**PARTICIPANT INFORMATION SHEET**

**Short Title:** **Lumbar Brace Deployed in the Emergency Department for Acute Low Back Pain**

**Title:** Lumbar Brace Deployment in the Emergency Department for Benign Low Back Pain: Effectiveness and Impact on Pain, Spine Function, Analgesic Use and Community Resources

**Protocol #: AKG-Curtin LBP Brace Study** V2.0

***Who is undertaking the project?***

This project is being conducted by clinicians and researchers from Armadale Hospital and Curtin University. The study is led by Associate Professor Dale Edgar, Coordinating Principal Investigator. The project equipment and researcher salaries are funded via the Curtin University collaboration, by the American Orthotics and Prosthetics Association.

**Sponsor Organisations**

Faculty of Rehabilitation Medicine, The University of Alberta, Edmonton, Canada.

Faculty of Health Sciences, Curtin University, Bentley, WA.

Armadale Kalamunda Group Health Service, Mt Nasura, WA.

**Coordinating Principal Investigator**:

Assoc Prof. Dale Edgar, Research Coordinator, Armadale Kalamunda Group Health Service.

**Armadale Hospital Research Team:**

*Principle Investigators:*

Dr Ashes Mukherjee – Consultant Physician, Armadale Emergency Department

Ryan Smith – Senior Physiotherapist, Physiotherapy Outpatients.

Consumer Advisors: TBC

**Curtin University Research Team:**

*Principle Investigators:*

Dr Rob Waller and Dr Nic Saraceni

**Location for Recruitment and Interventions:** Armadale Hospital, Emergency Department

***What is the project about?***

You are being invited to participate in this project because you have low back pain and are seeking treatment at Armadale Emergency Department (ED). The aim of the project is to find out if adding an abdominal brace to usual treatment, helps with low back pain. It is not known if using a back brace makes back pain better or worse.

The research is testing two regimens. One involves fitting a semi-rigid abdominal brace in addition to routine assessment and care in the ED. The second is routine assessment and care for low back pain in the ED. Thus, all patients with back pain joining this study receive evidence-based, standard care. This research aims to improve back pain recovery as well as streamline follow-up care for patients in the future.

***What will I be asked to do?***

Assessment and treatment for your low back pain in the ED will be as per usual practice, whether you join this study or not. If you consent to take part, a standard assessment will occur, including a comprehensive interview and physical examination by an experienced clinician. As with usual care, if required, investigations and, or scans will be conducted to guide your individualized treatment. The only addition to usual care, will occur if you are allocated into the group to be fitted with an abdominal brace. ***Only half of the participants***

***receive a brace, decided at random. Neither yourself, nor the researcher, can influence this choice as it is decided by random allocation software prior to today.*** If you are fitted with a brace, you will be asked to wear the brace as tolerated when awake, for up to 30 days when you are in pain. As there is no guarantee that a brace will help your back pain, you will also be asked to provide honest feedback about your low back pain and wearability of the brace during the study period. This type of brace is intended to allow you to remain active. You are requested to remove the brace during your daily hygiene functions and while sleeping. The brace is single person use and will be yours to keep after the study.

All information will be captured by sending you a text (SMS) link. Firstly, we will ask you to complete two surveys before you leave the hospital and at weeks 1 to 4; 8; and, 12 after discharge from the ED. These surveys will take about 10 minutes to complete. You can expect a ‘care call’ from a researcher, about one week after joining the study.

Further, in the first 4 weeks, we will ask you three (3) times per week to record the hours of wear time of the brace; your pain intensity (/10); a rating of your daily function; and, number of health services visited. This will take less than 5 minutes to complete.

Please feel free to ask any questions you may have and ensure that all your questions have been answered before you agree to participate.

***Are there any risks associated with participating in this project?***

We do not anticipate any significant risks associated with the study interventions. If you are asked to wear the brace, it may cause some initial discomfort and it will be important to keep a close check on and manage your skin under the brace. The exercise routine you receive as part of routine care, will be tailored to your current physical level and able to be completed at home. However, if you feel any symptoms such as light-headedness, persistent chest or shoulder deep aches or nagging pain heart palpitations, suspected strained muscles or ligaments and significant discomfort during the exercises, you do not have to continue the exercise routine. If you experience any of these symptoms, please contact the Dale Edgar (Mobile 0413070384) or Armadale Hospital researchers. Also, if you continue to experience a high level of lower back pain, please return to ED or visit your GP for further assessment and treatment.

***What are the benefits of the research project?***

There may be direct benefits to you in taking part in this research. You will benefit from increased surveillance for your low back pain, related to the study follow ups. We are investigating whether wearing a brace with minimal risk of side effects, offers added benefit to routine ED care.

Future patients at the Armadale Hospital may also benefit from your contribution due to translation of the study findings and recommendations.

***What if I change my mind?***

Participation in this study is completely voluntary. Even if you agree to participate, you can withdraw from the study at any time without change to your treatment, discrimination or prejudice. If you withdraw, please complete the Withdrawal Form. Please note that after withdrawal, information collected tp date will not be deleted, unless you notify us to instruct us to do so. **Non-participation or withdrawal will in no way whatsoever effect your ongoing treatment at the hospital.**

***Will anyone else know the results of the project?***

Your information will be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Computer based information will be stored on the WA Health provided mobile device only until backed up on a hospital server and protected on the device by 1) Password access

to log onto the device; and, 2) Password access to protect the spreadsheet. Once safely backed up on the password protected health server, all identifiable information will be erased from the device interface where

recording has taken place. Where data is to be shared for analysis, information will be de-identified and then be further protected via encryption on a password protected device.

