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From evidence collection and evaluation to new evidence production: a psychological focus on vulnerable populations

S.S.D. MED/25 - PSYCHIATRY

Coordinator: Prof. Michela Rimondini
Signature

Tutor: Prof. Marianna Purgato
Signature Firmato digitalmente da Marianna Purgato
Data: 07.05.2025 16:56:07 CEST

PhD Candidate: Dr. Camilla Cadorin
Signature

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LIST OF ABBREVIATIONS

ACT Acceptance and Commitment Therapy
AD Anxiety Disorders
ARMs Asylum Seekers, Refugees, and Migrants
BBAT Basic Body Awareness Therapy
CBT Cognitive Behaviour Therapy
CBT-BF Cognitive Behaviour Therapy - BioFeedback
CMDs Common Mental Disorders
COVID-19 Coronavirus Disease 2019
cNMA Component Network Meta-Analysis
CPT Cognitive Processing therapy
DALYs Disability-Adjusted Life Years
DIME Design, Implementation, Monitoring, and Evaluation'
DWM Doing What Matters in Time of Stress
EMDR Eye Movement Desensitization and Reprocessing
EQ-5D-5L EuroQol – 5-Dimension – 5-Level
GAD Generalized Anxiety Disorder
GAD-7 Generalized Anxiety Disorder
GBD Global Burden of Disease
GRID Global Report on Internal Displacement
HICs High-Income Countries
IASC Inter-Agency Standing Committee
iCBT internet-based Cognitive Behaviour Therapy
IDMC Internal Displacement Monitoring Centre
IDP Internally Displaced Person
IOM International Organization of Migration
IPD Individual Participant Data
IPT Interpersonal therapy
IRT Imagery Rehearsal Therapy
KIDNET Narrative Exposure Therapy for Children
LMICs Low- and Middle-Income Countries

MARD Meta-Analytic Research Domain

MDD Major Depressive Disorder

mhGAP Mental Health Gap Action Programme

MHPSS Mental Health and Psychosocial Support

MIMIS Mainz Inventory of Micro Stressors

NET Narrative Exposure Therapy

PCL-5 PTSD Checklist for DSM-5

PHEIC Public Health Emergency of International Concern

PHQ-9 Patient Health Questionnaire-9

PHQ-ADS Patient Health Questionnaire Anxiety and Depression Scale

PICO Participants, Intervention, Comparator, Outcome

PM+ Problem Management Plus

PMLDs Post-Migration Living Difficulties

PRISMA Preferred Reporting Items for Systematic reviews and Meta-analyses

PST Problem-Solving Therapy

PSYCHLOPS Psychological Outcome Profiles

PTSD Post-Traumatic Stress Disorder

RAS Refugees and Asylum Seekers

RCT Randomized Controlled Trial

RESPOND Preparedness of Health Systems to Reduce Mental Health and Psychosocial Concerns Resulting from the Covid-19 Pandemic

ROB-2 Risk Of Bias tool - version 2

SARS-CoV-2 Severe Acute Respiratory Syndrome – Coronavirus - 2

SDG Sustainable Developmental Goals

SIT Stress Inoculation Training

ST Stabilization therapy

TRT Teaching Recovery Technique

UNDESA United Nations - Department of Economic and Social Affairs

UNHCR United Nations High Commissioner for Refugees

WB World Bank

WHO World Health Organization

ABSTRACT

The wide range of potentially traumatic events that migrant populations may experience before, during, and after the migration process has been proven to have detrimental effects on mental health, including the increased risk for developing common mental disorders, such as anxiety, depression and post-traumatic stress disorder. Migrant's mental health is a public health concern, which needs to be adequately considered and addressed because of its broader and multi-level implications. Many studies have been conducted in the last years to address mental health problems experienced by migrant populations; nevertheless, a comprehensive synthesis of this whole research field is still lacking.

The present research project has been developed following two interrelated phases, 'collecting and assessing evidence' and 'producing new evidence'. The first phase aimed at developing a living and comprehensive systematic database of randomized controlled trials testing psychosocial interventions for migrant populations. The second phase is focused on the implementation of a randomized controlled trial within the European-funded RESPOND project, to implement and evaluate the effectiveness of a stepped-care intervention composed of two World Health Organization intervention strategies. The aim was to reduce mental health and psychosocial burden of migrants, including distress resulting from the covid-19 pandemic.

From a systematic search of nine databases up to January 2024, 149 studies were included in the living database. The majority of studies primarily focused on adult participants, mainly females. Studies mostly focused on forced migrants, such as refugees and asylum seekers, primarily originated from the Middle East and East Asia, and resettled to Europe and North America. By comparing the characteristics of these studies with the global epidemiological figures on migrant populations and migration flows, some important gaps between existing evidence and real-word data emerged. This is especially evident for age, gender, specific type of migrant populations, and countries of origin and resettlement involved in migratory processes.

The present work can guide future research to better understand and address the psychosocial needs of this vulnerable and diverse population. First, by conducting systematic reviews and meta-analyses to study the effectiveness of existing intervention and second, by developing and implementing effective and targeted psychosocial interventions. Future research priorities should consider age and gender disparities, diversify study populations in terms of reasons for displacement and mental health status, explore new delivery approaches, and take into consideration the global representation of migration. Ensuring data quality and real-time updates are important as well. This will, in turn, reflect more broadly on the development and application of policies and guidelines specifically designed to address migrants needs and vulnerabilities, both at national and international levels.

Keywords: migration, living database, randomized controlled trial, psychosocial intervention, mental health, epidemiological data

SUMMARY (Italian)

L'ampia gamma di eventi potenzialmente traumatici che le popolazioni migranti possono sperimentare prima, durante e dopo il processo migratorio ha effetti potenzialmente dannosi sulla salute mentale, determinando un aumento del rischio di sviluppare condizioni cliniche come ansia, depressione e disturbo da stress post-traumatico. La salute mentale dei migranti si dovrebbe configurare come un problema di salute pubblica, e dovrebbe essere adeguatamente considerato e affrontato a causa delle sue implicazioni più ampie e a più livelli, anche a fronte del crescente numero di migranti in tutto il mondo. Negli ultimi anni sono stati condotti molti studi focalizzati sui problemi di salute mentale delle popolazioni migranti; tuttavia, manca ancora una sintesi completa delle evidenze.

Il presente progetto di ricerca è stato sviluppato seguendo due fasi interconnesse, "raccolta e valutazione delle evidenze" e "produzione di nuove evidenze". La prima fase mirava a sviluppare un database sistematico di studi randomizzati e controllati che testavano interventi psicosociali per le popolazioni migranti. La seconda fase si è concentrata sull'implementazione di uno studio randomizzato controllato nell'ambito del progetto RESPOND, finanziato dall'Unione Europea, per implementare e valutare l'efficacia di un programma composto di due interventi psicologici sviluppati dall'Organizzazione Mondiale della Sanità per ridurre il disagio mentale e il carico psicosociale dei migranti.

Dalla ricerca sistematica di nove banche dati fino a gennaio 2024, sono stati inclusi 149 studi. La maggior parte degli studi si è concentrata sulla popolazione adulta, con una maggioranza femminile. In termini di tipologia di popolazione migrante, gli studi si sono concentrati soprattutto sui migranti 'forzati' come rifugiati e richiedenti asilo, provenienti principalmente dal Medio Oriente e dall'Asia orientale e reinsediati in Europa e Nord America. Confrontando le caratteristiche di questi studi con i dati epidemiologici globali sulle popolazioni migranti e sui flussi migratori, sono emerse alcune importanti lacune tra le evidenze derivanti dalla ricerca e i dati reali. Ciò è particolarmente evidente per l'età, il sesso, il tipo specifico di popolazione migrante e i paesi di origine e di reinsediamento coinvolti nei processi migratori. Il presente lavoro può, dunque, guidare la ricerca futura per

comprendere meglio e affrontare i bisogni psicosociali di questa popolazione vulnerabile e diversificata, in primo luogo conducendo revisioni sistematiche e meta-analisi per studiare l'efficacia degli interventi esistenti e, successivamente, sviluppando e implementando interventi psicosociali più efficaci e mirati. Le priorità della ricerca futura potrebbero considerare le disparità di età e di genere, la diversificazione delle popolazioni oggetto di studio in relazione alle ragioni della migrazione e allo stato di salute mentale, i nuovi approcci per l'erogazione degli interventi ed il fenomeno migratorio in generale. Sarebbe inoltre importante valutare la qualità dei dati e di aggiornarli in tempo reale. Questo, a sua volta, potrebbe avere un impatto sullo sviluppo e sull'applicazione di politiche e linee guida specificamente progettate per affrontare i bisogni e le vulnerabilità psicologiche dei migranti, sia a livello nazionale che internazionale.

Parole chiave: migrazione, database, studio controllato randomizzato, intervento psicosociale, salute mentale, dati epidemiologici

INTRODUCTION

CHAPTER 1 - BACKGROUND: VULNERABILITY IN RESEARCH

1.1 Vulnerability, Migration and Mental Health

1.1.1 Vulnerable Populations

Vulnerability denotes the "quality or state of being exposed to the possibility of being attacked or harmed, either physically or emotionally" (Oxford University Press, 2020). It is a key term in global mental health research, which primarily aims to address and fill the gaps in providing and improving mental health care for all people worldwide. Following the World Health Organization (WHO) definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO, 1948), it can be seen how the consequences of vulnerability affect individuals in terms of health, both physical and mental, as well as society, by creating vicious cycles of inequities and disadvantages (WHO, 2022a).

In mental health research, the term vulnerability identifies specific study populations, exposed to a wide range of risk factors: from socio-demographic characteristics like age, gender, health, and socio-economic status, to socio-cultural and geographical contexts, as living and working conditions, as well as stressors' exposures. Hence, vulnerable populations comprise the "economically disadvantaged, racial and ethnic minorities, the uninsured, low-income children, the elderly, the homeless, those with chronic health conditions, including mental health disorders" (AJMC, 2006).

Migrant populations are included in this category, presenting individual vulnerabilities related to the context of origin and to the migration process. Usually,

they are part of ethnic minorities, originating from humanitarian or low-resourced settings, with an history of trauma exposure and higher risk of mental health conditions, and, additionally, they endorse multiple challenges in the different phases of the migration process. In the present work, the term migrant refers to people who move from their country of origin for different reasons, including any type of forced or unforced migrants (i.e., refugees, asylum seekers, labor migrants, unaccompanied minors, internally displaced persons, economic migrants). As specified in the International Organization for Migration (IOM) glossary (2019), migrant is "an umbrella term, not defined under international law, reflecting the common lay understanding of a person who moves away from his or her place of usual residence, whether within a country or across an international border, temporarily or permanently, and for a variety of reasons" (IOM, 2019). The United Nations - Department of Economic and Social Affairs (UNDESA), on the other hand, defines 'international migrant' as "any person who changes his or her country of usual residence", excluding movements that are due to "recreation, holiday, visits to friends and relatives, business, medical treatment or religious pilgrimages" (IOM, 2019). Therefore, an inclusivist approach is followed, with migration being "the movement of persons away from their place of usual residence, either across an international border or within a State" (IOM, 2019), as opposed to the residualist approach, proposed by the United Nations High Commissioner for Refugees (UNHCR), which would not consider forced migration (i.e., people fleeing war or persecution) within the definition (Carling, 2017, 2023).

1.1.2 Migration Process and Risk Factors

Migrants are considered vulnerable populations exposed to multiple risk factors related to the migration process. There is a wide range of potentially traumatic events that can be experienced before, during and after migration, such as poverty, trauma, violence, economic difficulties, linguistic barriers, and discrimination (WHO, 2022b; Hebebrand et al., 2015; Jannesari et al., 2020; Carroll et al., 2020). Pre-migration factors could include war, poverty, trauma, disasters, violence, and living in humanitarian settings; and this is especially true for forced migration

(Hebebrand et al., 2015; Van Ommeren and Wessells, 2007). During migration people could be exposed to hardship, losses, imprisonment, multiple displacements, and traumatic events. Post-migration factors, as linguistic barriers, work and economic hardship, administrative and legal procedures, and discrimination, play a fundamental role, potentially affecting the integration process also in terms of mental and social wellbeing (WHO, 2022b; Jannesari et al., 2020; Hynie et al., 2018; see paragraph 1.1.3 for implications of post-migration factors for mental health). These potentially traumatic factors across all phases of the migration process are especially marked in case of forced migration, with refugees and asylum seekers being at heightened risk of negative consequences for mental health (Carroll et al., 2023). Wicki and colleagues (2021) conducted a network analysis to study the inter-relationships of postmigration living difficulties (PMLDs) in refugees and asylum seekers finding a strong association of communication difficulties and discrimination, and a high predictability of isolation and loneliness. Hebebrand and colleagues (2015) investigated the pre, during and post migration factors for young refugees resettled in Europe, underscoring the importance, for mental health professionals, to understand all these factors when planning reception services. The potentially traumatic events experienced pre-migration, commonly related to poverty, war, or war-like exposures, largely depend on the countries of origin, whereas education, social status, familial, religious, and sociocultural values will determine coping and help-seeking behaviors. The flight itself can be traumatic given the likelihood of separation, abuse, and trafficking experiences. Finally, "the arrival in the hosting country entails risks due to unsafe or problematic living conditions, lack of access to schooling, insecurity about the migration/ legal status, multiple moves, parental illness and unemployment, social exclusion. In the medium- and long-term migrants may experience maladaptation with respect to the cultural norms of the hosting country" (Hebebrand et al., 2015).

Bhugra and colleagues (2014) examined the motivations at the basis of the migration process, classifying them into push and pull factors, to differentiate between forced and voluntary migration. Pull factors include educational or economic growth or personal factors (i.e., family situation, personal economic and job opportunities), while push factors include political instability, poverty,

terrorism, displacement, war, or religious factors. Therefore, pull factors are linked to voluntary migration, whereas push factors are the trigger point for forced migration. Push factors can, then, be related to the concept of humanitarian settings which are places and populations affected by a broad range of disasters and armed conflicts (Tol et al., 2015). The exposure to these contexts has been linked to poverty, intimate partner violence, disrupted health and education systems, and degradation of social and moral links of communities (Tol et al., 2015; WHO, 2022a).

There are additional risk factors related to the personal and social context, which play a role in the migration process and outcomes, and that can be synthesized in the framework of the social determinants of health (Lund et al., 2018; Allen et al., 2014; Patel et al., 2018; WHO, 2022a). As stated by the WHO Commission on Social Determinants of Health (WHO, 2008a), the social determinants are the conditions in which people are born, live, work, age, which are shaped by the economic, social, environmental and health policies and politics (Lund et al., 2018; WHO, 2008a). These include both proximal and distal factors, depending on the level at which these factors influence people's lives, whether directly at individual level, or at a broader societal and political level. Poverty, income inequality, interpersonal and collective violence, as well as forced migration are found to be key determinants of mental health (Lund et al., 2018). Vulnerability, then, is intertwined with living unfavorable conditions as household income, low educational attainment, material disadvantages, unemployment, social isolation, and gender inequities. The social determinants' framework connects individual risk and protective factors to broader social, economic, and political factors in determining material and social post-migration living conditions. Therefore, risk factors for mental health are heavily associated with these social inequalities which are systematic, unfair, socially produced, but modifiable elements that can be found both between and within countries, often following a social gradient (Lund et al., 2018; WHO, 2022a).

The social determinants have been incorporated into the Sustainable Developmental Goals (SDG), a 17-points program for the 'Agenda 2030', an ambitious global developmental plan lead by the UN (Lund et al., 2018). Briefly, the 17 SDGs are

the following: ‘no poverty’ (SDG 1), ‘zero hunger’ (SDG 2), ‘good health and well-being’ (SDG 3), ‘quality education’ (SDG 4), ‘gender equality’ (SDG 5), ‘clean water and sanitation’ (SDG 6), ‘affordable and clean energy’ (SDG 7), ‘decent work and economic growth’ (SDG 8), ‘industry, innovation and infrastructure’ (SDG 9), ‘reduced inequalities’ (SDG 10), ‘sustainable cities and communities’ (SDG 11), ‘responsible consumption and production’ (SDG 12), ‘climate action’ (SDG 13), ‘life below water’ (SDG 14), ‘life on land’ (SDG 15), ‘peace, justice, and strong institutions’ (SDG 16), and ‘partnerships for the goals’ (SDG 17). The SDGs are theoretically based on the Bronfenbrenner’s bio-ecological approach (Bronfenbrenner, 1974, 1994; Lund et al., 2018), and goals are thus divided into six domains, namely demographic, economic, neighborhood, environmental events, social and cultural, mimicking the different socio determinants’ levels of health (Patel et al., 2018). Under the SDG 3, mental health care is directly included in terms of universal health coverage with a ‘mental health for all’ approach, highlighting the need to consider health as oneness, also in face of vulnerabilities (WHO, 2022a; Abubkar et al., 2018).

1.1.3 Mental Health of Migrant Populations and the Link with Trauma Exposure

Vulnerability can be conceived as a linking concept between populations’ characteristics and mental health outcomes. In many low-resources contexts, psychosocial distress caused by war, ongoing conflicts, lack of security, and limited resources intensifies mental suffering and diseases. Hardships and challenges faced during the entire migration process have been proven to have detrimental effects on mental health, including the increased risk for developing common mental disorders (CMDs). Symptoms like depression, anxiety, post-traumatic stress are shown to be heightened, while psychological wellbeing and quality of life often decrease (Carroll et al., 2023; WHO, 2022b).

As outlined by Hynie and colleagues (2018) pre-migration trauma predicts mental disorders and post-traumatic stress disorder (PTSD) in refugee populations, whereas post-migration factors may moderate the ability to recover from pre-

migration trauma. Particularly, low socio-economic status and increased length of displacement is associated with poorer mental health outcomes. Less favorable personal, economic, social, and environmental conditions and opportunities tend to result in experiences of accumulative stress that are, in turn, worsen by access to fewer resources which act as buffers. Therefore, refugee mental health is highly influenced by post-migration conditions in terms of material and personal variables, such as prolonged material deprivation, uncertainty, income, economic opportunities (right to work, access to employment, socioeconomic status), housing and living conditions, language skills, asylum seeking process, social exclusion, isolation, lack of social support and discrimination (Hynie et al., 2018). Post-migration living difficulties (PMLDs) have, indeed, been acknowledged as critical moderator factors of mental health outcomes (Porter and Haslam, 2005; Jannesari et al., 2020, Wicki et al., 2021; Lotito et al., 2023).

A recent systematic review of epidemiological studies by Carroll and colleagues (2023) reported on prevalence of common mental disorders (anxiety, depression, and PTSD) in international migrants, forced and voluntary, in all income countries. The prevalence of mental health problems in migrant populations has shown that PTSD was the most common diagnostic category (31.33%, ranging from 26.47% to 36.20%), followed by depression (28.65%, ranging from 25.28% to 32.39%) and anxiety (24.69%, ranging from 19.45% to 30.82%) (Carroll et al., 2023). Significant differences emerged when considering forced and voluntary migrants separately, with a higher prevalence of mental health problems among forced migrants than among voluntary migrants. The prevalence of CMDs, indeed, ranged from 10.71% to 34% for anxiety, 20.86% to 36% for depression and 6.13% to 34.46% for PTSD, whether considering voluntary migrants or forced migrants, respectively. There was also a difference in the prevalence of CMDs depending on the use of a diagnostic interview or a questionnaire, with rates almost doubled when participants were screened with questionnaires (Carroll et al., 2023).

Other reviews of prevalence studies have been conducted, specifically focused on different migrant sub-populations. Hasan and colleagues (2021) analyzed migrant workers, whose prevalence of depression and anxiety was nearly 40% and 30%, respectively. In irregular migrants resettled in European countries prevalence data

could not be pooled due to high heterogeneity, however the majority of included studies found higher prevalence rates of depression, anxiety, and PTSD than previous estimates for the general population. In refugee and asylum seeker populations, Patanè and colleagues (2022) found a prevalence of 32% for depression (major depressive disorder, MDD) and 31% for PTSD, 5% bipolar disorders and 1% for psychotic disorders. These prevalence data confirmed those of Blackmore and colleagues (2020), who additionally found a prevalence of 11% for anxiety disorders. Similar figures were obtained by Henkelmann and colleagues (2020) for PTSD, depression and anxiety disorders for asylum seekers/refugees resettling in high-income countries (HICs). In migrants exposed to armed conflict Mesa-Vieira and colleagues (2022), who conducted a systematic review of 34 prevalence studies, found a frequency of 31% for PTSD, 25% for major depressive disorder (MDD), and 14% for generalized anxiety disorder (GAD). Studies conducted in unaccompanied refugee minors suggested a high prevalence of mental health conditions in children and adolescents, which varied considerably between studies, ranging from 4.6% to 43% for PTSD, 2.9% to 61.6% for depression, 32.6% to 38.2% for anxiety and 4% to 14.3% for behavioural problems (Hutchinson et al., 2022).

Nevertheless, the migration process and, in general, the exposure to humanitarian settings itself, is not automatically linked to detrimental effects on mental health. Three main trajectories could derive from the exposure to humanitarian settings: 1) significant psychological distress, 2) resilience, or 3) post-traumatic growth (Tol et al., 2015). The first gives the path to mental health disorders, as PTSD, depression, and anxiety disorders, as well as substance use, somatoform disorders and worsening of pre-existing severe mental health conditions (i.e., schizophrenia, psychotic disorders, bipolar disorders). Resilience is the capacity to adapt and maintain mental health, as well as to quickly recover from stressful situations, difficulties, and toughness (Aburn et al., 2016; Kalisch et al., 2015, 2017; Wessells, 2022, 2021, 2017, 2016; Bogdanov et al., 2021). The third category denotes people who will experience post-traumatic growth, namely a better psychological state, through an improvement in relationships, sense of life appreciation, personal strength, and fulfillment (Sivan, 2023; Xu and Liao, 2011).

Therefore, we always need to take into consideration that mental health outcomes are the result of the interplay between biological, psychological, and social factors (Tol et al., 2015). All this has practical implications when considering and developing interventions, particularly for these vulnerable populations. Addressing vulnerability factors, in terms of individual variables (i.e., age, gender, coping styles, mental health history, potentially traumatic events experienced), exposure to structural adversity (i.e., poverty, social marginalization, violence) and the recovery environment (i.e., support systems, living and work conditions), becomes of pivotal importance.

1.1.4 Covid-19 Pandemic, Mental Health and Migration

The Covid-19 (Coronavirus 2019) pandemic was an unprecedent global health threat determined by the spread of the SARS-CoV-2 (severe acute respiratory syndrome – coronavirus – 2) virus, affecting all countries worldwide from December 2019, with the first official case in China, until 2023, across different waves and peaks. Containment and stringency measures were implemented from March 2020 when the pandemic was officially declared as a Public Health Emergency of International Concern (PHEIC) by the WHO, becoming a humanitarian crisis (WHO, 2020). Those included social distance, closure of public spaces and activities, confinement at home, and utilization of individual protection measures (Onyeaka et al., 2021; Hale et al., 2021).

Therefore, the Covid-19 pandemic has led to changes in many areas of our daily lives, especially within the health sector (Onyeaka et al., 2021; Murray et al., 2024). In this context, mental health has been particularly affected, widening the pre-existing gap in care and, therefore, increasing health inequalities and marginalities (WHO, 2020, 2022a; Bower et al., 2023; Ahmed et al., 2023; Camara et al., 2023). The Global Burden of Disease (GBD) 2020 study estimated that the Covid-19 pandemic led to an increase of 27.6% for major depressive disorders (MDD) and 25.6% for anxiety disorders (AD), determining 137.1 and 116.1 additional disability-adjusted life years (DALYs) per 100 million population, respectively

(Santomauro et al., 2021). Some authors described the longitudinal impact of the pandemic on mental health as an “hidden pandemic” (Bower et al., 2023).

Identified risk factors contributing to mental health deterioration included both individual vulnerabilities and socio-demographic factors (WHO, 2022a; Melchior et al., 2021). Among individual vulnerabilities, pre-existing mental health problems, Covid-19 infection severity, as well as loneliness were found to be crucial (Weber et al., 2023; Melchior et al., 2021). On the other hand, for demographic risk factors (i.e., age, gender, socioeconomic status, education), young age and female gender were associated to worse mental health (Moulin et al., 2023; Kunzler et al., 2021). In turn, social support showed a protective role for CMDs symptoms; in particular, the availability of close confidants and accessible practical help led to improvements in depressive symptoms (i.e., depressed mood, anhedonia, and negative self-appraisals) by reducing loneliness (Li et al., 2023; Lahman et al., 2021).

The WHO also released a scientific brief to investigate, through an umbrella review methodology, the main consequences of pandemic on different aspects of mental health, from prevalence of mental health symptoms, suicidality, impact on people with pre-existing mental disorders, to changes in access to mental health services and intervention delivery (WHO, 2022a). It pointed out the disruption of outpatient mental health services, which led to a reduced access to essential care. This was partially mitigated by a shift to e-mental health care, with psychological interventions adapted to be delivered remotely. Nevertheless, e-health barriers, such as low levels of technological literacy, inadequate resources and privacy, and pre-existing inequalities prevented full implementation and acceptability (WHO, 2022a; Witteveen et al., 2022).

The disruption of mental health care and status is remarkably true for vulnerable populations, such as migrant workers and socio-economically deprived populations, given the presence of pre-existing risk factors, leading to multiple concerns about present and long-term effects on mental health status and wellbeing (Choudari et al., 2020; Aragona et al. 2021; Singh, 2020). Main affected groups by the Covid-19 pandemic were people with somatic and psychiatric comorbidities, young people, and women (particularly pregnant and postpartum women), frontline

healthcare workers, socio-economically disadvantaged and minority groups (Melchior et al., 2021). In this situation, asylum seekers, refugees, and migrants (ARMs) displayed higher levels of psychological distress (depression and anxiety) and experienced a deterioration of pre-existing psycho-morbidities (Aragona et al., 2021), even though some authors found migration status not to be a significant predictor of higher anxiety and depression symptoms (Gemés et al., 2022). Main problems faced by migrants during the pandemic were disrupted access to mental health services (Aragona et al., 2020) and treatment discontinuation, workplace discrimination (Noor et al., 2020) and lower occupational health, financial constraints, and job loss, worsening pre-existing concrete life problems, as unemployment or lack of visa, as well as adverse psychosocial factors such as the absence of family support and social exclusion (Choudari et al., 2020). Singh and colleagues (2020) reported consequences on migrant laborers in terms of loss of income and job, insecurities, and social isolation, pointing out that the Covid-19 pandemic determined a deterioration of all social determinants of health by an increase of social inequalities related to gender, education, race, income, language, customs, traditions, and areas of residence. Looking at the specific impact of the pandemic on Syrian refugees in Jordan, main worries deriving from the pandemic were economic difficulties, shortage of essential supplies, and fear of infecting others or themselves, whose predictors were low depression before and higher anxiety symptoms during the pandemic (Akhtar et al., 2021).

1.2 Mental Health and Psychosocial Support interventions

Many studies have been conducted in the last ten years to address mental health problems experienced by migrant populations (Cadorin et al., 2024; Barbui et al., 2020; Uphoff et al., 2020; Soltan et al., 2022). Most studies implemented evidence-based psychosocial interventions, and/or tested different delivery or implementation approaches, such as stepped-care and task-shifting models for the delivery of culturally adapted interventions (WHO, 2017b, 2018a, 2020; Schäfer et al., 2023a, 2023b; Purgato et al., 2023).

1.2.1 The Promotion, Prevention, and Treatment Continuum

A public mental health approach, which combines population demography with health science and practice, has been considered to classify psychosocial interventions along the promotion-to-treatment continuum, based on a set of criteria as established by the IOM and other frameworks (Eaton, 2019; Institute of Medicine, 1994, National Academies of Sciences, Engineering, and Sciences, 2019). On one side of the continuum, promotion aims at strengthening psychological wellbeing and positive mental health factors (e.g., self-esteem, resilience, pro-social behaviors), as well as at creating living conditions and environments that support mental health and encourage healthy lifestyles. At the other side, treatment targets a probable or confirmed diagnosis of mental health disorder, acting on symptoms and/ or prognostic factors. Prevention aims to reduce the likelihood of developing mental disorders, and it is further sub-divided into universal, selective, and indicated prevention (Institute of Medicine, 1994; Eaton 2019; Tol et al., 2015; Purgato et al., 2020). Universal prevention targets the whole population, with a focus on empowerment, education, and skill development to improve overall wellbeing and quality of life; selective prevention addresses specific categories of people presenting an increased risk for mental health, as being vulnerable populations; whereas, indicated prevention targets high-risk people with increased levels of distress and subthreshold symptoms that could eventually lead to a diagnosis. Prevention is, therefore, the intermediate step in the continuum from promotion to treatment. This classification encompasses the previous classification into primary, secondary, and tertiary prevention, which was more focused on the timing of the intervention than on the target population (Bloom and Gullotta, 2003; Kisling and Das, 2023). Primary prevention acts before the event occurs aiming to prevent disease or injury beforehand; secondary prevention aims to reduce the impact of a disease already occurred, whereas tertiary prevention operates to alleviate the long-lasting effects of a chronic disease (Bloom and Gullotta, 2003; Kisling and Das, 2023).

1.2.2 The 'Mental Health and Psychosocial Support' Framework

The Inter-Agency State Committee (IASC) developed the 'IASC guidelines' grouping psychosocial interventions in the 'Mental Health and Psychosocial Support' (MHPSS) framework, that is "a composite term used to describe any type of local or outside support that aims to protect or promote psychosocial well-being and/or prevent or treat mental disorder" (IASC, 2007). In the acronym MHPSS, all the components of the prevention continuum are present; firstly, 'MH', which stands for 'mental health programming', is based on a treatment model, with psychiatric or clinical interventions targeting mental health disorders to reduce symptoms and severity. On the other hand, 'PSS', or psychosocial support', is more related to the prevention of mental disorders and promotion of wellbeing, by working on risk factors and strengthening resilience and protective factors. This distinction is often made in humanitarian settings, where MHPSS framework is a core component of humanitarian response (Miller et al., 2021; Lee et al., 2019; Tol et al., 2015).

MHPSS was conceived as a multi-layered system, graphically represented as a four-layered pyramid (Figure 1). It is linked to the stepped care approach, in which people are offered broad and generic interventions as a first line of intervention, or more specific and targeted strategies in case they are still distressed. Following a funneled path, interventions start from basic services delivered to all people independently from specific individual vulnerabilities and risk factors until clinical and therapeutical services, going through community and family support and focused psychosocial support interventions (UNHCR, 2024).

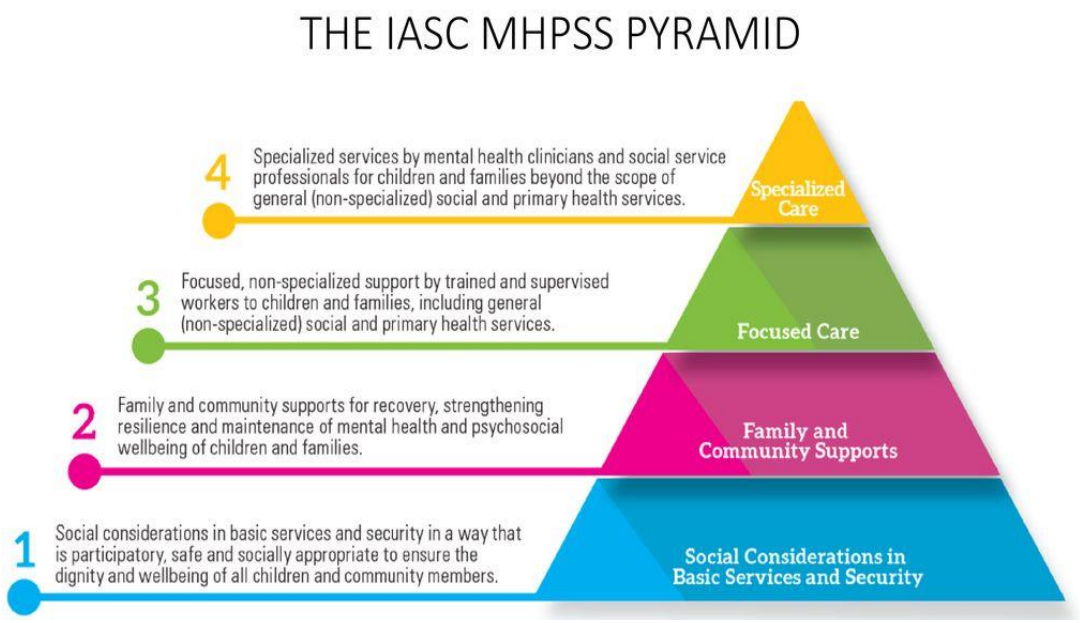
Starting from the bottom, the four layers of these scalable psychological programs, with emblematic examples from the WHO interventions, are:

1. basic services and security, aiming to protect the dignity and wellbeing of all people, in a participatory, rights-based, safe, and socially appropriate way (e.g., Psychological First Aid, PFA)
2. community and family support, aiming at the promotion and preservation of psychological wellbeing and mental health, by strengthening resilience,

social cohesion and coping mechanisms within and thanks to the communities themselves (e.g., Self Help Plus, SH+)

3. focused psychosocial support, in the form of non-specialized individual, family or group support interventions. They are usually related to general social and primary health services and delivered by trained and supervised workers to people in difficulty to cope within their own support network (e.g., Problem Management Plus, PM+)
4. Clinical mental health and psychosocial services delivered by mental health professionals (or by trained health workers) to people with sub-clinical symptoms or full-blown diagnoses (i.e., psychotherapies).

Figure 1: The MPHSS pyramid



Source: UNICEF, 2018.

1.2.3 Implementation Science: Intervention Perspectives in Global Mental Health

In the last years, research in global mental health has been primarily focusing on developing, implementing, and testing new approaches, or adapting already known evidence-based interventions (Singla et al., 2017; Van Ginneken et al. 2021; Purgato et al. 2020, 2021; Papola et al., 2023; Schäfer, 2023b; Barbui et al. 2020). This with the main aim to foster the implementability of psychosocial interventions, thus ensuring a broader reach of mental health care, as intended by the global SDGs (Patel et al., 2018; WHO, 2022a).

The core characteristics of these approaches are the following:

- scalability
- stepped care
- task-shifting
- evidence-based
- briefness
- feasibility and sustainability
- adaptability and flexibility
- use of technology
- cost-effectiveness and affordability.

Firstly, stepped care is a staged approach for the delivery of mental health services, which adopts different intervention strategies based on the needs and symptom severity of the target populations, starting from low-grade until high-intensity and resource-demanding interventions. This approach is at the foundations of the MHPSS pyramid, starting from self-delivered or low-intensity interventions for mild to moderate symptomatology, psychosocial therapy for more severe conditions, to end with specialist of physician consultation for very severe disorders (IASC, 2007; Singla et al., 2017; Barbui et al., 2020).

Secondly, scalable interventions enable to reach more people at lower costs through stepped-care approaches, guarantying basic health services and first-line interventions to as many people as possible (WHO, 2018a). This constitutes a research priority for psychosocial support programs in humanitarian settings, but

these approaches have been implemented also in high resourced settings to widen the accessibility to care, thus attempting to reduce health inequities and gaps in the healthcare systems (WHO, 2017b; Singla et al., 2017; Sijbrandij et al., 2017). Thirdly, task-sharing (or task-shifting) is the delivery of interventions by a non-specialist workforce (WHO, 2008b). Non-specialists could be lay people (volunteers, peers), paraprofessionals (e.g., trained lay health providers), community health workers (CHW) (e.g., trainers, social workers), and primary-level health workers (e.g., doctors, nurses, and other general health professionals). They undergo a training in the delivery of the intervention and basic psychological skills, and a constant supervision by mental health professionals before and during the intervention delivery. This approach is an essential component of mental health care delivery in low- and middle- income countries (LMICs), conceived as a means of improving access to healthcare in low-resourced settings in which availability of mental health professionals often lacks. In addition, the involvement of community workers and volunteers fosters acceptability and sustainability of interventions, given the pre-existing relationships within the community, which support trust building and reduction of help-seeking barriers (Singla et al., 2017; Barbui et al., 2020; Lee et al., 2019; Patel et al., 2018; Tol et al., 2015).

Fourthly, evidence-based interventions are chosen, primarily based on 'cognitive-behavioral therapy' (CBT) principles and techniques, and its developments and integrations, like 'acceptance and commitment therapy' (ACT) and mindfulness (Hayes, 2017; Hayes and Hofmann, 2021). Those intervention techniques are standardizable, brief and modular, and relatively easy to be taught and learnt, therefore conceived to be easily adapted and delivered. Consequently, a core feature of these approaches is their feasibility in a wide range of contexts and flexibility, given their contextual and cultural adaptability. Another key point is the adoption of new ways of intervention delivery that go beyond the traditional face-to-face interventions, thanks to the use of technology as online self-help or videoconference formats. This has also been fostered by the Covid-19 pandemic, with a general shift to e-mental health care, given its requirements of social distancing and home confinement (WHO, 2022a; Witteveen et al., 2022).

Finally, the focus on cost-effectiveness is related to the aim of delivering the highest-level effective interventions at the lowest costs, both economic and resource-related, thus improving affordability and sustainability, particularly relevant in humanitarian settings.

CHAPTER 2 - THE RESEARCH PROJECT: AIMS

2.1 Aims of the Thesis

The present thesis describes the development of a broad research project within the global mental health field, aiming at collecting, synthesizing, and updating the existing randomized evidence on psychosocial interventions for mental health of migrant populations. This work allowed comparisons with real-word data, identifying knowledge gaps, and informing future research directions. This also enabled the development of a randomized controlled trial, that was coordinated by the team at the University of Verona. The project consists in two phases 1) systematically collecting and assessing the evidence and 2) producing new evidence. These steps are respectively represented by the MARD migrants' database and the RESPOND randomized trial (see **Error! Reference source not found.** for an overview of their specific aims and sub-aims). The two research phases and designs mutually informed each other and they, in fact, be considered as "two sides of the same coin", given that they share a common goal in the research field, despite having different research methodologies, designs and specific aims.

The thesis could, therefore, be considered as a meta-research project. The meta-research approach, or "research on research", as conceived by Ioannidis (2018) at the Meta-Research Innovation Center at Stanford University (METRICS), is "the study of research itself: its methods, reporting, reproducibility, evaluation, and incentives" (Ioannidis, 2018). It is a relatively recent approach in research which aims to critically analyse the conduction of research itself, using an integrated and multidisciplinary approach to inform and plan future research accordingly.

Consequently, the present thesis is a more theoretical project, that does not present any statistical analysis of data on the effectiveness of interventions, in terms of meta-analysis or analysis of trial effectiveness; but, in turn, it has a strong focus on implementation for future research. Considering this focal point, the results will give space to multiple comparisons among the database, epidemiological data, and

trial outcomes, and the discussion will receive greater attention, to reflect on gaps and future directions, both for research and clinical practice.

Table 1: Summary of Projects' Aims

PROJECTS	GENERAL AIMS	SPECIFIC SUB-AIMS
MARD Database **Mapping systematic review**	Map the evidence of research on migration, summarizing the existing randomised evidence on psychosocial interventions with migrant populations Collect and synthesize the randomized evidence on psychosocial interventions for migrants' mental health • effectiveness of interventions and the role of moderator variables • assess the certainty of evidence	• Compare results from the database with real-word data, to determine whether the migrant populations included in experimental research matched global epidemiological figures on migrant populations and migration flows. • Assess the quality and certainty of existing evidence.
RESPOND Project **Randomized Controlled Trial – Italy**	Implement and evaluate the effectiveness of a stepped care psychosocial intervention for migrants • mental health outcomes (anxiety, depression, PTSD) • health systems' costs	• Translate, adapt, and assess the intervention manual and questionnaires • Implement the intervention at scale, to measure its acceptability, efficacy, and cost-effectiveness • Disseminate and utilize trial results

2.2 The MARD Database and Mapping Review

This first-phase research project aimed to develop a comprehensive database of randomized evidence on migration, constituting a 'meta-analytic research domain' (MARD) project, as described in the following chapter. The living database is a systematic and inclusive collection of evidence from all randomized controlled trials (RCTs) conducted so far, assessing the effectiveness of psychosocial interventions in preventing and/or treating common mental health disorders, as well as promoting psychological well-being, in migrants' populations.

The main objective of this MARD database was to map the evidence of research on migration, summarizing the existing randomised evidence on psychosocial

interventions with migrant populations. This was attained also by comparing results from the database with real-word data, to determine whether the migrant populations included in experimental research matched global epidemiological figures on migrant populations and migration flows. Along with this, a parallel focus was the assessment of the quality and certainty of existing evidence.

The database will then enable to evaluate the effectiveness of interventions by conducting statistical analyses of data (i.e., meta-analyses), as well as to study the role of moderator or mediator variables potentially affecting trial results. By using quantitative data from the MARD database, it will be possible to address the following unanswered research questions:

- what are the more effective interventions in terms of promotion, prevention, and treatment?
- are there differences in the effectiveness of interventions related to the specific type of migrant populations?
- which are the most effective delivery models and formats?
- does research support the new intervention approaches related to scalability?
- which are the mediators and moderators influencing the effectiveness of interventions? Do socio-demographic (i.e., gender, age, migration status) and clinical variables (i.e., symptoms) potentially affect the results? Which and how?

All this contributes to the ultimate goal of informing future research, in terms of collection of new evidence, development and conduction of new RCTs.

These aims have been partially accomplished by the publication of a mapping review describing the database development and results in a narrative synthesis (Cadorin et al., 2024). The present thesis updates the descriptive results published in the original mapping review, by adding data from the last year, 2023.

2.3 The RESPOND Project: Overall Project and RCT Trial

The RESPOND project, namely "Preparedness of Health Systems to Reduce Mental Health and Psychosocial Concerns Resulting from the Covid-19 Pandemic" has been a European funded research project, running from 2020 to 2024 (https://respond-project.eu/). It was conceived in the context of the Covid-19 pandemic to identify and address mental health issues potentially arising from it. Seven European countries were involved in the consortium: the Netherlands, Spain, Italy, Belgium, France, Germany, Sweden, with in addition, United Kingdom and Australia.

The project was divided into seven units of tasks (World Packages, WP), all interconnected but with specific aims:

1. management and overall coordination
2. identifying risk and resilience groups
3. health system preparedness
4. health and care workers
5. vulnerable groups
6. communication, dissemination, and knowledge transfer
7. ethics requirements.

The overall aim of the RESPOND project was to identify and implement effective strategies to reduce mental health and psychosocial burden resulting from the Covid-19 pandemic, thus improving health system preparedness for present and future events (**Error! Reference source not found.**).

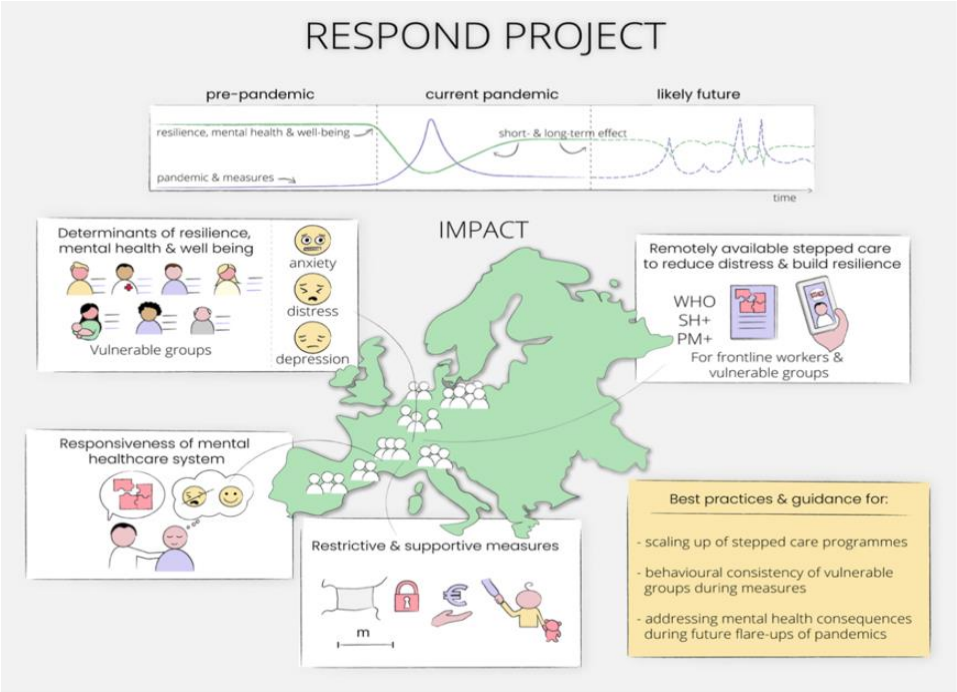
This general aim had three sub-aims, related to the different WPs:

1. identify vulnerable groups most at risk of developing adverse mental health outcomes and understand its determinants (WP2)
2. implement and adapt cost-effective programs to address negative mental health consequences (WP4, WP5)
3. identify effective strategies to improve health system preparedness in case of future pandemics. (WP3)

While WP1, WP6 and WP7 are related to general management of the whole project, these four central packages can be seen as intertwined and mutually connected

phases, where WP5 and WP4 are informed by WP2 and directly impacted recommendations for WP3. This was achieved by using different methodologies to comprehensively address the complexity of the pandemic context. Therefore, analyzing vulnerabilities and consequences of the pandemic through literature searches and cohort studies with longitudinal surveys (WP2), were channelled into practical action plans to promote mental health, with the development and conduction of RCTs within the WP4 and WP5 addressing high-risk vulnerable population groups. Results on acceptability, efficacy, and cost-effectiveness were used to review other packages and inform needs and future directions in research and practice, within a circular process.

Figure 2: The RESPOND Project



Source: https://fundament.eu/funded-respond-studying-mental-health-effects-of-the-covid-19-pandemic/.

The focus of this thesis will be on the fifth world package (WP5), which was led by the University of Verona, and was composed of different studies employing qualitative and quantitative methodologies. The quantitative part of WP5 aimed to conduct three randomized controlled trials in France, Italy, and the Netherlands

focused on different types of vulnerable populations. Participants were people in unstable housing (e.g., homeless people) in France, Polish labour migrants in the Netherlands, and migrants, refugees, and asylum seekers in Italy. The trials aimed at testing two WHO interventions, Doing What Matters in Times of Stress (DWM) and Problem Management Plus (PM+), integrated into a stepped-care intervention model (for a detailed description of the interventions see paragraph 34.4).

The main research aim of the RCT conducted in Italy and described in this thesis, was to implement and evaluate the effectiveness of delivering the stepped-care intervention model to migrants with psychological distress in terms of mental health outcomes (anxiety, depression, and PTSD symptoms) and health systems' costs (cost-effectiveness).

Three phases were developed for the trial, each with sub-specific aims:

1. translation, adaptation, and assessment of the intervention manual and questionnaires
2. implementation of the intervention at scale, to measure its acceptability, efficacy, and cost-effectiveness
3. dissemination and utilization of trial results.

On the other hand, the qualitative part of the WP5 preceded and followed the implementation of the three randomized trials, consisting in focus groups and interviews with principal stakeholders (i.e., migrants, clinicians, policymakers, researchers). Before the trial, need assessments of these vulnerable groups were conducted, whose results were then integrated into the adaptation of the WHO interventions. After the implementation of the trials, implementation outcomes, in terms of acceptability and feasibility, were assessed through interviews with migrants and facilitators (Lotito et al., 2023; Purgato et al., 2023; see also paragraph 24.2 on methodology for a detailed description).

METHODS

CHAPTER 3 - THE MARD MIGRANTS' DATABASE

3.1 What is a MARD?

The 'Meta Analytic Research Domain' or MARD, is an innovative research methodology to aggregate data from randomized controlled trials (RCTs) of a whole research field. The term, firstly developed by Cuijpers and colleagues (2022, 2023), emphasizes the aggregation of multiple PICOs (Population, Intervention, Comparator, Outcomes) (Eriksen and Frandsen, 2018) in one broad search, covering an entire research area. It can therefore be considered a living systematic review of an entire research domain that cannot be covered by one single PICO.

The main characteristics and advantages of the MARD approach can be listed as follow: living project, recency, completeness, consistency, multiplicity of outcomes and measures, methodological solidity, accessibility, and reusability. Being a living project, a database is developed and constantly updated by performing regular searches. This enables to always have up-to-date information on the topic, keeping the overview of findings, gaps, but also emerging topics. Completeness is attained by collecting all RCTs conducted in the research field; this is also related to the possibility to extract multiple outcomes and measures of potential interest. A consistent methodology is used to develop and maintain the database, from searches, to data extraction, and data analysis. Accessibility and reusability rely on the possibility to conduct different systematic reviews and meta-analyses using (and re-using) data always available from the database.

