

## Trial Description

### Title

**Improve-MH: Improving mental health in refugee families with young children**

### Trial Acronym

**IMPROVE-MH**

### URL of the trial

[https://www.kli.psy.ruhr-uni-bochum.de/kkjp/forschung/forschung\\_en-gr-intervention.html#link](https://www.kli.psy.ruhr-uni-bochum.de/kkjp/forschung/forschung_en-gr-intervention.html#link)

### Brief Summary in Lay Language

**Among refugees, mental health problems are highly prevalent. Approximately more than 50% of the refugees who fled armed conflicts are affected by mental health problems, such as depression or anxiety. Parental mental health problems as well as an unfavorable parenting style are major risk factors for children to develop mental health problems as well.**

**The goal of this BMBF-funded research project is to improve mental health in refugee families with young children. For this purpose, parents with mental health problems will receive an intervention (10 weeks) via general practitioners. This intervention includes a short treatment (4 consultations) to deal with symptoms of anxiety, stress and depression as well as an online training to promote a positive parenting style and accompanying phone calls with a psychologist. Psychologically strained refugee families with young children (0-6 years) and Arabic language skills can join the study.**

**To examine the effects of the Improve intervention program compared to a treatment as usual, parents are invited to take part in interviews on mental health outcomes and fill in questionnaires prior, during and after the treatment. The aim is to investigate, if the Improve intervention is superior to a treatment as usual,**

### Brief Summary in Scientific Language

**The planned research project is a multicenter cooperative project, including different sub-projects. The project is based on an intervention for refugee parents with mental health issues, implemented as a randomized control trial (P1). In this context, cultural sensitivity of the used assessments will be studied (P2.1). Additionally, the intervention will be evaluated (process evaluation, assessing barriers in care provision, P2.2) and a cost-effectiveness of the IMPROVE intervention will be assessed (P3).**

**Mentally strained refugee parents (with children between 0-6 years) with Arabic language skills, who experience elevated stress, depressive or anxious symptoms are invited to take part in the study.**

**The intervention will take 10 weeks and includes three aspects (4 consultations in the general practice, online parenting program Triple P and regular phone calls with a psychologist) and will be compared to a treatment as usual.**

**Primary outcomes are the parental and child mental health, as well as parenting style. As secondary outcomes, we will also assess sociodemographic, psychosocial variables, physical health, stress (hair cortisol), use of medical care and possible side-effects. Time points are pre (T0), post (T1), such as a 6- (T2) and 12 -month follow-up (T3) in the major assessment. Selected variables will be also assessed directly after the treatment in the general practice (minor assessment) or during the phone calls (intermediate assessment). Prior to the study, a pilot will be carried out.**

**To analyze the cultural sensitivity sub-project P2.1 aims to examine measurement invariance by comparing data across different cultures and time points. Additionally, selected questionnaires will be assessed situational using a smartphone app (ecological momentary assessment, time points T0-T3).**

**In order to investigate barriers in care provision for refugees, general practitioners will be asked to report their experiences in the primary care prior, during and after the intervention (development of a half-structured interview and a questionnaire, sub-project P2.2).**

**Subproject P3 aims to analyse the cost-effectiveness of the intervention at the level of parents and their children.**

**The sub-projects (P2.1, P2.2 und P3) will be registered separately to present their methods and hypothesis in more detail.**

**Hypothesis of the interventional study P1 include:**

**Hypothesis 1): The Improve program will be superior to a treatment as usual control condition with respect to parental mental health outcomes as well as parenting skills at post, 6- and 12-month follow-up**

**Hypothesis 2): The Improve program will be superior to treatment as usual for**

**Do you plan to share individual participant data with other researchers?**

**Yes**

**Description IPD sharing plan**

**A part of the anonymised data will be published on an internet database. No data that enables personal tracking will be published (e.g. data regarding the residence or date of birth). Data security officer will be consulted before data selection.**

## **Organizational Data**

- DRKS-ID: **DRKS00019072**
- Date of Registration in DRKS: **2020/03/16**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **602 , Bochum - Lokale Ethikkommission der Fakultät für Psychologie (RUB)**

