

Aim2Be an mHealth intervention for children with overweight and obesity: Study protocol for a randomized controlled trial

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Study protocol

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Abstract

Background: The prevalence of overweight and obesity remains high in Canada, and the current standard for the treatment of childhood obesity is in-person family-based multidisciplinary interventions that target lifestyle behaviours (e.g. diet, physical activity, and sedentary behaviours). These programs are costly to operate, have limited success, and report recruitment and retention challenges. With recent advances in technology, mobile health or mHealth has presented as a viable alternative to in-person interventions for behavior change, especially with teens.

Purpose: The primary aim of this study is to test the efficacy of Aim2Be, a gamified app based on behavior change theory with health coaching at improving weight outcomes (i.e., decrease in zBMI) and lifestyle behaviours (i.e. improve dietary quality, increase fruit and vegetable intake, reduce sugar-sweetened beverage intake, increase physical activity, and reduce screen time) among 10-17 year old children with overweight or obesity versus their peers randomized into a waitlist control condition. The secondary aims of this study are to: 1) test whether supplementing the Aim2Be program with health coaching increases adherence; and 2) examine the mediators and moderators of adherence to the Aim2Be intervention.

Methods: We will employ a randomized controlled trial design and recruit 200 child and parent dyads to participate in the study (2019-2020). Participants will be recruited from Canadian pediatric weight management clinics, and through online advertisements. Child participants must be between the ages of 10-17 years, have overweight or obesity, be able to read English at a grade 5 level, and have a mobile phone or home computer with internet access. Following baseline data collection, participants will be randomized into intervention and waitlist control groups. Intervention participants will receive access to Aim2Be, with access to health coaching. Following 3-month data collection, the control group will gain access to Aim2Be; with no access to health coaching. Participants will control their frequency and duration of app usage to promote autonomy.

Discussion: Findings from this study will determine the efficacy of using Aim2Be in improving child weight outcomes and lifestyle behaviours and guide future mHealth interventions for pediatric weight management.

Introduction

In Canada, about one third of children aged 5-17 years have either overweight (19.8%) or obesity(11.7%) (1). As children with overweight or obesity grow, they are more likely to develop a host of health issues including cardiovascular risk factors, Type 2 diabetes, asthma, sleep apnea, joint pain, and mental health issues (2-6). Furthermore, numerous reports have shown that childhood obesity tracks into adulthood (7, 8), highlighting the need to develop efficacious and accessible lifestyle interventions for children and teens.

The causes of childhood obesity are complex and multifactorial (9). Currently, the accepted standard of care for the management of childhood obesity is to provide in-person family-based multidisciplinary interventions that target lifestyle behaviours (e.g., diet, physical activity, and sedentary behaviours) and behavioural strategies at both the individual and familial levels (10, 11). While such strategies are efficacious at decreasing weight or Body Mass Index (BMI) z-score (10, 11), their effects are modest, not sustained, and high attrition is a common problem (12-16). In a German study that included 21,784 children attending a community weight management program, 76% and 92% of the participants dropped out after six and 24 months, respectively (14). If these pediatric weight management interventions are going to achieve optimal impact for children and their families, there is a need to develop and evaluate how more novel and engaging interventions can meet the needs of these families and improve health outcomes (17).

Mobile health (mHealth) technologies provide an opportunity to bring weight management interventions directly to individuals and to deliver such interventions on an ongoing basis throughout the day (18). In children, mHealth interventions have predominantly targeted 12-15 year olds although some studies have included 15-19 year olds (19). Data on the efficacy of mHealth interventions for managing childhood obesity is still emerging (19, 20). Importantly, mHealth interventions are ideally suited to: 1) address some of the barriers associated with in-person lifestyle behaviour modification interventions including lack of enthusiasm for in-person meetings, lack of financial resources, inconvenient location, and lack of time (12, 15, 21, 22); 2) emphasize the development of self-regulatory skills (e.g., goal setting, planning, and self-monitoring) that are a hallmark of effective lifestyle behavioural modification interventions (11), as specific app features can be designed to support self-regulatory processes; and 3) improve engagement by incorporating game-design elements without the context of what is traditionally considered a “game” (23). A review by Johnson et al. (24) identified that gamification can benefit health and wellbeing interventions, and that behavioural outcomes, in particular physical activity, may be the most ideal targets for gamification. With continued advances in wearable or transportable technologies (e.g. smart phones, smart watches, wireless activity trackers and other wireless devices) and the high penetrance of mobile phones use among children (5-15 year old spend an average of 15 hours per week on a mobile phone (25, 26)), there is a need to harness the potential of mHealth lifestyle behaviour modification interventions in the pediatric context, especially interventions targeting children 10 to 17 years of age.

To meet this need, an mHealth lifestyle behaviour intervention - Aim2Be - was developed to promote healthy behaviours related to nutrition, physical activity, screen time, and sleep among children with overweight or obesity and their families. This paper describes our plan to assess the efficacy of Aim2Be in the context of a randomized controlled trial (RCT).

Study aims and hypotheses

The primary aim of this RCT is to test the efficacy of Aim2Be with health coaching at improving weight outcomes and lifestyle behaviours among 10-17 year old children as compared to those randomized into a waitlist control condition. It is hypothesized that children whose families receive the Aim2Be with health

coaching will significantly decrease their age adjusted zBMI scores as well as significantly increase their moderate-vigorous physical activity, improve dietary behaviours (i.e., increase fruit and vegetable intake, improve dietary quality, and reduce sugar-sweetened beverage intake), and reduce screen time behaviours.

The secondary aims of the RCT are to: 1) test whether supplementing the Aim2Be program with health coaching increases adherence to the intervention; and 2) examine the mediators and moderators of adherence to the Aim2Be intervention. Given the exploratory nature of these aims, no hypotheses are stated.

