Pilot and Feasibility Studies

STUDY PROTOCOL

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A multi-center, randomized, 12-month, parallel-group, feasibility study to assess the acceptability and preliminary impact of family navigation plus usual care versus usual care on attrition in managing pediatric obesity: a study protocol

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Abstract

Background Pediatric obesity management can be successful, but some families discontinue care prematurely (i.e., attrition), limiting treatment impact. Attrition is often a consequence of barriers and constraints that limit families' access to obesity management. Family Navigation (FN) can improve access, satisfaction with care, and treatment outcomes in diverse areas of healthcare. To help our team prepare for a future effectiveness trial, the objectives of our randomized feasibility study are to (i) explore children's and caregivers' acceptability of FN and (ii) examine attrition, measures of study rigor and conduct, and responses to FN + Usual Care vs Usual Care by collecting clinical, health services, and health economic data.

Methods In our 2.5-year study, 108 6–17-year-olds with obesity and their caregivers will be randomized (1:1) to FN + Usual Care or Usual Care after they enroll in obesity management clinics in Calgary and Mississauga, Canada. Our Stakeholder Steering Committee and research team will use Experience-Based Co-Design to design and refine our FN intervention to reduce families' barriers to care, maximizing the intervention dose families receive. FN will be delivered by a navigator at each site who will use logistical and relational strategies to enhance access to care, supplementing obesity management. Usual Care will be offered similarly at both clinics, adhering to expert guidelines. At enrollment, families will complete a multidisciplinary assessment, then meet regularly with a multidisciplinary team of clinicians for obesity management. Over 12 months, both FN and Usual Care will be delivered virtually and/or in-person, pandemic permitting. Data will be collected at 0, 3, 6, and 12 months post-baseline. We will explore child and caregiver perceptions of FN acceptability as well as evaluate attrition, recruitment, enrolment, randomization, and protocol integrity against pre-set success thresholds. Data on clinical, health services, and health economic outcomes will be

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collected using established protocols. Qualitative data analysis will apply thematic analysis; quantitative data analysis will be descriptive.

Discussion Our trial will assess the feasibility of FN to address attrition in managing pediatric obesity. Study data will inform a future effectiveness trial, which will be designed to test whether FN reduces attrition.

Trial registration This trial was registered prospectively at ClinicalTrials.gov (#NCT05403658; first posted: June 3, 2022).

Keywords Attrition, Canada, Chronic Disease Management, Feasibility study, Obesity, Pediatric, Randomized trial

Background

Pediatric obesity is prevalent [1], persistent [2, 3], and complex [4, 5]. Without intervention, obesity and its consequences usually track into adulthood [6–8], a pattern that entrenches with increasing obesity severity [9] and underscores the value of accessible and effective interventions. However, successful obesity management (i.e., reducing or stabilizing weight gain; improving obesity-related consequences) is challenging. Multidisciplinary interventions centered on family lifestyle and behavior changes can help children to manage their obesity [10, 11]. Success in managing obesity is typically achieved by adhering to treatment regimens and regularly attending clinical appointments [12]. Effective lifestyle and behavioral interventions require a moderate to high intervention dose (i.e., > 25 h of clinic contact over 6–12 months [13]) to optimize health benefits [14, 15]. Achieving this dose is difficult for many families due to barriers and constraints to accessing care, such as schedule availability, transportation costs, and variable motivation [16, 17]. Even the best obesity management interventions are undermined when families discontinue care prematurely [18].

In managing pediatric obesity, we aim to minimize attrition (i.e., permanently discontinue care [19]) so children and families benefit from care. Attrition levels are as high as 80% [20]; 30–40% attrition is common [21–24]. Attrition wastes healthcare resources, discourages families from accessing services in the future [25, 26], and exacerbates health inequities for families with limited resources [27]. High attrition in pediatric obesity management was first reported as a problem > 50 years ago [28], but experimental research is lacking given the magnitude of the problem, highlighting the need to create and test interventions to improve access, reduce attrition, and manage obesity successfully [29].

