

Title: The Effectiveness of participation-focused interventions on body functions of youth with physical disabilities: An Interrupted Time Series Design

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Potential Impact

Participation of youth with physical disabilities in community activities is restricted¹, which is associate with poor health outcomes and undesired development targetories². Traditional therapies for this population focus primarily on remediation of impaired body functions (e.g., muscle tone, joint mobility, balance) in order to reduce activity limitations and participation restrictions. However, activity-based goal-directed interventions that are client-centered and implemented in the youth's natural environment are currently considered recommended practice to improve daily activities³. It is unclear; however, whether interventions targeting *activity and participation* **also** result in improvement of body functions and participation - both key rehabilitation outcomes and meaningful outcomes for youth and their families. While research in exercise programs suggest that therapist-prescribed exercise programs result in physical gains (e.g., postural control)⁴, the impact of participation in a chosen and meaningful, real-life activity (e.g., sledge hockey) on a range of body functions (i.e., motor, cognitive and affective) underlining the specific chosen activity has not been established. Moreover, effective methods for testing complex individual-based interventions and outcomes that are highly applicable to practice are lacking.

This study aims to better understand the benefits resulting from intervention strategies that improve participation. It thereby tackles one of the pressing knowledge gaps in the field of pediatric rehabilitation^{3b} and one of the urgent research priorities identified by both parents⁵ and clinicians⁶. To illustrate, in a worldwide survey of rehabilitation experts, social participation in leisure and recreational activities as well as movement-related components were ranked as the most relevant areas of functioning across all elements of the International Classification of Functioning Disability and Health (ICF)⁶. Aligned with this priority, this proposed project addresses outcomes at two key levels of the ICF, i.e., participation and body functions, with a single intervention strategy. These outcomes have not only been consistently identified as significant areas of restriction among children and youth with physical disabilities^{1, 7} but are also known to worsen with age⁸, and further complicating the challenging transition to adulthood⁹. Youth with disabilities utilize healthcare services 5 times more than the typical adolescent population¹⁰. This, therefore, highlights the need to find better and more efficient methods of delivering healthcare services. It also emphasizes the importance of focusing on this developmental stage, i.e., youth, during which life-long habits can be established through positive experiences and opportunities for participation, capacity building and empowerment⁹.

Interrupted Time Series design – a rigorous approach for studying complex interventions and outcomes

Given the complexity and highly subjective nature of the outcome of participation, particularly when occurring in the community¹¹, selecting pragmatic individual-based approaches that reflect and account for real-world clinical settings (e.g., variability of participants, their participation preferences/choices and their environmental characteristics) is critical¹². **This pilot study** will therefore employ a replicated individual-based multi-baseline experimental design across youth, termed Interrupted Time Series (ITS)¹³. In this design, the time-point in which the intervention is introduced for each youth is varied, and each youth serves as a unit of analysis and acts as its own control. By varying the baseline lengths across participants, extraneous variables are controlled for, which in turn strengthens the internal validity of the study allowing us to conclude with greater confidence that change in participation levels and body functions is due solely to the intervention. To further increase internal validity and to minimize potential bias, each youth is randomly assigned to the order (timing) of the intervention.

Embedded in Comparative Effectiveness Research (CER)¹² and in ITS designs¹⁴ we aim to achieve a broad and diverse sample of youth, as this provides an opportunity to replicate the intervention effect across different circumstances/environmental characteristics/community settings and, consequently, further supports the generalizability of results. ITS design is particularly relevant when targeting children with physical disabilities (e.g., CP) in which the variability in functioning is large¹⁵. It allows for heterogeneity within the studied sample and accommodates for complex cases, which is beneficial and meaningful in rehabilitation, as opposed to traditional Randomized Controlled Trials that employs strict exclusion criteria limiting the applicability of the findings to the clinical setting/reality. Furthermore, having a diverse sample allows for a better understanding of for whom and under what conditions the intervention is most and least effective – an important element of CER that can better inform clinical decision-making.

To systematically evaluate the overall treatment effect of aggregated single individual intervention effects, we proposed an innovative statistical solution that involves a combination of segmented regression¹⁶ and mixed-effects Hierarchical Linear Modeling (HLM) – a technique found effective in a recent intervention study that was funded by CIHR and led by D. Anaby (NPA), targeting the outcome of participation. Notably, such an analytical approach can detect a change in outcomes that is clinically significant (e.g., the extent to which the intervention can result in a 2-point change on the activity performance scale of the Canadian Occupational Performance Measure) rather than estimate a general effect size and, therefore, provides meaningful evidence that can directly/better inform clinical decision-making. **In summary, the proposed ITS design, accounting for intra-individual changes and involving innovative analytical solutions, is practical as it offers a rigorous alternative for efficacy studies and is considered most appropriate for studying participation-based interventions¹⁷.**

Anticipated impact for youth, clinicians and policy makers

To date, only a few small-scale studies among children with physical disabilities have demonstrated that participating in mainstream, real-life, community-based activities/programs such as ice-skating and yoga leads to improvement of motor functions (i.e., balance, flexibility, posture, strength)¹⁸. Moreover, these studies do not document the impact of the above-mentioned activities on other body functions (e.g. self-esteem, attention span) and/or on participation outcomes itself (e.g., social interactions, developing friendships)¹⁸. Concerted effort is therefore needed to evaluate the impact of interventions that are enjoyable, socially engaging, guided by

youth preferences and occur within their natural environment across a range of body functions. Such interventions hold promise as they are perceived as motivating to the youth¹⁹ and can thus promote adherence to healthcare treatment and sustainability following their completion²⁰.

This early study in the area will build knowledge that can guide clinicians, families and policy-makers in appraising the benefits of participation-based therapies on improving functional capacities as well as actual performance of meaningful life activities. Findings can also encourage rehabilitation practitioners to consider additional intervention options for improving outcomes at the level of body function rather than solely focusing change on remediation of impairment. Increasing therapeutic options can contribute to customized care that is more responsive to the needs, resources and preferences of the youth and families. Furthermore, describing the multiple benefits potentially generated by **one single** intervention can facilitate the development of efficient youth-engaging therapies, therefore contributing to the improvement of the provision of pediatric rehabilitation services. Finally, in-line with CER, our study proposes a flexible client-centered intervention protocol using the ITS design which builds on a *non-concurrency* principle – it does not require all participants to start the intervention simultaneously, which is a more accurate reflection of ‘real life’ practice.

Scientific Merit

With CIHR funding, we have established the effectiveness of the PREP intervention, i.e., Pathways and Resources for Engagement and Participation, in promoting youth participation^{21 22}. The PREP²³ is an environment-based approach aimed at improving participation in community activities by removing environmental barriers and coaching youth/parents. Using elements of the PREP, the **goals** of this study are to: 1) generate preliminary data of the effectiveness of youth engagement in a 6-week community-based activity program (e.g., sledge hockey) on underlying body functions (e.g., movement, attention, mood) and activity performance and 2) examine the feasibility and applicability of the proposed design and intervention protocol. Specifically, **we aim**: 1) to gather pilot data and explore the effectiveness of the intervention on change in 3 relevant body functions: **motor**, **cognitive** and **affective** and to systematically replicate this effect across 8 youth with physical disabilities; 2) to estimate the optimal length and intensity of the intervention/community program, the relevancy of the proposed assessment kit in effectively capturing change in the three body functions and the feasibility of identifying and repeatedly collecting data on the specific 3 body functions underpinning each chosen activity; and 3) to examine the extent to which the outcomes vary within and across participants in order to estimate sample size required for a larger study. **We anticipate**: 1) a significant positive change in at least 2 of the 3 body functions within 6 of the 8 participants (75%) following the intervention; 2) that the proposed intervention protocol and study design will be feasible and applicable in at least in 6 out of the 8 cases; 3) obtaining a better understanding of whom and under what conditions/circumstances the intervention is most and least effective.

Methods

Eight youth, aged 15 to 24 years as defined by the United Nations²⁴, will be purposefully selected from a pool of clients receiving services in two major rehabilitation centers in Greater Montréal from both the Anglophone and Francophone communities. Participants will be included if they have 1) a physical disability (e.g., cerebral palsy, spina bifida, musculoskeletal disorders, muscular dystrophy); 2) restricted mobility, such as an inability to navigate all surfaces and stairs independently and safely without the use of aids, physical assistance or external support. Multiple diagnostic categories will be used, as research among children and

youth with physical disabilities shows that participation does not vary across specific diagnostic categories²⁵. Moreover, such an inclusive approach reflects real-world clinical practice, where variability in functioning level is evident across patients, making the findings relevant to various conditions and, hence, highly applicable to practice. Youth who are recovering within the first year following a severe brain injury or an orthopedic surgery will be excluded, as their functional capacities are less likely to be stable.

