<To be printed on local headed paper>

Personal Consultee Information Sheet

A PHASE IIb, RANDOMISED-CONTROLLED, TWO-CENTRE CLINICAL TRIAL ON THE EFFICACY OF A HOME-BASED **EX**ERCISE AND MOTIV**A**TIONAL PROGRAMME IN PATIENTS BEFORE AND AFTER **L**IVER **T**RANSPLANTATION

1. What is the information sheet for?

You have been nominated to act as a Personal Consultee by a participant in the ExaLT Clinical trial. This is because, due to the nature of the liver disease, during the course of the study, the participant has lost mental capacity and cannot confirm that they are still happy to take part in the trial. In these situations, the law allows a representative to provide an opinion on their behalf.

We would like to invite you to give an opinion on whether the participant would want to continue taking part in the ExaLT clinical research trial. Before you decide, we would like you to understand why the research is being done and what the trial would involve. This Personal Consultee Information Sheet (PIS) tells you the purpose of the study. A member of our team will go through this information sheet with you and answer any questions. You can talk to others about this if you wish and please ask us if anything is not clear.

2. What is the purpose of this trial?

Liver transplantation is the main curative procedure for patients with liver failure and/or liver cancer, in which other treatments cannot help. Liver transplantation exerts a huge stress on the body and mind, especially in people who are already physically and mentally frail because of their liver disease. We know that frailty prior to transplant surgery results in more complications, longer hospital stays and contributes to approximately one in ten patients either dying whilst still on the transplant waiting list or shortly after liver transplantation.

Exercise is one of the most powerful medical therapies available, with numerous proven benefits to patients with diseases like diabetes, heart disease and cancer. Despite this, exercise is not currently used in patients with liver failure or recovering from liver transplantation, due to a lack of robust research evidence. Exercise may have the potential to improve the lives of people with liver failure and/or cancer and reduce the side-effects of liver transplant surgery. The current standard of care for NHS patients awaiting liver transplantation is an advice leaflet. Evidence-based exercise programmes around the time of transplantation do not exist. Only a few small studies have indicated that supervised, hospital-based exercise can improve physical function and quality of life.

The aim of this trial is to determine the effect of a home-based exercise and motivation-support programme in patients undergoing liver transplantation on their quality of life after surgery. Furthermore, we hope to better understand how the exercise works and what motivational support is needed to enable patients to engage with exercise in the long-term, not only while waiting for a liver transplant, but also long after the transplant is completed.

3. What is the intervention being investigated for this trial?

Participants will be randomly allocated to one of two groups. There will equal numbers of participants in each group (i.e. 133 in each group):

- **Group 1** (experimental treatment; known as 'intervention group'): A home-based exercise and motivation support programme delivered by a physiotherapist. The intervention will begin whilst patients are on the liver transplant waiting list and end approximately six months after liver transplantation. The patient will take up to five exercise sessions a week which will include three aerobic type exercise (e.g. walking) and two resistance-based bodyweight exercise sessions (e.g. chair stands). The intervention will consist of regular strength and endurance exercises, tailored to each patient's level of fitness. During clinic visits and via telephone calls a physiotherapist will provide motivational support throughout the exercise.
- **Group 2** (standard of care; known as 'control group'): Patient advice 'exercise' leaflets before and after liver transplantation. These will be provided and explained by the physiotherapists.

We shall assess the effectiveness of the intervention by measuring quality of life before and after liver transplantation in both groups of patients during the trial period. The home-based exercise and motivational support programme will be deemed effective if the quality-of-life scores are higher with the intervention (Group 1) than the control (Group 2).

4. What would taking part involve for me?

As a personal consultee, you may be a close friend, relative or carer for the participant. You will be asked to read this Personal Consultee Information Sheet and will be given time to discuss it with your family and/or friends and ensure that all of your questions have been answered by the ExaLT Clinical Trial team. If you agree to act as a Personal Consultee, you will be given this information sheet to keep and asked to sign a Personal Consultee Declaration Form.

