

This consent form is for Stroke patients at the Xuzhou Rehabilitation hospital.

Title of the study: The effectiveness of the two rehabilitation treatments on the upper limb function and quality of life of acute Stroke patients.

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Introduction: I am Bianca, a postgraduate student studying Neurological Rehabilitation at the Xuzhou Medical University. We are doing research on Stroke as a disease, how it affects upper limb function and how the two rehabilitation treatments can help improve upper limb function. I invite you to be part of this research and please read the information below;

Purpose of the study: You are being invited to take part in this project. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

This study will investigate the potential treatment effects of combining OT and Fourier M2 robotic machine coupled with kinesiotaping to improve upper limb function and quality of life of Stroke patients. The acute post-Stroke period from 1-3 months is a crucial period where all kinds of rehabilitation treatments can be initiated before patient enters the dormant/chronic stage of post-Stroke period which is from 6 months and beyond. This study wants you to engage in these treatments in order to justify if OT or Fourier M2 robotic machine can help you recover quickly because your upper limb function is our concern.

Procedures: The study will require you to engage in Occupational therapy (OT) treatments which includes carefully structured activities and use of Fourier M2 robotic machine on your affected hand to improve its' skills. There shall be two groups of participants, some with Fourier M2 and some with OT treatment because we do not know if the OT is better than the Fourier M2 and we need to compare the two treatments. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin. If you are in the group to be given Fourier M2 treatment, it will be done for 1 hour, 30 minutes each day and in combination with OT structured activities. If you are in the other group which is not given Fourier M2, you will be given a structured OT program which will be designed specifically for your affected hand and to be done 1 hour, 30 minutes each day. The whole study duration shall be 6 weeks with evaluations done at the beginning of the study, at 4 weeks and at 6 weeks marking the end of the study.

Risks: In this study, there will be no risks or harm to any of your body parts.

Benefits: In this study, there will be benefits that include:

- To improve your upper limb functional skills.

- To recover early and return back to engaging basic daily living skills independently.
- It will help therapists to improve their ways of treating your affected upper limb for your maximum function.
- It will also help therapists in knowing which treatment provides more effective recovery so that it can be done more to you so that you are able to do activities and have improved quality of life.
- It will also help the clinic/hospital to design good structured OT programs for making sure that your hand is able to function in different activities.

Confidentiality: Your responses to this study will be anonymous. For the purposes of this research study, your comments will not be anonymous. Every effort will be made by the researcher to preserve your confidentiality including the following:

Measures taken to ensure confidentiality will be done, such as those listed below:

- Assigning code names/numbers for participants that will be used on all research notes and documents.
- Keeping notes, interview transcriptions, and any other identifying participant information in a locked file cabinet in the personal possession of the researcher.
- Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

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, you will be offered the treatment that is routinely offered in this clinic/hospital for Stroke, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier. 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 any of the following; Phone number; Bianca = 139 1487 2850 / Chen Wei = 189 5217 2339 or email to biamachinez@gmail.com or chenwei2339@163.com

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: A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

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 about the study. 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 Consent Form 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