

Clinical Development

Clinical Trial Protocol ID: IRB_00138483

IMPROVING HEALTH INSURANCE LITERACY AMONG UTAH'S HISPANIC COMMUNITY

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Protocol Synopsis

Protocol number	00138483
Title	IMPROVING HEALTH INSURANCE LITERACY AMONG UTAH'S HISPANIC COMMUNITY
Sponsor and Clinical Phase	The National Center for Advancing Translational Sciences of the National Institutes of Health, Award Number(s) UL1TR002538
Study type	
Primary Objective(s)	<p>We wconducted with the purpose of gaining feedback on an existing health insurance education program (HIEP), originally created for young adult cancer patients. We will do this by the following study aims:</p> <p>Aim 2. Pilot test the HIEP with Hispanic community members to further refine the intervention and evaluate its efficacy.</p>
Study design	<p>Non-Experimental and/or Descriptive Research Design</p> <ul style="list-style-type: none"> • Survey/Questionnaire Research <p>Experimental and/or Interventional Research Design</p> <ul style="list-style-type: none"> • Prospective social/ Behavioral Intervention or Experiment
Population	Hispanic community members
Inclusion criteria	<ul style="list-style-type: none"> -18-64 years of age -Self-identify as Hispanic -Speak English and or Spanish -Resident of Utah -Primary policyholder -Recently enrolled in any kind of health insurance within the past year
Exclusion criteria	<ul style="list-style-type: none"> - Younger than 18 years of age <p>Hispanic Community Members:</p> <ul style="list-style-type: none"> - Not Hispanic of Latinx in origin <p>Key Informants:</p> <ul style="list-style-type: none"> - Work for an organization that does not serve the Hispanic or Latinx community

Data analysis	Analysis of the pre-post health literacy survey results: McNemar's tests will identify significant changes in the percent of questions answered correctly. We will utilize logistic regression models with generalized estimating equations to calculate the odds of improvement in health insurance literacy while accounting for within-person clustering. Models will control for acculturation and/or preferred language, current insurance status, sex, and age. We will stratify models to obtain group-specific effect estimates by current insurance status, sex, 10-year age groups, and employment status.
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Amendment 4

The amendment was necessary to remove personnel off the IRB who were no longer part of the team. The following sections reflected this change:

1. Contact and title - Study introduction
2. Study Location and Sponsors
3. Study information - consent process
4. Resources and Responsibilities

Amendment 3

We submitted the translated (Spanish) version of approved documents: this includes submitting the consent, baseline, follow up survey, and outline of the education pilot program. We also added new study personnel. The following sections reflect this change

1. Documents and attachments
2. Section 2: Study Location & Sponsors

Amendment 2

Amendment 2 was necessary because we needed to add new study personnel. We also needed to change the inclusion criteria to be more specific to our target population for aim 2 and to increase recruitment efforts, we also included social media as a form of recruitment. The consent form also needed to be submitted for this aim. For quality purposes, we decided to also include for the pilot sessions to be recorded. Participate compensation for aim 2 was decreased. Funding for the project ended and we needed to remove the sponsor from the study. We also increased the timeframe of the study since more time is needed to complete the study. The following sections reflect this change:

1. Study location and sponsors (Section 1, section 3)
2. Participants (section 5)
3. Study information (section 3, section 4a, section 4b, and section 6)
4. Consent process (Section 1)
5. Risk and Benefits (Section 4a and section 4c)
6. Data Monitoring Plan (Section 5)
7. Resources & Responsibilities (Section 1)
8. Documents and Attachments

Amendment 1

Translation of approved study documents needed to be submitted since a substantial portion of participants will be Spanish speaking.

1. Study information - Consent Process, Documents and attachments.

1. Background and Introduction

The 2010 Patient Protection and Affordable Care Act (ACA) increased health insurance coverage nationally by providing subsidies to lower insurance costs and expanding Medicaid. Through the ACA, funding was earmarked for health insurance navigators at community organizations to assist uninsured individuals in enrolling for coverage through the Health Insurance Marketplaces and Medicaid. In Utah, the **Utah Health Policy Project (UHPP)** is a trusted community resource, focused on advancing sustainable health care solutions for underserved Utahns through better access, education, and public policy. UHPP frequently works with the Hispanic community, who comprise 80% of the clients they serve. UHPP enrollment efforts have been stymied in recent years due to federal budget cuts that defunded health insurance navigators and the lack of state resources available to replenish cuts to the health insurance navigator program.

The goal of our CCTS project is to create materials to improve health insurance literacy for UHPP's Hispanic clients. Health insurance literacy is one's ability to make informed decisions about choosing and using health insurance. By providing Hispanic community members with resources to improve their understanding of insurance, this effort can help to address the gaps in navigation services and allow them to make informed decisions about selecting and using their insurance coverage. In this grant, we will adapt materials for Hispanic community members from Dr. Kirchhoff's existing health insurance literacy program that was designed for cancer patients (NCI R01 (1R01CA242729)). The content of the current literacy program includes information on insurance types (e.g., public vs. private), information on insurance cost sharing mechanisms (e.g., deductibles), an overview of health insurance laws including the ACA, and cost reduction strategies (e.g., understanding in- vs. out-of-network providers). *However, the current program was not designed for a general population audience nor considering the cultural or linguistic needs of the Hispanic community.* Thus, during the CCTS grant, we will adapt and pilot test the revised program with Hispanic community members recruited by the UHPP.

2. Purpose and Objectives

The purpose of this study is to adapt a health insurance education program to the Hispanic/Latinx population Utah's population.

Aim 2. Pilot test the HIEP with Hispanic community members to further refine the intervention and evaluate its efficacy. We will then refine the intervention by pilot testing the adapted intervention with Hispanic community members (n=10-15) recruited by UHPP. Pilot testing of the HIEP will be conducted to identify acceptability of content and potential implementation issue areas, as well as any discordance in cultural values, beliefs, or feelings about health insurance.

