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.)