The completed Personal Consultee Declaration Form will stay on record in the participant's trial file, be noted in their medical records, and be available for review by the research team, representatives of the Sponsor, regulatory authorities, or from the NHS Trust, where relevant to their participation in this research trial. A copy of the Personal Consultee Declaration Form will also be held at Birmingham Clinical Trials Unit, University of Birmingham and a copy will be made for you to keep.

5. What would taking part involve for the participant - the study procedures for this trial?

- **Monitoring of physical activity and exercise in the trial**: All patients will be provided with a 'participant exercise diary' (to keep a record of their exercises completed during the trial) and an accelerometer. The accelerometer is an electronic device like an activity wrist watch that the patient will be asked to wear on their wrist to monitor their daily physical activity levels.

  The accelerometer will be worn continuously for 14 days during each monitoring session.

  In total they will be asked to monitor their daily activity from 4 up to a maximum of 7 times during the study, depending on when they receive their liver transplantation.

  They will first receive the device/s during their initial clinic visit and asked to return device/s after 14 days using a Freepost envelope supplied. Device/s will then be posted to the patient at home prior each 14-day monitoring session. These sessions will occur approximately 14 days before their next scheduled clinic visit, and they will be asked to return the device/s at this next clinic visit.

  When they have finished the study intervention, they will be asked to return all the equipment to the research team.

  The trial physiotherapist will explain this to them throughout the trial.

  With regards to the accelerometer no personal identifiable data will be collected. There will be no download or app to sign up to. Data will be automatically extracted from the watch directly to a secure central server at Amazon Web Services and Microsoft Azure in the United States, with whom the trials unit have a contractual agreement.

- **Data collection:** As part of the trial we will collect some information about the patient's general health, physical fitness, quality of life and carry out blood tests. We will need to access the patient's data held by the NHS or their GP using their NHS number and other identifiable information. We have outlined below what will happen at each clinic visit regardless of which group the patient is in. Where possible, we will aim to perform each trial visit at the same time as the patient's routine liver clinic appointment. The flow chart at the end of this information sheet will provide you with more information. All the assessments and procedures shown below will be delivered by an appropriately trained clinical member of the study team:

  - Medical history, physical examination and clinical observations (including weight, blood pressure, oxygen saturations, heart rate)

- Questionnaires: During the study visits the patient will be asked to complete five health questionnaires (including quality of life). These will take approximately 30 minutes in total.

- Blood tests: The majority of the blood tests (e.g. full blood count, infection markers, kidney function, liver function, blood clotting) will be undertaken as part of the patient's routine clinical care. We will collect additional blood samples, required for the trial at the same time. This may mean an extra three bottles of blood, which is between 10 to 15 millilitres (equivalent to a tablespoon).

- Physical functional measurements – A brief (5 minute) functional test will be completed which will involve 5 chair stands, three 10 second standing balance tests and three squeezes of a piece of equipment called a 'handgrip' with a 30 second break in between.

- Nutrition Measurements –The patient will undertake a series of tests which will take approximately 10 mins as part of routine practise to assess the patient's muscle and fat masses. These include muscle arm measurements - a measurement of the muscles in the patient's right arm using a tape measure. For those who consent to the *optional* 'muscle' sub-study (described in full later in this leaflet) we will also measure the fat tissue in the same arm using a skin fold calliper. This will feel like a gentle pinch and would rarely cause a brief discomfort.

6. How many visits are there and how long will this take?

For both groups, as part of the trial, patients on the liver transplant waiting list will be assessed initially at a baseline visit (week 0), at which time they will undergo the assessments described above and be provided with either the exercise programme or the 'exercise' advice leaflet by the study physiotherapists. After the baseline visit, they will attend face-to-face trial visits at 6 to 12 weekly intervals until they have had their liver transplant. After their liver transplant, they will be assessed at 6 to 12 weekly intervals until 24-weeks after liver transplant, at which stage the study intervention will end.

