

BMJ Open Children and Teens in Charge of their Health (CATCH): A protocol for a feasibility randomised controlled trial of solution-focused coaching to foster healthy lifestyles in childhood disability

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ABSTRACT

Introduction Children with physical disabilities are rarely included in interventions to promote healthy lifestyles, despite being at higher risk for suboptimal dietary and physical activity behaviours. The Children and Teens in Charge of their Health study explores the feasibility and acceptability of conducting a randomised controlled trial (RCT) of a strengths-based, solution-focused coaching intervention for improving and sustaining physical activity and healthy dietary habits in children and young people with physical disabilities.

Methods and analysis Thirty children aged 10–18 years with a diagnosis of spina bifida or cerebral palsy who are able to set healthy lifestyle goals will be recruited from two children's rehabilitation hospitals in Ontario, Canada. Participants will be enrolled in the study for twelve months. All participants will receive standard care and printed information about healthy lifestyles. Of the 30 participants, 15 will be randomised to receive a coaching intervention for the first 6 months. Health indicators and psychosocial outcomes will be assessed by blinded assessors four times: at the start of the trial, immediately postintervention (6 months after randomisation), and at 3 and 6 months postintervention (9 and 12 months after randomisation, respectively). Predefined success criteria will be used to assess the feasibility of trial processes such as recruitment, attrition, stratification and intervention fidelity. Acceptability and perceived impact of the intervention will be explored qualitatively.

Ethics and dissemination The study has been approved by Holland Bloorview Kids Rehabilitation Hospital's Research Ethics Board (Ref: 17–752). A knowledge translation planning template will be used to ensure our findings have maximum reach.

Trial registration number NCT03523806.

INTRODUCTION

Background

The WHO's Global Strategy on Diet, Physical Activity and Health Promotion highlights that physical activity and dietary habits are central

Strengths and limitations of this study

- This study focuses on the feasibility and acceptability of using solution-focused coaching in paediatric rehabilitation to promote healthy lifestyles in children with spina bifida and cerebral palsy, who are routinely excluded from health promotion research.
- The study will identify if a later efficacy trial is warranted and if so, inform the processes, resources, management and methodology of such a study.
- A study strength is the rigorous methodology, including the use of randomisation, blinding and *a priori* success criteria, combined with in-depth qualitative inquiry.
- Participants will all be recruited from two centres in one part of Canada, which may reduce the generalisability of the findings.

to disease prevention and lifelong health.¹ Canadian children and youth (herein 'children') have increased health risks as their activity levels are drastically lower than recommendations.² The situation is even more critical for children with disabilities, representing 4.2% of Canadian children and rising.³ Due to complex and intersecting factors, children with physical disabilities (CWPD) are typically more sedentary, have lower rates of physical activity and have poorer quality diets than their peers without a disability.⁴ These factors can lead to exacerbated mobility and functional restrictions, osteoporosis, pressure ulcers, anaemia, obesity and reduced overall health and well-being.⁵ This is particularly true for young people with spina bifida (SB) and cerebral palsy (CP), two of the most prevalent non-progressive childhood physical disabilities.⁶ Both populations frequently experience considerable barriers to engaging

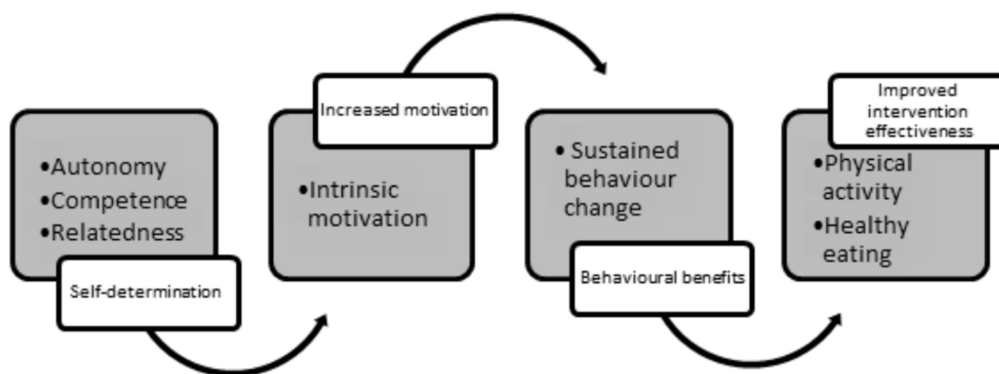


Figure 1 Link between self-determination theory, behavioural change and outcomes underpinning the intervention.

in physical activity and consuming an optimal diet; this threatens their health, independence and quality of life both in childhood and beyond.^{7 8}

