

**Online Education and Gentle Exercise Intervention (MY-Skills)**

**NCT03440320**

**Updated July 2, 2020**

## **ADULT PARTICIPANT INFORMED CONSENT**

**Department of Human Development and Family Studies and Occupational Therapy**

**Participant Study Title: Education and Gentle Movement Intervention**

**Formal Study Title: Education and Gentle Movement Intervention**

**PRINCIPLE INVESTIGATORS: Christine Fruhauf, PhD, Professor**  
**Arlene Schmid, PhD, Professor**

**CO-INVESTIGATOR(S):** Marieke Van Puymbroeck, Jennifer Dickman Portz, Julia Sharp, Heather J. Leach, J. Douglas Coatsworth

**SPONSOR: National Institute of Complementary and Integrative Health**

### **WHAT IF I HAVE QUESTIONS?**

For questions or concerns about the study, you may contact **Christine Fruhauf at 970-491-1118** or **Arlene Schmid at 970-491-7562**. For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact the CSU Institutional Review Board at: [RICRO\\_IRB@mail.colostate.edu](mailto:RICRO_IRB@mail.colostate.edu); 970-491-1553.

### **CONCISE STATEMENT OF STUDY**

This research study is aimed to see if education and gentle movement improves pain-related disability for pairs of people with pain. You may be interested because you are part of a pair who both experience chronic pain. This research study will consist of two online assessments, 16 online sessions of movement and education, and an online focus group or interview after the program. There are minimal risks to participating in this study, like feeling uncomfortable sharing information in a group. We hope that this research will benefit you by reducing pain-related disability and help adapt the program to benefit others in the future. You can find more details on this study following in the body of this consent form. If you are interested in continued discussion about presentation, we would like to discuss more with you through this consent presentation.

**WHAT IS THE PURPOSE OF THIS STUDY?** The purpose of this study is to examine an education and gentle movement intervention for two people who both experience chronic pain.

### **WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?**

You are being asked to take part in this study to see if a new intervention including education and gentle movement for caregiving dyads who experience chronic pain works. We are testing

education and gentle movement for pairs who both experience chronic pain. Additionally, you have stated that you currently have chronic pain as does the person you provide care to/provides care for you. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

**WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?** This study will take place online with all participants, including research group members and participants, joining via computer at their individual home residences. All online sessions will be hosted by a platform that is licensed by CSU and HIPAA-compliant. If you agree to take part in this study, you will be asked to join the online sessions using your computer at your home residence twice a week for 8 weeks (16 sessions). Each session will last approximately 2 hours. You will also use your computer for two different online assessment periods, one before the intervention, and one after the intervention.

**WHAT WILL I BE ASKED TO DO?** Assessments: You will be asked to complete an assessment just before the intervention and one after the intervention conducted by an assessor who will guide you online. Assessments will include information about:

- Pain related disability
- Anxiety, depression, and fatigue
- Quality of life
- Self-perceived health
- Injuries
- Self-efficacy
- Caregiver burden
- Relationship strain
- Satisfaction with the intervention

Education: You will be asked to participate in 45-60 minutes of online group education consisting of guided discussion and group activities each session. You will then have a 15 minute break, and transition into online group gentle movement.

Gentle Movement: You will participate in 1-hour of online group gentle movement each session.

Movement might include:

- Balance activities
- Stretching
- Strengthening activities

Focus Group or interviews: We will hold interviews or a focus group following the intervention. You will be asked to participate in online to hear your feedback on the program.

**ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY?** There may be no direct benefit to you from the research, but the knowledge gained in this study may help others, should the

results prove useful.

**WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

- We are going to ask you to do some walking and some balancing during the intervention, which will be delivered by a trained professional.
- While performing the intervention, you can use your cane or walker to maintain balance.
- Risk of completing the survey includes being uncomfortable answering the questions or being audio-taped and possible loss of confidentiality.
- Sessions will be recorded and only saved to the local computer for viewing by research group members to check for consistency of intervention delivery after each session. Once viewed, recordings will be deleted off of local computer.
- The nature of focus group prevents the researchers from guaranteeing confidentiality as others in the group may share your comments. However, other participants will be notified at the beginning of the focus group to keep each other's comments confidential.
- To reduce these risks, while completing the assessments, you can tell the researcher that you feel uncomfortable or do not care to answer a particular question. We will also work with you to modify the intervention to best accommodate you and your abilities.
- It is not possible to identify all potential risks in research procedures, but we have taken reasonable safeguards to minimize any known and potential, but unknown, risks.

**WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY?** You will receive supplies to help with the intervention such as a manual with information and exercise equipment for you to keep. You will also receive a \$50 gift card after each assessment (up to \$100) for compensation of your time during this intervention.