All our trial visits/assessments (*where possible*) will be scheduled to occur at the same time as the patient's routine liver clinic visit, in keeping with the pre-transplant and post-transplant protocols. Depending on when they have their liver transplant, we estimate up to 10 to 12 clinic visits over the duration of this study. As a consequence of a significant event such as the viral pandemic where there is local, regional, or national lockdowns a Telecall and/or video call visit may be used instead of a face to face visit.

The maximum time we expect any patient to remain in this study is approximately two years. This is made up of a maximum intervention period of a year (range 1 to 52 weeks due to

unpredictable nature of timing of liver transplant) before liver transplant and 24 weeks after liver transplant; with an additional 24 weeks of follow-up.

On a rare occasion, we may ask the patient to attend an extra clinic if we are unable to complete all the assessments during the patient's routine clinic visit. The patient will be informed well in advance to allow planning. If the patient is randomised to Group 1 their initial visit will take between 5 and 6 hours. Each visit thereafter, regardless of group allocation, will take 30-60 minutes in addition to their normal clinic time. In addition to the clinic visits and assessments, if the patient is selected to join Group 1, they will also receive telephone health calls every 2-4 weeks whilst on the transplant waiting list and after the liver transplant. These telephone calls will take approximately 15-30 mins. If the patient owns a smartphone or computer with internet access, there will be the opportunity to have virtual 'FaceTime' health call instead of a telephone call.

If the patient does not have a liver transplant within the 52 weeks of starting the trial intervention, they will be withdrawn from the trial intervention (as described in question 3) and their standard of care will resume as normal. Although this means that the patient will no longer receive the trial intervention, they can continue with the advice and experience gained. We would also like to continue to collect some health data from their medical notes including routine blood test results, complications of their liver disease (e.g. hospital admissions) and ask them to complete two questionnaires every 3 months after the trial intervention has ended. This will be done during the patient's routine post liver transplant clinic. This will only occur if they are still willing to participate in the study and once the study ends no more data will be collected. The patient can choose not to continue and this will not affect the clinical care they receive.

7. The patient will also have the option of being involved in a 'muscle' sub-study (optional).

What is this for and what does it involve?

At the beginning of the trial, at the baseline visit, the patient will have the opportunity to consent and take part in the 'muscle' sub-study of the ExaLT trial. This sub-study is optional. We would like to provide mechanistic information regarding how exercise (before and after liver transplantation) works directly on their muscles and physical fitness, which may in turn explain any changes in quality of life. This information will also aim to understand what 'dose' of exercise (i.e. intensity, duration, frequency) is required to see significant improvements in physical function and quality of life and how the motivation-support component may have contributed to these changes.

The sub-study will aim to recruit 100 out of the possible 266 participants in the main ExaLT trial. The aim would be to recruit equal numbers of patients from each group (1 and 2). The sub-study is completely **optional** and the patient will be asked to decide if they want to take part when they complete the consent form for the main trial. If the patient does not consent to the sub-study, it will not affect their routine clinical care or their ability to participate in the main ExaLT trial.

The sub-study will take place alongside 3 trial visits,

A- Visit 1 (baseline),
B- Visit 2 (6 weeks)
C- Visit 6 (if no transplant within the 1-year timeline) or Visit 9 (24 weeks after transplant).

If involved in the sub-study group, the patient may be asked to attend their clinic appointments earlier so we can complete these tests before their routine clinic time. We anticipate each visit in the sub-study group will take 60-90 minutes in addition to their normal clinic time and main trial visit. If at any stage the patient decides to withdraw their consent from the sub-study, they will still be able to participate in the main ExaLT clinical trial.

If they wish to participate in the sub-study they will be asked to take part in the following additional assessments:

- 6-minute walk test – the patient will be asked to walk along a corridor for a total period of 6 minutes. Their oxygen saturation, heart rate and perceived exertion will be recorded at the beginning and at the end of this test.

