childhood obesity management. Thus, the waitlist control group will have access to a modified program: four group sessions and full access to the 10-week online family portal after the study is completed.

Recruitment

Participants will be recruited using: Active Living Guide inserts; school newsletter inserts; local newspaper advertisements and interviews; mailed packages to physician offices, community health centers, diabetes clinics, allied health professionals; letters and email blasts to Provincial networks and organizations; posters and rack cards displayed in recreation centers, public community spaces, medical offices and schools; a customized website; social media domains such as Facebook, Instagram, and Twitter; webinars; booths at events and summer camps; and using local radio. Parents may contact the study team directly about enrollment via the study website, email or phone call. Also, parents who express interest will be asked to provide their name and contact details to the recreation center staff and will receive a follow up email or phone call delivering more information about program eligibility and enrollment. Next, parents will be asked to sign consent forms and children will sign the child assent form, confirming that they have discussed the intervention with their parents and understand the program's requirements.

Intervention: Early Intervention Program

The EIP design represents a community-based delivery model and was designed based on a systematic review of the literature[11,15], based on findings from previous implementation efforts[16,17] in British Columbia and extensive community stakeholder consultations across five health regions (more than 300 stakeholders). The EIP development was guided theoretically by the Multi-process action (M-PAC) framework[18,19] that emphasizes social cognitive approaches to intention formation, adoption of action control through self-regulation and the action control maintenance phase once a behavior becomes habitual and self-identified. Intervention activities were designed to support children and parents in learning behavioral change skills that will enable them to improve their health-related lifestyle behaviors. The M-PAC constructs are reflected in the EIP's curriculum to introduce and direct participants in making long-term lifestyle behavior changes. The M-PAC establishes seven constructs that are antecedent of behaviours: (a) instrumental attitude as the knowledge on health consequences, (b) affective judgement relating to intrinsic motivation, (c) perceived capability relating to self-efficacy, (d) perceived opportunity relating to perceptions of the social and physical environment (time and access), (e) behavioral regulation relating to tactics that people use to translate their intentions into behavior (e.g., goal setting, self-monitoring), (f) identity as a standard of conscious self-comparison, and (g) habit as a stimulus-enacted behavioural response under lowered conscious awareness. A recent review of 23 studies that have applied M-PAC provided general support of its tenets and strong support for the multivariate associations between these antecedents and behaviour[20]

Following the systematic review evidence, the 10-week intervention includes at least 26 contact hours[21] between participants and intervention activities and materials through in-person and online activities. Group sessions will be held once a week for 90 minutes and they include family PA, children-only PA aiming at improving enjoyment, confidence, motivation and fundamental movement skills (FMS), and parent-only group discussion to identify barriers and strategies for promoting family healthy behaviours. Additional hours will be obtained via the online family portal.

Curriculum

The intervention targets lifestyle changes in both children and their parents in regards to promoting healthy eating, reduction of sugary drink consumption, increasing cooking self-efficacy, engaging in family PA, reduction of recreational screen time and sedentary behaviour, improved sleep hygiene, positive mental health, self-esteem, gratitude, and self-compassion. Topics include introduction to healthy eating and active living; setting goals and using effective rewards; healthy body image and self-esteem, managing stress and active living for everybody; creating positive family mealtimes and PA experiences; family, food, and getting active outdoors; positive caregiving; and cooking and playing as a family. Behaviour change techniques used in the program include goal setting, self-monitoring, self-evaluation, communication and interpersonal skills. In-person sessions include family positive mental health strategies targeting gratitude and self-awareness; family physical and mindful eating activities; children-only physical activity aiming at improving enjoyment, confidence, motivation and fundamental movement skills; parent-only group discussions to identify barriers and strategies for promoting healthy behaviours as a family, and weekly family goal setting.

The EIP will also provide four extra community-based group sessions. Two of these extra sessions will be a session in a local park using the Agents of Discovery mobile application, which is an augmented reality mobile application designed to encourage families to engage in outdoor exploration, and a group grocery store tour led by a registered dietitian. The remaining two group activities will be chosen and scheduled by the facilitators based on group input. Researchers designing the EIP intend to create a flexible community-based family-intervention program able to accommodate families' demanding schedules.

Online Family Portal

The EIP online family portal will be considered as a weekly lesson to be completed by families. Lessons in the portal will offer additional resource information, healthy recipes, parent articles, videos, and suggested healthy eating and physical activities so that families engage in an extra 60 minutes per week of self-directed healthy lifestyle activities to promote healthy living. The online family portal will also be a repository of materials covered in each session, such as weekly handouts and worksheets. The portal will provide families with a step tracking tool, and a shared healthy places map feature to locate, save, and comment about healthy places in their communities.

Maintenance sessions

The intervention group will receive four one-hour, biweekly maintenance sessions, after the 10-week program. Sessions will include 30 minutes of discussion on maintaining healthy lifestyle, and 30 minutes of family PA.

Data Collection Protocol

Child and parent outcome measures will be collected at baseline, after the intervention (week 10) and after the maintenance sessions (week 18). Process evaluation metrics such as family satisfaction, issues, facilitators and barriers to attendance and maintenance will be collected during and after the intervention. Parent questionnaires will be sent online prior to the intervention start. After screening for eligibility, both intervention and wait-list control group parents will receive an email containing instructions followed by a link for completing the online parent questionnaire.

Data from intervention and waitlist control children will be collected at the Healthy Living Workshop, an interactive and fun ‘health fair style’ measurement approach that rotates between stations such as nutrition and PA games interspersed among questionnaire stations, FMS assessment, and BMI. All parents will be invited to attend a Healthy Living Workshop session

while children participate in the health fair. The measurement team will follow up with families who do not attend the measurement session. Program facilitators will follow up with families who do not come to the intervention. Data will be entered within two weeks of data collection. De-identified data will be securely stored at the University of Victoria server. Processes to promote data quality include double data entry; range checks for data values. Co-investigators will have access to de-identified final trial dataset.

Outcome Measures

Child Measures:

BMI

Measures of height and weight will be obtained from all children. Weight to the nearest 0.1 kg and height to the nearest 0.1 cm will be obtained. BMI will be calculated as weight (kilograms) divided by height (meters) squared, adjusted for child age and sex. BMI z-scores (standard deviation) will be calculated based on the Centers for Disease Control and Prevention (CDC) criteria[14].

Physical Activity Behavior and Skills

Changes in FMS will be assessed using the Canadian Agility and Movement Skill Assessment course that evaluates seven skills: two-foot jumping, sliding, catch, throw, skip, one-foot hop, and kick[22]. Children will observe two demonstrations, will complete two practice trials, and two timed and scored trials.

Child questionnaire will assess changes in PA predilection and adequacy, perceived PA intrinsic motivation and competence by the Motivation and Confidence subscale of the Canadian Assessment of Physical Literacy[22]; changes in PA engagement by the Physical Activity Questionnaire for Children (PAQ-C)[23]; changes in PA and sedentary behaviour and screen time

habits, confidence, and family support will be assessed using the Physician-based Assessment & Counseling for Exercise (PACE) Adolescent Psychosocial Measures[24].

Mental Health

Changes in self-compassion, gratitude, self-esteem, and sleep habits will be assessed using the Self-compassion Scale Short Form[25], the FLASHE questionnaire[26], subscales of the Project EAT survey[27], and the Gratitude Adjective Checklist[28].

Nutrition

Self-reported measures will assess changes in dietary behaviour using the 7-day recall questionnaire retrieved from the Behavioral Risk Factor Surveillance System Survey Questionnaire[29], healthy eating outcome expectations will be assessed using the Power Play! Survey [30], dietary behaviors self-efficacy will be assessed by the Physician-based Assessment & Counseling for Exercise (PACE) Adolescent Psychosocial Measures[31], healthy eating motivation will be assessed by the FLASHE questionnaire[26,32], and perceived cooking skills will be assessed by the Cooking with Kids questionnaire[33].

Parent Measures

Physical Activity and Quality of Life

Parent questionnaire will assess changes in parent PA support[34] and behavioral regulation of supporting child's PA using the Parent Support of Child Physical Activity questionnaire[35]; PA habit will be assessed by the automaticity subscale of the Self-Report Index of Habit[36]; and PA identity will be assessed by the Role-Identity subscale from the Exercise Identity Scale[37,38]. Changes in child quality of life and changes in parent support for child sleep habits will be assessed by the Pediatric Quality of Life Inventory[39].

Nutrition

Parent questionnaire will also assess changes in parent feeding practices will be assessed by subscales drawn from the FLASHES-EAT surveys[40]; parent feeding practices to support child's healthy eating behaviours will be assessed using the modified Parent Support of Child Physical Activity questionnaire[34]; structure of the home food environment will be assessed by the Fruit and Vegetable At Home Survey for Parents[41]; parent's personal dietary behaviours will be assessed by the FLASHE questionnaire[26]; parent food preparation self-efficacy will be assessed using questions drawn from the FLASHES-EAT survey[26]; behavioral regulation of supporting children's healthy eating will be assessed by the Action Control of Parent Support Behaviour[34]; changes in healthy eating habits will be assessed by the automaticity subscale of the Self-Report Index of Habit[36]; and parents' healthy eating identity will be assessed by the role-identity subscale from the Exercise Identity Scale[37,38].

Process Evaluation

The EIP will be assessed using Process Evaluation components identified by Linnan & Steckler[42]; and components of the RE-AIM framework[43], specifically the Reach, Efficacy, Implementation, and Maintenance components.

Reach assesses the effectiveness of marketing strategies, the effectiveness of program processes in generating appropriate referrals to the intervention, the extent that the intervention is reaching intended populations, and adherence and attrition rates. Reach will be assessed using site-specific recruitment plans, recruitment tracking forms, screening and phone calls tracking, demographic questionnaires, and program attendance tracking forms. Program coordinators for each community will record site-specific recruitment plans. Recruitment plans will outline and track all recruitment efforts undertaken at a local level. Centralized recruitment efforts will be tracked using a recruitment tracking form that will record all public inquiries including phone calls, emails, and social media interactions. Information recorded will include name, community, contact

information, date and form of contact, how they heard about the program, any follow-up communication, and the outcome of the inquiry.

The screening call tracking will record the individual's reasons for interest, ability to commit, and eligibility. Demographic questionnaires will be completed by parents or caregivers to determine participants' cultural backgrounds, gender, age, and household make-up, income levels, education levels, and employment status. Program attendance tracking forms will be completed by the program facilitators throughout the duration of the program. Attendance trackers will track weekly participant attendance, reasons for missed sessions, and participant drop-out.

Implementation addresses if families, staff, and stakeholders are satisfied with the EIP, implementation fidelity, facilitators and barriers to participate in the program, attendance, program delivery team perceptions of parent benefits and satisfaction, and negative outcome tracking. Implementation will be assessed using screening tracking form, facilitators pre- and post-workshop surveys, program attendance tracking forms, facilitator feedback surveys, parents and children satisfaction surveys and post-program interviews with parents, facilitators, and stakeholders.

The screening tracking form will identify potential facilitators and barriers to participate in the program. Program facilitators will complete a workshop survey before and after a three-day training workshop that will assess facilitator's knowledge and confidence with implementing the program curriculum and the effectiveness of the training workshop in these regards. Program attendance tracking forms will record participant attendance and reasons for drop-out, including possible barriers to attendance and completion of the program. Weekly facilitator feedback surveys will evaluate the successes and challenges of the weekly in-class sessions, as well as the facilitator's ability to delivery all components of the session: PA, healthy eating, and positive mental health components. Parent and child satisfaction surveys will be completed at the end of the 10-week program and will assess participant satisfaction with the program curriculum and

delivery. Parents will be asked to participate in post-program phone interviews in order to gain a deeper understanding of their perceptions and experiences with the EIP.

Program coordinators and facilitators from each site will also be asked to take part in post-program interviews to explore their perceptions of the success and challenges of the program delivery and the effectiveness of the facilitator training workshop for providing them with the knowledge and tools needed to deliver the content. Focus groups with the facilitation teams and program coordinators will be completed in-person immediately following the last session of the EIP program, or via phone call the week following the completion of the program. Provincial stakeholder interviews will be held in person or by phone and will be scheduled at the earliest available date following the completion of the program, and will be conducted by the EIP project coordinator.

Maintenance evaluates the conditions needed for successful long-term implementation of the EIP by assessing stakeholder support and integration and alignment with British Columbia's Continuum for the Prevention, Management, and Treatment of Health Issues Related to Overweight and Obesity in Children and Youth[44]. Maintenance will be assessed using stakeholders and advisory committee interviews. Stakeholder and advisory committee interviews will be conducted by the EIP project coordinator. Interviews will be held in person or by phone and will be scheduled at the earliest available date following the completion of the program.

Patient and Public Involvement

The development of the research questions and outcomes measures were informed by participants' priorities, experience and preferences. The EIP was designed based on previous childhood obesity weight management in BC and accounted for participants' feedback. Community stakeholders were actively involved in the study design. The EIP was pre-piloted in the Spring 2018 and participants' feedback on recruitment, burden of the intervention and measurement were taking into consideration for the full trial.

Data Analysis

Analysis of group differences at baseline will be conducted with analysis of variance (ANOVA) models for continuous variables, and with chi-square tests for categorical variables. We will analyze our outcomes using an intention-to-treat approach. We will evaluate the distribution of our primary and secondary outcomes. If the distribution is significantly skewed, will apply log transformation. We will use linear mixed models with a random effects intercept to evaluate changes in primary and secondary outcomes across assessment intervals between intervention and control group. Mixed modelling can efficiently deal with missing data at various time-points[45]. Post hoc analysis (Bonferroni correction) will be carried out for all significant interactions or main effects in our statistical models. Statistical significance criterion of will defined as $p<0.05$. Process evaluation data will be described using descriptive statistics and thematic analysis will be done by two independent coders to identify, analyze, and report themes[46]. Coders will read the transcripts, identify possible themes, draft and compare the codebook, discuss potential themes, and draft the first official version of the codebook. Then, coders will code all the transcripts, discuss and develop version two of the codebook. A third researcher will be consulted if agreements cannot be reached.

ETHICS AND DISSEMINATION

All participants will provide electronic and written consent. Children will provide written assent. Ethics was obtained from the University of Victoria Ethics Review Board prior to participant recruitment. Amendment to the protocol will be submitted to the University of Victoria Ethics Review Board and the Clinical Trials registration will be updated.

International recommendations agree that the core elements of any intervention to address childhood obesity should involve the whole family and include nutrition education, behaviour modification, and promotion of PA. Recent randomized controlled trials found family-

based behavioural programs that targeted families with obese 8-to 12-year olds showed positive outcomes in both short-term (10-weeks) and long-term (12 months) interventions[15].

The Province of British Columbia Ministry of Health has provided funding to the Childhood Obesity Foundation to design and implement a "made in BC" community-based Childhood Healthy Weights Early Intervention Program for children 8-12 years old. The EIP was developed following essential processes for scalability[47]: it was based on the current family-based childhood obesity management literature[11,15], based on lessons learned from previous programs conducted in the province[16], it was overseen by a stakeholder Steering Advisory Committee and based on an extensive regional stakeholder consultation and needs assessment process. The program will also include innovative topics on sleep hygiene and screen use as a holistic way to promote healthy lifestyles. The EIP was designed using a new meta-theoretical (M-PAC)[18].

We anticipate that findings from the trial will have high impact, given our collaboration with the Childhood Obesity Foundation and the structure of the initiative and its development. Additionally, while the pilot is running there will be a Sustainability sub-committee that is addressing systems of program integration and client triage. Advancements achieved with this study, concerning the content and methodology of family-based obesity programs, if effective and feasible will likely be widely disseminated in BC dependent on ongoing funding.

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AUTHOR STATEMENT

PJN and KS conceived the study. PJN, KS, SL, JW, GDCB, RER, and LCM contributed to the study design. IGM and MAP drafted and revised the manuscript. All authors edited and approved the final manuscript.

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COMPETING INTERESTS

Dr. Naylor is on the Board of Childhood Obesity Foundation and had course release to oversee the implementation of the evaluation of the EIP. Dr. Naylor reports grants from Childhood Obesity Foundation, during the conduct of the study.
Dr. Strange, Dr. Marques, Ms. Hartrick, Ms. Weismiller, and Ms. Perdew report personal fees from Childhood Obesity Foundation, during the conduct of the study.

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Research advisory committee: University of Victoria, University of Alberta, University of British Columbia.
Management committee: Childhood Obesity Foundation, University of Victoria, Juniper Consulting.
Oversight Committee: BC Ministry of Health, Provincial Health Services Authority (PHSA), Childhood Obesity Foundation, University of Victoria
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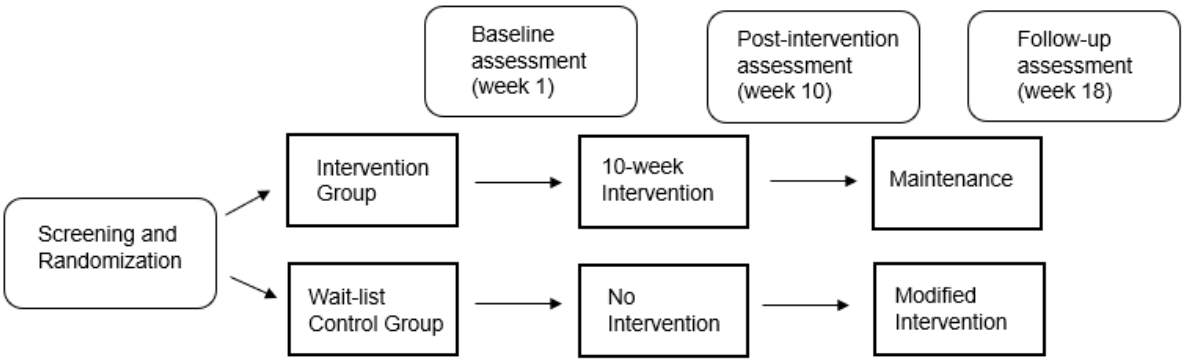
<Figure 1>: EIP Intervention and Assessment Description.



Reporting checklist for protocol of a clinical trial.

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		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	1
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 18
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	19

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2,3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4,5
Objectives	#7	Specific objectives or hypotheses	3
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4,5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-8

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	4,5
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	4
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	5,6
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	4
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	4,5

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	4,5
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	4,5
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-12
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset,	9

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

Family-based, Healthy Living Intervention for Children with Overweight and Obesity and their Families: a 'real world' feasibility trial protocol using a randomized wait-list control design

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Family-based, Healthy Living Intervention for Children with Overweight and Obesity and their Families: a 'real world' feasibility trial protocol using a randomized wait list control design

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ABSTRACT

Introduction: Family-based behavioral weight management interventions are efficacious and widely used to address childhood obesity. Curriculum and strategies vary extensively and scale-up often depends on ensuring that the intervention fits the adoption context. **Aims and Objectives**: To evaluate the impact and implementation of a "made in British Columbia" (BC) family-based early intervention program (EIP) for 8 – 12 year olds with overweight and obesity and their families. **Methods and analysis:** A randomized waitlist-control trial will assess a 10-week interactive, family-based lifestyle intervention followed by four maintenance sessions, in BC, Canada, from October 2018 to March 2019. We aim to enroll 105 families. The blended intervention includes at least 26 contact hours between participants and program providers, including interactive activities and educational materials through weekly 90-minute group sessions, an online family portal, and self-directed family activities. Curricular content includes information and activities related to healthy eating, physical activity, positive mental health, parenting practices, and sleep hygiene. The waitlist control group will receive a modified program with the same 10-weekly sessions in the family portal, and four group sessions. Families participate in data collection at baseline, post-intervention (week 10), and follow-up (week 18). The primary outcome is to assess changes in child BMI at 10-week between the groups. Secondary outcomes include changes at 10-week between the groups in child and parent physical activity behaviour and skills, healthy eating behaviour, and mental health. Process evaluation will address reach, implementation, and maintenance (baseline, 10- and18-week) using recruitment tracking forms, parent questionnaire, program attendance tracking forms, leader feedback surveys, parents and children satisfaction surveys and post-program interviews with facilitators, stakeholders, and parents. Intention-to-treat analyses will be conducted. Process evaluation will be analyzed thematically. **Ethics and dissemination:** Study procedures were designed to address research and community needs and will follow ethical standards.
NCT03643341, v2, 10/04/2018

Key words: Family-based, Behavioural weight-management, Childhood obesity

ARTICLE SUMMARY

Strengths and limitations of this study

- The randomized wait-list control design is a strong and ethical design
- Intervention informed by best available evidence and community stakeholders
- Innovative components include positive mental health and blended in-person/online delivery
- Participant enrollment and drop-out are challenges that can increase selection and attrition bias, respectively

INTRODUCTION

Obesity is one of the most common pediatric health problems[1] and has been linked to multiple physiological and psychosocial problems throughout childhood[2]. Over 25% of the children are either overweight or obese in British Columbia (BC), Canada. There is also a significant disparity in the prevalence of overweight and obesity across population groups (e.g. Indigenous children and those in the lowest income bracket)[3,4]. Without intervention, overweight children will likely continue to be overweight during adolescence and adulthood[5,6].

Family-based behavioral weight management interventions are a main approach for achieving weight control in children and adolescents[7]. Encouraging the whole family to make behavioral changes decreases the focus being placed solely on children's dietary and activity behaviors[8] and also focuses on providing a supportive environment for making lifestyle modifications in the home setting. Several randomized controlled trials have shown that family-focused behavioural programs delivered in-person can be effective strategies to manage childhood obesity[9–13]. Although these intervention programs can be effective in managing childhood obesity, the delivery methods must be scalable to enhance public health impact[14–16]. Unfortunately, in-person family-focused childhood weight management programs have limited reach (e.g. only available at specific locations) and are resource intensive (e.g. programs require significant human input)[15,16]. Consequently, there is an urgent need to develop innovative solutions to improve the scalability of these childhood obesity management programs to enhance public health impact.

With the advancement in Internet-enabled digital devices (e.g. smartphones, tablets, computers, wearables) and improved access to the Internet, there is emerging evidence these innovative digital technologies can help improve the scalability of in-person family-based childhood obesity management programs without overtaxing health care resources[14,17]**.** There are currently two main methods of using the Internet to deliver family-based health childhood

obesity management interventions: 1) a stand-alone Internet-based program, and 2) a blended intervention Internet and face-to-face program[18,19].

Stand-alone Internet-based interventions can be advantageous to administer over long distances, allow families to work at their own pace, save travelling time, and reduce the stigma of going to a childhood obesity management program. However, families may feel a lack of support compared with face-to-face programs[18]. Attrition with such programs is often a concern for stand-alone Internet-based programs[20]. By contrast, *a blended face-to-face and Internet-based program* can retain the positive aspects associated with both forms of therapy while mitigating the disadvantages. Adding Internet interventions might improve adherence to behaviour change as Internet, or mobile elements could be used to support behaviour change during face-to-face sessions and thereby increase the effectiveness of face-to-face intervention[18,19]. Currently, there is inadequate data to determine the efficacy blended Internet-based interventions aimed to manage childhood obesity by targeting the entire family[16]. Thus, it is critical to evaluate these approaches and understand how these modes of delivery can complement each other in a "real-world" setting.

The proposed research provides the opportunity to examine the feasibility of a blended (in-person and web-based), "made in B.C", Family Healthy Living Early Intervention Program (EIP) in managing obesity (BMI ≥ 85th percentile for age and sex) in children 8-12 years of age. EIP was developed to enhance implementation using an extensive needs assessment and stakeholder engagement process with over 300 stakeholders across the province who provided input based on their current clinical and professional practice and experience. EIP was designed to 1) align with existing evidence and theory-based (Multi-process action [M-PAC] framework) practices in the clinical and public health setting (e.g. a minimum of 26 hours of contact time, family involvement, physical activity, healthy living, sleep, mental health); 2) complement existing childhood obesity management programs in B.C. (HealthLink BC Eating and Activity Program for Kids: telephone-based support program for overweight children, Shapedown: a

community based designed for children with BMI ≥ 97th percentile for age and sex); 3) meet the needs of B.C. families and communities, by making the program accessible to diverse families (e.g. indigenous, multi-cultural or intercultural backgrounds, lower-income, single-parent). 4) address existing gaps documented in family-focused intervention literature (e.g. address lifestyle without focusing on weight, incorporate extensive mental health and resilience-based activities for families, trauma-informed practice training for leaders, blended delivery models)[21,22]. 5) incorporate the latest internet-based features (e.g. wearable data integration, interactive quizzes, reminders and notifications, online discussion forum). Stakeholder's input also emphasized the importance of: compatibility with existing resources, flexibility to adapt for different communities, a focus on healthy lifestyles rather than weight, one face-to-face contact per week to reduce family and community burden and enhance relative advantage.

The purpose of the proposed feasibility trial is to examine the efficacy of the experimental intervention vs wait-list control group on health and behaviour outcomes over a 10-week period. The primary outcome is to asses changes in child BMI. Secondary outcomes include changes in child fundamental movement skills; physical activity (PA) engagement, predilection, adequacy, intrinsic motivation, competence, confidence; sedentary habits and screen time, confidence, and family support; self-esteem, gratitude, self-compassion, and sleep. Also changes in dietary behaviors, healthy eating outcome expectation, motivation, self-efficacy, and perceived cooking skills will be assessed. Parent outcomes assessed include PA support, habit, and identity; changes in parent feeding practices, structure of the home food environment, parents' personal dietary behaviors, food preparation self-efficacy, habit and identity. Our primary hypothesis is that children participating in the EIP will maintain or reduce their BMI after 10 weeks, compared to those in the waitlist control group. Our secondary hypotheses are that EIP participants (parents and children) will make more positive lifestyle changes in PA and healthy eating, as well as parenting practices and mental health, after 10 weeks, relative to the

waitlist participants. We also hypothesize that the EIP will reach a broad demographic, and families and staff will be satisfied with the EIP.

METHODS AND ANALYSIS

The SPIRIT reporting guidelines was used to report the study protocol[23].

Study Design

A randomized waitlist-controlled trial will assess the 10-week interactive family-based lifestyle intervention followed by 4 maintenance sessions (Figure 1), in BC, Canada, from October 2018 to March 2019. The intervention includes at least 26 contact hours between participants and program providers, including interactive activities and educational materials through weekly 90-minute group sessions, an online family portal, and self-directed family activities.

We will aim to enroll 105 parent-child dyads. The sample size estimation was based on the meta-analysis[24] that evaluated the efficacy of randomized controlled trials of family-based intervention to reduce BMI. A significant mean effect size of −0.62 (95% CI = −0.80 to −0.44) was found for the family-behavioral treatments. Based on 2:1 randomization, and anticipating 20% drop out, the estimated sample for the intervention group is n=70 and the waitlist control group is n=35 (using a two-parallel group design, type 1 error=5% and power=80%). Randomization will be blocked (random permuted block design) within each of our six recruitment across BC representing all 5 health authority regions: Prince George (YMCA of Northern BC); Kelowna (YMCA of the Okanagan); Surrey (Tong Louie YMCA); Surrey (City of Surrey); Burnaby (City of Burnaby); Greater Victoria (Westshore Recreation and Parks Society) to ensure overall balance (2:1) in the number of participants assigned to the two groups. Randomization will be conducted by an independent researcher. The randomisation code will be hidden from research assistants during assessments and data processing of the primary and

secondary outcomes. In this pilot study, an allocation of 2:1 in favor of the intervention group will be used because of the availability of resources and the minimal number of participants required to carry out an intervention at each site. Blinding families is not possible as intervention and waitlist program start dates are different. Blinding the research team is also not possible due to real world constraints on scheduling whereby the measurement will be scheduled during scheduled group time and waitlisted families are scheduled at a further time. Thus, this is one of the study limitations. In order to minimize the chance of group contamination, participants will be instructed to not discuss details of their treatment with others outside the study. All participants' identifiers will be removed during data analyses.

<Figure 1>: Overview of the EIP study design.

Inclusion/Exclusion Criteria

Participants will be children aged 8 to 12 years old, with a BMI ≥85th percentile for age and sex[25], accompanied by a parent, family member, or legal guardian. At least one member of the family will have to be able to speak and read English, and families will have to agree to attend group meetings over 10 weeks. Families will be excluded if medical clearance was needed and not obtained, and if the child has a BMI <85th percentile.

Waitlist Control Group

An ethical imperative for any study of a family-based obesity early intervention program is to ensure that the control arm receives essential information about preventive guidelines for childhood obesity management. Thus, the waitlist control group will have access to a modified program at week-10: four group sessions and full access to the 10-week online family portal after the study is completed.

Recruitment

Participants will be recruited using: Active Living Guide inserts; school newsletter inserts; local newspaper advertisements and interviews; mailed packages to physician offices, community health centers, diabetes clinics, allied health professionals; letters and email blasts to Provincial networks and organizations; posters and rack cards displayed in recreation centers, public community spaces, medical offices and schools; a customized website; social media domains such as Facebook, Instagram, and Twitter; webinars; booths at events and summer camps; and using local radio. Parents may contact the study team directly about enrollment via the study website, email or phone call. Also, parents who express interest will be asked to provide their name and contact details to the recreation center staff and will receive a follow up email or phone call delivering more information about program eligibility and enrollment. Parents will be asked to confirm their participation in the program within a week from completing the screening call. Next, parents will be asked to sign consent forms and children will sign the child assent form, confirming that they have discussed the intervention with their parents and understand the program's requirements.

