Mental health care for unaccompanied young refugees in Germany through a stepped care approach versus enhanced usual care: a cluster-randomised hybrid effectiveness–implementation trial

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Summary

Background Unaccompanied young refugees are a vulnerable group with high rates of post-traumatic stress symptoms (PTSS). Stepped care approaches are recommended as a potential treatment framework, but research on the effectiveness of these models remains scarce. We aimed to compare a stepped care approach for unaccompanied young refugees with enhanced usual care under real-world conditions.

Methods In this cluster-randomised controlled type I hybrid implementation–effectiveness trial, we compared two active conditions, BETTER CARE and enhanced usual care, for unaccompanied young refugees in child and youth welfare service (CYWS) facilities across seven states in Germany. Eligibility criteria included age 12–20 years; arrival in Germany as unaccompanied minors; asylum application or intention; in CYWS facility care at baseline; and at least one traumatic event reported. Masking of participants was not possible due to each CYWS facility being randomly assigned to a specific treatment arm. Additionally, although study personnel were not masked to the condition, all data were self-reported and study personnel remained masked to data entry. BETTER CARE was a stepped care approach consisting of screening, prevention (via the Mein Weg [My Way] group intervention), and trauma-focused cognitive behavioural therapy (TF-CBT). Enhanced usual care included screening and a corresponding treatment recommendation. Clusters comprised one CYWS facility and were stratified and randomly assigned (1:1) using permuted blocks. Self-report questionnaires were used to assess PTSS, depressive symptoms, anxiety symptoms, and quality of life at baseline, 6 months, and 12 months. The primary outcome was a reduction in PTSS, analysed with the Child and Adolescent Trauma Screen (CATS-2) score in the intention-to-treat sample (all randomly assigned participants). The study was preregistered in the German Clinical Trials Register (DRKS00017453).

Findings The study was conducted between Oct 14, 2019, and July 27, 2023. 58 (11%) of 525 eligible facilities, including 627 unaccompanied young refugees originating from 40 countries, decided to participate and were randomly assigned. The mean age of the participants was 16·7 years (SD 1·3), with 569 (91%) identifying as male, 53 (8%) as female, and five (1%) as gender diverse. Participants reported a mean of six traumatic events (SD 3·3). 270 (43%) unaccompanied young refugees had clinically elevated levels of PTSS, and 357 (57%) were below the clinical threshold for PTSS (based on CATS-2 scores). 12 months after random assignment, there was a significant between-groups change over time effect size for PTSS in favour of BETTER CARE in the intention-to-treat sample (d=–0·17 [95% CI –0·34 to –0·004]). The dropout rate at 12 months was 38% (n=124) in BETTER CARE and 43% (n=131) in enhanced usual care. Service use and retention were low within the 12-month study period.

Interpretation This study shows the effectiveness of a stepped care model including screening, prevention, and evidence-based interventions for unaccompanied young refugees in a high-income country. The potential benefit of screening and structured care recommendations was highlighted further by improvements in the enhanced usual care condition. Dropout rates were high but similar to those in previous studies with young refugees. Future studies should address demand-side barriers to improve service use and retention.

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Introduction

Unaccompanied young refugees show high levels of trauma exposure and psychological distress. This population has an increased risk of developing post-traumatic stress disorder (PTSD), shows PTSD prevalence rates of up to 43%, and indicates sustained symptomatology over time.[1] Additionally, untreated post-traumatic stress symptoms (PTSS; ie, symptoms of intrusion, avoidance, and hyperarousal, as well as negative alterations in cognitions and mood) might lead

Research in context

Evidence before this study

We searched PubMed from database inception to Sept 30, 2025, without language restrictions, using a combination of controlled vocabulary terms and free-text keywords related to unaccompanied young refugees and stepped care interventions. The search strategy included the terms ("refugee minor" OR "unaccompanied minor" OR "unaccompanied child" OR "unaccompanied youth" OR "asylum-seek" OR "young refugee") AND ("stepped care" OR "stepped-care" OR "stepped psychological care" OR "low-intensity intervention" OR "collaborative care"). We screened the reference lists of relevant reviews and original articles to identify further eligible studies. We included empirical studies that examined psychological interventions delivered within a stepped care framework to traumatised refugee or asylum-seeking children, adolescents, or young adults, with a particular focus on unaccompanied populations. Both randomised and non-randomised study designs were considered. We excluded studies that did not report mental health outcomes, focused exclusively on adults, or evaluated single, stand-alone interventions without a stepped care component. Our search identified a substantial body of evidence documenting high levels of psychological distress and mental health disorders among traumatised unaccompanied young refugees. Several evidence-based treatments, such as trauma-focused cognitive behavioural therapy and manualised low-threshold interventions (eg, the group intervention Mein Weg), have shown efficacy across different refugee samples. However, the overall quality of evidence regarding stepped care approaches was low. Only 12 studies evaluated stepped care models, and those specific to young refugees frequently showed a high risk of bias due to uncontrolled study designs, small sample sizes, non-manualised or insufficiently described interventions, and short follow-up periods. To our knowledge, only one randomised controlled trial, also conducted in Germany, has directly compared a stepped care approach with treatment as usual in this population, finding no significant difference in effectiveness between conditions. However, this trial did not use manualised, evidence-based interventions.

Added value of this study

To our knowledge, this study is the first cluster-randomised controlled trial examining the effectiveness of a stepped care approach in unaccompanied young refugees in which the components were manualised evidence-based interventions examined specifically among refugee youth. Further added value of this study stems from the randomised controlled design and the considerably larger sample compared with previous studies, which is sufficiently powered to depict small treatment effects. Small effects are expected in naturalistic settings but might still have great clinical relevance due to high treatment needs.

Implications of all the available evidence

A stepped care model for unaccompanied young refugees in high-income countries, including screening, prevention, and gold-standard intervention, is effective in reducing post-traumatic stress symptoms and depressive symptoms, even under difficult post-migration conditions and with a high dropout rate. Improvements in the enhanced usual care group highlight the potential benefits of unaccompanied young refugees being cared for by social workers and receiving structured care recommendations. High dropout rates due to external factors should be considered in the unaccompanied young refugee population in future trials. Mental health literacy and stigma should also be addressed in this population to improve service use and treatment retention.

to chronic symptoms, impaired acculturation, and developmental difficulties.[2,3] Although this high number of mental health problems warrants treatment, multiple barriers to treatment hamper access and use, which can be subsumed as demand-side barriers (eg, poor understanding of mental health among unaccompanied young refugees) and supply-side barriers (eg, language barriers).[4] Accordingly, meta-analyses on the treatment of unaccompanied young refugees are unavailable due to such studies being few in number and small in size.[5–7] Quantitative reviews on young refugees in general reported medium-to-large effects for treatment for PTSS.[8–10] Although several effective treatment protocols for unaccompanied young refugees are available, few treatment providers offer them to these young people in practice.[4,5]

Stepped care approaches have been proposed for the treatment of traumatised refugees, offering tailored interventions based on individual distress levels instead of a one-size-fits-all approach. Given cultural differences and disparate conceptualisations of mental illness, comprehensive screening facilitates symptom identification and treatment initiation.[11] Stepped care is resource-efficient and improves treatment access, but, globally, this approach remains infrequently implemented.[6,7] The infrequent use of this approach might be due to the complex nature of such care, requiring extensive funding, time-intensive interprofessional coordination, and patient and provider adherence, which might challenge implementation.

