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Feasibility of an individualised, task-oriented, video-supported home exercise programme for arm function in patients in the subacute phase after stroke: protocol of a randomised controlled pilot study

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ABSTRACT

Introduction Stroke rehabilitation guidelines suggest a high-frequency task-oriented training at high intensity. A targeted and self-paced daily training with intermittent supervision is recommended to improve patients' self-management and functional output. So far, there is conflicting evidence concerning the most effective home-training delivery method.

Methods and analysis The purpose of this pilot study is to compare the feasibility and preliminary effects of task-oriented home-exercises in patients in the subacute stage after stroke. Twenty-four patients will be randomised (1:1) to a Video group (a) or Paper group (b) of an individualised, task-oriented home-training (50 min, 6×/week, for 4 weeks) based on Wulf and Lewthwaite's Optimizing Performance Through Intrinsic Motivation and Attention for Learning theory of motor learning. Patient-relevant goals will be identified using Goal Attainment Scaling and exercises progressively adapted. Semistructured interviews and a logbook will be used to monitor adherence, arm use and acceptability. Primary outcome will be the feasibility of the methods and a full-scale trial employing predefined feasibility criteria (recruitment, retention and adherence rates, patients' satisfaction with the home-exercise programme and their progress, affected hand use and acceptance of the intervention). Assessed at baseline, post intervention and 4-week follow-up, secondary outcomes include self-perceived hand and arm use, actual upper extremity function and dexterity, hand strength, independence in activities of daily living and health-related quality of life. Interview data will be analysed using qualitative content analysis. Medians (ranges) will be reported for ordinal data, means (SD) for continuous and frequency (percentage) for nominal data.

Ethics and dissemination This study follows the Standard Protocol Items: Recommendations for Interventional Trials-Patient-Reported Outcome (PRO) Extension guideline. Ethical approval was received from the Ethics Committee of the Medical University of Innsbruck, Austria (1304/2020). Written informed consent will be obtained from all participants prior to data collection. Study results will be disseminated to participating patients, patient organisations, via the clinic's homepage, relevant conferences and peer-reviewed journals.

Trial registration number DRKS-ID: DRKS00023395. Study protocol, second revision, 5 December 2021.

Strengths and limitations of this study

- The intervention groups of this study will receive a home exercise programme, based on relevant motor learning and action observation principles.
- Both subjective and objective assessments will be used in this study to assess hand and arm function and use in daily life in people after stroke.
- This pilot study will employ a mixed methods approach and a range of predefined feasibility criteria.
- Throughout this study, patient involvement is considered essential to target the intervention to patients' needs and preferences.
- The sample size of this pilot and feasibility study is too small to examine the effectiveness of the intervention.

INTRODUCTION

Stroke is a devastating disease and second most prevalent cause of disability in the European Union, with more than 1.1 million people being affected every year.[1] Survivors with mild to moderate stroke are often disabled in motor function, in their activities of daily living (ADL) and experience a loss in social participation which influences quality of life.[2] As many as 50%–80% of patients after stroke (PaS) have impaired upper limb function[3–5] and are in need of rehabilitation services. During rehabilitation, a discrepancy, however, is frequently seen between their

level of upper limb capacity and actual use in daily life activities.[6 7]

According to international stroke rehabilitation guidelines[8 9] and systematic reviews,[10 11] various evidence-based treatment strategies and programmes for the upper extremity are recommended. Shared characteristics of successful programmes are a high intensity, high repetition rate and a task-oriented training approach within a minimum period of 6 months post stroke; this includes home-based practice to enhance the training frequency.[8 10–12] Contrastingly, a Cochrane review and meta-analysis (2012) has failed to identify a sufficiently large number of high-quality studies, which investigated the effects of home-based upper limb training on ADL performance or functional arm movement after upper extremity training.[13] A systematic review (2020) showed that existing self-administered home-based practice is not superior to no intervention on upper limb activity and structured home-based practice is similarly effective as non-structured home-based practice in chronic, severely disabled stroke survivors.[14]

These results suggest that a home-based training needs to comply with relevant motor learning principles in order to be effective. According to Wulf and Lewthwaite's 'Optimizing Performance Through Intrinsic Motivation and Attention for Learning' (OPTIMAL) theory of motor learning,[15] there are three evidence-based key elements which boost motor learning: enhanced outcome expectancy, learner's autonomy and an external focus of attention. The combined approach has been found most effective due to the additive contributions of key factors.[16 17]

Rehabilitation guidelines suggest a targeted and self-paced daily training with intermittent supervision including a close monitoring of training adherence.[18] Various behavioural strategies have been recommended, for example, a joint goal setting, specific feedback and continuous support and monitoring via phone calls.[19 20] Modern technology is increasingly being used to increase patients' autonomy during client-specific and task-specific interventions.[21] It has been shown to encourage patients' self-management[22–24] and increase the therapy frequency in the subacute phase after stroke.[10 25 26] For example, action observation therapy combines video-based movement observation with actual performance of the same task-specific exercises.[27]

So far, there is controversial evidence concerning the effects of a video-supported home training as compared with conventional home-based training in the stroke population. In PaS, one study did not find any differences between these two interventions on adherence, upper limb function and patient satisfaction[28] whereas others observed a superiority of video-based training on patients' independence with ADL[29] and upper extremity performance in daily life.[30] Recent work has shown greater improvements in adherence, self-efficacy for exercises, mobility but not basic ADL after video-based when compared with paper-based home training in PaS.[31] A cross-sectional study reported the preference of patients receiving hand therapy of a video-based over a paper-based home training programme. Reported reasons were the more appealing design and patients' greater understanding and confidence in their ability to correctly perform the tasks.[32] None of these studies have however incorporated OPTIMAL motor learning principles in the training.

OBJECTIVES

The purpose of this pilot study is, therefore, to explore the feasibility of an individualised, task-oriented, video-based versus a paper-based home exercise programme based on the latest principles of the OPTIMAL theory of motor learning[15] in PaS in the subacute stage with mild to moderate arm paresis. A further aim is to compare the preliminary effects of the video-based with the paper-based home exercise programme on the paretic upper limb use in meaningful activities of daily life, in order to calculate the sample size for a full-size trial.

METHODS AND ANALYSIS

Study design, setting and timeline

The study is designed as a single-centre, randomised, parallel-group, assessor-blinded controlled pilot and feasibility trial in people after a first-ever stroke and follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 and SPIRIT-PRO Extension Checklist (online supplemental file 1). This study will be conducted at the Clinical Department of Neurology, Medical University of Innsbruck, Austria. The patient's exercise programme will be performed at home. The expected overall study duration is approximately 12 months, from 1 April 2021 to 30 April 2022.

Patient and public involvement

No patients were involved in the development of the study design and methods. Throughout this study, patient involvement is considered essential to target the intervention to patients' needs and preferences. Patients' perspectives on the intervention will be asked for during weekly phone call interviews and semistructured interviews at post intervention. The planned study intervention will be modified based on these findings.

Patients and sample size

Inclusion and exclusion criteria

Patients have to meet the inclusion criteria as follows: first-ever stroke leading to a mild to moderate arm paresis as assessed by the Motricity Index (MI) (includes a minimum pinch grip of 19 points and elbow flexion/shoulder abduction of 14 points and excludes normal scores of 33), in the subacute stage (from 7 days to 5 months after a stroke), age of >18 years, sufficient cognitive abilities (Mini Mental Status Test≥24[33]), living in Tyrol, discharged from the hospital and living at home.

People are excluded if they are severely disabled (modified Rankin Scale (mRS) score ≥4[34]), have a comorbidity potentially restraining participation, for example, a life expectancy <12 months or malignant disease, any physical or mental condition restricting participation in the study, for example, heart failure, being under guardianship, serious neuropsychological disorders, neglect, severe aphasia, severe cognitive deficits or dementia, psychiatric disorders, haemianopia, untreated severe visual impairment (ie, problems reading instructions and watching the study videos), pregnancy, military service. The study principle investigator (PI) will decide whether a participation in other studies is allowed.

The sample size for this pilot and feasibility study has been determined to include a number of 12 patients per group, as previously recommended.[35]

Recruitment and informed consent

Patients treated at the Clinical Department of Neurology at the Medical University of Innsbruck, Austria due to a first-ever stroke will be identified and checked for eligibility. The PI will inform patients about the study both orally and in writing. Eligible patients who provide their written informed consent will be enrolled into the study. Patients will be assured that their consent is voluntary, and they may withdraw from the study at any time without reasons and without treatment prejudice (online supplemental files 2 and 3).

Randomisation, allocation concealment and blinding

Stratified (for age: 70 and under, over 70[36]) blocked randomisation will be conducted with a software-based random number generator (Sealed Envelope, London, UK) by an independent researcher (BS) using permuted blocks of 2 and 4, allocation concealment and 1:1 allocation. Study results will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT).[37 38] A flow diagram is shown in online supplemental figure 1.

Allocation concealment will be performed to avoid allocation bias. Based on the randomisation list, sequentially numbered sealed opaque envelopes including group allocation letters V (Video group) and P (Paper group) will be created for the stratum of age. A unique identification number (ID) will be given to patients who will be asked to unseal the envelopes themselves and not discuss their group allocation until study completion. Assessors will be blinded to the group allocation of patients and will be asked on a random basis about their assumption concerning the group allocation of a patient. Blinding will be considered preserved if their guessing is correct in around 50% of responses, which is consistent with random guessing.[39] Patients will not be aware of the study hypotheses. Unplanned unblinding will be done in cases of emergency.