- Exercise capacity test (known as a CPET) – This is an exercise test to see how well the patient's heart, lung and muscle cope with exercise. This will be done using an exercise bike in our cardio-respiratory department. Before the test, the patient will need to avoid any heavy meals, remove any nail varnish, bring exercise or comfortable outfits, and bring a comfortable pair of shoes. Most people may prefer to have running shoes/trainers. During this test, the patient will have a breathing mask fitted and asked to perform breathing exercises to assess their lung function and to record the oxygen intake and carbon dioxide production when they exercise. This will be tightly fitted to avoid gas escaping which can give incorrect results. Electrodes will be placed on the patient's chest to record their heart rate and rhythm throughout the test. An oxygen sensor will be placed on one of the patient's fingers to monitor their blood oxygen levels and a blood pressure cuff will be fitted on their arm to measure their blood pressure. Rarely, the patients find that the blood pressure cuff can cause minor discomfort to their arm when inflated. The exercise will be done on a stationary exercise bike. They will be asked to start slowly and the speed and intensity will slowly over a period of time be increased to reach their maximum exercise capacity which is between 8 and

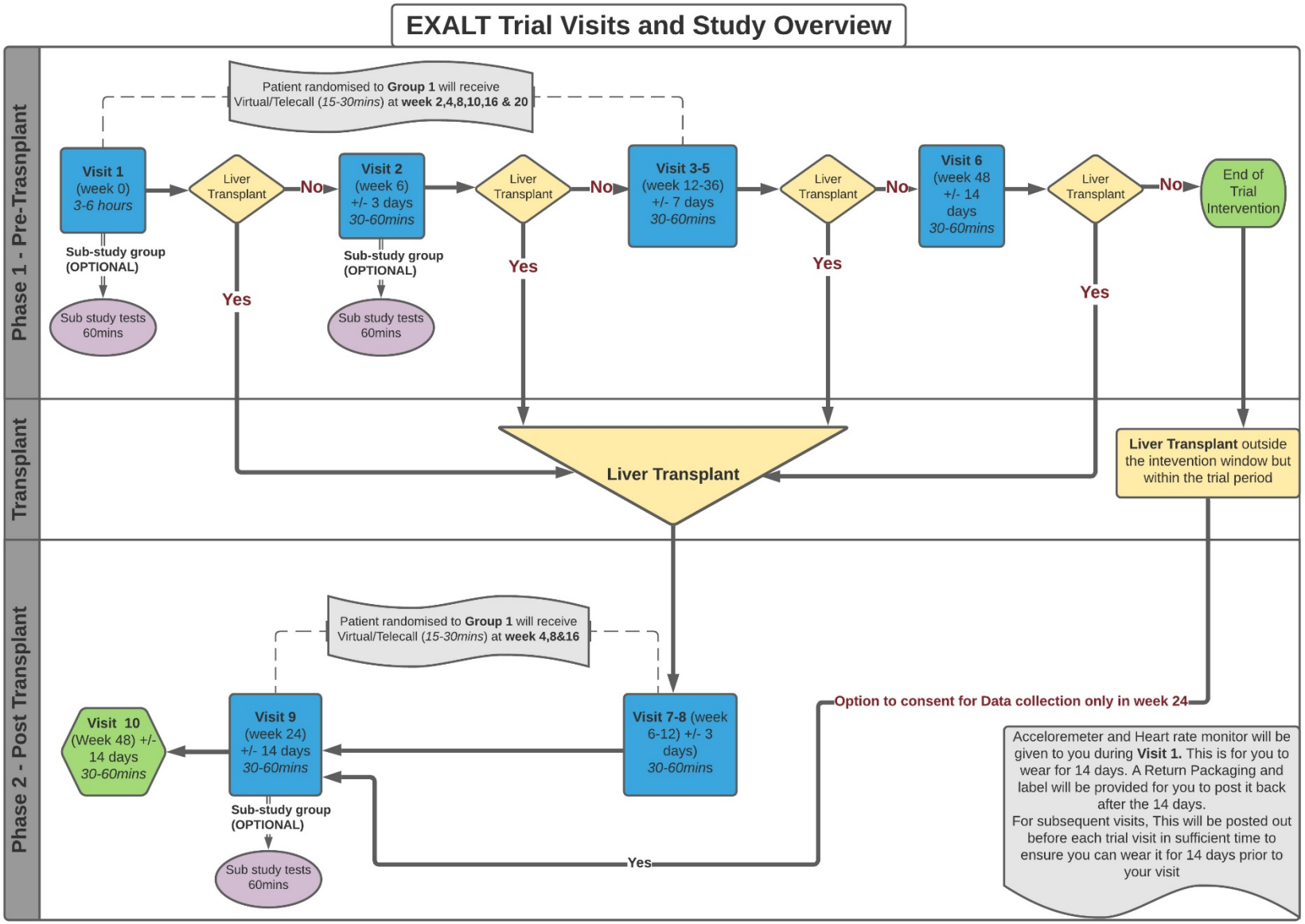
12 minutes. The test can be stopped at any time if the patient indicates by raising their hand in a stop signal. There is no pass or fail. As the patient will have gone through rigorous fitness assessments to get on the transplant waiting list, the research results (i.e. exercise capacity and oxygen consumption) of the CPET test will not be available to the patient's regular clinical doctors/trial team, and would not be used to make any decision regarding their care or liver transplant. However, any serious events such as an irregular heart rhythms or collapse will be recorded and the patient's clinical team will be made aware of this for their own clinical safety before and after transplant. The test carries a risk of significant complications in about 1 in 10,000 patients. These include the need for hospitalisation due to exercise injury or irregular heart rhythms.