The MARD, or living database, has some similarities and overlapping characteristics with systematic reviews and umbrella reviews, but these three methodologies have different aims and focuses. It is important to emphasize the difference between a systematic review and a living database, as the latter is a repository of studies used to conduct systematic reviews, which may have different

inclusion criteria, whereas the first is the specific sub-product of the database. For example, the present migrants' database could be used to develop systematic reviews for different sub-populations (i.e., refugees only, refugees and asylum seekers, economic migrants, or the whole migrant population), age groups (i.e., children and adolescents, adults, older adults), type of interventions (i.e., psychotherapies, WHO interventions, family or creative/expressive interventions), depending on the specific review's aim. The MARD focuses on efficiency, given that it is more comprehensive and constantly updated, whereas the focus of systematic review is specificity, being time-limited and following a narrow research domain and question. On the other hand, the MARD approach shares with the umbrella review the aim of synthesizing broader research fields to give an overview of findings and lacunae. Nevertheless, the umbrella review synthesis is based on previously conducted meta-analyses, constrained in terms of PICO characteristics, outcomes to analyze, and statistical analyses performed and reported.

The MARD approach has also some important limitations, firstly, the complexity and massive tone of work required to carry out a MARD project in terms of resources, time and workload required to develop it, as well as to keep it constantly updated. Secondly, the completeness reached by MARD databases has its counter side in the risk to become dominant in a research field. This is linked to and mitigated by the responsibility in conducting the project in all its phases, from string development to study screening and selection, as well as data extraction. Thirdly, the constant availability and usability of data could bring to 'data dredging' or 'data fishing' (Erasmus et al., 2022), searching for significant results by performing multiple analyses on the same data. Finally, the MARD methodology approaches the meta-research domain, in terms of clinical research integration and research on research, but it is limited to RCTs, with only randomized evidence included.

3.2 MARD Migrants: The Database Process

The present research project deals with the development of a living database of randomized controlled trials on psychosocial interventions for migrants'

populations. As this living database includes a wide range of migrant populations, different intervention and comparison groups, and several outcome measures, covering multiple PICOs simultaneously, it could be considered a MARD project. The protocol for the living project has been registered in the Open Science Framework (OSF) (https://osf.io/jd3zn), and a mapping review paper, describing the main features of the database, has been published (Cadorin et al., 2024).

3.2.1 Data Identification and Selection

Systematic searches were conducted in PubMed, PsycINFO, MEDLINE (Ovid), Web of Science (WOS), Cochrane Central Register of Controlled trials (CENTRAL), Pilots PTSDpubs (ProQuest), CINHAL, Scopus and Embase, from database inception until the last update in January 2024. Electronic database searches were supplemented by a manual search of reference lists from relevant systematic reviews and meta-analyses in the field (Hutchinson et al., 2022; Mesa-Vieira et al., 2022; Soltan et al., 2022; Turrini et al., 2021; Uphoff et al., 2020, Schäfer et al., 2023a, 2023b). Published and unpublished evidence was searched. Trial registrations and ongoing studies were retrieved from the CENTRAL database, which includes a wide range of trial registries[1], and subsequently checked for publication status. No language nor publication type restrictions were applied. Being a living database, searches are updated annually, each January. Full search strategy is reported in the appendices of the published mapping review (Cadorin et al., 2024).

Studies meeting the following criteria were included: a) randomized controlled trials (RCTs); b) including migrants of any type; c) assessing the efficacy of any type of promotion, prevention, and treatment psychosocial interventions; d)

[1] Australian New Zealand Clinical Trials Registry (ANZCTR), ClinicalTrials.gov (NCT), Clinical Trials Registry - India (CTRI), Chinese Clinical Trial Registry (ChiCTR), UK's Clinical Study Registry (ISRCTN), Pan African Clinical Trials Registry (PACTR), UMIN-CTR Clinical Trial, Iranian Registry of Clinical Trials (IRCT), German Clinical Trials Register (DRKS, Korean Clinical Trial Registry (KTC), Thai Clinical Trials Registry (TCTR), World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP).

comparing psychosocial interventions with active or inactive interventions; e) reporting at least one common mental health outcome (anxiety, depression, psychological distress, and PTSD).

Based on the PICO framework, expanded inclusion criteria were the following:

- Population: participants were migrants of any age, ethnicity, religion, health, and socio-economic status. The inclusive definition of migrants from the IOM was followed, including all different migrant populations such as migrant workers, asylum seekers, refugees, unaccompanied minors, internally displaced persons, and any other type of forced or unforced migrants (IOM, 2019). Second generation migrants were excluded unless they constituted a minority of the randomized participants, namely less than 20% of the sample. Migrants with or without any physical or mental health conditions were included.
- Interventions: RCTs assessing the efficacy of any type of promotion, prevention, and treatment interventions with a main psychosocial component were included. Psychosocial interventions were defined in accordance with IASC guidelines as 'mental health and psychosocial support' (MHPSS) interventions (IASC, 2007). We also followed the classification of interventions according to the prevention continuum (IOM, 1994; Eaton et al., 2019; Tol et al., 2015). Psychosocial interventions could be provided by any type of staff, mental health professionals and non-specialists, or in a self-help modality. Non-specialists included primary-level health workers (e.g., doctors, nurses, and other general health professionals), paraprofessionals (e.g., trained lay health providers), community workers (e.g., trainers, social workers), or lay people (e.g., peers, volunteers). Psychosocial interventions could be delivered through any modality (i.e., face-to-face, in person and online, or entirely digitally), format (individual and group), without any limit for the duration and the number of sessions.
- Comparators: comparison groups included active or inactive interventions, such as waiting list (WL), treatment-as-usual (TAU) or care-as-usual (UC) (i.e., any intervention that reflects the usual care in a given treatment

setting), enhanced care as usual (ECAU), psychological or attentional placebo, and any other type of non-pharmacological or pharmacological interventions.

- Outcomes: only RCTs reporting as primary or secondary outcome at least one common mental health outcome (anxiety, depression, psychological distress, PTSD) were included.
- Setting: RCTs conducted in any country, irrespective of the income level, and in any setting (e.g., healthcare, and clinical settings, as well as community settings such as refugee camps, schools, social care settings, and any other setting).
- Study design: only randomized controlled trials (RCTs) were included. Quasi RCTs were deemed includible only whether randomization procedures were respected.

3.2.2 Data Collection and Extraction

Based on the eligibility criteria, titles and abstracts' screening was conducted by independent reviewers from the research team; the same procedure was followed for the full texts' screening. Both screening phases were performed using an online software, Rayyan (Ouzzani et al., 2016). Any disagreement was resolved by consensus with a third senior researcher. Authors of eligible manuscripts were contacted to retrieve full texts or data whether missing.

Data extraction was performed by couples of reviewers independently, using an electronic spreadsheet developed for this purpose, in agreement with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2024). Following the PICO framework (Richardson et al., 1995), data on sociodemographic characteristics of participants (e.g., age, gender, migration status, country of origin and resettlement, years since resettlement, diagnosis and/or CMDs symptoms, setting), intervention and control groups (e.g., type, classification, duration, format, sessions), and outcomes (e.g., questionnaires, scores, follow-ups, randomized participants) were extracted.

During the extraction process, interventions were grouped into macro-categories (nodes): ‘counselling and psychosocial support’, ‘psychotherapy’, ‘family/parenting support interventions’, and ‘creative/expressive interventions’. Interventions were also classified following the ‘Mental Health Gap Action Programme’ (mhGAP) guidelines into ‘psychoeducation’, ‘reduce stress and strengthen social support’, ‘promote functioning in daily activities’, ‘psychological treatment’, adding a mixed category in case of elements from different categories (WHO, 2018b). The classification of psychosocial interventions into nodes was based on a critical examination of intervention framework and focus, as described in the papers, and reviewed by experts in the field (see Appendices 1 for a complete overview of included interventions following this classification; for definitions, see also Turrini et al., 2025, in supplementary materials). Firstly, a separation between ‘counselling and psychosocial support’ (i.e., psychosocial interventions) and psychotherapies was made to account for their different intervention structure, goals, and rationale, also following the MHPSS framework (see paragraph 1.2.2). The first macro-category comprised, on the one hand, interventions led by counsellors, such as trauma-focused, value-based, expressive, supportive counselling. On the other hand, the second sub-category comprised a pool of interventions having in common psychosocial support, such as the WHO interventions (SH+, PM+), life skills training, strengths-based, resilience-based interventions, psychoeducation, group interventions, and transdiagnostic interventions, as CETA (Common Elements Treatment Approach). Secondly, psychotherapy was classified two main theoretical frameworks, CBT-based/inspired, and trauma-focused psychotherapies, whit a third category (other psychotherapies) including less represented and more heterogeneous approaches (see Table 2 for a complete overview of included psychotherapies and Appendices 2 for their definitions). Thirdly, ‘family/parenting support interventions’ comprised programs or approaches focused on addressing family dynamics (parent-child relationships) and parenting skills, supporting parents and promoting child development. Finally, ‘creative-expressive interventions’ collected music therapy, expressive writing interventions, laughter therapy and other interventions.

The following outcomes were extracted, with a hierarchy[2] to adopt in case of multiple assessments of CMDs symptoms (Purgato et al., 2023):

- Depressive symptoms. In case of more than one questionnaire measuring depressive symptoms the following hierarchy was applied: 1) clinician-conducted standardized and validated measure (a) HAMD; b) BDI-I or II; c) MARD; d) another clinician-rated instrument); 2) self-report standardized instrument, with priority for: a) PHQ-9; b) CES-D; c) HADS-D; d) GDS; e) EPDS; f) MMPI-D; g) CDI for children/adolescents; h) RADS-R; another self-validated instrument). For studies conducted in children and adolescents, when ratings from both parents and children are reported we gave preference to parent ratings (Cuijpers et al., 2021a).
- Anxiety symptoms. In case of more than one questionnaire measuring anxiety symptoms, we followed this hierarchy: HRS-A; BAI; STAI; SPRA; SCL-90R – anxiety subscale; other validated self-rating instrument.
- Symptoms of post-traumatic stress disorder (PTSD). In case of more than one questionnaire measuring PTSD symptoms the following hierarchy: 1) clinician-conducted standardized and validated measure, such as a) UCLA PTSD Index; b) CPSS; c) CAPS/CAPS/CA; 2) self-report standardized instrument using a standardised measure, with priority for a) IES/CRIES; b) PROPS/CROPS; c) K-SADS; d) TSCC; e) PTCI/CPTCI; f) HTQ; g) PSS; h) CPTS-RI; i) PAPA; j) ADIS; k) another self -report instrument (Zhang et al., 2018).
- Psychological distress symptoms
- Psychological functioning and impairment, in terms of global functioning, relational/interpersonal functioning, functional impairment, and psychosocial functioning

[2] The hierarchy was based on already existing hierarchies for depression and PTSD (Cuijpers et al., 2021a, and Zhang et al., 2018; respectively). It was checked and adapted to account for all CMDs (adding anxiety) and other relevant questionnaires by internal consensus in the research team and consultation with experts. This hierarchy has already been published in the project protocol (Purgato et al., 2023), and used for subsequent papers (Turrini et al., 2025). Another similar hierarchy could be found in Papola and colleagues (2023), where all CMDs outcomes are considered together.

- Psychological well-being
- Quality of life
- Dropouts, as measured with the total number of participants leaving the study early out of the total number of randomized participants, for any reason at the different timepoints.

Outcome data were extracted as mean scores and standard deviations (SD) at each available timepoint, as measured with validated rating scales. If not available, mean change scores, 95% confidence intervals, or standard errors (SE) were taken and then applied conversion formulas.

3.2.3 Data Synthesis and Analysis

A narrative synthesis of the MARD database was conducted to summarize the characteristics of the included studies, by performing descriptive analyses of the main variables. Following the PICO framework, we aimed to describe the sociodemographic characteristics of migrants' population, as well as the main characteristics of psychosocial interventions for this broad population. No quantitative analysis of the effectiveness of the interventions was carried out, only a narrative description of intervention types and characteristics by frequency tables. We followed the Cochrane Handbook for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic reviews and Meta-analyses (PRISMA) 2020 guidelines for data reporting (Higgins et al., 2024; Page et al., 2021). The mapping review methodology was also followed to synthesize the results from the MARD database as a research field overview (Bates et al., 2007; Cooper, 2016; Miake-Lye et al., 2016).

To determine whether the characteristics of included studies were consistent with global epidemiological data on migrant populations and migration flows, the following additional information was retrieved and synthesized:

- sociodemographic characteristics of migrants: for the comparison, data were taken from the IOM Report (2022, 2024), and target group, reason for displacement, age, and gender were analysed.

- common mental health disorders: as the IOM Report (2022, 2024) did not include data on the frequency or prevalence of common mental health conditions, a brief literature search was additionally performed to retrieve systematic reviews of epidemiological studies that calculated the prevalence of common mental disorders (anxiety, depression, and PTSD) in migrant populations. The search was conducted in PubMed using some keywords, e.g., systematic review, mental health, prevalence, and migrants. The systematic review of Carroll and colleagues (2023) was selected given its comprehensiveness and recency, and information on the prevalence of anxiety, depression, and PTSD in migrant populations was extracted.
- migration flows: to investigate the geographical distribution of migratory flows and its representativeness in research, we performed a search to retrieve official reports on migrants. Then, among retrieved reports, data were taken from the IOM World Migration Report (2022, 2024) and from the original published spreadsheets by the UNDESA (2021) where complete information on migration flows over the years, as well as on countries of origin and destination, could be found. We followed the classification of countries according to the World Bank (WB), operating a subdivision of macro-regions in sub-regions to make data more comparable and understandable. All data on migration flows refer to mid 2020, as they are updated every five years. The last publication of the IOM Report (2024) is still based on these epidemiological data, thus the next publication of the report in 2026 will give an update on international migration flows.

To further analyze migrant sub-populations, specific reports were retrieved. For refugees and asylum seekers, the UNHCR Global Trends report (2024) was considered, whereas for internally displaced people (IDPs), the Global Report on Internal Displacement (GRID), published by the Internal Displacement Monitoring Centre (IDMC) (2024), was taken.

Finally, also comparative analyses between MARD database and RESPOND trial were performed on some common variables, namely socio-demographic variables (i.e., age, gender, country of origin, type of migrant populations), intervention and

outcomes' variables (i.e., baseline levels and timepoint assessments, intervention type and setting).

3.2.4 Data Quality Assessment: Risk of Bias

The Cochrane's risk of bias tool - version 2 (RoB-2) for RCTs was used to assess the risk of bias and integrity of randomization processes, as outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al., 2024). Assessments of risk of bias were performed by one reviewer of the team and independently checked by a second reviewer. Outcomes analysed were anxiety, depression, PTSD, and distress symptoms at the study endpoint, i.e., the first assessment after the intervention. For studies including mixed populations, separate RoB assessments were conducted for children and adults.

CHAPTER 4 - THE RESPOND TRIAL

4.1 What is an RCT?

Randomized controlled trials (RCTs) are considered at the top of the primary research hierarchy, reaching the highest level of methodological quality (Murad et al., 2016, Guyatt et al., 2011; Djulbegovic and Guyatt, 2017). The main characteristic of the RCT design is randomization, that is the random allocation of participants to intervention or control groups (i.e., by chance). This allows a causal interpretation of results on intervention effectiveness given that, thanks to the randomization process, possible differences in participants' characteristics at baseline are assumed to be related to chance, thus not systematically affecting trial results (Higgins et al., 2024).

In the following paragraphs we will deep into the process and main methodological aspects undertaken for the development of the RESPOND randomized trial.

4.2 RCT RESPOND: The Development of a Trial

The randomized trial to be performed in Italy was approved by the Ethics Committees of the 'Azienda Ospedaliera Universitaria Integrata Verona' (AOUI) and of the University of Verona (UNIVR), by the WHO Research Ethics Review Committee, and by the Ethics Committees of all participating sites. The Declaration of Helsinki on confidentiality of data was followed. For the RCT conducted in Italy a protocol paper was published, explaining the rationale, design and methodology of the trial (Purgato et al., 2023).

As outlined in chapter two (paragraph 2.3 on aims), before the implementation of the RESPOND trial, a preliminary qualitative phase was conducted as part of the WP5, to subsequently inform the adaptation process of trial interventions (Lotito et al., 2023). The 'Design, Implementation, Monitoring, and Evaluation' (DIME)

model was followed as theoretical basis (Kellner and Health, 2000). This model aims 1) to identify and assess mental health difficulties of the target population through qualitative methods, 2) to guide then the development and implementation (i.e., selection, adaptation, and testing) of interventions or mental health instruments, and 3) to monitor and evaluate provided interventions and services, in collaboration with involved stakeholders, like providers and community organizations, thus integrating bottom-up and top-down approaches (Kellner and Health, 2000). Within this framework, the assessment of needs of migrant populations were conducted, through semi-structured free-listing (FL) interviews and focus groups (FG), with both stakeholders and migrants. This preparatory phase aimed to identify and describe main needs and issues faced by migrant populations in the pandemic context, focusing on mental health, as well as to evaluate implementation factors, feasibility, preferences, and adaptation needs for the interventions. Specifically, the FL interviews were firstly used to list problems experienced by migrants and stakeholders from the pandemic start in Italy; then, based on problems selected from the FL interview data, FG discussions were conducted to gain more in-depth understanding (Lotito et al., 2023).

Then, based on results emerged from this preliminary project's phase, adaptation of trial interventions occurred. This to integrate contextually and culturally relevant elements to the already available WHO interventions**,** according to the needs of the target population. It thus implied modifications and adjustments of the intervention manuals in terms of language and contents (i.e., translation and cultural adaptation), as well as the adaptation of interventions to be delivered remotely, through the implementation on an online platform.

Finally, selection, training and supervision of trainers and helpers was conducted, following a task-shifting approach. Firstly, 'training of trainers' (ToT) program was implemented by training people who would then, in turn, train and supervise helpers (i.e., lay people delivering interventions). Training for all the trail interventions (PFA, DWM, PM+) involved the same volunteers as future helpers and focused on acquiring basic counselling skills and learning intervention strategies through the study of manuals, role-play activities, and practice on case studies. Helpers were then monitored and supervised across all study phases through recurrent meetings

with trainers/supervisors. Training and general supervision were provided by licensed mental health professionals (i.e., registered clinical psychologists) who were also master trainers in WHO interventions (Lotito et al., 2023; Purgato et al., 2023, 2025).

4.3 Recruitment, Screening and Randomization

Potential eligible participants were recruited through multiple sources, from social media to word-of-mouth, as well as in community and clinical (healthcare) settings in two cities in Italy (in Verona and Rome).

The following inclusion criteria were applied:

- being 18 years or older (i.e., only adult participants)
- being a migrant resettled in Italy, temporarily or permanently
- having elevated levels of psychological distress as measured by a score above 15.9 at the Kessler Psychological Distress Scale (K10)
- having sufficient mastery, both written and spoken, of one of the three languages of the intervention (i.e., English, Italian, French)
- giving oral and written informed consent before entering the study.

The following exclusion criteria were applied:

- acute medical conditions that required hospitalization
- imminent suicide risk, or expressed acute needs or protection risks that required immediate attention (PM+ suicide risk tool)
- severe mental disorder (e.g., psychotic disorder)
- severe cognitive impairment (e.g., severe intellectual disability or dementia)
- initiation or significant change (stopped, or significantly modified) of psychiatric drug treatment over the previous two months
- currently receiving specialized psychological treatment (i.e., psychotherapy)
- planning to permanently move back to home country before the last follow-up assessment (i.e., 21 weeks after baseline, T4).

Screening of potential participants was conducted by a research assistant through a face-to-face interview session and the administration of questionnaires, namely, K10 and PM+ tools for suicide risk and 'mental, neurological or substance use disorders' assessment. All participants deemed to be eligible for the study were then randomized to the intervention or the control group by using a random sequence generation allocation through the Castor Electronic Data Capture (EDC) platform (Castor, 2017). Blinding was not feasible neither for participants nor for interventionists; only outcome assessors were blinded to intervention allocation.

4.4 Intervention Structure

4.4.1 Psychological First Aid (PFA)

Psychological First Aid (PFA) was provided to all participants before randomization. It consisted in a single support session delivered through a phone call or a teleconferencing meeting with a research assistant. PFA is a support strategy developed by the WHO (2013) as a first-line emergency intervention to be delivered in humanitarian crises, by providing sympathetic, supportive, and practical help. Key structural elements of this first-line intervention are its briefness, the single-session format (up to 30-45 minutes), and the use of a task-shifting approach through of trained helpers. PFA aims at promoting five key protective factors, namely a sense of safety, calm, self- and social-efficacy, connectedness, and hope. Thus, main components are active listening, needs assessment, practical and emotional care, and support (WHO, 2013a).

4.4.2 Arm 1 – Intervention Group

The intervention consisted of a stepped-care program combining two psychosocial interventions developed by the WHO, namely 'Doing What Matters in Time of Stress' (DWM) (WHO, 2021) and 'Problem Management Plus' (PM+) (WHO, 2018b). Both interventions use evidence-based strategies whose theoretical

background is ‘Cognitive-Behaviour Therapy’ (CBT) and its recent developments, known as ‘third-wave CBT’, like ‘Acceptance and Commitment Therapy’ (ACT) (Hayes and Hofmann, 2017, 2021). Mindfulness techniques are key elements for DWM, whereas selected cognitive-behavioural techniques for PM+, and the general aim of both interventions is to address both psychological problems and underlying practical problems. Two main components of the intervention model implemented in this study were the stepped care model and the task-shifting approach. Specifically, the stepped care model firstly involved a lower intensity intervention (DWM) and then a more intense intervention (PM+) only delivered to individuals requiring further support. For task-shifting, in this case facilitators were trained people with a mental health background. Given the context of the pandemic, the DWM was developed as a guided self-help intervention with the use of a mobile or web app together with telephone calls, and PM+ was a structured videoconference intervention. Both DWM and PM+ interventions have been successfully implemented with different populations affected by psychosocial stress in humanitarian settings, proving to be effective prevention strategies. Specifically, DWM was tested with refugees in Europe, Turkey and Northern Uganda, and PM+ was implemented in Kenya and Pakistan (Tol et al., 2020; Purgato et al., 2021; Acarturk et al., 2022 for DWM[3]; Acarturk et al., 2022; Rahman et al., 2016; Spaaij et al., 2022 for PM+).

4.4.2.1 Doing What Matters in Time of Stress (DWM)

The DWM intervention is an illustrated self-help stress management guide based on ACT and mindfulness principles and techniques (WHO, 2021). It is part of a wider group stress management course, Self Hep Plus (SH+), developed by the WHO (2015) to respond to humanitarian crises in the form of a transdiagnostic guided self-help preventive psychosocial intervention aiming to reduce distress, develop adaptive coping and resilience skills, and enhance social support (WHO

[3] DWM was tested in its original and complete version, named Self Help Plus (SH+), as explained in the following paragraph.

2015; Dawson et al., 2016). The intervention consists of five weekly sessions, each focused on a different ACT principle:

1. grounding
2. unhooking
3. acting on your values
4. being kind
5. making room.

Analyzing the five intervention principles more in detail, the first session is focused on learning to engage in life thanks to the five senses, by bringing full attention to ongoing activities and grounding oneself during emotional storms. The second session teaches five steps for unhooking from difficult thoughts and emotions, namely notice, name, refocus, engage, and pay full attention. The third session points the difference between acting away or towards its own values; this session addresses the main principles of ACT, namely, change, accept, live by its own values, to find meaning and purpose in life. The following session examines how to act on the values of kindness and caring. The final session uses the metaphor of the weather (i.e., thoughts and feelings) to teach participants to be like the sky, making room for every kind of weather. The original intervention consisted in a pre-recoded audio course with bibliotherapy, a self-help book, whereas, for this specific trial, DWM has been adapted to be used online, delivered in a guided self-help modality, using an app (mobile or desktop version) in addition to brief weekly motivational support calls (up to 20 minutes) from a trained helper.

