

ClinicalTrials.gov Data Entry Cover Sheet

**Protocol ID:** 21985IRB      **Clinical Trials.gov ID:** NCT05521906

**Project Title:** *Evaluation of PRYSHM for LGBTQIA2S+ Youth*

**Principal Investigator:** Katie M. Edwards, PhD, University of Nebraska-Lincoln

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## Section 4 - Protocol Synopsis (Study 1)

### 4.1. Brief Summary

Alcohol use (AU) and dating violence (DV) are serious public health problems in the U.S. that disproportionately impact LGBTQ+ youth. To date there is no comprehensive prevention program that concurrently addresses AU and DV among LGBTQ+ youth, which is sorely needed given the preliminary data suggest that traditional prevention programs do not work as well for this population. The purpose of the proposed study is to develop and evaluate an innovative, online-delivered program for LGBTQ+ youth that seeks to prevent AU and DV.

### 4.2. Study Design

#### 4.2.a. Narrative Study Description

Following the initial creation of the online prevention program, we will conduct an online pilot trial to determine acceptability and feasibility to inform further refinement. Next, we will conduct a pilot RCT in which LGBTQ+ youth are recruited and randomly assigned to the intervention group (N=100) or to the wait list control group (N=100). Pre-, immediate, and three-month follow-up surveys will be used to assess the initial efficacy of the intervention in reducing AU and DV along with a number of other intermediary and secondary outcomes. Program observations as well as exit interviews will be used to further refine the intervention.

#### 4.2.b. Primary Purpose

Prevention

#### 4.2.c. Interventions

Type	Name	Description
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Radicalizing Respect and Relationships (R3)	The theoretically grounded R3 Prevention Initiative (R3-PI) follows best practices for effective health behavior prevention programming, and is expected to include eight, 45-minute modules intended for delivery as an online synchronous program

#### 4.2.d. Study Phase

Phase 1/2

Is this an NIH-defined Phase III Clinical Trial?  Yes  No

#### 4.2.e. Intervention Model

Parallel

#### 4.2.f. Masking

Yes  No

Participant  Care Provider  Investigator  Outcomes Assessor

#### 4.2.g. Allocation

Randomized

### 4.3. Outcome Measures

Type	Name	Time Frame	Brief Description
Primary	Alcohol Use	Past month at all time points	We will use the Timeline Followback to assess for alcohol use.
Primary	Dating Violence (Victimization and Perpetration)	Past 3 months (Baseline and 3-month follow-up); Past 1 month (immediate post-test)	We will use the Conflict in Adolescent Dating Relationships-Short Form and the Partner Cyber Abuse Questionnaire to assess for DV victimization and perpetration.
Secondary	Risky Sexual Behavior	Past 3 months (Baseline and 3-month follow-up); Past 1 month (immediate post-test)	We will use the Sexual Risk Survey to measure risky sexual behaviors.

Secondary	Depression	Past 3 months (Baseline and 3-month follow-up); Past 1 month (immediate post-test)	We will use the Kutcher Adolescent Depression Scale to measure depressive symptoms.
Secondary	Drug Use	Past 3 months (Baseline and 3-month follow-up); Past 1 month (immediate post-test)	We will use the Drug Use Disorders Identification Test to measure drug use.
Other	Identity Concealment (intermediary outcome)	N/A	We will use the Nebraska Outness Inventory to measure concealment of one's sexual identity.
Other	Internalized homonegativity (intermediary outcome)	N/A	We will use the Coming Out Self-efficacy Scale to measure internalized homonegativity.
Other	Sense of LGBTQ+ Community (intermediary outcome)	N/A	We will use the Psychological Sense of LGBT Community Scale to measure sense of LGBTQ+ community.
Other	Healthy Coping (intermediary outcome)	N/A	We will use items adapted from Hamby et al. Emotion Regulation Scale and the Drinking Motives Questionnaire-Revised.
Other	Conflict Resolution Skills (intermediary outcome)	N/A	We will use the Communication Skills & Response to Anger subscales to measure conflict resolution skills.
Other	Refusal Skills (intermediary outcome)	N/A	We will use the Sexual Assertiveness Scale-W and the Drinking Refusal Self-Efficacy Questionnaire-Revised to measure refusal skills for sexual DV and alcohol, respectively.
Other	Bystander Behavior (intermediary outcome)	N/A	We will use items adapted from Cook-Craig et al. (for DV) and items adapted from Oster-Aaland et al. and Krieger et al. (for AU).
Other	Social Norms (intermediary outcome)	N/A	We will use items adapted from the Readiness to Help Scale- Denial Subscale (for DV) and Drinking Norms Rating Form (for AU).
Other	Protective Behavioral Strategies (intermediary outcome)	N/A	We will use the Protective Behavioral Strategies Scale to measure protective behavioral strategies.
Secondary	Alcohol Consequences	Past month at all time points	We will use the Brief Young Adult Alcohol Consequences Questionnaire to assess for alcohol consequences.

## 4.4. Statistical Design and Power

StatisticalDesignandPower\_032020.pdf

## 4.5. Subject Participation Duration

&lt;1 year

## 4.6. Will the study use an FDA-regulated intervention?

Yes       No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

## 4.7. Dissemination Plan

DisseminationPlan\_032020.pdf