

# BMJ Open 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

## 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.

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.)<sup>1 2</sup> In

a recent systematic review, Henkelmann *et al*<sup>3</sup> 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.<sup>4</sup> 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.<sup>5–7</sup>

Despite high levels of mental distress, asylum seekers underuse mental healthcare services.<sup>8</sup> 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<sup>9</sup>); language and communication barriers due to insufficient language skills and the necessity for interpreters<sup>10</sup>; and cultural differences in help-seeking behaviours (eg, seeking social support or traditional healers<sup>11</sup>). Reduced healthcare utilisation can also be due to anxiety or shame caused by traumatic events or concerns about confidentiality.<sup>12</sup>

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.<sup>13–15</sup> Systematic reviews have also revealed that psychoeducation improves psychosocial functioning and reduces distress for people suffering from mental disorders, as well as for caregivers.<sup>16 17</sup>

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).<sup>18–20</sup> Furthermore, studies have used psychoeducation as part of a comprehensive psychotherapeutic intervention<sup>21–24</sup> or psychoeducation has served as a comparison condition for psychotherapeutic interventions.<sup>22 25</sup> 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.<sup>26 27</sup> The TG is culturally sensitive and adjusted to the unique situation of mentally distressed asylum seekers (cf. Methods section, and<sup>28</sup>). 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.<sup>26 28</sup> 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.<sup>29</sup> 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.<sup>30 31</sup>

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.<sup>32</sup>

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

## Box 1 Trial entry criteria

### 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<sup>36</sup> as well as Arab populations<sup>39 40</sup> 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.

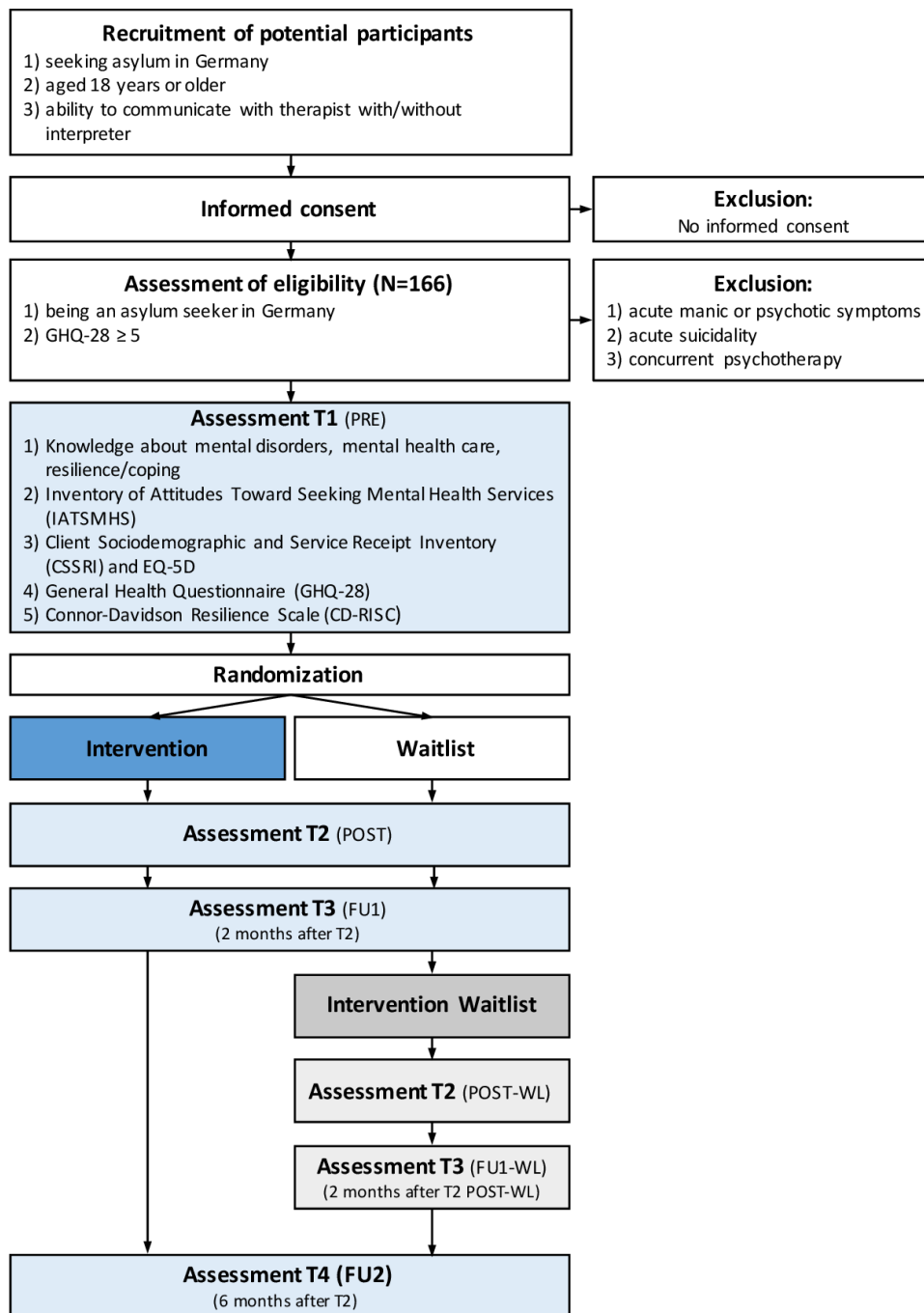
### Exclusion criteria:

- ▶ 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 suicidality. (These persons are in need of acute psychiatric intervention and may in addition be unable to follow the TGs.)

TG, Tea Garden.

women and men in accordance with their share in the population of adult asylum seekers in Germany.<sup>33</sup> The TG will be provided in the languages most frequently spoken by asylum seekers from the respective area of the trial sites. Thus, it is assumed that the investigated group is representative and the findings are highly generalisable to the wider population of both asylum seekers and asylum seekers living in Germany, and may easily be translated to other Western high-income host countries. To include as many mentally distressed asylum seekers in need of information as possible, the chosen inclusion criteria are as unrestricted as possible. The full list of participant inclusion and exclusion criteria is provided in [box 1](#).

**Participant recruitment:** Based on the experiences of the aforementioned pilot study,<sup>26</sup> the recruitment period is planned to last for 24 months. Recruitment will take place in close collaboration between the study sites and the respective local institutions active in the psychosocial or legal care of asylum seekers, who agreed to facilitate recruitment and provide access to the initial accommodations of asylum seekers. In addition, all study teams will visit initial reception facilities and community accommodations to inform about the study and provide the TG on-site, if desired. Recruitment will include strategies aimed at ensuring equal access of both genders to our interventions. For example, in order to increase women's access to the treatment, information will be distributed at known meeting places for women and via direct contact between female recruitment staff and potential female participants. Likewise, a male staff member is in charge of recruiting and screening potential male participants.



**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.

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

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 postassessment (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.<sup>28</sup> 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.<sup>28</sup>

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.<sup>34</sup> 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

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

\*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 FU1 (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').<sup>26</sup> For the primary outcome, the percentage of participants achieving significant knowledge growth (increase of  $\geq 3$  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<sup>35</sup> 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.<sup>35</sup>

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)<sup>36–38</sup>, 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.<sup>39–41</sup> Psychological resources will be assessed using the Connor-Davidson Resilience Scale (CD-RISC<sup>42</sup>); 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.<sup>42 43</sup> In addition, the CD-RISC has previously been used in asylum seeker populations.<sup>44</sup>

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 version of a specifically developed short scale previously used in the pilot trial.<sup>26</sup>

Following our rationale, the utilisation of mental healthcare is of interest to determine the success of the TG on a behavioural level and will be assessed using a modified Client Sociodemographic and Service Receipt Inventory

(CSSRI)<sup>45</sup>, as well as the Euroqol-5D (EQ-5D)<sup>46</sup>. 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.<sup>47</sup> 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,<sup>33</sup> 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 TG<sup>29</sup> 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  $\alpha$  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;<sup>48</sup> 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 the GHQ-28 (SD=8; effect size of 0.5; power=0.74) can be detected with this sample size.<sup>37 49</sup>

### 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  $\alpha=5\%$ . 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.<sup>26 28</sup> 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.<sup>28</sup>

### 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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