3. Study Population

Age of Participants: 18-64 years old

Sample Size: All Centers: 75

3.1 Inclusion Criteria:

- 18-64 years of age
- Self-identify as Hispanic
- Speak English and or Spanish
- Resident of Utah
- Primary policyholder
- Recently enrolled in any kind of health insurance within the past year

3.2 Exclusion Criteria:

- Younger than 18 years of age

Hispanic Community Members:

- Not Hispanic of Latinx in origin

4. Study design

Non-Experimental and/or Descriptive Research Design:

- Survey/Questionnaire Research

Experimental and/or Interventional Research Design:

- Prospective social/behavioral intervention or experiment

5. Study Procedures

5.1 Recruitment/Participant Identification Process

5.1.1 Enrollment Goals

Aim 2. Pilot test the HIEP with Hispanic community members to further refine the intervention and evaluate its efficacy.

- Hispanic community members (n=10-15)

5.1.2. Process

- Prior to the beginning of recruitment for the interviews with Hispanic community members, the Kirchhoff Team and UHPP staff will work together to develop a culturally tailored survey in English and Spanish (which will be submitted for approval via an amendment). All documents will be translated from English to Spanish and submitted for IRB approval prior to recruitment of any participants. Participants will be identified through the recruitment methods outlined above.

Aim 2

- Once the intervention is adapted we will again work with UHPP to recruit additional new Hispanic community members to pilot test the intervention. Pilot testing will be conducted primarily by UHPP staff. Prior to the start of the pilot test, participants will be asked to consent using a consent cover letter. The pilot session will be recorded through Zoom or audio recorded with team recorders for fidelity purposes. Pilot testing will include a short pre-post survey to assess change in health insurance literacy. The post survey may also include a short audio recorded interview about the intervention and areas of improvement. Pilot activities will primarily be conducted by UHPP staff but may be conducted a member of the Kirchhoff team.
- Further refinement of the intervention materials and statistical analyses will be conducted by the Kirchhoff Team, again contextualized by UHPP.
- Feedback on the results of each phase of the study will be elicited from UHPP staff. The Kirchhoff team will then lead manuscript writing for each aspect of the study with assistance from UHPP. All members of the UHPP team mentioned above have been trained in Human Subjects

Research jointly by CCTS and the IRB and are present on this application.

5.2 Informed Consent

Location(s) where consent will be obtained:

Utah Health Policy Project

Out in the community

Over the phone

Online

Description of the consent process(es), including the timing of consent: Study staff/UHPP staff/CCTS staff will reach out to referred participants to gauge interest in the study and obtain consent. There is no minimum amount of time between digital approach and consent as this study is quite minimal risk.

Potential participants will be given as much or as little time to decide if they would like to participate as they would like. Study staff will be available throughout to answer any questions. The voluntary nature of research studies will be stressed when potential participants are approached. Participants will be informed prior to the start of the interview/engagement studio/pilot test that they may stop at any time and have the right not to answer any question. Potential participants will be allowed to schedule their interview/pilot test whenever they find appropriate and will be encouraged to ask questions to the study coordinator, before the interview/pilot testing is conducted.

5.3 Study duration

- Study duration will be approximately 3 years

5.5 Procedures

- Prior to the beginning of recruitment for the interviews with Hispanic community members, the Kirchhoff Team and UHPP staff will work together to develop a culturally tailored survey and interview script in English and Spanish (which will be submitted for approval via an amendment). All documents will be translated from English to Spanish and submitted for IRB approval prior to recruitment of any participants.
- Participants will be identified through the recruitment methods outlined above. Qualitative interviews and studio sessions will be conducted with the purpose of gaining feedback on an existing health insurance education program (HIEP), originally created for young adult cancer patients in the HIAYA CHAT Study.

- Once the intervention is adapted we will again work with UHPP to recruit additional new Hispanic community members to pilot test the intervention. Pilot testing will be conducted primarily by UHPP staff. Prior to the start of the pilot test, participants will be asked to consent using a consent cover letter. The pilot session will be recorded through Zoom or audio recorded with team recorders for fidelity purposes. Pilot testing will include a short pre-post survey to assess change in health insurance literacy. The post survey may also include a short audio recorded interview about the intervention and areas of improvement. Pilot activities will primarily be conducted by UHPP staff but may be conducted a member of the Kirchhoff team.
- Further refinement of the intervention materials and statistical analyses will be conducted by the Kirchhoff Team, again contextualized by UHPP.
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6. Data Collection

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

- The potential risks to participants are minimal. Participants may feel slight psychological distress when answering questions about health insurance and cost concerns.
- There is also a risk of breach of confidentiality of the participants.
- No direct benefit. From the societal perspective though, the benefits include improved knowledge about the Hispanic perceptions of health insurance.

8. Cost and Compensation

- There is no cost to be in this study
- There will be gift card compensation available for participants,
 - Pilot testing pre and post surveys: \$40

9. Statistical Methods, Data Analysis and Interpretation

Further refinement of the intervention materials and statistical analyses will be conducted by the Kirchhoff Team, again contextualized by UHPP.

Feedback on the results of each phase of the study will be elicited from UHPP staff. The Kirchhoff team will then lead manuscript writing for each aspect of the study with assistance from UHPP. All members of the UHPP team mentioned above have been trained in Human Subjects Research jointly by CCTS and the IRB and are present on this application.

Analysis of the pre-post health literacy survey results: McNemar's tests will identify significant changes in the percent of questions answered correctly before and after intervention. We examine differences in Health Insurance Literacy Measure before and after intervention. We will stratify this variable by age and language spoken.

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