Protocol Number: HSC20200525H
Title: In-person vs. Remote Wellness Support
Date of approval: 11.25.2020

Consent to be part of a Research Study
To be conducted at
University of Texas Health Science Center at San Antonio

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Dawn I Velligan, PhD. Dr. Velligan is a Professor in the Department of Psychiatry at UTHSCSA and Chief of the Division of Community Recovery, Research and Training at UT Health San Antonio.

Funding
The National Institute of Mental Health, a federal agency that promotes scientific research, is funding this study. This organization is providing money to UTHSCSA so that the researchers can conduct the study.

Purpose of this study – "Why is this study being done?"

We know that only half of the medication prescribed by doctors is actually taken. If medication is not taken as prescribed it is difficult for the provider and person in treatment to make good decisions about changing medication or changing doses of medication. In standard community treatment there is often not enough help for people to take medication regularly. People can forget or get distracted. There are also other issues that come up for people such as not being able to get going on tasks or feeling stressed.

We are doing this study to compare In-person Wellness Support to Remote Wellness Support. We want to learn whether these programs can help people with behavioral health conditions take their medications more regularly, make everyday tasks easier to do and help them manage everyday stress in an effort to improve their outcomes. Wellness Support uses environmental supports such as signs, calendars, alarms, pill containers, and checklists as reminders to help people take medications and meet their wellness goals. In person Wellness Support is provided on weekly visits to the person's home. The provider brings helpful items to the home and helps the person set them up. Remote Wellness Support is provided via telephone, video chat and text messaging. In Remote Wellness helpful items are mailed to the person's home and the provider speaks with them over phone or video-chat to set the items up. You are being asked to participate in this research study of In-person versus Remote Wellness Support because new ways of helping people take medications regularly and meet their wellness goals are needed.

The researchers hope to learn which interventions people prefer, and if In-person and Remote Wellness Support added to standard community treatment increases regular medication taking and improves outcomes. This trial will be registered on www.ClinicalTrials.gov, a publicly available registry of clinical trials. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. We will also send information to a national data base for researchers. No information that can identify you will be sent.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are a member of Superior Medicaid with a behavioral health condition, you have been in the hospital or had a crisis visit in the past 12 months, and there were times in the last few months that you may have missed taking your medication based upon the dates you refilled your prescriptions. You are also being asked to participate because you have said that you have missed at least two doses of medication in the past three weeks and that you would be willing to participate in a program to help you take medication more regularly.

How many people are expected to take part in this study?
This study will enroll approximately 100 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to participate in 7 visits with the researchers or study staff for assessments conducted at your home, and/or visits via video-chat for counting medications. In addition, if you are assigned to In-person Wellness Support you will receive weekly visits at your home; and text and telephone contact between visits. If you are assigned to Remote Wellness Support you will receive weekly visits via video-chat, and text and telephone contact between visits

Please note that your participation in this study involved remote and/or virtual research interactions with our research staff. You will be audio and/or video recorded by the conferencing platform Zoom.

All procedures described below will be performed for research purposes only.

Baseline Visit – After you sign this consent to participate you will have a baseline visit conducted at your home or via video conferencing. *(Estimated time: 1 ½ - 2 hours)*

As a study participant, you will go through the following study procedures on the baseline visit:

- We will ask you about your behavioral health symptoms, your daily functioning and your medication taking habits. The interview will take about 45 minutes and will be audio-recorded.
- We will ask you to do some pen-and paper and computer tests of attention, memory and planning. These tests take about 15 minutes.
- We will ask that you bring out all of your prescription medications and allow us to count them in person or via video conferencing. We will ask you to place all of your empty medication bottles in a special box while you are in the study to make it easier for us to keep track. We may ask you to bag up old bottles of medication so that we know which bottles you are currently using. This will make it easier for the researcher to count the pills. Depending upon how many medications you take, pill counting may take 30 minutes to 1 hour.

Assignment to Study Groups – After the baseline visit, if you have chosen only to participate in In-Person Wellness Support you will be in that group. If you have chosen only to participate in Remote Wellness Support you will be in the Remote group. If you indicated no preference, you will be assigned by chance (like flipping a coin) to one of the two study groups. If one group fills up we will let you know that only the other group is available prior to you participating in the study.

- **Group 1:** Standard community treatment + In-Person Wellness Support – You will continue to go to all your community providers as needed, participate in study assessments and in In-Person Wellness Support for 6 months with an in-person provider from UT Health.

- **Group 2:** Standard community treatment + Remote Wellness Support – You will continue to go to all your community providers as needed, participate in study assessments and in Remote Wellness Support for 6 months with a remote provider from UT Health.

If you are assigned to a study group, someone from the research team will call you to let you know which group you were assigned to.

Follow-up visit Study Procedures - After the Baseline Visit you will be asked to participate in 6 assessment visits at your home. These will happen every month during the 6-month study period. Some of the visits will be longer than others. If you agree by signing this form, these follow-up visits will not be scheduled in advance, but we will call you a few hours before we arrive or want to video chat to make sure you are home and ready for a visit. We will try again if necessary, on another day.

