Social and Behavioral Intervention to increase solid organ and tissue donation

Clinical Trials Number: NCT02318849

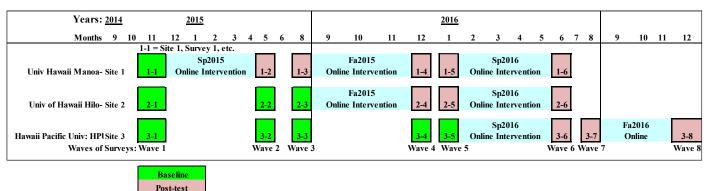
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Study Design/Intervention Protocols and Statistical Analyses Protocols

The eHealth study used a cross-sectional design that included a sequential, multiple baseline survey design that was introduced over two years at the three Hawaii university campuses. For example, undergraduate students at one site (University of Hawaii at Manoa-UHM) participated in three semesters of the DOD intervention and students at two sites (University of Hawaii at Hilo-UHH), Hawaii Pacific University-HPU) received two sequential semesters. **Figure 1** shows the study design with pre/post surveys and a sequential introduction of the intervention across three years (four semesters).

Figure 1. Study Design



Thus, either a baseline or post-test survey was administered at the start and/or the end of a semester depending on when the online intervention was introduced at a site. All students at the site were recruited to take the surveys regardless of whether or not they had completed a survey at any point in the past. Therefore, some survey analyses included cross-sectional samples and some analyses included a cohort sample of students. Data collection protocols for online surveys from undergraduate students were approved by the University of Hawaii's Human Studies Program in October 2014 (CHS 22372) with Hawaii Pacific University's Institutional Review Board ceding to the University of Hawaii's IRB.

Survey questions for primary outcomes:

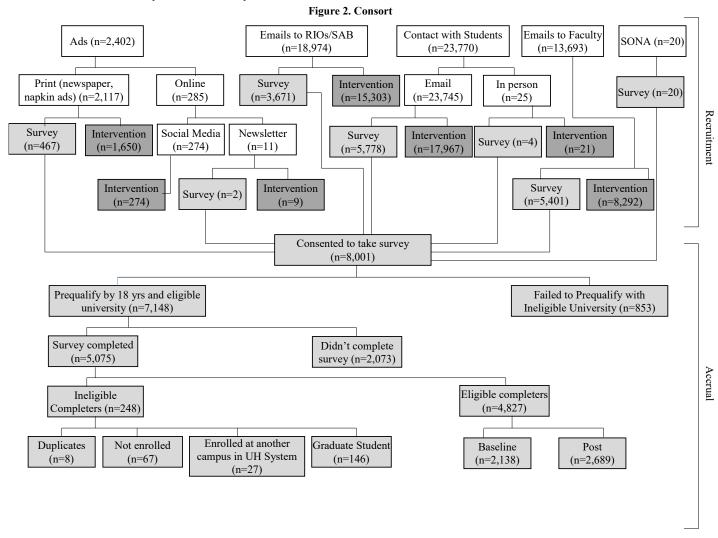
- 1. Status as a designated organ donor on Department of Motor Vehicles (DMV) issued driver's license, state-issued ID card or donor registry.
- 2. Reported discussion about their choice to be (or not be) an organ donor on their DMV issued driver's license with their parents or other family members.

Protocol for Sample Size / **Power calculations for surveys:** Simulations were run to determine the achieved power of our multiple baseline design resulting in an average of 240 participants per site for surveys collected at the beginning and end of four academic semesters at UHM and UHH and five academic semesters for HPU (20 data points, total n = 4,800). We assigned 60% of the students at baseline to already be a DOD (prior to being exposed to the intervention), based on the proportion we observed in previous work. Using an α =0.05 (two-sided) and a power of 80%, a simulation of 500 iterations found that the minimum detectable difference (MDD) in DOD prevalences comparing the 9 pre- and 11 post- intervention assessments, using our analysis approach, was 4 percentage points for an average change overall (3 campuses) and was 7 percentage points within a single campus; this was true assuming no change or a 3 percentage point drift in the pre-intervention prevalences over time.

