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RUNNING HEAD: PREGNANCY DECISION-MAKING AND PHYSICAL DISABILITY

DEVELOPMENT AND PILOT TEST OF A PREGNANCY DECISION-MAKING TOOL FOR WOMEN WITH PHYSICAL DISABILITIES

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ABSTRACT

Objective: Design and pilot test a new decision-making tool for women with physical disabilities (impairment of physical function due to chronic conditions) considering pregnancy.

Data Sources and Study Setting: Quantitative surveys and qualitative interviews were collected from participants living in the community.

Study Design: Clinical guidelines and survey and focus group data about pregnancy informational and decisional needs guided content development. The tool was pilot tested in a 12-week trial with women with physical disabilities considering or actively planning a pregnancy. Feasibility outcomes were acceptability, implementation, and demand (collected at end of the trial); preliminary efficacy focused on decisional conflict and readiness (baseline, 6 weeks, and end of trial).

Data Collection: Survey data were collected using an online form. One-on-one interviews were conducted to learn more about experience using the tool.

Principal Findings: 38 women with mild, moderate, or severe physical disabilities participated. Feasibility outcomes indicated that the tool provided participants with information, guiding questions, and helped them to consider multiple aspects of the decision about pregnancy. Most participants responded positively to the new decision-making tool, finding it easy to use and the information balanced. Feedback highlighted opportunity for improvement, such as more specific information, peer stories, and the limitations of a paper format. There was significant linear effect of time, with increased decisional certainty and readiness, values clarity, and decisional support (partial η^2 (90% CI) = 0.310 (0,08, 0.46), 0.435 (0.19, 0.60), 0.134 (0, 0.29), 0.178 (0,01, 0,35), respectively). Decisional certainty and readiness had high observed power (96.7%

and 99.3%, respectively) with lower observed power for clarity and support (60.6% and 75.1%, respectively).

Conclusions: The new tool shows promise for supporting women with physical disabilities in navigating pregnancy decision-making. Future development of complementary strategies to support health care providers will help improve shared decision-making and patient-centered care.

Keywords: pregnancy; physical disability; decision-making; feasibility studies; women's health; health disparities

What is known on this topic

- Women with physical disabilities are no different than their non-disabled peers in their desire to have children, but are almost twice as likely to be uncertain if they will be able to.
- Many women with physical disabilities experience bias and discrimination in health care settings when seeking counsel about pregnancy.
- Despite evidence that the pregnancy decision-making process is suboptimal, there are few, if any, solutions to support women with physical disabilities in deciding whether to pursue a future pregnancy.

What this study adds

- A pregnancy decision-making tool designed for women with physical disabilities shows promise for supporting certainty and decisional readiness.
- Results suggest that using a decision-making tool helps to organize thinking and planning by prompting questions to discuss with health care providers.
- Feedback from participants highlight the opportunities for expanding content and the limitations of a paper-based format.

INTRODUCTION

Uncertainty characterizes the pregnancy decision-making process of women with physical disabilities,¹ defined by limitations in physical function, mobility, dexterity, or stamina. While they are no different than their non-disabled peers in their desire or intention to have children, they are almost twice as likely to be uncertain if they will be able to realize their intention.² Despite this uncertainty, an estimated 200,000 American women with physical disabilities are pregnant in a given year,³ with birth rates tripling since 2000.⁴

Disability is a complex interaction of the person and their environment⁵ that can amplify common concerns about pregnancy and introduce disability-specific concerns. Reproductive age women with disabilities tend to have more preconception risk factors^{6,7} and poorer overall health.⁷⁻¹¹ They may be especially vulnerable to perinatal depression with an already elevated risk for depression.^{7,12} Additional potential complications during pregnancy, such as urinary tract infections¹³⁻¹⁶ or pre-eclampsia¹⁶⁻²⁰ highlight the need for informed and thoughtful deliberation.

Shared decision-making reflects the core values of patient-centered care in which patients and providers work together to produce the best possible outcomes.²¹ While the decision to get pregnant is ultimately, and solely, the choice of the individual, health care providers are seen as important allies in the pregnancy decision-making process and play an essential role in assessing risk and providing information.^{22,23} However, they also struggle with their own ambivalence or discomfort²⁴ and limited disability competence,^{24,25} and are often hesitant to either raise the topic of pregnancy with their patients or respond with openness when it is raised by their patient. Such hesitancy reflects broader societal expectations that women with disabilities are asexual and pregnancy is highly improbable.^{26,27} In these complex dynamics, women with physical disabilities often fear that such disability bias may compromise their decisional autonomy about

pregnancy.²³ Despite such challenges, there are few solutions to support women and their health care providers in making an informed decision about pursuing a pregnancy..

