Informed consent for the study:
The effect of functional relaxation on the quality of life in patients with periprosthetic joint infection

I. Information about the study

Within the framework of this study, we are investigating the influence of Functional Relaxation on the quality of life of patients with periprosthetic joint infections. Functional Relaxation is a body-oriented psychotherapy method, whereby small movements of the joints, combined with exhalation are performed. With consent, you would participate in 12 sessions (once a week) at 45 minutes at the University Hospital. Each session will be in a group of 2-5 people and will be guided by a certified psychotherapist.

Before the intervention, after 3 months, 6 months and 12 months we would ask you to answer two questionnaires about your health status and quality of life. We would also collect your daily step count during the course of the intervention by means of a sensor.

For further questions about the research project or a demonstration of Functional Relaxation, please contact the principal investigator at any time.

II. Privacy policy

For the purpose of conducting the study, medical findings and personal information (such as age, gender and ethnicity) about you will be collected and written down in your personal file or stored electronically by your study doctor*. Personal data from previous examinations by physicians* may also be added to your patient file at the study site. If necessary, the study physician* may contact your primary care physician* and/or treating physician* to obtain additional medical information about you. Your primary care physician* and/or treating physician* may disclose this information only if authorized by you.

The data important for the study will also be stored in encrypted (pseudo-nymized) form in a password-protected electronic database. Pseudo-nymized means that no name or initials are used, only a numerical or letter code. The data are secured against unauthorized access. Only your study physicians* and their associated team will be able to identify you personally from the encrypted data. Your study data will only be passed on to third parties in anonymized form; this means that it will no longer be possible to assign it to you personally.

Your name and date of birth will be entered on the consent form. It is possible that inspectors* from official monitoring authorities may inspect these documents to verify that the study is being conducted in accordance with regulations. Inspectors are required to keep your personal data confidential.

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SPITZE IN DER MEDIZIN. MENSCHLICH IN DER BEGEgnUNG.

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The legal basis for processing the personal data concerning you is your voluntary written consent in accordance with the DSGVO (pursuant to Art. 6(1)(a) DSGVO in conjunction with Art. 9(2)(a) DSGVO) when processing sensitive data. Your consent is voluntary and can be revoked at any time without adverse effect for the future.

Without your consent to the processing and disclosure of the data concerning you in encrypted form, you cannot participate in the above-mentioned study. Publications in journals and public trial registries (e.g. clinicaltrials.gov or EU Clinical Trials Register) or presentations of study results will not include any data from which you can be personally identified.

Your data will be processed in this study primarily for this purpose. However, it is possible that in the course of the investigation and data analysis, further research questions may arise that are related to the subject of this study. In this case, your data would also be used for this purpose. However, you can explicitly object to this in the consent form.

Your collected data will be stored by the study team for a period of up to 10 years after completion or termination of the study. After this period, your data, including the characteristics that identify you, will be deleted. After deletion, it is no longer possible to draw conclusions about you.
I have read and taken note of "I. Information about the study" and "II. Privacy policy". Any queries I may have had were answered satisfactorily by the person responsible for the study and I have had sufficient time to consider my participation in the project.

In the following, I give my consent for the ticked items:

- Participation in the study with the knowledge that the investigation and study may be terminated by me at any time.

- Processing of my data for study purposes.

In case of withdrawal of my consent:

- May all my data collected so far continue to be used for the purposes of this study.

- May all my data collected so far - with the exception of biomaterials - be further used for the purposes of this study.

- May all my data collected so far also be reused for purposes unrelated to the study in the Clinic and Polyclinic for Trauma Surgery.

- Must all data no longer required be deleted immediately.

My consent is voluntary and I can revoke it at any time without giving reasons for the future. The revocation of consent does not affect the lawfulness of the processing carried out on the basis of the consent until the revocation.

______________________________________________________________
(Date, Name & Signature [Principal Investigator])

______________________________________________________________
(Date, Name & Signature Participant)