

Recovery of mobility after stroke

Submission date 05/08/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 13/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/09/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Stroke is a major cause of death and the risk of stroke increases with age. If survived, stroke is the most common cause of disability in adults. Stroke often results in permanent limitations of mobility, and the need for the help of others in activities of daily living. Up to now, little is known about the recovery of mobility after stroke. In order to optimize the rehabilitation after stroke, detailed knowledge of the recovery process regarding mobility is needed. People's life-space mobility (i.e. their mobility in the environment), has not been investigated yet. This study aims to close this knowledge gap. Innovative data collection methods including wearable sensors and interactive digital maps will be used.

The study aims to describe mobility, including mobility function and life-space mobility, and changes in mobility within the first year after stroke. The study also aims to identify and describe subgroups with different recovery patterns of mobility; to evaluate if a change in mobility function goes along with a change in life space mobility; and to evaluate patients' motivation for going outdoors, transportation use, as well as assistance needed.

Who can participate?

Patients aged 18 years or older who are treated at the Stroke Center, University Hospital Basel with a first stroke can participate in this study. Patients with severe cognitive impairment or physical disability cannot participate in this study.

What does the study involve?

At 3, 6, 9, and 12 months after stroke, different mobility tests will be performed at the study center, including tests of balance, strength, and gait. The life space (physical area used/visited by participants) will be measured in participants' real life using GPS. In addition, participants will give information on visited locations including motivation for travel, use of transportation, and assistance needed by using interactive digital maps.

What are the possible benefits and risks of participating?

The study is purely observational. There are neither specific risks nor direct (health) benefits for the participants. A detailed knowledge of recovery patterns after stroke will help to improve the rehabilitation process for future patients. Knowledge about patients' motivation for outdoor mobility will allow to define individualized patient-oriented rehabilitation goals.

Where is the study run from?

The study will be run from the Department of Sport, Exercise, and Health, University of Basel (Switzerland) with participants recruited from the Department of Neurology & Stroke Center, University Hospital Basel (Switzerland) and measurements taken at the Basel Mobility Center, Department of Geriatric Medicine Felix Platter (Switzerland)

When is the study starting and how long is it expected to run for?

January 2018 to February 2022

Who is funding the study?

The project is financed by the Swiss National Science Foundation (Switzerland), Project-No. 182681

Who is the main contact?

1. PD Dr. med. Timo Hinrichs

timo.hinrichs@unibas.ch

2. Prof. Dr. Nils Peters

nils.peters@usb.ch

Contact information

Type(s)

Scientific

Contact name

Dr Timo Hinrichs

ORCID ID

<https://orcid.org/0000-0001-6200-307X>

Contact details

Division of Sports and Exercise Medicine
Department of Sport, Exercise and Health (DSBG)

University of Basel

Birsstrasse 320 B

Basel

Switzerland

4052

+41 61 207 47 43

timo.hinrichs@unibas.ch

Type(s)

Scientific

Contact name

Prof Nils Peters

Contact details

Department of Neurology & Stroke Center

University Hospital Basel

Petersgraben 4

Basel
Switzerland
4031
+41 61 556 58 53
nils.peters@usb.ch

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

32003B_182681

Study information

Scientific Title

Recovery of mobility function and life-space mobility after ischemic stroke (MOBITEC-Stroke)

Acronym

MOBITEC-Stroke

Study objectives

In order to be able to design rehabilitative measures for people after stroke and to maximize their effectiveness, knowledge of the details of stroke recovery (including timing and components) and of the association between mobility function and life-space mobility during the recovery process is needed.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/12/2019, The Ethics Committee of Northwestern and Central Switzerland (EKNZ) (Hebelstrasse 53, 4056 Basel, Switzerland; +41 061 268 13 50; eknz@bs.ch), ref: 2019-00989

Study design

Single-centre prospective cohort study

Primary study design

Observational

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Ischemic stroke (first event)

Interventions

Patients with incident first stroke who live in their own homes will be included in this cohort study. At 3, 6, 9, and 12 months after stroke a battery of mobility tests will be performed at the study centre, including laboratory-based tests of balance and strength, and quantitative gait analysis. Life-space assessment (including 1-week GPS measurements) will be performed in participants' real life. Semantic information on visited locations (reasons for going outdoors, transportation use, assistance needed) will be collected by using interactive digital maps. Linear mixed-effects models will be used to model the trajectories of mobility measures for the total sample and for predefined subgroups. As an exploratory analysis, growth mixture models (GMMs) will be used to identify relevant subgroups with different trajectories. Linear mixed effect models will be used to test whether changes in lower extremity physical function parameters are associated with changes in life-space. Participants' motivation for going outdoors, transportation use, and assistance needed for outdoor mobility will be analysed descriptively. Furthermore, clinical information for the time of the first admission to the Stroke Centre will be made available.

Intervention Type

Other

Primary outcome(s)

1. Walking ability and perceived mobility limitation assessed by self-report at 3, 6, 9, and 12 months after stroke
2. Lower extremity physical function measured using a battery of tests including quantitative gait analysis, tests of lower limb muscle power, balance tests and functional tests in a given order at the study centre assessed at 3, 6, 9, and 12 months after stroke
3. Life-space measured using GPS and by self-report questionnaire at 3, 6, 9, and 12 months after stroke
4. Reasons for going outdoors, transportation use, and need for assistance measured using a questionnaire tool that is based on digital maps at 3, 6, 9, and 12 months after stroke

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

08/02/2022

Eligibility

Key inclusion criteria

1. First ischemic stroke within the past 3 months
2. Aged ≥ 18 years
3. Able to communicate verbally with the study personnel
4. Able to understand the study information and to provide written informed consent
5. At least one of the following stroke-related symptoms potentially affecting gait/mobility must be present:
 - 5.1. Lower limb paresis or ataxia
 - 5.2. Stance/gait ataxia (cerebellar or sensory)
 - 5.3. Visual disturbance/field defect
 - 5.4. Central vestibular deficit
 - 5.5. Attentional deficit/neglect
6. Able to get up from a chair and sit down without external help

7. Able to walk for a minimum of 20 m at own pace, with or without pauses, with or without a walking aid, but without the physical assistance of another person (self-report)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

59

Key exclusion criteria

1. Not community-dwelling
2. Unable to walk without assistance, wheelchair-bound, or permanently bedridden (modified Rankin Scale, mRS >3 points)
3. Presence of severe cognitive impairment (Montreal Cognitive Assessment (MoCA) score <21 or, <20 for persons with 12 years of education or less)
4. Acute psychiatric disorder (e.g. severe depression)
5. Advanced terminal illness
6. Orthopaedic surgery of the lower extremities within the past year
7. On-going rehabilitation measures following an inpatient surgical procedure at the time of stroke
8. Major pre-stroke mobility limitations (major difficulties in walking or climbing stairs; self-report)

Date of first enrolment

01/01/2020

Date of final enrolment

22/06/2021

Locations

Countries of recruitment

Switzerland

Study participating centre

Basel Mobility Center

Department of Geriatric Medicine Felix Platter

Burgfelderstrasse 101
Basel
Switzerland
4055

Sponsor information

Organisation

University of Basel

ROR

<https://ror.org/02s6k3f65>

Funder(s)

Funder type

Government

Funder Name

Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

Data will be made freely available to external research groups by sharing them through a digital repository. Details of the data sharing plans are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/05/2023	09/05/2023	Yes	No
Results article		22/12/2022	18/09/2024	Yes	No
Protocol article	protocol	16/09/2020	21/09/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes