Pilot and Feasibility Studies

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Addressing unmet social needs of children with obesity: a pilot randomized controlled trial

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Abstract

Background Childhood obesity is an ongoing public health crisis, and recent clinical practice guidelines identify addressing the role of social inequities in the disparity of health among children with obesity as an area to address. This study aimed to assess the feasibility of a community navigation intervention in a pediatric weight management clinic.

Methods A single-center pilot randomized controlled trial (RCT) recruiting families from a tertiary hospital pediatric weight management program to evaluate the feasibility of a community navigation intervention. The primary feasibility outcomes were recruitment rates (goal to recruit 80% of the sample in 6 months), uptake of the intervention (goal > 80% of participants in the intervention group to have a visit with the navigator), and acceptability (goal > 90% of families in the intervention group complete all follow-up).

Results Eighty participants completed the social needs screening, and 42 (52.5%) participants screened positive for an unmet social need. In the first 6 months of recruitment, 18 participants were recruited out of a goal of 40 participants (the recruitment rate was 45% vs. the goal of 80% in 6 months), and complete recruitment was achieved in 12 months. Of the 21 participants randomized to the intervention arm, 20 completed the intervention (uptake of intervention was 95% vs. goal 80%). Ten participants in the intervention arm completed all four planned follow-up study visits (the acceptability of follow-up was 48% vs. the goal of 90%).

Conclusion We completed a pilot RCT of implementing a community navigator program in a pediatric weight management program. We found feasibility in the intervention's uptake but limited feasibility in recruiting participants and the acceptability of the follow-up.

Trial registration Clinicaltrials.gov, NCT04711707, https://clinicaltrials.gov/ct2/show/NCT04711707

Key messages regarding feasibility:

- What uncertainties existed regarding the feasibility? Uncertainty exists regarding the conduct of a study that addresses the unmet social needs of families in the clinical setting of a pediatric weight management program. Specifically, there was uncertainty about the feasibility of recruiting participants, the uptake of the intervention by families, and the acceptability of scheduled follow-up.

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- What are the key feasibility findings? This pilot RCT demonstrates the feasibility of the uptake of a social needs screening and navigation intervention in a pediatric weight management clinic. However, recruiting participants took longer than expected, and there was limited feasibility in attendance of all follow-up visits as scheduled.
- What are the implications of the feasibility findings for the design of the main study? The findings demonstrate the need to reevaluate and optimize recruitment strategies and the follow-up schedule before proceeding to the main study.

Introduction

Integrating and addressing the social determinants of health (SDoH) in healthcare can significantly impact the health trajectory of children and families [1, 2]. The SDoH are "*the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life.*" [3] There is an association between childhood social inequities and poorer health outcomes that persist into adulthood [4–7]. The global COVID-19 pandemic has revealed further disparities in health outcomes of those with unmet social needs [8]. This has impacted the public health crisis of childhood obesity [9], where individuals from lower socioeconomic backgrounds already had an increased risk of childhood obesity and related cardiometabolic complications [10]. Given the considerable role of obesity in non-communicable disease outcomes, including cardiovascular morbidity and mortality, understanding how to better integrate an SDoH framework within health services to improve health outcomes is an urgent priority [11].

Obesity is a complex condition with multi-level determinants nesting the interplay of individual, family, and neighborhood-level factors [12]. The 2023 Clinical Practice Guidelines for the evaluation and treatment of children and adolescents with obesity highlight the importance of recognizing and addressing the role of social inequities in the disparity of health outcomes among children with obesity [12]. Addressing unmet social needs may include evaluating social needs with subsequent referral and/or navigation to existing community supports and resources [13].

Evidence in pediatrics shows that interventions to screen and address social needs improve health outcomes [14, 15]. However, there is a paucity of studies addressing unmet social needs in clinical settings for children and families with obesity [4]. This pilot RCT aims to assess the feasibility of a community navigation intervention in a pediatric weight management clinic by evaluating the intervention's recruitment rates, uptake, and acceptability.