Despite the clear importance of healthy lifestyles in CWPD, a comprehensive scoping review⁹ and related literature have shown that: (1) CWPD have far fewer opportunities to engage in health promotion programmes than their peers without disabilities¹⁰; (2) Although structured exercise/dietary interventions can be efficacious, they are often unsustainable due to the extensive resources required¹¹; and (3) CWPD often need support to identify healthy lifestyle activities that are engaging and grounded in their abilities and daily life.¹²

A new intervention paradigm that produces sustainable results without undue burden (on children, families and healthcare services) is therefore urgently required to address the health promotion needs of CWPD. Interventions must empower children and their parents to make lifestyle changes that are personally meaningful in order to promote motivation and encourage sustainable changes.¹³ Interventions must also consider the child's circumstances (individual, environmental, familial) to ensure that healthy behaviours such as physical activity and diet can be integrated into everyday life and thereby have long-lasting impact.¹⁴ A strengths-based coaching approach may meet all of these requirements.

Solution-focused coaching in paediatrics

In coaching, clients are guided to identify their own goals, develop strategies to meet them and monitor their performance.¹⁵ Solution-focused coaching in paediatric rehabilitation (SFC-peds) has been recommended as a coaching model for working with children with disabilities, due to its strong theoretical basis and ability to be customised to children and families' resources, environmental settings, child age, developmental stage and abilities.¹⁶ SFC-peds combines coaching principles with aspects of brief solution-focused therapy to work in a strengths-based manner with children and families in a rehabilitation context. Using positive reframing and strategic questions, the coach supports clients to identify goals that are personally meaningful to them and develop practical attainment strategies to work towards them.¹⁶

Using a strengths-based approach such as SFC-peds is a departure from the deficit model usually employed by rehabilitation research (ie, what a child can't do), even though strengths-based approaches been shown to be more efficient and less costly than problem-based approaches.¹⁷

Theoretical framework

The primary aim of coaching is to enhance *self-determination*, that is, the feelings of choice and control over one's life.¹⁸ Self-determination theory posits that there are three basic psychological needs essential for behaviour change¹⁹: (1) *Autonomy*, the opportunity to make meaningful choices²⁰; (2) *Competence*, also termed 'self-efficacy',¹⁶ an individual's innate sense of belief in their ability to be successful at a particular activity²¹; and (3) *Relatedness*, feelings of support and acceptance that provide affirmation.²² The resulting *intrinsic motivation* is a powerful mechanism to foster sustained behaviour change through genuine interest, satisfaction and engagement.¹⁹ It is operationalised in coaching through the use of strategic questions to help children identify personally meaningful goals and develop practical solutions to move toward a vision of their 'preferred future' (facilitating feelings of *autonomy*); empowering children to assume ownership over their goals and develop robust self-regulatory behaviours (enhancing *competence* or *self-efficacy*); and the use of active listening, empathy and affirmative language (facilitating *relatedness*).^{16 23–25} Figure 1 depicts the relationship between self-determination, behaviour change and outcomes, which underpins this study.

Feasibility studies

Despite being a promising approach, no randomised controlled trials (RCTs) have employed SFC-peds to promote healthy behaviours with CWPD. Prior to running a fully powered efficacy trial, it is essential to obtain evidence of feasibility, especially for complex interventions that have multiple interacting components and/or target multiple behaviours (such as SFC-peds).²⁶ Feasibility studies rigorously examine the processes, resources, management and science of the intended efficacy trial.²⁷ As one part of assessing feasibility, it is also critical to

evaluate the acceptability of interventions for the target population, as well as those allocated to the control arm (eg, acceptability of group allocation), and the perceived burden of undertaking assessments.²⁸ Feasibility studies help ensure that resources are invested in efficacy trials likely to generate clinically meaningful results²⁶ and therefore have maximum impact on healthcare knowledge and outcomes.

Our primary objective is therefore to evaluate the feasibility of conducting an efficacy trial of SFC-peds, part of which includes the acceptability of the intervention to stakeholders. Our secondary objective is to determine the responsiveness of selected outcome measures to a SFC-peds coaching intervention over 12 months.

This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials guidelines for reporting of clinical trial protocols (<http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/>).

METHODS AND ANALYSIS

Design

We will use a feasibility RCT design²⁹ with two groups. Both groups will receive the same printed materials on healthy diet/physical activity and continue to receive standard care from their existing clinicians. The participants randomised to the intervention group (SFC-peds) will work with an SFC-peds trained coach for up to eight sessions over 6 months. A 6-month intervention is supported by meta-analyses of health promotion studies for typically developing children³⁰ and adults.³¹ The feasibility of trial processes, management and resources will be assessed quantitatively. The acceptability of the intervention, potential mechanisms of change and barriers to implementation will be explored qualitatively.³²

Sample and recruitment

Participants will be aged 10–18 years, diagnosed with SB or CP and live within approximately 2 hours of one of two children's rehabilitation hospitals in Ontario, Canada. These populations were selected due to the prevalence of the diagnoses,⁶ as well as their high levels of sedentary activities and dietary challenges.^{33 34} Full inclusion and exclusion criteria can be found in [table 1](#). Potential participants meeting the age and diagnosis criteria will be identified from medical records/caseloads by clinical staff and receive information about the study. The research coordinator will follow-up with them and screen for the remaining inclusion/exclusion criteria, answer any queries and identify those wishing to participate.

