BMJ Open

Improve Mental Health (Improve-MH) in refugee families using a culturally adapted, general practitioner-delivered psychotherapeutic intervention combined with Triple P Online parenting programme: study protocol of a multicentre randomised controlled trial

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To cite: Zagha K, Konietzny K, Brettschneider C, *et al*. Improve Mental Health (Improve-MH) in refugee families using a culturally adapted, general practitioner-delivered psychotherapeutic intervention combined with Triple P Online parenting programme: study protocol of a multicentre randomised controlled trial. *BMJ Open* 2024;**14**:e084080. doi:10.1136/bmjopen-2024-084080

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2024-084080).

Received 08 January 2024
Accepted 26 July 2024

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ABSTRACT

Introduction Germany and the European Union have experienced successive waves of refugees since 2014, resulting in over 1.6 million arrivals, including families with young children. These vulnerable populations often face xenophobia, discrimination, substandard living conditions and limited healthcare access, contributing to a high prevalence of mental health problems (MHP). Our primary goal is to proactively address MHP in refugee parents and prevent its potential impact on their children through effective early interventions. Using a low-threshold, primary care-based approach, we aim to enhance parenting skills and address parental psychopathology, creating a supportive environment for parents and children.

Methods and analysis In this randomised controlled trial, 188 refugee parents of 6-year-old children or younger who meet the clinical cut-off on the MHP scale will participate. They are randomly assigned to either the experimental psychotherapeutic intervention, delivered by general practitioners (10-week Improve intervention), or treatment as usual, in a ratio of 1:1. The randomisation will be masked only for outcome assessors. Improve includes face-to-face sessions with general practitioners, an interactive online parenting programme (Triple P Online) and regular protocol-based telephone calls by psychologists. Primary outcomes will assess the intervention's effects on parental and child MHP and parenting skills, with secondary outcomes including psychosocial and physical health indicators. Outcomes will be assessed at pre, post and at 3-month and 6-month follow-ups. The study is scheduled to run from February 2019 to July 2025.

Ethics and dissemination The project Improve-MH (application number 602) was approved by the local ethics committee of Ruhr-University of Bochum and is being conducted in accordance with the Declaration of Helsinki. The study is also conducted in full accordance with the German Data Protection Act, and the Good Clinical Practice guideline (GCP) and is sensitive to specific ethical considerations. Results will be disseminated at scientific conferences, published in peer-reviewed journals and provided to consumers of healthcare.

Trial registration number The trial was prospectively registered at the German Clinical Trials Register (Deutsches Register Klinischer Studien, DRKS-ID: DRKS00019072) on 16 March 2020.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Participants attend four primary care-delivered sessions for the treatment of depression, anxiety and stress among refugee parents.
⇒ The participants also actively take part in a positive parenting programme for the prevention of mental health problems in their children.
⇒ Intervention effects will be compared against a treatment as usual control group.
⇒ It is not possible to ensure the masking of patients and therapists involved.

INTRODUCTION

In recent years, Europe has experienced the largest wave of immigration since World War II.[1] Germany alone has received more than 1.6 million refugees since 2014.[2] About half of the asylum seekers came from Syria and Iraq, including families with children aged 6 years or younger. Among refugees, it is estimated that more than 50% who fled armed conflicts are affected by mental health problems (MHP),[3 4] with depression, anxiety and post-traumatic stress being the most prevalent.[5 6] Refugees are at a much higher risk of various MHP compared with the general population, stemming from their exposure to war, violence, torture, forced migration and exile, along with the uncertainty of their status in their host countries.[7] As mental health is crucial to the overall well-being of individuals and societies, treatment of MHP in refugees is of high relevance.[8]

Ample research demonstrated that cognitive behavioural therapy (CBT) approaches were effective in treating post-traumatic stress, anxiety and depressive symptoms in adult refugee populations in comparison to other forms of treatment (eg, relaxation or exposure).[9 10] This was extensively illustrated by a meta-analysis and review, which investigated psychosocial interventions for refugees and asylum-seekers, including 15 CBT intervention studies (Post-traumatic stress disorder (PTSD): 95% CI: (−1 to 01, −0.41), depression 95% CI: (−1.52, 0.51), anxiety 95% CI: (−1.55 to −0.56)).[11] In general, however, treatment rates among refugees are low, and treatment is typically provided only many years after the onset of MHP.[12 13] Moreover, the German psychotherapeutic care system is overwhelmed with meeting the demands associated with the influx of hundreds of thousands of immigrants.[14] This is exacerbated by the presence of several inequalities in healthcare services such as legal restrictions, language barriers, a lack of intercultural competence among providers, discrimination, racism, difficulties in navigating a novel health system for refugees and financial troubles which often prevent the treatment of MHP in refugees.[15–19]

Addressing the pressing issue of mental health policy for refugees poses a considerable challenge, particularly in devising more efficient approaches to deliver low-threshold, early and cost-effective interventions for the prevention and treatment of MHP. This randomised controlled trial (RCT was developed to provide policy recommendations aimed at enhancing general practice and routine care in Germany. In the context of Germany, where general practitioners (GPs) often serve as the primary point of contact for the population, with the majority of refugees using and having access to primary care,[20] incorporating them into the mental health intervention framework becomes crucial. GPs not only have a pivotal role in basic psychosocial care within their remit but also facilitate referrals to psychotherapists and other specialists. Therefore, integrating intracultural GP delivery of CBT-based interventions is a strategic and accessible avenue to promptly address the mental health needs of refugees, leveraging the existing healthcare infrastructure and ensuring a more cohesive and effective approach to MHP prevention and treatment.

The high prevalence of MHP in refugee parents is a risk factor, as parents' MHPs are known to have a negative impact on their children's mental health outcomes.[21] Since about a quarter of all asylum applications involve children under 6 years of age,[2] these refugee children are especially exposed to multiple direct and indirect risks. A first major risk factor is that up to 41% of refugee children have experienced traumatic events,[22 23] and many children have experienced stress associated with involuntary resettlement. In addition, MHP in parents are associated with an unfavourable parenting style, which is a second risk factor for children.[24] Indeed, parental mental health and impaired parenting have been identified as essential post-migration family risk factors in forcibly displaced children in a current systematic review.[25] Since early childhood is a susceptible phase for the development of psychological problems,[26–29] and refugee children represent a high-risk group, improving mental healthcare services is urgently needed in terms of prevention and potential positive long-term effects for society with a substantial cost-benefit ratio.

Parenting programmes may address this risk factor by assisting refugees with the increasingly demanding and challenging parenting roles they have to take up after resettlement.[30] A meta-analysis of 116 studies across 33 years with 16 099 families participating in the Positive Parenting Programme (Triple P) studies found positive, significant short and long-term effects among others for children's social, emotional and behavioural outcomes (short term 95% CI: (0.40, 0.54), long term 95% CI: (0.35, 0.69)), as well as parenting practices (short-term 95% CI: (0.49, 0.66), long-term 95% CI: (0.36, 0.63)).[31] The meta-analysis, by Sanders *et al*,[31] involved diverse ethnic groups from both collectivistic and individualistic cultures, demonstrating Triple P to be useful across cultures. While the evidence on the efficacy of Triple P with refugees is very limited, one qualitative study indicates that Triple P is a useful tool and resource in addressing parenting needs in refugee parents as well.[32]

The overarching goal of this clinical trial is to improve the mental health of refugee parents, and to prevent the development of MHP in their at-risk children by addressing the known risk factors of parental MHP[25 33–35] and impaired parenting skills.[25] Studies have shown that treatment of parental MHPs is associated with improved health outcomes in children[36–41] and a significantly reduced relative risk for children to develop MHPs.[42] Enhanced parenting skills mediated the improved outcomes of their at-risk children[43] and programmes enhancing the parent–child interaction were shown to affect the children's psychopathology.[44] A current study integrates the combination of treatment of parental MHP and the Triple P parenting programme to prevent the transmission of MHPs in children (COMPARE study).[45] Therefore, the Improve intervention combines

a GP-delivered, culturally adapted CBT intervention and a well-studied, culturally invariant parenting programme (Triple P), to reduce MHP in refugee parents and enhance parenting skills.

Aims of the clinical trial

The main objective of this trial is to provide and evaluate a low threshold, primary care-based intervention for the treatment of MHP and a parental training programme for refugees with young children (Improve intervention). In this context, a low threshold refers to the intervention's availability without referral from a GP first and without the requirement of prior consultation, which are both typically necessary prerequisites in Germany before receiving psychotherapy. Additionally, it signifies the intervention's low intensity, implying a lower number of sessions with a shorter duration in comparison to typical psychotherapeutic treatment. The effects of the Improve intervention will be studied through primary and secondary outcomes, which are measured before (T0), intermediately (weekly over the 10-week period) and directly after the 10-week long intervention (T1) as well as at 3-month (T2) and 6-month (T3) follow-ups (FUs).

The objectives are:

1. To implement and evaluate the Improve intervention in general practice.
2. To compare the Improve intervention to a control condition (treatment as usual, TAU, where the participants have the option to seek the standard treatment options), with regard to parenting style and the mental health of parents and their child (primary outcomes).
3. To test the effects of the Improve intervention on secondary outcomes including parental and child mental health status, psychosocial outcomes (family climate, child/parental language skills as indicators of acculturation, education, employment status, housing conditions, partnership satisfaction and social support), parental and child physical health outcomes and stress indicators (cortisol) in parents.
4. To identify predictors of intervention outcomes and to optimise and tailor treatment approaches.

It is hypothesised that the positive effects of the Improve intervention will be observable after our intervention. The primary hypothesis is that the Improve intervention will be superior to TAU for parental MHP and parenting skills at the post, 3-month and 6-month FU. Since changes in parental MHP and parenting skills are necessary preconditions to positive changes in child MHP, it is expected that the positive effects will be delayed to a certain degree. Treatment of parental psychopathology is followed by improvement in child symptomatology within the first 3–6 months.[38 46] As for parenting skills, studies implementing Triple P report significant changes in parenting and child behaviours after the intervention's completion.[31 47 48] The primary hypothesis is that the Improve intervention will be superior to TAU for child MHP at 3-month or at the latest at the 6-month FUs.

It is further hypothesised that Improve will have positive effects on secondary outcome measures and that positive mental health, psychosocial and biological stress markers will predict intervention outcomes.

METHODS AND ANALYSIS

Trial design

The current study is a multicentre, two-arm superiority RCT, involving three university recruitment centres in Germany (Bochum, Essen and Munich) and a central coordinating centre in Bochum, Germany. The project Improve-MH started on 01 February 2019 and is scheduled to run until 31 July 2025, with recruitment currently ongoing. Data collection for the main study started in 2022 and the last data (ie, last patient out) are planned to be collected in April 2025 (last FU assessments, end of data collection). The whole project (application number 602) was approved by the local ethics committee of Ruhr-University of Bochum and is being conducted in accordance with the Declaration of Helsinki.

The study protocol was written in accordance with the SPIRIT statement (Standard Protocol Items: Recommendations for Interventional Trials,[49]; for the SPIRIT checklist, see online supplemental appendix).

Given that there is no intervention study of the treatment and prevention of MHP in refugee parents and their children, the study aims to compare the Improve intervention against TAU. Participants in the TAU group have the possibility to seek any form of treatment or support for their symptoms. They are generally provided with a list of resources available to them based on their residence area if requested. After the last major assessment, participants in the TAU group have the option to receive the Improve treatment as well. As attention placebo control conditions for parenting programmes are difficult to implement and carry an elevated risk for high dropout rates and adverse side effects,[50] this option was excluded.

