



**CASE REPORT FORM**

**PARTICIPANT COPY**

**(Final section)**

**CONFIDENTIAL**

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

Participant’s Initials [ ] [ ] [ ]

Allocation Number [ ] [ ] [ ] [ ] [ ]

Baseline Date [ ] [ ] [ ] [ ] [ ] [ ]

d d m m y y

**This Case Report Form is to be completed by the participant one month after the conclusion of the two month massage treatment.**

**Modified Graded Chronic Pain Scale (GCPS)**

1. How would you rate your lower back pain on a 0 to 10 scale at the present time that is right now, where 0 is “no pain” and 10 is “pain as bad as could be”?

No Pain Pain as bad as

 could be

0 1 2 3 4 5 6 7 8 9 10

1. In the past month, how intense was your worst pain, rated on a 0 to 10 scale where 0 is “no pain” and 10 is “pain as bad as could be”?

No Pain Pain as bad as

 could be

0 1 2 3 4 5 6 7 8 9 10

1. In the past month, on the average, how intense was your pain rated on a 0-10 scale where 0 is “no pain” and 10 is “pain as bad as could be”? (That is you usual pain at times you were experiencing pain)

No Pain Pain as bad as

 could be

0 1 2 3 4 5 6 7 8 9 10

1. In the past month, how much as lower back pain interfered with your daily activities rated on a 0 to 10 scale where 0 is “no interference” and 10 is “unable to carry on any activities”?

No Interference Unable to carry

 on any activities

0 1 2 3 4 5 6 7 8 9 10

1. In the past month, how much as lower back pain changed your ability to take part in recreational, social and family activities 0 is “no change” and 10 is “extreme change”?

No change Extreme change

0 1 2 3 4 5 6 7 8 9 10

1. In the past month, how much has your lower back pain changed your ability to work (including housework) where activities 0 is “no change” and 10 is “extreme change”?

No change Extreme change

0 1 2 3 4 5 6 7 8 9 10

1. About how many days in the last month have you been kept from your usual activities (work, school or housework) because of lower back pain?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Days

****

****

****

|  |
| --- |
|  |
| Health Questionnaire |
|  |
|  |
| English version for Australia |

|  |
| --- |
| Under each heading, please tick the ONE box that best describes your health TODAY. |
| MOBILITY |  |
| I have no problems with walking around | ❑ |
| I have slight problems with walking around | ❑ |
| I have moderate problems with walking around | ❑ |
| I have severe problems with walking around | ❑ |
| I am unable to walk around | ❑ |
| PERSONAL CARE |  |
| I have no problems with washing or dressing myself | ❑ |
| I have slight problems with washing or dressing myself | ❑ |
| I have moderate problems with washing or dressing myself | ❑ |
| I have severe problems with washing or dressing myself | ❑ |
| I am unable to wash or dress myself | ❑ |
| USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)* |  |
| I have no problems doing my usual activities | ❑ |
| I have slight problems doing my usual activities | ❑ |
| I have moderate problems doing my usual activities | ❑ |
| I have severe problems doing my usual activities | ❑ |
| I am unable to do my usual activities | ❑ |
| PAIN / DISCOMFORT |  |
| I have no pain or discomfort | ❑ |
| I have slight pain or discomfort | ❑ |
| I have moderate pain or discomfort | ❑ |
| I have severe pain or discomfort | ❑ |
| I have extreme pain or discomfort | ❑ |
| ANXIETY / DEPRESSION |  |
| I am not anxious or depressed | ❑ |
| I am slightly anxious or depressed | ❑ |
| I am moderately anxious or depressed | ❑ |
| I am severely anxious or depressed | ❑ |
| I am extremely anxious or depressed | ❑ |

The best health you can imagine

|  |
| --- |
| We would like to know how good or bad your health is TODAY. |
| This scale is numbered from 0 to 100. |
| 100 means the best health you can imagine.0 means the worst health you can imagine. |
| Mark an X on the scale to indicate how your health is TODAY. |
| Now, please write the number you marked on the scale in the box below. |

YOUR HEALTH TODAY =

10

0

20

30

40

50

60

80

70

90

100

5

15

25

35

45

55

75

65

85

95

The worst health you can imagine

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Change to medications** | **Adverse events** | **Date** | **Signature** |
| **Diary 3 (Month 3)** | Y N | Y N |  |  |

|  |
| --- |
| **Adverse Event Form** |
| **Record all adverse experiences that you have had in the past month related to the massage treatment.** |
| **Adverse Event Details** | **Date of Onset**dd/mm/yy | **Date Ended***(Enter date or circle “O” if ongoing)*dd/mm/yy | **Severity**1 = Mild2 = Moderate3 = Severe | **Action Taken***(please mark all applicable)*0 = None1 = Medication – please record on medication page2 = Withdrawn from study3 = Other – please specify |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |

|  |
| --- |
| Change to Medications |
| **Record all changes to medication in the past month.** |
| **Medication**(Use Generic or Trade Name - Use trade name for fixed combinations only). | **Route**PO: oral IV: intravenous bolusINF: intravenous infusionIM: intramuscularO: other | **Dose\***(e.g 50mg, 10mL) | **Frequency** (e.g twice daily) | **Date Began**dd/mm/yy | **Date Ended***(Enter date or circle “O” if ongoing)*dd/mm/yy | **Indication** (please specify why medication taken) |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | O |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | O |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | O |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | O |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | O |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | O |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | O |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | O |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | O |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**\*Specify the dose given in a single administration**

|  |
| --- |
| **Symptom Form** |
| **Record all symptoms you have had during the past month.** |
| **Symptom Details** | **Date of Onset**dd/mm/yy | **Date Ended***(Enter date or circle “O” if ongoing)*dd/mm/yy | **Severity**1 = Mild2 = Moderate3 = Severe | **Action Taken***(please mark all applicable)*0 = None1 = Medication – please record on medication page2 = Withdrawn from study3 = Other – please specify |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  | O | 1 2 3  | 0 1 2 3 Details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |  |  |  |  |  |  |  |  |  |