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Recovery of mobility after stroke

Submission date
05/08/2020

Recruitment status
No longer recruiting

Registration date
13/08/2020

Overall study status
Completed

Last Edited
18/09/2024

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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; nad 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/visted 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?
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Study website
https://mobility.dsbg.unibas.ch/en/projects/mobitec-stroke/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)
Hospital

Study type(s)
Quality of life

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
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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/01/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
59

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
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Sponsor information

Organisation
University of Basel

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Sponsor type
University/education

Website
https://www.unibas.ch/de

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, SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publications in peer-reviewed scientific journals.

Intention to publish date
30/09/2022

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?
Protocol article	protocol	16/09/2020	21/09/2020	Yes	No
Results article	results	04/05/2023	09/05/2023	Yes	No

Results article	22/12/2022	18/09/2024	Yes	No