In the Improve intervention participants receive a 10-week intervention including a CBT-based treatment in the general practice, an online parenting programme to improve the parenting style (Positive Parenting Programme, Triple P Online, TPOL) and accompanying phone calls with a psychologist (see figure 1 or 'Improve intervention' for details).

Assessment time points include the baseline assessments (screening and 'major assessments' T0, before inclusion), intermediate assessments (including the 'Minor Assessments' every third week and additional progress assessments conducted during the weekly phone calls), post ('major assessment' T1, after 10 weeks intervention or TAU) and FU assessments ('major assessment' T2, 3-month FU and T3, 6-month FU). See figure 1 for a summary of the course of the study.

Patient and public involvement

Patients and members of the public were involved in various stages of the research process, including the

Baseline		Intervention 10 weeks										POST	3 FU	6 FU
Screening IC	Major Assessment T0	**Improve Intervention**										Major Assessment T1	Major Assessment T2	Major Assessment T3
		Week1	Week2	Week3	Week4	Week5	Week6	Week7	Week8	Week9	Week10			
		GP			GP			GP			GP			
			TPOL	TPOL	TPOL	TPOL	TPOL	TPOL	TPOL	TPOL				
		phone	phone	phone	phone	phone	phone	phone	phone	phone	phone			
	Hair	Minor Ass.			Minor Ass.			Minor Ass.			Minor Ass.			Hair
Screening IC	Major Assessment T0	**Treatment as usual (TAU)**										Major Assessment T1	Major Assessment T2	Major Assessment T3
	Hair	Minor Ass.			Minor Ass.			Minor Ass.			Minor Ass.			Hair

Figure 1 Diagram of study design. FU, follow-up; GP, improve session at general practitioner (four sessions, each 30 min); hair, hair sample to assess cortisol level; IC, informed consent; phone=phone call by psychologists, including assessments (weekly, 30 min); TAU, treatment as usual; Triple P, Positive Parenting Programme; TPOL, Triple P Online (eight modules, each 60 min).

design, pilot testing, implementation and recruitment. The study design was discussed and developed with collaborating GPs and paediatricians, many of whom share the same cultural background as the majority of our target group, who further helped to implement the treatment in participating general practices. Patients were involved already at an early stage, while applying for the project, to test the acceptability of the online parenting programme in Arab culture. Additionally, the whole intervention (treatment and assessments) was pilot-tested with refugee patients (n=7). Currently, with a participant advisory board, we involve refugee parents and members of the public who closely work with refugees in the recruitment process, to disseminate the project within the community (see Recruitment).

Sampling and eligibility criteria

Participants

Key inclusion criteria are being a refugee parent of children younger than 7 years old; the participating parent must meet clinical cut-off on MHP scale, the Depression-Anxiety-Stress-Scale (DASS)[51]; sufficient proficiency in the Arabic, German or English language; and informed consent. Refugee here is defined based on the Geneva Refugee Convention Article 1A as a person who is outside their country of origin and nationality, and is unable or unwilling to avail himself of the protection of their country of origin owing to a well-founded fear of being persecuted for reasons of race, religion, nationality, membership of a particular social group or political opinion.[52] Current or previous refugee status is screened through self-report. The inclusion criteria had to be restricted to these three languages due to the lack of availability of measurement instruments and parenting tools in other languages as well as the socio-demographic make-up of the target group.

Key exclusion criteria are: having a primary MHP other than depression, anxiety or PTSD; usage of neuroleptic drugs, irregular anticholinergic or irregular antiepileptic drug intake; showing indications of acute suicidality or psychosis; or general medical contraindications. Patients who are undergoing treatment psychotherapy by other psychotherapists or psychiatrists concomitantly for any MHP at baseline are also excluded. It is expected that, however, such cases will be rare. In case of acute suicidality, participants are seen by the GP and—in case of treatment—withdrawn from the trial and directed to the appropriate resources. After screening participants for the inclusion criteria, eligible participants are invited for an appointment to give their informed consent to participate. They then take part in a subsequent diagnostic baseline assessment (major assessment T0) to inspect further exclusion criteria (see table 1).

Recruitment

The recruitment of participants for the main study started in January 2022 and the last patient is planned to be included in August 2024 (ie, last patient in and end of recruitment). A total of 188 participants will be included in the study. Recruitment of participants is done in various ways, one of them being directly through the GP practices, a major access point into the German healthcare system. Participating GPs and medical assistants recruit potential participants when they come in for an appointment. The second major recruitment point is a participant advisory board comprised of potential participants to capture their expertise in understanding the challenges faced by the broader refugee community, and their needs when enrolling in an RCT, and to further enhance our recruitment and outreach strategies. The advisory board recruits participants by publicising the project in their community (eg, via social media) or by asking suitable known parents to participate. Additionally, the study also relies on broad and narrow-reach recruitment including reaching out to non-profit organisations that provide services to refugees, kindergartens and significant communal locations such as mosques, social media platforms, as well as information points in urban settings. This is supplemented by flyers, posters, videos and brochures that summarise the study's

Table 1 Eligibility criteria

Inclusion criteria	Exclusion criteria
Refugee background (self-report of current or previous residence status in Germany)	Any primary disorders other than depression, anxiety or PTSD.
Parent of young child(ren) (<7 years)	Drug intake (neuroleptic drugs, instable anticholinergic or instable antiepileptic drugs).
Sufficient proficiency in Arabic, German or English	Acute suicidality.
DASS-21* ► Depression score >10 and/or ► Anxiety score >6 and/or ► Stress score >10.	Acute psychosis† ► Positive screening in Diagnostisches Kurzinterview bei psychischen Störungen (Mini-DIPS). ► CAPE-15: distress score >1, 5.
	Concomitant psychotherapeutic treatment.
	General medical contraindications.

*DASS-21 (Depression Anxiety Stress Scale[51]) using clinical cut-offs.
†In case of positive psychosis screening during the Mini-DIPS (short structured clinical interview for diagnosing mental disorders[87]), the additional questionnaire CAPE-15 (Community Assessment of Psychic Experiences[88]), a measure of positive, psychosis-like experiences are be assessed using suggested cut-offs.[89]

offers for the participants as well as enabling the potential participants to sign up as interested subjects or call a study phone number directly.

Participants that are recruited outside of GP practices are allocated to a participating GP's practice depending on spatial accessibility (as close as possible to the participants' place of residence) and become a patient there.

Baseline

The screening (including inclusion criteria, drug intake and current treatment) is carried out in the general practice by medical assistants or study staff, respectively. Participants give their written informed consent after being informed by the study staff (eg, GPs or mental health experts, MHEs). Afterward, the baseline major assessment (T0) is conducted by the MHEs of the centres, assessing baseline variables and checking additional exclusion criteria (other primary MHP, suicidality, psychosis). Eligible refugee families are randomised to the Improve or TAU in a ratio of 1:1, after their inclusion into the study (positive screening and signed informed consent, see figure 2 participant flow chart). Participants are informed verbally by study staff (case manager, not involved in treatment or diagnostic interviews) about the group allocation after completing the first major assessment, T0. Randomisation takes place at the individual level and is done blockwise with strata defined as the study recruitment centres. Lists with random allocation sequence were prepared in advance before recruitment started from study staff not involved in recruitment or treatment (JK). Patients are allocated according to this list in chronological order of inclusion.

Complete masking of the treatment group from all the study staff and treating GPs is not fully possible. However, the masking for MHEs who conduct the diagnostic interviews and assign the severity ratings for MHP at the various assessment and FU measurement points is maintained, as MHEs are not informed about allocation and are not involved in the treatment.

Sample size

The current power calculation is based on earlier studies on the effects of (1) GP-delivered CBT (between-group effect size at 6-month FU: 0.25–0.36), and (2) TPOL (between-group effect size post-intervention: 0.44–0.89) showing small to large effect sizes on parental MHP and parenting skills.[48 53] For the a priori power analyses, we decided to use an effect size estimate that was at the lower limit of the range of previously observed post-intervention effect sizes of 0.4. This conservative approach ensured that our study would be sufficiently powered even if the effect was smaller than in previous studies. The desired power was set to 80%, alpha was set to 5%. Assuming a dropout rate of 20% during treatment, the total sample size to be enrolled is N=188 and to be analysed is N=156. Due to the limited number of literature available on the topic of refugees in Germany when the study was registered (2017), the rate of non-compliance and other dropout has been estimated based on the literature available back then, namely Gensichen *et al*,[53] and Sanders *et al*,[48] expecting an average loss at FU of 20%. However, as the target group is highly vulnerable, the actual dropout rate might even be higher.

Statistical analysis

Changes in continuous primary variables assessed at baseline, at post-treatment and during FU will be analysed with three-level linear mixed models for longitudinal data (growth curve models) with occasions on Level 1, persons on Level 2 and practitioners on Level 3. These models provide more efficient and less biased results compared with completer analyses or analyses in which missing values are imputed using the last observation carried forward method.[54] Further, linear mixed models do not require the omission of participants with missing data from the analyses, thereby minimising data loss, increasing power and allowing for participants who dropped out of the study to be included in the analyses. The primary hypothesis will be examined by testing the cross-level interaction between the time effect (degree of change from baseline to post and FU) and condition (Improve intervention vs TAU group). Random