Sample size

Feasibility studies do not assess intervention efficacy and therefore do not require formal sample size calculations.³⁵ The sample size (n=30) was set as the minimum needed to assess the key feasibility issues, which are to assess recruitment success and show whether testing

Table 1 Study inclusion/exclusion criteria

Child inclusion criteria	Child exclusion criteria
Between the age of 10 and 18 years.	Surgery in past 6 months or next 12 months impacting physical activity or dietary intake.
Diagnosis of spina bifida or cerebral palsy.	Medical condition severely restricting diet.
Has capability to execute independent body movement with or without a device.	Underweight (<5th percentile for age).
Cognitively able and willing to set physical activity or dietary goals.	Receiving specialist dietetic services.
Can communicate in English and respond to questions requiring some reflection/insight.	
Has a home internet connection.	
Parent inclusion criteria	
Primary caregiver to a study participant.	
Can communicate in English.	

procedures, coaching goals and follow-up sessions are consistent across groups, mobility levels and sites. Fifteen SFC-peds participants within the intervention group will suffice to show a tendency ($p < 0.10$) of behavioural change assessed by Goal Attainment Scaling (GAS; see list of outcome measures), equal to an effect size of 0.55 with a power of 0.80. Post hoc estimates of variance will be key, as they will inform the power calculations of a later efficacy trial.³⁵ This sample size is also considered adequate for the proposed qualitative work.³⁶

Randomisation

Once participants have provided written informed consent to the research coordinator, they will complete all baseline measures followed by randomisation into one of the two groups. Randomisation occurs after baseline testing to inform stratification, which will be by age (10–13 years vs 14–18 years); sex as assigned at birth (male vs female); and ambulatory/mobility level (ambulation without limitations [Gross Motor Function Classification System (GMFCS) level I] vs limited/no ambulation: GMFCS levels II, III, IV). The PLAN procedure of SAS/STAT software will assign group allocation, which will then be implemented by the research coordinator. Randomisation block size will not be known to research staff to ensure blinding.

Standard care

All participants will receive standard care throughout their time in the study. This may vary with the child's age, diagnosis, functional level and co-morbidities. Our

previous work shows that advice related to physical activity/diet is rarely part of standard care.³⁷ However, any time participants meet with service providers outside of the study context during the course of the study (eg, regular outpatient appointments with medical team, visits to the family doctor), they will request that the service provider completes a brief form that records whether they discussed diet or physical activity and the extent to which solution-focused communication was used. Service providers will also identify if they have any SFC-peds training. Coaches will not be part of the participants' team providing standard care.

Control information

After randomisation, all participants will be given printed information relating to physical activity and healthy diets based on Health Canada's *Eat Well and Be Active Toolkit* (www.health.gc.ca/eatwell-beactive).

Intervention: SFC-peds

Coaches delivering the intervention will have physiotherapy, therapeutic recreation, health promotion or similar training who have already been trained in SFC-peds. They will undertake an additional half day of training from expert team members on Canadian physical activity and dietary guidelines^{38 39} and their application to children with SB and CP. Coaches will then practice goal-setting and coaching with the Coaching expert on the team (SK).

Children randomised into the SFC-peds group (n=15) will be allocated the same coach for up to eight 60 min SFC-peds sessions over 6 months. The flexibility of SFC-peds means that there is not a strict schedule of coaching sessions. Time is allowed between sessions for children to work on their goals.¹⁶ Over the 6-month period, sessions will taper off to allow the child practice at sustaining the behaviour change.

The first coaching session will take place in the family's home to establish rapport. First, the coach will support children to identify his/her 'preferred future', that is, the 'big picture' the participant wants to work towards in the context of healthy diet/physical activity and co-create goals that are personally meaningful for the child. Using established SFC techniques,⁴⁰ the coach, along with the parents (if appropriate), will then support the child to identify realistic goal attainment strategies based on their own strengths and resources. Parental involvement in the goal-setting will depend on the child's age and abilities and will ensure that goals and goal-attainment strategies are realistic for the child, his/her environmental settings and the family context. Their exact involvement will be documented. In previous research, children with disabilities reached a participation-oriented goal within 3–5 sessions.⁴¹ In our study, children will each set at least one physical activity or one dietary goal. The number of coaching sessions taken to achieve the child's goals will be examined as part of the feasibility testing, both

quantitatively and qualitatively, and will inform future coaching protocols.