Despite the lack of experimental research, descriptive research has produced some insights about attrition. For example, a review [16] published by our team members revealed higher attrition in children ≥ 12 years old and among families receiving social assistance. Reasons for attrition included logistical barriers and unmet family needs or expectations. Often, attrition involves multiple factors [21, 26, 30], with a series of missed or cancelled appointments preceding attrition, reducing the potential for positive treatment outcomes. Conversely, families continue attending appointments for several reasons, including anticipated and actual treatment benefits and high-quality care [31]. Ongoing attendance can be facilitated by flexible family schedules, choice of clinic appointment times, adequate family resources, and high motivation in children [31]. Some families can reduce barriers and eliminate constraints that limit access to obesity management, but many lack social support and financial resources, so could benefit greatly from enhanced care.

Several strategies have the potential to reduce attrition. Along with using multiple modes of communication with patents and families [32], clinical researchers recommend combining strategies to enhance clinic appointment attendance [33], including reducing wait times, making reminder calls [34], and applying techniques such as motivational interviewing to reduce missed or cancelled appointments [35]. Missed appointments are lost opportunities, so clinicians who establish collaborative relationships with patients can enhance clinic attendance and adherence to therapy plans [36]. In a systematic review of longitudinal studies designed to reduce attrition in adults [37], a greater number of strategies was inversely related to attrition; however, of the 88 studies in this review, only 4 were randomized controlled trials (RCTs), underscoring the need for experimental research to test multiple strategies for reducing attrition. Telephone and electronic reminder systems that provided detailed information beyond basic appointment details, including resource sharing and rapport building, are effective in reducing attrition [38–41]. In adult obesity interventions, multi-component approaches, financial incentives, and self-monitoring decreased attrition [42]. Notably, none of the trials in this review were developed a priori to reduce attrition; they also neglected to include stakeholders as intervention co-designers, highlighting the need for well-designed trials that include families, clinicians, and researchers as partners.

People living with a chronic illness like obesity often have difficulty navigating the complex, fragmented

healthcare system [43]. Such experiences catalyzed research on the impact of support workers known as patient or family navigators. Navigators have diverse backgrounds but similar roles—to help patients and families coordinate care [44], access community services [31], attend clinical appointments [45], overcome communication and information barriers [46], and receive social support and education [47]. These activities can transform healthcare delivery by improving access, satisfaction, and outcomes [43, 48, 49]. Family Navigation (FN) is a multifaceted care model delivered by navigators who explore barriers to accessing clinical care and help patients and families by facilitating self-management and access to care. Rather than providing clinical care, FN addresses barriers and provides social support [43]. Navigators advocate for, educate, and assist families with tailored support and access to resources within and beyond the healthcare system [43]. In adults, navigation improves clinic appointment attendance [50], treatment outcomes [43], and satisfaction with care [51], especially when patients and families require services across settings and sectors [52]. FN is a direct response to recommendations [53] for tailored support to families in pediatric obesity management. FN is novel in pediatrics [54], and evaluations are rare, underscoring the need for robust evidence on the effectiveness of this intervention [55].

Our goal is to conduct a feasibility study to prepare our team for a definitive RCT in which we will test the effectiveness of FN to reduce attrition in 6–17-year-olds in pediatric obesity management. To help our team prepare for this future RCT, the objectives of our randomized feasibility study are to (i) explore children's and caregivers' acceptability of FN and (ii) examine attrition, measures of study rigor and conduct, and responses to FN + Usual Care vs Usual Care using clinical, health services, and health economic data.

Methods

Study design

Our 2.5-year, multi-method, multi-center randomized feasibility study has two arms and parallel assignment. Our protocol follows the Consolidated Standards of Reporting Trials (CONSORT) extension for randomized pilot and feasibility trials [56] and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT). Please see Table 1 for our SPIRIT checklist [57].

Study setting

Our study will be conducted at two clinical sites in Canada (Alberta Children's Hospital in Calgary, AB; Trillium Health Partners in Mississauga, ON). Children will be assigned to an experimental (FN + Usual Care) or control (Usual Care) group after they enroll in publicly funded,

Table 1 Schedule of enrollment, interventions, and data collection

	STUDY PERIOD				
	Enrollment	Allocation	Post-allocation		Close-out
TIMEPOINT	Pre-study	0-month	3-month	6-month	12-month
ENROLLMENT					
Eligibility Screen	X				
Informed Consent & Assent	X				
Allocation		X			
INTERVENTIONS					
Family Navigation + Usual Care			◆—	—	—◆
Usual Care Only			◆—	—	—◆
DATA COLLECTION					
Sociodemographics		X			
Acceptability of Family Navigation		X	X	X	X
Attrition			X	X	X
Study Rigour & Conduct	X	X	X	X	X
Clinical		X	X	X	X
Health Services		X	X	X	X
Health Economic		X	X	X	X

multidisciplinary, pediatric obesity management clinics at our two sites.