Intervention and Procedure

Based on the 5-Ms or steps of the PREP approach²³ found effective in improving youth participation²¹⁻²² (i.e., **M**ake goals; **M**ap out a plan; **M**ake it happen; **M**easure the process and outcomes; **M**ove forward), an Occupational Therapist (OT) will meet individually with each youth/family in their home. The intervention includes up to 12 hours of therapy time; the first 2-hour session will encompass setting a new participation goal or activity that the youth would like to engage in yet finds difficult. The Canadian Occupational Performance Measure (COPM)²⁶ will be used to identify participation issues from the youth's perspective. This process will lead to pinpointing a specific community-based activity that the youth will engage in for a period of 6 weeks (e.g., ice skating, sledge hockey, boccia, yoga). Together with the youth and family (as needed), this activity will be analyzed using the Task Analysis approach²⁷ to identify the specific underlying body functions that are required by the activity and that the youth finds most difficult and wants to improve on (e.g., posture, balance, strength, self-efficacy, attention). Three appropriate measures to monitor each corresponding function (motor, cognitive, affective) will be selected from a pool of 5 relevant scales. These 5 assessments, recommended by Majnemer²⁸ and guided by the ICF linking rules²⁹ include: the Spinal Alignment and Range of Motion Measure (SAROMM), the Trunk Impairment Scale (TIS), the Functional Reach Test (FRT), the Jamar dynamometer for evaluating **motor-related components**, and the Behavioral Assessment System for Children (BASC-2) to assess **cognitive and affective functions**. To illustrate, if task analysis of sledge hockey indicates that trunk control or range of motion of upper extremity is required for activity engagement, TIS or the SAROMM will be used, respectively.

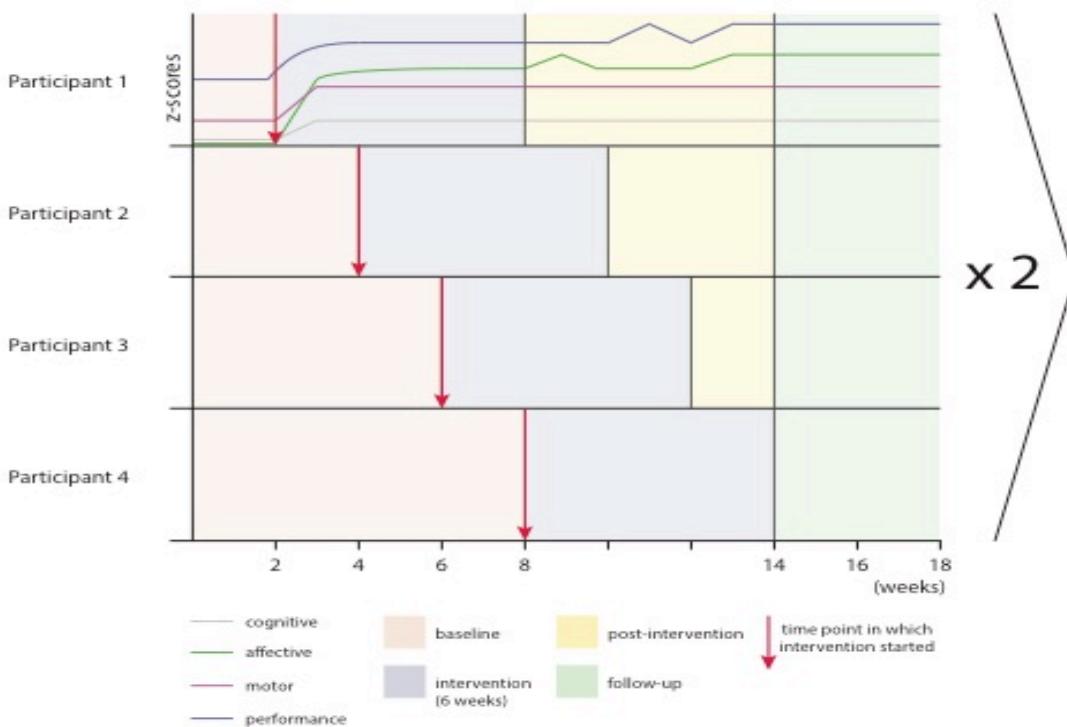
Two weeks following the first session, the baseline period will start and the identified body functions will be repeatedly measured every week, as will the performance of the chosen activity by an assessor, independent of the intervention. During this baseline period, the OT will use the 5-Ms of the PREP protocol to search for the appropriate community program, to identify and remove potential environmental barriers for participation in that activity (e.g., accessibility, equipment) and to educate program instructors regarding the specific needs and abilities of the youth. This will set the stage for enrolment and engagement of the youth in a structured program offered at least once a week. Using a structured form, the therapist will document information about the program and any specific circumstances involved. The OT will also serve as a consultant and perform site visits during this 6-week program to ensure youth engagement. Based on our experience employing the PREP intervention, a 6-week duration is sufficient to observe change in activity performance²¹⁻²². This timeframe also permits the building of motor functions^{18a, 30} while considering aspects of program management and adherence that can potentially reduce dropout rates²⁰.