- Thigh Muscle Ultrasound – this is an ultrasound of the patient's thigh muscles. This will take about 15-30mins. The patient will be required to expose their right upper thigh and lie at a 45-degree angle on an examining bed. The patient must wear appropriate clothes to allow for this or bring a pair of shorts to change into. The images captured will be stored as part of their test results and the data protection applies. The procedure is safe, does not hurt and does not involve any radiation exposure.

- Additional blood tests (21 millilitres, equivalent to one tablespoon) – will be taken at each of the three visits to assess the amount of muscle inflammation/stress during the sub-study. These blood samples will be processed and safely stored in a -80 degrees-freezer, using the patient's unique trial number.

- In addition, if the participant is willing and their care is within the Queen Elisabeth hospital in Birmingham, a sample of urine 20-30ml – will be taken at each of the three visits as part of their routine care, and will be safely stored in a -80 degrees-freezer, using your unique trial number, for future research projects.

All samples will be stored in keeping with Good Clinical Practice (GCP) guidance at the University of Birmingham prior analysis or use in future ethically approved research.


EXALT Trial Visits and Study Overview
Phase 1 - Pre-Trasnplant
Transplant
Phase 2 - Post Transplant
Patient randomised to Group 1 will receive Virtual/Telecall (15-30mins) at week 2,4,8,10,16 & 20
Visit 1 (week 0) 3-6 hours
Liver Transplant
No
Visit 2 (week 6) +/- 3 days 30-60mins
Liver Transplant
No
Visit 3-5 (week 12-36) +/- 7 days 30-60mins
Liver Transplant
No
Visit 6 (week 48 +/- 14 days 30-60mins
Liver Transplant
No
End of Trial Intervention
Sub-study group (OPTIONAL)
Sub study tests 60mins
Yes
Sub-study group (OPTIONAL)
Sub study tests 60mins
Yes
Yes
Yes
Liver Transplant
Liver Transplant outside the intevention window but within the trial period
Patient randomised to Group 1 will receive Virtual/Telecall (15-30mins) at week 4,8&16
Visit 10 (Week 48) +/- 14 days 30-60mins
Visit 9 (week 24) +/- 14 days 30-60mins
Visit 7-8 (week 6-12) +/- 3 days) 30-60mins
Option to consent for Data collection only in week 24
Sub-study group (OPTIONAL)
Sub study tests 60mins
Yes
Accelerometer and Heart rate monitor will be given to you during Visit 1. This is for you to wear for 14 days. A Return Packaging and label will be provided for you to post it back after the 14 days.
For subsequent visits, This will be posted out before each trial visit in sufficient time to ensure you can wear it for 14 days prior to your visit

