Clinical Development

00127029

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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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Protocol Synopsis

Protocol number	00127029
Title	Huntsman Intermountain Adolescent and Young Adult Cancer Care Program - Cancer Health insurAnce Tools Study (HIAYA CHAT Study)
Sponsor and Clinical Phase	NIH NATIONAL CANCER INSTITUTE, Federal Government, 11259
Study type	Interventional
Primary Objective(s)	In this study, we are adapting and testing educational modules to improve AYA cancer patients' knowledge of insurance and costs
Study design	Non-Experimental and/or Descriptive Research Design: Interviews and Focus Groups Survey/Questionnaire Research Experimental and/or Interventional Research Design: Randomized Trial
Population	Cancer patients between ages 18 and 40. Sites include University of Utah and Intermountain Primary Children's Hospital. Sample size of 120.
Inclusion criteria	Aim 2: 1. Are currently a cancer patient and within 1 year of their diagnosis and actively receiving chemotherapy, surgery, radiation, and/or hormonal therapy 2. Are a patient at Primary Children's Hospital, Intermountain Medical Center, or Huntsman Cancer Institute 3. Were between the ages of 17 and 39 years old when diagnosed with their first primary cancer and are currently aged 18 – 40 years old 4. Speak English Aim 3: 1. From participants in both the control group and intervention group, 20 participants will be invited to participate in an exit interview.
Exclusion criteria	Aim 2 & 3: 1. Are unable to participate due to developmental delay 2. Do not read or understand English comfortably 3. Do not have access to an electronic device with video conferencing capability (e.g., smartphone, laptop, etc.). 3. Currently do not have health insurance coverage

Data analysis	We will use descriptive statistics to report on the following endpoints: intervention feasibility (e.g., percent of AYA cancer patients enrolled), acceptability (e.g., satisfaction) and efficacy (e.g., health insurance literacy, cost-related literacy, provider communication about cost, financial toxicity). We will run descriptive statistics to examine group differences at baseline; any imbalanced covariates will be included as adjustment variables. We will use chi-squared and independent sample t-tests to compare end-of-treatment changes in preliminary efficacy outcomes between the two groups.

Amendment 4

The consent form included a section that stated a health insurance education booklet would be mailed to participants, however our study design does not include sending this booklet. The consent was updated to remove this language.

- The consent form was updated to reflect this change

Amendment 3

Recruitment materials will now be shared by Huntsman Cancer Institute social media as well as a HIAYA CHAT specific study social media.

- Section 5.1.2 was amended to reflect this change

Amendment 2

In addition to being emailed and called by study staff, they may receive text messages to ask if they are interested in participating in our study.

- Section 5.1.2 was amended to reflect this change

Amendment 1

Updated consent options, so participants will be able to easily consent to the study on their smart device or computer during all times of the day through REDcap. If participants have questions about the consent, we will publish our email addresses and phone numbers so they can contact us without delay. Nothing within the consent language will be altered, we simply want to add another method of consent.

- Section 5.2 was amended to reflect this change

1. Background and Introduction

Cancer patients in the United States often experience substantial distress about out-of-pocket costs from their cancer treatment that are not covered by their health insurance.[1-4] In 2013, the Institute of Medicine recommended efforts to improve cancer patients' understanding of cancer care costs as part of providing high-quality cancer care.[5] Adolescents and young adults (AYAs) diagnosed with cancer ages 15-39 are often underinsured – that is, even with insurance they face high out-of-pocket costs or have unmet health care needs due to costs.[6-8] In one study from our team, 20% of insured AYAs with cancer in a national sample reported skipping care due to costs in the past year compared to 10% of insured cancer-free controls.[8] Also, AYA cancer patients experience more gaps in their insurance coverage than older individuals with cancer. [9,10] As such, medical costs have substantial effects on AYA cancer patients as they are more likely to borrow money, go into debt,[1] and file for bankruptcy after a cancer diagnosis[11] than patients diagnosed at older ages.

Health insurance literacy is defined as a patient's ability to make informed decisions about choosing and using health insurance.[12] Cost-related literacy is a related concept that is defined as how well a patient understands financial concepts specific to cancer care and their comfort discussing financial burden with providers.[10,13] Our studies of AYA cancer patients demonstrate that they feel uninformed about their insurance and want to have cost conversations with providers, but feel uncomfortable doing so.[14] This is not surprising as AYA cancer patients tend to be healthy prior to diagnosis and therefore have little experience with the health care system and insurance.[15] At the same time, the Affordable Care Act (ACA) has expanded opportunities for AYA cancer patients to obtain insurance coverage,[16-18] but our studies demonstrate AYAs' low understanding of the ACA's provisions.[19,20] Under the ACA, many young adults with cancer are now insured through age 26 on their parents' insurance, whereas those over age 26 have not made the same insurance coverage gains.[17] However, our research demonstrates that regardless of age and insurance status, AYAs with cancer are worried about insurance and costs and want education on these issues.[14]

2. Purpose and Objectives

In this study, we are adapting and testing educational modules to improve AYA cancer patients' knowledge of insurance and costs.

Aim 2: Conduct a telemedicine-based pilot randomized controlled trial (RCT) of the health insurance education program (HIEP) among AYA cancer patients.

- Hypotheses: Among AYA cancer patients, the HIEP will be feasible and acceptable and improve their health insurance literacy and cost-related literacy compared to usual care.
- Intervention: Pre-intervention and post-intervention surveys will assess insurance literacy and cost literacy. The intervention will be comprised of four, 30 to 45-minute HIEP sessions which will be delivered by HIAYA Patient Navigators over the intervention period.
- Aim 2a: Determine (1) The feasibility (number of eligible enrolled/sessions completed) and (2) the acceptability (and/or satisfaction) of conducting a telemedicine-based HIEP with AYA cancer patients.
- Aim 2b: Assess the efficacy of the HIEP to improve AYAs' health insurance literacy and cost-related literacy.

Aim 3: Evaluate and refine the HIEP for dissemination in a larger RCT.

Conduct interviews with a selected subset of HIEP control and intervention arm participants, to understand AYA's (1) Satisfaction with usual care or the HIEP, (2) recommendations for modifications on delivery of usual care or HIEP and (3) recommendations for modifications to the intervention content.

3. Study Population

Age of Participants: 18-50
Sample Size: All Centers: 150

3.1 Inclusion Criteria:

Aim 2:

1. Are currently a cancer patient and within 1 year of their diagnosis and actively receiving chemotherapy, surgery, radiation, and/or hormonal therapy
2. Are a patient at Primary Children's Hospital, Intermountain Medical Center, or Huntsman Cancer Institute
3. Were between the ages of 17 and 39 years old when diagnosed with their first primary cancer and are currently aged 18 – 40 years old
4. Speak English

Aim 3:

1. From participants in both the control group and intervention group, 20 participants will be invited to participate in an exit interview.

3.2 Exclusion Criteria:

Aim 2 & 3:

1. Are unable to participate due to developmental delay
2. Do not read or understand English comfortably
3. Do not have access to an electronic device with video conferencing capability (e.g., smartphone, laptop, etc.).
4. Currently do not have health insurance coverage

4. Study design

Non-Experimental and/or Descriptive Research Design

- Interviews and Focus Groups Survey/Questionnaire Research

Experimental and/or Interventional Research Design

- Randomized Trial

5. Study Procedures

5.1 Recruitment/Participant Identification Process

5.1.1 Enrollment Goals

1. Aim 2: 6-7 participants per month, for a total of 80 participants. N=40 HIEPenhanced care, intervention (Group A), N=40 for usual care (Group B), stratified by age and treatment site and randomized to study arm (Group A or B) N=40 18-26 year-olds, N=40 27-40 year-olds.
2. Aim 3: Have 20 participants from Group A and B participate in study interviews, stratified by age. N=10 18-26 year-olds, N=10 27-40 year-olds