Stakeholder collaboration

Stakeholders have participated in several areas of our research. First, our application for research funding included both one caregiver and one colleague who works as a "community connector"; they played key roles in designing our study and conceptualizing our FN intervention. Second, our Stakeholder Steering Committee (SSC) is co-chaired by a (i) caregiver with experience in providing lived experience to academic teams through research studies and developing clinical practice guidelines and (ii) academic researcher with expertise in health, stress, and coping as well as navigation and peer-to-peer support for families of children with complex care needs. The SSC also includes other caregivers, older children, health care managers, clinicians, and research team members, who will meet regularly (e.g., monthly by videoconference; ad hoc by email) throughout our study.

As recommended [58], our SSC will work in partnership through several iterative stages, including the following tasks and outcomes: (i) engage in sharing experiences, perceptions, and preferences on access and attrition in managing pediatric obesity; (ii) discuss and evaluate existing navigation models with relevance to pediatric obesity; (iii) review FN design, theory, and implementation components, including logistical and relational strategies to increase access and reduce attrition; (iv) review and select outcome measures and data collection tools; (v) participate in qualitative and quantitative data interpretation to inform FN refinements and contextualize findings relevant to children, families, and clinicians; and (vi) contribute to knowledge translation products. Non-academic SCC members will receive $25 (CAN) gift cards for participating in each meeting. Finally, we consulted with several stakeholders who work with children and families, including social workers, school support workers, to ensure our FN intervention addressed the perceived needs of families who often access services to support child and caregiver health and well-being.

Sample size

We will recruit 108 participants (54 per group and per site). Feasibility studies do not include formal sample size calculations [56], but experts recommend 12–36 per arm [59, 60]. We will enroll 27 participants per arm per site. This sample will give a 95% CI of width ≤ 0.34 for the difference in group proportions, assuming attrition is ≤ 0.4 in the control group. A sample size of 54 per arm will also allow 95% CIs of width ≤ 0.29 for other outcomes (e.g., proportion recruited). The sample size calculation for our future definitive RCT will be based on data from this feasibility study.

Participant inclusion and exclusion criteria

At clinic enrolment, eligible participants must (i) be 6–17 years old, (ii) have a BMI $\geq$ 97th percentile [61], and (iii) have a primary caregiver (parent/guardian) agree to participate. Children of any sex or gender are eligible. Participants will be excluded if caregivers cannot communicate in English (< 5% of families in our clinics) since FN will be available in English only.

Recruitment and enrollment

Research staff will work with clinical teams to offer families details about our study at clinic enrollment. Clinical team members will ask families if they are interested in learning about research at our clinics (i.e., consent to contact). If families respond "yes," a research coordinator (RC) will contact caregivers to provide additional details about our study to enable enrollment. This process mirrors our approach in past multi-center studies at our two sites, including the Canadian Pediatric Weight management Registry (CANPWR; [62]). As an observational study, CANPWR offered no direct benefit to families, yet we recruited 66% ($n = 1320/1992$) of all children approached. We expect families to have a greater interest in this study because they have the potential to benefit directly from study participation via FN. Our annual volume of new referrals (Calgary: $n \sim 300$; Mississauga: $n \sim 240$) makes our study highly feasible. Recruitment will span ~ 12 months.

Randomization and blinding

Our team biostatistician will computer-generate a permuted-block randomization sequence using child age on the day of consent (6–9 years, 10–13 years, 14–17 years) and clinic (Edmonton, Calgary, Mississauga) as subgroups to achieve balance across ages and clinics. The randomization sequence will be uploaded to Research Electronic Data Capture (REDCap) for centralized online randomization. Research coordinators (RCs) will then enter participant details into REDCap and manage randomization at each site.

We will conduct our study to reduce the risk of errors, follow best practices for real-world trials [63], and apply pediatric-specific recommendations to minimize the risk of bias [64]. To minimize selection bias, our online allocation process will be managed by team members not delivering interventions. RCs will collect study data to minimize response bias. Data analyses will be led by team members with no family contact. Our team biostatistician will create the randomization sequence but be blind to group assignment to minimize detection bias.

RCs, navigators, clinicians, and families will know group assignment. Virtual appointments, which will remain the most common appointment type throughout our study, will limit interactions between families, minimizing ascertainment bias.

Trial interventions

Our experimental group will receive FN + Usual Care. FN will be co-designed by our SSC and aims to reduce attrition by managing barriers and eliminating constraints that limit access to care. FN will increase access to a moderate to high intervention dose, increasing success in managing pediatric obesity. Although the initial design has started, refinements to the FN intervention (e.g., enhance navigator training/support) will continue to be made with our SSC, informed by study data and experience. Our control group will receive Usual Care only.

Family navigation

The FN intervention will be co-designed with our SSC, including both theoretical and practical elements. Through co-design, we will maximize child- and family-centeredness, pragmatism, and intervention relevance by co-creating health services *with* and *for* children, caregivers, and clinicians [65].

Our participatory approach draws on key elements of Experience-Based Co-Design (EBCD) [66], an orientation that focuses on understanding SSC members' experiences with health services, identifying potential improvements, and making changes together. With co-design, we increase intervention relevance and appropriateness, bringing together people who possess experiential knowledge (children, caregivers) with people who have expert knowledge (clinicians, researchers); the two knowledge systems enrich each other. Our team members have substantial experience in co-designing and refining health services and interventions in partnership with stakeholders [67–71].

Our two clinics will have a navigator to deliver FN. Navigators will be trained and equipped with resources for individualized support to benefit families in managing pediatric obesity. Navigators will start by orienting families to the intervention and completing a detailed needs assessment, highlighting areas for support to manage barriers and remove constraints to accessing pediatric obesity management. Strategies used by the navigator may include (i) communicating via text message to schedule appointments, providing appointment reminders, celebrating successes, exploring solutions for barriers to care, and sharing educational resources; (ii) having flexible navigator appointments (evenings, weekends, virtual); and (iii) providing parking/transit passes in-person visits of families with navigators, clinicians, and researchers.

Navigator appointments will supplement family appointments with clinicians for pediatric obesity management, increasing professional contact. Navigators will use principles of motivational interviewing (MI) [72] and focus on listening to and validating family challenges, exploring the desire to continue pediatric obesity management. They will foster a safe, non-judgmental space for families to discuss expectations and experiences as well as empower families to access resources and services that optimize care within and beyond the clinic. Navigators will be flexible and responsive. In some cases, they will work intensively with families, liaising regularly with clinicians to integrate care. In other cases, they will interact with families exclusively. Family preferences and needs drive appointment frequency with navigators: weekly, biweekly, or monthly; virtual (videoconference or phone) or in-person, pandemic permitting; 30–60 min long. As a tailored intervention, FN acknowledges that the desire to maximize adherence to pediatric obesity management varies by family and that ambivalence is common in managing obesity [30]. Navigator–family discussions may include children and caregivers together or separately, based on preferences and needs. Navigators will work with the research and clinical teams to adhere to a communication and documentation protocol if families disclose information (e.g., child safety) beyond their scope of practice. Navigators will hold an undergraduate degree in a relevant field (e.g., psychology, nursing, social work), complete advanced training in MI, and receive ongoing mentorship to maintain proficiency [73]. Registered psychologist team members (JG, AB) will oversee training and mentorship with a model that maximizes MI skill development and fidelity. Each navigator will complete ~ 80 h of MI training (e.g., readings, workshop) as recommended to maintain competence [74]. At the study start, all navigators will participate in a virtual workshop on strategies to mitigate obesity bias and stigma [75, 76], which will be led by a team member with expertise in this area (AA). In readings and discussions, navigators will gain perspective and expertise on children and families from diverse backgrounds and cultures. During the study, psychologist team members (JG, AB) will use the MI Supervision & Training Scale [77] to provide structured feedback to navigators on proficiency, maximizing fidelity to MI within and between navigators. After giving detailed feedback to navigators on their first several sessions with families, our team members will review randomly selected sessions throughout the study to highlight areas of strength and improvement for navigators. Navigators' MI sessions with families will be recorded digitally and uploaded to a secure platform for data storage.