Intervention

Based on existing evidence showing that a higher dose of exercises facilitates motor recovery after stroke,[40] two

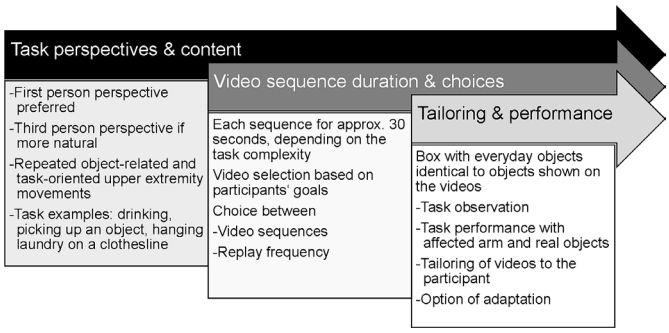

Figure 1 Key aspects of task-oriented training in the Video group.

intervention groups will be used in this study, in addition to usual care:

- Video group: patients will receive an Android tablet with access to the exercise platform where videos are available, based on existing studies of action observation[27] as shown in figure 1. The therapist will adjust the therapy goals, number of repetitions of the individual exercises, respective videos and instructions on a weekly basis. Adjustments regarding the exercise difficulty will be based on whether the intended goals and number of repetitions have been achieved. Patients will be invited to record the desired number of repetitions and actual number of repetitions, daily exercise duration, evaluate how they fared with the individual exercises and finally, their overall satisfaction and (self-) management in the logbook.
- Paper group: patients will receive a folder with photos and instructions for the home exercise programme including a logbook. Based on a weekly telephone conversation with the occupational therapist, they are asked to enter a jointly agreed weekly goal and desired number of repetitions, the actual number of repetitions, daily exercise duration and evaluate how they fared with the individual exercises and finally, their overall satisfaction and (self-)management in the logbook.

The intervention will involve an individualised, task-oriented home exercise programme oriented on motor learning and task-specific exercise programmes for PaS[41–47] and on the principles of the OPTIMAL theory (table 1), delivered either video-based (Video group) or paper-based (Paper group). The intervention will be offered by an experienced occupational therapist (MW) as an add-on to usual outpatient rehabilitation and performed six times per week, 50 min per session for 4 weeks. Before the start of the home exercise programme, two questions will be asked on self-confidence ('How confident are you in doing the 4-week home exercise programme?') and support of the environment ('Can people in your home environment support you in your training?'), and one patient-relevant goal will be agreed on for the first week using Goal Attainment Scaling (GAS). Exercises will be selected individually from a predesigned list/menu. All patients will be called by an occupational

Table 1 Principles of the Optimizing Performance Through Intrinsic Motivation and Attention for Learning theory adapted to this study

Motivational effects—enhanced performance expectancies	Autonomy support	Attentional effects—external focus of attention
Patients' encouragement regarding the learnability of the tasks at the programme start	Choice of the numbers of repetitions and sets	Exercises have a specific goal and are task-oriented
Conversation about previous positive outcomes, to enhance expectations of the programme.	Choice of the exercise sequence	Objects or markings which should be reached, drawing attention to the planned effect of a movement on the environment
General information on performance improvement alongside practice.	Choice of the difficulty level	Instructions focusing on the task goal, using metaphors or analogies as guidance
Explanatory model of neuroplasticity, motor learning and normative information provided on the platform or in the exercise folder.	Shaping, that is, a gradual increase in difficulty, adjusting one parameter at a time (eg, size or weight of an object)	Variability in the order of the exercises, random practice of the exercise
Realistic weekly goals evaluated through Goal Attainment Scaling.	Choice of an exercise-free day	
Weekly semistructured interview of the process to identify problems and progress related to arm use, level of support needed and programme satisfaction.	Choice of the amount of feedback	
Positive feedback of good performance, suggestive statement on better than average performance for example, 'you are doing well', 'active people with your experience usually do well with this task'.	Individual goal setting through Goal Attainment Scaling	
Progression of exercises based on weekly goals which are challenging, but achievable to provide experiences of success	Evaluation of the exercises using smileys (5-point Likert-Scale)	
Report of previously trained minutes		

therapist (MW) once a week (four times in total) who will provide support, identify any problems and evaluate adherence with structured questions (figure 2), define patient-relevant goals using GAS and adapt the exercises.

Data collection

Demographic (gender, age, date of birth) and stroke specific data (type and date of insult, previous neurorehabilitation based on current event, current outpatient therapy, patient-reported handedness, contextual factors such as life and employment situation) will be extracted from patients' charts at eligibility screening, followed by a screening for an impairment in upper limb and cognitive functions (MI; Mini Mental Status Test). Study specific outcome data will be collected at baseline (t1), post intervention (t2) and at 4-week follow-up (t3) by three blinded occupational therapists. These assessors will be trained before the start of the data collection. Assessments will be collected at random to avoid an order effect. Semistructured interviews will be performed by the intervention provider (MW) at t2 to gain in-depth information concerning acceptability of the study intervention (online supplemental table 1).

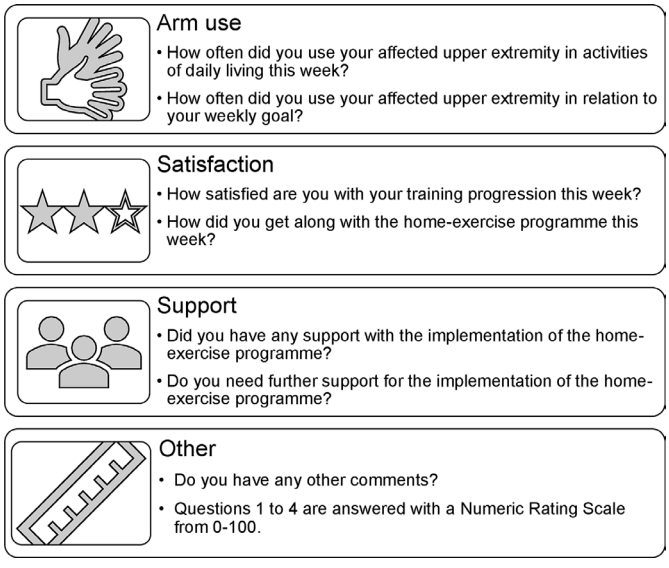

Figure 2 Questions asked in weekly semistructured interviews.

Adverse events will be monitored throughout the study and cared for. A logbook, platform recording and information gained from structured questions during weekly phone calls will be used to monitor adherence to the home-exercise programme. A schedule of enrolment, intervention and data collection during the study is shown in online supplemental table 2.

Primary outcome

The feasibility of the methods and of conducting a full-scale randomised controlled trial (RCT) will be explored using predefined feasibility criteria.

A logbook will be used to report adherence to the home exercise programme. Any non-adherence or non-retention (attrition) will be recorded including its reason and will be presented in a CONSORT flow diagram (online supplemental figure 1).

Feasibility criteria include (1) a target recruitment rate of 6% out of 450 eligible patients (or 2–3 patients per month). The number of 450 patients was estimated according to the number of people after stroke meeting the eligibility criteria at the study centre within the previous 12-month period and the recruitment rate based on the number of patients being discharged home, (2) a target retention rate of 80% (or 20 patients), (3) a target minimum adherence rate of 67% (4 home-based training sessions per week out of a maximum of 6), (4) an at least moderate satisfaction with one's individual exercise progress (≥3.5 out of 5 points on a Smiley Face Likert Scale, from 1=very unsatisfied to 5=very satisfied), (5) an at least moderate use of the affected hand in ADL and satisfaction with one's progress and the home exercise programme (≥60 points on a Numeric Rating Scale (NRS) from 0 to 100) and (6) an at least moderate acceptance of the intervention as evaluated by a semi-structured interview.

Secondary outcomes

Self-perceived arm and hand use arm function

A change in self-perceived arm and hand function will be measured by the German Motor Activity Log-30 (MAL-30),[48] a semistructured interview that scores the perceived amount of use and perceived quality of movement (QOM) in 30 ADL tasks, using a 6-point scale ranging from 0 (arm not used during activity; no satisfaction with QOM) to 5 (arm used as much as prestroke; full satisfaction with QOM). The German version is a valid, reliable and highly responsive assessment.[48] Minimal clinically important difference (MCID) values for the MAL were 1.0 and 1.1 points for the affected dominant and non-dominant hands, respectively.[49]

Arm motor function

Upper limb function will be assessed by the 19-item Action Research Arm Test (ARAT).[50] The ARAT uses movement observation and consists of 4 subtests (grasp, grip, pinch, gross arm movement), which are rated on a 4-point ordinal scale (0=can perform no part of test to 3=perform test normally). The ARAT has excellent test–retest and intrarater and inter-rater reliability and internal consistency.[50 51] MCID for the ARAT in acute stroke is 12 points if the dominant side is affected and 17 points if the non-dominant side is affected.[52]

Finger dexterity

Manual dexterity will be assessed by the Nine Hole Peg Test (NHPT),[53] where pegs are to be placed into the holes of a board and returned to the container as quickly as possible. Timing will be determined using a stopwatch and recorded in seconds, with shorter durations indicating better dexterity. Normative data for healthy adults are available.[53] The minimum detectable change (MDC) is a reduction of time by 54%.[52] Adequate to excellent psychometric properties have been shown for the NHPT.[53 54]

Gross motor arm and hand dexterity

The Box and Block Test (BBT)[55] measures unilateral gross motor dexterity of the arm and hand. As many blocks as possible should be moved from one box compartment to the other for a period of 60 s. The BBT is scored by counting the numbers of blocks. Normative data are available and higher scores indicate better gross manual dexterity.[55] MDC is 5,5 blocks per minute (18%) in acute and chronic stroke.[52] The BBT has shown excellent test–retest and inter-rater reliability and adequate to excellent criterion validity.[54]

Hand strength

The Jamar grip dynamometer is a quantitative and objective measure of isometric muscular strength of the hand and forearm, scored using force production in kilograms (0–90), with normative data available.[56] The MCID of Jamar grip dynamometer is 5.0 and 6.2 kg for the affected dominant and non-dominant sides.[49] The measure has an excellent test–retest and intrarater reliability and adequate validity.[56]

Independence in ADL

Scores of Independence for Neurologic and Geriatric Rehabilitation (SINGER)[57] based on the International Classification of Functioning, Disability and Health measures 20 aspects of 'independence in ADL'. Items are graded in six steps (0–5). The gradation refers to the type and amount of help required for the respective activity that is, 0=totally dependent on professional help to 5=independent without assistive device. Good to excellent psychometric properties and ceiling effects of 3.6% have been demonstrated for the SINGER.[57 58]

ADL collectively describe fundamental skills needed for self-care like eating, bathing and mobility.[59]

Health-related quality of life (HRQoL)

The EuroQol-5 Dimensions 5-level (EQ-5D-5L) questionnaire[60] measures five dimensions of HRQoL: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Responses are rated on five levels ranging from 1=no problems to 5=extreme problems. The present overall health is rated on a Visual Analogue Scale (VAS) from 0 to 100.[61] The MCID of the EQ-Index is 0.10 (33.8 %) based on an anchor-based approach, and 8.61 (41.5 %) for the VAS. The EQ-5D-5L has shown acceptable psychometric properties in people post stroke undergoing rehabilitation.[62]

Individual goal achievement

The GAS is a scale to quantify the achievement of goals set, which can be measured on a 5-point scale ranging from −2 (much less) to +2 (much more).[63] The GAS has good validity, reliability and sensitivity.[64]

Data management

Personal data are pseudonymised and handled strictly confidentially, according to the Austrian Data Protection Law. All data are digitised in double entry. Data and all study-related documents are stored safely at the trial site for 15 years. Access is granted only to authorised study team members. No data monitoring committee is required in this academic study (no competing interests).

