

Study Title: Examining Validity and Reliability of the Shared Decision Making Process Survey in Adults With Depression

Document Title: Design and Analysis plan for a study examining validity and reliability of the shared decision making process survey in adults with depression

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ClinicalTrials.gov: NCT04343534

Date: March 15, 2023

Purpose:

The purpose of this study is to test two differently worded versions of the Shared Decision Making Process scale in a sample of adults who have recently made a decision about treatment of depression. The main goals are to gather evidence of reliability, to test whether the generic version has similar psychometric performance to the original, and to extend generalizability of the findings to younger adults.

Design:

Staff worked with a national sampling firm to recruit subjects and obtain 500 responses to the baseline survey (n=250 for each version) and a subset will complete a retest survey (n=200; 50 from each age and survey type group). Eligible subjects are adults aged 18-75 who talked with a health care provider about treatment for depression in the preceding 12 months. The sample is not a national probability sample; however, the recruitment efforts will ensure about 50% of respondents aged 18-39 and 50% aged 40-75, and to ensure at least 25% of the sample is racial/ethnic minorities (Black or African American, Asian, Hispanic or Latino).

Subjects are randomly assigned to one of the two versions of the Shared Decision Making Process scale and complete a set of measures regarding their experiences with decision making for depression, demographics, and health status. A subset of respondents will complete the Shared Decision Making Process scale again 1 week later to examine short term test-retest reliability.

Randomization and Blinding:

Participants in each study were randomly assigned by the sampling firm to complete one of the two versions of the Shared Decision Making Process scale. Participants were blinded to their version, but no other blinding occurred.

Primary Outcome:

- SDM Process scale [baseline and retest]. The SDM Process scale measures the amount of SDM that occurs in an interaction. For this project, the scale items were adapted to be completed by an observer rather than a participant in the interaction. Scores range from 0 to 4; larger values indicate greater SDM occurred. This scale was altered so that one group received the original version with risks and benefits discussed as reasons not to [insert treatment], and reasons to [insert treatment], while the other completed the alternative version where risks and benefits were discussed as downsides of [insert treatment] and benefits of [insert treatment].

Secondary Outcome:

- Decisional conflict: The SURE scale is a 4-item short form of the decisional conflict scale. The response options are true or false and scores range from 0-4. Scores of 4 are considered top scores (no decisional conflict) while all scores less than 4 are indicative of some decisional conflict.
- Decisional regret: A single-item asked respondents if they would make the same decision now about how to treat their depression. Response options were 1=definitely yes, 2=probably yes, 3=probably no and 4=definitely no. Higher scores indicate more regret.
- Who made the decision: a single item asked respondents who made the final decision about how to manage their depression. Response options included 'mainly my decision', 'mainly the healthcare providers decision', and 'we made the decision together'. We compared those who made the decision alone or with the healthcare provider to those he said the healthcare provider mainly decided.

Sample Size:

The sample size was determined to ensure sufficient power to detect differences in key subgroups, including age (younger adults vs. older adults) and version (A vs. B). To detect a difference of about 0.33 standard deviations at 0.05 significance with 80% power would require 125 per group..

Statistical Methods:

Demographic data were examined using descriptive statistics by younger and older age groups, as well as by version groups. Differences between the groups were examined using two sample *t*-tests for continuous variables and chi-square analyses for categorical variables.

The SDM Process scale and items were compared by age group and version to determine if the scores spanned the range of total possible scores, were normally distributed, had low rates of missing data and whether there was evidence of floor or ceiling effects.

Data were analyzed to compare the version (A versus B) and age group (younger versus older) by participant characteristics, SDM Process scale items and construct validity to determine if there were differences. If differences did not exist, we planned to combine the data for the analyses. As there is no gold standard measure of SDM, we used the following hypotheses to test the construct validity of the scale given prior work.

- 1) Respondents with higher SDM Process scores would be more likely to report no decisional conflict. To test this, we used we used two 2 (group) \times 2 (no conflict v. some conflict) analyses of variance—one that looked for differences in the relationships between decisional conflict and SDM Process score by age group and one by version.
- 2) Respondents with higher SDM Process scores would have less regret. We used independent correlations to test if the relationship between SDM Process scores and regret scores differed by age group or version group.
- 3) Respondents who report that their decision-making process was mainly driven by the health-care provider will have lower SDM Process scores than those who report that they were more involved in selecting the treatment. To test this, we used we used two 2 (group) \times 2 (mainly healthcare provider v. patient involved) analyses of variance—one that looked for differences in the relationships between decision making process and SDM Process score by age group and one by version.

We assessed the retest reliability for the SDM Process score at retest and compared by version (A and B) and by age group (younger and older) using the intraclass correlation coefficient (ICC>.7 indicating reliability).