Official Title: Youth Engagement as a Strategy in Substance Misuse Prevention: Open Trial & Randomized Controlled Trial

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Study Title: Organization-level Youth Engagement Approach for Substance Misuse Prevention

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Background, Rationale and Context

Substance misuse is a major public health problem and opioid misuse is an acute problem in rural and high poverty communities. Adolescence and young adulthood is a formative time for positive social development, as young people increase their needs for maturity and autonomy, define their identities, and carve out their roles in society (Erikson, 1968). But many young adults (**YA**s) are isolated within communities, feel that they do not matter, and lack meaningful opportunities to engage with society and form positive connections with prosocial institutions (Eccles et al., 1991, 1993; Farrow, 1991). Further, community systems and settings that *serve* YAs often do not effectively *involve* them. Engaging youth and young adults in their communities and in the prevention systems targeting substance misuse may prevent the use of substances by targeting two pathways. The first is an individual pathway via bolstering psychosocial development and reducing risks for opioids by providing youth and young adults with meaningful prosocial opportunities to fulfill developmental needs. The second is an environmental pathway via *affecting health system and community-based settings* through improving prevention efforts targeting YAs. This project tests an organization-level Youth Engagement (**YE**) approach to improve prevention.

Objectives

Phase 1: To develop an organization-level YE prevention strategy and implement it in a community-based organization to test feasibility and acceptability in an open trial with one organization. This will include developing a manual for systematically incorporating YE into prevention efforts in community settings.

Phase 2: To evaluate the preliminary effectiveness of YE as a prevention strategy for opioid misuse in a small pilot randomized control trial (**RCT**). This pilot study will examine the effects of the YE prevention strategy on (a) organization-level outcomes, such as perceived value added to prevention programming and (b) individual-level outcomes such as personal skills and attitudes as well as knowledge and attitudes about substances including opioids.

Methods and Measures

Design

Phase 1 will consist of a small open trial. We will implement an organization-level YE prevention strategy by systematically incorporating YE into prevention efforts in a community setting. We will assess feasibility, acceptability, and usability to the community organization and to the young people with whom it works. The results of Phase 1 will inform Phase 2.

Phase 2 will consist of a small pilot RCT. Four prevention organizations will be randomized either to include YE in prevention efforts (treatment) or not (control). We will attempt to

match the treatment and control groups on relevant characteristics such as geographic location (e.g., urban, rural), population served (e.g., church-based, school-based), and/or prior YE involvement.

Setting
This study will be conducted with community-based prevention organizations.

Subjects selection criteria
Participants will consist of leaders or staff from community-based prevention organizations, as well as youth/YAs who are engaged as volunteers with the organization's opioid misuse prevention efforts. These youth/YAs will consist of a community sample, not clients at risk or in recovery for substance misuse. The below criteria apply to both Phase 1 and 2.

Inclusion Criteria:

Organizational leaders/staff

- Leaders or staff of community-based prevention organizations
- Organizations are youth/YA-serving and focused on opioid misuse prevention
- Organizations demonstrate readiness, interest, need, and resources to invest in YE as part of prevention
- Leaders or staff are or would be involved in implementing YE strategy at the organization
- Leaders or staff are able to speak and read English fluently

Youth/YA participants involved with organizations

- Adolescents and YAs age 11 – 29
- Interested in participating in YE with the community organization
- Able to speak and read English fluently

Exclusion criteria:

- Organizations already incorporating a high level of YE in their prevention work

Sample size

Phase 1
We plan to enroll up to 3 leaders/staff and up to 15 youth/YA participants working with one organization.

Phase 2
We plan to enroll up to 3 leaders/staff from each of four organizations (two of the organizations will receive the intervention, two will be control groups). For each organization randomized to receive the intervention, we will also enroll up to 60 youth/YA participants.

Total
Across both phases, we plan to enroll up to 15 organizational leaders/staff and up to 120 youth/YA participants, for a total possible N of up to 135 people.

Interventions and Interactions

All interviews will be conducted by study staff and may occur in-person, by telephone, or by video call, based on logistical considerations and participant preference. Interviews will be audio-recorded for transcription purposes. Interviews may be conducted individually or in groups and should last 30 minutes, and no more than 60 minutes. All surveys will be completed electronically via REDCap and should last around 20 minutes. Study staff will also periodically conduct and audio-record problem-solving check-ins with organizational leaders/staff.

Phase 1

For organizations, feasibility data will be collected of organization leaders/staff who are involved in implementing the YE strategy, via one survey and one interview per leader/staff. The organization will be paid $250 for their participation in the open trial. This token of appreciation is for the leaders/staff's time spent engaging with study staff and providing feasibility data through interviews and written feedback.

Study staff will administer (or we will train organization staff to administer) surveys via REDCap to assess their impressions of their YE work as well as constructs such as self-efficacy, connection, and knowledge about substances. Each survey should require no more than 30 minutes each and youth/YA participants will be paid a $15 gift card (e.g., Amazon) upon completion. The YE strategy manual will be revised based on information learned from the feasibility data.

The timeframe for this phase will be 6-12 months.

Phase 2

We will follow similar interview and survey data collection procedures as in Phase 1, with adaptations as needed based on participant feedback. However, only organizations randomized to treatment will include youth/YA participants. Youth/YA survey data will be collected at the start of their participation in the YE strategy (pre-YE) and 6 months later (post-YE). At the post-YE we will interview a subset of interested YE group participants to qualitatively assess their experiences and to identify, in their own voices, what aspects of YE emerge as important to youth development and their health-related decision-making. Youth/YAs will be paid $10 for the pre-YE survey, $15 for the post-YE survey, and $25 for an interview (for a subset of youth/YA), for a maximum total of $50 in gift cards.

The timeframe for this phase will be 12-18 months.

Outcome Measure(s)

Phase 1

For organizations, information collected from staff via surveys and interviews will include: the facilitators and barriers of incorporating YE into prevention, the acceptability

of the strategy, evaluation of the support and resources available and what else would be needed to successfully implement YE, and perceived usefulness for YAs and the organization.

For the youth/YAs, information collected via surveys will include: skills (e.g., leadership, communication) and attitudes (e.g., self-efficacy, social connectedness, self-confidence, meaningful social role) as well as knowledge and views of substance misuse. In interviews, we will ask youth/YAs about the facilitators and barriers of participating in the prevention effort, the acceptability of the YE strategy, evaluation of the experience working with the community organization, and likelihood of continued participation. For both organizations and individuals, feasibility data will be collected regarding retention of youth/YAs in the prevention work.

Phase 2
For organizations, information collected from staff via surveys and interviews will include: perceived value added to prevention programming; retention of YAs in prevention programming; reach of prevention efforts in the community; perceived usefulness of YE to the organization, the YAs, and to the community; and perceived effectiveness of incorporating YE into prevention efforts.

For the youth/YAs, information collected will include: skills (e.g., leadership, communication) and attitudes (e.g., self-efficacy, social connectedness, self-confidence, meaningful social role) as well as knowledge and views of substance misuse. The outcomes will be measured through self-reported surveys. These will serve as benchmarks that the YE intervention has the intended effect at the individual (psychosocial) level.

Analytical Plan

Phase 1 will examine descriptive statistics collected via surveys (from organizational staff and youth/YAs) and exploratory themes collected from interviews.

Phase 2 analyses will examine the effects of the YE prevention strategy on *organization* level outcomes such as perceived value of YE added to prevention programming, and secondarily, on *individual* level skills and attitudes of the youth/YAs involved in the YE. We hypothesize that YE-involved youth/YAs will show gains in skills (leadership, communication) and attitudes (self-efficacy, social connectedness, self-confidence, meaningful social role) as well as more knowledge and less favorable views of opioid misuse (compared to "pre" measures). These data will be used to estimate the effect sizes needed to power a larger study. These data will serve as additional information about the recruitment, feasibility, retention, fidelity and acceptability of the intervention. Comparison between groups will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Regression analysis will be performed to identify independent outcome predictors. Other inferential statistical analysis will be conducted as appropriate.

Human Subjects Protection

Subject Recruitment Methods
Community-based prevention organizations will be invited to submit an application to participate. Study staff will select viable candidates based on the eligibility criteria listed above. Participating organizations will be asked to select their leaders or staff who will participate in the study, which includes completing interviews. Organization staff will also invite their youth/YA volunteers to participate in the study and will forward the contact information of those interested to study staff via a secure transmission method (e.g., REDCap, fax, HIPAA-compliant cloud platform, direct phone call, postal mail, encrypted email). Study staff will receive contact information only for youth/YAs who have provided verbal approval to participate. We will attempt to recruit a minimum proportion of women and minorities corresponding to the populations from which we are drawing. Minors will be given a form to take home to their parent/legal guardian that explains the study and allows them to opt out of the study on behalf of their child. All forms will have contact information for the Project Manager of the study so that potential participants and/or parents/guardians can contact study staff with any questions.

Informed Consent
We are requesting a waiver of signed consent/assent, given that this study presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Participants will be provided with an information sheet (e.g., via REDCap, email, or paper) containing the relevant information necessary for them to make an informed decision about study participation.

Study staff will distribute information sheets to each organizational leader/staff participant and instruct organizational staff to distribute the information sheet to the youth/YAs with whom they decide to work. This may occur in-person or remotely via REDCap.

We are requesting a waiver of parental consent for minor youth to participate, given that the study population will consist of a community sample of adolescents, the survey and interview questions will consist of routine psychological questions and therefore present no more than minimal risk, we are recruiting adolescents through an organization with established relationships with their youth volunteers, we are providing notification to parents and an avenue for parents to opt out (see *Subject Recruitment Methods* above), and we anticipate that it would be difficult logistically to access parents for consenting. While we anticipate that most youth will be involved in community organizations rather than schools, some may be connected to school-based programming. We recognize that some school districts may require active parental permission. Therefore, we will obtain active parental permission in cases where it is required by a particular school district or organization.

Confidentiality and Privacy
Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. We will collect some identifiable information on the self-administered online survey so we can link youths' pre and post surveys. Upon receiving identifiable surveys, we will assign them a Participant Identification Number. Any collected patient identifying information

corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Participant identifying information will be kept for at least three years following study closure, then deleted or destroyed, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator (**PI**) will be responsible for the overall monitoring of the data and safety of study participants. The PI will be assisted by other members of the study staff and her project mentorship team consisting of a clinician and substance misuse specialist.

The PI will develop a protocol for reporting adverse events. If any of the youth/YA participants report clinical concerns or issues in the course of interviewing them, the PI will consult with co-investigator Dr. Daniel (licensed clinical psychologist) and will offer a referral to services as needed. We will develop an adverse event reporting form specific to this project and the nature of the intervention. The PI will monitor the progress of the trial and safety of participants on an ongoing basis and all study staff and investigators will be responsible for the reporting of possible adverse events. Using institutional guidelines (adapted from other sources), an **adverse event** is defined as "an undesirable and unintended result of therapy, intervention or interaction experienced by a subject participating in a research study." An **unexpected adverse event** is defined as "any adverse event, the specificity, severity, frequency or nature of which is not consistent with the general investigational protocol or protocol amendments." A **serious adverse event** is defined as "any adverse event that results in any of the following outcomes: death, a life-threatening adverse event, hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect." Medical events that do not result in death, are not life-threatening, and do not require hospitalization may still be classified as serious adverse life events when they "jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition." The PI and her mentorship team will determine whether the relationship of the adverse event to the treatment study is "not related," "possibly related," or "definitely related" using standard institutional criteria for clinical trials.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government organization if appropriate.

References

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