Statistical Analysis Plan

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Huntsman Intermountain Adolescent and Young Adult Cancer Care Program - Cancer Health insurAnce Tools Study (HIAYA CHAT Study)

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Amendment 1

Updated dated to include a day value. Added the NCT to each page of the document.

- Title page and headings were updated to reflect changes

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1. Study Overview

This study design plan is based off the most recent study protocol (Version 4) and is designed to explain the statistical analysis strategy and methodology for the HIAYA CHAT study.

1.1 Study Design & Randomization

This is a multi-site behavioral intervention study. The study will be run between August 2020 and December 2021. For randomization, participants will be stratified by age at cancer diagnosis (17-26; 27-39 years) and treatment site and blocked into groups of 4 patients (2 control, 2 intervention) to ensure that control and intervention groups are approximately balanced by age and within sites. Random allocations within strata will be computer generated and automatically assign individuals to a study arm after the study coordinator determines patients' eligibility and obtains consent. All participants will then take a baseline survey and meet with the patient navigator. Participants enrolled in the intervention group will attend 4 educational sessions to learn about health insurance. Participants not enrolled in the intervention group will have access to the patient navigator for assistance, as is standard care. Participants will all take a follow-up survey. A randomly selected group of all participants will be interviewed after the follow-up survey.

1.2 Study Objectives

The objectives of this study are to assess the feasibility, acceptability, and efficacy of the health insurance education program in AYA's recently diagnosed with cancer.

1.3 Study Outcomes

Primary Outcome:

Feasibility

The percent of AYA cancer patients enrolled in the study will be used as the measure of feasibility.

Acceptability

Information on acceptability of the program material and the Zoom format and what they liked or disliked about the intervention content

Satisfaction

Satisfaction with the Interpersonal Relationship with the Navigator score (PSN-I)[1-2] will be used as the measure of acceptability. This consists of the sum of 9 items with a higher score indicating greater participant satisfaction with the relationship between themselves and the navigator. Participants will be asked these questions during the follow-up survey.

Secondary Outcome:

Efficacy
Differences in baseline and follow up response values for health insurance literacy and financial toxicity will be used to measure efficacy.

Health insurance literacy will be measured using two sections of the Health Insurance Literacy Measure (HILM)[3] as well as questions concerning familiarity with provisions of the affordable care act, and laws surrounding insurance (e.g. COBRA, ADA). The sum of responses from each of these categories of questions will be used where higher scores indicate higher literacy.

Financial toxicity will be measured using the COmprehensive Score for financial Toxicity (COST)[4]. The COST score consists of 11 questions where lower scores indicate higher financial toxicity.

1.4 Sample Size Calculation

Sample size was calculated using the two mean sample test in STATA 14. The study should have at least 80% power to detect differences in the mean improvement in the COST score between the intervention and control groups which differ by 0.67 SD based for our target of N=72 completion.

1.5 Study Procedures

At the beginning of the study, all participants will consent to participation. The consent document has been reviewed and approved by the University of Utah IRB. All research will be completed in the timeline outlined in the study protocol.

All participants will be given a baseline survey on the REDCap platform, asking questions about basic, demographic, information, financial toxicity, and participant's knowledge and comfortability using insurance. All participants will meet with the patient navigator to determine other needs that may need to be met and will be connected with appropriate resources. Individuals who do not participate in the intervention will have access to this navigator throughout the course of the study, as part of their usual standard of care. Individuals who participate in the intervention will meet with the patient navigator four times for 30-minute biweekly insurance education sessions. Five months after the baseline survey is complete all participants will be given a follow up survey, asking the same questions asked at baseline.

A random group of participants in both the intervention and non-intervention group will be invited to participate in an end-of-project interview.

2. Statistical Methodology

2.1 Statistical Variables

2.1.1 Background and demographic characteristics

Basic demographic characteristics such as race, age and gender will be collected as well as background information on participant's cancer diagnosis such as age at diagnosis, type of insurance at diagnosis will be collected.

2.1.2 Efficacy

Our efficacy measures will be collected at both baseline and follow-up as this study is interested in examining the change between the two timepoints. These measures include 9 items on confidence using and being proactive with insurance selected from the Health Insurance Literacy Measure (HILM) and 7 items on familiarity with insurance protections under the Affordable Care Act (ACA). For each of these measures, we summed each item to evaluate overall mean differences from baseline to follow-up, with higher scores identifying higher knowledge or confidence. Financial hardship related to cancer was assessed by the COmprehensive Score for financial Toxicity (COST) which consists 11 items that cover worries about out-of-pocket costs, with lower scores indicating greater toxicity.

2.2 Statistical Analysis Population

The analysis populations include all participants who completed both the baseline and the follow-up survey. For the acceptability analysis individuals must have also complete the interview at study close.

2.3 Statistical Methods

2.3.1 Demography and baseline characteristics

Demographic information will be statistically summarized by treatment group.

2.3.2 Analysis of Feasibility

This will be the percentage of individuals who consented to be a part of the study out of the total number of approached individuals.

2.3.3 Analysis of Acceptability

Exit interviews were aucio recorded, transcribed, and qualitatively content analyzed in a deductive maner to provide context on acceptability.

2.3.4 Analysis of Satisfaction

The mean score will be summarized by treatment group and survey time point.

The difference between the mean values at each time point will be calculated by treatment group. Differences in these change values by group will be examined using sample t-tests.

2.3.5 Analysis of Efficacy

Mean values of the efficacy outcomes will be summarized by treatment group and survey time point.

The difference between the mean values at each time point will be calculated by treatment group. Differences in these change values by group will be examined using sample t-tests.

Multivariable linear regression models will be run for each efficacy outcome. We will control for facility, age at diagnosis, insurance type at diagnosis and gender while examining if treatment group is significantly different in the models.

We will run multivariable linear models stratified by age at diagnosis and insurance type to examine possible confounding.

2.4 Data Processing Conventions

2.4.1 Definition of baseline

For this study, baseline is defined as the information collected at time of first completed survey of each participant. For instances where a patient started multiple surveys, data from the last survey completed was used.

2.4.2 Missing data

Missing demographic information was supplemented using participant medical records.

For efficacy analyses, individuals missing any of the questions used to calculate the associated sums of questions were dropped from analysis.

2.4.3 Time window

Not applicable

2.4.4 Unscheduled Visits

Not applicable

2.4.5 Center Pooling

Participants were randomized in a manner that required approximately equal enrollment of participants from each site to control for any possible center effects, further we plan on including facility as a variable in our models. As such, no additional controlling for site will be done all participants will be pooled for analyses.

3. Changes to Planned Analysis from The Protocol

The protocol analysis plan was followed; however, we did run multivariable regressions to ensure that covariates did not influence our findings. We also performed sensitivity analyses examining report of policy holder status and by site of recruitment.

4. Interim Analysis

No official interim analyses are planned

5. Statistical Analysis Software

All statistical analysis and summary information will be completed in STATA 14.0 or higher.

6. References

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