Plan Overview

A Data Management Plan created using DMP Tool

Title: Data-Driven Approaches for Opioid Use Disorder Treatment, Recovery, and Overdose Prevention in Rural Communities via Mobile Health Clinics and Peer Support Services

Creator: Marisol Miranda

Affiliation: Prisma Health

Principal Investigator: Lior Rennert, Ph.D, Alain Litwin, MD, MPH, MS

Project Administrator: Lior Rennert, Ph.D

Funder: National Institutes of Health (nih.gov)

Funding opportunity number: RFA-DA-23-053

Grant: https://reporter.nih.gov/project-details/10812747

Template: NIH-Default DMSP

Project abstract:

Over 100,000 lives were lost due to drug overdose in the past year, of which 80% involved opioids. Despite the effectiveness of medications for opioid use disorder (MOUD) at reducing opioid misuse and risk of overdose, only 10% of
people in need receive treatment. Moreover, treatment retention is low (30-50%) with half of patients experiencing an opioid use recurrence. Peer support specialists (PSSs), who are individuals with direct experience with and successful recovery from Substance Use Disorder, can offer social support and directly address treatment and recovery barriers for individuals with Opioid Use Disorder (OUD). Our systematic review showed that OUD patients receiving a PSS intervention were more likely to initiate MOUD, but evidence of effectiveness for MOUD retention or opioid use remain inconclusive. Low treatment initiation and retention rates for OUD are especially concerning for rural populations and underserved communities, who rarely have access to clinicians who can prescribe MOUD and experience substantial barriers to care,

including limited social support, lack of insurance, homelessness, transportation issues, and stigma. Given that these populations are also at an elevated risk of opioid overdose due to many of these same factors, interventions to increase OUD treatment, retention, and overdose prevention in rural and medically underserved communities are urgently needed. Mobile health clinics (MHC) are an effective and versatile tool for timely delivery of interventions, including those for OUD treatment, to medically underserved and at-risk communities. However, effective intervention delivery for OUD treatment initiation, retention, and overdose prevention have not been explored in MHC settings. **The goal of our proposal is to increase MOUD treatment initiation, treatment retention, and prevent overdose deaths in medically underserved communities (via MHC)** through development, testing, delivery, and evaluation of an innovative 1) PSS intervention to increase MOUD initiation and retention rates in rural and underserved populations and 2) modeling framework to prioritize at-risk communities for MHC delivery (based on overdose deaths prevented). Research has shown
that such modeling frameworks can drastically increase the efficiency of resource allocation efforts for other diseases. The PSS intervention and modeling framework will be developed in the R61 phase (R61 Aims 1 and 2) and implemented in the R33 phase to systematically deliver MHCs with PSS services to the highest priority communities (identified via modeling) in South Carolina (SC) in order to increase MOUD treatment initiation, retention, and overdose prevention. In the R33 phase, we will conduct a randomized controlled trial (RCT) to evaluate the effectiveness of the PSS intervention
component (R33 Aim 1), and extend our modeling framework developed in the R61 phase in order to a) evaluate the population impact and cost-effectiveness of the PSS intervention on preventing fatal overdose (R33 Aim 2a) and b)
explore improvements to MHC protocols in order to increase effectiveness of MHC-based interventions for OUD (R33 Aim 2b). With opioid overdose deaths doubling over the past 2 years nationally and in SC, there are no signs that the
epidemic is slowing down. Our sustainable framework has potential to prevent hundreds to thousands of opioid overdoses in SC alone, and can be scaled up in other regions to save many more lives.

Start date: 01-01-2024

End date: 12-31-2029

Last modified: 07-08-2024

Copyright information:

Data-Driven Approaches for Opioid Use Disorder Treatment, Recovery, and Overdose Prevention in Rural Communities via Mobile Health Clinics and Peer Support Services

Data Type

Types and amount of scientific data expected to be generated in the project: *Summarize the types and estimated amount of scientific data expected to be generated in the project.*

Describe data in general terms that address the type and amount/size of scientific data expected to be collected and used in the project (e.g., 256-channel EEG data and fMRI images from ~50 research participants). Descriptions may indicate the data modality (e.g., imaging, genomic, mobile, survey), level of aggregation (e.g., individual, aggregated, summarized), and/or the degree of data processing that has occurred (i.e., how raw or processed the data will be)

Data collection will be performed at MHC located in rural settings with underserved populations with OUD.

This project will produce data collected from qualitative interviews and surveys with PSS and OUD patients and pilot data. Data will be pooled from approximately 75 interviews using a cross-sectional design with both open-ended, free response qualitative questions and Likert-scale, quantitative survey questions. Using aggregated data, we anticipate a validated intervention protocol with demonstrated acceptability, fidelity, and efficacy for MOUD initiation and retention outcomes.

Using integrated health system, statewide, and publicly available data sources, we will establish real-time surveillance and population-specific epidemiological measures which will be incorporated into a dynamic modeling framework to predict which communities will benefit most from MHC services.

Scientific data that will be preserved and shared, and the rationale for doing so: *Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.*

A web-based, direct data entry and management system (RedCap) will be used to collect and manage data, All data will be entered into RedCap without personal identifiers, and source documents will identify participants by study ID. Access to computers used for data entry, management, and analysis will be password protected and limited to the study personnel. Data control procedures will be conducted for all data collected. Data quality monitoring will be facilitated with periodic downloads using SAS. The data manger will provide descriptive reports to the multiple PIs monthly until study procedures have ceased.

Metadata, other relevant data, and associated documentation: Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

Aggregate participant data, study protocols, and data collection instruments will be made accessible to facilitate interpretation of data.

Related Tools, Software and/or Code

State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed.

A web-based, direct data entry and management system (RedCap) will be used to collect and manage data, All data will be entered into RedCap without personal identifiers, and source documents will identify participants by study ID. Access to computers used for data entry, management, and analysis will be password protected and limited to the study personnel. Data control procedures will be conducted for all data collected. Data quality monitoring will be facilitated with periodic downloads using SAS. The data manger will provide descriptive reports to the multiple PIs monthly until study procedures have ceased.

Standards

State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist

Question not answered.

Data Preservation, Access, and Associated Timelines

Repository where scientific data and metadata will be archived: Provide the name of the repository(ies) where scientific data and metadata arising from the project will be archived.

All data and related documentation/tools that can be shared will be exported and/or shared and stored in the NIMH Data Archive repository.

How scientific data will be findable and identifiable: Describe how the scientific data will be findable and identifiable, i.e., via a persistent unique identifier or other standard indexing tools.

NIMH Data Archive repository will be linked to the HEAL Ecosystem, which provides searchable study-level metadata for dataset discovery. NIMH Data Archive assigns DOIs as persistent identifiers, and has a robust preservation plan to ensure long-term access. Data will be discoverable online through standard web search of the study-level metadata as well as the persistent pointer from the DOI to the dataset.

When and how long the scientific data will be made available: Describe when the scientific data will be made available to other users (i.e., no later than time of an associated publication or end of the performance period, whichever comes first) and for how long data will be available.

Once the study is completed, results will be uploaded to clinialtrials.gov. Results will be submitted no later than 1 year after the completion date (referred to as the primary completion date) in accordance with NIH regulations. All participants will be informed in the informed consent form that information about the study, and study results, when obtained, will be available on clinicaltrials.gov.

To help the dissemination of our study results, we will present the results from this proposed study at at least two national conferences: The College on Problems of Drug Dependence and the American Psychological Association. We will also share the results of this study at the statelevel through the SC Governor's Opioid Summit. Additionally, we will present results locally through departmental meetings as well as at conferences.

The results of this study will also be disseminated through papers published in high impact journals. All final peer-reviewed manuscripts resulting from the proposed clinical trial will be deposited in PubMed Central.

Access, Distribution, or Reuse Considerations

Factors affecting subsequent access, distribution, or reuse of scientific data: NIH expects that in drafting Plans, researchers maximize the appropriate sharing of scientific data. Describe and justify any applicable factors or data use limitations affecting subsequent access, distribution, or reuse of scientific data related to informed consent, privacy and confidentiality protections, and any other considerations that may limit the extent of data sharing.

There are no anticipated factors or limitations that will affect the access, distribution or reuse of the scientific data generated by the proposal.

Whether access to scientific data will be controlled: State whether access to the scientific data will be controlled (i.e., made available by a data repository only after approval).

Data will be submitted and stored in the NIMH Data Archive. The repository requires an NDA user account creation or login and submission of a data access request.

Per the NDA, they have the following types of groups that may access data; "Broad Use Permission Groups consist of one or multiple NDA Collections that contain data that all have consented for broad research use. Controlled Access Permission Groups consist of one or multiple NDA Collections that contain data with the same subject consent-based data use limitations. Open Access Permission Groups consist of one or multiple NDA Collections that contain data that all have been consented for broad research use and can be accessed by users who are not affiliated with an NIH-recognized research

institution." U.S. Department of Health and Human Services. (n.d.). NDA - Getting Access to Shared Data. National Institutes of Health. https://nda.nih.gov/nda/access-data-info

Protections for privacy, rights, and confidentiality of human research participants: If generating scientific data derived from humans, describe how the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures).

In order to ensure participant consent for data sharing, IRB paperwork and informed consent documents will include language describing plans for data management and sharing of data, describing the motivation for sharing, and explaining that personal identifying information will be removed.

To protect participant privacy and confidentiality, shared data will be de-identified.

Oversight of Data Management and Sharing

Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).

Once we receive the approval from the Institutional Review Board and prior to initiating any study procedures, we will register this study on clinicaltrials.gov. The PIs (Rennert and Litwin) will be the contact persons regarding the study. The PIs will be responsible for keeping the information updated in clinicaltrials.gov.

A Data Submission Agreement (DSA) will be completed and submitted within six months of the Notice of Award issue date. De-identified data will be shared through the NIMH Data Archive (NDA). A list of data items to be collected in the project and the clinicaltrials.gov NCT number will be submitted in the Data Expected Tab of the NDA Collection within six months of the Notice of Award issue date. All data will be deposited within the second submission cycle from the Notice of Award and submitted every cycle thereafter.
