

FORENSIC-Australia: Brief Study Information

Study title: The clinical and cost-effectiveness of lumbar fusion surgery for patients with persistent, severe low back pain: FusiOn veRsus bEst conservative Care (FORENSIC-Australia) study.

- Research shows that both Lumbar Fusion Surgery and Best Conservative Care are options for treating patients with on-going, severe low back pain and certain features on imaging scans of the spine. This study is being done to find out if one is better than the other in a select group of people with low back pain.
- You might be suitable to take part in this study because you have had on-going, severe low back pain for at least 6 months, you have had some treatments for your back problem, and you are aged between 18-65.
- In this study, you will have an equal chance of being allocated to **one** of two treatments – this is done by random selection:



Lumbar Fusion Surgery

- The type of surgery is called **Lumbar Fusion Surgery (LFS)**.
- LFS is a surgery to connect two or more bones in your spine, so they heal into a single solid bone.
- During the surgery, a surgeon places bone or a bone-like material in the space between two spinal bones.
- The surgeon may use metal fixings to hold the bones in place while the bone graft heals.

OR

Personalised Spinal Care

- Best Conservative Care in the form of **Personalised Spinal Care**.
- Following your assessment, your clinician will work with you to create a personalised spinal care treatment plan.
- Your plan will involve treatment such as structured and supervised exercise therapy with or without manual therapy, which may include an individualised exercise programme; structured and supervised combined physical and psychological programme; a procedure called radiofrequency denervation; or other treatments that are recommended in guidelines.

To join the study, you should feel comfortable accepting either Lumbar Fusion Surgery or Personalised Spinal Care, if allocated to you.

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- Your clinician (e.g., surgeon, physiotherapist, or other health professionals) will need to do extra checks and ask you some questions to make sure you are suitable for the study.
- You may also be asked to have imaging scans of your lower back, if you have not had these in the last 12 months. These scans are part of your usual standard of care to check your suitability for Lumbar Fusion Surgery. Your clinician will let you know if you need a scan.
- Your expenses such as car parking fees, fuel, or transport costs for attending the study-related scans and/or for study-related visits for your treatment(s) will be reimbursed to the equivalent value in gift vouchers.
- If you choose to take part, you will be in the study for 24 months.
- This study is being led by researchers at The University of Queensland. Around 270 people will take part in this study, many from public hospitals and private hospitals/clinics around Australia. This study is funded by the National Health and Medical Research Council.
- **If you would like more information about the study and agree to have your contact details passed to the FORENSIC-Australia study team, please let your clinical team know. Alternatively, you can call or email the study team to request more information.**

Study team contact details	[Add Name]	[Add Phone Number/Email]
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Thank you for taking the time to read this and considering taking part.