Study design

Two blocks of an 18-week individual-based interrupted time series design with multiple baselines across 4 participants will be employed (Figure 1). To increase internal validity, each of the 4 participants will be randomly assigned to 4 different lengths of baseline: 2, 4, 6 and 8

weeks. A 6-week intervention will then be implemented for each participant. Four outcome measures will be monitored weekly throughout the three phases of the study: baseline, intervention and follow up (week 16 and 18). Figure 1 illustrates the ITS design across 4 participants; it will be replicated 2 times resulting in the examination of 8 participants. Three body functions: motor, cognitive and affective will be measured weekly, resulting in 3 individual trajectories of change – each based on 18 equally-spaced data points. The performance of each activity will also be monitored weekly using the performance scale of the COPM – a 10-point scale that is valid, reliable and sensitive-to-change²⁶. This will result in 24 trajectories of change in body function (8 participants X 3 body functions) and 8 additional trajectories illustrating change in performance in the actual activity (8 participants X 1 activity). Thus, a total of **32 trajectories**, 4 per participant, representing 8 profiles of change will be plotted and analyzed. A combination of 8 cases measured on 18 occasions allows us to estimate the overall effectiveness of the intervention (Aim 1) as well as to determine aspects of feasibility and applicability (e.g., duration of intervention, optimal number and intervals of data points, etc) of this design (Aim 2) and assist in calculating a sample size for a larger clinical trial (Aim 3)³¹.

Figure 1 - Study Design



A kit of outcome measures to assess body functions

A kit of 5 measures will be available to assess motor, cognitive and affective body functions over time. Based on the task analysis, the therapist and youth will select one aspect of each body function (3 total) required to complete the chosen activity, while considering the existing impairments and strengths of the youth; 4 options of assessments will be available for the **motor** aspect and a single tool for both **cognitive and affective** functions with multiple sub-scales for

each function. The therapist will match the assessment including specific sub-scales to the identified body functions by drawing on the ICF linking rules²⁹. If more than one component of a specific body function is identified, the most impaired one will be selected by the youth.

Assessors, independent of the intervention, will administer the assessments every week at the youth's home (30-60 min). They will be blinded to the time point in which the intervention begins and to the actual chosen activity/program.

To measure the **affective** (e.g., anxiety, social stress, self-esteem), and **cognitive** (e.g., attention problems, learning problems) aspects of body function, the self-report form or parent form of the **BASC-2** will be used, depending on the youth's ability. The **BASC-2**, completed in 15-30 minutes, is a valid and reliable 4-point scale for evaluating behavior and self-perception of children; such as externalizing and internalizing problems, behavioral symptoms and adaptive skills/personal adjustment³².

To measure **motor-related** body functions, four measures can be used: the **SAROMM**, the **TIS**, the **FRT** and the **Jamar dynamometer**. The **SAROMM** is administered by a trained rater and requires 15 to 30 minutes to complete; it measures active/passive range of motion of lower and upper extremities as well as spinal movements using a 5-point scale. The **SAROMM** has demonstrated good inter-rater and test-retest reliability (>.80) as well as sufficient construct validity³³. The **TIS** assesses trunk control and includes 3 sub-scales; static sitting balance, dynamic sitting balance and coordination, and is administered in less than 20 minutes. It contains 17 items rated on a 2-, 3- or 4-point scale. Total score ranges from 0 (low performance) to 23 (high performance). The **TIS** was found to be reliable and valid among youth with CP³⁴. The **FRT** assesses the maximum distance in inches the participant can reach forward while standing/sitting in a fixed position. It is a reliable, valid and responsive tool³⁵ and takes 5 minutes to administer. The **Jamar dynamometer** measures grip strength; scores range from 0 to 200 pounds of force and normative data has been established for youth³⁶.

