Efficacy of a Low-threshold, Culturally-Sensitive Group Psychoeducation Programme for Asylum Seekers (LoPe): study protocol for a multicentre randomised controlled trial

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ABSTRACT

Introduction Despite high levels of mental distress, accessing psychological treatment is difficult for asylum seekers in Western host countries due to a lack of knowledge about mental disorders, and the health system, as well as due to cultural and language barriers. This study aims to investigate whether brief culturally sensitive and transdiagnostic psychoeducation is effective in increasing mental health literacy.

Methods and analysis The study is a parallel two-group randomised controlled trial with 1:1 individual allocation to either culturally sensitive, low-threshold psychoeducation (‘Tea Garden’ (TG)) or a waitlist (WL) control group. It takes place at four study sites in Germany. A total of 166 adult asylum seekers who report at least mild mental distress will be randomly assigned. The TG consists of two 90 min group sessions and provides information about mental distress, resources and mental health services in a culturally sensitive manner. The primary outcome is the percentage of participants in the TG, as compared with the WL, achieving an increase in knowledge concerning symptoms of mental disorders, individual resources and mental healthcare from preintervention to postintervention. The further trajectory will be assessed 2 and 6 months after the end of the intervention. Secondary outcomes include changes in mental distress, openness towards psychotherapy and resilience. Furthermore, healthcare utilisation and economics will be assessed at all assessment points.

Ethics and dissemination The study has been approved by the Ethics Commission of the German Psychological Society (ref: WeiseCornelia2019-10-18VA). Results will be disseminated via presentations, publication in international journals and national outlets for clinicians. Furthermore, intervention materials will be available, and the existing network will be used to disseminate and implement the interventions into routine healthcare.

Trial registration number DRKS00020564; Pre-results.

Protocol version 2020-10-06, version number: V02F.

INTRODUCTION

The prevalence rates of mental disorders among asylum seekers (and refugees are high. (An ‘asylum seeker’ is defined as a person who is seeking international protection and whose claim for asylum has not yet been finalised. If protection is granted according to the 1951 Refugee Convention, the person is recognised as a ‘refugee’. Accordingly, all refugees were initially asylum seekers. Many of the studies cited investigated both asylum seekers and refugees. Due to the current study’s focus, we primarily use the term ‘asylum seekers’ and speak of refugees only if they are specifically addressed.)

Strengths and limitations of this study

▸ The multicentre, randomised controlled trial will investigate the efficacy of transdiagnostic, culturally sensitive psychoeducation for asylum seekers living in Germany.

▸ The primary and secondary outcomes have been selected based on previous studies on psychoeducation, as well as the researchers’ own pilot trials, and cover the different domains that are targeted by the psychoeducation sessions (eg, knowledge about mental disorders, resilience and coping strategies, healthcare utilisation).

▸ The psychoeducation sessions are designed to be culturally sensitive in different ways; for example, by using body-mind metaphors (eg, traumatic experience as a wound which requires care) or by highlighting culturally salient resources (such as religion and faith).

▸ Since there is currently no comparable intervention available in mental healthcare, a waitlist control is considered appropriate comparison group.

▸ Although the short duration of the Tea Garden is a strength as it is therefore easily accessible, it also means that it is not a full intervention and can only be understood as a first step in a more comprehensive stepped care approach.
a recent systematic review, Henkelmann et al identified prevalence rates of 30% for diagnosed depression and 29% for diagnosed post-traumatic stress disorder (PTSD) in asylum seekers resettling in high-income countries. Of note, these rates are not only higher than those in the general population in Western countries, but also considerably higher than those of populations living in conflict settings. This suggests that both the journey to a host country and postmigration factors such as a lengthy asylum procedure, fear of deportation, family separation or ethnic discrimination in Western resettlement countries pose a potential risk for the aggravation or manifestation of mental health problems, even after arriving in a safe host country.

Despite high levels of mental distress, asylum seekers underuse mental healthcare services. Reasons for this include a lack of awareness of mental health and of information about the available healthcare services; stigma and negative attitudes towards mental disorders and mental healthcare (eg, differing belief and explanation systems); language and communication barriers due to insufficient language skills and the necessity for interpreters; and cultural differences in help-seeking behaviours (eg, seeking social support or traditional healers). Reduced healthcare utilisation can also be due to anxiety or shame caused by traumatic events or concerns about confidentiality.

Previous research has shown that psychoeducational interventions (ie, offering information regarding mental health issues) are promising to address these barriers, namely to reduce the stigma associated with mental health issues and psychological treatment, to increase awareness and mental health literacy, and consequently to increase help-seeking. Systematic reviews have also revealed that psychoeducation improves psychosocial functioning and reduces distress for people suffering from mental disorders, as well as for caregivers.

To the best of our knowledge, no trial to date has investigated the efficacy of a basic psychoeducation programme addressing the aforementioned barriers faced by asylum seekers. Previous trials have focused primarily on asylum seekers with specific and mostly manifest mental disorders (in particular PTSD and depression). Furthermore, studies have used psychoeducation as part of a comprehensive psychotherapeutic intervention or psychoeducation has served as a comparison condition for psychotherapeutic interventions. In conclusion, psychoeducation focusing on mental health literacy, destigmatisation, reduction of barriers to help-seeking and information on mental healthcare in general has not yet been systematically evaluated.