Methods

Study design

A total of 200 Canadian children who have overweight or obesity and one of their parents will participate in the trial, taking place in 2019-2020. The majority of the participants will be recruited for a study funded in part by the Public Health Agency of Canada with matched funds from partners. A portion of the participants (n=60) will be recruited as part of a study embedded within a Canadian Institutes of Health Research (CIHR) Team Grant in Bariatric Care (Team ABC 3) (27). After consent and baseline measurements, families will be randomized into one of two conditions: 1) intervention or 2) waitlist control. Families randomized into the intervention condition will receive the Aim2Be app with health coaching (i.e., receive tailored messages from a health coach with the option of scheduled and unscheduled text support). All participants will receive a package containing a scale, measuring tape, activity tracker (Fitbit), and a brochure with current health recommendations. At 3 months, families randomized to the waitlist control conditions will move to the intervention for months 3 to 6, but they will not be supported by the health coach. Data collection will occur at baseline, 3-months, and 6-months utilizing REDCap (Research Electronic Data Capture)(28, 29) hosted at BC Children's Hospital Research Institute (BCCHRI). Staff involved in the data collection and analysis will not be involved in delivering the intervention. Ayogo Health Inc and the Childhood Obesity Foundation (COF) will deliver the Aim2Be intervention. The BCCHRI / School of Population of Public Health (SPPH) at the University of British Columbia (UBC) will collect and analyze the data. The study flow chart is shown in Figure 1.

(INSERT FIGURE 1 HERE)

Computer-generated (www.sealedenvelope.com) randomization schedule will be used to allocate participants in blocks of four, six, or eight participants with a randomization ratio of 1:1 (30). The allocation schedule will be concealed in the randomization module of REDCap and only assigned after informed consent and baseline assessments have been obtained. Research team members will not enter or modify the allocation schedule as it will be entirely computer generated. Participants will not be blinded to their allocation conditions as participants will know whether they receive the Aim2Be intervention immediately or in 3 months. Allocation assignment will be concealed to the researchers at the analysis stage.

Study participants

Inclusion and exclusion criteria. Child participants must be 10-17 years old and literate in English, able to read at the grade 5 level or above, and have a mobile phone or a computer with Internet access at home. Child participants must have either overweight or obesity, based on the World Health Organization cut-offs for children and adolescents aged 5 to 19 (BMI > 85th percentile). Parent participants must be the caregiver with whom the child primarily lives, and must be literate in English.

Children must not have: diagnosis of any musculoskeletal, cardiovascular, pulmonary, or orthopedic problems; disabilities precluding the participant from being physically active; any other physical condition that precludes the participant from being physically active; diagnosis of anorexia nervosa or bulimia nervosa; diagnosis of type 1 diabetes; dietary restrictions or special diets that limit a participant's ability to eat a variety of foods; simultaneous participation in another physical activity, nutrition, or weight management study/program; use of medication, nutritional supplements, or herbal preparations to help lose weight; pregnancy; or a history of psychiatric problems or substance abuse which would interfere with adherence to the study protocol.

Recruitment. Participants will be recruited using two main methods: clinical site referral and social media (i.e., Facebook advertisements with a link to study site). Seven clinical weight management programs across Canada are participating in this study and include: BC Children's Hospital (Vancouver, BC), Alberta Children's Hospital (Calgary, AB), Stollery Children's Hospital (Edmonton, AB), Misericordia Community Hospital (Edmonton, AB), McMaster Children's Hospital (Hamilton, ON), The Hospital for Sick Children (Toronto, ON), and Children's Hospital of Eastern Ontario (CHEO) (Ottawa, ON). Clinical sites will use a combination of mailing and e-mailing invitation and information packages as well as telephone contact. All potential participants will be provided an invitational package that describes the study and includes copies of the consent and assent forms, as well as a link to the study website.

For both groups of potential participants, interested individuals will be asked to complete a secure, online consent to contact form in REDCap and provide their contact information. Individuals who express interest in the study will be screened via telephone for eligibility.

Consent/assent process. All participants will provide informed consent or assent prior to taking part in this study. All parent participants, with the exception of parents of children 16 years of age or older recruited from CHEO, will be asked to sign a consent form consenting to their own and their child's participation in the study. Parents of children 16 years of age or older recruited from CHEO will be asked to sign a consent form agreeing to their own participation in the study. All child participants, with the exception of those 16 years of age or older recruited from CHEO, will be asked to sign an assent form agreeing to their own participation in the study. Child participants 16 years of age or older recruited from CHEO will be asked to sign a consent form agreeing to their own participation in the study.

Sample size calculation. Based on previously published data (31), the RCT will have 80% power at an alpha of .05 to detect a .5 decrease in BMI z-score when the sample size in each group is 60. BMI z-score

was used to calculate sample size as it is the most difficult variable to change, and requires the largest sample size of all of the primary outcomes. Based on this and accounting for both missing data and attrition, we project needing at least 80 families in each condition. However, to be able to detect a 20% difference in adherence (e.g., secondary aims outcome) between the two intervention groups (odds ratio of 2.33) at an alpha of .05 with 80% power using a one-sided t-test, 77 families are needed in each group. As the waitlist control group will receive the intervention at 3 months, we require 100 participants enrolled in each group (this accounts for 15% attrition from baseline to 3-month and that about 8% of the families will not download the Aim2Be app). Power calculations were conducted in nQuery (Statsols, USA). Based on these computations, we aim to enroll 200 participants in the RCT.

Development and description of Aim2Be

Aim2Be development. Aim2Be, which will be evaluated in this RCT, was built on the foundational knowledge learned in the first generation of the program called LiGHT (Living Green Healthy and Thrifty) and the second generation of the program, called Aim2Be version 1 (v1). LiGHT was an 11-module online program that integrated lifestyle behaviour modification principles with environmental and financial concerns to address childhood obesity among 10-17 year old children and their families (32). Modest and non-significant improvements in readiness to change were initially observed for both the child and parents, likely due to ceiling effects on the measure and small sample size (N=17 child-parent dyads). However, the qualitative feedback (N=10 child-parent dyads) suggested that the LiGHT approach held promise. Specifically, both children and parents indicated that they related strongly to the foundational approach of the LiGHT intervention, meaning they liked having behaviours linked with health, environmental, and financial concerns. The evaluation also uncovered key areas that needed further improvement including making the program more visually appealing, adding more interactivity, and creating a sense of community for the users.

The second generation of the intervention transitioned from a web-based intervention to a mobile app (iOs and Android) and was renamed Aim2Be. For those who do not have a smartphone, Aim2Be has remained accessible as a web-based platform via the internet. Aim2Be became a gamified app that supports children and their families to initiate sustainable behaviours in four primary areas: healthy eating, active living, reducing screen time, and healthy sleeping habits. It retained its focus on linking behaviours with health, and ~~and living green and economically~~ as well as adding emphasis on healthy body image and strong self-esteem. While Aim2Be retained some core elements from the LiGHT program, it: 1) became strongly grounded in theories of behaviour change (i.e., being family-based; supporting the development of self-regulatory skills at both the individual and familial levels; and enhancing self-efficacy through graded tasks)(10, 11, 19, 33); 2) integrated principles of maintenance of health behaviours and as such it included self-regulatory processes that support intrinsic motivation (34-38); 3) integrated gamification practices – designed to maximize for both enjoyment and motivation (39); 4) recognized the importance of body image and self-confidence in lifestyle management, 5) used the mHealth context to support self-regulatory processes (40); 6) aligned with best clinical practices and guidelines in three areas: a) the treatment of childhood obesity in Canada as it aligns with the curriculum of Canadian

Weight Management programs (e.g., being family based, multi-behavioural, and focus on supporting skill development at the individual and familial levels); b) clinical guidelines for the management of childhood obesity as it integrates the central elements that need to be incorporated in these interventions (e.g., family focused, focused on improving lifestyle behaviours, skill based support) (41); and c) Canadian health recommendations including the Canadian 24 Hour Movement Guidelines (42) and Canada's Food Guide (43); and 7) was designed specifically with and for children and their families (see details below).

Aim2Be was iteratively and incrementally developed. The first version of Aim2Be (v1) was field tested for 4.5 months among 301 teens 14-17 year and 315 parents. The quantitative evaluation revealed that teens who were moderately and/or highly engaged in the app (>30 min of app usage) as compared to those with low engagement (≤ 30 min of app usage) significantly increased their motivation and self-efficacy to improve their dietary habits (i.e., limit sugar-sweetened beverages and increase intake of fruits and vegetables) and sedentary behaviours (i.e., limit screen time). At 4.5 months, children significantly increased their previous day intake of fruits and vegetables, decreased their consumption of 100% fruit juice, and reduced their screen time. In addition, parents who were more engaged with Aim2Be v1 reported significant improvements in their dietary behaviours (i.e., increased intake of fruits and vegetables and decreased intake of sugar-sweetened beverages). Additionally, multiple rounds of qualitative evaluations were conducted among 36 teens/pre-teens and 24 parents. The qualitative evaluations included both focus groups and 2-week prototype testing followed by semi-structured interviews. The results of these evaluations led to numerous improvements in Aim2Be including: clarifying the overall purpose of Aim2Be, supplementing the tracking and check-in sections, adding more engaging features, and syncing the app with physical activity monitoring (i.e., Fitbit).

The conceptual framework of Aim2Be is shown in Figure 2. At its core, the behaviour change techniques (BCT) incorporated in Aim2Be are rooted in: 1) Social Cognitive Theory (SCT) (44); 2) the Player Experience and Need Satisfaction (PENS) model – an extension of the Self Determination Theory model for the gamified context which incorporates enjoyment to support intrinsic motivation and the basic psychological needs that promote intrinsic motivation (autonomy, relatedness, and competence/self-efficacy) (39, 45); and 3) the ACUDO framework (46). The ACUDO framework, is a best practice framework developed by Ayogo Health Inc. (46) to promote engagement and enjoyment by: a) supporting Agency, b) incorporating Challenges, c) infusing Uncertainty, d) supporting self-Discovery and exploration, and e) adding fun Outcomes such as rewards. Specifically, Aim2Be includes strategies that target: 1) **Gamified mediators** of behaviour change to ensure the experience is both enjoyable and engaging; 2) **Behavioural mediators** that aim to activate self-regulatory skills and support the development of intrinsic motivation and increase self-efficacy as a way to support behaviour change and ultimately support healthy body weights; and 3) **Environmental mediators** as it is recognized that behaviour change needs to be physically and emotionally supported in the familial environment and that social support from both peers and/or coach is also important to changing health behaviours (see Figure 2).

(INSERT FIGURE 2 HERE)

Aim2Be features. Aim2Be is not a prescriptive app, but instead it utilizes strategies to activate self-regulatory skills through a self-guided journey of self-discovery of current health behaviours and autonomy to select which health behaviours the user wants to work on. Strategies employed by the various app features are grounded in Michie’s behaviour change taxonomy which specifies the “active ingredients” of behaviour change interventions (47). Children will be subdivided into two versions of the app based on their age: teens (13-17 year olds) and pre-teens (10-12 year olds) and will be able to select which Aims they wish to address. Once an Aim is selected, teens start a stage and pre-teens start the Aim as a whole, and then are provided tasks to help them set incremental goals, plan, and self-monitor their behaviours. In the application environment, the user progresses along their journey by completing games, tasks and activities including quizzes. The user receives currency that they can use to unlock collectibles and ‘choose your own adventure’ stories. Users are provided with tools within the app to further support their journey including Check-Ins, Quick Wins, Articles, Quizzes, and a moderated Social Wall with daily topics to help engage users. Features that are incorporated in the pre-teen, teen, and parent apps, as well as the BCT (47) targeted by these features, are summarized in Table 1.

(INSERT TABLE 1 HERE)

Study conditions

Intervention condition participants will have access to the full version of the Aim2Be app (as described in Table 1) for six months. In addition, participants (teens and parents) will have the option to access a health coach who can support them in health behavior change using motivational interviewing techniques. The health coach has training in motivational interviewing and expertise in lifestyle management and working with families. The health coach will communicate with participants through the in-app text feature and participants have the option to schedule a live text session if they wish to. The health coach will send an initial contact to all participants, and follow-up supportive messages. The exact messaging and frequency of messaging that the health coach will provide to participants cannot be predicted, as this coaching will be individually tailored to the questions and concerns participants raise with the health coach, and the frequency with which they reach out to the health coach. This is in line with the autonomy support model featured throughout Aim2Be, where participants can choose which health behaviours to focus on.

