Plan Overview

A Data Management Plan created using DMP Tool

DMP ID: https://doi.org/10.48321/D1PP9G

Title: Pharmacogenomic Testing to Optimize Methadone Maintenance Treatment: Acceptability and Feasibility Trial

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Grant: https://grants.nih.gov/grants/guide/pa-files/PA-20-176.html

Template: NIH-Default DMSP

Project abstract:

Research on Pharmacogenomics (PGx) and opioid use disorder treatment is rapidly expanding and supports the likely high impact of using PGx in methadone maintenance treatment (MMT), however most of these studies are on pharmacokinetics or post-mortem examinations of

methadone blood concentrations and genetics. To address this critical gap and exert a high, sustained impact on this field this study will assess the acceptability and feasibility of PGx guided MMT; promoting the National Institute on Drug Abuse mission by advancing science on addiction treatment and applying that knowledge to improve individual and public health through advances in personalized medicine for people with substance use disorder. This study will: 1) Identify barriers and facilitators that impact the acceptability and feasibility of a PGx testing protocol to inform MMT by interviewing key stakeholders in MMT (patients, providers, clinic staff) and conducting qualitative analyses to identify barriers and facilitators; 2) Develop and evaluate educational resources for MMT providers and their patients by creating and evaluating digital education materials based on aim 1 results and current literature; and 3) Evaluate the acceptability and feasibility of PGx guided MMT through an 8-week randomized controlled trial (arms: PGx, services-as-usual) where primary outcomes of acceptability and feasibility are assessed. Secondary outcomes will be patient engagement, treatment adherence, cravings, and withdrawal symptoms. Post-intervention, MMT providers who had patients in the study will be surveyed to collect provider data on feasibility, acceptability, appropriateness, change in prescribing, comfort using PGx, and suggestions for improvement. Medication dosing based on PGx holds the potential to decrease deaths, increase treatment retention, and reduce the use of non-prescribed opioids through personalized medicine, this study will take the first steps toward examining that potential.

Situated in a richly supportive environment in the internationally regarded Program of Excellence in Addictions Research, I have access to many well established and funded mentors, space, equipment, software, finances, and protected time to conduct my research. The proposed training plan integrates mentorship from experts in clinical trials (McPherson), clinical application of PGx (Limdi), biomedical ethics related to genetics (May), substance use genetics (Agrawal), and opioid use disorder treatment (Layton); and training in Ethical, Legal and Social Implications central to patient and provider trust and uptake of genomics applied to substance use disorder treatment, clinical application of PGx to substance use disorder treatment, and guidance in developing my research career and laboratory. This Mentored Research Scientist Development Award will build on my previous training and allow me to pursue my long-term career goal of becoming an independent investigator with an established program of research poised for high scientific impact and focused on the intersection of Personalized Medicine and Substance Use, through PGx testing.

Start date: 04-01-2024

End date: 03-31-2029

Last modified: 07-08-2024

Copyright information:

Pharmacogenomic Testing to Optimize Methadone Maintenance Treatment: Acceptability and Feasibility Trial

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)

This project will produce the following data across 3 aims:

Aim 1) This aim will produce qualitative interview data and quantitative demographics data. Interviews will be conducted using Zoom software and saved in the Zoom cloud. Quantitative demographics data will be collected through the secure REDCap electronic data capture system. Interview recordings will be downloaded from the Zoom cloud to a secure, password protected WSU computer in order to upload them to the transcription company. Qualitative data will be transcribed and deidentified by a HIPAA compliant transcription company and returned to investigators in the deidentified form, then aggregated and summarized through qualitative content analysis methods. Quantitative data on the participants will also be aggregated to describe the sample and presented with the qualitative results. Data will be collected from 15 research participants, generating 2 datasets totaling approximately 2 MB in size. The following data files will be used or produced in the course of the project: docx (for interview transcripts); comma delimited csv files (for survey data); and dta files (for input into and data analysis with STATA software). Raw data will be utilized for statistical analyses. To protect research participant identities, only aggregated data will be made available for sharing.

Aim 2) This aim will produce quantitative and survey data generated through the Computerized Intervention Authoring System (CIAS 3.0), an NIH/NIBIB sponsored program designed for intervention design and testing. Data will be collected from 30 research participants, generating 2 datasets totaling approximately 100 KB in size. The following data files will be used or produced in the course of the project: comma delimited csv files (for survey data); and dta files (for input into and data analysis with STATA software). Raw data will be utilized for statistical analyses. To protect research participant identities and owing to the small sample size for this very specific educational materials feedback study only aggregated and summarized data will be made available for sharing.

Aim 3) This aim will produce quantitative and survey data generated through REDCap electronic data capture software. Data will be collected from 60 research participants, generating 1 dataset totaling approximately 1MB in size. The following data files will be used or produced in the course of the project: comma delimited csv files (for survey data); and dta files (for input into and data analysis with STATA software). Raw data will be utilized for statistical analyses. To protect research participant identities only aggregated and summarized data will be made available for sharing.

Data collection for all aims will be performed at clinical sites in Washington State with the following populations: people on methadone maintenance treatment, methadone prescribers, staff at methadone

clinics.

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.*

The final dataset will include self-reported demographic and behavioral data from interviews with participants as well as educational tool evaluation and acceptability/feasibility data from participants. We will only share aggregated and summarized survey data due to the incredibly sensitive nature of the research targeting genomics and substance use.

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.

To facilitate interpretation of the summary data, a data dictionary word document will be created, shared, and associated with the relevant datasets.

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.

Aggregate and summarized data will be made available in CSV or DOCX formats and will not require the use of specialized tools to be accessed or manipulated.

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

In accordance with FAIR Principles for data, data will be stored in common and open formats, such as DOCX and CSV for our aggregate summary survey data. Information needed to make use of this data [e.g., the meaning of variable names, codes, information about missing data, other metadata, etc.] along with references to the sources of those standardized names and metadata items will be included wherever applicable.

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; see Selecting a Data Repository)

Aggregate clinical trials data from all arms of the study will be available in clinicaltrials.gov, along with related metadata. All other data described above in the "data to be shared" section will be deposited into the National Addiction & HIV Data Archive Program (NAHDAP) 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.

NAHDAP provides searchable study-level metadata for dataset discovery. NAHDAP 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.

Sharable scientific aggregate data generated from this project will be made available as soon as possible, and no later than 3 years past the end of the funding period. The duration of preservation and sharing of the data will be a minimum of 5 years after the funding period.

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. See Frequently Asked Questions for examples of justifiable reasons for limiting sharing of data.

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).

Given the sensitive and possibly proprietary nature of the data, data will be made available in the NAHDAP data repository, which allows access to the data to qualified investigators that fill out a form providing sufficient information regarding an appropriate research question and approved data use agreement and IRB, and are reviewed by the NAHDAP.

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.

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).

Lead PI Smith, ORCID: 0000-0002-5095-2822 will be responsible for the day-to-day oversight of lab/team data management activities and data sharing. Broader issues of DMS Plan compliance oversight and reporting will be handled by the PI and Co-I team as part of general Washington State University, Spokane, stewardship, reporting, and compliance processes.
