Faculty of Medical Sciences, Government College University Faisalabad
Old Campus, Kotwali Road, Faisalabad 38000 Pakistan
https://gcuf.edu.pk/

Information Sheet and Participant Consent Form

INTRODUCTION

You are asked to participate in a study conducted by the Faculty of Medical Sciences at Government College University Faisalabad. You were selected as a potential participant in this study because you are over 18 years old and are diagnosed with chronic low back pain (CLBP).

Participation in this study is entirely voluntary. Your decision whether or not to participate will not adversely affect your relationship with the Faculty of Medical Sciences at Government College University Faisalabad. Please read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

PURPOSE OF STUDY

This clinical study is designed to investigate the efficacy and safety of a non-invasive treatment for CLBP with Dr Allen's Device. The results of this study will help us to understand how people with CLBP respond to treatment with Dr Allen's Device. Your participation in this study is crucial, and we want to thank you for wanting to assist us.

PROCEDURES

If you choose to participate in this study, you will be asked to do the following:

First, you must provide an official identification that verifies that you are over the age of 18. Next, the study will be described to you so you understand what you will be asked to do.

The treatment modality that we will study will be non-invasive Thermobalancing therapy with Dr Allen's Device for Low Back Pain Treatment. You will be asked to use it at home for a 3-month period as a monotherapy, that is without any other treatment for your low back pain.

In order to understand the effect of this treatment on CLBP, the intensity of your symptoms will be measured by 2 questionnaires before the start of your 3-month treatment. Questionnaires will be repeated at the end of 3 months to assess the change in the intensity of your CLBP symptoms.

HOW TO USE DR ALLEN'S DEVICE

Dr Allen's Device for Low Back Pain Treatment consists of a soft belt with 1 small thermoelement, which, when worn on the body, accumulates the naturally emitted heat of your body and maintains the required temperature. You will not feel the heat coming from the thermoelement while wearing Dr Allen's Device. The belt must be worn so that the thermoelement covers the sore area of your low back.

Ideally, you need to wear Dr Allen's Device as much as possible throughout the day and at night, aiming for 22 hours a day, for 3 months, even after pain or other troubling symptoms have disappeared.

It is particularly beneficial to wear Dr Allen's Device at night. You may take it off during the day, but long interruptions should be avoided.

Do not wear Dr Allen's Device while bathing, taking a shower, swimming, or exercising in the gym.

Do not take the thermoelement out of its protective white pouch.

Do not wash the thermoelement. You can wash the belt as a regular item of clothing with a mild detergent and in water of up to 40C. Let it dry naturally avoiding drying it on a heater.

POTENTIAL RISKS AND DISCOMFORTS

No risks or discomforts are expected. Should you experience any discomfort at any stage during the treatment, please contact your doctor immediately.

ANTICIPATED BENEFITS TO SUBJECTS

It is expected that you will benefit directly from this research, and your participation is expected to help us better understand how to treat people with CLBP. This is a very important scientific contribution.

PRIVACY AND CONFIDENTIALITY

After you sign this consent form, the researcher will give you an ID number, and that is the way in which you are identified during the study. No personally identifiable information about you collected during this research will be disclosed to others without your written permission, except:

- if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or

- if required by law.

Your individual privacy will be maintained in all publications or presentations resulting from this study. No one other than the researchers will have access to any records of this study, and none of the records will identify you using any personal information. The data will be stored on paper and in password protected electronic forms. All physical identifying information will be stored in a locked secure location.

PARTICIPATION AND WITHDRAWAL

Please understand that participation is completely voluntary. Your decision whether or not to participate will in no way affect your current or future relationship with the Government College University Faisalabad, or the faculty, students, or staff of the University. You have the right to withdraw from the research at any time.

RIGHTS OF RESEARCH PARTICIPANTS

You may withdraw your consent at any time and discontinue participation without penalty. If you have any questions or would like additional information about this research, please contact Dr Muhammad Akram, makram_0451@yahoo.com, Associate Professor, Department of Eastern Medicine, Government College University Faisalabad. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the chair of the Research Ethics Committee, Government College University Faisalabad.

If you would like a copy of this consent form for your records, please let us know and we will provide it.

Please read the following and sign your initials in the boxes provided if you agree.

1. I have read the information sheet, have asked questions and received satisfactory answers. ☐

2. I understand that this research project has been reviewed by, and received ethics clearance through, Ethics Review Committee, Government College University Faisalabad. ☐

3. I understand that my participation is voluntary and that I am free to withdraw my data or myself at any time, without giving any reason, and without any adverse consequences. ☐

4. I understand who will have access to the data I provided. ☐

5. I understand how personal data will be stored according to the Data Protection Act; and what will happen to the data at the end of this clinical study. ☐

6. I understand that this research will be written and published without compromising my anonymity, and that no one will be able to identify me using the resulting data from this research. ☐

7. I understand how to raise concerns or make a complaint. ☐

8. I agree to take part in the study. ☐

Signature of Research Participant

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction.
BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____
Name of Participant

_____ _____
Signature of Participant Date

Signature of Investigator

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

_____
Name of Investigator

_____ _____
Signature of Investigator Date