Pilot Testing a New Pregnancy Decision Making Tool for Women with Spinal Cord Injury

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INTRODUCTION

The decision to pursue pregnancy for many women with spinal cord injury (SCI) is too often made in a vacuum of knowledge, with limited guidance from clinicians, and in many cases, in the face of bias and discrimination. Literature suggests that knowledge about SCI and pregnancy is poorly disseminated to women[1] with many receiving inadequate information before becoming pregnant.[2] Uncertainty and anxiety about pregnancy is not uncommon for women with SCI[2,3] with the injury heavily influencing their decisions about pregnancy.[4] Their uncertainty is further compounded by difficulty finding clinicians with joint expertise in SCI, gynecology and obstetrics and the need for better care coordination during pregnancy.[1] Despite the importance of motherhood to many women with SCI, up-to-date educational and other materials to support pregnancy planning is extremely limited.[5]

Clinicians face their own ambivalence and uncertainty with limited knowledge of disability[6] and SCI[7,8] and training[9] to provide high quality care to women with SCI. This is compounded by a lack of clinical guidelines[10] to inform care. The ambivalence many clinicians have in providing care to women with SCI reflects broader societal expectations that women with disabilities are asexual and that pregnancy is highly improbable.[11,12] Unfortunately, this enduring stigma continues to influence the experience of many women seeking counsel about pregnancy.[13] Such longstanding myths, compounded by attitudinal and environmental barriers, have resulted in ill-informed and inadequate healthcare that is dramatically out of step with the hopes of women with SCI wishing to become mothers.

There is mounting and robust evidence that decision-making tools improve the quality of decisions and the decision-making process.[14] International standards to guide the development process[15] ensure rigor and relevance in their design. The purpose of this study is to test the efficacy and acceptability of a new pregnancy decision-making tool designed for women with SCI to support the decision-making process.

METHODS

Sample Characteristics – Women will have a traumatic or non-traumatic cause of SCI and at least 18 years old; aim-specific criteria are given below. Three items from the Behavioral Risk Factors Surveillance System[16] will determine disability severity based on the need for assistance with daily life activities and/or personal care; women with mild, moderate or severe severity will be eligible. Women who are eligible will be actively planning or in the process of making a decision about whether or not to get pregnant in the near future. The language is deliberately open based on feedback from women during development. The decision-making process for many women with SCI can be protracted given many uncertainties and a general lack of information and health care provider expertise.

Description of the Decision Making Tool – The decision making tool is a web-based site with a set of 9 downloadable worksheets (uploaded in Section 12, Exemption 3, #8 of the application). We developed the tool through iterative brainstorming sessions with stakeholders and used a survey, focus group, and interview data from women with SCI who have been pregnant, decided not to get pregnant, or are considering a future pregnancy. The tool covers topics relevant to women with disabilities in considering or planning a pregnancy and reflects core elements of decision making tools based on the Ottawa Framework for Decision Support.[17] This framework targets determinants of decisions that may be potentially modifiable by a decision-making tool, but are currently suboptimal for patients and health care providers due to factors such as inadequate knowledge, high uncertainty, or biased perceptions of others.

- Overview of Pregnancy – Reviews changes in a woman's body during pregnancy. This is not meant to be exhaustive but a general overview.

- Knowing what is important to you – Reflects Ottawa Framework's *values* component. Worksheet focuses on what is important to the woman as a foundation for decision making. It has several options to answer questions about values and learn more about how other women with disabilities answered the same question (links out to a summary report).

- Partners, family and important relationships – Reflects Ottawa Framework's *support* component. Guides the woman in talking about her decision and engaging those most important to her. The worksheet supports conversations that can be challenging to have.

- Physical function and independence – Reviews major domains of physical function and the possible effects of pregnancy on the woman's independence. The worksheet highlights topic areas to discuss with different health care providers.

- Health and wellbeing – Provides an overview of the different medical specialties that might be involved in care during planning and during a pregnancy and reviews major areas of mental and physical health that could be affected during pregnancy. The worksheet presents a series of questions a woman can review with her family and health care providers.

- Caring for an infant – Encourages women to consider various aspects of caring for an infant that may apply to them. The worksheet provides a list of considerations to support further dialog with her family and health care providers.

- SCI after pregnancy – Addresses possible changes after pregnancy, such as regaining physical fitness, to consider in decision-making.

- Financial resources & insurance – Addresses the need for financial planning in anticipation of a pregnancy and childcare. The worksheet reviews various aspects of planning a woman should consider as part of her decision making.

- How to find reliable information and resources – Provides guidance for how to find information and judge its quality. The worksheet provides a step by step guide for evaluating online resources.

- Connecting with other women with SCI – General guidance for connecting to their peers.

- Dealing with reactions of others, stigma and bias, pressure – Addresses the pressures women with disabilities can face during decision making about pregnancy.

- Reaching a decision – A closing section that highlights that it is OK to be wherever the woman is in the process, the different ways she may feel, and that it's OK to take a break if needed.

Intervention Delivery, Feasibility and Efficacy Testing – We will provide the tool for a 3-month trial to 40 women with SCI, allowing each woman to use the tool at her own pace. A pre-post design was selected following the recommendations of O'Connor and Jacobsen[18] for pilot testing new decision-making tools; this will help us prepare the tool for the next phase of testing that will utilize a parallel groups design. Similarly, the sample size was based on feasibility at this stage of the tool's development. We will assess outcomes at baseline, 6 weeks and the end of the trial period. For pilot testing at this stage of the tool's development, we are interested in several dimensions of feasibility and preliminary support for its efficacy. Using Bowen et al.'s[19] phases of intervention development, we are primarily concerned with assessing "can it work". Participants will be compensated $40 for their time.

Recruitment – Three methods will be utilized to recruit pilot participants: (1) study announcement published in our project newsletter requesting that interested women contact us, (2) social media postings on our project webpage and with groups we have connected with in the past, and (3) study announcement posted on *UM Health Research.* It is possible that women who participated in the earlier development work for this project, under HUM00149452, will choose to participate in this pilot study. Data generated under HUM00149452 will not be linked to data from this study.

Outcome Assessment – In pilot testing the new tool, we are interested in feasibility and preliminary effectiveness. Specifically, we are interested in the tool's acceptability, demand for it, and its implementation (or use of the tool). For preliminary efficacy, the goal for pilot testing is *not* for a woman to make a decision about pregnancy during the intervention period. Rather, assessment will focus on three domains of interest we expect to be influenced positively by the use of the tool.

We will also ask a sub-set of women if they would be interested in an opened ended interview to learn more about their experience using the tool and any other feedback they wish to share. This is not required and is not highly structured; it will be an informal conversation for those wishing to share more in depth feedback.

- Decisional conflict is characterized by uncertainty about a decision. The Decisional Conflict Scale[20] is a widely used outcome measure of decision-making with strong support for its validity.[20-22] We will use the *uncertainty sub-scale* for decisional conflict, the *support subscale* for having the support of others, and the *values subscale* for clarity of values.
- Decision or choice predisposition will be assessed using the single-item Stage of Decision-Making Scale.[23] The scale ranges from "haven't begun to think about choices" to "have already made a decision and unlikely to change my mind" but are modified to fit pregnancy and excludes the option of not having begun to think about choices since we are only including women actively planning or considering a future pregnancy.

Outcomes, measures, and time when collected are summarized in the table. Outcome measure items are presented on pages 6-8. All measures will be completed via online survey, or by telephone if requested by the participant.

Dimension of feasibility	Evaluates	Study-Specific Outcomes	Measures	When Collected (Baseline, 6 weeks, 12 weeks)
Acceptability	How participants react to the intervention	Satisfaction with tool; usefulness of the tool; intent to keep using the tool	Likert scales of overall satisfaction, usefulness; ratings of the presentation and balance of information.	12 weeks
Demand	How much the intervention is likely to be used	Frequency of actual use of the tool, interest in using the tool	Actual use (dates, duration) and interest in continuing to use the tool	Demand item: 6 and 12 weeks. Web Analytics: throughout
Implementation	How can the tool be delivered successfully	Factors affecting the use of the tool, ease or difficulty of using the tool	Likert scales of barriers and facilitators of tool use	12 weeks
Preliminary efficacy	Does the tool show promise of being successful with the intended population	Less decisional conflict; support of others; more clarity of values; greater readiness to make a	Decisional Conflict Scale sub-scales; Stage of Decision-Making Scale.	Baseline, 6 and 12 weeks

		decision (stage of decision making)		

Screening, Demographic and Background Variables – The list of screening, demographic and background variables are uploaded in the application, Section 12, Exemption 3, #8. These data will be collected at time of screening by phone; demographic and background variables will be collected post consent.

Analysis – Descriptive statistics will be used to summarize single item Likert scales. To examine preliminary efficacy of the tool, statistical analysis will include within-subjects, repeated measures analytic approaches (i.e., linear mixed models) to test the direction and magnitude of change on efficacy outcomes. Models will include selected disability characteristics (e.g., congenital vs. acquired) to test if the tool performs similarly across disability types.

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