**Fakultät für Psychologie  
Ethikkommission  
Der Vorsitzende  
Gebäude: IB 5/117**

DRKS-ID: **DRKS00019072**

Date of Registration in DRKS: **2020/03/16**

Date of Registration in Partner Registry or other Primary Registry: [---]\*

Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

Ethics Approval/Approval of the Ethics Committee: **Approved**

**Universitätsstraße 150  
44801 Bochum**

## Secondary IDs

- Other Secondary-ID: **DRKS00021189 (Verbundstudie Teilprojekt P3)**
- Other Secondary-ID: **DRKS00021227 (Verbundstudie Teilprojekt P2-1)**
- Other Secondary-ID: **DRKS00023325 (Verbundstudie Teilprojekt P2-2)**

## Health condition or Problem studied

- ICD10: **F41 - Other anxiety disorders**
- ICD10: **F32 - Depressive episode**
- ICD10: **F43 - Reaction to severe stress, and adjustment disorders**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F40 - Phobic anxiety disorders**

## Interventions/Observational Groups

- **Arm 1: Intervention: Parents will receive a 10-week intervention with 1) a treatment in the general practice (learning to cope with depression, stress and anxiety), 2) a well-established online training to improve the parenting style (positive-parenting program, "Triple P") and 3) accompanying phone calls with a psychologist.**

**1) The treatment consists of 4 consultations in the general practice, each about 30 min, including aspects of the cognitive behavioral therapy. This comprises psychoeducation, interoceptive exercises as well as special sessions focusing on depression or anxiety.**

**2) The online positive parenting program is one of the most effective evidence-based parenting programs in the world. It will be used in an Arabic version and includes 8 training modules, each 60 minutes, involving video-clips, tasks and activities to improve a positive parent-child relationship, to support positive behavior and support the development of the child. Patients are asked to participate in the program once a week.**

**■ Arm 2: Treatment as usual:**

**Half of the parents will be randomized to the treatment as usual. Treatment as usual is equivalent to the treatment that the general practitioner would give to the patient without participating in the study. The treatment as usual is mainly based on the symptoms/complaints of the patient. This may include further visits, physical examinations and/or the prescription of medication.**

**Parents will participate in the major assessments (pre, post, 6-, 12-months follow up), as well as in the minor assessments during the treatment as usual.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: **assessor**
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Primary outcomes are parenting style and the mental health of parents and their child.**

**- Parenting Scale (EFB-K): Original version by Arnold, Leary, Wolff, and Acker (1993), German short version by Miller (2001), our own Arabic translation is oriented on the German short version.**

**- Parental mental health: Severity Rating of the parent's mental health problems on a 0-8 scale (Clinician Severity Rating, Mini-DIPS, by Margraf, J., Cwik, J. C., Pflug, V., & Schneider, S. (2017)).**

**- Child mental health: Severity Rating of the children's mental health problems on a 0-8 scale (Clinician Severity Rating, Baby/Kinder-DIPS, hybrid version of the Baby- (Popp et al., 2016) and Kinder-DIPS (Neuschwander et al., 2017)).**

**All primary outcomes will be assessed pre (T0), post (T1) and 6- (T2) and 12-months (T3) follow-up.**

**Mixed models will be used to compare the degree of change from pre (T0) to post (T1) and follow-up (T2, T3) assessments between groups on primary outcomes,**

## Secondary Outcome

**Secondary endpoints are parenting sense of competence (PSOC), parental mental health (DASS-21, PMH, SDS-RI, GSR, RHS-15, selection and assessment of major complaints) and child mental health (Kiddy-Kindl, SDQ, selection and assessment of major problems in parenting), and parental physical health (EQ5D5L) as well as child physical health (WCHMP). In addition, psychosocial variables (trauma events (HTQ), acculturation and language skills (AQ and self-assessment of language skills using the European Framework of Reference for Languages), housing conditions, employment status, quality of life (cantril ladder), partnership satisfaction (PFB), social support, treatment expectations) are assessed. After the Improve-Intervention (post), the parents also give a feedback on the satisfaction with the Improve-treatment (self-generated questions and CSQ).**

**The data will be collected using questionnaires. Hair cortisol will be assessed as an additional biological stress-marker pre and six-months follow up (Major Assessment).**

**During the intervention (immediately after the treatment in the general practice), global health changes (GSR), changes in main complaints, mental health problems (DASS-21) and parenting style (EFB-K) will be assessed (Minor Assessment).**

**Beside questions regarding the parenting program, global health changes (GSR), disability (SDS-RI) and possible side effects of the treatment will be assessed during weekly phone calls (Intermediate assessment).**

**- Parenting Sense of Competence (PSOC): The original version was developed by Gibaud-Wallston and Wandersman (1978) for the parents of infants and adapted by Johnston & Mash (1989) for parents of older children. German version by Miller (2001), Arabic version by Kabiyea and Manor-Binyamini (2019).**

**- Depression Anxiety and Stress Scale (DASS-21): Original version by Lovibond and Lovibond (1995), German short version by Nilges and Essau (2015), Arabic version by Moussa, Lovibond, Laube, and Megahead (2017).**

**- PMH (Positive Mental Health): The English and German versions were developed in the current form by Lukat, Margraf, Lutz, van der Veld, and Becker (2016), the Arabic translation was conducted by us.**

**- SDS-RI (Sheehan Disability Scale - Religiosity Islam): The scale measures disability and functional impairment. The original English version is by Sheehan (2019), the Arabic translation was conducted by us.**

**- GSR (Global Success Rating): The scale assesses subjective treatment success, as perceived by the parent, by the physician and by the psychologist**

**- RHS-15 (Refugee Health Screener): Screening for common mental disorders in refugees. English and Arabic version by Hollifield et al. (2013).**

**- Kiddy-Kindl: Original German and Arabic versions by Ravens-Sieberer and Bullinger (2000). The scale assesses different areas of children's well-being, we only use the scales psychological well-being and self-worth.**

**- SDQ-P (Strengths and Difficulties Questionnaire): Original version by Goodman (1994), German version by Klasen et al. (2005), Arabic version by Alyahri et al. (2005); Alyahri and Goodman (2006).**

**- EQ5D5L: The questionnaire by Herdmann et al. (2011) measures the health status of the patient and has been translated into different languages by the EuroQol Group. We use the German and Arabic versions.**

**(1996), the German and Arabic translations were conducted by us.**

**- HTQ (Harvard Trauma Questionnaire): Original version by Mollica et al. (1992), German version by Maercker (1995), Arabic version by Kleijn, Hovens and Rodenburg (2001) and Shoeb, Weinstein, Mollica (2006). We only use the first part, assessing trauma events, and added items that were generated for the arabic refugee sample.**

**- AQ (Acculturation Questionnaire): We use the 18-item short version of the AQ by Leyendecker & Harwood, adapted for the use with Arabic populations. The AQ consists of two scales, the first is about orientation to one's own culture and language, the second is about orientation to the German culture and language.**

**- Cantril-Ladder: Single-item measure of people's attitudes towards their life. Original version by Cantril (1965), German version by Glatzer and Zapf (1984), Arabic version by the Foundation Center '45 Arq Psychotrauma Expert Group (2015).**

**- PFB (Partnership Questionnaire): Original German version by Hahlweg (1996; see also Kliem et al., 2012), the Arabic translation was conducted by us. We will only assess one item for the general perceived quality of the partnership.**

**- Social Support: The Social Support Scale by Sheehan, Harnett-Sheehan, and Raj (1996) assesses the received social support as a percentage of the amount the participants needed to cope in the past week. The Arabic translation was conducted by us.**

**- INEP (Inventory for the assessment of negative effects of psychotherapy), adapted according to Bieda et al. (2018) and translated and modified by us.**

**-CSQ (Client Satisfaction Questionnaire), as a Feedback on satisfaction with the positive-parenting program Triple P (Sanders et al., 2012) translated into Arabic by us.**

**Mixed models will be used to test improvement after intervention, ITT and completer effects, interactions between treatment mode and children's age, and**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

- Doctor's Practice **Bochum; Duisburg-Essen; München**

## Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2020/12/01**
- Target Sample Size: **375**

Planned/Actual: **Planned**

(Anticipated or Actual) Date of First Enrollment: **2020/12/01**

Target Sample Size: **375**

- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

### Additional Inclusion Criteria

**Inclusion criteria:**

- (1) Refugee parents**
- (2) child(ren) aged 0-6 years**
- (3) Arabic language skills**
- (4) meeting clinical cut-off on Depression Anxiety Stress Scales (DASS-21)**

### Exclusion criteria

**Key exclusion criteria:**

- (1) other primary mental health problems, especially comorbidity of psychosis**
- (2) concurrent psychotherapy**
- (3) (instable) intake of relevant medication**
- (4) acute suicidality**
- (5) general medical contraindications**