Usual care

Our control intervention is Usual Care for managing pediatric obesity, delivered similarly across our two clinics by multidisciplinary teams who follow family-centered care principles [78] and guidelines [79]. At clinic presentation, children will complete a comprehensive health assessment to inform lifestyle (e.g., diet, physical activity, sedentary activity, sleep) and behavioral goal setting and subspecialty medical referrals, if indicated. Children and caregivers attend clinic visits regularly to make and maintain healthy changes. Appointments with physicians occur at least every 6 months, and more frequently with other clinicians (e.g., dietitian, psychologist). The dose and duration of pediatric obesity management vary according to family needs, motivation, and illness severity. Our two clinics offer 1-on-1 virtual care by videoconference or phone, with in-person visits restarting, pandemic permitting.

Duration of treatment and follow-up

Intervention duration is 12 months for both experimental (FN + Usual Care) and control (Usual Care only) groups. Qualitative data will be collected at 3 intervals (0 [baseline], 3–6, and 12 months post-baseline). Quantitative data will be collected at 4 intervals (0 [baseline], 3, 6, and 12 months post-baseline).

Data collection and management

To assess children's and caregivers' perceived acceptability of FN (objective 1), we will complete ~ 30-min, semi-structured, 1-on-1 interviews with families (see Additional file 1 for caregiver interview guide). We will group children into 6–9 years, 10–13 years, and 14–17 years. These groupings are based on potential developmental differences that could influence participants' perceptions and experiences of the intervention. For the 6–9 years group, only caregivers will be interviewed as children of this age may have difficulty giving detailed insights on accessibility, and caregivers are responsible for virtually all decision-making for children in this age range. For 10–13 years and 14–17 years groups, children and caregivers will be interviewed independently, although child-caregiver (dyad) interviews will be offered (i.e., interviews will be completed as a family if children feel more comfortable with their caregiver present). We plan to interview participants in the experimental group ($n = 54$ caregivers; $n = 36$ 10–17-year-olds) three times: before FN intervention delivery (0 month [baseline]), mid-intervention (3–6 months post-baseline), and at intervention completion (12 months post-baseline). However, the final sample size may be lower if (i) data saturation is achieved along the way and/or (ii) families discontinue care prematurely or terminate study participation. RCs at our two sites will conduct interviews virtually (videoconference, phone) or in-person, pandemic permitting. Interviews will be audio-recorded, transcribed verbatim, and managed with NVivo 11 (QSR, Australia).

To evaluate attrition and measures of study rigor and conduct (objective 2), we will compare outcomes against pre-set success indicators. We have a conceptual definition of attrition (permanently discontinue care [19]), but a universal, operational definition does not exist [16, 17]. For this reason, our operational definition will include three categories: "yes," "no," and "unknown," which will be recorded identically for experimental (FN + Usual Care) and control (Usual Care only) groups. If a child discontinues pediatric obesity management at any point up to 12 months post-baseline or if an appointment is missed or cancelled without rescheduling and we have no follow-up communication with the family after four phone/text messages over 4 weeks and no scheduled upcoming appointments, they will be categorized as "yes." If a child remains active in pediatric obesity management at 12 months post-baseline, they will be classified as "no." If their status cannot be confirmed, they will be classified as "unknown." The exact date of attrition will be pinpointed as a child's last recorded interaction with a pediatric obesity management clinician or navigator, confirmed via primary (child's medical record, clinic scheduling system) and secondary sources (families, clinicians, navigators [experimental group only]).

In addition, we will measure several secondary outcomes given their established or possible links to attrition [80–85], which will be collected for descriptive purposes and hypothesis generation. RCs will review children's medical records to retrieve sociodemographic and clinical data, using standard case report forms and processes that adhere to recommendations for medical record reviews to optimize accuracy [86, 87]. For child- and caregiver-reported data, families will complete gender-neutral surveys created using REDCap that will be accessible virtually by desktop, tablet, or smart phone.

Clinical

Children's weight (nearest 0.1 kg) and height (nearest 0.1 cm) will be collected to calculate BMI, BMI percentile, and BMI *z*-score [61]. Families will complete questionnaires on (i) health-related quality of life (HRQoL) assessed by child (self-report; 8–12 years and 13–18 years versions) and caregiver (proxy report) using the PedsQL 4.0 [88] and the Health Utility Index-3 (HUI-3) [89]; (ii) child- and caregiver-reported experienced and implicit weight-related stigma [90]; (iii) Working Alliance Inventory to quantify the strength of therapy relationship between both caregivers and navigators as well

as caregivers and clinicians [91]; (iv) caregiver-reported treatment expectations for pediatric obesity management [83]; (v) child and caregiver motivation to change lifestyle and behavioral habits [92]; and (vi) caregiver-rated healthcare satisfaction using the PedsQL Healthcare Satisfaction Generic Module 3.0 [93]. RCs will document harms (i.e., adverse events ([AEs]), which may reveal unintended intervention effects. We will work with our SSC and Trial Steering Committee (TSC) to identify a list of potential harms related to managing pediatric obesity. Broader than adverse events, our list of potential harms will include unintended consequences experienced by families in FN + UC and UC groups.

Health services

RCs will track family health care use, including appointment (i) frequency (count); (ii) type (e.g., navigator, physician); (iii) mode (e.g., videoconference, in-person); (iv) duration (e.g., 15-min intervals); and (v) changes (e.g., cancelled, missed). Data will be retrieved from children's medical records and electronic scheduling systems.

Health economics

We will collect descriptive data for future planning, estimating costs for FN intervention development (e.g., mentoring navigators), intervention delivery (e.g., session frequency), healthcare resource use (e.g., physician visits), and family-related time lost (e.g., travel). To inform future economic evaluations, we will use the HUI-3, which measures eight domains of HRQoL and generates a health utility score to calculate quality-adjusted life years (QALYs) associated with each intervention under an area under the curve approach.

Sociodemographic data

We will collect birth date, relationship between child and caregiver, ethnicity, and socioeconomic status by self-report from families on the case report form (based on Statistics Canada classifications). Children and caregivers will report their sex at birth [94] and gender [95] according to Statistics Canada definitions.

Participant incentives

Families will be offered $25 (CAN) gift cards at each data collection time point.

Data analyses

To inform any modifications before our definitive RCT, we will compare study data to pre-set feasibility criteria (Table 2). For objective 1 (measuring acceptability), we will perform a theoretically informed analysis of interview data using the Theoretical Framework of Acceptability (TFA; [96]). Our theoretically informed analysis situates the professional knowledge of the researcher, allows transparent examination of the research by the reader, and has two main characteristics: how data are structured and how data are interpreted [97]. The structure of our analytic process will be anchored in the theoretical framework. We will interpret the meaning of participants' words vis-à-vis the theory while allowing new themes to develop. Our analysis will begin after the first interview and be ongoing during the study. RCs at each site will conduct initial coding, using TFA as a guide to structure themes while remaining open to identifying new themes, with line-by-line analysis. Initial findings will be shared with our SSC for review and discussion, then applied to the full data set. In analyzing the full data set, we will remain open to identifying new themes not accounted for in the TFA, reflecting our sensitive use of theory to guide analysis. For rigor and transparency, we will complete the Consolidated Criteria for Reporting Qualitative Research (COREQ) [98].

For objective 2 (measuring attrition; study rigor and conduct; clinical, health services, economic outcomes), we will describe continuous data by summaries (means, medians, ranges) and categorical variables with frequency distributions. Data will be described for each group (e.g., sex, gender), stratification (e.g., age [6–9 years, 10–13 years, 14–17 years]), and clinic (Calgary, Mississauga). Group differences in outcomes will be calculated with 95% CIs. To complete power calculations for our definitive RCT, the 95% CI for the primary outcome (attrition yes/no at 12 months post-baseline) will be used. *R* [99] will be used for statistical analysis by a data analyst blinded to group assignments. Our SSC will discuss and contextualize study findings. REDCap will house quantitative data and generate data files for analyses. Consistent with feasibility studies [56], our analyses will be descriptive. Uncertainty exists on what elements(s) of FN are essential to optimize intervention effects [43]. In response, the participatory nature of our research, inclusion of qualitative and quantitative data sources, and heavy participation of our SSC will provide a full assessment of FN, revealing vital insights into how our experimental intervention can optimize treatment impact for managing pediatric obesity in our future definitive RCT.