Methods

Study design

This is a single-center pilot randomized controlled trial designed in accordance with the SPIRIT guidelines (Defining Standard Protocol Items for Randomized Trials) [16]. The Hamilton Integrated Research Ethics Board approved the study (project #12697). The study is registered with the US National Institutes of Health clinicaltrials.gov website, and the trial protocol has been published [17].

Setting

This study recruited patients from a pediatric weight management program at the Children's Exercise and Nutrition Centre (CENC) at McMaster Children's Hospital in Hamilton, Ontario, Canada. The 2-year obesity treatment program enrolls approximately 200 new patients annually and is staffed by a multidisciplinary team of pediatricians, endocrinologists, nurse practitioners, dietitians, exercise physiologists, kinesiologists, and psychologists.

Participants

This study recruited families with children between ages 2 to 18 years, enrolled in the weight management program at CENC for less than 18 months. Children in the care of child protection services and/or living in a group or foster care and children of caregivers who were unable to read and write in English were excluded from this study.

Data collection

Social needs screening

Information regarding unmet social needs was collected through an adapted social needs assessment tool survey completed by a caregiver in each family at enrolment before randomization [18]. The social needs assessment tool collected information on unmet social needs, including income, food security, transportation, housing, education, legal status, literacy, and social support. Every unmet social need domain identified corresponded to one point. A final score of one or greater on the social needs assessment tool indicated a positive social needs screening, i.e., unmet social needs, and a final score of zero indicated a negative social needs screening, or no unmet social needs identified. *Demographic data* were collected at baseline and included child's age, sex, race/ethnicity, medical history, family structure, family's self-reported annual household income, parental employment status, parental education, and parental marital

status, and forward sortation area. *Clinical data* were collected at two time points, baseline and 6 months, including health-related quality of life measured using the Pediatric Quality of Life (PedsQL) survey [19], and anthropometric measurements collected at routine clinical encounters, including height, weight, blood pressure, body fat percentage, body mass index (BMI), and body mass index *z* score (zBMI).

Randomization and blinding

Only participants with a positive social needs screening were randomized to the community navigator (intervention) or self-navigation (control) arm. To help ensure balanced group sizes, block randomization was used with varying block sizes of 2, 4, and 6. The allocation ratio was 1:1, and a central REDCap randomization system was used to ensure allocation concealment. Data analysts were blinded to the group allocation, but participants, research staff, and clinical staff were not blinded.

Intervention

Participants randomized to the intervention arm were provided individualized resource guides specific to their region and needs. They were also invited to meet with a community navigator at 2 weeks, 2 months, 4 months, and 6 months after randomization. Based on the responses to the enrolment social needs assessment tool survey, the community navigator guided families to health or community resources as needed. The navigator met with participants to aid in reducing barriers to addressing social needs, such as financial insecurity, transportation, childcare, literacy, and understanding and navigating the healthcare system. Participant's needs led the discussion of these meetings without a prescribed meeting duration. Per the participant's preference, they took place by phone call, videoconference, or email. The role of the navigator was assumed by a member of the research staff, a non-healthcare provider, who had the knowledge and was trained in navigation resources. Participants randomized to the control group were provided individualized resource guides specific to their region and needs to self-navigate. The geographical area was determined by the postal code provided in demographics. The study team developed the resource guide by conducting an extensive search, aided by resources including the www.211ontario.ca website, for community resources and services available in regions from which patients commonly sought clinic services. For each resource outlined in the guide, the following information was provided: the resource's name, a summary of the resource, the website link, and, if applicable, contact information, eligibility criteria, and steps to apply for the service.

Outcomes

The primary outcome of this pilot study was the feasibility of implementing and delivering the community navigator intervention [20]. Feasibility measures included:

i. Recruitment rates: successful if 80% of the target sample is achieved in 6 months.
ii. Uptake of intervention: successful if the intervention was completed by > 80% of families in the intervention group, including completing the social needs screening and receiving at least one correspondence with the community navigator.
iii. Acceptability: successful if all study follow-up visits were completed by > 90% of families in the intervention group.

The study team determined the threshold for success based on previous experiences in clinical trials, pilot studies, and literature review [20]. The secondary clinical outcome of this pilot study was to examine changes in the participants' zBMI score, adiposity (i.e., percent body fat), and health-related quality of life 6 months from baseline to explore the impact of the intervention on changes in health measures.

Statistical considerations

Descriptive statistics were used for continuous variables, mean and standard deviation, and categorical variables were reported in proportions. SPSS software (version 28.0) was used to conduct all the statistical analyses, and an intention-to-treat analysis was used. The determination of sample size for pilot studies varies [21]. The CENC weight management program enrolls approximately 200 new patients per year. It was estimated that approximately 80 families would need to be screened to identify 40 families with unmet social needs. Our previous unpublished pilot work observed that more than half of families enrolled in the CENC program lived in neighborhoods with higher material deprivation. Material deprivation assesses inequalities in accessing material and social resources, including housing, nutritious meals, high-speed internet, personal transportation, or a neighborhood with recreational facilities [22]. As we estimated recruitment to be over 6 months and feasibility to be a primary consideration, we aimed to recruit 40 families over 6 months. With this planned sample size of 40, the criterion for success of a recruitment rate of 80% over 6 months could be estimated with a margin of error of approximately ± 12.4% at a 95% confidence level [20].

Results

Between January 2021 and January 2022, 225 patients in the CENC weight management program were assessed for study eligibility. Figure 1 details the flow of participants; 14 participants did not meet the inclusion criteria, 17 met the exclusion criteria, 4 had a sibling previously enrolled in the study were excluded, and 61 declined to be contacted. One hundred thirty-three patients were approached for consent, of which 84 consented to participate. Eighty of the 84 participants (95%) completed the social needs screening, of which 42 (52.5%) participants screened positive for unmet social needs and were