4.4.2.2 Problem Management Plus (PM+)

PM+ was the second intervention step, delivered to participants who still showed psychological distress after the delivery of DWM as measured at the first post-intervention assessment (T2, two weeks after the DWM completion). It is configured as an evidence-based problem-solving counseling with selected cognitive-behavioural techniques, namely problem solving, stress management, behavioural activation, and access to social support. PM+ was originally developed by the WHO (2015) as a low-intensity psychological intervention for adults impaired by distress in communities exposed to adversity with the aim to reduce

symptoms of CMDS (i.e., depression, anxiety, PTSD, and related conditions) notwithstanding severity levels, but also to improve mental health and psychosocial well-being. It consists of five weekly sessions, each focused on a problem-solving technique, structured as follow:

1. managing stress
2. managing problems
3. get going, keep doing
4. strenghtening social support
5. staying well and looking forward.

The first session teaches a brief stress management strategy, namely slow breathing, to manage stress and anxiety, by using motivational interviewing and psychoeducation. The second session focuses on teaching a problem management strategy to apply in self-identified situations where the participant is experiencing practical problems (e.g., unemployment, family conflicts), based on the analysis the problem and identification of possible solutions. The third session addresses behavioural activation, aiming to improve participants' level of activity which has proven to have a direct impact on mood. It was specifically conceived to address depressive mood and its consequences, by helping participants to engage on social activities or carry out necessary tasks or jobs. In session four participants are invited to strengthen their social network and activate social support, a key element to promote well-being and prevent isolation, which is a frequent consequence in people experiencing emotional problems; supportive networks addressed were trusted friends, family, co-workers, or community organizations. The fifth and final session aims to review and reinforce all previously learned strategies and adds psychoeducation on relapse prevention. In the RESPOND trial sessions were delivered in an individual format through videoconference calls and the original intervention duration of 90 minutes was shortened to 60 minutes (Lotito et al., 2023). Nevertheless, PM+ could also be delivered as group format, known as 'group Problem Management Plus' (gPM+) (WHO, 2015a; Acarturk et al., 2022; Bryant et al., 2022).

4.4.3 Arm 2 – Control Group

4.4.3.1 Enhanced Care as Usual (ECAU)

In addition to PFA, both intervention and control group received care-as-usual (CAU)[4]. It consisted of giving references to available services for this population in the local context; specifically, community care, social and/or legal support, psychoeducation, information about locally available referral options and specific assistance resources, with the distribution of specifically developed informative flyers (e.g., hotlines or support groups and available services).

4.5 Outcome Assessments

4.5.1 Screening

To be eligible for the trial, potential participants had to score positive for psychological distress and negative for suicide risk and severe mental disorder and cognitive impairment.

The Kessler Psychological Distress Scale (K10), a ten-item self-report questionnaire, was used to screen for psychological distress, in terms of anxiety and depression related distress. Items were rated on a five-point Likert scale; total score ranged from 10 to 50 with higher scores showing higher levels of distress experienced in the past 30 days. It has shown strong psychometric properties and diagnostic power, using a cut-off of 15.9 points.

Then, specific assessor-reported screening tools from the PM+ manual were used, namely the 'assessment of suicidal thoughts' tool for suicidality risk, and 'impairments possibly due to severe mental, neurological or substance use disorders' tool for symptoms of severe mental, neurological, or substance use disorders. Those were not diagnostic tools, but only indicated a suspicion of a disorder based on observations and judgment of the client's behaviors.

[4] Thus, for control group ECAU consisted in receiving CAU with, in addition, PFA.

4.5.2 Primary and Secondary Outcomes

Primary outcome of the study was the change in psychological distress, as a combination of symptoms of depression and anxiety, from baseline to two months after the PM+ intervention (21 weeks after baseline, at T4). It was measured through the 'Patient Health Questionnaire Anxiety and Depression Scale' (PHQ-ADS), which consisted in a combined sum score of the Patient Health Questionnaire 9-item (PHQ-9) and Generalized Anxiety Disorder 7-item (GAD-7). Then, the following secondary outcomes were assessed: depression, anxiety, posttraumatic stress disorder, self-identified problems, quality of life, resilience, resource use and economic outcomes. Additionally, the study also evaluated other outcomes: demographic data, COVID-19 exposure, positive appraisal style, exposure to adverse life events, treatment fidelity, satisfaction and acceptability of the program, adverse events, and implementation indicators.

4.5.3 Questionnaires

The administered questionnaires were self-reports compiled online through the Castor platform (Castor, 2017). See the study protocol (Purgato et al., 2023) for the full list of questionnaires and detailed descriptions; here, we will only focus on describing main primary and secondary outcome questionnaires.

Primary outcome:

- Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) for psychological distress (Kroenke et al., 2016). It is a 16-item self-reported instrument combining the PHQ-9 and GAD-7 into a composite measure of depression and anxiety. Total score ranges from 0 to 48, with higher scores indicating higher levels of depression and anxiety symptoms over the past 2 weeks.

Secondary outcomes:

- Patient Health Questionnaire-9 (PHQ-9) for depression (Spitzer et al., 1999; Kroenke et al., 2001). It is a nine-item questionnaire based on a likert scale (0-

3) with a severity score ranging from 0 to 27. PHQ-9 is commonly used to screen for depression using a recommended cut-off score of ten.

- Generalized Anxiety Disorder (GAD-7) for anxiety (Spitzer et al., 2006). It is a seven-item questionnaire, scored 0-3, providing a 0 to 21 severity score. It was initially developed to diagnose generalized anxiety disorder (GAD) and it is currently applied as a screening instrument with a recommended cut-off of ten.
- PTSD Checklist for DSM-5 (PCL-5) for post-traumatic stress disorder (Weathers et al., 2013). It is a self-reported instrument measuring PTSD symptoms over the past four weeks on eight items rated on a 0-4 scale. Total score ranges from 0 to 32, with higher scores indicating higher levels of PTSD symptoms.
- Psychological Outcome Profiles questionnaire (PSYCHLOPS) for self-identified problems (Ashworth et al., 2004). It is a patient-generated outcome measure used as an indicator of change occurred after therapy. Three domains are assessed, namely self-reported problems, function, and wellbeing. Free text responses are asked to the first two domains (three questions), scored on a six-point scale for a total score of 18.
- EuroQol – 5-dimension – 5-level questionnaire (EQ-5D-5L) for health-related quality of life (Herdman et al., 2011). It is a combination of the EQ-5D and the EQ-Visual Analog Scale (VAS) questionnaires. The first part (EQ-5D) rates the level of impairment across five dimensions, namely mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-VAS measures perceived health state on a scale ranging from 0 to 100.
- Mainz Inventory of Micro Stressors (MIMIS) – adapted version for resilience (Chmitorz et al., 2020). It is an objective measure micro-stressors or daily hassles exposure used as indicator of resilience capacity. The adapted questionnaire consists of 22-item assessing three general life events, six everyday stressors, five COVID-19-specific stressors and eight refugee and migrant population specific stressors. Items are rated on a likert scale; for general life events the past two months are considered, whereas remaining items are related to the last 14 days.

- Client Service Receipt Inventory – (CSRI) for resource use and economic outcomes (Chisholm et al., 2000). The adapted Italian version is a 13-item self-reported instrument used to collect data on service utilization (healthcare and other services) in terms of number and duration of contacts with healthcare professionals in the past 2 months, as well as time out of employment and other usual activities, and need for informal care.

Other outcomes:

- COVID-19 exposure questionnaire for impact of COVID-19
- Positive Appraisal Style Scale – content focused (PASSc) for resilience factors, namely positive appraisal style (PAS)
- Brief Trauma Questionnaire (BTQ) for traumatic exposure, as life threat or serious injury
- adverse events
- feasibility outcomes: treatment fidelity, satisfaction, acceptability
- implementation outcomes: reach, dose, resource use, costs (recruitment, training, delivery), adaptation and quality of intervention.

4.5.4 Timepoints

All outcomes were assessed at five timepoints, two before randomization (T0 and T1) and three after intervention delivery (T2, T3, T4)[5]. The primary study endpoint was at T4, namely 21 weeks post-randomization. Specifically, the following timepoints were considered:

- T0 was the screening for eligibility
- T1 was baseline assessment, before random allocation
- T2 at 7 weeks after randomization and two weeks after the end of the first intervention (DWM)
- T3 at 14 weeks after randomization and one week after the delivery of PM+

[5] A flexibility of maximum two weeks was applied at each timepoint in case of possible justified delays.

- T4 at 21 weeks after randomization and seven weeks after the end of the last intervention (PM+).

RESULTS

CHAPTER 5 - FROM EPIDEMIOLOGICAL DATA TO RCT DATA, THROUGH MARD DATABASES

5.1 Epidemiological Data on Migration

5.1.1 Real-World Socio-Demographic Characteristics of Migrants

International migrants were estimated 281 million in 2020, corresponding to 3.6% of the world's population, as outlined by the IOM reports (2022, 2024), based on the last updated UNDESA data (UNDESA, 2020, 2021). At that time, economic (labour) migrants were 169 million, representing 60% of all international migrants globally, whereas forcibly displaced people were 89,4 million, with 55 million internally displaced persons, 30,5 million refugees and asylum seekers, and 3,9 million in need of international protection, above all displaced Venezuelans.

The recently published IOM report (2024) reported data for displaced persons (i.e., refugees, asylum-seekers, IDPs and others in need of international protection) at the end of 2022, which have been, in turn, updated with the new UNHCR (2024) and IDMC (2024) reports, also considering the last year, i.e., 2023. At the end of 2023, 117,3 million people worldwide were living in displacement because of persecution, conflicts, violence, and human rights violations (UNHCR, 2024). Specifically, the new UNHCR report (2024) documented 37,4 million refugees, 6,9 million asylum-seekers and 5,8 million other displaced people in need of international protection, mainly Venezuelans, in 2023. On the other hand, from the 2024 GRID report on IDPs, there were 75,9 million IDPs globally at the end of 2023, 68,3 million (90%) as a result of conflict and violence and 7,7 million (10%)

due to disasters, reaching a record compared to the past ten years, with an increase of 51% over the past five years (IDMC, 2024)[6].

Taking only the year of 2023, 46,9 million people underwent internal displacement, with 26,4 million (56%) by disasters, and 20,5 million (44%) by conflict and violence[7]. Conflict and violence displacements occurred in 66 countries and territories, and they were almost three times higher than the annual average of the past ten years but registering a 28% decrease with respect to the previous year (28,3 million in 2022). Main types of violence triggering internal displacements in 2023 were non-international armed conflicts (NIAC) (14,4 million; 70%), international armed conflicts (IAC) (4,5 million, 22%) and communal violence (668 thousand, 3%), followed by crime-related violence (500 thousand, 2%), civilian-state violence (64 thousand, <1%) and other forms of violence (294 thousand, 1%). Displacements related to non-international armed conflicts registered a significant increase in the last years, mainly occurring in Democratic Republic of Congo (DRC) and Sudan, which accounted for almost half of conflict displacements in 2023. NIACS almost doubled the previous year, whereas IAC conflicts significantly decreased (i.e., 8,86 million NIACS and 17,05 million IAC in 2022, respectively); on the other hand, crime-related violence increased of 45%, mainly in Haiti and Nigeria. Disaster displacements occurred in 148 countries and territories in 2023, of which 77% (20,3 million) weather-related and 23% (6,1 million) geophysical hazards. Compared to the previous year, 2022, when the highest figures in the past ten years were reached (32,6 million), a 33% decline was registered, above all for fewer weather-related hazards (floods and droughts). Specifically, weather-related hazards in 2023 were mainly due to floods (9,8 million, 37%) and storms (9,5 million, 36%), with less represented causes being droughts (491 thousand, 2%) and wildfires (366 thousand,

[6] Percentages are calculated based on the total number of IDPs reported as the in each of the following paragraphs; namely, 1st IDPs at the end of 2023, 2nd IDPs in 2023, 3rd violence-related IDPs in 2023, 4th disaster-related IDPs in 2023.

[7] Conversely, at the end of 2022 there were 71,2 million IDPs globally, 62,5 million (88%) for conflict and violence and 8,7 million (12%) for disasters. Taking only the year of 2022, 60,9 million people underwent internal displacement, with 32,6 million (53%) by disasters, and 28,3 million (46%) by conflict and violence.

1%). Geophysical hazards (6,1 million, 23%) registered an increase from the previous year and they were almost all related to earthquakes (6,1 million, 23%).
Focusing on main socio-demographic characteristics of international migrants, from UNDESA data (2021) most migrants were adults (85%; 239,66 million), of which 73% (205,37 million) were adults aged 20-64 years and 12% (34,29 million) were older adults (>65 years). Children and adolescents (≤18 years) represented 15% of total international migrants (40,94 million), of which 4% (12,53 million) were adolescents aged 15-19 years. International child migrants (0-14 years) were 28,40 million (10%) in 2020, corresponding to 1.4% of the world's child population. Working aged people (14-65 years) represented 77% of all international migrants, corresponding to 217,90 million people. Gender was similarly distributed, with 52% males (145,66 million, or 3.7% of the world's male population) and 48% females (134,94 million, or 3.5% of the world's female population). Considering gender distribution in relation to age, a similar trend was observed, with male migrants being 8% under 20 years, 39% aged 20-64 and 5% over 65 years, and female migrants being 7% under 20 years, 34% from 20 to 64 years and 7% over 65 years (UNDESA, 2021).
For forcibly displaced migrants, adults (≥18 years) represented more than half of forced migrants (60%, with 53% aged 18-59 and 7% over 60 years), whereas children alone (0-17 years) accounted for the remaining 40%. Forcible displaced migrants were almost equally divided by gender across all age categories (UNHCR, 2024).

5.1.2 Real-World Migratory Flows: Countries of Origin and Resettlement

From the UNDESA data (2021), mostly international migrants came from Europe (63,27 million, 23%), followed by Latin America (42,89 million, 15%), South Asia (42,07 million, 15%) and East Asia (38,40 million, 14%). Sub-Saharan Africa (28,28 million) and Middle East (26,61 million) represented 10% and 9% of all countries of origin, respectively. Less represented world regions were Central Asia and North Africa (4%; respectively, 11,25 million and 12,28 million), North America (2%; 4,33 million) and Pacific (1%; 1,97 million). At the country-level,

India was the most represented (17,79 million, 6%), followed by México (11,07 million, 4%), Russian Federation (10,65 million, 4%), and China (9,80 million, 4%). Within the ten most represented countries of origin worldwide, the remaining six were Syria (over 8 million), Bangladesh (7,34 million), Pakistan (6,14 million, Ukraine (6,05 million), Philippines (6,01 million), and Afghanistan (5,85 million). Then, origin countries up to the 20th were Venezuela, Poland, UK, Indonesia, Kazakhstan, Palestinian territories, Romania, Germany, Myanmar, and Egypt, ranging from 4,49 million to 3,57 million. Middle income countries represented the majority of origin countries (63%; 177,40 million), almost equally subdivided between lower-middle (32%; 89,75 million) and upper-middle (31%; 87,65 million); high income countries accounted for 19% (52,81 million), whereas low-income countries for 14% (37,42 million).

On the other hand, main geographical regions of resettlement were Europe (31%; 86,71 million), North America (21%; 58,71 million) and Middle East (16%; 43,35million). Then, Sub-Saharan Africa (22,22 million) and East Asia (19,59 million) accounted for 8% and 7% of destination regions, respectively. Less represented regions were Central and South Asia (4%, 11,62 million and 11,07 million, respectively), Pacific (3%, 9,38 million), and North Africa (1%, 3,17 million). At the country level, USA and European countries were the destination for more than half of migrants (52%, 145,41 million), specifically USA alone accounted for 18% (43,43 million) of all international migrants, whereas in Europe, Germany for 6% (14,22 million). Other main recipient countries were, up to the 10th, Saudi Arabia (13 million), Russian Federation (11,58 million), UK (9,36 million), United Arab Emirates (8,72 million), France (8,52 million), Canada (8,05 million), Australia (7,69million), and Spain (6,84 million). Italy was the following country (11th), with 6,13 million (2%) immigrants; then, up to the 20th, resettlement countries were Türkiye, Ukraine, India, Kazakhstan, Thailand, Malaysia, Jordan, Pakistan, and Kuwait.

The majority of migrants (65%; 181,90 million) moved to a high-income country, 31% (85,90 million) to a middle-income country (20% upper middle (57,38 million), and 10% lower middle (28,51 million), respectively), whereas only 4% (12,32 million) moved to a low-income country.

Considering country-to-country corridors for international migration, ‘México to United States’ was the main migration corridor with almost 11 million migrants, followed by ‘Syria to Türkiye’, ‘Ukraine to Russian Federation’, ‘India to United Arabian Emirates’, and ‘Russian Federation to Ukraine’ corridors, being the five most represented worldwide (IOM, 2024).

When focusing refugees and asylum seekers, Afghanistan was the main country of origin, together with Syria (6,4 million both), followed by Venezuela (6,1 million), Ukraine (6 million) and Sudan (1,5 million) (UNHCR, 2024). Almost three quarters (73%) of refugees originated from just these five countries, and 87% from just ten countries worldwide. In terms of resettlement countries, refugee populations were mostly hosted in the Islamic Republic of Iran (3,8 million), Türkiye (3,3 million), Colombia (2,9 million), Germany (2,6 million) and Pakistan (2 million) at the end of 2023 (UNHCR, 2024). A slight change in resettlement countries occurred in the last few years; as a matter of fact, Türkiye was the main country of resettlement, followed by Colombia, Uganda, and Pakistan in 2021 (UNHCR 2022), whereas from 2022 Iran and Germany emerged as main hosting countries, in addition to Türkiye, Colombia, and Pakistan (UNHCR, 2023). Based on the new updated UNHCR report (2024), new countries of destination, in terms of individual applications’ requests, emerged, with the United States (USA) being the most represented, receiving 1,2 million refugees’ applications in 2023. It was followed by Germany (329 thousand), Egypt (183 thousand), Spain (163 thousand), and Canada (147 thousand). Other countries were main hosting countries when the proportion of refugees compared to their internal population was considered, namely Aruba island (1 refugee in 5 citizens), Lebanon (1 in 6), Montenegro (1 in 9), Curacao (1 in 13) and Jordan (1 in 16) (UNHCR, 2024). From a general overview of forcible displacement flows in the last year, 69% of refugees were hosted in neighborhood countries and 75% hosted in low- and middle- income countries (UNHCR, 2024). At the end of 2023, these forced displacements resulted in 6,1 million people returning to their home country (5,1 million IDPs and 1 million refugees), whereas 159 thousand refugees were resettled and 32 thousand received citizenship (UNHCR, 2024).

For internally displaced persons, considering all IDPs at the end of the 2023 for any cause, Sudan (9,1 million), Syria (7,2 million), and Democratic Republic of Congo (DRC) (6,8 million) were the three most affected countries, and Sub-Saharan African countries alone represented 46% of all IDPs globally (IDMC, 2024)[8]. Specifically, IDPs displaced for conflict and violence at the end of 2023, were above all in Africa within Sudan (9,1 million) and DRC (6,7 million), and in Middle East within Syria (7,2 million) and Yemen (4,5 million); massive violence-related internal displacements took place also in Colombia (5,1 million). Disaster-related internally displacements occurred, on the other hand, mostly in South Asia within Afghanistan (1,5 million) and Pakistan (1,2 million), in Ethiopia (881 thousand), in Türkiye (822 thousand) and in China (639 thousand). Conversely, considering all IDPs people displaced only in the year of 2023, five countries reporting highest numbers of IDPs due to disasters, namely China (4,70 million), Türkiye (4,05 million), Philippines (2,59 million), Somalia (2,04 million) and Bangladesh (1,79 million). The five countries most affected by violence-related internally displacements in 2023 were, in turn, Sudan (6,04 million), Democratic Republic of Congo (DRC) (3,77 million), Palestine (3,44 million), Myanmar (1,30 million) and Ethiopia (794 thousand). Compared to the previous year, new countries emerged as main recipients of IDPs, namely Sudan, Türkiye and Palestine, whereas other countries registered a decline in internal displacements, above all Ukraine and Pakistan[9].

Considering the Italian context to draw comparisons with the RESPOND trial, the Italian National Institute of Statistics (ISTAT) reported a consistent immigration for the years 2022-2023, with 697 thousand immigrants, respectively 336 thousand in 2022 and 360 thousand in 2023 (ISTAT, 2024). This highlighted an increased

[8] On the other hand, Syria (6,87 million), Afghanistan (6,55 million) and Democratic Republic of Congo (DRC) (5,96 million) were the three most affected countries by internal displacements at the end of the previous year, 2022.

[9] In 2022 the five most represented countries for disaster-related internal displacements were Pakistan (8,17 million), Philippines (5,45 million), China (3,63 million), India (2,51 million), and Nigeria (2,44 million); and for conflict and violence were Ukraine (16,87 million), Democratic Republic of Congo (DRC) (4 million), Ethiopia (2,03 million), Myanmar (1 million) and Somalia (621 thousand).

trend with respect to the pandemic phase, as well as a 43% increase compared to 2021 (244 thousand). During the last two years (i.e., 2022-2023), an increase in immigrations mainly from Europe (+40%), Africa (+39%) and Asia (+32%) was registered. Main European countries of origin were Ukraine (30 thousand in 2022 and 33 thousand in 2023), Albania (29 thousand yearly) and Romania (25 thousand), representing 24% of all migrations to Italy in 2022-2023. Main African and Asian countries accounted for 28% of all Italian immigrants, respectively 13% and 15%. Bangladesh (23 thousand), Pakistan (18 thousand) and India (13 thousand) were the three main countries of origin from Asia; on the other hand, from Africa main origin countries were Morocco (19 thousand), Egypt (17 thousand) and Tunisia (10 thousand). From 2021, there was also an increase of 80% in immigrations from Latin America, especially Argentina and Brazil, mainly related to the request of *iure sanguinis* citizenship (ISTAT, 2024).

5.1 Results of the MARD Database[10]

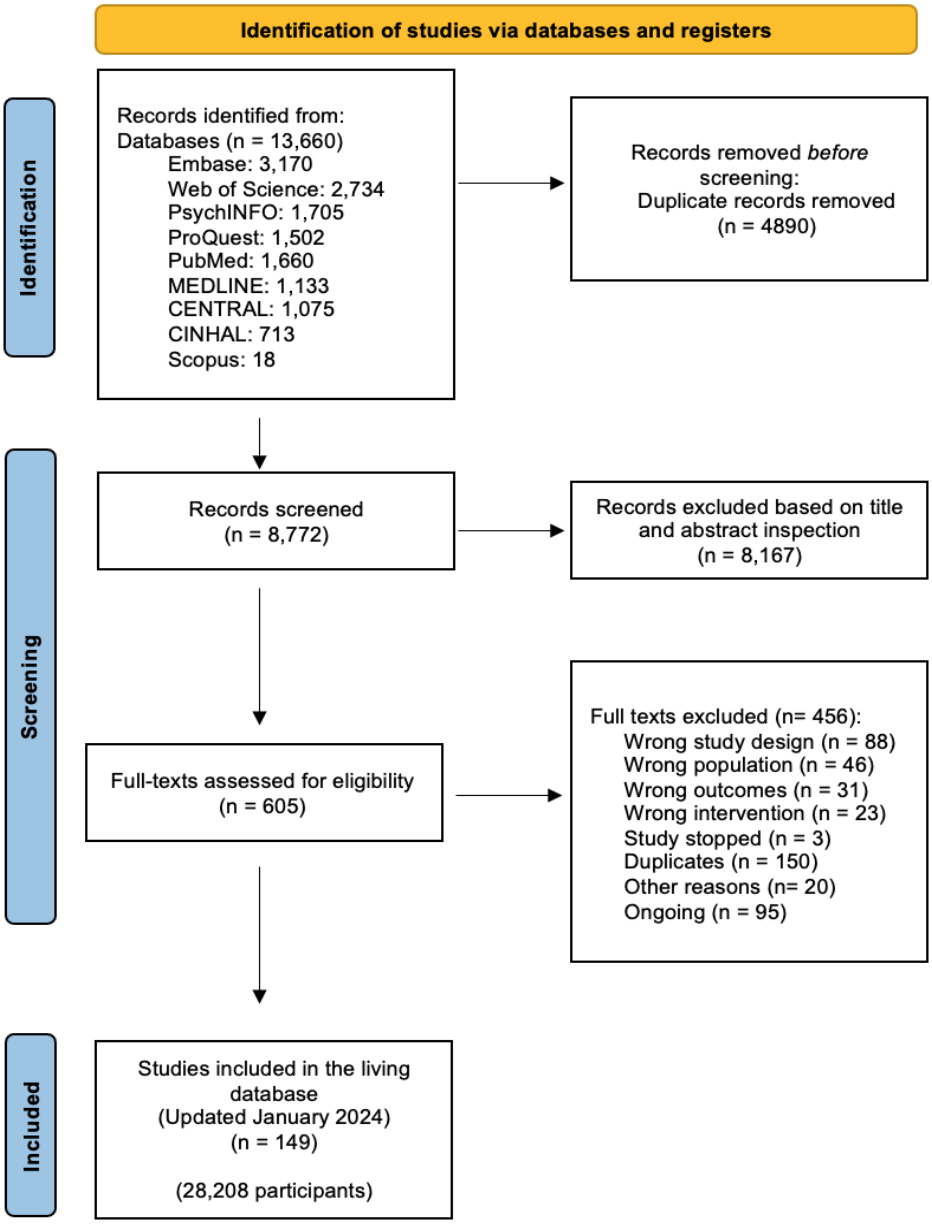
A total of 13,660 records were yielded from databases' searches until January 2024. After removing duplicates (k=6,938), 8,772 titles and abstract have been screened independently by two reviewers. The full-text screening was performed on 605 articles. Of them, 149 studies were included with a total of 28,208 participants (n=13,216 intervention group; n=14,455 control groups)[11] and 456 full texts were excluded. Main reasons for exclusion were duplicates (k=150), wrong study design (k=88), wrong population (k=46), wrong outcomes (k=31) and wrong interventions (k=23). The remaining papers included 95 ongoing studies, and 20 studies that were excluded for other reasons (four awaiting assessment, 13 full texts not retrieved,

[10] Reported percentages refer to the total number of included studies (k=149), if not otherwise specified, and are rounded without decimals. Therefore, there could be a slight discrepancy with respect to 100% due to rounding.