Once the study is completed, the hard copy questionnaires answers and signed consent forms will be stored securely in a locked filing cabinet in the Physiotherapy Department, Level 1 at Armadale Hospital for a period of seven years. The digital files containing physiological data collected from you will be de-identified and stored for the same period prior to being disposed of as per the WA Department of Health standards. The data may be used in future research approved by the RPH HREC, should you consent to that, but you will not be able to be identified. An example of a future project includes the use of your data as a historical comparison to determine if changes made to the exercise training has improved outcomes. It is anticipated the results of the study will be published or presented as summarised data in a professional scientific journal and, or presented at a health care conference. All data will remain anonymous.

***Will I be able to find out the results of the project?***

Once we have analysed the information from this study, we can send a copy via email if you provide an email address or mail you a summary of our findings if you provide your mailing address. You can expect to receive this feedback in late 2024.

***Who do I contact if I have questions about the project?***

If you have any questions about this project, please feel free to contact Associate Professor Dale Edgar, on Ph: 0413070384. We are happy to discuss with you any concerns you may have about this study.

***What if I have a complaint?***

This project has been granted ethical approval by the Royal Perth Hospital (RPH) Human Research Ethics Committee (HREC). If you have any concerns about the conduct of the project or your rights as a research participant, please call (08) 9224 2292 or email: EMHS.REG@health.wa.gov.au and quote the project RGS number (RGS0000005841).

***How do I sign up to participate?***

If you wish to participate, please sign the digital consent form OR both hard copies of the consent form, keep one for yourself and give the other one to the person talking to you about this research. If you use the digital consent option, we will email you a copy of this information sheet and your signed consent.

This information sheet is for you to keep. Thank you for your time and consideration.

Yours sincerely,

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**Dale Edgar**

**AKG Research Coordinator / Coordinating Principal Investigator**

**Consent form – Study Copy**

**Study Title: *Lumbar Brace Deployed in the Emergency Department for Acute Low Back Pain***

(Strike out any points below that don’t apply.)

* I agree to take part in this research project.
* I have read the Information Sheet provided and had the opportunity to ask questions.
* I understand that I will be asked to complete surveys to monitor my responses during this study.
* The researcher has answered all my questions and has explained possible risks that may arise as a result of the interview and how these risks will be managed.
* I understand that I do not have to answer specific questions if do not want to and may withdraw from participating in the project at any time without prejudice.
* I understand that all information provided by me is confidential and will not be released by any researcher to a third party unless required to do so by law.
* I agree that any research data gathered for the study may be anonymously published, my name or other identifying information is not collected in this study.
* I understand that once signed, this consent form will be retained by the researcher, and stored confidentially.
* I understand that research data gathered may be used for future research, with my privacy maintained, subject to approval by a Human Research Ethics Committee.

This project has been granted ethical approval by the Royal Perth Hospital (RPH) Human Research Ethics Committee (HREC). If you have any concerns about the conduct of the project or your rights as a research participant, please call (08) 9224 2292 or email: EMHS.REG@health.wa.gov.au and quote the project RGS number (RGS0000005841).

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| --- | --- | --- |
| Name of Participant(please print) |  |  |
| Signature of Participant(or indicate verbal consent) |  | Date: |

* I confirm that I have provided the Information Sheet concerning this research project to the above participant, explained what participating involves and have answered all questions asked of me.

|  |  |  |
| --- | --- | --- |
| Signature of Researcher |  | Date: |

**Consent form – Patient Copy**

**Study Title: *Lumbar Brace Deployed in the Emergency Department for Acute Low Back Pain***

(Strike out any points below that don’t apply.)

* I agree to take part in this research project.
* I have read the Information Sheet provided and had the opportunity to ask questions.
* I understand that I will be asked to complete surveys to monitor my responses during this study.
* The researcher has answered all my questions and has explained possible risks that may arise as a result of the interview and how these risks will be managed.
* I understand that I do not have to answer specific questions if do not want to and may withdraw from participating in the project at any time without prejudice.
* I understand that all information provided by me is confidential and will not be released by any researcher to a third party unless required to do so by law.
* I agree that any research data gathered for the study may be anonymously published, my name or other identifying information is not collected in this study.
* I understand that once signed, this consent form will be retained by the researcher, and stored confidentially.
* I understand that research data gathered may be used for future research, with my privacy maintained, subject to approval by a Human Research Ethics Committee.

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|  |  |  |
| --- | --- | --- |
| Signature of Researcher |  | Date: |

**Withdrawal from Participation**

|  |  |
| --- | --- |
| **Study Title:** | Lumbar Brace Deployed in the Emergency Department for Acute Low Back Pain |
|  |  |
| **Coordinating Principal Investigator****Principal Investigators** | A Prof Dale EdgarDr Ashes Mukherjee, Ryan Smith |
| **Location**  | Armadale Hospital |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that withdrawal from the study will not affect my routine treatment, my relationship with those treating me or my relationship with Armadale Hospital.

**Please choose one of the following:**

**□ I consent for the data collected from me to date to be kept and included in the study analyses.**

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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**Declaration by Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  |
|  | Name of Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.