Waitlist Control condition participants will be put on a waitlist for three months during which time they receive a brochure with Canadian health recommendations about physical activity, diet, screen time, and sleep habits (this represents the duration in which they are part of the efficacy trial - see Figure 1). Once their 3-month assessment is complete, they will have access to Aim2Be app with no health coach for the following three months. Participants will have access to all features of the Aim2Be app except the health coach and will be assessed three months after they were given access to the Aim2App with no health coach. This three-month period will be compared to the three-month period of the intervention condition to determine differences in adherence in Aim2Be with and without health coach support.

Study data

Data collection occurs at baseline, 3-months, and 6-months and at each time point the participating parent and their teen will complete an online survey administered using REDCap. The teen will also complete three 24 hour dietary recalls using the Waterloo Eating Behaviour Questionnaire (WEBQ) and parents will measure their teen's height and weight following the protocol and tools provided by the research team. Finally, the study team will extract 14 days of Fitbit Flex 2 (Fitbit Inc., San Francisco, CA) wear for each teen at each assessment time point using Fitabase (Small Steps Lab LLC, San Diego, CA, USA), an online platform designed specifically for research using Fitbits. Participants will receive their Fitbit at baseline. See the Figure 3 for the SPIRIT Figure (48, 49) to see when data collection occurs and for a detailed list of data that are collected to address the primary and secondary aims of this study. The complete SPIRIT checklist can be found in Additional File 1.

(INSERT FIGURE 3 HERE)

Primary outcomes

Change in weight outcomes. Height and weight will be measured by parents using the Centers for Disease Control and Prevention home protocol (50) and used to calculate Body Mass Index (BMI) kg/m^2 which is a valid and reliable method to assess BMI in children (51). Each participant will be mailed a digital scale (Active Era) and tape measure (HDX) so that all measurements are taken using the same instruments. This procedure has been validated to assess height and weight at home among adolescents and found to provide valid assessment (51). Teen BMI z-scores will be computed using a Stata macro developed by the World Health Organization whereby a BMI z-score > 1 and ≤ 2 Standard Deviation = overweight and >2 Standard Deviation = obese) (52).

Change in physical activity behaviours will be assessed using a Fitbit Flex 2, which can be immersed underwater (53) (Fitbit Inc., San Francisco, CA) and with a questionnaire. Each participant will be mailed their Fitbit Flex 2 at baseline. From the Fitbit Flex 2, total steps per day for a period of 14 days will be extracted using the Fitabase platform. The child physical activity questions were modelled after the International Physical Activity and the Environment Network questions (54) and ask about participation in physical education at school in past week, involvement in team sport, and number of days of moderate-vigorous physical activity in the previous week.

Change in dietary habits will be measured using the WEBQ, a 24 hour dietary recall web-questionnaire developed by the University of Waterloo which has been validated in children (55), and with a questionnaire. Three 24 hour dietary recall WEBQs (including 1 weekend day) will be analyzed using the Food Processor Software (ESHA Research, Salem, OR) using the 2015 Canadian Nutrient data file. An index of diet quality using the Healthy Eating Index adapted for Canadian food recommendations will be computed. The index computes a score from 0-100, where < 50 is categorized as poor diet; 50-80 as needing improvement, and ≥ 80 as being good (56, 57). In addition, seven dietary questions were included into the child's questionnaire and these questions were taken from the 2016 Canada Community Health Survey (58) with some questions originating from the Behavioral Risk Factors Surveillance System

(59) and Centers for Disease Control and Prevention National Youth Physical Activity and Nutrition Study (60). Questions asked about previous week and previous day consumption of fruits and vegetables, 100% fruit juices, and sugar-sweetened beverages.

Change in sedentary behaviours will be measured with an adapted version of French et al.'s assessment of screen time which has been found to be sensitive to intervention-mediated change (61). Two questions ask the amount of time children spend in front of screen in their free time on weekdays and weekend day.

Secondary outcomes

Adherence will be measure with web-analytic data that is internally collected within the Aim2Be app for children. Adherence will be first operationalized as time spent using Aim2Be, number of days using Aim2Be, and number of tasks completed. Given that web-analytic data tracks all features that children are using and the content utilized, if variability in the data allow profiles of users will be used as outcomes.

Mediators that will be examined with respect to adherece are linked to the theoretical framework of Aim2Be (see Figure 2). The list of mediators are included in Appendix 1 and include: 1) assessment of satisfaction with Aim2Be for gamification mediators; 2) measures of motivation, self-efficacy, and psychological autonomy for behavioural mediators; and 3) assessments of the household environment (family communication and functioning), parenting styles and practices, access/opportunities (cell phone, TV in bedroom, co-participation in physical activity), modeling healthy behaviours (e.g., parent own behaviours), and parental support for environmental mediators.

Moderators that will be examined will be taken from the demographic questions (i.e. age, gender), as well as assessment of enjoyment and preferences for engaging in the behaviours targeted by Aim2Be (5 items assessing food and sedentary behaviours preferences and enjoyment for physical activity), knowledge of current health recommendations (8 Yes/No items asking knowledge about the physical activity, diet, screen time, and sleep recommendations), weight concerns (2 items), self-esteem/optimism (6 items) (62), and anxiety/worries (3 items) (63).

Statistical analyses

To address the primary aims, multilevel mixed-effect linear and logistic models, which account for the repeated nature of the data, will test whether zBMI, dietary quality, fruit and vegetable intake, sugar-sweetened beverage intake, physical activity, and screen time behaviours at 3-months differ between Aim2Be and control condition participants. To address the secondary aim that examines whether health coaching influences adherence to the Aim2Be intervention, linear regressions will be used to compare time spent using Aim2Be, number of days using Aim2Be, and number of tasks completed. Three analyses will be run, one for each adherence variables (i.e., time spent in app, numbers of days in app, tasks completed). As the data are expected to be skewed, the dependent variables will be log transformed or

utilize the optimal transformation to deal with the skewness of the data. Finally, examination of the mediators and moderators of adherence will use path analyses and relevant socio-demographic covariates and explore whether recruitment routes influenced adherence (e.g., self-referral or healthcare facility referral). Multiple imputations techniques will be used to deal with the missing data. Analyses will be conducted in Stata (StataCorp LLC, College Station, TX, USA) and MPlus (Muthen & Muthen, Los Angeles, CA, USA).

