Cover Page for ClinicalTrials.gov

Document: Informed Consent

Study Title: Chronic Pain Self-management for Older Adults With Cognitive Impairment: A Randomized Pilot Trial

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STEPS-CI Consent Script

Introduction:

Voicemail: Hi, this message is for *(participant name)*. This is *(your name)* calling from the STEPS CI Study Team at the University of Michigan. We spoke a few days ago about your interest in participating in our project that is testing a program that helps older adults with cognitive impairment manage pain. We had a phone call scheduled for today for *(scheduled time* to go over the consent form. Please give me a call back at *(phone number)* at your earliest convenience and we can complete the call or reschedule at a time convenient for you. My phone number is [give direct #] Thanks and have a great day!

Outgoing Calls: Hello! My name is _____ *[your name]*, from the STEPS-CI Study. Is this Mr./Ms [last_name_elg] [*prospective participant name]*? *(confirm identity before proceeding)*

If it's someone else: Is Mr./Miss [first_name_elg] [last_name_elg] *[prospective participant name]* available?

(If no, ask if there is a good time to call back and record in Call Backs)

If you are speaking with the prospective participant: Hello, I am calling about a research project that we're conducting for older adults with cognitive impairment who also have chronic pain. Is it still a good time to go over the verbal consent today? It should take about 30 minutes.

[If yes, continue. If no, reschedule]

Great, we are happy that you are interested in participating in the STEPS-CI study! So again, for the consent process, I will go over all aspects of the study to make sure that you understand them and answer any questions you may have about participating. Are you in a comfortable place that has as much privacy as you would like? [offer to reschedule if not]

Did you receive the consent form in the mail?

If Yes: Great, if you have it available, you can follow along with me now. [proceed with the consent]

If No: Okay, would you like me to give you a call back once you have it? [offer to resend if necessary]

To make sure we are covering all necessary information about the study, we would like to record the verbal consent call. All recordings will be stored securely until the end of the project and then destroyed.

Is it okay with you if we record this conversation?

> *If participant is uneasy:* The only reason we ask to record this process is to make sure it's being done correctly. Someone else on the research team may listen to it to make sure we're following the protocol. (Yes/No)
>
> *If Participant agrees to be recorded:* Great! Let me turn on the recording. You'll hear an automated voice tell you we're recording *turn on recording*
>
> *If participant does not want to be recorded:* No problem. We can continue without recording. **Do NOT record**

Now I would like to go over the details of the STEPS CI Study and obtain your permission to participate. Please feel free to ask any questions you may have. As we go through the consent form, I'll ask you a few questions just to make sure we've communicated the important points.

Overview and Purpose:

We know that life with chronic pain can be challenging. The purpose of this study is to try out a new program that might help older adults live better with chronic pain. This program has been designed especially for adults age 50 and over with chronic pain who are also living with cognitive impairment.

Do you have any questions about the overview and purpose?

> *If Yes:* make a note of the question(s) and answer as best you can

Just to make sure I've conveyed it correctly, what is the main purpose of the study?

> If participant does not give correct answer, reiterate that the purpose of the study: "We are testing a chronic pain management program to see if it is effective. The program was developed specifically to help individuals that have cognitive impairment. Does that clarify things a bit for you?"
>
> If participant is confident in their understanding, proceed with next section. If not, propose revisiting the consent another day. For example, "If it a lot to wrap your head around today, we can definitely revisit this sometime later this week?"

Description of Involvement:

If you agree to be part of this study, you will be asked to complete two surveys with members of the study staff, primarily over the phone. The first survey will be about 45-60 minutes, and the second will be about 30 minutes. They can each be broken up and done in shorter time periods.

The first survey will be scheduled after completing the consent process, and the second telephone survey will take place 10-weeks later.

After completing the first survey, you will be randomized into one of two groups: either the **intervention group** or the **control group**. You have an equal (50/50) chance of being in either group.

If you are placed in the **intervention group**, you will participate in a 45-minute orientation session with your Health Coach to get you set up for the program. Over the following 6 weeks, you will do 3 things: meet by phone or Zoom with a Health Coach, watch two short videos on a website each week, and try out some new activities. After the end of the seven-week program, and about 10 weeks from the first survey, intervention participants will complete their follow-up telephone survey.

If you are placed in the **control group**, you will not take part in these activities, However, we will ask you to complete the two telephone surveys. After you complete the second survey, you will be offered the program materials and will be invited to participate in a workshop about chronic pain management.

(Table for reference-repeat of above) Participants in the **intervention group** will:

Activity	**Time Commitment**
Complete a baseline survey (phone with optional online or paper portion)	60 minutes (can be done over two shorter calls)
Participate in a Zoom or telephone orientation with Health Coach	45 minutes
Meet by phone or Zoom once a week with a Health Coach	30-45 minutes/week (6 weeks)
Watch 1 or 2 short videos on a website each week	10 minutes/week (6 weeks)
Try some new activities on your own each week	1 hour/week (6 weeks)
Complete a follow up telephone survey	30 minutes

Participants in the **control group** will:

Activity	Time Commitment
Complete a baseline telephone survey (phone with optional online portion)	60 minutes (can be done over two shorter calls)
Complete a follow up telephone survey	30 minutes
OPTIONAL: Attend a remote "workshop" session that will summarize key information from the program	Up to 2 hours

Again, there is a 50/50 chance that you will be in the intervention group or the control group.