The research team will follow COVID-19 guidelines of UTHCSA; for example, visits will occur outside your home for the safety of you and research personnel. Alternatively, we will conduct those visits via video conference on a secure platform.

During the follow-up visits at your home or via video conferencing on month 2,4 and 6: *(Estimated time: 1 hour and 15 minutes to 1 ½ hours per visit)*

- We will ask you about your behavioral health symptoms, your daily functioning, your medication taking habits, and your feedback on the treatment you are receiving. The interview will take about 45 minutes.
- We will ask that you bring out all of your prescription medications and allow us to count them.
    - Counting pills on follow-up visits may take 20 minutes to 45 minutes depending upon how many prescriptions you have and how much has changed since your last visit.

During the follow-up visits at your home or via video conferencing on month 1,3 and 5: (Estimated time: 20 min to 45 min per visit)

- We will be counting your pills or asking you to count them over video conferencing.

No matter what group you are in, you will continue to attend your regular visits with your providers during the study,

- If you are assigned to Group 1 In-Person Wellness Support + Standard Community Treatment
    - During the 6 months of In-person Wellness Support you will have weekly visits at your home from a study provider. These visits may last about an hour but may be shorter depending on your needs. Visits are audio-recorded to help us evaluate the provider's work.
    - The In-Person provider may also call or text you between home visits if you agree this would be helpful. Calls are recorded to help us evaluate the provider's work.
    - In-Person Wellness Support uses environmental supports such as signs, calendars, alarms, pill containers, and checklists to cue and sequence adaptive behaviors such as taking medication, socializing with others, coping with stress, and taking care of independent living skills.
    - The provider will bring you helpful supports and help you set them up at your home.
    - The provider may also ask to take pictures on home visits to show how your medications are set up or to show the supports they helped you with. These photos will not include any identifying data (such as your name or your pharmacy). These photos help us to evaluate the quality of the provider's work.

- If you are assigned to Group 2 Remote Wellness Support + Standard Community Treatment

- During the 6 months of Remote Wellness Support, you will have weekly video-chat visits from a study provider. These visits may last about an hour but may be shorter depending on your needs. Visits are audio-recorded to help us evaluate the provider's work.
- The provider may also call or text between visits if you agree this would be helpful. Calls are recorded to help us evaluate the provider's work.
- Remote Wellness Support uses, video chat, phone calls text message reminders and some items mailed to your home to help you take medication more regularly, cope with stress, and take care of independent living skills.
- You may get some packages in the mail that we would like you to open. Your provider will speak with you over phone or on video-chat to help you set the items up to support your wellness.
- The provider may also ask to take pictures on video visits to show how your medications are set up or to show the supports they helped you with. These photos will not include any identifying data (such as your name or your pharmacy). These photos help us to evaluate the quality of the study provider's work.

Please note that your participation in this study involves remote and/or virtual research interactions with our research staff. Therefore, privacy and confidentiality are not guaranteed due to the nature of the research environment. You will be audio recorded by the conferencing platform being utilized for the remote visit (i.e. Zoom).

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

You will continue with your standard community treatment when your participation in this study ends.

Risks – "What are the risks of participation in the research?"

Risks from the research

The investigators have designed this study to learn if In-person or Remote Wellness Support added to standard community treatment improves regular medication taking and wellness outcomes. There is a risk that In-Person or Remote Wellness Support may not help you to take your medication more regularly. There is a risk that both programs help you take medications more regularly and that you will then experience side effects from the medication prescribed by your community provider. If this happens, you may feel worse. The study provider will ask you to discuss these side effects with your regular/clinical provider and work with that provider to decide on a course of action. If you need help contacting your regular/clinical provider, your study provider will help you do this.

Risks from the specific research procedures

Risks associated with the home visits include those which are:

Less likely and not serious:

- Having researchers visit your home may make you feel uncomfortable. You may also feel anxiety associated with team members taking pictures in person or over video of how your prescriptions are kept. If at any point you feel uncomfortable or would like the researchers to stop and/or leave, please let us know. Your wishes will be granted, and there will be no penalty or loss of benefit to you if you decide to stop.
- You may get uncomfortable about not knowing exactly when follow-up visits will happen.
- You may get tired of participating in pill counting or interviews.

Risks associated with the surveys and assessments include those which are:

Less likely and not serious:

- Discomfort related to some of the questions. You do not need to answer any question that makes you feel uncomfortable.
- You may become upset or sad talking about your symptoms
- You may be uncomfortable doing the pen-and-paper tests at the baseline assessment.
- If assessments are done via video conference this may make you feel uncomfortable.
- You may get tired of counting your pills.

Rare and Serious:

- Due to the use of online conferencing systems, your privacy and confidentiality is not guaranteed. Breach of confidentiality, or unintentional release of your medical information or pictures taken from your home being accidentally released to someone outside of the research team. The researchers have taken steps to protect your information by using study codes instead of your name on the research materials collected from you, by not taking photos of any identifying information (e.g. your name) and by storing the research records, including any audio recordings, in a secure location with restricted access to members of the research team only.

Risks associated with the In-Person or Remote Wellness Support procedures may include those which are:

Less likely and not serious:

- You may become tired of weekly visits with the provider at home or by phone or video-chat or you may dislike the text messages or the items that are sent to you.
- You may be uncomfortable about being audio recorded or having pictures taken of how your medication is set up.
- Due to the use of online conferencing systems, your privacy and confidentiality are not guaranteed.

If you become upset or uncomfortable with research procedures, the PI and research staff will be happy to discuss this with you. If you dislike aspects of In-Person or Remote Wellness Support, you can discuss this with the study provider and make changes.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes a final interview to ask about symptoms, daily functioning and how you take your medication and a final count of your pills There is no risk to you if you do not complete the final withdrawal procedures, and you can choose not to participate in them.

Benefits – "How could you or others benefit from your taking part in this study?"

There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"

There are other options available to you. Your other choices may include not participating in the study. If you choose not to participate it will not impact the care or services provided by Superior Medicaid.

Payments – "Will there be any payments for participation?"

You will be compensated for the time you spend in study visits. For the baseline and each study visit you will receive $40. If you participate in all visits (7 total - 1 baseline, 3 in person follow up visits, and 3 video pill count visits) that means that you could receive a total of $280 during the 6 months of the study. You must complete the entire visit to receive $40. You will not be compensated for visits that are incomplete, but you may ask to

complete the visit on the next day. You will be compensated after the entire visit is complete. You will not be compensated for participating in Wellness Support, but you may receive helpful items.
The researchers will provide you with a MasterCard®. Compensation will be automatically credited after completion of each study visit. Your name, address and date of birth will be shared with a third-party solely for the purposes of compensation processing. This information will only be used for the administration of the compensation (ClinCard) and will be kept strictly confidential.

In addition to the compensation on the card, you may also elect to receive study-related messages (text and/or email). These messages will contain information confirming that money has been loaded onto your card. Please indicate your willingness to receive study-related messages:

- □ **Yes,** I would like to participate (please select the best method(s) for communication)
  - Cell Phone (text messages)
  - Email
- □ **No,** I choose not to participate

Costs –"Will taking part in this study cost anything?"

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as visits to your doctors and medications. It is important to understand that some insurance companies do not cover some costs (for example, there may be co-pays for medication) If your insurance company does not cover these treatments or procedures, you will be required to pay for them. Ask the researchers if you have any questions about what it will cost you to take part in this study (for example bills, fees, or other costs related to the research).

Confidentiality – "How will your records be kept confidential?"

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Federal Government. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under certain circumstances. Circumstances that warrant the release of your information without your permission include: abuse and/or neglect, intention to harm yourself or others, or certain communicable diseases.

Limits of Confidentiality

Even without your consent, suspected or known abuse or neglect of a child, disabled, or elder abuse, threatened violence to self or others or other local health reporting requirements will be reported to appropriate authorities.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The

information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include: information that is created or collected during your participation in the study including medical and treatment history and medication prescribed and charged to Medicaid, your follow-through with medications prescribed by your provider from monthly pill counts, audio recordings of sessions with your Wellness provider, pictures of how medication is set up in your home, information you give us during your participation in the study, such as during interviews or from questionnaires, results of tests of memory, attention, and planning, and demographic information like your age, marital status. the type of work you do and the years of education you have completed.

We will get this information from your Medicaid provider, from interviews and testing taking place on study visits and from pill counts conducted at your home.

How will your PHI be shared?
Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The National Institute of Mental Health who is funding this study
- The following collaborators at other institutions that are involved with the study: Superior Medicaid
- The committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- The members of the local research team
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of UTHSCSA for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.
After you enroll in this study, you may ask the researchers to stop using your health information at any time . However, you need to say this in writing and send your letter to: **Dawn I Velligan, Ph.D., 7703 Floyd Curl Drive, Mail Stop 7797 San Antonio TX, 78229-3900.** If you tell the researchers to stop using your health

information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. You will only have access to your PHI until 1 year after study completion.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact: Feiyu Li, Ph.D. can be reached at 210-452-7136.

If primary is not available, contact: Megan Fredrick, M.A. LPC can be reached at 210-237-9590

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.
SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.

Adult Signature Section

- You have voluntarily decided to take part in this research study.
- You authorize the collection, use and sharing of your protected health information as described in this form.
- You authorize to be audio and/or videotaped

			AM PM
Printed Name of Subject	Signature of Subject	Date	Time
			AM PM
Printed Name of Witness	Signature of Witness	Date	Time

☐ *Check if consent and authorization obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English. Have witness initial below.*
Declaration of witness: I was present for the entire consent process. _____ ←(initials of witness)

AM
PM

Title of Study: In-person vs. Remote Wellness Support (study sub-title: Remote Cognitive Adaptation Training to improve medication follow through in managed care (R-CAT))

Printed Name of Person Obtaining Consent and Authorization	Signature of Person Obtaining Consent and Authorization	Date	Time

☐Consent and authorization was obtained from this individual who is unable to read and/or write but can otherwise communicate and/or comprehend English.
The method used for communication with the subject was: _____.

The specific means by which the subject communicated agreement to participate was:
_____