**Comorbid mental health problems are not a criterion for exclusion as long as they are not primary.**

### Addresses

#### ■ Primary Sponsor

**Fakultät für Psychologie, Klinische Kinder- und Jugendpsychologie, Ruhr-Universität Bochum**  
**Ms. Prof. Dr. Silvia Schneider**  
**Massenbergstr. 9-13**  
**44787 Bochum**  
**Germany**

Telephone: **0234 3223168**

---

**Primary Sponsor**

**Fakultät für Psychologie, Klinische Kinder- und Jugendpsychologie, Ruhr-Universität Bochum**

**Ms. Prof. Dr. Silvia Schneider**

**Massenbergstr. 9-13**

**44787 Bochum**

**Germany**

Telephone: **0234 3223168**

Fax: **0234 3214435**

E-mail: **silvia.schneider at rub.de**

URL: **<http://www.kli.psy.ruhr-uni-bochum.de/kkjp/kkjp.html>**

■ **Contact for Scientific Queries**

**Ruhr-Universität Bochum Forschungs- und Behandlungszentrum für psychische Gesundheit (FBZ) Klinische Kinder- und Jugendpsychologie Fakultät für**

**Ms. Prof. Dr. Silvia Schneider**

**Massenbergstr. 9-13**

**44787 Bochum**

**Germany**

Telephone: **0234-3223168**

Fax: [---]\*

E-mail: **silvia.schneider at rub.de**

URL: [---]\*

■ **Contact for Public Queries**

**Ruhr-Universität Bochum Forschungs- und Behandlungszentrum für psychische Gesundheit (FBZ) Klinische Kinder- und Jugendpsychologie Fakultät für**

**Mr. Dr. Omar Chehadi**

**Massenbergstr. 9-13**

**44787 Bochum**

**Germany**

Telephone: **0234-3221505**

Fax: [---]\*

E-mail: **omar.chehadi at rub.de**

URL: [---]\*

■ **Contact for Scientific Queries**

**Ruhr-Universität Bochum Forschungs- und Behandlungszentrum für psychische Gesundheit (FBZ) Klinische Kinder- und Jugendpsychologie Fakultät für**

**Ms. Dr. Kerstin Konietzny**

**Massenbergstr. 9-13**

**44787 Bochum**

**Germany**





---

**Contact for Scientific Queries**

**Ruhr-Universität Bochum Forschungs- und Behandlungszentrum für psychische  
Gesundheit (FBZ) Klinische Kinder- und Jugendpsychologie Fakultät für  
Ms. Dr. Kerstin Konietzny**

**Massenbergstr. 9-13**

**44787 Bochum**

**Germany**

Telephone: **0234-3221507**

Fax: [---]\*

E-mail: **kerstin.konietzny at rub.de**

URL: [---]\*

■ **Collaborator, Other Address**

**Klinikum der Ludwig-Maximilians-Universität München Institut für  
Allgemeinmedizin Campus Innenstadt  
Mr. Prof. Dr. Jochen Gensichen**