8. What if I don't want the participant to continue taking part in the ExaLT trial?

As the participant is currently unable to provide consent for themselves, we are asking you to decide whether you think the participant would want to continue taking part in the trial. If you decide that the participant would not want to continue taking part, you can tell us this. You can do this at any time and do not need to give us a reason. The information collected up until their withdrawal may still be used as part of the trial research. Regardless of your decision, their care will continue as normal including all usual treatments and routine follow up whilst they are on the liver transplant waiting list. Their position in the liver transplant waiting list will not be affected and they will still be called up by telephone as normal when a donor organ liver has been allocated to them.

If you decide the participant would want to be withdrawn from the 'muscle' sub-study, blood samples already collected as part of the sub-study may have already been analysed so we cannot withdraw samples already collected, but no more samples will be taken.

9. Will my travel expenses be reimbursed?

We are aware of the many costs including travel expenses that the participant may incur for taking part in this trial. The Exalt Clinical Trial Team will ensure that the trial visits are on the same day and time as the routine liver waiting list clinic. If you are attending the trial visit with the participant, we will provide a fixed amount (£100 per participant for the entire study) towards the clinic visits and refreshments for you and the participant.

10. What are the possible benefits for taking part in this trial?

We do not know whether this trial will directly help the participant, but it will help improve the care of patients with liver failure (and/or liver cancer), who are waiting or who have had a liver transplant. The participant may feel the indirect benefits of being part of this trial, for example, they will receive care additional to the standard, taking part may also improve their patient experience and knowledge of the liver disease process and receive closer monitoring and follow up. They may also feel empowered knowing that their contribution to clinical research will help advance new and improved treatments/services for patients undergoing a liver transplant.

11. What are the possible risks for taking part?

The exercises will be matched to the participant's ability and individualised to their needs, however there is still the possibility of sprains or injuries if the exercises are not carried out correctly. In the event of this occurrence, please seek medical advice and inform the ExaLT Clinical Trial Team. The participant may experience temporary pain/discomfort when they have blood taken and may develop a bruise at the site where the needle has sampled blood.

To minimise this, additional blood tests for trial purposes will be taken (when possible) at the same time as blood tests as part of their routine clinical care.

In relation to an ongoing COVID pandemic, current government guidelines will be adhered to, and local NHS and University procedures will be followed to minimise the risk of exposure to the virus.

12. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the ExaLT Clinical Trial Team who will do their best to answer your questions (see contact details on the last page). If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Services (PALS).

Contact details are: << INSERT LOCAL DETAILS HERE>>.

In the unlikely event that something does go wrong and your friend/relative is harmed during the research due to someone's negligence, then they may have grounds for legal action and compensation against the sponsor (the University of Birmingham) but they may have to pay their legal costs. The normal NHS complaints mechanisms will still be available to them, if appropriate.

13. Will their details be kept confidential?

All information collected about your friend/relative for this trial will be subject to the General Data Protection Regulation GDPR) and Data Protection Act 2018 for health and care research and will be kept strictly confidential.

14. How will we use information about your friend/relative?

The University of Birmingham will be using information from your friend's/relative's medical records to undertake this trial and act as the data controller. This means that the University of Birmingham is responsible for looking after their information and using it properly.

