SPORT & SPINE REHAB
CHIROPRACTIC | PHYSICAL THERAPY | REHAB
Work Better, Play Harder

Research Participant Consent Form

For the research study entitled:

The Effect of Theraworx Relief on night-time cramps and spasms symptoms including quality of life, depression and sleep quality

I. Purpose of the research study

Robert Topp, RN, PhD is a professor in the School of Nursing and Health Professions at the University of San Diego. You are invited to participate in a research study he is conducting. The purpose of this study is to determine the effect of Theraworx Relief, a foam you apply to your skin, on the frequency and severity of night-time cramps and spasms symptoms, including quality of life, depression and sleep quality.

II. What you will be asked to do

If you decide to be in this study, you will be asked to:

Complete 5 questionnaires at the beginning of the study. One of these questionnaires will ask you about your health habits, medical conditions and medications you take. You will also be asked to complete a questionnaire about the presence and severity of night time cramps and spasms symptoms you experience. Other questionnaires will ask you about your quality of life, depression and sleep quality. These questionnaires will take about 30 minutes to complete. Once you have filled out these questionnaires and have been accepted to participate in the study, you will be asked to complete a 14-day no treatment period during which time you will be asked to engage in your usual activities and treatments. Each morning during this 14-day no treatment period you are asked to complete a Compliance and Symptom Log on which you will explain the incidence and severity of cramps and spasms you had during the previous night and any therapies you used to treat these cramps and spasms. This log will take 1-2 minutes to complete each morning. At the end of this 14-day no treatment period you will be asked to return to the Sport and Spine Rehab (SSR) and complete the same questionnaires (except for the health questions) you completed at the beginning of the study and to return your Compliance and Symptom Log. Once you have completed these questionnaires during your second visit, you will be randomly assigned to one of two study groups by selecting 1 of 50 shuffled envelopes. Within 25 of these envelopes a card will indicate "Foam A" and the remaining 25 envelopes will contain a card indicating "Foam B." After selecting and opening the envelope you will receive two 3 ounce foam dispensers corresponding with the treatment you've been assigned by the card in the envelope (Foam A of Foam B). One of the foams will contain Theraworx/[pH]uel (treatment) and the other will contain a physiologically inert substance (placebo control). Neither you nor the research staff will know the contents of the foam you receive until the entire study is completed. You will be asked to engage in your usual activities and treatments for the next 14 days. Every evening, for the next 14 evenings after receiving the foam, before retiring for bed, you are asked to apply the topical foam to the surface of both of your legs and feet using a total of 16 pumps from the product dispenser. If during the evening you experience a cramp or spasm you are asked to apply 2 pumps of the foam to the affected area. Each morning following the 14 evenings in which you

apply the foam to your legs you are asked to again complete the Compliance and Symptom Log. Following 14 consecutive days of applying the foam to your legs in the evening you are asked to return to SSR with your completed Compliance and Symptom Log. During this final visit you will be asked to again complete the same questionnaires that you completed during your second visit to SSR.

Your participation in this study will take a total of 3 hours.

III. Foreseeable risks or discomforts

Sometimes when people are asked to think about their feelings, they feel sad or anxious. If you would like to talk to someone about your feelings at any time, you can call toll-free, 24 hours a day:

San Diego Mental Health Hotline at 1-800-479-3339

IV. Benefits

While there may be no direct benefit to you from participating in this study, the indirect benefit of participating will be knowing that you helped researchers better understand the effect of topical foams on persons with night time leg cramps and spasms.

V. Alternatives

Your alternatives to participating in this study include receiving the standard care for night-time leg cramps or spasms, which consists of medications prescribed by your physician.

VI. Confidentiality

Any information provided and/or identifying records will remain confidential and kept in a locked file and/or password-protected computer file in the researcher's office for a minimum of five years. All data collected from you will be coded with a number or pseudonym (fake name). Your real name will not be used. The results of this research project may be made public and information quoted in professional journals and meetings, but information from this study will only be reported as a group, and not individually.

VII. Compensation

If you participate in the study, the researcher will give you $25 for completing each of the first two visits to SSR. You will be given an additional $100 for completing the final data collection visit at SSR. You will receive this compensation even if you decide not to complete the all of the questionnaires.

VIII. Voluntary Nature of this Research

Participation in this study is entirely voluntary. You do not have to do this, and you can refuse to answer any question or quit at any time. Deciding not to participate or not answering any of the questions will have no effect on any benefits you're entitled to, like your health care, or your employment or grades. You can withdraw from this study at any time without penalty.

X. Contact Information

If you have any questions about this research, you may contact either:

Robert Topp, Principal Investigator
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Jena Slaski, Director of Research Sport and Spine Rehab Clinical Research Foundation
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I have read and understand this form, and consent to the research it describes to me. I have received a copy of this consent form for my records.

Signature of Participant **Date**

Name of Participant (Printed)

Signature of Investigator