Intervention: Early Intervention Program

The EIP design represents a community-based delivery model and was designed based on a systematic review of the literature[26,27], based on findings from previous implementation efforts[28,29] in British Columbia and extensive community stakeholder consultations across five health regions (more than 300 stakeholders). The EIP development was guided theoretically by the M-PAC framework[30,31] that emphasizes social cognitive approaches to intention formation, adoption of action control through self-regulation and the action control maintenance phase once a behavior becomes habitual and self-identified. Intervention activities were designed to support children and parents in learning behavioral change skills that will enable them to improve their health-related lifestyle behaviors. The M-PAC constructs are reflected in the EIP's

curriculum to introduce and direct participants in making long-term lifestyle behavior changes. The M-PAC establishes seven constructs that are antecedent of behaviours: (a) instrumental attitude as the knowledge on health consequences, (b) affective judgement relating to intrinsic motivation, (c) perceived capability relating to self-efficacy, (d) perceived opportunity relating to perceptions of the social and physical environment (time and access), (e) behavioral regulation relating to tactics that people use to translate their intentions into behavior (e.g., goal setting, self-monitoring), (f) identity as a standard of conscious self-comparison, and (g) habit as a stimulus-enacted behavioural response under lowered conscious awareness. A recent review of 23 studies that have applied M-PAC provided general support of its tenets and strong support for the multivariate associations between these antecedents and behaviour[32]

Following the systematic review evidence, the 10-week intervention includes at least 26 contact hours[33] between participants and intervention activities and materials through in-person and online activities. Group sessions will be held once a week for 90 minutes and they include family PA, children-only PA aiming at improving enjoyment, confidence, motivation and fundamental movement skills (FMS), and parent-only group discussion to identify barriers and strategies for promoting family healthy behaviours. Additional hours will be obtained via the online family portal.

Curriculum

The intervention targets lifestyle changes in both children and their parents in regards to promoting healthy eating, reduction of sugary drink consumption, increasing cooking self-efficacy, engaging in family PA, reduction of recreational screen time and sedentary behaviour, improved sleep hygiene, positive mental health, self-esteem, gratitude, and self-compassion. The weekly topics covered are listed in Table 1. Behaviour change techniques used in the program include goal setting, self-monitoring, self-evaluation, communication and interpersonal skills. The EIP will also provide four extra community-based group sessions. Two of these extra

sessions will be a session in a local park using the Agents of Discovery mobile application, which is an augmented reality mobile application designed to encourage families to engage in outdoor exploration, and a group grocery store tour led by a registered dietitian. The remaining two group activities will be chosen and scheduled by the facilitators based on group input. Researchers designing the EIP intend to create a flexible community-based family-intervention program able to accommodate families' demanding schedules.

Online Family Portal

The EIP online family portal will be considered as a weekly lesson to be completed by families. Lessons in the portal will offer additional resource information, healthy recipes, parent articles, videos, and suggested healthy eating and physical activities so that families engage in an extra 60 minutes per week of self-directed healthy lifestyle activities to promote healthy living. The online family portal will also be a repository of materials covered in each session, such as weekly handouts and worksheets. The portal will provide families with i) a step tracking tool (e.g. steps, active minutes, diet), ii) an interactive map of healthy places in their communities on, iii) online weekly quizzes to help families assess and strengthen their self-guided learning, iv) a secure online diary to allow families to reflect on their progress and set new weekly goals, and v) proactive online messages to notify families about new content, login and survey assessments.

Maintenance sessions

The intervention group will receive four one-hour, biweekly maintenance sessions, after the 10-week program. Sessions will include 30 minutes of discussion on maintaining healthy lifestyle, and 30 minutes of family PA.

Table 1: Weekly topics covered in the family-based early intervention program (EIP)

Weeks	Topics
1	Healthy Living Workshop • Family Activities: Guide to Healthy Food Choices and the Canadian 24-hour Movement Guidelines • Children specific activities: Healthy Living Stations
2	Introduction to Healthy Eating & Active Living • Family activities: Intercultural Ice Breaker Games, Benefits of Physical Activity • Children specific activities: Fundamental Movement Skills
3	Setting Family Healthy Living SMART Goals • Family activities: Setting SMART goals • Children specific activities: Fun Small Group Physical Activity Games
4	Your Guide to Healthy Food Choices • Family activities: Grocery store tour, Eat Using the Plate Model, BC Grown Vegetables and Fruit, Focus on Food Groups • Children specific activities: Fun Small Group Physical Activity Games
5	Body Self-Compassion, Appreciation& Active Living for EveryBODY • Family activities: Bullying Prevention Tip Sheet for Parents • Children specific activities: Get Moving Stations
6	Creating Positive Healthy Family Mealtime& Physical Activity Experiences • Family activities: Bullying Prevention Tip Sheet for Parents, Health for EveryBODY, Hunger Scale and Mindful Eating Strategies, Listen to Your Body's Hunger & Fullness Signals, Meal Ideas for Everyone • Children specific activities: Fitness Scavenger Hunt, Smart Talk About Mindful Eating
7	Family, Food Culture & Getting Active Outdoors • Family activities: Removing Barriers to Physical Activity • Children specific activities: Playground Games
8	Positive Parenting, Sleep Hygiene & Brainiacs • Family activities: Live 5-2-1-0+ lifestyle • Children a Brainiac & Sport Skill Stations
9	Cooking & Playing Together • Family activities: Getting Kids in the Kitchen • Children specific activities: Ancient & Indigenous Games
10	Continuing Positive Change, Dance & Celebration • Family & children activities: Strategies to maintain healthy lifestyle behaviours

Data Collection Protocol

Child and parent outcome measures will be collected at baseline, after the intervention (week 10). Process evaluation metrics such as family satisfaction, issues, facilitators and barriers to attendance and maintenance will be collected during and after the intervention (at 10 and 18 weeks). Parent questionnaires will be sent online prior to the intervention start. After screening for eligibility, both intervention and wait-list control group parents will receive an email containing instructions followed by a link for completing the online parent questionnaire.

Data from intervention and waitlist control children will be collected at the Healthy Living Workshop, an interactive and fun 'health fair style' measurement approach that rotates between stations such as nutrition and PA games interspersed among questionnaire stations, FMS assessment, and BMI. All parents will be invited to attend a Healthy Living Workshop session while children participate in the health fair. The measurement team will follow up with families who do not attend the measurement session. Program facilitators will follow up with families who do not come to the intervention. Data will be entered within two weeks of data collection. De-identified data will be securely stored at the University of Victoria server. Processes to promote data quality include double data entry; range checks for data values. Co-investigators will have access to de-identified final trial dataset.

Outcome Measures

Child Measures:

- BMI will be calculated as weight (kilograms) divided by height (meters) squared, adjusted for child age and sex Weight to the nearest 0.1 kg and height to the nearest 0.1 cm will be obtained. BMI z-scores (standard deviation) will be calculated based on the Centers for Disease Control and Prevention (CDC) criteria[25].

- *FMS* will be assessed using the validated Canadian Agility and Movement Skill Assessment that evaluates seven skills: two-foot jumping, sliding, catch, throw, skip, one-foot hop, and kick[34]. Children will observe two demonstrations, will complete two practice trials, and two timed and scored trials.
- *Physical activity levels will be measured using the* Physical Activity Questionnaire for Children (PAQ-C)[35].
- *Sedentary behaviours* will be assessed using the Physician-based Assessment & Counseling for Exercise (PACE) Adolescent Psychosocial Measures[36].
- *Perceived PA intrinsic motivation and competence* will be measured by the Motivation and Confidence subscale of the Canadian Assessment of Physical Literacy[34];
- *Dietary behaviours* will be measured using the 7-day recall questionnaire retrieved from the Behavioral Risk Factor Surveillance System Survey Questionnaire[37],
- Healthy eating outcome expectations and self-efficacy will be assessed using the Power Play! Survey [38], and the Physician-based Assessment & Counseling for Exercise (PACE) Adolescent Psychosocial Measures[39], respectively.
- *Healthy eating motivation* will be assessed by the FLASHE questionnaire[40,41],
- *Perceived cooking skills* will be assessed by the Cooking with Kids questionnaire[42].
- *Quality of life* will be assessed using the Pediatric Quality of Life Inventory[43].
- *Self-compassion, gratitude, self-esteem* will be assessed using the Self-compassion Scale Short Form[44], the FLASHE questionnaire[40], subscales of the Project EAT survey[45], and the Gratitude Adjective Checklist[46].

Parent Measures

- Parent's physical activity and dietary behaviours will be assessed by subscales drawn from the FLASHES-EAT surveys[47] and the Action Control of Parent Support Behaviour[48].

- Structure of the home food environment will be assessed by the Fruit and Vegetable At Home Survey for Parents[49];
- Parent PA and dietary support and behavioral regulation of supporting child's PA will be measured using the Parent Support of Child Physical Activity questionnaire[48 50];
- PA and dietary habit will be assessed by the automaticity subscale of the Self-Report Index of Habit[51];
- PA and dietary identity will be assessed by the Role-Identity subscale from the Exercise Identity Scale[52,53].

Process Evaluation

The EIP will be assessed using Process Evaluation components identified by Linnan & Steckler[54]; and components of the RE-AIM framework[55], specifically the Reach, Efficacy, Implementation, and Maintenance components (See Table 2).

Table 2: Summary of the Process Evaluation

Component	Definition	Assessment
Reach	Effectiveness of marketing strategies, recruitment, the extent that the intervention is reaching intended populations, and adherence and attrition rates.	• Site-specific recruitment plans, recruitment tracking forms, screening and phone calls tracking, demographic questionnaires, and program attendance tracking forms.
Efficacy	The impact of the EIP intervention on family's health and well-being outcomes	• Child's Measures: BMI, FMS, Physical activity levels, sedentary behaviours, Intrinsic motivation and self-efficacy for PA and dietary behaviours, Quality of Life, Self-compassion, gratitude, self-esteem. • Parent's Measures: Physical activity and dietary behaviours, Structure of the home food environment, parent support for the child's PA and dietary

		behaviours, home food environment, habit and identity for PA and dietary behaviours
Implementation	EIP program satisfaction, program fidelity, attendance, barriers to program participation.	• Screening tracking form, facilitators pre- and post-workshop surveys, program attendance tracking forms, facilitator feedback surveys, parents and children satisfaction surveys and post-program interviews with parents, facilitators, and stakeholders.
Maintenance	Conditions needed for successful long-term implementation of the EIP	• Maintenance will be assessed using stakeholders and advisory committee interviews.

Reach assesses the effectiveness of marketing strategies, the effectiveness of program processes in generating appropriate referrals to the intervention, the extent that the intervention is reaching intended populations, and adherence and attrition rates. Reach will be assessed using site-specific recruitment plans, recruitment tracking forms, screening and phone calls tracking, demographic questionnaires, and program attendance tracking forms. Program coordinators for each community will record site-specific recruitment plans. Recruitment plans will outline and track all recruitment efforts undertaken at a local level. Centralized recruitment efforts will be tracked using a recruitment tracking form that will record all public inquiries including phone calls, emails, and social media interactions. Information recorded will include name, community, contact information, date and form of contact, how they heard about the program, any follow-up communication, and the outcome of the inquiry. The screening call tracking will record the individual's reasons for interest, ability to commit, and eligibility. Demographic questionnaires will be completed by parents or caregivers to determine participants' cultural backgrounds, gender, age, and household make-up, income levels, education levels, and employment status. Program attendance tracking forms will be completed

by the program facilitators throughout the duration of the program. Attendance trackers will track weekly participant attendance, reasons for missed sessions, and participant drop-out.

Implementation addresses if families, staff, and stakeholders are satisfied with the EIP, implementation fidelity, facilitators and barriers to participate in the program, attendance, program delivery team perceptions of parent benefits and satisfaction, and negative outcome tracking. Implementation will be assessed using screening tracking form, facilitators pre- and post-workshop surveys, program attendance tracking forms, facilitator feedback surveys, parents and children satisfaction surveys and post-program interviews with parents, facilitators, and stakeholders. The screening tracking form will identify potential facilitators and barriers to participate in the program. Program facilitators will complete a workshop survey before and after a three-day training workshop that will assess facilitator's knowledge and confidence with implementing the program curriculum and the effectiveness of the training workshop in these regards. Program attendance tracking forms will record participant attendance and reasons for drop-out, including possible barriers to attendance and completion of the program. Weekly facilitator feedback surveys will evaluate the successes and challenges of the weekly in-class sessions, as well as the facilitator's delivery of components of the session: PA, healthy eating, and positive mental health components. Parent and child satisfaction surveys will be completed at the end of the 10-week program and will assess participant satisfaction with the program curriculum and delivery. Parents will be asked to participate in post-program phone interviews in order to gain a deeper understanding of their perceptions and experiences with the EIP.

Program coordinators and facilitators from each site will also be asked to take part in post-program interviews to explore their perceptions of the success and challenges of the program delivery and the effectiveness of the facilitator training workshop for providing them with the knowledge and tools needed to deliver the content. Focus groups with the facilitation teams and program coordinators will be completed in-person immediately following the last session of the EIP program, or via phone call the week following the completion of the program.

Provincial stakeholder interviews will be held in person or by phone and will be scheduled at the earliest available date following the completion of the program, and will be conducted by the EIP project coordinator.

Maintenance evaluates the conditions needed for successful long-term implementation of the EIP by assessing stakeholder support and integration and alignment with British Columbia's Continuum for the Prevention, Management, and Treatment of Health Issues Related to Overweight and Obesity in Children and Youth[56]. Maintenance will be assessed using stakeholders and advisory committee interviews. Stakeholder and advisory committee interviews will be conducted by the EIP project coordinator. Interviews will be held in person or by phone and will be scheduled at the earliest available date following the completion of the program.

Patient and Public Involvement

The EIP was designed based on previous childhood obesity weight management in BC and accounted for participants' feedback. Community stakeholders were actively involved in the study design. The EIP was pre-piloted in the Spring 2018 and participants' feedback on recruitment, burden of the intervention and measurement were taking into consideration for the full trial.

Data Analysis

We will analyze our outcomes using an intention-to-treat approach. We will use descriptive to evaluate our primary and secondary outcomes at baseline. We will evaluate patterns of missing data in the treatment groups and we will perform multiple imputation to address missing data if data are missing at random. The distributions of the continuous variables will be evaluated and we will apply a suitable transformation if the distribution is significantly skewed. For our primary outcome (BMI), the difference among groups at 10-week

will be evaluated using a univariate linear regression adjusted for baseline outcome measures (e.g. BMI at baseline), social-economic status and recruitment sites. Secondary outcomes (FMS, physical activity levels, perceived PA intrinsic motivation and competence, dietary, healthy eating motivation, perceived cooking, quality of life self-compassion, gratitude, self-esteem, parent's PA and dietary behaviours and behavioral regulation of supporting child's PA, PA and dietary habit) will follow a similar statistical approach as the primary outcome analysis. Statistical significance criterion of will defined as $p<0.05$. Process evaluation data will be described using descriptive statistics and thematic analysis will be done by two independent coders to identify, analyze, and report themes[57]. Coders will read the transcripts, identify possible themes, draft and compare the codebook, discuss potential themes, and draft the first official version of the codebook. Then, coders will code all the transcripts, discuss and develop version two of the codebook. A third researcher will be consulted if agreements cannot be reached. Finally, we will evaluate program adherence as part of the process evaluation. We will be conducting a `per protocol' analysis including only intervention participant to evaluate adherence (number of in-class and online sessions completed) during intervention and maintenance period.

ETHICS AND DISSEMINATION

All participants will provide electronic and written consent. Children will provide written assent. Ethics was obtained from the University of Victoria Ethics Review Board prior to participant recruitment. Amendments to the protocol will be submitted to the University of Victoria Ethics Review Board and the Clinical Trials registration will be updated as needed.

International recommendations agree that the core elements of any intervention to address childhood obesity should involve the whole family and include nutrition education, behaviour modification, and promotion of PA. Recent randomized controlled trials found family-

based behavioural programs that targeted families with obese 8-to 12-year olds showed positive outcomes in both short-term (10-weeks) and long-term (12 months) interventions[26].

The Province of British Columbia Ministry of Health has provided funding to the Childhood Obesity Foundation to design and implement a “made in BC” community-based Childhood Healthy Weights Early Intervention Program for children 8-12 years old. The EIP was developed following essential processes for scalability[58]: it was based on the current family-based childhood obesity management literature[26,27], based on lessons learned from previous programs conducted in the province[28], it was overseen by a stakeholder Steering Advisory Committee and based on an extensive regional stakeholder consultation and needs assessment process. The program will also include innovative topics on sleep hygiene and screen use as a holistic way to promote healthy lifestyles as well as a novel blended (Internet-based and in-person) delivery approach. The EIP was designed using a new meta-theoretical (M-PAC)[30].

We anticipate that findings from the trial will have high impact, given our collaboration with the Childhood Obesity Foundation and the structure of the initiative and its development. Additionally, while the pilot is running there will be a Sustainability sub-committee that is addressing systems of program integration and client triage. Advancements achieved with this study, concerning the content and methodology of family-based obesity programs, if effective and feasible will likely be widely disseminated in BC dependent on ongoing funding.

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AUTHOR STATEMENT

PJN and KS conceived the study. PJN, KS, SL, JW, GDCB, RER, TH and LCM contributed to the study design. SL, PJN, IGM, MAP drafted and revised the manuscript. All authors edited and approved the final manuscript.

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COMPETING INTERESTS

Dr. Naylor is on the Board of Childhood Obesity Foundation and had course release to oversee the implementation of the evaluation of the EIP. Dr. Naylor reports grants from Childhood Obesity Foundation, during the conduct of the study.
Dr. Strange, Dr. Marques, Ms. Hartrick, Ms. Weismiller, and Ms. Perdew report personal fees from Childhood Obesity Foundation, during the conduct of the study.

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Management committee: Childhood Obesity Foundation, University of Victoria, Juniper Consulting.
Oversight Committee: BC Ministry of Health, Provincial Health Services Authority (PHSA), Childhood Obesity Foundation, University of Victoria
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<Figure 1>: Overview of the EIP study design.

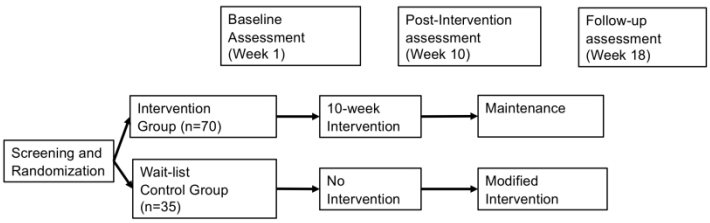

Figure 1: Overview of the EIP study design.

279x215mm (300 x 300 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	1
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 18
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	19

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2,3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4,5
Objectives	#7	Specific objectives or hypotheses	3
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4,5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-8

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	4,5
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	4
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	5,6
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	4
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	4,5

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	4,5
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	4,5
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-12
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset,	9

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

BMJ Open

Family-based, Healthy Living Intervention for Children with Overweight and Obesity and their Families: a 'real world' trial protocol using a randomized wait list control design

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Family-based, Healthy Living Intervention for Children with Overweight and Obesity and their Families: a 'real world' trial protocol using a randomized wait list control design

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ABSTRACT

Introduction: Family-based behavioral weight management interventions are efficacious and widely used to address childhood obesity. Curriculum and strategies vary extensively and scale-up often depends on ensuring that the intervention fits the adoption context. **Aims and Objectives**: To evaluate the impact and implementation of a "made in British Columbia" (BC) family-based early intervention program (EIP) for 8 – 12 year olds with overweight and obesity and their families. **Methods and analysis:** A randomized waitlist-control trial will assess a 10-week interactive, family-based lifestyle intervention followed by four maintenance sessions, in BC, Canada. We aim to enroll 186 families. The blended intervention includes at least 26 contact hours between participants and program providers, including interactive activities and educational materials through weekly 90-minute group sessions, an online family portal, and self-directed family activities. Curricular content includes information and activities related to healthy eating, physical activity, positive mental health, parenting practices, and sleep hygiene. The waitlist control group will receive a modified program with the same 10-weekly sessions in the family portal, and four group sessions. Families participate in data collection at baseline, post-intervention (week 10), and follow-up (week 18). The primary outcome is to assess changes in child BMI z-score at 10-week between the groups. Secondary outcomes include changes at 10-week between the groups in child and parent physical activity behaviour and skills, healthy eating behaviour, and mental health. Process evaluation will address reach, implementation, and maintenance (baseline, 10- and18-week) using recruitment tracking forms, parent questionnaire, program attendance tracking forms, leader feedback surveys, parents and children satisfaction surveys and post-program interviews with facilitators, stakeholders, and parents. Intention-to-treat analyses will be conducted. Process evaluation will be analyzed thematically. **Ethics and dissemination:** Study procedures were designed to address research and community needs and will follow ethical standards.
NCT03643341, v2, 10/04/2018

Key words: Family-based, Behavioural weight-management, Childhood obesity

ARTICLE SUMMARY

Strengths and limitations of this study

- The randomized wait-list control design is a strong and ethical design
- Intervention informed by best available evidence and community stakeholders
- Innovative components include positive mental health and blended in-person/online delivery
- Participant enrollment and drop-out are challenges that can increase selection and attrition bias, respectively

INTRODUCTION

Obesity is one of the most common pediatric health problems[1] and has been linked to multiple physiological and psychosocial problems throughout childhood[2]. Over 25% of the children are either overweight or obese in British Columbia (BC), Canada. There is also a significant disparity in the prevalence of overweight and obesity across population groups (e.g. Indigenous children and those in the lowest income bracket)[3,4]. Without intervention, overweight children will likely continue to be overweight during adolescence and adulthood[5,6].

Family-based behavioral weight management interventions are a main approach for achieving weight control in children and adolescents[7]. Encouraging the whole family to make behavioral changes decreases the focus being placed solely on children's dietary and activity behaviors[8] and also focuses on providing a supportive environment for making lifestyle modifications in the home setting. Several randomized controlled trials have shown that family-focused behavioural programs delivered in-person can be effective strategies to manage childhood obesity[9–13]. Although these intervention programs can be effective in managing childhood obesity, the delivery methods must be scalable to enhance public health impact[14–16]. Unfortunately, in-person family-focused childhood weight management programs have limited reach (e.g. only available at specific locations) and are resource intensive (e.g. programs require significant human input)[15,16]. Consequently, there is an urgent need to develop innovative solutions to improve the scalability of these childhood obesity management programs to enhance public health impact.

With the advancement in Internet-enabled digital devices (e.g. smartphones, tablets, computers, wearables) and improved access to the Internet, there is emerging evidence these innovative digital technologies can help improve the scalability of in-person family-based childhood obesity management programs without overtaxing health care resources[14,17]**.** There are currently two main methods of using the Internet to deliver family-based health childhood obesity management interventions: 1) a stand-alone Internet-based program, and 2) a blended intervention Internet and face-to-face program[18,19].

Stand-alone Internet-based interventions can be advantageous to administer over long distances, allow families to work at their own pace, save travelling time, and reduce the stigma of going to a childhood obesity management program. However, families may feel a lack of support compared with face-to-face programs[18]. Attrition with such programs is often a concern for stand-alone Internet-based programs[20]. By contrast, *a blended face-to-face and Internet-based program* can retain the positive aspects associated with both forms of therapy while mitigating the disadvantages. Adding Internet interventions might improve adherence to behaviour change as Internet, or mobile elements could be used to support behaviour change during face-to-face sessions and thereby increase the effectiveness of face-to-face intervention[18,19]. Currently, there is inadequate data to determine the efficacy blended Internet-based interventions aimed to manage childhood obesity by targeting the entire family[16]. Thus, it is critical to evaluate these approaches and understand how these modes of delivery can complement each other in a "real-world" setting.

The proposed research provides the opportunity to examine the efficacy of a blended (in-person and web-based), "made in B.C", Family Healthy Living Early Intervention Program (EIP) in managing obesity (BMI ≥ 85th percentile for age and sex) in children 8-12 years of age. EIP was developed to enhance implementation using an extensive needs assessment and stakeholder engagement process with over 300 stakeholders across the province who provided input based on their current clinical and professional practice and experience. EIP was designed to 1) align with existing evidence and theory-based (Multi-process action [M-PAC] framework) practices in the clinical and public health setting (e.g. a minimum of 26 hours of contact time, family involvement, physical activity, healthy living, sleep, mental health); 2) complement existing childhood obesity management programs in B.C. (HealthLink BC Eating and Activity Program for Kids: telephone-based support program for overweight children, Shapedown: a community based designed for children with BMI ≥ 97th percentile for age and sex); 3) meet the needs of B.C. families and communities, by making the program accessible to diverse families

(e.g. indigenous, multi-cultural or intercultural backgrounds, lower-income, single-parent). 4) address existing gaps documented in family-focused intervention literature (e.g. address lifestyle without focusing on weight, incorporate extensive mental health and resilience-based activities for families, trauma-informed practice training for leaders, blended delivery models)[21,22]. 5) incorporate the latest internet-based features (e.g. wearable data integration, interactive quizzes, reminders and notifications, online discussion forum). Stakeholder's input also emphasized the importance of: compatibility with existing resources, flexibility to adapt for different communities, a focus on healthy lifestyles rather than weight, one face-to-face contact per week to reduce family and community burden and enhance relative advantage.

The purpose of the proposed trial is to examine the efficacy of the experimental intervention vs wait-list control group on health and behaviour outcomes over a 10-week period. The primary outcome is to asses changes in child BMI z-score. Secondary outcomes include changes in child fundamental movement skills; physical activity (PA) engagement, predilection, adequacy, intrinsic motivation, competence, confidence; sedentary habits and screen time, confidence, and family support; self-esteem, gratitude, self-compassion, and sleep. Also changes in dietary behaviors, healthy eating outcome expectation, motivation, self-efficacy, and perceived cooking skills will be assessed. Parent outcomes assessed include PA support, habit, and identity; changes in parent feeding practices, structure of the home food environment, parents' personal dietary behaviors, food preparation self-efficacy, habit and identity. Our primary hypothesis is that children participating in the EIP will maintain or reduce their BMI z-score after 10 weeks, compared to those in the waitlist control group. Our secondary hypotheses are that EIP participants (parents and children) will make more positive lifestyle changes in PA and healthy eating, as well as parenting practices and mental health, after 10 weeks, relative to the waitlist participants. We also hypothesize that the EIP will reach a broad demographic, and families and staff will be satisfied with the EIP.

METHODS AND ANALYSIS

The SPIRIT reporting guidelines was used to report the study protocol[23].

Study Design

A randomized waitlist-controlled trial will assess the 10-week interactive family-based lifestyle intervention followed by 4 maintenance sessions (Figure 1), in BC, Canada, from October 2018 to Sept 2020. The intervention includes at least 26 contact hours between participants and program providers, including interactive activities and educational materials through weekly 90-minute group sessions, an online family portal, and self-directed family activities.

The parameters used for sample size calculation was based on the results of a published randomized controlled trial evaluating the efficacy of a family-based intervention to reduce BMI z-score relative to control[9]. Based on 2:1 randomization, and anticipating 20% drop out, the estimated sample for the intervention group is n=124 and the waitlist control group is n=64 (using a two-parallel group design, type 1 error=5% and power=80%). Randomization will be blocked (random permuted block design) within each of our six recruitment across BC representing all 5 health authority regions: Prince George (YMCA of Northern BC); Kelowna (YMCA of the Okanagan); Surrey (Tong Louie YMCA); Surrey (City of Surrey); Burnaby (City of Burnaby); Greater Victoria (Westshore Recreation and Parks Society) to ensure overall balance (2:1) in the number of participants assigned to the two groups. Randomization will be conducted by an independent researcher. The randomisation code will be hidden from research assistants during assessments and data processing of the primary and secondary outcomes. In this study, an allocation of 2:1 in favor of the intervention group will be used because of the availability of resources and the minimal number of participants required to carry out an intervention at each site. Blinding families is not possible as intervention and waitlist program start dates are different. Blinding the research team is also not possible due to real world constraints on

scheduling whereby the measurement will be scheduled during scheduled group time and waitlisted families are scheduled at a further time. Thus, this is one of the study limitations. In order to minimize the chance of group contamination, participants will be instructed to not discuss details of their treatment with others outside the study. All participants' identifiers will be removed during data analyses.

<Figure 1>: Overview of the EIP study design.

Inclusion/Exclusion Criteria

Participants will be children aged 8 to 12 years old, with a BMI ≥85th percentile for age and sex[24], accompanied by a parent, family member, or legal guardian. At least one member of the family will have to be able to speak and read English, and families will have to agree to attend group meetings over 10 weeks. Families will be excluded if medical clearance was needed and not obtained, and if the child has a BMI <85th percentile.

Waitlist Control Group

An ethical imperative for any study of a family-based obesity early intervention program is to ensure that the control arm receives essential information about preventive guidelines for childhood obesity management. Thus, the waitlist control group will have access to a modified program at week-10: four group sessions and full access to the 10-week online family portal after the study is completed.

Recruitment

Participants will be recruited using: Active Living Guide inserts; school newsletter inserts; local newspaper advertisements and interviews; mailed packages to physician offices, community health centers, diabetes clinics, allied health professionals; letters and email blasts

to Provincial networks and organizations; posters and rack cards displayed in recreation centers, public community spaces, medical offices and schools; a customized website; social media domains such as Facebook, Instagram, and Twitter; webinars; booths at events and summer camps; and using local radio. Parents may contact the study team directly about enrollment via the study website, email or phone call. Also, parents who express interest will be asked to provide their name and contact details to the recreation center staff and will receive a follow up email or phone call delivering more information about program eligibility and enrollment. Parents will be asked to confirm their participation in the program within a week from completing the screening call. Next, parents will be asked to sign consent forms and children will sign the child assent form, confirming that they have discussed the intervention with their parents and understand the program's requirements.

Intervention: Early Intervention Program

The EIP design represents a community-based delivery model and was designed based on a systematic review of the literature[25,26], based on findings from previous implementation efforts[27,28] in British Columbia and extensive community stakeholder consultations across five health regions (more than 300 stakeholders). The EIP development was guided theoretically by the M-PAC framework[29,30] that emphasizes social cognitive approaches to intention formation, adoption of action control through self-regulation and the action control maintenance phase once a behavior becomes habitual and self-identified. Intervention activities were designed to support children and parents in learning behavioral change skills that will enable them to improve their health-related lifestyle behaviors. The M-PAC constructs are reflected in the EIP's curriculum to introduce and direct participants in making long-term lifestyle behavior changes. The M-PAC establishes seven constructs that are antecedent of behaviours: (a) instrumental attitude as the knowledge on health consequences, (b) affective judgement relating to intrinsic motivation, (c) perceived capability relating to self-efficacy, (d) perceived

opportunity relating to perceptions of the social and physical environment (time and access), (e) behavioral regulation relating to tactics that people use to translate their intentions into behavior (e.g., goal setting, self-monitoring), (f) identity as a standard of conscious self-comparison, and (g) habit as a stimulus-enacted behavioural response under lowered conscious awareness. A recent review of 23 studies that have applied M-PAC provided general support of its tenets and strong support for the multivariate associations between these antecedents and behaviour[31]

Following the systematic review evidence, the 10-week intervention includes at least 26 contact hours[32] between participants and intervention activities and materials through in-person and online activities. Group sessions will be held once a week for 90 minutes and they include family PA, children-only PA aiming at improving enjoyment, confidence, motivation and fundamental movement skills (FMS), and parent-only group discussion to identify barriers and strategies for promoting family healthy behaviours. Additional hours will be obtained via the online family portal.

Curriculum

The intervention targets lifestyle changes in both children and their parents in regards to promoting healthy eating, reduction of sugary drink consumption, increasing cooking self-efficacy, engaging in family PA, reduction of recreational screen time and sedentary behaviour, improved sleep hygiene, positive mental health, self-esteem, gratitude, and self-compassion. The weekly topics covered are listed in Table 1. Behaviour change techniques used in the program include goal setting, self-monitoring, self-evaluation, communication and interpersonal skills. The EIP will also provide four extra community-based group sessions. Two of these extra sessions will be a session in a local park using the Agents of Discovery mobile application, which is an augmented reality mobile application designed to encourage families to engage in outdoor exploration, and a group grocery store tour led by a registered dietitian. The remaining two group activities will be chosen and scheduled by the facilitators based on group input.

Researchers designing the EIP intend to create a flexible community-based family-intervention program able to accommodate families' demanding schedules.

Online Family Portal

The EIP online family portal will be considered as a weekly lesson to be completed by families. Lessons in the portal will offer additional resource information, healthy recipes, parent articles, videos, and suggested healthy eating and physical activities so that families engage in an extra 60 minutes per week of self-directed healthy lifestyle activities to promote healthy living. The online family portal will also be a repository of materials covered in each session, such as weekly handouts and worksheets. The portal will provide families with i) a step tracking tool (e.g. steps, active minutes, diet), ii) an interactive map of healthy places in their communities on, iii) online weekly quizzes to help families assess and strengthen their self-guided learning, iv) a secure online diary to allow families to reflect on their progress and set new weekly goals, and v) proactive online messages to notify families about new content, login and survey assessments.

Maintenance sessions

The intervention group will receive four one-hour, biweekly maintenance sessions, after the 10-week program. Sessions will include 30 minutes of discussion on maintaining healthy lifestyle, and 30 minutes of family PA.

Table 1: Weekly topics covered in the family-based early intervention program (EIP)

Weeks	Topics
1	Healthy Living Workshop • Family Activities: Guide to Healthy Food Choices and the Canadian 24-hour Movement Guidelines • Children specific activities: Healthy Living Stations
2	Introduction to Healthy Eating & Active Living • Family activities: Intercultural Ice Breaker Games, Benefits of Physical Activity • Children specific activities: Fundamental Movement Skills
3	Setting Family Healthy Living SMART Goals • Family activities: Setting SMART goals • Children specific activities: Fun Small Group Physical Activity Games
4	Your Guide to Healthy Food Choices • Family activities: Grocery store tour, Eat Using the Plate Model, BC Grown Vegetables and Fruit, Focus on Food Groups • Children specific activities: Fun Small Group Physical Activity Games
5	Body Self-Compassion, Appreciation& Active Living for EveryBODY • Family activities: Bullying Prevention Tip Sheet for Parents • Children specific activities: Get Moving Stations
6	Creating Positive Healthy Family Mealtime& Physical Activity Experiences • Family activities: Bullying Prevention Tip Sheet for Parents, Health for EveryBODY, Hunger Scale and Mindful Eating Strategies, Listen to Your Body's Hunger & Fullness Signals, Meal Ideas for Everyone • Children specific activities: Fitness Scavenger Hunt, Smart Talk About Mindful Eating
7	Family, Food Culture & Getting Active Outdoors • Family activities: Removing Barriers to Physical Activity • Children specific activities: Playground Games
8	Positive Parenting, Sleep Hygiene & Brainiacs • Family activities: Live 5-2-1-0+ lifestyle • Children a Brainiac & Sport Skill Stations
9	Cooking & Playing Together • Family activities: Getting Kids in the Kitchen • Children specific activities: Ancient & Indigenous Games
10	Continuing Positive Change, Dance & Celebration • Family & children activities: Strategies to maintain healthy lifestyle behaviours

Data Collection Protocol

Child and parent outcome measures will be collected at baseline, after the intervention (week 10). Process evaluation metrics such as family satisfaction, issues, facilitators and barriers to attendance and maintenance will be collected during and after the intervention (at 10 and 18 weeks). Parent questionnaires will be sent online prior to the intervention start. After screening for eligibility, both intervention and wait-list control group parents will receive an email containing instructions followed by a link for completing the online parent questionnaire.

Data from intervention and waitlist control children will be collected at the Healthy Living Workshop, an interactive and fun 'health faipr style' measurement approach that rotates between stations such as nutrition and PA games interspersed among questionnaire stations, FMS assessment, and BMI. All parents will be invited to attend a Healthy Living Workshop session while children participate in the health fair. The measurement team will follow up with families who do not attend the measurement session. Program facilitators will follow up with families who do not come to the intervention. Data will be entered within two weeks of data collection. De-identified data will be securely stored at the University of Victoria server. Processes to promote data quality include double data entry; range checks for data values. Co-investigators will have access to de-identified final trial dataset.

Outcome Measures

Child Measures:

- BMI will be calculated as weight (kilograms) divided by height (meters) squared, adjusted for child age and sex Weight to the nearest 0.1 kg and height to the nearest 0.1 cm will be obtained. BMI z-scores (standard deviation) will be calculated based on the Centers for Disease Control and Prevention (CDC) criteria[24].

- *FMS* will be assessed using the validated Canadian Agility and Movement Skill Assessment that evaluates seven skills: two-foot jumping, sliding, catch, throw, skip, one-foot hop, and kick[33]. Children will observe two demonstrations, will complete two practice trials, and two timed and scored trials.
- *Physical activity levels will be measured using the* Physical Activity Questionnaire for Children (PAQ-C)[34].
- *Sedentary behaviours* will be assessed using the Physician-based Assessment & Counseling for Exercise (PACE) Adolescent Psychosocial Measures[35].
- *Perceived PA intrinsic motivation and competence* will be measured by the Motivation and Confidence subscale of the Canadian Assessment of Physical Literacy[33];
- *Dietary behaviours* will be measured using the 7-day recall questionnaire retrieved from the Behavioral Risk Factor Surveillance System Survey Questionnaire[36],
- Healthy eating outcome expectations and self-efficacy will be assessed using the Power Play! Survey [37], and the Physician-based Assessment & Counseling for Exercise (PACE) Adolescent Psychosocial Measures[38], respectively.
- *Healthy eating motivation* will be assessed by the FLASHE questionnaire[39,40],
- *Perceived cooking skills* will be assessed by the Cooking with Kids questionnaire[41].
- *Quality of life* will be assessed using the Pediatric Quality of Life Inventory[42].
- *Self-compassion, gratitude, self-esteem* will be assessed using the Self-compassion Scale Short Form[43], the FLASHE questionnaire[39], subscales of the Project EAT survey[44], and the Gratitude Adjective Checklist[45].

Parent Measures

- Parent's physical activity and dietary behaviours will be assessed by subscales drawn from the FLASHES-EAT surveys[46] and the Action Control of Parent Support Behaviour[47].
- Structure of the home food environment will be assessed by the Fruit and Vegetable At Home Survey for Parents[48];
- Parent PA and dietary support and behavioral regulation of supporting child's PA will be measured using the Parent Support of Child Physical Activity questionnaire[47] [49];
- PA and dietary habit will be assessed by the automaticity subscale of the Self-Report Index of Habit[50];
- PA and dietary identity will be assessed by the Role-Identity subscale from the Exercise Identity Scale[51,52].

Process Evaluation

The EIP will be assessed using Process Evaluation components identified by Linnan & Steckler[53]; and components of the RE-AIM framework[54], specifically the Reach, Efficacy, Implementation, and Maintenance components (See Table 2).

Table 2: Summary of the Process Evaluation

Component	Definition	Assessment
Reach	Effectiveness of marketing strategies, recruitment, the extent that the intervention is reaching intended populations, and adherence and attrition rates.	• Site-specific recruitment plans, recruitment tracking forms, screening and phone calls tracking, demographic questionnaires, and program attendance tracking forms.
Efficacy	The impact of the EIP intervention on family's health and well-being outcomes	• Child's Measures: BMI z-score, FMS, Physical activity levels, sedentary behaviours, Intrinsic motivation and self-efficacy for PA and dietary behaviours,

		Quality of Life, Self-compassion, gratitude, self-esteem. • Parent's Measures: Physical activity and dietary behaviours, Structure of the home food environment, parent support for the child's PA and dietary behaviours, home food environment, habit and identity for PA and dietary behaviours
Implementation	EIP program satisfaction, program fidelity, attendance, barriers to program participation.	• Screening tracking form, facilitators pre- and post-workshop surveys, program attendance tracking forms, facilitator feedback surveys, parents and children satisfaction surveys and post-program interviews with parents, facilitators, and stakeholders.
Maintenance	Conditions needed for successful long-term implementation of the EIP	• Maintenance will be assessed using stakeholders and advisory committee interviews.

Reach assesses the effectiveness of marketing strategies, the effectiveness of program processes in generating appropriate referrals to the intervention, the extent that the intervention is reaching intended populations, and adherence and attrition rates. Reach will be assessed using site-specific recruitment plans, recruitment tracking forms, screening and phone calls tracking, demographic questionnaires, and program attendance tracking forms. Program coordinators for each community will record site-specific recruitment plans. Recruitment plans will outline and track all recruitment efforts undertaken at a local level. Centralized recruitment efforts will be tracked using a recruitment tracking form that will record all public inquiries including phone calls, emails, and social media interactions. Information recorded will include name, community, contact information, date and form of contact, how they heard about the program, any follow-up communication, and the outcome of the inquiry. The screening call tracking will record the individual's reasons for interest, ability to commit, and eligibility.

Demographic questionnaires will be completed by parents or caregivers to determine participants' cultural backgrounds, gender, age, and household make-up, income levels, education levels, and employment status. Program attendance tracking forms will be completed by the program facilitators throughout the duration of the program. Attendance trackers will track weekly participant attendance, reasons for missed sessions, and participant drop-out.

Implementation addresses if families, staff, and stakeholders are satisfied with the EIP, implementation fidelity, facilitators and barriers to participate in the program, attendance, program delivery team perceptions of parent benefits and satisfaction, and negative outcome tracking. Implementation will be assessed using screening tracking form, facilitators pre- and post-workshop surveys, program attendance tracking forms, facilitator feedback surveys, parents and children satisfaction surveys and post-program interviews with parents, facilitators, and stakeholders. The screening tracking form will identify potential facilitators and barriers to participate in the program. Program facilitators will complete a workshop survey before and after a three-day training workshop that will assess facilitator's knowledge and confidence with implementing the program curriculum and the effectiveness of the training workshop in these regards. Program attendance tracking forms will record participant attendance and reasons for drop-out, including possible barriers to attendance and completion of the program. Weekly facilitator feedback surveys will evaluate the successes and challenges of the weekly in-class sessions, as well as the facilitator's delivery of components of the session: PA, healthy eating, and positive mental health components. Parent and child satisfaction surveys will be completed at the end of the 10-week program and will assess participant satisfaction with the program curriculum and delivery. Parents will be asked to participate in post-program phone interviews in order to gain a deeper understanding of their perceptions and experiences with the EIP.

Program coordinators and facilitators from each site will also be asked to take part in post-program interviews to explore their perceptions of the success and challenges of the program delivery and the effectiveness of the facilitator training workshop for providing them

with the knowledge and tools needed to deliver the content. Focus groups with the facilitation teams and program coordinators will be completed in-person immediately following the last session of the EIP program, or via phone call the week following the completion of the program. Provincial stakeholder interviews will be held in person or by phone and will be scheduled at the earliest available date following the completion of the program, and will be conducted by the EIP project coordinator.

Maintenance evaluates the conditions needed for successful long-term implementation of the EIP by assessing stakeholder support and integration and alignment with British Columbia's Continuum for the Prevention, Management, and Treatment of Health Issues Related to Overweight and Obesity in Children and Youth[55]. Maintenance will be assessed using stakeholders and advisory committee interviews. Stakeholder and advisory committee interviews will be conducted by the EIP project coordinator. Interviews will be held in person or by phone and will be scheduled at the earliest available date following the completion of the program.

Patient and Public Involvement

The EIP was designed based on previous childhood obesity weight management in BC and accounted for participants' feedback. Community stakeholders were actively involved in the study design. The EIP was pre-piloted in the Spring 2018 and participants' feedback on recruitment, burden of the intervention and measurement were taking into consideration for the full trial.

Data Analysis

We will analyze our outcomes using an intention-to-treat approach. We will use descriptive to evaluate our primary and secondary outcomes at baseline. We will evaluate patterns of missing data in the treatment groups and we will perform multiple imputation to

address missing data if data are missing at random. The distributions of the continuous variables will be evaluated and we will apply a suitable transformation if the distribution is significantly skewed. For our primary outcome (BMI z-score), the difference among groups at 10-week will be evaluated using a univariate linear regression adjusted for baseline outcome measures (e.g. BMI z-score at baseline), social-economic status and recruitment sites. Secondary outcomes (FMS, physical activity levels, perceived PA intrinsic motivation and competence, dietary, healthy eating motivation, perceived cooking, quality of life self-compassion, gratitude, self-esteem, parent's PA and dietary behaviours and behavioral regulation of supporting child's PA, PA and dietary habit) will follow a similar statistical approach as the primary outcome analysis.

Statistical significance criterion of will defined as $p<0.05$. Process evaluation data will be described using descriptive statistics and thematic analysis will be done by two independent coders to identify, analyze, and report themes[56]. Coders will read the transcripts, identify possible themes, draft and compare the codebook, discuss potential themes, and draft the first official version of the codebook. Then, coders will code all the transcripts, discuss and develop version two of the codebook. A third researcher will be consulted if agreements cannot be reached. Finally, we will evaluate program adherence as part of the process evaluation. We will be conducting a `per protocol' analysis including only intervention participant to evaluate adherence (number of in-class and online sessions completed) during intervention and maintenance period.

ETHICS AND DISSEMINATION

All participants will provide electronic and written consent. Children will provide written assent. Ethics was obtained from the University of Victoria Ethics Review Board prior to

participant recruitment. Amendments to the protocol will be submitted to the University of Victoria Ethics Review Board and the Clinical Trials registration will be updated as needed.

International recommendations agree that the core elements of any intervention to address childhood obesity should involve the whole family and include nutrition education, behaviour modification, and promotion of PA. Recent randomized controlled trials found family-based behavioural programs that targeted families with obese 8-to 12-year olds showed positive outcomes in both short-term (10-weeks) and long-term (12 months) interventions[25].

The Province of British Columbia Ministry of Health has provided funding to the Childhood Obesity Foundation to design and implement a “made in BC” community-based Childhood Healthy Weights Early Intervention Program for children 8-12 years old. The EIP was developed following essential processes for scalability[57]: it was based on the current family-based childhood obesity management literature[25,26], based on lessons learned from previous programs conducted in the province[27], it was overseen by a stakeholder Steering Advisory Committee and based on an extensive regional stakeholder consultation and needs assessment process. The program will also include innovative topics on sleep hygiene and screen use as a holistic way to promote healthy lifestyles as well as a novel blended (Internet-based and in-person) delivery approach. The EIP was designed using a new meta-theoretical (M-PAC)[29].

We anticipate that findings from the trial will have high impact, given our collaboration with the Childhood Obesity Foundation and the structure of the initiative and its development. Additionally, while the intervention is running there will be a Sustainability sub-committee that is addressing systems of program integration and client triage. Advancements achieved with this study, concerning the content and methodology of family-based obesity programs, if effective and feasible will likely be widely disseminated in BC dependent on ongoing funding.

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AUTHOR STATEMENT

PJN and KS conceived the study. PJN, KS, SL, JW, GDCB, RER, TH and LCM contributed to the study design. SL, PJN, IGM, MAP drafted and revised the manuscript. All authors edited and approved the final manuscript.

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COMPETING INTERESTS

Dr. Naylor is on the Board of Childhood Obesity Foundation and had course release to oversee the implementation of the evaluation of the EIP. Dr. Naylor reports grants from Childhood Obesity Foundation, during the conduct of the study.
Dr. Strange, Dr. Marques, Ms. Hartrick, Ms. Weismiller, and Ms. Perdew report personal fees from Childhood Obesity Foundation, during the conduct of the study.

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Steering committee: BC Ministry of Health, Childhood Obesity Foundation, University of Victoria, Juniper Consulting, ShapeDownBC, SCOPE 5 2 1 0, HealthLINK BC, YMCA of Greater Vancouver, BC Recreation and Parks Association (BCRPA).
Research advisory committee: University of Victoria, University of Alberta, University of British Columbia.
Management committee: Childhood Obesity Foundation, University of Victoria, Juniper Consulting.
Oversight Committee: BC Ministry of Health, Provincial Health Services Authority (PHSA), Childhood Obesity Foundation, University of Victoria

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<Figure 1>: Overview of the EIP study design.

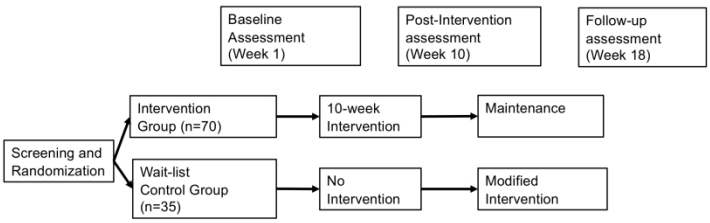

Figure 1: Overview of the EIP study design.

279x215mm (300 x 300 DPI)

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	1
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	1
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	18
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1, 18
Roles and responsibilities:	#5b	Name and contact information for the trial sponsor	19

sponsor contact information			
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	19
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	19
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2,3
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	4,5
Objectives	#7	Specific objectives or hypotheses	3
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4,5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-8

Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	N/A
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-11
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	4,5
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	4
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	5,6
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	4
Allocation concealment	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed	4,5

mechanism		envelopes), describing any steps to conceal the sequence until interventions are assigned	
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	4,5
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	4,5
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-12
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	9
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14

Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	N/A
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	N/A
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	14
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	14
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	14
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	9
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Data access	#29	Statement of who will have access to the final trial dataset,	9

		and disclosure of contractual agreements that limit such access for investigators	
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	N/A
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A