5.1.2. Process

- Referrals via healthcare provider (doctors, nurses, social workers, etc.) or navigator: Patients who are connected with the HIAYA Cancer Care Program will be approached for recruitment. The navigator will refer patients that are enrolled in the navigation program to members of the study team. AYAs who are referred will be contacted by study staff via phone, by text, by email, or in person to describe the study and determine if they are interested in participating.
- Referrals will be made from staff at the Cancer Learning Center at Huntsman Cancer Hospital.
- We will advertise this study through flyers left in clinics, on pin boards, and digital advertisements. Study advertisements will also be posted on the HIAYA program, Huntsman Cancer Institute, and study specific social media accounts
- Clinic screening: study team will screen clinic lists via EMRs. A recruitment letter or e-mail will be sent prior to the phone call. The consent cover letter will be sent along with the recruitment letter.

5.2 Informed Consent

Location(s) where consent will be obtained:
University of Utah - Huntsman Cancer Hospital
Intermountain Healthcare - Primary Children's Hospital and Intermountain Medical Center

Description of the consent process(es), including the timing of consent:

Participants will be offered enrollment and consented to the study by trained research staff through e-mail, over the phone, through text message, or in-person. The consenting process will take place through the REDCap process when participants choose to consent over email, through text message, or over the phone. When consenting inperson participants will be asked to read through and sign a paper consent while in a clinic room, or other private locations. There is no required waiting period before enrollment. Participants will be able to discuss the consent form, enrollment criteria, or any other questions related to the study with study staff over e-mail, phone, text message, or in-person. Documentation of consent will be recorded via a physical informed consent form, with signature and PHI authorization or a digital copy of informed consent with signature and PHI authorization, collected via REDCap.

5.3 Study duration

We will recruit patients to the RCT from approximately August 2020 through April 2021. Exit interviews after the RCT will last until late 2021, and data analysis is anticipated through June 2022.

5.4 Randomization

Aim 2: All participants will be randomized into one of two groups: A or B. Randomization 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.

Aim 3: 20 participants will be randomly invited to participate in an exit interview. Those 20 participants will be equally pulled from the control and intervention group.

5.5 Procedures

Aim 2:

Both Group A and Group B: After consent, all study participants will:

- Participate in a baseline survey, which will also collect contact information. Questions included in the baseline survey will assess familiarity with ACA policies, health insurance literacy, cost-related literacy, comfort discussing medical costs with providers, financial toxicity, insurance coverage, coverage-related variables and moderators (baseline demographic characteristics such as age, gender, education and health insurance status).

- Participate in a follow-up survey. This is anticipated to occur 3 months post-program completion for the intervention group and 5 months after taking the baseline survey for the control group. Questions will include many of the same questions regarding insurance coverage, cost-related, and patient needs, in

Commented [KR1]: Deleted Consent section. It was duplicated from informed consent section,

addition to the satisfaction, feasibility, and acceptability of the navigation program.

- The study coordinator will oversee data collection from the study participants. The research coordinator will review weekly, automated REDCap reports summarizing accrual information and information on missing data. Participants who do not complete REDCap assessments during specified time windows will receive reminders from the coordinator to complete the assessments. Reminders will be provided via telephone, mail, text, email, and/or in-person.

