Encouraging real-world upper limb use after stroke by applying a tracking and feedback device

Progress of a multi-center, assessor-blinded randomized controlled trial

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Background

- Effective paretic upper limb training post-stroke is characterized by intensity and specificity.
- Motivation, compensatory function, and effort are often limiting factors.
- Feedback technology has the potential to encourage self-administered, intensive arm training in the patients' home environment.

Aim

Primary objective

To investigate the short and long term effects of an activity tracking and multimodal feedback device on change in patient-reported daily life upper limb use from baseline to post-intervention and 6-week follow-up in hemiparetic subjects >3 months post-stroke, compared to control group subjects wearing a hardware-wise identical sham device providing no feedback at all.

Secondary objectives

To investigate the short and long term effects on change in upper limb motor function, upper limb capacity, global disability, patient-reported quality of daily life upper limb use, and quality of life from baseline to post-intervention and 6-week follow-up, as well as compliance and safety.

Methods

Design

- Multi-center randomized controlled trial ([Figure 1](#))
- Superiority design
- 1:1 allocation ratio, stratified based on severity of Upper extremity paresis subscale of the Fugl-Meyer Assessment (<32 and ≥32)
- Blinded assessors
- Sample size calculation based on the Amount of Use subscale of the Motor Activity Log (14 Item Version): **N=62**

Eligibility criteria

Inclusion criteria

- Above 18 years of age
- Unilateral stroke and residual hemiparesis
- At least 90 days post-stroke
- Ability to lift arm against gravity (>30° flexion or abduction)
- Ability to don/doff the "ARYSTM|tracker" devices on both wrists independently or with the assistance of a daily available caregiver
- Ability to give informed consent as documented by signature

Exclusion criteria

- Major untreated depression
- Severe cognitive impairment and/or comprehensive aphasia
- Severely impaired sensation
- Expected hospitalisation during study period
- Known intolerance to device material
- Known or suspected non-compliance, drug or alcohol abuse

Figure 1: Time line for participants

R, Randomization; T0, Baseline assessment; T1, Post-intervention assessment; T2, Follow-up assessment

Intervention

Experimental group

- Wrist-worn activity tracking device providing multimodal feedback on daily arm use for 6 weeks ([Figure 2](#))
- On-device feedback by LEDs and vibration
- Feedback in a smartphone application ([Figure 3](#))
- One-to-one instruction
- Instruction manual
- Weekly telephone calls for compliance and safety check

Control group

- Identical device providing no feedback ([Figure 2](#))
- One-to-one instruction
- Instruction manual
- Weekly telephone calls for compliance and safety check

Figure 2: (A) Motion tracker "ARYSTM me|tracker", black-silver tracker for the paretic side; (B) "ARYSTM pro|tracker healthy", black-brown tracker for the non-paretic side

Figure 3: (A) Android smartphone with the preinstalled Application "ARYSTM me|app"; (B) "Tree of Recovery", a figurative representation of the amount of upper limb use in daily life

Primary outcome

- Motor Activity Log – 14, Amount of Use (MAL-AOU)

Secondary outcomes

- Motor Activity Log – 14, Quality of Movement (MAL-QOM)
- Fugl-Meyer Assessment – Upper Extremity (FMA-UE)
- Action Research Arm Test (ARAT)
- EuroQol Five Dimensions Five Levels Questionnaire (EQ-5D)
- modified Rankin Scale (mRS)
- Adverse Events (AEs)
- Global Rating of Perceived Changes
- Quantitative Sensor Data

Progress

- Recruitment started in September 2017
- Till 10/05/2018, 22 participants have been enrolled ([Table 1](#))
- 15 participants have finished the study
- There were no related adverse events ([Table 2](#))

Patient characteristics

Male/female (N)	11/11
Age, years (median, IQR)	57, 50-65.5
Time post-stroke, months (median, IQR)	52.5, 22.5-69.25
Affected upper extremity, left/right (N)	10/12
FMA-UE (median, IQR)	39.5, 17.75-47.25
ARAT (median, IQR)	34.5, 5.25-46
MAL-14 AOU (median, IQR)	1.62, 1.21-2.46
MAL-14 QOM (median, IQR)	1.55, 1.15-2.21

Table 1: Baseline characteristics of enrolled patients

Adverse events

Adverse events	Frequency (N)
Related adverse events	0
Non-related adverse events	3
• Low back pain	1
• Fall	2

Table 2: Overview of adverse events

Conclusion

A positive result of this study will underline the importance of feedback on daily life arm use after stroke in the patients' home environment.

Reference

Held JPO, Luft AR, Veerbeek JM. Encouragement-induced real-world upper limb use after stroke by a tracking and feedback device: a study protocol for a multi-center, assessor-blinded, randomized controlled trial. Front Neurol. 2018;9:13. doi: 10.3389/fneur.2018.00013.