**WHO WILL SEE THE INFORMATION THAT I GIVE?** We will keep private all research records that identify you, to the extent allowed by law. All confidential information will be kept on the secure CSU electronic network specific for only our research team to access.

For this study, we will assign a code to your data so that the only place your name will appear in our records is on the consent and in our data spreadsheet which links you to your code. Only the research team will have access to the link between you, your code, and your data. The only exceptions to this are if we are asked to share the research files for audit purposes with the CSU Institutional Review Board ethics committee, if necessary. In addition, for funded studies, the CSU financial management team may also request an audit of research expenditures. For financial audits, only the fact that you participated would be shared, not any research data. When we write about the study to share with other researchers, we will write about the combined information we have gathered. You will not be identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

Additionally, given the nature of a group education, group movement, and a focus group, please be advised that although the researchers will take every precaution to maintain

confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of your fellow participants and not repeat what is said in the focus group to others.

Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits.

There are organizations that may inspect research records that may include yours. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are: The study sponsor, the CSU financial management team may request an audit of research expenditure, in which only your participating in the research may be shared, but not your research data. The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study. Department of Health and Human Services, the Food and Drug Administration, and similar ones if other countries are involved in the study.

National Institutes of Health (NIH) has additional protections for research they fund. Namely, they consider your data to be protected under a "Certificate of Confidentiality." This Certificate gives added protection for your privacy even if the records are subpoenaed. We will not give information to anyone unless you provide a signed release telling us to do so, or unless we have reason to suspect: 1) abuse, neglect, or endangerment of a child or elder; 2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these situations, we may have to make a report to the appropriate authorities.

If the U. S. Department of Health and Human Services (DHHS) audits our research project, they can have access to information about you. However, they cannot report it to the police or use it for any reason besides the audit. Even though a Confidentiality Certificate was issued, it does not mean that the Secretary of DHHS supports this research project.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. 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.

Participation in a focus group involves some loss of privacy. The researchers will make every effort to ensure that information about you remains confidential, but cannot guarantee total confidentiality. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study. While we will ask all group members to keep the information they hear in this group confidential, we cannot guarantee that everyone will do so.

The research team works to ensure confidentiality to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. However, your participation in this online survey involves risks similar to a person's everyday use of the internet.

If you choose to take part in this study, your private information (i.e. name, phone number, and home address) will be collected. Any identifiers linking you to your private information will be removed. After we remove those identifiers, the information collected during assessments could be used for future studies or distributed to another researcher for future research studies without your permission.

You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court OR *to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else.*

#### **DO I HAVE TO TAKE PART IN THE STUDY?**

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with CSU. You are encouraged to ask questions about this study at the beginning or any time during the research study.

#### **PARTICIPANT CONSENT**

You acknowledge that you have read the information stated and voluntarily wish to participate in this research and also that you have received, on the date signed, a copy of this document.

#### **Do you agree to participate?**

Yes

No

#### **PERMISSION TO RECONTACT**

By clicking below, you authorize permission for the researchers to contact you again in the future to follow-up on this study or to participate in new research projects.

Yes

No

#### **PERMISSION TO USE AUDIO/VIDEO/PHOTOGRAPH**

The researchers would like your permission to use your audio/video/photograph from the online intervention for research and teaching purposes. The online intervention will be video recorded. We will video record and audio record the sessions to ensure research application continuity. Video records will be used to document the intervention but will not be shared with the public.

We will also video/audio record the interview/focus group to be sure that your comments are accurately recorded. Only our research team will have access to the audio records, and they will be destroyed when they have been transcribed. If you do not wish to be audio or video recorded during the focus group, the researchers ask that you write down your responses to the questions asked.

Photos and video recording will be used for research and teaching purposes.

Please select all that apply below. If applicable, a research team member will reach out to you regarding your choices to ensure that your needs during the study are addressed.

I agree for the research group to use my audio records for teaching and research purposes.

Yes

No

I agree for the research group to use my video records for teaching and research purposes.

Yes

No

I agree for the research group to use my photographs for teaching and research purposes.

Yes

No

I agree for the research group to audio record me during focus groups.

Yes

No

I agree for the research group to video record me during focus groups.

Yes

No

I agree for the research group to photograph me during focus groups.

Yes

No

#### **ELECTRONIC SIGNATURE**

Your signature acknowledges that you have read the information stated and willingly sign this consent form electronically.

To indicate that you agree to sign electronically and that you consent to participate in the study, type your name in the space below.

Thank you for completing your electronic consent for the MY-Skills study at Colorado State University.