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**Predictors of outcome of the culturally sensitive group psychotherapy
Empowerment for refugees with affective disorders:
A multicenter randomized controlled trial**

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List of abbreviations

| | |
|--------|--|
| AIC | Akaike's Information Criterion |
| ANOVA | Analysis of Variance |
| APA | American Psychological Association |
| BAMF | Bundesamt für Migration und Flüchtlinge |
| BIC | Schwarz's Bayesian Criterion |
| BRS | Brief Resilience Scale |
| CA-CBT | Culturally Adapted Cognitive Behavioral Therapy |
| CBT | Cognitive Behavioral Therapy |
| CI | Confidence Interval |
| DSM | Diagnostic and Statistical Manual of Mental Disorders |
| eCRF | electronic Case Report File |
| EQ-5D | European Quality of Life 5 Dimensions |
| EMDR | Eye Movement Desensitization and Reprocessing |
| FDR | False Discovery Rate |
| FU | Follow-up |
| GAF | Global Assessment of Functioning |
| GCP | Good Clinical Practice |
| GSE | Generalized Self-Efficacy Scale |
| HTQ | Harvard Trauma Questionnaire |
| IASC | Inter-Agency Standing Committee |
| ICC | Intra-cluster Correlation |
| ICD-10 | International Classification of Diseases 10th Revision |
| ITT | Intention-to-treat |
| KKS | Koordinierungszentrum für klinische Studien |
| kNN | k-Nearest-Neighbor |
| MADRS | Montgomery Asberg Depression Rating Scale |
| MEHIRA | Mental Health in Refugees and Asylum Seekers |

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| MRV | Mannheimer Modul Ressourcenverbrauch |
| M.I.N.I. | Mini-International Neuropsychiatric Interview |
| NET | Narrative Exposure Therapy |
| PAI | Personalized Advantage Index |
| PDS-5 | Posttraumatic Diagnostic Scale for DSM-5 |
| PHQ-9 | Patient Health Questionnaire 9 |
| PI | Post-intervention |
| PP | Per protocol |
| PROM | Patient-reported Outcome Measure |
| PTE | Potentially traumatic events |
| PTSD | Post-traumatic stress disorder |
| RCT | Randomized Controlled Trial |
| RHS-15 | Refugee Health Screener 15 |
| SCCM | Stepped and Collaborative Care Model |
| SD | Standard Deviation |
| SDS | Sheehan Disability Scale |
| SDQ | Strengths and Difficulties Questionnaire |
| TAU | Treatment-as-usual |
| TF-CBT | Trauma-focused Cognitive Behavioral Therapy |
| TFI | Therapeutic Factors Inventory |
| TGIF | Therapeutic Group Interactions Factors Scale |
| UN | United Nations |
| UNHCR | United Nations High Commissioner for Refugees |
| VIF | Variance Inflation Factor |
| WHODAS 2.0 | World Health Organization Disability Assessment Schedule |
| WHOQoL-BREF | World Health Organization Quality of Life Questionnaire, brief version |
| WHO-5 | World Health Organization Well-Being Index |

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Abstract

Theoretical background: Due to various pre-, peri-, and post-displacement stressors that are active in the context of forced migration, refugees are at significant risk of developing mental disorders in the post-migration environment. It is a major challenge for researchers and clinicians to provide effective, culturally sensitive, and accessible mental health interventions to cover the urgent need for psychosocial care in this population. First, this dissertation gives an overview on the existing mental health interventions for refugees and asylum seekers. Second, a systematic overview of available predictor studies in this field is provided. Predictor studies represent a key element in transcultural health care research as they target the question of which refugees benefit from specific treatment options and which ones do not. Data on outcome predictors can be used to allocate refugees to those interventions which they are most likely to benefit from or modify treatment for non-responders, finally providing an empirical foundation to structure the health care system in the most effective and pragmatic possible way. As the number of available predictor studies in the field of refugee treatment is scarce, this dissertation aims to provide a comprehensive predictor analysis of psychotherapeutic treatment for refugees based on a novel group intervention named *Empowerment*.

Methods: This dissertation was conducted within the framework of the multicenter randomized controlled trial MEHIRA (Mental Health in Refugees and Asylum Seekers), investigating a stepped and collaborative care model (SCCM) for refugees with affective disorders. 149 participants who reported moderate depressive symptoms at baseline were allocated to level 3 of the SCCM and randomly assigned either to the *Empowerment* group therapy or Treatment-as-usual (TAU). *Empowerment* is a 12-week culturally sensitive group treatment that was developed to equip refugees with functional self-help skills to deal with depressive symptoms and post-migration stressors. Depressive symptoms were assessed at baseline (T0) and post-intervention (T1) using the self-rated Patient Health Questionnaire 9 (PHQ-9) as a primary outcome, and the clinician-rated Montgomery Asberg Depression Rating Scale (MADRS) as a secondary outcome. Predictor analysis was conducted using regression models with change scores (T1-T0) of PHQ-9 and MADRS. Predictors were selected following a mixed-method approach. First, hypothesis-guided hierarchical regression models were calculated with five literature-based predictors. These were baseline depression (PHQ-9, MADRS), post-migration context factors (residence status, employment, housing), and a comorbid PTSD. Second, explorative bivariate regression models were calculated with multiple

further baseline variables. Third, final regression models were calculated integrating both findings from hypothesis-guided and explorative models. All analyses were applied both to the Intention-to-treat (ITT) and Per protocol (PP) sample and both to the treatment (*Empowerment*) and control (TAU) condition.

Results: Primary evaluations showed that *Empowerment* was effective in reducing depressive symptoms (PHQ-9 and MADRS) compared to TAU. Concerning the ITT sample, baseline PHQ-9 ($\beta=-0.35$, $t=-3.27$, $p=.002$) and baseline self-efficacy ($\beta=-0.24$, $t=-2.26$, $p=.027$) predicted PHQ-9 change scores, and baseline MADRS ($\beta=-0.71$, $t=-8.65$, $p<.001$) predicted MADRS change scores, in *Empowerment*. Concordantly, baseline self-efficacy ($\beta=-0.30$, $t=-2.41$, $p=.020$) predicted PHQ-9 change scores, and baseline MADRS ($\beta=-0.56$, $t=-5.50$, $p<.001$) predicted MADRS change scores, in TAU. Thus, analyses were repeated in the pooled ITT sample of both conditions to identify general predictors of refugee treatment outcome. It was found that baseline PHQ-9 ($\beta=-0.30$, $t=-3.82$, $p<.001$) and baseline self-efficacy ($\beta=-0.29$, $t=-3.65$, $p<.001$) were predictors of change in PHQ-9, and baseline MADRS ($\beta=-0.71$, $t=-10.36$, $p<.001$) and housing ($\beta=-0.17$, $t=-2.51$, $p=.013$) were predictors of change in MADRS. Concerning the PP sample, concomitant psychotherapy ($\beta=0.57$, $t=3.66$, $p=.001$) and identification as a migrant ($\beta=0.44$, $t=2.80$, $p=.010$) were predictors of MADRS change scores in *Empowerment*. In TAU, baseline self-efficacy ($\beta=-0.43$, $t=-2.89$, $p=.006$) and baseline MADRS ($\beta=-0.34$, $t=-2.65$, $p=.012$) predicted change in PHQ-9 and MADRS, respectively.

Discussion: High rates of baseline depression severity and perceived self-efficacy predicted symptom improvement in participants of both conditions. Although these factors seem to represent global predictors of successful refugee treatment, they may be of high practical relevance in implementing the *Empowerment* intervention under real-life conditions. Contrary to the hypotheses, post-migration context factors and comorbid PTSD did not predict outcomes in *Empowerment*. It appears that *Empowerment* represents a suitable low-threshold intervention to treat a broad and diversified population of refugees in different post-migration stages and settings. A widespread dissemination of the intervention into routine practice may contribute to significant improvements in culturally sensitive mental health care. Ultimately, the presented results may find application in the development of decision-making tools that allow for optimized treatment allocations and ensure a pragmatic health care delivery to refugees in need. To extend the database on relevant outcome predictors, future studies should examine further important socio-cultural variables, such as discrimination and racism, social participation, and strategies of acculturation in the context of culturally sensitive treatment.

Zusammenfassung

Theoretischer Hintergrund: Fluchtmigration ist mit einer Vielzahl spezifischer Prä-, Peri- und Post-Migrationsstressoren assoziiert und führt dazu, dass geflüchtete Menschen ein erhöhtes Risiko für psychische Erkrankungen im Ankunftsland aufweisen. Es ist eine zentrale Herausforderung für die Gesundheitssysteme asylbietender Länder, diesen Menschen effektive und kultursensible Behandlungsangebote bereitzustellen, um den hohen Bedarf an psychosozialer Versorgung zu decken. In dieser Dissertation werden zunächst die aktuell verfügbaren psychotherapeutischen Behandlungsangebote für geflüchtete Menschen beschrieben. Anschließend wird ein Überblick über die zugehörigen Prädiktorstudien gegeben. Prädiktorstudien sind ein wichtiger Baustein kultursensibler Psychotherapieforschung, um zu untersuchen, welche Faktoren Therapieerfolg vorhersagen können. In der Praxis sind diese Daten relevant, um anhand spezifischer Faktoren geflüchtete Menschen denjenigen Therapieangeboten zuzuweisen, von denen sie am wahrscheinlichsten profitieren, oder bestehende Therapieangebote anzupassen. Vor diesem Hintergrund wird in dieser Dissertation eine umfangreiche Prädiktorenanalyse der Behandlung von geflüchteten Menschen im Rahmen der kultursensiblen Gruppenpsychotherapie *Empowerment* beschrieben.

Methoden: Diese Arbeit wurde im Rahmen der multizentrischen randomisierten kontrollierten Studie MEHIRA (Mental Health in Refugees and Asylum Seekers) verfasst, in der ein gestuftes Versorgungsmodell für geflüchtete Menschen mit affektiven Störungen untersucht wurde. Die Stichprobe umfasste 149 Teilnehmende mit moderaten depressiven Symptomen, die auf Stufe 3 des Versorgungsmodells entweder in die *Empowerment*-Bedingung oder Treatment-as-usual (TAU) Bedingung randomisiert wurden. *Empowerment* ist eine 12-wöchige kultursensible Gruppentherapie, die funktionale Strategien zum Umgang mit depressiven Symptomen und Post-Migrationsstressoren vermitteln soll. Depressive Symptome wurden zur Baseline (T0) und Post-Intervention (T1) anhand des Patient Health Questionnaire 9 (PHQ-9) und der Montgomery Asberg Depression Rating Scale (MADRS) erfasst. Es wurden Regressionsmodelle mit Änderungswerten (T1-T0) von PHQ-9 und MADRS als abhängige Variablen gerechnet. Die Prädiktorselektion wurde im Methodenmix aus konfirmativen und explorativen Analysen durchgeführt. Zunächst wurden hypothesenbasierte Regressionsmodelle mit fünf Prädiktoren gerechnet (Baseline Depression, Aufenthaltsstatus, Beschäftigung, Wohnsituation, komorbide PTBS). Im Anschluss wurden explorative bivariate Modelle und zuletzt finale Modelle unter Berücksichtigung relevanter Variablen aus beiden Ansätzen

gerechnet. Alle Analysen wurden sowohl in der Intention-to-treat (ITT) als auch der Per protocol (PP) Stichprobe sowie der *Empowerment*- und TAU-Bedingung durchgeführt.

Ergebnisse: Primäranalysen haben die Wirksamkeit von *Empowerment* im Vergleich zu TAU gezeigt (signifikante Symptomreduktion in PHQ-9 und MADRS). In der *Empowerment*-Bedingung der ITT Stichprobe waren Baseline PHQ-9 ($\beta=-0.35$, $t=-3.27$, $p=.002$) und Baseline Selbstwirksamkeit ($\beta=-0.24$, $t=-2.26$, $p=.027$) Prädiktoren für eine Symptomreduktion im PHQ-9 und Baseline MADRS ($\beta=-0.71$, $t=-8.65$, $p<.001$) war Prädiktor für Symptomreduktion im MADRS. Übereinstimmend dazu wurden in der TAU-Bedingung Baseline Selbstwirksamkeit ($\beta=-0.30$, $t=-2.41$, $p=.020$) und Baseline MADRS ($\beta=-0.56$, $t=-5.50$, $p<.001$) als Prädiktoren für Reduktion im PHQ-9 bzw. MADRS gefunden. Daher wurden die Analysen in der gepoolten ITT Stichprobe wiederholt, um allgemeine Outcomeprädiktoren in der Behandlung von Geflüchteten zu ermitteln. Es zeigte sich, dass Reduktion im PHQ-9 durch Baseline PHQ-9 ($\beta=-0.30$, $t=-3.82$, $p<.001$) und Baseline Selbstwirksamkeit ($\beta=-0.29$, $t=-3.65$, $p<.001$) und Reduktion im MADRS durch Baseline MADRS ($\beta=-0.71$, $t=-10.36$, $p<.001$) und Wohnsituation ($\beta=-0.17$, $t=-2.51$, $p=.013$) vorhergesagt werden konnten. In der *Empowerment*-Bedingung der PP Stichprobe waren eine begleitende Psychotherapie ($\beta=0.57$, $t=3.66$, $p=.001$) und das Identifikationsmaß als Migrant ($\beta=0.44$, $t=2.80$, $p=.010$) Prädiktoren von Symptomreduktion im MADRS. In der TAU-Bedingung zeigte sich erneut, dass Baseline Selbstwirksamkeit ($\beta=-0.43$, $t=-2.89$, $p=.006$) und Baseline MADRS ($\beta=-0.34$, $t=-2.65$, $p=.012$) Symptomreduktion im PHQ-9 bzw. MADRS vorhersagten.

Diskussion: Hohe Werte von Depression und Selbstwirksamkeit waren signifikante Prädiktoren für Therapieerfolg in beiden Bedingungen. Obwohl diese Faktoren globale Prädiktoren in der Behandlung von Geflüchteten zu sein scheinen, sind sie gleichzeitig relevant, um die *Empowerment* Intervention in der Praxis zu implementieren und verbreiten. Entgegen den Erwartungen konnten Post-Migrationsstressoren und Komorbidität Therapieerfolg nicht vorhersagen, was jedoch auf eine breite Anwendbarkeit von *Empowerment* als eine effektive, niedrighschwellige Intervention hinweist, die für die Behandlung vieler geflüchteter Menschen in diversen Phasen und Lebensumständen nach der Migration geeignet ist. Eine Dissemination von *Empowerment* in das bestehende Gesundheitssystem könnte erheblich zur Verbesserung der psychotherapeutischen Versorgungslandschaft beitragen und eine kultursensible, pragmatische Gesundheitsversorgung gewährleisten. Zukünftige Studien sollten weitere soziokulturelle Prädiktoren wie Diskriminierung und Rassismus, soziale Teilhabe und Akkulturationsstrategien im Kontext kultursensibler Versorgungsangebote untersuchen.

1 Introduction

What is the appropriate question to be asked of outcome research? In all its complexity, the question towards which all outcome research should ultimately be directed is the following: *What* treatment, by *whom*, is most effective for *this* individual with *that* specific problem, and under *which* set of circumstances? (Paul, 1967, p. 3)

This groundbreaking question was raised by Gordon Paul about 50 years ago and has since then substantially affected the direction of psychotherapy research. At the time, it marked a shift of paradigm in how researchers and clinicians conceptualized successful mental health care, basically moving the focus from the question *Which specific interventions work?* to the more complex question *What works for whom?*. Gordon Paul's approach addressed one of the key problems in the research and practice of psychotherapy: although it has repeatedly been documented that psychotherapeutic interventions were generally effective for patients, there was substantial variation in individual treatment outcomes (Kazdin, 2007; Lambert, 2015). Despite receiving equivalent treatment, some patients showed better treatment responses than others, and some patients did not respond to treatment at all. Lambert (2013) reported that 5-10% of patients who were treated within routine care structures even deteriorated, leaving with worse mental health than before. This problem remains unsolved up until today. Recent meta-analytic data suggests that more than 50% of patients do not respond to evidence-based depression treatment (Cuijpers et al., 2021). Patients seem to show highly individualized responses to overall effective treatment (Kaiser et al., 2020). The following questions remain: What are the underlying mechanisms of response and non-response, and which are the factors associated with differential treatment outcomes? Modern treatment approaches have integrated these questions into a new framework of mental health care in which psychotherapy represents a complex interplay of numerous client-related, therapist-related, context-related, and treatment-related factors that potentially generate an effective symptom change for a specific individual (Cohen & DeRubeis, 2018; Delgadillo & Lutz, 2020; Hofmann & Hayes, 2019). Among all these factors at play, the pre-treatment factors that allow for a prediction of positive or negative treatment outcomes, i.e., predictors of outcome, are of particular importance (Steyerberg, 2019). Delineating outcome predictors can be of clinical relevance as it provides information on patient groups with specific characteristics and the associated outcomes of particular treatments. In practice, this may act in support of matching patients to those treatment

options which they most likely benefit from, or to modify treatment for non-responders. Against this background, the relevance of predictor studies has been emphasized repeatedly in recent publications on current trends of psychotherapy research (Cohen & DeRubeis, 2018; Delgadillo & Lutz, 2020; Hofmann & Hayes, 2019).

These recent trends in psychotherapy research set the framework for the present dissertation. In this work, the comprehensive predictor analysis of a novel, culturally sensitive group psychotherapy, named *Empowerment* (Wiechers et al., 2019), for refugees and asylum seekers with affective disorders will be presented. Predictor studies in the field of culturally sensitive treatment are rare but urgently needed as refugees represent a population that are in particular need of effective and pragmatic mental health care. In 2020, the United Nations (UN) refugee agency recorded an all-time high of forcibly displaced individuals worldwide (United Nations High Commissioner for Refugees [UNHCR], 2021a). Burdened by the causes and consequences of forced migration and distress in post-migration environments, many refugees have inadequate access to adequate culturally sensitive mental health services in Western countries of asylum (Satinsky et al., 2019). The high demand for psychosocial care that follows forced migration remains widely uncovered, resulting in a treatment gap for refugees and asylum seekers (Silove et al., 2017). To provide needs-based mental health care to this population will require, on one hand, the broadening of the landscape of low-threshold interventions. On the other hand, it will require conducting corresponding predictor studies to identify the relevant factors in culturally sensitive health care provision and ensure successful treatment rates and allocations. This dissertation focuses on the second aspect, aiming to describe significant predictors of outcome of the *Empowerment* intervention and thus contribute to creating a well-functioning mental health care provision to refugee and asylum seekers in Germany.

2 Theoretical Background

2.1 Definitions and numbers of migration

2.1.1 *Definitions of essential terms to differentiate migrant populations*

Researchers and clinicians come across a variety of terms and denotations that are used to describe treatment populations in the field of culturally sensitive mental health care. The terminology can be puzzling and difficult to differentiate as heterogeneous denotations circulate in the literature, such as migrants, immigrants, refugees, asylum seekers, forced migrants, labor migrants, irregular migrants, and many more. In parts, this is a representation of the multifaceted nature of migratory processes, i.e., its diverse causes, conditions and consequences, resulting in an actual diversity of migrant subgroups (Sieben & Straub, 2018). However, essential terms are often used inconsistently, blurring the lines between different migrant subpopulations and complicating universal definitions. In UK public debate, for instance, the term *migrant* is frequently used interchangeably with asylum seekers or ethnic minorities (Baker et al., 2008). A universal and unambiguous terminology seems to be absent. From a mental health care perspective, however, a meticulous differentiation between migrant subpopulations seems of crucial importance as they differ substantially regarding relevant health-related factors. Among others, these factors relate to the motivation of migration (e.g., forced migrants), the current residence permit (e.g., asylum seekers) and the experience of traumatic events (e.g., torture survivors), and are associated with mental health outcomes (Porter & Haslam, 2005). It has also been suggested that cultural differences between migrant populations determine the presentation of mental distress and the incidence of specific mental disorders (Bhugra et al., 2011). In consequence, the nomenclature of migrant populations entails relevant implications for epidemiological considerations and culturally sensitive diagnostics, and the treatment of mental disorders. To avoid confusion and ensure a clear terminology within this dissertation, the most relevant terms are introduced hereinafter.

The common basis for the definition of the term *migrant* is the temporary or permanent relocation of one's habitual residence across national borders (Bundesamt für Migration und Flüchtlinge [BAMF], 2020). Further criteria used for definition may refer to the country of birth, nationality, and length of stay in the host country. The terms *migrant* and *immigrant* are used interchangeably, even if some sources refer to migrants as temporary residents and immigrants as permanent residents in the host country (Anderson & Blinder, 2015). For

convenience, the term migrant is preferred hereafter. Among migrants, several subpopulations can be subsumed. The term *refugee* relates to the legal status of individuals meeting the criteria of applicable international, national, or regional definitions. Most prominent is the United Nations' (1951) definition recorded in the 1951 Geneva Convention, and its 1967 Protocol. Accordingly, a refugee is a person who

owing to well-founded fear of being persecuted for reasons of race, religion, nationality, membership of a particular social group or political opinion, is outside the country of his nationality and is unable or, owing to such fear, is unwilling to avail himself of the protection of that country; or who, not having a nationality and being outside the country of his former habitual residence as a result of such events, is unable or, owing to such fear, is unwilling to return to it. (p. 152)

A distinction is made for the legal status of *asylum seekers*. Asylum seekers are defined as individuals who “have sought international protection and whose claims for refugee status have not yet been determined” (UNHCR, 2021b, Asylum-seekers). Refugees and asylum seekers are subsumed under the umbrella term *forced migrants* due to the involuntary nature of their migration (UNHCR, 2021a). In contrast, *labor migrants* (or migrant workers) are rather associated with the voluntary decision to cross national borders for economic reasons. Economic inequalities, seeking employment, national and local economic crises, and demographic development may be key motivations underlying labor migration (Global Migration Group, 2017). Importantly, labor migrants do not meet criteria for refugee status and have no legal entitlement to international protection (UNHCR, 2021b). The term *irregular migrant* (or undocumented migrant) refers to individuals without a legal permit to stay in the country of arrival. This may be due to illegal immigration, rejection of initial asylum application, and expired or invalid visa. As irregular migrants do not have official entitlements to stay, they have limited or no access to health care services (Priebe et al., 2016).

The introduced terminological framework will be used as precisely as possible in this dissertation. However, describing results and study populations from cited publications inevitably refers to the terminology used in the original work. In the following chapter, forced displacement worldwide and migration to Germany in the recent past will be outlined.

2.1.2 Facts and numbers on forced migration to Germany in recent years

In 2020, 82.4 million individuals were displaced by force from their habitual residence worldwide (UNHCR, 2021a). While 48.0 million of these were displaced inside their own country, 26.4 million refugees and 4.1 million asylum seekers were registered seeking international protection in other countries. The refugee population under UNHCR's mandate was twice as high as in 2010 and represented an all-time high in global history. Compared to 2019, an additional 11.2 million individuals have been displaced in 2020 due to war, persecution, human rights violations, and other precarious living conditions. Five countries were the primary regions of origin of forced displacement: the Syrian Arab Republic (6.7 million refugees), Venezuela (4.0 million), Afghanistan (2.6 million), South Sudan (2.2 million), and Myanmar (1.1 million). Taken together, these numbers accounted for more than two thirds of all refugees worldwide. The main proportion of forced migrants was internally displaced or found refuge in neighboring countries (e.g., Syrian refugees in Turkey). The main host countries for refugees and asylum seekers in 2020 were: Turkey with 3.7 million refugees, Colombia with 1.7 million refugees, Pakistan with 1.4 million refugees, Uganda with 1.4 million refugees, and Germany with 1.2 million refugees (UNHCR, 2021a).

In European comparison, Germany was the main destination of forced migration in the recent decade (BAMF, 2020). Between 2014 and 2018, around 1.7 million people have applied for asylum in Germany, with most applicants coming from the Syrian Arab Republic, Afghanistan, and Iraq. Following the humanitarian crisis in Syria, in 2015 Germany registered the highest immigration rate since 1950, resulting in a net immigration of around 1.14 million individuals (net immigration refers to the difference between total immigration and emigration numbers). Since then, immigration numbers followed a decreasing trend. In 2019, net immigration was 327,060. The number of asylum applications decreased simultaneously. While 722,370 asylum applications were registered in 2016, the numbers reduced to 198,317 in 2017, 161,931 in 2018, and 142,509 in 2019 (BAMF, 2020). Despite the decline in numbers of immigration and asylum applications in recent years, the total number of refugees (1.2 million) and asylum seekers (0.2 million) who were hosted by Germany by the end of 2020 was estimated at almost 1.5 million (UNHCR, 2021a).

2.2 The psychology of migration

Migration represents the permanent or semi-permanent geographical relocation of residence (Bhugra et al., 2011). Migration occurs both within and across national borders, between rural and urban areas, and may vary in terms of duration (e.g., seasonal migration) and dimension (e.g., individuals, families, or populations). Reasons for initiating migratory movements are manifold, including educational, political, socio-economic, and environmental motivations (Bhugra et al., 2011). Two major aspects shape the process of migration: the decision to migrate and the direction of migration (BenEzer & Zetter, 2014; Rügger & Bohnet, 2018). The classic understanding of migration is that migration represents a rational flow between two endpoints (King, 2012). On one side, adverse push factors drive migrants out of their original residence by activating avoidance target-directed behavior. Push factors may be natural disasters, climate change, poverty, unemployment, political or religious repression, war, or humanitarian crises (Iqbal, 2007; King, 2012). On the other side, pull factors drag migrants towards a favorable environment of destination by activating approach target-directed behavior. Common pull factors are economic wealth, political stability and freedom, good educational and welfare systems, and good occupational and income prospects (King, 2012; Rügger & Bohnet, 2018). Later in time, this classic approach has been criticized to be simplistic and determinist and has therefore been extended with micro- and meso-level factors, stressing the complex interplay of the heterogeneous individual processes, motivations, and experiences of migrants (Klaus & Pachocka, 2019; van Hear et al., 2018). It has also been documented that forced migration requires particular theoretical consideration as it is accompanied by push factors of a violent nature that leave migrants no room for a deliberate decision to migrate, whereas other migrants may be more in control over this decision (Rügger & Bohnet, 2018).

Despite the heterogeneity and complexity of migratory experiences, recurrent patterns in the process and the impact of migration have been identified across different cultural backgrounds and migrant subgroups (Berry, 1997; Machleidt & Heinz, 2011; Sluzki, 1979). Psychological models of migration aim to describe these commonalities under population-based theoretical considerations. These models contribute to understanding the associations between migration-specific external events and individual reactions, and providing valuable information on potential predictors of refugee mental health and the outcomes of psychological treatment for those who develop psychopathological phenomena (Nickerson, 2018). Two prominent theoretical frameworks of migration are introduced hereafter.

2.2.1 Theoretical concepts of migration: The stage model

Based on previous work by Oberg (1960), Sluzki (1979, 2001) and Machleidt and Heinz (2011), Kizilhan (2018) developed a comprehensive theoretical framework of migration that describes sequential stages of migration and their impact on the migrating individual. The stage model relies on a stress management approach which assumes that migrants have to cope with a number of developmental tasks and intrapsychic conflicts throughout the migration process. Specific challenges, achievements, and frustrations characterize each stage and affect the emotional states and the level of functional adjustment of the migrating individual (figure 1).

The classification of the stages follows the earlier psychodynamic model of Sluzki (1979, 2001). After a possible *internal migration* or *migration to neighboring countries*, the *preparatory stage* represents the initial stage of migration. Collecting information that supports or opposes the decision to migrate characterizes this stage. The opportunities and feasibility of migration are considered, such as legal requirements of immigration, resources to migrate, and the route of migration. The preparatory stage is accompanied by an initial euphoria and curiosity towards new experiences, followed by feelings of overload and dismay due to the efforts exerted. Once the decision to migrate has been made, the *act of migration* is carried out. It may vary substantially in terms of duration and conditions. The act of migration may only take a couple of hours (e.g., a train ride) but also endure for days, weeks, or months. Forced migrants may have to stay in intermediate camps or countries along their route of flight. The migratory act can be a burdening experience and may evoke feelings of aggression and pain of parting. Upon arrival in the country of destination, migrants enter the *period of overcompensation*. Migrants commonly experience emotional states of relief and happiness, subsumed under the so-called honeymoon phase. The arrival in a safe environment, combined with the cessation of acute peri-migration stressors, results in a state of overcompensation. Migrants may yet be unaware of the delayed impact of the stressful experiences they endured in the context of migration. High expectations in a better future life, hope and interest in the host country's culture, or even fascination, are likely to cumulate to a joyful elation entailing an absence of post-migration distress. The dissonance between expectations of the new life and the reality in the country of arrival is frequently misperceived or denied. After around six months of overcompensation, the *period of decompensation* sets in, which is split into a *period of critical adjustment* and a *period of grief* in the model of Kizilhan (2018). Frustration, disillusionment, and a low level of functionality characterize this stage. Migrants tend to become aware of the discrepancies between their expectations and the reality, evoking feelings of disappointment

Sluzki (1979, 2001) primarily developed the stage model to conceptualize voluntary migration. However, Kizilhan (2018) argued that forced migration entails a multitude of push factors and stressors that exceed those of other migration forms. The pre- and peri-migration experience of trauma and existential threat may accelerate and aggravate the period of decompensation, or even skip the period of overcompensation. Due to major push factors such as war and persecution in the country of origin, refugees may already have developed severe mental distress upon arrival in the host country. Further post-migration difficulties (e.g., uncertain residence status, missing permission to work, and limited access to health care) may hamper functional adaptation processes in the new environment. Therefore, Kizilhan (2018) suggested different trajectories of functional adjustment between refugees and non-refugee migrants. In comparison with non-refugee migrants, the curve of adjustment remains on an inferior level until the period of bi-/multi-culturality (figure 1). Regarding refugees that seek for psychological treatment, the stage model of migration suggests potential influence factors on mental health indicators and the outcomes of mental health interventions. The cessation of unrealistic expectations towards the post-migration environment and the onset of major post-migration stressors that normally occur in the period of decompensation may represent important predictors of symptom trajectories and interfere with the success of mental health treatment for refugees and asylum seekers.

2.2.2 Theoretical concepts of migration: The acculturation model

While the stage model aims to capture the entire chronological process of migration, the acculturation model (Berry, 1997) delivers a framework for describing different acculturation strategies that migrants implement upon confrontation with an unknown socio-cultural environment. Acculturation represents the bilateral adaptation processes that emerge when two groups of different cultural backgrounds come into enduring first-hand interaction (Berry, 1997). Even though the definition of acculturation implies that cultural adaptation involves both groups, the cultural minority is commonly charged with more expectations to change towards the cultural majority than vice versa. Upon arrival in the host country, migrants usually experience a discrepancy between their traditional cultural identity and the novel cultural value system of the host society. Berry (1997) assumed two dimensions of response to this intercultural discrepancy. *Cultural maintenance* defines the degree of adherence to the original cultural identity and its associated behavioral patterns, while *contact and participation*

determines the degree of interaction with members of the host culture and adoption of new cultural values. Based on these diametrically opposed dimensions, four acculturation strategies can be distinguished (figure 2). *Assimilation* means that original cultural values and norms are abandoned in favor of the new host culture. In daily interaction, migrants conform to the new culture and adopt behavioral habits. In contrast, *segregation* represents the maintenance of the original cultural identity combined with the avoidance of participation in the new host culture. *Integration* describes the efforts to achieve both maintenance of original cultural values and participation in the host society. Basic behavioral patterns and cultural norms aren't only retained but extended by essential features of the host culture. *Marginalization* corresponds to neither cultural maintenance nor active participation or interest in the larger society of the host country. Both cultural identities are denied.

Figure 2

Acculturation strategies (Berry, 1997)

| | | Is it considered to be of value to maintain one's identity and characteristics? | |
|--|-----|---|-----------------|
| | | Yes | No |
| Is it considered to be of value to maintain relationships with larger society? | Yes | Integration | Assimilation |
| | No | Segregation | Marginalization |

The different acculturation strategies seem to be differently associated with acculturative stress and mental health (Berry et al., 1987; Berry et al., 1989; Zheng & Berry, 1991). Acculturative stress refers to the psychological distress that is caused by the process of acculturation within a new cultural environment. When acculturative stress exceeds individual coping strategies, it may negatively affect the mental health of migrants and contribute to the development of mental disorders. Recent meta-analytic data revealed significant associations between integration and good mental health, and between marginalization and poor mental health outcomes (Yoon et al., 2013). Further examinations have shown that integration was associated with lower levels of depression compared to segregation (Ince et al., 2014), assimilation (Nakash et al., 2015), and marginalization (Lincoln et al., 2016). Moreover, the acculturation model points towards important potential predictors that affect the process and outcomes of psychological treatment. The level of social participation, building new social relationships, the experience of discrimination or racism, and the maintenance of cultural resources such as religiosity may be factors that play a relevant role.

2.3 Migration-related risk factors for mental health

Modelling the diverse experiences and challenges of migration sheds light on possible associations with the mental health status of the migrating individuals. Bhugra (2004) pointed towards the large variety of biological, psychological, and social factors that are at play throughout the process of migration and constantly interact with health-related outcomes. Considering the heterogeneity of migration-related influence factors, these health-related outcomes are manifold as well. Contrary to common perceptions, migration does not unequivocally lead to the development of mental illness (Nickerson, 2018). Meta-analytic research documented that mental health problems were frequent among refugees and asylum seekers, but the majority of the samples did not develop manifest mental disorders upon resettlement in the host country (Blackmore et al., 2020; Henkelmann et al., 2020; Hoell et al., 2021). The process of migration appears to comprise not only negative influence factors but also protective factors for the mental health status of migrants. Machleidt and Heinz (2011) pointed out that migration bears the opportunity for personal development and positive mental health outcomes such as resilience and adaptive growth. Completing an act of migration and surviving potentially traumatic events may represent psychological resources. Together with new impressions and perspectives in the country of arrival, refugees may find strength and

meaning in their suffering. These phenomena were subsumed under the concept of *adversity-activated development* and found to be associated with a decreased risk of developing mental disorders (Papadopoulos, 2007).

Even though some refugees show positive trajectories of mental health status and may not require professional health care, many are burdened by the causes and consequences of forced migration and develop clinically relevant psychological distress in the post-migration setting (Walther et al. 2020). From a health care supply perspective, this population is at the center of focus, and the pathways between forced migration and psychopathological phenomena are of particular relevance (Nickerson et al., 2017). Therefore, the subsequent sections focus on the description of the multitude of migration-related factors that have been found to be associated with poor mental health outcomes of refugees and asylum seekers. First, the predominantly trauma-related stressors that operate prior to migration and during the act of migration are outlined (pre- and peri-migration stressors). Second, the various contextual stressors of the post-migration setting are delineated (post-migration stressors). Third, a contemporary integrative conceptualization of refugee mental health and illness is provided.

2.3.1 Existential threat to life: Pre- and peri-migration stressors

Pre- and peri-migration stressors are major push factors that frequently involve the exposure to potentially traumatic events (PTE). Many refugees have been exposed to armed conflicts or war, and witnessed the actual or threatened death of family members and beloved persons. Women are especially at risk of experiencing sexual violence. In a meta-analysis investigating the prevalence of sexual violence among female refugees in humanitarian emergencies, more than one out of five women reported exposure to sexual violence (Vu et al., 2014). Traumatic events may also occur in the context of persecution due to political, ethnic, and religious reasons, involving imprisonment and severe human rights violations such as torture. Human rights violations can be assessed using the Political Terror Scale (Gibney et al., 2019), a 5-point rating scale to categorize countries in terms of civil and political violence that is experienced by the domestic population. Scoring ≥ 4 indicates severe violations of international human rights standards, including imprisonment for political activity, political murders, torture, and persecution as a common part of daily life. The main countries of origin of refugees in Germany (i.e., the Syrian Arab Republic, Afghanistan, and Iraq) consistently scored 4 or higher within the past decade. During migration, refugees are further at risk of

experiencing PTE. They may become victims of interpersonal violence, including physical and sexual harm, extortion, and imprisonment by local police or people smugglers. Also, travelling in unsafe boats or closed spaces in trains and other vehicles, represent frequently experienced peri-migration stressors (Priebe et al., 2016).

In a large study, Chen et al. (2017) found that 2399 refugees relocated in Australia experienced a mean of 2.1 pre-migration traumatic events. In the Netherlands, 384 Afghan, Iranian and Somali refugees reported 6.1 traumatic events on average (Gerritsen et al., 2006). Mollica et al. (1992) found an average of 15.2 experienced traumatic events among 91 refugees from Southeast Asia. In total, the existing data indicated that refugees experience at least two pre-migration PTE on average. The exposure to pre-migration trauma is likely to affect mental health outcomes among migrants. Shrestha et al. (1998) found that exposure to torture and human rights violations substantially elevated the risk of developing PTSD, depression, and anxiety among Bhutan refugees. Another large-scale study documented that the number of pre-migration traumatic events seemed to predict the development of mental disorders among war-affected refugees (Bogic et al., 2015).

Beyond the experience of trauma-related stressors, pre-migration risk factors encompass several economic aspects in the country of origin, such as extreme poverty, economic hardship, and the lack of basic supplies (Giacco et al., 2018). The routes of migration bear further risk factors. As most refugees were unable to plan their flight, they tended to be financially and materially undersupplied, and emotionally unprepared for their way. Exposure to heat, cold, starvation, and thirst may be the consequences due to lack of shelter and supplies. Injuries or infectious diseases can be life threatening due to the unavailability of medical care during the migration. Disorientation and defenselessness are commonly reported among forced migrants, and the separation from family members represents a frequently reported peri-migration stressor (Giacco et al., 2018).

2.3.2 Psychosocial stressors in the post-migration environment

Post-migration stressors are embedded within the economic, societal, political, and physical environment that refugees encounter in the country of asylum (Mawani, 2014). They represent the negation of some major pull factors (e.g., good occupation and income, economic wealth) which may initially have dragged refugees towards the country of destination. In the following, four major stressors of the post-migration context are introduced. First, refugee

mental health seems to be determined by socio-economic indicators. Regardless of the socio-economic status prior to forced displacement, refugees usually arrive at a state of relative poverty in host countries and maintain a low socio-economic status in long-term resettlement. Insufficient job capacities and a lack of permission to work are frequently reported structural barriers that refugees encounter. Asylum seekers in particular may not be permitted to work, or may find themselves in unstable work situations (Beiser, 2009). In turn, significant associations between unemployment and low income, a lack of social contacts, and a lack of daily structure have been found, causing substantial psychological distress among forced migrants (Mölsä et al., 2014). The combination of a restricted access to the labor market and disparities in country-level income distribution ultimately leads to refugees ending up in lower social strata (Hynie, 2018). With regard to mental health, low socio-economic status has repeatedly been found to predict mental disorders such as PTSD and depression in large samples of refugees (Bogic et al., 2015; Lindert et al., 2009; Porter & Haslam, 2005).

Second, housing conditions seem to determine mental health in post-migration settings (Bogic et al., 2012; Porter & Haslam, 2005). Most refugees live in institutional or temporary accommodations in the country of arrival. Recurring shortcomings of such accommodations are overcrowding, location in precarious neighborhoods, poor quality of accommodation, reduced access to health services and infrastructure, and poor safety (Mawani, 2014). A recent systematic review reported that various indicators of poor housing conditions correlated with mental distress among refugees (Ziersch & Due, 2018).

Third, social exclusion in the country of asylum seems to play a major role in predicting mental health outcomes (Mawani, 2014). Individual and community-based social exclusion strongly depends on the degree to which host societies allow social participation for minority groups. Poor tolerance towards diversity in the host country may lead to discrimination of minorities on multiple levels (e.g., systemic, institutional, interpersonal). Associations between discrimination and poor mental health have been found consistently (Beiser & Hou, 2016; Schouler-Ocak et al., 2021). In contrast, social support represents a protective factor for mental health. It refers to the quantity and quality of interpersonal relationships (e.g., marital status, number of friends, communities) and the quality of support (e.g., emotional or material support). The existence of established like-ethnic social networks in the region of arrival can be specifically valuable for refugees, providing them with a sense of identity and belonging. Good social support has been identified as a predictor of mental health (Mawani, 2014). In turn,

loss of social support and social isolation were risk factors for developing mental health issues (Bogic et al., 2015; Priebe et al., 2016).

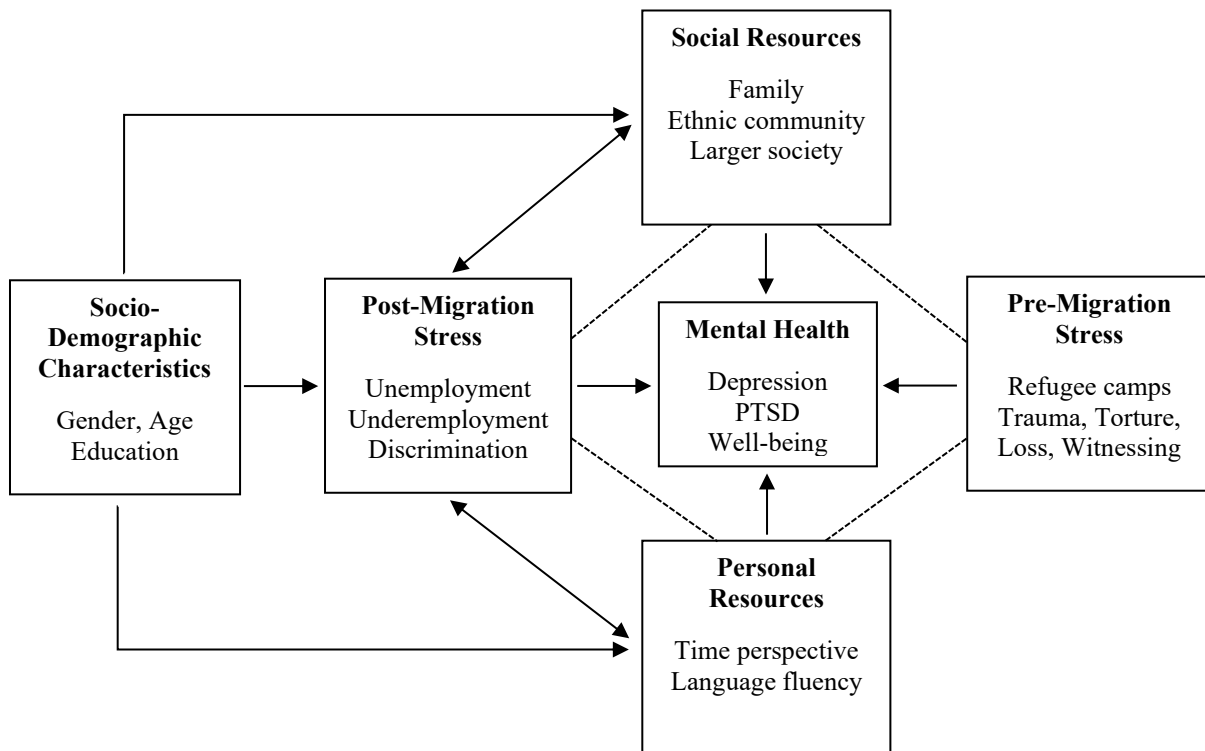
Fourth, the procedure of asylum application represents a migration-related risk factor. Unlike accepted refugees, asylum seekers wait for their claim of asylum to be processed by the authorities of the host country. Many asylum applications and the associated processing are protracted and may last for months or years. Holding an uncertain residence status (Momartin et al., 2006) and prolonged asylum procedures (Laban et al., 2004) were found to predict poor mental health outcomes among forced migrants and may be intensified through a permanent fear of deportation. Throughout the asylum procedure, legal employment may not be permitted. Denied asylum applications may lead to detention, which has been identified as a strong determinant of mental disorders among asylum seekers, with growing impact over time of detention (Juárez et al., 2019; Priebe et al., 2016).

2.3.3 An integrative framework of refugee mental health

In conclusion of this chapter, there is a large number of potential risk but also protective factors for refugee mental health that operate at different stages of migration and on multiple levels, interacting in a dynamic and cumulative way. It is likely that these factors not only show an impact on the mental health status of refugee populations but also play a specific role in the provision of health care to those who seek for psychological treatment. Contemporary frameworks acknowledge both the impact of trauma-related and ongoing psychosocial stressors that are associated with the process of migration (Hou et al., 2018; Miller & Rasmussen, 2017). A recent study by Hou et al. (2020) even showed that associations between pre-displacement traumatization and mental illness (PTSD, depression and anxiety) were fully mediated by the exposure to post-displacement daily stressors such as discrimination, isolation, accommodation difficulties, and employment-related issues. Therefore, the mental health status of forced migrants needs to be understood in a multi-facet integrative framework where mental disorders represent the endpoint of an imbalance in the multitude of protective and risk environmental factors that affect refugees' mental health rather than the manifestation of intrapsychic problems (Silove et al., 2017). Figure 3 shows an approach of how mental health may be conceptualized as a function of both resources and stressors in the context of forced migration and gives an overview of potential predictors that affect the outcomes of mental health treatment at the same time (Beiser, 2009).

Figure 3

Risk and protective factors for refugee mental health (Beiser, 2009)



2.4 Mental disorders among refugees and asylum seekers

Considering the multitude of migration-related risk factors for mental health, a large body of research has been conducted to examine the actual prevalence of manifest mental disorders among forced migrants. Most of the studies addressed refugee populations while research on asylum seekers is limited. Within the past two decades, several reviews and meta-analyses have been published that examine mental disorders in refugee populations on an international and national level (Blackmore et al., 2020; Bogic et al., 2015; Fazel et al., 2005; Giacco et al., 2018; Hajak et al., 2021; Henkelmann et al., 2020; Hoell et al., 2021; Lindert et al., 2009; Priebe et al., 2016; Steel et al., 2009). In general, the meta-analytic data indicated that there was a high inter-survey variability of prevalence rates across the included studies. Bogic et al. (2015) included 29 studies on the mental health of war-affected refugees and found that the prevalence for depressive disorders ranged from 2.3% to 80.0%. Steel et al. (2009) analyzed a total of 181

surveys and found the PTSD prevalence to vary between 0% and 99% in the original studies. Different reasons are conceivable for this kind of variability.

On the one hand, the original studies showed high variation in terms of quality and study design. When aggregating multiple data sets, methodological shortcomings of the original studies impact the validity and quality of meta-analyses. Prevalence rates of mental disorders showed a tendency to be higher in studies of poorer quality compared to studies with higher methodological quality (Blackmore et al., 2020; Bogic et al., 2015; Giacco et al., 2018; Priebe et al., 2016). In particular, sample size (more than 200 vs. less than 200 participants), sampling method (random vs. non-random), instrument (clinical assessment vs. semi-structured interview), and language of interviewer (native vs. non-native) were found to account for inter-survey variability (Blackmore et al., 2020; Fazel et al., 2005; Steel et al., 2009). On the other hand, the variability in prevalence rates may reflect the actual diversity of refugee subpopulations that come from heterogeneous cultural contexts and with different migratory experiences (Priebe et al., 2016). Differences in socio-cultural characteristics and levels of exposure to pre-, peri-, and post-migration stressors have been shown to affect the development of mental illness (Porter & Haslam, 2005). In the following, the available epidemiological findings will be outlined.

2.4.1 International prevalence data

Two reviews reported on substance use among refugees (Giacco et al., 2018; Priebe et al., 2016). Prevalence for alcohol dependence varied from <1-42% and from 1-20% for drug dependence. Most findings pointed towards less frequent or similar harmful substance use among short-term resettled refugees compared to native populations. Prevalence rates converged to those of the host country populations in long-term resettlement.

The prevalence of psychotic disorders among short-term resettled refugees was estimated at 1.5-2% (Blackmore et al., 2020; Fazel et al., 2005; Giacco et al., 2018). In a study on long-term mental health outcomes of war-refugees, 1.3% were diagnosed with psychotic illness (Bogic et al., 2012). Giacco et al. (2018) concluded that prevalence rates of psychotic disorders do not differ significantly from those in host populations. In contrast, four recent comprehensive works reported elevated relative risk ratios for developing a psychotic disorder among refugees compared to non-refugee migrants and native populations (Brandt et al., 2019; Dapunt et al., 2017; Henssler et al., 2020; Selten et al., 2020).

Prevalence data on mood disorders is heterogeneous. The comprehensive analysis by Fazel et al. (2005) revealed 5% prevalence for major depressive disorder among refugees when only considering original studies with $n > 200$. Other reviews and meta-analyses reported pooled prevalence rates for depression of 31.5% (Blackmore et al., 2020), 30% (Henkelmann et al., 2020), 44% (Lindert et al., 2009), and 30.8% (Steel et al., 2009). However, all analyses reported that prevalence rates were prone to bias due to variation in methodological quality of the original studies. Lower rates were calculated after adjustment for methodological quality. Nearly half of the high-quality studies estimated prevalence rates for depression $< 25\%$ according to Bogic et al. (2015). Studies with large sample sizes ($n > 1,000$) and high quality, diagnosed 13.3% of refugees with depression on average (Steel et al., 2009). Two recent analyses concluded that mood disorders among refugees are not significantly increased compared to host populations until 5 years upon arrival (Giacco et al., 2018; Priebe et al., 2016). An exclusive investigation among asylum seekers ($n = 581$) reported a 7.3% prevalence of depression (Firenze et al., 2016).

Fazel et al. (2005) reported 4% of refugees diagnosed with Generalized Anxiety Disorders. Lindert et al. (2009) found combined prevalence rates for anxiety of 40% among refugees compared to 21% in first-generation labor migrants. Other estimations of prevalence for diagnosed anxiety disorders were 11% (Blackmore et al., 2020) and 13% (Henkelmann et al., 2020). Giacco et al. (2018) concluded that diagnoses of any anxiety disorder were increased in long-term resettled refugees (prevalence ranging from 20-88%), but not in short-term resettlement compared to the host population.

Concordantly, research pointed towards increased prevalence rates for PTSD in refugees compared to non-refugees. Fazel et al. (2005) reported an average prevalence of 9% among 6,743 refugees resettled in high-income countries compared to 1-3% in host populations. Other calculations of the pooled prevalence for PTSD were 31.5% (Blackmore et al., 2020), 29% (Henkelmann et al., 2020), 36% (Lindert et al., 2009), and 30.6% (Steel et al., 2009). Studies of high quality tended to find lower prevalence rates, e.g., two thirds of high-quality assessments found prevalence rates $< 15\%$ (Bogic et al., 2015). Studies with large sample sizes ($n > 1,000$) showed combined prevalence estimates of 15.7% for PTSD (Steel et al., 2009). Increased prevalence of PTSD seemed to persist in long-term assessment (i.e., five years of resettlement or longer; Bogic et al., 2015). Regarding asylum seekers in particular, 17.4% in a sample of 581 participants were diagnosed with PTSD (Firenze et al., 2016).

2.4.2 National prevalence data

Analogous to international findings, prevalence data of mental disorders among refugees residing in Germany showed substantial variation. Several selective studies have been published since 2015, mostly conducted in primary reception facilities and refugee accommodations (Biddle et al., 2019; Dietrich et al., 2019; Georgiadou et al., 2018; Kröger et al., 2016; Manok et al., 2017; Nesterko et al., 2020; Richter et al., 2015; Schaffrath et al., 2017; Winkler et al., 2019). Measures, participants, and settings varied between studies. Overall, the reported screening rates ranged from 14.5% to 61.3% for depression and 8% to 41.7% for PTSD. Recently, a meta-analytic investigation summarized findings from 31 epidemiological surveys conducted in Germany (Hoell et al., 2021). Pooled prevalence rates were 29.9% for symptoms of PTSD and 39.8% for symptoms of depression. Another recent systematic review aggregated information from 13 articles, and found prevalence rates of 14.5-61.3% for depressive symptoms and 11.4-46.5% for PTSD symptoms among refugees and asylum seekers in Germany (Hajak et al., 2021). When compared to prevalence rates in the host population, rates of PTSD and depression seem to be increased among refugees and asylum seekers. The 12-month prevalence rates in the general adult German population have been quantified at 2.3% for PTSD, 6.8% for Major Depression and 8.2% for unipolar depression (Jacobi et al., 2016).

2.5 Existing mental health interventions for adult refugees and asylums seekers

The elevated prevalence rates for PTSD and depression, as well as the multiple migration-related risk factors that may negatively affect refugees' mental health status, highlight the evident need for available mental health services which are targeted towards the needs of flight-affected individuals in the countries of asylum. In Germany, refugees have legal access to the regular health care system 18 months upon arrival in the country, according to §4 of the Asylum Seekers Benefits Act (AsylbLG). Health services are covered by statutory health insurance, including mental health services such as psychiatrists in university hospitals and outpatient psychotherapeutic treatment (Führer et al., 2021). Despite being granted full access to the health care system, it has been documented that refugees and asylum seekers have less contact with mental health services, have less information on available treatment options, and make less frequent use of preventive and therapeutic interventions than the host population (Schouler-Ocak, 2015). Current data pointed towards various access barriers to health care systems for

minority groups (Byrow et al., 2020; Satinsky et al., 2019). The following issues appeared to be the most salient barriers for refugees and asylum seekers: difficulties in communication (Byrow et al., 2020), stigmatization (Chowdhury, 2016), mistrust in public organizations (Sandhu et al., 2013), unawareness of mental disorders and mental health services (Satinsky et al., 2019), and a shortage of culturally sensitive treatment options (Satinsky et al., 2019). In response, there has been a call in research and practice for the intercultural opening of the German health care system and the development of more low-threshold, culturally sensitive mental health interventions for refugees (Bhugra et al., 2014; Penka et al., 2012). Compared to conventional therapy approaches, culturally sensitive interventions have shown significantly higher effect sizes in refugee treatment (Griner & Smith, 2006). In the following, the current landscape of mental health interventions to treat the most prevalent mental disorders (PTSD, depression, anxiety) among refugees and asylum seekers is outlined and available evidence on effectiveness is given.

2.5.1 Narrative Exposure Therapy (NET)

Narrative Exposure Therapy (NET; Schauer et al., 2011) is a manualized short-term psychotherapy that has been developed specifically for victims of multiple traumatic events, such as refugees. NET integrates therapeutic elements of Cognitive Behavioral Therapy (CBT) and testimony therapy. NET represents a culturally sensitive treatment concept as it incorporates narratives and storytelling which are inherent to many cultural origins of flight-affected patients. The therapist guides the patient in creating a cohesive autobiographical narrative that covers the entire life span in a chronological context, including all experienced traumatic events. The main therapy focus is set on the traumatic passages in order to ensure exposure of the trauma, helping patients to process the stressful events they have experienced. At the end of the therapy, patients may also use the written testimonial to document human rights violations (Schauer et al., 2011). The effectiveness of NET has been subject to several meta-analyses (Kip et al., 2020; Nosè et al., 2017; Turrini et al., 2019). Kip et al. (2020) concluded that NET was effective in reducing trauma and depressive symptoms with medium to large effects compared to different control conditions. This was in line with Nosè et al. (2017) but contradicted the results of Turrini et al. (2019) who found that NET failed to show effectiveness in reducing PTSD and depression.

2.5.2 Cognitive Behavioral Therapy (CBT)

Cognitive Behavioral Therapy (CBT) is a suitable treatment option for PTSD, depression, and anxiety. CBT encompasses different forms of CBT-based treatment, including standard CBT, trauma-focused CBT (TF-CBT) and culturally adapted CBT (CA-CBT; Hinton et al., 2012). In CA-CBT, the conventional CBT treatment approach can be modified to suit patients with different cultural backgrounds, e.g., by implementing mindfulness strategies and using easily understandable language (Hinton et al., 2012). Two meta-analyses investigated the effectiveness of CBT in subgroup analyses among refugees and asylum seekers (Nosè et al., 2017; Turrini et al., 2019). Turrini et al. (2019) reported that CBT proved effective in reducing trauma and anxiety symptoms, and recommended TF-CBT for refugee patients with PTSD. Nosè et al. (2017) documented the evidence of two studies supporting TF-CBT. Results for other CBT-based forms were mixed and inconclusive.

2.5.3 Eye Movement Desensitization and Reprocessing (EMDR)

Eye Movement Desensitization and Reprocessing (EMDR; Shapiro, 2017) is a trauma-focused psychotherapeutic intervention. Key component of EMDR is the repeated imagination of trauma-associated stimuli (e.g., images, memories, thoughts) while simultaneously focusing on visual, auditory or tactile distractors. Commonly, the patient is instructed to follow the finger of the therapist who performs horizontal movements. A current theory suggests that this kind of bilateral stimulation supports patients in reprocessing traumatic memories, although the exact working mechanism of EMDR is not yet clear (Shapiro, 2017). The effectiveness of EMDR in treating refugees and asylum seekers with PTSD has been subject to several meta-analyses and systematic reviews (Nosè et al., 2017; Thompson et al., 2018; Turrini et al., 2019). Thompson et al. (2018) reported a large effect of EMDR compared to an inactive control group. No effects were found when EMDR was compared to an active control group. Turrini et al. (2019) showed that EMDR was effective in reducing symptoms of depression but not PTSD and anxiety. Nosè et al. (2017) concluded that EMDR could not be evaluated due to the limited number of trials.

2.5.4 Group interventions

Few investigations were conducted to evaluate the effectiveness of group interventions for refugees and asylum seekers. The Den Bosch model of group therapy was introduced by Drozdek (1997) and evaluated in subsequent trials (Drozdek & Bolwerk, 2010; Drozdek et al., 2012; Drozdek et al., 2014). The intervention is a trauma-focused, phase-based combination of cognitive-behavioral, psychodynamic, and supportive treatment elements. Participation in the group intervention led to a significant reduction of trauma symptoms, depression, and anxiety at post-intervention and at a seven-year follow-up, compared both to an inactive and active control group (Drozdek & Bolwerk, 2010; Drozdek et al., 2014). Another peer-provided and resource-oriented group intervention for trauma-affected refugees was examined by Renner et al. (2011) and found to be effective in improving symptoms of PTSD, depression and anxiety among Chechen refugees in Austria. Meta-analytic works did not conduct subgroup analyses for group interventions (Kip et al., 2020; Nosè et al., 2017; Turrini et al., 2019). However, Turrini et al. (2019) reported no differences between individual and group therapy.

2.5.5 Multidisciplinary treatment

Numerous trials were conducted to evaluate multidisciplinary treatment approaches in refugee mental health care (Arcel et al., 2003; Brune et al., 2002; Buhmann et al., 2016; Carlsson et al., 2005; Carlsson et al., 2010; Kinzie et al., 2012; Palic & Elklit, 2009; Raghavan et al., 2013; Westermeyer, 1988; Westermeyer et al., 1984). Multidisciplinary treatment comprises different combinations of psychotherapy, pharmacotherapy, counselling, physiotherapy, social assisting, and family therapy. A recent systematic review noted the difficulty to evaluate the effectiveness of multidisciplinary treatment due to large differences in methodology and intervention combinations (Tribe et al., 2019). The effects of multidisciplinary treatment were mixed, ranging from non-significant trials to medium effect sizes. Overall, the number of significant trials outweighed the number of non-significant trials.

2.6 Predictor studies on refugee treatment

As shown in the previous chapter, there appears to be a limited number of effective treatment options for refugees and asylum seekers in the post-migration environment (Kip et al., 2020; Turrini et al., 2019). However, the mixed results on effectiveness of the interventions described above could also be due to the presence or absence of specific characteristics that affect the outcomes of treatment. Depending on predictors of outcome (e.g., client-related, therapist-related, or context-related factors), the presented mental health interventions may show differential treatment effects for different patient groups (Slobodin & de Jong, 2015). So, moving on from the question of which mental health interventions exist and show effectiveness, this chapter takes the individual trajectories of treatment responses among patients into account. The available data on outcome predictors of culturally sensitive treatment are subject to this chapter. The selection of potential predictor variables in the presented studies is closely related to the theoretical models of migration (Berry, 1997; King, 2012; Kizilhan, 2018; Sluzki, 1979) and the literature on risk factors for refugee mental health (Hynie, 2018; Mawani, 2014; Priebe et al., 2016) that were described before. Push and pull factors, such as the pre-migration exposure to war, persecution, and other traumatic events, and the post-migration lack of employment, or low income, represent frequently examined predictors. Also, aspects of the acculturation model, such as social participation and religiosity, were investigated in predictor studies. Considering the stage model of migration, the level of functioning, quality of life, and the time since arrival in the host country, represent potential predictor variables that are associated with the different stages and circumstances of the post-migration context. An overview of the key relevant factors for refugee mental health, which may also prove relevant in predictor analyses, has already been shown in figure 3 (Risk and protective factors for refugee mental health; Beiser, 2009).

Generally, the number of existing predictor studies in the field of refugee treatment is limited. Therefore, all available studies were considered in this chapter irrespective of potential differences in the types of interventions and outcomes. One promising predictor study on minor refugees was also included to add some essential information to the overview. The findings are clustered in three sections representing the most common categories of outcome predictors (for a short overview of the presented predictor variables, see figure 4).

Figure 4*Overview of presented predictors*

| Socio-demographic predictors | Post-migration context predictors | Clinical predictors |
|---|---|---|
| <ul style="list-style-type: none"> • Age • Gender • Marital status • Region of origin • Education • Income • Religiosity | <ul style="list-style-type: none"> • Post-migration stressors • Housing conditions • Residence status • Employment • Time in country since arrival • Social relationships • Proficiency in host language | <ul style="list-style-type: none"> • Baseline symptoms • Exposure to traumatic events • Comorbidity • Pain • Previous treatment • Number of sessions • Level of functioning • Quality of life |

2.6.1 Socio-demographic predictors

Most frequently, the variables *age* and *gender* were included as socio-demographic variables in predictor studies. Stammel et al. (2017) showed that younger patients profited more from multidisciplinary trauma-focused treatment than older ones regarding the reduction of somatoform symptoms. Nordin and Perrin (2019) found a small effect of *age* on PTSD symptom reduction as younger refugee patients showed better treatment response than older ones. Four studies reported contradictory results. An investigation among torture survivors who received 6-month multidisciplinary treatment did not find any significant associations between *age* and change in PTSD symptoms, depression, anxiety and somatization (Raghavan et al., 2013). Two studies from Denmark showed non-significant associations between *age* and outcomes of PTSD, depression, anxiety, and quality of life in two samples of trauma-affected refugees (Buhmann et al., 2015; Carlsson et al., 2005). A recent predictor study reported that *age* did not predict trauma-related and depression outcomes after having received trauma-focused treatment (Pfeiffer et al., 2019).

One predictor study found that male *gender* significantly predicted non-response to trauma-focused treatment for refugees and asylum seekers (Stenmark et al., 2014). However, the individual prediction effect of *gender* may have been driven by another significant predictor, which was violent offenders. In contrast, seven studies did not find any predictive value of *gender* on multiple treatment outcomes (Carlsson et al., 2005; Haagen et al., 2017; Nordin &

Perrin, 2019; Raghavan et al., 2013; Stammel et al., 2017; Stenmark et al., 2013; Whitsett & Sherman, 2017).

Marital status was examined in two predictors studies, neither of which found a significant effect on multidisciplinary trauma-focused treatment outcomes (Raghavan et al., 2013; Sonne et al., 2021).

Region of origin was examined in three predictor studies (Pfeiffer et al., 2019; Raghavan et al., 2013; Stammel et al., 2017). *Region of origin* was a significant predictor of improvement in trauma-focused treatment of young refugees as patients from the Middle East profited more than their African counterparts (Pfeiffer et al., 2019). The second evaluation found that refugee patients from Asian and African regions showed better response to multidisciplinary PTSD treatment compared to European refugee patients (Raghavan et al., 2013). This was related to a reduction of PTSD and somatization symptoms, but not depression. In the investigation of Stammel et al. (2017), *region of origin* was not associated with any of the outcomes of a multidisciplinary treatment for traumatized refugees.

Three predictor studies included *education* in their analyses (Buhmann et al., 2015; Sonne et al., 2016; Sonne et al., 2021). One study reported that higher levels of *education* were significantly correlated with higher symptom reductions on depression and anxiety outcomes of multidisciplinary PTSD treatment (Sonne et al., 2016). No associations between *education* and treatment outcomes were found in the works of Buhmann et al. (2015) and Sonne et al. (2021).

Income was a factor of interest in two predictor studies (Buhmann et al., 2015; Raghavan et al., 2013). A decrease in *income* from baseline to post-treatment assessment negatively predicted improvement of PTSD and depressive symptoms in the study of Raghavan et al. (2013). The other study did not reveal a significant effect of *income* on treatment outcomes (Buhmann et al., 2015).

Religiosity was examined in three predictor studies (Carlsson et al., 2005; Raghavan et al., 2013; Sonne et al., 2021). Carlsson et al. (2005) and Raghavan et al. (2013) did not find any predictive effect of religion on symptom changes. In contrast, Sonne et al. (2021) found that Muslim faith was associated with poor treatment response among trauma-affected refugees.

2.6.2 *Post-migration context predictors*

Two studies have investigated the impact of the total number of *post-migration stressors* on treatment outcomes in the refugee field in general (Bruhn et al., 2018; van Wyk et al., 2012). Both investigations did not find a significant impact of total scores on the outcomes of multidisciplinary and psychotherapeutic refugee treatment. However, a closer examination of individual post-migration context factors in other predictor studies revealed different results.

Housing conditions were examined in two predictor studies (Sonne et al., 2016; Whitsett & Sherman, 2017). Whitsett and Sherman (2017) reported that poor *housing conditions* (i.e., unstable and/or overcrowded accommodation) had a negative impact on post-treatment symptoms of PTSD, depression and anxiety in a sample of 105 refugees who were exposed to torture. No associations between *housing conditions* and symptom changes were found in the second study evaluating trauma-focused refugee treatment (Sonne et al., 2016).

The predictive impact of *residence status* has been examined in five studies (Buhmann et al., 2015; Drozdek et al., 2013; Haagen et al., 2017; Raghavan et al., 2013; Stenmark et al., 2013). Drozdek et al. (2013) conducted a study on treatment outcomes of a trauma-focused group therapy for Afghan and Iranian refugees. While the pre-treatment *residence status* (refugee vs. asylum seeker) did not predict symptom change, a positive effect on symptom reduction was found when patients obtained a permanent *residence status* during treatment. The change of legal status was related to symptom improvement in PTSD, depression, and anxiety. Likewise, Raghavan et al. (2013) pointed out that obtaining a permanent *residence status* during treatment was associated with reduction of PTSD and depressive symptoms in a multidisciplinary trauma-focused treatment for refugees. Another study revealed that refugees had lower depression scores at every stage of treatment compared to asylum seekers, even though no significant effect of *residence status* was found in subsequent prediction models (Stenmark et al., 2013). Two other studies reported no associations between *residence status* and treatment outcomes among refugees (Buhmann et al., 2015; Haagen et al., 2017).

Employment was included in six predictor studies (Buhmann et al., 2015; Carlsson et al., 2005; Raghavan et al., 2013; Sonne et al., 2016; Sonne et al., 2021; Whitsett & Sherman, 2017). Higher status of *employment* was the strongest predictor of trauma-related symptom reduction in the study by Sonne et al. (2016). This was in line with findings from another study that detected being on public financial support was a significant predictor of increased post-treatment trauma scores (Buhmann et al., 2015). Full-time *employment* proved to have a

significant impact in reducing symptoms of depression and anxiety in the analysis by Sonne et al. (2021). In contrast, three other studies did not find any predictive effect of *employment* on treatment outcomes (Carlsson et al., 2005; Raghavan et al., 2013; Whitsett & Sherman, 2017).

Time in the country since arrival was examined in four predictor studies (Pfeiffer et al., 2019; Raghavan et al., 2013; Sonne et al., 2021; Whitsett & Sherman, 2017). Two studies found that the longer refugee patients had stayed in the country of arrival prior to treatment, the worse post-treatment depression and trauma scores were assessed (Sonne et al., 2021; Whitsett & Sherman, 2017). A recent study from Germany among unaccompanied minor refugees revealed contradictory results. The length of stay in Germany did not interact significantly with post-treatment trauma and depressive symptoms (Pfeiffer et al., 2019). This was in line with the findings by Raghavan et al. (2013) among adult trauma-affected refugees in the United States.

Several studies included measures of *social relationships* in their predictor studies (Pfeiffer et al., 2019; Raghavan et al., 2013; Sonne et al., 2016; Sonne et al., 2021). One study reported that increased rates of post-treatment depression and anxiety were associated with a lack of social support and poor integration (Sonne et al., 2016). Refugees who were reunified with their family showed significantly better symptom improvement throughout treatment than refugees who were not (Sonne et al., 2021). Pfeiffer et al. (2019) investigated if young refugee patients were in contact with their family or not. The dichotomous predictor was unrelated to change in depressive and trauma symptoms over treatment. Raghavan et al. (2013) considered whether adult refugee patients were separated from their family and neither found a predictive impact on treatment outcomes.

The impact of *proficiency in the host language* was a factor of interest in five studies (Buhmann et al., 2015; Carlsson et al., 2005; Haagen et al., 2017; Sander et al., 2019; Whitsett & Sherman, 2017). *Proficiency in the host language* was sometimes operationalized inversely as the need to use interpreters during treatment sessions. A study among 825 trauma-affected refugees reported that the use of interpreters during psychotherapy sessions was associated with less improvement on several clinical outcome measures compared to not involving interpreters (Sander et al., 2019). The remaining studies concordantly reported no effects of language proficiency or difficulties on treatment-associated outcomes (Buhmann et al., 2015; Carlsson et al., 2005; Haagen et al., 2017; Whitsett & Sherman, 2017).

2.6.3 Clinical predictors

The two most frequently examined clinical predictors and predictors in general were *baseline symptoms* and the *exposure to traumatic events*. *Baseline symptoms* meaning the pre-treatment scores of the respective outcomes were included in predictor analyses of nine studies (Buhmann et al., 2015; Carlsson et al., 2005; Drozdek et al., 2013; Haagen et al., 2017; Pfeiffer et al., 2019; Raghavan et al., 2013; Sonne et al., 2021; van Wyk et al., 2012; Whitsett & Sherman, 2017). Most studies reported that *baseline symptoms* of PTSD, depression and anxiety were associated with treatment response on the respective symptom scales (Carlsson et al., 2005; Drozdek et al., 2013; Pfeiffer et al., 2019; Raghavan et al., 2013; Sonne et al., 2021; van Wyk et al., 2012; Whitsett & Sherman, 2017). Findings on the direction of this effect were mixed. While four studies indicated that those with high baseline symptoms showed better response to treatment (Carlsson et al., 2005; Drozdek et al., 2013; Pfeiffer et al., 2019; Sonne et al., 2021), three studies pointed towards the fact that high baseline symptoms were associated with poor treatment response (Raghavan et al., 2013; van Wyk et al., 2012; Whitsett & Sherman, 2017). Two other studies did not find initial symptom scores to predict symptom trajectories over the time of intervention at all (Buhmann et al., 2015; Haagen et al., 2017).

The *number and nature of traumatic events* that patients experienced was examined in eight predictor studies (Buhmann et al., 2015; Carlsson et al., 2005; Haagen et al., 2017; Pfeiffer et al., 2019; Sonne et al., 2021; Stenmark et al., 2014; van Wyk et al., 2012; Whitsett & Sherman, 2017). In general, no study found that the *number of traumatic events* experienced by refugees predicted treatment outcomes (Buhmann et al., 2015; Haagen et al., 2017; Pfeiffer et al., 2019; van Wyk et al., 2012; Whitsett & Sherman, 2017). However, some studies further investigated the specific nature of the *trauma events*. The exposure to war (Buhmann et al., 2015), torture (Buhmann et al., 2015; Carlsson et al., 2005; Haagen et al., 2017; Sonne et al., 2021; Stenmark et al., 2014), combat situations (Buhmann et al., 2015; Haagen et al., 2017; Sonne et al., 2021), imprisonment (Buhmann et al., 2015; Haagen et al., 2017; Sonne et al., 2021), persecution (Buhmann et al., 2015), serious injury (Haagen et al., 2017), and rape or sexual abuse (Haagen et al., 2017) were examined. The single significant association was found between the exposure to torture and poor treatment response in the study of Carlsson et al. (2005). All other *trauma events* did not predict treatment outcomes.

Comorbidity of a psychiatric disorder was considered in two studies (Haagen et al., 2017; Silove et al., 2005). The comorbid diagnosis of a major depressive disorder, and its severity, predicted significantly worse response to a trauma-focused treatment for refugees (Haagen et

al., 2017). Silove et al. (2005) reported that a comorbid depressive disorder was a significant predictor of poor response to a psychosocial group intervention for refugees. Vice versa, the impact of a comorbid diagnosis of PTSD on outcomes of depression has not yet been evaluated. However, this might be a specific factor of interest as psychiatric comorbidity is a frequently observed psychopathological pattern among refugees (Fazel et al., 2005). This applies in particular to dual diagnoses of PTSD and depression (Haagen et al., 2017; Marshall et al., 2005; Nickerson et al., 2017).

Physical pain was examined in three predictor studies (Buhmann et al., 2015; Nordin & Perrin, 2019; Sonne et al., 2016). The first study found that higher levels of *pain in the arms* were associated with higher post-treatment levels of depression and anxiety among refugees who received treatment at a psychiatric trauma clinic (Buhmann et al., 2015). Nordin and Perrin (2019) investigated the impact of self-rated *pain severity* and *interference*, measured with the Brief Pain Inventory (BPI), on post-treatment symptoms of PTSD, depression, and anxiety. High pre-treatment *pain interference*, but not severity, was associated with poor response to multidisciplinary treatment. The third study found a significant negative effect of clinician-rated *pain severity* on treatment outcomes of depression, but not PTSD (Sonne et al., 2016).

Two studies investigated the impact of *previous treatment* on treatment outcomes but did not find significant predictive effects (Buhmann et al., 2015; Sonne et al., 2016).

Five predictor studies considered the therapeutic dose, measured by the *number of sessions*, in their analyses (Buhmann et al., 2015; Carlsson et al., 2005; Haagen et al., 2017; Nordin & Perrin, 2019; van Wyk et al., 2012). All studies reported that there were no associations between the number of attended treatment sessions and treatment outcomes. In contrast, a meta-analysis reported that the attendance of more trauma-focused sessions was associated with a better average treatment response in trauma-focused treatment of refugees (Lambert & Alhassoon, 2015).

Two studies investigated the impact of transdiagnostic clinical scales on outcomes of refugee treatment (Buhmann et al., 2015; Sonne et al., 2021). *Level of functioning* as measured with the Global Assessment of Functioning (GAF-F) and the Sheehan Disability Scale (SDS) had a significant positive effect on symptom improvement in the study of Sonne et al. (2021), but not in the study of Buhmann et al. (2015). *Quality of life* as assessed with the World Health Organization Well-Being Index (WHO-5) did not predict symptom improvement in PTSD, depression and anxiety (Buhmann et al., 2015).

2.7 Contextual embedding and subject of this dissertation

The presented theoretical background and the status quo of research literature set the framework in which this dissertation is embedded. Previous research has pointed out that there is a substantial level of psychological distress among forcibly displaced individuals residing in Western countries of resettlement (Walther et al., 2020). The prevalence numbers of PTSD and depression were elevated and associated with various migration-specific risk factors that are active before, during, and after the act of migration (Bogic et al., 2012; Henkelmann et al., 2020; Porter & Haslam, 2005). However, research has pointed out that Western health care systems are poorly accessible for marginalized ethnic groups and characterized by a scarcity of culturally sensitive expertise (Jefee-Bahloul et al., 2016). This led to a significant treatment gap and underutilization of mental health services among refugees and asylum seekers, leaving the high demand for psychosocial care widely uncovered (Satinsky et al., 2019; World Health Organization [WHO], 2018). In consequence, there is a need for intelligent and effective supply models that are capable of allocating the limited health care resources in the best-possible way to a large treatment population (Silove et al., 2017). In particular, culturally sensitive, needs-based and tailored psychotherapy interventions for refugees and asylum seekers are needed (Hinton & Patel, 2018). In addition to that, predictor research is needed to ensure a reasonable dissemination and allocation of these interventions. Predictor studies provide valuable information of how to predict differential treatment trajectories and identify patient groups that show treatment response, remission, partial response, or non-response (Nierenberg & DeCecco, 2001). In practice, this information is of essential value to create effective and pragmatic health care structures for an undersupplied treatment population, enabling clinicians to improve treatment allocations or modification of existing treatments. However, the number of currently available predictor studies is limited, and the reported findings tended to draw an incomplete and inconclusive picture (see section 2.6), leaving a research gap which is targeted by this dissertation.

2.7.1 *The MEHIRA project and the Empowerment intervention*

Against this background, the multicenter research project *Mental Health in Refugees and Asylum Seekers* (MEHIRA) was initiated in 2017. The study was designed to investigate the effectiveness of a stepped and collaborative care model (SCCM) for refugees and asylum

seekers with affective disorders (Böge et al., 2020). Stepped care models represent a promising approach to close the gap between high demand for mental health care and limited available resources (Bower & Gilbody, 2005), and have explicitly been recommended in the mental health care delivery to refugees and asylum seekers (Inter-Agency Standing Committee [IASC], 2007; Schneider et al., 2017). Stepped care models follow two central principles. First, the applied treatment within the stepped care structure should be the least restrictive while still providing significant health gain for the individual patient, which aims at an optimal allocation of therapist time and treatment costs according to the symptom severity of patients (Bower & Gilbody, 2005). High-intensity treatment options are reserved for those patients who suffer from severe symptomatology or who did not benefit from lower-intensity treatment. Thereby, available treatment resources can be allocated effectively to an elevated number of patients. Second, stepped care has a self-correcting mechanism in terms of treatment allocation. If patients do not profit from the initial treatment level they have been assigned to, they will step up and receive a more intense treatment (Bower & Gilbody, 2005). The MEHIRA study was the first project to evaluate such a stepped and collaborative care structure among refugees and asylum seekers resettled in Germany.

