ISRCTN63166587 https://doi.org/10.1186/ISRCTN63166587

Rehabkompassen® – A digital structured follow-up tool for facilitating patient-tailored rehabilitation in persons after stroke

Submission date
18/08/2023

Recruitment status
No longer recruiting

Registration date
21/08/2023

Overall study status
Ongoing

Last Edited
10/10/2023

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Stroke is a leading cause of disability among adults worldwide. A timely structured follow-up tool to identify patients' rehabilitation needs and develop patient-tailored rehabilitation regimens to decrease disability is largely lacking in current stroke care. The overall purposes of this study are to evaluate the effectiveness of a novel digital follow-up tool, Rehabkompassen®, among persons discharged from acute care settings after stroke.

Who can participate?
Adults aged 18 years or older, within the first 4 months after stroke

What does the study involve?
The intervention will consist of the usage of digital tool Rehabkompassen® (intervention) or a paper-version Post-stroke Check list (control) and usual in- or outpatient visits within 3 months after stroke onset. A treatment plan will then be generated and performed as the clinical rutine. All participants will use Rehabkompassen as a structured follow-up tool at the 12-month visit.

What are the possible benefits and risks of participating?
Benefits: 1. improving their function, activity and/or quality of life; 2. gaining greater influence over their individualized rehabilitation; 3. being able to follow their symptom changes over time and 4. being able to complete surveys in peace and quiet at home before a clinical visit.
Risks: The physical risk of participating in this study is extremely low. Some transient fatigue may be experienced when answering questionnaires. To avoid fatigue, it is possible to pause between the questionnaires and to continue later. No long-term risks are envisaged.

Where is the study run from?
University Hospital of Umeå (Sweden)

When is the study starting and how long is it expected to run for?
April 2021 to December 2026

Who is funding the study?
1. Swedish research consul (2022-00316 and 2022-00746)
2. Forte (2020-00136)
3. Västerbotten County Council and Umeå University (ALF Foundation, 2021-967513)
4. The Heart-Lung Foundation (2020676)
5. VINNOVA Medtech4Health (2019-01389)
6. The Swedish Stroke Foundation (Strokeförbundet)

Who is the main contact?
Dr Xiao Lei Hu, xiaolei.hu@umu.se

Contact information

Type(s)
Principal investigator

Contact name
Dr Xiaolei Hu

ORCID ID
https://orcid.org/0000-0001-9864-7432

Contact details
Neuro-Rehabilitation
University Hospital of Umeå,
Umeå
Sweden
907 37
+46 90 785 0000
xiaolei.hu@umu.se

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT04915027

Protocol serial number
Swedish research consul (2022-00316 and 2022-00746)

Study information

Scientific Title
A randomized, controlled, multicentre, pragmatic trial with Rehabkompassen® – A digital structured follow-up tool for facilitating patient-tailored rehabilitation in persons after stroke

Study objectives

The incorporation of the digital Rehabkompassen® tool in usual care within 3 months after stroke onset will improve daily and social activities for patients at the 12-month follow-up after stroke onset compared to those receiving usual care with the Post-Stroke Checklist (PSC).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/04/2021, Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46 010 475 08 00; registrator@etikprovning.se), ref: Dnr 2021-01880

Study design
Parallel open-label two-arm prospective multicentre pragmatic randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Stroke

Interventions
Rehabkompassen® is a novel digital graphic follow-up tool to embrace the heterogeneity of rehabilitation needs among stroke patients in real time based on 6 well-validated and reliable patient-reported outcome measures.

This multicentre, parallel, open-label, two-arm pragmatic randomized controlled trial with an allocation ratio of 1:1 will be conducted in Sweden. Adult stroke patients will have follow-up visits in usual care settings at 3 and 12 months after stroke onset. At the 3-month follow-up, participants will have a usual outpatient visit without (control group) or with (intervention group) the Rehabkompassen® tool. All participants will receive the intervention at the 12-month follow-up visit. Feedback from the end-users (patient and health care practitioners) will be collected after the visits.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rehabkompassen®

Primary outcome(s)
1. Daily activity measured using the smRSq at the 3- and 12-month visits
2. Social participation measured using Domain 8 of the SIS (SIS-D8) at the 3- and 12-month visits

Key secondary outcome(s))

Measured at the 3- and 12-month visits:
1. End-users' satisfaction measured using a patient satisfaction questionnaire
2. Barriers and facilitators for adopting the instrument measured using a bespoke questionnaire
3. Other stroke impacts measured using Stroke Impact Scale (SIS)
4. Health-related quality of life measured using EQ-5D-5L
5. The cost-effectiveness of the instrument measured using resource utilization data

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older.
2. Time since stroke onset: Individuals must be within the first 4 months after stroke, starting from Day 1 after the occurrence of the stroke.
3. Patients discharged from acute care settings

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
1106

Key exclusion criteria
1. Unable to answer the evaluation questions
2. Unable to see the Rehabkompassen®graph
3. Not using BankID, an e-identification tool commonly used in Sweden

Date of first enrolment
31/01/2022

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Strokecenter
University Hospital of Umeå
Umeå
Sweden
907 37

Study participating centre
Stroke- and neurorehabilitation
University Hospital of Umeå
Umeå
Sweden
907 37

Study participating centre
Rehabiliteringsmedicinska mottagningen
Västmanlands sjukhus
Västerås
Sweden
721 89

Study participating centre
Minnes- och geriatrikmottagning
Akademiska universitetssjukhuset
Uppsala
Sweden
751 85

Study participating centre
Rehabiliteringsmedicin
Sahlgrenska universitetssjukhuset
Göteborg
Sweden
421 37

Study participating centre
Strokemottagning
Centralsjukhuset
Karlstad
Sweden
65185

Study participating centre
Strokemottagningen
Sundsvalls sjukhus
Sudsvall
Sweden
851 86

Study participating centre
Strokeavdelning
Nyköpings lasarett
Nyköping
Sweden
611 85

Sponsor information

Organisation
Region Västerbotten

Funder(s)

Funder type
Research council

Funder Name
Swedish research consul (2022-00316 and 2022-00746)

Funder Name
Forte (2020-00136)

Funder Name
Västerbotten County Council and Umeå University (ALF Foundation, 2021-967513)

Funder Name
The Heart-Lung Foundation (2020676)

Funder Name
VINNOVA Medtech4Health (2019-01389)

Funder Name
The Swedish Stroke Foundation (Strokeförbundet)

Results and Publications

Individual participant data (IPD) sharing plan
The study protocol, including statistical analyses, will be available in conjunction with the scientific publication. Upon study completion, anonymized data will also be available to the scientific community at large through publications. Moreover, any party may apply to the Chief Investigator for access to the full protocol, deidentified participant-level data, and the statistical code for academic research purposes by a study collaboration request. The steering committee will govern data access.
xiaolei.hu@umu.se

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		06/10/2023	10/10/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes