

## **“WHICH EXERCISE FOR CHRONIC LOW BACK PAIN?”**

### **PARTICIPANT INFORMATION STATEMENT**

You are invited to take part in a research study entitled “Which exercise for chronic low back pain?” The object is to discover which type of exercise program is best for people suffering chronic low back pain. To date there is evidence that an exercise program designed to increase mobility, strength and aerobic fitness is useful in patients with low back pain. There is also evidence to suggest that an exercise program designed to improve control and co-ordination of the low back and pelvis is also useful. However no-one has discovered which of these programs is best for people with low back pain of greater than 3 months duration. This study will investigate which of these exercise programs best improves pain, disability and quality of life.

#### **The study is being conducted by:**

- Prof. Paul Hodges, Division of Physiotherapy, The University of Queensland
- Dr. Jane Latimer, Senior Lecturer, School of Physiotherapy, The University of Sydney
- Ms. Elaine Unkles, Physiotherapy Department, Royal Brisbane Hospital
- Mr. Ryan Stafford, Division of Physiotherapy, The University of Queensland

#### **Who can participate in this study?**

- You must have had low back pain for at least 3 months
- Be currently seeking treatment for your low back pain

#### **What is involved in this study?**

If you agree to participate in this study you will be asked to attend The University of Queensland, St. Lucia Campus, for measurements of your low back. These sessions will take approximately 3 hours.

These measurements include:

- Answering questions about your age, height, weight and low back pain to check you are suitable for our study
- Undergoing a simple examination of your low back where we will measure your movement and check that the nerves in your back are working properly and that you are suitable for our study
- Completing 14 questionnaires designed to measure the amount of pain and disability you are experiencing (7), your beliefs and attitudes about pain (6), and your current level of physical activity (1).
- Performing a three minute test of your fitness
- Completing four simple tests (none of which are invasive or painful) designed to measure the control and co-ordination of your low back and pelvis. These tests are:
  - A brief questionnaire.
  - A trunk stiffness test where we place some measurement devices on your spine and pelvis and measure the amount of vibration transmitted when you walk.
  - A test of how your trunk muscles respond when we apply a gentle force to your body in standing. To measure the activity of the muscles here we will place adhesive electrodes on your skin
  - A test of skill and co-ordination. This involves moving your low back and pelvis to different target positions.
  - A test of your stomach and back muscles. In this test we get you to either bend your knees or straighten them against resistance and we measure the activity of your muscles using ultrasound (similar to the ultrasound used to picture unborn babies) while you perform this activity.

Following this you will be allocated to receive one of the 2 exercise programs. You will be required to attend for 12 one hour exercise sessions over an eight week period and 2 one hour follow-up sessions (4 and 10 months). Both exercise programs are currently used to treat chronic low back pain. One program will contain exercises that will increase your mobility, strength and fitness, while the other program will contain exercises that work specifically at improving the control and co-ordination of your low back and pelvis. During the conduct of this study we will ask you not to seek other forms of treatment for your low back pain.

This treatment would either be conducted at the University of Queensland, St. Lucia or at a local physiotherapy clinic associated with this study.

At 2, 6 and 12 months following your entry into the study we will telephone you to answer 5 questionnaires about your pain, disability and quality of life over the phone. This phone call will take approximately 1 hour. In addition we will ask you to report your average pain over the last week for one year either by a monthly SMS, e-mail or telephone call. If you agree, you will also be invited to complete the 4 simple tests of trunk control at 2 and 12 months.

#### **Are there any risks associated with being in this study?**

Some participants may experience some temporary muscle soreness following exercise. This is a normal response to unaccustomed exercise and should resolve quickly within a day or so. Your physiotherapist will ask you about this at every treatment session. Occasionally following exercise patients will have a temporary exacerbation in their low back symptoms. If this occurs you should tell your treating physiotherapist who will decide whether to modify your exercise program and whether to reduce the intensity of your exercise. The exercise programs being trialled in this study are used by physiotherapists every day to treat patients with chronic low back pain. Therefore the risks associated with this study are similar to the risks associated with receiving physiotherapy treatment for your low back pain.

#### **Will the results of this study be kept confidential?**

All aspects of the study, including results, will be strictly confidential and only the investigator's named above will have access to information on participants, except as required by law. A report of the study will be submitted for publication, but individual participants will not be identifiable in such a report.

#### **Can I pull out of the study if I wish?**

Participation in this study is entirely voluntary: you are not obliged to participate and - if you do participate - you can withdraw at any time. Whatever your decision, it will not affect your medical treatment or your relationship with the researchers or physiotherapy staff.

When you have read this information, one of the investigators named above will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact Mr Ryan Stafford at the University of Queensland, St Lucia on (07) 3346 7751 or (07) 3346 5576. This information sheet is for you to keep.

**Any person with concerns or complaints about the conduct of a research study can contact the Ethics Officer, Research and Research Training Division, Cumbrae-Stewart (Building 72), The University of Queensland, Brisbane, 4072 AUSTRALIA  
Phone: +61 7 336 53560, Fax: +61 7 336 54455, Email: [oper@research.uq.edu.au](mailto:oper@research.uq.edu.au)**