Consent Form (includes HIPAA Authorization)

Title of Research Study: Mechanisms of a Dynamic Stability Approach

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Corey McGee **Investigator Departmental Affiliation**: Occupational Therapy **Phone Number**: 612-626-5645 **Email Address**: mcge0062@umn.edu	**Study Staff**: Karin Burbach **Phone Number**: 612-624-5781 **Email Address**: kburbach@umn.edu

If your therapist is also the person responsible for this research study, please note that they are interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the National Institutes of Health's National Center for Advancing Translational Sciences, grants KL2TR002492 and UL1TR002494 and the Program in Occupational Therapy.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Health care providers and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you were referred to occupational therapy for thumb carpometacarpal osteoarthritis and you are 18 years or older.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Arthritis is the leading cause of disability in the United States, with an estimated 25.6 million Americans affected by osteoarthritis (OA) of the hand. Thumb carpometacarpal osteoarthritis (CMC OA) is the most common and limiting form of hand osteoarthritis, causing chronic pain, weakness, reduced joint movement, and difficulty carrying out common daily tasks.

The purpose of this research study is to find out if an 8-week dynamic stability program can help people with a range of CMC OA severity and symptoms.

Dynamic stability (DS) is a new occupational therapy program that uses a series of exercises to strengthen specific muscles around the thumb CMC joint. By strengthening these muscles, the DS approach aims to reduce joint pain, delay further damage, and improve function and participation in daily activities.

How long will the research last?

We expect that you will be in this research study for 9 weeks, for a total of about 15 hours of participation. You will have 4 occupational therapy (OT) study visits (about 60 minutes each), 2 assessment visits (at baseline and 9 weeks) where we will using a computerized tomography (CT) device, a type of Xray, and ultrasound to take measures of your affected joint and have you complete questionnaires related to pain and disability, and will be asked to do home exercises for 8 weeks.

What will I need to do to participate?

You will be asked to come in for 6 study visits and do a series of exercises at home:

- 2 in-person assessment visits: You will be asked to complete questionnaires and a CT scan and ultrasound (for the baseline and 9 week visit) of your affected joint will be performed.
- 4 in-person OT study visits: Your therapist will teach you exercises for home.
- 8 weeks of home exercises.

Screening, consenting, and all interventions will be carried out at The University of Minnesota Health's Clinics and Surgery Center. Both assessments will occur at the Center for Clinical Imaging Research. All treatments are part of your routine care and will be billed to your insurance. The sonographic assessments and CT scans will not be billed to your insurance.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

You may experience some mild hand fatigue and muscle aches for 2-3 days following study visits and at the onset of the home exercises, because of the repetitive nature of the tasks involved.

Questionnaires: You will be asked to give some information that sensitive in nature; this may make you feel uncomfortable. Just let the study team know and you can skip any questions that you do not want to answer.

CT and Pregnancy: This procedure involves ionizing radiation. There are risks with this procedure and pregnancy. If you are pregnant or think you may be pregnant, you won't be able to participate in the study.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include the reduction of pain, learn new ways to manage your hand osteoarthritis, and reduce your experience with disability.

What happens if I do not want to be in this research?

You do not have to participate in this research. Instead of being in this research study, your choices may include participating in occupational therapy services not linked to this study or choosing to decline occupational therapy altogether.

There are no risks associated with participating in non-study-related occupational therapy.

Detailed Information about This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 50 people will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

You will be asked to do the following:

Attend Therapy Visits: (Weeks 1, 3, 5 & 7)

You'll attend four 60-minute occupational sessions over an 8-week period. These visits will focus on teaching you the exercises for your home program.

Home Program: (Weeks 1-8)

You'll be asked to perform a series of exercises daily (5x/week) for 8 weeks. This will take about 15-20

minutes per day. You'll also be asked to complete weekly exercise logs.

Assessment Visits: (Baseline, and Week 9)
CT: Will be performed by the study team, which is a type of x-ray that makes a real-time image of the movements inside a part of the body. We will be using CT to take measurements of your affected joint. You'll be asked to position your hand in 4 different ways while making a pinching motion. Each CT session is expected to take 20 minutes.

Ultrasound: Will be performed by the study team, we will use an ultrasound machine to take additional measurements in the 4 same positions. These measurements will help us look for changes in your joint before, during, and after your therapy program. This will be done at your baseline and 9 week visit only.

Questionnaires: You will be asked to complete questionnaires about your thumb-related pain and disability.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for: Attending the study visits and completing study questionnaires.

What happens if I say "Yes", but I change my mind later?
If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care or future employment.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

If you stop being in the research, information about you that has already been collected may not be removed from the study database. The data that has been collected will be securely stored and analyzed.

We will ask for you to consider allowing us to collect data on your medical outcomes related to this study. If you agree, a ***Consent Collection after Withdrawal form*** will be given to you to review and sign.

Can I be removed from the research?
It's possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)
Privacy & Confidentiality Risks
There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

It may be necessary for the researcher to touch your hands or sides to ensure that you are in the correct

positions. This may make some participants feel uncomfortable.

Radiation Risks- CT scans
Radiation-related risks associated with CT scans include possible burn to the skin, which occur shortly after the exposure, and radiation-induced cancers, which may occur sometime later in life.

As part of this study, you will undergo up to 8 individual CT scans of the wrists. These procedures involve exposure to ionizing radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The average amount of radiation that the average person would receive from these procedures is approximately 2% of that received from natural sources of radiation by a Minnesota resident in one year (3 mSv).