Protocol for recruiting students for Study Surveys and Intervention activities Before taking the iDecide survey, students had to confirm they had read the consent form and actively consent (click yes). Eligibility was the verified. Only undergraduates enrolled at the three participating universities (UHM, UHH, HPU) were eligible, with enrollment verified by the respective university. Age was the only other eligibility criteria (18 years or older). Of the 8,001 online

consent forms completed, 853 (10.7%) reported enrollment at a nonparticipating university, and 2,073 (25.9%) didn't finish the survey. After verifying enrollment status for the remaining 5,075 survey entries, 248 (4.9%) were excluded because the student was not currently enrolled or was a graduate student, or their survey was a duplicate within that assessment; 4,837 was the final count.

Between November 2014 and December, 2016, undergraduate students were independently recruited to complete surveys (compensated for their time with a \$10 Amazon gift code) and to participate in the social media contests during the intervention. That is, students who completed a survey were not informed by project staff about the contests, and students who entered a contest were not recruited by staff to complete a survey. The most commonly used method for recruitment was email with 14,868 emails sent to recruit for the surveys and 41,562 emails to recruit for contests. These emails were sent to faculty at the sites (asking them to inform students about survey), Registered Independent (student) Organizations (RIOs), survey respondents (if student agreed to receive future recruitment notices about surveys offered later in the semester). Previous contest entrants were emailed about remaining contests in that semester. Both print and online advertisements for the various different contests and different ads were used to recruit for the surveys resulting in 467 print ads for surveys and 1,254 print ads for the contests. The ads were placed in campus newspapers, on napkin holders on cafeteria tables in dorms, and on bulletin boards around campuses. Two social media posts for the survey and 282 posts for the contests were designed. They included posts for the contests on the project's homepage /website, and on the project's social media accounts/pages on Instagram and Facebook and on our YouTube channel. Students were also recruited in person via classroom presentations or tables set up periodically at campus centers at each university. Finally, students were recruited for the survey via departmental research websites that gave extra credit to students who participated in research studies. Figure 2 is the Consort Figure for recruitment protocols used for the surveys and contests across all sites/ years and survey accrual results.



Leaders/officers from RIOs on each campus were recruited to serve on the project's Student Advisory Board (SAB) each semester, resulting in a total of 40 RIOs participating. The SAB held up to 4 monthly teleconferences per semester where they provided input on recruitment for surveys and contests plus were informed about current and upcoming contests (for which only RIOs were eligible). At the end of a semester, RIOs that participated in the SAB received \$100.

eHealth Intervention's Study Protocols: The protocols for staff who delivered intervention content were focused on the project's website and social media sites.

Protocols for implementing the intervention: The University of Hawaii at Manoa core research team who designed the project's website (and collected /wrote all the deceased organ donation educational content for it) also designed and conducted the social media based intervention and included the principal investigator, project supervisor, and a Graduate Research Assistant (GRA). A private website developer (Hedges Creative Company in San Diego) was contracted to develop and maintain the project website, its logo, with considerable input from the team and usability/navigation testing done by UH Manoa team. The Hedges Creative Company also took the surveys we designed and our consent form and programmed them into a separate website. After the website was developed and the social media pages created, the UHM team began to recruit students to take the online baseline surveys and enter contests on the study website via presentations in class, booths at the sites' campus centers, posts on social media, print fliers on each campus, and weekly emails to student organizations and to faculty at all 3 sites. We also had two faculty members from the different sites (one from UH Hilo and one from HPU) who helped recruit students to participate in the contests and surveys. Students were involved as well: an unpaid student intern and 40 members of a Student Advisory Board (SAB) across all sites and all semesters. The student intern helped keep students engaged in the contests and informed them about surveys via campus fliers and provided continued awareness about the project during the summer months when the contests were not being held via posts on social media. The SAB consisted of RIOs at each site where at least one member from each organization attended monthly teleconferences to strategize and recruit their peers/members to enter contests and/or take a survey. The number of members on the SAB ranged from 2-4 per semester per site. In summary, there were 46 people involved in implementing the intervention throughout the study from Fall 2014 until the end of Fall 2016.

Training protocols for intervention personnel: All staff on the core research team took IRB required online CITI training modules on Human Subjects Research. The Project Supervisor and GRA were both trained in OD issues by reading articles about deceased organ donation process, using the donor.gov website, and reading research articles written about educating adolescents and college students about the choice to be a DOD on their "adult ≥ 21 driver's license. In addition, the research team was trained by Dr. Thomas Feeley during a consultant meeting on how he had conducted pledge contests with college students/student organizations to increase student engagement in DOD.

Recruitment protocols for study participants to complete surveys and/or enter study contests

The intervention's was designed as open-access; thus, anyone with internet access could read its OD related information and view winning contest entrees. However, only undergraduates currently enrolled at a participating university, during periods when the intervention was active, were eligible to enter a contest. Entrants to all contests agreed to follow contests' rules and regulations (clicked agree), entered their age (only \geq 18 y/o eligible), selected university they were attending, and provided their university email.

Between January 2015 and December 2016, undergraduate students were recruited to enter social media contests during the active intervention periods at their site (see Figure 2). The primary recruitment method was email (n = 41,562 across all contests/all years). Emails were sent to faculty at the sites (to inform students about contests), registered student organizations, and previous contests entrants. Both print and online advertisements (n= 1,254) were created for contests and appeared in campus newspapers, napkin holders on cafeteria tables, and printed flyers on bulletin boards around the campuses. Also, 282 posts were designed by intervention staff and posted on the project's website and social media accounts (i.e., Instagram, Facebook, YouTube). Students were also recruited in person via classroom presentations or tables set up periodically at campus centers of active intervention sites.

Design Protocols of eHealth Intervention website: The home page of the website was designed with three main "links" related to Stage of Change and how users felt about organ donation or their reason for coming to the site. For example, the link "I'm uncomfortable" provided information for those who were Precontemplators or might be disgusted

by the thought of OD, while the "I'm interested, need resources" or "I want to win" links provided information for those in the action stage and came to the site for resources or to register for a contest. See Figure 3 on next page:

Figure 3. Website home page



Protocol for Social Media Contests

Along with the iDecide Hawaii website, project accounts / pages on various social media sites including Facebook, Instagram, and a YouTube channel were created. Facebook and Instagram pages were used to announce the contests, and these platforms, along with YouTube, were used to post the winning entries. Links to our social media pages were located atop each page of the project website. RIOs/SAB members were asked to "like" or "follow" our pages and "share" our posts, so they would be seen by their club members. In order to maximize our social media presence, students were asked to post their picture/video entries on their personal accounts and include our project hashtag (e.g., #idecidehawaiiphoto). This allowed their "followers" to see the video/picture and to be connected to others' entries from the current and previous contests by simply clicking the hashtag.

Protocols included total of 15 to 22 contests per site per semester were held during the intervention, with the largest number of contests (n=58) being held in the Spring of 2016 when all three sites were active in the intervention (see Figure 1). As an indicator of the dose for our gamification protocol, up to seven Instagram picture contests and six Instagram caption contests were held per semester, and five YouTube/Instagram video contests. Additionally, an essay (first person "reporter" story) contest and a pledge contest (members and any currently enrolled student could pledge on behalf of a specific RIO to become a DOD on next license renewal). In addition, two random drawings were held: one in the first week of classes at a campus center table, and another at the end of a semester for contest entrants who entered but did not win a contest. Finally, a referral program was created where those who won a contest more than two times in one semester (and, thus, were no longer eligible to enter that semester) could win a prize by referring another student to enter a contest if that student subsequently won. There were nine themes for the Instagram picture/caption contests, and five themes for Instagram/YouTube (15-60 seconds) video contests.

Table 1 (see next page) lists the specific intervention protocols / themes for each contest on a social media site.

Table1: Organ donation related themes for Social Media contests			
Theme	Instagram picture contest	Instagram Caption contest	YouTube video contest
Hug a Heart!	Sp2015 Fa2015 Sp2016 Fa2016	Sp2015 Fa2015 Sp2016 Fa2016	
Go green recycle yourself!	Sp2016	Sp2016	Sp2015 Fa2015 Fa2016
Be a SUPER HERO! Organ donors can save 8-20 people	Sp2015 Fa2015 Fa2016	Sp2015 Fa2015 Fa2016	Sp2015 Sp2016
What are the odds? You're more likely to need an organ transplant than to be a donor when you die	Sp2015 Sp2016	Sp2015 Sp2016	Sp2015 Fa2015 Fa2016
Bust a myth! Find a myth about organ donation and expose the truth	Sp2015 Fa2015 Fa2016	Sp2015 Fa2015 Fa2016	Sp2015 Sp2016
Not as many as you think! Only 20% of Hawaii college students are designated organ donors	Sp2015 Fa2015 Fa2016	Sp2015 Fa2015 Fa2016	
I'm gonna tell MOM! Talk to your mom (and other family) about your wishes to be a donor	Sp2015 Fa2015 Sp2016 Fa2016	Sp2015 Fa2015 Sp2016 Fa2016	Sp2015
This is what a donor looks like	Sp2015		
I'll do it if YOU do it first! Be an advocate, tell someone you know THEY can save 8 lives and improve the quality for up to 20 more, just by being an organ donor. Spread the word!	Sp2016	Sp2016	

4) Statistical Analyses Protocols

Two types of data sets would be created: a cross-sectional set and a longitudinal set. The cross-sectional dataset would include data from all surveys at each of the 20 assessment points (see Figure 1). The design allowed for students

to complete surveys at more than one assessment point. Due to uniqueness of student email addresses, those with repeat surveys could be identified. Thus, students could complete one or more pre-intervention surveys, one or more post-intervention surveys, or complete both pre and post-intervention surveys. The longitudinal dataset would include only those students who completed one or more baseline surveys and one or more post-test surveys.

The primary hypothesis was that exposure to the intervention would increase the percentage of students who reported being DODs on license and/or who spoke to their parents about their choice to be (or not be) a DOD on their license, and exposure would also improve knowledge and attitudes about OD. The primary analysis of the cross-sectional data used a logistic model of the outcomes DOD status or "talk to parents" regressed on a set of indicator variables reflecting each of the 20 assessment points (time by school combinations), adjusted for student's age, sex, race, and religion. Predicted DOD status (or family talk status) was computed from the model for each assessment point and the predicted statuses were compared between pre-intervention and post-intervention assessments using a t-test to test the primary hypothesis. We also repeated the test within subgroups defined by school and by covariates, such as race, to determine if the intervention effect differed by subgroups. Linear models regressing knowledge and attitude scores on assessment indicator variables and adjustment factors were used to determine the intervention effect on these scores.

The primary analysis models were repeated in the longitudinal sample, accounting for repeated measures. Further, a logistic model of post-intervention DOD status was performed among the longitudinal sample where the students never reported being a DOD at any pre-intervention assessment. All post repeated measures for these individuals were included in one model (allowing for repeated yes answers) and all post repeated measures up until when the first yes reported for DOD was included in a second model. The independent variables included the assessment indicators, age, sex, ethnicity and religion. The predicted percentage adopting DOD would be obtained from the model and tested against 0 using a t-test. This comparison was repeated for each post-intervention time (e.g., 1st post-test) and for each school, as well as by subgroups defined by covariates. A similar analysis was performed for the "talk to parents" outcome in the subset who never reported having this conversation on any pre-intervention survey.

Lastly, in order to determine if the intervention was more effective in students less likely to be a donor, protocols stratified the statistical analyses using a "propensity score" based on static student characteristics. We anticipated that students with characteristics making them less likely to become a DOD might be more influenced by our intervention. Propensity scores were developed for DOD status by using a logistic regression of DOD status using pre-intervention data to determine predictors from among demographic/sociocultural variables (e.g., age, sex, race, religion, place of birth, years lived in HI, college year, tuition source, college major, college credits, recruitment method, study site and time). The resulting DOD model based on 2129 surveys (Donor: Yes=1137, No=992) included significant factors of age, sex, race, college year, religion, and tuition source, using stepwise variable selection. The resulting logistic regression equation would then be applied to all surveys to obtain predicted probabilities that were used as "propensity scores." The primary analyses for the cross-sectional data set was performed separately for surveys with a low propensity score < 50% and for surveys with a high propensity score ≥ 50%. The analyses for the longitudinal data set were also stratified by low and high pre-intervention propensity scores, based on the average for students who provided ≥ 1 pre-test survey.