


BMJ Open Family-based, healthy living intervention for children with overweight and obesity and their families: a 'real world' trial protocol using a randomised wait list control design

Sam Liu,¹ Isabela Gouveia Marques ,¹ Megan A Perdew,¹ Karen Strange,² Teresa Hartrick,² Joy Weismiller,³ Geoff D C Ball,⁴ Louise C Mâsse,⁵ Ryan Rhodes,¹ Patti-Jean Naylor¹

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For numbered affiliations see end of article.

Correspondence to
Dr Patti-Jean Naylor;
pjnaylor@uvic.ca

Dr Sam Liu; samliu@uvic.ca

ABSTRACT

Introduction Family-based behavioural 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 programme (EIP) for 8–12 years old with overweight and obesity and their families.

Methods and analysis A randomised waitlist-control trial will assess a 10-week interactive, family-based lifestyle intervention followed by four maintenance sessions, in BC, Canada. We aim to enrol 186 families. The blended intervention includes at least 26 contact hours between participants and programme providers, including interactive activities and educational materials through weekly 90-min group sessions, an online family portal, and self-directed family activities. Curricular content includes information and activities related to healthy eating, physical activity (PA), positive mental health, parenting practices and sleep hygiene. The waitlist control group will receive a modified programme with the same 10-week sessions in the family portal, and four group sessions. Families participate in data collection at baseline, postintervention (week 10) and follow-up (week 18). The primary outcome is to assess changes in child body mass index z-score at 10 weeks between the groups. Secondary outcomes include changes at 10 weeks between the groups in child and parent PA behaviour and skills, healthy eating behaviour, and mental health. Process evaluation will address reach, implementation and maintenance (baseline, 10-week and 18-week) using recruitment tracking forms, parent questionnaire, programme attendance tracking forms, leader feedback surveys, parents and children satisfaction surveys and postprogramme interviews with facilitators, stakeholders and parents. Intention-to-treat analyses will be conducted. Process evaluation will be analysed thematically.

Strengths and limitations of this study

- The randomised 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 enrolment and drop-out are challenges that can increase selection and attrition bias, respectively.

Ethics and dissemination Study procedures were designed to address research and community needs and will follow ethical standards.

Trial registration number NCT03643341.

INTRODUCTION

Obesity is one of the most common paediatric health problems¹ 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 (eg, 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 behavioural weight management interventions are a main approach for achieving weight control in children and adolescents.⁷ Encouraging the whole family to make behavioural changes decreases the



focus being placed solely on children's dietary and activity behaviours⁸ and also focuses on providing a supportive environment for making lifestyle modifications in the home setting. Several randomised controlled trials have shown that family-focused behavioural programme delivered in-person can be effective strategies to manage childhood obesity.^{2 9-12} Although these intervention programme can be effective in managing childhood obesity, the delivery methods must be scalable to enhance public health impact.¹³⁻¹⁵ Unfortunately, in-person family-focused childhood weight management programme have limited reach (eg, only available at specific locations) and are resource intensive (eg, programme require significant human input).^{14 15} Consequently, there is an urgent need to develop innovative solutions to improve the scalability of these childhood obesity management programme to enhance public health impact.

With the advancement in internet-enabled digital devices (eg, 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 programme without overtaxing healthcare resources.^{13 16} 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 programme and (2) a blended intervention internet and face-to-face programme.^{17 18}

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 programme. However, families may feel a lack of support compared with face-to-face programme.¹⁷ Attrition with such programme is often a concern for stand-alone internet-based programme.¹⁹ By contrast, *a blended face-to-face and internet-based programme* 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.^{17 18} Currently, there is inadequate data to determine the efficacy blended internet-based interventions aimed to manage childhood obesity by targeting the entire family.¹⁵ 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 BC', family healthy living early intervention programme (EIP) in managing obesity (body mass index (BMI) ≥ 85 th 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 (eg, a minimum of 26 hours of contact time, family involvement, physical activity (PA), healthy living, sleep, mental health); (2) complement existing childhood obesity management programme in BC (HealthLink BC Eating and Activity Programme for Kids: telephone-based support programme for overweight children, shapedown: a community based designed for children with BMI ≥ 97 th percentile for age and sex); (3) meet the needs of BC families and communities, by making the programme accessible to diverse families (eg, indigenous, multi-cultural or intercultural backgrounds, lower-income, single-parent); (4) address existing gaps documented in family-focused intervention literature (eg, 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)^{20 21}; (5) incorporate the latest internet-based features (eg, wearable data integration, interactive quizzes, reminders and notifications, online discussion forum). Stakeholder's input also emphasised 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 versus wait-list control group on health and behaviour outcomes over a 10-week period. The primary outcome is to assess changes in child BMI z-score. Secondary outcomes include changes in child fundamental movement skills (FMS); 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 behaviours, 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 behaviours, 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 with 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 hypothesise that the EIP will reach a broad demographic, and families and staff will be satisfied with the EIP.