Do you have any questions about what you would be doing in the study? Would you like me to repeat anything?

If Yes: make a note of the question(s) and answer as best you can

Again, I want to make sure I've described the study well. If you participate in this study, what are some of the things that you will be asked to do?

If participant does not give correct answer, reiterate the expectations of participants: "Each participant will complete a baseline and a follow up survey to compare aspects of their health. Only half of the participants will complete the program, which will involve talking with a health coach, watching weekly videos, and trying out activities. The participants are assigned to the groups randomly. Does that make sense?"

If participant is confident in their understanding, proceed with next section. If not, propose revisiting the consent another day. For example, "If it a lot to wrap your head around today, we can revisit this sometime later this week?"

Intervention Program Overview – for participants randomized to the Intervention Group only

- The program that we are testing has 7 weeks of content that can be completed over the course of 7-10 weeks. All study activities can be completed remotely, either by phone or video.
- Sessions with your Health Coach will be recorded for research purposes. No personal details will be shared in a way that someone outside of the study would know it was you.
- Sessions will include a discussion with your Health Coach about a pain management topic. Together, you will set goals to work on new skills. You can follow along in a workbook, which we will send to you.

- We will ask you to watch short videos, on our website, each week. Some videos will teach skills for managing pain. Other videos will feature people who are living with both cognitive impairment and pain, sharing their experiences.
- In the surveys and in the sessions with the Health Coach, you may be asked about your health history, your experience with chronic pain and cognitive impairment, and your daily activities.

Do you have any questions about what you will be doing in the study?

If Yes: make a note of the question(s) and answer as best you can

Voluntary nature of the study

Taking part in this research project is completely voluntary. You do not have to participate, and you can stop at any time. During the surveys with staff members or conversations with the Health Coach, you may choose to not answer a question for any reason.

Do you have any questions so far?

If Yes: make a note of the question(s) and answer as best you can

To clarify, do you have to participate in this study if you don't want to?

If participant does not give correct answer, reiterate the voluntary nature of the study: "This study will always be voluntary. Even if you complete the consent today, at any point you are welcome to stop participating in the study and there will be no penalty if you do so. You can also choose to not answer specific questions or engage in activities if you do not want to. Did that help to clarify things?

If participant is confident in their understanding, proceed with next section. If not, propose revisiting the consent another day. For example, "If it a lot to wrap your head around today, we can revisit this sometime later this week?"

Benefits

You may find that the strategies you learn will help you manage your pain or memory challenges better. The information we learn from this research may help other people like you in the future.

I want to double check that I conveyed this correctly. Is it possible that being in this study will not have any benefit to you?

If participant does not give correct answer, reiterate the investigatory nature of the study: “Since we are testing the program to see if it is effective, unfortunately we cannot guarantee that you will benefit from the study. The results of the study may help us learn more about how to help people with chronic pain and cognitive impairment. Does that make sense?

If participant is confident in their understanding, proceed with next section. If not, propose revisiting the consent another day. For example, “If it a lot to wrap your head around today, we can revisit this sometime later this week?”

Risks and discomforts

Some people may find it uncomfortable to talk to a stranger about difficult personal matters, like health problems. You do not have to answer any questions you don’t want to, and you can end your participation whenever you like. You don’t have to tell us why.

There is also the risk that someone outside of the study accidentally finds out something you shared privately. The research team takes your personal data seriously and will be careful to protect it. Only members of the study team will have access to the information you share, which will be stored on a password-protected computer. We will use an identification number without your name to track your responses.

Do you have any questions about the potential risks of participating in the study? Would you like me to repeat anything?

If Yes: make a note of the question(s) and answer as best you can

Just to clarify, could you describe some of the risks or discomforts that people may experience if they participate in this study?

If participant does not give correct answer, reiterate the potential risks of the study: “You may experience some discomfort when talking about personal things with your health coach. Also, because we are collecting information about you there is a chance that someone gets access to it that shouldn’t, despite the protections that are in place to protect your privacy. Any questions about these risks?

If participant is confident in their understanding, proceed with next section. If not, propose revisiting the consent another day. For example, “If it a lot to wrap your head around today, we can revisit this sometime later this week?”

Compensation

As a thank you for participating, we will mail you one $40 check after you complete the first survey. You will receive another $40 check at the end of the study if you choose to complete the second survey 10 weeks later.

If you decide to withdraw early, you may keep the $40 check, but you will not receive the remaining $40 unless you finish the second survey.

Privacy and Confidentiality:

There are some reasons why people other than the researchers may need to see information you provided as part of the study. This includes organizations responsible for making sure the research is done safely and properly, including the University of Michigan or government research offices. Also, if you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

We plan to publish the results of this study but will not include any information that could identify you. To keep your information safe, the recording of your surveys and weekly sessions will be placed in a password protected database. The researchers will keep study data on a secure university server that only the study team will have access to.

