

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

Submission date 18/08/2023	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/08/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/10/2023	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 routine. 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

Study website

<https://rehabkompassen.se>

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

NCT04915027

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Home, Hospital

Study type(s)

Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Rehabkompassen®

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

26/04/2021

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

120 Years

Sex

Both

Target number of participants

940

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

Sponsor details

Neuro-Rehabilitation
University Hospital of Umeå
Umeå
Sweden
907 37
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regionen@regionvasterbotten.se

Sponsor type

Hospital/treatment centre

Website

<https://www.regionvasterbotten.se/vara-sjukhus/norrlands-universitetssjukhus>

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

Publication and dissemination plan

Upon completion of the trial, investigators will report results, regardless of the direction or magnitude of the effect, through peer-reviewed journal articles, scientific presentations, patient education websites, public media and ClinicalTrials.gov. We endeavour to facilitate knowledge transfer and exchange among different stakeholders.

Intention to publish date

30/06/2027

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.

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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