Insert local contact details where applicable

e.g. TRUST LOGO

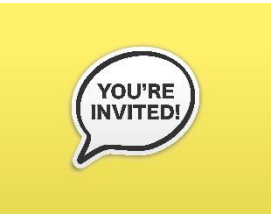
FORENSIC UK

FUSION VERSUS BEST CONSERVATIVE CARE

FORENSIC-UK Study: spinal fusion surgery or non-surgical treatment?

PARTICIPANT INFORMATION SHEET

V3.0 30 April 2025



We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please ask us.

Summary

Low back pain is common for many people and often improves without specific treatment. However, for some people their low back pain does not go away, and the use of painkillers and physiotherapy (which we call non-surgical treatment) is often successful as the first line of treatment. There has also been good research to show this treatment is beneficial. However, this approach does not work for everyone, and some people are left with on-going, severe low back pain impacting their health, daily activities and work.

Some medical professionals including doctors, nurses and physiotherapists think that 'wear and tear' may be the cause of on-going low back pain (or may contribute to it) and that an operation called '**spinal fusion**' may help.

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 relieving low back pain.*

(Image of lower back vertebrae provided by iStock)

FORENSIC-UK is a research study that has been designed by a team of spinal surgeons, physiotherapists, patients, pain specialists, researchers, statisticians, and health economists from several universities and hospitals.

For any person that takes part in FORENSIC-UK they will be involved for 2 years from the date of being placed into one of the treatment groups described below.

FORENSIC-UK is designed to see if, in a carefully selected group of people with ongoing low back pain, if they can benefit from either **Spinal Fusion Surgery** or from a personalised non-surgery treatment plan. This non-surgical treatment will be specially created for the patient and is an enhancement of the treatment patients' may have already had. It includes looking and adjusting an individual's medication, exercise and pain control management plans. We call this **Best Conservative Care.**

What is the purpose of the study?

We currently do not know if treating low back pain with surgery is better than using non-surgical treatment for patients, and we also want to find out if the spinal fusion surgery is good value for money for the NHS.

Spinal Fusion Surgery used to be standard care in the NHS for patients with low back pain but it wasn't clear how good the fusion surgery was. It also wasn't clear if the surgery was better for the patient than treating their low back pain with non-surgery care such as pain medication and physiotherapy. As a result **Spinal Fusion Surgery** is now rarely used to treat low back pain in the NHS and previous research results have also not been clear to finding out what is the best way to treat low back pain.

We would like to see if **Spinal Fusion Surgery** could still be a useful option for patients with longstanding low back pain that have not responded to previous non-surgery treatment.

Because of this, we would like to find out how **Spinal Fusion Surgery** compares with non-surgery treatments in the care of low back pain by comparing two groups of participants in the study. One group will receive **Spinal Fusion Surgery**, the other group will receive **Best Conservative Care**. This way, we will be able to find out what is the best treatment for long term low back pain.

We are hoping/aiming to recruit 270 patients (called participants) from several NHS Hospital Trusts across the UK and compare all the information collected to find out what is the best treatment to use. Participants who want to join the study will help us find the best way to treat low back pain.

We will give our results of the study to patients, the general public, healthcare providers, clinicians, and healthcare policy makers as well as publish our results in healthcare journals.

Why have I been invited?

You have been invited to consider joining the FORENSIC-UK study because you:

- have severe and on-going low back pain for 6 months or more.
- have had some non-surgical care to help with your back pain in the past 6 months or more, that has been unsuccessful.
- are aged between 18 and 65.
- you may be suitable to receive either Spinal Fusion Surgery or the Best Conservative Care.

Do I have to take part?

Taking part in the study is completely voluntary. You do not have to take part just because we have spoken to you or given you this Information Sheet and it will not affect any medical care you currently have or hope to have in the future.

What will happen to me if I decide to take part?

The NHS clinical team looking after your low back pain will first review your past care, including and imaging take of your back as part of standard care, to see if this study is suitable for you.