To reduce family burden and enhance adherence, all coaching sessions after the initial session will be held remotely using secure online meeting software requiring families only to have internet access. Ninety per cent of Canadians have internet access,⁴² but any instances of internet access being a barrier to study participation will be noted and inform our assessment of study feasibility.

Coaching sessions will always be directed to the child primarily, although parents may provide input if they are needed as a resource to enable the child attain their goal. At every coaching session, coaches will employ SFC-peds best practices by asking key questions that: Elicit any changes since previous sessions (eg, *What's better? What worked?*); amplify successes (eg, *How did you figure that out?*); reinforce key learnings (eg, *What have you learnt as a result of that success?*); and then revisit the child's action plan for appropriate next steps (eg, *With your new skills, what's next?*).⁴⁰

Patient and public involvement

All aspects of the protocol described here were reviewed by members of the Holland Bloorview Research Family Engagement Committee (RFEC). Members of the RFEC all have experience of living with a child with a disability and bring this lived experience perspective when providing recommendations to researchers. In addition, the research team includes two parents—one of a child with SB and one of a young person with CP. They provided critical input when designing both the intervention implementation protocol and assessment schedule. They will participate in regular team meetings while the study is being conducted to provide advice as appropriate. The family team members as well as members of the RFEC will assist with knowledge translation (KT) at the end of the study. Study participants will receive an infographic summarising the main findings of the study once complete.

STUDY OUTCOMES AND PROCEDURES

Assessment timings

To assess participant retention, we will use four assessment points over 12 months: time 1 (immediately preceding randomisation); time 2 (immediately postintervention/6 months postrandomisation); time 3 (3 months postintervention or 9 months postrandomisation); time 4 (6 months postintervention or 12 months postrandomisation). See [table 2](#) for the time schedule of enrolment, intervention, assessments and follow-up. Assessors will be blinded to the child's group allocation.

Study assessments

Primary objective

To evaluate the feasibility of conducting an efficacy trial of a novel, brief, coaching intervention (SFC-peds) for improving and sustaining physical activity and dietary habits in CWPDP.

Table 2 Schedule for enrolment, intervention, assessments and follow-up

Baseline Time 1	Randomisation	Months 1–5 Coaching begins within 2 weeks of randomisation	Month 6 Time 2 postrandomisation†	Month 7–8	Month 9 Time 3 3 months±2 weeks of last coaching session‡	Months 10–11	Month 12 Time 4 6 months±4 weeks of last coaching session§
Demographics			Demographics (meds and sports involvement only)		Demographics (meds and sports involvement only)		Demographics (meds and sports involvement only)
ISCOLE—full			ISCOLE—selected scales		ISCOLE—selected scales		ISCOLE—full
6MWT/6MPT			6MWT/6MPT		6MWT/6MPT		6MWT/6MPT
HAES			HAES		HAES		HAES
DSQ			DSQ		DSQ		DSQ
ASDS			ASDS		ASDS		ASDS
PHASES			PHASES		PHASES		PHASES
SEHE			SEHE		SEHE		SEHE
Body composition*			Body composition*		Body composition*		Body composition
FEAHQ-R			FEAHQ-R COPM/GAS (intervention only)		FEAHQ-R		FEAHQ-R
Semistructured survey (all)		COPM/GAS (intervention only)	In-depth interview (intervention participants+their parents only)				Follow-up survey (controls only)
		PRIME-SP SFFI (intervention only—after each coaching session)			Photovoice (intervention only) 1–2 photos/month (months 7–12)		In-depth interview (intervention + parents only)

*Body composition: weight, height/length, waist circumference and skinfold thickness.

†Time 2: 6 months±2 weeks from randomisation for Controls.

‡Time 3: 9 months±2 weeks from randomisation. for Controls

§Time 4: 12 months±4 weeks from randomisation for Controls.

6MWT/6MPT, 6 min walk test/6 min push test; ASDS, Arc's Self-Determination Scale; COPM, Canadian Occupational Performance Measure; DSQ, Dietary Screener Questionnaire; FEAHQ-R, Family Eating and Activity Habits Questionnaire-Revised; GAS, Goal Attainment Scaling; HAES, Habitual Activity Estimation Scale; ISCOLE, International Study of Childhood Obesity, Lifestyle and the Environment Questionnaire; PHASES, Physical activity self-efficacy scale; PRIME-SP, Pediatric Rehabilitation Intervention Measure of Engagement–Service Provider; SEHE, Self-Efficacy for Healthy Eating Scale; SFFI, Solution Focused Coaching Fidelity Instrument.

Trial *feasibility* will be assessed using preidentified criteria addressing recruitment, attrition, adherence, stratification and fidelity (see [table 3](#)). Trial *acceptability* will be explored using surveys and qualitative interviews at different time points across both the intervention and control groups.

Semistructured survey I

At time 1, all participants (n=30) and their parents (n=30) will complete a semistructured survey exploring their expectations of, and motivations for, joining the study, as well as their views on healthy lifestyles.

Qualitative interview I

At time 2 (6 months postrandomisation), SFC-peds participants (n=15) and their parents (n=15) will participate in a semistructured qualitative interview to explore: (1) satisfaction with coaching sessions (eg, relationship with coach, experiences of virtual coaching; whether they would recommend it to others); (2) coaching experiences (eg, new opportunities, challenges experienced); (3) perceived

optimal coaching dose; (4) perceived impact of SFC-peds on children's (and family's) healthy behaviours (physical activity and diet); and (5) role/experiences of parent involvement in supporting coaching goals and subsequent activities. SFC-peds participants will then be asked to start taking one to two naturalistic photos per month (using either a camera provided or their cellphone) between time 2 and time 4, to provide insights into their lifestyles post-coaching (termed 'Photovoice'). Photovoice uses photographic images taken by participants to help researchers understand what is meaningful for them while also acting as a prompt for rich dialogue and discussion.⁴³

Qualitative interview II

At time 4 (12 months postrandomisation), children and their parents in the SFC-peds group will undertake individual in-depth qualitative interviews to explore their experiences of health and wellness in the 6 months since coaching ended. Prompts may include the perceived impact of coaching, barriers/facilitators to maintaining

Table 3 A priori success criteria to assess trial feasibility

	Success criteria I	Success criteria II
Recruitment	2–3 participants/month recruited over 12 months (for target sample size n=30).	≥10% recruitment response rate achieved (min. feasible RCT response rate).
Attrition	85% participants successfully complete study (ie, complete T1 and T4 evaluations).	75% participants complete all assessments (ie, protocol adherence).
Adherence	Successful completers participate in ≥75% meetings with coach.	75% of the participants complete evaluations in ≤2 hours (to assess burden).
Stratification	Intervention/control groups similar for age and gender.	Intervention/control groups comparable on diagnosis and functional mobility.
Fidelity	High intervention fidelity (>8/10 on the Solution-Focused Fidelity Instrument).	Challenges/ease of remote coaching (coach, child, family report).

RCT, randomised controlled trial.

physical activity and dietary habits, and any unmet needs. However, the interviews will be guided largely by the participants recounting their experiences. Children's interviews will be guided by their selection of 6–8 of their photographs taken since time 2 to share with the interviewer and speak in more depth about their feelings and experiences of health and wellness since the coaching sessions.⁴⁴

Survey II

At time 4 (12 months postrandomisation), children in the control group (n=15) and their parents (n=15) will complete a brief survey regarding what they liked most/least about the study, any changes in healthy behaviours (physical activity and diet) in the previous 12 months, acceptability of group allocation and acceptability of outcome measure completion (eg, frequency, ability to complete multiple measures at one time, etc).

Qualitative interview—coaches

At the end of the study, the coaches will be interviewed to explore their experiences of delivering the intervention, for example, challenges/facilitators, optimal coaching doses, use of technology.

Secondary objective

To determine the responsiveness of outcome measures to SFC-peds coaching over 12 months. (table 4 provides an overview of all outcome measures).

Measurement of participant characteristics

Demographic information will be gathered at time 1, including sex assigned at birth and gender (if different), age and ethnicity. Diagnoses, medications and sports involvement will be assessed at all four timepoints. Functional mobility will also be assessed at every time point using the 6 minute walk test for ambulatory children⁴⁵ and the 6 minute push test for those using a manual wheelchair.⁴⁶ If a child meeting the inclusion criteria uses an electric wheelchair, functional mobility will not be assessed.

Issue identification and goal attainment (primary outcome measure)

The validated Canadian Occupational Performance Measure (COPM) identifies the person-centred goal performance issues individuals wish to improve and assesses changes in performance and satisfaction over time.⁴⁷ The identified goal issue will then be operationalised using Goal Attainment Scaling (GAS), through the use of rigorous procedures to ensure that all five attainment levels are mutually exclusive and measurable (see table 5, for an example of COPM and GAS goals). To minimise bias, GAS and COPM reassessment will be conducted by a coach who has not worked with the child.

