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**Comparative Effectiveness Study of the Clinical and Cost Outcomes of Massage for the Management of Chronic Low Back Pain in Australia.**

Protocol Number: ETH16-0812

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Draft or Version Number: 3

7th September, 2016

# KEY ROLES AND CONTACT INFORMATION

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**STATEMENT OF COMPLIANCE**

The study will be conducted in accordance with the Declaration of Helsinki and the ethical clearance from Endeavour College of Natural Health Human Research Ethics Committee and the UTS Human Research Ethics Committee.

**Abbreviations**

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| EQ-5D-5L | Europe Quality of Life 5 questionnaire |
| PIF | Patient Information Form |
| PRACI | Practitioner Research and Collaboration Initiative |
| PROM | Patient Reported Outcome Measure |
| VAS | Visual Analogue Scale |

PROTOCOL SUMMARY

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| --- | --- |
| **Title:** | **Comparative Effectiveness study of the Clinical and Cost Outcomes of Massage for the Management of Chronic Low Back Pain in Australia** |
| **Précis:** | The study will use a combination of observational quantitative and descriptive qualitative methods to measure the clinical and cost effectiveness of massage for chronic low back pain. The clinical and cost effectiveness will be compared between massage and standard care for chronic low back pain within Australia. |
| **Objectives:** | **Primary**: To substantiate the clinical and cost effectiveness of massage plus standard care for the treatment of chronic low back pain compared to standard care. |
|  | **Secondary**: To compare the treatment effectiveness of massage to massage plus other interventions (standard care) for chronic low back pain in Australia. |
| **Population:** | Massage therapists throughout Australia will be contacted in regards to participating in this study.  The sample size will be 50 participants with 20% attrition rate (n=60)  Gender: mixture of male and females  Age: 18-80 years old  Demographic group: generally healthy individuals  Geographic location: throughout Australia |
| **Study Duration:** | Recruitment will be a year from commencement to completion. |
| **Subject Participation Duration:** | Each participant will be followed for 2 months of treatment and then a follow up one month later. |
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# Schematic of Study Design:

Therapist confirms participant involvement and allocates participant identification number, keeps the completed participant consent forms and Case Report Form for 2 months.

Participant to complete online PROMs including retrospective data for standard care in the last month (GCPS). Therapist completes Case Report Form.

**Research Assistant to email therapists:**

Agreement

Study Protocol

Patient Information Form (PIF)

Consent forms and Case Report Forms (CRF)

Outline of requirements and procedures

Online link to PROMs

Research assistant assigns de-identified number to participant. Inputs information into Excel spreadsheet.

Participants identified and diary for first month allocated.

OVER PAGE

Ask participant if they are interested in participating – give PIF.

Send thank you email

Yes

No

Yes

No

No

Participant reads PIF and signs consent form.

Exclude patient

Exclude patient

Screening of patients to meet inclusion/exclusion criteria

Massage therapist consents to participating and starts recruitment

Email identified therapists to ascertain interest in participating in the study

PRACI Massage therapists identified on Contact list

Subsidy of $50 towards third treatment sent to Therapist upon invoice and confirmation of participation

PROMs completed online on same day as participant treatment

**One month Follow-Up**

Research Assistant to contact participant to prompt follow-up reporting. Final Case Report Form with PROMs completed by participant and returned with completed third diary to Research Assistant.

**First month of massage treatment**

Therapist to complete Case Report Form. First diary collected and second diary distributed. Participant to complete diary throughout second month of treatment.

PROMs completed online on same day as participant treatment.

Therapist informs Research Assistant that the participant has finished two months of treatment.

**Completion of two months of massage treatment**

Therapist to complete Case Report Form. Second diary collected and third diary with final case report form distributed to participant.

Thank you letter sent to participant and therapist.

**Massage therapist treats participant as they normally would for two months.**

Participant to complete participant diary throughout the first month of treatment.

PROMs completed online on same day as participant treatment

# Protocol for Comparative Effectiveness study of the Clinical and Cost Outcomes oF Massage for the Management of CHRONIC Low Back Pain in Australia

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| --- | --- | --- |
| Purpose | To substantiate the clinical and cost effectiveness of massage and standard care for the treatment of chronic low back pain compared to standard care only. | |
| Design | Study status | Comparative Effectiveness observational study |
| Comparator | Standard treatment |
| Study Duration: | 3 months including 1 month of follow-up |
| Endpoint Classification: | Modified Graded Chronic Pain Scale (Von Korff) |
| Participants | The sample size will be 50 participants with 20% attrition rate (n=60 max)  Gender: mixture of male and females  Age: 18-80 years old | |
| Key Inclusion Criteria | 1. Between the age of 18 and 80 years old 2. No massage for low back pain previously from a qualified, registered massage therapist 3. Grade 1 or higher on the Modified Graded Chronic Pain Scale 4. Chronic low back pain for longer than 6 months | |
| Key Exclusion Criteria | Disclaimer: The Key exclusion criteria is based on standard recommendations to avoid massage. **The massage therapist is to decide if they would normally conduct massage on the participant or not.**   1. Any person who is unable to read, understand or acknowledge what it means to be in the study. 2. A person with open wounds on the back including cuts, lacerations or grazes 3. Diagnosed muscle or tendon tears, partial tears or ruptures around the back or buttocks 4. A person with contusions on the back or buttocks 5. A person with burns, chilblains or broken bones. 6. Diagnosed periostitis or bursitis 7. A person with infections of the skin or soft tissue on their back 8. Diagnosed with haemophilia 9. A person with a solid tumour on their back or abdomen | |
| Duration | Two month of massage treatment for each participant plus one month follow up. A retrospective analysis of what they have been doing for the last month will stand as the standard care. | |
| Study Site | Massage clinics throughout Australia | |
| Ethics approval | Endeavour College of Natural Health HREC  University of Technology Sydney HREC | |
| Primary Endpoint | 1. Modified Graded Chronic Pain Scale (GCPS) 2. Oswestry Lower Back Pain Disability score | |
| Secondary Endpoints | 1. EQ-5D-5L – Europe Quality of Life 5 questionnaire 2. McGill Pain Scale 3. Visual Analogue Scale (VAS) | |
| Adverse Events | All adverse events will be recorded by the Research Assistant and an adverse event form will be completed by the massage therapist. | |
| Analysis | Intention to treat analysis  Data will be analysed using STATA statistics package.  Cost effectiveness and cost utility will be conducted comparing standard care to massage plus standard care for chronic low back pain. | |