

Individual balance training vs. Group balance training to improve walking speed post stroke

A controlled, randomized pilot study

This study is organized by: Prof. Dr. med. Peter Sandor (Sponsor person)

Investigator: Wiebke Weigert, BA

Dear lady, dear sir ,

I would like to ask you if you want to participate in a clinical trial. The following is a presentation of this study project : first in a short summary, so that you know what it is about, then in a detailed Description .

1. Study goal

We want to use this study to investigate whether there is a difference in efficiency between single-balance training and group-balance training in terms of walking speed.

There is a feasibility study, which means I want to find out how many patients would be needed to obtain meaningful results.

2. Selection

There are open to all those who suffered a stroke. In addition , they must be at least 18 years of age and able to understand the therapy instructions. There must be a first stroke. In addition, they are at least able to walk with aids .

Additionally , have diagnosed pAVK or polyneuropathy, or have a dizziness that is not related to the stroke.

Also, they should be cardially stable and have no so-called neurodegenerative diseases.

Normally, our therapists have already done a screening, and you therefore addressed. If you are still unsure whether any of the above conditions exist, then please contact your individual therapist, or directly Wiebke Weigert.

3. General information

- In Switzerland, approximately 16,000 patients suffer a stroke each year
- 40% of stroke survivors have limitations in the Activities of everyday life
- In a study that covered the therapeutic goals of hemiplegic patients, walking was the most commonly mentioned
- The interaction with the environment is facilitated by safe and efficient walking, and therefore allows the gait speed measurement parameters of this study.
- For each patient, the study lasts 3-4 weeks.
- They are randomly assigned to single-balance training or group balance training. This works by closed, r, r opaque envelopes.
- A total of approximately 20 patients will be recruited over the period 07.01.2019 to 26.04.2019 .
- All patients are recruited at RehaClinic Kilchberg.
- We do this study as required by law in Switzerland. In addition, we follow all internationally recognized guidelines

4. Procedure

- Starting and ending with the assessment of walking speed and balance ability.
- For two weeks, in addition to the normal program , individual balance or group-balance training takes place twice a week .
- These units last 25min each

It may be that we need to exclude you from the study prematurely. This can happen if they have to be transferred to another hospital during the period or if they leave prematurely. In this case, you will be examined again for your safety.

5. Use

If you participate in this study , it may give you an additional training effect.

The results may also be important for others who have the same disease. Because it is about the efficiency of balancing therapy.

6. Rights

Your participation is voluntarily. If you do not want to join or later withdraw your participation, you do not need to justify it. Your medical treatment / care is guaranteed regardless of your decision. You are always welcome to ask questions about participating in the study . Please contact the person named at the end of this information.

7. Obligations

As participant it is necessary that you

- to the necessary specifications and requirements of the study by the protocol hold in. Please do not perform balance training in your free time. This is for your safety and prevents the falsification of the study results.
- Inform your doctor about the course of the disease and report new symptoms, new complaints and changes in the condition

8. Risks and burdens for the participants

There are no risks to be expected. These are standardized and established exercises.

9. Other treatment options

You do not have to participate in this study . If you do not participate, you will receive the normal rehab program provided by the insurance.

10. Result from the study

The therapist will be you information during the study of any new findings that may affect the usefulness of the study or your security and therefore your consent to participate a n the study. You will receive the information verbally and in writing.

11. Confidentiality of data

Your personal and medical data will be recorded for the study . Very few upp people see your unencrypted data, although exclusively to carry out tasks under the study. When collecting data for study purposes, the data is encrypted . Encryption means that all reference Data, that you could identify (name, date of birth), deleted and replaced by a key. The key list always stays in the institution / hospital. Those individuals who not know the key, can not draw any conclusions on your person. Therefore, in a publication, the summarized data is not traceable to you as an individual . Your name never appears on the internet or a publication. Sometimes there is a requirement for a magazine to publish that individual data (so-called raw data) must be transmitted. If individual data needs to be transmitted, then the data is always encrypted and therefore not traceable to you as a

person. All persons who have access to your data as part of the study are subject to secrecy. The requirements of data protection are complied with and you as a participating person have the right to access your data at any time.

Maybe this study will through the responsible ethics committee checked. The investigator may need to disclose your personal and medical data for such controls.

It is possible that your doctor will be contacted to provide information about your state of health.

12. Resignation

You can always end and withdraw from the study if you want that. The data collected so far and samples are not encrypted for values, because the whole project otherwise it loses its value.

After the evaluation, your data will be completely anonymised, your key assignment will be destroyed, so that after that nobody can find out that the data originated from you.

13. Compensation for participants

If you participate in this study, you will not receive any compensation.
There are no costs for you or your health insurance due to participation.

14. Liability

The liability insurance is given during the inpatient stay.

15. Financing of the study

There is no financing.

16. Contact person

If you have questions, uncertainties or emergencies that arise during or after your study, you can contact any of our ward doctors or contact person at any time.

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Content

Written declaration of consent to participate in a study project

Please read this form carefully. Please ask if you do not understand or want to know something.

BASEC-Number:	2018-01700
Title of project	Individual balance training vs. Group balance training post stroke - a randomized, controlled pilot study
responsible institution (Project management with address):	
Place of implementation	RehaClinic Kilchberg
Leader / leader of the project at the study location :	Dr. med. Caroline Jagella
Participant: Name and first name in block letters: Date of birth:	<div style="text-align: right;"> <input type="checkbox"/> female <input type="checkbox"/> male </div>

- I was informed verbally and in writing about the purpose, the course of the project, about possible advantages and disadvantages as well as about possible risks by the signatory examiner.
- I voluntarily participate in this project and accept the content of the written information submitted for the above project. I had plenty of time to make my decision.
- My questions related to participation in this project have been answered to me. I keep the written information and receive a copy of my written consent.
- I agree that the experts in charge of the project management / project principal and the ethics committee responsible for this project may inspect my unencrypted data for audit and control purposes, while strictly respecting confidentiality.
- For study results or incidental findings that directly affect my health, I will be informed. If I do not want that, I inform my doctor.
- I know that my health-related and personal information may be disclosed only in encrypted form for research purposes for this project.
- I can resign from participation at any time without stating any reasons, and therefore I have no disadvantages in further medical treatment / care. The data collected so far will still be used for the evaluation of the project.
- The liability insurance of the RehaClinic is payable for any damage.
- I am aware that the obligations stated in the participant information must be adhered to. In the interest of my health, the leader can exclude me at any time .

Place and date	Signature participant
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Confirmation from the investigator : I hereby certify that I have explained to this participant the nature, significance and scope of the project. I declare that I will fulfill all obligations under this project in accordance with applicable law. If, at any time during the implementation of the project, I discover any aspects that could affect the participant's willingness to participate in the project, I will promptly inform you.

Place and Date	Name and first name of the informing examiner doctor in block letters Signature examiner doctor
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