

Study Director UKT

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Informed Consent Form

Experimental laboratory study – “Chairless Chair Exoskeleton. Work-Physiological-Biomechanical Analysis of the Lower Extremities”

Ethical approval number: 184/2017BO2
NCT number at ClinicalTrials.gov: NCT03134144

The consent to participate in the study is only effective if it is personally signed by a person capable of consent and if it can be revoked informally at any time. The approval is only legally relevant if the study participant has been sufficiently informed.

Information to Data Protection

Your data collected as part of the scientific study will be treated confidentially and will only be passed on in encrypted form. The data important for the scientific analysis are entered in an encrypted form (pseudonymized, without naming names) in a separate documentation sheet.

The assignment of the encrypted data to your person is only possible on the basis of a re-identification list, which is kept in a locked cupboard, separate from the study documents and is only accessible to the director of the study and the medical director of the department. After publication of the study results, the data are kept for a period of 10 years in the Institute for Occupational and Social Medicine and Health Services Research. Should you withdraw from the study, you can decide whether the existing data must be destroyed or may continue to be used.

Informed Consent

I was informed today by _____ (name of the study supervisor) about the goals and the course of the examination program. I was informed about the measurement methods used, more precisely the measurement of muscle activity by surface electromyography, the measurement of posture and postural control using position sensors and a force plate. I know that the investigations are partially documented with photos and I am willing to take part in these investigations.

I will answer the questionnaire on complaints and illnesses to the best of my knowledge. Acute illnesses like pain, fever, nausea or similar are not with me today.

I have been informed of the following side effects or risks of this investigation:

- Skin irritation or reddening due to the adhesive electrodes and the necessary skin preparation – in rare cases allergic reactions;
- Feeling of tingling or tension in the area of the derived electrodes due to adhesive electrodes and cable pull;
- Feeling of tension and muscle fatigue as part of the examination program;
- Possibility of dizziness, drop in blood pressure and low risk of fainting due to long standing.

The examinations can be interrupted at any time at my request and my consent can be withdrawn without giving reasons. I have no disadvantages from this.

I agree to the use of the data collected in the context of the study “Work-Physiological-Bio-mechanical Analysis of the Exoskeleton ‘Chairless Chair’ for the Lower Extremities” in the manner described above.

I also agree that the data collected may be used in further studies by the Institute for Occupational Medicine, Social Medicine and Health Services Research* (* if not, please delete this section).

I can view my data from the study director at any time.

Study Participant

Tübingen, date

Signature

Name of the Participant in block letters

Study Leader

Tübingen, date

Signature

Name of the Study Leader in block letters (employee of the Institute of Occupational and Social Medicine and Health Services Research)