Evidence on the effectiveness and feasibility of stepped care approaches remains insufficient. Studies of existing models of care for unaccompanied young refugees are scarce and methodologically inadequate—often lacking control groups, standardised interventions, and adequate follow-up[12,13]—and there are few good examples of stepped care models for traumatised refugee children and adolescents.[8,9] As stepped care models have not yet been evaluated in unaccompanied young refugees, the use of evidence-based interventions is essential. The

model in this study, therefore, relies exclusively on well-validated treatments.

Group-based interventions are commonly used to provide low-threshold support in educational and community settings. However, few have been rigorously evaluated in young refugees, with some evidence for the Mental Health for Immigrants Program and Cognitive Behavioral Intervention for Trauma in Schools[14] and uncertain evidence for the Effectiveness of the Early Adolescent Skills for Emotions intervention.[15] Strong evidence exists for the preventive group intervention Mein Weg (translating as My Way),[16] a programme specifically developed for unaccompanied young refugees that has been shown to be effective in a randomised controlled trial within German child and youth welfare service (CYWS) facilities.[16]

Trauma-focused cognitive behavioural therapy (TF-CBT) according to Cohen and colleagues[17] has the strongest evidence base regarding individual treatment for unaccompanied young refugees. TF-CBT is the most extensively studied intervention for paediatric PTSD and is recommended by several guidelines.[18] The efficacy of this therapy within the German health-care system has been shown in a randomised controlled trial involving eight outpatient clinics,[19] and its feasibility for unaccompanied young refugees has been confirmed.[20] With the exception of one alternative,[21] this therapy remains the only individual PTSD treatment to have been evaluated in unaccompanied young refugees.

Given the effectiveness of Mein Weg within German CYWS facilities[16] and of TF-CBT in the German health-care system,[19] as well as the feasibility of TF-CBT for unaccompanied young refugees,[20] we developed the BETTER CARE stepped care approach. This approach comprises screening for PTSS, depression, and anxiety with treatment referral, recommending Mein Weg for unaccompanied young refugees with subclinical symptoms and individual TF-CBT by trained community therapists for those with PTSD. BETTER CARE was implemented within the routine care provided by CYWS facilities and health services in Germany. In this implementation and dissemination trial, we compared BETTER CARE with enhanced usual care, with the aim of examining improvement in PTSS as a primary outcome and improvements in depression, anxiety, and quality of life as secondary outcomes.

Methods

Study design and participants

This cluster-randomised controlled type I hybrid implementation–effectiveness trial compared two active conditions, BETTER CARE and enhanced usual care, and was conducted in CYWS facilities accommodating unaccompanied young refugees throughout seven German states. In the BETTER CARE condition, participants could be treated with the group intervention Mein Weg or with TF-CBT.

Assessments and interventions were conducted in a naturalistic setting. The screening and implementation process was coordinated by mental health coordinators, primarily CYWS facility-appointed staff members (ie, mainly social workers), who were responsible for communication, scheduling, and preparation of the screenings in consultation with the research team. Interventions were delivered by CYWS facility staff members (Mein Weg) and community-based therapists (TF-CBT). A detailed overview of the care situation (including living situation) and legal protection for unaccompanied young refugees in Germany is provided in the appendix (pp 63–64).

See Online for appendix

Inclusion criteria for CYWS facilities were accommodation of at least five eligible unaccompanied young refugees interested in study participation, willingness to participate in screenings, appointment of at least one mental health coordinator, commitment to implement Mein Weg if assigned to BETTER CARE, commitment to provide a caregiver (ie, a CYWS facility staff member) to participate in TF-CBT sessions, and availability of at least one eligible therapist within a 1-h travel radius. Therapist inclusion criteria were licensure (child and adolescent psychotherapist, psychological psychotherapist, or child and adolescent psychiatrist); willingness to participate in TF-CBT training and case consultations; written informed consent; and willingness to treat up to three participants. No exclusion criteria were applied.

Eligibility criteria for unaccompanied young refugees were age 12–20 years; arrival in Germany as an unaccompanied minor (ie, younger than 18 years); asylum application or intention; in CYWS facility care at baseline; written informed consent provided by the unaccompanied young refugee or their legal guardian (for unaccompanied young refugees younger than 16 years, who also provided consent); and at least one self-reported traumatic event. No exclusion criteria were applied. Eligibility for TF-CBT required a diagnosis of PTSD or any mental disorder according to ICD-10 confirmed by the therapist. Exclusion criteria for TF-CBT included acute danger to oneself or others, acute psychosis, acute suicidality, severe substance abuse, or severe mental disability.

The study was approved by the institutional review boards of the involved universities (Catholic University Eichstätt-Ingolstadt, approval number 004-19; Ulm University, approval number 243/19 – FSt/Sta) and was registered in the German Clinical Trials Register (registration number DRKS00017453). The study protocol is provided in the appendix (pp 1–41).

Randomisation and masking

Clusters were randomly assigned after the initial information meeting with the CYWS facilities and completion of baseline screening of participants in the respective facility. Randomisation was done by the

Institute of Epidemiology and Medical Biometry of Ulm University using a stratified permuted blocks design, with clusters being stratified by facility size (ie, number of unaccompanied young refugees; large [n>20] and small [n≤20]). Facilities were then randomly assigned (1:1) to either BETTER CARE or enhanced usual care using permuted blocks, with block sizes of four and six for small clusters and a block size of two for large clusters (appendix p 30). Masking of participants was not possible due to each CYWS facility being randomly assigned to a specific treatment arm. Study personnel were also not masked to the condition, but all data were self-reported and study personnel remained masked to data entry. All unaccompanied young refugees within a CYWS facility and all therapists assigned to that facility were allocated to the same condition.

Procedures

After CYWS facilities expressed interest in the trial, mental health coordinators within those facilities were informed about the study procedures via telephone or online meetings, and cooperation agreements were signed by facility heads and principal investigators. Baseline screening (T0) was conducted on site by the research team and coordinators. The participants provided written informed consent and completed self-report questionnaires on sociodemographic characteristics, psychological outcomes, and quality of life (by use of paper and pencil or digital assessment via tablet). In cases of illiteracy or comprehension difficulties, language mediators were involved. Caregivers at the CYWS facilities provided proxy PTSS ratings. If suicidal ideations were apparent in the self-reports, a structured clinical interview (Columbia Suicide Severity Rating Scale) was conducted by the research team. Participants received a €30 voucher for participation at every assessment timepoint. After screening was complete, random assignment outcomes were communicated to mental health coordinators via post and telephone. At every assessment timepoint, individual screening summaries with treatment recommendations were sent in sealed envelopes to the mental health coordinators, who gave them directly to participants; caregivers were present to explain the summaries and help with planning the next steps. Follow-up screenings were conducted at 6 months (T1) and 12 months (T2; primary endpoint) after baseline in both study groups. In both conditions, recommendations were based on Child and Adolescent Trauma Screen (CATS-2)[22] scores for PTSS; in BETTER CARE, the Mein Weg preventive group programme was recommended for individuals with subclinical PTSS (CATS-2 sum score 16–24) and individual TF-CBT therapy was recommended for those with clinically elevated PTSS (CATS-2 sum score ≥25). In enhanced usual care, treatment recommendations were non-specific (ie, a preventive group programme or individual therapy). For the enhanced usual care condition, screenings and written reports with treatment recommendations served as the enhanced care component; no further interventions were provided by the study, and these CYWS facilities were referred to the general German health-care system, which includes community therapists and psychiatric services, usually paid for by general health insurance. Participants in the BETTER CARE group with a CATS-2 sum score of 25 or higher who declined TF-CBT or could not begin TF-CBT within 3 months were offered Mein Weg. Conversely, if CYWS facilities perceived that individuals required more intensive treatment than had been indicated in the screening, eligibility for TF-CBT could be re-examined by the corresponding therapist. The recommendations were not binding—ie, participants could choose not to pursue any intervention as well as to step up or step down interventions. This flexibility was deemed necessary to accommodate the complex needs of unaccompanied young refugees in the real-world setting and ensure adequate access to care. For CATS-2 sum scores lower than 16, only continued follow-ups were recommended in both conditions.

Serious adverse events were monitored by mental health coordinators and regularly reported to and discussed with an independent Data and Safety Monitoring Board consisting of three experts in the field of clinical psychology (appendix p 3). Serious adverse events were defined in line with Good Clinical Practice guidelines and were assessed at baseline, T1, and T2. Any serious adverse events occurring before, after, or between screening appointments were to be reported by the coordinators to the study centre immediately (within 2 working days; appendix p 32).

The manualised group intervention Mein Weg consisted of six to eight sessions, each lasting 90–120 min, covering psychoeducation, relaxation, trauma narrative, and cognitive restructuring (appendix pp 19–20).[16] Mein Weg was delivered by specifically trained and supervised social workers in CYWS facilities (some of these social workers were also the mental health coordinators in the study). Within the BETTER CARE project, two to three sessions on asylum-related problem management were added if necessary. CYWS facilities' staff members completed 2 days of training (in person or online) led by certified trainers and received weekly case consultations during implementation (via telephone).

TF-CBT, a manualised individual therapy, usually comprises 12–15 parallel sessions of 50 min each for the patient and caregiver. The treatment manual includes psychoeducation and parenting skills, relaxation, affect modulation, cognitive coping, a trauma narrative, in-vivo exposure, conjoint parent–child sessions, and enhancement of safety and development.[17] In the context of the BETTER CARE project, three additional sessions addressed relapse prevention and problem management related to asylum stressors (appendix p 20). Community therapists completed a self-paced web-based training

For the **online TF-CBT training programme** see http://tfkvt.ku.de

programme (provided by Catholic University Eichstätt-Ingolstadt), enriched by cultural adaptations, and a 2-day online workshop led by certified trainers specialised in working with refugees; during implementation, therapists also received biweekly online case consultations with supervisors experienced in working with refugees. Trained interpreters were included in the TF-CBT sessions when needed.[23]

Some adaptations were required because of the COVID-19 pandemic. At the outset of the BETTER CARE project, the pandemic caused a substantial delay in the project plan due to factors such as travel restrictions, staffing shortages, and increased workload in CYWS facilities. Additionally, arrivals of unaccompanied young refugees decreased substantially,[24] and, as refugees grew older and left the CYWS facilities (programmes normally end at age 18 years), many CYWS facilities closed or shifted focus. To address these challenges, several protocol adaptations were implemented: the minimum number of unaccompanied young refugees per facility was reduced from ten to five; recruitment was expanded from Bavaria and Baden-Württemberg to five additional German states (Hesse, Thuringia, Rhineland-Palatinate, North Rhine-Westphalia, and Berlin); inclusion of newly arrived unaccompanied young refugees at participating CYWS facilities during implementation (ie, after other participants had started their intervention) was permitted; and all in-person activities, including trainings, meetings, screenings, and TF-CBT, were made available online—remote formats for screening and treatment were used only when necessary.

To address the supply-side barriers, funding for treatment as well as the search for community therapists willing to treat unaccompanied young refugees and interpreters in each region were provided by the research team. In 21 of the cases that started with TF-CBT, costs were reimbursed through the project. Moreover, therapists, interpreters, and mental health coordinators were specifically trained to support and provide the BETTER CARE interventions. Demand-side barriers were addressed by the research team offering information on mental health, therapy, and stigma in various languages, as well as individual telephone calls for hesitant individuals. Mental health coordinators and caregivers were also encouraged to explain and advocate for the interventions.

PTSS, depressive symptoms, anxiety symptoms, and quality of life were assessed using existing scales at baseline, T1 and T2 (appendix pp 22–23). CATS-2[22] explores individual trauma histories in children and adolescents by means of a 15-item event checklist of potentially traumatic events and identifies the traumatic event most bothersome to the individual. Additionally, PTSS according to diagnostic criteria in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) is self-reported by means of 20 items ranging from 0 (never) to 3 (almost always), and functional impairment is self-reported with five dichotomous items. A parallel caregiver version is included. The Patient Health Questionnaire-9 (PHQ-9)[25] is a nine-item depression rating scale based on diagnostic criteria in the DSM-IV (still meeting present standards as the core criteria did not change in DSM-5). The total score (0–27) indicating the degree of impairment over the previous 2 weeks is derived by adding up the item scores, with items ranging from 0 (not at all) to 3 (nearly every day). The Generalized Anxiety Disorder (GAD-7)[26] is a seven-item GAD rating scale. The total score (0–21) indicating the degree of impairment over the previous 2 weeks is derived by adding up the item scores, with items ranging from 0 (not at all) to 3 (nearly every day). The WHO quality of life self-report instrument WHOQOL-BREF[27] is a 26-item quality-of-life scale, assessing four domains (physical health, psychological health, social relationships, and environment) over the previous 4 weeks. The 26 items range from 1 (very poor or dissatisfying; not at all, never) to 5 (very good or satisfying; an extreme amount, extremely, completely, always), and domain scores can be derived by multiplying the mean score of the respective scale by four.

Existing validated versions of the questionnaires were used when possible; otherwise, the questionnaires were translated, backtranslated, and proofread by two independent professional translation agencies for the 12 most commonly spoken languages among unaccompanied young refugees in Germany (Arabic, Dari, English, Farsi, French, German, Kurmanji, Pashto, Russian, Somali, Tigrinya, and Ukrainian). Implementation measures are detailed in the appendix (pp 55–61).

Outcomes

The primary outcome was a reduction in PTSS, analysed in the intention-to-treat sample; reduction in PTSS was also analysed as a secondary outcome for the per-protocol sample. Additional secondary outcomes were reduction in depressive symptoms and symptoms of anxiety, as well as changes in quality of life (encompassing physical, psychological, social and environmental domains), analysed in both the intention-to-treat sample and per-protocol sample.

Statistical analysis

Sample size estimation was carried out in two separate steps, given the hierarchical structure assumed for the data (appendix p 16). With no previous data on effectiveness of stepped care approaches for unaccompanied young refugees available, power analysis was based on effect sizes from previous studies (appendix p 16) concerning the Mein Weg intervention and TF-CBT. Effect sizes (Cohen's *d*) of 0·2 for Mein Weg and 0·5 for TF-CBT were assumed, due to the controlled study setting. Comparing the conditions BETTER CARE and enhanced usual care, we expected a small effect (Cohen's

d>0·30) in favour of the BETTER CARE condition. Power analyses showed that a total sample size of 540 participants was needed. An intraclass correlation coefficient of 0·05 for the outcome measure of participants within facilities was assumed. Additionally, study dropout rates (ie, participants who did not continue screenings) of 20% of participants within facilities and 10% of whole facilities were assumed and incorporated into the analyses (pp 16–17).

The intention-to-treat sample consisted of all randomly assigned participants. The per-protocol sample for the control group consisted of all randomly assigned participants who provided data at the baseline measurement and 12-month follow-up and, for the treatment group (BETTER CARE), consisted of all randomly assigned participants who followed the treatment recommendation received at baseline or 6-month follow-up and completed at least one of the indicated interventions within the 12-month study period. Completion required participants to partake in at least five group sessions for Mein Weg and at least eight sessions, including a trauma narrative, for TF-CBT.

For the primary and secondary outcomes, we used the lme4 package in R (version 4.4.3) to conduct linear mixed-effects model analyses of the intention-to-treat sample to account for the data structures of participants being nested within CYWS facilities (appendix p 31). In an iterative model-building process, the base model consisted of the fixed effects of treatment and time as a factor, as well as their interaction term over the three timepoints (baseline, 6 months, and 12 months), and random effects for facility and participant clusters; the expanded final model incorporated additional fixed effects for age, gender, and asylum status, which were associated with missingness, to ensure valid likelihood-based estimation under the missing at random mechanism (appendix p 32). To assess the main hypothesis, a two-sided *t*-test with Satterthwaite-approximated degrees of freedom and α value of 0·05 were used for the treatment over time interaction effect. The same analytic strategy was used for analyses of secondary outcomes and of the per-protocol sample. Missing values were not imputed. Effect sizes for change over time between groups were calculated on the basis of comparison of within-group mean differences (standardised mean difference in change scores),[28] allowing for a precise estimation of effect size by accounting for the pre–post design.

Results

The study was conducted between Oct 14, 2019, and July 27, 2023, with a total of 1601 CYWS facilities assessed for eligibility and 58 (11%) of 525 eligible facilities deciding to participate (figure; an extended study flowchart is provided in the appendix [p 67]). 627 participants from these 58 facilities were screened for eligibility, and all were enrolled. Fifteen participants who did not report a traumatic event were randomly assigned incorrectly but were included in the analysis. 29 CYWS facilities were randomly allocated to BETTER CARE and 29 to enhanced usual care, resulting in 324 unaccompanied young refugees in the BETTER CARE group and 303 in the enhanced usual care group. All 58 CYWS facilities and 627 unaccompanied young refugees were included in the intention-to-treat analyses. The observed differences in the sample sizes allocated to each condition were within the expected range and a result of the varying size of the CYWS facilities. No significant difference in the number of participants enrolled per CYWS facility was found between conditions (t[56]=0·3, 95% CI −3·2 to 4·6; p=0·71). Reasons for facilities to be excluded are reported in the appendix (p 55). The internal consistency for the primary and secondary outcome measures was good (ω=0·84 to ω=0·92) for all questionnaires except the WHOQOL-BREF, for which internal consistency ranged from poor to acceptable (ω=0·55 to ω=0·78). Participants reported a mean of six traumatic events (SD 3·3). 270 (43%) unaccompanied young refugees had clinically elevated levels of PTSS, and 357 (57%) were below the clinical threshold for PTSS (based on CATS-2 scores).

Dropout rates at T1 were 23% (n=75) in the BETTER CARE group and 29% (n=88) in the enhanced usual care group (figure). Dropout at T2 compared with baseline was 38% (n=124) in the BETTER CARE group and 43% (n=131) in the enhanced usual care group. Participants who did not participate at T1 were significantly older (p<0·010) and more likely to identify as gender diverse (p<0·010) than those who did participate at T1. Reasons for dropout were mostly external (163 [64%] of 255 dropouts), with the most common being participants moving out of the CYWS facility without leaving any contact information (137 [54%]). However, participants feeling a loss of motivation or too much stress (84 [33%]) were also notable reasons. Dropout did not significantly differ between treatment groups (χ^2 [1, N=627]=1·60; p=0·21; appendix p 46).

569 (91%) of the 627 participants identified as male, and 53 (8%) as female, with five (1%) identifying as gender diverse; mean age was 16·7 years (SD 1·3; table 1). Participants originated from 40 countries, with most coming from Afghanistan (269 [43%]), Syria (106 [17%]), and Somalia (43 [7%]). 554 (88%) participants lived in a residential CYWS setting at the time of their baseline assessment and had spent a mean of 16·2 months (SD 18·5; range 0–112 months) in Germany before the assessment; 401 (64%) were indicated to be in contact with their family in the country of origin at least monthly. The per-protocol sample was considerably smaller than the intention-to-treat sample due to dropout, non-compliance with treatment recommendation, and late completion of treatment (figure, table 1).

In the BETTER CARE condition, 127 CYWS facility workers completed the training for the intervention Mein

Weg, and 83 therapists completed TF-CBT training. Between baseline assessment and 12-month follow-up, 24 Mein Weg groups were initiated by 42 trained CYWS facility workers, and 84 (26%) of the 324 participants in the intervention group started Mein Weg. As participants were allowed to step up and step down interventions, six (2%) participants were able to complete both interventions (figure). 50 (15%) participants completed

