



Berufsgenossenschaftliches
Universitätsklinikum Bergmannsheil
Neurologische Klinik und Poliklinik
Direktor Prof. Dr. med. M. Tegenthoff
Bürkle-de-la-Camp-Platz 1
44789 Bochum
Tel. 0234 302 6808 · Fax 0234 302 6888



Subject information and declaration of consent to participate in the study

VAFES # 1: Analysis of arm-hand function in virtual reality on healthy people

(NOTE: THIS TEXT WILL BE DISPLAYED AFTER STARTING THE VAFES APP)

Dear test subject!

We invite you to take part in the above study!

The important things first:

Participation in a study is voluntary and you can terminate it at any time without giving reasons, without incurring any disadvantages.

Studies are necessary in order to obtain reliable new research results. However, an indispensable prerequisite for carrying out a study is that you give your consent to participate in this study.

Please read the following text carefully!

If you have any questions, ask the test director directly or contact us at the telephone number or email address listed below!

Please only agree

- if you have fully understood the nature and process of the study,
- when you are ready to agree to participate and
- if you are aware of your rights as a participant in this study!

This study, the subject information, the data protection regulations and the declaration of consent were checked by the responsible ethics committee of the medical faculty in Bochum and assessed positively.

1. What is the purpose of the study?

The purpose of this study is to find out what movement parameters and motor performance are for different motor exercises in virtual reality. It is pure data collection from healthy people.

2. What happens in this study and how does it proceed?

This study takes place within the VAFES app. You perform the exercises at home with your VR glasses. A total of around 100 people will take part.

The VAFES app can be downloaded for free. The games in virtual reality consist of a total of 6 small games and tests using your VR glasses. You acquire points with the games and will then be assessed with your total score.

The main focus here is on movements with the arms and hands.

Your participation in this study will take place in 1 day. The total duration is approximately 30 minutes.

3. Additional medication intake?

Before starting the study, please state whether you are taking any medication. You can only participate in this study if you are not taking any medication that would affect your ability to react.

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

No health risks are to be expected from participating in the study. The general recommendations apply when using your VR glasses (e.g. risk of falling, injuries from objects lying around). Some people get dizzy and nauseous when using VR glasses. If you already feel sick while sailing, you are more likely to experience something similar with VR glasses and should refrain from participating in the experiment (so-called "vertigo", "kinetosis", "motion sickness").

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

Should any symptoms, side effects or injuries occur in the course of the study, you must inform the study director of these, in the case of serious side effects immediately, if necessary by telephone (telephone numbers, etc. see below).

6. Insurance

As a participant in the VAFES # 1 study, you have the statutory insurance protection (personal injury insurance) that covers all damage to your life or health that may be caused by the study measures carried out on you; genetic damage is excluded.

The insurance for you is with XYZ. If you wish, you can inspect the insurance documents. In order not to jeopardize the insurance cover, you must immediately notify the above-

mentioned insurance company of any damage to your health that could have occurred as a result of the clinical trial.

7. When will the study be terminated early?

Your participation in the study is voluntary. You can refuse or revoke your willingness to participate and withdraw from the study at any time, even without giving reasons and without incurring any disadvantages of any kind.

However, it is also possible that the study director may decide to end your participation in the study early.

8. How will the data collected in this study be used?

As part of this study, the following data are collected, stored and evaluated: gender, age range, handedness and degree of physical activity (self-assessment by the test participant). The data is processed anonymously. A traceability of your data via the user account in the App-Plattform is not possible and also not the aim of the study. In addition, non-personal data, reaction times and movements from the experiment in the virtual environment are anonymously stored and evaluated. Your data will be used for the purpose of the study "VAFES # 1: Analysis of arm-hand function in the virtual space of healthy people". The use of the data takes place in accordance with legal regulations and requires your voluntarily given declaration of consent before participating in the study, i.e. you cannot participate in the study without your consent.

The consent to the collection and processing of data by you is revocable, from the time of termination of participation.

You will be informed prior to participation that you may terminate your participation in the study at any time. In the event of such revocation of consent to participate in the study, you agree that the data stored up to that point may continue to be used to the extent necessary in order to

1. obtain valid results for the study,
2. ensure that your interests worthy of protection are not impaired
3. since the data is completely anonymized and therefore cannot be attributed to you as a natural person, you, as an individual study participant, have no claim to deletion.
4. you agree that your anonymized data will be stored for at least ten years or permanently after termination or discontinuation of the study.
5. your participation in the study can be terminated at any time, but with regard to anonymized data, no claim for deletion can be made due to non-existing allocation possibilities.

Contact person: If you have any questions about this study, please contact: Dr. med. Matthias Sczesny-Kaiser, senior physician, specialist in neurology, BG University Clinic Bergmannsheil Bochum gGmbH, Neurological University and Polyclinic, Bürkle-de-la-Camp-Platz 1, 44789 Bochum, T: 0234-302-3258, F: 0234- 302-6888, email: matthias.sczesny-kaiser@bergmannsheil.de

Unless otherwise provided by law, only the study director and his staff as well as affiliated project-partners have access to the respective data. These persons are subject to confidentiality. The data will not be passed on to third parties.

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

You will not incur any additional costs by participating in this study.

10. Opportunity to discuss further questions

The study director and his staff will be happy to answer any further questions you may have in connection with this study. We will also be happy to answer questions relating to your rights as a test subject and participant in this study.

Name of contact person: Dr. med. Matthias Sczesny-Kaiser, senior physician, specialist in neurology, BG University Clinic Bergmannsheil Bochum

Available at: 0234-302-3258, matthias.sczesny-kaiser@bergmannsheil.de

NOTE: In this study, the test subject gives his / her consent online by clicking on the box to give his / her consent (online app).