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Does online psychological resilience training combined with chiropractic care for chronic low back pain prevent long term disability?

PARTICIPANT INFORMATION STATEMENT

You are being invited to take part in a research study. Before you decide, it is important to understand why the research is being done and what it will involve.

(1) What is this study about?

The purpose of this study is to help people suffering from chronic low back pain to get back to leading a productive and happy life. Sometimes recurrent low back pain leads to other associated symptoms, including depression, anxiety, stress, social isolation, cardiovascular diseases, dependence on medication, and loss of muscle tone.

Best practice clinical guidelines indicate that people who experience recurrent low back pain may benefit from a program of cognitive behaviour therapy. This is a program that helps people identify unhelpful thoughts and behaviors and learn healthier skills and habits.

This is a clinical trial looking into the benefits of combining chiropractic care with an online psychological resilience training tool called Online psychological training tool.

Participation in this research study is voluntary. So it's up to you whether you wish to take part or not.

(2) What will the study involve for me?

At the beginning of the study you will be randomly allocated to a group. There are two groups; one group will receive the usual high standard of care targeted to your back pain. The other group will also receive this high quality care as well as the use of Online psychological training tool.

(3) How much of my time will the study take?

"Your involvement in the trial will last a maximum of eight weeks excluding follow-up. If you are randomly allocated to the;
Online psychological training tool group you will be required to log on and complete the modules each week for the first 5 weeks of the trial. You will also receive your chiropractic treatments during these 5 weeks and for the three weeks after this (total of eight weeks). A maximum of 12 half-hourly visits will be scheduled across the 8 weeks. You will also receive a weekly phone call during the first 5 weeks as a reminder to log onto the online psychological training tool.

If you are randomly allocated to the control group (chiropractic treatment only) your involvement will include a maximum of 12 half-hourly visits scheduled across the 8 weeks.

All participants will be required to fill in a set of questionnaires prior to commencing treatment at the end of the 8 week trial, as well as two follow-up intervals, 12 and 52 weeks from the start of the trial."

You will be required to fill in a set of questionnaires at two follow-up intervals, 12 and 52 weeks from the start of the study.

The questionnaires that you will be filling in are to gather information about your pain and your mental state in relation to your back pain. The majority of these questionnaires are part of normal chiropractic care. There are a few that are aimed at finding out more about your ability to cope with your back pain.

(4) Do I have to be in the study? Can I withdraw from the study once I've started?

Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with your treating practitioner.

(5) Are there any risks or costs associated with being in the study?

As with any form of chiropractic intervention there are some risks that you need to be aware of.
a. In rare circumstances the treatment may not be successful and you may be in the same position you were prior to treatment.
b. Medical literature has reported rare risks associated with manipulation of the spine which may include although are not limited to muscle and joint soreness or strains, nausea and dizziness, fracture, disc injuries, strokes (or like episodes) and an exacerbation and/ or aggravation of an existing underlying condition. Most of these rare risks are associated with manipulation of the neck joints. Treatment will mostly be localised to the middle and low back regions further minimising these named risks.
c. You are required to give consent prior to taking part in the study and can withdraw consent at any time without reason.

In regard to the online psychological training tool there are no known risks associated with its use. Though there may be a risk of psychological distress in completing the questionnaires. As such, participants will be given the opportunity to contact an experienced clinical psychologist to discuss any issues of psychological distress that may arise throughout the entirety of the study. Contact person is Dr Mairwen Jones of The University of Sydney Ph: 02 9351 9571 email: mairwen.jones@sydney.edu.au

"Your costs associated with being part of this study are no different to those of a normal private patient and normal charges for any chiropractic treatment you receive will apply for your care. You will not be reimbursed for your time in relation to filling out any questionnaires or follow up contact involved in the study."

(6) What will happen to information about me that is collected during the study?

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications.

(7) Can I tell other people about the study?

Yes, you are welcome to tell other people about the study.

(8) What if I would like further information about the study?

When you have read this information, John Petrozzi will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Dr Martin Mackey Senior lecturer at The University of Sydney 02 9351 9374 / martin.mackey@sydney.edu.au

(9) What if I have a complaint or any concerns about the study?

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

- **Telephone:** +61 2 8627 8176
- **Email:** ro.humanethics@sydney.edu.au
- **Fax:** +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep