Coaching Caregivers of Children with Spinal Cord Injury
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Background and Rationale:

Parents of young children serve as caregivers, providing a variety of assistance until youth are able to do tasks and care for themselves on their own. When a child has a chronic health condition, such as a SCI, parents often become lifelong caregivers. A majority of caregivers of youth with SCI are mothers. This caregiving role is associated with poor outcomes in health related quality of life, for example caregivers are at high risk for emotional stress, fatigue, social isolation and frequent episodes of ill health. Interventions for caregivers of youth with chronic conditions and special needs have been investigated previously, but none for caregivers of youth with SCI.

Occupational Performance Coaching (OPC) is an intervention that provides a framework where professionals specifically coach caregivers to identify and solve issues that are barriers to their performance in their parenting and caregiving roles. Currently there are no studies on OPC in pediatric SCI but it has potential to fill the gap in interventions for caregivers of youth with SCI. OPC may be the intervention to fill this void because it employs problem solving, it focuses on identifying solutions to participation challenges that are associated with the social and physical environments which have been identified as problematic and lastly the evidence on OPC with caregivers of youth with other conditions shows positive outcomes on parent self-efficacy, stress and competency.

Specific Aims:

The specific aim of this study is twofold. First, to establish the feasibility of the OPC for caregivers of youth with SCI, and second to establish standardized methodological procedures for a future multi-center study on the effectiveness of OPC as an intervention for caregivers of youth with SCI.

Within this twofold aim, there are seven study objectives:

1. To determine the degree to which caregivers of youth with SCI believe in their ability to create and achieve meaningful participation goals.
2. To determine the degree to which therapists implement OPC, with fidelity.
3. To determine caregiver and therapist satisfaction and acceptance with OPC.
4. To establish the reliability of the OPC fidelity measure.
5. To determine the degree to which outcome instruments are completed in their entirety, and with accuracy and validity.
6. To establish parameters for a future randomized-controlled trial (RCT) on OPC including dosage and delivery specifications for OPC intervention; sample size estimation; and cost and time requirements for OPC study implementation.
7. To determine the feasibility of randomizing caregivers of youth with SCI into a treatment groups.

Risks and Benefits:

1. The risks involved in this research are minimal. Participants may become bored or tired during the coaching sessions or they may become upset or frustrated. Additionally, there may be a loss of confidentiality. In order to protect against risk, coaches are trained clinicians with experience working with parents of children with SCI. In order to minimize the risk of loss of confidentiality,

an identification number will be assigned to all participants. Identification number and corresponding name will be kept in a secure location separate from any participant data.

2. Potential benefits include an intervention developed specifically to meet the needs of female primary caregivers of children with SCI including but not limited to mothers, grandmothers and aunts surrounding caregiving of a child with a chronic condition. This intervention employs problem solving, which is an approach that has been identified as highly relevant for caregivers with SCI, and one that has shown to be highly effective for caregivers of children with other chronic conditions. Secondly, it explicitly focuses on identifying solutions to participation challenges that are associated with the social and physical environments which are areas identified by children with SCI and their caregivers as being problematic.

Research Strategy

Significance: This study addresses the unmet needs of female primary caregivers of youth with SCI. This is significant in that if these needs are not addressed through interventions that are explicitly designed to empower caregivers in their caregiving and parenting roles, both caregivers of youth with SCI and youth with SCI will remain vulnerable to the well-established adverse implications of information caregiving. This is the first study to establish the feasibility of an intervention explicitly for female primary caregivers of youth with SCI, and it will inform the development of standardized methodological procedures for the use of OPC as an intervention for caregivers of youth with SCI as well as a future RCT that will assess the efficacy of OPC for caregivers of youth with SCI.

Design: A sample of convenience will be used. Following consent and baseline data collection, participants will be assigned to one of two coaching methods, face to face format or phone. Participants who receive coaching over the phone will follow the exact procedures as face to face except coaching will be provided over the phone. The OPC intervention will last up to 10 weeks. Participants will be involved in the study for up to 18 months including baseline data collection, the intervention, and follow up data collection.

Sample: A convenience sample of up to 20 female primary caregivers, including but not limited to mothers, grandmothers and aunts of children with SCI will be recruited from three facilities specializing in pediatric SCI care and rehabilitation using the following inclusion and exclusion criteria:

Inclusion Criteria

1. Female primary caregivers of children with traumatic or acquired, non-progressive SCI between 6 and 13 years of age
2. Female primary caregivers will have legal guardianship of their child with SCI;
3. Speak, read and comprehend English
4. be available for face-to-face visits at a location in close proximity to the coach who will be providing coaching
5. have a cell phone with text messaging capabilities; be willing to utilize cell phone or land line for coaching
6. be able to verbalize challenges in their own participation or their child's participation during initial screening
7. Provide written consent

Exclusion Criteria

1. Severe mental health condition (female primary caregiver) as documented in the child's medical record or reported to research staff by child's treating physician or medical team member
    a. If potential participants experience emotional distress, a qualified mental health professional will be available to provide appropriate resources or referrals if needed.
    b. This would be documented in the child's medical record as standard procedure by the qualified mental health professional
2. Abuses or addictions (female primary caregiver) to illicit or prescribed substances or alcohol at the time of screening as documented in the child's medical record or reported to research staff by the child's treating physician or medical team member
3. Have a child with a diagnosis of suspected conversion syndrome at the time of screening as documented in the child's medical record or reported to research staff by the child's treating physician or medical team member
4. Have a child who is suicidal at the time of screening as documented in the child's medical or reported to research staff by the child's treating physician or medical team member
    a. If suicidal ideation (including intent and/or plan) is communicated at any point research staff will connect the participant with the qualified mental health professional who will conduct a suicide risk assessment and if needed, break confidentiality to call emergency personnel.
    b. This would be documented in the child's medical record as standard procedure by the qualified mental health professional

Facilities: Three facilities specializing in pediatric SCI care and rehabilitation will recruit for and enroll participants in the study 1) Shriners Hospitals for Children- Chicago 2) Shriners Hospitals for Children – Philadelphia and 3) TIRR Memorial Hermann- Houston. Thomas Jefferson University is the regulatory and lead site, however no participants will be enrolled at this site. Each enrolling site will have 1-2 trained coaches who will each recruit, enroll, and complete the study procedures for data collection with up to 5 participants.

Data Collection and Study Procedures:

1. Following consent, screening, and enrollment, baseline data collection will occur including baseline demographics of caregiver and child characteristics, the Beck Anxiety Inventory, the International Spinal Cord Injury Basic Data Set for Primary Caregivers, and the International Spinal Cord Injury Pediatric Activities and Participation Basic Data Set.
2. Each coach will provide the intervention to up to 5 participants. Participants will be assigned to coaching method based on their order of enrollment. Depending on the coach, the first 1-2 participants enrolled will have face to face coaching. The next 1-3 participants will have phone coaching. Seven female primary caregivers will receive the face to face and 9 will receive the phone coaching, for a total of 16 participants to receive the intervention.
3. In the event that face to face is not feasible, participants will have coaching via phone.
4. Caregivers who are have face to face coaching will receive up to 10 coaching sessions at a location that is mutually convenient for the caregiver and coach.
    a. The caregiver and coach will decide on how the sessions will be distributed over a 10 week period
    b. All 10 sessions must be completed within a 10 week period
    c. Each session will not exceed 90 minutes
    d. If goals are accomplished before 10 sessions, coaching will cease
    e. The general content, format and purpose of each coaching session is outlined in Table 1 below.
    f. All coaching sessions will be audio-recorded for assessment of treatment fidelity
5. Caregivers who are enrolled but who have not started coaching will receive monthly text messages from the project coordinator starting 1 month after enrollment. This is for retaining the participant.
6. The start and stop time of each OPC session will be documented on a study specific CRF that will also include information on caregiver attendance.
7. If coaching sessions are cancelled, rescheduled and/or missed coaches will document the occurrence and the caregivers' reasons for missing the session will be documented.
8. Caregivers who received and finished face to face coaching will be contacted on a monthly basis by the project coordinator via phone and asked about how goal focused problem solving skills have been generalized to other participation challenges and goals. This will be done to keep the caregivers engaged while assessing generalization of skills gained through coaching.
9. Assessments (primary).
    a. Canadian Occupational Performance Measure: This outcome will evaluate performance of and satisfaction with performance in self-identified goals.

Performance and satisfaction will be rated on a scale between 1-10, where 1 is "cannot perform" "not satisfied" and 10 is "performs without a problem" and "very satisfied". Goals will be rated by the caregivers before and after coaching.

10. Secondary (exploratory)
    a. Parenting Sense of Competence Scale (PSOC): most widely used measure of parental self-efficacy, it contains 17 items rated on a 6 point scale and evaluates satisfaction with parenting
    b. Parenting Stress Index Short Form-4 (PSI-SF-4): one of the most widely used measures of parental stress, it provides a method to evaluate parent stress with few items. It is comprised of 3 subscales including Parental Distress, Parent-Child Dysfunctional Interaction and Difficult Child as well as a Total Stress Scale.
    c. Pediatric Measure of Participation Short Form (PMoP SF) Parent Report: used to measure a caregiver's perception of their child's participation
11. Satisfaction – following completion of coaching, caregivers will participate in a semi-structured interview to explore satisfaction (Table 2)

Table 1: General Content and Sequence of Coaching Session

Session	General Goals	General Tasks
1	Build rapport, COPM, BIGSS	*Identify three participation goals; coach towards caregiver visualizing goals using guided imagery "what would it look like?"; "how do you see it and want it?"
2	Rapport building, goal focused problem solving	*Explain goal focused problem solving – review goals, explore options, plan actions, carry out plan, assess outcome *Caregiver selects one goal to apply problem solving, examine strengths, challenges, barriers, requirement of goal. *Define action towards goal *Follow through, agree upon action towards goal
3	Progress toward goal using goal focused problem solving, Begin problem-solving for remaining two goals	*Check progress on first goal *Review goals – explore options, plan actions, carry out plan, assess outcome *Identify one, two action step for each goal * Follow through, agree upon action towards goal
4-8	Progress toward goal using goal focused problem solving	* Review goals – explore options, plan actions, carry out plan, assess outcome *Check progress, plan action for each goal
9	Progress toward goal using goal focused problem solving	Review goals – explore options, plan actions, carry out plan, assess outcome *Check progress, plan action for each goal *Begin to close therapeutic relationship
10	COPM, BIGSS, Identify status of each goal, promote ongoing work, close relationship	Review goals – explore options, plan actions, carry out plan, assess outcome *Check progress, plan action for each goal *Close therapeutic relationship, reminder of phone calls

