

Evaluating the Effectiveness of a Family-based Lifestyle Intervention for Managing Childhood Overweight: Protocol for a Randomized Control Trial

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Abstract

Background: Family-focused interventions promoting lifestyle behaviours such as physical activity and healthy eating can be effective strategies for obesity management in children. To maximize public health impact, there is an urgent need to develop innovative solutions to improve the scalability of childhood obesity management interventions. Stand-alone web-based interventions are easily administered but may be hindered by low participant engagement and limited support. A blended intervention that includes both facilitated virtual group sessions and self-guided resources may enhance engagement, thereby optimizing improvements in children's health outcomes. However, the long-term effectiveness of stand-alone vs. blended web-based interventions to manage childhood obesity have not yet been evaluated.

Objective: The primary objective of this trial is to evaluate the long-term effectiveness of a blended web-based family-focused healthy living program (Early Intervention Program; EIP) relative to active control (self-guided web-based educational resources) in lowering BMI z-score in children with overweight or obesity over 12 months. The secondary objective is to examine intervention effects on children's physical activity, dietary behaviours, and health-related quality of life as well as parental self-efficacy and motivation to support children's lifestyle behaviours.

Methods: This single-blind 2x4 trial aims to recruit 278 parent-child dyads across Canada to be randomly assigned to the EIP intervention group or an active control group (1:1 ratio). The 10 weeks of EIP activities have been designed based on the multi-process action control framework to support children and parents in learning behavioural change skills that will enable them to improve their healthy lifestyle behaviours, and the EIP delivery has been piloted previously. Families in the intervention group will receive weekly virtual group sessions and access to additional web-based resources and suggested activities. Families in the control group will receive access to 10 weeks of self-guided web-based educational resources only. Outcomes including child's height and weight, daily physical activity, dietary behaviours, health-related quality of life, and parental support will be measured via online questionnaire at four assessment timepoints over one year (baseline, 10 weeks, 6 months, and 12 months). Intervention engagement and attrition will also be recorded. Multiple linear regression models will be used to examine the effectiveness of the EIP intervention compared to stand-alone web resources only.

Results: This study was funded in 2020, with 270 participants enrolled between January 2021 and May 2024. The 12-month data collection period will end in June 2025. Study results will be disseminated via conference presentations, peer-reviewed

publications, and other media channels.

Conclusions: The blended web-based EIP healthy living program has the potential to become a scalable solution for prevention of obesity and related health conditions. Clinical Trial: ClinicalTrials.gov NCT06777888

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Original Manuscript

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Abstract

Background:

Family-focused interventions promoting lifestyle behaviours such as physical activity and healthy eating can be effective strategies for obesity management in children. To maximize public health impact, there is an urgent need to develop innovative solutions to improve the scalability of childhood obesity management interventions. Stand-alone web-based interventions are easily administered but may be hindered by low participant engagement and limited support. A blended intervention that includes both facilitated virtual group sessions and self-guided resources may enhance engagement, thereby optimizing improvements in children's health outcomes. However, the long-term effectiveness of stand-alone vs. blended web-based interventions to manage childhood obesity have not yet been evaluated.

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This study was funded in 2020, with 270 participants enrolled between January 2021 and May 2024. The 12-month data collection period will end in June 2025. Study results will be disseminated via conference presentations, peer-reviewed publications, and other media channels.

Conclusions:

The blended web-based EIP healthy living program has the potential to become a scalable solution for prevention of obesity and related health conditions.

Trial registration:

ClinicalTrials.gov NCT06777888

Keywords:

Childhood obesity, web-based intervention, family-based intervention, behaviour change

Introduction

Background and Rationale

Childhood obesity is a prevalent pediatric health issue linked to a range of physical and psychological problems, including type 2 diabetes, hypertension, sleep apnea, and low self-esteem, all of which contribute to a diminished quality of life during childhood [1–3]. In Canada, over 30% of children are classified as overweight, defined based on a body mass index (BMI) $\geq 85^{\text{th}}$ percentile for their age and sex [1]. These children have a high risk of remaining overweight into adolescence and adulthood without effective interventions [4]. As a result, fostering healthy eating habits and encouraging physical activity during childhood has become a central focus for policymakers and public health initiatives at the global, national, and provincial levels [5–7].

Family-focused behavioral obesity management interventions that include both parents and children as co-recipients have been shown to be an effective approach for promoting healthy lifestyles and achieving weight control in children [8,9], particularly when the intervention content is grounded in behavioural theory [10]. Several randomized controlled trials have demonstrated that family-focused behavioural interventions delivered in person can be effective strategies in improving children's lifestyle behaviours and reducing BMI z-score [11–13]. However, to enhance their public health impact, such interventions must be delivered through scalable and accessible methods.

Leveraging the internet to deliver these interventions can be an innovative strategy to enhance program accessibility and scalability, making it easier for families to participate regardless of their geographic location [14]. Previous studies have shown that internet-based programs can be effective in improving lifestyle behaviors and clinical outcomes including BMI [15,16]. However, a limitation often observed in self-guided, asynchronous web-based interventions (with no human support) is reduced engagement over time [17]. Web-based virtual synchronous sessions (delivered using video chat), on the other hand, may provide distinct advantages, such as fostering engagement through real-time interaction, personalized support, and opportunities for families to connect and

share experiences. These virtual sessions retain the scalability and flexibility of internet-based interventions while offering live interaction, which may enhance motivation, promote accountability, and improve adherence to the program [18]. This could make synchronous delivery a powerful and adaptable option for managing childhood obesity effectively.

Drawing on the evidence supporting the effectiveness of family-based interventions and use of the internet for program delivery, the research team partnered with stakeholders (Childhood Healthy Living Foundation and the British Columbia Ministry of Health) to develop a 10-week early intervention lifestyle management program (EIP) that combines online resources with weekly live, interactive group sessions led by trained facilitators. This intervention targets families with children aged 8 to 12 years who are above the healthy weight trajectory ($\text{BMI} \geq 85^{\text{th}}$ percentile for age and sex). Interventions aimed at this age group are particularly impactful, as prepubertal children have a greater potential to return to a healthy growth pattern [19,20]. Extensive stakeholder consultation was conducted with over 100 healthcare professionals to develop an evidence-based 10-week family-focused intervention involving both parent- and child-specific interactive activities. The EIP intervention was designed to align with existing best practices in the clinical and public health setting; complement an existing childhood obesity management clinical intervention in British Columbia; and meet the needs of diverse families and communities [21]. EIP aims to target children who are off the healthy weight trajectory by managing overweight and prevent progression to obesity. The EIP curriculum targets 5 different behavioural domains to support healthy living (physical activity, healthy eating, sleep, media use, and mental well-being), which was previously identified as a key gap since the majority of family-based childhood obesity interventions address only activity and nutrition [22].

The EIP was designed using the Multi-Process Action Control (M-PAC) framework, a meta-theoretical behaviour change framework emphasizing a social cognition approach to intention formation (reflective processes), adoption of action control through self-regulation (regulatory

processes), and the action control maintenance phase once a behaviour becomes habitual and self-identified (reflexive processes) [23,24]. One advantage of the M-PAC framework is its ability to address the ‘intention to behaviour’ gap, which poses a particular challenge for childhood obesity interventions because almost all families joining these interventions have already formed an intention to adopt a healthy lifestyle [23,25,26]. Addressing this intention to behaviour gap can therefore improve the effectiveness of physical activity interventions [24,27]. Several previous randomized controlled trials, including studies focusing on families with children in our target age range, have demonstrated that the M-PAC framework can be applied to promote a healthy lifestyle in various community-based interventions [27–31]. Thus, EIP curriculum begins with intention formation (physical and mental health benefits of physical activity; perceived capability), then moves into action control adoption (restructuring the physical and social environment to create opportunities for physical activity; goals and planning; feedback and monitoring), and concludes with action control maintenance (habit formation; identity formation).

The EIP intervention was initially piloted as the Family Healthy Living Program in 2018 [21] and delivered in-person at community sites across British Columbia, Canada. The intervention content has since been adapted for delivery as a blended web-based intervention, and previous evaluation showed a positive impact on children’s lifestyle behaviours and parental support in the short term [32,33]. However, the EIP intervention has yet to be evaluated in a randomized control trial, and the long-term effectiveness of the intervention and impact on children’s anthropometry have not been examined.

Objectives

The primary objective of this study is to evaluate the effectiveness of the virtual EIP intervention relative to an active control group in lowering BMI Z-scores in children (8–12 years) with BMI $\geq 85^{\text{th}}$ percentile for age and sex over a 12-month period. Secondary objectives include evaluation of the effectiveness of EIP relative to the active control in improving lifestyle behaviours

and health-related quality of life (HRQoL) in children (8–12 years) with BMI $\geq 85^{\text{th}}$ percentile for age and sex, and parental self-efficacy and motivation to support their child's healthy living behaviours. The trial hypotheses are that the EIP intervention will result in significantly greater reduction in BMI Z-scores than the active control, and that intervention participants will shower greater improvements across all domains than those in the control group.

Trial Design

This study is a single-blind randomized controlled trial (ClinicalTrials.gov NCT06777888) with a 2 x 4 design (see Figure 1). Participating households will be randomized 1:1 into two groups: EIP intervention and control. Data will be collected at four assessment timepoints: baseline (week 0), post-intervention (week 10), 6-month follow-up (week 26), and 12-month follow-up (week 52; see Figure 1).

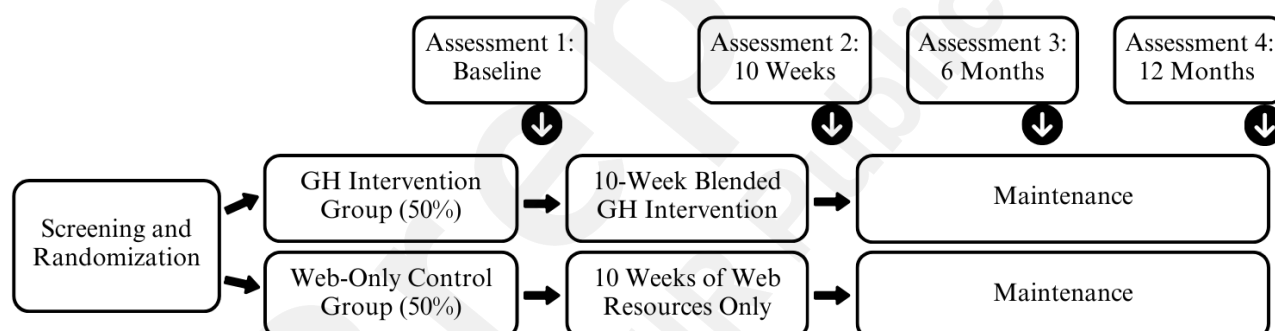


Figure 1: Overview of the study design and assessment timeline.

Trial preparation, implementation, and evaluation will adhere to Consolidated Standards of Reporting Trials (CONSORT) criteria [34] and the trial protocol will adhere to Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [35]. Data collection began in January 2021 and is projected to be completed in June 2025.

Methods

Eligibility Criteria

Child participants must be aged 8–12 years old, have a BMI $\geq 85^{\text{th}}$ percentile for-age and sex, and have at least one primary caregiver (parent or guardian) who agrees to participate in the study

along with the child. Exclusion criteria will include the inability to communicate (speak, read, and write) in English and any conditions that prevent children from being physically active.

Recruitment

Participants will be recruited from three regions across Canada (British Columbia, prairie provinces, and Ontario) using advertising via social media, local community newsletters, posters and rack cards within communities, and direct mailings to physician offices, health clinics, and allied health professionals. Interested parent-child dyads will be screened for eligibility by a trained research assistant at the central site (University of Victoria, British Columbia, Canada).

During the consent process, participants will be made aware of the differences between the two groups and informed that they will be randomly assigned to either the full intervention or the web resources only. Participants from both groups will be offered technical support from the research coordinator if needed for viewing web-based content, using the FitBit Inspire tracker, or accessing the online questionnaires.

Assignment of Interventions and Blinding

Participating households will be randomly assigned to the EIP intervention or the active control group. To reduce selection bias, the centralized randomization process will be managed by a research coordinator not directly involved with intervention delivery. The research coordinator will use computer-generated random numbers to assign the participants to either the intervention or control group. Post-randomization, data will be collected electronically via Research Electronic Data Capture (REDCap) automated invitations to reduce response bias. Other research team members including the PI, Co-Investigators, and data analysts will be blinded to group assignment to minimize detection bias and ensure impartiality in decisions about trial activities.

Participant Timeline and Data Collection

The intervention period will be 10 weeks; the full assessment duration will be 12 months. Online questionnaire assessments will be completed at baseline and then at 10-week, 6-month, and

12-month intervals following randomization (see Figure 1). The assessments will include self-reported height and weight measurements and 7 days of step counts for each child as measured by FitBit Inspire activity trackers. Questionnaire data will be collected and managed using SurveyMonkey and REDCap (Research Electronic Data Capture) tools hosted at the University of Victoria. REDCap is a secure, web-based software platform designed to support data capture for research studies [36,37]. Survey responses will be stored on a secure network drive at the University of Victoria. Participants will be compensated with grocery cards valued at \$25 CAD for completing all questionnaires at each assessment point, for a total of \$100 incentive value over the study duration.

Sample Size

The parameters used for sample size calculation are based on the results of a published randomized controlled trial evaluating the effectiveness of a family-based intervention to reduce BMI z-score relative to control [38]. The estimated sample is 232 children in total, using a two-parallel group design and power = 80%. Based on previous research [17,38,39], the attrition (loss on follow-up) is expected to be similar between the groups (20%). In sum, the trial aimed to recruit a study population of 278 subjects, which accounts for an attrition rate of 20%. In practice, the trial successfully recruited a total of 270 subjects.

Intervention

The Early Intervention Program (EIP) intervention aims to target children who are off the healthy weight trajectory, with the goal of managing overweight and preventing progression to obesity. EIP curriculum activities have been designed to support children and parents in learning behavioural change skills that will enable them to improve their health-related lifestyle behaviours. The details of the intervention content have been previously published [21]. Families attend weekly 2-hour virtual group healthy living sessions comprising family-based and parent-only components. Family-based components consist of interactive lessons and active games to keep children engaged

in learning and enhance their reflexive processes that lead to habit formation. For the final 30 minutes of each session, parent-only components focus on food and physical activity-related practices and strategies for improving the home environment.

The EIP intervention will be delivered by a team of two facilitators with backgrounds in nutrition or physical education. These individuals will receive training from the centralized research team (based at the University of Victoria), including attending virtual EIP sessions delivered in BC by the Childhood Healthy Living Foundation. Facilitators will be participants' main point of contact during the 10-week intervention duration and will call each enrolled family (via phone or video chat) individually prior to the first group session to orient them to the program. They will send weekly email reminders for group sessions and reach out to participants following absences.