Quality assurance and monitoring

Operating procedures will be documented in a Standard Operating Procedure manual to standardize administration of trial conditions, data collection methods, tracking procedures, and checking programming into REDCap (e.g., randomization, administration of tools within specified timeline). Any adverse events will be reported to both the Childhood Obesity Foundation and the University of British Columbia Children's and Women's Research Ethics Board and accordingly added to the trial registry.

Post-trial care

Study participants will be provided access to the app, and any updates to the app, for as long as the app is supported by the providers. At the end of the evaluation period, participants will receive emails and a push notification alerting them that the study is complete, at which time they will need to sign a new agreement with the providers if they wish to continue using the Aim2Be app. If a user does not agree to continue using the app their user account will be deactivated and a reactivation code will be emailed to them. If they chose to return to the app, they will need to agree to the provider's agreement. Participants are given the option to continue using the app after the study ends, as there are ethical concerns associated with discontinuing access once the evaluation window is over, particularly if the participant found the program useful.

Data confidentiality

All questionnaire data will be collected in REDCap hosted at BCCHRI. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources (28, 29). Personal identifiable information about participants will be kept separate from the main dataset and will not be shared. The main dataset will be deidentified. All data will be stored securely on site at BCCHRI, University of British Columbia with access limited to authorized study personnel.

Trial Status

The trial is scheduled to be completed by November 30, 2020. Recruitment began on January 2, 2019 and will be completed by approximately October 31, 2019.

Reporting

Study results will be reported according to CONSORT guidelines. Study findings will be submitted to a peer-reviewed scientific journal for publication and be presented at academic conferences. The study results will also be reported in the ClinicalTrials.gov registry.

Discussion

Although in-person family-based interventions are the standard for supporting families of children with overweight or obesity, these programs are costly and may not outreach all those who can benefit from such programs. In addition, these programs often do not meet the needs of many families (12-16). Therefore, mHealth interventions may provide a viable alternative to in-person family-based interventions; however, the efficacy of such interventions have not been evaluated robustly in the current literature. Evidence from the current RCT will strengthen add to the current mHealth literature. This RCT will examine the efficacy of Aim2Be in decreasing zBMI score, and improving lifestyle behavior factors. Beyond this, the RCT will examine whether Aim2Be can provide a practical and accessible intervention that improves adherence to lifestyle interventions.

One limitation to the study is the short intervention period which may not allow for sufficient time to observe changes in BMI z-score, particularly in an adolescent population. However, the co-primary outcome data on lifestyle behavior (physical activity, diet quality), may provide greater insight into overall efficacy of Aim2Be. Furthermore, the mediators of behavior change and predictors of adherence will provide insights as to whether the intervention worked as intended. As the trial has a number of inclusion and exclusion criteria, we will gain a better understanding of who is reached by these mHealth lifestyle interventions in of these criteria and for whom it appeals to the most. Gaining a better understanding of the mediators and moderators that are linked with intervention adherence will serve to advance the understanding of how mHealth interventions work.

Declarations

Ethics approval and consent to participate

This study was approved by the Children and Women's Research Ethics Board at the University of British Columbia (H16-03090, H17-02032), University of Alberta Health Research Ethics Board (Pro00076869), Hamilton Integrated Research Ethics Board (2019-4250-A), The Hospital for Sick Children Research Ethics Board (1000059362), and the Children's Hospital of Eastern Ontario Research Ethics Board (18/01E). All participants will provide electronic informed consent or assent, and parents of all participants will provide electronic informed consent.

Consent for Publication

Not applicable.

Availability of data and material

Contact Dr. Louise C. Mâsse at the BC Children's Hospital Research Institute / School of Population and Public Health University of British Columbia (lmasse@bcchr.ubc.ca).

Competing interests

The Childhood Obesity Foundation (COF) (Janice Macdonald – Director of LiGHT Program, Jennifer Bradbury – COF Executive Director, Tom Warshawski – COF Chair of the Board of Directors) owns the content of LiGHT and Aim2Be. Aim2Be app features are built on Ayogo Health Inc.'s Empower™ Platform and Goal Store architecture which they own. As Aim2Be was developed, in part, with funds from the Public Health Agency of Canada (PHAC), the app can only be commercialized outside of Canada and as such both Ayogo Health Inc. and the Childhood Obesity Foundation own intellectual property and have financial interests.

PHAC has mandated that the evaluation be separated from the administration of the intervention. The COF staff will be involved in recruiting participants for the evaluation, but will not be involved with any other evaluation activities. The evaluation of Aim2Be is conducted by the BC Children's Hospital Research Institute (BCCHRI) / School of Population and Public Health (SPPH), University of British Columbia (UBC) under the supervision of Dr. Louise C. Mâsse. Dr. Louise C. Mâsse has provided scientific expertise in the development of Aim2Be but does not own any of the intellectual property or have any financial interests in Aim2Be. All reports prepared by UBC will be reviewed by a Faculty member from the School of Population and Public Health (SPPH) at UBC to ensure an impartial peer review is completed prior to submission. BCCHRI/SPPH/UBC will maintain the rights to publish the evaluation data regardless of the outcomes of the evaluation and own the data collected as part of the evaluation.

Composition, roles, and responsibilities for the trial

Development of Aim2BE app (COF, Ayogo with expert input from LCM but see above LCM has no ownership). Delivery of intervention (COF staff under guidance of JM and JB – Health coach hired by COF). Data coordinating centre (led by BCCHRI/SPPH/UBC under guidance of LCM with EJB and JV). Recruitment sites send participants to data coordinating centre (J Hamilton, J Ho, AB, KM, GB). Initial recruitment of participants will be conducted by COF staff and data coordinating centre staff – note that consenting, baseline data collection, and follow-up data collection will be completed by the data coordinating centre staff. Data coordinating centre will collect the data, oversee the trials, analyze the data, write the report, maintain authority to publish the report regardless of the outcomes of the trial. Reviewing outcomes of trials: All recruitment sites (who have no vested interests in the outcomes of the trial will review the outcomes and be involved in reporting the outcomes) and a Faculty member from SPPH to be appointed by SPPH. Note that COF will be responsible for ensuring the report appropriately describes the intervention. Strategies to support user retention were integrated into the app features (e.g. gamification, notifications). Strategies for completing follow-ups will be handled by the data coordinating centre. Outcomes of participants who are lost to follow-up will be analyzed but outcomes of participants

who request to be removed from the trial will be deleted and removed from the analyses. Auditing procedures: The app will be continuously monitored by the Health Coach (oversight every 2nd day or daily) to identify adverse events (e.g., inappropriate comments or disclosure of reportable information) and will report to COF (JB or designated alternate) and data coordinating centre (LCM or designated alternate). All events will be reported to the UBC research ethics board.

