Invitation to participate in a multi-centric study

Title: High-intensity Upper limb rehabilitation Training in sub-acute Stroke survivors in a low-resource setting: The HUTS trial - an RCT *(CTRI/2024/08/072450)*

Dear esteemed members of the World Federation for NeuroRehabilitation (WFNR),

I am delighted to extend this invitation to your centre/hospital/clinic to participate in our research initiative, the HUTS trial. My name is Ananya Rakesh Sharma, and I am leading this study, which aims to investigate the impact of high-intensity training on upper limb recovery in stroke survivors within low-resource settings.

Objective: The primary objective of the HUTS trial is to compare the effectiveness of low-intensity, low-dose (60 minutes) versus high-intensity, high-dose (180 minutes) upper limb rehabilitation training in sub-acute stroke survivors.

Target Population:
We are seeking participation from subacute stroke survivors (>18 years old) with Fugl Meyer Score-Upper extremity ranging from 0 to 44. Eligible patients must have a Montreal Cognitive Assessment (MoCA) score above 25 to comprehend the protocol. Exclusions apply to individuals diagnosed with other neurological disorders, experiencing recurrent stroke, medically unstable patients, and those with shoulder pain (Numerical Pain Rating Scale > 7) during movement.

Target Centres/Hospitals/Clinics:
We are particularly interested in collaborating with hospitals, outpatient centres, and community settings in low-resource areas.

Study design:

- It is aimed to be a prospective, assessor-blinded RCT on subacute stroke survivors.
- The patients will be randomly assigned to an intervention group or active-control group in a 1:1 ratio for 3 weeks. The treatment protocol will be the same for both the groups (a therapist and caregiver manual will be provided), the only difference would be the intensity.

✓ Intervention group-
The intervention group will receive high-intensity upper limb training: 180mins/day for 6 days/week for 3 weeks.

- Therapist: 120mins/day (two sessions of 60mins).
- Caregiver: 60 mins/ day (3 sessions of 20mins).

- The caregiver sessions will be conducted under supervision of a therapist at least for the first three sessions and as required.

✓ Active-control group-
The active-control group will receive 60mins/day for 6 days/week for 3 weeks.
- Therapist: 40mins/day.
- Caregiver: 20 mins/ day.
- The caregiver sessions will be conducted under supervision of a therapist at least for the first three sessions and as required.

Study Materials required:

To be able to follow the manual, following materials may be required:

1. An electrical stimulator
2. Pegboard/different shapes of blocks
3. Sensory stimuli (ice pack/hot pack/cotton)
4. Mirror box/or a wall mirror
5. Towel/skates (with handgrip)
6. Arm gaiter brace (preferred)
7. Basic amenities: A treatment bed, table and chair. s

How to Join the Study?

If your institution is interested in joining our study, please send me an email expressing your interest. Kindly include your country and the name of your institute/centre/organization. Upon confirmation that your centre meets the criteria, I will provide you with further details regarding the study protocol, data collection procedures, and any additional information you may require.

Contact Information:

-Principal Investigator: Ananya Rakesh Sharma, MPT (Neurological Science)
-Designation: Neuro-Physiotherapist at St. John's Medical College Hospital, Bangalore, Karnataka, India.
-Email: *ananya.sharma@stjohns.in / ananyarakeshsharma1994@gmail.com*

Your collaboration and participation are immensely valued, and I eagerly anticipate the possibility of working together on this study.