[11] Total number of randomized does not coincide with the number for each trial arm due to discrepancies in two studies, namely, one did not report participants divided by group, and another did not report the number of dropouts from randomization to intervention start by group.

and three studies stopped). For full references of included and excluded studies with reasons see Cadorin and colleagues (2024), and the flowchart below (Figure 3) and appendices S2-S3[12]. The main characteristics of included studies are presented in Table 3, at the end of the chapter.

Figure 3: PRISMA Flowchart



[12] Full references of included and excluded studies in Cadorin and colleagues (2024) are updated until January 2023, not including the last search update in January 2024, that yielded 116 new records screened at full text, of which 102 excluded, mainly duplicates, and 14 new studies included.

Of 149 included studies, 47 (32%) were published before 2015, 49 (33%) between 2015 and 2020, and 53 (36%) from 2021 until January 2024, with an average of four studies published per year. Starting from the first year of publication in 1990, papers were mostly published in the last four years, between 2020 and 2023 (k=19 (13%) in 2020, k=14 (9%) in 2021, k=23 (15%) in 2022, and k=16 (11%) in 2023) (see Figure 7 in paragraph 5.4). For asylum seekers and refugees, 98 studies were published from 1990 to 2023, with an increase from 2020 to 2022 (k=16 (11%) in 2020, k=14 (9%) in 2021, and k=17 (11%) in 2022) but registering a decline in 2023 (k=9, 6%).

Regarding the study design, most studies were individual RCTs (k=107, 72%), followed by pilot randomized trials (k=22, 15%), cluster RCTs (k=14, 9%), quasi-RCTs (k=4, 3%), and crossover RCTs (k=2, 1%).

In terms of risk of bias, 118 (79%) included studies were assessed for the outcome depression, 95 (64%) for the outcome PTSD, 77 (52%) for the outcome anxiety, and 33 (22%) studies for the outcome psychological distress. Eighteen (15%) studies were considered at low risk of bias for the outcome depression, 17 (18%) for the outcome PTSD, 13 (17%) for the outcome anxiety, and one (3%) for the outcome distress. Eighty-three (70%) studies were evaluated as having 'some concerns' for the outcome depression, 68 (72%) for the outcome PTSD, 53 (69%) for the outcome anxiety, and 27 (82%) for the outcome distress. Finally, 17 studies (14%) resulted at high risk of bias for the outcome depression, ten (11%) for the outcome PTSD, 11 (14%) for the outcome anxiety, and five (15%) for the outcome psychological distress[13]. See Appendices 3 for the results of RoB-2 assessments, divided by outcome (both overall graphs and single-study assessments are provided).

[13] Percentages were firstly calculated with respect to the total included studies (k=149); then, when considering RoB results for each outcome, percentages referred to total studies assessed for that specific outcome, namely, k=118 for depression, k=95 for PTSD, k=77 for anxiety and k=33 for distress.

5.2.1 Participants: Socio-demographic Characteristics

Studies included mostly adults (k=114, 77%), and two studies (1%) focused on older adults. N studies focused on children and adolescents (k=23, 15%)[14]. The remaining studies (k=12, 8%) included mixed populations of children and adults. Eighty-four studies (56%) included mostly females (more than 50% of trial participants), whereas in 52 studies (35%) more than a half of participants were males. The mean age of participants was reported in 134 studies, and was 33.5 years, with a median of 34.5 years, and ranging from nine to 73 years.

Participants were mostly refugees and asylum seekers (k=98, 66%), with refugees accounting for the 46% of the population group included in the studies (k=69). Forty studies (27%) included economic migrants and other studies included internally displaced persons (IDPs) (k=11, 7%). Most studies (k=104, 76%) reported humanitarian crises as reason for displacement, and 4% (k=6) specified economic/personal reasons (k=4 (3%) labour and k=2 (1%) marriage). In 28 studies (19%) the reasons for displacement were not specified, and in 7% (k=11) of studies there were mixed reasons. Humanitarian crises included war (k=57, 38%), general humanitarian crises (k=33, 22%), conflicts (k=11, 7%), and genocides (k=3, 2%). There was a high percentage of studies for which the time since resettlement resulted not specified (k=63, 42%) or comprised a wide range of years (i.e., mixed) (k=26, 17%). Nevertheless, many migrants had resided in the host country for more than five years (k=33, 22%), of which a high percentage for more than ten years (k=18, 12%). In 26 studies (17%) participants were resettled for less than five years. The geographical setting where included participants lived was mostly urban (k=107, 72%), and refugee camps accounted for 18 studies (12%); 21 studies (14%) were mixed or not specified, and rural contexts accounted only for 2% (k=3).

In terms of participants' mental health conditions, the presence of CMDs was assessed as diagnosis or presence of symptoms at baseline, as reported by study authors. The diagnostic criteria used were cut-off scales (k= 84, 56%), clinical interviews (k= 10, 7%), and DSM or ICD manuals (k= 31, 21%). The presence of

[14] Age groups were considered as follow: children and adolescents (<18 years), adults (18-65 years), older adults (≥65 years).

CMDs was classified as ‘diagnosis’ (k=40, 27%), ‘probable diagnosis’ (k=29, 20%) in case of symptomatology meeting cut-off at questionnaires, ‘symptoms’ when symptoms were present but subthreshold (k=62, 42%), and ‘no symptoms’ (k=18, 12%). At baseline no studies reported on anxiety in terms of diagnosis and only two studies (1%) included participants having anxiety symptoms. Twelve studies (8%) included participants with a diagnosis of depression at baseline (of which k=5 (3%) probable and k=7 (5%) actual diagnosis) and other 12 (8%) with depressive symptoms. Forty-seven studies (32%) included participants with a diagnosis of PTSD (of which k=18 (12%) probable and k=29 (19%) actual diagnosis) and seven (5%) with PTSD symptoms at baseline. Ten studies included participants with mixed diagnoses, and 24 (16%) included participants with mixed symptoms, whereas distress symptoms were assessed in 16 studies (11%). Comorbidities with other mental disorders and use of concomitant medication were reported in 33 studies (22%). The main comorbidities included depression in five studies (3%), CMDs in nine (6%), addiction in two (1%) and mixed in 12 (8%) studies. Considering only refugees and asylum seekers (RAS), in 32 studies (33%) participants had a diagnosis (mainly PTSD) (k=27, 18%) and in 21 studies (21%) a probable diagnosis (mainly PTSD) (k=14, 9%). In 39 studies (40%) participants presented with symptoms at baseline, mostly mixed or distress symptoms (k=17 (11%) and k=11 (7%), respectively), whereas 6 studies (6%) included participants without mental health symptoms at baseline.

Recruitment of participants occurred in community settings (k=53 (36%), and in nine studies (6%) both community and social media recruitment) and clinical settings (k=42, 28%). Outpatient settings were community clinics in 25 studies (17%), healthcare clinics or hospitals in nine (6%), and in seven studies (5%) participants were recruited in university clinics. One patient (1%) was recruited from an inpatient setting. Other recruitment settings were refugee camps in 18 studies (13%), schools in 13 studies (9%), and five studies adopted online recruitment (3%), whereas door-to-door (i.e., home) recruitment was performed in two studies (1%) only. For 12 studies (8%) recruitment setting was mixed or not specified, specifically nine (6%) for mixed and three (2%) for not specified.

5.2.2 Migration Flows: Countries of Origin and Resettlement

Participants included in the studies of the MARD database mostly originated from Middle East (k=39, 26%; three countries), followed by East Asia (k=26, 17%; five countries) and Sub-Saharan Africa (k=15, 10%; eight countries). Many studies (k=38, 26%) included migrants originating from mixed countries (i.e., belonging to different geographical regions). No studies included participants from Pacific and North America. The remaining studies included participants from Latin America (k=11, 7%; two countries), South Asia (k=4, 3%; four countries), Europe (k= 5, 3%; two countries) and Central Asia (k= 4, 3%; one country). At the country level, Syria alone accounted for 20% of studies (k=29), followed by China (k=10, 7%), Afghanistan (k= 6, 4%), Burma or Myanmar (k=5, 3%). Other countries of origin were represented in four studies (Cambodia and Türkiye; 3% each), three (Iraq; 2%), two (Bosnia and Herzegovina, Mexico, Nigeria, South Sudan, Sri Lanka, Sudan, Uganda; 1%) or one study (Bangladesh, Burundi, Chechnya, Colombia, Democratic Republic of Congo (DRC), Eritrea, Iran, Kenya, Pakistan, Somalia, South Korea, Vietnam; 1%). See Figure 4 below for the geographical map of single countries of origin represented in the database[15].

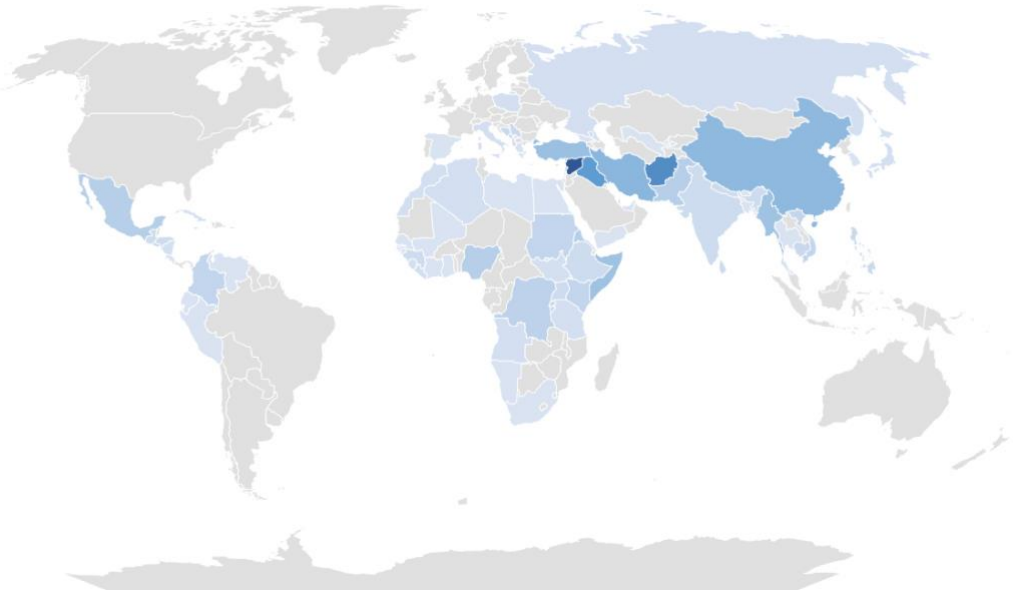
Following the World Bank (WB) classification for income, countries of origin were mostly low income (k=54, 36%); middle income countries accounted for 30% (k=44; specifically, k=16 (11%) lower-middle, k=22 (15%) upper-middle, and k=6 (4%) mixed, both lower- and upper-middle), whereas only 1% of studies (k=2) included participants from high-income countries. In many studies the income was mixed (k=47, 32%); nevertheless, among them, 27 studies (18%) included only low- and middle-income countries and four studies (3%) only included middle- and high-income countries.

For asylum seekers and refugees, Syria was the most represented country of origin (k= 29, 19%), followed by Afghanistan (k= 5, 3%), Myanmar (k= 4, 3%) and

[15] For the geographical maps, all available single countries were inserted. Therefore, in case of mixed country classification, each single country was retrieved and considered for the map, when available. A total of 78 countries of origin and 39 countries of resettlement were included for the geographical maps.

Cambodia (k= 4, 3%). Other countries were Iraq, Nigeria, South Sudan, Sudan, and Sub-Saharan Africa with two studies each (1%) The remaining countries were represented in individual primary studies (Bosnia and Herzegovina, Burundi, Chechnya, Democratic Republic of Congo (DRC), Eritrea, Iran, Sri Lanka, and Vietnam).

Figure 4: Countries of Origin – MARD Database



According to the database, the main destination of international migrants was Europe (k=52, 35%; ten countries), followed by North America (k=29, 20%; two countries), Middle East (k=18, 12%; five countries), and East Asia (k=15, 10%; six countries). In the remaining studies the countries of resettlement were distributed across the WB regions with percentages under 10%, ranging from 7% for Central Asia and Sub-Saharan Africa (both k=10, 7%; one and three countries, respectively) to 1% for Pacific and North Africa (both k=1 and one country), through Pacific (k=6, 4%, one country), South Asia (k=4, 3%; four countries) and Latin America (k=2, 1%; three countries). At the country level, the most represented countries were USA (k= 27, 18%), Germany (k= 17, 11%), Türkiye (k= 10, 7%), Jordan (k= 9, 6%), and Uganda (k=7, 5%). Other countries of origin were respectively

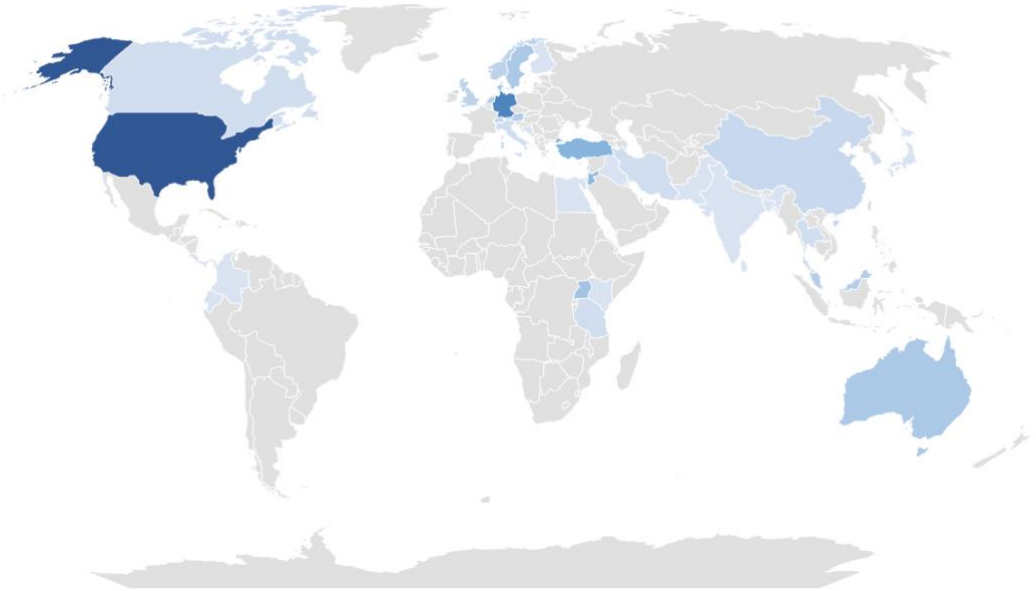
represented in six studies (Australia, Denmark, Lebanon, Sweden; 4% each), five (Netherlands; 3%), four (Austria, Malaysia; 3% each), three (China, Norway; 2% each), two (Canada, Hong Kong, Iran, South Korea, Switzerland, Tanzania, Thailand, United Kingdom; 1% each) or one study (Bangladesh, Bosnia and Herzegovina, Colombia, Egypt, India, Iraq, Israel, Italy, Japan, Kenya, Pakistan, Sri Lanka; 1%). See Figure 5 below for the geographical map of single countries of resettlement represented in the database.

Most studies were conducted in high income countries (k=94, 63%), followed by upper-middle income countries (k=36, 24%). Nine studies (6%) were conducted in lower-middle countries and ten (7%) in low-income countries.

For refugees and asylum seekers as well, most studies were conducted in high income countries (k=56, 38%), particularly in the United States of America (USA) (k=13, 9%) and Germany (k= 14, 9%), followed by Türkiye (k= 10, 7%) and Jordan (k=9, 6%) (that are upper-middle income countries). Denmark and Lebanon were the countries of resettlement in six studies (4%), Uganda was represented in five studies (3%) and Malaysia in four (3%). Australia, Austria, Sweden, and the Netherlands were the countries of resettlement in 12 studies (3 studies per country) (2%).

For internally displaced persons, the few included studies (k=11, 7%) were conducted in two countries, China, and Uganda, with three (2%) and two studies (1%), respectively. Other included countries of internal displacement were Bosnia and Herzegovina, Colombia, Iraq, Kenya, Pakistan, and Sri Lanka, represented by one study each (1%). From a broader geographical perspective, East Asia and Sub-Saharan Africa were the two geographical areas most represented, with three studies (2%) each. Five studies (3%) were conducted in upper-middle income countries, and three studies (2%) in low- and lower-middle income countries each.

Figure 5: Countries of Resettlement – MARD Database



5.2.3 Interventions

Following the Institute of Medicine guidelines (2009) for the classification of psychosocial interventions, based on the target population almost half of the included studies (k=73, 49%) were classified as treatment[16]. The other half (k=76, 51%) were classified as preventive studies, with 39 indicated prevention (26%) and 37 (25%) selective prevention studies. When applying the classification to the type of intervention, most studies (k= 89, 60%) were preventive in their nature, and 40% (k= 60) were designed for treatment. Adopting the classification of psychosocial interventions from the mhGAP guidelines (WHO, 2010), half of studies (k=78, 52%) tested interventions classified as 'psychological treatment', followed by 'reduce stress and strengthen social support' (k=44, 30%), 'psychoeducation' (k=15, 10%), 'promote functioning in daily activities' (k=6, 4%) and another 4% (k=6) had mixed components.

[16] Treatment classification comprised interventions delivered both to participants with confirmed mental health diagnoses and to participants with probable diagnoses, as also described in sub-paragraph 5.2.1.

The most studied intervention was ‘counselling and psychosocial support’ (k=69, 46%), followed by ‘psychotherapy’ (k=51, 36%); ‘family/parenting support interventions’ accounted for 11% (k=16) and 13 studies (9%) focused on ‘creative/expressive interventions’ (see Appendix for the full list of included interventions based on this classification).

Within the first category, psychosocial support accounted for 39% (k=58), whereas counselling for 7% (k=11) of total included studies. For psychosocial support, general psychosocial interventions were used in 12 studies (8%), psychoeducation in eight studies (5%), mindfulness and ‘Teaching Recovery Techniques’ (TRT) intervention in four studies each (3%). Two studies (1%) tested ‘care management and collaborative stepped-care model’ interventions and transdiagnostic interventions, respectively. The other psychosocial support interventions were tested in one study, focused on risk or protective factor, namely, strengths, stress management, need-satisfaction, life skills, resilience, personal resources, and trauma. The WHO psychosocial interventions, also classified as ‘psychosocial support’, represented 11% (k=17) of all interventions. The WHO interventions included in the database were mainly ‘Problem Management Plus’ (PM+) (k=8, 5%) in its individual (k=4, 3%) and group (gPM+) (k=3, 2%) formats, and in an adapted version (aPM+) (k=1, 1%). ‘Early Adolescent Skills for Emotion’ (EASE) was used in four studies (3%), ‘Self-Help Plus’ (SH+) in three (2%), ‘Doing What Matters in Time of Stress’ (DWM) and ‘Step-by-Step’ (SbS) in one study (1%) each. Different types of counselling interventions were applied, with supportive counselling used in six studies (4%), counselling with psychoeducation in two (1%), and expressive group, value-based and trauma counselling in one study each (1%).

Psychotherapy was the second category in terms of representativeness, with main interventions being ‘Cognitive Behavioural Therapy’ (CBT) - based/inspired interventions implemented in 22 studies (15%), and trauma-focused psychotherapies in 21 studies (14%) (see Table 2 for a complete overview of included psychotherapies and Appendices 2 for definitions of included psychotherapies). For CBT-based/inspired interventions, traditional CBT represented 9% (k=13) of all interventions, and an internet-based CBT (iCBT) was

delivered in three studies (2%). Two studies focused on two specific sub-types of CBT, namely 'Acceptance and Commitment Therapy' (ACT) and 'Cognitive Processing Therapy' (CPT), whereas remaining studies proposed integrations of CBT with biofeedback, mindfulness, 'Basic Body Awareness Therapy' (BBAT), or pharmacological intervention. For trauma-focused psychotherapies, 'Narrative Exposure Therapy' (NET) was the most represented, applied in 9% of studies (k=13), followed by 'Eye Movement Desensitization and Reprocessing' (EMDR) used in six studies (4%), with the remaining two studies using 'Imagery Rehearsal Therapy' (IRT) and 'Narrative Exposure Therapy for Children' (KIDNET), the adapted version of NET for children. Other types of psychotherapy were less represented (k=8, 5%), including 'Problem Solving Therapy' (PST) in three studies (2%), 'Interpersonal Therapy' (IPT) in two studies (1%), and psychodynamic, stabilization and intensive psychotherapy with care management in one study each (1%).

Table 2: Types of included psychotherapies

Established psychotherapies	N studies (%)
CBT-based/inspired	**22 (15%)**
Acceptance and Commitment Therapy (ACT)	1 (1%)
Cognitive Behaviour Therapy (CBT)	13 (9%)
CBT + Basic Body Awareness Therapy (BBAT)	1 (1%)
CBT + pharmacological intervention	1 (1%)
CBT + Biofeedback (CBT-BF)	1 (1%)
CBT + mindfulness	1 (1%)
Cognitive Processing Therapy (CPT)	1 (1%)
internet-based Cognitive Behaviour Therapy (iCBT)	3 (2%)
Trauma-focused psychotherapies	**21 (14%)**
Eye Movement Desensitization and Reprocessing (EMDR)	6 (4%)
Imagery Rehearsal Therapy (IRT)	1 (1%)
Narrative Exposure Therapy (NET)	13 (9%)
Narrative Exposure Therapy for Children (KIDNET)	1 (1%)
Other psychotherapies	**8 (5%)**
Intensive psychotherapy and case management	1 (1%)
Interpersonal therapy (IPT)	2 (1%)
Problem-solving therapy (PST)	3 (2%)
Psychodynamic therapy	1 (1%)
Stabilisation therapy (ST)	1 (1%)

Then, within family/parenting support interventions, parenting and family skills interventions were used in nine studies (6%), general family-based interventions in five (3%) and parental training in two (1%) studies.

Finally, within the creative/expressive interventions, expressive writing and music therapy programs accounted for three studies each (2%), two studies used play therapy (1%), and game-based learning intervention, laugher therapy, and structured sensory intervention were applied in one study (1%) each.

Regarding the delivery of interventions, group and individual levels were similarly represented with 73 studies (49%) and 70 studies (47%), respectively; mixed interventions accounted for six studies (4%). Within group interventions, dyad and family formats were used in few studies, one (1%) and two (1%), respectively. Almost all interventions were delivered face-to-face (k=123, 83%) and 11% (k=16) online, with synchronous (k=2, 1%), asynchronous (k=5, 3%), online guided self-help (k=5, 3%) or guided self-help (k=4, 3%) modalities. Other delivery modalities were mixed (k=3, 2%) or telephone-based (k=1, 1%); the latter was almost used in mixed formats, in adjunct to face to face (k=4, 3%) or to online (k=3, 2%) interventions.

People who delivered interventions were non-specialists (k=71, 48%) or mental health professionals (k=52, 35%). Non-specialists mainly included trained volunteers/facilitators (k=45, 30%), followed by paraprofessionals (k=10, 7%), community workers (CWs) (k=9, 6%), trained facilitators with a mental health background (k= 5, 3%), and primary-level healthcare workers (PHWs) (k=2, 1%). Interventionists were delivered in a ‘mixed’ modality in 12 studies (8%), engaging both mental health professionals and non-specialists. The delivery modality was not specified in ten studies (7%) and in four studies (3%) the intervention was delivered in a self-help modality, through app or website, without any personal interactions. Training and/or supervision were provided in most of the included studies (k=106, 71%); specifically, both training and supervision were applied in 78 studies (52%), training only in 21 (14%), and supervision only in seven (5%) studies.

Interventions were mostly delivered in clinical settings (k=47, 32%), followed by community settings (k=27, 18%). Other settings were similarly represented, namely, online and refugee camps (k=15, 10% both), schools (k=12, 8%), and home

(k=7, 5%). In 16 studies (11%) setting was not specified, whereas mixed and other settings both represented five (3%) studies. Clinical settings were almost all outpatient facilities (k=45, 30%); specifically, community clinics (k=26, 17%), university clinics (k=12, 8%), healthcare clinics or hospitals (k=4, 3%) and other healthcare facilities (k=3, 2%); for only two studies (1%) intervention was delivered in inpatient settings.

In terms of sessions, intervention duration ranged from one to 60 weeks with an average of 11 weeks and a median of eight; the number of sessions ranged from one to 46, with an average of ten sessions and a median of eight.

5.2.3.1 A focus on Psychotherapies

Among the 51 studies implementing psychotherapies, sub-datasets analyses on type of migrant population, age group, prevention level, baseline symptomatology, income of resettlement, delivery modes and format, were conducted[17].

Considering the type of migrants, for forced migrants (i.e., refugees, asylum seekers, and IDPs) psychotherapies were delivered in 41 studies (80%), of which the most represented were trauma-based psychotherapies (k=21, 41%). Specifically, NET accounted for 14 studies (27%, of which one KIDNET), EMDR for six studies (12%) and IRT for one study (2%). CBT-based interventions were applied in 15 studies (29%) with traditional CBT in ten studies (20%) and CBT-based[18] in five studies (10%), whereas IPT was used in two studies (4%) and the remaining four studies (8%) implemented other kinds of psychotherapies. On the other hand, for general migrants, psychotherapies were delivered in ten studies (20%), of which CBT was the most represented, accounting for seven studies (14%), with three (6%) traditional CBT, two (4%) iCBT and one (2%) ACT; other

[17] The following percentages are calculated on the total number of studies on psychotherapies, k=51.

[18] CBT-based interventions comprise CBT psychotherapies delivered in combination with other strategies, namely Basic Body Awareness Therapy, pharmacological intervention, biofeedback, and mindfulness, or interventions derived from CBT, like Acceptance and Commitment Therapy (ACT), Cognitive Processing therapy (CPT) and internet-based Cognitive Behaviour Therapy (iCBT) (see Table 2).

psychotherapies were PST in two studies (4%) and psychodynamic psychotherapy in one study (2%).

For age group, adult participants received psychotherapies in 44 studies (86%), with CBT-based being the most represented (k=22, 43%), delivered as traditional CBT (k=13, 25%), iCBT (k=3, %) and in combination with other strategies (k=6, 12%). Trauma-based psychotherapies accounted for 15 studies (29%), with NET used in ten studies (20%) and EMDR in five studies (10%). Remaining studies applied other types of psychotherapies, of which PST accounted for three studies (6%). For children six studies (12%) delivered psychotherapies, of which NET accounted for half of them (k=3, 6%), whereas EMDR, IPT and stabilization therapy for the remaining half (k=3, one study each).

Taking into account the type of prevention, treatment was the most represented with 34 studies (67%), mainly trauma-focused psychotherapy with NET accounting for 14 studies (27%, of which one KIDNET), EMDR for six (12%) and IRT for one study; CBT was applied in 11 studies (22%), of which seven (14%) traditional CBT and four (8%) integrated CBT, whereas other psychotherapies were used in remaining two studies (4%). For prevention/treatment six studies (12%) used psychotherapies, mostly CBT (k=4, 8%) of which two iCBT, and the remaining two studies used PST and IPT, respectively. For indicated prevention psychotherapies were applied in eight studies (16%), mostly CBT (k=5, 10%), of which traditional CBT in four studies (8%) and combined CBT in one; the remaining three studies (6%) applied IPT, PST and stabilization psychotherapy. Finally, for selective prevention only three studies (6%) applied psychotherapy, namely ACT, CBT, and PST.

Focusing on the type of diagnosis and/or symptoms at baseline, most psychotherapies addressed PTSD symptomatology, whereas for anxiety and distress no studies adopted psychotherapies. Among the 31 studies (61%) addressing PTSD, participants had a diagnosis in 25 studies and a probable diagnosis in four studies at baseline; trauma-focused psychotherapies were mostly implemented (k=20, 39%) with NET in 13 studies (25%), EMDR in six (12%) and IRT in one study (2%); CBT-based psychotherapy accounted for ten studies (20%) of which six (12%) for its traditional version, and the remaining study used IPT.

For depression, nine studies (18%) implemented psychotherapy, with CBT in five studies (10%, three (6%) traditional CBT and two (4%) iCBT); remaining studies used PST (k=2, 4%), IPT and intensive with care management (k=1, 2%, each). Psychotherapy addressed participants with depressive symptoms at baseline in four studies, probable diagnosis in two and diagnosis in three studies. Within the nine studies (18%) addressing mixed CMDs as symptoms (k=5), probable diagnosis (k=1) or diagnosis (k=3), CBT accounted for five studies (10%) of which three (6%) traditional CBT, whereas remaining four studies (8%) adopted NET, PST, psychodynamic and stabilization psychotherapy, respectively. Two studies (4%) including migrant participants without symptoms at baseline used psychotherapies, specifically CBT and ACT.

For income of resettlement, high income countries accounted for the majority of studies implementing psychotherapy (k=36, 71%), with CBT-based psychotherapy being the most applied (k=18, 35%, with k=10, 20% for traditional CBT and k=3, 6% for iCBT), followed by trauma-based psychotherapies (k=12, 24%), namely NET in nine studies (18%), EMDR in two (4%) and IRT in one study (2%); remaining psychotherapies were PST in three studies (6%) and other types (k=3, 6%). Eight studies on psychotherapies (16%) were conducted in upper-middle income countries, half of which implementing EMDR (k=4, 8%), while CBT was used in three studies (6%) and NET in one study (2%). Lower-middle income countries were represented in two studies (4%), one implementing NET and the other IPT; finally, low-income countries accounted for five studies (10%), of which three (6%) delivered NET, and the other two IPT and CPT.

In terms of comparators, psychotherapies were mostly compared to waiting list (k=26, 42%), followed by CAU/ECAU (k=12, 19%), active psychosocial interventions (k=7, 11%), psychological and attentional placebo (k=4, 6%) and no treatment (k=2)[19]. Excluding WL and no treatment, main control interventions were psychotherapies (k=12, 19%), basic services (k=6, 10%), counselling (k=4, 6%) and other mixed interventions (k=12, 19%). For psychotherapies in control conditions, almost half (k=6, 10%) were psychotherapies in association with a

[19] Total number of comparators was k=62, considering two- to four-arm studies together; percentages for this paragraph are thus related to the total number of comparators.

pharmacological intervention, whereas CBT, EMDR and stabilization therapy accounted for two studies (3%) each, and exposure therapy for one study (2%).
Finally, considering intervention format, almost all psychotherapies were delivered face-to face (k=45, 88%), whereas four studies (8%) provided self-guided psychotherapies and mixed formats was used in two studies (4%). Individual-level psychotherapy was delivered in 36 studies (71%), group psychotherapy in 12 studies (24%) and mixed-level, both individual and group psychotherapy, in three studies (6%). Psychotherapies were mostly delivered by mental health professionals (k=35, 69%), while non-mental health professionals accounted for the remaining 31% (k=16) with trained facilitators for seven studies (14%), CWs or PHWs for three (6%), paraprofessionals and mixed personnel for two studies (4%) each. The number of psychotherapeutic sessions ranged from two to 46, with a median of nine sessions, and the total duration of these interventions ranged from three days to one year.

5.2.4 Comparators

Almost all the included studies used a two-arm parallel design (k=127, 85%). Seventeen studies (11%) used a three-arm design (i.e., two control conditions) and five (3%) a four-arm design (i.e., three control conditions). When compared to intervention groups (i.e., all active interventions), a classification of control conditions into active, neutral, or inactive was performed[20]. The first control groups were almost inactive (k=117, 79%), active in 20 studies (13%) and neutral in 12 (8%) studies. In three- and four-arm studies, while for the first control condition

[20] According to this classification, control groups were considered inactive when no specific intervention was provided (i.e., waiting list or no intervention), neutral when an intervention was provided but without specific psychological ingredients added or it was also provided to the intervention group (i.e., usual care in terms of basic health/social services), and active when it was deemed comparable to the intervention in terms of type, structural ingredients, and intensity.

was considered the inactive intervention, the second and third controls were active, almost all psychosocial interventions[21].

Considering all control conditions together (k=176)[22], most studies (k=66, 38%) used waiting list (WL) and 44 studies (25%) delivered (enhanced-)care-as-usual, respectively, TAU in 27 studies (15%) and ETAU in 17 studies (10%). Thirty-eight studies (22%) delivered an alternative psychosocial intervention, 15 studies (9%) an attentional placebo (k=8, 5%) or a psychological placebo (k=7, 4%), whereas for 13 studies (7%) control participants received no treatment. Excluding waiting list and no treatment, among "active" control conditions (k=97, 55%) studies mostly provided basic health/social services (k=30, 17%), psychotherapies (k=22, 13%), psychoeducation (k=17, 10%), and psychosocial interventions (k=12, 7%). Creative/expressive interventions (k=4, 2%), parenting and family skills intervention (k=3, 2%) studies and other control groups (k=9, 5%) were less represented.

Psychotherapies mainly comprised CBT (k=6, 3%), in its traditional form (k=5, 3%) or in association with physical activity (k=1, 1%), EMDR (k=3, 2%) and stabilisation therapy (k=2, 1%). Other types of psychotherapy were exposure therapy, trauma focused psychotherapy, cognitive restructuring, and 'Stress Inoculation Training' (SIT) (k=1, 1% each). Seven studies (4%) included psychotherapy in adjunct to pharmacological interventions. Psychosocial interventions were used in 29 studies (16%), mainly psychoeducation (k=17, 10%). Specifically, supportive counselling was delivered in three studies (2%), non-directive supportive therapy and general psychosocial intervention in two studies each (1%). Other psychosocial interventions were mindfulness, problem solving intervention, WHO psychosocial intervention, trauma counselling, 'Teaching Recovery Technique' (TRT), used in one study each (1%). Creative/expressive interventions included general creative/expressive interventions (k=3, 1%) and

[21] Three- and four-arm studies were 22 for the second control condition (k=17 for three-arm studies and k=5 for four-arm studies, respectively), and five for the third control group (only four-arm studies).

[22] Reported percentages refer to the total number of control groups, considering all comparators together (k=176).

expressive writing (k=1, 1%). Remaining control groups included lectures on different topics (k=3, 2%), pharmacological interventions alone (k=2, 1%), interviews and exercise therapy (k=1, 1% each) and not specified (k=2, 1%).
Considering the intervention format, control interventions were mainly provided at individual level (k=57, 32%); group level format accounted for 23 studies (13%) and other formats for the remaining 17 studies (7%), specifically, three (2%) mixed, and 14 (8%) not specified. The duration of control interventions ranged from one to 46 sessions.

5.2.5 Outcomes

A total of 117 studies (79%) assessed symptoms of depression, 91 studies (61%) of PTSD, 75 studies (50%) of anxiety and 30 studies (20%) of psychological distress[23].
Positive mental health outcomes were assessed in 31% of studies (k=46), with 26 (17%) and 20 studies (13%) reporting on well-being and quality of life, respectively. Functioning was reported by 43 studies (29%), with functional impairment being the most represented sub-type (k=26, 17%), followed by relational/interpersonal functioning (k=9, 6%), psychosocial (k=6, 4%) and global functioning (k=2, 1%).
In terms of study endpoints, almost all the included studies (k=134, 90%) assessed outcomes within one month after the end of the intervention, 14 studies (9%) from one to six months, and one study (1%) from seven to 24 months post-intervention.
More than half of studies (k=87, 58%) had follow-up measurements after the end of the intervention, compared to 42% having no medium or log-term follow-ups (k=62, 42%). The number of follow-ups was one in 46% of studies (k=69), two in 16 studies (11%), and three in two studies (1%). Follow-ups reached up to 36 months (three years) post-intervention, whereas most represented follow-up timepoints occurred one, three and six months after intervention completion.

[23] For both depression and anxiety symptoms in 17 studies (11%) were used proxies, namely, questionnaires measuring internalizing symptoms, or a combination of anxiety and depression.

Table 3: Characteristics of included studies – MARD migrants

POPULATION							
Age group	**N studies (%)**	**Target group**	**N studies (%)**	**Reason for displacement**	**N studies (%)**	**Time since resettlement**	**N studies (%)**
Adults (≥18)	114 (77%)	Refugees/asylum seekers	98 (66%)	Humanitarian crisis	104 (76%)	< 5 years	26 (17%)
Children/adolescents (<18)	23 (15%)	Internally displaced persons	11 (7%)	Work/family	6 (4%)	> 5 years	33 (22%)
Mixed (children and adults)	12 (8%)	Other types of migrants	40 (27%)	Not specified	28 (19%)	Not specified	63 (42%)
						Mixed	27 (18%)
INTERVENTION							
Goal	**N studies (%)**	**Type of intervention**	**N studies (%)**	**Delivery level and format**	**N studies (%)**	**Delivered by**	**N studies (%)**
Promotion	0 (0%)	Psychotherapy	51 (36%)	Level		Professionals	52 (35%)
Universal prevention	0 (0%)	Counselling/psychosocial support	69 (46%)	Group	73 (49%)	Non-specialists	61 (45%)
Selective prevention	37 (25%)	Creative-expressive activity	13 (9%)	Individual	70 (47%)	Not specified	8 (6%)
Indicated prevention	39 (26%)	Family/parenting support	16 (11%)	Mixed	6 (4%)	Mixed	12 (9%)
Treatment	73 (49%)			Format		Other (online)	4 (3%)
				Face-to-face	123 (83%)		
				Online	17 (11%)		
				Mixed	9 (6%)		
CONTROL				**SETTING AND PUBLICATION YEAR**			
Number of study arms	**N studies (%)**	**Control condition**	**N studies (%)***	**Setting**	**N studies (%)**	**Publication year**	**N studies (%)**
Two	127 (85%)	Attentional placebo	8 (5%)	Clinical	47 (32%)	2021 – today	53 (36%)
Three	17 (11%)	Treatment as usual	27 (15%)	Community	27 (18%)	2015 – 2020	49 (33%)
Four	5 (3%)	Enhanced treatment as usual	17 (10%)	Home/online	22 (15%)	Before 2015	47 (32%)
		No treatment	13 (7%)	Refugee camp	15 (10%)		
		Psychological placebo	7 (4%)	School	12 (8%)		
		Psychosocial intervention	38 (22%)	Not specified	16 (11%)		
		Waiting list	66 (38%)	Mixed/other	10 (7%)		
OUTCOMES							
Common mental disorders - symptoms	**N studies (%)**	**Positive mental health**	**N studies (%)**	**Functioning**	**N studies (%)**	**Follow-up**	**N studies (%)**
Post-traumatic stress	91 (61%)	Well-being	26 (17%)	General	2 (1%)	0-1 months	134 (90%)
Anxiety	75 (50%)	Quality of life	20 (13%)	Relational	9 (6%)	1-6 months	14 (9%)
Depression	117 (79%)			Functional impairment	26 (17%)	7-24 months	1 (1%)
Psychological distress	30 (20%)			Psychosocial	6 (4%)		

Notes:
Reported percentages refer to the total number of included studies (k=149), if not otherwise specified, and are rounded without decimals. Therefore, there could be a slight discrepancy with respect to 100% due to rounding.
*For control condition percentages refer to the total control conditions (k=176).

5.3 Results of the RCT[24]

5.3.1 RCT Participants: Socio-demographic Characteristics

In total, 238 potentially eligible subjects were screened, of which 217 were included and randomized, 108 in the intervention group (stepped-care program, DWM and PM+) and 109 in the control group (ETAU). Trial participants were mostly recruited through Non-Governmental Organizations (NGOs), community-based organizations providing psychosocial services to migrant populations, as well as through social media and word-of-mouth.

Regarding main sociodemographic characteristics of all trial participants, mostly participants (63%) were women and 36% were men; age ranged from 19 to 68 years, with 36 years on average. In terms of migration status, only 18% were asylum seekers or refugees, also comprising migrants without documents; more than half of participants had a permanent residence in Italy (60%) or a temporary permit to stay (22%). The trial reported a duration of the migration journey of less than six months for most participants (84%), whereas for 16% of participants it lasted more than six months.

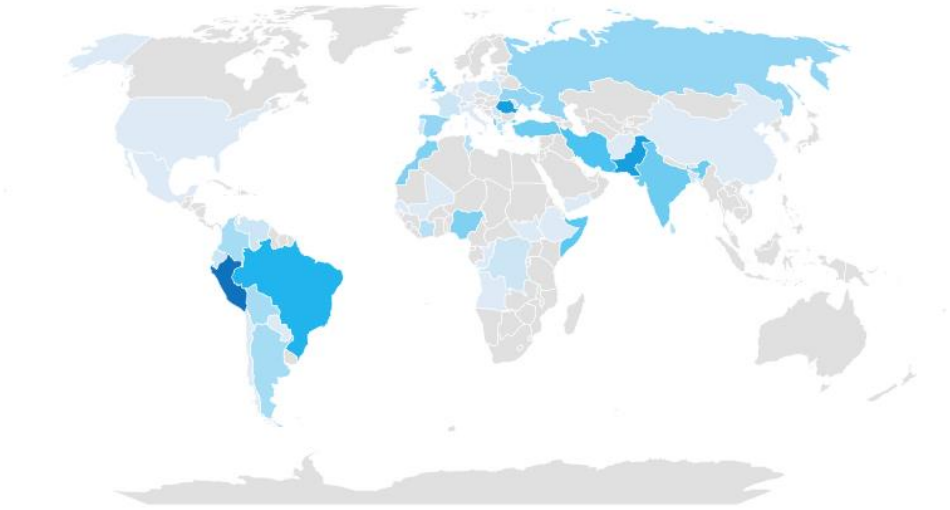
Countries of origin were in total 54, mostly including more than one participant each; for a graphic representation of countries of origin see Figure 6 below. Considering individual countries, participants mainly originated from Perú (n=24, 11%), Pakistan and Romania (n=16, 7% each), Brazil (n=12, 6%), Iran (n=9, 4%), and Somalia (n=8, 4%). For eight participants (4%) data were missing, whereas other countries had seven to one participant each. Namely, three countries had seven, six and five participants each; four countries had four participants each; five countries had three participants each; ten countries included two participants each and remaining 19 countries had only one participant each. Following the same geographical classification applied for the MARD database using the WB criteria,

[24] Results from the trail have been fully reported in a recently published paper (Purgato et al., 2025). Secondary papers analyzing other study outcomes (e.g., resilience and cost-effectiveness) will be published elsewhere.

Europe was the most represented geographical region with 64 participants (30%) across 18 countries. It was then followed by Latin America with 55 participants (25%) across nine countries, South Asia with 29 participants (13%) from five countries, and Sub-Saharan Africa with 28 participants (13%) from 11 countries. Then, all the other geographical areas had percentages below ten, namely, Middle East with 14 participants (7%) from three countries, North Africa with nine participants (4%) from two countries, Central Asia with seven participants (3%) from one country (Türkiye). Finally, least represented WB regions were East Asia with two participants (1%) from two countries, North America with one participant (1%) from USA, and no participants originated from Pacific. In terms of income, study participants mostly came from middle income countries (n=138, 64%), almost equally divided between low-middle (k=66, 30%; 14 countries) and upper-middle (k=72, 33%; 14 countries). High-income countries accounted for 23% (n=49; 17 countries) and low-income for 8% (n=18; 8 countries), whereas for the remaining 4% (n=8) income was not specified (See

Table **5** at the end of the chapter).

Figure 6: Countries of Origin – RESPOND Trial



5.3.2 RCT Interventions and Outcomes

As for the stepped-care model process, after the first intervention level (i.e., DWM), more than half participants stepped to the second-level intervention (i.e., PM+), still showing symptoms of distress by scoring above the cut-off of 16 at the K10, as assessed at T2 (i.e., seven weeks after baseline and two weeks post-intervention). Nevertheless, 32% of participants in the intervention group (35/108) showed a clinically significant improvement in their psychological distress, compared to 21% of participants (23/109) from the control group, thus not stepping to the PM+ intervention.

From effectiveness analysis of trial results, intervention group showed a greater reduction in psychological distress (i.e., the primary outcome of the study, based on the composite measure of anxiety and depression symptoms by the PHQ-ADS) compared to the control group, at T4 (i.e., primary endpoint), as well as at all other timepoints. The effect of the intervention was more pronounced in participants with higher baseline levels of anxiety and depression. Positive effects of the intervention were also observed for the secondary outcomes of depression, anxiety, and PTSD symptoms and for self-identified problems (PSYCHLOPS) at the different timepoints post-intervention (i.e., T2, T3, T4).

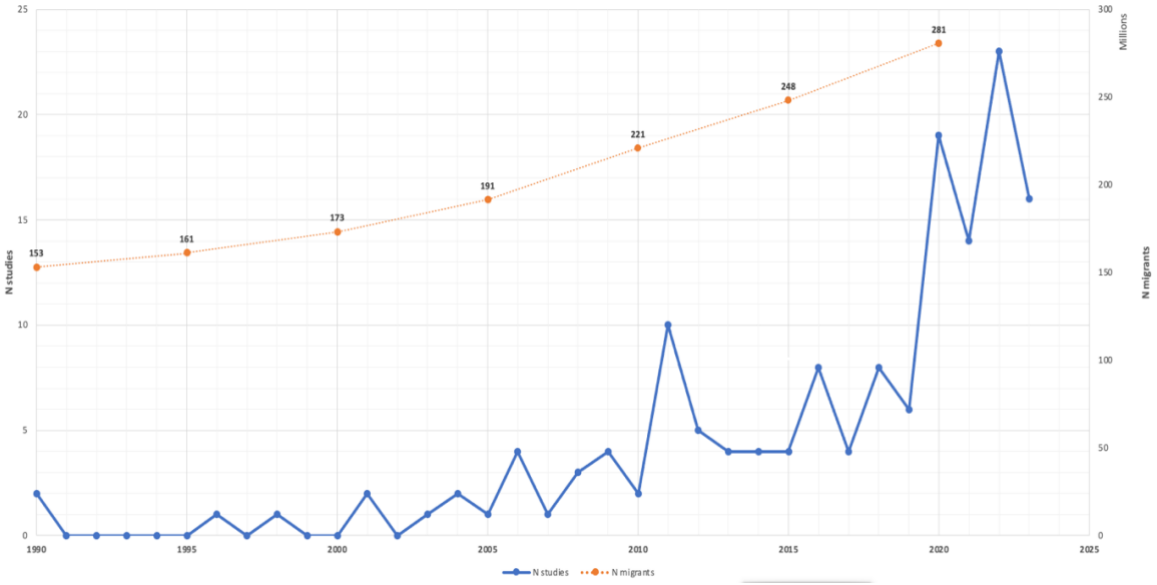
In terms of interventions' completion, 88% of participants (95/108) completed the first intervention level (DWM), attending at least three intervention sessions; high rates were also observed for the second intervention level (PM+) with 80% of participants (49/61) considered completers, attending at least four sessions. On the other hand, for outcome assessments, an attrition rate of 7-10% was observed at all assessments, without significant differences between the two groups. A total of only 17% of randomized participants were considered lost to follow-up, namely, dropouts at the final and primary study endpoint (T4), 21 weeks after baseline.

