INFORMED CONSENT

Tracking post-stroke gait improvements from the clinic to the home

Invitation to Participate:
You are invited to participate in a study to understand how people who have had a stroke walk in the clinic and the home. We will also assess which factors influence real-world walking after stroke to guide treatment strategies. This study is being conducted by Dr. Kendra Cherry-Allen, PhD, DPT, PT in the Department of Physical Therapy at Western University.

Basis for Subject Selection:
We are recruiting two groups of people.

- Group 1: Approximately 25 people who have had a stroke will be recruited for this study.
- Group 2: Approximately 25 people who have not had a stroke will also be recruited.

If you have been invited to participate in **Group 1**, you:

- have had a stroke more than six months ago
- are able to walk with or without an assistive device (e.g., cane, walker)
- have a walking deficit including step asymmetry (unequal step lengths)
- have normal or corrected normal vision
- and live in the community.

If you have been invited to participate in **Group 2**, you:

- have not had a stroke
- are able to walk with or without an assistive device (e.g., cane, walker)
- have normal or corrected normal vision
- and live in the community.

If you have been invited to participate in either group, you will be excluded from the study if you have:

- other neurological conditions
- aphasia limiting comprehension of task instructions
- pregnancy
- uncontrolled hypertension (>150/90 mmHg at rest)
- dementia
- cognitive impairments, or psychiatric disorders limiting the ability to provide informed consent
- orthopedic issues including or pain limiting walking ability
- currently receiving physical therapy or participating in other research study.

Overall Purpose of Study:
A chief goal of rehabilitation after stroke is to improve a person's mobility and walking *in their home and community*. This project uses new video-based movement tracking technology to begin to 1) compare the walking patterns of persons post-stroke as

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observed in-clinical versus in-home settings, and 2) understand how long walking improvements achieved in the clinic last when patients go home. This study will allow us to better understand how people with stroke walk in the real-world and how we can improve it.

Data from a group of people without stroke (Group 2) will allow us to better understand whether our findings are specific to the history of stroke, or universal differences experienced based on whether walking is taking place in the clinic vs in the home.

Explanation of Procedures:

Study Procedures

1) Eligibility Screening (Group 1 and Group 2)
   First, you and a member of the study team will be in contact to confirm your interest in learning more about the study. The study team member will explain the study procedures. If you still express interest, the study team member will review inclusion and exclusion criteria with you to determine if you are eligible. This screening may take place over the phone, over email, or in-person. If eligibility criteria are met, and you are interested in enrolling, a member of the study team will schedule your visits, and review this informed consent form. No data will be collected or stored until you have signed the informed consent form.

2) Clinical Examination (Day 1) (Group 1 and Group 2)
   The clinical examination will take place in the clinical laboratory, in a private and accessible room. It will be conducted by a licensed physical therapist and will last approximately 1.5-2 hours. This examination will include a battery of standardized motor, sensory, and psychosocial assessments.

3) Clinic/Laboratory video recording of movement (Group 1 and Group 2)
   The PI or a member of the study team will use a 1-2 stationary tablet(s) or smartphone(s) to record a video of you as you walk in the clinical laboratory for 2 minutes. The recording device will either be the participant's own device or a device designated for laboratory use only. Between set-up, 2-minute walking period, and video transfer, we anticipate walking assessments to take approximately 15 minutes.

4) Home video recording of movement (Group 1 and Group 2)
   You or a member of your household will be trained to use a single stationary tablet or smartphone to record a video of you as you walk in your home for 2 minutes A member of the research team will be available virtually during the walking assessment for safety and to troubleshoot any technical difficulties that arise in video recording or video transfer. If you are unable to record your own videos, members of the study team are able to assist you in your home. Between set-up, 2-minute walking period, and video transfer, we anticipate walking assessments to take approximately 15 minutes.

5) Fitbit Step Counter (Group 1 and Group 2)

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You will be asked to wear a Fitbit step counter for up to one week. This device will be worn on your non-paretic (Group 1) or dominant (Group 2) ankle. You will be instructed in how to take it on and off and will be permitted to remove it during showers, sleeping, or as needed for skin checks or due to discomfort. Ideally you will wear this device near full-time during waking hours. The device will be returned to study personnel upon the completion of your participation in the study.

6) Walking training (Group 1 only)
You will engage in five, 2-minute periods of step symmetry training during session 2. Two-minute sitting rest breaks will be given between training blocks or at your request. Training will be conducted by the PI, a licensed physical therapist with expertise in post-stroke gait rehabilitation. A video recording will be taken of the first and final two minutes of training. Step Symmetry Training, including active bouts of walking and rest breaks, will take approximately 30 minutes to complete.

Location of study procedure elements

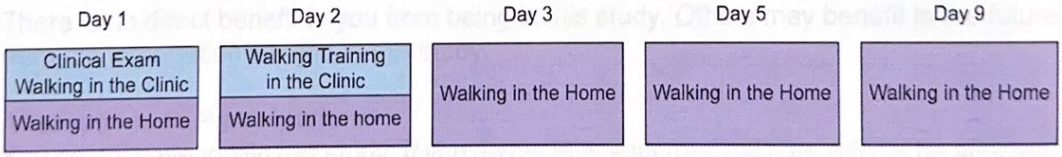
The clinical examination, clinic/laboratory video recording of movement, and walking training will take place either at the laboratory (2665 S Santiam Highway Lebanon, OR 97355) or at a community clinic/center/studio that mimics the clinic environment (e.g., rented studio space at University of Oregon).

The home video recordings and wearing the Fitbit will take place at your own home.

Timeline of study procedures/time commitment

You will be in this study for no longer than 10 days. Group 1 will have two days where you come to the clinical laboratory (Day 1 and Day 2). Group 2 will only have one day where you come into the laboratory (Day 1). There are five days that you will record videos of your walking in the home (Days 1, 2, 3, 5, 9). The duration of on-site study visits can vary from about 30 mins to 2 hours, with most visits lasting about 1.5 hours. The duration of in-home aspects of the study will be between 15-30 minutes, including time for video recording set-up.

Green = in the clinic
Purple = at home



Potential Risks and Discomforts:

The risks associated with this study are minimal and do not exceed the risks of general movement of physical activity in daily life. Risk involved includes,
Fall risk: Investigators/physical therapist will monitor you throughout the study and interventions sessions. Safety precautions will be taken to avoid falls and fall injuries. You will use the assistive devices you use during your daily life in addition you will wear

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a gait belt and be closely guarded by a licensed PT during the session. The environment will be set up to optimize safety both onsite and at home. Families and caregivers will be trained to safely guard you. You will be instructed to exercise only when your family members or caregiver are around and you have a phone within reach.

Cardiovascular Risk, Exercise Tolerance and Fatigue/discomfort: We anticipate these risks mainly during the training part of the You will be trained individually, and the PT/trainer (member of the research team) will modify the exercise intensity based on your endurance and exercise tolerance. PT will periodically ask you to report rating of perceived exertion (RPE) and monitor HR and BP, and in case of reported RPE greater than 16 and or BP > 170/110 mmHg. You will be given a rest break and the exercise will be resumed after the reported RPE is less than or equal to 12 and BP and HR return to baseline. You will also be given rest breaks upon request and will be provided multiple opportunities for hydration. For Home Exercise Program, you will be encouraged to monitor yourself or have a family member monitor you with a home BP cuff and stop exercising if any of the symptoms listed under red flags appear. All researchers and therapists will be AED trained and the equipment will be available at the study site.

Mentally tired or bored: Participation in the assessment including questionnaires might be associated with mental tiredness or boredom. You can stop participation at any time.

Embarrassment: Investigators will educate you about the benefits of exercise program and encourage you to perform the exercises to the best of your ability. Individualized training sessions will be conducted in a private area.

Loss of confidentiality: As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure your personal information to ensure confidentiality. At the time of participation, you will be assigned a study identification number. This number will be used on data collection forms and in the database instead of names and other private information. A separate list will be maintained that will links each participant's name to the study identification number for future reference and communication.

Potential Benefits:
There is no direct benefit to you from being in this study. Others may benefit in the future from the information we find in this study.

Alternatives to Participation:
You do not have to join this study. If you do not join, your medical care will not be affected. If you are an employee or student at Western University of Health Sciences and do not join, your employment/education at the Western University of Health Sciences will not be affected. Participants seeking long-term help with their mobility may wish to pursue clinical physical therapy with their health care team.



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You can agree to be in the study now and change your mind later. If you wish to stop, please tell us right away. Leaving this study early will not stop you from getting regular medical care. If you are an employee or student at the Western University of Health Sciences, leaving this study early will not affect your employment/education. If you leave the study early, Western University of Health Sciences may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

Compensation for Participation:
It will not cost participants anything to be in this study. Participants are volunteers only and there is no compensation associated with this study.

Assurance of Confidentiality:

We will do everything that we can to avoid a loss of confidentiality. First, we will take away personal health information (PHI) from our experimental records and give you a code number. Any data that is deemed protected health information (PHI) or that personally identifies study participants will be stored on the University's OneDrive, a secure HIPPA-compliant database. De-identified data will be stored in a manner appropriate for protecting against inappropriate and unauthorized disclosure. Specifically, all written and digital data will be stored in a locked room that is only accessible to authorized study personnel. Photos or images will be modified to eliminate the possibility that study participants can be identified. All digital data will be stored on a secure computer protected by appropriate network restrictions and security software. These data will also be archived on local hard drives within the lab. When any personnel leave the study, their right to access any protected data will be terminated. At the conclusion of the study, all data will be retained for study record keeping in accordance with institutional policy at Western University of Health Sciences.

Data and records created by this project are the property of the University and the investigator. You may have access to information collected on or about you by making a written request to the principal investigator. This right of access extends only to information collected on or about you and not to information collected on or about others participating in the project.

Statement of Injury or Special Costs:
In the event that this research activity results in an injury, you should contact Dr. Cherry-Allen at the following telephone number(s) 541-259-0473. Treatment will be available, including first aid, emergency treatment and follow-up care as needed. You and your third party payer (such as health insurance, Medicare) must provide payment for any such treatment. This paragraph does not mean that you are releasing or waiving any legal right you might otherwise have against the investigator or WESTERNU as a result of your participation in this research activity.



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Withdrawal from the Study:
Your participation is voluntary. Your decision whether or not to participate will not affect your treatment nor your present or future relationship with the university or healthcare providers. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time. Any significant new findings developed during the course of the study that may relate to your willingness to continue participation will be provided to you. The investigator may terminate your participation before study completion if you experience an adverse reaction or no longer meet eligibility criteria (e.g. resting blood pressure elevates beyond inclusion safety parameters), or if concerns for your safety develop.

Offer to Answer Questions:
You should feel free to ask questions now or at any time during the study. If you have questions about this study, you can contact Dr. Kendra Cherry-Allen (541-259-0473; kcherryallen@westernu.edu). If you have questions about the rights of research subjects, contact the WESTERNU IRB Office, (909) 469-5606.

Consent Statement:
You are voluntarily making a decision whether or not to participate. Your signature indicates that you have decided to participate, having read the information provided above. You will be given a copy of this consent form to keep.

I have read this information, which is printed in English. This is a language that I read and understand.

_____
Printed Name of Subject

_____ _____
Signature of Subject Date

_____
Printed Name of Consenting Investigator

_____ _____
Signature of Consenting Investigator Date



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