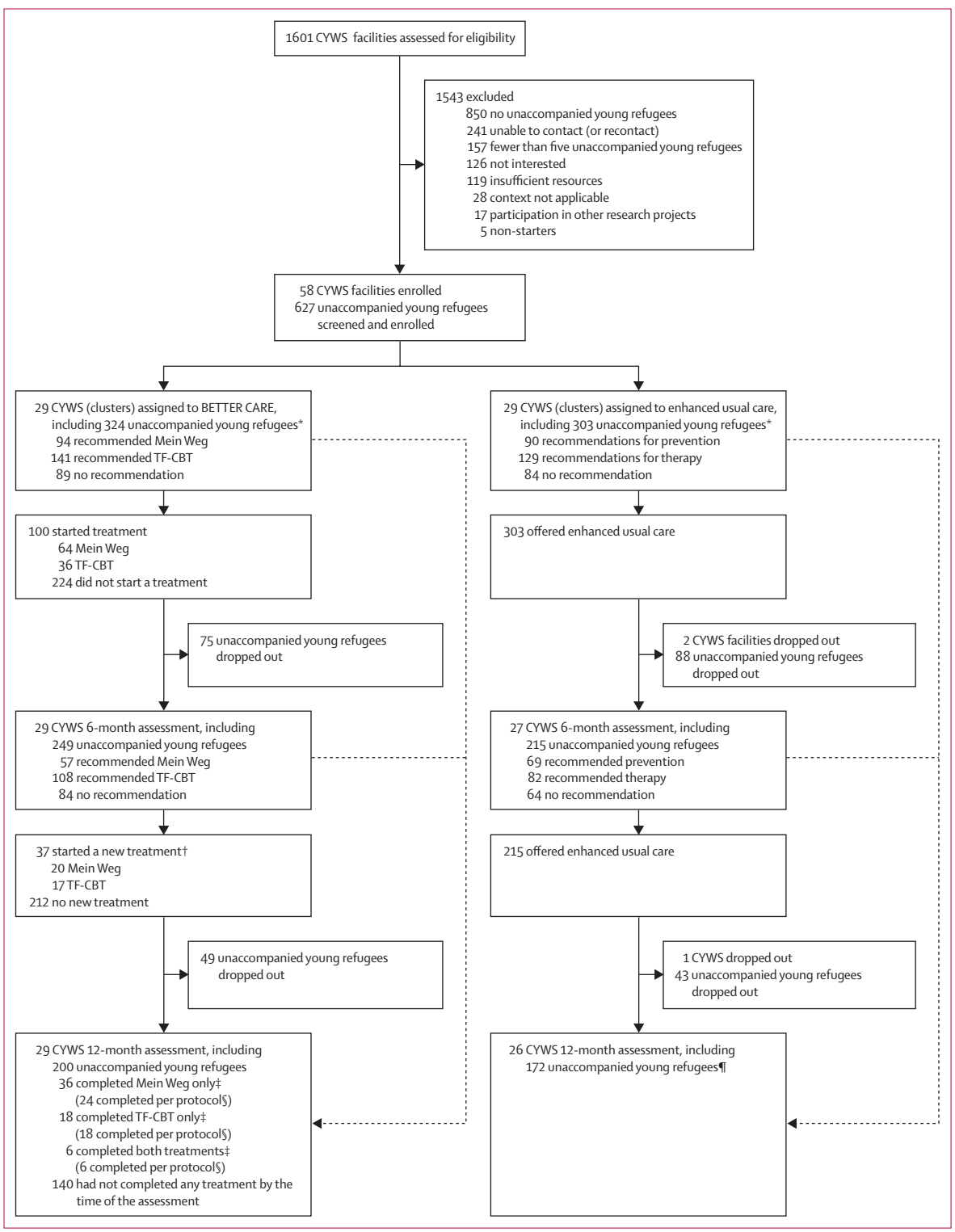

Figure: **Study profile**
Participants in the BETTER CARE group were able to step up and step down between treatments, and six received both treatments. Participants with CATS-2 sum scores lower than 16 received recommendations to continue follow-ups only (ie, no treatment recommendation). An extended study flowchart is provided in the appendix (p 67). CYWS=child and youth welfare service. TF-CBT=trauma-focused cognitive behavioural therapy. *Intention-to-treat sample. †Only participants receiving a new treatment after the 6-month assessment point (ie differing from one they received previously, including no treatment) are shown. ‡11 additional individuals completed an intervention within the 12-month study period but did not participate in the 12-month assessment (eight Mein Weg and three TF-CBT). §Per-protocol intervention sample. ¶Per-protocol control sample.

	Total (N=627)	BETTER CARE group (n=324)	Enhanced usual care group (n=303)	Per-protocol sample, Mein Weg (n=30)	Per-protocol sample, TF-CBT (n=24)
Age, years	16·7 (1·3)	16·7 (1·3)	16·7 (1·3)	16·8 (1·3)	16·3 (1·0)
Gender					
Male	569 (91%)	293 (90%)	276 (91%)	26 (87%)	19 (79%)
Female	53 (8%)	29 (9%)	24 (8%)	4 (13%)	5 (21%)
Diverse	5 (1%)	2 (1%)	3 (1%)	0	0
Country of origin*					
Afghanistan	269 (43%)	152 (47%)	117 (39%)	15 (50%)	13 (54%)
Syria	106 (17%)	51 (16%)	55 (18%)	3 (10%)	2 (8%)
Somalia	43 (7%)	19 (6%)	24 (8%)	4 (13%)	3 (13%)
Iraq	24 (4%)	14 (4%)	10 (3%)	1 (3·%)	0
Iran	23 (4%)	9 (3%)	14 (5%)	1 (3%)	0
Other	162 (26%)	79 (24%)	83 (27%)	6 (20%)	6 (25%)
Religious beliefs					
No belief	34 (5%)	18 (6%)	16 (5%)	0	0
Islam	539 (86%)	282 (87%)	257 (85%)	26 (87%)	23 (96%)
Christian	33 (5%)	10 (3%)	23 (8%)	3 (10%)	1 (4%)
Other	18 (3%)	12 (4%)	6 (2%)	1 (3%)	0
Missing	3 (1%)	2 (1%)	1 (1%)	..	..
Time in Germany, months	16·2 (18·5)	15·8 (19·2)	16·7 (18·0)	13·2 (10·2)	8·4 (4·4)
Type of welfare facility					
Outpatient care	72 (11%)	39 (12%)	33 (11%)	3 (10%)	1 (4%)
Residential care	554 (88%)	284 (88%)	270 (89%)	27 (90%)	23 (96%)
Missing	1 (1%)	1 (1%)	..	..	..
Asylum status					
Secure	120 (19%)	60 (19%)	60 (20%)	5 (17%)	2 (8%)
Insecure	507 (81%)	264 (81%)	243 (80%)	25 (83%)	22 (92%)
Active schooling					
Yes	552 (88%)	285 (88%)	267 (88%)	27 (90%)	23 (96%)
No	73 (12%)	38 (12%)	35 (12%)	3 (10%)	1 (4%)
Missing	2 (1%)	1 (1%)	1 (1%)	..	..
Employed					
Yes	90 (14%)	45 (14%)	45 (15%)	2 (7%)	1 (4%)
No	535 (85%)	278 (86%)	257 (85%)	28 (93%)	23 (96%)
Missing	2 (1%)	1 (1%)	1 (1%)	..	..
In contact with family					
No	162 (26%)	72 (22%)	90 (30%)	6 (20%)	7 (29%)
Once a year or less	29 (5%)	16 (5%)	13 (4%)	3 (10%)	3 (13%)
Several times a year	34 (5%)	19 (6%)	15 (5%)	3 (10%)	1 (4%)
Monthly	123 (20%)	72 (22%)	51 (17%)	7 (23%)	7 (29%)
Weekly	173 (28%)	84 (26%)	89 (29%)	9 (30%)	4 (17%)
Daily	105 (17%)	60 (19%)	45 (15%)	2 (7%)	2 (83%)
Missing	1 (1%)	1 (1%)	..	..	..
Clinical characteristics					
Trauma load*					
Self	6·0 (3·3)	6·1 (3·4)	6·0 (3·2)	5·9 (2·7)	8·5 (2·7)
Proxy	4·6 (2·7)	4·6 (2·6)	4·6 (2·9)	4·6 (2·6)	5 (2·9)
CATS-2 score					
Self	23·5 (12·3)	24·1 (12·6)	22·9 (11·9)	25·6 (11·2)	36·0 (8·6)
Proxy	17·2 (10·5)	16·8 (9·8)	17·8 (11·3)	15·8 (11·9)	18·3 (10·9)
PHQ-9 score	8·6 (5·9)	8·9 (6·2)	8·2 (5·5)	9·1 (5·8)	13·7 (6·3)
GAD-7 score	8·6 (5·9)	7·1 (5·6)	6·6 (5·1)	7·1 (5·2)	11·4 (4·8)

(Table 1 continues on next page)

	Total (N=627)	BETTER CARE group (n=324)	Enhanced usual care group (n=303)	Per-protocol sample, Mein Weg (n=30)	Per-protocol sample, TF-CBT (n=24)
(Continued from previous page)					
WHOQOL-BREF					
Physical	66·1 (18·6)	65·9 (19·7)	66·2 (17·4)	69·5 (21·4)	60 (13·6)
Psychological	60·2 (20·6)	59·2 (21·6)	61·5 (19·4)	64·2 (23·1)	51·3 (17·5)
Social	66·2 (22·6)	66·8 (22·2)	65·6 (23·1)	69·9 (21·9)	57·9 (20·4)
Environmental	59·5 (17·6)	59·6 (17·8)	59·4 (17·4)	66·6 (17·9)	61·9 (15·3)

Data are mean (SD) or n (%). Percentages might not add up to 100% due to rounding. Gender was assessed as a three-level variable; sex was not assessed within this study. CATS-2=20-item Child and Adolescent Trauma Screen. PHQ9=nine-item Patient Health Questionnaire. GAD-7=seven-item Generalized Anxiety Disorder questionnaire. TF-CBT=trauma-focused cognitive behavioural therapy. WHOQOL-BREF=26-item WHO Quality of Life questionnaire. *Assessed with a 15-item checklist for potentially traumatic events (part of CATS-2).

Table 1: **Baseline characteristics of the intention-to-treat and per-protocol samples**

	Control group				Treatment group (intention-to-treat sample)				Linear mixed model		Between-group effect size, *d* (95% CI)*
	Participants, n	Raw mean (SD)	Estimated mean (SE)	Estimated change (SE)	Participants, n	Raw mean (SD)	Estimated mean (SE)	Estimated change (SE)	Treatment effect (95% CI)†	p value	
CATS-2											
Baseline	303	22·9 (11·9)	..	..	324	24·1 (12·6)	..	..	..	..	..
6 months	215	21·7 (11·4)	25·0 (1·9)	−0·09 (0·4)	249	21·8 (11·8)	25·1 (1·8)	−0·1 (0·3)	−1·40 (−3·28 to 0·48)	0·14	−0·09 (−0·26 to 0·07)
12 months	172	20·7 (9·8)	24·5 (1·9)	−0·5 (0·4)	200	19·8 (10·9)	23·3 (1·8)	−1·8 (0·4)	−2·69 (−4·73 to −0·64)	0·010	−0·17 (−0·34 to −0·004)
PHQ-9											
Baseline	303	8·2 (5·5)	..	..	324	9·0 (6·2)	..	..	..	..	..
6 months	214	7·5 (5·3)	8·6 (0·9)	−0·3 (0·2)	248	7·9 (5·8)	9·2 (0·9)	−0·1 (0·2)	−0·39 (−1·44 to 0·66)	0·46	−0·05 (−0·23 to 0·11)
12 months	172	8·0 (5·2)	9·1 (0·9)	0·1 (0·2)	200	7·3 (5·6)	8·7 (0·9)	−0·6 (0·2)	−1·40 (−2·53 to −0·26)	0·016	−0·23 (−0·42 to -0·05)
GAD-7											
Baseline	302	6·6 (5·1)	..	..	322	7·1 (5·6)	..	..	..	..	..
6 months	214	6·0 (4·6)	6·9 (0·8)	−0·1 (0·2)	248	6·3 (4·8)	7·4 (0·8)	−0·009 (0·1)	−0·18 (−1·07 to 0·72)	0·69	−0·03 (−0·19 to 0·12)
12 months	172	6·0 (4·7)	7·0 (0·8)	−0·1 (0·2)	200	5·5 (4·6)	6·8 (0·8)	−0·5 (0·2)	−0·77 (−1·74 to 0·20)	0·11	−0·18 (−0·36 to −0·005)
WHOQOL-BREF											
Physical											
Baseline	266	66·3 (17·4)	..	..	277	65·9 (19·7)	..	..	..	..	..
6 months	195	68·3 (17·9)	67·7 (2·8)	1·1 (0·8)	221	68·2 (17·6)	67·4 (2·8)	0·5 (0·7)	0·13 (−3·45 to 3·71)	0·94	0·01 (−0·17 to 0·19)
12 months	157	66·9 (17·2)	65·9 (2·9)	−0·5 (0·8)	188	68·7 (16·8)	67·6 (2·8)	0·7 (0·8)	2·05 (−1·78 to 5·89)	0·29	0·11 (−0·08 to 0·30)
Psychological											
Baseline	266	61·5 (19·4)	..	..	277	59·2 (21·6)	..	..	..	..	..
6 months	195	63·3 (19·7)	55·1 (3·1)	0·1 (0·8)	221	63·4 (19·1)	55·1 (3·0)	0·8 (0·7)	1·79 (−1·94 to 5·51)	0·34	0·11 (−0·06 to 0·29)
12 months	157	64·6 (18·9)	56·0 (3·1)	1·1 (0·9)	188	64·4 (18·3)	55·8 (3·1)	1·6 (0·8)	1·59 (−2·40 to 5·59)	0·43	0·09 (−0·09 to 0·29)
Social											
Baseline	266	65·6 (23·1)	..	..	277	66·8 (22·2)	..	..	..	..	..
6 months	195	66·2 (22·2)	57·5 (3·4)	0·003 (0·9)	221	67·3 (20·5)	59·2 (3·3)	−0·6 (0·9)	0·24 (−4·10 to 4·54)	0·91	−0·01 (−0·19 to 0·17)
12 months	157	66·3 (20·9)	57·5 (3·4)	−0·07 (1·0)	188	69·6 (20·2)	61·1 (3·4)	1·3 (0·9)	2·30 (−2·34 to 6·92)	0·33	0·09 (−0·10 to 0·28)
Environmental											
Baseline	266	59·4 (17·4)	..	..	277	59·6 (17·9)	..	..	..	..	..
6 months	195	58·8 (17·7)	54·8 (2·8)	−0·4 (0·7)	221	58·9 (18·3)	54·6 (2·8)	−1·1 (0·6)	−0·46 (−3·77 to 2·85)	0·78	0·00 (−0·20 to 0·19)
12 months	157	60·0 (16·7)	55·7 (2·8)	0·4 (0·8)	188	61·8 (16·4)	57·1 (2·8)	1·3 (0·7)	1·07 (−2·48 to 4·62)	0·55	0·09 (−0·10 to 0·29)

CATS-2=20-item Child and Adolescent Trauma Screen. PHQ-9=nine-item Patient Health Questionnaire. GAD-7=seven-item Generalized Anxiety Disorder questionnaire. WHOQOL-BREF=26-item WHO Quality of Life questionnaire. *Standardised mean difference in change based on the difference in pre–post raw mean change between groups, standardised by the pooled pretest SD. 95% CIs were computed using post-test SDs and post-test sample sizes to account for attrition between baseline and 12-month follow-up; negative values are in favour of the treatment group. †Group × time interaction effect on original scale 6 months or 12 months after baseline, with age, gender, and asylum status as fixed effects and facility and participant levels as random effects.

Table 2: **Raw and estimated means, treatment effects, and effect sizes for primary and secondary outcomes in the linear mixed model based on the intention-to-treat sample**