Behavioural outcomes

To assess physical activity, we will use the Habitual Activity Estimation Scale⁴⁸ which is a child self-report measure of the time spent inactive, somewhat inactive, somewhat active and very active. The scale shows good correlation with moderate to vigorous physical activity measured by accelerometry in our population.⁴⁹ The child self-report Dietary Screener Questionnaire will be used to assess dietary intake over the past 30 days which has been validated against 24 hours recall.⁵⁰

Psychosocial outcomes

The child-reported Arc's Self-Determination Scale has excellent reliability/validity with children with disabilities¹⁸ and will provide insight into potential mechanisms of behaviour change. The Physical Activity Self-Efficacy Scale assesses confidence in the ability to be physically active when faced with challenges and has good internal consistency ($\alpha=0.54-0.71$) and test-retest reliability (Intraclass Correlation Coefficient (ICC)=0.61–0.82).⁵¹ High self-efficacy scores are associated with greater moderate-vigorous physical activity.⁵² The Self-Efficacy for Healthy Eating scale assesses participants' self-reported feelings of competence for making healthy food choices in social, emotional and typical situations. Higher scores are associated with healthy food intake ($\beta=0.33$, $p<0.01$). Test-retest reliability is high (ICC=0.80).⁵³

Body composition

Anthropometric assessments will be conducted according to established protocols.⁵⁴ Rigorous training will be provided to assessors and strong inter-rater and intrarater reliability established prior to data collection

Table 4 Outcome measures used in study

Outcome measure	Approach/ method	Informant	Variable(s)	Completion time	Assessment timepoint
Participant characteristics					
Demographic information	Questionnaire	Child/parent	Sex assigned at birth, gender (if different), age, ethnicity.	5 min	Time 1
Participant characteristics	Questionnaire	Child/parent	Diagnoses, medications and sports involvement.	5 min	Time 1, 2, 3, 4
Mobility: 6 min walk test	Physical assessment	Child who is ambulatory	Distance walked (metres) in 6 min.	6 min+5 min setup time	Time 1, 2, 3, 4
Mobility: 6 min push test	Physical assessment	Child who propels a manual wheelchair	Distance covered (metres) in 6 min.	6 min+5 min setup time	Time 1, 2, 3, 4
Issue identification and goal attainment					
Canadian Occupational Performance Measure (COPM)	Semistructured interview	Child with parent support if required	Client identifies an issue and then rates self: 1 (can't perform/not satisfied) to 10 (can perform/very satisfied).	5 min	Time 1,2 (intervention group only)
Goal Attainment Scaling (GAS)	Interview using information from COPM goal-setting	Child with parent support if required	5-point scale, ranging from -2 (current level) to +2 (exceeds expectations). Zero is expected level of attainment after intervention.	10 min	Time 1,2 (intervention group only)
Behavioural assessments					
Habitual Activity Estimation Scale	Self-completed questionnaire	Child	28 questions assessing intensity and duration of typical weekday and weekend activity.	10 min	Time 1,2,3,4
Dietary Screener Questionnaire	Self-completed questionnaire	Child	30-day dietary intake: fruits, vegetables, sugars & sugar-sweetened beverages, dairy, whole grains, calcium, fibre, red and processed meat.	10 min	Time 1,2,3,4
Psychosocial assessments					
Arc Self-Determination Scale	Self-completed questionnaire	Child	Three subscales that assess autonomy (21 items), empowerment (15 items) and self-realisation (15 items).	15 min	Time 1,2,3,4
Exercise Self-Efficacy Assessment	Self-completed questionnaire	Child	17 items assessing perceived confidence in ability to be successful at being physically active. Yes/no response.	5 min	Time 1,2,3,4

Continued

Table 4 Continued

Outcome measure	Approach/ method	Informant	Variable(s)	Completion time	Assessment timepoint
Self-Efficacy for Healthy Eating	Self-completed questionnaire	Child	Nine items assessing confidence eating 'healthy foods' across three domains: Social, emotional and normal situations. Response on 5-point Likert scale.	5 min	Time 1,2,3,4
Body composition					
Weight	Physical assessment	Assessor	Chair scale, to nearest 100 g.	5 min	Time 1,2,3,4
Height/length	Physical assessment	Assessor	Standing height or supine length (segmental if contractures); ulna and arm length as proxies if height/length not possible.	5 min	Time 1,2,3,4
Waist circumference	Physical assessment	Assessor	Flexible tape measure at the narrowest level between the lower costal border and the iliac crest, over light clothing.	5 min	Time 1,2,3,4
Skinfold thickness	Physical assessment	Assessor	Tricep and subscapular skinfold thickness using Lange callipers.	10 min	Time 1,2,3,4
Home and environment assessment					
Revised Family Eating and Activity Habits Questionnaire	Parent-completed questionnaire	Parent	32 items about the health behaviours of family members as well as the nature of the home environment.	10 min	Time 1,2,3,4
International Study of Childhood Obesity, Lifestyle and the Environment Questionnaire	Parent-completed questionnaire	Parent	Full scale is 103-items assessing the child's neighbourhood and home environments. Responses vary from 4 to 5-point Likert scale, yes/no and frequency.	10 min	Full scale: time 1,4 Sub-scales D,E,G,H: time 2,3 only
Coach measures					
Solution Focused Fidelity instrument	Self-complete questionnaire	Coach	13 items rating key aspects of Solution Focused Coaching best practices on a 10-point Likert scale.	5 min	After every coaching session

