Protocol

Study Title

Feasibility Trial of the TELL Tool Intervention

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Human Subject Protections/Institutional Review Board Approval:

University of Illinois Chicago IRB Protocol # 2020-1086
University of Michigan Protocol # HUM00230985

STUDY DESIGN

Narrative Study Description

The proposed research is clinically relevant as a paradigm shift is underway in medical reproduction. The secrecy that has historically shrouded the practice of gamete donation is lifting. Technology, especially in the form of direct-to-consumer genetic testing (e.g., Ancestry.com, 23andMe), is rapidly removing any illusion of secrecy and anonymity in gamete and embryo donation families. To preempt trauma to modern families due to DR parents' non-disclosure of their children's donor origins and promote shared knowledge of actual genetic heritage our study will provide an accessible and self-administered decision support tool (TELL Tool) to assist DR parent's disclosure to their child(ren). This project aims to examine the feasibility, acceptability, and preliminary effects of the TELL Tool intervention in a pilot randomized-controlled feasibility trial. The objective and aims are consistent with the goals of the NIH R34 program and the TELL Tool will be the first in the U.S. to address health promotion for DR parents and their donor-conceived children, a scientific priority of NINR.

Assignment of Participants

Our recruitment pool will consist of a convenience sample of DR parents and clinicians actively recruited through a broad-based, multifaceted plan. Interested DR participants will be asked to contact the Principal Investigator (PI) to schedule a phone interview for targeted recruitment screening. During the initial phone interview all potential DR parents will have the study fully explained and permission will be sought to screen for eligibility. Interested participants will be screened for eligibility by determining whether they are DR parents who used donated eggs, sperm, or embryos to have child(ren) and have not told their donor-conceived child(ren) about their donor origins. If the potential participant meets all eligibility requirements and expresses interest in the study, they will be directed to the study website and provided with a unique code that will allow them access to complete the online Informed Consent. Both the DR parents and practicing clinicians will complete an online Demographic Form immediately after providing Informed Consent. The form asks questions about personal characteristics such as age, race/ethnicity, and education. There are several questions that are specific to DR parents such as questions about the type of donation they used (e.g., donated egg or donated sperm) and questions specific to practicing clinicians such as what is their current professional role (e.g., nurse, physician). These questions are in accordance with our plans to establish a wide range of both DR parent and practicing clinician participants as well as enhancing our understanding of our sample of participants.

Group Randomized Trial

The study is a pilot randomized-controlled trial in which the units of assignment are DR parent groups and the units of observation are members of two groups (DR **intervention** parents and **attention-control** parent groups). Eligible DR parents who have consented and completed the Demographic Form, will be randomized into two groups (either the TELL Tool **intervention** group or the **attention-control** eBook group) using a permuted block approach that is stratified by the age categories of the DR parent's children and using an online (REDCap) randomization module.

Delivery of Interventions

During the initial phone recruitment interview, the PI will explain the nature of the study, risks, benefits, length, voluntary nature of participation, and the right to discontinue participation at any time without consequences and will screen potential participants for eligibility according to the inclusion and exclusion criteria. DR parents that are screened and meet eligibility requirements will be informed of the study website and provided the URL and a unique study code, which will serve as a portal for enrolling and providing demographic information and obtaining Informed Consent, completing the online Surveys and administering the TELL Tool or eBook interventions.

DR parents that are randomized to the TELL Tool **intervention group** will complete four online modules that are based on our prior research with DR parents. These four modules center on DR parents' cognitive, emotional, moral and relationship concerns that arise when DR parents consider whether to tell or not to tell their child(ren) about their donor-conception origins. The TELL Tool is designed using several strategies that enable DR parents to engage with the online materials. In addition, the TELL Tool is custom-tailored for DR parents by the type of family (for example a single-parent family versus a two-parent family), the type of donation (egg, sperm, or embryo) the DR parents used, and the age(s) of the DR parent's child or children. It will take DR parents about 60 minutes to complete the TELL Tool online modules. Immediate post-intervention DR parents will be directed to the post-test web page to complete (1) the *Outcomes Survey** measuring our (preliminary) outcomes for intention, competence, and anxiety about disclosing the donor conception to their children, and (2) the *Acceptability of the TELL Tool or eBook Survey*.** Then, at 4-weeks and 12-weeks post-intervention, DR parents will complete the *Survey on Actual Parental Disclosure*.

The DR parents that are randomized to the **attention-control** eBook **group** will complete a 60-minute online program that has up-to-date information about strategies that promote good parenting skills. The eBook has graphics and photographs that make it visually engaging for DR parents and easy to use. Immediate post-attention control, DR parents will be directed to the post-test web page to complete the (1) *Outcomes Survey** measuring our (preliminary) outcomes for intention, competence, and anxiety about disclosing the donor conception to their children, and (2) the *Acceptability of the TELL Tool or eBook Survey*.** Then, at 4-weeks and 12-weeks post-attention control, DR parents will complete the *Survey on Actual Parental Disclosure*.*** After all data are obtained, we will complete Year 1 analyses and make modifications to the TELL Tool, eBook, and protocols, as needed.