All scores will be converted to z-scores based on available data of standard deviations and mean scores of this population; this will allow for comparison across trajectories and the examination of the overall effect of the intervention statistically (Aim 1).

Anticipated output #1: A significant change in at least 2 of the 3 body functions will be observed in 6 of the 8 participants (75%) following the intervention.

Two evaluators, both experts in analyzing multi baseline single-system replicated data, will analyze the data independently using a visual inspection approach following the guidelines of Hawkins et al³⁷ to detect changes in body function over time. To minimize bias, experts will be blinded to the time point in which the intervention was introduced. Specifically, experts will indicate if/when a change in body function and activity performance has occurred, and the direction of that change (increase/decrease). Consensus between experts will be reached via discussion and consultation with a third expert. The number of trajectories indicating a significant positive change in outcomes will be counted.

To complement visual inspection, the overall effect of the intervention will be statistically estimated within and across participants. Specifically, we will use an innovative analytical technique that combines segmented regression¹⁶ and mixed-effects HLM that was found useful in evaluating replicated individual-based ITS designs³⁸. This meta-analysis of treatment effect uses a small-sample bias-correction method and accounts for autocorrelation and individual variance. Moreover, it can estimate the extent to which a change in outcomes (youth's performance and functions) is clinically significant rather than solely reporting the effect size, as is common in traditional analytical approaches.

Anticipated output # 2: Proposed intervention protocol and study design will be feasible and applicable in at least 6 out of the 8 cases.

Information about the feasibility and applicability of the proposed approach in terms of length and duration of the program, length of baselines, number of completed data points/repeated measures, relevancy of assessments in capturing change in performance and body function will be recorded using a structured form/checklist. This form/checklist draws on the recommendations of Tickle-Degnen³⁹ for examining feasibility elements. Two reviewers, independent of the study, will autonomously evaluate these elements for each case and any discrepancies will be resolved through a discussion until consensus is reached.

Anticipated output # 3: To better understand to whom and under what conditions the intervention is most and least effective.

The two experts will independently conduct a systematic classification process¹⁷. Each expert will detect similarities and differences in patterns of change within each case using Hawkins et al.³⁷ guidelines. In this process, cases will be clustered based on aspects of change that reflect the extent of the intervention effect. Examples include: number of replicated effects across body function and level and trend of change. Once an agreement is reached and clusters are formed, group members/cases will be described in terms of age, sex, income, the characteristics of the community-based activity programs, the length, intensity and activity type (based on the therapist's structured form) as well as functional issues (based on assessment of body functions). Such an analysis will allow us to identify the profiles of youth for whom the treatment is more effective and less effective as well as the conditions under which the change is observed or partially observed. Furthermore, this information, analyzed with the input of stakeholders, can inform the design of a larger clinical trial testing this intervention.

Potential Challenges and ways to overcome them

Like in many 'real-life' studies, youth may wish to continue participating in the chosen program beyond the 6-week period or decide to engage in an additional activity simultaneously. Such occurrences will be documented by the therapist and will be incorporated into the analysis. This information will assist in identifying specific circumstances that may influence the results (Anticipated output #3). It is plausible that specific programs prioritized by youth will not be available in their community at a certain time (e.g., seasonal sports). A discussion will take place to identify ways to engage in a similar activity while adhering to the area of interest that was expressed. The therapist will document this process. Additionally, some youth might prefer to start the intervention before completing the assigned baseline period (either 2, 4, 5, or 8 weeks). Through a discussion with the youth and their family, the reason for employing such procedure will be described. Furthermore, during the baseline period, youth are allowed to continue and receiving any ongoing rehabilitation services and this will not be affected by such a delay.