If they think the study is a good fit, they will ask if you're interested in taking part. You'll be a Participant Information Sheet to read, either in paper form or as an on-line link, depending on your preference.

After reading the information, if you are interested, you will be invited to a meeting at your local NHS Trust with a spinal surgeon who is part of FORENSIC-UK study. During this meeting (called a consultation) the surgeon will ask questions to see if you are a good candidate for the study. They will explain the two treatment options: Spinal Fusion Surgery and Best Conservative Care (a non-surgical option).

If you decide to take part, you'll be asked to sign a consent form to confirm you are happy to participate. During the consultation, we will also discuss your pain, record your medical details, and ask about your previous treatment for low back pain. We'll need to ensure that you have had an image of your back taken in the last year as part of your routine care and that you are able and willing to give informed consent for the study.

You will have the opportunity to ask any questions about the study at this time and if you would like to read more information about Spinal Fusion Surgery, an information booklet has been produced by the British Association of Spinal Surgeons (BASS) and is available either by electronic link: BASS Patient Information Booklet or in paper version from your clinical team

The medical images we would look at during your consultation could be either:

MRI Scan (a medical imaging test that produces detailed images of the human body, including the organs, bones, muscles and blood vessels. You will be placed inside a scanning machine and will be asked to lay down

CT Scan (a medical procedure that uses X-rays to create detailed images inside the body).

SPECT (a type of imaging test that uses a radioactive substance and a special camera to create 3D pictures)

If you join the study, you will have an equal chance (50:50) of receiving either **Spinal Fusion Surgery** or **Best Conservative Care**. The treatment that you are allocated to will be decided by what we call randomisation. This is the only way to ensure the groups are as similar as possible before any treatment starts and then allows a fair comparison between how people in each treatment group benefit or not. The process is undertaken by a computer, and we will try to do this as soon as you have completed the questionnaire described above. That way you will know as soon as possible what treatment you will have in the FORENSIC-UK study.

You will not be able to choose between **Spinal Fusion Surgery** or the **Best Conservative Care** and neither can any of the researchers or your clinical care team.

To join the study you should feel comfortable accepting either **Spinal Fusion Surgery or Best Conservative Care**.

If you are put into (allocated) the Spinal Fusion Surgery Group:

The NHS Hospital Trust which you are in will oversee your Spinal Fusion Surgery and you will be seen by a Consultant Spinal Surgeon.

- You will have the operation under general anaesthetic.
- You may be in hospital between 3-5 days
- Your clinical care will include before and after surgery consultations with your surgeon who will go through the type of fusion surgery they will perform as this is specific to each hospital and surgeon.
- You will have x-rays during and after surgery (a type of radiation image of the bones inside of the body)
- You will have clinical appointments (some appointments maybe by telephone) as part of the usual clinical care for surgery.
- Your post-operative care will include rehabilitation sessions using techniques to help manage any pain and help you to return to daily activities. This is part of the usual clinical care for surgery.
- We will invite you to have a CT scan 2 years after randomisation as part of the research study. We will use this scan for information only. (*You will only be contacted about your scan if a doctor thinks it is medically important that any findings from the scan have clear implications about your current or future health*).

If you are put into (allocated) the Best Conservative Care Group:

You will be seen by a senior spinal practitioner - usually a senior physiotherapist who will perform a detailed assessment of your needs and together with you as the patient, design a personalised treatment plan based on your previous care, your goals and expectations. This personalised plan is different from the standard care available as it will recognise that each person is different, and the treatment will be tailored accordingly.

The treatment plan will include at least one of the following:

- A course of physiotherapy including an individualised exercise plan.
- Support for active self-management, this may include exercise or lifestyle advice.
- A pain management programme with different elements which usually include, exercise, advice (for examples more suitable pain medication), specialist physiotherapy, and psychological support.
- Radiofrequency ablation/denervation – this is a non-surgical procedure to stop the nerves in your lower back sending pain signals to your brain.
- A programme of rehabilitation which uses a combination of psychological techniques to help you get through pain, become fitter and return to daily activities.

For all Participants:

Three further sets of questionnaires (sent around 6 months, 1 year and 2 years after being placed into your group) will be sent to you either in a paper form or via an e-mail link (whichever you prefer), for you to answer the questions on your computer or tablet or return via a pre-paid envelope in the post.

The questionnaires help us to find out how you are, how you feel, how you are managing your pain, and how your low back pain may be affecting your daily life, your mobility, and your mood and will form part of the participation in the study.

Some of the questions in the questionnaires are of a personal nature and you do not have to answer all of them. The questionnaires are not identified with your name but will have your study ID number instead. If you opt for paper forms to complete, we will need to use your home address for postal delivery of your questionnaires but when they are returned to us in the self-addressed envelope, we will only see your study ID number.

You will be able to answer all the questionnaires at home and it should take you around 15 to 20 minutes to complete each set.

We will also ask you to complete a question on your back pain once a month sent to your phone either by a text message, by a link sent to your email address or by post in a paper form, whichever you prefer. This question will ask you to score your pain level between 0 and 10 with 0 being no pain and 10 being the worst possible pain you feel.

We would also like to keep your details from taking part in this study to allow us to complete a 5-year follow-up by using your NHS records – we would not need to contact you for this. We would do this by checking your routine NHS medical notes including Hospital Episode Statistics (HES Data Linkage). We would also like to register your details with the British Spine Registry (BSR).

You will be able to choose to allow us to do this or not, and it will not affect you taking part in the study, but we will ask your permission for this when we go through your study consent with you.

At the end of the study you will return to your usual care within the NHS and from your treating Hospital.

Information Study:

FORENSIC-UK also has an Information Study within it which is run by researchers from University of Bristol.

The Information Study will look at what type of information people need and would like to have to help them decide whether to take part in the FORENSIC-UK study.

- You may be asked if we can audio-record the conversations you have about the study with your doctors or other healthcare professionals, so that we can learn more about how best to explain this study and new studies in the future (this will be done by a simple recorder during your consultation)
- You may be asked to take part in an interview with a researcher about your experience of being invited to take part in the FORENSIC-UK study. (this may be done via a telephone call or via a Zoom link)
- All the interviews would be carried out by researchers from the University of Bristol.
- You can choose if you would like to take part in the information study or prefer not to and it will not affect your participation in the FORENSIC-UK study

Possible benefits for taking part in the Information Study?

- You will be helping researchers develop better ways of explaining studies in the future to possible participants.
- You will be helping researchers in the design of future studies and the design of FORENSIC-UK.

Possible risks for taking part in the Information Study?

- Taking part in an interview may involve discussion of sensitive issues; however, the research team and interviewer will be fully trained and will support you during the discussion.
- Completing the interview will take up approximately 45 minutes of your time**.**

The following Flow Diagram gives an idea of what happens if you were to take part in the study:

1st Contact

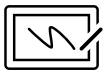
- via Back Pain Clinic
- via GP
- via Pain Management MSK Hub
- via Hospital or similar

Clinic

- As a patient, your clinic team will check you match what the study is looking for
- They will look at your medical records, imaging** and asses your previous treatments
- After learning more about FORENSIC-UK, they will ask if want to join the study
- They may also ask if you would like to take part in the Information Study

Are you eligible

- You will be able to ask questions about the study
- We will ask you to give your consent
- We will ask you to answer your first set questionnaire

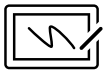


Treatment

- You will be allocated to either:
- Spinal Fusion Surgery
- Best Conservative Care

Timeline

- Treatment will take place in the 2 years of the study
- NHS waiting lists may affect some treatment timelines
- Sent a monthly text message or email to ask about your back pain
- Further 3 sets of questionnaires over the 2 years (6 months,1 year, 2 years)



CT Scan

- If you have been placed in the Surgery group, you may be asked to have an CT Scan 2 years after you were allocated to your surgery group.

We may invite you to agree to audio-record the discussion we have with you about taking part in FORENSIC and we may invite you to take part in an *interview.

The *interview will be done using ZOOM, telephone or similar and at a time to suit you.

The *interview would last around 45 minutes.

What should I consider:

To be able to take part in this study you would need to:

- Be aged between 18 and 65.
- Have suffered with severe low back pain for 6 months or more.
- If you had to describe your back pain in the last 6 months by numbers 0 to 10, with 10 being the worst pain ever, your back pain score would be more than 6.
- Have recently had some form of imaging on your lower back (MRI, CT/SPECT) within the last year where some degenerative disease, (wear and tear of the discs in the lower part of your spine) was found.
- Have had some form of non-surgery treatment for your back pain i.e.: medication, physiotherapy, pain management.
- Be able to have Spinal Fusion Surgery or receive the Best Conservative Care (as described earlier in this leaflet).
- Be able to understand the information provided in this leaflet about the study and are willing and able to provide consent.

If you have or had <u>any</u> of the following, unfortunately you will not be able to take part in this study but your continued care from your treating clinician at your NHS Hospital would continue:

- Low back related leg pain which is more painful than your low back pain including Claudication (pain in thigh, leg or bottom).
- Pain in other areas of your body that is more severe than your low back pain.
- The surgeon feels that an operation is needed to remove pressure from the nerve to help symptoms and signs of nerve compression
- Other conditions that may need Spinal Fusion Surgery for example, spine deformity, infection, tumours, spinal instability, spinal fracture, systemic inflammatory disease.
- Have had Spinal Fusion Surgery or attempted Spinal Fusion Surgery in the past.
- Have or have had some type of psychiatric difficulties i.e. diagnosed personality disorders, post-traumatic stress disorder, drug and alcohol abuse/addictions, diagnosis of severe depression. Psychiatric difficulties will be assessed at the discretion of the FORENSIC-UK clinical team at your NHS hospital.

It is important for you to report any conditions that you may still be having to your clinician or your GP practice especially if they are new or still on-going and where your recent treatment may have ended.

Are there any possible disadvantages or risks from taking part?

Spinal Fusion Surgery is a very well-known type of surgery used commonly in the NHS for other conditions. The surgeon and hospital you are in will decide on the best type of fusion to use. You will need to have a general anaesthetic, but your surgeon will go through this with you. You will be able to ask them questions about your surgery, recovery time and about having a general anaesthetic. With all surgery and medical procedures, there is always a very slight chance of risk of problems, We have considered all the known risks of Spinal Fusion Surgery, both during the surgery, straight after surgery whilst you are in hospital and during your time at home recovering.

We have also considered all risks of having a general anaesthetic and what this may mean for you as a patient. All risks to you will be assessed by your treating surgeon and discussed with you. You will be able to speak to your surgeon at any time to talk about the risks of spinal fusion surgery and you can also contact the central study team if you have any worries or concerns.

Spinal Fusion Surgery will be part of your hospital site NHS routine wait list. We will not be able to know the time from randomisation to when you will have your surgery. Your surgeon will monitor you for any symptomatic changes to your low back pain during this time. If the wait list is long until the planned date of your surgery and if needed your surgeon will reassess you following the routine care of your NHS Trust for surgery patients.

Best Conservative Care is a personalised treatment plan. We will use safe movement and exercise plans and known pain medications. Risks are low as all treatments are tailored to the individual and already used in the NHS. Your treating physiotherapist will talk through all the Best Conservative Care options with you in your first appointment to assess your treatment plan.

We do not expect a long wait list for your BCC treatment but if there is, you will be given routine care for your back pain whilst you are waiting.

All procedures in this study are known in the NHS and deemed safe

What are the possible benefits of taking part?

You will receive either **Spinal Fusion Surgery** or personalised **Best Conservative Care** to treat your pain. You will be seen by specialists in low back pain and be part of research to help us find out what is the best way to treat low back pain.

If you agree to take part in the **Information Study**, you will also be helping us find out how to improve how research is discussed with patients.

This table shows the benefits and risks of taking part in this study:

	Spinal Fusion Surgery	Best Conservative Care
What may be involved?	• X-rays during/before surgery. • Out-patient appointment with surgeon before surgery and pre-surgery assessment. • A stay in hospital to recover from surgery. • General anesthetic. • Aftercare following surgery may include attending rehabilitation sessions/doing exercises. • A CT scan 2 years after the date of Randomisation.	• A personalised treatment plan drawn up for you which will include <u>at least</u> 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

What are the possible benefits?	• Your pain may improve. • You may no longer require physiotherapy or pain relief following your surgery.	• Your pain may improve. • You may no longer require physiotherapy or pain relief following your personalised treatment plan.
What are the possible disadvantages?	• Your pain may not improve. • Risk of side-effects of medication. • Risks associated with any operation for example: bleeding from wound site, bone fracture, vascular injury, nerve damage, breakage of screw/rods, surgery not fusing, needing further or repeat surgery. • Risks with any general anaesthetic of nausea. dizziness, tiredness, headache, sore throat. • Exposure to low-level radiation due to the CT Scan at 2 years post-surgery	• Your pain may not improve. • Risk of side-effects of medication • Risk of increased pain associated with exercise

If you take part in this study, you will have x-rays of your lumbar spine. These will be computed tomography (CT), radiographic and/or fluoroscopy examinations, which all use x-rays.

Some of these procedures will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.

We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will increase the chances of this happening to you from 50% to 50.1%.

Will my General Practitioner (GP) be informed of my participation?

Your GP will be informed by letter that you have agreed to take part in this study and be provided with a copy of the Participant Information Sheet. Your GP will also be informed of the treatment group you have been allocated to.

Will I be reimbursed for taking part?

As a thank you for taking part in completing the study questionnaires we will send you a voucher. If you have to attend an appointment that is not part of your normal NHS care, for example separate appointments due to taking part in this study, we will reimburse your travel expenses, but you must keep any receipts.

Will my taking part in the study be kept confidential?

The FORENSIC-UK study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which will require data to be de-identified as soon as it is practical to do so. Personal data on all documents will be regarded as confidential. The processing of the personal data will be minimised by using a unique Participant Identification number on all study documents and any electronic databases.

All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participant's personal data.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research study and as explained in this information sheet for example text messaging service providers/companies to send study related text messages to you. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions. The Third-Party providers will have been referred to the University's Information Security for Third Party Security Assessment (TPSA): grc@infosec.ox.ac.uk

Your email address, home address and phone number will be collected in this study but only for the following reasons (and not all may apply):

- To send you the follow-up questionnaires and any reminder messages
- To send you the monthly SMS text message or email to ask about your pain.
- To send a copy of your signed and dated Consent Form and a copy of this Participant Information Sheet.
- To contact you about future research, but only if you have agreed to this.
- To contact you to invite you to take part in an interview if you have agreed to do this.

Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

Responsible members of the University of Oxford, the University of Bristol and regulatory authorities including your NHS Trust may be given access to data for monitoring and/or audit purposes of the study to ensure that the research is complying with ethical regulations.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study. It is the data controller and is responsible for looking after your information and using it properly.

Personal data during the study will be stored and used in accordance with the Oxford Clinical Trial Research Unit's (OCTRU) Standard Operating Procedure for confidentiality, protection and breach of personal data in relation to research subjects. This ensures that all personal data collected during the study is recorded, handled and stored in such a way that

is satisfies the requirements of the UK General Data Protection Regulation and requires data to be anonymised as soon as it is practical to do so .

All electronic patient-identifiable information will be held on a secure, password-protected database accessible only to authorised personnel. The processing of your personal data will be minimised wherever possible by the use of a unique participant study number on study documents and any electronic databases.

If you decide to take part in this study your local NHS Trust (Hospital) will use your identifiable data e.g. name, NHS number, home address and contact details to contact you about the research study, and to oversee the quality of the study. A copy of your fully signed consent form from this study will be given to you and a further copy kept in your medical records for as long as those records are retained, which will be 5 years after the end of the study.

We will also keep a copy of your signed consent in the central Clinical Trials Unit if you have agreed to any of the optional aspects of consent i.e. contact about future research, to assess long-term outcomes following your participation in the study, your data to be shared with the British Spine Registry or if you would like to receive a summary of the results of this study for 5 years after the end of the study.

We will store any research documents with personal information, such as consent forms, securely at the University of Oxford for 5 years after the end of the study, as part of the research record.

Anonymised research data from this study will be kept by the University of Oxford for 5 years after the end of the study.

We will be using information from you/ your hospital/GP records/ NHS England, and other central NHS registries where relevant to you being able take part in this study and will use the minimum personally identifiable information possible.

We will also ask you for consent for suitably qualified researchers to access your digital routine NHS records, British Spine Registry (BSR) and Hospital Episode Statistics (HES Data linkage) to be potentially accessed at 5 years from the point of entry into the study to assess the long-term outcomes following any participation in this study.

We will store any research documents with personal information, such as consent forms, securely at the Oxford Research Archive, University of Oxford for 5 years after the end of the study.

If you claim travel expenses for your additional clinic visits due to taking part in FORENSIC-UK, your bank details will be stored for 7 years in accordance with the University of Oxford Financial Policy.

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form, and your details separate from one another and any research data for 5 years after the end of the study.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting forensic@ndorms.ox.ac.uk

What will happen to the data collected for the Information Study?

If you give written consent to take part in the Information Study any audio files, made using encrypted audio-recorders, will be saved by a member of the research team and sent directly to the local NHS Trust secure servers. Electronic data (audio files) will then be transferred to the University of Bristol servers via an encrypted electronic data transfer method. Data sent via this method is encrypted preventing any third party from reading the exchanged data. University of Bristol is the data controller for the Information Study and is responsible for looking after your information and using it properly.

All details will be saved under your participants' unique ID number and secured in password protected files. Oxford will retain a links document containing your personal identifier and this will not be shared with the University of Bristol.

Interview data will be transcribed by University of Bristol employees or by a University of Bristol approved transcription service that meets data security protocols.

Only authorised members of staff involved in the research will be able to access the data. University of Bristol may use this data as part of publications, teaching and presentations. All quotes will be completely anonymised. If a section of audio is played (i.e. for training), voices will be modified, and any personal information will be removed. At the end of the study, the researchers at the University of Bristol will keep audio-recordings for at least 10 years before they will be destroyed.

Pseudo-anonymised transcriptions (this is making a written copy but hiding your identity) of interviews and audio recorded recruitment discussions will be made "Controlled Access" at the end of the study. This means that transcripts will be stored in an online database for 20 years, which can be accessed by approved individuals who are interested in conducting their own analyses of the data. These individuals will have to apply for permission to do this, and applications will be assessed by an independent committee. We will therefore have no control over how these data are used in future. There will be no way to identify you, or other individuals mentioned in your interviews/appointments.

Sharing access of research data and findings is considered good research practice and is a requirement of many funding bodies and scientific journals. Sharing data helps to maximise the impact of money invested into conducting research studies and can encourage new avenues of research."

What will happen if I don't want to carry on with the study?

Taking part in the FORENSIC-UK Study (and the optional related Information Study) is voluntary; if you decide to withdraw from either study, you can do so at any time. You do not need to give a reason for your decision, and it will not affect your future medical care.
If you were to decide to stop taking part in the study at any time, any data collected on you would be kept. You would not be contacted about the study again or have any further data collected. Any data collected up to the point of withdrawal may be used for the study.
Any data we have collected during you time in the study before you choose to stop taking part will be kept and used at the end of the study and analysed with all other data collected.

If you decide that you do not want to take part in any aspect of the FORENSIC-UK study, we would be interested in interviewing you to understand why. This will help us to improve the design of future studies.

What will happen to the results of this study?

With your agreement, we will send you a summary of the study results at the end of the study. When you join the study, we will ask if you would like to have a copy of the results, and how you would like to receive these (either by post or email).