With the stepped-care structure of the MEHIRA trial, several interventions of differing intensity were incorporated. On level three of the model, refugees and asylum seekers with moderate depressive symptoms were provided with a group psychotherapy named *Empowerment* (Wiechers et al., 2019). The *Empowerment* intervention was developed at the Psychiatric University Hospital of the Ludwig-Maximilians-University Munich. *Empowerment* is a manualized, culturally sensitive 12-week treatment program that is specifically tailored to treat depressive and stress-related symptoms in a post-migration context. Combining evidence-based cognitive behavioral therapy strategies with culturally sensitive contents, the treatment was delivered under the support of professional language and cultural mediators and aims to empower refugee patients with knowledge and skills to deal both with post-migration stressors and depressive symptoms. As existing mental health interventions mainly cover the treatment of trauma-related symptoms (Uphoff et al., 2020), the *Empowerment* intervention was conceptualized to broaden the landscape of effective and resource-saving treatment options and focus on affective disorders. The primary evaluation of the intervention has shown its clinical effectiveness in reducing both self-rated and clinician-rated depressive symptoms (Wiechers, unpublished doctoral dissertation).

2.7.2 Predictor analysis of the *Empowerment* intervention

The subject of this dissertation is to conduct a comprehensive predictor analysis on the outcomes of the *Empowerment* group intervention which was implemented under the scientific scope of the MEHIRA research project. The overarching aim of this work is to identify pre-treatment patient characteristics and contextual factors that are significantly associated with post-treatment mental health indicators in a sample of refugees and asylum seekers with moderate depressive symptoms. This could provide valuable insights into the differential impact of the intervention on different patient groups and its applicability under naturalistic conditions.

The dearth of data on predictors of culturally sensitive treatment outcomes has been described above, delineating the considerable research gap in this area. Many of the existing studies on socio-demographic, post-migration context, and clinical predictors yielded an incomplete and, in parts, inconclusive pattern. Therefore, several recent publications explicitly noted the need for more studies to enlarge the database on outcome predictors (Bruhn et al., 2018; Haagen et al., 2017; Pfeiffer et al., 2019).

The findings of this dissertation aim to have relevant practical implications on how to provide effective health care in the most pragmatic way and improve the current routine care practices for refugees and asylum seekers in Germany. Delineating the critical factors that are associated with good and poor treatment response may guide decision-making about which patients are suitable for receiving *Empowerment* and for which patients treatment modifications or alternative treatment options may be indicated.

2.8 Research questions and hypotheses

The research gap and the inconclusive picture of the current literature regarding outcome predictors in the field of culturally sensitive treatment has been described. Most of the available studies reported non-significant results (e.g., marital status), inconclusive findings (e.g., employment) or sporadic evidence (e.g., quality of life). The *Empowerment* intervention is a novel, culturally sensitive treatment option that has proved overall effective in reducing depressive symptoms among refugees and asylum seekers in Germany. Targeting the scarcity of knowledge on outcome predictors, the following research questions will be investigated in this dissertation:

Research question 1: Which pre-treatment variables predict the outcomes of the *Empowerment* intervention?

Research question 2: Which patient groups benefit from the *Empowerment* intervention, and which patient groups do not?

These research questions are to be answered based on the data collected within the scope of the MEHIRA trial. Considering the presented theoretical background and the current literature, five specific a-priori hypotheses were deduced. Psychological models of migration (Berry, 1997; King, 2012; Kizilhan, 2018; Sluzki, 1979) suggested different factors that may have a relevant influence on refugee mental health and illness. These factors are also likely to be relevant for the process and the outcomes of psychotherapeutic treatment. Many refugees reach out for help during the period of decompensation (Sluzki, 1979), when they are burdened with feelings of frustration, disappointment, and overload. Individual coping strategies tend to be insufficient to handle the acculturative stress emerging in the dichotomy between traditional cultural values and the cultural system of the host country (Berry, 1997). Furthermore, the society of the host country, and the associated post-migration context factors (e.g., unemployment), determine a socio-cultural framework in which severe mental distress may arise and accumulate the impact of possible pre- and peri-migration experiences of trauma (Miller & Rasmussen, 2010; Miller & Rasmussen, 2017). Research has repeatedly shown that post-migration context factors represent major risk factors in the context of refugee mental health. Poor housing conditions (Ziersch & Due, 2018), complications in the asylum procedure (Laban et al., 2004), holding an uncertain residence status (Momartin et al., 2006), employment issues (Mölsä et al., 2014), and social isolation (Mawani, 2014) were negatively associated with mental health indicators of refugees and asylum seekers. The most robust predictor of outcomes that was found in previous predictor studies was the pre-treatment symptom level (e.g., Drozdek et al., 2013; Whitsett & Sherman, 2017). In contrast, classic push factors, such as the number and nature of pre-migration traumatic events, were not found to have a predictive impact (e.g., Haagen et al., 2017; Pfeiffer et al., 2019). Beyond that, the relevance of comorbidity, in particular dual diagnoses of PTSD and depression (Nickerson et al., 2017), has been emphasized in research and identified as an important predictor of culturally sensitive treatment outcome (Haagen et al., 2017; Silove et al., 2005).

Based on theoretical considerations and concrete study results from previous work, five variables with the most robust foundation were selected as predictors of primary interest. The following a-priori hypotheses were formulated to be investigated in this dissertation:

Hypothesis 1: Baseline depression is associated with depressive symptom change from baseline to post-intervention in the treatment condition.

Hypothesis 2: Holding an insecure residence status is negatively associated with symptom improvement from baseline to post-intervention in the treatment condition.

Hypothesis 3: Current unemployment is negatively associated with symptom improvement from baseline to post-intervention in the treatment condition.

Hypothesis 4: Living in a refugee accommodation is negatively associated with symptom improvement from baseline to post-intervention in the treatment condition.

Hypothesis 5: A comorbid PTSD diagnosis is negatively associated with symptom improvement from baseline to post-intervention in the treatment condition.

In addition to the hypothesis-guided approach, the analytical strategy was extended to a mixed-methods approach. After testing literature-based hypotheses, an explorative analysis approach was applied in a second step in order not to neglect relevant predictor variables. Regarding the shortage of data in this field, multiple trial-bound baseline variables were examined in an explorative manner. Compared to strict a-priori hypothesis testing, this procedure seems essential to generate a sound empirical foundation for future hypotheses. Predictor variables were included that have yielded mixed results so far or have been evaluated sporadically or not at all. The following variables were considered: (1) socio-demographic predictors (age, gender, marital status, education, social status, religious affiliation), (2) post-migration context predictors (single room, time since arrival in Germany), and (3) clinical predictors (identification as a migrant, concomitant medication, concomitant psychotherapy, number of diagnoses, comorbid anxiety disorder, comorbid substance use disorder, war, persecution, number of traumatic events, trauma symptoms, resilience, self-efficacy, emotional and conduct problems, emotional distress and stress-related symptoms, quality of life).

3 Methods

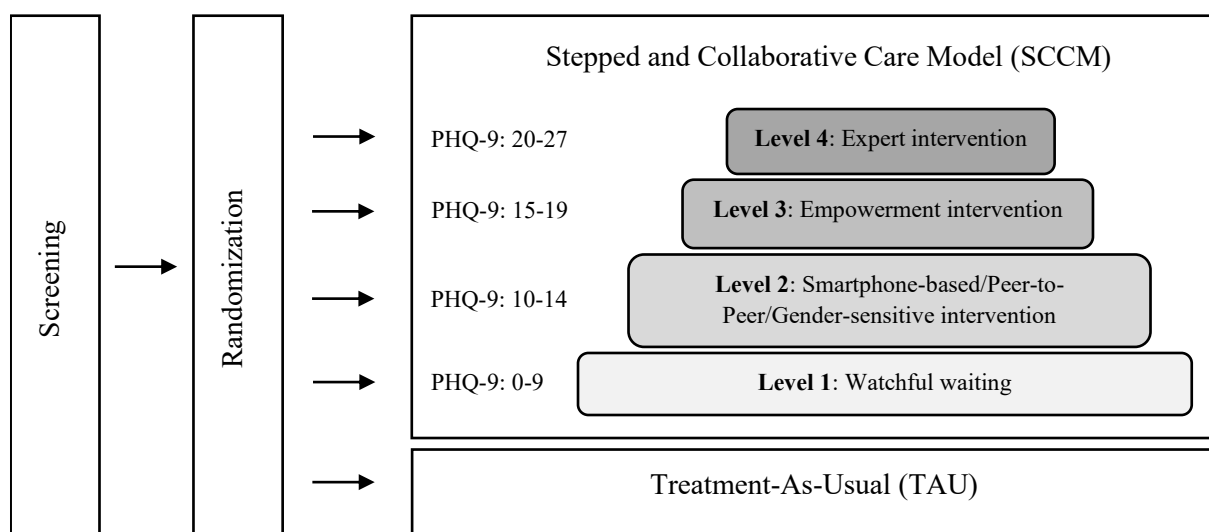
3.1 Research design

3.1.1 Design of the MEHIRA trial

This dissertation is an ancillary predictor analysis of the *Empowerment* intervention which was incorporated in the multicenter randomized controlled MEHIRA trial. Seven university hospitals in Aachen, Berlin (2 study sites), Mannheim, Marburg, Munich, and Ulm were involved. The overall study aim was to compare a four-level SCCM for refugees with affective disorders with routine care practice (TAU). Based on depressive symptoms at baseline which were measured with the Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001), participants were randomly assigned either to SCCM or TAU (figure 5). Level one treatment was watchful waiting for participants with minimal depressive symptoms (PHQ-9: 5-9). Participants with mild depressive symptoms (PHQ-9: 10-14) received a smartphone application, a peer-to-peer group intervention or a gender-sensitive intervention on level two. Treatment on level three was the *Empowerment* group intervention for patients with moderate depressive symptoms (PHQ-9: 15-19). Participants with severe depressive symptoms received an expert intervention on level four (PHQ-9: 20-27).

Figure 5

Study design for adult participants



Notes. PHQ-9 = Patient Health Questionnaire 9.

The trial was registered on ClinicalTrials.gov (registration number: NCT03109028, registration date: 11.04.2017). The study protocol was generated in line with the current version of the Declaration of Helsinki and has been approved by the ethics committees of all collaborating study sites. The ethical vote of the ethics committee of the Ludwig-Maximilians-University Munich is provided in Appendix A. Detailed information on the trial was reported elsewhere (Böge et al., 2020).

3.1.2 Randomization and blinding

Participants were randomized in a 1:1 scheme with fixed block size. Randomization was performed to achieve a random distribution of participant characteristics (e.g., gender, age) across conditions and minimize bias due to participant assignment. Randomization was performed by the Berlin-based coordination center for clinical trials (Koordinierungszentrum für klinische Studien; KKS) using a computer-generated electronic case report file (eCRF). Independent raters were responsible for data collection at all timepoints without knowledge of the participants' treatment condition, to ensure an observer-blinded setting. Randomization, data entry and treatment were performed by unblinded study staff. Raters had no authorization to access eCRF and remained blinded for the entire study.

3.1.3 Data protection and management

Operational project management was executed by the KKS in Berlin, including data protection and safety management. Data collection and processing was limited exclusively to the data being relevant for the investigation of the efficacy, quality, and utility of the MEHIRA trial. Compliance with current data privacy protection laws and regulation was ensured. Source data was collected by local study staff and entered online. Data was transferred to eCRF shortly after the source data was documented. All staff members involved in data collection were provided with individualized access to the online portal, and were trained prior to the first data input to become familiar with the eCRF system. The KKS supplied the underlying study software SecuTrial® (interactive systems, Berlin) to ensure safe web-based data management and assured secure data storage on a KKS server. Patient data was pseudonymized using codes generated by the SecuTrial software. Automated plausibility checks of missing data or incorrect values were provided. A query management system was integrated into the software. All

modified documents were documented via an Audit Train. At the end of the study, the data was exported and checked for plausibility and consistency using SAS. Inconsistent data was corrected, and missing data was confirmed. The database was closed after successful data cleaning. The final electronic documentation contained all exported files, SAS scripts, data logs, and the closed database.

3.2 Participants

3.2.1 Inclusion and exclusion criteria

Inclusion criteria of this predictor analysis were (a) legal status of a refugee or asylum seeker according to the UN refugee agency (UNHCR, 2021a), (b) age between 18 and 65 years, (c) mother tongue in Farsi or Arabic or speaking fluent English/German, and (d) moderate depressive symptoms at baseline (PHQ-9: 15-19). Exclusion criteria were (a) diagnosis of a psychotic or degenerative disorder, (b) acute suicidality determined by the investigator throughout the screening procedure or by a score ≥ 4 on item 10 of the Montgomery Asberg Depression Rating Scale (MADRS; Montgomery & Asberg, 1979), and (c) missing informed consent.

3.2.2 Stopping rules

Stopping rules were established to ensure the safety of participants. Participants were withdrawn from study treatment in case of increased risk of suicidality at any stage of the study. This applied to participants who scored ≥ 4 on item 10 of the MADRS. Study staff enforced study withdrawal if it appeared to be of best interest for the patient to quit study participation, e.g., due to serious adverse events. Further stopping rules concerned withdrawal from the study for any of the following reasons: (a) violation of inclusion or exclusion criteria, (b) violation of treatment condition, and (c) withdrawal of informed consent.

3.2.3 Sample size calculation

The initial sample size calculation of the MEHIRA trial was based on an expected baseline PHQ-9 score of 15, an expected difference of 2.5 points after twelve months ($SD=5$),

a significance level of 0.05, a power of 0.8 and an effect size of $f=0.1$. The calculation for a RCT design with a 2 (SCCM vs. TAU) x 4 (times of measurement) matrix resulted in a required sample size of 138 participants per group. Considered an intra-cluster correlation (ICC) of 0.03 and 6 facilities per study site, a design effect of $1+(n-1)*ICC=1.72$ was estimated. The initial sample size of 138 was adjusted to $1.72*138=238$ per group, yielding a total sample size of $N=476$ participants. Taking an estimated dropout rate of 50% into account, recruitment of 952 participants was intended.

3.3 Procedure

Recruitment of participants was performed at university facilities of the involved study sites and in local refugee accommodations. Allocation of refugees and asylum seekers was organized by heterogeneous regional referrers, including general practitioners and primary care workers, social workers, refugee accommodations and reception centers, central clearing and outpatient clinics, hospital staff, refugee schools and language courses, and religious institutions. Potential participants were screened for clinically relevant depressive and stress-related symptoms. Screening was performed by trained study staff using the Refugee Health Screener-15 (RHS-15; Hollifield et al., 2013) and the PHQ-9. Positive screening was indicated when participants reached an RHS-15 sum score ≥ 12 on items 1-14 or a score ≥ 5 on item 15 and a PHQ-9 sum score ≥ 5 (i.e., at least five questions were rated *several days* or higher). Eligible participants were given detailed information about the study process, potential risks, the expected benefit of participation, expense allowances, and data safety. Unresolved questions could be addressed. Participants were required to read and sign the informed consent and the data protection declaration of the study. Screening (T-1) was performed within four weeks prior to baseline assessment (T0). Baseline assessment included socio-demographic data and clinical rating scales. Diagnostics were performed using the Mini-International Neuropsychiatric Interview (M.I.N.I.; Sheehan et al., 1998). Afterwards, participants were randomized either to SCCM or TAU and received 12 weeks of intervention. Following assessments were conducted at post-intervention (T1) and follow-up after 24 weeks (T2) and 48 weeks (T3). All study-related material was available in German, English, Arabic and Farsi. Data collection was supported by professional interpreters if necessary. Table 1 shows the detailed schedule of assessments at all time points. All scales that were used in this work and the entire baseline assessment are provided in Appendix B.

Table 1*Time and assessment schedule*

| Time point | Screening (T-1) | Baseline (T0) | Post (T1) | FU1 (T2) | FU2 (T3) |
|---|--------------------|------------------|--------------|-------------|-------------|
| Week | -4 to 0 | 0 | 12 | 24 | 48 |
| Refugee Health Screener (RHS-15) | X | X | X | X | X |
| Patient Health Questionnaire (PHQ-9) | X | X | X | X | X |
| Demographics | | X | | | |
| Montgomery Asberg Depression Scale (MADRS) | | X | X | X | X |
| M.I.N.I. International Neuropsychiatric Interview | | X | | | |
| Mannheimer Modul Ressourcenverbrauch (MRV) | | X | X | X | X |
| Harvard Trauma Questionnaire (HTQ) | | X | | | |
| Strengths and Difficulties Questionnaire (SDQ) | | X | X | X | |
| Brief Resilience Scale (BRS) | | X | X | X | X |
| General Self-Efficacy Scale (GSE) | | X | X | X | X |
| WHO Quality of Life (WHOQoL-BREF) | | X | X | X | X |
| Cultural Differences Subscale (CCI) | | X | X | | |
| Credibility/Expectancy Questionnaire (CEQ) | | X | X | | |

Notes. Post = Post-intervention, FU1 = Follow-up 1, FU2 = Follow-up 2.

3.4 Treatment arms

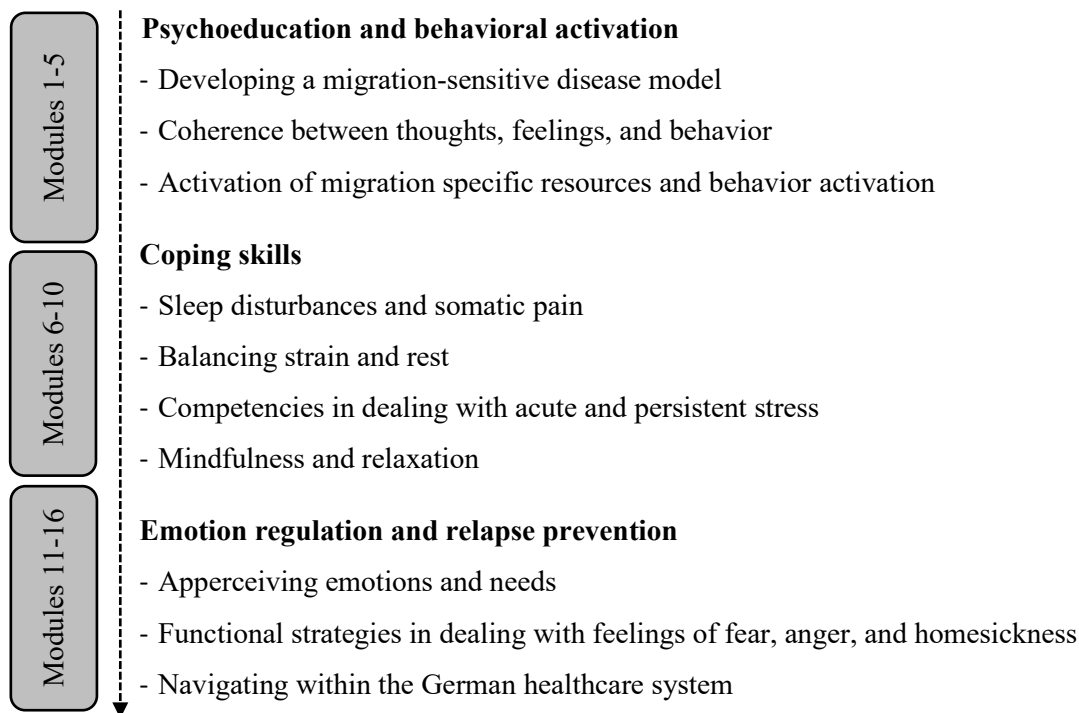
3.4.1 Empowerment

The *Empowerment* intervention is a manualized group psychotherapy for migration- and flight-affected individuals (Wiechers et al., 2019). The development of the *Empowerment* manual was inspired by well-established and evidence-based treatment manuals on cognitive behavioral treatment of depression (Schaub et al., 2013), emotion regulation (Bohus & Wolf-Arehult, 2013) and culturally sensitive treatment for individuals with migration background (Assion et al., 2017; Liedl et al., 2013). Treatment was conceptualized for reducing depressive and stress-related symptoms among refugees and asylum seekers, with a particular focus on empowering the participants with knowledge and functional coping strategies to deal with stressors of the post-migration context. *Empowerment* comprised 16 sessions of 90 minutes within 12 weeks. Groups were held in a closed setting with an intended group size between four and ten participants. Treatment was provided twice a week in the first four weeks and once a

week in the following eight weeks. Key elements of the therapy were psychoeducation, behavioral activation, stress management, emotion regulation and mindfulness (figure 6). The first part of the manual (modules 1-5) focused on psychoeducation and behavioral activation. Information on symptoms of depression was elaborated within the cultural framework of the participants. A culturally sensitive disease model was developed, integrating individual flight-associated stressors and post-migration difficulties of the participants. The second part of the manual (modules 6-10) covered functional coping skills in dealing with sleep disturbances, somatic pain, and stress. The third part of the manual (modules 11-16) was tailored to improve emotion regulation strategies of participants. The perception and functionality of the emotions of fear, anger, and homesickness, were at focus. Furthermore, the final sessions covered relapse prevention by giving orientation within the German health care system and reviewing the development throughout the group therapy process.

Figure 6

Content of the Empowerment intervention



Sessions were conducted by German-speaking therapists under the support of professional interpreters or by native-speaking therapists. The use of interpreters was implemented following evidence-based recommendations (Abdallah-Steinkopff, 2017; Kluge, 2018). All written therapy material was provided in participants' native language. Groups were conducted by mental health care professionals with advanced or completed postgraduate clinical education. Supervision was offered continuously throughout the intervention period. The group sessions followed a consistent structure to provide a reliable setting for participants. Each session started with a welcome round and mindfulness exercise. Contents of the previous session were recapitulated and feedback on the transfer task was collected. Positive experiences could be validated, and difficulties could be discussed. Each session covered a specific topic (e.g., sleep disturbances) of the respective module (e.g., coping skills). At the end, homework tasks were given to ensure a successful transfer of contents. Sessions were finished with a closing round and participants received a take-home handout.

3.4.2 Treatment-as-usual

Participants in the active control condition did not receive trial-bound treatment but stayed within the existing routine mental health care structures (TAU), including all available psychosocial, psychotherapeutic, and psychiatric treatment options at the respective study sites. Type of treatment, treating person and location were not determined. Participants could receive any treatment without restrictions in terms of time, frequency, and intensity.

3.5 Outcome measures

3.5.1 Primary outcome

Change in self-rated depressive symptoms from baseline (T0) to post-intervention (T1) was the primary outcome. Depression severity was assessed using the PHQ-9 (Kroenke et al., 2001), the depression module of the PHQ. It is frequently used as a screening tool for depressive disorders and can be applied both as clinical interview and self-rating scale. The American Psychiatric Association [APA] (2013) has recommended the use of the PHQ-9 as a general assessment for depression severity. The scale assessed nine depressive symptoms within the past two weeks which are equivalent to the DSM-IV criteria for a major depressive episode: (1)

Little interest or pleasure in doing things, (2) Feeling down, depressed, or hopeless, (3) Trouble falling or staying asleep, or sleeping too much, (4) Feeling tired or having little energy, (5) Poor appetite or overeating, (6) Feeling bad about yourself – or that you are a failure or have let yourself or your family down, (7) Trouble concentrating on things, such as reading the newspaper or watching television, (8) Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual, (9) Thoughts that you would be better off dead or of hurting yourself in some way. Item scores reached from 0 (*Not at all*) to 3 (*Nearly every day*) and sum scores ranged from 0 to 27.

The original version of the PHQ-9 showed good internal consistency (Cronbach's $\alpha = .86-.89$) and test-retest reliability of .84 (Kroenke et al., 2001). Several studies validated the PHQ-9 across different cultural backgrounds and populations and confirmed good quality criteria (Kohrt et al., 2016; Naveed et al., 2019; Reich et al., 2018).

3.5.2 Secondary outcome

Change in clinician-rated depression severity from baseline (T0) to post-intervention (T1) served as the secondary outcome. Depression severity was measured using the MADRS (Montgomery & Asberg, 1979), a clinical interview which is specifically sensitive to treatment effects. The scale comprised 10 items targeting major depressive symptoms: (1) Apparent sadness, (2) Reported sadness, (3) Inner tension, (4) Reduced sleep, (5) Reduced appetite, (6) Concentration difficulties, (7) Lassitude, (8) Inability to feel, (9) Pessimistic thoughts, and (10) Suicidal thoughts. Item ratings reached from 0 to 6 and included four exemplary symptom descriptions per item (e.g., for Item 1: 0=No sadness. 2=Looks dispirited but does brighten up without difficulty. 4=Appears sad and unhappy most of the time. 6=Looks miserable all the time. Extremely despondent.). MADRS sum scores ranged from 0 to 60.

Montgomery and Asberg (1979) reported interrater reliability between .89 and .97. Acceptable validity and reliability scores were detected across several cultural contexts and languages (Davidson et al., 1986; Hallit et al., 2019; Ozer et al., 2001).

3.6 Predictors

3.6.1 *Socio-demographic predictors*

The socio-demographic indicators analyzed in this dissertation were age, gender, marital status, education (school years), change in social status, and religious affiliation. Gender was coded 0=male, 1=female. Response options for marital status were: *Single*, *Married*, *Divorced/Separated*, and *Widowed*. Item responses were aggregated to obtain the categories 0=No (*Single*, *Divorced/Separated*, and *Widowed*) and 1=Yes (*Married*). Change in social status refers to the difference between two self-rated items. The items were: *How was your social status before your immigration?* and *How is your social status now?*. Item responses ranged from 1 (*Upper*) to 5 (*Lower*). The variable was obtained by subtracting pre-migration scores from post-migration scores (i.e., positive change scores indicated social decline). Religious affiliation was assessed based on the item *Do you feel affiliated to one or more religions?* and coded 0=No and 1=Yes.

3.6.2 *Post-migration context predictors*

The post-migration context predictors analyzed in this dissertation were residence status, employment, housing, single room, and time in Germany since arrival.

Residence status was assessed with the item: *What is your current state of residence?*. Available response options were: *Permanent residence permit*, *Temporary residence permit*, *Permit for permanent residence in the EU*, *No (legal) residence permit*, and *Other*. The variable was aggregated by building two categories, 0=No (*Temporary residence permit*, *No legal residence permit*, and *Other*) and 1=Yes (*Permanent residence permit*, *Permit for permanent residence in the EU*). Employment was quantified based on the question: *How is your current occupational situation?*. Available item responses were: *Unemployed*, *Protected employment service/voluntary social year*, *Employee*, *Retirement/pension*, *Military service/community*, and *Self-employed*. Employment was dichotomized and coded 0=No (*Unemployed*) and 1=Yes (*Protected employment service/voluntary social year*, *Employee*). The remaining categories were not chosen by participants. Housing was operationalized based on the item *Housing situation* with the options of *Private flat*, *Refugee accommodation*, *Shared flat*, *Assisted living*, *Without permanent residence*, and *Other*. The variable was aggregated to obtain the categories 0=refugee accommodation and 1=other (*Private flat*, *Shared flat*, *Assisted living*, and *Other*).

The remaining category was not chosen by participants. To specify housing conditions, the variable Single room was generated by using the item: *How many people besides you live in your household?*. The variable was dichotomized by building two categories based on the number of co-habitants, with 0=No (1 or more co-habitants) and 1=Yes (0 co-habitants). The variable time in Germany since arrival (years) was obtained by subtracting the date of migration (*When did you migrate to Germany?*) from the date of study inclusion.

3.6.3 Clinical predictors

The clinical predictors analyzed in this dissertation were baseline depression, comorbidity (PTSD, anxiety disorder, substance use disorder, number of diagnoses), trauma-related indicators (war, persecution, trauma symptoms, number of traumatic events), identification as a migrant, concomitant medication, concomitant psychotherapy, resilience, self-efficacy, psychological and stress-related symptoms, emotional and behavioral problems, and quality of life.

Baseline depression was assessed using the baseline scores of the respective depression outcome measures (baseline PHQ-9, baseline MADRS).

Indicators of comorbidity were diagnosis of a comorbid PTSD (0=No and 1=Yes), comorbid anxiety disorder (0=No and 1=Yes), comorbid substance use disorder (0=No and 1=Yes), and total number of diagnoses. To obtain these variables, data from the structured clinical interview M.I.N.I. was used. The interview is particularly suitable for epidemiological studies and multicenter trials. With approximately 15 minutes of administration time, it represents a timesaving, yet accurate tool to assess psychiatric disorders according to DSM-IV and ICD-10. 16 sections cover the most common psychiatric disorders. Sensitivity/specificity scores for psychiatric diagnoses in the clinician-rated version ranged from .45-.96/.86-1.00. Interrater kappa scores were estimated between .79 and 1.00 and test-retest kappa scores between .35 and 1.00 (Sheehan et al., 1998).

Trauma-related indicators included war and persecution (both coded 0=No, 1=Yes) as possible causes of migration (*Why did you migrate?*). Trauma symptoms and the number of traumatic events were assessed using the Harvard Trauma Questionnaire (HTQ; Mollica et al., 1992). Participants indicate whether they have experienced any of 41 potentially traumatic events and may provide a personal description of the most terrifying events they experienced. In addition, head injury and loss of consciousness during traumatic events is assessed. Trauma

symptoms according to DSM-IV are assessed with 40 items (e.g., *Recurrent thoughts or memories of the most hurtful or terrifying events*), rated on a scale from 1 (*Not at all*) to 4 (*Extremely*). Item responses are summed up and divided by the number of completed items to obtain a mean HTQ score. Scoring 2.5 or higher points towards the presence of PTSD. Mollica et al. (1992) reported interrater reliabilities of .93 for the trauma events and .98 for the trauma-related symptoms, Cronbach's alpha of .90 (events) and .96 (symptoms) and 1-week test-retest reliability of .89 (events) and .92 (symptoms).

Identification as a migrant was examined using the item *Would you call yourself a migrant?* with response options from 1 (*Yes, definitely*) to 5 (*No, definitely not*).

Concomitant medication and concomitant psychotherapy (both coded 0=No, 1=Yes) were examined in the socio-demographic baseline assessment of the study (*Is any concomitant medication given? Is any concomitant psychotherapy provided?*).

Resilience was assessed using the Brief Resilience Scale (BRS; Smith et al., 2008), a six-item self-rating scale assessing the participants' ability to bounce back or recover from stress. Six statements can be rated on a 5-point Likert scale ranging from 1 (*Strongly disagree*) to 5 (*Strongly agree*). Total scores ranged from 6 to 30. Sum scores were divided by the number of completed items to obtain mean scores. Increasing scores indicated higher resilience. In a comparative study, the BRS ranked among the resilience measurement scales with the most satisfying psychometric properties (Windle et al., 2011). Good internal consistency was found with Cronbach's α ranging from .80-.91 (Smith et al., 2008). Test-retest reliabilities of .69 for one month and .62 for three months were reported. Good convergent validity and discriminant predictive validity were estimated for multiple related health outcomes. The BRS was validated across a variety of languages and cultural contexts with constantly good quality criteria (Kyriazos et al., 2018).

Self-efficacy was operationalized by using the Generalized Self-Efficacy Scale (GSE; Schwarzer & Jerusalem, 1995). The self-rating questionnaire assesses effective personal action control and the perceived ability to achieve desired effects with one's actions. It consists of ten statements that address the participants' beliefs of being able to cope with everyday challenges, solve problems and deal with stressful events. Items can be rated on a four-point Likert scale ranging from 1 (*Not at all true*) to 4 (*Exactly true*). Item responses were summed up to obtain a total score between 10 and 40, with higher scores indicating a higher level of perceived self-efficacy. In a comparative study across 25 countries, the scale showed internal consistency of

Cronbach's α ranging from .75 to .91 (Scholz et al., 2002). Convergent and divergent validity were found to be acceptable in another study (Schwarzer & Jerusalem, 1999).

Psychological and stress-related symptoms were assessed via the RHS-15 (Hollifield et al., 2013). The scale comprised 13 items with responses ranging from 0 (Not at all) to 4 (Extremely). An additional coping item was rated from 0 (*able to handle or cope with anything that comes your way*) to 4 (*unable to handle or cope with anything*). Item 15 was a visual rating scale (Distress Thermometer). Patients indicated the distress they experienced within the last week on a scale from 0 (*No distress – things are good*) to 10 (*Extreme distress – I feel as bad as I ever have*). Items 1-14 were summed up to obtain a total score. Hollifield et al. (2016) reported full scale internal consistency of Cronbach's $\alpha = .95$ and sensitivity/specificity of .87-.98/.77-.82 for PTSD, anxiety, and depression. An evaluation among refugees in Germany detected high Cronbach's α ranging from .91-.93 and sensitivity/specificity of .90/.70 for self-rating and 1.00/.70 for interview (Kaltenbach et al., 2017).

Emotional and behavioral problems were measured by the self-administered Strengths and Difficulties Questionnaire (SDQ; Goodman, 1997). The slightly adapted adult version was used as the scale was originally conceptualized to investigate adolescents. The questionnaire comprised 25 items that were distributed across the following five subscales: emotional problems, conduct problems, hyperactivity or inattention, peer problems, and prosocial behavior. Response options were 0 (*Not true*), 1 (*Somewhat true*) and 2 (*Certainly true*). Satisfactory psychometric properties have been reported for the adolescents' version of the scale (Muris et al., 2003).

The World Health Organization Quality of Life – BREF version (WHOQoL-BREF; WHO, 1998) was used to measure quality of life. The scale covers four domains of well-being: physical health, psychological health, social relationships, and environment. As the 26-item short version of the comprehensive WHOQoL-100 assessment, the WHOQoL-BREF is specifically useful in large clinical trials with limited time of assessment. Participants rated 26 questions on *how much, how completely, how often, how good, or how satisfied* they were with the respective aspect of their life in the past two weeks (Skevington et al., 2004). Items were answered on 5-point Likert scales. Findings from a multi-national survey pointed towards acceptable Cronbach's α values across domains (0.68 – 0.82) and provided good indicators for the validity of the scale (Skevington et al., 2004).

A final overview of all potential predictors that were used for the comprehensive predictor analysis of this dissertation is provided in figure 7.

Figure 7

Overview of potential predictors analyzed in this study

| Socio-demographic predictors | Post-migration context predictors | Clinical predictors |
|--|---|--|
| <ul style="list-style-type: none"> • Age • Gender • Marital status • Education • Change in social status • Religious affiliation | <ul style="list-style-type: none"> • Residence status • Employment • Housing • Single room • Time in country since arrival | <ul style="list-style-type: none"> • Baseline depression (PHQ-9, MADRS) • Comorbidity (PTSD, anxiety disorder, substance use disorder, number of diagnoses; M.I.N.I.) • Reason of migration (war, persecution) • Trauma symptoms (HTQ) • Number of traumatic events (HTQ) • Identification as a migrant • Concomitant psychotherapy • Concomitant medication • Resilience (BRS) • Self-efficacy (GSE) • Psychological and stress-related symptoms (RHS-15) • Emotional and behavioral problems (SDQ) • Quality of life (WHOQoL) |

Notes. PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, PTSD = Post-traumatic stress disorder. M.I.N.I. = MINI International Neuropsychiatric Interview, HTQ = Harvard Trauma Questionnaire, BRS = Brief Resilience Scale, GSE = Generalized Self-Efficacy Scale, RHS-15 = Refugee Health Screener 15, SDQ = Strengths and Difficulties Questionnaire, WHOQoL = World Health Organization Quality of Life – BREF version.

3.7 Other measures

Some assessments were part of the MEHIRA investigations but not subject to this dissertation. The Acceptance of Cultural Differences Subscale, as part of the Cultural Competence Inventory (CCI), was used to collect information on the participants' attitudes towards mental health care professionals and services. The Credibility/Expectancy Questionnaire (CEQ) was administered to quantify expectations and plausibility towards treatment within the trial. Individual health care utilization patterns were assessed with the Mannheimer Modul Ressourcenverbrauch (MRV), an adapted tool for measuring resource use in the German health care system. In addition, four scales were exclusively administered to the

subsample of adolescents. These were the MRV Additional Questionnaire Screening, the Patient Health Questionnaire-Adapted (PHQ-A), the M.I.N.I. KID International Neuropsychiatric Interview, and the Child and Adolescent Trauma Screening (CATS).

3.8 Statistical analyses

Data analysis was applied both to the Intention-to-treat (ITT) and Per protocol (PP) sample. To avoid group adherence bias and to enhance statistical power, outcome data in the ITT sample was imputed. Missing PHQ-9 and MADRS sum scores at baseline (T0) and post-intervention (T1) were estimated with the non-parametric k-nearest-neighbor (kNN) imputation. The kNN algorithm uses generalized distance functions for approximating missing data based on the closest neighboring data points in a multi-dimensional space (Kowarik & Templ, 2016). Approximation of missing values was based on baseline data from all available participants. No other variables were imputed. The PP data set remained unimputed, representing the actual empirical data of those participants who received and completed the *Empowerment* intervention ($\geq 50\%$ session attendance). Differences between conditions at baseline were tested using χ^2 -tests or Exact Fisher tests (if expected cell frequencies were less than 5) for categorical variables and independent t-tests or Welch tests (if homogeneity of variance was violated) for continuous variables. Two-sided alpha level was set at 0.05 for all analyses.

3.8.1 Primary analysis of effectiveness

The primary analysis of the effectiveness of the *Empowerment* intervention was subject to another dissertation (Wiechers, unpublished doctoral dissertation). Here, the most important results, that are relevant for the interpretation of the present dissertation, are briefly summarized. Effectiveness analysis was conducted by calculating linear mixed models (LMM). By using multilevel modeling, unbalanced data structure and missing data was handled. Data was nested within three hierarchical levels (level 3: study center, level 2: patient, level 1: time of measurement). Time (T0 vs. T1) was included in the models as a level 1 predictor, and condition (*Empowerment* vs. TAU) was included as a predictor on level 2. Thereby, cross-level interaction (time \times condition) was modulated. Dependent outcome variables were PHQ-9 sum scores (primary outcome) and MADRS sum scores (secondary outcome) as time-varying

measures on level 1. Effectiveness analysis was conducted using R (version 4.0.5; R Core Team, 2018).

