CONSENT FORM AND HIPAA AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

INVESTIGATOR'S NAME: TIMOTHY J. WOLF, OTD, PHD, OTR/L
PROJECT IRB #: 2015868

STUDY TITLE: EFFICACY OF METACOGNITIVE-STRATEGY TRAINING TO IMPROVE ACTIVITY PERFORMANCE AND REDUCE MOTOR IMPAIRMENT IN SUB-ACUTE STROKE

We invite you to take part in this research study. This consent form tells you why we are doing the study, what will happen if you join the study, and other important information about the study.

Please take as much time as you need to read this consent form. You can discuss it with your family, friends, or personal doctor. If there is anything you do not understand, please ask us to explain. Then you can decide if you want to take part in the study or not.

The Principal Investigator is Timothy J. Wolf, OTD, PhD. The people working with Timothy J. Wolf on this study are called the study team.

National Institute of Child Health and Human Development (called the sponsor in this form) is paying for this study.

WHAT SHOULD I KNOW BEFORE I DECIDE WHETHER TO TAKE PART IN THIS STUDY?

- Research studies help us to learn new things and test new ideas about treating certain conditions/diseases.
- Taking part in a research study is voluntary. You decide if you want to take part, and you can stop taking part at any time. Your regular medical care at the University of Missouri

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Hospitals and Clinics will not be affected now or in the future if you decide you do not want to be in this study.

- The goal of this proposed project is to evaluate the effectiveness of a treatment called the Cognitive Orientation to daily Occupational Performance (CO-OP) approach, to improve activity performance and reduce stroke impairment for individuals with stroke.
- We invite you to take part in this study because you have experienced a stroke within the last 9 months.
- About 135 people will take part in this study at the University of Missouri.
- If you take part in this study, you will come to the Department of Occupational Therapy Performance, Participation, and Neurorehabilitation Laboratory 4 times. You will have questionnaires and cognitive and physical assessments to complete. We will explain these procedures in this form.
- The total amount of time you could be in this study is about 19-24 weeks.
- Taking part in this study may or may not make your health better. We hope that the information we learn from this study will help in the future treatment of people with stroke. **There is no guarantee that taking part in this research will result in any improvement in your condition.**
- As with any research study, there are risks that we know about and there may be some we don't know about. We will explain these risks in this form.
- We will only include you in this study if you give us your permission first by signing this consent form.

WHY ARE THE RESEARCHERS DOING THIS STUDY?

The long-term goal of this research is to improve activity performance and reduce movement problems in individuals with stroke. There are two main gaps in current stroke rehabilitation practice that must be addressed to achieve this goal: (1) current movement rehabilitation approaches are not improving significant activity performance; and (2) current stroke rehabilitation interventions are often not designed to be practical and are rarely used in rehabilitation. The overall hypothesis of this proposal is that a clinically-usable, activity-based intervention, metacognitive strategy training (MCST), will produce a significant improvement a

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number of measures of activity performance and motor function in comparison to a usual care occupational therapy (OT) group.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Screening Tests

If you decide to join this study, you will sign this form and then you will have some screening tests to see if you qualify to be in the study. These are the screening tests:

- Canadian Occupational Performance Measure (COPM)
- Patient Health Questionnaire – 9 (PHQ-9)
- Montreal Cognitive Assessment (MoCA)
- Medical Chart Review: The study doctors will review your medical chart.

If the results of these tests show that you can be in the study, you will start treatment in one week**.** If you do not qualify to be in the study, the research coordinator will discuss other options with you.

Research Study Groups

This study has 2 groups. One group will do CO-OP and the other group will do usual care occupational therapy for stroke rehabilitation.

Because we don't know which of the interventions is best, we will "randomize" you into one of the 2 study groups. "Randomize" means putting you into a group by chance. It is like flipping a coin or pulling a number from a hat. You will have an equal chance of being placed in either group. A computer program chooses which group you go in. You and the Principal Investigator cannot choose which group you go into.

This study is "single - blinded", which means that the outcome assessors will not know which intervention you are getting when they score your assessments.

Study Tests and Procedures

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If you take part in this study, you will have the following tests and procedures:

- 4 assessment visits and 10 treatment visits. One to two treatments per week. The study will last for 19-24 weeks with a total time commitment between 14-15 hours as follows:
    - Baseline assessment: visit 1 (2.5 hours)
    - Baseline assessment: visit 2 (30 minutes)
    - CO-OP or usual care outpatient occupational therapy (ten, 45 minute sessions)
    - Post-intervention assessment (2 hours)
    - Follow-up assessment (2 hours)
- The visit assessments will consist of the Canadian Occupational Performance Measure, Performance Quality Rating Scale, National Institutes of Health (NIH) Toolbox Cognition Battery, Upper Extremity Fugl-Meyer, Patient Health Questionnaire- 9, Stroke Impact Scale, Life Space Questionnaire, Performance Quality Rating Scale (PQRS),
- and Patient-Reported Outcomes Measurement Information System (PROMIS) version 2 Satisfaction with Social Roles and Activities. You will also be asked to the Montreal Cognitive Assessment and the NIH Stroke Scale at the first visit only. You will also be asked to complete a contact information and demographics form at the first visit.

The information we collect from you for this study will not be used or shared with other investigators for future research studies. This applies even if we remove all information that could identify you from the data.

Individual research results will not be disclosed to you. Clinically relevant research results will only be disclosed to you if you request it and after the study has been completed, including data analysis. Any information provided will be removed of any information that could identify you.

HOW LONG WILL I BE IN THE STUDY?

You will be in this study for 19-24 weeks. The intervention will last for 5-10 weeks.
After the intervention is finished, we want to keep in touch with you to follow your health over time. We will ask you to come in to the clinic one more time, 3 months after finishing the intervention, to do the final assessment.

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CAN I STOP BEING IN THE STUDY?

You can stop being in the study at any time without giving a reason. If you stop being in the study, your regular medical care will not change. Leaving the study will not affect your future medical care at the University of Missouri.

There is no penalty to you if you do not join the study or if you leave it early. You will not lose any benefits you are entitled to if you leave the study.

If you decide to stop participating in the study, you should discuss your decision with the Principal Investigator.

The Principal Investigator may decide to take you off this study at any time, even if you want to stay in the study. The Principal Investigator will tell you the reason why you need to stop being in the study. These reasons may be:

- If it is in your best medical interest
- Your condition gets worse
- You do not follow the study rules
- The whole study is stopped
- New information becomes available about the intervention

WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE STUDY?

There are risks to taking part in any research study. There is a risk that you may get an intervention that does not help your condition. There may also be problems (also called side effects) we do not know about yet. If we learn about new important risks and side effects, we will tell you. We will tell you about any new information we learn that may affect your decision to continue taking part in the study.

Interventions can affect people in different ways. We will closely watch everyone in the study for side effects. You need to tell the Principal Investigator immediately if you have any

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problems, side effects, or changes in your health. Timothy Wolf's telephone number is (573) 882-8403.

In other studies, the side effects that other people have experienced so far with are:

- **Physical injury:** You will perform their chosen activity-related goals with trained rehabilitation personnel. Some of these goals involve physical activity (e.g., cooking), in which you could sustain a physical injury, such as a cut on the hand.
- **Randomization risks**: You will be put into a group by chance. The intervention you receive may turn out to be less effective or have more side effects than that in the other groups. It may also be less effective and have more side effects than other interventions available for stroke rehabilitation.
- **Unknown risks**: The experimental intervention in this study may have side effects that no one knows about yet. The study team will tell you if they learn anything that might make you change your mind about being in the study.

WHAT OTHER RISKS ARE THERE?

Other procedures and drugs that are part of this study might also involve some risks:

- **Breach of confidentiality:** With any research study involving human subjects, there is a possible risk of a breach of confidentiality where identifiable health information related to the subjects is inadvertently made available to individuals beyond the research team.
- There is the risk that confidentially will be initially broken if during the PHQ-9 interview, the participant indicates they have considered the following over the last two weeks, "Thoughts that you would be better off dead, or of hurting yourself in some way," their treating physician will be notified. The interviewer will also give the participant mental health resources, including a psychiatrist and psychologist contact information. If someone states they have intentions of hurting themselves we will encourage them to go to the emergency room for immediate support and care. If necessary, security will be called to escort them to the emergency room.

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- **Psychological distress**: In rare circumstances, subjects may experience psychological distress while discussing changes in their abilities following stroke.
- There is the low risk that some questions during testing may make the participant feel bored or frustrated.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may potentially experience benefit from participating in either the CO-OP intervention or from usual care outpatient occupational therapy by performing the activities addressed in treatment better and/or experiencing less stroke-related impairment (e.g., motor impairment). The potential benefits definitely outweigh the risks. The potential benefits of this study could also extend to your family members and friends through decreases in caretaker burden as a result of potential gains in function on the part of the subject.

We hope that in the future other people might benefit from this study because it will help health care professionals determine the best intervention and assessment methods to use for persons with stroke in order to improve their ability to participate in everyday life activities and/or reduce stroke-related impairment, e.g., motor impairment. This study can help address this very important clinical issue.

WHAT OTHER CHOICES DO I HAVE?

You do not have to take part in this study. You are free to say yes or no. If you do not want to join this study, your doctor will discuss other choices with you.

Your other choices include:

- Joining another research study
- Not joining this study and continuing your regular medical care

The Principal Investigator can discuss the possible benefits and risks of the other options available to you.

WHAT ABOUT PRIVACY AND CONFIDENTIALITY?

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The study team needs to access and collect some of your health/personal information. This information comes from questions we ask you, forms you fill out, and your medical record. One risk of taking part in a research study is that more people will handle your personal health information. We are committed to respecting your privacy and to keeping your personal information confidential. The study team will make every effort to protect your information and keep it confidential to the extent allowed by law. However, it is possible that an unauthorized person will see it.

State and federal privacy laws (HIPAA) protect the use and release of your health information. If you decide to take part in this study, you also give us your permission to use your private health information, including the health information in your medical records and information that can identify you.
You have the right to refuse to give us your permission for us to use your health information. However, doing so would mean that you could not take part in this study.

The following identifiers will be obtained from your health records:

- ☒ Name
- ☒ Address
- ☒ Dates related to you
- ☒ Telephone number(s)
- ☐ Fax Number
- ☒ Email Address
- ☐ Social Security Number
- ☒ Medical Record Number
- ☐ Health Plan Beneficiary Number
- ☐ Account Numbers
- ☐ Certificate or License Numbers
- ☐ Any vehicle or device serial number
- ☐ Web Address (URL)
- ☐ Internet Protocol (IP) Address(es)
- ☐ Biometric Identifiers (finger/voice print)
- ☐ Photographic images
- ☐ Any other characteristic that could identify you

The following is the type of protected health information that will be used in the study:

- ☒ Radiology Images
- ☒ Discharge Summaries
- ☒ Radiology Reports
- ☒ Health Care Billing or Financial Records
- ☒ EKG Recordings/Reports
- ☐ Consultations
- ☒ Progress Notes
- ☒ Medications

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☒History and Physical Exams
☐Operative Reports
☐Pathology Reports
☐Laboratory Reports
☐Photographs/Video Recordings
☐Emergency Medicine Reports
☐Dental Records
☒Demographics (age, race, etc.)
☒Questionnaires, Surveys, Diaries
☐Audio Recordings

☒Social Security Number (This is only collected for billing/payment purposes and will not be shared with the study sponsor)
☐Other:

We may share any of this information with the following:

- Authorized members and staff of the University of Missouri Institutional Review Board (IRB).
- Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
- Study monitors and auditors who make sure that the study is being done properly.
- National Institute of Child Health and Human Development, who is sponsoring the study, and their contractors and partners.
- University of Missouri Department of Occupational Therapy

Any research information shared with outside entities will not contain your name, address, telephone or social security number, or any other personal identifier unless it is necessary for review or required by law.
The people who get your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

Your permission for us to use and/or release your information will last until the end of the study unless you cancel your permission.

You can cancel your permission at any time by writing to:

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Institution: University of Missouri
Department: Occupational Therapy
Address: 810 Clark Hall, Columbia, MO 65211

The information we have already collected may still be used for this research study, but we will not collect anymore information after we receive your letter.

You will not be allowed to access your protected health information that is obtained or created during this research project until the end of the study.

If you have not already received a copy of the University of Missouri Healthcare Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights, you may contact the Privacy Officer at 573-882-9054.

Information collected will be stored in the investigator's electronic/computer or paper files. Computer files are protected with a password and the computer is in a locked office that only study team members can open. Paper files are kept in a locked drawer in a locked office that only study team members can open.

Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location. Information that may identify you may not be given to anyone who is not working on this study without your written consent, or if required by law.

The people who may use and/or release your research information include:

- Those working on the study team at the University of Missouri
- The study sponsor, National Institute of Child Health and Human Development
- The members of the University of Missouri Institutional Review Board (IRB)
- Those who check on research activities to make sure it is being done correctly and safely
- Other government or inspection agencies

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We will collect information from you that indicate the possibility of intent to harm yourself or others. One or more of the study staff are mandated reporters. This means that they are required by law to report any of these findings to the appropriate state agencies. These agencies include your treating physician and if necessary, University of Missouri Security.

If the study investigator is not your regular doctor, he/she must ask your permission before contacting your regular doctor for your health history.