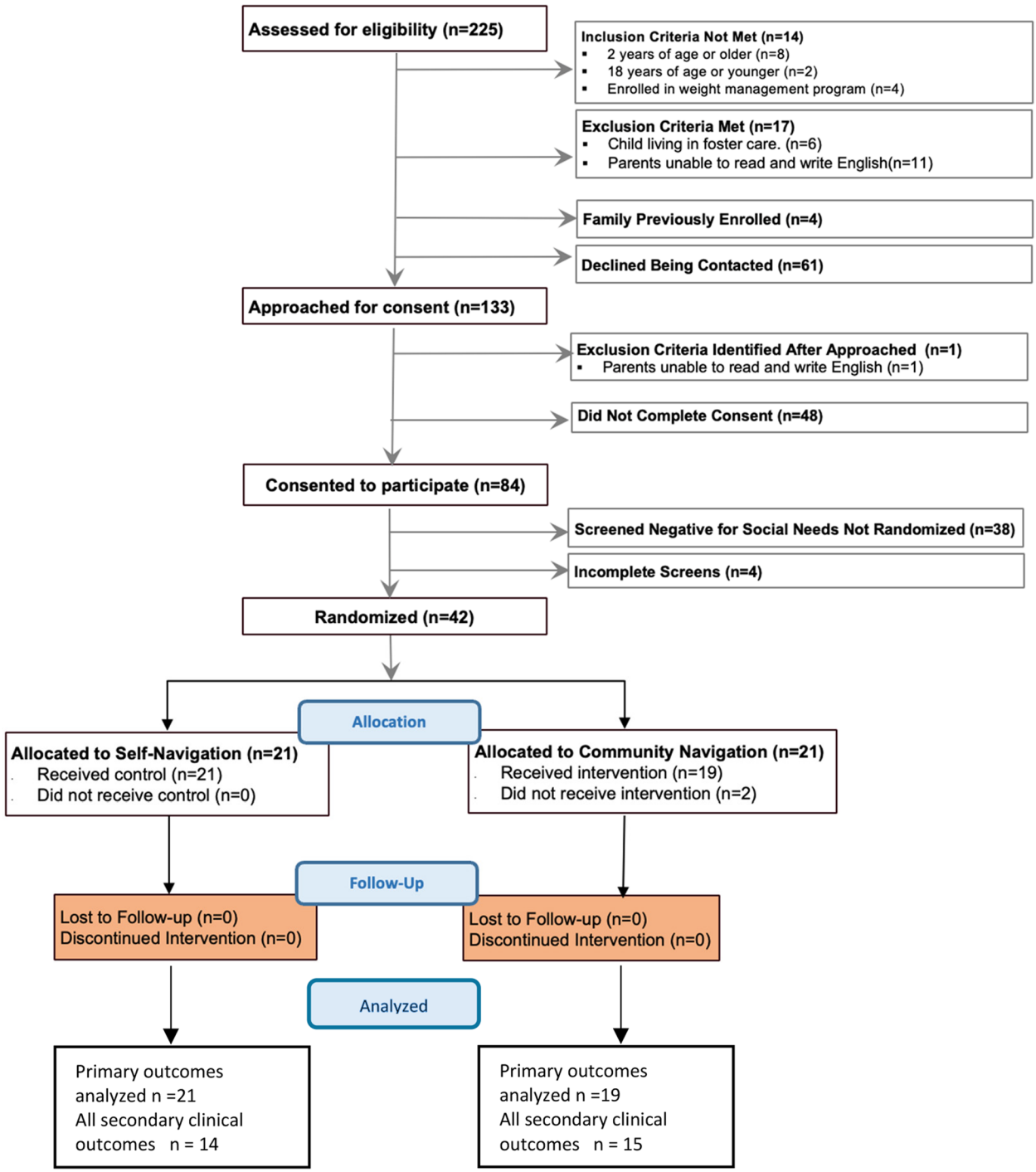

Fig. 1 Flow of study participants

therefore eligible for the trial. Among eligible participants, 21 were randomized to the intervention and 21 to the control.

Demographics

Of the 80 participants who consented to participate in the study and completed the baseline screening assessment, the children's mean age (SD) was 10.8 (3.6) years, and 40 (50%) were female. Race/ethnicity data were available for 64 participants, from which 49 (77%) identified as white Caucasian. Of the family demographics, 55 (69%) of the caregivers were married, and 25 (31%) of the families had a household income of less than $50,000. In the caregiver-reported child health questionnaire, 36 (45%) of caregivers identified that their child had a physical health condition, 27 (34%) identified their child had a learning or communication disability, and 20 (25%) had a mental health condition. From the responses to the social needs assessment tool questionnaire, 13 of 42 participants (31%) indicated one unmet social need, and 29 (69%) had two or more unmet social needs. The unmet social needs that were most frequently identified included income insecurity (76%), food insecurity (50%), and support required for accessing benefits or community services (50%). In comparing the intervention group to the control group, there was a similarity in child and family demographics. In the intervention group, compared to the control group, fewer children had physical health conditions (33% vs. 67%), learning or community disorder/disability (24% vs. 48%), and fewer had mental health conditions (24% vs. 43%). Table 1 outlines the demographics of participants randomized to the intervention and control groups. In comparing the characteristics of the participants who screened positive for unmet social needs and those who screened negative for unmet social needs, differences were found in parental marital status (55% parents married/common law vs. 84%), family annual household income less than $50,000 (45% vs. 16%), and homeownership (48% vs. 76%). The complete demographics and baseline clinical data of participants who were screened for meeting the criteria for randomization are outlined in Table 2.

Primary outcome

The feasibility criteria for all outcomes were not met. We found feasibility in the uptake of the intervention, limited feasibility in recruiting participants, and acceptability of the follow-up. Of the 40 participants we planned to recruit in 6 months, only 18 were recruited (45% vs. goal of 80%). However, by 10 months, 36 participants (90% of goal) and by 12 months, 42 participants (105% of goal) were recruited. Of participants randomized to the intervention arm ($n=21$), 20 (95%) completed the intervention, surpassing our target of 80%. However, only 10 participants randomized to the intervention arm had completed all four study visits (48% vs. goal of 90%). That said, 19 (90%) participants completed at least one