Decision support tools help to decrease uncertainty, increase knowledge of problems, risks, options and outcomes, foster realistic expectations and enhance participation in decision-making.²⁸ There is evidence for their effectiveness across a variety of health conditions, patient populations, and health care settings.²⁹ There is also emerging support for improving outcomes among socially disadvantaged groups³⁰ and reducing health inequities (e.g., low literacy, people of color).³¹ Most decision support tools related to pregnancy focus on birth planning or prenatal testing, with evidence for their efficacy in reducing decisional conflict,³²⁻³⁴ increasing knowledge,^{33,34} decreasing anxiety and increasing risk perception accuracy.³⁴ They are also effective in other areas of reproductive health, such as contraception, pregnancy termination, infertility³⁵ and obstetrics.³⁶

To address the need to support pregnancy decision-making in women with physical disabilities, we developed a pregnancy decision-making tool. In this first iteration, we focused on its acceptability and preliminary efficacy when provided directly to women considering pregnancy. Future work will expand to include clinical implementation to support health care providers as partners in decision-making. Our expectation was that the new tool would be acceptable and reduce decisional conflict and promote decisional readiness. This paper describes the development of the tool and initial pilot testing.

METHODS

The Ottawa Decision Support Framework (ODFS)^{37,38} was used as a conceptual foundation to guide the development of the tool. The ODFS targets determinants of decisions that are suboptimal due to factors such as inadequate knowledge, high uncertainty, or biased

perceptions of others but modifiable. The ODFS' orientation around uncertainty closely aligns with the pregnancy decision-making experience of many women with physical disabilities.²²

Development of the Decision-Making Tool Content

We followed best practices of decision support tool development³⁹ and stakeholder engagement to ensure that the content and design of the tool was scientifically rigorous, clinically accurate, and responsive. The team was comprised of women with lived experience with physical disability (JK, RP, SB) and pregnancy (BO, MB), clinicians with expertise in psychiatry (HH, SR) and OB/GYN (SE, SC), and research expertise in women's reproductive health and disability (CK, LM).

A review of existing decision support tools to highlight desirable and undesirable features helped to determine initial organization and format. We held three in-person brainstorming sessions to iteratively generate and prioritize topics and worksheets, content, and design features. Content was further developed in iterative rounds of feedback. Focusing on functional impairment (physical disability) rather than a specific health condition required us to continually balance content specificity with generality. Since pregnancy can amplify adverse effects on health, function, and well-being, we were mindful of not overwhelming a user with too much information or topics. An additional challenge was integrating literature on pregnancy and disability that is largely, but not exclusively, focused on a specific disease or condition. Ultimately, we opted to defer explicit reference to specific literature for a future iteration. Results of an informational and decisional needs survey²² helped to prioritize potential topics. The tool was professionally designed, with images reflecting a diverse range of women in terms of race, ethnicity, and mobility devices.

Description of the Pregnancy Decision-making Tool

The decision-making tool is a 23-page PDF booklet with 11 sections and 8 worksheets. We followed guidance for key components (italicized below) that should be included in patient decision aids,^{40,41} with some slight modifications given the decision and target population. A *description of the decision* is framed around making a decision about a pregnancy in the near future. The *description of the health problem* is not specified because the focus is on physical function, irrespective of cause; rather, the intersection of physical function and pregnancy was emphasized. *Values clarification* focuses on knowing what is important relevant to a pregnancy in the context of a physical disability. Values related to maintaining independence, risk of long-term impacts on health and function, and risks to the baby are also embedded in *guidance in deliberation and communication*. *Personal stories* are reflected in quotes from women with physical disabilities about pregnancy decision-making gathered in our related work.²³ We endeavored to select quotes that represented both sides of the decision to pursue a pregnancy. In its current form, the tool is written in English. See Table 1 for an overview of the tool's content.

INSERT TABLE 1 HERE

Sample and Recruitment

Physical disability was defined by loss or impairment of physical function limiting one or more important life activities. It can occur as a result of but not limited to: 1) traumatic injury, such as spinal cord injury; 2) neuro-developmental conditions, such as cerebral palsy; 3) chronic medical conditions, such as Multiple Sclerosis; or 4) a combination of these. Three items from the Behavioral Risk Factors Surveillance System⁴² were used to determine disability severity based on the need for assistance with daily life activities and/or personal care. Participants with a mild, moderate or severe severity of disability were eligible. Participants had to be at least 18

years old and actively planning or in the process of making a decision about a pregnancy in the near future. Language regarding this future orientation was deliberately open-ended and based on feedback during development of the information and decision needs survey tool.²³ Participants were recruited from the community across the United States, using social media outreach (e.g., Facebook groups related to pregnancy and disability), snowball sampling (encouraging participants to share study information with their social networks), and participants engaged in other current or previous studies on reproductive health and disability.

The University of Michigan IRBMED approved this study under Exemption 3 (benign behavioral intervention); all elements of consent were provided in an informational sheet. The study was registered on Clinicaltrials.gov (NCT04651114). Enrollment began in November 2020 and ended in March 2021; final data collection took place in May 2021. Participants were given a \$25 incentive for each data collection and the post-trial interview.