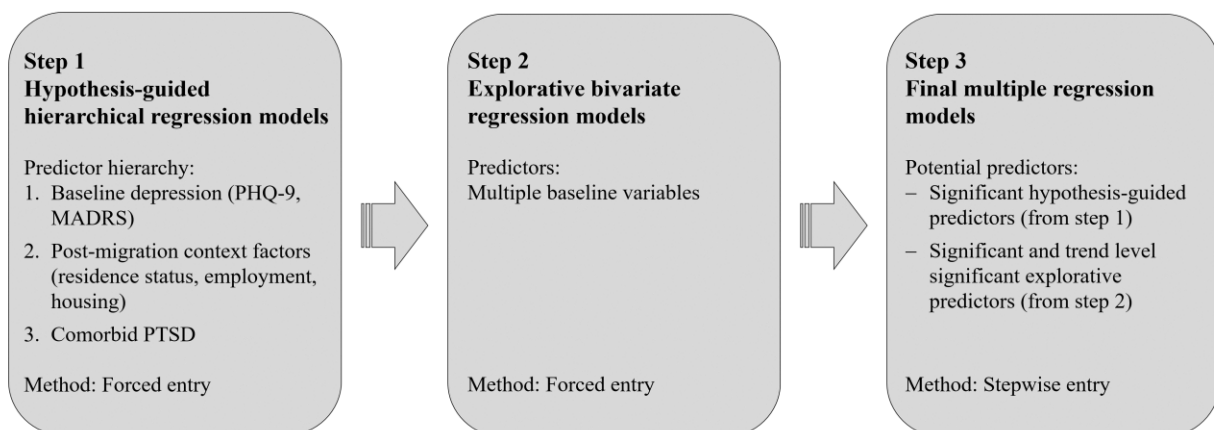
3.8.2 Predictor selection and regression model building

Predictor analyses were conducted by fitting regression models with change scores of PHQ-9 and MADRS as dependent variables. Change scores were calculated by subtracting baseline from post-intervention scores (T1–T0). Negative change scores indicated symptom improvement from baseline to post-intervention, positive change scores indicated symptom deterioration. Predictor selection followed a mixed-methods approach combining a confirmative and explorative strategy. First, hierarchical regression models were built to test a-priori hypotheses (hierarchical refers to successive testing of model complexity). Hierarchical models were built using a hypothesis-guided predictor hierarchy, according to evidence from previous studies. Representing the most robust predictor of treatment outcome in the literature, baseline depression (PHQ-9 or MADRS) was entered in the first model step. The impact of post-migration stressors on refugee mental health has been documented in a broad range of publications and yielded promising primary results in predictor studies. Therefore, a set of three post-migration context factors (residence status, employment, housing) was added in the second model step. In the third model step, comorbid PTSD was added as the co-occurrence of depression and PTSD represents the most frequently observed comorbidity pattern in refugee populations. All predictors of the hierarchy were forced into the model. Significant predictors were considered in further analyses. Second, explorative bivariate regression models were fitted to identify outcome predictors in a hypothesis-generating way. Variables that showed significant ($p < .05$) or trend level ($p < .10$) effects were considered in further analysis. Third, findings of both the confirmative and explorative strategy were combined. Multiple regression models were built by integrating relevant predictors from the previous hierarchical and bivariate regression models. To provide a parsimonious solution, the stepwise entry method was used for model building. Stepwise entry refers to iterative model building where the selection of potential predictor variables is based on probabilities of F-values. Step-by-step, the predictor with the smallest probability of F-value is entered. Predictors with probabilities of F-values ≥ 0.100 are excluded from the model. P-values of the final multiple regression models were adjusted by correction of the False Discovery Rate (FDR; Benjamini & Hochberg, 1995) to account for multiple hypothesis testing. The analytical procedure is summed up in figure 8.

Identical analyses were applied to the treatment and control condition of the ITT and PP sample. As the analyses revealed similarities in both conditions, analyses were extended to the pooled ITT sample to evaluate general predictors of outcome in refugee mental health care. Pooling patient data has been recommended to enhance the predictive power of predictor analysis (Haagen et al., 2017; Moons et al., 2009). All models in the pooled sample were controlled for condition. Verification of the pre-requisites of all regression models was ensured. Linearity between predictor and outcome variables, normal distribution and independence of residuals, and variance homogeneity were checked by plotting scatterplots of standardized predicted values and standardized residuals, histograms, and P-P plots of standardized residuals. Multicollinearity was assessed based on tolerance values and variance inflation factors (VIF). Predictor effect sizes were calculated using Cohen's d for dichotomous variables and Cohen's f^2 for continuous variables. According to Cohen (1988), $d=0.2$ and $f^2 \geq 0.02$ represent small effects, $d=0.5$ and $f^2 \geq 0.15$ represent moderate effects, and $d=0.8$ and $f^2 \geq 0.35$ represent large effects. Overall model fit was tested, comparing the goodness-of-fit measures Akaike's information criterion (AIC; Akaike, 1974) and Schwarz's Bayesian criterion (BIC; Schwarz, 1978). The BIC represents a more conservative measure than the AIC. Both indicators are adjusted log-likelihood values, with smaller values indicating better model fit. Regression coefficients were rounded off to two decimals. Predictor analyses were carried out using SPSS (version 26; IBM Corp., Armonk, NY, USA).

Figure 8

Analytical procedure



Notes. PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, PTSD = Post-traumatic stress disorder.

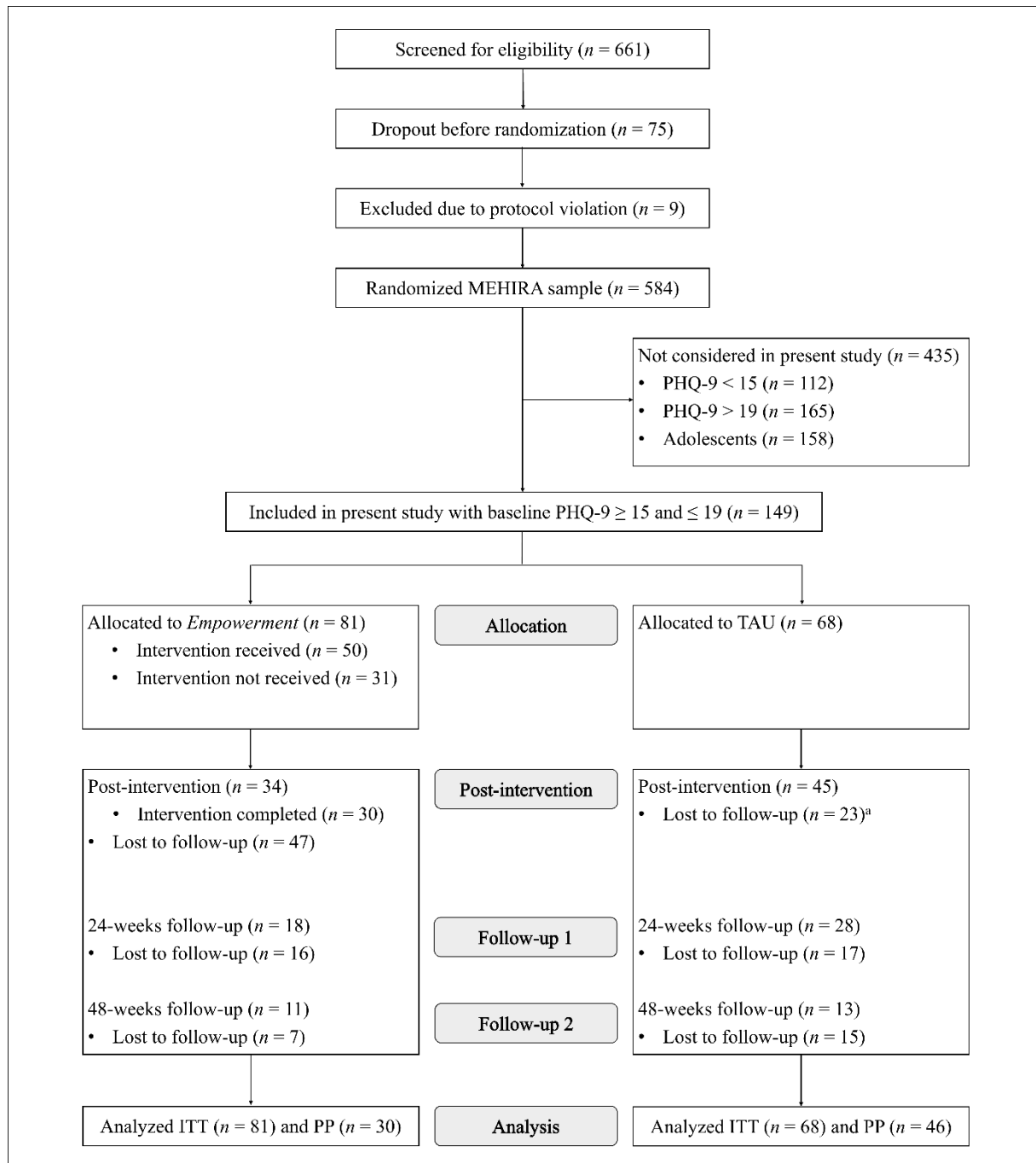
4 Results

4.1 Participant flow

Recruitment of participants was conducted between May 2018 and March 2020. In total, 661 individuals were screened for eligibility and 584 participants were randomized in the MEHIRA trial (figure 9). 149 participants fulfilled the inclusion criteria for level 3 with moderate depressive symptoms at baseline and build the ITT sample of this study (Empowerment=81, TAU=68). Participants were categorized as study completers per-protocol (PP) when they completed the 12-week intervention period. In the treatment condition, participants were considered completers when they attended at least 50% of the *Empowerment* group treatment (i.e., 8 or more group sessions). 73 participants were dropouts from baseline to post-intervention. Reasons for dropout were (a) refusal of group participation, (b) cancellation of group participation during intervention period, (c) finding alternative treatment, (d) relocation, (e) no initiation of the group due to insufficient group size, (f) unknown/participant no longer available. The PP sample comprised 76 participants (Empowerment=30, TAU=46).

4.2 Baseline characteristics

Table 2 shows the characteristics of participants at baseline. In the treatment condition of the ITT sample (n=81), participants had a mean age of 32.6 years (SD=9.1) and lived in Germany on average for 3.0 years (SD=1.8). Most participants were male (56.8%), unemployed (89.7%), and had no secure residence status (95.1%). Nearly half of the participants were married (46.9%) and lived in a refugee accommodation (49.4%). 41.8% were diagnosed with a comorbid PTSD and 36.7% with a comorbid anxiety disorder. The participants experienced an average of 10.1 (SD=6.4) traumatic events and had a mean trauma symptom score of 2.7 (SD=0.6) in the HTQ, pointing towards the presence of a clinically relevant PTSD. In the ITT sample, the mean baseline BRS score was higher among control participants compared to treatment participants ($t_{(134,64)}=-2.16$, $p=.033$). All other variables did not significantly differ between conditions. Also, no significant differences between conditions were detected in the PP sample.

Figure 9*Flow chart of participant recruitment and allocation*

Notes. MEHIRA = Mental Health in Refugees and Asylum Seekers, PHQ-9 = Patient Health Questionnaire 9, TAU = Treatment as usual, ITT = Intention to treat, PP = Per protocol, n = number.

^a No post-intervention measurements but follow-up measurements were available for one control participant. This participant was not considered a dropout and included in the PP sample.

Table 2*Comparison of outcome predictors at baseline in both samples*

| Predictors | ITT (n=149) | | PP (n=76) | |
|--|-----------------------|---------------|-----------------------|---------------|
| | Empowerment (n=81) | TAU (n=68) | Empowerment (n=30) | TAU (n=46) |
| <i>Hypothesis-guided</i> | | | | |
| Baseline PHQ-9, mean (SD) | 16.9 (3.1) | 17.0 (1.3) | 16.9 (3.2) | 17.0 (1.4) |
| Baseline MADRS, mean (SD) | 23.3 (9.7) | 24.5 (9.9) | 23.5 (9.3) | 26.3 (9.7) |
| Permanent residence status, n/n total (%) ^a | 4/81 (4.9) | 7/66 (10.6) | 1/30 (3.3) | 4/46 (8.7) |
| Employed, n/n total (%) | 8/78 (10.3) | 10/66 (15.2) | 3/30 (10.0) | 9/46 (19.6) |
| Refugee accommodation, n/n total (%) ^b | 40/81 (49.4) | 35/66 (53.0) | 16/30 (53.3) | 26/45 (57.8) |
| PTSD, n/n total (%) | 33/79 (41.8) | 22/63 (34.9) | 13/30 (43.3) | 18/45 (40.0) |
| <i>Explorative</i> | | | | |
| Age, mean (SD) | 32.6 (9.1) | 31.6 (9.8) | 31.9 (9.0) | 32.6 (10.8) |
| Male, n/n total (%) | 46/81 (56.8) | 46/68 (67.6) | 16/30 (53.3) | 33/46 (71.7) |
| Married, n/n total (%) | 38/81 (46.9) | 23/67 (34.3) | 12/30 (40.0) | 17/46 (37.0) |
| Education, mean (SD) | 8.8 (4.4) | 8.8 (4.7) | 7.7 (4.2) | 8.3 (4.8) |
| Social status change, mean (SD) | -1.2 (1.2) | -1.1 (1.2) | -0.9 (1.2) | -1.1 (1.0) |
| Religious affiliation, n/n total (%) | 67/79 (84.8) | 55/67 (82.1) | 27/30 (90.0) | 38/46 (82.6) |
| Single room, n/n total (%) | 18/75 (24.0) | 16/60 (26.7) | 5/28 (17.9) | 11/44 (25.0) |
| Time in Germany, mean (SD) | 3.0 (1.8) | 3.2 (2.4) | 3.0 (2.5) | 3.2 (1.1) |
| Identification migrant, mean (SD) | 1.7 (1.1) | 1.7 (1.2) | 1.6 (1.1) | 1.7 (1.1) |
| Concomitant medication, n/n total (%) | 31/80 (38.8) | 28/67 (41.8) | 14/30 (46.7) | 22/46 (47.8) |
| Concomitant psychotherapy, n/n total (%) | 15/79 (19.0) | 12/66 (18.2) | 5/30 (16.7) | 8/45 (17.8) |
| Number of diagnoses, mean (SD) | 1.8 (1.0) | 1.9 (1.2) | 1.8 (1.0) | 2.0 (1.2) |
| Anxiety disorder, n/n total (%) | 29/79 (36.7) | 26/63 (41.3) | 12/30 (40.0) | 18/45 (40.0) |
| Substance use disorder, n/n total (%) | 5/79 (6.3) | 4/63 (6.3) | 0/30 (0.0) | 2/45 (4.4) |
| War, n/n total (%) | 49/81 (60.5) | 44/68 (64.7) | 21/30 (70.0) | 30/46 (65.2) |
| Persecution, n/n total (%) | 28/81 (34.6) | 28/68 (41.2) | 9/30 (30.0) | 17/46 (37.0) |
| Number of trauma events, mean (SD) | 10.1 (6.4) | 10.5 (6.4) | 10.5 (6.4) | 10.5 (6.1) |
| Trauma symptoms, mean (SD) | 2.7 (0.6) | 2.7 (0.5) | 2.7 (0.6) | 2.7 (0.5) |
| Baseline RHS-15, mean (SD) | 35.0 (9.3) | 35.2 (7.8) | 36.1 (9.0) | 35.7 (7.4) |
| Baseline BRS, mean (SD) | 2.7 (0.8) | 2.9 (0.6) | 2.7 (0.8) | 2.8 (0.5) |
| Baseline GSE, mean (SD) | 24.2 (7.2) | 24.4 (7.2) | 23.7 (7.0) | 24.0 (6.9) |
| Baseline SDQ, mean (SD) | 55.4 (7.2) | 53.3 (8.3) | 57.3 (6.2) | 54.0 (7.4) |
| Baseline WHOQoL, mean (SD) | 73.6 (15.1) | 73.0 (12.7) | 74.2 (13.1) | 72.5 (12.6) |

Notes. ITT = Intention to treat, PP = Per protocol, TAU = Treatment as usual, n = number, SD = Standard deviation, PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, PTSD = Post-traumatic stress disorder, RHS-15 = Refugee Health Screener 15, BRS = Brief Resilience Scale, GSE = Generalized Self-Efficacy Scale, SDQ = Strengths and Difficulties Questionnaire, WHOQoL = World Health Organization Quality of Life.

^a Residence status upon study admission.

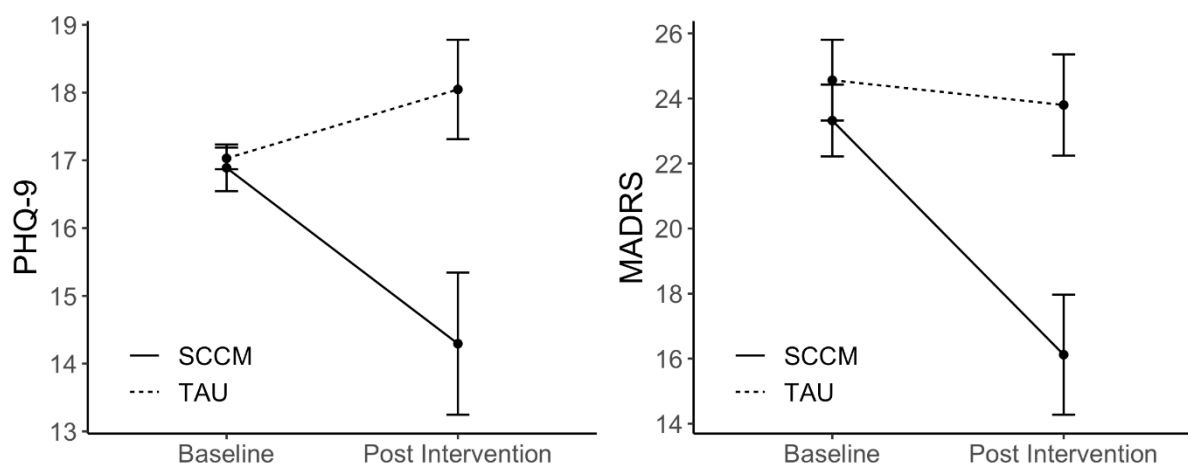
^b Refugee accommodation includes initial reception centers, AnKER centers, collective accommodation centers, and decentralized accommodation.

4.3 Primary evaluation of effectiveness

Linear mixed models (LMM) were calculated to examine the effectiveness of the *Empowerment* intervention compared to TAU. In the ITT sample, analyses revealed a significant group×time interaction of mean PHQ-9 sum scores, with $F_{(1, 147)}=13.32$ and $p<.001$. Post-hoc analyses indicated that depressive symptoms decreased significantly in the *Empowerment* condition from baseline to post-intervention ($\beta=-2.60$, $t_{(153.62)}=-3.59$, $p<.001$), but not in the control condition ($\beta=1.03$, $t_{(130.95)}=1.51$, $p=.133$). Considering the MADRS, analyses also showed a significant group×time interaction ($F_{(1, 140)}=6.91$, $p=.010$). Post-hoc contrasts revealed a significant symptom reduction in the *Empowerment* condition from baseline to post-intervention ($\beta=-7.27$, $t_{(137.44)}=-4.43$, $p<.001$), whereas there was no significant effect in the control condition ($\beta=-1.41$, $t_{(107.28)}=-0.93$, $p=.352$). The mean sum scores of PHQ-9 and MADRS by condition are displayed in figure 10.

Figure 10

Mean sum scores of PHQ-9 and MADRS from baseline to post-intervention by condition in the ITT sample



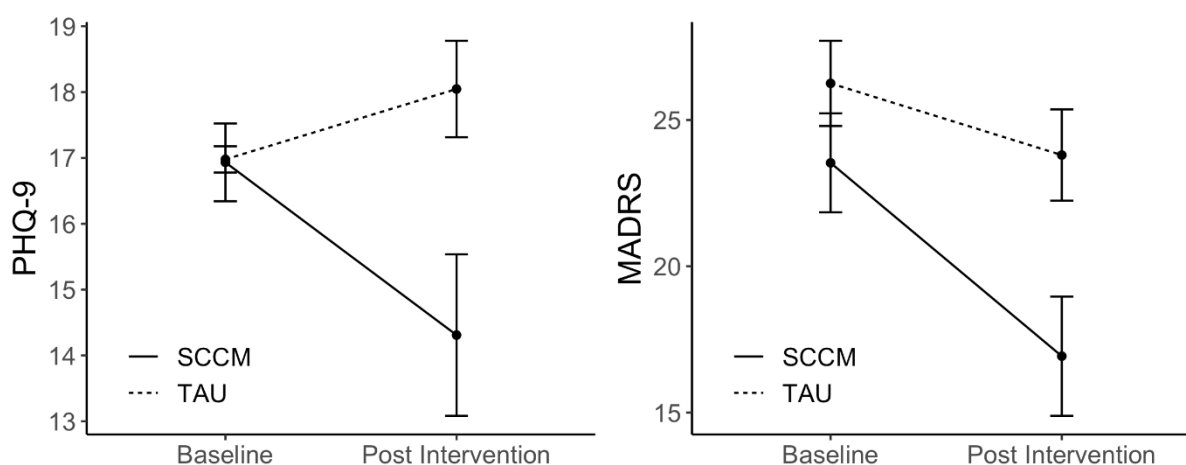
Notes. PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, SCCM = Stepped and Collaborative Care Model (i.e., *Empowerment*), TAU = Treatment-as-usual. Error bars represent ± 1 Standard Error.

In the PP sample, analyses showed a significant group×time interaction of mean PHQ-9 sum scores, with $F_{(1, 74)}=8.25$ and $p=.005$. Post-hoc contrasts revealed that depressive symptoms

decreased significantly in the *Empowerment* condition from baseline to post-intervention ($\beta=-2.63$, $t_{(73.55)}=-2.60$, $p=.011$), but not in the control condition ($\beta=1.12$, $t_{(74.73)}=1.35$, $p=.180$). Considering the MADRS, analyses revealed a significant group \times time interaction ($F_{(1, 72)}=4.06$, $p=.048$). Post-hoc analyses indicated a significant symptom reduction in the *Empowerment* condition from baseline to post-intervention ($\beta=-7.10$, $t_{(73.84)}=-3.53$, $p<.001$), whereas there was no significant effect in the control condition ($\beta=-1.89$, $t_{(73.45)}=-1.16$, $p=.250$). The mean sum scores of PHQ-9 and MADRS by condition are displayed in figure 11.

Figure 11

Mean sum scores of PHQ-9 and MADRS from baseline to post-intervention by condition in the PP sample



Notes. PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, SCCM = Stepped and Collaborative Care Model (i.e., *Empowerment*), TAU = Treatment-as-usual. Error bars represent ± 1 Standard Error.

4.4 Intention-to-treat predictor analysis (n=149)

4.4.1 *Empowerment* (n=81)

Table 3 shows the hypothesis-guided hierarchical regression model of change in PHQ-9 with three model steps. Baseline PHQ-9 was a significant predictor of PHQ-9 change in every model step (step 1: $t=-3.34$, $p=.001$; step 2: $t=-3.11$, $p=.003$; step 3: $t=-2.94$, $p=.004$). Negative regression coefficients indicated a linear relationship between increasing PHQ-9 scores at baseline and decreasing PHQ-9 change scores. The effect sizes were small to moderate

($f^2=0.12-0.15$). All other predictors were not significantly different from zero. Analysis of Variance (ANOVA) was significant in model step 1 ($F_{(1,75)}=11.135$, $p=.001$) and step 2 ($F_{(4,72)}=2.779$, $p=.033$), but not step 3 ($F_{(5,71)}=2.192$, $p=.065$). The first step explained 12.9% of the outcome variation. Adding post-migration context factors in step 2 ($\Delta R^2=0.004$, $p=.946$) and comorbid PTSD in step 3 ($\Delta R^2=0.000$, $p=.998$) did not improve the model significantly. Goodness-of-fit indicators approved that the first model step represented sample data best, as lower indicators (AIC=234.587, BIC=239.275) were observed compared to those of the second (AIC=240.192, BIC=251.911) and third step (AIC=242.192, BIC=256.255).

Table 3

Hierarchical regression model of PHQ-9 change in the treatment condition of the ITT sample

| | b [95% CI] | β | F | p | R ² |
|------------------|----------------------|---------|--------|-------------|----------------|
| <i>Step 1</i> | | | 11.135 | .001 | 0.129 |
| (constant) | 9.40 [3.24, 15.57] | | | .003 | |
| Baseline PHQ-9 | -0.60 [-0.95, -0.24] | -0.36 | | .001 | |
| <i>Step 2</i> | | | 2.779 | .033 | 0.134 |
| (constant) | 8.07 [-2.37, 18.51] | | | .128 | |
| Baseline PHQ-9 | -0.58 [-0.95, -0.21] | -0.35 | | .003 | |
| Residence status | 0.60 [-4.84, 6.04] | 0.02 | | .826 | |
| Employment | -0.39 [-3.85, 3.07] | -0.03 | | .824 | |
| Housing | 0.55 [-1.60, 2.71] | 0.06 | | .609 | |
| <i>Step 3</i> | | | 2.192 | .065 | 0.134 |
| (constant) | 8.07 [-2.48, 18.63] | | | .132 | |
| Baseline PHQ-9 | -0.58 [-0.97, -0.19] | -0.35 | | .004 | |
| Residence status | 0.60 [-4.88, 6.08] | 0.02 | | .827 | |
| Employment | -0.39 [-4.03, 3.26] | -0.03 | | .833 | |
| Housing | 0.55 [-1.68, 2.78] | 0.06 | | .622 | |
| PTSD | -0.00 [-2.41, 2.40] | 0.00 | | .998 | |

Notes. ITT = Intention to treat, PHQ-9 = Patient Health Questionnaire 9, PTSD = Post-traumatic stress disorder, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values <.05 are printed in bold.

In the hierarchical regression model of change in MADRS, baseline MADRS was a significant predictor, with $t=-8.65$, $p<.001$ in step 1, $t=-8.14$, $p<.001$ in step 2, and $t=-8.25$, $p<.001$ in step 3 (table 4). Negative regression coefficients pointed towards a linear relationship between increasing baseline MADRS scores and decreasing MADRS change scores. The effect

sizes were large in all model steps ($f^2=0.84-1.00$). Residence status, employment, housing, and comorbid PTSD did not prove predictive value. All model steps were significant in ANOVA (step 1: $F_{(1,75)}=74.892$, $p<.001$; step 2: $F_{(4,72)}=18.226$, $p<.001$; step 3: $F_{(5,71)}=14.997$, $p<.001$). Baseline MADRS accounted for 50.0% of the outcome variation in the first model step. Including post-migration context factors increased R^2 by 0.003 and including comorbid PTSD increased R^2 by 0.011, which was non-significant in both cases ($p=.918$ and $p=.219$). Compared with step 2 and step 3, the first model step showed superior goodness-of-fit criteria, with $AIC=316.409$ and $BIC=321.096$.

Table 4

Hierarchical regression model of MADRS change in the treatment condition of the ITT sample

| | b [95% CI] | β | F | p | R^2 |
|------------------|----------------------|---------|--------|-----------------|-------|
| <i>Step 1</i> | | | 74.892 | <.001 | 0.500 |
| (constant) | 14.58 [9.84, 19.31] | | | <.001 | |
| Baseline MADRS | -0.81 [-0.99, -0.62] | -0.71 | | <.001 | |
| <i>Step 2</i> | | | 18.226 | <.001 | 0.503 |
| (constant) | 18.60 [5.13, 32.07] | | | .007 | |
| Baseline MADRS | -0.82 [-1.02, -0.62] | -0.72 | | <.001 | |
| Residence status | -1.26 [-10.61, 8.09] | -0.02 | | .788 | |
| Employment | -0.85 [-6.75, 5.05] | -0.02 | | .775 | |
| Housing | -1.01 [-4.78, 2.76] | -0.05 | | .596 | |
| <i>Step 3</i> | | | 14.997 | <.001 | 0.514 |
| (constant) | 15.87 [1.74, 29.99] | | | .028 | |
| Baseline MADRS | -0.84 [-1.05, -0.64] | -0.74 | | <.001 | |
| Residence status | -1.10 [-10.43, 8.22] | -0.02 | | .814 | |
| Employment | -1.79 [-7.86, 4.28] | -0.05 | | .558 | |
| Housing | -0.50 [-4.35, 3.35] | -0.02 | | .798 | |
| PTSD | 2.45 [-1.49, 6.39] | 0.11 | | .219 | |

Notes. ITT = Intention to treat, MADRS = Montgomery Asberg Depression Rating Scale, PTSD = Post-traumatic stress disorder, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R^2 = Determination coefficient. P-values $<.05$ are printed in bold.

Explorative bivariate regression models are displayed in table 5. No significant predictors of change in PHQ-9 were found. Baseline GSE ($t_{(75)}=-1.96$, $p=.054$, $f^2=0.05$) and baseline SDQ ($t_{(75)}=-1.67$, $p=.099$, $f^2=0.04$) showed trend level effects. Change in MADRS was predicted by

number of trauma events ($t_{(77)}=-2.29$, $p=.025$, $f^2=0.07$). The predictor accounted for 6.4% of the outcome variation. Gender ($t_{(79)}=1.89$, $p=.063$, $d=0.43$), marital status ($t_{(79)}=1.68$, $p=.097$, $d=0.37$), time in Germany ($t_{(74)}=-1.85$, $p=.068$, $f^2=0.05$), identification as a migrant ($t_{(78)}=1.94$, $p=.056$, $f^2=0.05$), the number of diagnoses ($t_{(77)}=-1.87$, $p=.065$, $f^2=0.04$), and baseline WHOQoL ($t_{(75)}=1.78$, $p=.078$, $f^2=0.04$) showed trend level effects.

Table 5*Bivariate regression models in the treatment condition of the ITT sample*

| Predictors | PHQ-9 change | | | MADRS change | | |
|---------------------------|---------------------|---------|-------------|----------------------|---------|-------------|
| | b [95% CI] | β | p | b [95% CI] | β | p |
| Age | -0.05 [-0.17, 0.07] | -0.09 | .406 | 0.03 [-0.24, 0.29] | 0.02 | .829 |
| Gender | -0.33 [-2.56, 1.90] | -0.03 | .770 | 4.47 [-0.24, 9.17] | 0.21 | .063 |
| Marital status | 0.43 [-1.78, 2.65] | 0.04 | .697 | 3.97 [-0.73, 8.66] | 0.19 | .097 |
| Education | -0.08 [-0.33, 0.18] | -0.07 | .539 | 0.03 [-0.53, 0.60] | 0.01 | .905 |
| Social status change | -0.03 [-0.93, 0.87] | -0.01 | .948 | 0.52 [-1.48, 2.52] | 0.06 | .603 |
| Religious affiliation | -0.31 [-3.32, 2.69] | -0.02 | .836 | 1.82 [-4.89, 8.54] | 0.06 | .590 |
| Single room | -1.44 [-4.05, 1.18] | -0.13 | .277 | 3.32 [-2.36, 9.00] | 0.14 | .248 |
| Time in Germany | 0.13 [-0.84, 1.10] | 0.03 | .791 | -1.98 [-4.11, 0.15] | -0.21 | .068 |
| Identification migrant | 0.48 [-0.49, 1.46] | 0.11 | .328 | 2.10 [-0.05, 4.26] | 0.22 | .056 |
| Concomitant medication | -0.19 [-2.38, 1.99] | -0.02 | .861 | -2.30 [-7.18, 2.59] | -0.11 | .352 |
| Concomitant psychotherapy | 1.49 [-1.37, 4.35] | 0.12 | .304 | 2.21 [-3.94, 8.37] | 0.08 | .476 |
| Number of diagnoses | 0.03 [-1.07, 1.13] | 0.01 | .955 | -2.17 [-4.49, 0.14] | -0.21 | .065 |
| Anxiety disorder | -0.69 [-3.03, 1.65] | -0.07 | .559 | 0.00 [-5.05, 5.05] | 0.00 | .999 |
| Substance use disorder | 2.95 [-1.65, 7.55] | 0.14 | .206 | -7.22 [-17.08, 2.64] | -0.16 | .149 |
| War | -1.15 [-3.39, 1.10] | -0.11 | .314 | -2.30 [-7.15, 2.55] | -0.11 | .349 |
| Persecution | -0.50 [-2.83, 1.82] | -0.05 | .667 | -2.32 [-7.30, 2.67] | -0.10 | .358 |
| Number of trauma events | -0.08 [-0.25, 0.09] | -0.11 | .355 | -0.42 [-0.79, -0.06] | -0.25 | .025 |
| Trauma symptoms | -0.19 [-1.98, 1.61] | -0.02 | .837 | -2.79 [-6.80, 1.22] | -0.16 | .170 |
| Baseline RHS-15 | -0.09 [-0.21, 0.03] | -0.17 | .120 | -0.11 [-0.37, 0.15] | -0.10 | .395 |
| Baseline BRS | -0.72 [-2.14, 0.70] | -0.12 | .314 | 1.92 [-1.15, 5.00] | 0.14 | .217 |
| Baseline GSE | -0.15 [-0.30, 0.00] | -0.22 | .054 | -0.14 [-0.47, 0.19] | -0.10 | .406 |
| Baseline SDQ | -0.13 [-0.28, 0.02] | -0.19 | .099 | -0.02 [-0.36, 0.31] | -0.02 | .890 |
| Baseline WHOQoL | -0.01 [-0.08, 0.06] | -0.03 | .823 | 0.14 [-0.02, 0.30] | 0.20 | .078 |

Notes. ITT = Intention to treat, PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, RHS-15 = Refugee Health Screener 15, BRS = Brief Resilience Scale, GSE = Generalized Self-Efficacy Scale, SDQ = Strengths and Difficulties Questionnaire, WHOQoL = World Health Organization Quality of Life, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value. P-values <.10 are printed in bold.

The final multiple regression model of change in PHQ-9 was fitted with baseline PHQ-9, baseline GSE and baseline SDQ as potential predictors, using the stepwise entry method (table 6). Baseline PHQ-9 entered the model in step 1 and baseline GSE entered the model in step 2 while baseline SDQ was excluded due to a probability of F-value ≥ 0.100 . Baseline PHQ-9 predicted the outcome in both model steps (step 1: $t=-3.07$, $p=.003$; step 2: $t=-3.27$, $p=.002$) and baseline GSE predicted the outcome in the second step ($t=-2.26$, $p=.027$). Effect sizes were small for both predictors ($f^2=0.06-0.13$). The predictors accounted for 16.9% of the outcome variation. ANOVA indicated the significance of both model steps. AIC and BIC were higher for step 1 (AIC=234.162, BIC=238.850) compared to step 2 (AIC=231.035, BIC=238.066), indicating the superiority of the second model. The final regression model of change in MADRS was built with the predictors baseline MADRS, number of trauma events, gender, marital status, time in Germany, identification as a migrant, number of diagnoses, and baseline WHOQoL. All predictors but baseline MADRS were excluded from the analysis. Therefore, the final regression model did not provide additional information compared to the first step of the hierarchical regression model (see table 4).

Table 6

Multiple regression model of PHQ-9 change in the treatment condition of the ITT sample

| | b [95% CI] | β | F | p | R ² |
|----------------|----------------------|---------|-------|-------------|----------------|
| <i>Step 1</i> | | | 9.429 | .003 | 0.112 |
| (constant) | 8.63 [2.37, 14.90] | | | .008 | |
| Baseline PHQ-9 | -0.56 [-0.92, -0.20] | -0.33 | | .003 | |
| <i>Step 2</i> | | | 7.519 | .001 | 0.169 |
| (constant) | 12.85 [5.70, 20.00] | | | .001 | |
| Baseline PHQ-9 | -0.58 [-0.93, -0.23] | -0.35 | | .002 | |
| Baseline GSE | -0.16 [-0.30, -0.02] | -0.24 | | .027 | |

Notes. ITT = Intention to treat, PHQ-9 = Patient Health Questionnaire 9, GSE = Generalized Self-Efficacy Scale, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values of regression coefficients were adjusted using Benjamini-Hochberg correction. P-values <.05 are printed in bold.

4.4.2 Treatment-as-usual (n=68)

The hierarchical regression model of change in PHQ-9 in the control condition of the ITT sample is shown in table 7. None of the model steps was significant in predicting the outcome, and accordingly all individual predictors were non-significant. Table 8 shows the hierarchical regression model of change in MADRS, where baseline MADRS was a significant predictor in model step 1 ($t=-5.49$, $p<.001$), step 2 ($t=-6.03$, $p<.001$), and step 3 ($t=-5.67$, $p<.001$) with large effect sizes ($f^2=0.50-0.63$). Housing was a significant predictor in step 2 ($t=-2.41$, $p=.019$) and 3 ($t=-2.39$, $p=.020$) with small effect sizes ($f^2=0.07$). Negative regression coefficients indicated that living in housing conditions other than a refugee accommodation was associated with decreased MADRS change scores. Adding post-migration context factors in step 2 ($\Delta R^2=0.062$, $p=.133$) and comorbid PTSD in step 3 ($\Delta R^2=0.000$, $p=.961$) did not improve the model significantly. Goodness-of-fit indicators showed mixed results. The AIC yielded the lowest values for the second model step (AIC=267.764) while the BIC pointed towards the superiority of the first model step (BIC=272.047).

Table 7

Hierarchical regression model of PHQ-9 change in the control condition of the ITT sample

| | b [95% CI] | β | F | p | R ² |
|------------------|---------------------|---------|-------|------|----------------|
| <i>Step 1</i> | | | | | |
| (constant) | 7.75 [-5.72, 21.22] | | 1.026 | .315 | 0.017 |
| Baseline PHQ-9 | -0.40 [-1.19, 0.39] | -0.13 | | .254 | |
| <i>Step 2</i> | | | | | |
| (constant) | 7.56 [-6.96, 22.09] | | 0.374 | .826 | 0.026 |
| Baseline PHQ-9 | -0.42 [-1.24, 0.40] | -0.14 | | .309 | |
| Residence status | -0.23 [-4.35, 3.88] | -0.02 | | .910 | |
| Employment | 0.98 [-2.02, 3.98] | 0.09 | | .515 | |
| Housing | -0.26 [-2.50, 1.98] | -0.03 | | .818 | |
| <i>Step 3</i> | | | | | |
| (constant) | 5.92 [-9.29, 21.13] | | 0.413 | .838 | 0.036 |
| Baseline PHQ-9 | -0.42 [-1.24, 0.41] | -0.14 | | .314 | |
| Residence status | 0.07 [-4.14, 4.27] | 0.01 | | .974 | |
| Employment | 0.95 [-2.07, 3.96] | 0.09 | | .531 | |
| Housing | -0.18 [-2.43, 2.08] | -0.02 | | .875 | |
| PTSD | 0.88 [-1.44, 3.20] | 0.10 | | .449 | |

Notes. ITT = Intention to treat, PHQ-9 = Patient Health Questionnaire 9, PTSD = Post-traumatic stress disorder, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values <.05 are printed in bold.

Table 8*Hierarchical regression model of MADRS change in the control condition of the ITT sample*

| | b [95% CI] | β | F | p | R ² |
|------------------|-----------------------|---------|--------|-------|----------------|
| <i>Step 1</i> | | | | | |
| (constant) | 13.26 [7.15, 19.36] | | 30.113 | <.001 | 0.334 |
| Baseline MADRS | -0.62 [-0.85, -0.40] | -0.58 | | <.001 | |
| <i>Step 2</i> | | | | | |
| (constant) | 20.60 [6.50, 34.71] | | 9.338 | <.001 | 0.396 |
| Baseline MADRS | -0.73 [-0.97, -0.49] | -0.68 | | <.001 | |
| Residence status | 2.03 [-6.04, 10.10] | 0.05 | | .616 | |
| Employment | 1.27 [-4.74, 7.29] | 0.05 | | .673 | |
| Housing | -5.73 [-10.49, -0.97] | -0.28 | | .019 | |
| <i>Step 3</i> | | | | | |
| (constant) | 20.73 [5.13, 36.39] | | 7.340 | <.001 | 0.396 |
| Baseline MADRS | -0.73 [-0.99, -0.47] | -0.68 | | <.001 | |
| Residence status | 1.99 [-6.33, 10.31] | 0.05 | | .634 | |
| Employment | 1.27 [-4.81, 7.35] | 0.05 | | .677 | |
| Housing | -5.73 [-10.53, -0.92] | -0.28 | | .020 | |
| PTSD | -0.12 [-4.96, 4.72] | -0.01 | | .961 | |

Notes. ITT = Intention to treat, MADRS = Montgomery Asberg Depression Rating Scale, PTSD = Post-traumatic stress disorder, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values <.05 are printed in bold.

In bivariate regression models (table 9), education ($t_{(61)}=-2.16$, $p=.035$, $f^2=0.08$), substance use disorder ($t_{(61)}=-2.75$, $p=.008$, $d=0.70$), baseline GSE ($t_{(57)}=-2.90$, $p=.005$, $f^2=0.15$), and religious affiliation ($t_{(65)}=2.48$, $p=.016$, $f^2=0.09$) significantly predicted change in PHQ-9. Change in MADRS was predicted by number of diagnoses ($t_{(61)}=-2.10$, $p=.039$, $f^2=0.07$) and social status change ($t_{(61)}=2.66$, $p=.010$, $f^2=0.12$). Trend level effects were found for concomitant medication ($t_{(65)}=-1.73$, $p=.089$, $d=0.43$) and anxiety disorder ($t_{(61)}=-1.85$, $p=.069$, $d=0.47$).

Multiple regression models were fitted to predict change in PHQ-9 (table 10) and MADRS (table 11). Using the stepwise entry method, four potential predictors were selected to build the final model of PHQ-9 change. Baseline GSE entered the model in step 1 and substance use disorder entered the model in step 2, while religious affiliation and education were excluded due to probabilities of F-values ≥ 0.100 . ANOVA indicated the significance of both model steps. In model step 1, baseline GSE predicted the outcome ($t=-2.86$, $p=.006$) and explained 13.1% of the outcome variation.

Table 9*Bivariate regression models in the control condition of the ITT sample*

| Predictors | PHQ-9 change | | | MADRS change | | |
|---------------------------|----------------------|---------|-------------|----------------------|---------|-------------|
| | b [95% CI] | β | p | b [95% CI] | β | p |
| Age | -0.03 [-0.14, 0.07] | -0.08 | .535 | -0.10 [-0.36, 0.16] | -0.09 | .458 |
| Gender | 0.49 [-1.68, 2.65] | 0.06 | .656 | -3.92 [-9.32, 1.48] | -0.18 | .152 |
| Marital status | -0.76 [-2.92, 1.41] | -0.09 | .488 | -0.22 [-5.63, 5.20] | -0.01 | .937 |
| Education | -0.24 [-0.47, -0.02] | -0.27 | .035 | -0.20 [-0.75, 0.35] | -0.09 | .467 |
| Social status change | 0.05 [-0.85, 0.95] | 0.01 | .911 | 2.71 [0.67, 4.74] | 0.32 | .010 |
| Religious affiliation | 3.19 [0.62, 5.76] | 0.29 | .016 | 1.05 [-5.65, 7.75] | 0.04 | .755 |
| Single room | -0.40 [-2.90, 2.10] | -0.04 | .751 | -1.80 [-7.90, 4.30] | -0.08 | .557 |
| Time in Germany | -0.14 [-1.06, 0.78] | -0.04 | .760 | -0.35 [-2.39, 1.69] | -0.04 | .734 |
| Identification migrant | 0.22 [-0.66, 1.10] | 0.06 | .617 | -0.20 [-2.38, 1.97] | -0.02 | .852 |
| Concomitant medication | -0.41 [-2.50, 1.67] | -0.05 | .694 | -4.40 [-9.50, 0.69] | -0.21 | .089 |
| Concomitant psychotherapy | -1.12 [-3.78, 1.55] | -0.10 | .407 | -2.58 [-9.30, 4.15] | -0.10 | .446 |
| Number of diagnoses | -0.38 [-1.28, 0.52] | -0.11 | .402 | -2.33 [-4.55, -0.12] | -0.26 | .039 |
| Anxiety disorder | -0.55 [-2.66, 1.56] | -0.07 | .606 | -4.84 [-10.08, 0.40] | -0.23 | .069 |
| Substance use disorder | -5.54 [-9.57, -1.51] | -0.33 | .008 | 3.06 [-7.77, 13.90] | 0.07 | .574 |
| War | 0.38 [-1.74, 2.51] | 0.04 | .719 | -0.72 [-6.09, 4.64] | -0.03 | .789 |
| Persecution | -0.57 [-2.63, 1.49] | -0.07 | .582 | -2.01 [-7.20, 3.18] | -0.10 | .443 |
| Number of trauma events | -0.04 [-0.22, 0.14] | -0.06 | .667 | 0.10 [-0.31, 0.51] | 0.07 | .618 |
| Trauma symptoms | -0.56 [-2.68, 1.57] | -0.07 | .602 | -3.77 [-8.69, 1.16] | -0.20 | .131 |
| Baseline RHS-15 | 0.02 [-0.12, 0.15] | 0.03 | .789 | -0.17 [-0.50, 0.16] | -0.13 | .311 |
| Baseline BRS | -0.50 [-2.49, 1.49] | -0.07 | .615 | 2.42 [-2.29, 7.12] | 0.13 | .308 |
| Baseline GSE | -0.22 [-0.37, -0.07] | -0.36 | .005 | 0.12 [-0.25, 0.49] | 0.09 | .524 |
| Baseline SDQ | 0.01 [-0.13, 0.14] | 0.01 | .917 | -0.15 [-0.47, 0.18] | -0.12 | .373 |
| Baseline WHOQoL | -0.03 [-0.12, 0.06] | -0.09 | .483 | 0.11 [-0.10, 0.32] | 0.14 | .281 |

Notes. ITT = Intention to treat, PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, RHS-15 = Refugee Health Screener 15, BRS = Brief Resilience Scale, GSE = Generalized Self-Efficacy Scale, SDQ = Strengths and Difficulties Questionnaire, WHOQoL = World Health Organization Quality of Life, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value. P-values <.10 are printed in bold.

In model step 2, baseline GSE ($t=-2.41$, $p=.020$) and substance use disorder ($t=-2.08$, $p=.042$) accounted for 19.7% of the outcome variation. Adding the second predictor significantly improved the model ($\Delta R^2=0.066$, $p=.042$). The effect sizes were small to moderate for baseline GSE ($f^2=0.10-0.15$) and small for substance use disorder ($f^2=0.07$). Goodness-of-fit indicators were lowest for model step 2 (AIC=153.750, BIC=159.826). Modelling change in MADRS, six potential predictors were considered (baseline MADRS, housing, social status change, number of diagnoses, anxiety disorder, and concomitant medication). Baseline MADRS entered the model in step 1 and social status change entered the model in step 2. All

other variables were excluded. Baseline MADRS was significant in predicting the outcome (step 1: $t=-5.14$, $p<.001$; step 2: $t=-5.50$, $p<.001$) with large effect sizes ($f^2=0.45$), followed by social status change ($t=3.11$, $p=.003$) showing a small effect size ($f^2=0.11$). Together, both predictors explained 41.2% of variation in MADRS change scores. ANOVA confirmed the significance of both model steps. The second model step (AIC=250.804, BIC=257.087) represented sample data better than the first model step (AIC=258.188, BIC=262.377).

Table 10

Multiple regression model of PHQ-9 change in the control condition of the ITT sample

| | b [95% CI] | β | F | p | R ² |
|------------------------|----------------------|---------|-------|-------------|----------------|
| <i>Step 1</i> | | | 8.149 | .006 | 0.131 |
| (constant) | 5.94 [2.12, 9.76] | | | .003 | |
| Baseline GSE | -0.21 [-0.36, -0.06] | -0.36 | | .006 | |
| <i>Step 2</i> | | | 6.492 | .003 | 0.197 |
| (constant) | 9.67 [4.50, 14.83] | | | .000 | |
| Baseline GSE | -0.18 [-0.33, -0.03] | -0.30 | | .020 | |
| Substance use disorder | -4.26 [-8.36, -0.16] | -0.26 | | .042 | |

Notes. ITT = Intention to treat, PHQ-9 = Patient Health Questionnaire 9, GSE = Generalized Self-Efficacy Scale, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values of regression coefficients were adjusted using Benjamini-Hochberg correction. P-values <.05 are printed in bold.

Table 11

Multiple regression model of MADRS change in the control condition of the ITT sample

| | b [95% CI] | β | F | p | R ² |
|----------------------|----------------------|---------|--------|-----------------|----------------|
| <i>Step 1</i> | | | 26.414 | <.001 | 0.313 |
| (constant) | 12.88 [6.58, 19.18] | | | <.001 | |
| Baseline MADRS | -0.60 [-0.83, -0.37] | -0.56 | | <.001 | |
| <i>Step 2</i> | | | 20.002 | <.001 | 0.412 |
| (constant) | 16.27 [10.00, 22.54] | | | <.001 | |
| Baseline MADRS | -0.60 [-0.82, -0.38] | -0.56 | | <.001 | |
| Social status change | 2.81 [1.00, 4.62] | 0.32 | | .003 | |

Notes. ITT = Intention to treat, MADRS = Montgomery Asberg Depression Rating Scale, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values of regression coefficients were adjusted using Benjamini-Hochberg correction. P-values <.05 are printed in bold.

4.4.3 Analysis of the pooled sample (n=149)

Similarities in predictors (i.e., baseline depression, baseline self-efficacy) were found in the treatment and control condition of the ITT sample. Therefore, statistical analyses were extended to the entire ITT sample in order to identify general predictors of refugee treatment. The same strategy of predictor selection and model building was used to analyze the pooled sample (n=149).

Change in PHQ-9 was predicted by baseline PHQ-9 both in the hierarchical and the final multiple regression models (table 12). Baseline GSE was a significant predictor in bivariate analyses and the final regression model of PHQ-9 change. All other potential predictors did not show significance. The final step of the multiple regression model of change in PHQ-9 included baseline PHQ-9 ($\beta=-0.30$, $t=-3.82$, $p<.001$) and baseline GSE ($\beta =-0.29$, $t=-3.65$, $p<.001$). All regression coefficients were negative, indicating a linear relationship between increasing baseline scores and decreasing PHQ-9 change scores. Effect sizes were small for baseline PHQ-9 ($f^2=0.10$) and baseline GSE ($f^2=0.09$). Together, the predictors explained 19.1% of the outcome variation. ANOVA confirmed the significance of the final model step with $F_{(3,128)}=10.062$, $p<.001$ and goodness-of-fit values were lower for model step 2 (AIC=388.798, BIC=397.447) than model step 1 (AIC=399.091, BIC=404.856).

Table 12

Multiple regression model of PHQ-9 change in the pooled ITT sample

| | b [95% CI] | β | F | p | R ² |
|----------------|----------------------|---------|--------|-----------------|----------------|
| <i>Step 1</i> | | | 7.687 | .001 | 0.106 |
| (constant) | 7.47 [1.27, 13.68] | | | .019 | |
| Baseline PHQ-9 | -0.57 [-0.91, -0.24] | -0.28 | | .001 | |
| <i>Step 2</i> | | | 10.062 | <.001 | 0.191 |
| (constant) | 12.69 [6.12, 19.26] | | | <.001 | |
| Baseline PHQ-9 | -0.62 [-0.94, -0.30] | -0.30 | | <.001 | |
| Baseline GSE | -0.19 [-0.29, -0.09] | -0.29 | | <.001 | |

Notes. ITT = Intention to treat, PHQ-9 = Patient Health Questionnaire 9, GSE = Generalized Self-Efficacy Scale, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. All models were controlled for condition. P-values of regression coefficients were adjusted using Benjamini-Hochberg correction. P-values <.05 are printed in bold.

Modelling change in MADRS, baseline MADRS and housing were significant predictors both in the hierarchical and final multiple regression models (table 13). The final model step included baseline MADRS ($\beta = -0.71$, $t = -10.36$, $p < .001$) and housing ($\beta = -0.17$, $t = -2.51$, $p = .013$) and explained 47.0% of the outcome variation. The effect sizes were large for baseline MADRS ($f^2 = 0.85$) and small for housing ($f^2 = 0.03$). ANOVA indicated the significance of the final model step with $F_{(3,124)} = 36.632$, $p < .001$, and goodness-of-fit values indicated the superiority of the final model step (AIC=531.555, BIC=540.111).

Table 13

Multiple regression model of MADRS change in the pooled ITT sample

| | b [95% CI] | β | F | p | R ² |
|----------------------|----------------------|---------|--------|-----------------|----------------|
| <i>Step 1</i> | | | 49.699 | <.001 | 0.443 |
| (constant) | 10.49 [5.07, 15.91] | | | <.001 | |
| Baseline MADRS | -0.74 [-0.89, -0.59] | -0.66 | | <.001 | |
| <i>Step 2</i> | | | 36.632 | <.001 | 0.470 |
| (constant) | 17.39 [9.78, 24.99] | | | <.001 | |
| Baseline MADRS | -0.80 [-0.95, -0.65] | -0.71 | | <.001 | |
| Social status change | -3.63 [-6.49, -0.77] | -0.17 | | .013 | |

Notes. ITT = Intention to treat, PHQ-9 = Patient Health Questionnaire 9, GSE = Generalized Self-Efficacy Scale, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. All models were controlled for condition. P-values of regression coefficients were adjusted using Benjamini-Hochberg correction. P-values <.05 are printed in bold.

4.5 Per protocol predictor analysis (n=76)

4.5.1 Empowerment (n=30)

In the treatment condition of the PP sample, no significant predictors were found in the hierarchical regression model of change in PHQ-9 (table 14). ANOVA indicated that none of the three model steps was significant. Change in MADRS was significantly predicted by baseline MADRS (table 15). This was true for all model steps (step 1: $t = -2.68$, $p = .013$; step 2: $t = -2.09$, $p = .048$; step 3: $t = -2.24$, $p = .035$). Negative regression coefficients pointed towards a linear relationship between increasing baseline depression and decreasing MADRS change scores. Effect sizes were moderate in all steps ($f^2 = 0.17-0.28$). All other hypothesis-based variables did not show individual predictive value. ANOVA indicated the significance of the first model step ($F_{(1,26)} = 7.202$, $p = .013$), but not of the second and third step.

Table 14*Hierarchical regression model of PHQ-9 change in the treatment condition of the PP sample*

| | b [95% CI] | β | F | p | R ² |
|------------------|----------------------|---------|-------|------|----------------|
| <i>Step 1</i> | | | | | |
| (constant) | 6.13 [-7.15, 19.41] | | 1.865 | .183 | 0.065 |
| Baseline PHQ-9 | -0.52 [-1.29, 0.26] | -0.25 | | .183 | |
| <i>Step 2</i> | | | | | |
| (constant) | 4.30 [-10.67, 19.28] | | 0.664 | .623 | 0.100 |
| Baseline PHQ-9 | -0.43 [-1.28, 0.42] | -0.21 | | .308 | |
| Residence status | 2.18 [-12.48, 16.84] | 0.06 | | .761 | |
| Employment | -2.91 [-11.72, 5.90] | -0.14 | | .502 | |
| Housing | 1.22 [-4.20, 6.64] | 0.09 | | .646 | |
| <i>Step 3</i> | | | | | |
| (constant) | 4.69 [-11.49, 20.88] | | 0.515 | .762 | 0.101 |
| Baseline PHQ-9 | -0.47 [-1.49, 0.55] | -0.23 | | .352 | |
| Residence status | 2.37 [-12.84, 17.57] | 0.01 | | .750 | |
| Employment | -3.15 [-12.74, 6.43] | -0.15 | | .503 | |
| Housing | 1.37 [-4.51, 7.24] | 0.11 | | .635 | |
| PTSD | 0.56 [-6.99, 8.11] | 0.04 | | .879 | |

Notes. PP = Per protocol, PHQ-9 = Patient Health Questionnaire 9, PTSD = Post-traumatic stress disorder, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values <.05 are printed in bold.

Table 15*Hierarchical regression model of MADRS change in the treatment condition of the PP sample*

| | b [95% CI] | β | F | p | R ² |
|------------------|-----------------------|---------|-------|-------------|----------------|
| <i>Step 1</i> | | | | | |
| (constant) | 6.85 [-4.77, 18.47] | | 7.202 | .013 | 0.217 |
| Baseline MADRS | -0.59 [-1.03, -0.14] | -0.47 | | .013 | |
| <i>Step 2</i> | | | | | |
| (constant) | 6.64 [-9.41, 22.69] | | 1.912 | .142 | 0.250 |
| Baseline MADRS | -0.54 [-1.08, -0.01] | -0.43 | | .048 | |
| Residence status | -2.76 [-26.59, 21.07] | -0.05 | | .813 | |
| Employment | -6.57 [-20.35, 7.20] | -0.18 | | .334 | |
| Housing | -0.05 [-9.64, 9.53] | -0.00 | | .991 | |
| <i>Step 3</i> | | | | | |
| (constant) | 6.32 [-9.89, 22.53] | | 1.654 | .188 | 0.273 |
| Baseline MADRS | -0.62 [-1.20, -0.05] | -0.50 | | .035 | |
| Residence status | -1.01 [-25.42, 23.42] | -0.02 | | .933 | |
| Employment | -8.82 [-23.76, 6.13] | -0.24 | | .234 | |
| Housing | 0.99 [-9.01, 11.00] | 0.04 | | .839 | |
| PTSD | 4.48 [-6.50, 15.46] | 0.20 | | .406 | |

Notes. PP = Per protocol, MADRS = Montgomery Asberg Depression Rating Scale, PTSD = Post-traumatic stress disorder, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values <.05 are printed in bold.

Baseline MADRS explained 21.7% of the outcome variation. Inspection of AIC and BIC confirmed the superiority of the first model step, with AIC=132.496 and BIC=135.160.

Bivariate regression models revealed no significant predictors for change in PHQ-9 (table 16). Single room ($t_{(25)}=-1.99$, $p=.058$, $d=0.79$), concomitant psychotherapy ($t_{(27)}=1.92$, $p=.065$, $d=0.74$), baseline BRS ($t_{(26)}=-1.78$, $p=.086$, $f^2=0.12$), and baseline GSE ($t_{(26)}=-1.78$, $p=.087$, $f^2=0.12$) showed trend level effects. Change in MADRS was significantly predicted by concomitant psychotherapy ($t_{(26)}=2.81$, $p=.009$, $d=1.10$). Marital status ($t_{(26)}=1.89$, $p=.070$, $d=0.74$) and identification as a migrant ($t_{(26)}=1.73$, $p=.095$, $f^2=0.12$) showed trend level effects.

Table 16

Bivariate regression models in the treatment condition of the PP sample

| Predictors | PHQ-9 change | | | MADRS change | | |
|-------------------------------------|----------------------|---------|-------------|-----------------------|---------|-------------|
| | b [95% CI] | β | p | b [95% CI] | β | p |
| Age | -0.09 [-0.37, 0.20] | -0.12 | .542 | 0.05 [-0.45, 0.55] | 0.04 | .834 |
| Gender | 0.38 [-4.77, 5.52] | 0.03 | .882 | 5.04 [-3.79, 13.87] | 0.22 | .251 |
| Marital status | 1.79 [-3.38, 6.97] | 0.14 | .483 | 7.98 [-0.69, 16.66] | 0.35 | .070 |
| Education | -0.41 [-1.02, 0.21] | -0.26 | .190 | -0.07 [-1.18, 1.04] | -0.03 | .902 |
| Social status change | -0.63 [-2.90, 1.63] | -0.11 | .570 | 0.53 [-3.63, 4.69] | 0.05 | .794 |
| Religious affiliation | 0.87 [-7.56, 9.31] | 0.04 | .834 | -3.43 [-17.97, 11.12] | -0.10 | .632 |
| Single room | -6.32 [-12.87, 0.23] | -0.37 | .058 | -0.62 [-11.47, 10.23] | -0.02 | .907 |
| Time in Germany | -0.71 [-1.68, 0.27] | -0.28 | .148 | -0.61 [-2.36, 1.14] | -0.14 | .477 |
| Identification migrant | 0.45 [-1.90, 2.80] | 0.08 | .699 | 3.27 [-0.61, 7.15] | 0.32 | .095 |
| Concomitant medication | 1.07 [-4.06, 6.19] | 0.08 | .673 | 0.21 [-8.82, 9.25] | 0.01 | .962 |
| Concomitant psychotherapy | 5.98 [-0.40, 12.37] | 0.35 | .065 | 14.11 [3.78, 24.45] | 0.48 | .009 |
| Number of diagnoses | 0.34 [-2.24, 2.92] | 0.05 | .791 | -2.58 [-7.21, 2.05] | -0.22 | .262 |
| Anxiety disorder | 0.37 [-4.85, 5.59] | 0.03 | .885 | -2.52 [-11.60, 6.55] | -0.11 | .573 |
| Substance use disorder ^a | N/A | N/A | N/A | N/A | N/A | N/A |
| War | -2.66 [-8.32, 2.99] | -0.18 | .343 | -1.43 [-11.41, 8.56] | -0.06 | .772 |
| Persecution | -3.55 [-9.13, 2.03] | -0.24 | .202 | -5.05 [-14.84, 4.74] | -0.20 | .299 |
| Number of trauma events | -0.14 [-0.54, 0.27] | -0.13 | .499 | -0.47 [-1.18, 0.24] | -0.26 | .186 |
| Trauma symptoms | 1.51 [-2.78, 5.80] | 0.14 | .476 | 2.38 [-5.92, 10.67] | 0.12 | .561 |
| Baseline RHS-15 | 0.03 [-0.26, 0.32] | 0.04 | .834 | 0.15 [-0.35, 0.66] | 0.12 | .538 |
| Baseline BRS | -2.61 [-5.62, 0.40] | -0.33 | .086 | -1.53 [-8.31, 5.25] | -0.09 | .646 |
| Baseline GSE | -0.30 [-0.65, 0.05] | -0.33 | .087 | -0.52 [-1.19, 0.16] | -0.30 | .130 |
| Baseline SDQ | -0.10 [-0.54, 0.34] | -0.09 | .649 | -0.11 [-0.88, 0.67] | -0.06 | .783 |
| Baseline WHOQoL | -0.13 [-0.31, 0.07] | -0.26 | .187 | -0.03 [-0.41, 0.36] | -0.03 | .893 |

Notes. PP = Per protocol, PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, RHS-15 = Refugee Health Screener 15, BRS = Brief Resilience Scale, GSE = Generalized Self-Efficacy Scale, SDQ = Strengths and Difficulties Questionnaire, WHOQoL = World Health Organization Quality of Life, N/A = Not applicable, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value. P-values <.10 are printed in bold.

^a Models for substance use disorder could not be fitted due to missing correlations between predictor and outcomes.

The final multiple regression model to predict change in PHQ-9 was fitted with single room, concomitant psychotherapy, baseline BRS, and baseline GSE as potential predictors, using the stepwise entry method. All variables were excluded from the model due to probabilities of F-values ≥ 0.100 . Fitting the same model using the forced entry method confirmed this finding as none of the variables showed a significant predictive value. Predicting change in MADRS, a multiple regression model with the potential predictors of baseline MADRS, concomitant psychotherapy, marital status, and identification as a migrant was fitted (table 17). Concomitant psychotherapy entered the model in step 1 and identification as a migrant entered the model in step 2, while baseline MADRS and marital status were excluded from the model due to probabilities of F-values ≥ 0.100 . Concomitant psychotherapy was a significant predictor in step 1 ($t=2.81$, $p=.009$) and step 2 ($t=3.66$, $p=.001$). The effect sizes were moderate to large ($f^2=0.30-0.45$). Positive regression coefficients indicated a linear relationship between receiving concomitant psychotherapeutic treatment and increased MADRS change scores. Identification as a migrant was a significant predictor of outcome in step 2 ($t=2.80$, $p=.010$), showing a moderate effect size ($f^2=0.22$). The positive regression coefficient indicated a linear relationship between decreasing identification scores at baseline and increasing MADRS change scores. ANOVA indicated the significance of both model steps (step 1: $F_{(1,26)}=7.876$, $p=.009$; step 2: $F_{(2,25)}=8.894$, $p=.001$). Goodness-of-fit criteria were $AIC=131.933$ and $BIC=134.597$ in step 1 and $AIC=126.294$ and $BIC=130.291$ in step 2, pointing towards the superiority of the second model which explained 41.6% of the outcome variation.

Table 17

Multiple regression model of MADRS change in the treatment condition of the PP sample

| | b [95% CI] | β | F | p | R ² |
|---------------------------|-------------------------|---------|-------|-----------------|----------------|
| <i>Step 1</i> | | | 7.876 | .009 | 0.232 |
| (constant) | -9.91 [-14.28, -5.55] | | | <.001 | |
| Concomitant psychotherapy | 14.11 [3.78, 24.45] | 0.48 | | .009 | |
| <i>Step 2</i> | | | 8.894 | .001 | 0.416 |
| (constant) | -17.83 [-24.83, -10.82] | | | <.001 | |
| Concomitant psychotherapy | 16.70 [7.29, 26.11] | 0.57 | | .001 | |
| Identification migrant | 4.44 [1.17, 7.71] | 0.44 | | .010 | |

Notes. PP = Per protocol, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values of regression coefficients were adjusted using Benjamini-Hochberg correction. P-values <.05 are printed in bold.

4.5.2 Treatment-as-usual (n=46)

In the control condition of the PP sample, none of the hypothesis-guided variables predicted change in PHQ-9 (table 18). All model steps remained non-significant in ANOVA. Modelling change in MADRS (table 19), all steps of the hierarchical regression model were found to be significant, with $F_{(1,41)}=11.602$, $p=.001$, $F_{(4,38)}=4.474$, $p=.005$, and $F_{(5,37)}=3.729$, $p=.008$. Baseline MADRS was a significant predictor in model step 1 ($t=-3.41$, $p=.001$), step 2 ($t=-3.97$, $p<.001$), and step 3 ($t=-3.06$, $p=.004$). The effect sizes were moderate to large ($f^2=0.20-0.39$). Housing showed significant predictive value in model step 2 ($t=-2.34$, $p=.024$) and step 3 ($t=-2.16$, $p=.038$) with small effect sizes ($f^2=0.09-0.11$). Including post-migration context factors increased R^2 by 0.100 and including comorbid PTSD increased R^2 by 0.015, which was non-significant in both cases ($p=.154$ and $p=.368$). Compared with step 2 and step 3, the first model step showed superior goodness-of-fit criteria, with $AIC=194.951$ and $BIC=198.473$.

Table 18

Hierarchical regression model of PHQ-9 change in the control condition of the PP sample

| | b [95% CI] | β | F | p | R ² |
|------------------|----------------------|---------|-------|------|----------------|
| <i>Step 1</i> | | | 0.098 | .756 | 0.002 |
| (constant) | 3.94 [-14.81, 22.70] | | | .673 | |
| Baseline PHQ-9 | -0.17 [-1.28, 0.94] | -0.05 | | .756 | |
| <i>Step 2</i> | | | 0.142 | .965 | 0.015 |
| (constant) | 3.70 [-16.07, 23.48] | | | .707 | |
| Baseline PHQ-9 | -0.17 [-1.33, 0.99] | -0.05 | | .766 | |
| Residence status | -1.08 [-6.50, 4.34] | -0.07 | | .689 | |
| Employment | 0.80 [-3.05, 4.64] | 0.07 | | .677 | |
| Housing | 0.40 [-2.78, 3.59] | 0.04 | | .800 | |
| <i>Step 3</i> | | | 0.233 | .945 | 0.031 |
| (constant) | 3.81 [-16.09, 23.72] | | | .700 | |
| Baseline PHQ-9 | -0.21 [-1.38, 0.96] | -0.06 | | .720 | |
| Residence status | -0.54 [-6.17, 5.10] | -0.03 | | .848 | |
| Employment | 0.78 [-3.09, 4.64] | 0.07 | | .686 | |
| Housing | 0.36 [-2.85, 3.57] | 0.04 | | .821 | |
| PTSD | 1.26 [-2.03, 4.54] | 0.13 | | .442 | |

Notes. PP = Per protocol, PHQ-9 = Patient Health Questionnaire 9, PTSD = Post-traumatic stress disorder, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values <.05 are printed in bold.

Table 19

Hierarchical regression model of MADRS change in the control condition of the PP sample

| | b [95% CI] | β | F | p | R ² |
|------------------|-----------------------|---------|--------|-----------------|----------------|
| <i>Step 1</i> | | | | | |
| (constant) | 11.63 [3.18, 20.07] | | 11.602 | .001 | 0.221 |
| Baseline MADRS | -0.51 [-0.82, -0.21] | -0.47 | | .001 | |
| <i>Step 2</i> | | | | | |
| (constant) | 16.77 [6.87, 26.67] | | 4.474 | .005 | 0.320 |
| Baseline MADRS | -0.62 [-0.94, -0.30] | -0.57 | | <.001 | |
| Residence status | 2.92 [-7.27, 13.12] | 0.08 | | .565 | |
| Employment | 1.96 [-5.44, 9.36] | 0.07 | | .594 | |
| Housing | -7.16 [-13.36, -0.97] | -0.34 | | .024 | |
| <i>Step 3</i> | | | | | |
| (constant) | 15.94 [5.84, 26.04] | | 3.729 | .008 | 0.335 |
| Baseline MADRS | -0.54 [-0.90, -0.18] | -0.50 | | .004 | |
| Residence status | 1.85 [-8.65, 12.35] | 0.05 | | .723 | |
| Employment | 2.04 [-5.38, 9.47] | 0.08 | | .581 | |
| Housing | -6.70 [-13.00, -0.41] | -0.32 | | .038 | |
| PTSD | -3.05 [-9.83, 3.73] | -0.14 | | .368 | |

Notes. PP = Per protocol, MADRS = Montgomery Asberg Depression Rating Scale, PTSD = Post-traumatic stress disorder, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values <.05 are printed in bold.

Explorative bivariate regression models are displayed in table 20. Substance use disorder ($t_{(40)}=-2.30$, $p=.027$, $d=0.73$) and baseline GSE ($t_{(38)}=-2.88$, $p=.007$, $f^2=0.22$) were significant predictors of change in PHQ-9, while religious affiliation ($t_{(41)}=1.93$, $p=.061$, $f^2=0.09$) showed a trend level effect. Change in MADRS was significantly predicted by social status change ($t_{(40)}=4.12$, $p<.001$, $f^2=0.42$) and number of diagnoses ($t_{(41)}=-3.19$, $p=.003$, $f^2=0.25$). Anxiety disorder ($t_{(41)}=-1.79$, $p=.081$, $d=0.56$) showed a trend level effect.

Table 20*Bivariate regression models in the control condition of the PP sample*

| Predictors | PHQ-9 change | | | MADRS change | | |
|---------------------------|-----------------------|---------|-------------|----------------------|---------|-----------------|
| | b [95% CI] | β | p | b [95% CI] | β | p |
| Age | -0.04 [-0.17, 0.10] | -0.09 | .583 | -0.09 [-0.39, 0.22] | -0.09 | .564 |
| Gender | 1.53 [-1.61, 4.67] | 0.15 | .331 | -3.13 [-10.40, 4.14] | -0.14 | .390 |
| Marital status | -1.34 [-4.29, 1.61] | -0.14 | .365 | -1.11 [-8.01, 5.79] | -0.05 | .747 |
| Education | -0.23 [-0.54, 0.08] | -0.23 | .136 | -0.41 [-1.09, 0.27] | -0.19 | .233 |
| Social status change | 0.62 [-0.95, 2.19] | 0.13 | .427 | 5.76 [2.94, 8.58] | 0.55 | <.001 |
| Religious affiliation | 3.61 [-0.18, 7.39] | 0.29 | .061 | 3.08 [-5.32, 11.48] | 0.12 | .463 |
| Single room | -0.60 [-2.84, 4.05] | 0.06 | .725 | -2.15 [-9.65, 5.35] | -0.09 | .566 |
| Time in Germany | 0.12 [-1.30, 1.55] | 0.03 | .864 | -1.36 [-4.26, 1.54] | -0.15 | .348 |
| Identification migrant | 0.14 [-1.20, 1.47] | 0.03 | .835 | -1.10 [-4.01, 1.81] | -0.12 | .449 |
| Concomitant medication | -1.53 [-4.41, 1.35] | -0.17 | .290 | -4.50 [-10.93, 1.93] | -0.22 | .165 |
| Concomitant psychotherapy | -2.22 [-5.91, 1.47] | -0.19 | .231 | 2.94 [-5.93, 11.80] | 0.10 | .507 |
| Number of diagnoses | -0.42 [-1.61, 0.77] | -0.11 | .477 | -3.85 [-6.28, -1.41] | -0.45 | .003 |
| Anxiety disorder | -1.25 [-4.21, 1.71] | -0.13 | .398 | -5.70 [-12.12, 0.73] | -0.27 | .081 |
| Substance use disorder | -7.40 [-13.92, -0.89] | -0.34 | .027 | 2.35 [-13.25, 17.96] | 0.05 | .762 |
| War | 0.97 [-2.08, 4.01] | 0.10 | .525 | -0.79 [-7.59, 6.02] | -0.04 | .816 |
| Persecution | 0.70 [-2.27, 3.68] | 0.07 | .635 | -4.19 [-10.87, 2.49] | -0.19 | .212 |
| Number of trauma events | 0.00 [-0.25, 0.25] | 0.00 | .984 | 0.07 [-0.50, 0.64] | 0.04 | .806 |
| Trauma symptoms | -0.62 [-3.53, 2.30] | -0.07 | .671 | -3.09 [-9.86, 3.67] | -0.15 | .361 |
| Baseline RHS-15 | 0.03 [-0.17, 0.24] | 0.05 | .754 | -0.11 [-0.57, 0.34] | -0.08 | .622 |
| Baseline BRS | -0.29 [-3.09, 2.52] | -0.03 | .837 | 0.29 [-6.26, 6.83] | 0.01 | .930 |
| Baseline GSE | -0.32 [-0.55, -0.10] | -0.42 | .007 | 0.10 [-0.40, 0.60] | 0.07 | .690 |
| Baseline SDQ | 0.10 [-0.12, 0.32] | 0.15 | .374 | -0.24 [-0.71, 0.23] | -0.17 | .309 |
| Baseline WHOQoL | -0.03 [-0.15, 0.09] | -0.08 | .637 | 0.09 [-0.19, 0.36] | 0.10 | .529 |

Notes. PP = Per protocol, PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, RHS-15 = Refugee Health Screener 15, BRS = Brief Resilience Scale, GSE = Generalized Self-Efficacy Scale, SDQ = Strengths and Difficulties Questionnaire, WHOQoL = World Health Organization Quality of Life, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value. P-values <.10 are printed in bold.

The final multiple regression model of change in PHQ-9 was fitted considering baseline GSE, substance use disorder, and religious affiliation as potential predictors (table 21). Baseline GSE entered the model while substance use disorder and religious affiliation were excluded from the model due to probabilities of F-values ≥ 0.100 . Baseline GSE was a significant predictor ($t=-2.89$, $p=.006$) with a moderate effect size ($f^2=0.23$) and explained 18.4% of the outcome variation. ANOVA confirmed the significance of the model ($F_{(1,37)}=8.351$, $p=.006$). The final multiple regression model of change in MADRS was built with five potential predictors which were baseline MADRS, housing, social status change, number of diagnoses,

and anxiety disorder (table 22). Social status change entered the model in step 1 and baseline MADRS entered the model in step 2 while housing, number of diagnoses, and anxiety disorder were excluded due to probabilities of F-values ≥ 0.100 . Both model steps were significant (step 1: $F_{(1,40)}=16.991$, $p<.001$; step 2: $F_{(2,39)}=13.281$, $p<.001$). In model step 2, social status change ($t=3.69$, $p=.001$) and baseline MADRS ($t=-2.65$, $p=.012$) were significant predictors of outcome and explained 40.5% of the outcome variation. The effect sizes were moderate for social status change ($f^2=0.26$) and small for baseline MADRS ($f^2=0.12$). Smaller goodness-of-fit criteria (AIC=180.861, BIC=186.074) pointed towards the superiority of model step 2 compared to step 1 (AIC=185.809, BIC=189.284).

Table 21

Multiple regression model of PHQ-9 change in the control condition of the PP sample

| | b [95% CI] | β | F | p | R ² |
|---------------|----------------------|---------|-------|-------------|----------------|
| <i>Step 1</i> | | | 8.351 | .006 | 0.184 |
| (constant) | 8.62 [2.96, 14.28] | | | .004 | |
| Baseline GSE | -0.32 [-0.55, -0.10] | -0.43 | | .006 | |

Notes. PP = Per protocol, PHQ-9 = Patient Health Questionnaire 9, GSE = Generalized Self-Efficacy Scale, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values of regression coefficients were adjusted using Benjamini-Hochberg correction. P-values <.05 are printed in bold.

Table 22

Multiple regression model of MADRS change in the control condition of the PP sample

| | b [95% CI] | β | F | p | R ² |
|----------------------|----------------------|---------|--------|-----------------|----------------|
| <i>Step 1</i> | | | 16.991 | <.001 | 0.298 |
| (constant) | 4.15 [0.04, 8.26] | | | .048 | |
| Social status change | 5.76 [2.94, 8.58] | 0.55 | | <.001 | |
| <i>Step 2</i> | | | 13.281 | <.001 | 0.405 |
| (constant) | 13.35 [5.34, 21.36] | | | .002 | |
| Social status change | 4.94 [2.24, 7.65] | 0.47 | | .001 | |
| Baseline MADRS | -0.38 [-0.67, -0.09] | -0.34 | | .012 | |

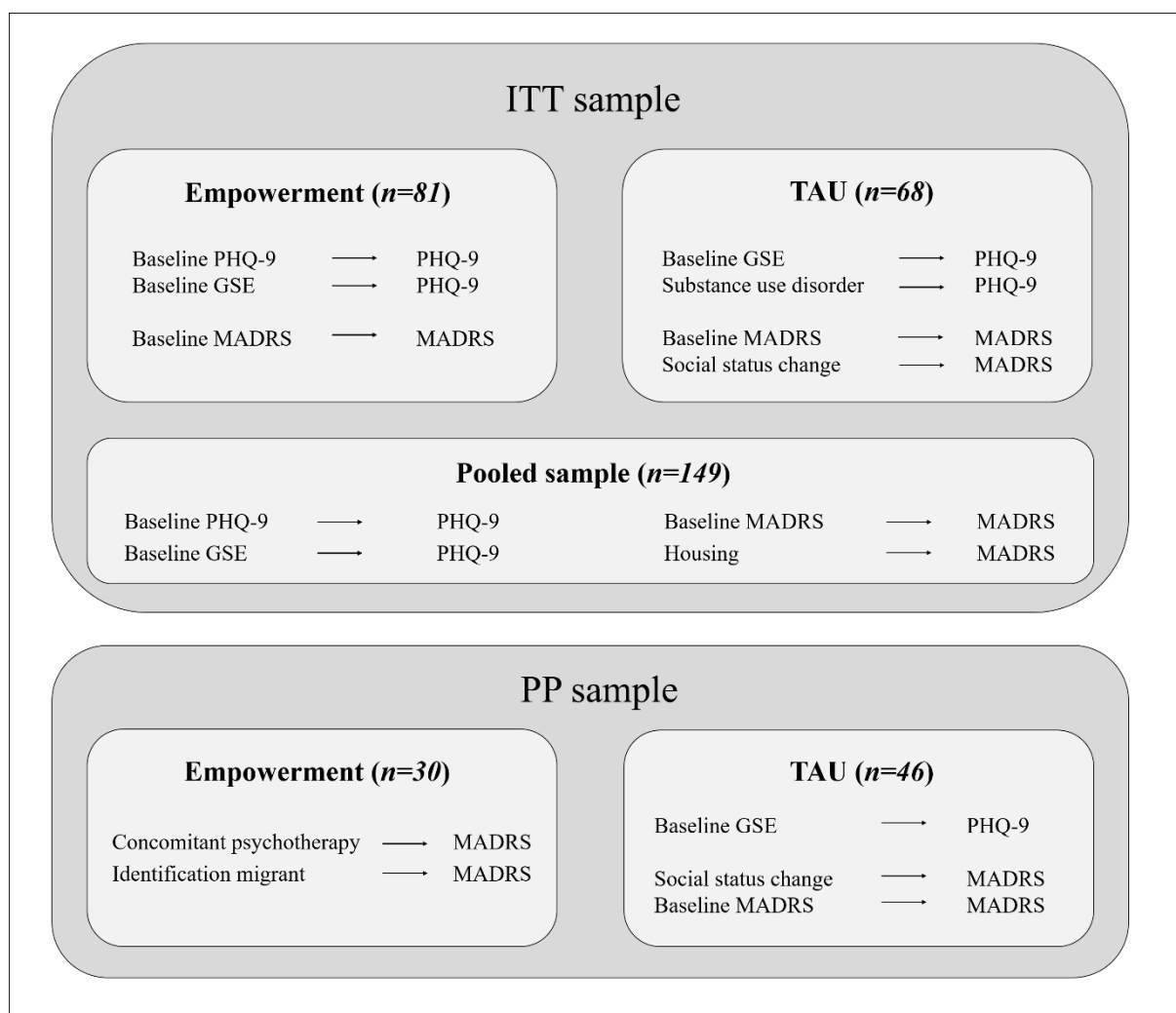
Notes. PP = Per protocol, MADRS = Montgomery Asberg Depression Rating Scale, b = Unstandardized regression coefficient, β = Standardized regression coefficient, CI = Confidence interval, p = P-value, F = F statistic, R² = Determination coefficient. P-values of regression coefficients were adjusted using Benjamini-Hochberg correction. P-values <.05 are printed in bold.

4.6 Final overview of significant predictors

To provide a concise overview of the comprehensive statistical analyses and respective results, the significant predictors of change in the primary (PHQ-9) and secondary outcome (MADRS) are shown in figure 12. The overview includes results of all samples (ITT, PP) and conditions (Empowerment, TAU) in the final regression models (i.e., combination of hypothesis-guided and explorative models).

Figure 12

Overview of significant predictors in all final regression models



Notes. ITT = Intention to treat, PP = Per protocol, TAU = Treatment as usual, PHQ-9 = Patient Health Questionnaire 9, MADRS = Montgomery Asberg Depression Rating Scale, GSE = Generalized Self-Efficacy Scale. Arrows show the direction of prediction.

5 Discussion

5.1 Summary

The aim of this dissertation was the identification of outcome predictors of the novel culturally sensitive *Empowerment* group intervention for refugees and asylum seekers with affective disorders. The impact of multiple baseline variables on change scores of a primary self-rated depression outcome (PHQ-9) and a secondary clinician-rated depression outcome (MADRS) was examined. Data came from the multicenter randomized controlled trial MEHIRA, investigating the effectiveness of a four-level SCCM compared to routine care practice (TAU).

The hypotheses of this dissertation were that (a) baseline depression is associated with depressive symptom change from baseline to post-intervention in the treatment condition, (b) holding an insecure residence status is negatively associated with symptom improvement from baseline to post-intervention in the treatment condition, (c) current unemployment is negatively associated with symptom improvement from baseline to post-intervention in the treatment condition, (d) living in a refugee accommodation is negatively associated with symptom improvement from baseline to post-intervention in the treatment condition, and (e) a comorbid PTSD diagnosis is negatively associated with symptom improvement from baseline to post-intervention in the treatment condition.

The analyses revealed that in the treatment condition of the ITT sample, baseline depression had a significant impact on both change in the primary (PHQ-9) and the secondary outcome (MADRS). Participants who showed higher symptoms at baseline benefited more from treatment than those with less symptoms. Baseline self-efficacy (GSE) significantly predicted PHQ-9 change scores. The higher participants rated their self-efficacy at baseline, the more they benefited from the treatment. No significant associations were found between the outcomes and post-migration context factors as well as all indicators of trauma and comorbidity.

In the control condition of the ITT sample, hypothesis-guided variables did not predict change in the primary outcome (PHQ-9). Explorative and final models revealed that baseline self-efficacy (GSE) and the presence of a substance use disorder predicted the outcome. Change in the secondary outcome (MADRS) was predicted by baseline depression and housing in the hypothesis-guided models. Participants with higher depressive symptoms at baseline and those who lived in housing conditions other than a refugee accommodation profited more from treatment than participants with less symptoms and those who lived in refugee

accommodations. Final integrated analyses excluded housing, and pointed towards a significant impact of socio-economic status. The more social decline participants had experienced, the less they benefited from treatment in the control condition.

In the pooled ITT sample, baseline depression was a significant predictor of both change in PHQ-9 and MADRS, with higher baseline scores predicting more symptom improvement. In addition, baseline self-efficacy (GSE) was found to predict change in PHQ-9, and housing was found to predict change in MADRS. Participants with higher perceived self-efficacy (GSE) at baseline, and those who lived in housing conditions other than a refugee accommodation, benefited more from treatment than others.

In the treatment condition of the PP sample, no variables predicted change in the primary outcome (PHQ-9). MADRS change scores were predicted by baseline depression. The regression coefficient was negative, indicating that more depressed participants benefited more from treatment. Explorative and final models pointed towards a significant impact of the variables concomitant psychotherapy and identification as a migrant. If participants received concomitant psychotherapeutic treatment, they benefited less from the intervention than those who did not. The less participants identified as a migrant, the less they benefited from treatment.

In the control condition of the PP sample, no hypothesis-guided variables showed significant impact on change of PHQ-9. Baseline self-efficacy (GSE) was the single variable to predict change in the primary outcome (PHQ-9). MADRS change scores were predicted by baseline depression and housing. Using the stepwise entry method, the final model included change of social status and baseline depression as significant predictors. Participants who experienced social decline benefited less from treatment, and participants with higher depressive symptoms at baseline benefited more from treatment.

Regarding the a-priori hypotheses of this dissertation, the first hypothesis was confirmed. Baseline depression was a significant predictor of the primary outcome (PHQ-9) in the ITT sample and of the secondary outcome (MADRS) in the ITT and PP samples. Higher baseline scores of depression were associated with decreased change scores in both outcomes. All other a-priori hypotheses were not confirmed. No significant impact of post-migration context factors (residence status, employment, housing) and comorbidity (PTSD) was found in the treatment condition.

5.2 Interpretation of results and comparison with previous studies

Baseline depression was a significant predictor of change in the ITT (PHQ-9, MADRS) and PP sample (MADRS) in the treatment condition. This was the most consistent finding of this dissertation and confirmed the first a-priori hypothesis. The linear relationship between baseline depression and change scores was negative, indicating that participants with more depressive symptoms at baseline had better symptom trajectories than those with less depressive symptoms. The effect sizes in the ITT sample were small ($f^2=0.12$ to 0.15) for predicting change in PHQ-9 and large ($f^2=0.84$ to 1.00) for predicting change in MADRS. This effect has also been found in previous predictor studies (Drozdek et al., 2013; Pfeiffer et al., 2019; Sonne et al., 2021) and a meta-analysis investigating low-intensity interventions in a general population of 2470 depressed patients (Bower et al., 2013). Most studies did not report effect sizes for single predictors, or the reported measures were not comparable to those of the present work. Two possible explanations for this finding are conceivable which are in line with the arguments of Pfeiffer et al. (2019) and Sonne et al. (2021). First, the symptom trajectories of *Empowerment* participants may to some extent display regression to the mean. Regression to the mean refers to the statistical effect that high baseline scores can lead to lower post-intervention scores as participants approximate the average of symptom scores over time, dragging symptom trajectories to the middle. Second, participants with high baseline depression may have had more room for improvement than the less depressed. The intervention showed overall effectiveness in reducing depressive symptoms (Wiechers, unpublished doctoral dissertation), for instance from an average MADRS score of 23.3 at baseline to 16.1 at post-intervention in the treatment condition of the ITT sample. However, the range of MADRS scores at baseline for all participants was 3 to 45. Therefore, highly depressed participants may have had larger individual slopes (i.e., negative regression coefficients) than participants with mild or minimal depressive symptoms at baseline, leading to a significant statistical effect of baseline depression on treatment outcomes.

Baseline self-efficacy (GSE) was a significant predictor of change in the primary outcome (PHQ-9) in the treatment condition of the ITT sample. Participants with higher self-efficacy scores at baseline had better symptom trajectories than those with lower self-efficacy scores. The effect size for predicting change in PHQ-9 was small ($f^2=0.06$). Self-efficacy (GSE) and depression (PHQ-9) were not correlated significantly at baseline ($r=-.05$). At this point in time, no predictor study was found that has yet investigated or found this relationship, making this

result the first of its kind. Accordingly, the effect sizes could not be compared. However, perceived self-efficacy has been found as a general factor underlying psychological well-being and mental health, and was negatively correlated with psychological distress, depression, and anxiety (Luszczynska et al., 2005; Sulaiman-Hill & Thompson, 2013). Interventions that enhance self-efficacy among refugees and asylum seekers have been found to contribute significantly to the reduction of trauma-related symptoms (Morina et al., 2018) and general psychopathology (van Heemstra et al., 2019). To provide a possible explanation in the context of this dissertation, the concept of Cheavens et al. (2012) who illustrated two different models of depression treatment, is proposed. The capitalization approach is guided towards promoting resilience and developing the individual strengths of depressive patients, whereas the compensation approach aims at the reduction of the patients' individual deficits. When comparing both models, the superiority of the capitalization model has been shown in reducing depressive symptoms. As the *Empowerment* group intervention is specifically tailored to equip participants with self-help skills and coping strategies, participants with high baseline self-efficacy may have profited especially as available individual resources may have been activated and strengthened through the treatment (IASC, 2007). Positive symptom trajectories of those participants may have been amplified in response to the capitalization mechanism of the *Empowerment* intervention.

In the treatment condition of the PP sample, concomitant psychotherapy and the measure of identification as a migrant predicted change in the secondary outcome (MADRS). Participants who received an additional psychotherapeutic treatment benefited less from the treatment than those who did not, with a large effect size of $f^2=0.45$. The less participants identified themselves as migrants, the less they profited from the treatment, which had a medium effect ($f^2=0.22$). Together, the predictors explained 41.6% of variation in the outcome. No comparable findings were reported in other predictor studies. Both substantive and methodological explanations are conceivable for these results. As comorbidity between depression and PTSD is frequent among refugees and asylum seekers (Nickerson et al., 2017), concomitant psychotherapeutic treatment may have been of high intensity, such as trauma-focused treatment, and may have involved the activation of trauma-related memories and emotions. In the present sample, participants who received concomitant psychotherapy experienced 11.4 traumatic events on average, and had a mean HTQ score of 3.0 (values > 2.5 are considered symptomatic for PTSD). As psychotherapy, and trauma-focused treatment in particular, bears the risk of an initial symptom exacerbation (Larsen et al., 2016), the additional

treatment may have negatively affected symptom trajectories of participants in the *Empowerment* intervention. Considering the identification measure, the prediction effect may be explained by the fact that the *Empowerment* intervention manual was specifically designed to suit the needs of flight-affected participants. Each one of the 16 modules was designed in a culturally sensitive way, covering specific migration-related topics such as homesickness and coping with specific stressors of the post-migration environment. It seems plausible that participants benefit more from this kind of treatment the more they identify themselves as migrants, whereas treatment may be inappropriate for participants who do not feel that they belong to this group. Thus, future investigations may consider screening participants for eligibility by including an initial identification item to check whether culturally sensitive treatment is indicated. However, these content-related interpretations need to be considered with caution as the results may also represent statistical artefacts. Predictor data was imbalanced (5 participants had concomitant psychotherapy vs. 25 who did not) and left-skewed (identification measure, mean=1.6, range=1-5), and the PP sample size in the treatment condition was relatively small (n=30). Therefore, effects may be artificial and not persistent in larger samples, which is supported by the fact that these predictors were no longer found in the treatment condition of the ITT sample (n=81).

Baseline depression (PHQ-9, MADRS) and self-efficacy (GSE) did not predict outcomes in the treatment condition exclusively but were also significant predictors in the control condition and in the pooled sample of both conditions. Analyses of the pooled ITT sample (n=149) revealed that baseline depression was associated with change in both outcomes. Additionally, baseline self-efficacy predicted change in the primary outcome, and housing predicted change in the secondary outcome. Therefore, the baseline levels of depressive symptoms and perceived self-efficacy, and the quality of housing conditions, may rather represent general factors of relevance in post-migration mental health care provision to refugees and asylum seekers than specific predictors of the *Empowerment* intervention. This may be explained by the fact that TAU already represents a well-developed and evidence-based treatment structure in the German health care system. 18 months after arrival in Germany, refugees are legally entitled (§4 AsylbLG) to receive the same regular health care as the host population, including e.g., mental health professionals in outpatient departments of hospitals (Führer et al., 2021). As no information was collected on the frequency and kind of health care utilization in the control condition, this hypothesis could not be evaluated reliably and might be subject to future investigations.

Contrary to the hypotheses of this work, post-migration context factors (residence status, employment status, housing) did not show predictive effects on outcomes of the *Empowerment* intervention. This was counterintuitive both from a scientific and clinical viewpoint. Previous predictor studies have documented the moderating impact of residence status (Drozdek et al., 2013; Raghavan et al., 2013; Stenmark et al., 2013), employment (Buhmann et al., 2015; Sonne et al., 2016; Sonne et al., 2021), and housing (Whitsett & Sherman, 2017) on outcomes of culturally sensitive mental health care. Concordantly, the negative relationship between post-migration environment stressors and refugee mental health in general has been emphasized repeatedly (Hynie, 2018; Mawani, 2014), as outlined in the theoretical background of this dissertation. Moreover, many *Empowerment* therapists shared the clinical impression that factors of the participants' post-migration reality had a relevant impact. Dealing with the asylum procedure, missing permission and opportunity to work, and the fear of deportation were frequently discussed issues throughout the intervention period. It was all the more surprising that the predictors did not show significant effects in the treatment condition. A possible explanation for the findings on post-migration factors might be of statistical nature and is discussed under limitations.

Similarly, no significant effects were found for all indicators of trauma and comorbidity. Even though many treatment participants in the ITT sample were diagnosed with a comorbid PTSD (41.8%) or anxiety disorder (36.7%) and reported the exposure to an average of 10.1 traumatic events in the past, these indicators did not predict change in the outcomes. This was in line with findings from recent investigations such as those of Pfeiffer et al. (2019) and Whitsett and Sherman (2017) who reported that trauma load was unrelated to multiple post-treatment indicators, including depression, anxiety, and trauma-related symptoms. A potential explanation might be that the traumatic events in the present sample of refugees and asylum seekers occurred years ago. At baseline, *Empowerment* participants lived, on average, for 3.0 years in Germany. Therefore, trauma load may have played an important role in the etiopathogenesis of psychopathological symptoms, however other ongoing stressors of the post-migration context might be more relevant for the current mental health status of refugees and asylum seekers. A recent study by Hou et al. (2020) concluded that the associations between pre-migration trauma and post-migration mental disorders were fully mediated by daily stressors in the post-migration environment, such as social exclusion and racism (Schouler-Ocak et al., 2021). Therefore, trauma indicators may be of primary interest in trauma-focused

psychotherapy but not undermine the effectiveness of the *Empowerment* intervention for refugees and asylum seekers with affective disorders.

5.3 Strengths and limitations

In light of the urgent need for psychological interventions targeting refugee mental health, this dissertation is of high relevance and interest as it provides a comprehensive investigation of predictors of psychological treatment for refugees. In comparison to previous studies in the field, this dissertation has some major methodological strengths. First, data from a high-quality prospective RCT was used to examine a large and representative sample at four different time points. This is a considerable improvement over previous predictor studies with rather small sample sizes and no control condition (e.g., Haagen et al., 2017; Pfeiffer et al., 2019). Multicenter cooperation allowed for a nation-wide data collection at seven different university hospitals with unique characteristics. The trial was pre-registered and followed all principles of Good Clinical Practice (GCP). High adherence to the *Empowerment* manual was ensured through one-day training sessions for therapists prior to the beginning of the study and through regular supervision in person or via phone during the intervention phase. Second, confirmative (top down) and explorative (bottom up) analytical strategies were combined to examine a wide range of putative outcome predictors and not to oversee small statistical effects. Consequently, this investigation represents one of the most comprehensive ones in this research area. The analyses provide insight into various possible moderator effects on the effectiveness of an evidence-based culturally sensitive intervention on depression outcomes. Reliable and validated clinical scales were used that have been applied in various cultural settings. Both a self-rated (PHQ-9) and clinician-rated (MADRS) outcome measure were included to ensure the robustness of the results and provide good comparability to measures of other studies. In particular, the use of the PHQ-9 has been recommended by the APA (2013) as a general assessment for depression severity and patient-reported outcome measure (PROM) to ensure patient-centered care (Weldring & Smith, 2013). Third, analyses were applied both to the ITT and PP sample. ITT analysis is generally recommended for clinical trials to preserve the initial experimental design and ensure unbiased comparisons between conditions (Lachin, 2000). Outcome values (PHQ-9, MADRS) were imputed to obtain a robust data scenario. In addition, the PP sample was analyzed with non-imputed data to ensure the sensitivity of the analyses. Thereby, the empirical data of those participants who completed the study without major

protocol deviations was reflected without dilution of the treatment effect. Thus, a broad base of information is provided which allows for a differentiated interpretation of the collected data. Fourth, the center of investigation was a specialized intervention that was tailored to reach flight-affected participants in post-migration settings. The treatment manual was designed to integrate both Western and Eastern cultural norms and values, explanations of health and disease, and ways of expressing and coping with symptoms. The treatment followed key criteria of culturally sensitive work, based on a consensus of numerous non-governmental organizations (NGOs), academic institutions, and humanitarian actors which were summarized by the IASC (2007). Thereby, this dissertation follows the call for more cultural competence in health care (Schouler-Ocak et al., 2015) and contributes to the dissemination of culturally sensitive treatment concepts into practice and research (Soto et al., 2018).

This dissertation should also be viewed considering its limitations. First, two important predictors (i.e., residence status, employment status) could only be evaluated to a limited extent due to an unbalanced data distribution. In the treatment condition of the ITT sample, only 4 participants (4.9%) had a permanent residence status, and 8 participants (10.3%) were employed. In the PP sample, this was true for 1 participant (3.3%) and 3 participants (10.0%), respectively. Despite the dichotomization of item responses (secure vs. insecure residence status, employed vs. unemployed), the cell numbers of participants holding a secure residence status and current employment status remained small. Therefore, the data structure may have failed to satisfy minimum distribution requirements, e.g., as proposed by Fournier et al. (2009), which may have led to invalid statistical analyses and non-discovery of actually existing predictor effects. Future research with more heterogeneous samples that allow for a valid predictor evaluation of these post-migration context factors is needed. Second, the operationalization of the post-migration factor residence status might have been insufficient. The available item responses were: (1) Permanent residence permit, (2) Temporary residence permit, (3) Permit for permanent residence in the EU, (4) No legal residence permit, and (5) Other. There was a risk of an inaccurate assignment of participants to these categories. For instance, the denotation ‘temporary residence permit’ may apply to legal entitlements of differing quality, including actual permits of varying duration (from weeks to years), tolerations, deportation bans, rejected asylum applications, or pending asylum decisions. However, previous research has emphasized the impact of the differential stages during the asylum procedure on levels of psychological distress among refugees and asylum seekers (Walther et al., 2020; Winkler et al., 2019). Therefore, a meticulous categorization and analysis

of this variable (e.g., by creating multiple separate dummy variables) seems of crucial importance and should be considered in future studies. Third, interaction terms (predictor x condition) were not tested in regression models. Also, higher-level effects of study center and therapists were not modelled (e.g., by using multilevel modelling). These restrictions were due to the comprehensive number of tests and predictors that were analyzed by implementing the mixed-method approach of this dissertation. It was intended to examine as many predictors as possible, using as few models as necessary and keeping the amount of type I errors to a minimum. As the primary focus of this dissertation was placed on the predictors of intervention outcome, it was decided to omit interaction models and to avoid excessive model testing. Fourth, the sample was restricted to patients with moderate depressive symptoms (PHQ-9: 15-19). The generalizability of the identified predictors in depression treatment should be considered with caution. Future research is needed to examine the prediction effects in a broader spectrum of symptom severity in refugee populations. Finally, the double-blinded setting could not be maintained in one study center (Munich) due to limited study staff. Clinicians were both raters and therapists. Therefore, clinician-rated data of participants of this study center (n=40) may be biased in favor of the treatment condition to some extent. In parts, this may reflect the discrepancy between large predictor effects on the secondary clinician-rated outcome (MADRS) and small predictor effects on the primary self-rated outcome (PHQ-9).

5.4 Implications and future research

This dissertation entails relevant practical implications for clinicians and researchers. The primary evaluation of the *Empowerment* intervention provided evidence for its clinical effectiveness as self- and clinician-rated depressive symptoms were significantly reduced at post-intervention compared to TAU (Wiechers, unpublished doctoral dissertation). Building on that, this work provides important information on varying individual treatment effects despite overall effectiveness, on a reasonable treatment allocation under real-life conditions, and recommendations for future research.

The *Empowerment* intervention seems to be more effective for patients who have an elevated level of depressive symptoms at baseline. Significant associations with baseline depression were found in both outcomes. Initially, the intervention was developed to treat refugees with moderate depressive symptoms and inclusion criteria of this work comprised a PHQ-9 sum score between 15 and 19 at baseline. As indicated by predictor analysis, however,

Empowerment may also be suitable for patients with higher levels of symptom severity, i.e., to treat severe depressive symptoms in refugees in the post-migration environment. This hypothesis requires consideration in future studies which should evaluate the intervention in samples without an upper limit for symptom severity. In case outcome studies with severely distressed patients also prove to be effective, *Empowerment* may be combined with psychopharmacological treatment and considered as a treatment of choice for severe depression, following German national guidelines for the treatment of unipolar depressive disorders (Hautzinger & Kühner, 2016) that recommend a combination of psychotherapy and psychopharmacotherapy for severe depressive disorders. Eventually, establishing *Empowerment* in routine mental health care structures may allow for care to be provided to a large number of patients with variable symptom severity in the group setting, and thereby save treatment capacities for those patients that showed little or no improvement or need other forms of treatment (e.g., individual trauma-focused treatment).

Moreover, it appears that the *Empowerment* intervention was effective irrespective of several post-migration context factors and clinical indicators. The presence of post-migration difficulties (e.g., unemployment) and factors of comorbidity (e.g., trauma symptoms) did not affect individual treatment trajectories significantly. Also, *Empowerment* was effective irrespective of the time interval since arrival in Germany, pointing towards the fact that the intervention may be suitable for patients at any stage of the post-migration experience (Kizilhan, 2018). Overall, the *Empowerment* intervention seems to be suitable for a broad and diverse population of refugees with different individual constellations of post-migration circumstances and psychopathology. There was no contraindication to provide *Empowerment* to patients with temporary residence permits, patients who lived in unstable residential settings, patients who were unemployed, patients who suffered from comorbid psychiatric disorders, and patients who experienced traumatic events in the past. The latter may be of particular relevance as PTSD was found to be highly prevalent in refugee populations (Henkelmann et al., 2020; Hoell et al., 2021), and dual diagnoses of PTSD and depressive disorders were frequent (Nickerson et al., 2017).

The findings of this dissertation require replication in future samples to ensure the validity of the results. In addition, future investigations may consider further measures of outcome, shifting from a mere depression-focused set of outcomes towards the inclusion of trauma-related indicators. Comparable interventions for affective disorders were found not only to reduce depressive symptoms but also symptoms of post-traumatic stress and anxiety (Bolton et

al., 2014). Suitable outcome measures might be the HTQ (Mollica et al., 1992) or the Posttraumatic Diagnostic Scale for DSM-5 (PDS-5; Foa et al., 2016), both representing validated scales that have successfully been applied in transcultural research. It is also important to consider more clinically relevant outcome measures than change scores of symptoms, such as rates of response, remission, non-response, partial response, and clinically significant change (Nierenberg & DeCecco, 2001). Using measures like the Reliable Change Index (RCI; Jacobson & Truax, 1991) allows for data interpretation beyond the magnitude of statistically significant effects, indicating which kind of symptom change is also clinically significant and meaningful for the patient. This kind of clinical outcome research might be specifically relevant in identifying clearly definable patient groups of responders and non-responders to the *Empowerment* intervention. In addition to clinical indicators, further patient-reported outcome measures (PROM) such as the level of functioning (e.g., assessed with the WHODAS 2.0; Üstün et al., 2010) and quality of life (e.g., assessed with the EQ-5D; Herdman et al., 2011) may be considered in future analyses as they place the patient in the center of evaluation and ensure the ecological validity of the investigations (Weldring & Smith, 2013).

Taken together, the results of this dissertation point towards a large-scale applicability of this culturally sensitive psychotherapeutic intervention. *Empowerment* represents a promising and clinically effective tool for German-speaking therapists that may serve as a valuable improvement of the inadequate health care delivery to refugees with mental illness in Germany. A comprehensive dissemination of the intervention into national care routines may support mental health professionals in reducing the existing treatment gap and overcoming access barriers to mental health services. The treatment is manualized and versatile as it can be applied both in group and individual settings (Wiechers et al., 2019), and may be used by a heterogeneous range of clinicians, including medical doctors, psychotherapists, trained social workers, and nursing staff. *Empowerment* incorporates recommendations of providing culturally competent care (Schouler-Ocak et al., 2015) and key principles of health aid in humanitarian emergency settings (IASC, 2007). Implementing *Empowerment* as a standard intervention in routine care practice may support the German health care system to take a step towards intercultural opening (Penka et al., 2012).

In the long run, the results of this dissertation may also be useful in the greater context of individualized mental health care (Hofmann & Hayes, 2019). In combination with findings from other comprehensive predictor studies (e.g., Sonne et al., 2021), it might be possible to delineate robust factors that identify certain patient groups as high-responders, low-responders

and non-responders. In turn, the data may support the development of precise decision tools that guide treatment allocations for these patient groups to achieve more successful treatment rates and individual treatment prognoses (Maj et al., 2020). Tools such as the Personalized Advantage Index (PAI; DeRubeis et al., 2014) have already been introduced, following a current trend in psychotherapy research towards personalized mental health care where treatment allocation is based on individual biopsychosocial variables rather than diagnoses (Cohen & DeRubeis, 2018; Delgadillo & Lutz, 2020). It is conceivable that such methods may also be applied in transcultural health care at some future point, including advanced analytical strategies such as machine learning (Dwyer et al., 2018) and big data analysis (Passos et al., 2019). However, a large amount of predictor studies and high-quality data will be needed before such analyses are possible. Until then, the priority of research and practice should be to ensure pragmatic care with effective culturally sensitive treatment options and cultural competence in the German health care system.

When looking towards future studies, it might be useful to consider further possible predictor variables. As described in the theoretical background of this dissertation, refugee mental health is at the center of a complex interplay of socio-cultural factors that shape the background against which either resilience or psychological distress may emerge (Beiser, 2009). In a recent publication, Schouler-Ocak et al. (2021) emphasized the impact of discrimination and racism on the poor mental health of ethnic minorities. Patients with refugee backgrounds may become a target of interpersonal, institutional, and structural racism, causing psychological stress responses and enhancing the risk to develop a manifest psychiatric disorder. Furthermore, indicators of social participation or exclusion, respectively, are likely to have a significant impact on refugee mental health. Recently, a cross-sectional panel data analysis revealed that refugees reported the highest levels of social isolation and loneliness compared to non-refugee migrants and German individuals without a migration background (Löbel et al., 2021). Strong associations between social isolation and mental illness have repeatedly been documented (Beutel et al., 2017; Holt-Lunstad, 2017). In contrast, good social participation seemed to operate as a protective factor for refugee mental health and a prerequisite to develop resilience and allow for integration (Niemi et al., 2019). Indicators of social participation stand in close relation to the concept of acculturation and the associated acculturation strategies as proposed by Berry (1997). It has been documented that the strategy of *integration* was associated with good mental health outcomes while the strategy of *marginalization* entailed high psychological distress and increased risk for developing

depression or anxiety (Choy et al., 2021). Overall, it might be of particular interest to include these further patient- and context-related socio-cultural variables as they might provide an in-depth understanding of how differential treatment responses arise and contribute to outcome variance clarification.

Finally, the range of patient- and context-related predictor variables might be extended to the inclusion of process- and therapist-related factors. Process-outcome research aims at delineating significant associations between change processes and therapeutic outcome (Crits-Christoph & Gibbons, 2021). Conducting a process evaluation could provide clinicians with valuable insights into the working mechanisms and causal connections between the therapeutic process and outcomes, thus allowing for a more profound understanding of the *Empowerment* intervention. For instance, the 11 therapeutic factors in group interaction, as proposed by Yalom (1995), may be examined and tested for predictive value on the treatment outcomes. Appropriate scales such as the Therapeutic Factors Inventory (TFI; Lese & MacNair-Semands, 2000) and the Therapeutic Group Interaction Factors Scale (TGIF; Hastings-Vertino et al., 1996) have already been developed to measure factors such as the group cohesiveness and altruism (Yalom, 1995). Furthermore, therapist-related factors may deliver valuable information to enhance successful treatment chances. For instance, it has been reported that the level of client-rated therapist cultural competence was strongly associated with the outcomes of transcultural treatment (Soto et al., 2018). Practical recommendations to the implementation of process evaluations can be found in the guidelines of the Medical Research Council for complex interventions (Moore et al., 2015).

5.5 Conclusion

This dissertation stands in the tradition of the search for factors that generate an effective psychotherapeutic treatment which has been initiated by Gordon Paul in 1967. The work was conducted in the contemporary framework of large migratory movements due to forced displacement that represent a major challenge for Western mental health care structures and require high-quality research in the field of culturally sensitive care for refugees and asylum seekers. Therefore, a comprehensive predictor analysis was applied to a sample of refugees and asylum seekers with moderate depressive symptoms that were treated within the multicenter randomized controlled trial MEHIRA. In conclusion, *Empowerment* appears to be an effective treatment option for a broad population of refugee patients. The pre-treatment level of

depression and self-efficacy stood out as the most promising aptitude-related patient characteristics to ensure successful participation rates in the *Empowerment* intervention. The results contribute to an advanced understanding of the applicability of *Empowerment* in real-world care structures and may support a widespread dissemination of the treatment in current mental health care routines. Future studies are needed to replicate the presented findings and extend the data on relevant predictor variables in the field of culturally sensitive mental health interventions for refugees and asylum seekers.

It can be assumed that predictor studies in this research field will continue to be of explicit relevance both in the near and distant future. The number of forcibly displaced individuals is expected to stay at a high level or even rise due to major global challenges such as climate change, economic crises, pandemics, and ongoing armed conflicts (Berwick & Shine, 2020; Pfefferbaum & North, 2020; UNHCR, 2021a). In this light, health care providers and researchers all over the globe will be required to steadily monitor rising psychosocial needs and flexibly adapt regional, national and international care structures to provide adequate psychosocial support for treatment populations coming from different parts of the world with different cultural imprints. To ensure health care preparedness for large, forced migration flows and ensure satisfying health care coverage for vulnerable patient populations like refugees and asylum seekers in the future, more research is needed to answer the ongoing question of interest: Which factors predict the outcomes of culturally sensitive mental health interventions, and how can we use this information to ensure the best possible mental health care provision in the context of forced migration?

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Appendix A

Ethical vote of the ethics committee of the Ludwig-Maximilians-University Munich

Figure A1

Positive vote on ethics by the ethics committee in Munich



Ethikkommission · Pettenkoferstr. 8 · 80336 München

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31.01.2018 Hb/ck

Projekt Nr: **17-883** (bitte bei Schriftwechsel angeben)

Beratung nach Fakultätsrecht

Studententitel: Mental Health in Refugees and Asylum Seekers: Gestuftes Versorgungsmodell zur Förderung der mentalen Gesundheit von Flüchtlingen (MEHIRA)
Antragsteller: Prof. Dr. Frank Padberg, Klinikum der Universität München, Klinik für Psychiatrie und Psychotherapie, Nußbaumstr. 7, 80336 München
Untersucher: Prof. Dr. Peter Falkai, Klinikum der Universität München, Klinik für Psychiatrie und Psychotherapie, Nußbaumstr. 7, 80336 München

Sehr geehrter Herr Prof. Padberg,

der Antrag zur o.g. Studie wurde auf der Basis der vorgelegten Unterlagen und Informationen entsprechend § 15 der Berufsordnung und des Fakultätsrechts beraten.

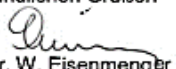
Die Ethikkommission (EK) erhebt keine Einwände gegen die Durchführung der Studie.

Allgemeine Hinweise:

- Änderungen im Verlauf der Studie sind der EK zur erneuten Prüfung vorzulegen.
- Schwerwiegende unerwartete studienabhängige Ereignisse sind der EK mitzuteilen.
- Das Ende der Studie ist anzuzeigen und das Ergebnis vorzulegen.
- Die ärztliche und juristische Verantwortung bei der Durchführung der Studie verbleibt uneingeschränkt bei Ihnen und Ihren Mitarbeitern.

Die Ethikkommission wünscht Ihnen für Ihr Vorhaben viel Erfolg.

Mit freundlichen Grüßen


Prof. Dr. W. Eisenmenger
Vorsitzender der Ethikkommission

Mitglieder der Kommission:

Prof. Dr. W. Eisenmenger (Vorsitzender), Prof. Dr. E. Held (Vorsitzender), Prof. Dr. H. Angstwurm, Prof. Dr. C. Bausewein, PD Dr. Th. Beinert, Prof. Dr. C. Belka, Prof. Dr. H. Dörfner, Prof. Dr. B. Emmerich, Prof. Dr. S. Endres, Prof. Dr. H. U. Gallwas, Prof. Dr. O. Genzel-Boroviczány, Prof. Dr. A. Gerbes, Prof. Dr. Prof. Dr. K. Hahn, Prof. Dr. N. Harbeck, Dr. B. Henriks, Prof. Dr. Ch. Heumann, Prof. Dr. V. Klaus, Prof. Dr. G. Marckmann, Dr. V. Münch, Prof. Dr. A. Nassehi, Prof. Dr. D. Nowak, Prof. Dr. R. Penning, Prof. Dr. J. Peters, Prof. Dr. K. Pfeifer, Dr. I. Saaka, Prof. Dr. M. Schmauss, Prof. Dr. U. Schroth, Prof. Dr. A. Spickhoff, Prof. Dr. O. Steinlein, PD Dr. U. Wandl, Dr. A. Yassouridis, Dr. Ch. Zach

Appendix B

Baseline assessment of the MEHIRA trial, including the complete socio-demographic data section and all questionnaires that were used in this dissertation (english version). These were the PHQ-9, the MADRS, the RHS-15, the M.I.N.I., the HTQ, the BRS, the GSE, the SDQ, and the WHOQoL-BREF.

Figure B1

Socio-demographic baseline assessment

| <u>Inclusion and Exclusion Criteria</u> | Date of visit: |
|--|--|
| RHS-Screening positive? | <input type="radio"/> yes <input type="radio"/> no →EXCLUDE |
| PHQ-9 at least 5 times "Several days" or higher marked? | <input type="radio"/> yes <input type="radio"/> no →EXCLUDE |
| Mother tongue is Arabic or Farsi? | <input type="radio"/> yes <input type="radio"/> no →EXCLUDE |
| Age: ≥18 and ≤65 years? Age: <input type="text"/> <input type="text"/> years | <input type="radio"/> yes <input type="radio"/> no →EXCLUDE |
| Does an Informed Consent exist? | <input type="radio"/> yes <input type="radio"/> no →EXCLUDE |
| Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> (dd/mm/yyyy) | |
| Does Schizophrenia or Degenerative Disorder exist? (based on M.I.N.I. Module L) | <input type="radio"/> yes →EXCLUDE <input type="radio"/> no |
| What is your sex? | <input type="radio"/> male <input type="radio"/> female |

Demographics

- Marital status: Single Married
 Divorced / Separated
 Widowed
- If *married*: does your partner live with you? Yes No
- Children: Yes No
- How many? _____
- Do/Does your children/your child live with you? Yes No
- How many people besides you live in your household? _____

Please Mark:

- Housing situation: Private flat
 Refugee accommodation
 Shared flat
 Assisted living
 Without permanent residence
 Other: _____

Cultural Belonging

Think about your cultural values and traditions: Towards which culture do you feel the strongest sense of belonging?

- German culture
 Culture of your country of origin
 Other culture: _____
 No culture

Current treatment

Who sent you to us?

- Doctor/psychologist/social worker or similar
 Organization for migration issues
 Family/relatives
 Former patients
 Other organization
 Other: _____

How important is a treatment currently for you?

- Very important Important Moderately important Unimportant Very unimportant

Do you wish for a treatment in your mother tongue?

- Yes No

Current Medication / Treatment

Is any antidepressant or antipsychotic agent given?

- No Yes, please specify

| No. | Name of compound | Dose & Unit | Start date | <i>Not known</i> |
|-----|------------------|-------------|----------------------|--------------------------|
| 1 | | | _____ D D M M Y Y | <input type="checkbox"/> |
| 2 | | | _____ D D M M Y Y | <input type="checkbox"/> |
| 3 | | | _____ D D M M Y Y | <input type="checkbox"/> |

Is any concomitant medication given?

- No Yes, please specify:

| No. | Name of compound | Dose & Unit | Start date | <i>Not known</i> |
|-----|------------------|-------------|----------------------|--------------------------|
| 1 | | | _____ D D M M Y Y | <input type="checkbox"/> |
| 2 | | | _____ D D M M Y Y | <input type="checkbox"/> |
| 3 | | | _____ D D M M Y Y | <input type="checkbox"/> |

Is any **concomitant psychotherapy** provided? No Yes, *please specify:*

| No. | Kind of psychotherapeutic intervention | Frequency | Start date | <i>Not known</i> |
|-----|--|--|---|--------------------------|
| 1 | <input type="radio"/> Group therapy <i>Please specify:</i> _____ | <input type="radio"/> Once <input type="radio"/> Daily <input type="radio"/> Weekly <input type="radio"/> As required | ____ _ ____ _ ____ _ D D M M Y Y | <input type="checkbox"/> |
| 2 | <input type="radio"/> Individual therapy <i>Please specify:</i> _____ | <input type="radio"/> Once <input type="radio"/> Daily <input type="radio"/> Weekly <input type="radio"/> As required | ____ _ ____ _ ____ _ D D M M Y Y | <input type="checkbox"/> |

Antidepressant Treatment History Form (Athf)

Please document Antidepressant drug attempt (ADTs) during the current depressive episode on chronological order, start with the first ADT. Please report the current ADT with SSRI.

