Enhancing Geriatric Pain Care with Contextual Patient Generated Data Profiles

NCT04560920

December 6, 2022

VA Consent Cover Letter

DESCRIPTION OF RESEARCH BY INVESTIGATOR

Our study is about the use of Patient Generated Data (PGD) to enhance delivery of patient centered care to improve management of chronic pain in older Veterans. The development and implementation of novel approaches to manage chronic pain is a top priority for Veterans Health Administration (VHA) and the broader United States population. Cutting-edge pain management recognizes the importance of functional ability, home environment, and social support. A whole person perspective is required, embodied by the determination of what matters to the patient. The use of PGD is a potentially powerful way to convey this information to clinicians and to support shared decision making. PGD significantly advances pain management beyond existing evidence based approaches. However, to effectively incorporate PGD into clinical workflow, several key issues need to be addressed: which elements of PGD are most important, how should these elements be collected and delivered to clinicians, and how should this information be presented to enhance Veteran-centric care and shared decision making. Our study will directly address these questions and will help propel VA closer to delivering a model of geriatric care consistent with Aging Friendly Healthcare Systems.

We would like you to participate in interactive collection processes for providing contextual PGD elements and creating contextual PGD profile displays. This will involve completing surveys and photo documentation of your environment.

PROCEDURES

Once the participant has agreed to participate in the study, they will be randomized to one of two groups: Control group (will be given the study tablet and app after their next Primary Care appointment); Study group (will be given the study tablet and app prior to their next Primary Care appointment). After participants are randomized, they will be asked to participate in an orientation meeting (about 30 minutes) to explain how the study application works.

Study group participants

Prior to the next Primary Care visit individuals in the study group will be contacted by the study team to follow up with the participant to ensure that the participant was able to complete the study related tasks. At the next Primary Care appointment, the participant will meet with their care provider as they normally would. The visit will be both audio and video recorded for the purpose of the study. The participant and provider will both be asked to complete study surveys at the end of the visit (about 20 minutes).

30 days after the Primary Care visit the participant will be contacted and asked to complete some additional study surveys via telephone interview (about 30 minutes).

Control group participants

After the next Primary Care visit, both Control group participants and their provider will be asked to complete some study surveys (about 20 mnutes).

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Prior to the following Primary Care visit (study visit) individuals in the control group will be contacted by the study team to complete the study orientation and dispense the study tablet. The week before the study visit, the study team will follow up with the participant to ensure that the participant was able to complete the study related tasks. At the next Primary Care appointment, the participant will meet with their care provider as they normally would. The visit will be both audio and video recorded for the purpose of the study. The participant and provider will both be asked to complete study surveys at the end of the visit.

30 days after the Primary Care visit the participant will be contacted and asked to complete some additional study surveys via telephone interview.

CONFLICT OF INTEREST
There is no real or apparent conflict of interest by investigators in this study.

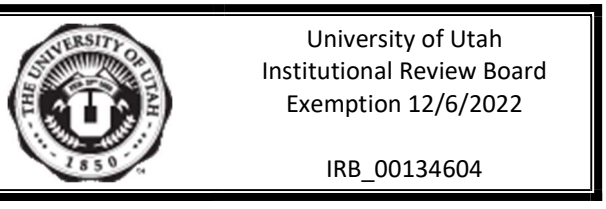
CONFIDENTIALITY
Our authorized research team will have access to your interview data. The interview will be recorded and downloaded onto a secure VA server. Electronic data containing information that could identify you will be stored on a secure server behind the VA firewall with restricted access. Any paper documents will be stored in locked file cabinets behind locked doors within the VA facility with restricted access. Any information that could identify you will be deleted or replaced with a code prior to the study data being removed from the VA, e-mailed or otherwise disclosed. If the identifiers are replaced with a code, the documentation of the procedure by which the code is used will remain with the VA at all times.

All information gathered will be kept strictly confidential, and no corrective or disciplinary action will ensue due to the results of the observations or your answers to our questions. Aggregate data only will be reported in research-related publications and reports.

PERSON TO CONTACT
If you have any questions complaints or if you feel you have been harmed by this research please contact Jorie Butler, PhD at [redacted] during the hours of 9am - 5pm Monday through Friday.

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at [redacted]

MEDICAL TREATMENT OR COMPENSATION FOR INJURY
The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S.



Government. If you sign this document you are not giving up your right to make a legal claim against the United States.

COSTS TO PARTICIPANTS AND COMPENSATION

A veteran participant will not be required to pay for care and services (treatment) received as a subject in a VA research project. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

Each Patient Generated Data contributing patient will receive $50 or a gift card for contextual Patient Generated Data contribution; $25 or a $25 gift card for study visit; and $25 or a $25 gift card for the 30-day follow up telephone call. Each caregiver will receive $25 or a $25 gift card ($125 per dyad).

PARTICIPATION IS VOLUNTARY

Participation in this study is voluntary. You can choose not to take part in one, some or any of the components described above. You can choose not to finish the interview or omit any question you prefer not to answer without penalty or loss of benefits. Participation in this study is voluntary. You can choose not to take part. You can choose not to finish the interview or omit any question you prefer not to answer without penalty or loss of benefits.

Your participation in this study is greatly appreciated. The information gathered will be used to better understand and characterize the clinician's models, strategies and information needs relevant to delivering patient centered care (PCC).

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We would like to conduct a focus group with patients 65 or older with chronic pain and their caregivers. We will ask questions about the experience of living with and supporting a patient with chronic pain and discuss recent decisions made with clinicians related to pain management. Participants will be introduced to the concept of contextual PGD profile displays and will discuss barriers and facilitators of contributing PGD and address how PGD might influence their communication with clinicians.

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Each Veteran and caregiver participant in the focus groups will receive a $25 gift card for participation.

PARTICIPATION IS VOLUNTARY

Participation in this study is voluntary. You can choose not to take part in one, some or any of the components described above. You can choose not to finish the interview or omit any question you prefer not to answer without penalty or loss of benefits. It should take 60 to 90 minutes to complete the focus group/ interview. Participation in this study is voluntary. You can choose not to take part. You can choose not to finish the interview or omit any question you prefer not to answer without penalty or loss of benefits.

Your participation in this study is greatly appreciated. The information gathered will be used to better understand and characterize the clinician's models, strategies and information needs relevant to delivering patient centered care (PCC).

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