Pilot Testing

A pre-post design was selected following the recommendations for pilot testing new decision support tools.⁴³ We selected a 12-week trial period given the complexity of the decision-making process, and instructed participants to use the tool at their own pace. Once enrolled, they were sent the tool as an email attachment. The target sample size of 40 was based on feasibility at this stage of the tool's development. All feasibility and outcome measures were collected using an online survey form (REDCap⁴⁴). Feasibility outcomes were collected at the end of the trial period (12 weeks); preliminary efficacy outcomes were assessed at baseline, 6 and 12 weeks. We also conducted brief post-trial interviews to gather more in-depth information about participants' experience using the tool. Those completing the final assessment were invited to participate.

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To guide outcome assessment, we used Bowen et al.'s phases of intervention development⁴⁵ and were primarily concerned with assessing four selected components of “can it work”. *Acceptability* (how participants react to the intervention) was assessed using 9 items drawn from O'Connor and Cranney's User Manual - Acceptability⁴⁶ to evaluate aspects of the tool such as presentation of information, length and amount of content, usefulness of worksheets, and suggestions for improvement. *Implementation* (how the tool can be delivered successfully) was assessed with questions about the ease of using the tool. *Demand* (how much the intervention is likely to be used) was assessed with a single item administered about the likelihood of continuing to use the tool after the study ended. In addition to standardized measures, open-ended items were collected to learn more about what participants liked and did not like about the tool, suggestions for improvement, things that made the tool easy or difficult to use, and usefulness of the tool. Interviews assessed first impressions of the tool, missing content, what was most and least helpful, the amount of information presented, an estimate of how often they used it, and how the tool affected their decision making. To track tool use during the trial, participants were given the choice of filling out a paper or online log (REDCap survey form). The log included a check list of tool chapters and open comment box for thoughts about their experience on that day.

For *preliminary efficacy*, we focused on domains related to decisional conflict (or a state of uncertainty about a course of action) that we expected to be influenced positively by using the tool: decisional certainty, values clarity, decisional support, and decisional readiness. The Decisional Conflict Scale (DCS)⁴⁷ is a measure of decisional conflict with extensive support for its validity.⁴⁷⁻⁴⁹ We used three of the five DCS subscales most relevant for pregnancy decision-making: decisional certainty, values clarity, and decisional support. We modified values clarity

items referring to “side effects” and “benefits” that were awkward for pregnancy. All items were rated on 5-point Likert scales of agreement (strongly agree to strongly disagree). Internal consistency for sub-scales scores at each timepoint were high (> 0.80) for all but decisional support at 6 and 12 weeks (0.69 and 0.68, respectively). The objective of pilot testing was not that a decision was made, but to support participants in moving towards making a decision. We used the single-item *Stage of Decision-Making Scale*.⁵⁰ Instructions were modified to refer to pregnancy and we excluded the first two response options given inclusion criteria.

In addition to standardized measures, open-ended items were collected to learn more about what participants liked and did not like about the tool, suggestions for improvement, factors that made use easy or difficult to, and whether the tool was useful. All participants who completed the trial were invited to provide additional feedback in a one-on-one telephone interview. See Table 2 for an overview of study measures.

INSERT TABLE 2 HERE

Analysis

For feasibility outcomes, we used descriptives to summarize closed-ended survey items. Qualitative data, from open-ended survey items and post-trial interviews, were synthesized using thematic analysis to identify common themes. General linear models (GLM) repeated measures were used to model decisional conflict sub-scales and decisional readiness as a function of time. Mean imputation was used for missing data. IBM® SPSS 27® was used for analysis.

RESULTS

Sample Characteristics

Of the 45 potential participants screened, 38 were eligible and all enrolled in the study. Among those screened but ineligible, the primary reason was not considering a pregnancy in the

near future, having already decided against a pregnancy, or currently pregnant ($n = 6$) or not having a physical disability ($n = 1$). Another 17 potential participants responded to an advertisement but did not complete screening due to a lack of response to outreach. Thirty participants completed the final data collection (78% retention); of those, 12 completed the post-trial interview. Seventy percent of the sample had a moderate or severe level of physical disability and 70% ($n = 21$) were born with a disability. Among the most common conditions were Arthrogryposis multiplex congenita ($n = 7$), spinal cord injury ($n = 5$), cerebral palsy ($n = 4$), Ehlers-Danlos syndrome ($n = 4$), Multiple Sclerosis ($n = 4$), musculoskeletal disorders ($n = 3$), and Spina Bifida ($n = 3$). Other conditions, represented once, were ankylosing spondylitis, complex regional pain syndrome, pseudoachondroplasia, Erb's Palsy, Muscular Dystrophy, spinal muscular atrophy, Tetra Amelia syndrome, and vestibular hypofunction disorder. Sixteen participants (42%) had a previous pregnancy. Among these, 11 (68.9%) had one or more pregnancy losses, one had a termination, and seven (43.8%) had difficulty getting pregnant with five of those having sought medical treatment. See Table 3 for all participant characteristics.