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Author' contributions

LM Conceived the efficacy and adherence studies

LM, JB, TW, GB Assisted / provided input in the development and review of the Aim2Be content

JM Oversaw the development and review of Aim2Be content and features

LM Led the development of the study design with contributions from GB, JB, TW

LM Led the selection of the study tools with contributions from AB, GB, J Ho, KMM, J Hamilton

LM Drafted the manuscript and subsequent versions with substantial contributions from JV, EJB

All authors read, edited and approved the final manuscript.

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Abbreviations

ACUDO: Agency, Challenge, Uncertainty, Discovery, Outcomes

BCCHRI: British Columbia Children's Hospital Research Institute

BCT: Behaviour Change Techniques

BMI: Body Mass Index

CHEO: Children's Hospital of Eastern Ontario

LIGHT: Living Green Health and Thrifty

PENS: Player Experience and Need Satisfaction

RCT: Randomized Controlled Trial

SCT: Social Cognitive Theory

SDT: Social Development Theory

SPIRIT: Standard protocol items: Recommendations for interventional trials

WEBQ: Waterloo Eating Behaviour Questionnaire

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Tables

Table 1 Aim2Be features

App Feature	Description	Behaviour Change Taxonomy(47)
Gamification Components		
Profile/Onboarding <i>PT, T</i>	After a user creates their Aim2Be account, they can play the game, “What animal are you?” The game involves answering a variety of questions about the user’s preferences, with various question formats. For example, a user might be asked whether they prefer spending time with people or spending time alone. At the end of the game, the user is presented with an animal avatar recommendation (e.g., Lynx, Tiger, Panda, etc.) along with adjectives describing that identify profile (e.g., “Wild, Determined, Unafraid, Intelligent, & Habitual”). The user is given the option to select a different animal avatar, if they wish, to represent them in the app and the option to further customize their animal avatar, by selecting clothes and accessories.	13.4 Valued self-identity
Daily Bonus <i>PT, T</i>	Each time a user opens the app, they are invited to break a piñata from which they can gain extra currency.	10.2 Material reward (behaviour)
Quick Wins <i>PT, T, P</i>	Each day, a new Quick Wins appear on a side bar of the users home page. Quick Wins are quick, simple, and straightforward tasks that prompt the user to do something positive for their health that day (e.g., “Stand up. Shake it out. Stretch. Reach up to the sky, then to the floor.”) or to encourage them to explore a new aspect of the app (e.g., “Check out Aimbot for help.”). Users earn currency dollars for each day they complete a Quick Win.	4.1 Instruction on how to perform a behaviour 8.1 Behavioural practice/rehearsal 8.2 Behaviour substitution 8.3 Habit formation 8.4 Habit reversal 8.7 Graded tasks 10.4 Social reward
Quizzes <i>PT, T</i>	Users can complete short quizzes within the app. Whether the user selects the correct or incorrect answer, a pop up appears after each question with an explanation of the correct answer. Users earn currency diamonds for each quiz they complete.	2.2 Feedback on behaviour 4.2 Information about antecedents 5.1 Information about health consequences 5.3 Information about social and environmental consequences 5.6 Information about emotional consequences 6.2 Social comparison
Currencies <i>PT, T</i>	Users collect currency dollars and currency diamonds for engaging with different components of the app. These currency dollars and diamonds can be used to purchase collectibles and stories, respectively.	10.2 Material reward (behaviour)
Collections <i>PT, T</i>	Collections include a variety of virtual items (e.g., skateboard, phone, lipstick, sneakers, etc.), divided by level, that a user can purchase with a certain number of currency dollars.	10.2 Material reward (behaviour)

App Feature	Description	Behaviour Change Taxonomy(47)
<p>Stories <i>PT, T</i></p>	<p>Users can use their currency diamonds to purchase interactive and/or engaging stories. Each story is divided into multiple chapters that are “unlocked” as a user reaches a new level.</p> <p>Stories present users with a fictional situation and character who is faced with a series of decisions. Users guide the fictional character through the situation by making decisions in a choose-your-own-adventure format. A recent study suggests that when individuals “lose themselves” in the world of a fictional character, they change their own behaviour and thoughts to match that of the character. This phenomenon has been termed experience-taking (64). Stories are designed such that users will empathize and identify with the fictional characters, allowing them to have experiences that they may not have yet had the chance to encounter in their regular lives. This allows them to shift their self-perception to include their “new experiences” and begin to identify themselves as the type of person who chooses healthy patterns of action.</p>	<p>10.2 Material reward (behaviour) 9.3 Comparative imagining of future outcomes 16.1 Imaginary punishment 16.2 Imaginary reward 6.1 Demonstration of behaviours (symbolic role modeling)</p>
Behavioural Components		
<p>Aim <i>PT, T, P</i></p>	<p>Aims are high level goals that users can choose to pursue, such as “Be sugar smart”. Users may pursue one Aim at a time, or may pursue up to three Aims concurrently.</p> <p>Once a user selects an aim to pursue, the user is first asked to indicate why they selected the Aim, by completing the sentence, “I want this because...”. Next, the user is asked to indicate on a likert scale the importance of the aim, and their confidence in being able to achieve it. Following this, the user is asked to note any obstacles they might face in working toward the Aim. Lastly, the user is asked to adopt a time frame for achieving their Aim; they can either accept a recommended time frame or create a custom time frame.</p> <p>Users also have the option to request support from their parent or guardian, or from a peer. Users can write their specific needs related to tasks and aims, and send these to their desired recipient in email form through the application.</p> <p>Users are given daily tasks related to the Aim they set and are congratulated and awarded currency as they complete tasks and stages. When an Aim is completed (all the tasks have been accomplished), the Aim is moved to the “Completed Aims” folder.</p>	<p>1.3 Goal setting (outcome) 1.4 Action planning 1.6 Discrepancy between current behaviour and goal 1.9 Commitment 13.5 Identity associated with changed behaviour</p>
<p>Stage <i>T, P</i></p>	<p>Aims consist of several stages which break the high level goal into more focused components. For example, the Aim “Be sugar smart” includes the stages “Be sugar aware”, “Swap some sugar out”, and “Find a balance”. The Pre-teen app does not include stages – only Aims and Tasks.</p>	<p>1.1 Goal setting (behaviour) 1.5 Review behaviour goal(s) 1.7 Review outcome goal(s)</p>

