**Participant Information Sheet/Consent Form**

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| **Title** | A pilot study of telerehabilitation for people with chronic liver disease. |
| **Short Title** | Telerehabilitation for people with chronic liver disease. |
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| **Coordinating Principal Investigator/ Principal Investigator** | Professor Andrew Maiorana – Fiona Stanley Hospital  |
| **Associate Investigators** | Dr Koya Ayonrinde – Fiona Stanley HospitalNikil Redipali – Curtin University |
| **Location**  | Fiona Stanley Hospital  |

**1 Introduction**

You are invited to take part in this research project, to investigate whether an exercise program provided via video calls (known as telerehabilitation)can improve the health and fitness of participants with chronic liver disease.

This Participant Information Sheet/Consent Form outlines the research project and what would be required of you if you choose to consent to participate.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Exercise has been shown to improve the health of people with chronic liver disease. It may improve a person’s strength and endurance and help them manage their weight. Exercise programs for conditions like chronic liver disease are often provided at hospitals or community centres which can be inconvenient for people to attend and incur costs associated with travel and parking. Telerehabilitation is an alternative treatment which involves completing an exercise program at home, with exercise guidance provided through a video call with the exercise supervisor.

The aim of this study is to investigate the effects of a telerehabilitation program on the health and fitness of people with chronic liver disease. If shown to be effective, telerehabilitation will make an exercise program much easier to access for people with chronic liver disease and may lead to this form of exercise becoming more available.

This project is being conducted by Nikil Redipali and will form the basis of a Physiotherapy with Honours degree at Curtin University, under the supervision of Prof Andrew Maiorana (Exercise Physiologist, Fiona Stanley Hospital) and Dr Koya Ayonrinde (Gastroenterologist, Fiona Stanley Hospital).

**3 What does participation in this research involve?**

Participation involves the following:

**1. Screening Appointment**

**Questionnaires**

We will ask you to complete a questionnaire about your liver health, body pain, mental health, energy-levels and your perceptions of health.

**Tests of your health and fitness**

Breathing

Your breathing will be measured while you walk or jog on a treadmill. The exercise will start at a low intensity and then the speed and steepness of the treadmill will be progressively increased until you get too tired to continue. The test will require you to breathe through a mask so that the air you exhale can be analysed. Your heart rate and rhythm will be continuously monitored throughout the test using an electrocardiogram (small sticky dots attached to your chest) and testing will be stopped immediately if any adverse changes occur. This test is used to determine how well your body can deliver and use oxygen and the fitness of your heart and lungs.

Strength

A test of your leg, arm and hand strength will be conducted using machines in the hospital’s gym. You will initially lift a light weight 6 times to warm up and then the weight will be made progressively heavier, with you lifting the weight once each time, until it is too heavy for you to lift.

Body measures

Several parts of your body will be measured with a tape measure and the thickness of your skin and underlying body fat will be measured with callipers. We will weigh you on a set of scales and measure around your waist and hips with a tape measure. We will also measure your height.

Blood Test

A blood sample (<10ml) will be taken to assess the function of your liver and other markers of your health. This will be performed at the PathWest centre at the hospital. Your blood sample will be analysed at PathWest for the purposes of this research and any remaining sample will be disposed of at the site.

Fibroscan

A Fibroscan scans your liver to assess structure and health. The fibroscan machine measures the stiffness of your liver. It does this by measuring the speed of a vibration (pulse) that travels through your liver. This will be performed at the Gastroenterology department of FSH.

The tests and measures will take about 2.5 hours in total and will be conducted at Fiona Stanley Hospital

After the assessments have been completed you will be allocated to one of 2 groups

1. Exercise group

2. Control group - where you will be asked to continue your general level of activity and not engage in any new exercise program for 8 weeks. At the end of the 8 weeks, people allocated in the control group will be provided with an individualised home exercise program to complete independently.

**2. 8 week telerehabilitation program**

If you are in the exercise group, we will teach you the exercise program at Fiona Stanley Hospital. A flexible approach will be utilised, where the exercise program will be either taught to you on the same day as the initial screening appointment or a different day. You will have the option to choose either day.

The exercise program involves a walking program 3 times a week plus strength exercises 2 days per week.

Walking

This will begin with 15 minutes per day 3 days per week, building up to 30 minutes with increasing speed and intensity over the course of 8 weeks.

Strength

This will begin with whole body exercises of 10 repetitions at moderate intensity, 2 days per week with increasing intensity over the course of 8 weeks.

The strength exercises will be performed with resistance bands, ‘gym sticks’ or using your own body weight. You should aim to complete all of the exercise sessions.

We will give you an exercise log to record the days when you have completed the exercise program. The exercises can be changed to suit your requirements. For example, if the program is too easy for you, we can give you harder exercises or give you more repetitions to complete.