Research team

Our cross-province interdisciplinary team (occupational therapy, physical therapy and pediatric medicine) includes three researchers in the field of childhood disabilities, from two institutions: McGill University and McMaster University, and are all individually associated with the CanChild Research Centre and have full access to its resources including its vast networks and collaborative partnerships. All members have strong backgrounds in the development,

functioning and participation of children and youth with physical disabilities and in developing and evaluating intervention programs and executing clinical trials. The research laboratory of **Dr. Anaby**, Nominated Principal Applicant, is located at a large rehabilitation center, ie., MAB-Mackay Rehabilitation Centre of CIUSSS du Centre-Ouest-de-l'Île-de-Montréal, which provides service for individuals with disabilities, and is where she has formed strong collaborative research partnerships with clinicians and managers. To illustrate, two experienced healthcare professionals from this organization, who have delivered the PREP approach and are engaged in knowledge translation activities, have joined the team as Principal Knowledge Users. Dr. Anaby is a recipient of the FRQ-S Research Scholar Salary Award and the primary co-developer of the PREP approach and has led the examination of its effectiveness with funding she received from CIHR as a PI. She brings knowledge in the areas of participation-based interventions, collaborative knowledge translation initiatives, advanced statistical analysis as well as unique methodological approaches such as Interrupted Time Series (ITS) design. She will oversee the entire project from recruitment, implementation and evaluation of the intervention and will build upon her network with major rehabilitation centers, health networks, and research associations in Québec to attract additional stakeholders. A post-doc trainee from her research laboratory will be involved in the study to gain skills in patient-oriented research. **Dr. Gorter**, Principle Applicant, is a dual (pediatric and adult) trained specialist in physical medicine and rehabilitation (physiatrist), professor of pediatrics, holder of the Scotiabank Chair in Child Health Research, and Director of CanChild, a world-renowned center for Childhood Disability Research since its founding in 1989, and is the named Investigator of a SPOR-funded initiative in Chronic Disease (CHILD-BRIGHT). He has a remarkable track record in supervising graduate students including Post-doctoral trainees. Dr. Gorter brings extensive knowledge in the transition of youth with physical disabilities and their participation in physical activities as well as abundant experience in forming collaborative partnerships with families, practitioners and organizations. He will provide ongoing feedback throughout the entire study with a special focus on engaging stakeholders, analyzing and interpreting the data and will serve as a liaison to his extensive network in Ontario and around Canada for partner resources. He will also provide supervision for a PhD-level trainee who will be joining the team. **Dr. Levin**, a Principal Applicant and a senior researcher who has many years of experience in mentoring trainees, is an expert in motor control and motor learning of children with CP and brings abundant experience in conducting intervention studies and various types of clinical trials from single-case studies to RCT. She will serve as a consultant throughout the intervention phase and will advise about the evaluation and analysis of changes in body functions, in particular motor-related functions, methodological challenges and overall interpretation of the results. **Rachel Teplicky**, a collaborator, is a Knowledge Broker at CanChild and an occupational therapist. She is a co-developer of the PREP approach and the Participation Knowledge Hub and has extensive experience, of nearly 15 years, in knowledge translation, stakeholder engagement and implementation strategies. To illustrate, she is currently involved in the implementation of the Measure of Process of Care across the Applied Behavioural Analysis program in Ontario - a project funded by the Ontario Ministry of Children and Youth Services. She will facilitate the development of a consultation committee (described below) through building on her existing networks and will engage stakeholders in the research process. We are thus well-positioned to develop and systematically test the proposed intervention and to advance knowledge about innovative methods that can effectively test participation-based intervention strategies resulting in evidence that is highly applicable to practice and can lead to a multitude of benefits related to the youth's development, function, health and social integration.

Engagement and Partnership

Drawing on elements of participatory action research⁴⁰, we plan to fully engage relevant groups of stakeholders within the research process. Our team has established connections with seven key stakeholders in both Québec and Ontario. Our current partners include a youth/young adult (J. Hanes) and a family representative (L. Bonta), two healthcare professionals (A. Leduc, I. Cormier), a national NGO community organization that offers and advocates for leisure programs (J. Coulter) as well as two policy makers both managers of large scale health care centre/college that provide rehabilitation and accessibility services (L. Turner, M. Aziz). Specifically, a Principle Knowledge User (M. Aziz), is an active member of a committee mandated to develop 3-year action plan related to social participation of individuals with disabilities across the MUHC – a major healthcare network in Quebec. Such a partnership will be pivotal in influencing and informing the direction and focus of rehabilitation services. Our partners will serve as knowledge brokers and will help develop networks by facilitating access to a range of potential knowledge users for on-going feedback and comprehensive input. Building upon their networks, a consultation committee including local representatives from both provinces (Québec, Ontario) and at the national level will be created to ensure inclusiveness and diversity of perspectives.

The consultation committee will meet twice through a two-hour long web-based conference, and each will be followed by on-line interactive feedback. The first meeting will take place at the beginning of the study using the GoToMeeting program- an advanced videoconference tool that allows face-to-face discussion, screen sharing and an exchange of information across all attendees. During this meeting, the discussion will focus on elements of the intervention and fine-tuning according to the needs of youth/families, the clinical reality, the emphasis of current programs as well as the direction, vision and action plans of health and rehabilitation services that support participation. Specifically, representatives will be asked to advise about the optimal duration of program, applicability of the measurement kit and availability of local community participation programs, among others. They will also assist in identifying relevant target groups for collaboration including non-federal governmental resources interested in promoting the engagement of youth with disabilities in their community. Suggestions generated from the meeting will be integrated and circulated via FluidSurvey to all representatives who will then be asked to review the summarized information, provide comments and additional ideas. Responders will also have the opportunity to suggest other relevant stakeholders for further feedback. Input from all perspectives will be integrated to form a final comprehensive plan of the study. The second web-based conference meeting will take place during the later stages of the project once data collection is completed and initial analysis has been performed. During this meeting, stakeholders will advise about additional ways to examine the data, review and discuss preliminary findings and interpret the results to ensure meaningful recommendations are formulated and that subsequent knowledge meets their actual practice needs. Key recommendations will be then circulated to all representatives using a secondary online survey for final feedback.

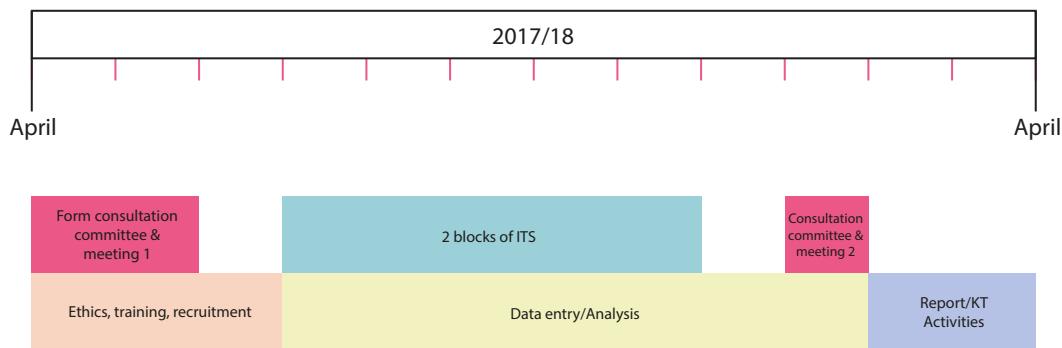
Such partnership activities will foster trust and result in a dedicated interdisciplinary research team that will jointly develop a strong and competitive large-scale research strategy to improve youth participation that is supported by partner funding. This research strategy will later be submitted to the SPOR multi-year iCT grant program.

Mentoring and training

Given that this project involves many stakeholder-researcher partnerships, it offers a unique and stimulating interdisciplinary learning experience in patient-oriented research. Trainees involved in this 1-year project will benefit from the mentoring of researchers in the following areas: strategies for stakeholder engagement and partnership development, crafting individual-based youth-engaging interventions to promote the subjective outcome of participation as well as examining unique methods for designing clinical trials using the ITS approach. Specifically, we plan to invite two trainees in the field of pediatric rehabilitation: a post-doc who is currently being supervised by D. Anaby and a PhD student being supervised by JW Gorter, who will both work closely with these mentors throughout the process and will meet with them on a regular basis. The trainees will attend all meetings with the consultation committee and will assist in analyzing the interactive feedback provided by all parties. Specific learning goals will be jointly developed in the early stages of the study and will be monitored periodically, with a particular emphasis on gaining methodological skills related to Comparative Effectiveness Research, including alternative clinical trials as well as acquiring experience in collaborative approaches for fostering equitable and trustful partnerships. The trainees will also assist in analyzing the data and will be introduced to and apply innovative analytical solutions for conducting systematic analysis of replicated individual-based treatment effects for ITS design. This project will complement the trainees' own area of interest and research focus, i.e., developing and testing intervention strategies for improving youth participation. Such an original learning opportunity will build capacity and foster additional merit for these young trainees, which can in turn facilitate further iCT patient-oriented initiatives in Canada.

Timeline

Figure 2 - Study Timeline



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