Against this background, we developed a basic, transdiagnostic psychoeducation programme for asylum seekers, the ‘Tea Garden’ (TG), and tested its feasibility and efficacy using a single-group pilot study. The TG is culturally sensitive and adjusted to the unique situation of mentally distressed asylum seekers (cf. Methods section, and). It aims to (1) increase attendees’ knowledge about mental disorders, psychological and psychiatric treatments, mental health, and specific pathways to treatment for asylum seekers; (2) reduce stigmatisation against mental disorders and mental healthcare, and thereby increase asylum seekers’ openness towards psychotherapy and psychiatric treatments; and (3) strengthen psychological resources and relieve mental distress. Since it is designed as a group intervention, it is possible to address a large group of asylum seekers at once. In the pilot study, a total of 31 asylum seekers participated in the TG. After the intervention, participants reported increased knowledge about mental healthcare, psychotherapy and self-help options, relief from general distress, improved perceptions of resources and high overall satisfaction with the programme. The generalisability of these results, however, is limited due to the uncontrolled study design. Furthermore, the relevance of participants’ gender was not specifically investigated in the earlier study. However, investigating a potentially moderating role of gender appears important as there is preliminary evidence from a study examining psychoeducation for caregivers of persons suffering from schizophrenia suggesting that female participants showed a larger benefit than their male counterparts. Despite the limitations of the pilot study investigating the TG, it provides promising first evidence on the importance of psychoeducation in facilitating access to mental healthcare for asylum seekers, and thus the potential for improving their mental health; such a programme might therefore be promising as a basic intervention within a stepped care model.

Against this background, the current multicentre randomised controlled trial (RCT), entitled ‘Efficacy of a Low-threshold, Culturally-Sensitive Group Psychoeducation Programme in Asylum Seekers’ (LoPe), investigates the efficacy of the TG in comparison to a waitlist (WL). LoPe is part of the ‘Culturally Adapted Psychotherapy for Refugees’ consortium, which proposes interventions with varying degrees of treatment intensity for asylum seekers and refugees at different stages of motivation and treatment need. Thereby, LoPe will comprise level one of an evidence-based and cost-effective stepped-care approach for the benefit of mentally distressed asylum seekers.

**Aims and hypotheses**

The principal research question addressed in LoPe is whether the short, low-threshold and culturally sensitive psychoeducation TG is effective in reducing the primary barriers to adequate mental healthcare for asylum seekers. To this end, the effects of the TG on increase of knowledge about mental health and healthcare in Germany, openness towards psychotherapy and the stigmatisation of mental disorders and treatment will be assessed. The project will also investigate whether the TG improves resources and reduces distress. Moreover, gender differences in knowledge increase will be investigated exploratively.

The primary hypothesis is that, compared with the WL control group, more participants in the TG will achieve
significant increase of knowledge growth at postintervention. Additional analyses will be conducted to address the following secondary hypotheses:
1. Participation in the TG will increase openness towards psychotherapy and reduce stigmatisation against mental disorders in comparison to participation in the WL.
2. In participants with a mental disorder, TG participation will increase the intention to seek mental healthcare.
3. Participation in the TG will improve resources (ie, individual resilience and coping strategies), and reduce the distress of participants in comparison to participation in the WL.
4. Women will report a higher knowledge increase than men.
Furthermore, the trial will estimate the economic consequences of the TG (ie, healthcare utilisation), moderators of treatment outcome, predictors of drop-out from treatment and expectations about the TG.

METHODS AND ANALYSIS
Design and setting
The present study is a multicentre, parallel two-group RCT with 1:1 individual allocation to either: (1) a state-of-the-art, culturally sensitive, low-threshold psychoeducation group intervention (the TG) or (2) a WL control group across four study sites in Germany. We used the SPIRIT statement (Standard Protocol Items: Recommendation for Interventional Trials) when writing our report.  

The study will be conducted at four study sites in Germany. Participants will be recruited in equal numbers from each of the four sites for both TG and WL. At all sites, outpatient mental health clinics with specialised subdivisions for asylum seekers will provide the infrastructure for the project. In addition, established collaborations with service providers for asylum seekers at each site will aid recruitment, build on their long-lasting experience in providing psychosocial care for asylum seekers, and ensure high quality standards for treatment and supervision.

Study population
The target population will comprise adult asylum seekers from different countries of origin who are largely still in the asylum process and who experience mental distress. Originally, we aimed to recruit participants who have been in Germany for less than 18 months; however, given the changing numbers of asylum seekers arriving in Germany and the constraints of the COVID-19 pandemic, we needed to adapt this criterion to 36 months in order to achieve the necessary sample size. Since the assessment of participants’ eligibility will be performed separately at each study site, the distribution of participants regarding countries of origin and main languages will depend on the distribution within the population of asylum seekers living in the corresponding regions. We aim to include women and men in accordance with their share in the population of adult asylum seekers in Germany.  

Inclusion criteria:
- Being an asylum seeker in Germany.
- A score of 5 or more points in the General Health Questionnaire-28. This threshold was determined in line with consistent evidence from studies using populations from Western 36 as well as Arab populations 38, 40 indicating that a cut-off value of 4–5 is associated with the optimal detection of psychiatric disorders. In the asylum seeker population, however, with a high prevalence rate of mental disorders, the chosen cut-off value might be too low for the detection of mental disorders, but will nevertheless be appropriate to indicate asylum seekers in mental distress.
- Being at least 18 years old. (The TG offers information matching the needs of an adult population.)
- Signed informed consent.

Exclusion criteria:
- Concurrent psychotherapy. (Persons who are already receiving psychotherapy may not require the information provided in the TG and attending such a treatment could influence the results of the study in a confounding way.) Psychotherapy after the end of the TG is allowed and will be assessed.
- Persons with acute manic or psychotic symptoms or acute suicidal- ity. (These persons are in need of acute psychiatric intervention and may in addition be unable to follow the TGs.)