INSERT TABLE 3 HERE

Feasibility Outcomes

Acceptability: Overall, most respondents rated each section of the tool as good or excellent (see Figure 1). Sections Overview of Pregnancy, Knowing What is Important to You, Partners, Family and Important Relationships, and Health and Wellbeing were rated as good or excellent by 90% or more of participants. The lowest rated sections were financial resources & insurance and connecting with other women with physical disabilities. In general, most found that the information in the tool was balanced and the amount of information and overall length of the tool just right, with a third rating the tool as having too *little* information (see Figure 2).

INSERT FIGURE 1 HERE

INSERT FIGURE 2 HERE

Usefulness ratings of the worksheets (see Supplemental Figure 1) were slightly more variable with Worksheet #4 - Your Physical Function & Independence rated as the most useful (80% found it somewhat or very useful) and Worksheet #8 - How to Find Reliable Information & Resources rated as the least useful (63.3% found it somewhat or very useful). In general, participants liked the range of topics and found them to be helpful in organizing and keeping track of their thinking and documenting their questions or reflections. Open-ended feedback also highlighted the challenges of using a paper versus an online format, such as the placement of the worksheets requiring flipping back and forth between pages.

Comments from open-ended survey items and interviews about how the tool was useful largely focused on its provision of information and resources that prompted participants to consider many aspects of pregnancy and identify questions to discuss with their health care providers. For some participants, the information and questions helped them think about what was most important. For the few who did not find the tool useful, they cited it could be overwhelming or the information was too vague. A handful of participants who had reached a decision during the trial period noted that, while the tool did not necessarily help them reach the decision, they found the information and resources valuable for planning. They also mentioned that the tool helped organize their thoughts, made them feel less alone reading quotes from other women, and encouraged them to involve loved ones in the decision-making process.

Implementation: While the majority (73%) found the tool somewhat or very easy to use, the rest found it neither easy or hard, somewhat or very hard (see Supplemental Figure 2). Open-ended feedback focused on the challenges of a paper-based format, such as navigating pages,

flipping between chapters and worksheets. Others found it well organized and easy to follow. Most found the language accessible and appreciated the plain language used, though a handful commented that sometimes the language was simplistic.

Demand: A slight majority of participants (63.4%) were somewhat or very likely to keep using the tool after the study was over and nearly a quarter were definitely or not likely (23.3%) to keep using the tool and the remaining were uncertain (see Supplemental Materials Figure 3). Twenty-two (73.3%) thought the tool would be helpful to other women with physical disabilities; seven (23.3%) were uncertain, and one (3.3%) did not think it would be helpful. Open-ended comments from those who thought the tool would be helpful focused on the provision of information, considerations to think about, and questions to discuss. For those who were uncertain, a handful cited other women were different, or that the tool was not specific enough. One participant commented they were uncertain whether the tool would promote making a decision or may be more useful as a general resource for pregnancy planning. About two-thirds (68.4%) completed at least one log entry. Log entries ranged from very brief reactions to more detailed thoughts on where they were in their decision-making process. Participants also used their logs as a repository for feedback and suggestions for improving the tool. Interview data suggested that participants used the tool a range of time, from not at all (one participant) to as much as 10 times. A variety of factors affected how often it was used, some of which were circumstantial (e.g., learned they were unable to have children during the trial) or due to limitations of the format (e.g., hard to manage the pages in a PDF format).

Preliminary Efficacy

Results of the GLM indicated a statistically significant linear effect of time for each of the four preliminary efficacy outcomes, indicating that on average during the testing period,

decisional certainty and readiness, values clarity, and decisional support increased over the course of the trial. Partial eta squared values suggested that effect sizes were largest for decisional certainty (0.310; 90% CI 0.08, 0.46) and readiness (0.435; 90% CI 0.19, 0.60) with high observed power (96.7% and 99.3%, respectively). See Supplemental Table 1 for all GLM results.

Suggestions for Improvement

Thematic analysis of open-ended comments and interviews highlighted several themes related to improvements of the tool. Participants disliked having to flip back and forth between worksheets and the chapters, and some had difficulty filling in the worksheets. Several commented that they would like to see more personal stories and more images of women who do not use assistive devices. A number wanted more specific information, particularly around finances, providing childcare in early infancy, and more information relevant to their particular conditions. One participant suggested adding content about dealing with the potential involvement of child protective services; one suggested the inclusion of more links to information sources such as scientific publications and other reliable information.

DISCUSSION

This new pregnancy decision-making tool is, to our knowledge, the first to be designed for women with physical disabilities and not a specific health condition. Its conceptual foundation highlights the need for support when there is inadequate knowledge, high uncertainty, or the biased perception of others that influence decision-making. The involvement of end users and a multidisciplinary team in the design of the tool and results of a decisional needs survey helped to ensure that it would be responsive to end users. Results suggest that the tool provides

users with information, guiding questions, and helping them to consider multiple aspects of the decision to promote decisional certainty and readiness.