We may present the results of this study in public talks or written articles, but we will not use information that can identify you.

You must give us permission to use the video recordings we take of you during the study. Video recordings will not contain anything that might identify you, except for your image and voice.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.
The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the University of Missouri or National Institute of Child Health and Human Development, which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer,

medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of self-reported intention of harm yourself or others.

ARE THERE ANY COSTS TO BEING IN THE STUDY?

There is no cost to you for taking part in this study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

You will receive $340.00 over the course of the study:

- $60.00 for Baseline assessment: 1st visit
- $10.00 for Baseline assessment: 2nd visit
- $10.00 for each of the 10 treatment visits (totaling $100.00)
- $60.00 for Post-intervention assessment
- $110.00 for Follow-up assessment

$10.00 will be provided for each treatment session, unless transportation is required, this $10.00/session AND assessment will be utilized to schedule and pay for transportation to/from study location.

If transportation is required for a participant, payment is as outlined below

- Baseline Assessment 1st visit ($50.00)
- Post-intervention assessment ($50.00)
- Follow-up Assessment ($100.00)

A teared approach to payment will be implemented for participants living outside of Boone County, outlined below:

- Individuals living outside of 50-mile radius from the University of Missouri will receive $20 per treatment visit, excluding assessments
- Individuals living outside of a 100+ mile radius from the University of Missouri will receive $40 per treatment visit, excluding assessments

Example:

- Baseline assessment 1st visit ($60.00)
- Baseline assessment 2nd visit ($20.00/$40.00)
- Treatment visits ($20.00/$40.00 per 10 treatment visits, totaling $200.00/$400.00)
- Post-intervention assessment ($60.00)

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- Follow-up assessment ($110.00)

The payments will be in the form of a University issued check mailed to your home within 2 to 3 weeks of each assessment completion date. If you decide to leave the study early, you will still receive a payment for each visit you completed.

We will need your social security number in order to pay you. Any payment may need to be reported as income on your tax return. If you are not a resident/citizen (non-resident alien) of the United States, you will need to work with the MU Nonresident Tax Specialist at 573-882-5509.

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What Happens If I am Injured During The Study?

In the rare circumstance that physical injury occurs, first aid will be rendered and/or the subject will be transferred to the emergency department (if necessary). The incident will be reported to Dr. Joseph Burris, the medical monitor for this study, who will make a determination as to whether or not continued participation in this study is safe for you.

In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information.
This statement is not to be construed as an admission of liability.

What Are My Rights as a Study Participant?

Taking part in this study is voluntary. You do not have to take part. Your present or future medical care will not be affected if you decide not to take part.

If you do decide to take part, you can change your mind and drop out of the study at any time. This will not affect your current or future care at the University of Missouri Hospitals and Clinics. There is no penalty for leaving the study and you will not lose any benefits that you are entitled to receive.

If the study investigator decides to take you off the study, he will explain the reasons and help arrange for your continued care by your own doctor, if needed.

We will tell you about any new information discovered during this study that might affect your health, welfare, or change your mind about taking part.

Where Can I Get More Information About This Study?

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A description of this clinical trial is available on www.ClinicalTrials.gov (ID: NCT04099511), 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.

Who Can Answer My Questions About The Study?

If you have more questions about this study at any time, you can call Dr. Timothy Wolf at (573) 882-8403.

You may also contact the University of Missouri Institutional Review Board (IRB) if you:

- Have any questions about your rights as a study participant;
- Want to report any problems or complaints; or
- Feel under any pressure to take part or stay in this study.

The IRB is a group of people who review research studies to make sure the rights of participants are protected. Their phone number is 573- 882-3181.

If you want to talk privately about your rights or any issues related to your participation in this study, you can contact University of Missouri Research Participant Advocacy by calling 888-280-5002 (a free call), or emailing MUResearchRPA@missouri.edu.

We will give you a copy of this consent form. Please keep it where you can find it easily. It will help you to remember what we discussed today.

Signature Of Study Participant

My initials below indicate my choice about using my data for future research:

My data may be stored and used for future research.

Yes _____ No _____

Consent to Participate in Research

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By signing my name below, I confirm the following:

- I have read/had read to me this entire consent form.
- All of my questions were answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits were explained to me.
- I voluntarily agree to take part in this research study. I have been told that I can stop at any time.

Subject's Signature	**Date**

Signature of Witness (if applicable)*	**Date**

**A witness is required when a participant is competent to provide consent but is blind, or cannot read or write.*

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