UNIVERSITY OF WOLLONGONG AUSTRALIA

FULMA
motion analysis for the upper limb impairment

Participant Information Sheet

Title	Motion Analysis for Upper Limb Impairment (FULMA) – Software Development for Stroke Participants
Short Title	FULMA
Study Sponsor	The George Institute for Global Health

1. Introduction

You are invited to take part in a study called FULMA. You have been invited because you have expressed interest in helping us test a new technology which will help therapists (occupational therapists and physiotherapists) measure upper limb movement for people who have had a stroke. You can participate in this study as:

a) A 'healthy' individual who has not had a previous stroke and/or any difficulties with upper limb movements (e.g. shoulder, arm, wrist, trunk) or
b) An individual who has suffered a previous stroke more than 6 months ago and now experience some difficulty with moving your upper limb.

The FULMA software development study aims to see if a new technology developed for a laptop with a video camera can accurately capture and measure upper limb movement. Eventually this technology will be tested on smart portable devices such as phones and tablets.

Currently occupational therapists and physiotherapists, who support the physical rehabilitation of people after a stroke, use many different tools which look at how well someone can move their upper limbs. However, a problem with the available assessment tools is that they rely on the therapist's subjective observations and different ways to describe upper limb movement as 'normal' or not 'normal'. This way of measuring can be biased or inaccurate, which can be influenced by a therapist's level of experience. This new technology may allow therapists to conduct more accurate upper limb assessments with stroke patients, with the aim to provide more accurate information to patients, families, and other clinical staff.

The FULMA software has been developed at the School of Computing and Information Technology, at the University of Wollongong. It uses 3D computer vision and machine learning for the software to trace and measure the movements of participants' arms, shoulders, and wrists. Eventually the aim of the FULMA technology will be to use a smart phone/tablet to determine what percent of arm function a patient has after a stroke compared to someone with full movement (for example, a person has 30% of normal arm movement).

The study will involve approximately 40 people who do not have upper limb impairment and 40 people who have upper limb impairment because of a previous stroke more than 6 months ago.

This study is funded by The George Institute for Global Health (TGI) and University of Wollongong. The brain health strategic funding from TGI has provided funding for the initial software development.

This Participant Information and Consent Form tells you about the research. It explains what you will do if you are a part of the study, so that you can decide if you want to join. Please read this carefully. Ask questions to the study Researcher (contact details at the end of this information sheet) about anything that you don't understand or want to know more about. Before you decide, you may want to talk about it with a relative or friend.

If you decide you want to take part in the study, you will be asked to sign the consent section of this form. By signing this form, you are telling us that you:

- understand what you have read
- consent to take part in the study
- consent to complete the assessments that are described in this information sheet
- consent for the use of your personal and health information as described in the information sheet

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

2. What does joining this study involve?

The study will involve attending the Department of Rehabilitation Medicine at the Prince of Wales Hospital, Randwick at a convenient time which suits you and a researcher. You will be asked to complete various tasks with your arms with a researcher while being recorded on video using the FULMA laptop software (see below for more details about the assessment tasks). Your visit will take approximately 60 minutes to complete. Additionally you will also be asked to fill out a questionnaire which can be done prior to or at the beginning of your visit, which will take approximately 10-15 minutes.

Occupational Therapy assessment tasks

You will be asked to complete 2 assessment tasks with your upper limbs either with an Occupational Therapist or Researcher during your visit to the Prince of Wales Hospital:

1. Range of motion exercises – this task involves the Occupational Therapist measuring the angle of your elbow, wrist, and shoulder while doing basic exercises such as raising your arm to shoulder height. A goniometer is used to by the therapist, which is like a large protractor, to determine what each angle is
2. Fugl-Meyer Assessment (FMA) - an assessment which involves completing a set of tasks with your hand, arm, shoulder and wrist. All tasks are non-invasive (e.g., no physical contact from the therapist or researcher will be required) and will not cause any unnecessary pain or discomfort.
3. Functional Movements – an assessment of 9 movements which occur during daily activities, such as reaching for a cup, or brushing your hair.

Along with doing the tasks above, you will be asked to complete a questionnaire of 20 questions called the Upper Extremity Functional Index (UEFI). This can be done at home prior to your visit or at the start of your visit.

Interviews (with stroke participants only)

If you have suffered a previous stroke, you are also invited to participate in an interview at a later time over videoconference with a researcher. This component of the study is optional. The interview will include questions about how you felt about joining and participating in the study, completing the assessments with the FULMA system, and how the system could be used in routine clinical care. The interview process is informal and flexible, as our main aim is to encourage you to talk about your experiences and views. The following are some examples of the questions that will be discussed:

- Can you tell me about your stroke and rehabilitation experience?
- What are your thoughts about the FULMA technology system?
- What are your thoughts about the FULMA study in general, and participating in the study?
- Are there things we can do better to improve the study?

These interviews will take approximately 20-30 minutes. be audio recorded and written verbatim. We appreciate your work commitments and will fit with your schedule. If necessary we can talk to you over more than one visits if that is more convenient. Please let us know what works best for you.

3. What are the alternatives to participation?

Being part of this study is voluntary. You may leave the study at any time, without penalty. You can discuss being a part of this study with the researcher and/or family and friends before you decide whether or not to take part in this study. Your decision whether to participate in the study will not affect any therapy, or your relationship with the staff who provide the services (if applicable).

For stroke participants, the interview component is optional. You may participate in the assessment tasks only and not complete the interview. Your decision to participate in the interview will have no impact on your relationship with the study team.

4. Are there any benefits?

This study is testing technology which aims to help health care therapists accurately measure upper limb movements for patients after a stroke. Being in the study will not directly benefit you. Instead, it may benefit future stroke patients' clinical care.

5. Are there any risks or discomforts?

There are no serious risks or discomforts with participating in the study. You may have some discomfort completing the upper limb assessment tasks if you generally experience discomfort during everyday movement. Additionally, you may be inconvenienced by coming to the Prince of Wales Hospital to complete the assessment tasks for approximately 60 minutes.

6. Compensation for injuries or complications

If you suffer any injuries or complications as a result of this study, you should contact your doctor as soon as possible, who will assist you in arranging appropriate medical treatment. If you are eligible for public health care or medical insurance, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any public hospital.

In addition, you may have the right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe equipment, or by negligence of one of the parties involved in the study (for example, the researcher). You do not give up any legal rights to compensation by participating in this study. If you are eligible for Medicare, you can receive this for your injury or complication free of charge as a public patient in any public hospital.

7. Will taking part in this study cost me anything, and will I be paid?

Participating in the study will not cost you anything. You will be compensated $50 total for getting to and from the Department of Rehabilitation Medicine at Prince of Wales Hospital, Randwick. For your time, you will also be given $100 gift voucher to Myer/David Jones/Woolworths/Coles/other e-gift card.

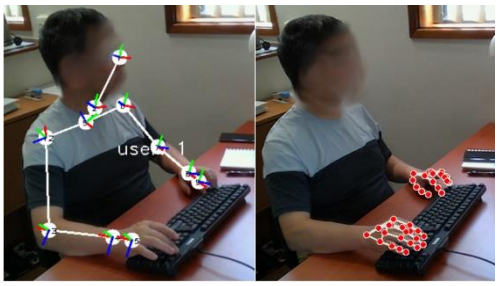
8. Can I participate in other therapy during this research project?

If you are currently going to occupational or physiotherapy that aims to improve your upper limb movement, you can still participate in the study.

9. What happens when the study ends?

Once the study ends, you may request the results of the study if this is of interest to you. When results have been published the outcomes can be sent to you.

10. Confidentiality / Privacy



Videos collected by the FULMA system will automatically blur your face so your facial features cannot be identified (demonstrated in picture shown). Blurring your face is used to take steps towards keeping you anonymous, however this may not de-identify you completely. Any identifiable information that is collected about you in this study will remain confidential and will be disclosed only with your permission, or as required by law. Only the study researchers, monitors, representatives of regulatory authorities and ethics committee may have direct access to the images. Access is required to check the accuracy of the information collected and to ensure that this trial is being carried out according to local requirements and/or regulatory guidelines.

Ratings of the different assessments will be entered into an electronic database called REDCap. This is a secure, web-based database application, hosted and backed up to The George Institute for Global Health servers on a daily basis. Your name and other personal information will not be used in the database, to protect your confidentiality and computer records will be password protected. Only the information about your stroke (if applicable) will be included in the database.

For stroke participants who complete the interview, it will be audio-recorded and then transcribed word for word. Your participation and personal information will be protected and confidential. Information of this interview will be coded as a number instead of your name. Your identity will not be disclosed to others (except the study team), only if granted your permission or legal request. The interview recording as well as transcript documents will be stored securely with encryption and only be accessed by study team. Your personal information will not be disclosed in the publications or disseminations of this study.

Study monitors, auditors, representatives of regulatory authorities and ethics committee may also be granted direct access to the records for verification of trial procedures and/or data.

The data will be analysed by the researchers at the George Institute. All video files and audio files (if the interview is completed) will be retained for a minimum of 15 years from the day the study is completed.

11. What happens with the results?

The blurred video images and measures taken from the assessment tasks from the FULMA system will be reviewed by machine learning experts at the University of Wollongong to develop the software.

For stroke participants who complete an interview, if you would like, we will provide a copy of the transcript for feedback which can include:

- Agreeing that the transcript is a satisfactory representation of your views,
- Asking for minor changes to be made to the existing transcript,
- Asking us for a repeat interview to expand on or change things that you said, or
- Withdrawing your data and consent to participate in the interview evaluation.

All information collected from you for this study will be stored electronically in a database maintained by The George Institute for Global Health in Australia. It is intended for the results of this study to be presented or published at medical conferences and in scientific journals.

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you if you wish. By signing the consent form, you agree to your data being included in the results published for this study.

Further information

When you have read this information, the Researcher will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact

Study Researcher:

Ross Black, Principal Investigator at POWH – Ross.Black@health.nsw.gov.au

12. Permission to use your data for future research projects

Your de-identified data may be shared with other local or international collaborators and used for future research purposes, however, Human Research Ethics Committee (HREC) approval will be sought to prior to any future use of the data. You can indicate your agreement to this on the Consent Form.

Complaints:

This study has been approved by the Ethics Review Committee of the South Eastern Sydney Local Health District. Any person with concerns or complaints about the conduct of

this study should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote 2022/ETH01871.

Ethics Approval

All research involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC) or Institutional Review Board (IRB). This study has been approved by the Ethics Review Committee of the South Eastern Sydney Local Health District.

This study will be carried out in accordance with the *National Statement on Ethical Conduct in Human Research (2007, updated May 2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached Consent Form. This Information Sheet is for you to keep.

The visual aids have been obtained from Flaticon.com and phil.cdc.gov