During the 10-week intervention, the facilitation team will deliver 1 individual orientation call and 9 weekly group sessions over Zoom. Weekly group sessions will follow the EIP curriculum with modules on healthy eating, physical activity, behaviour change skills, mental health, parenting practices, sleep routines, and media use. Participants will be provided with a physical kit containing hard-copy binders of the session handouts along with materials to use during session activities (jump ropes, water bottles, juggling scarves, hacky sacks). Throughout all sessions, facilitators will accentuate behavioural change skills (cognitive and behavioural regulation processes) such as goal setting and monitoring. One group session will include a "Healthy Eating Q&A" led by a Registered Dietician in addition to the regular facilitation team; participants will also have the option to attend up to 3 virtual live cooking classes led by a Registered Dietician and child assistant.

In addition to the facilitated weekly sessions and cooking classes, participants in the intervention group will have access to a self-guided online family portal offering additional resources and information, healthy recipes, articles for parents, videos, and suggested healthy eating and physical activities. This will also serve as a repository of materials covered in each session, maximizing flexibility in terms of participants interacting with intervention content.

Active Control Group

To match the weekly intervention delivery frequency, the active control group will be given access to a similar secure web portal where they can view weekly educational content aligned with the EIP topics. This information is based on EIP curriculum and relevant information and resources from the Canadian public health agencies (e.g., Canada's Guide to Healthy Living, Canada's Food Guide, Canada's Physical Activity Guide). These materials are guideline-based, user-friendly, and visually appealing, and they include child-specific content.

At baseline, a member of the research team will meet with each control participant for a 10-15 minute online video meeting to orient parents to the online portal and ensure they have sufficient internet literacy to access the online resources. However, the control group will not receive other personal contact such as the EIP facilitated group sessions, physical kits, virtual cooking classes or Q&A sessions, regular check-ins, or email reminders to access the resources. All families in both study groups will maintain the same delivery schedule (10 weeks in total; see Figure 1).

Primary Outcome

Each child's BMI z-score will be calculated based on the World Health Organization criteria [40]. Height and weight will be self-reported at each timepoint via online questionnaire, with parents provided with instructions to accurately measure their child's height and weight at home [41].

Secondary Outcomes

Child Physical Activity Behaviours

Changes in physical activity will be measured using accelerometry via FitBit Inspire wrist-worn activity trackers. Seven consecutive days of daily step counts will be measured at each assessment timepoint. Changes in physical activity predilection and adequacy and perceived intrinsic motivation and competence in physical activity will be measured using the Motivation and Confidence subscale of the Canadian Assessment of Physical Literacy (CAPL-2) [42]. Physical activity self-report will be measured using the Physical Activity Questionnaire for Older Children

(PAQ-C) [43] and CAPL-2 [42]. Changes in physical activity confidence, sedentary behaviour, and family support for physical activity will be assessed using the Physician-based Assessment & Counseling for Exercise (PACE) Adolescent Psychosocial Measures [44]. Physical activity and screen time self-efficacy will be measured using the FLASHE questionnaire [45].

Child Dietary Behaviours

Changes in dietary behaviour will be assessed using the seven-day recall questionnaire retrieved from the Behavioral Risk Factor Surveillance System Survey Questionnaire [46]. Healthy eating outcome expectations will be assessed using the Power Play! Survey [47]. Dietary behaviour self-efficacy will be assessed using the PACE Adolescent Psychosocial Measures [44]. Healthy eating motivation will be assessed using the FLASHE and Modified Child Nutrition questionnaires [45,48], and perceived cooking skills will be assessed using the Cooking with Kids questionnaire [49].

Child Mental Well-Being and Quality of Life

Changes in a child's self-reported self-esteem, gratitude, and self-compassion will be measured using the Self-Esteem Measure from Project EAT [50], the Gratitude Adjective Checklist [51], and the Self-Compassion Scale for Children [52], respectively. Children's self-reported sleep quantity will be measured using the FLASHE questionnaire [45]. Changes in a child's health-related quality of life (HRQoL) will be assessed by parents (proxy report) using the Pediatric Quality of Life Inventory [53].