Statistical analyses

Descriptive statistics will be performed using IBM SPSS software, V.26.0. Statistical significance is defined as two-tailed p value of <0.05. To avoid missing data, patients will be asked to complete missing responses in questionnaires. Intention-to-treat analysis will be performed for all cases with complete follow-up data, which are analysed by original assigned groups. Descriptive statistics will be reported for all outcomes. Continuous data will be checked for outliers and normality using the Shapiro-Wilk test, histograms and Q–Q plots. Medians (IQRs, ranges) will be reported for ordinal data (mRS, MAL, ARAT, SINGER, EQ-5D-5L, NRS, GAS, Smiley Face Likert Scale). Means (95% SD) will be reported for continuous data (age, NHPT, BBT, muscle strength in kg) and raw count (frequency, percentage) will be reported for counted (N adverse events and missing data if any, eligibility, recruitment, retention and adherence rates) and nominal data (gender, lesion side, ischaemic/haemorrhagic stroke, living alone/with partner and handedness).

The eligibility rate is the percentage of patients who are eligible using the inclusion and exclusion criteria. The recruitment rate (%) will be determined by dividing the number of patients consented by the number of patients eligible. The retention rate is the percentage of patients who completed the study out of the total sample, times 100. The adherence rate (%) is the percentage of actually performed number of exercise sessions over the planned number of exercise sessions, times 100.[65] Eligibility and consent rates will be calculated with 95% CIs according to the Wilson 'score' method cited by Newcombe.[66] In the case of a proportion close to 0 or 1, a Poisson approximation according to Brown will be used.[67]

Preliminary effects will be evaluated: for ordinal variables, differences between post intervention and baseline will be calculated, and between follow-up and baseline, and between follow-up and post intervention. A Mann-Whitney U test will be performed on these new variables. For continuous data, a repeated measures analysis of variance will be conducted if the assumption of sphericity is met, or correction procedures applied as appropriate. In the case of a non-normal distribution, continuous data will be treated like ordinal data. Corrections for multiple comparisons will be performed as appropriate.

The sample size for a full-scale RCT will be calculated using effect sizes for the Mann-Whitney U test (baseline, post intervention)[68] based on the group differences in self-perceived arm use (MAL). The correlation coefficient r will be estimated using the equation $r = \frac{Z}{\sqrt{n}}$,[69] where Z is the standardised value for the U value and n is the total number of observations on which Z is based. The r value will be converted into r^2, which is equivalent to a partial eta squared effect size and (multiplied by 100) signifies the percentage of variance in the dependent variable as explained by the independent variable.[68]

Qualitative data analysis

Interview data will be analysed by Steigleder's modified variant of Mayring's qualitative content analysis approach.[70] Using a combined deductive–inductive approach, main-content and subcontent categories will be developed, which are continuously adapted according to the data material. Interviews will be manually transcribed and analysed by MAXQDA software (VERBI GmbH, Berlin, Germany).

Reoccurring ideas, concepts, words and phrases will be identified and scrutinised. Based on that, a coding frame will be developed to group them into meaningful categories. Categories and subcategories are required to be mutually exclusive and exhaustive, apparent one dimensional and saturated. Saturation is reached after all the codes in the population have been observed once in the sample.[71] Relevant material will be selected and text segments structured and generated, marked and defined. Defined text segments will then be subdivided, revised and expanded and central subcategories identified, based on the research question.[72 73] Categories will be defined, named and characterised, and decision rules defined for any cases of overlapping subcategories, to allow for a consistent assignment of data segments. The material will progressively be summarised, subsumed and contrasted. Categories and subcategories will be illustrated using citations. This will be followed by creating a data matrix suitable for quantitative data analysis. Descriptive statistics (frequencies) will be used. Throughout the analyses, rigour and reliability will be maximised[74 75] by following a systematic and consistent approach and the concepts of credibility, dependability and transferability will be applied to achieve trustworthiness.[76] In addition, the entire dataset will be double coded by two researchers within 2–3 weeks after the initial coding (MW, BS). The researchers are aware of their effect on the interview process and outcomes based on the concept of reflexivity.[77]

DISCUSSION

The pilot study will investigate the feasibility of an individualised, task-oriented, video-based versus a paper-based home-exercise programme in PaS in the subacute stage with mild to moderate upper limb paresis. For the study intervention, the principles of the OPTIMAL theory of motor learning are applied.

Home environment training is challenging because sessions often lack structuring, which may negatively impact on patient engagement.[19] It is key for outpatient rehabilitation to maintain high levels of patients' motivation, even more for the home environment.[78] Numerous studies have demonstrated that familiar environments enhance rehabilitation outcomes as they facilitate meaningful task-specific training, sense of control, confidence and skill transfer

into daily life.[78 79] Thus, outpatient rehabilitation typically is client-centred and involves content-specific training.[78 80 81]

During the intervention development phase, we decided to include the three aspects of the OPTIMAL-theory from Wulf and Lewthwaite,[15] such as enhanced performance expectancies, autonomy support and an external focus of attention. Evidence has shown that a focus on the task goal boosts motor performance and motor learning. In addition, intermittent supervision, self-monitoring combined with client-centred goals, progression and feedback are crucial for encouraging adherence and advancement.[82]

With respect to the outcome measures, not having chosen the Fugl-Meyer Assessment (FMA)[83] for this study may be a significant study limitation because the FMA is the most frequently used and a highly recommended tool in stroke research and so, it could be valuable to compare the current patient group to other studies. Therefore, the FMA will be used as an outcome measure in the planned follow-up study.

The primary aim of this pilot study is to assess the feasibility of two intervention delivery methods and its acceptability in patients in the subacute phase after stroke, and to prepare a full-scale RCT.[84]

Contributors Authors critically and substantially revised the manuscript and approved the current version to be submitted for publication. MW and BS devised and designed the study and drafted the manuscript. GS substantially contributed to the conception and design of the study. SK, MK and CM provided substantial input on the study methodology and quantitative analysis. MK is a study manager at his centre. All authors critically revised and approved the final manuscript.

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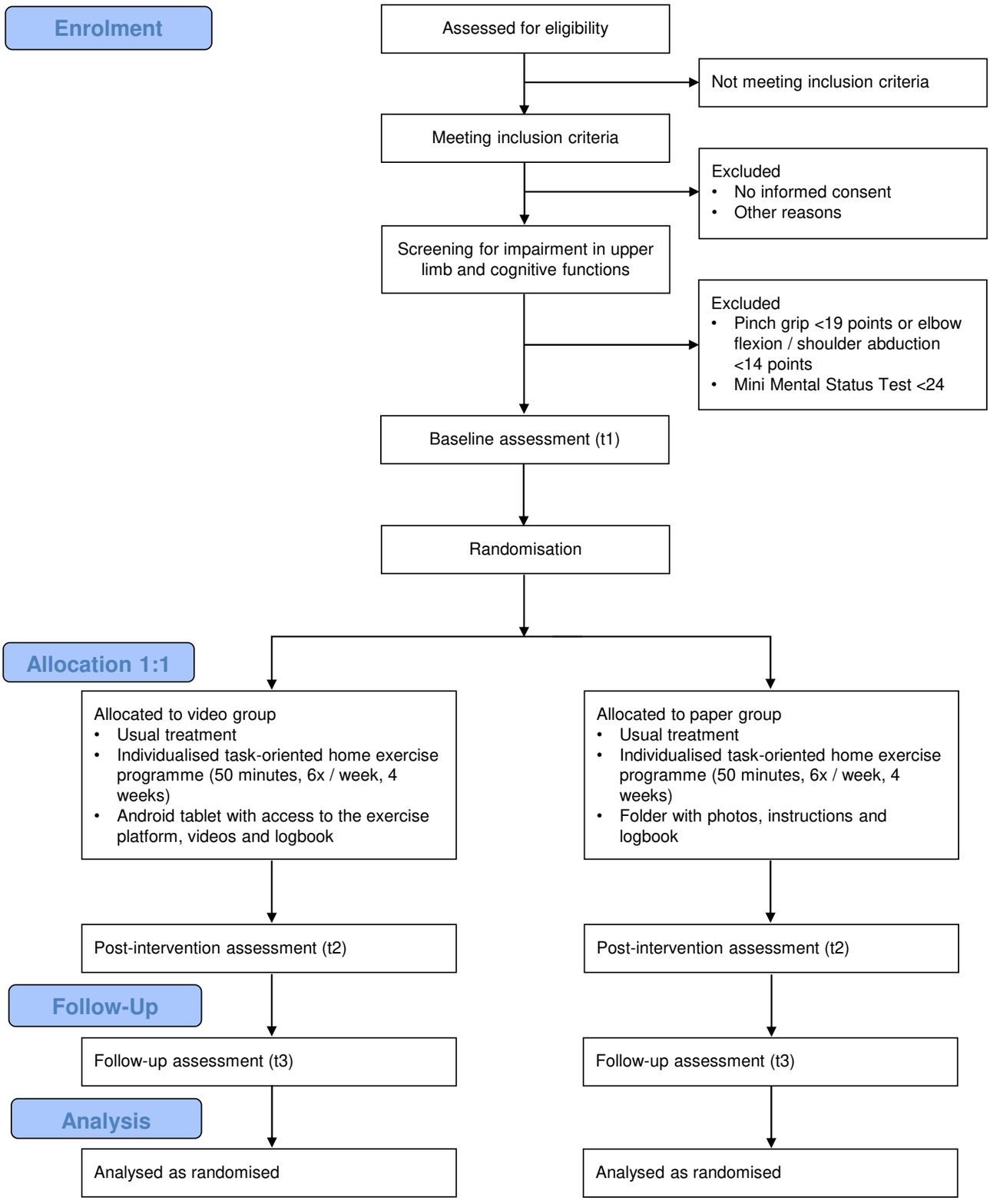
CONSORT Flow Diagram (Extension to randomised pilot and feasibility trials; Eldridge et al., 2016)



SPIRIT 2013 and SPIRIT-PRO Extension Checklist: Recommended Items to Address in a Clinical Trial Protocol

Calvert M, Kyte D, Mercieca-Bebber R, et al. Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension. JAMA : the journal of the American Medical Association 2018;319(5):483-94 doi: 10.1001/jama.2017.21903[published Online First: Epub Date])

Section/item	ItemNo	Description	SPIRIT-PRO Item No.	SPIRIT-PRO Extension or Elaboration Item Description	Addressed on Page No.
Administrative information					
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym			1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry			3
	2b	All items from the World Health Organization Trial Registration Data Set			See below
Protocol version	3	Date and version identifier			3
Funding	4	Sources and types of financial, material, and other support			25

Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors			1; 25
	5b	Name and contact information for the trial sponsor	SPIRIT-5a-PRO Elaboration	Specify the individual(s) responsible for the PRO content of the trial protocol.	1; BS
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities			25
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)			8-9; 25
Introduction					

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	SPIRIT-6a-PRO Extension	Describe the PRO-specific research question and rationale for PRO assessment and summarize PRO findings in relevant studies.	5-6
	6b	Explanation for choice of comparators			5-6
Objectives	7	Specific objectives or hypotheses	SPIRIT-7-PRO Extension	State specific PRO objectives or hypotheses (including relevant PRO concepts/domains).	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)			7
Methods: Participants, interventions, and outcomes					
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained			7

Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	SPIRIT-10-PRO Extension	Specify any PRO-specific eligibility criteria (eg, language/reading requirements or prerandomization completion of PRO). If PROs will not be collected from the entire study sample, provide a rationale and describe the method for obtaining the PRO subsample.	8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered			9-11; Figure 1; Figure 2, Supplemental Table 1
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)			15
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)			2, 10-11, 15-18
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial			8-9

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	SPIRIT-12-PRO Extension	Specify the PRO concepts/domains used to evaluate the intervention (eg, overall health-related quality of life, specific domain, specific symptom) and, for each one, the analysis metric (eg, change from baseline, final value, time to event) and the principal time point or period of interest.	17-20; Supplemental Table 2
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	SPIRIT-13-PRO Extension	Include a schedule of PRO assessments, providing a rationale for the time points, and justifying if the initial assessment is not prerandomization. Specify time windows, whether PRO collection is prior to clinical assessments, and, if using multiple questionnaires, whether order of administration will be standardized.	Supplemental Table 2; Supplemental Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	SPIRIT-14-PRO Extension	When a PRO is the primary end point, state the required sample size (and how it was determined) and recruitment target (accounting for expected loss to follow-up). If sample size is not established based on the PRO end point, then discuss the power of the principal PRO analyses.	8

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size			8-9
Methods: Assignment of interventions (for controlled trials)					
Allocation:					9
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions			9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned			9
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions			8-9

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how			9
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial			9
Methods: Data collection, management, and analysis					
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	SPIRIT-18a (i)-PRO Extension	Justify the PRO instrument to be used and describe domains, number of items, recall period, and instrument scaling and scoring (eg, range and direction of scores indicating a good or poor outcome). Evidence of PRO instrument measurement properties, interpretation guidelines, and patient acceptability and burden should be provided or cited if available, ideally in the population of interest. State whether the measure will be used in accordance with any user manual and specify and justify deviations if planned.	14-15
			SPIRIT-18a (ii)-PRO Extension	Include a data collection plan outlining the permitted mode(s) of administration (eg, paper, telephone, electronic, other) and setting (eg, clinic, home, other).	14-15

			SPIRIT-18a (iii)-PRO Extension	Specify whether more than 1 language version will be used and state whether translated versions have been developed using currently recommended methods.	NA
			SPIRIT-18a (iv)-PRO Extension	When the trial context requires someone other than a trial participant to answer on his or her behalf (a proxy-reported outcome), state and justify the use of a proxy respondent. Provide or cite evidence of the validity of proxy assessment if available.	NA
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	SPIRIT-18b (i)-PRO Extension	Specify PRO data collection and management strategies for minimizing avoidable missing data.	21
			SPIRIT-18b (ii)-PRO Elaboration	Describe the process of PRO assessment for participants who discontinue or deviate from the assigned intervention protocol.	21, Supplemental File 2
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol			21

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	SPIRIT- 20a-PRO Elaboration	State PRO analysis methods, including any plans for addressing multiplicity/type I (α) error.	21-23
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)			21-23
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	SPIRIT- 20c-PRO Elaboration	State how missing data will be described and outline the methods for handling missing items or entire assessments (eg, approach to imputation and sensitivity analyses).	21-23
Methods: Monitoring					
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed			21

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial			NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	SPIRIT- 22-PRO Extension	State whether or not PRO data will be monitored during the study to inform the clinical care of individual trial participants and, if so, how this will be managed in a standardized way. Describe how this process will be explained to participants; eg, in the participant information sheet and consent form.	15; Patient Information Sheet and Informed Consent Form (English, German versions)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor			NA
Ethics and dissemination					
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval			24-25

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)			Study protocol (Supplemental Files 2 an 3; English and German versions)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)			24-25
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable			NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial			21
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site			25
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators			25

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation			15
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions			25
	31b	Authorship eligibility guidelines and any intended use of professional writers			25
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code			26
Appendices					

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates			Supplemental Files 2 and 3; Patient Information Sheet and Informed Consent Form (English, German versions)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable			NA

Abbreviations: SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; PRO, patient-reported outcome.
*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license and is reproduced with permission.

Spirit Item 2B WHO Trial Registration Dataset

Data Category	Information

Primary registry and trial identifying number	German Clinical Trials Register https://www.drks.de/drks_web/ Trial ID: DRKS00023395
Date of registration in primary registry	14.01.2021
Secondary identifying numbers	1304/2020
Source(s) of monetary or material support	Investigator-funded academic study; an open-access publication fee will be covered by VASCage, Research Centre on Vascular Ageing and Stroke, Innsbruck, Austria.
Primary sponsor	Medical University of Innsbruck, Austria
Secondary sponsor(s)	N/A
Contact for public queries	Miriam Wanner, BSc, Phone: +435050483500, Email: miriam.wanner@tirol-kliniken.at
Contact for scientific queries	Assoz. Prof. PD Dr. Michael Knoflach, Phone: +435050481697 Email: michael.knoflach@tirol-kliniken.at

Public Title	Feasibility of an individualised, task-oriented, video-supported home exercise programme in people after stroke (INAUVIS)
Scientific Title	Use of an individualised, task-oriented, video-supported home exercise programme in people after subacute stroke with mild to moderate arm paresis: a randomised, single blinded, controlled feasibility study (INAUVIS)
Countries of recruitment	Austria
Health condition(s) or problem(s) studied	Stroke
Intervention(s)	Intervention group 1 (Video-group): video-based individualised, task-oriented, video-supported home exercise programme Intervention group 2 (Paper-group): paper-based individualised, task-oriented, video-supported home exercise programme
Key inclusion and exclusion criteria	Inclusion criteria: first-ever stroke leading to a mild to moderate arm paresis, as assessed by the Motricity Index (MI); minimum pinch grip of 19 points and elbow flexion / shoulder abduction of 14 points; subacute phase, from seven days to five months after a stroke; age of >18 years; sufficient

	cognitive abilities (Mini Mental Status Test ≥24); Tyrolean residency; after discharge from the hospital or living at home. Exclusion criteria: severe disability (modified Rankin Scale (mRS) score ≥4); comorbidity potentially restraining participation e.g., a life expectancy <12 months or malignant disease, any physical or mental condition restricting participation in the study e.g., heart failure, being under guardianship, serious neuropsychological disorders, neglect, severe aphasia, severe cognitive deficits or dementia, psychiatric disorders, hemianopia, severe visual impairment, pregnancy; military service providers.
Study type	Single-centre, randomised, parallel-group, assessor-blinded controlled feasibility trial Allocation: stratified blocked randomisation Intervention model: parallel assignment Masking: assessor-blinded Primary purpose: to explore the feasibility of the methods and of conducting a full-scale randomised controlled trial.

Date of first enrolment	01.04.2021
Target sample size	24
Recruitment status	Not yet recruiting
Primary outcome(s)	Explore the feasibility of the methods and of conducting a full-scale randomised controlled trial.
Key secondary outcomes	Changes in self-perceived arm and hand use arm function (Motor Activity Log-30 (MAL-30)); arm motor function (Action Research Arm Test (ARAT)); finger dexterity (Nine Hole Peg Test (NHPT)); gross motor dexterity (Box and Block Test (BBT)); hand strength (Jamar grip dynamometer); independence in activities of daily living (Scores of Independence for Neurologic and Geriatric Rehabilitation (SINGER)); health-related quality of life (EuroQol-5 Dimensions 5-level (EQ-5D-5L) questionnaire and individual goal achievement (Goal Attainment Scaling (GAS)).

Patient Information Sheet and Informed Consent Form for participation in the clinical study

Use of an individualised, task-oriented, video-supported exercise programme in people after subacute stroke with mild to moderate arm paresis: a randomised, single blinded, controlled feasibility study

Dear Patient,

We invite you to take part in the above mentioned clinical study. The patient information on the study details will take place as part of a medical consultation.

Your participation in this clinical study is entirely voluntary. You can withdraw from the study at any time without giving a reason. The refusal to participate or a withdrawal from this study will not have any negative consequences for your medical care.

Clinical studies are necessary for obtaining reliable new medical research results. An indispensable prerequisite for the conduct of a clinical study is that you provide written informed consent to participate in this clinical study. Please read the following text carefully - as a supplement to the consultation with your study physician - and do not hesitate to ask questions.

Please only provide written informed consent

- if you fully understand the type and process of the clinical trial,
- if you are ready to agree to participate and
- if you are aware of your rights as a participant in this clinical trial.

The responsible ethics committee issued a favourable opinion to this clinical study as well as on the patient information sheet and the informed consent form.

1. What is the purpose of this clinical study?

You have a functional impairment of your arm and/or your hand due to a stroke. As a consequence of this condition, you may have difficulties to use your arm and/or hand skilfully in meaningful activities of daily living at home.

Current guidelines recommend continuing with a training at home using a specific, intensified home exercise programme with a high number of repetitions, in addition to usual therapy.

The aim of the study is to investigate whether an individualised, task-oriented, video-supported home exercise programme based on the latest learning motor principles of the OPTIMAL theory is feasible in stroke patients with mild to moderate arm paralysis. In addition, it is planned to collect data to analyse training effects i.e., whether the home exercise programme improves the use of the affected arm/hand in meaningful activities of daily life.

This treatment will be compared with an individualised, task-oriented, paper-based home exercise programme, also based on the latest learning motor principles of the OPTIMAL theory.

Previous studies have shown good results of other video-supported and paper-based home exercise programmes in stroke patients with limited arm mobility.

Explanation of the term "feasibility study"

A feasibility study gathers information about the feasibility of a planned larger study. The aim of this feasibility study is to explore the feasibility of an individualised, task-oriented, video-supported home exercise programme based on the learning motor principles of the OPTIMAL theory as a basis for a follow-up study.

2. How does the clinical study work?

This clinical study will be conducted at the Clinical Department of Neurology at the Medical University of Innsbruck. A number of 24 participants is planned for the feasibility study.

Your participation in this clinical trial is expected to take a period of 8 weeks. The duration of the home exercise programme will be 4 weeks and involve a practice of 6 times per week, for 45-60 minutes. After another 4 weeks without the home exercise programme, a follow-up test will be conducted.

<u>The following measures will be carried out exclusively for study reasons:</u>

The first assessment for the study will be performed during your inpatient stay or on the day of your Stroke Card examination. There will be a detailed medical consultation and information about the clinical study before you give your written informed consent. Information on your neurological history will be collected on the basis of existing inpatient/outpatient doctor's documentation. After that, your symptoms will be evaluated by an occupational therapist.

You will be randomly assigned to one of the two home exercise programmes:

Paper-based home exercise programme: You will receive a folder with a collection of exercises with photos. In addition, you will get a logbook in which you can enter your exercise progress daily over the 4-week period. At the beginning, you will be asked to create weekly goals together with your therapist. The therapist will then choose suitable exercises according to your weekly goals. The recommendation of the number of repetitions for each exercise will be noted in the logbook.

OR

Video-supported home exercise programme: You will receive an Android tablet with access to an exercise platform. At the beginning, you will be asked to create weekly goals together with your therapist. The therapist will then choose suitable exercises according to your weekly goals. You can access the exercises via videos on the exercise platform. Your exercise progress will be recorded via the platform.

The goal is to do the home exercise programme 6 times a week for 45-60 minutes. Within the 4 weeks, you will be contacted 3 times by phone for a short interim evaluation after each week, to set new goals and to adapt your home exercise programme.

An outpatient assessment will be conducted after the 4-week period at the Clinical Department of Neurology in Innsbruck, Neurorehabilitation Unit. In addition, a 20-30 minute interview is planned with questions about your experience with the home exercise programme. This interview will be recorded with

an audio recording device. The data collection will be evaluated only in the context of this clinical study. You can give your consent to the interview regardless of the informed consent to participate in the clinical study.

After a further 4 weeks, a follow-up assessment will be conducted to see whether the training was effective and to classify residual symptoms. You will be asked to visit the Clinical Department of Neurology in Innsbruck, Neurorehabilitation Therapy.

After this last outpatient check-up, the study will end for you. Your data will be indirectly personal i.e., your name will be replaced by a code and then transferred to a database to ensure an analysis in accordance with the applicable data protection regulations.

So, a total of two visits (excluding the initial inpatient assessment) will be necessary. Adhering to appointments and instructions from the study physician is critical to the success of this clinical trial.

3. What are the benefits of participating in the clinical study?

If the intervention will be found to be effective, the participants in both groups will have a direct benefit.

The study will serve as basis for further studies for stroke patients with mild to moderate arm paresis.

4. Are there any risks, complaints and side effects?

According to current medical knowledge, the expected benefit for research faces low health risk and low burden on participants.

The travel to the Clinical Department of Neurology, Medical University of Innsbruck for the post-intervention and follow-up assessments, the physical examination, the collection of the scores of the assessments and the interview represent a low health risk.

5. Does participation in the clinical trial have any other lifestyle effects and what are the obligations?

The study intervention is an intensified therapy programme that requires increased commitment and time. If you are already participating in other clinical studies, it makes sense to consult the responsible investigators of those other studies in advance to clarify possible interactions.

6. What should be done if symptoms, side effects and/or injuries occur?

If any symptoms, side effects or injuries occur during the clinical study, you should inform your study doctor. Should there be any serious side effects, you need to immediately contact them by phone (telephone numbers, etc. see below).

7. Insurance

As a participant in this clinical study, you have the legally required indemnity insurance coverage that covers all damage to your life or health that may be caused by the clinical study measures, with the exception of damage due to changes in the genetic material in germline cells.

The insurance has been taken out for you at Zürich Versicherungs-Aktiengesellschaft, [redacted], A-1010 Vienna, phone.: [redacted], policy number [redacted]. If you wish, you can inspect the insurance documents.

In the event of damage, you can contact the insurer directly and make your own claims. Austrian law applies to the insurance contract. Any insurance claims are enforceable in Austria.

You can also contact the patient representative for support.

In order to not endanger the insurance cover

- You may only undergo other medical treatment during your participation in this clinical study with the consent of your treating study doctor (with the exception of emergencies). This also applies to taking additional medication or participating in another study.
- you need to immediately notify the attending study doctor or the above-mentioned insurance company of any damage to your health occurs that could be a result of this clinical study.
- you need to do everything reasonable to clarify the cause, course and consequences of the insured event and to keep the damage to a minimum. This may also include authorising your treating doctor to provide information requested by the insurer.

Please note that the insurance does not provide cover for an accident that occurs to you on your way to and from the study.

8. When will the clinical trial be prematurely terminated?

You can revoke your willingness to participate and withdraw from the clinical study at any time without giving reasons, without incurring any disadvantages for your further medical care.

Your study doctor will inform you immediately of any new information that becomes known in relation to this clinical study and that could become material to you. On this basis, you can reconsider your decision to continue participating in this clinical study.

However, it is also possible that your study doctor may decide to terminate your participation in the clinical trial prematurely without first obtaining your consent. The reasons for this can be:

a) You cannot meet the requirements of the clinical study.

b) Your study doctor has the impression that your further participation in the clinical study is not in your interest.

9. Data protection

As part of this clinical study, data about you will be collected and processed. There is a fundamental distinction between

1) those personal data by which a person can be directly identified (e.g., name, date of birth, address, social security number, pictures, ...).
2) Pseudonymised personal data i.e., data in which all information is removed that allows directly draw conclusions about a specific person, or replaced by a code (e.g. a number) or made illegible (e.g. in the case of pictures). Despite compliance with these measures, it cannot be completely ruled out that inadmissible re-identification occurs.

3) anonymised data that cannot be traced back to the specific person.

The study doctor and other employees of the study centre who are involved in the clinical study or your medical care have access to the data by which you can be directly identified (see point 1). In addition, authorised representatives of the sponsor [redacted] as well as representatives of national and/or international health authorities and the respective responsible ethics committees can inspect these data insofar as this is necessary or prescribed for the verification of the proper conduct of the clinical study. All persons who have access to this data are subject to the respective applicable national data protection regulations and/or the EU Data Protection Law (DSGVO) when handling the data.

The code that enables the pseudonymised data to be assigned to you will only be stored at your study centre.

Only the pseudonymised or anonymised data will be used for any publications.

In the context of this clinical study, no data will be transferred to countries outside the EU (third countries).

Your consent form is the legal basis for the processing of your personal data. You can revoke your consent to the collection and processing of your data at any time without giving a reason. After your revocation, no further data will be collected about you. The data collected up to the point of revocation can, however, continue to be processed in the context of this clinical study.

According to the DSGVO, you have the right to information, correction, deletion, restriction of processing, data portability and objection, as long as this does not make the aims of the clinical study impossible or seriously impaired and unless other legal regulations contradict this.

The expected overall duration of the clinical study is 12 months. The duration of the storage of your data beyond the end or termination of the clinical study is regulated by legal provisions.

If you have any questions about the handling of your data in this clinical study, please contact your study doctor first. If necessary, they can forward your request to the persons responsible for data protection.

Contact details of the data protection officers of the institutions involved in this clinical study:

- Data protection officer of the Medical University of Innsbruck: [redacted]
- Data protection officer of the Tirol Kliniken: [redacted]
- You have the right to lodge a complaint with the Austrian data protection authority about the handling of your data [redacted]

10. Data protection the INAUVIS platform

Your access data, such as username and password, are pseudonymised. You do not have to enter any personal data, such as age or gender, on the platform. The therapist will do the first log in.

Pseudonymised data will be registered on the platform and are stored on a study-specific server in Steinach am Brenner.

The following data will be recorded:

- Time at access
- Accessed videos together with time-stamps
- User activities (according to the data protection regulation).

The server-logfiles including the above-described data will be deleted automatically after study completion.

- Number of repetitions per exercise
- Rating of patients after each exercise / task
- Total patients' rating
- User activities

All data collected on the platform will be treated confidentially. Data transfer will be made using state-of-the-art encryption and thus, data will be protected against unauthorised access.

You have the right to be informed about the type of data stored, the right of data correction and deletion, the right of withdrawal of already provided consent, the right of restricting or objection against the data processing.

11. Are there any costs for the participants? Is there a reimbursement or compensation?

No additional costs will be incurred for you by participating in this clinical study. Unfortunately, we cannot reimburse you for any travel costs that may arise.

12. Opportunity to discuss further questions

Your study doctor and his staff will answer any further questions you may have in connection with this clinical study. We will also answer any questions you may have about your rights as a patient and participant in this clinical study.

Name of the contact person: [redacted]

Tel .: [redacted]

If you have any questions about the informed consent, you can also contact the Tyrolean patient representative:

[redacted]

[redacted]

[redacted]

A-6020 Innsbruck

Tel .: [redacted]

Fax: [redacted]

E-mail: [redacted]

WWW: [redacted]

13. Informed Consent Form

Name of the patient: ....

Date of birth: ....

I agree to take part in the clinical study '**Use of an individualised, task-oriented, video-supported exercise programme in people after subacute stroke with mild to moderate arm paresis: a randomised, single blinded, controlled feasibility study'**. I have been informed that I can refuse participation without any negative consequences, in particular for my medical care.

I have been informed by Ms / Mr (MD) .... in detail and understandably about the clinical study, possible burdens and risks, as well as about the type, meaning and scope of the clinical study and the requirements resulting for me. I have also read the text of this patient information and informed consent, which comprises a total of 9 pages. Questions that arose were answered comprehensibly and satisfactorily by the study doctor. I had enough time to make up my mind. At the moment, I do not have any further questions.

I will comply with the medical instructions required to carry out the clinical study, but I reserve the right to terminate my voluntary participation at any time without incurring any disadvantages, in particular for my medical care.

I particularly agree that my data collected as part of this clinical study will be processed as described in the "Data Protection" section of this document.

I have received a copy of this patient information and informed consent. The original remains with the study doctor.

....

(Date and signature of the patient)

....

(Date, name and signature of the responsible study doctor)

(The patient receives a signed copy of the patient information and informed consent, the original remains with the study doctor's folder.)

14. Informed consent to the audio recording of the interview

Name of the patient: ....

Date of birth: ....

I declare that I agree in course of the clinical study '**Use of an individualised, task-oriented, video-supported exercise programme in people after subacute stroke with mild to moderate arm paresis: a randomised, single blinded, controlled feasibility study'** that data from the interview may be collected and evaluated using audio recording.

I have been informed personally and written the type and scope of the collection, the writing, data storage and evaluation of the interview and I agree,

- that the interview is digitally recorded by audio recording,
- that the interview is transcribed and anonymised indirectly (i.e., the name will be replaced by a code),
- that excerpts of the interview will be transcribed and indirectly pseudonymised or anonymised in the context of the clinical study and used in a publication.

I have been informed that if can decline participation without any negative consequences, in particular for my medical care, and that I am allowed to withdraw consent at any time.

I have received a copy of this informed consent. The original remains with the study doctor.

....

(Date and signature of the patient)

....

(Date, name and signature of the responsible study doctor)

(The patient receives a signed copy of the patient information and informed consent, the original remains with the study doctor's folder.)

PatientInneninformation und Einwilligungserklärung zur Teilnahme an der klinischen Studie

Einsatz eines individualisierten, aufgabenorientierten, videounterstützten Heimübungsprogrammes bei subakuten Schlaganfallpatient*innen mit leichter bis mittelschwerer Armparese: randomisierte, einfach verblindete, kontrollierte Machbarkeitsstudie

Sehr geehrte Patientin, sehr geehrter Patient!

Wir laden Sie ein, an der oben genannten klinischen Studie teilzunehmen. Die Aufklärung darüber erfolgt in einem ausführlichen ärztlichen Gespräch.

Ihre Teilnahme an dieser klinischen Studie erfolgt freiwillig. Sie können jederzeit ohne Angabe von Gründen aus der Studie ausscheiden. Die Ablehnung der Teilnahme oder ein vorzeitiges Ausscheiden aus dieser Studie hat keine nachteiligen Folgen für Ihre medizinische Betreuung.

Klinische Studien sind notwendig, um verlässliche neue medizinische Forschungsergebnisse zu gewinnen. Unverzichtbare Voraussetzung für die Durchführung einer klinischen Studie ist jedoch, dass Sie Ihr Einverständnis zur Teilnahme an dieser klinischen Studie schriftlich erklären. Bitte lesen Sie den folgenden Text - als Ergänzung zum Informationsgespräch mit Ihrem Studienarzt - sorgfältig durch und zögern Sie nicht, Fragen zu stellen.

Bitte unterschreiben Sie die Einwilligungserklärung nur

- wenn Sie die Art und den Ablauf der klinischen Studie vollständig verstanden haben,
- wenn Sie bereit sind, der Teilnahme zuzustimmen und
- wenn Sie sich über Ihre Rechte als Teilnehmer*in an dieser klinischen Studie im Klaren sind.

Zu dieser klinischen Studie sowie zur Patienteninformation und Einwilligungserklärung wurde von der zuständigen Ethikkommission eine befürwortende Stellungnahme abgegeben.

1. Was ist der Zweck der klinischen Studie?

Sie haben aufgrund eines Schlaganfalles eine Funktionseinschränkung Ihres Armes und/oder Ihrer Hand erlitten. Damit verbunden kann es Ihnen schwerfallen, den Arm und/oder die Hand zielgerichtet in Alltagsaktivitäten im häuslichen Umfeld, die für Sie wichtig sind, einzusetzen.

Aktuelle Leitlinien empfehlen, zusätzlich zur normalen Therapie das Training zu Hause mittels eines spezifischen, intensivierten Heimübungsprogrammes mit hoher Wiederholungsanzahl weiterzuführen.

Das Ziel der Studie ist es, zu untersuchen, ob ein individualisiertes, aufgabenorientiertes, videounterstütztes Heimübungsprogramm, angelehnt an aktuellste, lernmotorische Prinzipien der

OPTIMAL-Theorie, bei Schlaganfallpatient*innen mit leichter bis mittelschwerer Armlähmung durchführbar ist. Zudem sollten Ergebnisse zur Wirksamkeit erhoben werden, d.h., ob mit dem Heimübungsprogramm ein verbesserter Einsatz des betroffenen Armes/ der betroffenen Hand für die bedeutungsvollen Aktivitäten Ihres Alltags zu erreichen ist.

Verglichen wird dies mit einem individualisierten, aufgabenorientierten, papierbasierten Heimübungs-programm, ebenfalls angelehnt an den aktuellsten, lernmotorischen Prinzipien der OPTIMAL-Theorie.

Bereits bestehende Studien zeigten gute Ergebnisse, sowohl hinsichtlich eines videounterstützten als auch für ein papierbasiertes Heimübungsprogramm bei Schlaganfallpatient*innen mit Einschränkungen der Armbeweglichkeit.

Begriffserklärung „Machbarkeitsstudie“

Eine Machbarkeitsstudie sammelt Informationen zur Durchführbarkeit einer geplanten Studie. Das Ziel dieser Machbarkeitsstudie ist die Untersuchung der Durchführbarkeit eines individualisierten, aufgabenorientierten, videounterstützten Heimübungs-programmes, beruhend auf den lernmotorischen Prinzipen der OPTIMAL-Theorie für eine mögliche Folgestudie.

2. Wie läuft die klinische Studie ab?

Diese klinische Studie wird an der Universitätsklinik für Neurologie an der Medizinischen Universität Innsbruck durchgeführt. Es werden insgesamt ungefähr 24 Personen daran teilnehmen.

Ihre Teilnahme an dieser klinischen Studie wird voraussichtlich 8 Wochen dauern. Davon sind 4 Wochen für die Durchführung des Heimübungsprogrammes - 6x pro Woche zu je 45-60 - Minuten vorgesehen. Nach weiteren 4 Wochen ohne das zusätzliche Heimübungsprogramm findet eine Nachuntersuchung statt.

Folgende Maßnahmen werden ausschließlich aus Studiengründen durchgeführt:

Während Ihres stationären Aufenthaltes bzw. am Tag Ihrer Stroke Card Untersuchung wird die erste Untersuchung für die Studie durchgeführt. Vor dem Unterschreiben der Einwilligungserklärung erfolgt ein ausführliches ärztliches Gespräch über die klinische Studie. Ebenso werden Informationen zu Ihrer neurologischen Vorgeschichte auf Basis von vorhandenen stationären/ambulanten Arztbriefen erhoben. Nachfolgend werden Sie von ergotherapeutischer Seite hinsichtlich Ihrer Symptomatik evaluiert.

Per Zufallsprinzip werden Sie einem der beiden Heimübungsprogramme zugeteilt:

1. **Papierbasiertes Heimübungsprogramm:** Sie erhalten eine Mappe mit einer Sammlung von Übungen mit Fotos. Zusätzlich bekommen Sie ein Logbuch, in dem Sie Ihren Übungsverlauf der 4 Wochen täglich eintragen. Zu Beginn erstellen Sie mit der Therapeutin gemeinsam Wochenziele. Die Therapeutin wählt entsprechend Ihrer Wochenziele die Übungen mit Ihnen aus. Die Empfehlung der Wiederholungsanzahl jeder Übung wird im Logbuch notiert.

ODER

2. **Videounterstütztes Heimübungsprogrammes:** Sie erhalten ein Android-Tablet mit Zugang zu einer Übungsplattform. Zu Beginn erstellen Sie mit der Therapeutin gemeinsam Wochenziele. Die Therapeutin wählt entsprechend Ihrer Wochenziele Übungen mit Ihnen aus. Auf der Übungsplattform bekommen Sie den Zugang zu den Übungen mit den Videos. Ihr Übungsverlauf erfolgt in den 4 Wochen über die Plattform.

Das Ziel ist es, das Heimübungsprogramm 6x pro Woche für 45-60 Minuten durchzuführen. Innerhalb der 4 Wochen, werden Sie 3x telefonisch für eine kurze Zwischenanalyse nach jeder Woche, für eine neuerliche Zielformulierung und zur Anpassung Ihres Heimübungsprogrammes kontaktiert.

Nach 4 Wochen wird eine ambulante Untersuchung durchgeführt. Sie werden gebeten, hierzu in die Universitätsklinik für Neurologie in Innsbruck, Neurorehabilitative Therapie, zu kommen. Zusätzlich ist ein ca. 20-30 minütiges Interview geplant, mit Fragen zu Ihren Erfahrungen mit dem Heimübungsprogramm. Dieses Interview wird mit einem Audio-Aufnahmegerät aufgezeichnet. Die erhobenen Daten werden ausschließlich im Rahmen dieser klinischen Studie ausgewertet. Hierfür können Sie unabhängig von der Einwilligungserklärung zur Teilnahme an der klinischen Studie Ihre Einwilligung geben.

Nach weiteren 4 Wochen wird eine Nachuntersuchung (Follow-Up) zur Effektivitätskontrolle und Restbeschwerdeeinstufung für Sie organisiert. Sie werden gebeten, hierzu in die Universitätsklinik für Neurologie in Innsbruck, Neurorehabilitative Therapie, zu kommen.

Nach dieser letzten ambulanten Kontrolle ist die Studie für Sie beendet. Ihre Daten werden indirekt personenbezogen, d.h. Ihr Name wird durch einen Code ersetzt, in eine Datenbank übertragen, um eine Auswertung gemäß der geltenden Datenschutzbestimmungen zu gewährleisten.

Insgesamt sind zwei Besuche (exklusive Erstuntersuchung) notwendig. Die Einhaltung der Besuchstermine, einschließlich der Anweisungen des Studienarztes ist für den Erfolg dieser klinischen Studie von entscheidender Bedeutung.

3. Worin liegt der Nutzen einer Teilnahme an der Klinischen Studie?

Sollte die Intervention effektiv sein, haben die Teilnehmer*innen beider Gruppen einen direkten Nutzen.

Die Studie dient als Basis für weiterführende Studien für Schlaganfallpatient*innen mit leichter bis mittelschwerer Armparese.

4. Gibt es Risiken, Beschwerden und Begleiterscheinungen?

Dem zu erwartenden Nutzen für die Forschung stehen nach derzeitigem medizinischem Wissen ein geringes Gesundheitsrisiko und lediglich geringe Belastungen der Teilnehmer*innen gegenüber.

Die Anreise zur Universitätsklinik für Neurologie, Medizinische Universität Innsbruck zu den beiden Nachuntersuchungen, die körperliche Untersuchung, die Erhebung der Werte der Assessments und die Befragung stellen ein geringes Gesundheitsrisiko dar.

5. Hat die Teilnahme an der klinischen Studie sonstige Auswirkungen auf die Lebensführung und welche Verpflichtungen ergeben sich daraus?

Es handelt sich um ein intensiviertes Therapieprogramm, welches erhöhtes Engagement und erhöhten Zeitaufwand erfordert. Falls Sie bereits an anderen klinischen Studien teilnehmen, ist es sinnvoll, vorab

eine Absprache mit den jeweiligen zuständigen Prüfern dieser anderen Studien zu halten, um mögliche Interaktionen zu klären.

6. Was ist zu tun beim Auftreten von Symptomen, Begleiterscheinungen und/oder Verletzungen?

Sollten im Verlauf der klinischen Studie irgendwelche Symptome, Begleiterscheinungen oder Verletzungen auftreten, müssen Sie diese Ihrem Studienarzt mitteilen, bei schwerwiegenden Begleiterscheinungen gegebenenfalls umgehend telefonisch (Telefonnummern, etc. siehe unten).

7. Versicherung

Als Teilnehmer an dieser klinischen Studie besteht für Sie der gesetzlich vorgeschriebene verschuldensunabhängige Versicherungsschutz, der alle Schäden abdeckt, die an Ihrem Leben oder Ihrer Gesundheit durch die an Ihnen durchgeführten Maßnahmen der klinischen Studie verursacht werden können, mit Ausnahme von Schäden auf Grund von Veränderungen des Erbmaterials in Zellen der Keimbahn.

Die Versicherung wurde für Sie bei der Zürich Versicherungs -Aktiengesellschaft, [redacted], A-1010 Wien, Tel.: [redacted] unter der Polizzennummer [redacted] abgeschlossen. Auf Wunsch können Sie in die Versicherungsunterlagen Einsicht nehmen.

Im Schadensfall können Sie sich direkt an den Versicherer wenden und Ihre Ansprüche selbständig geltend machen. Für den Versicherungsvertrag ist österreichisches Recht anwendbar. Die Versicherungsansprüche sind in Österreich einklagbar.

Zur Unterstützung können Sie sich auch an die Patientenvertretung wenden.

Um den Versicherungsschutz nicht zu gefährden

- dürfen Sie sich während der Dauer der klinischen Studie einer anderen medizinischen Behandlung nur im Einvernehmen mit Ihrem behandelnden Studienarzt unterziehen (ausgenommen davon sind Notfälle). Dies gilt auch für die zusätzliche Einnahme von Medikamenten oder die Teilnahme an einer anderen Studie.
- müssen Sie dem behandelnden Studienarzt oder der oben genannten Versicherungsgesellschaft eine Gesundheitsschädigung, die als Folge der klinischen Studie eingetreten sein könnte, unverzüglich mitteilen.
- müssen Sie alles Zumutbare tun, um Ursache, Hergang und Folgen des Versicherungsfalles aufzuklären und den entstandenen Schaden gering zu halten. Dazu gehört ggf. auch, dass Sie Ihre behandelnden Ärzte ermächtigen, vom Versicherer geforderte Auskünfte zu erteilen.

Wir machen Sie darauf aufmerksam, dass die Versicherung keinen Schutz bietet für einen Unfall, der Ihnen auf dem Weg zur und von der Teilnahme an der Studie zustößt.

8. Wann wird die klinische Studie vorzeitig beendet?

Sie können jederzeit auch ohne Angabe von Gründen, Ihre Teilnahmebereitschaft widerrufen und aus der klinischen Studie ausscheiden, ohne dass Ihnen dadurch irgendwelche Nachteile für Ihre weitere medizinische Betreuung entstehen.

Ihr Studienarzt wird Sie über alle neuen Erkenntnisse, die in Bezug auf diese klinische Studie bekannt werden und für Sie wesentlich werden könnten, umgehend informieren. Auf dieser Basis können Sie dann Ihre Entscheidung zur **weiteren** Teilnahme an dieser klinischen Studie neu überdenken.

Es ist aber auch möglich, dass Ihr Studienarzt entscheidet, Ihre Teilnahme an der klinischen Studie vorzeitig zu beenden, ohne vorher Ihr Einverständnis einzuholen. Die Gründe hierfür können sein:

a) Sie können den Erfordernissen der klinischen Studie nicht entsprechen.

b) Ihr Studienarzt hat den Eindruck, dass eine weitere Teilnahme an der klinischen Studie nicht in Ihrem Interesse ist.

9. Datenschutz

Im Rahmen dieser klinischen Studie werden Daten über Sie erhoben und verarbeitet. Es ist grundsätzlich zu unterscheiden zwischen

1) jenen personenbezogenen Daten, anhand derer eine Person direkt identifizierbar ist (z.B. Name, Geburtsdatum, Adresse, Sozialversicherungsnummer, Bildaufnahmen,…).
2) pseudonymisierten personenbezogenen Daten, das sind Daten, bei denen alle Informationen, die direkte Rückschlüsse auf die konkrete Person zulassen, entweder entfernt, durch einen Code (z. B. eine Zahl) ersetzt oder (z.B. im Fall von Bildaufnahmen) unkenntlich gemacht werden. Es kann jedoch trotz Einhaltung dieser Maßnahmen nicht vollkommen ausgeschlossen werden, dass es unzulässigerweise zu einer Re-Identifizierung kommt.
3) anonymisierten Daten, bei denen eine Rückführung auf die konkrete Person ausgeschlossen werden kann.

Zugang zu den Daten, anhand derer Sie direkt identifizierbar sind (siehe Punkt 1), haben der Studienarzt und andere Mitarbeiter*innen des Studienzentrums, die an der klinischen Studie oder Ihrer medizinischen Versorgung mitwirken. Zusätzlich können autorisierte und zur Verschwiegenheit verpflichtete Beauftragte des Sponsors [redacted] sowie Beauftragte von in- und/ oder ausländischen Gesundheitsbehörden und die jeweils zuständige Ethikkommissionen in diese Daten Einsicht nehmen, soweit dies für die Überprüfung der ordnungsgemäßen Durchführung der klinischen Studie notwendig bzw. vorgeschrieben ist. Sämtliche Personen, die Zugang zu diesen Daten erhalten, unterliegen im Umgang mit den Daten den jeweils geltenden nationalen Datenschutzbestimmungen und/oder der EU-Datenschutz-Grundverordnung (DSGVO).

Der Code, der eine Zuordnung der pseudonymisierten Daten zu Ihrer Person ermöglicht, wird nur an Ihrem Studienzentrum aufbewahrt.

Für etwaige Veröffentlichungen werden nur die pseudonymisierten oder anonymisierten Daten verwendet.

Im Rahmen dieser klinischen Studie ist keine Weitergabe von Daten in Länder außerhalb der EU (Drittland) vorgesehen.

Ihre Einwilligung bildet die Rechtsgrundlage für die Verarbeitung Ihrer personenbezogenen Daten. Sie können die Einwilligung zur Erhebung und Verarbeitung Ihrer Daten jederzeit ohne Begründung widerrufen. Nach Ihrem Widerruf werden keine weiteren Daten mehr über Sie erhoben. Die bis zum Widerruf erhobenen Daten können allerdings weiter im Rahmen dieser klinischen Studie verarbeitet werden.

Nach der DSGVO stehen Ihnen grundsätzlich die Rechte auf Auskunft, Berichtigung, Löschung, Einschränkung der Verarbeitung, Datenübertragbarkeit und Widerspruch zu, soweit dies die Ziele der klinischen Studie nicht unmöglich macht oder ernsthaft beeinträchtigt und soweit dem nicht andere gesetzliche Vorschriften widersprechen.

Die voraussichtliche Dauer der klinischen Studie ist 12 Monate. Die Dauer der Speicherung Ihrer Daten über das Ende oder den Abbruch der klinischen Studie hinaus ist durch Rechtsvorschriften geregelt.

Falls Sie Fragen zum Umgang mit Ihren Daten in dieser klinischen Studie haben, wenden Sie sich zunächst an Ihren Studienarzt. Dieser kann Ihr Anliegen ggf. an die Personen, die für den Datenschutz verantwortlich sind, weiterleiten.

Kontaktdaten der Datenschutzbeauftragten der an dieser klinischen Studie beteiligten Institutionen:

- Datenschutzbeauftragter der Med. Universität Innsbruck: datenschutzbeauftragter@i-med.ac.at
- Datenschutzbeauftragte der Tirol Kliniken: datenschutzbeauftragte@tirol-kliniken.at
- Sie haben das Recht, bei der Österreichischen Datenschutzbehörde eine Beschwerde über den Umgang mit Ihren Daten einzubringen ([redacted].

10. Datenschutz der INAUVIS Plattform

Ihre Zugangsdaten, wie Benutzername und Passwort, sind pseudoanonymisiert. Sie müssen keine personenbezogenen Daten, wie z.B. Alter oder Geschlecht, auf der Plattform angeben. Die Anmeldung erfolgt beim ersten Login durch die Therapeutin.

Die pseudonymisierten Daten über Ihre Zugriffe auf die Plattform werden aufgezeichnet und auf einem studienspezifischen Server in Steinach am Brenner gespeichert.

Folgende Daten werden protokolliert:
- Uhrzeit zum Zeitpunkt Ihres Zugriffes
- besuchte Videos mit Zeitstempel
- Aktivitäten des Benutzers (datenschutzkonform).

Die erhobenen und gespeicherten Daten werden automatisch nach Ablauf des Studienzeitraumes gelöscht.

Folgende Daten werden für die Auswertung der Studie verwendet:
- Anzahl der Wiederholungen pro Übung
- Bewertung der Patient*innen nach jeder Übung
- Bewertung der Patient*innen gesamt
- Aktivitäten des Benutzers.

Die Daten der Plattform werden vertraulich behandelt. Die Datenübermittlungen werden durch Verschlüsselungen nach dem anerkannten Stand der Technik gegen Zugriff durch Dritte geschützt.

Sie haben das Recht, Auskunft darüber zur erhalten, welche Daten gespeichert wurden, das Recht auf Berichtigung und Löschung von Daten, das Recht auf Widerruf erteilter Einwilligungen, das Recht auf Einschränkung der Verarbeitung und das Recht auf Widerspruch gegen die Verarbeitung.

11. Entstehen für die Teilnehmer Kosten? Gibt es einen Kostenersatz oder eine Vergütung?

Durch Ihre Teilnahme an dieser klinischen Studie entstehen für Sie keine zusätzlichen Kosten. Die möglicherweise anfallenden Anreisekosten können wir Ihnen leider nicht ersetzen.

12. Möglichkeit zur Diskussion weiterer Fragen

Für weitere Fragen im Zusammenhang mit dieser klinischen Studie stehen Ihnen Ihr Studienarzt und seine Mitarbeiter gern zur Verfügung. Auch Fragen, die Ihre Rechte als Patient und Teilnehmer an dieser klinischen Studie betreffen, werden Ihnen gerne beantwortet.

Name der Kontaktperson: [redacted]

Tel.: [redacted], Mo-Fr von 08:00 bis 15:00

Sollten Sie Fragen zur Einverständniserklärung haben, können Sie sich gerne auch an die Tiroler Patientenvertretung wenden:

[redacted]

[redacted]

[redacted]

A-6020 Innsbruck

Tel.: [redacted]

Fax: [redacted]

Email: [redacted]

WWW: [redacted]

13. Einwilligungserklärung

Name des*r Patient*in: .....

Geb.-Datum: .....

Ich erkläre mich bereit, an der klinischen Studie **Einsatz eines individualisierten, aufgabenorientierten, videounterstützten Heimübungsprogrammes bei subakuten Schlaganfallpatient*innen mit leichter bis mittelschwerer Armparese: randomisierte, einfach verblindete, kontrollierte Machbarkeitsstudie** teilzunehmen. Ich bin darüber aufgeklärt worden, dass ich die Teilnahme ohne nachteilige Folgen, insbesondere für meine medizinische Betreuung, ablehnen kann.

Ich bin von Frau/Herrn (Dr.med.) ..... ausführlich und verständlich über die klinische Studie, mögliche Belastungen und Risiken, sowie über Wesen, Bedeutung und Tragweite der klinischen Studie und die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text dieser Patientenaufklärung und Einwilligungserklärung, die insgesamt 9 Seiten umfasst, gelesen. Aufgetretene Fragen wurden mir vom Studienarzt verständlich und zufriedenstellend beantwortet. Ich hatte ausreichend Zeit, mich zu entscheiden. Ich habe zurzeit keine weiteren Fragen mehr.

Ich werde den ärztlichen Anordnungen, die für die Durchführung der klinischen Studie erforderlich sind, Folge leisten, behalte mir jedoch das Recht vor, meine freiwillige Mitwirkung jederzeit zu beenden, ohne dass mir daraus Nachteile, insbesondere für meine medizinische Betreuung, entstehen.

Ich stimme ausdrücklich zu, dass meine im Rahmen dieser klinischen Studie erhobenen Daten, wie im Abschnitt „Datenschutz“ dieses Dokuments beschrieben, verarbeitet werden.

Eine Kopie dieser Patienteninformation und Einwilligungserklärung habe ich erhalten. Das Original verbleibt beim Studienarzt.

.....

(Datum und Unterschrift des*r Patient*in)

.....

(Datum, Name und Unterschrift des*r verantwortlichen Studienarztes*ärztin)

(Der*die Patient*in erhält eine unterschriebene Kopie der Patienteninformation und Einwilligungserklärung, das Original verbleibt im Studienordner des Studienarztes.)

14. Einwilligungserklärung zur Audio-Aufzeichnung des Interviews

Name des*r Patient*in: .....

Geb.-Datum: .....

Ich erkläre mich bereit, dass im Rahmen der klinischen Studie **Einsatz eines individualisierten, aufgabenorientierten, videounterstützten Heimübungsprogrammes bei subakuten Schlaganfallpatient*innen mit leichter bis mittelschwerer Armparese: randomisierte, einfach verblindete, kontrollierte Machbarkeitsstudie** Daten des Interviews mittels Audioaufnahme erhoben und ausgewertet werden dürfen.

Ich bin über die Art und den Umfang der Erhebung, der Verschriftlichung, Datenspeicherung und Auswertung des von mir gegebenen Interviews persönlich und schriftlich informiert worden und einverstanden,

- dass das Interview digital durch Audioaufnahme aufgezeichnet wird,
- dass das Interview transkribiert und indirekt personenbezogen anonymisiert (das heißt, der Name wird durch einen Code ersetzt) wird,
- dass Ausschnitte des Interviews in transkribierter und indirekt personenbezogener anonymisierter bzw. anonymisierter Form im Rahmen der klinischen Studie interpretiert und in einer daraus hervorgehenden Veröffentlichung verwendet werden.

Ich bin darüber aufgeklärt worden, dass ich die Teilnahme ohne nachteilige Folgen, insbesondere für meine medizinische Betreuung, ablehnen und die Einwilligung jederzeit widerrufen kann.

Eine Kopie dieser Einwilligungserklärung habe ich erhalten. Das Original verbleibt beim Studienarzt.

.....

(Datum und Unterschrift des*r Patient*in)

.....

(Datum, Name und Unterschrift des*r verantwortlichen Studienarztes*ärztin)

(Der*die Patient*in erhält eine unterschriebene Kopie der Patienteninformation und Einwilligungserklärung, das Original verbleibt im Studienordner des Studienarztes.)

Supplemental Table 1 Semi-structured interview questions

No	Question
1	Can you please share your experiences with the home exercise programme (e.g., instructions, pictures, videos, logbook, platform, amount, duration and personal evaluation)?
2.	Please tell me about your experiences with the weekly phone calls (e.g., questions about evaluation, goal setting, amount and duration).
3.	Tell me about your experiences with personal goal setting (e.g., joint goal agreement, duration, amount, goal setting and specific example of a goal).
4.	Describe your observations with regard to the use of your affected arm or your affected hand in everyday life. (e.g., specific example, self-care, domestic life, work and employment, recreation and leisure).
5.	Who or what supported you in attending the home exercise programme (e.g., family, friends and telephone contact)?
6.	What should the home exercise programme be like that you would carry it out for a longer period of time?
7.	How should the home exercise programme be for you to recommend it to others?

Supplemental Table 2 Schedule of enrolment, intervention and data collection during the study

	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-allocation**		
	Screening		Pre-test Day 1	Post-test Week 4	Follow-up Week 8
TIMEPOINT	***-t₁***	***0***	***t₁***	***t₂***	***t₃***
ENROLMENT					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS					
Video group			♦—	—	—♦
Paper group			♦—	—	—♦
OUTCOMES (ASSESSMENTS)					
Baseline variables					
Demographics	X				
Clinical characteristics (Motricity Index, modified Rankin Scale, Mini-Mental-Status-Test	X				
Primary outcomes					
Feasibility					
Recruitment rate			X	X	X
Retention rate					X

Adherence rate			X	X	X
Adverse events				X	X
Adherence and satisfaction (logbook, platform recording, weekly interviews)				X	
Acceptability (semi-structured interviews)				X	
Secondary outcome					
Self-perceived arm and hand use (Motor Activity Log-30)			X	X	X
Arm motor function (Action Research Arm Test)			X	X	X
Finger dexterity (Nine Hole Peg Test)			X	X	X
Gross motor hand and arm dexterity (Box and Block Test)			X	X	X
Hand strength (dynamometer)			X	X	X
Independence in activities of daily living (*Score of Independence for Neurologic and Geriatric Rehab.)*			X	X	X
Health-related quality of life (European Quality of Life-5 Dim.)			X	X	X
Goal achievement (Goal Attainment scaling)				X	