All information collected by the research team will be safely and securely stored in the ExaLT Trial Office, at the University of Birmingham, on paper and electronically and will only be accessible by authorised personnel. Your friend/relative will be identified by a unique trial number. The only people in the University of Birmingham who will have access to information that identifies your friend/relative will be people who manage the study or audit the data collection process. In routine communication between their hospital and the ExaLT Trial Office, the participant will be identified by trial number, initials and date of birth.

Your friend/relative has signed a consent form, agreeing to allow research staff from the ExaLT Trial Office to look at their study records, including their medical records. They have also been

informed that it may be necessary to allow authorised personnel from government regulatory agencies (e.g. the Sponsor and/or NHS bodies to have access to their medical and research records. This is to ensure that the study is being conducted to the highest possible standards.

The research team will use your name and contact details to contact you about the trial. With your permission, a copy of your signed Personal Consultee Declaration Form will also be sent to the University of Birmingham for this trial.

Health and care research should serve the public interest which means that we have to demonstrate that the research serves the benefits of society as a whole. We do this by adhering to the UK Policy Framework for Health and Social Care Research.

15. What will happen to the data the participant provides?

As part of this trial, we will be collecting personal data such as name, date of birth, NHS number and information held in their NHS records such as health information and medical history. This information will be held securely at the University of Birmingham and will be kept separate from the research data.

Clinical trial assessments in the form of results of their functional tests, questionnaires and medical history will firstly be stored at the hospital where they are being treated and will then be transferred to the University of Birmingham for analyses and storage. The assessment/questionnaires will be pseudo-anonymised. This means any identifying information such as their name will be replaced with their own unique trial number, their initials, date, and time point (e.g. visit 1). The results may be shared with collaborators involved in the ExaLT Trial at the end of the trial in a pseudo-anonymised way (i.e. trial number, initials, date and time point).

During the trial, the participant would be asked to wear a watch to record information about any exercise they might do. This information will then be downloaded to a secured, password protected, cloud server where it will be formatted into a report. They will only be identified by their unique trial number. The data will be stored on the cloud for a maximum of 3 years after the end of the trial.

In some instances, the participant would have been asked permission and consented to video or audio recording of some of their visits with the study physiotherapists. This is so the information can be reviewed and analysed to assess whether the physiotherapist has delivered the exercise and motivation support in keeping with their trial training and protocol.

Where possible, the recordings will be made in a way to ensure your friend/relative's anonymity (identifying features) will not be shown on video recordings and will not be shared with anyone outside of the research team.

The information collected will then be analysed from the recording by the research team, and the details written into a document for storage at the University of Birmingham. Personal information will be replaced with person A, B etc. when we write the details of the visit into the document, in order to conceal your friend's/relative's personal details (e.g. name). Once the recordings have been analysed, the video and audio files will be stored on a password protected, secure online system at the University of Birmingham. Video and audio files will be securely deleted prior to the end of the trial. Only members of the research team will have access to these files, using their University details. All the information collected about your friend/relative will enable us to run the trial and analyse the results.

16. What will happen to the blood samples given?

The only blood samples that will be collected and stored are part of the optional 'muscle' sub-study - described above. The blood samples will be pseudo-anonymised (i.e. all personal information like their name will be removed) and labelled using their assigned unique trial number, initials, date, and time point (e.g. visit 1). It may be required that we send their samples to partners (including commercial companies) to help analyse the samples and answer the study questions. We therefore ask that their samples are given as a gift, whereby they will become the property of the University of Birmingham.

17. Donating samples for future research.

If the participant is taking part in the muscle sub-study, the participant will be asked if they are willing for samples to be donated for future research. During this sub-study, it is likely that the blood samples will be used up. However, in some cases there may be remaining samples which if the participant is willing can be securely stored for future ethically approved research. In addition, participants attending the Queen Elizabeth Hospital in Birmingham, will have the option for routine urine samples to be collected at the three sub-study visits and securely stored for future research.

