Study Protocol and Statistical Analysis Plan

Culturally Tailoring an Advance Care Planning Intervention for American Indians

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Study Aims

This project had three specific aims: 1. Culturally tailor the content of the Make Your Wishes About You (MY WAY) ACP curriculum and guide for one American Indian Tribe; 2. Assess the feasibility of the culturally tailored MY WAY ACP curriculum and patient education guide with the tribe; and 3. Examine the preliminary outcomes of the culturally tailored MY WAY ACP curriculum guide with 70 tribal members.

Study Protocol

Study Design

We used a quasi-experimental waitlist-controlled study design to test the hypothesis that after participating in the tailored MY WAY intervention, participants would experience decreased ACP barriers and increased ACP facilitators, readiness, self-efficacy, and completion. This design split our total participant pool into two cohorts to allow for a comparison group while still providing the intervention to all participants. Cohort 1 received the intervention immediately after study enrollment and served as the intervention group. Results from Cohort 1 were then compared to the waitlisted cohort, or Cohort 2, who waited over 3 months on average to receive the intervention.

Intervention

The intervention consisted of two steps: attendance at a Community Information Session (CIS) and attendance at an individual Sharing Session (SS).

Recruitment

Study eligibility criteria included being an enrolled Tribal member, spouse of a Tribal member, first descendant, or a member of another AIAN Tribe, aged ≥18 years, and residing within the Tribal service area. We recruited potential participants using convenience sampling

techniques. We made in-person study recruitment announcements at 13 Tribal venues and left flyers and hung posters at 26 locations. We also ran an ad in the Tribal newspaper and on three billboards. Tribal programs distributed MY WAY information on our behalf via their social media and/or email listserv. We also developed a project website and ran a short video on the local Tribal television station. Interested people were directed to call the Project Coordinator by telephone and/or speak with staff at a CIS and then screened for study eligibility and enrolled, if eligible.

Data Collection

All study participants completed informed consent documents before study participation and all who completed the full intervention and the interviewer-administered surveys received $85 in gift card incentives. Data were collected via surveys from Cohort 1 immediately before the CIS ("intervention baseline survey"), 8-9-weeks after the CIS at posttest ("post-program survey"), and 6-month follow up ("follow-up survey"). For Cohort 2, survey data was collected at baseline ("control baseline survey"), an average of 13 weeks immediately before CIS attendance ("intervention baseline survey"), and an average of 12-weeks after the CIS ("post-program survey"). The first survey administered with Cohort 2 participants occurred at study enrollment and served as a control baseline comparison to Cohort 1.

Measures

ACP barriers and facilitators were assessed with 16 yes/no questions (8 barriers and 8 facilitators) derived from qualitative data regarding ACP and developed during the original MY WAY clinical trial, but never published.

ACP readiness and self-efficacy were captured with the 9-item ACP Engagement Survey Process Measures identified from Behavioral Change Theory. The 6-item readiness and

the 3-item self-efficacy subscales have 5-point, Likert responses of "not at all, a little, somewhat, fairly, extremely." In a field test of these subscales, they demonstrated good reliability and discriminant validity (Sudore et al., 2017; 2013).

For **ACP completion**, participants were asked if they had a legal advance directive. To confirm self-reports post-program, project staff documented whether the participant's advance directive was notarized after SS and compared this to notary records. All sources of the participant's advance directive completion measure were combined into a single binary variable (yes/no).

Interview-administered intervention and control baseline surveys also included self-reported demographic characteristics of age (in years), gender (male or female), marital status (married or not married), Tribal affiliation (member, first descendent, family of a member, member of another Tribe), education (on a scale of 1 = less than high school education to 5 = graduate degree), self-rated health (on a scale of 1 = very poor to 6 = excellent), and self-reported diagnosis of any chronic conditions. Chronic conditions included chronic obstructive pulmonary disease, history of stroke, history of heart attack, cancer, chronic kidney disease, type 2 diabetes, heart disease, high cholesterol, and chronic pain.

Analyses

All analyses were conducted in IBM SPSS Statistical Software (27) or Microsoft Excel. We examined participant demographic characteristics using descriptive statistics and stratified analyses. To determine if there were demographic or other differences between the cohorts, we conducted crosstabulation analyses with Bonferroni correction applied. To compare intervention baseline and post-program levels of barriers and facilitators, as well as analyze change over time in ACP readiness, self-efficacy, and completion, we combined the cohorts. As barriers and

facilitators were asked as simple “yes/no” questions, the number of barriers and facilitators listed by participants was calculated before and after the intervention for comparison.

Before combining the individual readiness and self-efficacy items, we ran selectivity and reliability analyses. To check for differences in the sample due to attrition, we computed Little's missing completely at random (MCAR) test. We then conducted crosstabulations again to look for relationships between demographic characteristics and ACP readiness, self-efficacy, and completion measures at intervention baseline. With our combined sample, we conducted a 3 (readiness, self-efficacy, and completion) x 2 (pretest to 8-week posttest) way repeated measures analysis of variance (ANOVA) with demographic characteristics found to be related to intervention baseline measures as between-subjects variables. For 6-month follow-up surveys with Cohort 1, we conducted a separate one-way ANOVA (intervention baseline, post-program, follow-up) for ACP readiness and self-efficacy. We tested the hypothesis that Cohort 2 participants did not change ACP-related readiness and self-efficacy from control baseline to intervention baseline by conducting a third separate one-way repeated measures ANOVA. We also calculated difference scores from control baseline to intervention baseline among Cohort 2 participants and intervention baseline to post-program among all participants.