In Year 2 of the study, Cognitive Interviews will be conducted on a selected sub-sample of 10 DR parents and 10 practicing clinicians. Participants will be asked to complete individual interviews where they will be asked specific questions about how the TELL Tool and eBook and its design and administration can be improved further. We will use an Interview Guide, developed for the study that builds on our prior research and also uses guidelines and standards for developing decision aids to elicit information from DR parents and clinicians. In keeping with good scientific practice, the PI will use an Interviewer Summary Form to make field notes about observations when DR parents and clinicians are completing the cognitive interviews and interacting with the TELL Tool and/or eBook. The information we obtain from the Cognitive Interviews and from the Interviewer Summary Form will allow us to make final revisions and improvements to the TELL Tool, eBook, and/or the study protocol in Year 2.

Measures
Primary Outcome

***Survey on Actual Parental Disclosure**. This 6-item survey is an accepted method for obtaining meaningful information about actual DR parent's disclosure about the donor-conception origins to their child(ren). Within this survey, we will use the question "*Have you told your child or one or more of your children about their donor conception*?" [Response options: Yes or No] to establish whether DR parents have/have not disclosed to their child(ren).

Sample Size

We anticipate recruiting 75 DR parents in order to retain 60 DR parents through follow-up, conservatively assuming 80% retention given the 86% retention rate in our 12-year pilot study. The planned recruitment of 75 DR parent participants will allow point estimates and confidence intervals of our feasibility metrics (e.g., recruitment and retention) and means and standard deviations by treatment arm in outcome measures.

For the cognitive interview sample of 20 participants, we will include a sub-sample of 10 DR parents from our larger sample of DR parents, based on their 1) responses to the *Acceptability of the TELL Tool or eBook Survey* (e.g., participants who give detailed responses) and 2) in consideration of the maximum variation sampling plan (e.g., DR parent's gamete donation type, parent type, age category of the children to be told, and the 10% minority DR parent composition requirement). Maximum variation sampling will also be used to obtain the sample of 10 practicing clinicians for the cognitive interviews to allow for representation of nurses, physicians, psychologists, and social workers. The sample size for the 20 cognitive interviews (10 DR parents/10 clinicians) is consistent with International expert recommendations for decision aid development; other investigators that have developed decision aids; the needs of the study, and the acceptability evaluation and cognitive interviews used successfully in the development of the CHOICES intervention, a similar reproductive intervention.

Statistical Analysis Plan

We will emphasize descriptive statistics such as means, standard deviations, effect sizes, medians, interquartile ranges, frequencies, and percentages to demonstrate the feasibility of recruitment, adherence, retention, acceptability, and treatment effects of change in outcomes between the TELL Tool and the attention control eBook groups. Confidence intervals will be used to estimate a plausible range of values for these estimates.

Because our data analysis plan includes looking ahead to a full efficacy trial where we will use a mixed-effect model for repeated measures (MMRM), which is recommended for primary analysis of clinical trials with continuous endpoints using an intent-to-treat approach. We have considered the data analysis needed for our future efficacy trial in this proposed study. Noteworthy, the MMRM model can accommodate correlations due to dyad respondents and repeated measurements and handles missing outcomes with a maximum likelihood method appropriate when data are assumed to be missing at random. We will examine the planned model using our pilot data to assess if the statistical plan will need modification.

We will examine the extent of missing data and determine correlates of missingness through associations with our other measures and through our qualitative interviews. Including predictors of missing data will support the missing at random assumption in our future efficacy trail. Other goals of quantitative analyses will be to examine measurement scale psychometric properties, including adequate variability and ability to detect change. We will examine the pattern of outcomes over time to identify the optimal endpoint for outcome assessment. Purported mediators will be examined for change over time and change scores of mediators and outcomes will be correlated. In addition, we will explore our pilot results for trends to identify potential moderators such as age group of the child. These analyses will further inform future improvement of the TELL Tool.

Primary Purpose

The primary purpose of this pilot trial is feasibility because our objective is to examine the feasibility, acceptability, and preliminary effects of the TELL Tool intervention in a pilot randomized-controlled feasibility trial.

STATISTICAL DESIGN AND POWER

In this mixed-method study, we will use a 1:1 parallel groups randomized-controlled trial with targeted recruitment of 60 DR parents. A parent dyad will count as 1 DR parent as does a single parent or a family with multiple donor-conceived children. In view of our prior research with DR parents, we expect about 90% of the 60 DR parent participants (n = 54) will be dyadic DR parents (108 individuals) and 6 individuals will comprise 6 “single” DR parents in the sample for a total of 114 DR parent participants. Because this is a pilot randomized-controlled feasibility trial, the focus of the analyses will be on the feasibility of study procedures, however, our planned enrollment of 75 DR parent participants will allow point estimates and confidence intervals of our feasibility metrics (e.g., recruitment and retention) and means and standard deviations by the intervention (TELL Tool) and attention control (eBook) groups in our primary outcome measure.

04-06-2023 Update

A reliance agreement was obtained between the IRBs from the University of Illinois Chicago and the University of Michigan as Dr. Hershberger is now Professor Emerita at the University of Illinois Chicago and also a Professor at the University of Michigan.