	Control group (per-protocol sample)				Treatment group (per-protocol sample)				Linear mixed model		Between-group effect size, *d* (95% CI)*
	Participants, n	Raw mean (SD)	Estimated mean (SE)	Estimated change (SE)	Participants, n	Raw mean (SD)	Estimated mean (SE)	Estimated change (SE)	Treatment effect (95% CI)†	p value	
CATS-2											
Baseline	303	22·9 (11·9)	..	..	48	30·0 (11·6)	..	..	..	..	..
6 months	215	21·7 (11·4)	23·6 (2·2)	−0·1 (0·4)	47	28·6 (10·4)	29·9 (2·7)	1·2 (0·8)	−0·36 (−3·66 to 2·95)	0·83	−0·02 (−0·30 to 0·26)
12 months	172	20·7 (9·8)	23·2 (2·2)	−0·5 (0·4)	48	23·9 (9·63)	25·1 (2·7)	−3·5 (0·8)	−4·74 (−8·05 to −1·42)	0·0054	−0·33 (−0·59 to −0·06)
PHQ-9											
Baseline	303	8·2 (5·5)	..	..	48	10·9 (6·5)	..	..	..	..	..
6 months	214	7·5 (5·3)	8·9 (1·1)	−0·3 (0·2)	47	9·9 (5·3)	11·0 (1·3)	0·2 (0·5)	−0·24 (−2·08 to 1·61)	0·80	−0·03 (−0·33 to 0·25)
12 months	172	8·0 (5·2)	9·4 (1·1)	0·1 (0·2)	48	8·4 (5·6)	9·4 (1·3)	−1·3 (0·4)	−2·31 (−4·17 to −0·46)	0·015	−0·39 (−0·70 to −0·07)
GAD-7											
Baseline	302	6·6 (5·1)	..	..	47	8·9 (5·5)	..	..	..	..	..
6 months	214	6·0 (4·6)	7·3 (0·9)	−0·1 (0·2)	47	8·6 (4·8)	9·7 (1·1)	0·8 (0·4)	0·42 (−1·20 to 2·05)	0·61	0·06 (−0·23 to 0·35)
12 months	172	6·0 (4·7)	7·3 (0·9)	−0·1 (0·2)	48	6·2 (4·2)	7·3 (1·1)	−1·6 (0·4)	−2·03 (−3·66 to −0·40)	0·015	−0·40 (−0·67 to −0·12)
WHOQOL-BREF											
Physical											
Baseline	266	66·3 (17·4)	..	..	43	67·0 (19·2)	..	..	..	..	..
6 months	196	68·3 (17·9)	69·7 (3·5)	1·1 (0·7)	44	63·1 (17·3)	65·3 (4·2)	−2·6 (1·6)	−6·01 (−12·19 to 0·17)	0·058	−0·33 (−0·66 to −0·01)
12 months	157	66·9 (17·2)	68·0 (3·5)	−0·5 (0·8)	47	67·1 (15·4)	69·1 (4·2)	1·0 (1·6)	−0·58 (−6·76 to 5·61)	0·85	−0·03 (−0·32 to 0·25)
Psychological											
Baseline	266	61·5 (19·4)	..	..	43	59·5 (22·9)	..	..	..	..	..
6 months	195	63·3 (19·7)	57·0 (3·9)	0·2 (0·8)	44	58·3 (15·5)	52·7 (4·6)	−2·8 (1·7)	−3·58 (−10 to 2·83)	0·27	−0·15 (−0·42 to 0·11)
12 months	157	64·6 (18·9)	58·0 (3·9)	1·2 (0·9)	47	64·9 (15·3)	59·3 (4·6)	3·7 (1·6)	2·01 (−4·41 to 8·43)	0·54	0·11 (−0·15 to 0·37)
Social											
Baseline	266	65·6 (23·1)	..	..	43	66·0 (22·7)	..	..	..	..	..
6 months	195	66·2 (22·2)	60·6 (4·4)	0·05 (1·0)	44	60·6 (19·6)	55·7 (5·3)	−5·5 (2·1)	−6·36 (−14·29 to 1·56)	0·11	−0·26 (−0·55 to 0·02)
12 months	157	66·3 (20·9)	60·5 (4·4)	−0·03 (1·1)	47	70·7 (20·5)	66·0 (5·2)	4·7 (2·0)	4·06 (−3·88 to 11·98)	0·31	0·16 (−0·12 to 0·46)
Environmental											
Baseline	266	59·4 (17·4)	..	..	43	64·6 (17·8)	..	..	..	..	..
6 months	195	58·8 (17·7)	55·3 (3·5)	−0·4 (0·7)	44	57·3 (16·9)	54·3 (4·2)	−4·0 (1·4)	−6·91 (−12·46 to −1·37)	0·015	−0·38 (−0·70 to −0·06)
12 months	157	60·0 (16·7)	56·3 (3·5)	0·5 (0·7)	47	62·5 (15·4)	59·3 (4·1)	0·9 (1·4)	−2·94 (−8·50 to 2·60)	0·30	−0·15 (−0·44 to 0·14)

CATS-2=20-item Child and Adolescent Trauma Screen. PHQ-9=nine-item Patient Health Questionnaire. GAD-7=seven-item Generalized Anxiety Disorder questionnaire. WHOQOL-BREF=26-item WHO Quality of Life questionnaire. *Standardised mean difference in change based on the difference in pre–post raw mean change between groups, standardised by the pooled pretest SD. 95% CIs were computed using post-test SDs and post-test sample sizes to account for attrition between baseline and 12-month follow-up; negative values are in favour of the treatment group. †Group × time interaction effect on original scale 6 months or 12 months after baseline, with age, gender, and asylum status as fixed effects and facility and participant levels as random effects.

***Table 3*: Raw and estimated means, treatment effects, and effect sizes for primary and secondary outcomes in the linear mixed model based on the per-protocol sample**

Mein Weg, but eight of these participants did not undergo the 12-month assessment. 36 participants of the participants who underwent the 12-month assessment completed Mein Weg as their only treatment; six completed Mein Weg in addition to TF-CBT. 30 (9%) participants completed Mein Weg per protocol (as defined in the study protocol) as a sole treatment (24 participants) or in addition to TF-CBT (six). 53 (16%) unaccompanied young refugee participants enrolled in TF-CBT, which was conducted by 36 unique therapists. 27 (8%) participants completed TF-CBT, but three of these participants did not undergo the 12-month assessment. 24 (7%) completed this intervention per protocol as their only treatment (18) or in addition to Mein Weg (six). 48 (15%) participants completed any intervention per protocol.

The linear mixed-effects model of PTSS (CATS-2) in the intention-to-treat sample showed a significant time by treatment interaction at the 12-month timepoint (p=0·010), with a significant between-groups change over time effect size in favour of the intervention group (*d*=−0·17 [95% CI −0·34 to −0·004; table 2). In the per-protocol analysis, the interaction effect of treatment by time remained significant (p=0·0054) and produced a significant between-groups change over time effect size in favour of the intervention group (*d*=−0·33 [−0·59 to −0·06]; table 3).

The analysis of depressive symptoms (PHQ-9) also showed a significant interaction effect (p=0·01) over time at 12 months and produced a significant effect size (−0·23 [95% CI −0·42 to −0·05]) for the change in symptom severity scores at 12 months between groups,

favouring the intervention group (table 2). The analysis for anxiety symptoms (GAD-7) produced a non-significant treatment over time interaction (p=0·11) but a significant effect size (d=–0·18 [–0·36 to –0·005]) for the change in symptom severity between groups at 12 months, favouring the intervention group. In the per-protocol analysis, there was a significant interaction effect of treatment over time for both depressive symptoms (p=0·01) and anxiety symptoms (p=0·01), with significant effect sizes for the changes between groups favouring the per-protocol condition (d=–0·39 [–0·7 to –0·07] for depressive symptoms; d=–0·4 [–0·67 to –0·12] for anxiety). The four domains of the WHOQOL-BREF did not show significant treatment-over-time effects or significant effect sizes (tables 2, 3). Within-group pre–post effect sizes, analysis of missingness, intraclass correlation coefficient analysis, and sensitivity analyses are in the appendix (pp 47–54).

19 participants reported a total of 23 serious adverse events (11 events in the BETTER CARE group and 12 in the enhanced usual care group). For two serious adverse events, a causal relationship could not be ruled out. The number of serious adverse events did not differ significantly between groups (χ^2 [1, N=627]=0·15; p=0·70; table 4).

	BETTER CARE				Enhanced usual care*	
	Events in male participants	Male participants affected	Events in female participants	Female participants affected	Events in male participants	Male participants affected
Serious adverse event						
Unexpected hospitalisation (>7 days)	2	2	0	0	6	6
Failed suicide attempt	5	4	2	1	3	3
Event leading to death—suicide	0	0	0	0	0	0
Event leading to death—other causes	0	0	0	0	0	0
Life-threatening event	2	2	0	0	2	2
Event resulting in physical disability	0	0	0	0	1	1
Total	9	8	2	1	12	10
Response to serious adverse event						
None	2	2	1	1	0	0
Hospital admission	7	6	1	1	12	10
Study treatment interrupted	0	0	0	0	0	0
Therapy—non-pharmacological	0	0	0	0	0	0
Therapy—pharmacological	0	0	0	0	0	0
Other	0	0	0	0	0	0
Total	9	8	2	1	12	10
Consequences of serious adverse event						
Recovered	4	4	2	1	4	4
Improved	2	2	0	0	4	4
Recovered with sequelae	2	2	0	0	3	3
Not recovered	0	0	0	0	1	1
Fatal	0	0	0	0	0	0
Unknown	1	1	0	0	0	0
Total	9	8	2	1	12	10
Expectedness						
Expected	2	2	1	1	3	3
Unexpected	7	7	1	1	9	8
Total	9	8	2	1	12	10
Causality in relation to study treatment						
No causal relationship	7	7	2	1	12	10
Relationship cannot be ruled out	2	2	0	0	0	0
Causal relationship confirmed	0	0	0	0	0	0
Total	9	8	2	1	12	10

Data are n. Due to some individuals having more than one serious adverse event, the total number of affected participants can be lower than the column totals. Gender was assessed as a three-level variable; participants identifying as diverse did not report any serious adverse events. *No serious adverse events occurred in female participants in the enhanced usual care group.

Table 4: **Serious adverse events in the BETTER CARE and enhanced usual care groups, by participant gender**

Discussion

To our knowledge, this trial is the largest intervention study involving young refugees, particularly unaccompanied young refugees, and the first to implement and evaluate a stepped care approach in this heavily burdened group. Results indicate a small but significant effect for BETTER CARE compared with enhanced usual care in terms of PTSS improvement and a small-to-medium significant effect on depressive symptoms. Anxiety symptom severity decreased at endpoint in both conditions. No significant effects were found for quality of life. Per-protocol analysis showed effects consistent with the initial power calculations. These findings suggest that a stepped care approach with evidence-based components is effective for unaccompanied young refugees in high-income countries, without causing harms. The fact that participants in the enhanced usual care group also showed improvements compared with baseline highlights the potential benefit of screening and structured care recommendations.

Comparisons with existing reviews remain limited by the amount of previous evidence—ie, small numbers of unaccompanied young refugee samples, case reports, and cohort studies.[5–7] Meta-analyses of studies in young refugees report medium-to-large treatment effects, although studies rarely include unaccompanied refugees and are constrained by small sample sizes, paucity of follow-up, low certainty of evidence, and substantial heterogeneity.[8–10] A meta-analysis of prevention studies in young refugees[9] found only a small, non-significant effect on depressive symptoms. Quality of life, often proposed as a relevant outcome for unaccompanied young refugees, given the challenging living conditions of these

individuals, has been studied infrequently, yielding few results (limited by small sample sizes, few female participants, no control group, and changes contingent on asylum status),[7] which is in line with our findings. Considering that about 57% of unaccompanied young refugees in our sample scored below clinical thresholds for PTSS at baseline, the observed effects are promising, particularly as stepped care models—although considered a gold standard for personalised care—remain rare. One study, by Höhne and colleagues,[12] examined a stepped care model versus treatment as usual in young refugees and asylum seekers. In this study, the primary outcome was depressive symptom reduction after 12 weeks, but no significant difference between conditions was found for the primary or secondary outcomes.[12] Unlike our study, the study by Höhne and colleagues[12] was not limited to unaccompanied young refugees, and its interventions were neither pilot-tested nor guideline-based and lacked manualisation, likely reducing condition differentiation. Given these methodological limitations, there is little scope for meaningful comparison.

The significant improvements in PTSS and depressive symptoms are notable, given the three major disruptions during the study. First, sampling coincided with the onset of the COVID-19 pandemic, which disproportionately worsened living conditions for unaccompanied young refugees. In addition, the pandemic delayed treatment initiation, and not all participants were able to successfully complete their treatment by the 12-month follow-up. Many of the young refugees aged out of CYWS facilities and were relocated to adult institutions, further destabilising their physical and social environments. Second, as most unaccompanied young refugees were from Afghanistan, the US withdrawal from Afghanistan between May and August, 2021, caused considerable distress related to family safety and the political situation. Third, the Russian invasion of Ukraine led to an influx of unaccompanied young refugees into Germany, increasing sample heterogeneity in our study. Moreover, the perception of Europe as a safe haven was likely influenced by this new external threat. As post-migration stressors are associated with reduced treatment effects,[29] these unforeseen events might have attenuated the effectiveness of BETTER CARE.

The dropout rate in our study was substantial, at 41%. However, 64% of dropouts were attributable to external reasons common during the transitional age of the participants in this study (eg, service termination due to participant age or being moved to different CYWS facilities), organisational barriers (eg, CYWS facility dropout), or refugee-specific factors (eg, postmigration stressors). Considering internal reasons only (33%), the dropout rate was within the normal range for clinical trials, with a meta-analysis of previous efficacy studies with adult refugees reporting dropout rates ranging from 0 to 64%.[30] Comparisons with stepped care studies in young refugees remain limited by the fact that, to date, none have focused specifically on unaccompanied young refugees. Höhne and colleagues[12] reported a dropout rate of 34% in their study of adolescent refugees and asylum seekers, closely aligning with the rate in our study. Although the dropout rate was higher than anticipated, a significant treatment over time interaction was still observed. This finding suggests that the study retained sufficient sensitivity to detect the longitudinal treatment effect. Nevertheless, the higher attrition likely reduced precision and might have limited the robustness of the estimates.

Service use, treatment retention, and proportions of per-protocol completers were low. Refugees typically report a high mental health burden, but even with the favourable conditions offered by this study, treatment uptake was low. Although supply-side barriers to access were addressed (ie, training therapists to provide treatment adapted to culture, supplying psychoeducation materials in many languages, providing access to trained interpreters, and covering treatment costs), demand-side barriers affecting service use and retention persisted despite mitigation efforts. These barriers might have weakened treatment effects, highlighting the need to address demand-side barriers such as mental health literacy and stigma in unaccompanied young refugees. The predominance of young men as participants—who are generally under-represented in psychotherapy regardless of migration status—might also have influenced engagement rates.[31] Cost–benefit analyses will be presented separately and will help clarify whether the intervention remains economically viable despite the modest effect sizes and high dropout rates. This study has several advantages, including a gold-standard design integrating screening, prevention, and evidence-based treatment. In addition, the study sample of unaccompanied young refugees is the largest such sample to date, with high generalisability due to minimal exclusion criteria, recruitment in different German regions, and 40 countries of origin. The enhanced usual care condition serves as a robust control group, as these participants received screening-based treatment recommendations. Limitations include the high proportion of participants with subclinical PTSS, external events during the study, and delayed treatment completion related to the COVID-19 pandemic.

To improve service use and retention, future research involving unaccompanied young refugees should track dropout reasons systematically and apply a mixed-methods approach to target demand-side barriers directly during implementation. We propose that stepped and collaborative care approaches for unaccompanied young refugees should be routinely implemented in standard care to improve access to treatment and facilitate individual needs-oriented care.

Contributors

RR, EP, and CS conceptualised and designed the study. All authors collected data for the study. JFBT, BK, RR, JK, and LRFM drafted the initial manuscript. All authors critically reviewed the manuscript. JK and CS did the statistical analysis. RR, EP, and CS obtained funding and provided supervision. All authors approved the final version of the

manuscript. CS and JK accessed and verified the data. All authors had full access to all the data in the study and take responsibility for the integrity of the data, accuracy of the data analysis, and the decision to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

The datasets generated for this study and the analysis script are available from the corresponding author on request. Details regarding availability of study materials are provided in the appendix (p 62).

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