If you are pregnant or nursing, you cannot be in this research study. If you are nursing a baby, please tell your doctor. If you join in this study, you should use contraception to keep from getting pregnant while you are in the study. If you get pregnant while you are in this study, or if you think you are pregnant, please tell the study doctor right away.

You may not be eligible if you have participated in any other study within the past 12 months. You are responsible for letting the investigator know, before you enroll in this study, if you have participated in another study.

Will it cost me anything to participate in this research study?

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

If your insurance will not pay for the costs associated with the fluoroscopic assessment, the study team will cover the costs. Note that unlike a standard of care diagnostic x-ray, this fluoroscopic assessment will not be interpreted by a radiographic technologist.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and

shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission to be collected and used by study teams as part of the research study you are participating in.

If the research study you are participating in requires the sensitive information below, the "Applicable" box will be marked by the study team and you will be asked to indicate whether you permit or refuse the collection of this information by the research team, as described in the Consent Form, by providing your initials next to the correlating statement. Note, if you refuse the collection of this information, you may not be able to participate in the study. Please let the study team know if you have any questions about this.

If the research study you are participating in will <u>not</u> be collecting the sensitive information below, the N/A box <u>will be marked by the study team</u> and you will be asked to provide your initials under "**N/A"** next to the correlating statement.

Note: Initials must be obtained for each line item to acknowledge either 1) permission or refusal granted to collect the applicable information or 2) non applicability. Furthermore, if any of the sensitive health information becomes relevant at any point in the study (i.e. changing from

"N/A" to "Applicable"), study teams are required to update this section accordingly and request that participants complete and sign the entirety of this form again.

Checked by Study Team			Initialed by Research Participant		
Yes (Applicable to study)	**N/A (Not applicable to study)**		**Yes (willing)**	**No (unwilling)**	**N/A (Not applicable to study)**
☐	☒	My drug and alcohol abuse, diagnosis and treatment records	_____	_____	_____
☐	☒	My HIV/AIDS testing records	_____	_____	_____
☐	☒	My genetic testing records	_____	_____	_____
☐	☒	My mental health diagnosis/treatment records	_____	_____	_____
☐	☒	My sickle cell anemia records	_____	_____	_____

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

- If you agree to participate in this research study, a signed copy of this consent document and the HIPAA authorization form *may* be filed in your electronic medical record (EMR) and your study participation *may* be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or within preceding three years child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

- *More information about Minnesota's Reportable Disease Rule:
  - FAQ Link: chrome-https://www.health.state.mn.us/diseases/reportable/rule/hippacomm.pdf
  - List of diseases: chrome-https://www.health.state.mn.us/diseases/reportable/rule/poster.pdf

What will be done with my data when this study is over?

We will use and may share data for future research. They may be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also 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, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

A description of this clinical trial is available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include your name or any other direct identifiers such as your contact information. The Web site may include a summary of the results of this research. You can search this Web site at any time.

Will I receive research test results?

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

To reach the research team: Please see the "Investigator Contact Information" section at the beginning of this form.

To reach someone outside of the research team: This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid,

emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you $25 for each study visit you attend (up to 7 visits for a total of $175) for your time and effort. You will be paid after each study visit. We will also compensate you an additional $6/visit for parking.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, date of birth, and social security number. They will use this information only as part of the payment process. Greenphire will only need your social security number if the payment exceeds $599. Greenphire will not receive any information about your health status or the study in which you are participating.

Additionally, you will have the option to receive updates related to appointment reminders and payment reminders and updates via text message and email message (Standard text messaging rates will apply). You will have the opportunity to opt-in to receive these messages, you are not required to provide your cell phone or email address to be enrolled in the study or use a ClinCard. If you choose to receive messages and decide at a later date that you want to stop these messages, you will have the ability to opt-out. If you choose to receive any communications via texts or emails, you will be asked to sign a separate form.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Optional research activity

The research study that you are participating might have optional research activities associated with it, meaning that you do not have to agree to these activities in order to participate in the research study. Please indicate your willingness to participate in these optional activities and authorize use of your information from these optional activities as described below by placing your initials next to each activity.

If the research study you are participating in has optional research activities associated with it, the "**Applicable**" box will be marked by the study team and you will be asked indicate whether or not you are willing to participate in these optional activities by providing your initials next to the correlating statement.

If the research study you are participating in will not have optional research activities associated with it, the N/A box will be marked by the study team and you will be asked to provide your initials under "**N/A"** next to the correlating statement.

Checked by Study Team			**Initialed by Research Participant**		
Yes (Applicable to study)	**N/A (Not applicable to study)**		**Yes (willing)**	**No (unwilling)**	**N/A (Not applicable to study)**
☐	☒	The investigator may audio or video record me to aid with data analysis. Recordings will not be shared outside of immediate study team.	_____	_____	_____
☐	☒	The investigator may audio or video record me for use in scholarly presentations or publications. Recordings will be shared broadly for these purposes and my identity may be shared as part of this activity	_____	_____	_____
☒	☐	The investigator for this research may contact me in the future to see whether I am interested in participating in other research studies conducted by the investigator.	_____	_____	_____
☒	☐	I would like to receive reminders using Greenphire.	_____	_____	_____
☒	☐	The investigator may continue to collect information from my medical records if I withdrawal from the study for up to 12 weeks.	_____	_____	_____

SIGNATURES:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent