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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
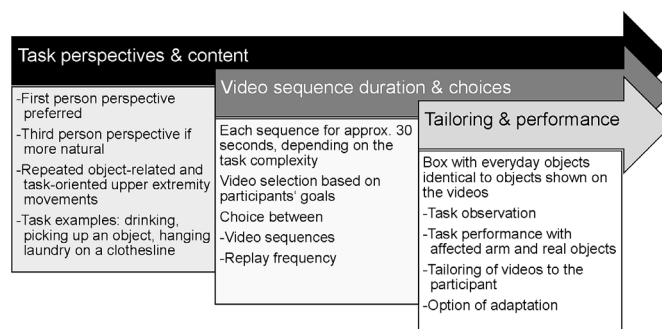

Figure 1 Key aspects of task-oriented training in the Video group.

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).

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.

Arm use
- How often did you use your affected upper extremity in activities of daily living this week?
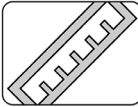- How often did you use your affected upper extremity in relation to your weekly goal?

Satisfaction
- How satisfied are you with your training progression this week?
- How did you get along with the home-exercise programme this week?

Support
- Did you have any support with the implementation of the home-exercise programme?
- Do you need further support for the implementation of the home-exercise programme?

Other
- Do you have any other comments?
- Questions 1 to 4 are answered with a Numeric Rating Scale from 0-100.

Figure 2 Questions asked in weekly semistructured interviews.

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]

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