Continued

Table 4 Continued

Outcome measure	Approach/ method	Informant	Variable(s)	Completion time	Assessment timepoint
Pediatric Rehabilitation Intervention Measure of Engagement–Service Provider	Self-complete questionnaire	Coach	Three-part questionnaire: (1) One overall rating of child’s engagement during the coaching session; (2) Likert scale rating on three different aspects of engagement; (3) Any comments on factors that may have influenced the child’s engagement during the session.	5 min	After every coaching session

Table 5 Example of ‘preferred future’, goals and attainment strategies (10-year-old child)

Preferred future	
I feel fit and can keep up with my friends on the playground	
COPM goal	
I want to be more physically active	
GAS goals	
Present level or much less than expected (–2)	I do not do any sports or physical activities
Somewhat less than expected (–1)	I have looked into different accessible sports/activities
Expected level or programme goal (0)	I have tried a new sport or physical activity group
Somewhat better than expected (+1)	I attend one sports group regularly
Much better than expected (+2)	I attend two sports groups regularly
Goal attainment strategies	
Ask my friends what sports they play	
Check out my local parks and recreation website	
Ask my mother to take me to visit an activity I am interested in	
Try wheelchair basketball with my cousin	

COPM, Canadian Occupational Performance Measure; GAS, Goal Attainment Scaling.

commencing. Weight will be assessed using a chair scale. Standing height or supine length will be measured. For those with severe contractures, supine length will be based on segmental measurement. Where this is not possible, arm span and ulna length will be measured as a proxy for height.⁵⁵ Body mass index will be calculated from weight and height or length as kg/m² and classified using Centers for Disease Control and Prevention cut-offs (85th–95th percentile=overweight, above 95th percentile=obese). Waist circumference will also be measured as it has been shown to correlate well with fat mass as measured by dual-energy X-ray absorptiometry.⁵⁶ Tricep and subscapular skinfold thickness will be assessed and the Slaughter equation used to assess body fat.⁵⁷

Home and environment information and outcomes

The parent-reported Revised Family Eating and Activity Habits Questionnaire assesses the health behaviours of family members as well as the nature of the home environment, and has strong test-retest reliability (0.76–0.89).⁵⁸ These data will allow us to examine the impact of the coaching on the family over time, which will be further examined in qualitative interviews. Questions from the International Study of Childhood Obesity, Lifestyle and the Environment survey about the child’s environment (eg, accessibility of play areas) will also be asked.⁵⁹

Intervention fidelity and child engagement

After each coaching session, coaches will complete a standardised fidelity measure to ensure intervention consistency.⁶⁰ Participant engagement in each session will be rated by the coaches using the Pediatric Rehabilitation Intervention Measure of Engagement–Service Provider.⁴¹

DATA ANALYSES

The data will be entered in an Access Database that will provide drop-down menus and will restrict values within the range allowed for each variable. All statistical analyses will use SAS/STAT software.⁶¹ Although inferential

statistics are not required in feasibility studies,²⁹ we will explore preliminary effects of the SFC-peds intervention on the main outcomes through two-way repeated measures Analysis of Variance (ANOVA) to see changes on variables over time and between groups, followed by an Analysis of Covariance (ANCOVA) using T1 as a covariate to control basal variability. The GLIMMIX procedure of SAS will be used for that purpose. Estimates of effect sizes with 95% CIs will be calculated. These will provide important information for sample size calculation in future efficacy trials.

Feasibility will also be assessed with descriptive statistics compared against our a priori success criteria. We will explore any sample/group differences between completers (ie, those who complete time 1 and time 4 measures) and non-completers. We will also determine if there are sample and outcome variable differences (means) between sites, diagnoses and functional mobility.

The software NVIVO V.10⁶² will be used to manage the qualitative data. Transcripts from interview I (SFC-peds group at time 2) will undergo conventional content analysis⁶³ to explore the immediate perceived impact of the coaching sessions. Data will be coded guided by the data and then sorted into categories.⁶⁴ Transcripts from the coach interviews will be analysed in a similar manner. We will use inductive thematic analysis from a relativist ontological position to analyse the time 4 interviews (interview II), drawing on the phenomenological tradition.⁶⁵ This analytic approach is consistent with our intent to explore the child and family's experiences of health and wellness following the coaching and any changes in how they make sense of their social and personal world.^{66 67} Once transcribed, the research team will read the transcripts and develop codes by noting words, phrases or data segments that occur commonly in participants' narratives. Similar codes will then be grouped, from which a consolidated list of master themes will be created that show patterns in participant experiences. Characteristics (eg, child age, gender, diagnosis and mobility) will be considered to understand the context of the participants' experiences. Code-recode, peer examination and team discussions will help establish trustworthiness.⁶⁸

Measure responsiveness will be established by pre-post intervention differences using effect sizes (Cohen's *d*) and CIs both within and between groups. It is well accepted to examine mean score changes for clinically significant differences pre and post intervention without calculating statistical significance (eg, a score change of at least two points on the COPM is considered clinically significant).⁴⁷ We will therefore assess the potential value of SFC-peds over only receiving printed materials by examining goal scores over time. Our secondary outcomes will be compared with behaviour change (goal attainment) for concordance (eg, whether successful goal attainment corresponds with increased self-determination). We will examine differences in outcome measures by disability, mobility, gender and age.

ETHICS AND DISSEMINATION

All participants will provide written informed consent to the trained research coordinator prior to any study activities. Identifying information for potential participants will be stored on an encrypted server, in a password protected folder. If a participant chooses not to participate in the study, his/her identifying information will be deleted immediately. Identifying information for those who agree to participate in the study will be stored on the same encrypted server, in a password-protected folder that requires authorisation from a member of the research team. This information will be retained for the life of the study. The principal investigator will be the guardian of the dataset and only allow authorised individuals access.

Given that we are providing printed information on healthy lifestyles to all study participants, every child will have exposure to information on healthy habits, not just those in the intervention group. In order to reduce burden on families, our intervention (SFC-peds) is largely virtual.

Using a KT planning template,⁶⁹ we will ensure our findings have maximum reach yet are appropriate for the nature of feasibility study outcomes. Integrated KT is being promoted by the involvement of clinical, family and knowledge user stakeholders, to ensure that the outputs meet the needs of the end users.⁷⁰ End of grant KT will include dissemination of study findings using traditional knowledge diffusion strategies (eg, conference presentations and publications) and communications to lay forums with summaries, stories and infographics. We will use the Template for the Intervention Description and Replication checklist⁷¹ when we report the results from the trial, so that we can provide information on context, tailoring, modifications and so on. We will track all KT activities.

DISCUSSION

This protocol describes a RCT to evaluate the feasibility of delivering a novel, complex intervention to promote healthy lifestyles in children with SB and CP (SFC-peds), including the acceptability of both the intervention and study participation for participants. This is a critical first step given that we currently do not have robust evidence regarding intervention strategies to improve and sustain healthy lifestyles in CWPD.⁵ Any complex intervention requires rigorous evaluation in order to provide evidence-based recommendations to improve short-term and long-term health. This feasibility study will therefore provide critical guidance for any future efficacy trial to ensure that it generates clinically meaningful results.²⁶ The strengths of this study include the involvement of two populations with demonstrated high needs regarding healthy lifestyles, as well as the use of rigorous methodology to evaluate a complex intervention. Using two distinct populations will help guide future decisions about whether single or mixed populations should be included in the same trial. Strengths also include the use

of a standardised yet flexible intervention, with rigorous training and fidelity measures. The use of a priori feasibility success criteria adheres to best practices⁷² and integrating qualitative inquiry lends insight into potential mechanisms of change and barriers to implementation.³²

Given that feasibility studies are not powered to assess intervention efficacy, the proposed feasibility RCT will not confirm whether SFC-peds should be routinely recommended for CWPD. However, addressing the feasibility (study design, methods, processes) and acceptability (family/child/clinician satisfaction, perceived usefulness) of an intervention before any efficacy trial begins increases the later likelihood of success and confidence in the findings.²⁶ This study will recruit from two sites in one area of Canada which may limit the generalisability of the findings. However, both sites serve diverse socio-cultural communities.

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Contributors ACM conceptualised the project, wrote the protocol and drafted the manuscript. EB reviewed and provided input on study design. LC advised on anthropometric assessment methods and training protocols. PTC provided expertise on medical considerations for children with spina bifida and cerebral palsy and the coach training protocol. JFdeG participated in the early design of the protocol and provided expertise on physical activity assessment. SK contributed training in SFC-peds and implementation of goal attainment measures. GK provided input on the conceptual basis and key features of the SFC-peds intervention. TL provided input on the implementation of the protocol and assessment schedule. DM contributed to the conceptualisation and design of the study and writing of the protocol. CM provided expertise on randomisation methods and statistical analysis. HM contributed methodological expertise in the design of the study and the research protocol. FM contributed to writing the qualitative research and photovoice components of the protocol. HS contributed to the early conceptualisation of the protocol and study design. All authors have read and agree with the contents of the final manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethical approval has been obtained for this study from Holland Bloorview Kids Rehabilitation Hospital's Research Ethics Board (Ref # 17-752).

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