Does a history of antidepressant treatment exist? No Yes, *please specify:*

| No. | Antidepressant drug attempt (ADT) | Dose & unit | Therapy | Response | Duration in weeks | On-going |
|-----|-----------------------------------|-------------|--|---|-------------------|--------------------------|
| 1 | | | <input type="radio"/> Monotherapy <input type="radio"/> Combination with No. ____ , ____ | <input type="radio"/> No <input type="radio"/> Yes | ____ _ | <input type="checkbox"/> |
| 2 | | | <input type="radio"/> Monotherapy <input type="radio"/> Combination with No. ____ , ____ | <input type="radio"/> No <input type="radio"/> Yes | ____ _ | <input type="checkbox"/> |
| 3 | | | <input type="radio"/> Monotherapy <input type="radio"/> Combination with No. ____ , ____ | <input type="radio"/> No <input type="radio"/> Yes | ____ _ | <input type="checkbox"/> |

Figure B2

English version of the Patient Health Questionnaire 9 (PHQ-9)

Instructions

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(Use " ✓ to indicate your answer)

| | Not at all | Several days | More than half the days | Nearly every day |
|---|------------|--------------|-------------------------|------------------|
| 1. Little interest or pleasure doing things | 0 | 1 | 2 | 3 |
| 2. Feeling down, depressed, or hopeless | 0 | 1 | 2 | 3 |
| 3. Trouble falling or staying asleep, or sleeping too much | 0 | 1 | 2 | 3 |
| 4. Feeling tired or having little energy | 0 | 1 | 2 | 3 |
| 5. Poor appetite or overeating | 0 | 1 | 2 | 3 |
| 6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down | 0 | 1 | 2 | 3 |
| 7. Trouble concentrating on things, such as reading the newspaper or watching television | 0 | 1 | 2 | 3 |
| 8. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual | 0 | 1 | 2 | 3 |
| 9. Thoughts that you would be better off dead or of hurting yourself in some way | 0 | 1 | 2 | 3 |

= Total Score: _____.

If you checked off any problems, how difficult they have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult
at all

Somewhat
difficult

Very
difficult

Extremely
difficult

Figure B3

English version of the Montgomery Asberg Depression Rating Scale (MADRS)

Instructions

The ratings should be based on a clinical interview moving from broadly phrased questions about symptoms to more detailed ones which allow a precise rating of severity. The rater must decide whether the rating lies on the defined scale steps (0, 2, 4, 6) or between them (1, 3, 5). It is important to remember that it is only rare 0 occasions that a depressed patient is encountered who cannot be rated 1 on the items in the scale. If definite answers cannot be elicited from the 2 patients, all relevant clues as well as information from other sources 3 should be used as a basis for the rating in line with customary clinical 4 practice. This scale may be used for any time interval between ratings, be it weekly or otherwise, but this must be recorded.

| | |
|--|--|
| 1. Apparent Sadness Representing despondency, gloom and despair, (more than just ordinary transient low spirits) reflected in speech, facial expression, and posture. Rate on depth and inability to brighten up. | 0 No sadness. 1 2 Looks dispirited but does brighten up without difficulty. 3 4 Appears sad and unhappy most of the time. 5 6 Looks miserable all the time. Extremely despondent. |
| <hr/> 2. Reported Sadness Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or feeling of being beyond help without hope. Rate according to intensity, duration and the extent to which the mood is reported to be influenced by events. | <hr/> 0 Occasional sadness in keeping with the circumstances. 1 2 Sad or low but brightens up without difficulty. 3 4 Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances. 5 6 Continuous or unvarying sadness, misery or despondency. |
| <hr/> 3. Inner Tension Representing feelings of ill-defined discomfort, edginess, inner turmoil mounting to either panic, dread or anguish. Rate according to intensity, frequency, duration and the extent of reassurance called for. | <hr/> 0 Placid. Only reflecting inner tension. 1 2 Occasional feelings of edginess and ill-defined discomfort. 3 4 Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty. 5 6 Unrelenting dread or anguish. Overwhelming panic. |

| | |
|---|--|
| 4. Reduced Sleep Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well. | 0 Sleeps as usual. 1 2 Slight difficulty dropping off to sleep or slightly reduced light or fitful sleep. 3 4 Sleep reduced or broken by at least two hours. 5 6 Less than two or three hours sleep. |
| 5. Reduced Appetite Representing the feeling of loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat. | 0 Normal or increased appetite. 1 2 Slightly reduced appetite. 3 4 No appetite. Food is tasteless. 5 6 Needs persuasion to eat. |
| 6. Concentration Difficulties Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced. | 0 No difficulties in concentrating. 1 2 Occasional difficulties in collecting one's thoughts. 3 4 Difficulty in concentrating and sustaining thought which reduces ability to read or hold conversation. 5 6 Unable to read or conserve without great initiative. |
| 7. Lassitude Representing a difficulty getting started or slowness initiating and performing everyday activities. | 0 Hardly no difficulty in getting started. No sluggishness. 1 2 Difficulty in starting activities. 3 4 Difficulties in starting simple routine activities which are carried out with effort. 5 6 Complete lassitude. Unable to do anything without help. |

| | |
|---|---|
| <p>8. Inability to Feel Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.</p> | <p>0 Normal interest in the surroundings and in other people. 1 2 Reduced ability to enjoy usual interest. 3 4 Loss of interest in surroundings. Loss of feelings for friends and acquaintances. 5 6 The experience of being emotionally paralyzed, inability to feel anger, grief or pleasure and a complete or even painful failure to feel for close relatives and friends.</p> |
| <hr/> <p>9. Pessimistic Thoughts Representing thoughts of guilt. Inferiority, self-reproach, sinfulness, remorse and ruin.</p> | <p>0 No pessimistic thoughts. 1 2 Fluctuating ideas of failure, self-reproach or self-depreciation. 3 4 Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future. 5 6 Delusions of ruin, remorse or unredeemable sin. Self-accusations which are absurd and unshakeable.</p> |
| <hr/> <p>10. Suicidal Thoughts Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and the preparations for suicide. Suicidal attempts should not in themselves influence the rating.</p> | <p>0 Enjoys life or takes it as it comes. 1 2 Weary of life. Only fleeting suicidal thoughts. 3 4 Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention. 5 6 Explicit plans for suicide when there is an opportunity. Active preparations for suicide.</p> |

= Total Score:

Figure B4

English version of the Refugee Health Screener 15 (RHS-15)

Instructions:

Using the scale beside each symptom, please indicate the degree to which the symptom has been bothersome to you over the past month. Place a mark in the appropriate column. If the symptom has not been bothersome to you during the past month, circle "NOT AT ALL."

| Symptoms | Not at all | A little bit | Mode rately | Quite a bit | Extre mely |
|--|------------|--------------|-------------|-------------|------------|
| 1. Muscle, bone, joint pains | 0 | 1 | 2 | 3 | 4 |
| 2. Feeling down, sad, or blue most of the time | 0 | 1 | 2 | 3 | 4 |
| 3. Too much thinking or too many thoughts | 0 | 1 | 2 | 3 | 4 |
| 4. Feeling helpless | 0 | 1 | 2 | 3 | 4 |
| 5. Suddenly scared for no reason | 0 | 1 | 2 | 3 | 4 |
| 6. Faintness, dizziness, or weakness | 0 | 1 | 2 | 3 | 4 |
| 7. Nervousness or shakiness inside | 0 | 1 | 2 | 3 | 4 |
| 8. Feeling restless, can't sit still | 0 | 1 | 2 | 3 | 4 |
| 9. Crying easily | 0 | 1 | 2 | 3 | 4 |

The following symptoms may be related to traumatic experiences during war and migration. How much in the past month have you:

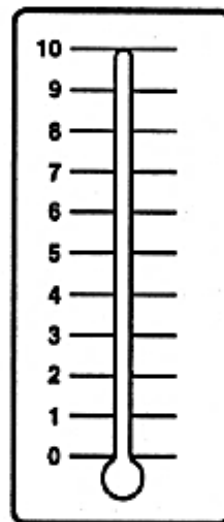
| | | | | | |
|---|---|---|---|---|---|
| 10. Had the experience of reliving the trauma; acting or feeling as if it were happening again? | 0 | 1 | 2 | 3 | 4 |
| 11. Been having PHYSICAL reactions (for example, break out in a sweat, heart beats fast) when reminded of the trauma? | 0 | 1 | 2 | 3 | 4 |
| 12. Felt emotionally numb (for example, feel sad but can't cry, unable to have loving feelings)? | 0 | 1 | 2 | 3 | 4 |
| 13. Been jumpier, more easily startled (for example, when someone walks up behind you)? | 0 | 1 | 2 | 3 | 4 |

14. Generally over your life, do you feel that you are:
- | | |
|---|---|
| Able to handle (cope with) anything that comes your way | 0 |
| Able to handle (cope with) most things that come your way | 1 |
| Able to handle (cope with) some things, but not able to cope with other things..... | 2 |
| Unable to cope with most things..... | 3 |
| Unable to cope with anything | 4 |

15.

Distress Thermometer

FIRST: Please circle the number (0-10) that best describes how much distress you have been experiencing in the past week including today.



Extreme distress

"I feel as bad as I ever have"



No distress

"Things are good"

Add total Score of items 1-14: _____

Scoring

Screening is **POSITIVE**

If Items 1-14 is ≥ 12 OR Distress Thermometer is ≥ 5

Otherwise it is **NEGATIVE**

Self-administered

Not self-administered

MARK ONE:

SCREEN NEGATIVE

SCREEN POSITIVE

Figure B5

English version of the Mini-International Neuropsychiatric Interview (M.I.N.I.)

Instructions**INTERVIEW:**

In order to keep the interview as brief as possible, inform the patient that you will conduct a clinical interview that is more structured than usual, with very precise questions about psychological problems which require a yes or no answer.

GENERAL FORMAT: The M.I.N.I. is divided into **modules** identified by letters, each corresponding to a diagnostic category.

- At the beginning of each diagnostic module (except for psychotic disorders module), screening question(s) corresponding to the main criteria of the disorder are presented in a **gray box**.
- At the end of each module, diagnostic box(es) permit the clinician to indicate whether diagnostic criteria are met.

CONVENTIONS:

Sentences written in « normal font » should be read exactly as written to the patient in order to standardize the assessment of diagnostic criteria.

Sentences written in « CAPITALS » should not be read to the patient. They are instructions for the interviewer to assist in the scoring of the diagnostic algorithms.

Sentences written in « bold » indicate the time frame being investigated. The interviewer should read them as often as necessary. Only symptoms occurring during the time frame indicated should be considered in scoring the responses.

Answers with an arrow above them () indicate that one of the criteria necessary for the diagnosis (es) is not met. In this case, the interviewer should go to the end of the module, circle « **NO** » in all the diagnostic boxes and move to the next module.

When terms are separated by a *slash (/)* the interviewer should read only those symptoms known to be present in the patient (for example, question H6).

Phrases in (parentheses) are clinical examples of the symptom. These may be read to the patient to clarify the question.

RATING INSTRUCTIONS:

All questions must be rated. The rating is done at the right of each question by circling either Yes or No. Clinical judgment by the rater should be used in coding the responses. The rater should ask for examples when necessary, to ensure accurate coding. The patient should be encouraged to ask for clarification on any question that is not absolutely clear.

The clinician should be sure that each dimension of the question is taken into account by the patient (for example, time frame, frequency, severity, and/or alternatives). Symptoms better accounted for by an organic cause or by the use of alcohol or drugs should not be coded positive in the M.I.N.I. The M.I.N.I. Plus has questions that investigate these issues.

A. MAJOR DEPRESSIVE EPISODE

(→ Means: Go to the diagnostic boxes, circle NO in all diagnostic boxes, and move to the next

module)

| | | | |
|-----------|---|----|------|
| A1 | Have you been consistently depressed or down, most of the day, nearly every day, for the past two weeks? | NO | YES |
| A2 | In the past two weeks, have you been much less interested in most things or much less able to enjoy the things you used to enjoy most of the time? | NO | YES |
| | | → | |
| | IS A1 OR A2 CODED YES? | NO | YES |
| A3 | Over the past two weeks, when you felt depressed or uninterested: | | |
| A. | Was your appetite decreased or increased nearly every day? Did your weight decrease or increase without trying intentionally (i.e., by $\pm 5\%$ of body weight or ± 8 lbs. or ± 3.5 kgs., for a 160 lb./70 kg. person in a month)? IF YES TO EITHER, CODE YES. | NO | YES* |
| B. | Did you have trouble sleeping nearly every night (difficulty falling asleep, waking up in the middle of the night, early morning waking or sleeping excessively)? | NO | YES |
| C. | Did you talk or move more slowly than normal or were you fidgety, restless or having trouble sitting still almost every day? | NO | YES* |
| D. | Did you feel tired or without energy almost every day? | NO | YES |
| E. | Did you feel worthless or guilty almost every day? | NO | YES |
| F. | Did you have difficulty concentrating or making decisions almost every day? | NO | YES |

| | | |
|---|----|-----|
| G. Did you repeatedly consider hurting yourself, feel suicidal, or wish that you were dead? | NO | YES |
|---|----|-----|

| | | |
|--|--|------|
| ARE 5 OR MORE ANSWERS (A1-A3) CODED YES? | NO | YES* |
| | <i>Major Depressive Episode, current</i> | |

IF PATIENT HAS CURRENT MAJOR DEPRESSIVE EPISODE CONTINUE TO A4, OTHERWISE MOVE TO MODULE B:

| | | | | |
|----|--|----|------|--|
| A4 | a. During your lifetime, did you have other episodes of two weeks or more when you felt depressed or uninterested in most things, and had most of the problems we just talked about? | → | | |
| | | NO | YES | |
| | b. In between 2 episodes of depression, did you ever have an interval of at least 2 months, without any depression and any loss of interest? | NO | YES* | <i>Major Depressive Episode, recurrent</i> |

MAJOR DEPRESSIVE EPISODE WITH MELANCHOLIC FEATURES (optional)

(→ Means: Go to the diagnostic boxes, circle NO, and move to the next module)

IF THE PATIENT CODES POSITIVE FOR A CURRENT MAJOR DEPRESSIVE EPISODE (A3 = YES), EXPLORE THE FOLLOWING:

| | | | |
|----|---|----|-----|
| A5 | a. During the most severe period of the current depressive episode, did you lose almost completely your ability to enjoy nearly everything? | NO | YES |
| | b. During the most severe period of the current depressive episode, did you lose your ability to respond to things that previously gave you pleasure, or cheered you up? IF NO: When something good happens does it fail to make you feel better, even temporarily? | NO | YES |

* If patient has Major Depressive Episode, Current, use this information in coding the corresponding questions on page 5 (A6d, A6e).

| | | |
|---|---|------------|
| IS EITHER A5a OR A5b CODED YES? | → | |
| | NO | YES |
| A6 Over the past two-week period, when you felt depressed and uninterested: | | |
| A. Did you feel depressed in a way that is different from the kind of feeling you experience when someone close to you dies? | NO | YES |
| B. Did you feel regularly worse in the morning, almost every day? | NO | YES |
| C. Did you wake up at least 2 hours before the usual time of awakening and have difficulty getting back to sleep, almost every day? | NO | YES |
| D. IS A3c CODED YES (PSYCHOMOTOR RETARDATION OR AGITATION)? | NO | YES |
| E. IS A3a CODED YES FOR ANOREXIA OR WEIGHT LOSS? | NO | YES |
| F. Did you feel excessive guilt or guilt out of proportion to the reality of the situation? | NO | YES |
| ARE 3 OR MORE A6 ANSWERS CODED YES? | NO | YES |
| | <i>Major Depressive Episode With Melancholic Features, current</i> | |


B. DYSTHYMIA

(→ Means: Go to the diagnostic box, circle NO, and move to the next module)

IF PATIENT'S SYMPTOMS CURRENTLY MEET CRITERIA FOR MAJOR DEPRESSIVE EPISODE,
DO NOT EXPLORE THIS MODULE.

| | | | |
|-----------|---|---------|---------------------------------|
| B1 | Have you felt sad, low or depressed most of the time for the last two years? | → NO | YES |
| B2 | Was this period interrupted by your feeling OK for two months or more? | → NO | YES |
| B3 | During this period of feeling depressed most of the time: | | |
| a. | Did your appetite change significantly? | NO | YES |
| b. | Did you have trouble sleeping or sleep excessively? | NO | YES |
| c. | Did you feel tired or without energy? | NO | YES |
| d. | Did you lose your self-confidence? | NO | YES |
| e. | Did you have trouble concentrating or making decisions? | NO | YES |
| f. | Did you feel hopeless? | NO | YES |
| | ARE 2 OR MORE B3 ANSWERS CODED YES? | → NO | YES |
| B4 | Did the symptoms of depression cause you significant distress or impair your ability to function at work, socially, or in some other important way? | NO | YES <i>Dysthymia current</i> |

C. SUICIDALITY

| In the past month did you: | | | Points |
|---|---|------------------|--|
| C1 | Suffer any accident? IF NO TO C1, SKIP TO C2; IF YES, ASK C1a,: | NO YES | 0 |
| C1a | Plan or intend to hurt yourself in that accident either passively or actively? IF NO TO C1a, SKIP TO C2; IF YES, ASK C1b,: | NO YES | 0 |
| C1b | Did you intend to die as a result of this accident? | NO YES | 0 |
| C2 | Think that you would be better off dead or wish you were dead? | NO YES | 1 |
| C3 | Want to harm yourself or to hurt or to injure yourself? | NO YES | 2 |
| C4 | Think about suicide? | NO YES | 6 |
| IF YES, ASK ABOUT THE INTENSITY AND FREQUENCY OF THE SUICIDAL IDEATION: | | | |
| Frequency | | Intensity | |
| Occasionally | <input type="radio"/> | Mild | <input type="radio"/> |
| Often | <input type="radio"/> | Moderate | <input type="radio"/> |
| Very often | <input type="radio"/> | Severe | <input type="radio"/> |
|  | | | |
| | | | Can you control these impulses and state that you will not act on them while in this program? Only score 8 points if response is NO. |
| | | | NO YES 8 |
| C5 | Have a suicide plan? | NO YES | 8 |
| C6 | Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die? | NO YES | 9 |
| C7 | Deliberately injure yourself without intending to kill yourself? | NO YES | 4 |

| | | | | | |
|-----------|-------------------------------|--------------------------|-----------|------------|-----------|
| C8 | Attempt suicide? | | NO | YES | 10 |
| | Hoped to be rescued / survive | <input type="checkbox"/> | | | |
| | Expected / intended to die | <input type="checkbox"/> | | | |

In your lifetime:

| | | | | | |
|-----------|---|--|-----------|------------|----------|
| C9 | Did you ever make a suicide attempt? | | NO | YES | 4 |
|-----------|---|--|-----------|------------|----------|

IS AT LEAST 1 OF THE ABOVE (EXCEPT C1) CODED YES?

NO YES
Suicide Risk Current

IF YES, ADD THE TOTAL NUMBER OF POINTS FOR THE ANSWERS (C1-C9) CHECKED 'YES' AND SPECIFY THE LEVEL OF SUICIDE RISK AS INDICATED IN THE DIAGNOSTIC BOX:

| | | |
|--------------------|-----------------|--------------------------|
| 1-8 points | Low | <input type="checkbox"/> |
| 9-16 points | Moderate | <input type="checkbox"/> |
| ≥ 17 points | High | <input type="checkbox"/> |

MAKE ANY ADDITIONAL COMMENTS ABOUT YOUR ASSESSMENT OF THIS PATIENT'S CURRENT AND NEAR FUTURE SUICIDE RISK IN THE SPACE BELOW:

D. (HYPO) MANIC EPISODE

(→ Means: Go to the diagnostic boxes, circle NO in all diagnostic boxes, and move to the next module)

| | | | |
|--------------|---|----|-----|
| D1 A. | Have you ever had a period of time when you were feeling 'up' or 'high' or 'hyper' or so full of energy or full of yourself that you got into trouble, or that other people thought you were not your usual self? (Do not consider times when you were intoxicated on drugs or alcohol.) | NO | YES |
|--------------|---|----|-----|

IF PATIENT IS PUZZLED OR UNCLEAR ABOUT WHAT YOU MEAN BY 'UP' OR 'HIGH' OR 'HYPER', CLARIFY AS FOLLOWS: By 'up' or 'high' or 'hyper' I mean: having elated mood; increased energy; needing less sleep; having rapid thoughts; being full of ideas; having an increase in productivity, motivation, creativity, or impulsive behavior.

IF NO, CODE NO TO **D1b**: IF YES ASK:

| | | | |
|----|--|----|-----|
| B. | Are you currently feeling 'up' or 'high' or 'hyper' or full of energy? | NO | YES |
|----|--|----|-----|

| | | | |
|--------------|--|----|-----|
| D2 A. | Have you ever been persistently irritable, for several days, so that you had arguments or verbal or physical fights, or shouted at people outside your family? Have you or others noticed that you have been more irritable or over reacted, compared to other people, even in situations that you felt were justified? | NO | YES |
|--------------|--|----|-----|

IF NO, CODE NO TO **D2b**: IF YES ASK:

| | | | |
|----|---|----|-----|
| B. | Are you currently feeling persistently irritable? | NO | YES |
|----|---|----|-----|

IS **D1a** OR **D2a** CODED YES?

| | |
|----|-----|
| → | |
| NO | YES |

D3. IF D1b OR D2b = YES: EXPLORE THE CURRENT AND THE MOST SYMPTOMATIC PAST EPISODE, OTHERWISE IF D1b AND D2b = NO: EXPLORE ONLY THE MOST SYMPTOMATIC PAST EPISODE

During the times when you felt high, full of energy, or irritable did you:

| | <u>Current Episode</u> | | <u>Past Episode</u> | |
|--|------------------------|-----|---------------------|-----|
| A. Feel that you could do things others couldn't do, or that you were an especially important person? | NO | YES | NO | YES |
| IF YES, ASK FOR EXAMPLES. THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA. | NO | YES | | |
| B. Need less sleep (for example, feel rested after only a few hours sleep)? | NO | YES | NO | YES |
| C. Talk too much without stopping, or so fast that people had difficulty understanding? | NO | YES | NO | YES |
| D. Have racing thoughts? | NO | YES | NO | YES |
| E. Become easily distracted so that any little interruption could distract you? | NO | YES | NO | YES |
| F. Become so active or physically restless that others were worried about you? | NO | YES | NO | YES |
| G. Want so much to engage in pleasurable activities that you ignored the risks or consequences (for example, spending sprees, reckless driving, or sexual indiscretions)? | NO | YES | NO | YES |
| D3 (SUMMARY): ARE 3 OR MORE D3 ANSWERS CODED YES (OR 4 OR MORE IF D1a IS NO (IN RATING PAST EPISODE) AND D1b IS NO (IN RATING CURRENT EPISODE)? RULE: ELATION/EXPANSIVENESS REQUIRES ONLY THREE D3 SYMPTOMS WHILE IRRITABLE MOOD ALONE REQUIRES 4 OF THE D3 SYMPTOMS. | NO | YES | NO | YES |

D4 Did these symptoms last at least a week **and** cause significant problems at home, at work, socially, or at school, **or** were you hospitalized for these problems?

NO YES NO YES
 ↓ ↓ ↓ ↓

THE EPISODE EXPLORED WAS A

HYPOMANIC EPISODE *MANIC EPISODE* *HYPOMANIC EPISODE* *MANIC EPISODE*

IS **D4** CODED **NO**?

NO YES

SPECIFY IF THE EPISODE IS CURRENT OR PAST.

HYPOMANIC EPISODE
 CURRENT
 PAST

IS **D4** CODED **YES**?

NO YES

SPECIFY IF EPISODE IS CURRENT OR PAST.

MANIC EPISODE
 CURRENT
 PAST

E. PANIC DISORDER

(→ Means: Circle NO is E5, E6 and E7 and skip to F1)

| | | | |
|-------|--|---------|-----|
| E1 A. | Have you, on more than one occasion, had spells or attacks when you suddenly felt anxious, frightened, uncomfortable or uneasy, even in situations where most people would not feel that way? | → NO | YES |
| B. | Did the spells surge to a peak within 10 minutes of starting? | → NO | YES |
| E2 | At any time in the past, did any of those spells or attacks come on unexpectedly or occur in an unpredictable or unprovoked manner? | → NO | YES |
| E3 | Have you ever had one such attack followed by a month or more of persistent concern about having another attack, or worries about the consequences of the attack or did you make a significant change in your behavior because of the attacks (e.g., shopping only with a companion, not wanting to leave your house, visiting the emergency room repeatedly, or seeing your doctor more frequently because of the symptoms? | NO | YES |
| E4 | During the worst spell that you can remember: | | |
| A. | Did you have skipping, racing or pounding of your heart? | NO | YES |
| B. | Did you have sweating or clammy hands? | NO | YES |
| C. | Were you trembling or shaking? | NO | YES |
| D. | Did you have shortness of breath or difficulty breathing? | NO | YES |
| E. | Did you have a choking sensation or a lump in your throat? | NO | YES |
| F. | Did you have chest pain, pressure or discomfort? | NO | YES |
| G. | Did you have nausea, stomach problems or sudden diarrhea? | NO | YES |

| | | | |
|----|---|----|--|
| H. | Did you feel dizzy, unsteady, lightheaded or faint? | NO | YES |
| I. | Did things around you feel strange, unreal, detached or unfamiliar, or did you feel outside of or detached from part or all of your body? | NO | YES |
| J. | Did you fear that you were losing control or going crazy? | NO | YES |
| K. | Did you fear that you were dying? | NO | YES |
| L. | Did you have tingling or numbness in parts of your body? | NO | YES |
| M. | Did you have hot flushes or chills? | NO | YES |
| E5 | ARE BOTH E3, AND 4 OR MORE E4 ANSWERS, CODED YES? IF YES TO E5, SKIP TO E7. | NO | YES <i>PANIC DISORDER LIFETIME</i> |
| E6 | IF E5 = NO, ARE ANY E4 ANSWERS CODED YES? THEN SKIP TO F1. | NO | YES <i>LIMITED SYMPTOM ATTACKS LIFETIME</i> |
| E7 | In the past month, did you have such attacks repeatedly (2 or more) followed by persistent concern about having another attack? | NO | YES <i>PANIC DISORDER CURRENT</i> |

F. AGORAPHOBIA

F1 Do you feel anxious or uneasy in places or situations where you might have a panic attack or the panic-like symptoms we just spoke about, or where help might not be available or escape might be difficult: like being in a crowd, standing in a line (queue), when you are alone away from home or alone at home, or when crossing a bridge, traveling in a bus, train or car? **NO YES**

IF F1=NO CIRCLE NO IN F2.

F2 Do you fear these situations so much that you avoid them, or suffer through them, or need a companion to face them? **NO YES**

*AGORAPHOBIA
CURRENT*

IS F2 (CURRENT AGORAPHOBIA) CODED NO and **NO YES**

IS E7 (CURRENT PANIC DISORDER) CODED YES?

*PANIC DISORDER without
Agoraphobia CURRENT*

IS F2 (CURRENT AGORAPHOBIA) CODED YES and **NO YES**

IS E7 (CURRENT PANIC DISORDER) CODED YES?

*PANIC DISORDER
with Agoraphobia
CURRENT*

IS F2 (CURRENT AGORAPHOBIA) CODED YES and **NO YES**

IS E5 (PANIC DISORDER LIFETIME) CODED NO?

*AGORAPHOBIA,
CURRENT without
history of Panic
Disorder*

G. SOCIAL PHOBIA (Social Anxiety Disorder)

(→ Means: Go to the diagnostic box, circle NO, and move to the next module)

- | | | | |
|----|--|---------|-----|
| G1 | In the past month, were you fearful or embarrassed being watched, being the focus of attention, or fearful of being humiliated? This includes things like speaking in public, eating in public or with others, writing while someone watches, or being in social situations. | → NO | YES |
| G2 | Is this social fear excessive or unreasonable? | → NO | YES |
| G3 | Do you fear these social situations so much that you avoid them or suffer through them? | → NO | YES |
| G4 | Do these social fears disrupt your normal work or social functioning or cause you significant distress? | NO | YES |

*SOCIAL PHOBIA
(Social Anxiety
Disorder)
CURRENT*

SUBTYPES

Do you fear and avoid 4 or more social situations?

- | | | |
|--------|--|--|
| If YES | Generalized social phobia (social anxiety disorder) | GENERALIZED <input type="checkbox"/> |
| If NO | Non-generalized social phobia (social anxiety disorder) | NON-GENERALIZED <input type="checkbox"/> |

NOTE TO INTERVIEWER: PLEASE ASSESS WHETHER THE SUBJECT'S FEARS ARE RESTRICTED TO NON-GENERALIZED ("ONLY 1 OR SEVERAL") SOCIAL SITUATIONS OR EXTEND TO GENERALIZED ("MOST") SOCIAL SITUATIONS. "MOST" SOCIAL SITUATIONS IS USUALLY OPERATIONALIZED TO MEAN 4 OR MORE SOCIAL SITUATIONS, ALTHOUGH THE DSM-IV DOES NOT EXPLICITLY STATE THIS.

EXAMPLES OF SUCH SOCIAL SITUATIONSTYPICALLY INCLUDE INITIATING OR MAINTAINING A CONVERSATION, PARTICIPATING IN SMALL GROUPS, DATING, SPEAKING TO AUTHORITY FIGURES, ATTENDING PARTIES, PUBLIC SPEAKING, EATING IN FRONT OF OTHERS, URINATING IN A PUBLIC WASHROOM, ETC.

H. OBSESSIVE-COMPULSIVE DISORDER

(→ Means: Go to the diagnostic box, circle NO, and move to the next module)

- | | | | |
|---|---|--------------------------------|---|
| H1 | In the past month, have you been bothered by recurrent thoughts, impulses, or images that were unwanted, distasteful, inappropriate, intrusive, or distressing? (For example, the idea that you were dirty, contaminated or had germs, or fear of contaminating others, or fear of harming someone even though you didn't want to, or fearing you would act on some impulse, or fear or superstitions that you would be responsible for things going wrong, or obsessions with sexual thoughts, images or impulses, or hoarding, collecting, or religious obsessions.) | NO ↓ SKIP TO H4 | YES |
| (DO NOT INCLUDE SIMPLY EXCESSIVE WORRIES ABOUT REAL LIFE PROBLEMS. DO NOT INCLUDE OBSESSIONS DIRECTLY RELATED TO EATING DISORDERS, SEXUAL DEVIATIONS, PATHOLOGICAL GAMBLING, OR ALCOHOL OR DRUG ABUSE BECAUSE THE PATIENT MAY DERIVE PLEASURE FROM THE ACTIVITY AND MAY WANT TO RESIST IT ONLY BECAUSE OF ITS NEGATIVE CONSEQUENCES.) | | | |
| H2 | Did they keep coming back into your mind even when you tried to ignore or get rid of them? | NO ↓ SKIP TO H4 | YES |
| H3 | Do you think that these obsessions are the product of your own mind and that they are not imposed from the outside? | NO <input type="checkbox"/> | YES <input type="checkbox"/> obsessions |
| H4 | In the past month, did you do something repeatedly without being able to resist doing it, like washing or cleaning excessively, counting or checking things over and over, or repeating, collecting, arranging things, or other superstitious rituals? | NO <input type="checkbox"/> | YES <input type="checkbox"/> compulsions |
| IS H3 OR H4 CODED YES? | | → NO | YES |

- | | | | |
|-----------|---|-----------|------------|
| H5 | Did you recognize that either these obsessive thoughts or these compulsive behaviors were excessive or unreasonable? | → | |
| | | NO | YES |
| H6 | Did these obsessive thoughts and/or compulsive behaviors significantly interfere with your normal routine, your work or school, your usual social activities, or relationships, or did they take more than one hour a day? | NO | YES |
- OCD CURRENT*

I. POSTTRAUMATIC STRESS DISORDER (optional)

(→ Means: Go to the diagnostic box, circle NO, and move to the next module)

- | | | | |
|----|--|---------|-----|
| 11 | Have you ever experienced or witnessed or had to deal with an extremely traumatic event that included actual or threatened death or serious injury to you or someone else? | → NO | YES |
|----|--|---------|-----|

EXAMPLES OF TRAUMATIC EVENTS INCLUDE: SERIOUS ACCIDENTS, SEXUAL OR PHYSICAL ASSAULT, A TERRORIST ATTACK, BEING HELD HOSTAGE, KIDNAPPING, FIRE, DISCOVERING A BODY, SUDDEN DEATH OF SOMEONE CLOSE TO YOU, WAR, OR NATURAL DISASTER.

- | | | | |
|----|--|---------|-----|
| 12 | Did you respond with intense fear, helplessness or horror? | → NO | YES |
|----|--|---------|-----|

- | | | | |
|----|---|---------|-----|
| 13 | During the past month, have you re-experienced the event in a distressing way (such as, dreams, intense recollections, flashbacks or physical reactions)? | → NO | YES |
|----|---|---------|-----|

14 In the past month:

- | | | | |
|----|---|----|-----|
| A. | Have you avoided thinking about or talking about the event? | NO | YES |
| B. | Have you avoided activities, places or people that remind you of the event? | NO | YES |
| C. | Have you had trouble recalling some important part of what happened? | NO | YES |
| D. | Have you become much less interested in hobbies or social activities? | NO | YES |
| E. | Have you felt detached or estranged from others? | NO | YES |
| F. | Have you noticed that your feelings are numbed? | NO | YES |
| G. | Have you felt that your life will be shortened or that you will die sooner than other people? | NO | YES |

| | | | |
|-----------|--|----|--|
| | ARE 3 OR MORE I4 ANSWERS CODED YES? | → | |
| | | NO | YES |
| I5 | In the past month: | | |
| A. | Have you had difficulty sleeping? | NO | YES |
| B. | Were you especially irritable or did you have outbursts of anger? | NO | YES |
| C. | Have you had difficulty concentrating? | NO | YES |
| D. | Were you nervous or constantly on your guard? | NO | YES |
| E. | Were you easily startled? | NO | YES |
| | ARE 2 OR MORE I5 ANSWERS CODED YES? | → | |
| | | NO | YES |
| I6 | During the past month, have these problems significantly interfered with your work or social activities, or caused significant distress? | NO | YES |
| | | | <i>POSTTRAUMATIC STRESS DISORDER</i> |
| | | | <i>CURRENT</i> |

J. ALCOHOL ABUSE AND DEPENDENCE

(→ Means: Go to the diagnostic boxes, circle NO in both and move to the next module)

| | | | |
|-----------|---|---------|------|
| J1 | In the past 12 months , have you had 3 or more alcoholic drinks within a 3-hour period on 3 or more occasions? | → NO | YES |
| J2 | In the past 12 months: | | |
| A. | Did you need to drink more in order to get the same effect that you got when you first started drinking? | NO | YES |
| B. | When you cut down on drinking did your hands shake, did you sweat or feel agitated? Did you drink to avoid these symptoms or to avoid being hung-over, for example, "the shakes", sweating or agitation? IF YES TO EITHER, CODE YES. | NO | YES |
| C. | During the times when you drank alcohol, did you end up drinking more than you planned when you started? | NO | YES |
| D. | Have you tried to reduce or stop drinking alcohol but failed? | NO | YES |
| E. | On the days that you drank, did you spend substantial time in obtaining alcohol, drinking, or in recovering from the effects of alcohol? | NO | YES |
| F. | Did you spend less time working, enjoying hobbies, or being with others because of your drinking? | NO | YES |
| G. | Have you continued to drink even though you knew that the drinking caused you health or mental problems? | NO | YES |
| | ARE 3 OR MORE J2 ANSWERS CODED YES? | NO | YES* |

* IF YES, SKIP J3 QUESTIONS, CIRCLE N/A IN THE ABUSE BOX AND MOVE TO THE NEXT DISORDER.
DEPENDENCE PREEMPTS ABUSE.

*ALCOHOL
DEPENDENCE
CURRENT*

J3 In the past 12 months:

- | | | |
|---|-----------|---------------------|
| A. Have you been intoxicated, high, or hung-over more than once when you had other responsibilities at school, at work, or at home? Did this cause any problems? (CODE YES ONLY IF THIS CAUSED PROBLEMS.) | NO | YES |
| B. Were you intoxicated more than once in any situation where you were physically at risk, for example, driving a car, riding a motorbike, using machinery, boating, etc.? | NO | YES |
| C. Did you have legal problems more than once because of your drinking, for example, an arrest or disorderly conduct? | NO | YES |
| D. Did you continue to drink even though your drinking caused problems with your family or other people? | NO | YES |
| ARE 1 OR MORE J3 ANSWERS CODED YES? | NO | N/A YES |

*ALCOHOL ABUSE
CURRENT*

K. NON-ALCOHOL PSYCHOACTIVE SUBSTANCE USE DISORDERS

(→ Means: Go to the diagnostic boxes, circle NO in all diagnostic boxes, and move to the next module)

Now I am going to show you / read to you a list of street drugs or medicines.

K1 A. In the past 12 months, did you take any of these →
 drugs more than once, to get high, to feel better, or to NO YES
 change your mood?

CIRCLE EACH DRUG TAKEN:

Stimulants: amphetamines, "speed", crystal meth, "crank", "rush", Dexedrine, Ritalin, diet pills.

Cocaine: snorting, IV, freebase, crack, "speedball".

Narcotics: heroin, morphine, Dilaudid, opium, Demerol, methadone, codeine, Percodan, Darvon, OxyContin.

Hallucinogens: LSD ("acid"), mescaline, peyote, PCP ("angel dust", "peace pill"), psilocybin, STP, "mushrooms", "ecstasy", MDA, MDMA, or ketamine ("special K").

Inhalants: "glue", ethyl chloride, "rush", nitrous oxide ("laughing gas"), amyl or butyl nitrate ("poppers").

Marijuana: hashish ("hash"), THC, "pot", "grass", "weed", "reefer".

Tranquilizers: Quaalude, Seconal ("reds"), Valium, Xanax, Librium, Ativan, Dalmane, Halcion, barbiturates, Miltown, GHB, Roofinol, "Roofies".

Miscellaneous: steroids, nonprescription sleep or diet pills.

Any others?