The results will be shared with other healthcare researchers and professionals to improve future patient care. The results may also be published in an anonymised form, and presented in research reports, at scientific conferences, and in scientific journals. Any data that could identify you will not be included in the results. A similar study called FORENSIC-AUS is also being run with a linked team of healthcare researchers and professionals in Australia. The team in Australia will be collecting similar information to the FORENSIC-UK study with participants with low back pain. This will enable us to collect more information to help us find the best way to treat low back pain. With further funding, the anonymised results will be shared between the UK and Australia at the end of the study for data analysis. No information will be shared which could identify you.

After the end of the study an anonymised study dataset (this is a form of information that we use from the study but has no identification of any participants) will be created and stored for as long as it is useful and may be shared with other researchers upon request.

We will work with our Patient Participant Involvement (PPI) group and other organisations (e.g. Versus Arthritis and Back Care) to ensure the study results are seen by the public. We may also use social media (e.g. Blue Sky).

What if I have a concern or a complaint?

If you have a concern about any aspect of this study, please speak with FORENSIC-UK research team: forensic@ndorms.ox.ac.uk. They will do their best to answer your questions.

The investigators recognise the important contribution that volunteers make to medical research and will make every effort to ensure your safety and wellbeing.

The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. This insurance also includes a 'No Fault' clause which is a legal provision stating that nobody needs to prove who is at fault to receive compensation or take action. This clause will remove the need to assign blame if something does go wrong, or you are harmed, as **a result of the research**. If harm is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint.

The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, please contact the study research team by email: forensic@ndorms.ox.ac.uk **or** the study Chief Investigator: Prof. David Beard David.beard@ndorms.ox.ac.uk

You may also contact University of Oxford Research Governance, Ethics & Assurance (RGEA) on 01865 616480, or the director of RGEA at rgea.complaints@admin.ox.ac.uk

The Patient Advisory Liaison Service (PALS) is a confidential NHS service for England and Wales that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team, please contact <insert relevant NHS site phone number and email> or visit the PALS website: https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/

For support in Scotland, please contact the Patient Advice & Support Service (PASS)
PASS national helpline phone number: 0800 917 2127
PASS website (webchat): www.patientadvicescotland.org.uk

For support in Northern Ireland please contact the Patient and Client Council (PCC)
PCC national helpline number: 0800 9170 222
PCC website: www.patientclientcouncil.hscni.net

PALS, **PASS** or **PCC** can advise those who wish to raise concerns, give feedback or comments, or make a complaint regarding the NHS care in England & Wales, Scotland or Northern Ireland.

How have patients and the public been involved in this study?

Members of the public that have undergone low back pain and treatment have helped develop this research study and what research questions should be asked. The patients and public members will continue to be involved in the study and we have a patient advisor as part of our study team

Further information on public involvement of clinical trials can be found through the following links:

https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-take-part-in-a-study.htm

Who is organising and funding the study?

FORENSIC-UK is sponsored by the University of Oxford and funded by the National Institute for Health and Care Research (NIHR) and their Health Technology Assessment (HTA) programme.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by Cambridge East Research Ethics Committee.

Participation in future research:

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form, and your details separate from one another and any research data.

Further information and contact details:

The FORENSIC-UK research study team can be contacted:

by email: forensic@ndorms.ox.ac.uk

by post:

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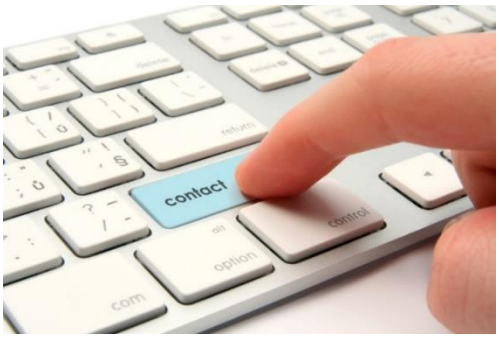

Thank you for considering taking part in the FORENSIC-UK Study.