TG, Tea Garden.
Study procedure: In the first step, potential participants will be carefully informed about the study by the local coordinator, assisted by a trained translator (see also the study flow chart in figure 1). They will distribute the participant information sheet, which is available in different languages (see the Outcomes section for details). To ensure correct and full understanding and to compensate for different levels of reading comprehension, the information sheet will be explained in detail section by section. During this information session, participants’ questions will be answered, and further explanation will be provided whenever necessary. Afterwards, potential participants will have sufficient time to consider their participation in the trial. In the second step, researchers will obtain consent from individuals who wish to participate (see online supplemental appendix 1 for Informed Consent Sheet). After the provision of signed informed consent, screening for inclusion and exclusion criteria will take place. In the third step, eligible individuals are invited to participate in the preassessment (T1), which is conducted by trained assessors (either native speakers or supported by trained translators) either at the study centres or at the respective accommodations. If appointments take place in the accommodations, it is ensured that rooms are available.

Figure 1  Study flow chart of the LoPe randomised controlled trial. FU, follow-up, LoPe, Low-threshold, Culturally-Sensitive Group Psychoeducation Programme in Asylum Seekers.
in which confidentiality can be guaranteed. During the assessments, assessors and translators will be available for questions about the linguistic meaning of the items, and to support illiterate participants (assisted self-report). Following the completion of the questionnaires, the local project manager will complete the randomisation form for eligible individuals and request randomisation. As soon as a sufficient number of participants speaking one language is randomised to the intervention group, all participants are informed about their group allocation and the start of the TG. The TG will take place in two 90 min sessions over the course of 2 weeks. Directly after the end of the intervention, the postassessments (T2) takes place in the same manner as the T1 assessment. Two and 6 months after the end of the TG, participants will be invited to participate in the follow-up assessments. Participants assigned to the WL receive the TG intervention after the first follow-up (FU1). In addition, they have assessments at post intervention (POST-WL), as well as two (FU1-WL) and 6 months later (FU2) (see figure 1). Participants who drop out during the course of the study will be contacted to fill in postfollow-up and follow-up assessments. We aim to provide gender-congruent care in the study whenever possible. If due to missing personnel full gender congruence is not possible, we aim to include at least one person (eg, translator, assessor or therapist) who is gender-congruent to the participants.

Randomisation
Randomisation will be performed by the central office of the Coordinating Centre for Clinical Studies (KKS) in Marburg, Germany, and can take place if all inclusion criteria and none of the exclusion criteria are fulfilled. The chance of allocation to the intervention group (TG) and the control group (WL) is 1:1. The randomisation will be stratified by gender and study site to ensure balance between the two study arms across all four investigation centres. The lists are generated using an R script developed by the KKS. Randomisation of an eligible participant will be requested by the site investigator who completes the study specific randomisation form and sends it to the KKS Marburg via email. The KKS informs the site investigator about the randomisation result and the study coordinator informs the participant of their allocation. Each participant will be given a unique study code by the randomisation provider.

Intervention
The TG is a psychoeducation programme that will be provided in group format to provide help to several asylum seekers simultaneously. It consists of four modules, which are presented interactively by two trained therapists and with the aid of interpreters in two 90 min sessions 1 week apart. TG groups will consist of four to eight participants, with women and men being assigned to separate groups. The four modules (M1–M4) focus on different topics; that is, establishing trust and confidence (M1), symptoms of mental disorders (M2), resources and self-care (M3) and available treatment options (M4).

The TG is provided in the participants’ native language and is culturally sensitive in several ways. For example, the TG works with images that are easy to understand (eg, for symptoms), symbols (eg, for the course of symptoms), metaphors (eg, a wound that needs to be cared for following a traumatic experience), examples from participants’ previous living environments (eg, from nature and agriculture), and body and animal analogies.28 By using these techniques and material free of written language, communication between therapists and participants is facilitated and the participants’ differing educational levels are considered. Furthermore, cultural sensitivity is achieved by providing gender-homogeneous and language-homogeneous groups, by using a group setting to introduce social support and to account for the collectivistic background of many of the participants, as well as by offering tea and snacks to promote a relaxing and welcoming atmosphere. A detailed description of the development of the TG can be found elsewhere.28

Interventions will take place in the affiliated outpatient clinics, all of which have long-standing experience in treating asylum seekers and/or trauma-related disorders, or in the initial reception facilities or community accommodation. Trained clinical psychologists will administer the TGs. Adherence to the treatment protocol will be secured by a specific 2-day training session prior to the beginning of the study, a detailed manual specifying each step of the TG, and close supervision by psychotherapists experienced in the field. In addition, therapists provide short written protocols of the actual course of each session; the study’s coordinator will collect the protocols, check for adherence and clarify potential confusion. In addition, these protocols may be used in the supervision that is provided during the course of the TGs.

Control group
We have chosen a 3-month WL as a comparator for the TG, because there are no typical treatments or similar interventions that the TG could be compared with in order to assess its additional impact on the healthcare situation of asylum seekers. Given the fact that no comparable treatments exist, providing the treatment to the WL after the waiting period is an ethically sound procedure.

Outcome measures
All study information materials and all measurement instruments have been translated into the five languages most frequently spoken by asylum seekers in Germany (Arabic, Farsi/Dari, Tigrinya, English and French) using the forward-translation and backward-translation method.34 A detailed overview of the assessments and time points is presented in table 1.

Primary endpoint
The primary outcome for the study is knowledge growth on (1) the symptoms of mental disorders, (2) individual
Table 1  Summary of assessment schedule

<table>
<thead>
<tr>
<th>Assessment of eligibility</th>
<th>Baseline T1 (Pre) (before randomisation)</th>
<th>Intervention (TG)*</th>
<th>Postintervention T2 (Post)</th>
<th>Follow-up 1 T3 (2 months after T2)</th>
<th>Follow-up 2 T4 (6 months after T2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>x</td>
<td></td>
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<td></td>
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<tr>
<td>Eligibility screen: inclusion/exclusion criteria</td>
<td>x</td>
<td></td>
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<tr>
<td>Randomisation</td>
<td>x</td>
<td></td>
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<tr>
<td>Sociodemographic information</td>
<td>x</td>
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<td></td>
</tr>
<tr>
<td>General Health Questionnaire-28</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge about mental disorders, mental healthcare</td>
<td>x</td>
<td></td>
<td></td>
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<tr>
<td>Evaluation of TG</td>
<td>x</td>
<td></td>
<td></td>
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<tr>
<td>Inventory of Attitudes Toward Seeking Mental Health Services</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Client Sociodemographic and Service Receipt Inventory (CSSRI)</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>x†</td>
</tr>
<tr>
<td>EuroQol (EQ-5D)</td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Connor-Davidson Resilience Scale</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Post-Migration Living Difficulties Questionnaire</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Expectations about TG</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Serious) adverse events; risk of suicidality or behaviours imposing a risk on the participant or others</td>
<td>x</td>
<td></td>
<td>x (after each session)</td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>

*For WL: Intervention and evaluation of TG only after T3 (FU1); after the intervention postassessment (post-WL; incl. evaluation of TG), and FU1-WL with same questionnaires as post (T2) and FU (T3) shown in table 1.

†An additional assessment of EQ-5D and CSSRI is to be performed in the WL Group after the 3-month waiting period, before the TG intervention.

TG, Tea Garden; WL, waitlist.
resilience and coping strategies, and (3) the mental healthcare offered in Germany. An updated version of a questionnaire developed by our workgroup will be used to assess knowledge with three items on a 5-point Likert scale ranging from 0 (‘know nothing’) to 4 (‘know very much’). For the primary outcome, the percentage of participants achieving significant knowledge growth (increase of ≥3 points) between T1 and T2 will be determined. We assume that most asylum seekers know little about the issues addressed in the primary endpoint before the intervention (T1) and that an effective intervention will increase their knowledge at least from ‘little’ to ‘some’ (equalling 1 point) on each of the three rating scales.

Secondary endpoints

To enable mentally ill asylum seekers to pursue adequate mental healthcare, a reduction of feared stigmatisation and an increase in openness towards mental healthcare are core aims to achieve in the TG. Thus, the validated Inventory of Attitudes Toward Seeking Mental Health Services (IATSMS) will be used to assess the factors that influence the seeking of mental health services. It consists of 24 items representing three factors: psychological openness, help-seeking propensity and indifference to stigma. The items are rated on a 5-point Likert-scale ranging from 0 (‘disagree’) to 4 (‘agree’). Good internal consistency coefficients for the total score (Cronbach’s alpha of 0.87) as well as for the subscales (0.76–0.82) have been reported.

Furthermore, changes in distress and psychological resources will be assessed because distress reduction, as well as improvement of resources, are core concerns for persons with a mental illness. Distress will be assessed using the 28-item General Health Questionnaire (GHQ-28), a well-validated questionnaire that is sensitive to short-term changes. The GHQ-28 is rated on a 4-point Likert-scale with higher values indicating elevated levels of distress. It has been validated in different languages, eg, Farsi and Arabic. Psychological resources will be assessed using the Connor-Davidson Resilience Scale (CD-RISC); this contains 25 items which are rated on a 5-point Likert-scale ranging from 0 (‘not true at all’) to 4 (‘true nearly all the time’) with higher levels indicating elevated levels of resilience. Good internal consistency has been reported for the original versions as well as different language versions. In addition, the CD-RISC has previously been used in asylum seeker populations.

Furthermore, participants’ expectations of and satisfaction with the TG and whether participants were able to understand the content presented (at T1, four items and at T2, 13 items, respectively) will be assessed with a modified Client Sociodemographic and Service Receipt Inventory (CSSRI), as well as the Euroqol-5D (EQ-5D). Thereby, the modified CSSRI will be used to assess resource use, while utilities will be assessed with the EQ-5D. Healthcare utilisation will be monetarily valued by unit costs. By synthesising costs and (clinical) outcomes, the cost analyses will be extended to a cost-effectiveness analysis and/or a cost-utility analysis depending on data quality. Economic outcomes include the incremental cost-effectiveness ratio (ICER).

Additional analyses will investigate the moderators of treatment outcomes, as well as the predictors of drop-out from treatment, using baseline data as well as the Post-Migration Living Difficulties Questionnaire. This questionnaire comprises 27 items representing possible difficulties, alongside a 5-point Likert-scale ranging from 0 (‘no problem at all’) to 5 (‘a very serious problem’) regarding how much they are troubled by any of these problems.

Sociodemographic data including information on gender, age, education, country of origin, duration of stay in Germany, command of language, family status, residence status and current living conditions are collected at T1 from all participants.

Blinding

To avoid detection bias, study personnel involved in the assisted self-report assessments will be blinded. As a complete blinding of all study personnel is not possible due to the nature of the intervention, precautions will be taken: Both PIs (CW and RM) are not involved in recruitment, assessment or data entry. The study coordinator (FG) as well as personnel involved in recruiting, screening, assessment, data entry or analyses will not conduct the TG. Vice versa, therapists providing the TG are not involved in recruitment, screening, assessment, data entry or analyses. During the TG, translation is provided by independent translators who are not involved in other steps of the study process. Therapists and translators of the TG are not aware of the participants’ group allocation. Data entry is carried out by a person who was not involved in any of the steps during the study. The personnel conducting the assessments will be monitored throughout the trial. Additionally, to prevent selection bias, randomisation will be performed externally by the KKS. Bias due to confounding will be addressed by stratified and multivariable analyses to adjust for potential confounders. Bias due to measurement error will be minimised by applying reliable and validated instruments.

Sample size

The sample size calculation is based on the primary endpoint. Due to the existing evidence, we assume that most asylum seekers have little awareness of the three items addressed in the primary endpoint before the intervention (T1) and that an effective intervention will increase this level of knowledge from at least ‘little’ to ‘some’ (equalling 1 point on the scale) on each of the three rating scales (T2). In accordance with the numbers...
of adult asylum seekers living in Germany, we assume that the trial will comprise 33% women and 67% men. Furthermore, we hypothesise that more women (50%) than men (31%) will achieve knowledge growth following the TC and that women will also acquire more knowledge than men during the waiting time (20% vs 10%). To detect the corresponding OR of approx. four in each stratum between groups at a two-sided α of 5% with a power of 80%, 116 persons (58 per group) are required (Cochran-Mantel-Haenszel test, software PASS V.14, V.14.0.4.48). Compensating for a 30% drop-out rate, 166 participants have to be randomised. We expect that a screening of 208 persons will therefore result in 166 subjects being eligible for the study.

In addition to the primary endpoint, a meaningful change in mental distress from T1 to T2 of four points in subjects being eligible for the study.

### Adverse events

Based on earlier trials, no serious adverse events (SAEs) attributable to the planned intervention are to be expected. Close supervision by expert clinicians will be provided at each site to ensure high quality and safety. Potential adverse events will be monitored by both the project coordinator and the therapists involved. To reflect the differing severity of adverse events, they are separated into two categories. AEs include the following: (1) Occurrence of clinically significant symptoms of a severe mental disorder (eg, manic or psychotic symptoms, substance abuse); (2) Clinically significant worsening of anxiety symptoms and/or depression and (3) Unforeseen hospitalisation due to psychiatric problems. On the other hand, SAEs are defined as: (1) Death (suicide or other cause of death); (2) Suicide attempt/self-harm; (3) Harm of others; (4) Life-threatening event and (5) Event that led to physical disability.

(S)AEs are documented at each assessment. All SAEs and AEs are reported to the coordinating investigators, as well as the central project manager within 24 hours on notice of the event. In the case of SAEs, the Independent Data Safety and Monitoring Board (IDSMB) is additionally informed at short notice. Resolution of a complication is evaluated at the last assessment. Furthermore, for every complication the relation to the treatment is evaluated and documented (certain; likely; possible; unlikely; no relationship; unknown). If study participation is no longer possible due to the occurrence of (S)AEs, treatment options for post-trial care (eg, outpatient clinic) are recommended.

Participants assigned to the WL will particularly benefit from the safety measures, as their mental health status and potential crises will be monitored at much closer time intervals than usual.

### End of protocol treatment

In accordance with the Declaration of Helsinki, study participation is voluntary and each subject may withdraw from the study at any time without giving reasons. The decision to withdraw from the study treatment has no negative consequences or disadvantages for the participant.

Study participation may also be terminated by the investigator if there are (A) Severe serious complications which make it necessary to stop participation or (B) Non-compliance with the study protocol. Furthermore, participation will be terminated if (A) the participant withdraws his/her consent to study participation or (B) the investigator terminates the intervention for the participant.

The coordinating investigators together with the KKS Marburg and the Ethics Committee (EC) have the right to discontinue this study in any single site or to terminate the study as a whole at any time for reasonable medical or administrative reasons; for example, unsatisfactory enrolment with respect to quantity or quality, unexpected accumulation of safety issues or a change of risk–benefit considerations.

A premature discontinuation of a single site or of the study as a whole will be documented adequately with reasons being stated and information must be conveyed according to national requirements (eg, those of the EC).

### Data management

The trial will use an electronic data capture system (EDC system) with electronic case report forms (e-CRF) for data collection and documentation, hosted by KKS Marburg, Germany. Access to the e-CRF is only allowed for persons who are documented as trial personnel and who have received the necessary training. In order to ensure the anonymity of participants’ data, such data is recorded only with a study code and without identifying data in the e-CRF.

In a multistage procedure, the given data will be checked electronically for its plausibility and consistency. The EDC system has an implemented audit trail assuring that any documentation and/or changes to database items are traceable at any time. At the end of the trial, the database will be closed after a data cleaning process. The principal and coordinating investigators as well as the responsible biometrician have access to the final dataset. The pseudonymised participant data recorded in the e-CRF are stored by the KKS Marburg in accordance with legal requirements.

### Statistical analysis

#### Analysis populations

The intention-to-treat (ITT) population will be defined as all participants randomised, regardless of whether they received treatment. The per-protocol (PP) population will be a subgroup of the ITT population containing all participants without a major protocol violation.

#### Primary outcome

The null hypothesis, ‘no difference in the percentage of participants achieving knowledge growth from T1 to T2 between the two groups’, will be tested against...
the alternative hypothesis, ‘difference in the primary endpoint between the two groups’ by a two-sided Cochran Mantel-Haenszel test stratified for gender at α=5%. Mixed effects logistic regression analyses will be performed to analyse the influence of baseline covariates (eg, study site, language).