If the participants does not wish for their samples to be stored and used in future research, the samples will be destroyed either at the end of the study (in the case of blood samples) or as part of routine practice (in the case of urine sample).

18. How will the personal data be kept secure?

The University of Birmingham takes great care to ensure that personal data is handled, stored, and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

Any physical paperwork containing identifiable data will be kept in an access-controlled and secured room inside a locked filing cabinet.

In relation to this trial, electronic data will be kept on secure servers within the University of Birmingham.

When the trial is published, no identifiable or personal information will be published and so no-one, will be identified from it.

We may share information with other organisations for the purpose of improving clinical care and knowledge. These organisations include NHS organisation, companies that work with the NHS/NHS Bodies, Universities, or government regulatory agencies. We have appropriate agreements in place with them to protect and safeguard yours and your friend/relative's data. No personal information will be included and this will not affect your friend/relative's future care, access to services and insurance.

You can withdraw your consent to our processing of your data at any time. Under the provisions of the General Data Protection Regulation (GDPR), you have the right to know what information the trial has recorded about you. If you wish to view this information please contact Legal Services (Legal Services University of Birmingham Edgbaston Birmingham, B15 2TT). Please note that a small administrative fee may be payable to retrieve this information. All individuals who have access to your information have a duty of confidentiality to you.

19. How long will the personal data be kept?

The University of Birmingham and the NHS will keep identifiable information about your friend/relative for at least 10 years after the study has finished, to allow the results of the study to be verified if needed. If you withdraw your friend/relative from the trial, we will keep the information we have already obtained, but to safeguard their rights we will use the minimum personally identifiable information possible.

20. What will happen to the results of the research trial?

At the end of the trial, we will report results to the funder of the research and publish them in appropriate academic and professional journals and at conferences. The publications will be made available to the general public on websites, should you be interested. You can also access the trial website to follow its progress and see the results when available.

21. What happens when the research trial stops?

After the trial has finished, the participant's clinical care will go back to the current standard of care and their routine liver clinic follow-up.

22. What happens if new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, a member the ExaLT Clinical Trial Team will share the new information with you and provide advice on whether the participant should continue in the trial. You will have the option to decide if they should continue or withdraw from the study. If you will like the participant to continue, a member of the ExaLT Clinical Trial Team may ask you to re-sign a Personal Consultee Declaration Form. If you recommend that they do not to continue, their care will be transferred to their normal team to continue as standard.

23. Involvement of General Practitioner / other healthcare practitioner

The Participant's GP has been informed that they are taking part in the trial and your friend/relative has also given consent for us to share their progress in the trial with their GP, as needed for their clinical care.

24. Who is organising and funding the research?

The ExaLT trial is funded by the National Institute for Health research (NIHR) Efficacy and Mechanism Evaluation (EME) Programme (reference number – 129318). It is sponsored by the University of Birmingham and is being organised and run on their behalf by the Birmingham Clinical Trials Unit. No member of the research team is being paid for including your friend/relative in this study.

25. How have patients and the public been involved in this trial?

A group consisting of patients and members of the public helped to develop this research topic and the research questions that should be asked. Potential participants were involved in describing the inclusion and exclusion criteria for people taking part in this trial. In designing this trial, we have considered patient opinions on the frequency of participant visits and the tests that will be carried out.

Two members of this group are also co-applicants in this trial and helped to develop and review this Information Sheet. They will continue to be involved in the trial.

26. Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your friend/relatives' interests. This trial has been reviewed and given favourable opinion by Hampshire A Research Ethics Committee.

27. Who can I talk to if I have any other questions or concerns?

You can speak to a member of the ExaLT Clinical Trial Team on the number below and speak to someone. We will do our best to answer any of your questions.

If you have any queries about the processing of your data, please contact dataprotection@contacts.bham.ac.uk for the attention of the Data Protection Officer.

Thank you for taking the time to read this information sheet.

Exalt Clinical Trials Team:

Contact details are: << INSERT LOCAL DETAILS HERE>>.