Table 2: Example of Questions for Final Caregiver Satisfaction Interviews

The purpose of the interview is to gather your thoughts and feedback about the Occupational Coaching Intervention that you participated in.....	
Questions	**Helpful Probes**
Can you tell me about the intervention	• What did you do during the visits • What did you talk about • What was the coach like • Tell me more about that • Anything else
Tell me about the goals you chose	• How did you choose them • Tell me more about that
What did you do to work towards your goals	• Did you achieve them • Why do you think you achieved (or did not achieve) them • What helped you move towards your goals • What did not help you move towards your goals • Say more • Anything else
How will you approach future goals	• What skills will you take with you • How successful do you think you will be • Tell me more
Was there anything you really liked about the intervention	• Tell me about these • What was most helpful • Can you say more about that
Was there anything you disliked about the intervention	• Tell me about these • What was most helpful • Can you say more about that • What would you change
Is there anything else you would like to tell me that I may have missed	

Recruitment: Primary female caregivers, including but not limited to mothers, grandmothers and aunts of children with SCI will be identified and recruited from the SCI practices at each facility. A member of the research team at each facility will make personal contact with the potential participant either 1) during their child's scheduled appointment or 2) via phone. Both methods will introduce the study and inquire about interest. If there is interest a contact form will be completed and a future appointment will be scheduled.

Informed Consent Process: Informed consent will be obtained from participants who have the capacity to give informed consent by a member of the research team who is authorized to consent for this study. The process will include a thorough discussion of all the elements outlined in the informed consent document, including but not limited to what is expected to happen during the study, risks and benefits of the planned intervention, and any possible alternatives. Potential participants will be given sufficient time to consider consenting to the study. The participant will be given a copy of the signed consent form. The original consent will be maintained in the participant's study binder/folder and kept in a locked storage cabinet.

Data Storage and Transmission

1. Original Site Data: Data will be recorded on standardized or study-specific case report forms. Participants will be assigned a confidential study identifier. The original data and subject identifiers from each site will be kept in a locked file cabinet, accessible only to the key research staff working on the study.
2. Data Transmission from Participating sites to the Lead Site: All data transmitted from the participating site will be de-identified, and coded with a unique subject identifier. Copies of all de-identified measures, CRFs, and audio recordings will be sent to the lead site via secure upload to a study specific Sharefile Account. The PI and/or project coordinator at the lead site will retrieve all data from the Sharefile account and save it to the designated file on the research drive. Once the data of participating sites are saved, they will be permanently removed from the Sharefile account.

Data Handling and Analysis: All data will be recorded on study specific CRFs and standardized measures and assessments. It will be sent to the lead site following the procedure above and will be entered into a study specific database.

Primary Outcome

1. Canadian Occupational Performance Measure: A 2-point change on the COPM indicates a clinically meaningful change, and 0.9 and 1.9 were found to be optimal cut-off points for performance and satisfaction, respectively. We will examine changes in COPM performance and satisfaction scores using non-parametrics.

Secondary Exploratory

2. BIGSS: We will calculate Spearman rank correlation coefficients (r_s) and create a correlation matrix to examine the relationships among caregivers' confidence in achieving goals, goal attainment (COPM), parent competency, stress, anxiety and participation, parent perceptions of child's participation, and caregiver and child characteristics. We will use these associations to better define inclusion and exclusion criteria for a future RCT on OPC, and to define primary and secondary endpoints for a future RCT.
3. Fidelity: Descriptive and summary statistics will be used to identify the number (mean, mode and range) of coaching sessions conducted for the face-to-face OPC group and the phone OPC group, and the average number and range of sessions required for goal attainment. We will also identify the average time per OPC session for both groups. The number of missed sessions and reasons for missing sessions will be identified. We will examine variability among the four coaches, and will determine if significant differences in these variables exist between OPC face-to-face and phone OPC. These data will be used to define the dosing parameters of OPC for a future RCT.
4. The audio-recordings of each OPC session will be transcribed verbatim. The transcriptions will be read and evaluated on treatment fidelity. Inter-rater reliability on treatment fidelity between the two graduate assistants will be evaluated by calculating intraclass correlation coefficients (ICC, Model 2,1) with 95% confidence intervals (CI). The PI will randomly select 10 transcribed face-to-face OPC sessions and 10 phone OPC sessions, and will also assess

treatment fidelity. Agreement between the assessments of fidelity will serve as an internal quality control, but will also further assess reliability using ICC (2,1) with 95% CI.