Three pregnancy decision-making tools designed specifically for multiple sclerosis,⁵¹ rheumatoid arthritis,⁵² and epilepsy⁵³ and given directly to women considering pregnancy found similar efficacy for reducing overall decisional conflict as well as increasing knowledge in users. We did not measure knowledge, given the diversity of causes of disability; this is an area for further development. Our results and trials of these disease-specific tools collectively show great promise for effectiveness of pregnancy decision-making tools to support women with complex health conditions and disabilities. While most participants responded positively to the tool, some did not find it to be useful. Reasons varied from not liking the tool itself, wanting more specific and relevant information, or other circumstantial factors such as unexpected health problems that were unrelated to the study.

Findings from this study help to understand potential mechanisms of change in pregnancy decision-making. Examining feasibility helps to understand *how* the tool is useful. Feedback pointed to the value of the structure, such as worksheets, and relevant information. This helped to expand and organize thinking which enabled action (e.g., write a list of questions, form a plan to talk with a health care provider, involve loved ones in the decision-making process), leading to greater decisional certainty and readiness. Our data do not explore whether having information and structure had a direct or indirect effect on decisional certainty and readiness. A deeper understanding of mechanisms of change^{54,55} will guide the selection of optimal outcome measures in future trials.

Preliminary efficacy outcomes help to understand *how* the tool has impact. This study suggests that the greatest impact is improving decisional certainty and readiness; there was a

lesser impact on values clarity and decisional support. For many women with physical disabilities, reaching a point of simply considering a pregnancy has already involved much thought and consideration about their desire and ability to care for children.²³ Participants reported a high degree of decisional support, suggesting that those who have significant support are more likely to consider a pregnancy than those with little support.

Strengths and Limitations

The strengths of this pilot study include using the ODFS to guide the initial development of the tool, working collaboratively with end-users,⁵⁶ clinicians and researchers, and by incorporating pregnancy informational and decisional needs of women with physical disabilities. While our sample size was based on feasibility, observed power for decisional certainty and readiness was over 90%, supporting their preliminary efficacy. Low observed power for values clarity and decisional support indicates that those results should be considered with caution until replicated in larger samples.

Participants had a range of different disabling conditions which supports generalizability in terms of cause of disability. Nevertheless, while relatively straightforward in concept, assessing the intensity and impact of disability is highly contextual and influenced by an individual's outlook. Defining and classifying disability in research, even within a specific population, is a recognized challenge.⁵⁷ Another limitation of the sample is being predominantly White, non-Hispanic, and well-educated, with the majority living in areas that were not medically underserved, limits the generalizability of findings to the broader population of reproductive age American women with physical disabilities.³ Finally, although our results are promising, the trial period was relatively brief given the magnitude of the decision; further work is needed to understand the longer-term effects of the tool. Additionally, the duration and

intensity of use was difficult to assess using self-report logs, limiting the ability to examine the relationship of dose and outcomes.

Future Development and Testing of the Pregnancy Decision-making Tool

Ultimately, this new tool is intended to be available to users via multiple pathways. Considering pregnancy can begin several years before active decision-making begins with extended periods of pre-contemplation²³ and anticipating parenting challenges.⁵⁸ Moreover, decision-making is often not a linear path; the tool is intended to support users at *any* point in the process that may or may not involve a health care provider. As such, user's direct access to the tool *before* discussion with health care providers helps to prepare for shared decision-making. Women with physical disabilities often work with multiple health care providers who may play a role in informing pregnancy decision-making. For example, they may work with physiatrists and physical therapists to preserve function and independence, primary care physicians for overall health needs, gynecologists for reproductive health, and obstetricians and high-risk specialists during pregnancy. Depending on the cause of disability, other specialties such as neurology, nephrology, or rheumatology may be involved in pregnancy decision-making, particularly around managing disease processes and medications. The development of complementary guidance, tailored by specialty, to promote its use in clinical encounters will give providers information and strategies to engage their patients in shared decision-making. Although decision support tools are still generally underutilized in clinical practice^{59,60} despite robust evidence to support their effectiveness in pregnancy³²⁻³⁴ and reproductive health care,³⁵ involving providers in all stages of design will be important to overcome barriers to their clinical implementation.

Our pilot testing results suggest that the tool is feasible and acceptable with support for its potential efficacy. As such, it can be a foundation for tailoring content to meet the needs of other groups of users. This can include specific disabling conditions and/or adding topics that address additional challenges, such as for women of color or transgender individuals who often face added discrimination and bias. Versions tailored for users with lower levels of education and literacy, such as modifying language or using more graphical representation of information, will help to make the tool more accessible. Challenges in contraceptive decision-making for women with physical disabilities⁶¹ or chronic health conditions⁶² and unintended pregnancy⁶³ highlight the opportunity to complement the tool with contraceptive support, particularly during a prolonged decision-making process or when a decision is made to not pursue pregnancy.

We used a paper-based format in this first iteration of the tool, with a longer-term plan of transforming content to a web application. The Internet is increasingly used to deliver decision support tools,⁶⁴ combining text, images, media, social networking, animation, and other features,⁶⁵ promoting engagement which can enhance decision-making.⁶⁶ There is also some evidence that computer-based decision aids are superior in reducing decisional conflict compared to usual care or alternative aids.⁶⁴ For users with disabilities, additional advantages include accessibility and ease of navigation and ability to rapidly update content as new evidence emerges. There is also emerging evidence that women with physical disabilities benefit from social support among Internet networks during pregnancy.⁶⁷ A digital version of the tool connecting users and enabling them to share information and worksheets with family, friends, and health care providers may be an additional benefit. Our intention is to eventually host a suite of digital pregnancy decision-making tools on a single website for direct access by both users and health care providers at minimal or no charge.

Preliminary efficacy effect sizes suggest that the decision-making tool has some important impact on decisional certainty and readiness during a relatively short trial period. However, the extent to which this is also a meaningful change is an open question without further research. More work is needed to understand a longer-term impact on decision-making and the overall quality of decision-making that results from using the tool. Randomized controlled trials in larger samples are needed to confirm efficacy and to test against control conditions (e.g., tip sheet) and in more racially and ethnically diverse samples of women and others with physical disabilities. There is also a need for greater breadth of outcome measures in decision support tool trials.⁶⁸ For example, constructs such as self-efficacy, psychological well-being, communication with health care providers, and personal factors, such as resilience and identity as a person with a disability, are especially relevant for future trials.

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Table 1. Content of the Pregnancy Decision-making Tool

Section Title	Content
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 ODSF' <i>values</i> component. It has several options to answer questions about values to explore what is important to guide decision-making. The associated worksheet (#1) focuses on what is important as a foundation for decision-making.
Partners, family and important relationships	Reflects ODSF' <i>support</i> component. Guides talking about the decision and engaging those most important in discussions. The two associated worksheets support conversations about pregnancy and decision-making that can be challenging to have (#2 and #3).
Physical function and independence	Reviews major domains of physical function and the possible effects of pregnancy on independence. The associated worksheet (#4) highlights topic areas to discuss with different health care providers.
Health and wellbeing	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 associated worksheet (#5) presents a series of questions to review with family and health care providers.
Caring for an infant	Encourages consideration of various aspects of caring for an infant that may be relevant. The associated worksheet (#6) provides a list of considerations to support further dialog with family and health care providers.
Financial resources & insurance	Addresses the need for financial planning in anticipation of a pregnancy and childcare. The associated worksheet (#7) reviews various aspects of planning to consider as part of decision-making.
How to find reliable information and resources	Provides guidance for how to find information and judge its quality. The associated worksheet (#8) provides a step-by-step guide for evaluating online resources.
Connecting with other women with physical disabilities	General guidance for connecting to 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 acceptance of wherever the user is in the decision-making process, the different ways they may feel, and encourages taking breaks if needed.

ODSF = Ottawa Decision Support Framework

Table 2. Study Feasibility and Efficacy Outcome Measures

CONSTRUCT AND ITEMS	RESPONSE SET	SCHEDULE OF COLLECTION
Acceptability (how participants react to the intervention)		
Please rate each section about how the information was presented in section [each section header given].	Poor, fair, good, excellent	12 weeks
The length of the tool was ...	Too long, too short, just right	12 weeks
The amount of information in the tool was ...	Too much information, too little information, just right	12 weeks
The way information was presented in the tool was ...	Slanted toward getting pregnant, slanted towards not getting pregnant, balanced	12 weeks
How was this tool useful or not in supporting your decision-making about pregnancy?	Open ended comments	12 weeks
How useful was the worksheet for [each one in separate item]?	Very useful, somewhat useful, uncertain, not very useful, not at all useful	12 weeks
Do you think the tool will help women with a disability make a decision about whether or not to get pregnant?	Yes, No, Uncertain; Comments	12 weeks
What did you like or not like about the tool and worksheets?	Open-ended response	12 weeks
What suggestions do you have to improve the tool and worksheets?	Open-ended response	12 weeks
Demand (how much the intervention is likely to be used)		
Logbook of use	Paper or digital log of dates and duration of tool use	Collected during trial
How likely are you to keep using the tool after the study is over?	Very likely, somewhat likely, not sure, not likely, definitely not likely	12 weeks
Implementation (how can the tool be delivered successfully)		
In general, how easy was it to use the tool? This would be things like going through the chapters, using the worksheets.	Very easy, somewhat easy, neither easy nor hard, somewhat hard, very hard	12 weeks
What made the tool easy or hard to use?	Open-ended response	12 weeks

