ISRCTN13455548 https://doi.org/10.1186/ISRCTN13455548

The clinical utility of robotic-assisted therapy in the treatment of post-stroke shoulder pain

Submission date
20/02/2025

Recruitment status
No longer recruiting

Registration date
24/02/2025

Overall study status
Completed

Last Edited
24/02/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hemiplegic shoulder pain (HSP) is a common issue for stroke survivors. This study aims to explore how effective a robotic device is in reducing HSP pain by comparing robotic-assisted therapy to conventional treatment.

Who can participate?
The study will involve stroke survivors with shoulder pain.

What does the study involve?
Participants will be randomly assigned to one of two groups. One group will receive standard rehabilitation therapy, while the other group will receive the same therapy combined with robotic-assisted training using the ArmMotus M2 device. Evaluators, who do not know which group participants are in, will measure shoulder pain and range of motion before and after the intervention.

What are the possible benefits and risks of participating?
Participants in the robotic therapy group are expected to experience meaningful reductions in pain scores, while those in the conventional therapy group are expected to see significant improvements in shoulder movements. As with any therapy, there may be risks, but these are not specified in the study details.

Where is the study run from?
Universiti Teknologi MARA (Malaysia)

When is the study starting and how long is it expected to run for?
September 2022 to September 2023.

Who is funding the study?
Universiti Teknologi MARA (Malaysia)
Fourier Intelligence (Malaysia)

Who is the main contact?
Dr Natiara Mohamad Hashim, natiara_hashim@yahoo.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Natiara Mohamad Hashim

ORCID ID
https://orcid.org/0000-0002-6466-2551

Contact details
No 56,Jalan Pulau Lumut 76E/U10
Taman Alam Budiman
Shah Alam
Malaysia
40170
+60 193803105
natiara@uitm.edu.my

Additional identifiers

Protocol serial number
REC/09/2022 (ST/FB/12)

Study information

Scientific Title
The clinical utility of robotic assisted therapy in the management of hemiplegic shoulder pain: a pilot randomized control study

Study objectives
We hypothesize that the end- effector robotic device can provide adequate range of motion exercise that includes protraction and retraction, forward flexion, internal and external of shoulder joint movement, that helps to increase flexibility and reduce stiffness, that contributing to the shoulder pain. It also provides immersive interactive experiences through gaming that simulate various degrees of resistance, inertial force and elasticity that provide strengthening exercise that helps to increase the strength of the shoulder girdle muscle and increase patient participation towards exercise.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 05/09/2022, UiTM RESEARCH ETHICS COMMITTEE (Universiti Teknologi MARA,Aras 3, Bangunan Wawasan, Shah Alam, 55442004, Malaysia; +60 355442004; recsecretariat@uitm.edu.my), ref: REC/08/2022 (FB/36)

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Treatment of post-stroke shoulder pain

Interventions
Patients allocated to the intervention group underwent a comprehensive pre-intervention assessment before commencing the robot-assisted therapy. The therapy involved utilising the ArmMotus M2 for robot-assisted training, accompanied by physical modalities consistent with those received by the control conventional group. The duration of the treatment ranged from 45 minutes to 1 hour, with the robotic-assisted training specifically lasting 30 minutes, interspersed with 5-minute rest periods as needed. Each patient was seated in a chair, and their affected upper limb was secured to the robot arm using straps. Initially, participants commenced the training in robot-assistive mode to gauge their initial performance and motor severity level. The ArmMotus M2 provided task-oriented training incorporating bio-sensory feedback through interactive games. As the therapy progressed, the game's difficulty level was adjusted based on the patient’s performance, transitioning from passive-partially assistive to active-resistive modes. In the passive mode, the robot moved the arm without active participation from the patient, whereas in the active mode, the patient moved the arm entirely if capable. If a patient was unable to perform actively due to post-stroke weakness, the robot-assisted in moving the arm during the therapy. The therapy would cease immediately if a patient reported any pain or exhaustion. A total of 12 sessions were scheduled to be completed within a 3–4-week period, followed by post-intervention assessments upon completion of the therapy. On occasions where participants are unable to fulfil this requirement within the stipulated duration, they will be considered dropouts.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ArmMotus2

Primary outcome(s)
Pain at baseline using VAS at baseline and upon completion of therapy at 3-4 weeks

Key secondary outcome(s)

Range of motion measured clinically at baseline and upon completion of therapy at 3-4 weeks

Completion date
25/09/2023

Eligibility

Key inclusion criteria
1. Individuals who had experienced stroke
2. Presented with hemiplegia who scored Motor Assessment Scale score of 0 to 4 on item 6
3. Reported shoulder pain localised around the shoulder girdle muscles, glenohumeral joint, bicipital groove, or acromial clavicular area during passive shoulder range of motion, with a minimum Numerical Pain Rating Scale (NPRS) score of 3

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Diminished cognitive function as assessed by an Mini Mental State Examination score of less than 23
2. Individuals with severely restricted shoulder range of motion (limited to 20 degrees across all motions)
3. Shoulder joint contractures or the presence of significant heterotrophic ossification

Date of first enrolment
10/09/2022

Date of final enrolment
12/07/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
Hospital Al Sultan Abdullah
Bandar Puncak Alam, Selangor
Kuala Selangor
Malaysia
42300

Sponsor information

Organisation
Universiti Teknologi MARA

Funder(s)

Funder type
Industry

Funder Name
Fourier Intelligence

Funder Name
Universiti Teknologi MARA

Alternative Name(s)
Universiti Teknologi MARA - UiTM, MARA Technological University, Universiti Teknologi MARA (UITM), Universiti Teknologi MARA in Malaysia, Universiti Teknologi MARA MIMI, Universiti Teknologi MARA | Shah Alam, Malaysia | UiTM, Universiti Teknologi MARA, Malaysia, Universiti Teknologi Mara (UiTM), Malaysia, UiTM – Universiti Teknologi MARA, Universiti Teknologi MARA (UiTM) (Klang, Malaysia), UiTM - Universiti Teknologi MARA, Universiti Teknologi MARA Malaysia, , University of Technology MARA, UiTM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Natiara Mohamad Hashim, natiara_hashim@yahoo.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3		24/02/2025	No	Yes