PARTICIPANT INFORMATION

'BETTER CARE – Improving mental health care for unaccompanied young refugees through a stepped-care approach'

We would like to ask you to participate in the following study:

General information

Many young people who found refuge in another country have experienced bad events. Post-traumatic stress disorder (PTSD) is one potential consequence. In addition, we know that many young refugees suffer other consequences such as sadness, anxiety or uncertainty. An early intervention can help to avoid long-term problems.

With our study, we would like to examine whether a specialized stepped care approach is able to reduce psychological stress and improve mental health care for (unaccompanied) young refugees in Germany.

'Stepped care approach' means: Each participant receives the most suitable support. This can either be a group prevention program ('Mein Weg") or individual therapy (TF-CBT). Both options are explained in detail below. These treatment options will be examined in this study and are tailored to the needs of young refugees in the child and youth welfare system (CYWS). In order to find out whether these treatments are efficacious, CYWS facilities will be randomly allocated to two different groups: A treatment group (BETTER CARE) and a control group (USUAL CARE+). In the treatment group, all participants receive either of the options mentioned above. In the control group, we assess the treatments young refugees normally receive in Germany and the kind of support they use. Participation in the study grants a chance to receive a treatment already shown to be very helpful for young refugees. Additionally, we examine how participants are currently doing.

Study procedure

At the beginning of the study, we would like to ask you and your caregiver to fill out several questionnaires. We would like to find out what kind of problems you might have. We ask questions about traumatic events, psychological stress, anxiety and sadness. Furthermore, we ask about your substance use, quality of life as well as your general health condition. For the assessment, we will use standardized digital questionnaires.

Subsequently, your CYWS facility will be randomly allocated to the treatment or the control group. In case your CYWS facility will be assigned to the treatment group, you will be informed which treatment is most suitable for you. In the following weeks, you receive the respective treatment. After the first assessment, we would like to ask you the same questions again after 6

and 12 months – independent of the group your CYWS facility has been assigned to. Thereby, we want to assess how the problems of young refugees in the two groups change within one year.

We would like to follow part of the study participants in the BETTER CARE study within the first year over a period of 2 years and survey them altogether 5 times in intervals of 6 months.

In order to participate, you need to agree to take part in the assessment and live in a residential facility when we first survey you. The assessment contains questions about your mental health but also about difficulties with the general life in Germany, well-being in the facility you are living in, as well as how you experience the agencies and organizational structures in Germany. For the first three assessments, the questionnaires can be filled in together within all the other questionnaires via tablet. Afterwards, we will ask some more questions. After 18 and 24 months, we will reach out to you again with the same questions – these can be answered via tablet or telephone.

Treatment information

In case your CYWS facility is randomly assigned to the treatment group, you have the opportunity to participate in one of the two treatments. Based on your answers in the questionnaires, we suggest which treatment fit to your needs:

- Group program: The group program 'Mein Weg' takes place in the CYWS facility and will be led by two caregivers who work in your facility. A group of 2-5 participants meets weekly over a period of 7 to 9 weeks. In the group, you receive information about your problems and how to deal with them in a better way. Moreover, you can speak about your past and you will learn how to deal with stressful situations in the future. All the information you give in the group are bound to confidentiality.

  or

- Individual therapy: The individual therapy (TF-KVT) comprises approximately 15-20 weekly sessions in a therapist's office nearby. You will learn technics that help you deal with your thoughts, feelings and memories. Additionally, you will learn how to deal with stressful situations in the future. If you give your written informed consent, your caregiver will be included in the treatment. If you want, an interpreter can be included as well. All the information you provide during the therapy are bound to confidentiality.

Expected benefits from participating in the study

Participating in our study has certain benefits:

1. You get a thorough evaluation of your problems with well-evaluated questionnaires available in your mother tongue.
2. You and your caregivers receive feedback whether or not you need treatment.
3. You have the opportunity to participate in a group program or individual therapy.
4. Individual therapy or the group program can help you to reduce your problems.
5. Through our study, we can also improve access to good treatment for other (unaccompanied) young refugees.
6. For your participation in the assessment, you receive a voucher worth 30€ for each time you participate. You receive an additional voucher worth 5 - 20€ if you also participate in the assessment over the period of 2 years.

Who can participate?

Unaccompanied young refugees aged 12- 20 years, living in a participating CYWS facility, planning to submit an application for asylum or did so already can participate in the study. If you want to participate, we would like to ask you and your legal guardian/parents to give consent to participate in the study.

Adverse effects

Earlier evaluations have shown no long-lasting adverse effects. However, the assessments and certain treatment sessions may intensify your problems temporarily. In this case, you should let your caregiver or therapist know. They can help you to handle the situation.

Voluntary participation

Participation in the research project is voluntary. You can revoke your consent and withdraw from the study at any time without giving reasons. Then, all the collected study-related data will be deleted. Study withdrawal would not have any consequences for your medical care.

Availability of responsible study personal:

Should there be any questions over the course of the research project, you can always contact us via e-mail or phone:

Study administration:
Prof. Dr. Rita Rosner (Contact: Phone: +49 8421 93-1581/-1033;
e-mail: rita.rosner@ku.de)

Study personal:
Eichstätt: Jonathan Thielemann (Contact: Phone: +49 8421/93 23164;
e-mail: jonathan.thielemann@ku.de)
Ulm: Elisa Pfeiffer (Contact: Phone: +49 731/500 62626;
e-mail: elisa.pfeiffer@uniklinik-ulm.de)
Günzburg: Tamara Waldmann (Contact: Phone: +49 8221/9629211;
e-mail: tamara.waldmann@uniklinik-ulm.de)
München: Fabienne Hornfeck (Contact: Phone: + 49 89 62306 240;
e-mail: hornfeck@dji.de)

In case of emergencies, the following telephone numbers apply:

In case of a psychological emergency that requires a fast response and non-availability of study personal (in person or by phone), please call your attending psychiatrist/psychotherapist. In the event that you require medical attention outside the office hours, you can get through to the medical on-call service by dialing 116117. In life-threatening situations, please call an emergency doctor/emergency service by dialing 112 (all these numbers are free of charge).

Insurance

While participating in the research project, you have an insurance. The Catholic University Eichstätt-Ingolstadt, the Ulm University Hospital and the German Youth Institute e.V., as well as their staff have a liability insurance in the event that you suffer harm with culpability on their part. Please note that on the way to the study center and the way back, you do not have an accident

insurance. However, study participation does not entail a visit in the study center since the data collection will be conducted in the respective CYWS facility. Should there be any harm as a result of this research project, please report immediately to the responsible person (see above).

Confidentiality/Data protection

All people and project partners involved with you throughout the study are bound to (medical) confidentiality and data secrecy. For research purposes, all project partners have access to the data collected in the project. In an anonymized manner, the results of the study will be used for scientific publications. If necessary, authorized persons (e.g. sponsor of the university) may access part of the data relevant to the study. In case the authorized persons granted access are not bound to the medical confidentiality mentioned above, the personal data acquired in the context of the inspection constitute a company secret that must be kept secret.

The study personnel will keep all of your responses strictly confidential. We will not talk to anyone about the information you give us, not even with your Betreuer, Vormund or Jugendamt. The only case where we would have to take action is if you intend to harm yourself or others. Only then, may we inform your Betreuer, Vormund or Jugendamt to find a solution to help you. This may also involve talking to a psychologist or psychiatrist. If we get the impression that your life is in imminent danger and we cannot reach you, we may have to call the police to make sure nothing happens to you.

The software used for collecting your data is operated by the company zone35 GmbH & Co. KG (Wilhelmstraße 118, 10963 Berlin, 030/44 01 360, info@zone35.de), depository of the data is run by the company Strato AG (Pascalstraße 10, 10587 Berlin) and server maintenance is carried out by the company ITK-Informations Technologie Krockor (Inh. Michael Krockor, Max-Beckmann-Str. 21, 04109 Leipzig). As a matter of course, all data will be transmitted encrypted and treated strictly confidential. In order to secure the data traffic between your browser and the server, a SSL-encryption (Secure Socket Layer) will be used. Thereby, we ascertain that the data transmission from your browser to the server and the other way around cannot be controlled and no one other than the transmitter and receiver has access to legible data. While the study is conducted, the data will be saved on a server of the hosting in the ISO 27001-certified data center using current system software (CentOS7) and system components. Research data will be deleted from the server of the provider within three months and transferred to the secured servers of the study center. There, it will be stored for at least 10 years. The companies (zone35 GmbH & Co. KG, Strato AG und die Firma ITK-Informations Technologie Krockor) are bound to data secrecy. Sensitive treatment of your data is assured by contractual arrangements. Extensive security measures are in place to protect your data from access by unauthorized persons, loss of data and data misuse.

In this project, the following person is responsible for data processing:
Dr. Cedric Sachser (Steinhövelstr. 1, 89075 Ulm, Phone: 0731-500-62659,
e-mail: cedric.sachser@uniklinik-ulm.de)

In case of questions regarding the usage or processing of your data, please contact:

1.) Data protection officer of the local study center Ulm University Clinic:
Clinic administration, Albert-Einstein-Allee 29, 89081 Ulm, Phone: 0731 /50069290,
e-mail: dsb.ukl@uniklinik-ulm.de

2.) Data protection officer of the central study administration:

Sarah Hertenberger, Steinhövelstr. 1, 89075 Ulm, Phone: 0731-500-62678,
e-mail: sarah.hertenberger@uniklinik-ulm.de

In case you have concerns or complaints regarding the processing of your data, please contact the data protection authority of your study center. You can find the respective contact details on the website of the state representative for data protection and freedom of information Baden-Württemberg: *https://www.baden-wuerttemberg.datenschutz.de/dsb-online-melden/*

.....	.....
Place, date	Name of the explaining person

INFORMED CONSENT

'BETTER CARE – Improving mental health care for unaccompanied young refugees through a stepped-care approach'

Content, procedure, risks and aim of the research project mentioned above, as well as authorizations to access collected data has been thoroughly explained to me by

.....

I had additional questions:
.....

.....

I had the opportunity to ask questions and they were answered.

I had enough time to decide upon my participation in the project.

I received a copy of the patient information and the informed consent.

I consent to participate in the research project.

Participant first name and last-name	Participant date of birth
Place, date	Participant signature

.....
Mobile number/ e-mail (for communication purposes)

☐ I agree to participate in the assessments over a period of 24 months (in intervals of 6 months).
I consent that my contact details (name, mobile number, e-mail address) are conveyed to, stored and used by the German Youth Institute. This agreement can be revoked at any time with effect for the future (at the German Youth Institute, Fabienne Hornfeck, hornfeck@dji.de). Contact details will be stored separately from the research data and deleted on completion of the project. Consent is voluntary and no disadvantages will result from denying or revoking consent.

INFORMATION AND CONSENT FOR DATA PROTECTION

In scientific studies, personal data and medical reports are collected. Storage, evaluation and transfer of these study-related data occurs according to legal provisions and requires the following voluntary consent before participating:

1. I consent that data / morbidity data collected in the frame of this study are recorded via questionnaires and electronic data media and are processed anonymously.
2. In addition, I consent that an authorized person bound to confidentiality (e.g. sponsor of the University) can access my collected personal data insofar as necessary for the inspection of the project. For this procedure, I release the doctor from the medical confidentiality obligation.
3. I understood that I have the right to request information on my personal data (including a free copy), as well as to request their correction or deletion.

I consent to the use of my data as described above.

.....
(Participant name)

.....
(Place, date)

.....
(Participant signature)

Informed Consent

In the current situation of the corona pandemic, it may become necessary in the BETTER CARE study to use video consultation tools to enable a screening. In this way, you can take part in the study and get the right help despite the limitation of personal contacts. The video consultation providers that will be used in this project are REDconnect and Click Doc.

