**FORENSIC-UK Study: Recruitment Tips**

Tips and suggestions that may help with recruitment and informed consent when speaking to potential participants. Use this Tips sheet alongside other study documents e.g. Participant Information Sheet (PIS) as an aid to recruitment.

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| **A reminder of how the study is described to participants in the Patient Information Sheet:** | |
| **Spinal Fusion Surgery** | **Best Conservative Care (BCC)** |
| * Spinal fusion is a surgical operation on the small bones in the spine called vertebrae. It is essentially a welding process to fuse together two or more vertebrae so that they heal into a single, solid bone and can be used to treat low back pain. | * A personalised treatment plan using shared-decision-making and including at least one of:   + A course of physiotherapy exercises   + Support for pain self-management   + Pain management, which may include medication   + Rehabilitation sessions to support a return to daily activities |

**Introduce the FORENSIC-UK study**

We don’t know what works best - fusion surgery or BCC. This study is trying to find out

* Establish uncertainty from the start – it is really important potential participants understand we do not know if spinal fusion surgery works.
* Use the term ‘study’ rather than ‘trial’. People can interpret ‘trial’ as testing something experimental, with themselves cast in role of ‘guinea-pig’.
* Explain that FORENSIC-UK is funded by the UK’s government funding body (NIHR) and is taking place across the UK.

**Presenting the two arms: spinal fusion surgery and best conservative care (BCC)**

* Present balanced information about spinal fusion surgery and BCC, including risks (as outlined in the PIS).
* Patients often ask clinicians what they think is best.

Explain that the spinal clinical community are uncertain what is the best option, which is why we’re doing FORENSIC-UK, and entering the study is a good option for them, as both arms offer something additional that people won’t have received previously.

* Ensure potential participants understand that BCC is not just ‘more of the same’. Emphasise the personalised nature and shared decision-making of BCC. (You could refer to BCC as a “personalised treatment plan drawn up for you” or “a package of best care, tailor-made for you as an individual”)
* Avoid loaded terminology to describe surgery (e.g. ‘gold standard’) as we don’t know if surgery is better
* Do not frame the study as providing access to spinal fusion surgery –participants may be disappointed if allocated to BCC and may be non-adherent or drop out.

**Data so far** suggests that some recruiters may promise spinal fusion surgery after the study as a motivation to take part. We recommend avoiding this and instead explaining that whichever option is proven effective will be available after the study, and taking part in FORENSIC-UK still allows them to benefit in the long run from whichever is found to be effective.

**Exploring** **potential participant preferences**

What were your thoughts when you first heard about the study?

* An indirect, open question early on can elicit concerns or preferences
* ****If a potential participant indicates a preference for, or concerns about, surgery or BCC, gently explore the reasons so you can uncover any misunderstandings and ensure they make an informed decision.
* Do not assume that potential participants will have a preference for fusion surgery. This assumption on your part can be interpreted by potential participants as you giving a recommendation for surgery.

**Explain randomisation**

There is [evidence](https://pubmed.ncbi.nlm.nih.gov/29505860/) that it helps to explain first why then how randomisation is done:

You have a 50:50 chance of receiving surgery or BCC

This gives a fair comparison between groups: if one group does better, we know it is because of the group you are in, not because of differences that were there between the groups from the start

Participants are allocated by chance to two groups. This is the best way to make sure these groups are as similar as possible. If clinicians or participants picked which group to be in, that would introduce differences to the groups, for example, younger and fitter people being allocated to surgery

* Avoid terms such as ‘tossing a coin’ or ‘decided by computer’ to describe randomisation, as potential participants can feel that such terms trivialise treatment and may be misinterpreted.

**Discuss next steps**

* Once you have presented FORENSIC-UK, explained the study arms and randomisation, and explored potential participant preferences, ask if they have any further questions.
* If the potential participant would like more time to consider participation/discuss with family/friends, ensure they have the PIS and the study team’s contact details.
* If the potential participant is willing to enter the study, confirm that they are willing to accept random allocation to either arm and explain the next steps.
* If the potential participant is not willing to enter the study, ask if they are willing to be interviewed by the QRI team.

**The QRI team are here to help. For further questions and support please contact** [**ava.lorenc@bristol.ac.uk**](mailto:ava.lorenc@bristol.ac.uk)