Secondary outcome
Changes in secondary outcomes will be analysed by appropriate hierarchical regression models (ie, Poisson or binomial models) adjusting for baseline covariates. Furthermore, longitudinal analyses will be performed by applying (generalised) linear mixed models with first order autoregressive covariance matrices (repeated measures analyses) and random effects for participant, centre, and language; main effects for group, gender and time; and interaction terms for group-by-time and group-by-gender.

All efficacy analyses will be performed for the ITT population. The analysis of the primary endpoint will also be performed for the PP population as a sensitivity analysis.

Safety and tolerability endpoints
Missing values will be handled according to Rubin’s concept. If required, sensitivity analyses will be performed to investigate the effect of different modelling strategies for missing values on the primary endpoint.

Safety analyses will be based on the as-treated population, that is, participants receiving at least one session (TG) or none (WL) will be evaluated according to the treatment they actually received.

Monitoring
An IDSMB has been established; this will periodically review the accumulating data and participant safety. Furthermore, it will regularly be advised of all safety aspects and the inclusion rate of the trial, in addition to reviewing its progress to ensure adherence to the protocol and advising whether to continue, modify or stop the trial.

Patient and public involvement
(Former) Asylum seekers, experienced counsellors and therapists were involved in the development of the TG and the primary outcome measure.26 28 Furthermore, (former) asylum seekers sharing the participants’ cultural background will be involved in the recruitment and running of the project as research assistants, interpreters and/or therapists. The experiences and preferences of asylum seekers with regard to the TG, the burden of taking part in the TG, and the outcome measure were evaluated in three independent pilot evaluations with asylum seekers from a variety of countries of origin and different educational backgrounds.28

Ethics and dissemination
Ethics approval was obtained by the Ethics Commission of the German Psychological Society (ref: WeiseCornelia2019-10-18VA). The EC approved the ethical aspects of the study, safety rules, and the participant information sheet, as well as the informed consent form. Any substantial amendments to the protocol will be submitted to the EC and the DRKS registry; it will also be communicated in the primary RCT report.

The trial will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and will follow the principles of Good Clinical Practice. Members of the IDSMB, the principal investigators, as well as the KKS Marburg will ensure adherence to these guidelines.

Results will be presented at national and international conferences and published in peer-reviewed scientific journals by both the principal investigators and the associated researchers. In addition, findings will be published in local and national outlets to facilitate their easy accessibility to practitioners. Manuals and instructional videos for therapist training will be available for future dissemination. Moreover, all participating sites are actively involved in providing clinical training and continuing education for psychotherapists and psychiatrists, and will disseminate findings through this route.

After trial completion and publication of the study results, data requests can be submitted to the principal investigators.

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Contributors CW, RM and FG wrote the first draft of the manuscript; CW and RM are the principal/coordinating investigators, and FG is the study coordinator for LoPe; J-PR, CS-B, US, JJ, TE, NM and RS contributed to the conceptualisation of the study design, TE, NM and US are study site leaders. All authors critically evaluated and commented on the manuscript and have given final approval of the manuscript.

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REFERENCES


Information on the LoPe study – Effectiveness of the Health Tea Garden

Dear prospective study participant,

Please read the participation information carefully or listen attentively to the participation information being read out loud. If there is anything you have not understood or if you require additional information, please ask the study team.

What is the aim of our study?

We would really like to know how well or poorly the Health Tea Garden helps people who have fled to Germany. We are interested in whether the Health Tea Garden helps you to learn something about the emotional consequences of flight and about possible treatments. Your participation in the study helps us to improve the Health Tea Garden.

What is the Health Tea Garden?

The Health Garden consists of two meetings in a group of men or a group of women, who all speak the same language. The two meetings take place one week apart and each last for around 1.5 hours. The groups are led by two male or female psychologists, who talk about the emotional consequences of flight and burdensome experiences, and together with you, look at which personal strengths help you to deal with such burdens. In addition, they will tell you about how emotional problems are treated here in Germany. At each meeting, interpreters who speak your language are there to translate everything.

What is the procedure of the study?

First of all, we conduct a preliminary discussion and an initial so-called diagnostic assessment (examination appointment). In this, we ask you to answer some questions about yourself (e.g. your age, how long you have been in Germany), your health and possible emotional problems. This will last for about 1 hour. After that, we decide whether the Health Tea Garden and this study might be helpful for you or whether you need another type of support.

If you are able to take part in our study, we invite you to a further examination appointment, in which you again answer questions about yourself (e.g. your origin, whether you have trained for a profession), on your health, on possible emotional problems, on your knowledge about emotional problems and about how you deal with emotional problems (around one hour). After this, we randomly (by lottery) allocate you to one of two groups. Half of the participants will be allocated to group 1, and the other half to group 2. This is necessary in order to be able to tell how well the Health Tea Garden helps.

**Group 1**

In this group, the Health Tea Garden begins directly after the examination appointment.

**Group 2**

In this group, the Health Tea Garden begins after a waiting time of about three months.

