Title: A brief intervention for PTSD versus treatment as usual: Study protocol for a non-inferiority randomized controlled trial
Ethical approval by REK vest: 24.09.2024
Trial: 191548

UNIVERSITY OF BERGEN

DO YOU WANT TO PARTICIPATE IN A RESEARCH PROJECT ON THE TREATMENT OF TRAUMA?

SYKEHUSET I VESTFOLD

THE PURPOSE OF THE PROJECT AND WHY YOU ARE ASKED

WHAT DOES THE PROJECT MEAN TO YOU?

In the project, we will collect and register information about you. The collection of information will take place at three different times: the first time will be within one week before treatment, the second time within three weeks after completed treatment, and the last time 6 months after completed treatment. The testing will consist of a clinical interview (approximately 1 - 2 hours), where you will be asked questions regarding the presence and severity of various Post-Traumatic Stress Disorder (PTSD) symptoms. In addition, you will be asked to fill out various questionnaires (about 30 minutes), with questions regarding your trauma, perceived quality of life, general functioning and different thought patterns. You will also be asked to fill out a form for satisfaction with therapy after completing treatment.

Based on the initial interview, we will find out if you have PTSD symptoms and if you are therefore finally offered treatment. If you are not offered treatment, you will be given information about what kind of help may be best for you. For those who are offered treatment, this will involve receiving trauma-specific treatment for your symptoms – either a short-term treatment of 1 hour, or a standard treatment with standard trauma treatment methods.

Which of the treatments you will receive is determined by a computer program. This means that it is random (50/50 chance) which treatment you receive, and neither we nor you can choose treatment.

The short-term treatment means that you think consciously about traumatic memories while trying to create new, more manageable memories together with a psychologist that can potentially make it easier to deal with the pain in the traumatic memories. If you are assigned standard treatment, you will talk about and gradually expose yourself to the painful memories and try to put this into a system. The treatments will therefore be fairly similar in content, but the shorter treatment will be more direct than the long treatment. The vast majority of people who receive trauma treatment find parts of the treatment uncomfortable because they consciously think about and talk about what is painful, and this applies to both treatments you will be able to receive in this project.

POSSIBLE ADVANTAGES AND DISADVANTAGES

Advantages for you as a participant in the study are that you will gain insight into trauma treatment and contribute to new knowledge about trauma. There is no guarantee that you will get better or completely free of symptoms after your participation. Some may experience an increase in symptoms in the first period after starting treatment. By participating in the project, you agree not to receive treatment for your symptoms from anyone else until the last measurement (six months after the last trauma treatment) is finished, unless you withdraw from the study.

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VOLUNTARY PARTICIPATION AND THE POSSIBILITY TO WITHDRAW YOUR CONSENT

Participation in the project is voluntary. If you wish to participate, please sign the declaration of consent on the last page. You may withdraw your consent at any time and without giving any reason. There will be no negative consequences for you or your treatment if you do not want to participate or later choose to withdraw. If you withdraw your consent, no further research will be conducted on your health information. You can also demand that your health information in the project is deleted or disclosed within 30 days. The right to demand destruction, deletion or disclosure does not apply if the material or information is anonymised. This access may also be restricted if the information has been included in analyses carried out. If you later wish to withdraw or have questions about the project, you can contact the project manager (see contact information on the last page).

WHAT HAPPENS TO THE INFORMATION ABOUT YOU?

The information registered about you will only be used as described under the purpose of the project, and is planned to be used until 2029. Any extensions in use and storage period can only take place after approval from REC and other relevant authorities. You have the right to access what information is registered about you and the right to have any errors in the information that is registered corrected. You also have the right to access the security measures when processing the data. You can complain about the processing of your data to the Norwegian Data Protection Authority and the institution's data protection officer.

All information will be processed without name and national identity number or other directly recognizable information (coded information). A code links you to your information through a list of names that is stored in a way that makes it inaccessible to unauthorized persons. Only project employees at Vestfold Hospital Trust (Patricia Polgar and Tore Børtveit) have access to this list. This means that no one else will be able to identify you, and that your information is completely anonymous. If you are offered short-term treatment: to ensure that the project is carried out in accordance with protocol, the concentrated treatment will be recorded on video. Afterwards, the video recording will be scored by a psychologist specialist with expertise in the approach. The video recordings are encrypted and stored locked at Vestfold DPS.

The information about you will be stored for five years after the end of the project for control purposes.

APPROVALS

The Regional Committee for Medical and Health Research Ethics has carried out a research ethics assessment and approved the project. [ID #191548] The University of Bergen and Vestfold Hospital, represented by project managers Åsa Hammar and Patricia Polgar, are responsible for the privacy of the project. The University of Bergen and Vestfold Hospital are responsible for the processing of personal data. The data is processed on the basis of the EU General Data Protection Regulation Article 6 (1) (a) and Article 9 (2) a, and your consent.

CONTACT INFORMATION

If you have any questions about the project or wish to withdraw from participation, please contact Professor Åsa Hammar by phone +47 97167225 or by e-mail **aasa.hammar@uib.no** or Patricia Polgar by phone +47 91879439 or by e-mail **patpol@siv.no**

If you have any questions about privacy in the project, you can contact the data protection officer at the University of Bergen: **personvernombud@uib.no** or the data protection officer at Vestfold Hospital**: pvo@siv.no**

The Data Protection Authority's email address is: **postkasse@datatilsynet.no**

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I CONSENT TO PARTICIPATE IN THE PROJECT AND TO MY PERSONAL DATA BEING USED AS DESCRIBED

Place and date

Participant's signature

Participant's name in printed letters

I confirm that I have provided information about the project

Place and date

Signature

Rolle i prosjektet