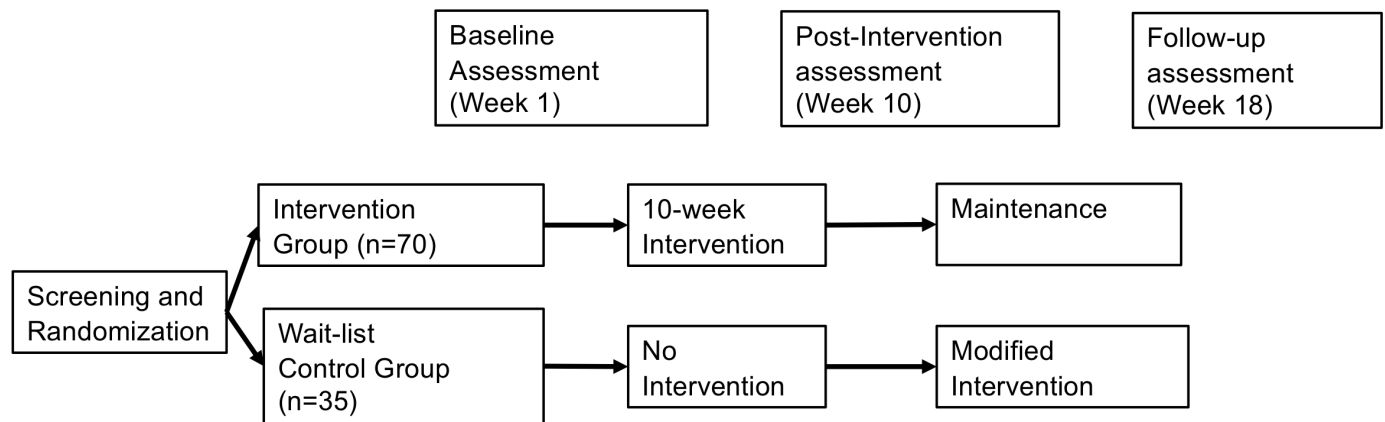


Figure 1 Overview of the early intervention programme study design.

METHODS AND ANALYSIS

The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines was used to report the study protocol.²²

Study design

A randomised waitlist-controlled trial will assess the 10-week interactive family-based lifestyle intervention followed by four maintenance sessions (figure 1), in BC, Canada, from October 2018 to September 2020. The intervention includes at least 26 contact hours between participants and programme providers, including interactive activities and educational materials through weekly 90-min 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 randomised controlled trial evaluating the efficacy of a family-based intervention to reduce BMI z-score relative to control.² Based on 2:1 randomisation, 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%). Randomisation will be blocked (random permuted block design) within each of our six recruitment across BC representing all five 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. Randomisation 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 favour 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 programme 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 minimise 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.

Inclusion/exclusion criteria

Participants will be children aged 8–12 years old, with a BMI ≥85th percentile for age and sex,²³ 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 EIP 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 programme 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 centres, diabetes clinics, allied health professionals; letters and email blasts to Provincial networks and organisations; posters and rack cards displayed in recreation centres, public community spaces, medical offices and schools; a customised 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 enrolment 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

centre staff and will receive a follow-up email or phone call delivering more information about programme eligibility and enrolment. Parents will be asked to confirm their participation in the programme 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 programme's requirements.

Intervention: EIP

The EIP design represents a community-based delivery model and was designed based on a systematic review of the literature,^{24 25} based on findings from previous implementation efforts^{26 27} in BC and extensive community stakeholder consultations across five health regions (more than 300 stakeholders). The EIP development was guided theoretically by the M-PAC framework^{28 29} that emphasises social cognitive approaches to intention formation, adoption of action control through self-regulation and the action control maintenance phase once a behaviour becomes habitual and self-identified. Intervention activities were designed to support children and parents in learning behavioural change skills that will enable them to improve their health-related lifestyle behaviours. The M-PAC constructs are reflected in the EIP's curriculum to introduce and direct participants in making long-term lifestyle behaviour changes. The M-PAC establishes seven constructs that are antecedent of behaviours: (1) instrumental attitude as the knowledge on health consequences, (2) affective judgement relating to intrinsic motivation, (3) perceived capability relating to self-efficacy, (4) perceived opportunity relating to perceptions of the social and physical environment (time and access), (5) behavioural regulation relating to tactics that people use to translate their intentions into behaviour (eg, goal setting, self-monitoring), (6) identity as a standard of conscious self-comparison and (7) 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.³⁰

Following the systematic review evidence, the 10-week intervention includes at least 26 contact hours³¹ between participants and intervention activities and materials through in-person and online activities. Group sessions will be held once a week for 90 min and they include family PA, children-only PA aiming at improving enjoyment, confidence, motivation and 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 programme 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 programme 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 min 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 (1) a step tracking tool (eg, steps, active minutes, diet), (2) an interactive map of healthy places in their communities on, (3) online weekly quizzes to help families assess and strengthen their self-guided learning, (4) a secure online diary to allow families to reflect on their progress and set new weekly goals and (5) proactive online messages to notify families about new content, login and survey assessments.

Maintenance sessions

The intervention group will receive four 1 hour, biweekly maintenance sessions, after the 10-week programme. Sessions will include 30 min of discussion on maintaining healthy lifestyle, and 30 min of family PA.

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,

Table 1 Weekly topics covered in the family-based early intervention programme

Weeks	Topics
1	Healthy living workshop ► Family activities: guide to healthy food choices and the Canadian 24 hours movement guidelines. ► Children specific activities: healthy living stations.
2	Introduction to healthy eating and 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 and active living for EveryBODY ► Family activities: bullying prevention tip sheet for parents. ► Children specific activities: get moving stations.
6	Creating positive healthy family mealtime and 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 and fullness signals, meal ideas for everyone. ► Children specific activities: fitness scavenger hunt, smart talk about mindful eating.
7	Family, food culture and getting active outdoors ► Family activities: removing barriers to physical activity. ► Children specific activities: playground games.
8	Positive parenting, sleep hygiene and brainiacs ► Family activities: live 5-2-1-0+lifestyle. ► Children a brainiac and sport skill stations.
9	Cooking and playing together ► Family activities: getting kids in the kitchen. ► Children specific activities: ancient and Indigenous games.
10	Continuing positive change, dance and celebration ► Family and children activities: strategies to maintain healthy lifestyle behaviours.

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. Programme facilitators will follow-up with families who do not come to the intervention. Data will be entered within 2 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 (metres) 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 (SD)

will be calculated based on the Centers for Disease Control and Prevention criteria.²³

- *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.³² Children will observe two demonstrations, will complete two practice trials, and two timed and scored trials.
- *PA levels* will be measured using the Physical Activity Questionnaire for Children.³³
- *Sedentary behaviours* will be assessed using the Physician-based Assessment & Counseling for Exercise (PACE) Adolescent Psychosocial Measures.³⁴
- *Perceived PA intrinsic motivation and competence* will be measured by the Motivation and Confidence subscale of the Canadian Assessment of Physical Literacy.³²
- *Dietary behaviours* will be measured using the 7-day recall questionnaire retrieved from the Behavioral Risk Factor Surveillance System Survey Questionnaire.³⁵
- Healthy eating outcome expectations and self-efficacy will be assessed using the Power Play! Survey,³⁶ and



the PACE Adolescent Psychosocial Measures,³⁷ respectively.

- ▶ *Healthy eating motivation* will be assessed by the Family Life, Activity, Sun, Health, and Eating (FLASHE) questionnaire.^{38 39}
- ▶ *Perceived cooking skills* will be assessed by the Cooking with Kids questionnaire.⁴⁰
- ▶ *Quality of life* will be assessed using the Pediatric Quality of Life Inventory.⁴¹
- ▶ *Self-compassion, gratitude, self-esteem* will be assessed using the Self-compassion Scale Short Form,⁴² the FLASHE questionnaire,³⁸ subscales of the Project EAT survey,⁴³ and the Gratitude Adjective Checklist.⁴⁴

Parent measures

- ▶ Parent's PA and dietary behaviours will be assessed by subscales drawn from the FLASHES-EAT surveys⁴⁵ and the Action Control of Parent Support Behaviour.⁴⁶
- ▶ Structure of the home food environment will be assessed by the Fruit and Vegetable At Home Survey for Parents.⁴⁷
- ▶ Parent PA and dietary support and behavioural regulation of supporting child's PA will be measured using the Parent Support of Child Physical Activity questionnaire.^{46 48}
- ▶ PA and dietary habit will be assessed by the automaticity subscale of the Self-Report Index of Habit.⁴⁹
- ▶ PA and dietary identity will be assessed by the Role-Identity subscale from the Exercise Identity Scale.^{50 51}

Process evaluation

The EIP will be assessed using process evaluation components identified by Linnan and Steckler⁵²; and

components of the RE-AIM framework,⁵³ specifically the reach, efficacy, implementation and maintenance components (see table 2).

Reach assesses the effectiveness of marketing strategies, the effectiveness of programme 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 programme attendance tracking forms. Programme coordinators for each community will record site-specific recruitment plans. Recruitment plans will outline and track all recruitment efforts undertaken at a local level. Centralised 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 programme, 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. Programme attendance tracking forms will be completed by the programme facilitators throughout the duration of the programme. Attendance trackers will track weekly participant attendance, reasons for missed sessions, and participant drop-out.

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.	<ul style="list-style-type: none"> ▶ Site-specific recruitment plans, recruitment tracking forms, screening and phone calls tracking, demographic questionnaires, and programme attendance tracking forms.
Efficacy	The impact of the EIP intervention on family's health and well-being outcomes.	<ul style="list-style-type: none"> ▶ Child's measures: BMI z-score, FMS, PA levels, sedentary behaviours, Intrinsic motivation and self-efficacy for PA and dietary behaviours, quality of life, self-compassion, gratitude, self-esteem. ▶ Parent's measures: PA 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 satisfaction, programme fidelity, attendance, barriers to programme participation.	<ul style="list-style-type: none"> ▶ Screening tracking form, facilitators preworkshop and postworkshop surveys, programme attendance tracking forms, facilitator feedback surveys, parents and children satisfaction surveys and postprogramme interviews with parents, facilitators and stakeholders.
Maintenance	Conditions needed for successful long-term implementation of the EIP.	<ul style="list-style-type: none"> ▶ Maintenance will be assessed using stakeholders and advisory committee interviews.

BMI, body mass index; EIP, early intervention programme; FMS, fundamental movement skills; PA, physical activity.

Implementation addresses if families, staff, and stakeholders are satisfied with the EIP, implementation fidelity, facilitators and barriers to participate in the programme, attendance, programme delivery team perceptions of parent benefits and satisfaction, and negative outcome tracking. Implementation will be assessed using screening tracking form, facilitators preworkshop and postworkshop surveys, programme attendance tracking forms, facilitator feedback surveys, parents and children satisfaction surveys and postprogramme interviews with parents, facilitators and stakeholders. The screening tracking form will identify potential facilitators and barriers to participate in the programme. Programme facilitators will complete a workshop survey before and after a 3-day training workshop that will assess facilitator's knowledge and confidence with implementing the programme curriculum and the effectiveness of the training workshop in these regards. Programme attendance tracking forms will record participant attendance and reasons for drop-out, including possible barriers to attendance and completion of the programme. 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 programme and will assess participant satisfaction with the programme curriculum and delivery. Parents will be asked to participate in postprogramme phone interviews in order to gain a deeper understanding of their perceptions and experiences with the EIP.

Programme coordinators and facilitators from each site will also be asked to take part in postprogramme interviews to explore their perceptions of the success and challenges of the programme 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 programme coordinators will be completed in-person immediately following the last session of the EIP programme, or via phone call the week following the completion of the programme. 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 programme, 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 BC's Continuum for the Prevention, Management, and Treatment of Health Issues Related to Overweight and Obesity in Children and Youth.⁵⁴ 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 programme.

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 analyse 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 weeks will be evaluated using a univariate linear regression adjusted for baseline outcome measures (eg, BMI z-score at baseline), socioeconomic status and recruitment sites. Secondary outcomes (FMS, PA 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 behavioural 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, analyse and report themes.⁵⁵ 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 programme 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.

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 randomised controlled trials found family-based behavioural programme that targeted families with obese 8–12 years old showed positive outcomes in both short-term (10 weeks) and long-term (12 months) interventions.²⁴

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 Programme for children 8–12 years old. The EIP was developed following essential processes for scalability⁵⁶: it was based on the current family-based childhood obesity management literature,^{24 25} based on lessons learnt from previous programme conducted in the province,²⁶ it was overseen by a stakeholder Steering Advisory Committee and based on an extensive regional stakeholder consultation and needs assessment process. The programme 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).²⁸

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 subcommittee that is addressing systems of programme integration and client triage. Advancements achieved with this study, concerning the content and methodology of family-based obesity programme, if effective and feasible will likely be widely disseminated in BC dependent on ongoing funding.

Author affiliations

¹School of Exercise Science, Physical and Health Education, University of Victoria, Victoria, British Columbia, Canada

²Childhood Obesity Foundation, Vancouver, British Columbia, Canada

³Juniper Consulting, Victoria, British Columbia, Canada

⁴Department of Pediatrics, University of Alberta, Edmonton, Alberta, Canada

⁵Faculty of Medicine, University of British Columbia, Vancouver, British Columbia, Canada

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Contributors P-JN and KS conceived the study. P-JN, KS, SL, JW, GDCB, RR, TH and LCM contributed to the study design. SL, P-JN, IGM, MAP drafted and revised the manuscript. All authors edited and approved the final manuscript.

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Competing interests P-JN is on the Board of Childhood Obesity Foundation and had course release to oversee the implementation of the evaluation of the EIP. P-JN reports grants from Childhood Obesity Foundation, during the conduct of the study. KS, GM, TS, JW and MAP report personal fees from Childhood Obesity Foundation, during the conduct of the study.

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ORCID iD

Isabela Gouveia Marques <http://orcid.org/0000-0002-4174-0705>

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