Telerehabilitation appointments

The exercise group will be provided with telerehabilitation appointments on week 1,3 and 5 of the intervention period. These telerehabilitation appointments are to supervise one of your strength training sessions that week, to help you complete your exercises correctly. On week 7 there will be a telerehabilitation appointment as an opportunity to ask questions and connect with other participants.

You can elect to join a Facebook messenger® group chat with the exercise supervisor and other participants to ask questions about the exercise program and stay motivated.

Furthermore, you will receive a digital copy of the exercise program with pictures on the Physitrack® application.

**3. Follow-up appointment**

This appointment involves you repeating the same tests as the initial screening appointment, plus a questionnaire about your experiences during the study.

**4 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. This can be done by contacting a member of the research team (details at the end of this form).

**5 What are the potential risks in taking part?**

The risk of adverse events during exercise is very low and the benefits far outweigh the risks. :

People with diagnosed or undiagnosed heart problems are at slightly increased risk of adverse events during exercise compared with rest. For the breathing test, the risk of complications serious enough to require hospitalisation is 1 to 3 per 10, 000 tests. The risk of death is estimated to be 2 to 5 per 100, 000 tests. This is much lower for people who don’t have heart disease. Because the telerehabilitation program will be tailored to your fitness the risk of an adverse response is very low.

Similarly, there is a risk of muscle or bone injury during exercise, but the risk is also very low. Care will be taken when prescribing your exercise program to ensure it is aligned with your level of fitness, helping prevent injury. After starting a new exercise program you may feel muscle soreness. However, this should only last around 48 hours and is a normal reaction to completing an exercise program with new exercises and occurs less as you get use to the exercises. We will give you advice on how to manage any muscle soreness you experience.

**5 What are the possible benefits of taking part?**

If you are in the telerehabilitation group, you may benefit from improved fitness from the exercise program. If you are in the control group (no exercise group), you will be given the exercise program after the study to complete if interested, however no supervision will be provided.

Findings from the study will inform future research that may make telerehabilitation an option for people with chronic liver disease. This can be a useful option if travel to the exercise venue is difficult (e.g. rural patients or lack of transport).

**6 What if I withdraw from this research project?**

If you decide to withdraw from the research, please notify a member of the research team. Your decision to withdraw is completely your own and won’t affect your medical care in any way.

**7 What happens when the research project ends?**

At the conclusion of the project, we will report the findings from the research in a conference presentation and a scientific journal. We will keep the data for at least seven years in accordance with legislative requirements.

**8 What will happen to information about me?**

Any information obtained in connection with this research project that will be de-identified and stored in a secure location to maintain your confidentiality.

All research data will only be accessible to the research team. When the research is complete, data will be uploaded to the Curtin University Digital platform, which has been created with high security for research data and stored for a period of at least 7 years post-publication. The data will be stored on a password protected computer in the Curtin University Allied Health building. Hard copies of data will be stored in a locked filing cabinet in a locked room at Fiona Stanley Hospital. Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

In any publication and/or presentation arising from the project, information will be provided in such a way that you cannot be identified.

**9 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC).

The ethical aspects of this research project have been approved by the South Metropolitan Health Service HREC (reference number 5780) and Curtin University by reciprocal approval.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**10 Further information and who to contact**

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, please contact the Coordinating Principal Investigator:

 **Research contact person**

|  |  |
| --- | --- |
| Name | Professor Andrew Maiorana |
| Position | Research Academic, Curtin School of Allied Health |
| Telephone | +61 8 9266 9225 |
| Email | A.Maiorana@curtin.edu.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | South Metropolitan Health Service Research Support and Development Unit |
| Position | Manager |
| Telephone | 6152 3214 |
| Email | smhs.rgo@health.wa.gov.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | South Metropolitan Health Service Human Research Ethics Committee |
| HREC Executive Officer | Ethics Coordinator |
| Telephone | 6152 2064 |
| Email | smhs.hrec@health.wa.gov.au |

**Reviewing HREC approving this research** **and** **HREC Executive Officer details**

**Local HREC Office contact**

|  |  |
| --- | --- |
| Name | South Metropolitan Health Service Research Support and Development Unit |
| Position | Research Governance Coordinator |
| Telephone | 08 6152 2646 |
| Email | smhs.rgo@health.wa.gov.au |

**Consent Form -** *Adult providing own consent*

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**Declaration by Participant**

I have read the Participant Information Sheet

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project.

I understand that I will be given a signed copy of this document to keep.

I understand that the information I provide will be used in publications and presentations of the research outcomes but I will not be identifiable

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

I believe that the participant has understood the information provided and consents to participation in this research.

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

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

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

**Withdrawal of Consent Form**

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| **Location**  | Fiona Stanley Hospital  |

**Declaration by Participant**

I wish to withdraw from taking part in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the treating hospital or Curtin University.

Name of Participant (please print)

Signature Date

In the event that the participant’s decision to withdraw is communicated verbally, the study doctor/senior researcher must describe the circumstances:

**Declaration by study doctor/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.

Name of study doctor/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.