Parent Support for Healthy Family Lifestyle Environment

Parents will complete a questionnaire assessing changes in parental support, habit, role identity, and behavioural regulation of supporting their child's physical activity and healthy eating practices using the Parent Support of Child Physical Activity and Eating Behaviours questionnaire [54], the Exercise Identity Scale [55], the Activity Support Scale for Multiple Groups [56], and the Perceived Behavioral Control Over Child Physical Activity Support scale [57]. Changes in parental

feeding practices and food preparation self-efficacy will be assessed using the FLASHES-EAT survey [58]. The structure of the home food environment and parent's habits and dietary behaviours will be assessed using the Fruit and Vegetable At Home Survey for Parents [59]. Family eating habits and family physical activity habits will be measured using the Self-Report Habit Index [60].

Intervention Engagement and Attrition

For the control group, engagement with web content will be assessed based on the number of web portal logins, percentage of content accessed, and time spent viewing pages. For the EIP intervention group, engagement will be assessed based on the number of Zoom-based group sessions attended as well as web portal usage (logins, percentage of content accessed, and time spent viewing pages). Attrition will be recorded when a family withdraws from the study.

Data Analysis

All analyses will be intention-to-treat. Patterns of missing data in the study groups will be examined, and multiple imputations will be applied to address missing data if data are missing at random. Generalized linear mixed models will be used to compare the effectiveness of the two treatments in improving the primary outcome, BMI z-scores, over time. The models will include fixed effects for treatment group, time, and their interaction, and will adjust for baseline BMI z-score and child's sex and/or gender. A random intercept will be included to account for within-subject correlations across repeated measures. Similar to the primary outcome analysis, generalized linear mixed models will be used to examine changes in secondary outcomes over time. Models will adjust for the baseline value of the outcome, child's gender, and parent's relationship to the child, and a random intercept will be included to account for repeated measures.

Subgroup Analyses

Analyses will be performed to i) describe intervention engagement and attrition to explore potential differences by parental income and education, sites, ethnicity; ii) conduct descriptive analyses to explore whether intervention effectiveness differed between children's gender or sex in

the treatment group, and iii) use regression analysis to evaluate the dose-response relationship in the intervention group and improvements in children's health-related outcomes at 10 weeks, 6 months, and 12 months. Intervention dose will be defined as intervention engagement.

Results

This study was funded in January 2020; recruitment began in January 2021. A total of 270 participants have been enrolled. Data collection is expected to be completed by June 2025.

Discussion

Anticipated findings

This study aims to evaluate the effectiveness of the EIP intervention compared to a web-only control group in improving BMI Z-scores and related health outcomes in children aged 8–12 years. Based on the study objectives, it is hypothesized that children in the EIP intervention group will show greater reductions in BMI Z-scores than those in the control group over the 12-month period. In addition, improvements in secondary outcomes are anticipated, including healthier lifestyle behaviors, enhanced quality of life for children, and increased parental self-efficacy and motivation to support their child's healthy living. The blended delivery model, which combines self-guided resources with virtual synchronous sessions, is likely to foster greater engagement and adherence, promoting sustainable behavior changes.

Strengths and Limitations

The study has several strengths. First, the innovative blended intervention design combines the scalability and flexibility of internet-based programs with the added benefits of real-time support through virtual synchronous sessions. This hybrid approach has the potential to address common challenges in traditional in-person or self-guided online programs, such as limited accessibility and engagement, respectively. Second, the program was developed in collaboration with community stakeholders and informed by feedback from pilot participants, ensuring its relevance and practical applicability. Third, the intervention is grounded in the M-PAC framework, a robust theoretical

model that emphasizes intention formation, action control, and maintenance, supporting sustained behavior change. Fourth, the rigorous randomized controlled trial design enhances the validity and reliability of the findings. Finally, the study incorporates comprehensive outcome measures, providing a holistic understanding of the program's impact on both children and parents.

However, this study also has limitations. The reliance on parent-reported data for height, weight, and dietary behaviors may introduce reporting bias. Protocol for parent-report measure for child height and weight were adopted due to COVID-19 restrictions at start of the trial. However, previous research has shown that parent measurements of height and weight can be effective in classifying child weight status in the absence of professional measurements [61] and providing instructional guides may improve accuracy [62]. Therefore, participating parents will be instructed to measure children as accurately as possible and provided with a link to an online guide titled "Measuring Children's Height and Weight" from the US Centres for Disease Control and Prevention [41].

Despite these limitations, this study has the potential to significantly advance the field of childhood obesity management by providing evidence on the effectiveness of internet-based intervention. The results will offer valuable insights into how virtual synchronous sessions can enhance engagement, support behavior change, and improve health outcomes. These findings will inform policymakers, healthcare providers, and community organizations on the development and implementation of scalable, flexible, and effective interventions for managing childhood obesity.

Conclusion

The Early Intervention Program (EIP) represents an innovative, scalable, and family-focused intervention designed to address the growing public health challenge of childhood obesity. Leveraging feedback from community stakeholders and pilot participants has allowed tailoring of the EIP to meet the diverse needs of families while maintaining flexibility and accessibility. By integrating self-guided web-based resources with online synchronous group sessions, the virtual EIP

aims to enhance engagement, promote sustainable behavior changes, and improve BMI Z-scores and related health outcomes in children aged 8–12 years.

This trial will provide critical insights into the relative effectiveness of blended versus stand-alone web-based interventions, addressing a key gap in the current literature. Findings from this study will inform future program development and implementation strategies, offering a practical, evidence-based solution to support families in adopting healthier lifestyles. Ultimately, the EIP has the potential to make a meaningful contribution to public health efforts aimed at reducing childhood obesity and improving the quality of life for children and their families.

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Conflict of Interest

None to declare.

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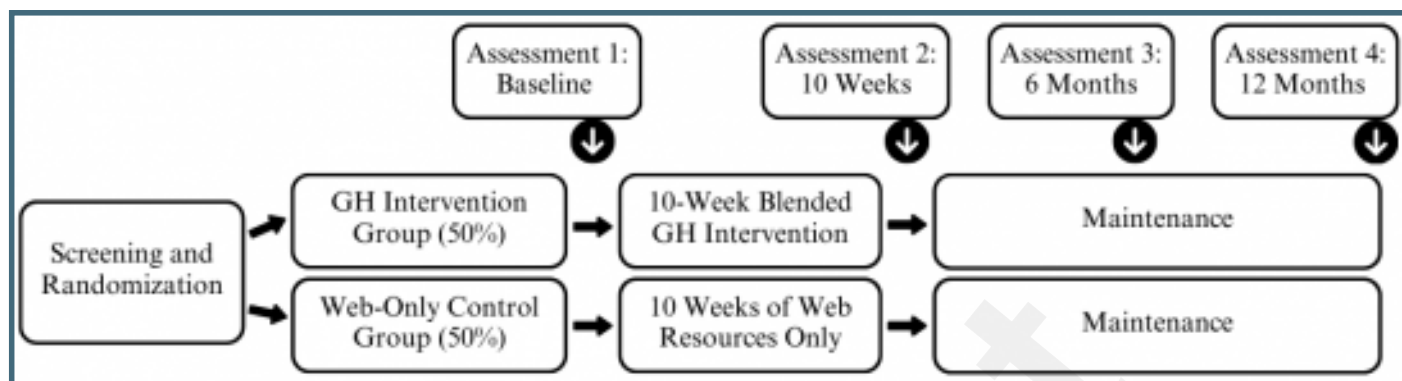
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Supplementary Files

Figures

Overview of the study design and assessment timeline.



Multimedia Appendixes

Peer-review feedback from CIHR granting agency.

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