App Feature	Description	Behaviour Change Taxonomy(47)
Task <i>PT, T, P</i>	Stages consist of a number of tasks that break the Aim and stage down into small, achievable tasks. For example, the stage “Swap some sugar out” contains tasks such as replacing sugary drinks with water, reading a specific article in the app, reading labels to identify sugary foods in the home, and making a list of snacks they eat and circling those that are high in sugar.	1.2 Problem solving 1.4 Action planning 4.1 Instruction on how to perform a behaviour 4.2 Information about antecedents 7.1 Prompt/cues 8.1 Behavioural practice/rehearsal 8.2 Behaviour substitution 8.3 Habit formation 8.4 Habit reversal 8.7 Graded tasks 10.4 Social reward 13.2 Framing/reframing
Check-In <i>PT, T, P</i>	At any time, users can access and update their health behaviour status. The Check-In area provides a graph-format overview of how they’re doing in terms of six self-rated health behaviours: sugary drinks, veggies & fruit, activity, family meals, screen time, and sleep. Each behaviour has a short description of the health behaviour recommendation, and users are asked to rate how they think they’re doing on a scale from poorly-not very well-okay-well-great.	2.2 Feedback on behaviours 2.3 Self-monitoring of behaviours 2.4 Self-monitoring of outcome(s) of behaviour
Discover <i>PT, T, P</i>	Articles are an in-app resource for users who wish to learn more about particular topics. The Discover Centre allows users to explore educational content at their own pace. Content is organized by health behaviour topic and takes the form of relevant health articles that users can consume quickly and refer back to over time. Users are prompted to provide a short written response to a question related to the article content (e.g. “What is your biggest challenge in sticking to a healthy breakfast routine?”). They are provided with currency when they respond. Users are also prompted to indicate the value they derived from articles; user ratings are combined to indicate popular articles.	4.1 Instruction on how to perform a behaviour 4.2 Information about antecedents 5.1 Information about health consequences 5.3 Information about social and environmental consequences 5.6 Information about emotional consequences 7.1 Prompts/cues
Environmental Components		

App Feature	Description	Behaviour Change Taxonomy(47)
Social Wall <i>PT, T, P</i>	The Social Wall offers a safe social space within the application where users can come together and share thoughts, feelings, successes, and challenges around their healthy lifestyle goals. Prompts guide behaviour change through feeling connected, listening, having a voice, and shifting norms. Humans are social creatures and our social networks play a huge part in our lives. Social networks have been shown to influence health outcomes like weight and medication adherence. This is especially true if the health issue has stigma surrounding it. When uncertainty is high, users are more influenced by their peers. Offering a safe social space where users can come together around common health goals is therefore considered imperative for long-term success. Self-efficacy, the most important influence on behaviour change, is boosted by having access to a social space that is promoting healthy behaviours. The social wall will be moderated by the health coach and has some automated moderation built in to hold posts with inappropriate language. The moderator can review and approve the held posts, otherwise posts go live immediately.	3.1 Social support (unspecified) 3.2 Social support (practical) 3.3 Social support (emotional) 6.1 Demonstration of behaviours 6.2 Social comparison 13.1 Identification of self as role model
Virtual Coach <i>PT, T, P</i>	The Virtual Coach, Aimbot, is a digital bot with a range of pre-programmed prompts, questions, and answers designed to guide users in the app with behaviour change in an empathetic way. All app users can access Aimbot. The content is based on queries that arose during the pilot.	3.2 Social support (practical)
Health coach <i>PT, T, P</i>	The health coach, trained in motivational interviewing, provides support to app users through an in-app coaching interface in which the Coach and user can have one-on-one messaging conversations to provide more tailored and more personal health behaviour guidance.	2.2 Feedback on behaviour 3.1 Social support (unspecified) 3.2 Social support (practical) 3.3 Social support (emotional) 10.4 Social reward
Parent Companion App <i>P</i>	The Parent Aim2Be Companion App complements the child's Aim2Be app. It includes many of the same components (Quick Wins, Aims, Stages, Tasks, Health Behaviour Check-Ins, Articles, Social Wall, Virtual Coach, health coach) and similar nutrition, activity, screen time, and sleep related content, but focuses primarily on how parents can support their children in making healthy behaviour changes. The child and parent apps are not connected. The parent app is not gamified.	3.1 Social support (unspecified) 3.2 Social support (practical) 3.3 Social support (emotional) 12.1 Restructuring physical and social environment
PT = Pre-teens; T=Teens, P=Parents		