**Pettenkoflerstr. 10**

**80336 München**

**Germany**

Telephone: **089 4400-53779**

Fax: **089 4400-53768**

E-mail: **Jochen.Gensichen at med.uni-muenchen.de**

URL: [---]\*

■ **Collaborator, Other Address**

**Ruhr-Universität Bochum Medizinische Fakultät Allgemeinmedizin Gebäude  
Mr. Prof. Dr. Horst Christian Vollmar**

**Universitätsstraße 150**

**44801 Bochum**

**Germany**

Telephone: **0234 / 32 27 12 7**

Fax: **0234 / 32 14 36 4**

E-mail: **horst.vollmar at rub.de**

URL: [---]\*

■ **Collaborator, Other Address**

**Universitätsmedizin Essen Universitätsklinikum Institut für Allgemeinmedizin  
Ms. Martina Heßbrügge**

**Hufelandstr. 55**

**45122 Essen**

**Germany**

Telephone: **0201 / 723 8020**

**Collaborator, Other Address**

**Universitätsmedizin Essen Universitätsklinikum Institut für Allgemeinmedizin**

**Ms. Martina Heßbrügge**

**Hufelandstr. 55**

**45122 Essen**

**Germany**

Telephone: **0201 / 723 8020**

Fax: [---]\*

E-mail: **Martina.Hessbruegge-Bekas at uk-essen.de**

URL: [---]\*

■ **Collaborator, Other Address**

**Ruhr-Universität Bochum Fakultät für Psychologie Arbeitseinheit  
psychologische Methodenlehre IB 4/185**

**Ms. Prof. Dr. Maike Luhmann**

**Universitätsstraße 150**

**44801 Bochum**

**Germany**

Telephone: **+49 234 / 32 24624**

Fax: [---]\*

E-mail: **maike.luhmann at rub.de**

URL: [---]\*

■ **Collaborator, Other Address**

**Universitätsklinikum Hamburg-Eppendorf Institut für Gesundheitsökonomie  
und Versorgungsforschung W37, 6. Etage, Raumnummer 603a**

**Mr. Prof. Dr. Hans-Helmut König**

**Martinistrasse 52**

**20246 Hamburg**

**Germany**

Telephone: **+49 40 7410 - 54464**

Fax: [---]\*

E-mail: **H.Koenig at uke.uni-hamburg.de**

URL: [---]\*

■ **Contact for Scientific Queries**

**Forschungs- und Behandlungszentrum für psychische Gesundheit (FBZ)**

**Klinische Kinder- und Jugendpsychologie Fakultät für Psychologie**

**Ms. Angela Köster**

**Massenbergstr. 9-13**

**44787 Bochum**

**Germany**

---

**Contact for Scientific Queries**

**Forschungs- und Behandlungszentrum für psychische Gesundheit (FBZ)  
Klinische Kinder- und Jugendpsychologie Fakultät für Psychologie  
Ms. Angela Köster**

**Massenbergstr. 9-13**

**44787 Bochum**

**Germany**

Telephone: **0234/32 23816**

Fax: [---]\*

E-mail: **angela.koester at rub.de**

URL: [---]\*

■ **Collaborator, Other Address**

**Ruhr-Universität Bochum Fakultät für Psychologie AE Genetic Psychology**

**Mr. Prof. Dr. Robert Kumsta**

**Universitätsstraße 150**

**44801 Bochum**

Telephone: **0234 / 32 22676**

Fax: [---]\*

E-mail: **robert.kumsta at rub.de**

URL: [---]\*

■ **Collaborator, Other Address**

**Ruhr-Universität Bochum Fakultät für Psychologie Klinische Psychologie**

**Mr. Prof. Dr. Jürgen Margraf**

**Massenbergstr. 9-13**

**44787 Bochum**

**Germany**

Telephone: **0234 / 32 23169**

Fax: **0234 / 32 14369**

E-mail: **juergen.margraf at rub.de**

URL: [---]\*

■ **Collaborator, Other Address**

**Universitätsklinikum Hamburg-Eppendorf Institut für Gesundheitsökonomie  
und Versorgungsforschung**

**Mr. Dr. Christian Brettschneider**

**Martinistrasse 52**

**20246 Hamburg**

**Germany**

Telephone: **+49 40 7410 - 56535**

Fax: [---]\*

### **Collaborator, Other Address**

**Universitätsklinikum Hamburg-Eppendorf Institut für Gesundheitsökonomie  
und Versorgungsforschung  
Mr. Dr. Christian Brettschneider  
Martinistrasse 52  
20246 Hamburg  
Germany**

Telephone: **+49 40 7410 - 56535**

Fax: [---]\*

E-mail: **C.Brettschneider at uke.de**

URL: [---]\*

### **Sources of Monetary or Material Support**

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and**

**Bundesministerium für Bildung und Forschung Dienstsitz Bonn  
Heinemannstr. 2  
53175 Bonn  
Germany**

Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: **www.bmbf.de**

### **Status**

- Recruitment Status: **Recruiting planned**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]\*
- Reason, if Reason for Recruiting Stop "Other": [---]\*
- Study Closing (LPLV): [---]\*
- Number of Participants in Germany after Recruiting complete: [---]\*
- Total Number of Participants (all Sites worldwide) after Recruiting complete: [---]\*

### **Trial Publications, Results and other documents**

DRKS-ID: **DRKS00019072**

Date of Registration in DRKS: **2020/03/16**

Date of Registration in Partner Registry or other Primary Registry: [---]\*



**Deutsches Register  
Klinischer Studien**

German Clinical  
Trials Register

---

*\* This entry means the parameter is not applicable or has not been set.*

*\*\*\* This entry means that data is not displayed due to insufficient data privacy clearing.*