Qualitative data analysis will occur throughout the study. Quantitative data analysis will occur at study completion only. Based on literature reviews of attrition and pediatric obesity management [16, 17], subgroup analyses will be exploratory and descriptive. We will describe attrition and other outcomes (e.g., HRQoL, intervention dose received) in experimental and control groups to explore potential differences by age, sex,

Table 2 Acceptability and study rigor and conduct data, with thresholds for assessing feasibility of future definitive randomized controlled trial

Methodological issues	Comments[a]	Feasibility data[a]	Criteria[b]	Feasible? (Y/N)	Need to modify pre-RCT? (Y/N)
1.Was the Family Navigation intervention acceptable to children and caregivers based on the 7 domains from the Theoretical Framework of Acceptability (TFA), including: a. Affective attitude b. Burden c. Perceived effectiveness d. Ethicality e. Intervention coherence f. Opportunity costs g. Self-efficacy	(e.g., data from 1-on-1 interviews)	(e.g., data will be analyzed using thematic analysis, which precludes quantification; 7 themes, plus additional sub-themes)	For each of the 7 domains, findings will be reviewed, discussed, and interpreted with our Stakeholder Committee and research team to determine whether parts of the Family Navigation intervention should remain unchanged or if changes are needed before implementing in our definitive RCT	(e.g., "yes" for all 7 domains)	(e.g., "yes" for 1 domain; "no" for 6 domains)
2.What proportion of participants approached were eligible?			≥ 90% approached were eligible		
3.Did recruited participants complete consent/assent procedures?			≥ 95% recruited participants completed consent/assent procedures		
4.Did recruitment lead to successful enrollment?			100% sample size goal achieved		
5.Did participants agree to randomization?			≥ 95% participants agreed to be randomized		
6.Did randomization yield equality across groups?			Equal numbers of participants randomized to experimental and control groups		
7.Were blinding procedures effective?			100% analysts remained blinded to group assignment		
8.Were outcome assessments completed?			≥ 95% participants retained in the study completed outcome assessments		
9.How complete were outcome assessments at all study measurement intervals?			≥ 95% outcome assessments were complete		
10. Were outcome assessments burdensome for families?			≥ 90% children and caregivers disagreed that outcome assessments were burdensome		
11. Was study protocol acceptable to children and caregivers?			≥ 90% children and caregivers agreed study protocol was acceptable		
12. Was the level of attrition adequate within experimental (Family Navigation + Usual Care) and control (Usual Care only) groups at 12 months?			Experimental (FN + UC): 15–25% attrition Control (UC): 30–40% attrition		
13. Was collection of attrition data adequate to calculate sample size for definitive RCT?			≥ 95% participants had attrition data collected by 12 months post-baseline		

Table 2 (continued)

Methodological issues	Comments[a]	Feasibility data[a]	Criteria[b]	Feasible? (Y/N)	Need to modify pre-RCT? (Y/N)
14. Were logistics of running a multi-center trial assessed?			Review procedures (ongoing and end-of-grant) with investigators, research staff, navigators		
15. Did all components of the protocol work together adequately?			Review procedures (ongoing and end-of-grant) with investigators, research staff, navigators		

[a] Comments and Feasibility Data columns will be populated with study data collected during our study; example provided for context

[b] Criteria column thresholds based on objective criteria (when possible) and experience gained through study implementation as well as data analysis and interpretation with Stakeholder Committee and research team

gender, clinic, and changes within and between these subgroups over time.

Ethical considerations

Children and caregivers can have emotional responses when discussing obesity-related issues. Our study takes place in multidisciplinary clinics, which include mental health professionals. Our study leaders (GDCB, JH, IZ) will work with research staff, navigators, clinicians, and administrative staff at our clinics to develop clear and specific processes to ensure children and caregivers are able to access mental health support (within or beyond our clinics, if relevant) when support is needed.

Discussion

Attrition in managing pediatric obesity is a common occurrence. Families who attend more intervention sessions for obesity management and remain enrolled in care for longer achieve the greatest health improvements [100–103], observations that highlight the value of our study. We anticipate our findings will provide evidence that attrition has the potential to be reduced. The heterogeneity of approaches tested, small number of studies, sub-optimal study quality, and variable responses highlight the imperative for experimental research like ours to test evidence-based, theory-informed strategies such as FN that may reduce attrition in managing pediatric obesity. Our feasibility study represents a key next step in addressing obesity in children to help families get the most out of their care and optimizing the use of valuable health care resources.

Knowledge translation

Our knowledge translation (KT) plan includes a blend of integrated and end-of-grant activities, which were informed using an established framework [104]. Children, caregivers, and clinicians from our SSC will partner with study leaders to co-author summaries of study results for our target audiences, providing real-world context for our findings and emphasizing key messages in plain language. Our integrated KT includes purposeful activities that are essential for study success, including formal meetings for our SSC and TSC, daily communication between research staff and clinicians, qualitative data analysis and interpretation that spans our project, and regular email correspondence to update stakeholders. Several of our team members lead multidisciplinary clinics for managing pediatric obesity, so study-related discussions and decisions will influence how our clinics plan and offer health services. We also lead provincial health system networks, with direct communication lines to enable province-level dissemination to clinicians and decision makers. Team members have established relationships with colleagues from Obesity Canada. We will share study data with public and professional audiences through newsletters and social media in the Obesity Canada community (> 50,000 members), with reach beyond academia and healthcare. At study completion, team members will work with public affairs experts at Obesity Canada and their respective institutions on press releases about findings. Results will be applied directly to inform our future definitive RCT to reduce attrition in pediatric obesity management.

Trial oversight

Our TSC will meet at the start of our study and annually thereafter. TSC members include three arms-length, national research experts with backgrounds in pediatrics, obesity, clinical trials, and qualitative research who will form the committee with our three study leaders (GDCB, JH, IZ). Our TSC will review the study progress, approve the protocol and any amendments, and resolve any emerging challenges. A Data Safety and Monitoring Committee will not be established because the UAlberta Human Research Ethics Board views our study as a low-risk intervention.

Trial status

Study activities were delayed due to the COVID-19 pandemic. Funding was received in July, 2021, preparatory study activities began in September, 2021, and participant recruitment began in October, 2022.

Abbreviations

AE	Adverse event
BMI	Body mass index
CANPWR	CANadian Pediatric Weight management Registry
CI	Confidence interval
CIHR	Canadian Institutes of Health Research
CONSORT	Consolidated Standards of Reporting Trials
EBCD	Experience-Based Co-Design
FN	Family Navigation
HRQoL	Health-related quality of life
HUI	Health Utility Index
KT	Knowledge translation
MI	Motivational interviewing
QALY	Quality-adjusted life years
RC	Research Coordinator
RCT	Randomized controlled trial
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
SSC	Stakeholder Steering Committee
TFA	Theoretical Framework of Acceptability
TSC	Trial Steering Committee

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40814-023-01246-w.

Additional file 1: Supplementary File 1. Perceived Acceptability of Family Navigation Intervention – Caregiver Interview Guide (DRAFT).

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Authors' contributions
GDCB conceived of the study. GDCB, RA, AA, AB, JG, JH, NLH, RJR, JET, and IZ established the study design. MGO and RN will help with study implementation. GDCB, MGO, RN, RA, ME, TL, and IZ contributed expertise in intervention development and refinement, along with members of our Stakeholder Steering Committee. GDCB, RA, AA, AB, ME, JG, JH, NLH, TL, RJR, and IZ are grant holders. NLH provided expertise in designing qualitative parts of the study and will lead qualitative data analysis. RJR provided statistical expertise in clinical trial design and will lead quantitative data analysis. JET provided expertise in health economics and will lead economic data analysis. All authors reviewed and edited the study protocol and approved the final version of the manuscript.

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Availability of data and materials
The datasets generated and/or analyzed during the current study are not publicly available since participants will complete informed and written consent (or assent) procedures explaining that study data are confidential and will only be shared within our research team. Summary data are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
Our research received ethics approval from the Health Research Ethics Boards at the University of Alberta (Pro00111932), University of Calgary (Pro00111932 / pSite-21–0030), and the University of Toronto (pending as of June 30, 2022). Administrative approvals were received from Alberta Health Services and Trillium Health Partners. All participants will complete informed and written consent (or assent for adolescents, when relevant) procedures before data collection commences.

Consent for publication
Not applicable.

Competing interests
GDCB received research funding from the Canadian Institutes of Health Research, Public Health Agency of Canada, Alberta Innovates, Alberta Health Services, Women and Children's Health Research Institute (University of Alberta). JH and IZ serve as medical directors of the two multidisciplinary pediatric obesity management clinics included as study sites in this trial. GDCB and IZ served as consultants for Novo Nordisk Canada. The other authors declare that they have no competing interests.

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