Table 1 Baseline demographics of randomized participants

	Community navigator (intervention), *N* = 21	**Self-navigation (control), *N* = 21**
Demographics		
Age of child (years), mean (sd)	11.0 (3.2)	10.3 (4.6)
Child sex, female, ***n*** (%)	12 (57%)	9 (43%)
Ethnicity, white Caucasian, ***n*** (%)	11 (69%)	12 (71%)
Parental marital status, married, ***n*** (%)	12 (57%)	11 (52%)
Parental education, more than high school, ***n*** (%)	17 (81%)	16 (76%)
Employed, ***n*** (%)	15 (71%)	12 (57%)
Family household income, < $50,000, ***n*** (%)	11 (52%)	8 (38%)
Housing ownership, ***n*** (%)	9 (43%)	11 (52%)
Child health		
Child has a physical health condition, ***n*** (%)	7 (33%)	14 (67%)
Child has a learning or communication disorder/disability, ***n*** (%)	5 (24%)	10 (48%)
Child has a mental health condition, ***n*** (%)	5 (24%)	9 (43%)
Clinical characteristics		
zBMI score, mean (sd)	3.3 (0.6), $n=16$	3.8 (1.3), $n=14$
Health-related quality of life		
PedsQL parent, mean (sd)	55.2 (16.1), $n=20$	59.3 (21.3), $n=20$
PedsQL child, mean (sd)	62.0 (19.2), $n=15$	64.5 (18.9), $n=14$

Table 2 Demographics and baseline characteristics of all screened participants

	Total screened ***n*** **= 80**	**Unmet social needs** ***n*** **= 42**	**No unmet social needs** ***n*** **= 38**
Demographics			
Age of child (years), mean (sd)	10.8 (3.6)	10.7 (4.0)	10.9 (3.2)
Child sex, female, ***n*** (%)	41 (51%)	21 (50%)	20 (53%)
White Caucasian, ***n*** (%)	49 (77%)	23 (70%)	26 (84%)
Parental marital status, married, ***n*** (%)	55 (69%)	23 (55%)	32 (84%)
Parental education, more than high school, ***n*** (%)	68 (85%)	33 (79%)	35 (92%)
Employed, ***n*** (%)	56 (70%)	27 (64%)	29 (76%)
Income, less than $50,000, ***n*** (%)	25 (31%)	19 (45%)	6 (16%)
House ownership, ***n*** (%)	49 (61%)	20 (48%)	29 (76%)

follow-up visit, and 17 (81%) completed two or three follow-up study visits.

Secondary outcome

There was no difference between the control and intervention groups in the change in zBMI, parent-reported PedsQL, or child-reported quality of life from baseline to 6 months (see Table 3). Only two participants had complete data available at baseline and 6 months for measures of adiposity; therefore, change in adiposity was excluded from the exploratory analysis of clinical outcomes.

Discussion

We led a pilot RCT of implementing a community navigator program within a tertiary pediatric weight management program; not all feasibility metrics were met. While we did not meet the a priori recruitment rate of 80% of our goal sample size in 6 months, we ultimately met our recruitment target with more time allotted. Completion of the intervention was high. However, less than half of the participants completed all four study visits, though 90% completed one visit, and 80% completed at least two follow-up visits.

In this exploratory work, just over 50% of families screened for intervention eligibility and completed the screening tool self-identified with at least one unmet social need. An association between the social determinants of health, such as low household income, and risk of childhood obesity, as well as adverse childhood health outcomes, are well documented [23–25]. Given that childhood obesity interventions often employ a family-based, multicomponent health-behavior approach [26], our study informs additional potential treatment strategies that take a broader socioecological approach, acknowledging the intricate interplay of individual health behaviors and family-level socioeconomic factors [12, 27, 28].

Table 3 Change in clinical measurements from baseline to 6-month follow-up

	Intervention group (mean, SD)	**Control group (mean, SD)**
zBMI (*n* = 30)	−0.02 (0.15)	−0.11 (0.23)
Parental PedsQL (*n* = 40)	−1.38 (9.7)	2.10 (15.69)
Child PedsQL (*n* = 29)	3.65 (13.76)	−0.13 (5.40)