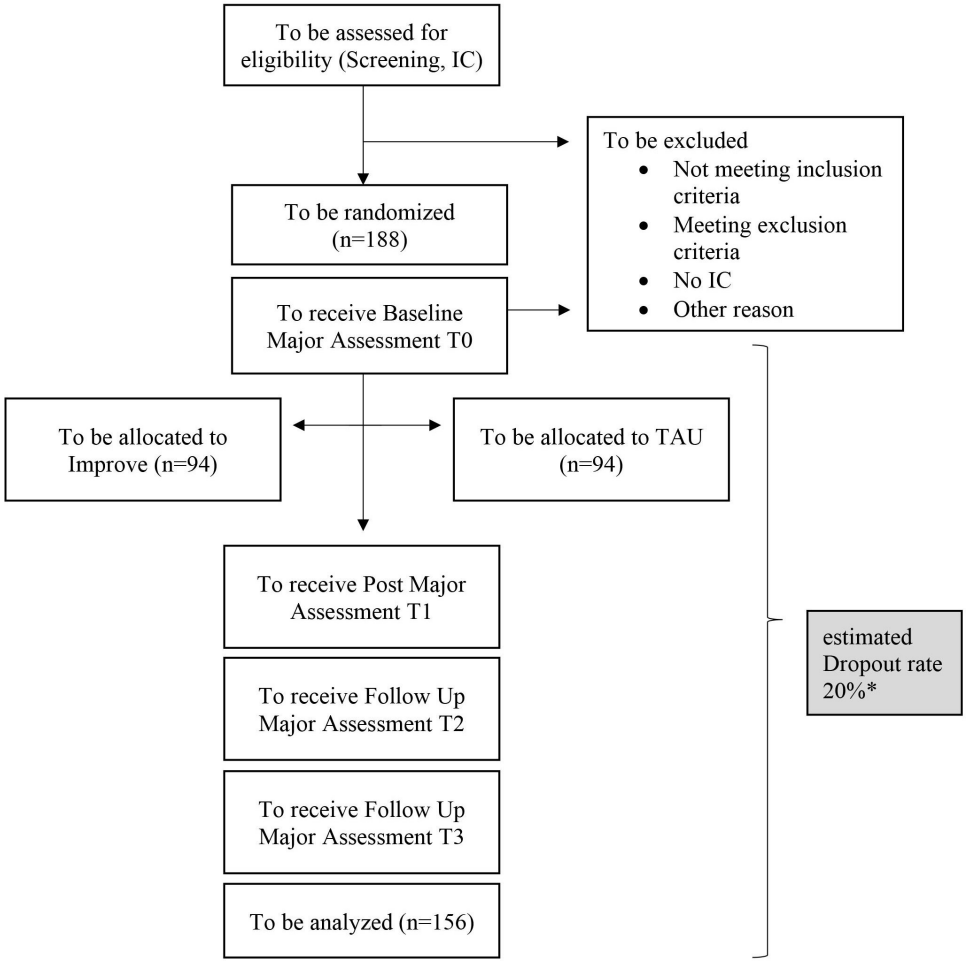

Figure 2 Participant flow chart of the RCT. Note: T1: directly after the Improve treatment/TAU; T2: 3-month follow-up; T3: 6-month follow-up Note: *dropout has been estimated based on Gensichen *et al*[53] and Sanders *et al.*[48] IC, informed consent; RCT, randomised controlled trial; TAU, treatment as usual.

slopes will be modelled if this improves model fit. The model allows to test (1) whether temporal courses differ between Improve and TAU during the treatment and FU periods, and (2) whether treatment-specific trajectories observed during treatment are maintained during FU. Furthermore, covariates such as age or participant status (eg, completer vs dropout) will be included to test interactions between these variables and changes in primary outcomes (eg, intent-to-treat analyses). Changes in secondary variables assessed at baseline, post-treatment and during FU (ie, DASS, Strengths and Difficulties Questionnaire (SDQ)) will be analysed with the same statistical models as above, with consideration for alpha inflation through methods such as the Bonferroni correction. These models can be extended to include predictors of intervention outcome and child mental health development. Cohen's d will be applied to quantify effect sizes for differences between groups at post-treatment and at FU. Analyses will be conducted in R and SPSS. Statistical weights will be applied to adjust for different sampling probabilities in different study centres, if necessary. The alpha level will be set to 0.05.

Diagnostic domains and instruments

Primary outcomes are parenting style and the mental health of parents and their target child will be assessed. All primary outcomes will be assessed during the major assessments pre (T0), post (T1) and at 3 (T2) and 6 months (T3) FU.

Additionally, secondary outcomes and psychosocial variables will be assessed throughout the study (see online supplemental appendix table for a full description of instruments). The selection of the listed instruments was based on their psychometric values. In cases where Arabic or English translations were not available, standard procedures such as translation and back translation were implemented. In these cases, the study will include an evaluation of the reliability and validity of the internally translated versions. An additional biological stress marker hair cortisol level will be assessed pre and at the 6-month FU (during the 'Major Assessment'). For this purpose, hair strands are collected from the back of the head as close to the scalp as possible. As human hair grows approximately 1 cm per month,[55 56] the most proximal 1 cm segment to the scalp corresponds to the cortisol

production in the last month, as a measure of chronic stress.

All questionnaires are digitised and can be filled out in Arabic, English or German, on participants' smartphones. Moreover, for participants with low literacy levels, there are audio files available in Arabic for every item, to simplify the fill-in process. The digitisation of the assessments allows immediate access to standardised data files across sites to enhance the objectivity and quality of assessments and reduces data cleaning efforts. For the assessment of MHP to be validated, culturally sensitive scales that have already been successfully applied across different cultures are used.[57]

In order to reduce the burden for the participants, from some questionnaires only subscales were used (see online supplemental appendix table) and some topics are only queried by one item (*). The study, including all assessments, has been pilot-tested by refugee parents with MHP, to ensure readability, understanding and assess acceptability. The completion of the major assessment questionnaires takes about one and a half hours, and the completion of the minor assessments about 10 min.

Treatment procedure

Improve intervention

The Improve intervention comprises 10 weeks of four GP-delivered, modular CBT sessions with a focus on coping with depression, anxiety and stress and worry (30 min face-to-face sessions) and the well-established Positive Parenting Programme (TPOL, eight 60 min online modules) to improve parenting style. The intervention is accompanied by 10 protocol-based telephone calls with psychologists proficient in Arabic, English and/or German, ensuring effective communication tailored to the participants' language skills. GP sessions are held every third week, and the interactive, self-directed TPOL sessions are done in parallel weekly (see figure 1).

GP-delivered intervention

The GP-delivered intervention was developed for the study, based on core CBT components based on Margraf and Schneider.[58 59] It is instructed by a treatment manual, which is modular, highly structured by session with verbatim instructions. Parts of the manual were tested in previous RCTs of a GP intervention for panic disorder, demonstrating moderate to high compliance and treatment integrity.[53 60]

The Improve intervention contains both transdiagnostic and disorder-specific content. The disorder-specific content is divided into three different topics, which are further subdivided, namely (1) depression, (2) anxiety (phobia or panic disorder) and (3) stress (stress and worry or post-traumatic stress). Depending on the patient's primary diagnosis in the clinical interview ('Major Assessment', T0), the GP uses the respective focus of treatment.

Every treatment starts with psychoeducation and behavioural activation in the first session. The second and third sessions focus on the primary diagnosis and contain disorder-specific exercises, such as (interoceptive) exposure exercises. Additionally, the third session contains a transdiagnostic module, focusing on self-care (sleep, exercise, nutrition). In the last session, participants reflect on their progress and learn how to build on the first successes of the intervention and how to deal with future relapses through the activation of their reflected-upon resources.

Participants get exercises to work on from home at the end of every session, with their progress and experiences with those exercises reviewed with the GP at the beginning of each session with the study psychologists weekly between sessions. The tasks are integrated into specific sections of the modular patient workbook and both, independently and cooperatively, filled out by the patient and GP. The patient workbook is available in Arabic, English and German.

All details concerning the standardised GP-delivered intervention are specified in the Improve treatment manual. The GPs have been trained to deliver the Improve intervention according to the manual. The number of GP-delivered sessions aligns with those tested in the previously mentioned RCT for panic disorder in the general practice.[53] The compliance and treatment integrity of similar interventions have also been investigated and are moderate to high.[61–64]

Cultural adaptations

Classical CBT components for MHP have been shown to be effective in different cultures, including Arab countries.[65] Furthermore, some aspects of the intervention are culturally adapted to improve the acceptability and outcome of the intervention. The intervention sessions and accompanying phone calls are carried out in the mother tongue of the patients which allows for intracultural communication and understanding between the patients, the GP and psychologists. The Improve intervention focuses on behavioural aspects of CBT. The manual includes treatment components that fit into the culture of participants, for example, adapted activities of behavioural activation, such as common religious practices of the target group. In addition to this, adjustments have been made to some of the assessments included in the study to contextualise them to common difficulties that the patients have experienced in their home countries or their post-migration difficulties in a transit country or Germany. For the cultural adaptation process, input was given by the study staff and participant board belonging to the same cultural background as the vast majority of the target group (refugees from Arabic-speaking countries, practicing the Islamic faith). Moreover, the treatment was pilot-tested with refugees from Arab countries, to inspect acceptability. Detailed information about the process of adaptation will be illustrated in a separate paper (Heller *et al*, in preparation).

Cultural sensitivity in delivering the GP-centred intervention is ensured by prioritising the recruitment of GPs

with the same cultural background as the participants. The participating GPs are trained and sensitised to the most common issues arising among the refugee population, in particular the difficulties they experience in their home countries, on their flight journeys and in the host countries after resettling.

Parenting programme

TPOL is based on the Triple P programme, which is recommended byNational Institute for Health and Care Excellence (NICE),[66] and by the WHO as the most extensively evaluated and evidence-based parenting programme.[67] Among positive effects on children's social, emotional and behavioural development, it was shown to affect parental outcomes, such as parenting practices, parenting satisfaction and efficacy as well as parental relationship in several meta-analyses.[31 68 69] Moreover, Triple P was shown to be useful for parents with mental health problems.[70]

TPOL is a modular, standardised, interactive, self-directed parenting programme delivered via the internet. It includes eight training modules, each lasting around 60 min, with video clips, tasks and activities to enrich a positive parent–child relationship, encourage positive behaviour and support the child's development. The intervention includes core positive parenting skills (eg, descriptive praise, quiet time) and promotes parental self-regulation.[48] In this clinical trial, we use the Arabic, English and German versions of TPOL. As TPOL was shown to be useful independent of culture,[71] no cultural adaptations were made. This is evident as culturally diverse parents rated the programme materials as very culturally suitable.[71] Participants taking part in the Improve intervention are asked to participate in the programme once a week, on their own (see figure 1).

While the GP does not extensively integrate the parenting programme in the sessions they offer, the GPs are informed of the topics covered in TPOL via the treatment manual.

Phone calls

The intervention is accompanied by regular phone calls with psychologists proficient in Arabic, English or German weekly (ca. 30 min) to integrate the GP-session disorder-specific techniques and the parenting programme into everyday life and ensure participant compliance with the intervention's time plan. The calls follow a semi-structured guide where the content of the GP sessions and TPOL are discussed. In addition, an assessment of the parent and child health status is made based on a self-report measure of symptoms-induced impairment and mental health status in comparison to the baseline measurement. After each session with the GP, serious adverse events (SAEs) and unexpected side effects are monitored during the weekly phone calls and reported to the Data Safety Monitoring Board (DSMB), if necessary.

Treatment as usual

The control condition is TAU for 10 weeks where the participants are free to seek the regular treatment options that are typically available for mental health support such as seeking psychotherapy, participating in a support group, or simply receiving a psychosocial consultation. Participants will be forwarded a list of resources based on their location that could offer them support if requested. Furthermore, they are able to receive the Improve-intervention following the 6-month FU assessment. Using TAU will allow the study to evaluate aspects of the typical utilisation rates among migrant populations in Germany. According to a systematic review by Klein and von dem Knesebeck,[72] first generation migrants are especially prone to lower utilisation of the healthcare system in comparison to natives in Germany in general. This is especially the case for outpatient care (specialists), paediatricians, rehabilitation, therapy and counselling services, medication and complementary medicine, early detection of diseases and general health check-ups. This can be somewhat explained by disparities in socioeconomic status. Other explanations could be attributed to access barriers such as cultural differences and misunderstandings, language limitations, lack of knowledge of the healthcare system, lower health literacy, discrimination, stigma and distrust in western mental healthcare systems.[72 73] This can be further observed in refugees originating from Arab countries as they are less likely than other ethnicities to visit mental health providers and are more reluctant to seek help from formal contacts with the exception of GPs.[73] Lower rates of healthcare (including mental healthcare) utilisation are also reported among refugee children.[74] To further assess the utilisation of standard treatment options available to the participants, they must specify whether they sought regular treatment options and what they consisted of after the 10-week period of the start of their participation.

Study personnel and adherence

To ensure safety and minimise risk, only licensed and trained GPs and MHEs certified in diagnostics conduct interventions and assessments. Protocol violations, including deviations from the manual, treatment schedule or non-participation in parts of the study are regularly documented and could lead to the exclusion of participants, GPs, MHEs or the centre.

General practitioners

To take part in the clinical trial, GPs need to have at least 1 year of medical experience and undergo the study's modular treatment manual training. GPs with the same cultural background as the participants and with the participants' first language, that is, Arabic as their mother tongue, are preferentially recruited for the study. The central study centre in Bochum conducts multiple training seminars before the start of any treatment sessions. GPs have the opportunity to receive continuing education points for participating in the training seminars.

Following the seminar, they get certified for the study once they pass a set of multiple-choice questions. During the intervention phase, each GP receives additional supervision phone calls to fortify learning outcomes from the training. Participating study doctors included general practices, recruited by the three recruitment centres and a hired study doctor at the central coordinating centre.

Manual compliance with the GP-delivered intervention is additionally monitored. GPs are required to videotape their sessions if participants give their informed consent. After each session, GPs fill in a questionnaire, noting which aspects of the treatment manual have been used during the sessions. A random 5% of the tapes are monitored for project violations and manual adherence. The GPs receive the study standardised operating procedures (SOPs), all necessary documents and a laptop to carry out the screening and video recordings.

Mental health experts

MHEs are trained, multilingual (proficient in Arabic, English and/or German) staff of the recruitment centres to carry out the assessments. Before the MHEs can start conducting the assessments, they undergo a certification process including extensive training and a controlled practice phase. Accordingly, all MHEs are trained in conducting the clinical diagnostic interviews through[1] an online course, DiSkO[75] and a 1-day workshop and[2] a practice phase where they counter-code prerecorded diagnostic interviews and subsequently record practice diagnostic videos. Additionally, they are trained in organisational procedures and in navigating the different platforms (REDCap, LimeSurvey, RedMedical) used in the study. All of this is established, standardised and computerised by accompanying SOPs that guide the study staff.

Data management and safety

The study is conducted in full accordance with the Declaration of Helsinki, the German Data Protection Act and the GCP-guideline and is sensitive to specific ethical considerations. Due to the particular situation of the group examined here, great emphasis is placed on not exposing the participants to unnecessary risks and the protection of personal data is given top priority. High standards to guarantee participants' confidentiality are implemented (eg, secure storage of personal data). The participants' personal research data are stored pseudonymously on a password-protected, secure web application for managing online surveys and databases,REDCap database, (digital data) or are stored pseudonymously in an office in locked filing cabinets (paper pencil data), using participant numbers and without mentioning the participants' legal names. Access to all data is controlled by passwords/keys and highly restricted access rights.

The trial was prospectively registered under the German Clinical Trials Register (www.germanctr.de) on 16 March 2020. Any protocol modifications can be tracked in the trial registration.

A DSMB, consisting of four members entirely independent of the clinical trial and the sponsor, is installed to monitor the participants' safety and treatment efficacy data during the trial. The DSMB meets every year for auditing trial conducts. Additionally, possibly occurring unexpected side effects and SAEs (eg, suicide attempts, dangerous intentional self-injury, domestic abuse, criminal offences, delinquent behaviour) are routinely assessed over the course of the Improve intervention and are immediately reported to the DSMB for discussion and assessment. The DSMB is in charge give advice on protocol changes or even on discontinuation of the trial in cases of SAE. This procedure is analogous to that of pharmacological trials according to Good Clinical Practice.

METHODS OF ADD-ON PROJECTS

Culturally sensitive assessment of mental health in refugee populations

This project comprises two objectives. First, the project strives to establish validity and measurement invariance (MI) across cultural groups and time for existing self-report measures of mental health. In order to meet the objective of comparing the primary and secondary outcomes of the clinical trial (Improve intervention) with a control condition, valid and culturally sensitive measures are required. This is highly relevant to the clinical trial, as it ensures the cultural sensitivity and comparability of mental health measures while ensuring that meaningful interpretation of changes over time is possible. Therefore, well-validated mental health measures with previously established cross-cultural and longitudinal MI are used.[76 77] For this purpose, we use existing self-report measures of mental health and, if necessary, translate them into the relevant languages in a first step (see also section Sampling and eligibility criteria). We conducted a pilot study (N=220) prior to the start of the clinical trial to establish cross-cultural MI and to test the validity of measures for which no sufficient evidence of validity exists to date and, if necessary, adjust the measures on the basis of the results to achieve good psychometric quality. Further, we will use the longitudinal data of the clinical trial and of the ecological momentary assessment (EMA) study described below to establish longitudinal MI before interpreting the results. It is hypothesised that MI will be established both across groups and across time within the refugee populations. The second main objective involves the creation and validation of supplementary self-report measures for the clinical trial's primary and secondary outcomes, using EMA methodologies.[78 79]

Conventional mental health assessment typically relies on clinician reports or global self-reports referring to a specified time frame. Similarly, parenting and parent–child interaction data collection is usually done by either observational or self-report methods.[80] Although these approaches are generally reliable and valid, they sometimes suffer from limitations such as ecological validity, retrospective bias and socially desirable responses. To

address these issues, EMA has gained traction in clinical research to enhance the credibility of conventional assessment methods.[79]

It is hypothesised that convergent validity between conventional and EMA assessment methods will be good. It is further hypothesised that EMA assessments will significantly improve the predictability of primary outcomes measured at the 6-month FU of the clinical trial. To test these hypotheses, 75% of all participants are randomly invited to participate in an add-on EMA module for which they receive additional compensation. EMA data is collected once a day (end-of-day diary) over a period of 7 days pretreatment, post-treatment and at the 3-month and 6-month FUs, via the smartphone application MovisensXS that participants download onto their own smartphones. To test the convergent validity between conventional and EMA assessment methods, EMA data will be merged with the data from the clinical trial. The measures used in the EMA module are adapted versions of the instruments used to assess the primary and secondary outcomes that are pretested (eg, in terms of MI across cultural groups) in a pilot study prior to the start of the main study (see above).

Assessment of cost-effectiveness of the Improve intervention in refugee families

While the Improve intervention aims to assess the intervention's effectiveness, this subproject focuses on evaluating the cost-effectiveness of the Improve intervention from a societal perspective. The time horizon will be 6 months. Using data collected in the Improve intervention, this analysis takes into account two primary stakeholders: parents, who directly receive the intervention and their children, who might indirectly benefit through the addressed parenting behaviours. The effects on parents and their children will be assessed differently. For parents, the EQ-5D-5L, a brief, multiattribute, generic, health status measure composed of 5 questions with Likert response options and a visual analog scale, will be used for the calculation of quality-adjusted life years (QALY) and the DASS will be employed to calculate mental-health-burden-free days (BFD) according to the approach of Lave *et al*.[81] For children, the SDQ will be used to calculate BFD. The assessment of resource use will cover the categories of inpatient, outpatient physician and outpatient non-physician services as well as drugs and informal care. Incremental cost-effectiveness ratios as point estimates of cost-effectiveness and cost-effectiveness acceptability curves based on the net-benefit approach as a measure of uncertainty of cost-effectiveness will be calculated.[82] In the primary analysis focusing on the parents, the analysis will be based on € per QALY gained. In the secondary analyses focusing on the family, the cost and effects of parents and children will be summarised. The analysis will be based on € per BFD gained.

