Digital Home Exercise Program Versus Standard of Care for Chronic OA-related Knee Pain: a Non-inferiority Randomized Controlled Trial

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STUDY INFORMATION:

Study Title: Digital home exercise program versus standard of care for chronic OA-related knee pain: a non-inferiority randomized controlled trial

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai Beth Israel/Mount Sinai Union Square

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SUMMARY OF THIS RESEARCH STUDY:

This document explains the screening process for a research study you might be interested in joining. This is a prescreening informed consent. If you meet the requirements for inclusion, and choose to participate, you will then sign a full informed consent form. Participation in this screening process is completely voluntary. You can decide to provide permission or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

We are conducting a clinical research study to investigate whether a remote physical therapy program is as effective as traditional in-person physical therapy (PT) in reducing chronic knee pain in people with mild to moderate osteoarthritis. This research will help clinicians and healthcare software developers make knowledgeable advances in developing technology-delivered physical therapy.

Confidentiality: All information obtained will be kept strictly confidential and used solely for this prescreening in accordance with HIPAA regulations.

Your Choice: You have the right to refuse to provide access to your medical records. Your decision will not affect your current medical care.

If you choose to take part, you will be asked to provide us with the following information: name, contact information, date of birth, and/or medical record number. We will use this information to contact you and access your medical records to confirm your diagnosis of Knee Osteoarthritis by your physician and determine your eligibility for participation in our study.

If you choose to take part, the main risk to you is loss of private information: this risk always exists, but there are procedures in place to minimize the risk.
You will not benefit directly from taking part in this prescreening.

Instead of taking part in this research, you may obtain physical therapy outside of our research, and cortisone injections are among the options that exist. Potential risks associated with these alternative treatments are minimal.

If you are interested in learning more about the prescreening process for this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you have clinical indications for Knee Osteoarthritis and were recommended by your physician to attend physical therapy for pain relief.

We require access to your medical records to review relevant health information to determine if you may be eligible to participate. If you choose to participate in this prescreening process to determine your eligibility to participate, the information that will be accessed is described below**.**

Information that will be accessed from your medical record will include imaging reports such as x-rays, and MRIs of your knee and medical diagnoses including Knee Osteoarthritis and others related to our study according to the inclusion and exclusion criteria as follows.

Inclusion Criteria:

- Diagnosis of mild to moderate Knee Osteoarthritis (OA) by a medical doctor
- Adults (age ≥ 18 years)
- Living in the tristate area - CT/NY/NJ
- Are able to walk

- Chronic knee pain (>3 months) as a primary pain complaint
- Average pain score ≥ 4 on an 11-point numeric rating scale at baseline

Exclusion Criteria:

- Prior documented history of cognitive impairment
- History of total Knee Replacement Surgery
- History of Inflammatory arthritis (e.g., rheumatoid arthritis)
- Nerve pain affecting the legs, spinal cord injury, spine fractures
- Problems of moving your legs
- Surgery or invasive procedure within the last 90 days
- [1]Knee arthroscopy within 90 days
- Fall within 90 days
- High risk of fracture
- History of knee injury, within the last 3 months
- Currently engaged with other PT or knee strengthening program
- Show signs of an unstable/uncontrolled cardiovascular condition, advanced heart disease, bleeding issues (e.g., hemophilia)
- Undergoing active chemotherapy

There are 225 people expected to take part in this research study at Mount Sinai Hospital and Mount Sinai Union Square.

Funds for conducting this research study are provided by SimpleTherapy® Inc. under the clinical trial agreement with the Abilities Research Center at Mount Sinai Hospital. SimpleTherapy® is the company that will be providing the remote therapy being tested in this study, via their app.

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.

DESCRIPTION OF WHAT IS INVOLVED:

[1] Knee arthroscopy is a surgical procedure that allows doctors to view the knee joint without making a large incision (cut) through the skin and other soft tissues. Arthroscopy is used to diagnose and treat a wide range of knee problems.

If you choose to participate in this prescreening process to determine your eligibility to participate, your medical record will be accessed for eligibility purposes described above.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of additional information about you, discuss how your private information, study data might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If "Yes", please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone [ ] Letter [ ] Text

USE OF YOUR DATA

The research team will never use or share your personal information (such as, name, address, date of birth, medical record number), or any data that are collected as part of this study for future research, even if your identity is removed. Your data will only be used to complete this study and then they will be destroyed.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

You will need to sign this consent form which will allow the study team to review your medical records in order to confirm you may be eligible to participate in the clinical trial. If, after the medical chart review, the team determines you may be eligible, you will sign an additional consent form that will go into greater detail about the clinical trial.

By signing this consent form, you are not consenting to participate in the clinical trial, you are consenting to a review of your medical chart.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for taking part in this prescreening process.

POSSIBLE RISKS AND DISCOMFORTS:

Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

OTHER OPTIONS TO CONSIDER:

You may decide not to agree to participate in this prescreening and not participate in the research study and follow standard of care for Knee Osteoarthritis (OA) as recommended by your specialist.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may revoke your permissions for the obtainment and storage of your health information at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or any benefits to which you are otherwise entitled. If you decide to stop screening for this study, please contact the Principal Investigator or the research staff.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data have already been shared with researchers, those researchers will be asked to stop using them. However, if any data that have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data that have already been used will not be affected by your decision. If your data have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

Withdrawal without your consent: The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher at phone number *212-824-8369.*

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.
The company sponsoring this research study manufactures the programming being tested and has a financial interest that could be affected by the outcome of this research study.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, email, telephone number, and age. The researchers will also get information from your medical record provided by our study physicians.

During the prescreening, the researchers will gather information by:

– Reviewing and/or taking your medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.
- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.)

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- The commercial sponsor and/or their representative (who will use the results for submissions to the Food and Drug Administration (the government organization that approves drugs or devices for medical use): SimpleTherapy®® Inc.

*A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.*In all disclosures outside of Mount Sinai, you will not be identified by name, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead

Researcher will ensure that the key to the code will be kept in a locked file,or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?: Your authorization for use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will not be able to access your medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used

or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

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

ADULT PARTICIPANT:

Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

Signature of Participant	Printed Name of Participant	Date	Time
_____	_____	_____	_____

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time
_____	_____	_____	_____