Chronic Pain Trial 2020
Invitation to Participants, with Inclusion and Exclusion Criteria

Dates: Access to the trial will commence 1 September 2020. However provided places are still available, participants may actually commence the trial at any time following that date.

We invite you to participate in a clinical trial of a novel method to relieve non-malignant chronic pain where that pain is not explained, or is inadequately explained, by pathology.

Nature and Purpose of the Study

The aim of this study is to investigate the efficacy or otherwise of a novel treatment method that has as its aim the switching off of pain signalling amongst a specific group of chronic pain patients, in comparison with treatment "as usual".

There is currently a lack of any existing treatment which benefits the majority of chronic pain patients, and it is hoped that this novel approach may provide an inexpensive, convenient, and easily-deliverable treatment with a high efficacy rate.

Two very small studies have already been completed, with efficacy rates of 85% and 100% respectively, but as it is recognised that small trials tend to have exaggerated outcomes, it is appropriate that the method be subjected to robust scrutiny in a much larger trial.

If you consent to take part in this research, it is important that you understand the purpose of the study and the tasks you will be asked to complete. Please make sure that you ask any questions you may have, and that all your questions have been answered to your satisfaction before you agree to participate.

What the Study Will Involve – Criteria of Inclusion and Exclusion

The trial will consist of a step-by-step online program which you work through at your own rate. It is strongly supported by access to telephone and email support, a Facebook support group for those who prefer social media, and weekly video conferencing where you can ask questions and participate in discussions with other participants, led by trial director Christine Sutherland.

Treatment will consist of learning and practising strategies to:

- Switch off direct triggers to chronic pain signalling
- Resolve contributing factors which serve to heighten sensitivity of the nervous system generally

To participate in this study, you will need to have a formal diagnosis of non-malignant chronic pain with no or insufficient pathology to explain the pain. This will generally include long-term back pain, post-surgical pain (including surgery to remove malignancy), post-injury pain, post-cancer pain, “nerve” pain, and phantom pain.

In addition:

- Your pain should be confined to only one area of the body
- No recent injury or surgery which is related to the pain (this means that by now in the healing stage the person should not being experiencing pain, or should not be experiencing the degree of pain). See note at end.
- Pain should not be due to current malignancy or due to an acute cause (eg not migraine pain, endometriosis, adenomyosis, rheumatoid arthritis)
- No diagnosed severe mood or personality disorder
- No addiction to alcohol or illicit drugs
- No alternative therapies being utilised (eg chiropractic, acupuncture, naturopathic, supplements, etc)
- You have sufficient cognitive competence to engage in treatment (ie; not suffering cognitive impairment)
- You may or may not have tried medications prescribed by your doctor, physiotherapy, or psychological support – this isn’t important for the purposes of the study
- You may or may not be a workers compensation client
- You must agree to continue to work with your doctor in relation to any prescribed medication and not alter medication without consultation with your doctor

If you decide to request participation in this study and are accepted on the trial, you can be assured that you will be in a treatment group, as a placebo or control group will not be required (extensive and robust data on other treatment methods has already been collected and analysed). You will be asked to learn and practise particular methods aimed at directly

reducing your experience of pain, and to continue using those methods for a few minutes each day for as long as your pain persists.

You will be asked to provide a number of subjective measures of pain, quality of life and other issues before and after your program, as well as 6, 12 and 24 months later to measure whether or not the treatment has been successful for you longer term.

Voluntary Participation and Withdrawal from the Study

Your participation in this study is entirely voluntary. You may withdraw at any time without discrimination or prejudice. All information is treated as confidential and no names or other details that might identify you will be used in any publication arising from the research. If you withdraw, all information you have provided will be destroyed, excepting raw data.

Privacy

Your privacy is very important. Any members of the research team who are associated with you in other roles (e.g., the coordination or administration team of a unit) will not know whether you have elected to participate and will view only anonymous data. It will thus not be possible to identify you, neither will you be identified in any publication arising out of this study. If you provide any identifiable information in your responses, this will be removed before analysis of the data.

You must agree that we report back to your supervising doctor, as this is a critical part of your ongoing care by your medical team.

Benefits of the Study

It is not possible to achieve a 100% success rate with any therapy, so it is possible that there may be no direct benefit to you from participation in this study. However, from participating in this research you may gain further insight into how a variety of things may have an impact on pain signalling and this could offer clarity for your future plans including discussions with health providers. Feedback at the end of the study will provide you with information about the effectiveness or otherwise of treatment approaches for you as an individual, which may help you in your future lifestyle choices.

While there is no guarantee that you will personally benefit, the knowledge gained from your participation may help others in the future. By understanding the factors that affect

pain signalling, future patients and therapists may benefit from selecting treatment options in more alignment with individuals' needs.

Possible Risks

There are no specific risks anticipated with participation in this study and no adverse events are anticipated. However, if you find for any reason that you are becoming distressed, you can choose not to participate, or to only partially participate. Participation is completely voluntary and anonymous.

Reimbursement

There is no reimbursement for participation in this trial, however all participants receive treatment at no cost, and will be offered free ongoing access to the Online SDR Chronic Pain Program for 12 months.

Once we have analysed the data from this trial we will provide all participants with a summary of our findings, in addition to writing a trial paper and submitting that for peer review and publication. The summary will be available towards the end of 2020 and the full paper will be offered for peer review shortly afterwards.

If you are willing to participate in this study please contact us to register your interest.

Thank you for your assistance with this research project.

Sincerely

Christine Sutherland
Clinical Director

If you have any questions about this project, or any reservation or complaint about the ethical conduct of this research, please feel welcome to call Christine Sutherland on 0409 689 741 or email on office@lifeworks-group.com.au.

Note: Chronic back pain is a special case because it is widely known that degree of damage or deterioration does not generally correlate with pain – therefore this pain can usually be considered appropriate for the trial, even though it could be said that pathology is present.