It is hypothesised that the Improve intervention will prove cost-effective in both primary and secondary analyses. Therefore, the outcomes of the RCT hold potential implications for the German healthcare system and society.

In the context of challenges posed by integrating a significant number of refugees into German society, mental health and familial stability play pivotal roles. Information on Improve's ability to deliver good value for money contributes to tackling resource constraints in healthcare through a comprehensive cost-effectiveness analysis.

Process evaluation to study GPs' experience/attitudes towards refugees with MHP and to identify facilitating and inhibiting factors of implementation

GPs are confronted with a large number of refugees who primarily present psychosomatic disorders and mental health issues. These problems are beyond the scope of their preparation and training. A considerable portion of these patients comprises young children and their parents. The primary aim of this add-on project is to explore the professional and clinical experiences of GPs with refugee families and determine their requirements for effectively addressing the health issues of these patients. Moreover, we seek to assess the implementation of GP-based case management, developed in Improve, for MHP. This evaluation aims to overcome barriers to dissemination and prepare the programme for practical integration into primary care. A mixed methods design (t1, t2, t3) was initially chosen for this substudy.[83] Initially, a qualitative data collection (t1) consisting of semi-structured individual interviews (n=25) was conducted to reconstruct the routine primary care of refugee families with young children. During the implementation of the Improve intervention, a second interview (t2) is planned exclusively with study GPs who carried out the Improve-MH treatment followed by a quantitative survey (t3) to address any outstanding issues with all study GPs. Due to the smaller number of recruited study GPs (n=17) in the Improve-MH main study P1, the planned approach appeared to be methodologically unfeasible. Instead, a decision was made within the study team to interview all study GPs in the qualitative data collection, regardless of whether or not they had implemented the intervention, by incorporating all relevant aspects of the project into the qualitative interview guidelines (t2). It is intended to conduct qualitative interviews with all 17 included study GPs with the aim of reconstructing the processes of conducting the RCT and implementing the intervention from the perspective of the GPs, and to identify potential areas for optimisation. In addition, due to the challenges of conducting the RCT, the project staff at the Improve-MH study centres were interviewed to reconstruct the actions and processes derived throughout the study, providing a comprehensive overview of the implementation of the intervention.

DISCUSSION

This RCT proposes an innovative approach to address one of the major challenges threatening the healthy development of refugee families, namely the high prevalence of MHP in refugee parents and the potential for the development of MHP in their children. Depression, anxiety and PTSD are the most prevalent MHP among refugees, with a prevalence of more than 50%. As having a parent with MHP is a high-risk factor for the most prevalent MHP, this study aims to interrupt the top–down transmission of MHP from parents to their children. Therefore, the Improve intervention combines the reduction of parental MHP and the enhancement of parenting skills and strategies for these families.

Because the psychotherapeutic care system in Germany currently struggles to manage the demands of high numbers of refugees with MHP, this study proposes a low threshold way of delivering mental health services by using the main entry into the primary healthcare system, GPs. The CBT-based intervention with participating parents is carried out by the GPs. This is supported by an online parenting tool (TPOL) and phone contacts with psychologists.

Since the family represents simultaneously a protective and a risk factor for refugee children,[84] the study's incorporation of TPOL provides a preventative intervention to interrupt the intergenerational transmission of MHP. The parenting programme tackles possibly existing maladaptive approaches to parenting. This in turn can help maintain the family as a protective factor for young refugee children. Mental resilience and fortified parenting skills of refugee parents can help prevent the development of MHP in their children, which in turn can ease the resettlement process.[25]

The overarching goal is to examine whether the Improve intervention reduces parental MHP and enhances parenting skills, thereby finally improving their children's mental health status.

In summary, this project's results can be expected to have substantial clinical, public health and scientific benefits. They address the major challenge posed by the unprecedented influx of highly stressed and often traumatised refugees. With no end in sight to the current migration movement, there exists an even greater need to assist families, facilitating their better and faster integration into German society through a prevention programme. Successful treatment and prevention strategies for MPH need to target individuals at risk for MHP early. Targeting MHP of parents and improving parent–child interaction will improve mental health outcomes in adult refugees and help prevent top–down transmission of MHP. In addition, interventions in the early years are highly cost-effective[85] and have been shown to impact both childhood development and long-term adult health outcomes.[86] Therefore, this research holds great potential to maximise the chances of successful integration of refugees into German society, foster the healthy development of their children and help maximise their full developmental potential.

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Acknowledgements The authors would like to thank the entirety of the Improve-MH study group for all their efforts in recruitment, and implementation including diagnostics and data management.

Contributors SS, JG, ML, JM, CB, H-HK, RK and AS collaborated on the study design and jointly drafted the grant proposal. KZ and KK formulated the study protocol. SS is the guarantor. JG, ML, KZ, KK, HCV, KL, NC, JK, AC-K, OC and VP all made significant contributions to the implementation of the study. In terms of study coordination, SS, KK, HCV, LH and JidS played essential roles. KZ, ND, KL, NC, JK, LH and DR were instrumental in the meticulous process of data collection. F-MH, KL, DR, AD and MH supervised the process of participant recruitment. All authors reviewed and approved the final version of the manuscript. KZ is the first and corresponding author. SS is the guarantor.

Funding This study is funded by the German Federal Ministry of Education and Research, grant number 01EF1801A. The funding source has no role in study design, data collection, analysis and interpretation of the data, or the writing and publication of results.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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