Group A: HIEP-enhanced intervention

- All participants will be provided information on how to log onto Zoom for video conferencing capabilities.
- Participants enrolled in this intervention group will also complete the usual care needs assessment when they first meet with the navigator, who will ensure that they are connected with appropriate resources same as the usual care arm. This includes various support materials as they receive standard cancer patient services.
- Following this first navigation visit, the main intervention will be delivered by one of the two trained patient navigators and will consist of 4 bi-weekly sessions over 2 months.
- These sessions will last up to 30 minutes each, and may be delivered in-person, over the phone, or via a videoconferencing portal (Zoom). The videoconferencing portal will be the preferred method, but the participant preferences will be considered. All navigation sessions will be recorded through Zoom or audio recorded with team recorders when navigation is given in person, for fidelity purposes. The navigator will use each participant's baseline survey responses and age to personalize these sessions.
    - Sessions 1 and 2 will provide information on current insurance policies and types of insurance, as well as to obtain information on the participant's health insurance and understanding of financial concepts related to medical care.
    - Session 3 will provide an overview of insurance policies (e.g., Affordable Care Act), how to navigate resources, and options for covering services.
    - Both Sessions 3 and 4: The navigators will work with the participants to address barriers such as coverage denials, seeking lower-cost alternatives, and discussing out-of-pocket costs with their providers.
    - Session 4 will provide in-depth information on cost-sharing components of insurance and strategies for helping participants to estimate costs of care and to budget.

Group B: Usual care

- Usual care will consist of standard patient navigation appointments, which do not currently include education to address health insurance or cost-related literacy. If the patient asks for information concerning health insurance or cost of their treatment in-person, navigators audio record the conversation for fidelity purposes
- When patients first meet with a navigator, they complete a brief intake form on health education needs, work and school, gaps in support, fertility concerns, and finances and insurance. Please see Appendix A for intake information.

Aim 3:

- Group A and B participants will be included in these procedures.
- After the follow-up survey is complete, an interview will be scheduled with selected participants (N=20), stratified by age. The two age subset groups are 18-26 year-olds and 27-39 year-olds. This one time interview will be scheduled and conducted by a study team member, and will be delivered through the videoconferencing portal, via phone, or inperson (just like the health insurance education intervention sessions). These are estimated to be about 60 minutes long in duration.
- Data from participants in these interviews will be recorded and transcribed.

6. Data Collection

Following written informed consent, at pre-intervention we will collect data on participants' demographics, medical history, financial status, and family history through a protected online questionnaire, by communicating in person, over the phone, or by email.

The team will use the Research Electronic Data Capture (REDCap) software application to collect and manage the data for this project. The REDCap database is on a secure server maintained by the Huntsman Cancer Institute (HCI) bioinformatics shared resource and the HCI Computer and Technology Group (CATG).

Voice recordings will be stored securely on the Kirchhoff Team drive at Huntsman Cancer Institute or on password protected computers at HCI.

7. Risks and Benefits

Questions and discussion about health insurance and medical costs can be psychologically stressful to participants, and there is the risk of loss of confidentiality and/or loss of privacy.

Participants may learn more about health insurance coverage and access. Societal benefits include greater insight of AYA cancer patients and insurance understanding.

8. Cost and Compensation

- There is no cost to be in this study
- There will be gift card compensation available for participants, ranging from $40 to $60 depending on procedures completed.
    - Baseline Survey completion: $20 gift card Follow-up
    - Survey completion: $20 gift card
    - Post-intervention session interview completion: $20 gift

9. Statistical Methods, Data Analysis and Interpretation

9.1 Aim 2

We will use descriptive statistics to report on the following endpoints: intervention feasibility (e.g., percent of AYA cancer patients enrolled), acceptability (e.g., satisfaction) and efficacy (e.g., health insurance literacy, cost-related literacy, provider communication about cost, financial toxicity). We will run descriptive statistics to examine group differences at baseline; any imbalanced covariates will be included as adjustment variables. We will use chi-squared and independent sample t-tests to compare end-of-treatment changes in preliminary efficacy outcomes between the two groups.

Although a 3-month post treatment follow-up period is brief, we will also conduct exploratory comparisons with other study outcomes to see if trends change in the expected direction. We will compare baseline/end-of-treatment, within groups, with paired t-tests for continuous outcomes and McNemar's tests for categorical outcomes. In addition, we will use bivariate statistics to examine demographic and cancer-related factors (type of diagnosis, age at diagnosis, treatment), and health status with feasibility, acceptability, and preliminary efficacy outcomes. Multivariate analyses, adjusting for imbalanced covariates, will be conducted in the context of linear or logistic models, potentially with random effects for patient, as appropriate. We will test for differences by sex, age, sexual orientation, and race/ethnicity in the effects. We will also conduct analyses to determine moderators of the intervention effects. Tests of interactions between covariates (moderation analyses) will be conducted in the context of both the unadjusted and adjusted versions of the regression models with effects for both the covariate of interest and the treatment arm, as well as additional covariate by covariate interaction terms.

Our primary outcomes of interest are feasibility and acceptability of the HIEP program. We expect 80 participating AYAs to enroll throughout 1 year of the pilot RCT implementation. We expect at least 72 to complete the 3 month follow-up (10% attrition rate) based on retention in our previous studies. However, for our secondary outcomes we anticipate adequate sample size to explore meaningful differences in the outcomes. For example, for financial toxicity, our

preliminary data show that for the 11-item COST score,77 average scores at enrollment in the navigation program for AYAs ranges from 25.79 (standard deviation, SD=10.11) for younger AYAs to 18.22 (SD=10.81) for older AYAs. Lower COST scores indicate greater financial distress. We expect to have >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 N=72 completing the RCT.

9.2 Aim 3

Interviews will be conducted either in person or over the phone or through Zoom videoconferencing, recorded, and transcribed for analysis in NVivo 11 (or the most recent version of NVIVO). Our goal will be to understand (1) satisfaction with the intervention, (2) recommendations for modifications on delivery modality, and (3) recommendations for intervention topics and content modifications to identify components of the HIEP that require refinement prior to scaling the intervention to a larger sample, and (4) understanding of current patient navigator program and how that can be improved.

Using NVivo, we will conduct a modified framework thematic analysis. The goal of a modified framework thematic analysis is to provide a highly structured thematic summary of qualitative data, particularly from semi-structured interviews. The qualitative coding will be led by Dr. Kirchhoff and research staff with input from other qualified study team members. A Kappa ≥0.80 after double coding the first 3 transcripts to ensure high reliability is the goal. Particular focus will be given to identifying intervention implementation barriers for AYAs by age, insurance, and cancer type, as well as feasibility concerns from the navigators, to inform future intervention dissemination steps.

University of Utah
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Appendix A

Find COVID vaccine information. View masking and visitor policy. Close

UNIVERSITY OF UTAH HUNTSMAN CANCER INSTITUTE HEALTH UNIVERSITY OF UTAH SEARCH MENU

REQUEST A NAVIGATOR

Call **801-585-9669**

Refer a Patient >

Full Name *

Phone Number *

Email Address *

Relationship to Patient

- ○ Self
- ○ Parent
- ○ Significant Other
- ○ Friend

Please select your top three concerns

- ☐ Cancer or treatment questions
- ☐ Fertility and cancer
- ☐ Survivorship resources
- ☐ Financial assistance (medications, co-pays, etc.)
- ☐ Employment concerns
- ☐ Education concerns
- ☐ Emotional support
- ☐ Peer connection
- ☐ Relationships and sexuality
- ☐ Family dynamics
- ☐ Physical appearance (e.g. body image, wigs)

- [ ] Transportation assistance
- [ ] Housing
- [ ] Childcare
- [ ] Spiritual/Chaplain services
- [ ] End-of-life concerns
- [ ] Clinical trials information
- [ ] Genetic counseling
- [ ] Nutrition and Physical Activity
- [ ] Physical, occupational, and speech therapy
- [ ] Other (please explain)

Questions or concerns

Submit

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- About Us
- Careers
- Media Relations
- Directions & Parking
- Giving

Helpful Links

- Branded Merchandise
- Cancer Learning Center
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- Non-Discrimination Policy
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- Privacy Statement
- Webmaster
- Wellness & Support

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