



UNIVERSITY of LIMERICK
UNIBScoil LUIMNIGH

Title of research project: The effect of cognitive functional therapy on patients with non-specific chronic back pain: a multi-centre randomized trial

Introduction:

This research aims to assess the effect of cognitive functional therapy and exercise classes on improving pain symptoms and function in people with back pain

Procedure:

After being deemed as suitable for treatment by your physiotherapist, you will be assigned to one of two treatments. Both treatments have been shown to result in reduced pain and disability but we want to examine which is more effective. Both treatments involve exercise, education and relaxation. Both treatments will be completed at the local site. You will be asked to complete a number of questionnaires before, and at the end of your treatment. In addition, you will be asked to fill in the questionnaires in the future; 6 months and 12 months after completing your treatment. The data from these questionnaires will be collated locally in the hospital you are attending, and then forwarded to a group of researchers in the University of Limerick. Only your treating physiotherapist and the research investigators will have access to your name and contact details in order to post the questionnaires to you, after 6 and 12 months. They will keep this information confidential. These researchers will analyse the data from a number of hospitals around Ireland collectively.

Benefits:

Participation in this research project will allow the researchers to better understand if the two types of physiotherapy treatment are effective in helping you achieve your goals of reducing pain and improving function.

Risks:

There are no associated risks involved in participating in this research project, apart from a mild risk of some initial soreness due to beginning exercise. You may still take part in treatment, even if you do not wish to be part of this study.

Inclusion Criteria:

You must be referred by your physiotherapist to take part in one of the treatments.

- Patients must have chronic back pain greater than 6 months
- Patients must be over 18 and under 75.
- Patients must be mentally and physically capable of participating in a treatment programme.
- Patients must not be pregnant

Confidentiality:

Your identity will only be known to the treating physiotherapist on site and by the research investigators who have to post the questionnaires to you at 6 and 12 months after starting treatment. They will keep this information confidential. Your name will not be published and your information will not be disclosed to anyone outside of the physiotherapists who are directly dealing with your care. Following completion of the data analysis, data may be stored for up to 7 years to allow for publication of the results. Thereafter, all data will be destroyed.

Voluntary participation:

If you volunteer to participate in this research project, you are free to withdraw at any time. If you decide to withdraw or to not participate, you will not be penalised in any way.

Attendance:

Since both treatments involve exercise, it is advisable to bring light clothes, comfortable shoes/runners, a bottle of water and a towel if you wish.

Contact Details:

For further information contact Dr Kieran O' Sullivan, Clinical Therapies, University of Limerick. Email Kieran.osullivan@ul.ie