In a video consultation, the conversation between you and the study personnel is similar to the usual procedure. You and the other person are just not in the same place. The communication takes place on the screen. This saves time and effort.

You do not need any special equipment for the video consultation: a computer or tablet with a screen or display, camera, microphone and loudspeaker as well as an Internet connection are sufficient. The technical connection is established via a video consultation provider, who must meet special security requirements and is commissioned by the study staff. This ensures that what you discuss with us remains confidential.

Step-by-step to the video consultation:

1. You will receive an appointment for the video consultation, the Internet address of the video consultation provider and the access code for the video consultation.
2. On the day of the video consultation, dial in about 5 minutes before the appointment on the website of the video consultation provider with your access code. This should be possible without having to create an account.
3. The video service provider may ask for your name when you dial in. Please enter this correctly.
4. You will then be taken to the virtual waiting room. As soon as we join the video consultation, your consultation can begin.
5. When the consultation hour is over, log out of the website.

Data safety for RED connect:

- The video consultation hours are transmitted over the Internet using a so-called peer-to-peer (computer-to-computer) connection, without using a central server.
- The video service provider guarantees that all content of the video consultation is encrypted end-to-end during the entire transmission according to the current state of the art and is neither viewed nor saved by him.
- All metadata will be deleted after 3 months at the latest and will only be used for the processes necessary to handle the video consultation.
- The video service provider and we are prohibited by law from disclosing or making data accessible to unauthorized third parties.

Data safety for ClickDoc:

- The provider, as a company of CGM SE & Co. KGaA, regards the responsible handling and the respect for the protection of personal data as the highest principle. The provider ensures that all relevant laws are strictly adhered to when storing and processing personal data.
- In accordance with the Data Protection Act, the provider undertakes to delete all contract data, all log data and all data on technical operation after a contract has been terminated. However, we are legally obliged to respect retention periods under commercial and tax law, which may extend beyond the duration of the contractual relationship. Data on technical operation are only kept for as long as it is technically necessary, but deleted at the latest after the termination of a contract.
- To set up the video session using CLICKDOC VIDEOSPRECHSTUNDE, the IP address of the customer and that of his patients / guests are transmitted to the LaWell Systems GmbH server. The IP address is not stored permanently. In a video session using CLICKDOC VIDEOSPRECHSTUNDE, video and voice, chat messages and screen sharing are SSL-encrypted and transmitted via a peer-to-peer connection, i.e. directly between the participants without an intermediary server. There is no storage or recording of this data.
- When using the whiteboard within the CLICKDOC VIDEOSPRECHSTUNDE, the uploaded files are temporarily stored in encrypted form on the La-Well Systems GmbH server. When the video session ends, the files will be deleted.
- The server location of CLICKDOC VIDEOSPRECHSTUNDE is Germany. There is no data transfer to third countries.

Informed consent – Data safety

I hereby declare:

_____
First and last name

_____ _____
E-mail Date of birth

that I have been sufficiently informed about the procedure of the video consultation as well as its technical requirements and data protection security aspects. I know that participation in the video consultation is voluntary and that the use of the software is free of charge for me.

I assure that

- the video consultation will take place in closed rooms and in a quiet environment to ensure data security and a conversation without interference.
- everyone present in the room will be introduced at the beginning of the video consultation.
- no screenshots, video and/or sound recordings will be made during the video consultation.
- Assisting persons will be made aware of the protection of secrets and, if necessary, data protection.
- I have the technical requirements for using video consultation.

I agree that

the collection, processing and use of the health data is carried out by the study personnel for a report and for documenting the video consultation. In principle, data protection laws apply to indirect contact between you and us during the video consultation, analogous to direct personal contact.

I am aware that I can revoke my consent at any time. Verbal communication to study personnel is sufficient for that.

With my signature, I declare that I give the above consent and that I have read the attached information on data processing during the video consultation with RED Connect / ClickDoc.

Please sign both fields on the next page!

RED connect informed consent:

_____ _____

(Place, date) (signature participant)

Clickdoc informed consent:

_____ _____

(Place, date) (signature participant)