Investigators
Universita Di Pisa (Italy), University of Strathclyde (United Kingdom), Universita Ta' Malta (Malta), Oulun Yliopisto (Finland), University College of London (United Kingdom), Loud1design Limited (United Kingdom), Kerubiel Kereskedelmi es Szolgaltato KFT (Hungary), Flying Squirrel Games Malta Limited (Malta) , Capitola Digital BV (Netherlands), Crowdhelix Limited (Ireland), Inlecom Innovation Astiki Mi Kerdoskopiki Etaireia (Greece), Saint James (Capua) Limited (Malta), Kinisiforo Ltd (Cyprus) and Global Disability Innovation Hub CIC (United Kingdom).

Informed Consent Form
This Informed Consent Form (ICF) is for adult men and women who attend Planet Physio at Saint James Capua Hospital, and who are invited to participate in research on the use of virtual reality (VR) in an out-patient rehabilitation environment. The title of this research project is Personalised Recovery Through a Multi-User Environment: Virtual Reality for Rehabilitation "PRIME-VR2"

Name of Sponsor
European Union (EU)

Name of Project Coordinator
Prof Sandro Barone (Professor of Design and Methods of Industrial Engineering at the Faculty of Engineering, University of Pisa)

Name of Proposal
Personalised Recovery Through a Multi-User Environment: Virtual Reality for Rehabilitation "PRIME-VR2"

This Informed Consent Form has two parts:
- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

PART I: Information Sheet

Introduction
I am Milos Stanisavljevic, working for Planet Physio, located at Saint James Capua Hospital. We are participating in research on the use of VR in an outpatient rehabilitation environment. I am going to give you information and invite you to be part of this research. You do not have to decide today, whether or note you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them to me, the study doctor or the staff.

Purpose of the research
VR concepts have existed for more than three (3) decades. Currently the focus of VR has been in the entertainment world. VR environments are now increasingly being used in other industries, including healthcare. The support of patient recovery is well suited to VR, and there are a number of emerging applications being developed to address patient rehabilitation.

Our study aims to create a VR rehabilitation platform to facilitate collaboration between all parties (doctors, therapists, patients etc) of the programme, and producing a more effective rehabilitation environment.

Type of Research Intervention
This research will involve an initial assessment, and the use of tailormade headsets (goggles) and controllers. You will be using these VR headsets (goggles) and controllers to test games. You will have the opportunity to participate in exercises together with your therapist and other participants in a VR environment. Throughout the research photos, videos, and audio recordings of spoken responses will be taken and recorded.

Participant selection
We are inviting all adults who are suffering from pain and / inhibited function of the upper limbs: fingers, and / or hand, and / or wrist, and / or arm.

Voluntary Participation
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, we will offer the treatment that is conventionally used in Planet Physio for physical rehabilitation of your injury. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol
<u>Description of the Process</u>
During the research you will make ten visits to the clinic.

- In the first visit we will provide you with the information relating to testing and the project:

    - Consent will be discussed and completed
    - Questionnaires will be completed (personal details, lifestyle, work environment etc)
    - The initial assessment will be carried out
- At the next visit (second visit), the manual tests will be carried out to create the ergonomic profile. These manual tests include:
    - Limb measurements (or measurement of a part of the limb): length and volume will be measured using a measuring tape
    - Range of motion of the affected area will be measured using a goniometer
    - The strength of the hand will be measured using a pinch force
    - The first session of physical therapy will take place
- During the third visit, you will be tested for movement. This motion will be captured using 3-dimentsional scanners. A session of physical therapy will take place
- During the fourth visit and when the personal console is ready, you will be asked to test the equipment and initial assessments are done
- During the fifth, sixth, seventh, eighth, ninth and tenth sessions, measurements will be taken, and progress is recorded

Duration
The research takes place over then (10) sessions and you will need to attend for all ten (10) sessions.

The research will be carried out in two parts:
1. Initial scanning: The first three (3) sessions will last approximately two hours and will include physical therapy sessions. This needs to be carried out over three (3) consecutive days
2. Equipment sessions: seven (7) sessions spread over a two (2) week period

In total, you will be asked to come ten (10) times to the clinic. At the end of these visits, the research will be finished.

Side Effects
We do not expect to have any side effects from the research. The 3D scanning and ergonomic profile will not be harmful in any way for the patients. Scanning will be performed with vision-based techniques, which are contactless, and any physical tests will be performed in conjunction with physiotherapists or other healthcare providers as part of a routine rehabilitation treatment.

Users of virtual reality sometimes experience some degree of nausea. If at any time you wish to stop taking part in the study for this or any reason, please tell the researcher who will immediately end the experiment.

As a safety precaution, we advise any participant not to operate heavy machinery (including driving) for two hours after the study.

Some users report 'flashbacks' and other side effects of using virtual reality equipment. Research suggests using virtual reality may cause short-term disturbances in vision. Virtual reality can be a trigger for photosensitive epilepsy. You will be asked to confirm that you do not have photosensitive epilepsy.

However, we will follow you closely, keep track and watch for any unwanted effects or any problems such as nausea, eye strain, dizziness, virtual reality sickness, imbalance or any other potential unwanted effect.

Collection and / or Use of Personal Data

Personal data is data which relates to a living individual who can be identified from that data OR from the data and other information that is either currently held, or will be held by the data controller (the researcher).

Throughout the sessions mentioned above photos, videos, and audio recordings of spoken responses will be taken and recorded. These photos, videos, and audio recordings will be stored securely. They will be used to assist in the interpretation of the results. They may also be used for publishing and promoting the research study. It is imperative to note that if your Personal Data will be used for publishing and promoting the research your identity will be always protected. Throughout the project and after the project, your identity will only be known by the personnel who will be dealing with you directly for this study.

Risks

By participating in this research, the potential of any risks is very low, however you should still be aware of the possibility of some risks, and these include physiological consequences, real world injuries, game transfer phenomena (GTP) and virtual reality addiction. We will do our utmost to decrease the chances of these events from occurring.

Reimbursements

We will give you with free physical therapy sessions throughout this research programme. You need to complete the research programme. If you opt not to complete it, you will not be charged for the physical therapy sessions that were performed.

Confidentiality

The information that we collect from this research project will be kept confidential and in line with the relevant European Policies. Information about you that will be collected during the research will be put away. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is, and the information is treated confidentially. It will not be shared with or given to anyone except the investigators that are listed in the first page of this document, regulatory authorities and your clinician (if relevant). Refer to the document: Saint James Hospital – General Data Protection Regulation *What Do You Need to Know?* for more information regarding the management of patient information at Saint James Capua Hospital.

Sharing the Results

The knowledge that we get from doing this research will be shared with you during the rehabilitation sessions. The results from the study will be published in order that other interested people may learn from our research. Confidential information including your personal information will not be shared.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic / hospital in any way. You will still have all the benefits that you would otherwise have at this clinic / hospital. You may stop participating in

the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic / hospital will not be affected in any way.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact Milos Stanisavljevic, Saint James Capua Hospital, George Borg Olivier Street, Sliema. Tel: +356 23291020; or by email milos.stanisavljevic@stjameshospital.com

This proposal has been reviewed and approved by the Ethics Committee of Saint James Hospital Group, which is a Committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the Ethics Committee of Saint James Hospital Group, contact Charlotte Sant Portanier, Saint James (Capua) Hospital, George Borg Olivier Street, Sliema. Tel: +356 23292003; or by email charlotte.santportanier@stjames hospital.com

You can ask me any more questions about any part of the research study, if you wish to.

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day / month / year

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____

Signature of witness _____

Date _____

Day / month / year

Statement by the researcher / person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. Completion of all questionnaires and consent form
2. Attend the programme for ten (10) sessions which will include scanning, assessments and physical therapy

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher / person taking the consent _____

Signature of Researcher / person taking the consent _____

Date _____

Day / month / year