

Don't Throw Your Heart Away: Clinician Study 3 Protocol

NCT04455893

Last IRB Check-In: Jan 10 2024

Study Information

Hypotheses

Hypothesis 1 When transplant centers present information on their transplant success rate only, evaluators will respond by selecting hospitals with higher transplant success. However, if information presented on transplant outcomes is stratified by the number and quality of donors used, or displayed in addition to total survival rates, then participants will respond by selecting hospitals with higher organ acceptance rates rather than the hospital with higher transplant outcomes. Thus, preference for the non-selective transplant center (relative to the selective center) will be lower in condition 1 (baseline: combined transplant survival only), compared to condition 2. That is, a higher proportion of participants will prefer the non-selective center over the selective center in condition 2, relative to condition 1. Hypothesis 2 The effect of information condition on choice will be mediated by ratings of the importance of getting a heart at all. That is, viewing information about stratified transplant survival will lead participants to think that the chance to "get a heart at all" is a more important factor in their decision which will in turn be associated with higher preference for the non-selective hospital. Specifically, ratings of importance (0-100 continuous scale) for the item "likelihood of getting any heart" will be lower in condition 1 than in condition 2. Furthermore, ratings on this item will be associated with choice, such that higher ratings will be associated with choice of the non-selective center. A bootstrapped mediation analysis will test for an indirect effect. Hypothesis 3 The difference in hospital preference between the treatment (stratified transplant survival) and control (combined transplant survival) conditions for the clinician participants will be smaller than the analogous difference observed in a previous study of layperson (Amazon Mechanical Turk) participants exposed to the same two conditions. In an analysis combining the data from the current study and the layperson study from the same two conditions in the previous study, we predict a 2 (information condition) x 2 (participant population) interaction, such that that effect of information condition is smaller for expert clinicians than for lay people.

Design Plan

Study type

Experiment - A researcher randomly assigns treatments to study subjects, this includes field or lab experiments. This is also known as an intervention experiment and includes randomized controlled trials.

Blinding

- For studies that involve human subjects, they will not know the treatment group to which they have been assigned.

Is there any additional blinding in this study?

n/a

Study design

We have a between-subjects design in which participants are randomized to one of two information conditions (independent variable). In each condition, they make a choice (dependent variable) between two hospitals (one with a non-selective donor acceptance strategy, and another with a more selective donor acceptance strategy). Independent variables: (1) Condition 1 ("baseline" condition): view only combined transplant survival (e.g. transplant

survival rate not stratified by number and quality of donor hearts accepted at each center) (2) Condition 2: view only stratified transplant survival (e.g. transplant survival rate stratified into patients who received excellent donor organs and patients who received less than optimal donor organs) These two conditions will be analyzed for our primary analysis: a 1x2 design with 2 arms (control arm or combined transplant survival, and experimental arm or stratified transplant survival).

Randomization

We will use simple randomization, where each participant will be randomly assigned to one of the two predetermined conditions. The Qualtrics randomizer function will be used for randomization into a condition.

Sampling Plan

Existing Data

Registration prior to creation of data

Explanation of existing data

n/a

Data collection procedures

125 transplant clinical personnel participants will be recruited from the International Society for Heart and Lung Transplantation (ISHLT) and the Pediatric Heart Transplant Society (PHTS). Participants will be recruited via (1) the ISHLTConnect Discussion Board webpage, (2) the PHTS Basecamp Discussion Board webpage and corresponding Listserv, and (3) the PHTS July 2020 Live Webinar (via Zoom). Inclusion criteria: Participants who are transplant clinical personnel will be asked to participate if they confirm the following inclusion criteria in the consent form. (1) 18 years of age or older (2) must read and understand the information in the consent form (3) must want to participate in the research and continue with the survey Payment: Participants will be given the option to select a transplant-related charity at the end of the survey that will receive a \$1.50 donation (anonymously) if they complete the survey.

Sample size

Our target sample size is 122 participants. We expect that this will amount to approximately 61 participants per condition, although due to the nature of the randomization technique used (Qualtrics randomizer function), we may end up with slightly more or slightly less than 61 per condition.

Sample size rationale

A sample size of 61 per group was calculated to yield at least 90% power to detect a 30 percentage point difference between conditions (e.g., 35% vs. 65%) with $\alpha=0.05$ (GPower 3.1.9.4).

Stopping rule

We will stop data collection after the first of the following three scenarios is achieved: (1) 122 responses collected (2) August 31, 2020 and at least 100 responses collected (3) October 31, 2020.

Variables

Manipulated variables

We will manipulate how transplant center outcomes are presented. Different components of the same outcome statistics for two transplant centers will be varied over two different conditions. (1) Condition 1 ("combined" condition): view only combined transplant survival (e.g. transplant survival rate not stratified by number and quality of donor hearts accepted at each center) (2) Condition 2 ("stratified" condition): view only stratified transplant survival (e.g. transplant survival rate stratified into patients who received excellent donor organs and patients who received less than optimal donor organs) The two conditions will be included in our main analysis, which is a 2x1 design with 1 factors (transplant survival) and 2 levels per factor: "combined": reference level, in which transplant survival rate is not stratified by number and quality of donor hearts accepted at each center "stratified": transplant survival rate stratified into patients who received excellent donor organs and patients who received less than optimal donor organs

Measured variables

The outcome variable will be a binary choice between two hospitals: one with a selective donor-heart acceptance strategy and one with a non-selective donor heart acceptance strategy. Participants will respond to the question "Which Hospital do you consider to be higher performing? Please click on one of the two tables below to indicate which hospital is the better choice." Participants will choose between two outcome tables featuring the selective and non-selective hospital (counterbalanced, such that each of the two choices is equally likely to be presented at top of the choice scenario in each condition). The number of participants that choose each hospital will be the measured outcome variable used in analyses. On the next page of the survey, participants will respond to three mediator questions: "There are many reasons why one transplant hospital might outperform another. Which reasons were most important in your decision? Please move the slider to indicate how much you considered each of the reasons below (0=reason was not important, 100=reason was extremely important)." Participants will then move a slider bar (0-100) to indicate the importance of the following three items: (1) Patients were more likely to receive an excellent donor heart at the hospital I picked. (2) Patients were less likely to receive a marginal donor heart at the hospital I picked. (3) Patients were more likely to receive any kind of heart at the hospital I picked. The third item (more likely to receive any kind of heart) will be the only variable that is included in the planned mediation analysis.

Indices

n//a

No files selected

Analysis Plan

Statistical models

To test Hypotheses 1, we will use a binomial logistic regression analysis. The categorical independent variable will be 'stratified transplant survival'; the dependent variable is binary choice of hospital. -We will test whether the main effect of "stratified transplant survival" is statistically significant and in the predicted positive direction. To test Hypothesis 2, we will conduct a causal mediation analysis to determine whether information display had a mechanistic effect on hospital choice through our proposed mediator. We will estimate the average causal mediation effect (ACME), average direct effect (ADE), and the total effect. The ACME is the effect of the experimental information display condition (stratified) on the outcome of hospital choice (selective vs. non-selective), mediated through the hypothesized mediator (the importance of "getting any heart" at each hospital when considering the choice). The remaining effect of information display on hospital choice that is not mediated through the hypothesized mediator represents the ADE. The entire effect of the information display on hospital choice via the hypothesized mediator and the direct effect is the total effect. The proportion of the total effect that is accounted for by the ACME is called the proportion mediated.{Imai, 2010}. Analyses will be performed using the "mediation" package in R (The R Foundation for Statistical Computing).{Tingley, 2014}. We will generate 95% confidence intervals by using 1000 bootstrap simulations. The unstandardized point estimate of the ACME and its 95% confidence intervals will be interpreted. -A significant ACME for "stratified transplant survival" would suggest that stratifying transplant survival by number and quality of accepted donors works via increasing the perceived importance of "getting any heart" to increase preference for the non-selective hospital. If the ACME is non-significant, we will identify where the causal path breaks down. To test Hypothesis 3, we will conduct an analysis combining the data from the current study and the layperson study from the same two conditions in the previous study. We predict a 2 (information condition) x 2 (participant population) interaction, such that that effect of information condition is smaller for expert clinicians than for laypeople.

No files selected

Transformations

Logistic regression analysis: The categorical predictor "transplant survival stratified" will be dummy coded (0=not stratified, 1=stratified), with 'stratified' as the reference category. The outcome variable "choice of hospital" will be dummy-coded (0=selective hospital, 1=non-selective hospital). The reference category is 'selective hospital'. Mediation analysis: The categorical predictor "transplant survival stratified" will be dummy coded (0=not stratified, 1=stratified), with 'stratified' as the reference category. The continuous mediator variable "get any heart" will be mean-centered for each analysis. The outcome variable "choice of hospital" will be dummy-coded (0=selective hospital, 1=non-selective hospital). The reference category is 'selective hospital'.

Inference criteria

We will use the standard $p=0.05$ criteria for determining if the results are significantly different from those expected if the null hypothesis were correct.

Data exclusion

n/a

Missing data

If a participant does not complete the entire survey, they will not be included in the analysis.

Exploratory analysis

No response

Other

Other

No response