If you are in group 1, you can take part in the next Health Tea Garden in your language. As we want to examine how well the Health Tea Garden helps, the first examination appointment will be followed by three further appointments. Each time, we ask you questions about your health, about possible emotional problems, about your knowledge regarding emotional problems, and about how you deal with these types of problem: (1) directly after the Health Tea Garden; (2) two months after the end of the Health Tea Garden; and (3) six months after the end of the Health Tea Garden. Each of these appointments will last for about an hour.
If you are in group 2, you can take part in the next Health Tea Garden in your language after a waiting time of three months. We will then telephone you, arrange an appointment for answering the questions, and tell you when the Health Tea Garden will start. To examine whether the Health Tea Garden is helpful, we later ask you questions about your health, about possible emotional problems, about your knowledge regarding emotional problems, and about how you deal with these types of problem. These questions will be asked on three occasions: (1) at the end of the Health Tea Garden; (2) two months after the end of the Health Tea Garden; and (3) six months after the end of the Health Tea Garden.

For filling out the questionnaires, at each appointment, you will receive an expense allowance of 8 Euros per hour (for answering the questions). Upon arrangement, the public transport costs to attend the appointments can also be covered.

What does “voluntary participation” mean?
Participation in this study is voluntary. When answering the questions, you can take a break at any time. You can also tell us at any time if you no longer wish to participate in this study. If you’re feeling bad, the study team can suggest stopping participation. In that case, together with you, we look for a possible treatment.

Are there any risks involved in participating in the study?
It may be that other participants of the Health Tea Garden say something that brings back unpleasant memories for you. If this happens, you can take a break at any time and get support from the study staff who are present. We will then do an exercise with you that helps to interrupt unpleasant memories.

What benefits can the study have for you?
If you join our study, you can take part in the Health Tea Garden and learn about the emotional consequences of flight and burdensome experiences. Together with trained psychologists, you will see which personal strengths help you to deal with emotional burdens. In addition, you will learn how emotional problems are treated here in Germany. If you take part in the study, you will be helping us to improve the Health Tea Garden so that we will then be able to better help other people who have had to flee their countries. In this way, you will be making an important contribution to improved treatment for refugees in Germany.

What alternative options are there?
As far as we are aware, there are currently no other initiatives similar to the Health Tea Garden in Germany. If you do not want to take part in a scientific study but feel that psychotherapy may help you, we can briefly inform you about what you need to do. If you do decide to take part in our study, it will not be possible to attend psychotherapy at the same time, but you can then start psychotherapy after completing the Health Tea Garden.

Taking medication would not exclude you from taking part in this study. We would like to know which medications you take in order to rule out any influence on our results.

Information on data protection
The study team and the employees of the coordination center for clinical studies in Marburg, and all people involved in the study, are legally bound to confidentiality and are explicitly obligated to data
secrecy. This also applies to the psychologists who lead the Health Tea Garden, the persons who ensure that these psychologists are doing a good job (supervision) and the interpreters. In this study, personal data will be collected from you. All gathered data will be retained under strict observation of the legal regulations on data protection. We will only collect data that are necessary for achieving the study goal.

At the start, we will allocate a personal code to you (e.g. 01281992), which will be saved together with your data. Through this code, we will be able to assign your answers to the different time points. This procedure is called "pseudonymization".

Your name and your contact details will only be saved – separately from your answers in the questionnaires – together with the code in a list. This list is only accessible to the study leaders. Only the study leaders, with the help of this list, will be able to assign the answers in the questionnaire to your person. The list will be saved on a password-protected computer at the Phillips University of Marburg. For as long as the list exists, you can request that your name and your answers in the examination appointments are deleted. The list will be deleted once the study is complete. Your data are then anonymized. From that point, nobody will be able to connect your data with your name. Your answers, which are saved separately from this list, will be retained for at least 10 years after the end of the study.

You can withdraw your consent to participate in the study at any time, in which case your contact details will be deleted. As long as your answers to the questionnaires have not yet been anonymized, you can also request that these are deleted. Otherwise, your answers in the questionnaires will be anonymized and used further in this form. It is not possible to delete data that have already been anonymized.

The results of our study will be published in scientific journals and at conferences. This will not include any personal information about you.

Insurance
During the study, you are insured against accidents at all examination appointments, the Health Tea Garden appointments and on the journeys to and from the appointments.

Payment
You will receive 8 Euros per hour for filling out the questionnaires at the different appointments. The money will be paid to you in cash. We will note down your name and you will provide your signature. This information will be saved separately to the other data collected from you, and will only serve as proof of payment in the case of potential audits of expenses. It will be deleted by the end of the research project at the latest.

Contact persons and your study team
This study information is part of the declaration of consent for the LoPe study. If you have any further questions on the study, the procedure or your rights as a participant, you are welcome to contact us by telephone (06421-2824073) or E-Mail (teegarten.studie@uni-marburg.de).

Your LoPe study team
Dr. Dr. Ricarda Nater-Mewes & Dr. Cornelia Weise (06421-28 26738)
Dr. Freyja Grupp (06421 28-24073)
Additionally, we hereby inform you of the rights laid down in the European General Data Protection Regulation (GDPR) (article 12 ff. GDPR):

**Legal basis**
The legal basis for the processing of personal data relating to you in the case of clinical studies is your voluntary written consent in accordance with the GDPR and the Declaration of Helsinki (declaration of the World Medical Association on the ethical principles for medical research involving human subjects) and the guidelines for Good Clinical Practice.

**With regard to your data, you have the following rights** (article 13 ff. GDPR):

**Right to information**
You have the right to information about personal data relating to you which are collected or processed in the framework of the LoPe study (delivery of a free-of-charge copy) (article 15 GDPR).

**Right to notification**
You have the right to be informed of inaccurate personal data relating to you (articles 16 and 19 GDPR).

**Right to erasure**
You have the right to erasure of personal data relating to you, e.g. if these data are no longer necessary for the purpose for which they were collected (articles 17 and 19 GDPR).

**Right to restriction of processing**
Under certain circumstances, you have the right to demand a restriction of processing, i.e. your data may only be saved and not processed. You will have to apply for this. For this purpose, please contact your examiner or the data protection officer of the test center (articles 18 and 19 GDPR).

**In the case of a notification, erasure or restriction of processing**, all those who have your data will additionally be informed (article 17 (2) and article 19 GDPR).

**Right to data portability**
You have the right to receive the personal data relating to you which you provided to the persons responsible for the LoPe study. With this, you can request that these data are either transmitted to you or, where technically feasible, another body designated by you (article 20 GDPR).

**Right to object**
You have the right to object to concrete decisions or measures for processing of personal data relating to you (article 21 GDPR). Subsequently, such processing in principle no longer takes place.

**Consent for the processing of personal data and right to withdraw this consent**
The processing of your personal data is only lawful with your consent (article 6 GDPR). You have the right to withdraw your consent for the processing of personal data at any time. However, the data collected up until this point by the entities mentioned in the patient information and declaration of consent of the LoPe study can processed (article 7, paragraph 3 GDPR).

**Communication of personal data breaches**
If a personal data breach is likely to result in a high risk to your rights and freedoms, this will be communicated to you without undue delay (article 34 GDPR).
If you wish to exercise one of these rights, please contact your tester or the data protection officer of your test center. Furthermore, you have the right to lodge a complaint to the supervisory body if you are of the view that the processing of your personal data violates the GDPR (see contact details).

Contact details
Data protection officer of the Philipps University of Marburg:
Biegenstraße 10
35032 Marburg
Telephone: 06421-28 26155
E-Mail: datenschutz@uni-marburg.de

Data protection officer Hesse:
Prof. Dr. Michael Ronellenfitsch
Gustav-Stresemann-Ring 1, 65189 Wiesbaden
Telephone: 0611 1408 – 0
E-Mail: poststelle@datenschutz.hessen.de

Responsible for data processing:
President of the Philipps University of Marburg
Biegenstrasse 10, 35047 Marburg
+49 6421 28 20
info@uni-marburg.de

Test center:
Fachbereich Psychologie
Gutenbergstr. 18
35032 Marburg

Controller:
Dr. Cornelia Weise
Philipps-Universität Marburg
Fachbereich Psychologie, AG Klinische Psychologie & Psychotherapie
Gutenbergstraße 18
35032 Marburg
Tel.: 06421 28 26738
Declaration of consent to participate in the LoPe study – Effectiveness of the Health Tea Garden

- The undersigned project employee has informed me of the aims, procedure and potential risks of the study both verbally and in writing.
- I have read or listened to the study information provided about the above-mentioned study and have understood it. I have received satisfactory answers to my questions relating to participation in this study. I can keep the written study information and will receive a copy of my written declaration of consent.
- I have had sufficient time to make my decision.
- My participation in this study is voluntary. I can withdraw my agreement to participate at any time.
- I consent to take part in a diagnostic examination and to be subsequently randomly allocated to one of two study groups.
- If I am allocated to group 1, I can participate directly in the next Health Tea Garden in my language. I consent to take part in three further examination appointments after the Health Tea Garden (directly following the second Health Tea Garden session, two months and six months following the second Health Tea Garden session).
- If I am allocated to group 2, I consent to take part in the next Health Tea Garden in my language after a waiting period of three months, and to take part in examination appointments before participation in the Health Tea Garden, directly after the second Health Tea Garden appointment, and two months and six months afterwards.
- I have been informed that I will receive an expense allowance of 8 Euros per hour for participating in the examination appointments.
- I consent to the described collection and processing of data on my psychological burdens as well as sociodemographic information. The recording and evaluation of these data will be pseudonymized at the Philipps University of Marburg and by the coordination center for clinical studies in Marburg using a number (code) and without specification of my name.
- A coding list exists on a password-protected computer, which links my name to this number (code). This code is only accessible to the study leaders, meaning that only these persons can link the collected data to my name. The coding list will be deleted when the study is complete. My data will then be anonymized, and it will no longer be possible for the study leaders to link the collected data with my name.
- I have been informed that I can withdraw my consent for storing/saving these data without any disadvantage to me. I can request the deletion of all of my data at any time. In case of the withdrawal of consent, the already collected data will be deleted or anonymized and further used in this form. A deletion of already anonymized data is not possible.
- In the case of any uncertainties regarding the study or my rights as a study participant, and if unexpected or undesired events occur during the study, I can contact the study staff at any time. Additionally, the study team can be reached through the telephone numbers or email addresses in the letterhead.

Name of participant (please print)  

Date and signature of participant  

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Additional agreement for future contacts in the scope of the study
I give my consent that in the case of a later continuation of this study or of follow-up studies, the coding list is not deleted after the end of the current study, but is kept for five more years, and I may be contacted for follow-up studies. At any time, I can withdraw my consent for storage of the coding list and for being contacted, without any disadvantage.

☐ Yes  ☐ No

Name of participant (please print)  Date and signature of participant

Confirmation of the informing project employee and the interpreter:
I hereby confirm that I have informed the participant about the aims, the study procedure and about potential risks. I assure that I have answered all questions comprehensively. I am confident that the participant has understood my explanations and has given his/her voluntary consent to participate in the study. I hereby confirm that study participation is voluntary and no coercion was used or will be used in order to recruit participants or prevent dropouts.

Name of person providing information (please print)  Date and signature of person providing information

I hereby confirm the to the best of my knowledge and belief, that I have correctly implemented the translations regarding the study information.

Name of interpreter (please print)  Date and signature of interpreter