Figures

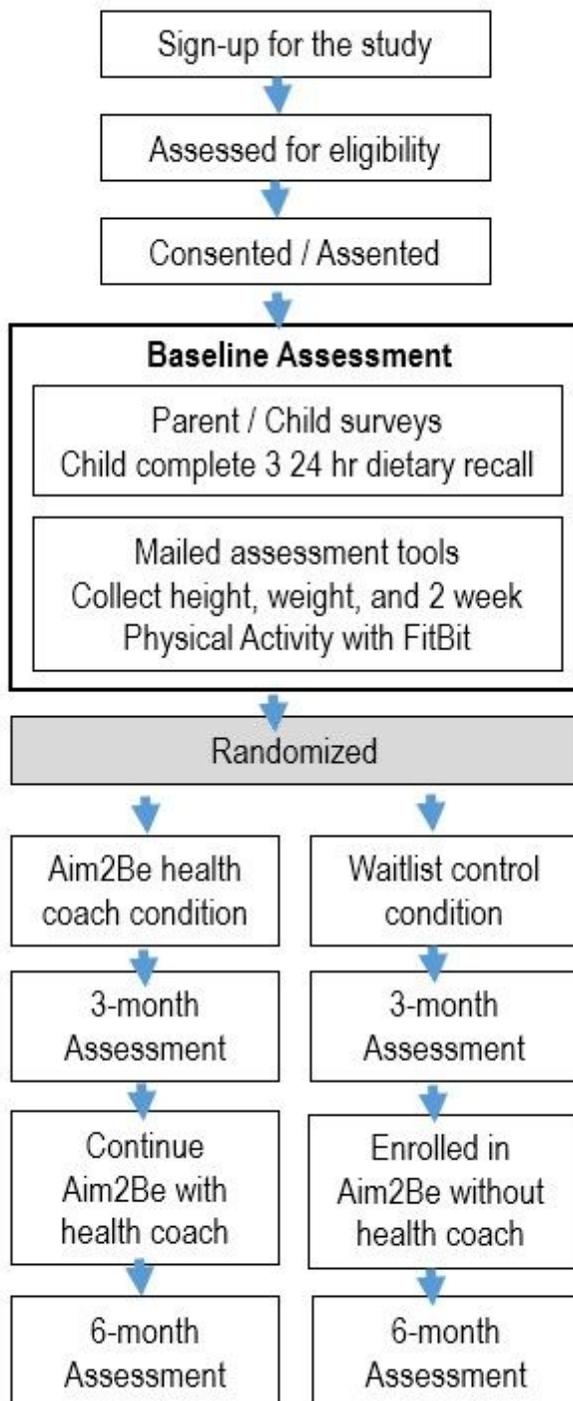


Figure 1

Study flow chart

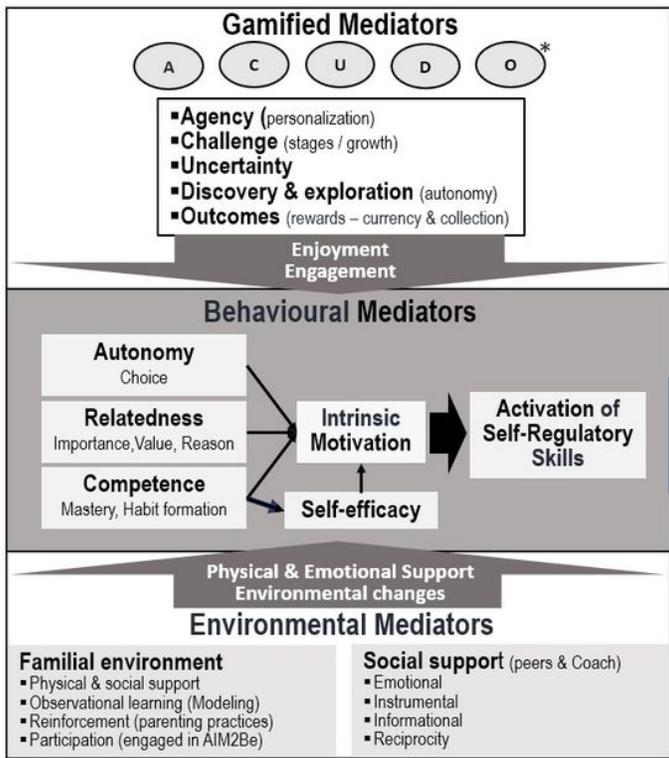
INTERVENTION

- Onboarding identity quiz
- Daily bonus
- Quick Wins
- Quizzes
- Currencies
- Collections
- Stories

- Aims – Stages – Tasks
- Check-Ins
- Discover knowledge centre

- Social wall
- Virtual Coach
- Live Coach
- Companion Parent Aim2Be app

MEDIATORS



OUTCOMES

- Behavioural**
 - ↑ Fruits & Vegetables intake
 - ↓ SSBs intake
 - ↑ Dietary quality
 - ↑ Physical activity
 - ↓ Screen time
- Metabolic**
 - Healthy body weight

* ACUDO framework developed by Ayogo Health Inc

Figure 2

Conceptual framework of Aim2Be

TIMEPOINT	Enrolment	Baseline	Allocation	Post-allocation	
	0	0	0 Months	3 Months	6 Months
ENROLMENT					
Eligibility Screen	X				
Informed Consent	X				
Randomization			X		
INTERVENTION CONDITIONS					
Aim2Be@ with health coach + Fitbit					
Waitlist control + Fitbit/Aim2Be@ without health coach					
ASSESSMENTS					
Demographics (P)		X			
Health History (C,P)		X			
Pediatric Quality of Life Inventory (P)		X		X	X
Self-esteem/optimism and Anxiety/worries (C)		X			
Food preferences (P)		X			
Physical activity enjoyment (P)		X			
Sedentary preferences (P)		X			
Weight concerns (C,P)		X			
KNOWLEDGE					
Knowledge – Physical activity, Nutrition, Sedentary behavior and Sleep (C)		X		X	X
BEHAVIOURS					
Physical activity monitoring – Fitbit wear (7-14 days)		X		X	X
Physical activity behaviours questionnaire (C,P)		X		X	X
Dietary behaviours questionnaire (C,P)		X		X	X
Waterloo 3 24hr dietary recall (WEBQ) (C)		X		X	X
Screen behaviours (C,P)		X		X	X
Sleep behaviours (C,P)		X		X	X
WEIGHT OUTCOMES					
Self-reported height and weight (C)		X		X	X
Self-reported height and weight (P)		X			
Measured height and weight (C)		X		X	X
ADHERENCE					
Web-analytics (min & days in App & content viewed)					
Profile of use					
GAMIFIED MEDIATORS					
Aim2Be@ Satisfaction (C,P)				X	X
BEHAVIOURAL MEDIATORS					
Self-efficacy - Physical activity, Dietary behaviours, and Screen time (C)		X		X	X
Motivation – Fruit and vegetables, Physical activity, Sedentary behaviours (C)		X		X	X
Psychological autonomy (C)		X			
ENVIRONMENTAL MEDIATORS					
Cell phone (P)		X		X	X
Co-participation in physical activity (C)		X		X	X
Family communication (C)		X			
Family functioning (P)		X			
Family meals (C,P)		X		X	X
Fast food consumption (C)		X		X	X
Parenting practices (P)		X		X	X
Parenting styles (P)		X			
TV in bedroom (P)		X		X	X

Figure 3

SPRIT Figure

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [AdditionalFile2DocumentationofConsentandAssent.pdf](#)
- [AdditionalFile1Revised.doc](#)