If you withdraw from the study, we will use the data we have already collected from you.

We may use or share your research information for future research studies. If we share your information with other researchers, it will not contain your name or other information that can directly identify you.

Do you have any questions about how your data would be accessed and stored?

If Yes: make a note of the question(s) and answer as best you can

Do you give your permission for us to use your information in future studies? Again, it will not contain your name or other information that could identify you.

Yes___ No___

Special Protections:

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means no one can make us give your information to anyone else unless we have your permission. However, you are welcome to talk about your involvement in this research if you wish.

The Certificate does not stop researchers from reporting suspected abuse, neglect, or risk of substantial harm to self or others.

If we share any information with other researchers or in reports, it will not allow someone to identify you.

If you have more questions about Certificates of Confidentiality and the protections they provide, there is a link on your copy of the consent form where you can find more information. If you'd like also like to write it down, I'm happy to give you the link now too:

(if participant would like to write it down give them this link - https://grants.nih.gov/policy/humansubjects/coc.htm)

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. The website will include a summary of the results. You can search this website at any time. This website will also be listed on your copy of the consent document.

Contact Information:

If you have questions about this research, including questions about scheduling or your compensation for participating, you may contact the Principal Investigators directly. You can also call the study hotline number. 844-862-2737

Co-Principal Investigator: Mary Janevic

Email: mjanevic@umich.edu

Co-Principal Investigator: Donovan Maust

Email: maustd@umich.edu

Contact information is listed on your copy of the consent form that was sent to you for your own recordkeeping. Would you also like to write it down?

(If participant would like to write anything down, please give them time to get something to write with)

If you have questions about your rights as a participant, or wish to get information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 2144 Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
E-mail: irbhsbs@umich.edu

Consent to Participate in the Research Study:

We want to make sure that you understand that you are being asked to be in a research study about this program. You should have reviewed the consent form, which was mailed or emailed to you, and had a chance to ask any questions you have.

By verbally consenting, you are agreeing to be in the study. Remember that you are always free to leave the study at any time. **Do you consent to participate in this research study?**

> *If no or need more time to think about it:* Thank you for your time; you are welcome to take some time to think about it, or to reach back out if you change your mind. We hope you have a wonderful day. [*End phone call*.]
>
> *If yes:* Great, thank you. The copy of the consent document that you have is for your records. You do not have to mail anything back to us. We will note your name and date of consent in our records. Your name will be kept separate from any other information you share with us.

I have a couple more questions for you. These are optional consents, so they are things you can opt in or out of. If you do not consent to the following questions, you can still take part in the study.

Optional Consents:

Consent to be Contacted for Participation in Future Research

Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project. Would you be interested in being contacted about other research projects in the future? [*This consent also to be obtained verbally*.]

> Yes
> No

Consent to use audio recordings for purposes of this research.

This study involves audio recordings for quality control purposes. If you do not agree to be audio recorded, you can still take part in the study. Recordings will only be accessed by study staff, and we will always ask you before we begin audio recording in case you change your mind. Do you consent to being audio recorded for future calls? (Yes/No)

- **Yes**, I agree for the researchers to ask if future calls can be recorded, OR
- **No**, I do not agree for the researchers to record future calls

Scheduling Baseline Survey:

Thank you so much. We are all done with the consent. The next step is to set up your baseline survey, which will be mostly completed over the phone and is expected to take up to about an hour. If an hour seems like too long to be on the phone, we can also schedule it in two parts.

Would you like to do one or two sessions? Is there a good day and time that works for you? [Note scheduled date(s) and time(s) in REDCap.]

Would you like me to give you a reminder call or send you a text the day before or morning of the survey? [Note preferences in REDCap]

Introducing the QDRS:
Before we complete the telephone survey on [give first scheduled date], we would like for you to complete a brief questionnaire. It is meant to approximate your cognitive function— similar to what you might see in a doctor's office. We encourage you to complete it with a family member who knows you well.

There are two ways to complete this survey. First, a paper copy of the survey was sent with the consent form and the baseline survey scales. You can fill out the survey on the paper and I can get the answers from you during the baseline survey telephone call. The second way is to use the link listed on the paper to submit the survey online.

> Do you think you will fill it out on the paper or online? *If online, offer to send a text message or email with their personal link if that would be helpful and note that we will be looking out for their responses. Remind them that they don't have to stick to this preference.*

You should have received the baseline scales in the envelope with the consent form. Do you remember seeing it?

> If participant doesn't remember seeing it, see if they have access to it. If not, arrange for it to be sent over mail or email. If resending by mail, be sure that the BSL is scheduled with enough time to get to them.
>
> If needed, explain: "The survey scales are a document with the response options for each question listed that you can refer to so I don't need to read off the response options each time, so it will help the survey go faster."

It was a pleasure talking with you. Please have both the "STEPS Baseline Survey Scales" and the QDRS if you fill it out on paper out in front of you when we call for the survey as they will help you answer the survey questions more easily.

If you have any questions or need to reschedule the baseline survey for any reason, please give us a call. Again our hotline number is listed in the Contact Information section of the consent document: (844) 862-2737]

Have a great rest of your day!