CONSTRUCT AND ITEMS	RESPONSE SET	SCHEDULE OF COLLECTION
Were there things that made the tool hard to use, if any?	Open-ended response	12 weeks
Were there things that made the tool easy to use?	Open-ended response	12 weeks
Decisional Conflict Scale (preliminary efficacy)		
<i>Decisional Certainty</i>		Baseline, 6 and 12 weeks
I am clear about the best choice for me.	Strongly disagree, disagree, neither disagree or agree, agree, strongly agree	Baseline, 6 and 12 weeks
I feel sure about what to choose.		Baseline, 6 and 12 weeks
This decision is easy for me to make.		Baseline, 6 and 12 weeks
<i>Values Clarity</i>		Baseline, 6 and 12 weeks
I am clear about which values matter most to me. ^a	Strongly disagree, disagree, neither disagree or agree, agree, strongly agree	Baseline, 6 and 12 weeks
I am clear about which risks matter most. ^a		Baseline, 6 and 12 weeks
I am clear about what is important to me. ^a		
<i>Decisional Support</i>		Baseline, 6 and 12 weeks
I have enough support from others to make a choice.	Strongly disagree, disagree, neither disagree or agree, agree, strongly agree	Baseline, 6 and 12 weeks
I am choosing without pressure from others.		Baseline, 6 and 12 weeks
I have enough advice to make a choice.		
Stage of Decision-Making Scale (preliminary efficacy)		
Making a decision about whether or not to get pregnant can be complicated. At this time, would you say you:	haven't begun to think about it ^b haven't begun to think about it, but am interested in doing so ^b are considering the decision now are close to making a decision have already made a decision, but am willing to reconsider have already made a decision and am unlikely to change my mind	Baseline, 6 and 12 weeks

^a Items modified from original scale; ^b Items not presented given eligibility criteria

Table 3. Sample Characteristics

	N = 38
Age at disability onset (if not birth; M, SD; Range)	23.5 (7.4), 12 to 37
Current age (M, SD; Range)	33.1 (5.1), 21 to 42
Pregnant before (yes)	16 (42.1%)
Severity of disability	
Mild	7 (18.4%)
Moderate	15 (39.4%)
Severe	16 (42.1%)
Highest education completed (N, %)	
High school/GED	1 (2.6%)
Associates degree	2 (5.3%)
Some college (no degree)/Other	8 (21.1%)
Bachelor's degree	13 (34.2%)
Postgraduate degree	14 (36.8%)
Marital status (N, %)	
Single, never married	3 (7.9%)
Married	19 (50%)
Significant Other	15 (39.4%)
Separated	1 (2.6%)
Living situation (N, %)	
Lives alone	2 (5.2%)
Lives with spouse/significant other (with or without children)	29 (76.3%)
Lives with parent(s)	3 (7.9%)
Lives with children only (no spouse/significant other)	1 (2.6%)
Other	3 (7.9%)
Race and Ethnicity (N, %)	
White or Caucasian	33 (86.8%)
African American	3 (7.9%)
Asian	1 (2.6%)
American Indian/Alaska Native	0 (0%)
Native Hawaiian/Other Pacific Islander	0 (0%)
More than one race	1 (2.6%)
Hispanic Ethnicity	2 (5.3%)
Living in a medically underserved area (N, %)*	8 (21.1%)
Living in a health professional shortage area (N, %)*	
Primary care	15 (39.5%)
Dental care	15 (39.5%)
Mental health care	20 (52.6%)

See Supplemental Information for the method to determine medically underserved and health professional shortage areas.

Figure 1. Ratings of the Decision-Making Tool Sections

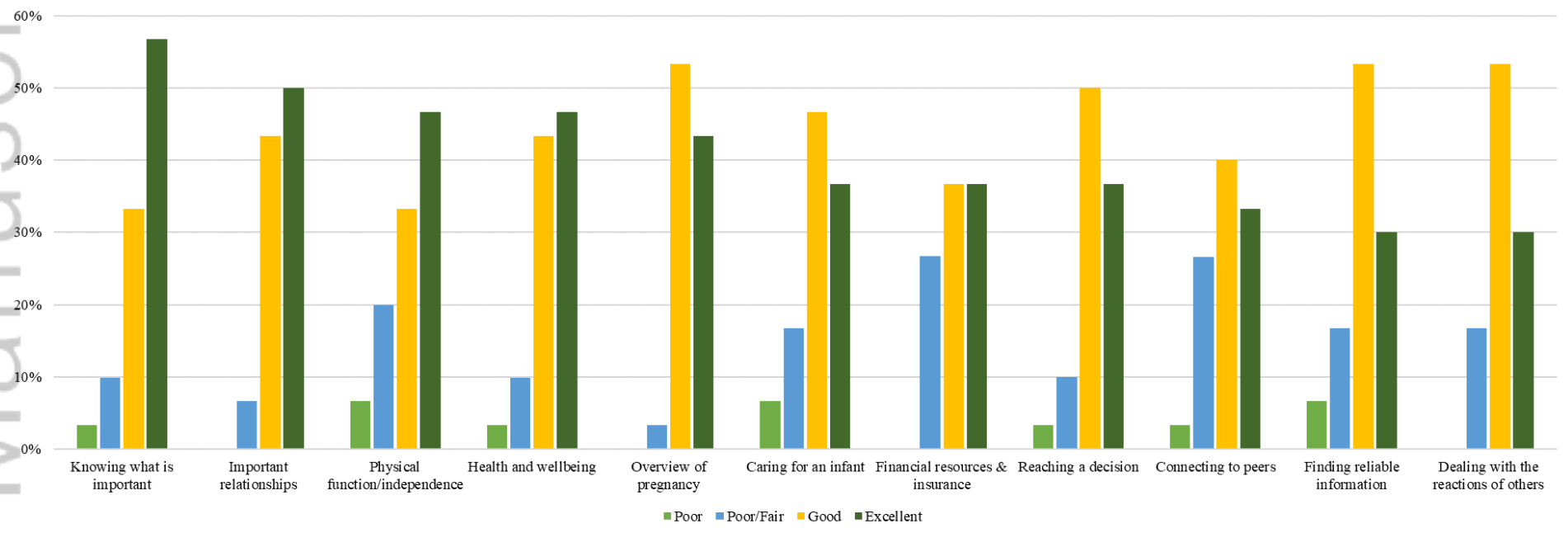
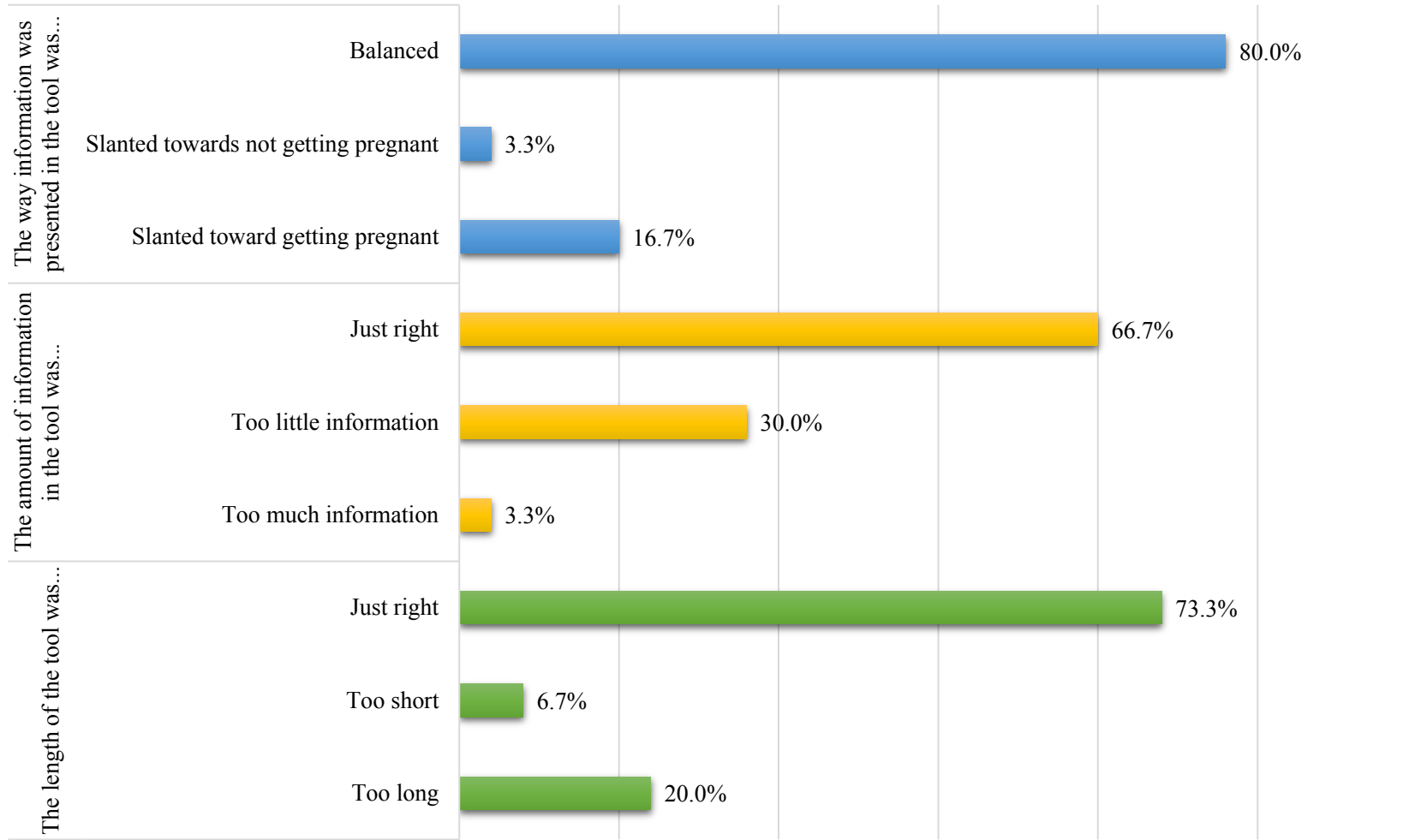


Figure 2. Ratings of the Presentation of Information in the Tool



DEVELOPMENT AND PILOT TEST OF A PREGNANCY DECISION-MAKING TOOL FOR
WOMEN WITH PHYSICAL DISABILITIES

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