Recruitment of participants for the study took longer than anticipated. Of the 132 eligible patients, 48 (36%) did not consent after discussion with the research staff. There could be many reasons for this finding, including the context of conducting this pilot trial during the COVID-19 pandemic, which led to changes in protocol that may have impacted recruitment and intervention implementation [17]. Specifically, the conversations with research staff occurred remotely, most often over the phone instead of in the clinical setting. Hospital policy and public health restrictions led to the decision to conduct this as a remote clinical trial with consent, surveys and community navigation conducted remotely through online surveys, email, phone calls, and videoconferencing. Some future study considerations include the accessibility of remote clinical trials and the exploration of a hybrid model [29]. The low recruitment rate may have also been impacted by the intervals of COVID-19 lockdowns and restrictions where families with children had additional stresses and the burden of remote school scheduling and managing fluctuating workplace environments, perhaps leaving them less willing to participate in clinical research [30].

Completion of the intervention was successful. However, less than half of the participants completed the four follow-up visits over 6 months. Many clinical research organizations opted not to initiate new trials due to

difficulties recruiting new subjects and lower follow-up rates [31]. The remote community navigator meetings could have affected the missed follow-up visits. Although previous work that compared in-person and remote patient navigators in a pediatric primary health clinic found no significant differences in the number of times the navigator had contact with the families, it is uncertain if similar expectations would occur in tertiary care environments [32]. Future trial design options, such as having study visits coincide with clinical appointments, could be considered. Also, the number of follow-up visits should be tailored based on family preferences and needs.

An intervention to address unmet social needs must acknowledge barriers inherent to the intervention, including perceived discrimination and stigma associated with families reporting unmet needs and accessing services within the healthcare setting [33]. Some populations warrant further consideration, including racialized patients and families, as experiences of discrimination may further impact trust with healthcare and research personnel [33]. To better support patients and families, it is essential to understand the context and impact of the intervention, including unintended consequences. Though this intervention was designed through a literature review [13], co-creating future interventions in the tertiary care setting with patients, families, and care teams with experience with chronic medical conditions and diverse cultures and experiences would be necessary [33].

Limitations to this study include the lack of complete clinical data for secondary clinical outcomes. The missing baseline and 6-month clinical data resulted from restrictions on in-person clinic visits during the COVID-19 lockdowns, as the quality-of-life questionnaires and anthropometric data are only collected at in-person visits. To mitigate this in future studies, data for study outcomes could be collected by study staff instead of relying on clinical datasets. A significant limitation to the inclusiveness of this study was the exclusion criteria of English language proficiency. Families with the primary use of languages other than English are often at greater risk of difficulty navigating health and social systems due to barriers of not speaking the dominant languages, which can lead to poor healthcare access and health outcomes [34, 35]. Given these considerations, future studies from this pilot RCT should include families with non-English language needs despite funding hurdles, time, or other potential barriers. Finally, restriction to in-person recruitment by research staff limited recruitment strategies.

Although all the predetermined feasibility success criteria were not fulfilled, much was learned about improving the implementation of integrating social needs interventions in healthcare settings, which aims to positively impact health outcomes. Future work would be strengthened by understanding patient and family perspectives on interventions and co-creating integrated social and health systems interventions [36].

Abbreviations

CENC	Children's Exercise and Nutrition Centre
PedsQL	Pediatric Quality of Life
RCT	Randomized controlled trial
SDoH	Social determinants of health
zBMI	Body mass index *z* score

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Not applicable.

Authors' contributions
Dr. Gita Wahi conceptualized and designed the study, drafted the initial manuscript, and critically reviewed and revised the manuscript. Dr. Stacey Marjerrison conceptualized and designed the study and critically reviewed and revised the manuscript. Simrat Gill collected data, conducted the initial analyses, and critically reviewed and revised the manuscript. Kimberley Kraseich coordinated and supervised data collection, conducted the initial analyses, and critically reviewed and revised the manuscript. Dr. Katherine Morrison critically reviewed and revised the manuscript for important intellectual content. Dr. Lehana Thabane critically reviewed and revised the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agreed to be accountable for all aspects of the work.

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Data availability
Deidentified individual participant data will not be made available.

Declarations

Ethics approval and consent to participate
The study received approval from Hamilton Integrated Research Ethics Board project #12697.

Consent for publication
Not applicable.

Competing interests
The authors have no conflicts of interest to disclose.

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