SPECIFY MOST USED DRUG(S): _____

CHECK ONE BOX

ONLY ONE DRUG / DRUG CLASS HAS BEEN USED
 ONLY THE MOST USED DRUG CLASS IS INVESTIGATED
 EACH DRUG CLASS USED IS EXAMINED
 SEPARATELY (PHOTOCOPY K2 AND K3 AS NEEDED)

B. SPECIFY WHICH DRUG/DRUG CLASS WILL BE EXPLORED IN THE INTERVIEW BELOW IF THERE IS CONCURRENT OR SEQUENTIAL POLYSUBSTANCE USE: _____

K2 Considering your use of (NAME THE DRUG / DRUG CLASS SELECTED), in the past 12 months:

- | | | |
|---|----|-----|
| A. Have you found that you needed to use more (NAME OF DRUG / DRUG CLASS SELECTED) to get the same effect that you did when you first started taking it? | NO | YES |
| B. When you reduced or stopped using (NAME OF DRUG / DRUG CLASS SELECTED), did you have withdrawal symptoms (aches, shaking, fever, weakness, diarrhea, nausea, sweating, heart pounding, difficulty sleeping, or feeling agitated, anxious, irritable, or depressed)? Did you use any drug(s) to keep yourself from getting sick (withdrawal symptoms) or so that you would feel better? | NO | YES |
| IF YES TO EITHER, CODE YES. | | |
| C. Have you often found that when you used (NAME OF DRUG / DRUG CLASS SELECTED), you ended up taking more than you thought you would? | NO | YES |
| D. Have you tried to reduce or stop taking (NAME OF DRUG / DRUG CLASS SELECTED) but failed? | NO | YES |
| E. On the days that you used (NAME OF DRUG / DRUG CLASS SELECTED), did you spend substantial time (>2 HOURS), obtaining, using or in recovering from the drug, or thinking about the drug? | NO | YES |
| F. Did you spend less time working, enjoying hobbies, or being with family or friends because of your drug use? | NO | YES |
| G. Have you continued to use (NAME OF DRUG / DRUG CLASS SELECTED), even though it caused you health or mental problems? | NO | YES |

ARE 3 OR MORE K2 ANSWERS CODED YES? NO YES*

SPECIFY DRUG(S): _____

* IF YES, SKIP K3 QUESTIONS, CIRCLE N/A IN THE ABUSE BOX FOR THIS SUBSTANCE AND MOVE TO THE NEXT DISORDER. DEPENDENCE PREEMPTS ABUSE.

Considering your use of (NAME THE DRUG CLASS SELECTED), in the past 12 months:

K3 A. Have you been intoxicated, high, or hung-over from (NAME OF DRUG / DRUG CLASS SELECTED) more than once, when you had other responsibilities at school, at work, or at home? Did this cause any problem? NO YES

(CODE YES ONLY IF THIS CAUSED PROBLEMS.)

B. Have you been high or intoxicated from (NAME OF DRUG / DRUG CLASS SELECTED) more than once in any situation where you were physically at risk (for example, driving a car, riding a motorbike, using machinery, boating, etc.)? NO YES

C. Did you have legal problems more than once because of your drug use, for example, an arrest or disorderly conduct? NO YES

D. Did you continue to use (NAME OF DRUG / DRUG CLASS SELECTED) even though it caused problems with your family or other people? NO YES

ARE 1 OR MORE K3 ANSWERS CODED YES? NO N/A YES

SUBSTANCE ABUSE
CURRENT

SPECIFY DRUG(S): _____

L. PSYCHOTIC DISORDERS AND MOOD DISORDER WITH PSYCHOTIC FEATURES

ASK FOR AN EXAMPLE OF EACH QUESTION ANSWERED POSITIVELY. CODE YES ONLY IF THE EXAMPLES CLEARLY SHOW A DISTORTION OF THOUGHT OR OF PERCEPTION OR IF THEY ARE NOT CULTURALLY APPROPRIATE. BEFORE CODING, INVESTIGATE WHETHER DELUSIONS QUALIFY AS "BIZARRE".

DELUSIONS ARE "BIZARRE" IF: CLEARLY IMPLAUSIBLE, ABSURD, NOT UNDERSTANDABLE, AND CANNOT DERIVE FROM ORDINARY LIFE EXPERIENCE.

HALLUCINATIONS ARE SCORED "BIZARRE" IF: A VOICE COMMENTS ON THE PERSON'S THOUGHTS OR BEHAVIOR, OR WHEN TWO OR MORE VOICES ARE CONVERSING WITH EACH OTHER.

Now I am going to ask you about unusual experiences that some people have.

| | | | BIZARRE |
|---|---|-----------|----------------|
| L1 | A. Have you ever believed that people were spying on you, or that someone was plotting against you, or trying to hurt you? | NO YES | YES |
| NOTE: ASK FOR EXAMPLES TO RULE OUT ACTUAL STALKING. | | | |
| | B. IF YES OR YES BIZARRE: do you currently believe these things? | NO YES | YES → L6 |
| L2 | A. Have you ever believed that someone was reading your mind or could hear your thoughts, or that you could actually read someone's mind or hear what another person was thinking? | NO YES | YES |
| | B. IF YES OR YES BIZARRE: do you currently believe these things? | NO YES | YES → L6 |
| L3 | A. Have you ever believed that someone or some force outside of yourself put thoughts in your mind that were not your own, or made you act in a way that was not your usual self? Have you ever felt that you were possessed? | NO YES | YES |
| | B. IF YES OR YES BIZARRE: do you currently believe these things? | NO YES | YES → L6 |

| | | | | |
|----|--|----|-----|-------------|
| L4 | A. Have you ever believed that you were being sent special messages through the TV, radio, or newspaper, or that a person you did not personally know was particularly interested in you? | NO | YES | YES |
| | B. IF YES OR YES BIZARRE: do you currently believe these things? | NO | YES | YES →L6 |
| L5 | A. Have your relatives or friends ever considered any of your beliefs strange or unusual? INTERVIEWER: ASK FOR EXAMPLES. ONLY CODE YES IF THE EXAMPLES ARE CLEARLY DELUSIONAL IDEAS NOT EXPLORED IN QUESTIONS L1 TO L4, FOR EXAMPLE, SOMATIC OR RELIGIOUS DELUSIONS OR DELUSIONS OF GRANDIOSITY, JEALOUSY, GUILT, RUIN OR DESTITUTION, ETC. | NO | YES | YES |
| | B. IF YES OR YES BIZARRE: do they currently consider your beliefs strange? | NO | YES | YES |
| L6 | A. Have you ever heard things other people couldn't hear, such as voices? HALLUCINATIONS ARE SCORED "BIZARRE" ONLY IF PATIENT ANSWERS YES TO THE FOLLOWING: | NO | YES | |
| | IF YES: Did you hear a voice commenting on your thoughts or behavior or NO did you hear two or more voices talking to each other? | NO | YES | |
| | B. IF YES OR YES BIZARRE TO L6a: have you heard these things in the past month? HALLUCINATIONS ARE SCORED "BIZARRE" ONLY IF PATIENT ANSWERS YES TO THE FOLLOWING: Did you hear a voice commenting on your thoughts or behavior or did you hear two or more voices talking to each other? | NO | YES | YES →L8b |
| L7 | A. Have you ever had visions when you were awake or have you ever seen things other people couldn't see? CLINICIAN: CHECK TO SEE IF THESE ARE CULTURALLY INAPPROPRIATE. | NO | YES | |
| | B. IF YES: have you seen these things in the past month? | NO | YES | |

CLINICIAN'S JUDGMENT

| | | | |
|--------------|--|-----------|---------------------|
| L8 b | IS THE PATIENT CURRENTLY EXHIBITING INCOHERENCE, DISORGANIZED SPEECH, OR MARKED LOOSENING OF ASSOCIATIONS? | NO | YES |
| L9 b | IS THE PATIENT CURRENTLY EXHIBITING DISORGANIZED OR CATATONIC BEHAVIOR? | NO | YES |
| L10 b | ARE NEGATIVE SYMPTOMS OF SCHIZOPHRENIA, E.G. SIGNIFICANT AFFECTIVE FLATTENING, POVERTY OF SPEECH (ALOGIA) OR AN INABILITY TO INITIATE OR PERSIST IN GOAL-DIRECTED ACTIVITIES (AVOLITION), PROMINENT DURING THE INTERVIEW? | NO | YES |
| L11 a | ARE 1 OR MORE « a » QUESTIONS FROM L1a TO L7a CODED YES OR YES BIZARRE AND IS EITHER: MAJOR DEPRESSIVE EPISODE, (CURRENT OR RECURRENT) OR MANIC OR HYPOMANIC EPISODE, (CURRENT OR PAST) CODED YES? | NO | YES →L13 |

IF NO TO L11 a, CIRCLE NO IN BOTH 'MOOD DISORDER WITH PSYCHOTIC FEATURES' DIAGNOSTIC BOXES AND MOVE TO L13.

| | | |
|--|-----------|---|
| B. You told me earlier that you had period(s) when you felt (depressed/high/persistently irritable). Were the beliefs and experiences you just described (SYMPTOMS CODED YES FROM L1a TO L7a) restricted exclusively to times when you were feeling depressed/high/irritable? | NO | YES |
| | | <i>MOOD DISORDER WITH PSYCHOTIC FEATURES LIFETIME</i> |

IF THE PATIENT EVER HAD A PERIOD OF AT LEAST 2 WEEKS OF HAVING THESE BELIEFS OR EXPERIENCES (PSYCHOTIC SYMPTOMS) WHEN THEY WERE NOT DEPRESSED/HIGH/IRRITABLE, CODE NO TO THIS DISORDER. IF THE ANSWER IS NO TO THIS DISORDER, ALSO CIRCLE NOTO L12 AND MOVE TO L13

| | | |
|---|--|-------------------|
| <p>L12 a ARE 1 OR MORE « b » QUESTIONS FROM L1b TO L7b CODED YES OR YES BIZARRE AND IS EITHER:</p> <p style="padding-left: 20px;">MAJOR DEPRESSIVE EPISODE, (CURRENT) OR MANIC OR HYPOMANIC EPISODE, (CURRENT) CODED YES?</p> | <p>NO</p> <p><i>MOOD DISORDER WITH PSYCHOTIC FEATURES</i></p> <p><i>CURRENT</i></p> | <p>YES</p> |
|---|--|-------------------|

IF THE ANSWER IS YES TO THIS DISORDER (LIFETIME OR CURRENT), CIRCLE NO TO L13 AND L14 AND MOVE TO THE NEXT MODULE.

| | | |
|--|---|-------------------|
| <p>L13 ARE 1 OR MORE « b » QUESTIONS FROM L1b TO L6b, CODED YES BIZARRE? OR ARE 2 OR MORE « b » QUESTIONS FROM L1b TO L10b, CODED YES (RATHER THAN YES BIZARRE)? AND DID AT LEAST TWO OF THE PSYCHOTIC SYMPTOMS OCCUR DURING THE SAME 1 MONTH PERIOD?</p> | <p>NO</p> <p><i>PSYCHOTIC DISORDER</i></p> <p><i>CURRENT</i></p> | <p>YES</p> |
|--|---|-------------------|

L14 IS L13 CODED YES

NO

YES

OR

**ARE 1 OR MORE « a » QUESTIONS FROM
L1a TO L6a, CODED YES BIZARRE?**

PSYCHOTIC DISORDER
LIFETIME

OR

**ARE 2 OR MORE « a » QUESTIONS FROM
L1a TO L7a, CODED YES (RATHER THAN
YES BIZARRE) AND DID AT LEAST TWO
OF THE PSYCHOTIC SYMPTOMS OCCUR
DURING THE SAME 1 MONTH PERIOD?**

M. ANOREXIA NERVOSA

(→ Means: Go to the diagnostic box, circle NO, and move to the next module)

M1 A. How tall are you? _____ Cm

B. What was your lowest weight in the past 3 months? _____ Kg

C. IS PATIENT'S WEIGHT EQUAL TO OR BELOW
THE THRESHOLD CORRESPONDING TO
HIS / HER HEIGHT? (SEE TABLE BELOW) →
NO YES

In the past 3 months:

M2 In spite of this low weight, have you tried not
to gain weight? →
NO YES

M3 Have you intensely feared gaining weight or
becoming fat, even though you were underweight? →
NO YES

M4 A. Have you considered yourself too big / fat or that
part of your body was too big / fat? NO YES

B. Has your body weight or shape greatly influenced
how you felt about yourself? NO YES

C. Have you thought that your current low body weight
was normal or excessive? NO YES

M5 ARE 1 OR MORE ITEMS FROM M4 CODED YES? →
NO YES

M6 FOR WOMEN ONLY: During the last 3 months, did you
miss all your menstrual periods when they were expected
to occur (when you were not pregnant)? →
NO YES

FOR WOMEN: ARE M5 AND M6 CODED YES? NO YES

FOR MEN: IS M5 CODED YES?

ANOREXIA NERVOSA
CURRENT

HEIGHT / WEIGHT TABLE CORRESPONDING TO A BMI THRESHOLD OF 17.5 KG/M2**Height/Weight**

| | | | | | | | | | | | | | | |
|----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| cm | 145 | 147 | 150 | 152 | 155 | 158 | 160 | 163 | 165 | 168 | 170 | 173 | 175 | 178 |
| kg | 37 | 38 | 39 | 41 | 42 | 43 | 45 | 46 | 48 | 49 | 51 | 52 | 54 | 55 |

Height/Weight

| | | | | | |
|----|-----|-----|-----|-----|-----|
| cm | 180 | 183 | 185 | 188 | 191 |
| kg | 57 | 59 | 60 | 62 | 64 |

The weight thresholds above are calculated using a body mass index (BMI) equal to or below 17.5 kg/m² for the patient's height. This is the threshold guideline below which a person is deemed underweight by the DSM-IV and the ICD-10 Diagnostic Criteria for Research for Anorexia Nervosa.

N. BULIMIA NERVOSA

(→ Means: Go to the diagnostic boxes, circle NO in all diagnostic boxes, and move to the next module)

- | | | | |
|----|--|-------------|-----|
| N1 | In the past three months, did you have eating binges or times when you ate a very large amount of food within a 2-hour period? | → NO | YES |
| N2 | In the last 3 months, did you have eating binges as often as twice a week? | → NO | YES |
| N3 | During these binges, did you feel that your eating was out of control? | → NO | YES |
| N4 | Did you do anything to compensate for, or to prevent a weight gain from these binges, like vomiting, fasting, exercising or taking laxatives, enemas, diuretics (fluid pills), or other medications? | → NO | YES |
| N5 | Does your body weight or shape greatly influence how you feel about yourself? | → NO | YES |
| N6 | DO THE PATIENT'S SYMPTOMS MEET CRITERIA FOR ANOREXIA NERVOSA? | NO ↓ | YES |
| | | Skip to N8 | |
| N7 | Do these binges occur only when you are under (_____kg.)? | NO | YES |

INTERVIEWER: WRITE IN THE ABOVE PARENTHESIS THE THRESHOLD WEIGHT FOR THIS PATIENT'S HEIGHT FROM THE HEIGHT / WEIGHT TABLE IN THE ANOREXIA NERVOSA MODULE.

**N8 IS N5 CODED YES AND IS EITHER
N6 OR N7 CODED NO?**

NO YES

*BULIMIA NERVOSA
CURRENT*

IS N7 CODED YES?

NO YES

*ANOREXIA NERVOSA
Binge Eating/Purging Type
CURRENT*

O. GENERALIZED ANXIETY DISORDER

(→ Means: Go to the diagnostic box, circle NO, and move to the next module)

| | | | |
|-----------|---|---------|-----|
| O1 | A. Have you worried excessively or been anxious about several things over the past 6 months? | → NO | YES |
| | B. Are these worries present most days? | → NO | YES |
| | IS THE PATIENT'S ANXIETY RESTRICTED EXCLUSIVELY TO, OR BETTER EXPLAINED BY, ANY DISORDER PRIOR TO THIS POINT? | → NO | YES |
| O2 | Do you find it difficult to control the worries or do they interfere with your ability to focus on what you are doing? | → NO | YES |
| O3 | FOR THE FOLLOWING, CODE NO IF THE SYMPTOMS ARE CONFINED TO FEATURES OF ANY DISORDER EXPLORED PRIOR TO THIS POINT. | | |
| | When you were anxious over the past 6 months, did you, most of the time: | | |
| | A. Feel restless, keyed up or on edge? | NO | YES |
| | B. Feel tense? | NO | YES |
| | C. Feel tired, weak or exhausted easily? | NO | YES |
| | D. Have difficulty concentrating or find your mind going blank? | NO | YES |
| | E. Feel irritable? | NO | YES |
| | F. Have difficulty sleeping (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)? | NO | YES |
| | ARE 3 OR MORE O3 ANSWERS CODED YES? | NO | YES |

*GENERALIZED ANXIETY
DISORDER CURRENT*

P. ANTISOCIAL PERSONALITY DISORDER (optional)

(→ Means: Go to the diagnostic boxes, circle NO.)

P1 Before you were 15 years old, did you:

| | | |
|--|----|-----|
| A. repeatedly skip school or run away from home overnight? | NO | YES |
| B. repeatedly lie, cheat, "con" others, or steal? | NO | YES |
| C. start fights or bully, threaten, or intimidate others? | NO | YES |
| D. deliberately destroy things or start fires? | NO | YES |
| E. deliberately hurt animals or people? | NO | YES |
| F. force someone to have sex with you? | NO | YES |
| ARE 2 OR MORE P1 ANSWERS CODED YES? | → | |
| | NO | YES |

DO NOT CODE YES TO THE BEHAVIORS BELOW IF THEY ARE EXCLUSIVELY POLITICALLY OR RELIGIOUSLY MOTIVATED.

P2 Since you were 15 years old, have you:

| | | |
|---|----|-----|
| A. repeatedly behaved in a way that others would consider irresponsible, like failing to pay for things you owed, deliberately being impulsive or deliberately not working to support yourself? | NO | YES |
| B. done things that are illegal even if you didn't get caught (for example, destroying property, shoplifting, stealing, selling drugs, or committing a felony)? | NO | YES |
| C. been in physical fights repeatedly (including physical fights with your spouse or children)? | NO | YES |
| D. often lied or "conned" other people to get money or pleasure, | NO | YES |

| | | |
|---|-----------|------------|
| E. exposed others to danger without caring? | NO | YES |
| F. felt no guilt after hurting, mistreating, lying to, or stealing from others, or after damaging property? | NO | YES |
| ARE 3 OR MORE P2 QUESTIONS CODED YES? | NO | YES |

*ANTISOCIAL PERSONALITY
DISORDER LIFETIME*

Figure B6

English version of the Harvard Trauma Questionnaire (HTQ)

Instructions

We would like to ask you about your past history and present symptoms. This information will be used to help us provide you with better medical care. However, you may find some questions upsetting. If so, please feel free not to answer. This will certainly not affect your treatment. The answer to the questions will be kept confidential.

PART 1: TRAUMA EVENTS

**Please indicate whether you have experienced any of the following events
(check YES or NO)**

| | | | |
|-----|--|-----|----|
| 1. | Lack of shelter | YES | NO |
| 2. | Lack of food or water | YES | NO |
| 3. | Ill health without access to medical care | YES | NO |
| 4. | Confiscation or destruction of personal property | YES | NO |
| 5. | Combat situation (e.g. shelling and grenade attacks) | YES | NO |
| 6. | Forced evacuation under dangerous conditions | YES | NO |
| 7. | Beating to the body | YES | NO |
| 8. | Rape | YES | NO |
| 9. | Other types of sexual abuse or sexual humiliation | YES | NO |
| 10. | Knifing or axing | YES | NO |
| 11. | Torture, i.e., while in captivity you received deliberate and systematic infliction of physical or mental suffering (If YES, see Appendix) | YES | NO |
| 12. | Serious physical injury from combat situation or landmine | YES | NO |
| 13. | Imprisonment | YES | NO |
| 14. | Forced labor (like animal or slave) | YES | NO |
| 15. | Extortion or robbery | YES | NO |
| 16. | Brainwashing | YES | NO |
| 17. | Forced to hide | YES | NO |
| 18. | Kidnapped | YES | NO |
| 19. | Other forced separation from family members | YES | NO |
| 20. | Forced to find and bury bodies | YES | NO |
| 21. | Enforced isolation from others | YES | NO |
| 22. | Someone was forced to betray you and place you at risk of death or injury | YES | NO |
| 23. | Prevented from burying someone | YES | NO |
| 24. | Forced to desecrate or destroy the bodies or graves of deceased persons | YES | NO |
| 25. | Forced to physically harm family member, or friend | YES | NO |
| 26. | Forced to physically harm someone who is not family or friend | YES | NO |
| 27. | Forced to destroy someone else's property or possessions | YES | NO |
| 28. | Forced to betray family member, or friend placing them at risk of death or injury | YES | NO |

| | | | |
|-----|--|-----|----|
| 29. | Forced to betray someone who is not family or friend placing them at risk of death or injury | YES | NO |
| 30. | Murder, or death due to violence, of spouse | YES | NO |
| 31. | Murder, or death due to violence, of child | YES | NO |
| 32. | Murder, or death due to violence, of other family member or friend | YES | NO |
| 33. | Disappearance or kidnapping of spouse | YES | NO |
| 34. | Disappearance or kidnapping of child | YES | NO |
| 35. | Disappearance or kidnapping of other family member or friend | YES | NO |
| 36. | Serious physical injury of family member or friend due to combat situation or landmine | YES | NO |
| 37. | Witness beatings to head or body | YES | NO |
| 38. | Witness torture | YES | NO |
| 39. | Witness killing/murder | YES | NO |
| 40. | Witness rape or sexual abuse | YES | NO |
| 41. | Another situation that was very frightening or in which you felt your life was in danger. Specify: | YES | NO |

PART 3: HEAD INJURY

If you answer yes to the following trauma events, please indicate if you lost consciousness and for how long.

| | Experienced? | | Loss of consciousness? | | If Yes, for how long? | |
|---|--|----|------------------------|--------------------|-----------------------|---------|
| | Yes | No | Yes | No | Hours | Minutes |
| 1. Beatings to the head | | | | | | |
| 2. Suffocation or strangulation | | | | | | |
| 3. Near drowning | | | | | | |
| 4. Other types of injury to the head (e.g. shrapnel, burns, etc.) | | | | | | |
| 5. Starvation | | | | | | |
| If Yes: | Normal weight: | | | Starvation weight: | | |
| If Yes: | Were you near death due to starvation? | | | Yes | No | |

PART 4: TRAUMA SYMPTOMS

The following are symptoms that people sometimes have after experiencing hurtful or terrifying events in their lives. Please read each one carefully and decide how much the symptoms bothered you in the past week.

| | | Not at all | A little | Quite a bit | Extremely |
|-----|---|------------|----------|-------------|-----------|
| 1. | Recurrent thoughts or memories of the most hurtful or terrifying events | 1 | 2 | 3 | 4 |
| 2. | Feeling as though the event is happening again | 1 | 2 | 3 | 4 |
| 3. | Recurrent nightmares | 1 | 2 | 3 | 4 |
| 4. | Feeling detached or withdrawn from people | 1 | 2 | 3 | 4 |
| 5. | Unable to feel emotions | 1 | 2 | 3 | 4 |
| 6. | Feeling jumpy, easily startled | 1 | 2 | 3 | 4 |
| 7. | Difficulty concentrating | 1 | 2 | 3 | 4 |
| 8. | Trouble sleeping | 1 | 2 | 3 | 4 |
| 9. | Feeling on guard | 1 | 2 | 3 | 4 |
| 10. | Feeling irritable or having outbursts of anger | 1 | 2 | 3 | 4 |
| 11. | Avoiding activities that remind you of the traumatic or hurtful event | 1 | 2 | 3 | 4 |
| 12. | Inability to remember parts of the most hurtful or traumatic events | 1 | 2 | 3 | 4 |
| 13. | Less interest in daily activities | 1 | 2 | 3 | 4 |
| 14. | Feeling as if you don't have a future | 1 | 2 | 3 | 4 |
| 15. | Avoiding thoughts or feelings associated with the traumatic or hurtful events | 1 | 2 | 3 | 4 |
| 16. | Sudden emotional or physical reaction when reminded of the most hurtful or traumatic events | 1 | 2 | 3 | 4 |
| 17. | Feeling that you have less skills than you had before | 1 | 2 | 3 | 4 |
| 18. | Having difficulty dealing with new situations | 1 | 2 | 3 | 4 |
| 19. | Feeling exhausted | 1 | 2 | 3 | 4 |
| 20. | Bodily pain | 1 | 2 | 3 | 4 |
| 21. | Troubled by physical problem(s) | 1 | 2 | 3 | 4 |
| 22. | Poor memory | 1 | 2 | 3 | 4 |
| 23. | Finding out or being told by other people that you have done something that you cannot remember | 1 | 2 | 3 | 4 |
| 24. | Difficulty paying attention | 1 | 2 | 3 | 4 |
| 25. | Feeling as if you are split into two people and one of you is watching what the other is doing | 1 | 2 | 3 | 4 |
| 26. | Feeling unable to make daily plans | 1 | 2 | 3 | 4 |

| | | Not at all | A little | Quite a bit | Extremely |
|-----|--|------------|----------|-------------|-----------|
| 27. | Blaming yourself for things that have happened | 1 | 2 | 3 | 4 |
| 28. | Feeling guilty for having survived. | 1 | 2 | 3 | 4 |
| 29. | Hopelessness. | 1 | 2 | 3 | 4 |
| 30. | Feeling ashamed of the hurtful or traumatic events that have happened to you | 1 | 2 | 3 | 4 |
| 31. | Feeling that people do not understand what happened to you. | 1 | 2 | 3 | 4 |
| 32. | Feeling others are hostile to you | 1 | 2 | 3 | 4 |
| 33. | Feeling that you have no one to rely upon | 1 | 2 | 3 | 4 |
| 34. | Feeling that someone you trusted betrayed you | 1 | 2 | 3 | 4 |
| 35. | Feeling humiliated by your experience. | 1 | 2 | 3 | 4 |
| 36. | Feeling no trust in others. | 1 | 2 | 3 | 4 |
| 37. | Feeling powerless to help others. | 1 | 2 | 3 | 4 |
| 38. | Spending time thinking why these events happened to you | 1 | 2 | 3 | 4 |
| 39. | Feeling that you are the only one that suffered these events. | 1 | 2 | 3 | 4 |
| 40. | Feeling a need for revenge. | 1 | 2 | 3 | 4 |

PART 5: SCORING PART 4 --TRAUMA SYMPTOMS

Add up item scores and divide by the total number of the answered items.

$$\text{DSM-IV Score} = \frac{\text{ITEMS 1-16}}{16} \rightarrow$$

$$\text{TOTAL Score} = \frac{\text{ITEMS 1-40}}{40} \rightarrow$$

Individuals with scores on DSM-IV and/or total > 2.5 are considered symptomatic for PTSD

Appendix: Torture History

Now I would like to ask you about events that many people consider torture. I will ask you whether an event occurred; please answer yes or no.

| | | |
|---|-----|----|
| 1. Beating, kicking, striking with objects | YES | NO |
| 2. Threats, humiliation | YES | NO |
| 3. Being chained or tied to others | YES | NO |
| 4. Exposed to heat, sun, strong light | YES | NO |
| 5. Exposed to rain, body immersion, cold | YES | NO |
| 6. Placed in a sack, box, or very small space | YES | NO |
| 7. Drowning, submersion of head in water | YES | NO |
| 8. Suffocation | YES | NO |
| 9. Overexertion, hard labor | YES | NO |
| 10. Exposed to unhygienic conditions conducive to infections or other diseases | YES | NO |
| 11. Blindfolding | YES | NO |
| 12. Isolation, solitary confinement. | YES | NO |
| If yes, how long? <input type="text"/> <input type="text"/> months <input type="text"/> <input type="text"/> weeks <input type="text"/> <input type="text"/> days | | |
| 13. Mock execution | YES | NO |
| 14. Made to witness other being tortured | YES | NO |
| 15. Starvation | YES | NO |
| 16. Sleep deprivation | YES | NO |
| 17. Suspension from a rod by hands and feet | YES | NO |
| 18. Rape, mutilation of genitalia | YES | NO |
| 19. Burning | YES | NO |
| 20. Beating the soles of the feet with rods | YES | NO |
| 21. Blows to the ears | YES | NO |
| 22. Forced standing | YES | NO |
| 23. Throwing urine or feces at victim or being made to throw it at other prisoners | YES | NO |
| 24. Medicine administration (non-therapeutic) | YES | NO |
| 25. Needles under toes or fingernails | YES | NO |
| 26. Writing confessions numerous times | YES | NO |
| 27. Shocked repeatedly by electric instrument | YES | NO |
| 28. Other (specify): | YES | NO |

Figure B7*English version of the Brief Resilience Scale (BRS)***Instructions**

| Please respond to each item by marking <u>one box per row</u> . | | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|---|---|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| BRS 1 | I tend to bounce back quickly after hard times | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| BRS 2 | I have a hard time making it through stressful events. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 |
| BRS 3 | It does not take me long to recover from a stressful event. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| BRS 4 | It is hard for me to snap back when something bad happens. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 |
| BRS 5 | I usually come through difficult times with little trouble. | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| BRS 6 | I tend to take a long time to get over setbacks in my life. | <input type="checkbox"/> 5 | <input type="checkbox"/> 4 | <input type="checkbox"/> 3 | <input type="checkbox"/> 2 | <input type="checkbox"/> 1 |

Scoring

Add the responses varying from 1-5 for all six items giving a range from 6-30. Divide the total sum by the total number of questions answered.

My score: ____ item average / 6

Figure B8

English version of the Generalized Self-Efficacy Scale (GSE)

| | Not at all true | Hardly true | Moderately true | Exactly true |
|--|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. I can always manage to solve difficult problems if I try hard enough | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. If someone opposes me, I can find the means and ways to get what I want. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. It is easy for me to stick to my aims and accomplish my goals. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. I am confident that I could deal efficiently with unexpected events. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Thanks to my resourcefulness, I know how to handle unforeseen situations. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. I can solve most problems if I invest the necessary effort. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. I can remain calm when facing difficulties because I can rely on my coping abilities. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. When I am confronted with a problem, I can usually find several solutions. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. If I am in trouble, I can usually think of a solution | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. I can usually handle whatever comes my way. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Scoring

The total score is calculated by finding the sum of the all items. For the GSE, the total score ranges between 10 and 40, with a higher score indicating more self-efficacy.

Figure B9

English version of the Strengths and Difficulties Questionnaire (SDQ)

Instructions

For each item, please mark the box for Not True, Somewhat True or Certainly True. It would help us if you answered all items as best you can even if you are not absolutely certain. Please give your answers on the basis of how things have been for you over the last six months.

| | Not True | Somewhat True | Certainly True |
|--|----------|---------------|----------------|
| I try to be nice to other people. I care about their feelings | | | |
| I am restless, I find it hard to sit down for long | | | |
| I get a lot of headaches, stomach-aches or sickness | | | |
| I usually share with others, for example food or drink | | | |
| I get very angry and often lose my temper | | | |
| I would rather be alone than with other people | | | |
| I am generally willing to do what other want | | | |
| I worry a lot | | | |
| I am helpful if someone is hurt, upset or feeling ill | | | |
| I am constantly fidgeting or squirming | | | |
| I have at least one good friend | | | |
| I fight a lot. I can make other people do what I want | | | |
| I am often unhappy, depressed or tearful | | | |
| Other people generally like me | | | |
| I am easily distracted, I find it difficult to concentrate | | | |
| I am nervous in new situations. I easily lose confidence | | | |
| I am kind to children | | | |
| I am often accused of lying or cheating | | | |
| Other people pick on me or bully me | | | |
| I often offer to help others (family members, friends, colleagues) | | | |
| I think before I do things | | | |
| I take things that are not mine from home, work or elsewhere | | | |
| I get along better with older people than with people my own age | | | |
| I have many fears, I am easily scared | | | |
| I finish the work I'm doing. My attention is good | | | |

Figure B10

English version of the World Health Organization Quality of Life Questionnaire, brief version (WHOQoL-BREF)

Instructions

This questionnaire asks how you feel about your quality of life, health, or other areas of your life. Please answer all the questions. If you are unsure about which response to give to a question, please choose the one that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the last two weeks. For example, thinking about the last two weeks, a question might ask:

You should circle the number that best fits how much support you got from others over the last two weeks. So you would circle the number 4 if you got a great deal of support from others.

| | Not at all | A little | Moderately | Mostly | Completely |
|---|------------------|-------------|------------|--------|------------|
| Do you get the kind of support from others that you need? | 1 | 2 | 3 | 4 | 5 |

You would circle number 1 if you did not get any of the support that you needed from others in the last two weeks.

| | Not at all | A little | Moderately | Mostly | Completely |
|---|------------------|-------------|------------|--------|------------|
| Do you get the kind of support from others that you need? | 1 | 2 | 3 | 4 | 5 |
| | Not at all | A little | Moderately | Mostly | Completely |
| Do you get the kind of support from others that you need? | 1 | 2 | 3 | 4 | 5 |

Please read each question, assess your feelings, and circle the number on the scale that gives the best answer for you for each question.

| | Very poor | Poor | Neither poor nor good | Good | Very good |
|---|----------------|--------------|------------------------------------|-----------|-------------------|
| 1. How would you rate your quality of life? | 1 | 2 | 3 | 4 | 5 |
| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very Satisfied |
| 2. How satisfied are you with your health? | 1 | 2 | 3 | 4 | 5 |
| | Not at all | A little | A moderate amount | Very much | An extreme amount |
| 3. To what extent do you feel that physical pain prevents you from doing what you need to do? | 1 | 2 | 3 | 4 | 5 |

The following questions ask about **how much** you have experienced certain things in the last two weeks.

| | Not at all | A little | A moderate amount | Very much | An extreme amount |
|---|------------|----------|-------------------|-----------|-------------------|
| 4. How much do you need any medical treatment to function in your daily life? | 1 | 2 | 3 | 4 | 5 |
| | Not at all | A little | A moderate amount | Very much | An extreme amount |
| 5. How much do you enjoy life? | 1 | 2 | 3 | 4 | 5 |

| | Not at all | A little | A moderate amount | Very much | An extreme amount |
|---|------------|----------|-------------------|-----------|-------------------|
| 6. To what extent do you feel your life to be meaningful? | 1 | 2 | 3 | 4 | 5 |
| | Not at all | Slightly | A moderate amount | Very much | Extremely |
| 7. How well are you able to concentrate? | 1 | 2 | 3 | 4 | 5 |
| | Not at all | Slightly | A moderate amount | Very much | Extremely |
| 8. How safe do you feel in daily life? | 1 | 2 | 3 | 4 | 5 |
| | Not at all | Slightly | A moderate amount | Very much | Extremely |
| 9. How healthy is your physical environment? | 1 | 2 | 3 | 4 | 5 |

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

| | Not at all | A little | Moderately | Mostly | Completely |
|--|------------|----------|------------|--------|------------|
| 10. Do you have enough energy for everyday life? | 1 | 2 | 3 | 4 | 5 |
| | Not at all | A little | Moderately | Mostly | Completely |
| 11. Are you able to accept your bodily appearance? | 1 | 2 | 3 | 4 | 5 |
| | Not at all | A little | Moderately | Mostly | Completely |
| 12. Have you enough money to meet your needs? | 1 | 2 | 3 | 4 | 5 |

| | Not at all | A little | Moderately | Mostly | Completely |
|--|------------|----------|------------|--------|------------|
| 13. How available to you is the information that you need in your day-to-day life? | 1 | 2 | 3 | 4 | 5 |

| | Not at all | A little | Moderately | Mostly | Completely |
|--|------------|----------|------------|--------|------------|
| 14. To what extent do you have the opportunity for leisure activities? | 1 | 2 | 3 | 4 | 5 |

| | Very poor | Poor | Neither poor nor well | Well | Very well |
|--|-----------|------|-----------------------|------|-----------|
| 15. How well are you able to get around? | 1 | 2 | 3 | 4 | 5 |

The following questions ask you to say how **good** or **satisfied** you have felt about various aspects of your life over the last two weeks.

| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
|--|----------------|--------------|------------------------------------|-----------|----------------|
| 16. How satisfied are you with your sleep? | 1 | 2 | 3 | 4 | 5 |

| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
|--|----------------|--------------|------------------------------------|-----------|----------------|
| 17. How satisfied are you with your ability to perform daily activities? | 1 | 2 | 3 | 4 | 5 |

| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
|--|----------------|--------------|------------------------------------|-----------|----------------|
| 18. How satisfied are you with your capacity for work? | 1 | 2 | 3 | 4 | 5 |

| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
|--|----------------|--------------|------------------------------------|-----------|----------------|
| 19. How satisfied are you with yourself? | 1 | 2 | 3 | 4 | 5 |

| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
|---|----------------|--------------|------------------------------------|-----------|----------------|
| 20. How satisfied are you with your personal relationships? | 1 | 2 | 3 | 4 | 5 |

| | | | | | |
|---|----------------|--------------|------------------------------------|-----------|----------------|
| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
| 21. How satisfied are you with your sex life? | 1 | 2 | 3 | 4 | 5 |
| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
| 22. How satisfied are you with the support you get from your friends? | 1 | 2 | 3 | 4 | 5 |
| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
| 23. How satisfied are you with the condition of your living place? | 1 | 2 | 3 | 4 | 5 |
| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
| 24. How satisfied are you with your access to health services? | 1 | 2 | 3 | 4 | 5 |
| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
| 25. How satisfied are you with your mode of transportation? | 1 | 2 | 3 | 4 | 5 |

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

| | Very satisfied | Dissatisfied | Neither satisfied nor dissatisfied | Satisfied | Very satisfied |
|--|----------------------|--------------|---|-----------|-------------------|
| 26. How often do you have negative feelings, such as blue mood, despair, anxiety, depression? | 1 | 2 | 3 | 4 | 5 |
| Did someone help you to fill out this form? <i>(Please circle Yes or No)</i> | | | Yes | No | |
| How long did it take to fill out this form? | <input type="text"/> | | | | |

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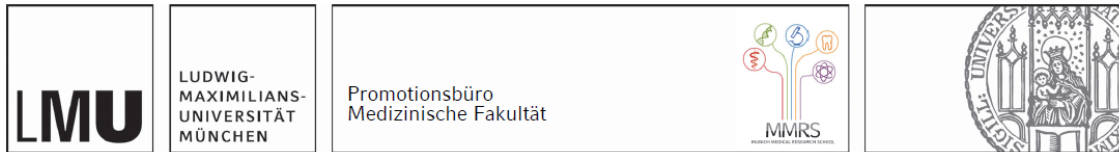
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Affidavit**Eidesstattliche Versicherung**

Strupf, Michael

Ich erkläre hiermit an Eides statt, dass ich die vorliegende Dissertation mit dem Titel:

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Empowerment for refugees with affective disorders:
A multicenter randomized controlled trial

selbständig verfasst, mich außer der angegebenen keiner weiteren Hilfsmittel bedient und alle Erkenntnisse, die aus dem Schrifttum ganz oder annähernd übernommen sind, als solche kenntlich gemacht und nach ihrer Herkunft unter Bezeichnung der Fundstelle einzeln nachgewiesen habe.

Ich erkläre des Weiteren, dass die hier vorgelegte Dissertation nicht in gleicher oder in ähnlicher Form bei einer anderen Stelle zur Erlangung eines akademischen Grades eingereicht wurde.

München, 22.11.2022

Michael Strupf

Ort, Datum

Michael Strupf

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