TELEYOGA FOR CHRONIC LOW BACK PAIN: A QUANTITATIVE AND QUALITATIVE STUDY

10/10/2025

KUMC

Please please reach out if you have any questions at all or would like to hop on a phone call to discuss this consent form. I am more than happy to assist.

RESEARCH CONSENT FORM

Feasibility of TeleYoga for Chronic Low Back Pain: A Quantitative and Qualitative Study

Primary Investigator: Neena Sharma, PT, PhD
Contact: 913-588-4566

- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called "informed consent."
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

Dr. Neena Sharma is doing the study at the University of Kansas Medical Center (KUMC). About 40 people will be in the study.

Why is this study being done?
Chronic low back pain is a common condition in the world. About 85% of people with chronic low back pain do not know the cause of their pain. This leads to ineffective treatments. Through this study, we hope to gain a better understanding of how effective virtual therapies are at treating chronic low back pain.

How long will I be in this study?
The study will last 4 weeks.

What will I be asked to do?
Screening:

- We will ask a series of questions via phone call to determine if you are eligible for this study.
- If you are eligible for this study, you will be asked to consent

Initial Measurements
If you are eligible and decide to participate in this study, your participation will last for approximately 4 weeks once you are able to begin your treatment. Your participation will involve completion of online surveys.

During the online surveys, the following will occur:

- You will be asked to complete seven surveys about your pain and related symptoms; dysfunction, pain, anxiety, depression, and sleep. These surveys will approximately take 30 minutes to complete.
- Your basic information (such as age, sex, height, weight, etc.) and medications will also be obtained from your medical record or by an in-person interview.

Randomization:
You will be randomized, like flipping a coin, into one of the following groups

- yoga treatment group (1 in 2 chance of being assigned to this group)
- stretching treatment group (1 in 2 chance of being assigned to this group)

Intervention
You will be asked to participate in a live, virtual class (yoga or stretching) two times a week for 4 weeks. The class will be recorded and the link will be sent to you following the completion of class in the event you cannot attend one of your classes.

After the 2nd week and after the 4th week, you will be asked to fill out online surveys and participate in a semi structured phone interview. If at any time you experience adverse symptoms, we ask that you inform your instructor and/or the PI immediately.

Follow up
There will be no follow up after you complete all surveys at the end of the 4 weeks.

What are the risks of being in the study?
There are no physical risks involved in collecting information about you. There is a small risk of breach of confidentiality. For that reason, your information will be protected as described in the Privacy section below.

<u>For everyone filling out forms online, the following risks apply:</u>
You may also feel uncomfortable when completing a few questions in the surveys. These risks are minimal. You can choose not to answer any questions that make you feel uncomfortable. In addition, you will complete the questionnaires in a private and quiet room to keep it confidential.

<u>IN THE EVENT OF INJURY</u>

If you have a problem during this study, you should immediately contact Dr. Neena Sharma at 913-588-4566.

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

Are there benefits to being in this study?
We are helpful that you will have a decrease in back pain symptoms, but will otherwise not get personal benefit from being in this study. Researchers hope this study may be helpful in improving treatments for patients with chronic low back pain

Will I have any costs or payments for being in the study?
You will not be charged for being in the study. There is no payment for participation.

Will the researchers get paid for doing the study?
No.

What other choices do I have if I don't want to be in the study?
You can choose not to be in the study. You can decide to leave the study at any time. Leaving will not affect the treatment or services you get at KUMC.

How will my confidentiality and privacy be protected?
The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and from your medical record. Your health care providers may release your private health information to Dr. Neena Sharma and the research team. The team may use any and all of your information needed for the study. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your participation in this study and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health information from your clinical care. The health system may use and share this information for other purposes described in the Notice of Privacy Practices.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record will be kept indefinitely.

All study information that is sent outside KU Medical Center will have information that could easily identify you (such as name and address) removed. By limiting the information that is released, we are lowering the risk that your identity could be discovered and used for unauthorized purposes.

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Dr. Neena Sharma. The mailing address is Dr. Neena Sharma, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of yoga or stretching. They are permitted to use and share information that was gathered before they received your cancellation.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

What if I decide to leave the study?
You can choose to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Neena Sharma using the contact information on the first page of this document. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of the study intervention. They are permitted to use and share information that was gathered before they received your cancellation.

Will I be told about research results?
At the end of the study, we can send you a letter with a summary of the results upon request.

How will my research information and specimens be used in the future?
In the future, researchers at KUMC and at other locations might re-use the information and specimens from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

Who can I talk to about the study?
Dr. Neena Sharma or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may contact the KUMC Institutional Review Board at (913) 588-1240 or IRBhelp@kumc.edu.

CONSENT
Dr. Neena Sharma or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

In the future, the researchers may conduct additional studies about chronic low back pain. If you agree, the researchers will contact you to see if you want to join future studies. You would receive a separate consent form describing the future studies.

☐ Yes, I would like to be contacted if I qualify for future studies. _____
Signature

☐ No. Please do not contact me about future studies. _____
Signature