5.4 Comparisons MARD, RCT, and Epidemiological Data[25]

5.4.1 Comparison MARD and Epidemiological Data

Comparing publication year of included studies with the five-year migration flows' trends, migratory flows of international migrants grew constantly over the years since 1990 (UNDESA, 2021; Figure 7). Publication of studies followed an increased pattern as well, with peaks in 2011, 2020, and 2022. There was a quite equal distribution of publications within macro-categories of years (i.e., before 2015, 2015-2020, and 2021-present), even though publication rate notably changed across single years. Nevertheless, a different pattern emerged considering only asylum seekers and refugees, with a slow decline from 1990 to 2005 in the number of forced migrations, as well as publications, followed by a constant increase until present days. There were no studies published from 1991 to 2000, whereas peaks were in 2011, 2018, 2020 and in 2022.

Figure 7: Publication Years and Migration Flows



[25] For a brief overview of the general comparison between the MARD database, the RCT trial and epidemiological data see Table 5 at the end of the chapter.

Taking into account the sociodemographic characteristics of migrants, studies on asylum seekers and refugees were over-represented in the database, whereas, instead, economic and labour migrants were main migrant populations worldwide. From international reports, main reason of displacement was economic (labour); within humanitarian crises, disasters also played an important role along with war- or conflict-related displacements, which, in turn, constituted the majority in the database. For population age, there were fewer studies in the database including older adults (2%), compared to real-world situation (12%), whereas children and adolescents were almost comparable. Nevertheless, when considering refugees and asylum seekers, research studies did not match with epidemiological figures, showing an under-representation of children and adolescents (13% in the database versus 40% worldwide). For gender, men and women were almost equally distributed worldwide (52% males and 48% females), both for international migrants and forced migrants; on the other hand, in the database, for more than half of studies (58%) women constituted the majority of study participants. Considering mental health screening and diagnoses, Carroll and colleagues (2023) found that in general, prevalence of CMDs was similar across disorders, whereas anxiety and depressive disorders were less represented with respect to PTSD in the database.

One main focus of analysis was on migratory flows, where differences in terms of representativeness of single countries or World Bank regions between database and literature emerged. At the World Bank geographical level, for countries of origin, there was a lower representation of Europe, Latin America, and South Asia in the database, with, in turn, an over-representation of Middle East. In terms of single countries, Syria, China, Afghanistan, and México were included both in the database and in international reports within the first ten countries, even though with different weights, whereas some of the most represented countries worldwide were not accounted in studies, namely India, Russian Federation, Pakistan, Ukraine and Philippines. There was a higher representation in the database of low-income countries (36%) with respect to middle-income countries that were prevalent worldwide (63% versus 26% in the database). High-income countries were less represented in the database with two studies, while accounting for 19% of all international migrants. For countries of resettlement there was a greater

comparability between database and world reports, with the only difference for Latin America that was under-represented in the database. At the country level, studies followed the international trend for the two main destination countries, USA, and Germany. Nevertheless, some countries were not included in the database but represented in the world's migration flows, such as Saudi Arabia, Russian Federation, UK, United Arab Emirates, France, Canada, and Spain. On the other hand, Türkiye, Jordan and Uganda were included in the database as other main countries, not being the same at the global level.

Differences in migration flows emerged also for the type of migrant populations, when only considering refugees and asylum seekers or internally displaced people. As a matter of fact, for internally displaced persons countries did not correspond between the database and the GRID 2024 report (IDMC, 2024). Sudan, Syria, and Democratic Republic of Congo (DRC) were the most represented worldwide at the end of 2023, but they were not included in the database for IDPs, in which Uganda and China were the two main countries for internal displacement. For refugees and asylum seekers, Afghanistan and Syria were the two main countries of origin, both for the database and the UNHCR 2024 report, whereas Venezuela and Ukraine were not represented in the database despite massive displacements since 2020 (UNHCR, 2024). RAS populations were mostly hosted in the Islamic Republic of Iran, Türkiye, Colombia, Germany, and Pakistan, while most studies were conducted in USA, Germany, Türkiye, and Jordan, determining only a partial overlap between migration reports and research studies. For a complete overview of the comparison between the MARD database and epidemiological data see Table 4 below.

Table 4: Comparison characteristics MARD – Epidemiological data

MIGRATORY FLOWS											
Country of origin			**Income country of origin**			**Country of resettlement**			**Income country of resettlement**		
	DATABASE N studies (%)	**N migrants millions (%)**		**DATABASE N studies (%)**	**N migrants millions (%)**		**DATABASE N studies (%)**	**N migrants millions (%)**		**DATABASE N studies (%)**	**N migrants millions (%)**
East Asia	26 (17%)	38,40 (14%)	Low	54 (36%)	37,42 (14%)	East Asia	14 (9%)	19,59 (7%)	Low	10 (7%)	12,23 (4%)
Pacific	0 (0%)	1,97 (1%)	Lower Middle	16 (11%)	89,75 (32%)	Pacific	5 (4%)	9,38 (3%)	Lower Middle	9 (6%)	28,51 (10%)
Europe	5 (3%)	63,27 (23%)	Upper Middle	22 (15%)	87,65 (31%)	Europe	52 (35%)	86,71 (31%)	Upper Middle	36 (24%)	57,38 (21%)
Central Asia	4 (3%)	11,25 (4%)	High	2 (1%)	52,81 (19%)	Central Asia	10 (7%)	11,62 (4%)	High	94 (63%)	181,90 (65%)
Latin America	11 (7%)	42,89 (15%)	Mixed*	53 (36%)	NA (NA)	Latin America	2 (1%)	14,79 (5%)			
Middle East	39 (26%)	26,61 (9%)	Not specified	8 (5%)	12,97 (5%)	Middle East	18 (12%)	49,40 (16%)			
North Africa	0 (0%)	12,28 (4%)				North Africa	1 (1%)	3,17 (1%)			
North America	0 (0%)	4,33 (2%)				North America	29 (20%)	58,71 (21%)			
South Asia	4 (3%)	42,07 (15%)				South Asia	4 (3%)	11,07 (4%)			
Sub-Saharan Africa	15 (10%)	28,28 (10%)				Sub-Saharan Africa	10 (7%)	22,22 (8%)			
Mixed regions	39 (26%)	NA (NA)				Mixed regions	2 (1%)	NA (NA)			
Not specified	7 (5%)	9,25 (3%)									
MIGRANTS' POPULATION											
Target group			**Reasons displacement**			**Age group**			**Gender**		
	DATABASE N studies (%)	**N migrants millions (%)**		**DATABASE N studies (%)**	**N migrants millions (%)**		**DATABASE N studies (%)**	**N migrants millions (%)**		**DATABASE N studies (%)**	**N migrants millions (%)**
refugees/asylum	98 (66%)	30,5 (11%)	humanitarian	104 (76%)	40,5 (14%)	children/adolescents	25 (15%)	40,9 (15%)	males§§	52 (35%)	146 (52%)
internally displaced	11 (7%)	55 (20%)	economic	6 (4%)	169 (60%)	adults§	114 (77%)	239,7 (85%)	females	84 (56%)	135 (48%)
economic migrants	40 (27%)	169 (60%)**	not specified	28 (19%)	NA (26%)	mixed	12 (8%)	NA (NA)	other#	10 (7%)	NA (NA)
COMMON MENTAL DISORDERS (CMDs)											
Anxiety				**Depression**					**PTSD**		
	DATABASE N studies (%)	**Carroll 2023 N studies (%)**	**Carroll 2023 Prevalence (95%CI)**		**DATABASE N studies (%)**	**Carroll 2023 N studies (%)**	**Carroll 2023 Prevalence (95%CI)**		**DATABASE N studies (%)**	**Carroll 2023 N studies (%)**	**Carroll 2023 Prevalence (95%CI)**
Diagnosis##	0 (0%)	95 (39%)	24.69 (19.45-30.82)	diagnosis	12 (8%)	199 (81%)	28.65 (25.28-32.29)	diagnosis	47 (32%)	136 (55%)	31.33 (26.47-36.20)
symptoms	2 (1%)	NA (NA)	NA (NA)	symptoms	12 (8%)	NA (NA)	NA (NA)	symptoms	7 (5%)	NA (NA)	NA (NA)

Notes:
CMDs = common mental health disorders; NA = not applicable; PTSD = post-traumatic stress disorder
Percentages (%) were calculated based on: total number of studies (n=149) for the database; total n migrants' population (n=280 598 105 for migration flows, approximated to 281 million for migrants' population); total number of studies (n=246) for Carrol's review. For international migration flows from and to each geographical region, data are taken from UN DESA (2021).
* Here we added also the six studies comprising both lower- and upper-middle income countries
** The sum of percentages does not return 100% because here only labour migrants are reported.
§ Adults are considered within working age people (18-65 years), as well as older adults (>65 years). Older adults (>65 years) contribute with 2 studies (1%) from the database and 34,23million (12%) worldwide. Age categories applied were: children and adolescents (<18 years); adults (>=18 years); mixed if both children and adults together.
§§ Here, for the database, we consider studies with more than 50% males; and for the category females studies with more than 50% females.
# Other comprises "not specified" with 10 studies (7%) and "both genders" in which there is an equal subdivision between males and females (both 50%) with 3 studies (2%).
In the database CMDs diagnoses are based on DSM/ICD, clinical interview, cut-off scores.

5.4.2 Comparison MARD and RCT

Compared to the whole MARD database, there were some differences already from the design of the trial itself; as a matter of fact, the RESPOND trail comprised all adults, resettled in Italy, and symptomatic for distress at baseline. Therefore, to draw a better comparison, a two-step process was undertaken, firstly, a comparison between the trial and the whole database based on common variables and, secondly, studies with corresponding population characteristics were selected from the database and described. The following combination of variables was thus analyzed: adults recruited in HICs, and, in addition, WHO interventions and baseline screening applied.

5.4.2.1 General Comparison

Following the PICO framework, for population variables, age and gender were comparable, comprising mostly adults and female participants both in the database and in the trial; also mean age resulted similar, being on average around 33-36 years old. Nonetheless, for age category, the database also comprised studies with children and mixed populations (i.e., 77% adults in the database versus 100% in the trial). Recruitment of participants mainly occurred in community settings, also through social media, both in the trial and in the database. For inclusion of trial participants, a baseline screening using cut-off point at a questionnaire for CMDs symptoms was adopted in more than half of MARD studies (56%), which was comparable to the selection process performed for the RESPOND trial. As a matter of fact, inclusion in the trial required presence of psychological distress symptoms, as assessed with a score above 15.9 at the K10, configuring the trial as, at least, indicated prevention.

For type of migrant populations, refugees and asylum seekers (RAS) were mostly represented in the database (66%), whereas in the trial they were around 18%. In terms of other migration-related variables, reasons for migration were not assessed in the trail; nonetheless, considering the legal status as a rough indication, 82% of study participants had a permanent or temporary permit of residence, which is mainly acquired for study, work, or family reunion reasons. In the database, instead,

only 4% of studies stated economic/personal reasons for migration (i.e., study, work, marriage), while the majority of studies (76%) included participants affected by humanitarian crises. As well, while years of resettlement were extracted in the database, the duration of migration journey and legal status were assessed in the trial, which could give a proximate view of the migration process, even if not comparable.

Focusing on migration flows, Italy was the country of resettlement for the trial, a European high-income country; in the database there was only another study (1%) conducted in Italy, but the majority of studies were conducted in HICs (63%) and in Europe (35%). For country of origin, following the same WB classification, a different representation of geographical regions and countries emerged. For the trial main geographical areas were Europe (30%), Latin America (25%), South Asia and Sub-Saharan Africa (13% each); whereas for the database Middle East (26%), East Asia (17%), Sub-Saharan Africa (10%) and Latin America (7%) were the most represented. Nevertheless, there was a slight comparability for Sub-Saharan Africa (13% in the trial versus 10% in the database) and Latin America, which was still represented despite a greater variability (25% in the trial versus 7% in the database). At the country level no overlapping country was found, as a matter of fact, Perú (11%), Pakistan and Romania (7% each), Brazil (6%), Iran (4%), and Somalia (4%) were main origin countries for the trial, whereas Syria (20%), China (7%), Afghanistan (4%), Myanmar (3%) for the database. Pakistan, Iran, and Somalia were represented only by one study in the database, whereas for the other countries of origin of the trial there were not any study.

Considering intervention variables, WHO interventions alone accounted for 11% of total studies in the MARD, being implemented in 17 RCTs. PM+ was the most represented with eight studies (5%), half in individual format; only one study implemented DWM (1%) and there was no study conducted so far combining two WHO interventions together. Interventions were mostly conducted at individual level (49%), as for the RESPOND trial, and a minority of studies used online, i.e., (guided-)self-help modalities, opposed to the RESPOND trial design. The delivery mode through trained facilitators with mental health background- was applied in five studies in the database (3%), compared to the more extensive use of trained

volunteers and facilitators without a background in mental health (30%). The number of sessions, considering a total of ten sessions for the trial (i.e., five for each intervention step), was in line with the average of ten sessions in the database.
For the comparator, contrary to the RESPOND trial, in the database most studies (44%) applied a waiting list control condition, while only 11% had ETAU as control type.
Regarding outcomes, the RESPOND trial assessed all CMDs symptoms (i.e., anxiety, depression, PTSD), as well as quality of life; in the database 32% (k=47) of studies evaluated all these CMDs together, reduced to 7% (k=10) if also quality of life was considered. The trial had different timepoint assessments, in line with 58% of MARD studies with one or more follow-ups.
Finally, for general study characteristics, the use of a two-arm study and individual RCT designs was comparable to the majority of included studies in the database, respectively 85% and 72%.

5.4.2.2 Sub-datasets Comparison

Among the 114 trials with adults (77%) and 94 studies (63%) conducted in HICs, trials considering both criteria (i.e., adults and HIC) were 81 (54%)[26]. Considering main characteristics of these 81 studies conducted in HIC with adults, for the target group most studies (k=47, 58%) included refugees and asylum seekers, while general migrants accounted for 38% (k=31), contrary to the RESPOND trial. Specifically, refugees alone represented 32% of studies (k=26), asylum seekers 5% (k=4), IDPs were only in one study (1%), and remaining were mixed, with both asylum seekers and refugees (k=16, 20%). Main countries of recruitment were, respectively, USA (k=24, 30%), Germany (k=11, 14%), Denmark (k=6, 7%), the Netherlands and Sweden (k=5, 6% both). In terms of geographical regions, more than half studies were conducted in Europe (k=43, 53%) and North America (k=26, 32%). On the other hand, specific countries of origin were mainly mixed (k=26,

[26] Here, percentages remain related to the total studies included in the database, k=149. Then, all the following percentages will be referred to new sub-database (k=81) and, when selecting only WHO interventions, percentages will refer to k=6.

32%), followed by China (k=8, 10%), Syria (k=5, 6%), Turkey and Cambodia (k=4, 5% both), unlike the RESPOND trial. Considering geographical representation of origin countries, East Asia was the first (k=18, 22%), followed by Middle East (k=9, 11%) and Latin America (k=8, 10%). In terms of income classification, middle income countries were the majority (k=21, 26%, respectively, upper-middle were 20%, k=16, and lower-middle 6%, k=5); low-income countries alone accounted for 19% (k=15), and only two studies had high-income countries (3%).

Focusing on studies screening for symptoms (and probable diagnoses), symptoms were present in 29 studies (36%), above all mixed (k=11, 14%) and distress symptoms (k=5, 6%), whereas probable diagnoses in 15 studies (19%), of which seven (9%) for PTSD; almost half of studies (k=39, 48%) screened participants using a questionnaire as diagnostic criteria, like in the RESPOND trial.

In term of interventions, the use of 'counselling and psychosocial support' (k=34, 42%) was almost comparable to 'psychotherapy' (k=33, 41%). Family-parenting interventions were used in nine studies (11%) and the least represented were creative-expressive interventions with five studies (6%).

When considering only WHO interventions, six (7%) studies remained[27]. Differently form the RESPOND trial, migrant participants were all refugees and asylum seekers, of which half were refugees only, and mostly were war-affected (k=4, 67%). All participants presented with symptoms at baseline, assessed with cut-off questionnaires; in four studies (67%) those were probable diagnoses, above all mixed and PTSD, and in the other two (33%) were subthreshold symptoms, mainly mixed and distress. As for the RESPOND trial, all these six studies were conducted in European countries, namely Austria, Denmark, Netherlands, Switzerland, United Kingdom (UK) and mixed EU countries (i.e., Italy, Germany, Austria, Finland, UK) for one study. Middle East was the main geographical region of origin (k=4, 67%) and, at the country level, Syria alone accounted for half studies (k=3, 50%), while Afghanistan for one study and the other two were mixed (i.e., Afghanistan, Iraq, Nigeria, Pakistan, Syria, Iran, India, Namibia, Yemen). All

[27] Those six studies were: de Graaf et al., 2020, de Graaf et al., 2023, Dowrick et al., 2022, Knefel et al., 2022, Purgato et al., 2021, and Spaaij et al., 2022. They were mainly related to the 'STRENGHT', a European funded project.

included countries were LMICs, with low income being most represented (k=4, 67%), unlike the RESPOND trial. Deepening on the type of WHO interventions, PM+ was applied in almost all studies (k=5, 83%), of which four (67%) used the individual format and one the adapted version, while the only remaining study delivered SH+. Comparator was TAU in four studies and ETAU in two; one study had a three-arm design, which compared the individual version of PM+ (considered as intervention group) with its group version (second control group) and TAU (first control group).

Table 5: Comparison countries MARD – RCT – Epidemiological data

Country of origin				Country of resettlement			
Country of origin	**DATABASE N studies (%)**	**UNDESA N migrants millions (%)**	**RESPOND RCT N participants (%)**	**Country of resettlement**	**DATABASE N studies (%)**	**UNDESA N migrants millions (%)**	**RESPOND RCT N participants (%)**
East Asia	26 (17%)	38,40 (14%)	2 (1%)	East Asia	14 (9%)	19,59 (7%)	NA (NA)
Pacific	0 (0%)	1,97 (1%)	0 (0%)	Pacific	5 (4%)	9,38 (3%)	NA (NA)
Europe	5 (3%)	63,27 (23%)	64 (30%)	Europe	52 (35%)	86,71 (31%)	217 (100%)
Central Asia	4 (3%)	11,25 (4%)	7 (3%)	Central Asia	10 (7%)	11,62 (4%)	NA (NA)
Latin America	11 (7%)	42,89 (15%)	55 (25%)	Latin America	2 (1%)	14,79 (5%)	NA (NA)
Middle East	39 (26%)	26,61 (9%)	14 (7%)	Middle East	18 (12%)	49,40 (16%)	NA (NA)
North Africa	0 (0%)	12,28 (4%)	9 (4%)	North Africa	1 (1%)	3,17 (1%)	NA (NA)
North America	0 (0%)	4,33 (2%)	1 (1%)	North America	29 (20%)	58,71 (21%)	NA (NA)
South Asia	4 (3%)	42,07 (15%)	29 (13%)	South Asia	4 (3%)	11,07 (4%)	NA (NA)
Sub-Saharan Africa	15 (10%)	28,28 (10%)	28 (13%)	Sub-Saharan Africa	10 (7%)	22,22 (8%)	NA (NA)
Mixed regions	39 (26%)	NA (NA)	NA (NA)	Mixed regions	2 (1%)	NA (NA)	NA (NA)
Not specified	7 (5%)	9,25 (3%)	8 (4%)				
Income country of origin	**DATABASE N studies (%)**	**UNDESA N migrants millions (%)**	**RESPOND RCT N participants (%)**	**Income country of resettlement**	**DATABASE N studies (%)**	**UNDESA N migrants millions (%)**	**RESPOND RCT N participants (%)**
Low	54 (36%)	37,42 (14%)	18 (8%)	Low	10 (7%)	12,23 (4%)	NA (NA)
Lower Middle	16 (11%)	89,75 (32%)	66 (30%)	Lower Middle	9 (6%)	28,51 (10%)	NA (NA)
Upper Middle	22 (15%)	87,65 (31%)	72 (33%)	Upper Middle	36 (24%)	57,38 (21%)	NA (NA)
High	2 (1%)	52,81 (19%)	49 (23%)	High	94 (63%)	181,90 (65%)	217 (100%)
Mixed	53 (36%)*	NA (NA)	NA (NA)				
Not specified	8 (5%)	12,97 (5%)	8 (4%)				

DISCUSSION

CHAPTER 6 - PRESENT GAPS AND FUTURE DIRECTIONS

6.1 Summary of Findings

One main goal of this thesis was to map the state of art of research on mental health of migrant populations and draw comparisons between information retrieved from the database and data from international figures, juxtaposing this with the results from the RESPOND trial.

The study selection process for the living database revealed a moderate volume of research in this domain, with 149 studies involving a total of 28,208 participants included up to January 2024. The distribution of studies per years of publication reflected the public health impact of migrant populations over the time, with increasing numbers of migrants worldwide, as well as of RCTs conducted (Figure 7; UNDESA, 2021; IOM, 2024).

Compared to real-world data, main gaps were found in the type of population and related reasons of displacement, as well as in countries of resettlement and associated incomes. Examining them more in detail, firstly, for the type of population, asylum seekers and refugees were more represented in the database compared to general migrants' population (Table 4). This over-representation of refugees and asylum seekers in research studies could be linked to their increased vulnerability and risk for mental health disorders with respect to other migrants (Carroll et al., 2023; Mesa-Vieira et al., 2022; Uphoff et al., 2020; Hynie et al., 2018). On the other hand, the RESPOND trial showed a difference with respect to the database, with a greater alignment to global figures, having more economic migrants in the trial and less refugees and asylum seekers. Internally displaced people constitute the largest part of forced migrants, as emerged from the GRID and UNHCR reports (2024), but they were not adequately taken into consideration

in research studies, compared to refugees (Table 4), or, as pointed by Uphoff and colleagues (2020), not appropriately specified in the inclusion criteria.

Secondly, for age, older adults were less represented in included RCTs with respect to real-world situation. It is important to pay adequately attention to it given the increasing population age, a phenomenon that is forecasted to grow over the next years (Murray et al., 2024; Vollset et al., 2024). For gender a quite equal distribution emerged worldwide, whereas in the database women constituted the majority of participants for most studies. This could be related to the heightened gender-related vulnerability, as well as to the type of interventions, with family and parenting interventions involving predominantly mothers, and on the type of migrant population (Nyikavaranda et al., 2023; Rabbani et al., 2024; Table 3). For the RESPOND trial age and gender were almost consistent with the database, with a prevalence of women and young adult age, and an average of 33-36 years.

Regarding epidemiological data, the prevalence of anxiety and depressive disorders, compared to PTSD, was lower in the database, contrary to findings from the literature on epidemiological prevalence (Carroll et al., 2023). This could be related to the prevalence of forced migrants in research studies and, at the same time, to comorbidities, and lack of common diagnostic metric or criteria was applied across studies (Carroll et al., 2023; Henkelmann et al., 2020; Patanè et al., 2022; Blackmore et al., 2020; Koesters et al., 2018; Uphoff et al., 2020).

Focusing on migratory flows, for countries of origin, there was a higher representation of low-income countries with respect to middle-income and an under-representation of high-income countries in the database compared to global figures (UNDESA, 2021); on the other hand, the trial better reflected the epidemiological data, with almost comparable prevalence. In terms of representativeness of geographical areas, an over-representation of Middle East and a lower representation of Europe, Latin America and South Asia emerged in the database (Table 4). This trend could be related to the prevalent type of migrants in randomized studies, refugees and asylum seekers, and with the presence of many mixed income levels. On the other hand, for the RESPOND trial, Europe and Latin America were the most represented regions of origin, more aligned with epidemiological data (UNDESA, 2021). Heterogeneity of single origin countries

distribution prevented full comparability across database, RCT and epidemiological figures. For countries of resettlement, instead, there was a similar correspondence between the database and international reports, with the only difference for Latin America, slightly under-represented in the database and not all countries being included in research studies. One interesting finding was the lack of an excess of studies conducted in high-income countries as evidenced, instead, from other reviews as being predominant in the field (Abubakar et al., 2018; Uphoff et al., 2020; Wainberg et al., 2017). Nevertheless, this was valid only for international migrants, as a matter of fact, when considering studies with refugees and asylum seekers separately, findings from the database were consistent with the literature, with most studies conducted in high income countries (Uphoff et al., 2020; Soltan et al., 2022; Sijbrandij et al., 2018; Nosé et al., 2017; Turrini et al., 2019), but not aligned with related global figures (UNHCR, 2024).

Regarding the interventions, a diverse range of psychosocial programs were applied, mostly counselling and psychosocial support interventions. Psychotherapy was widely applied as well, whereas family/parenting support and creative-expressive interventions were less represented.

From literature, a lack of a comprehensive synthesis and analysis of psychological interventions for all migrant populations emerged, with most reviews addressing forced migrants, in particular delivering psychotherapies (Uphoff et al., 2020; Turrini et al., 2017, 2021). Recently, the effectiveness of psychosocial interventions based on task-shifting and transdiagnostic approaches has been investigated (Schafer et al., 2023a, 2023b), as well as of community-based interventions for children and adolescents (Soltan et al., 2022). Few reviews focused on creative-expressive interventions, with creative arts therapies demonstrated to be effective for the treatment of general adults with PTSD (Baker et al., 2018) and art-based interventions and art therapy for health promotion of migrant populations (Oepen and Gruber, 2023).

For most studies interventions were compared to waiting list and CAU/ECAU, reflecting the trend in research trails, even though this approach is controversial (Cuijpers et al., 2021b; Furukawa et al., 2014; Cristea, 2017). There was almost an equal representation of mental health professionals and trained non-specialists, as

well as group and individual delivery formats. Interventions were primarily delivered face-to-face, while online format was less common. Nevertheless, a variety of delivery settings, providers and formats emerged from the database (Table 3). The RESPOND trial was an example of a task-shifting intervention delivered in an online format and through a stepped-care approach. The effectiveness of this intervention model further supports the potentiality of applying these new approaches focused on scalability (Bryant, 2023; WHO, 2022a, 2022b; Singla et al., 2017), evidence-based and transdiagnostic programs (Schäfer et al., 2023a, 2023b), task-shifting (Singla et al., 2017; Hoeft et al., 2016), also in high income settings. Nevertheless, this potentiality should be considered with caution, given the need of more studies testing real-world implementation, cost-effectiveness, and analysis of active components and factors of these interventions (Bryant, 2023).

Overall, our findings from the MARD database were consistent with an overview of systematic reviews by Uphoff and colleagues (2020) on mental health interventions for promotion, prevention, and treatment of CMDs for refugees, asylum seekers, and internally displaced persons, which identified as main gaps the missing evidence for internally displaced people, promotive and preventive interventions, as well as the prevalent focus on PTSD, neglecting anxiety and depression. Nevertheless, even though forced migrants experience higher rates of mental health problems, economic migrants constitute the majority of international migrants (IOM, 2024; UNDESA, 2021; Table 3). Thus, it would be advisable to focus future research on all these aspects, by addressing each of them, enhancing promotive and preventive interventions also for these high-risk populations, as well as focusing on the entire range of migrant populations and interventions.

6.1.1 Findings for Interventions: a Focus on Psychotherapies

Given potential implications for clinical practice, a closer examination of psychotherapeutic interventions was deemed necessary. In general, the database showed a quite equal distribution of CBT-based and trauma-focused psychotherapies, with traditional CBT and NET being the most represented

psychotherapies (k=13, 9% of all included studies each). Specifically, all trauma-focused psychotherapies (i.e., NET, EMDR, KIDNET and IRT) were delivered for forced migrants, in particular refugees. These were all treatment interventions for PTSD-related symptomatology with a baseline diagnosis or probable diagnosis, and CBT was the second psychotherapeutic intervention used for treatment interventions. In parallel, a lack of psychotherapies for anxiety disorders in migrants emerged; nevertheless, from literature on anxiety-related disorders, CBT is suggested as a first-line intervention, alone or complemented by third-wave CBTs and relaxation therapy (Papola et al., 2023, Van Dis et al., 2020; Cuijpers et al., 2016a). Considering the prevalence in the database of trials with participants exposed to forced migration, these findings are consistent with the general trend in literature. The literature is focused on forced migrants and PTSD, with CBT and NET being the most studied interventions (Uphoff et al., 2020; Turrini et al., 2017, 2021; Kip et al., 2020; Thompson et al., 2018). It is also aligned with existing guidelines recommending trauma-focused CBT (TF-CBT) or EMDR for adults and children with PTSD in the general population, complemented by stress management interventions for adults (WHO, 2013b; WHO and UNHCR 2015; Turrini et al., 2017, 2021). In terms of effectiveness, a recent NMA showed that CBT and EMDR ranked best in reducing PTSD symptoms in asylum seekers and refugees (Turrini et al., 2021). Other recent network meta-analyses on psychotherapies for PTSD in the general adult population demonstrated the effectiveness of all psychotherapies, with and without a trauma focus, for the treatment of PTSD (Hoppen et al., 2023; Mavranezouli et al., 2020; Cusack et al., 2016). Most research has been conducted for TF-CBT, which yields the highest efficacy in improving PTSD symptomatology and remission rates, but with higher dropouts' rates compared to non-trauma-focused interventions (Hoppen et al., 2023; Mavranezouli et al., 2020). Beyond the proved efficacy of trauma-focused psychotherapy for the acute phase of PTSD, also long-term efficacy (at least six months) of psychotherapy for PTSD has been investigated and proved, and it was not significantly linked to trauma and population type or intended duration of treatment (Kline 2018). Burgund and colleagues (2024) investigated trauma-informed approached for forced migrants, finding that psychotherapy is equally effective regardless of care seekers' ethnicity.

Deeping the literature on psychotherapies focused on trauma, previous systematic reviews of EMDR proved its effectiveness for PTSD (Mavranezouli et al., 2020; Cheng et al., 2015), as well as for general mental health problems (Cuijpers et al., 2020) and depression (Carletto et al., 2021). Main supported mechanisms of action of EMDR therapy are the 'working memory hypothesis' (i.e., reduction of vividness and decrease of the emotionality of traumatic imagery through disruption of working memory by eye movements, EMs) and physiological changes (i.e., de-arousal response related to parasympathetic changes), even though research is still needed (Landin-Romero et al., 2018). On the other hand, NET was originally developed as a short-term therapy addressing PTSD symptoms resulting from traumatic experiences (i.e., conflict and organized violence) for low-income countries, but it has been mostly applied to treat asylum seekers and refugees in high-income settings, which explains its relative high prevalence in the database (Robjant and Fazel, 2010). Results from treatment trials have demonstrated effectiveness of NET in reducing PTSD symptoms in adults, as well as of KIDNET in children, compared with other therapeutic approaches (Robjant and Fazel, 2010; Schauer et al., 2006). Thus, for migrant populations trauma appears a central element to be addressed given the link to traumatic events potentially experienced during the forced migration process (see also paragraphs 1.1.2 and 1.1.3).

Comparing trauma-based with CBT approaches, firstly, all CBT interventions included in the database were delivered to adults, whereas for children the focus was on trauma-based approaches. Many different interventions, family- and child/adolescent-oriented, addressing mental health problems in children and adolescents have been demonstrated to be effective, despite a high heterogeneity in formats and contents (Della Rocca et al., 2024). Nevertheless, a meta-analysis on psychotherapies for PTSD and depression for refugees and internally displaced children and adolescents did not prove their efficacy, requiring further research (Morina and Sterr, 2019). Secondly, for depression and general CMDs, CBT was the most used approach in the database, and this reflects the main application of CBT interventions, originally developed to address depressive symptomatology and anxiety (Cuijpers et al., 2016a, 2019a, 2021, 2023a, 2023b; Ünlü Ince et al., 2014). Thirdly, in the database CBT-based approached were more used in HICs

followed by trauma-focused psychotherapies, whereas in LMICs countries trauma-focused were more used compared to other psychotherapies. A systematic review of psychotherapies for adults in LMICs evidenced larger treatment effects for trials conducted in non-Western countries, with CBT being the most represented and effective psychotherapy, but with higher heterogeneity and risk of bias in study designs (Tong et al., 2023). An umbrella review of psychosocial interventions for LMICs showed evidence for the efficacy of CBT for adults with depression, as well as IPT for adults with CMDs in this context (Barbui et al., 2020).

Finally, compared to its traditional form, the Internet version of CBT (iCBT) demonstrated its effectiveness for depression (Karyotaki et al., 2021) and a component-network meta-analysis (cNMA) showed that specific elements, like behavioural activation, are highly effective while others, like relaxation, could also have detrimental effects (Furukawa et al., 2021). A recent systematic review pointed the poor reporting of information on ethnicity in trials of iCBT for depression, not adequately addressing needs and characteristics of ethnic minorities (De Jesús-Romero et al., 2024).

Among other types of psychotherapies, less represented in the database, all the three studies on problem-solving psychotherapy (PST) addressed adults living in HICs, endorsing depressive and general CMDs symptomatology. This approach has, indeed, been studied as an effective psychotherapeutic intervention for depression, comparable to other psychological treatments (Cuijpers et al., 2018a). For interpersonal psychotherapy (IPT), the only two studies in the database were delivered for forced migrants with CMDs in lower-middle and low-income countries. This is in line with literature on migration, being IPT another frequently used approach for forced migrants, following CBT and NET (Uphoff et al., 2020). In the general population, IPT showed to be effective in treating depression in its acute phase, as well as in preventing new depressive disorders and relapses, and in the treatment of eating disorders and anxiety disorders, with promising applications also for other mental health disorders (Cuijpers et al., 2016b). Finally, psychodynamic psychotherapy accounted for one study only, even though a meta-analysis of RCTs showed equivalence in the effectiveness of this psychotherapy compared to CBT or pharmacological interventions (Steiner et al., 2017). Within

psychodynamic approaches, in particular psychoanalysis, effectiveness is still a controversial issue, despite increasing research efforts and empirical evidence for pre/post changes patients with complex mental disorders (de Maat et al., 2013).

Finally, in terms of delivery, given that included psychotherapies were also delivered by non-specialized providers (31%), it would be important to study the impact of different delivery personnel (i.e., mental health professionals compared to non-specialized personnel) on the efficacy of psychotherapies, both in terms of intervention effectiveness and implementation. At the intervention level, comparing face-to-face to online formats would also be of interest (Cuijpers et al., 2010), as well as also investigating cultural adaptation of digital psychotherapies (Spanhel et al., 2021; De Jesús-Romero et al., 2024; see also the adaptation process for the RESPOND trial in paragraph 4.2).

In conclusion, despite general evidence on the effectiveness of psychotherapies for different mental health conditions and populations, their mechanism of action, the so-called 'theory of change' or 'theory of action', is still under examination (Cuijpers et al., 2018b; Kazdin, 2007, 2009; Cuijpers and Cristea, 2016; Dragioti et al., 2017; UNDAF, 2017). "A theory of change is a method that explains how a given intervention, or set of interventions, are expected to lead to a specific development change, drawing on a causal analysis based on available evidence." (UNDAF, 2017). Kazdin (2007, 2009) systematically addressed this issue in his seminal work analyzing requirements of mediators, moderators, and mechanisms of therapeutic change, starting from the consideration that "demonstrating a cause does not say why the intervention led to change or how the change came about" (Kazdin, 2007). Controversial theories and results emerged so far, supporting, on the one hand, specific therapy models and, on the other hand, a common factors model, i.e., non-specific or universal factors model (Cuijpers et al., 2018b). Thus, on the one hand, psychotherapy explains its effectiveness through specific effects based on the theoretical approaches themselves, for example, addressing cognitive distortions in cognitive therapy or maladaptive behaviors in behavioral therapies. On the other hand, the importance of non-specific or universal factors emerged, namely, the presence of transversal components across disorders or therapeutic approaches with an active (and therapeutic) role (Cuijpers et al., 2018b). Examples

of these common components are therapeutic alliance, therapist's characteristics like empathy, warmth, respect, acceptance, and validation, among others, with the first one being the most studied and acknowledged as therapeutic moderator. The concept of common factors was firstly introduced in 1936 (Rosenzweig, 1936), then developed in the 'contextual model', which emphasizes the role of three elements, firstly therapeutic alliance, then expectations and hope, and finally, specific elements of psychotherapies (Wampold, 2015; Ahn and Wampold, 2001). To better address these controversies, it would be advisable to study psychotherapies from a comprehensive approach, considering the whole process, from development (i.e., theoretical background and rationale) to testing, as well as implementation into real world. The paper by Cuijpers and colleagues (2018b) gives an overview of issues in this field, which are still unsolved despite some years have passed since its publication and methodological advances (i.e., component-NMAs).

Additionally, for psychotherapy with migrant populations, culture-related issues, such as gender differences, individualist versus collectivist approach, stigma, and religion, may play an important role in determining psychotherapeutic effects (Caroppo et al., 2009). Duden and colleagues (2021) investigated the supportive and hampering elements in psychotherapy with refugee patients, across eight different levels, namely patient, therapist, relationship patient-therapist, setting, psychotherapeutic approach, patient's and therapist's personal contexts and societal context. From their analysis, focused on the Brazilian context but with potentially wider implications, "hindering elements in the therapy include missing preparation for the integration of refugees, lack of interpreters, patients' mistrust and therapists feeling untrained, helpless and becoming overinvolved. Supportive elements include a trusting therapeutic relationship, therapists' cultural humility and structural competence, patients' societal inclusion as well as working with groups and networks" (Duden and Martins-Borges, 2021).

6.2 Strengths

This thesis project had its main strengths in combining data from different methodological approaches, the MARD database and the RESPOND trial, to outline the existing evidence, reaching an overview of the field. The present work added a further step to the two research projects' phases, by drawing a comparison between evidence from research and from international reports on migration documenting real-world migratory flows and sociodemographic characteristics of migrants. There were then specific strength points deriving from each one of the two phases of the research project, that will be covered separately, with a focus on the MARD, as being the preparatory phase of the whole project.

6.2.1 Strengths of the MARD Database

The MARD project and its related mapping review aimed to synthesize the existing evidence on psychosocial interventions for migrants' mental health, giving a complete overview of the field by joining multiple PICOs in one database. To our knowledge, it was, indeed, the first research project, conducted so far, that collected all randomized studies assessing interventions for preventing and/or treating CMDs in migrants' populations. This was exemplified by the broad inclusion criteria, which enabled to consider the whole range of migrant populations[28]. Recently, some systematic reviews have been published, analyzing specific sub-populations of migrants and settings (Hutchinson et al., 2022; Mesa-Vieira et al., 2022; Soltan et al., 2022; Turrini et al., 2021; Uphoff et al., 2020), but they could not reach the completeness of the database. Another added value of including any type of migrant was the ability to make comparisons; therefore, considerations for gaps and future research were made possible by including all randomized studies conducted with these populations in the same living database. For example, the paucity of studies

[28] Giving the heterogeneity of included migrant populations, a key point is, thus, the definition of migrant applied; here, 'international migrant' was taken as a broad umbrella term including all possible migrant populations, even though a debate is currently ongoing on the terminology to identify different types of migrants (IOM, 2019).

on economic migrants compared to refugees and asylum seekers emerged as a key research gap, as well as a lack of studies conducted on older migrant adults (Table 4). From a methodological perspective, being a MARD project, the database is living, yearly updated, and this enables to always have up-to-date information on the topic (Cuijpers et al., 2022, 2023a). Another important methodological strength is the inclusion of RCTs only, which are considered the highest level of evidence, as well as quality, in research (Murad et al., 2016). Finally, the use of global epidemiological figures on migration to analyze and juxtapose MARD data was pivotal for the descriptive analyses. The need of a multi-level and integrated approach emerged as unavoidable for this field of research, to better understand, address and inform research, so to be aligned with the real-world context.

6.2.2 Strengths of the RESPOND Trial

The RESPOND trial could be considered a good example of the new implementation science endorsing all its main characteristics, namely scalability through stepped-care models, adaptability, cultural and contextual flexibility, evidence-based interventions, and use of technology. In addition, it was the first RCT to apply the stepped care model with two WHO interventions, and in general, one of the few to test a stepped-care model, as emerged from the comparison with the MARD database[29]. The proved effectiveness of this intervention model (Purgato et al., 2025) evidenced the flexibility of implementing (self-help) guided online interventions and the feasibility of a task-shifting approach also in a high-income country. Another key strength of the RESPOND trial was the quick response given to the new pandemic context thanks to the adaptability and flexibility of interventions. Within the pandemic context a general adaptation of mental health interventions was required, usually a switch to e-mental health (Witteveen et al., 2022, 2023; WHO, 2022). Nevertheless, in this case, a new adapted intervention was developed based on a rapid appraisal of needs and problems of populations deemed particularly vulnerable in that context (Melchior et al., 2021).

[29] The only two included studies applying a stepped-care approach in the database were Böge et al., 2022 and Wiechers et al., 2023.

6.3 Limitations

Main strengths of the thesis could also be seen, within a certain degree, as limitations. The major obstacle was the complexity and heterogeneity of data and sources, which revealed a difficulty in summarize evidence from these different and diverse methodological sources. Then, in the thesis only post-hoc comparative analyses were presented, giving a narrative synthesis and overview of the field, without the support of advanced statistical analyses. Finally, another general shortcoming was the lack of research studies and systematic reviews addressing the different facets of migrations and types of migrant populations, which hinders the comparability and generalizability of findings.

6.3.1 Limitations of the MARD Database

Despite its strengths, the database project has also some limitations; firstly, only descriptive analyses were conducted to summarize the characteristics of included studies. Therefore, quantitative analyses of data were not performed to examine the effectiveness of included interventions; this will constitute a future step of the project (Turrini et al., 2023; see Turrini et al., 2025 for the results of a NMA on psychosocial interventions for adult migrants). Then, not always complete information was available for many variables in the database, resulting in high percentages of not specified or mixed information from included studies, which made the synthesis of evidence less accurate. In addition, data from reports was not always complete and international data and reports on migration flows were not up to date, still referring to mid 2020 (UNDESA, 2021). This prevented the exact comparison between research studies and real time world processes. In addition, published systematic reviews and meta-analyses of randomized studies of psychosocial interventions were almost predominantly focused on refugees and asylum seekers, with a lack of synthesis studies considering all international migrants and economic migrants alone (Uphoff et al., 2020; Turrini et al., 2021; Schäfer et al., 2023a, 2023b). Additionally, awareness needs to be raised when

comparing epidemiological data on prevalence of CMDs to representativeness of studies.

Other limitations are related to the database development process itself, in terms of inclusion criteria and selection of variables. As a matter of fact, not all potential moderator and mediator variables were extracted in the database. Examples of those missing variables were cultural adaptation of interventions, presence of traumatic events experienced before or during migration, and post-migration difficulties, which were only assessed by a minority of studies. Nevertheless, giving their importance, those variables should be considered for extraction in a future update of the database as well as in future studies. For the inclusion criteria, there were some categories of mental health conditions excluded given that only studies focusing on CMDs outcomes were eligible. Therefore, substance use disorders, psychotic disorders and somatoform conditions were excluded in case they did not assess at least one CMD outcome (anxiety, depression, PTSD, or distress). That same inclusion criteria led to a possible bias in the inclusion of interventions given that promotion interventions may not plan to assess CMDs symptoms; therefore, a presumably small part of studies only assessing positive mental health outcomes was not included in the database.

At a methodological level, the inclusion of only RCTs could be seen also as a limitation related to the risk of losing some important information on the field, and to the fact that research should also be informed by other sources and study designs (e.g., observational studies, qualitative studies). Nevertheless, preference for RCTs is supported by ethically and methodologically legitimate reasons; still, the importance to assess the quality of included studies remains a fundamental step to undertake considering that, from the new pyramid of evidence, some well conducted observational studies could be potentially better than RCTs of poor quality (Murad et al., 2016). Linked to this point, an overall picture of the quality of evidence of included studies is missing; the risk of bias assessment was applied but the RoB-2 tool only specifically assesses single data outcomes, not allowing for a general synthesis of the quality of evidence as a whole. Given the narrative nature of the thesis, also a synthesis of the certainty of evidence is missing; this will constitute a future step when assessing the effectiveness of interventions by

applying the GRADE methodology (Guyatt et al., 2011; Djulbegovic and Guyatt, 2017).

Regarding statistical analyses of data, the database only enables study-level analyses on aggregated data, testing whether interventions worked or not for the total included sample, and from this drawing more general conclusions on similar populations. Collecting 'Individual Participant Data' (IPD) of included studies would enable to conduct analyses based on single participants' data to study what worked for whom, so to analyze the personal socio-demographic and clinical characteristics which act as mediators and moderators of treatment effects (Stewart et al., 2012; Debray et al., 2015; Simmonds, 2015).

6.3.2 Limitations of the RESPOND Trial

Beyond its promising findings, also for the RESPOND trial there are some limitations; firstly, the wide timeframe of conduction of the study, from acute epidemic to post-pandemic context, has to be acknowledged as a potential influential variable. As a matter of fact, various phases of the pandemic were included, therefore related to different needs and concerns of the participants.

For the intervention delivery, facilitators were trained people with a mental health background; this could result in a dissimilar effectiveness compared to the use of lay trained people, giving that having a mental health background could help facilitators themselves in delivering the intervention and manage difficult psychological situations, but further studies are needed to test this hypothesis.

In terms of intervention process, even though the intervention group showed less symptomatology compared to the control group at the first assessment (T2), the first intervention phase, DWM, was not effective for all participants of the intervention group given that more than half stepped to the second intervention level. This evidences the need to further investigate these self-help online interventions, also in terms of treatment mediators and moderators, preferably through IPD analyses.

Moreover, there were also methodological constraints related to the recruitment process, the lack of a double-blind study design, and the use of self-assessment questionnaires (Purgato et al., 2025). In particular, the absence of a longer follow-

up period prevented evaluation of long-term effect of the interventions, which are essential from a preventive perspective.

Therefore, an important limitation regards the generalizability of findings, both in terms of research directions and real-world implementation, given the peculiarities and specificities of the pandemic context and of the included population, in terms of socio-demographic and migration characteristics.

6.4 Implications for Research, Clinical Practice and Policy

Migrant's mental health should be regarded as a public health concern, which needs to be adequately considered and addressed because of its broader implications at multiple levels, from individuals to the whole society (Hasan et al., 2021; WHO, 2020; Abubakar et al., 2018).

All studies in the living database included populations that shared migration as a common factor, which could be considered as a social determinant of mental health (Lund et al., 2018; Patel eta al., 2018). The process of migration, regardless reasons behind it, is more often associated with a deterioration in subjective well-being, quality of life and mental health, and an increased risk of developing mental disorders (WHO 2022a, 2022b). The COVID-19 pandemic worsened the already existing social and psychological vulnerability for migrants, who additionally struggled with many everyday living difficulties in their resettlement country due to social and economic issues, thus revealing a strong influence of contextual factors in determining mental health (Lotito et al., 2023).

To adequately address mental health of migrant populations, a multilevel framework needs to be taken, with an integrated action across all sectors (i.e., health, education, judicial, employment, welfare, transport, housing) by prioritizing mental health equity in all policies (Tol et al., 2015; Lund et al., 2018; Laverack, 2018; Papola et al., 2024). Additionally, a life-course approach should be considered and applied in research and policies, addressing pre- and perinatal periods, early and later childhood, working and family building years, until older age. Based on the social determinants' framework, actions need to be taken both at

the community- and at the country- level, addressing the political, social, economic, and environmental factors, as well as cultural and social norms, by developing and implementing specific policies and strategies to reduce social inequities and improve access to mental health services (Lund et al., 2018). Given the peculiarity of migrant populations, post-migration factors should be considered for mental health interventions and services, as well as the importance to integrate mental health into primary healthcare settings (Cuijpers et al., 2019b). To this regard, multimodal approaches targeting the different post-migration living conditions which could affect mental health of migrant populations could be seen as a key implementation strategy. Interventions also focused on practical aspects and protective factors, as well as assistance with practical issues (i.e., medication, settlement, social support) are thus recommended.

Main principles to guide prevention and promotion of mental health, also applicable for treatment purposes, were synthesized in the PACTS model, developed by Tol and colleagues (2015). This approach suggests taking a socioecological perspective (P for place), an intersectoral and interdisciplinary approach (C for collaboration), a lifespan developmental perspective (T for timing), and a competency-enhancement approach within the community to identify existing resources for mental health (S for strengths) (Tol et al., 2015).

From these general principles, specific implications for policymakers, clinicians and researchers could be drawn, which are still intertwined. One of the aims of research is to study and synthesize the complexity of the world through figures, making it more accessible to all people at different levels and expertise. Therefore, mapping the existing evidence of a research field simplifies the complex panorama of research studies, enabling to identify and address current gaps, as well as to develop scientific reports and guidelines to improve implementability of interventions into the real-world practice, both at the clinical and policy levels. The need to develop constantly updated guidelines, as well as evidence-based treatment recommendations based on gaps and findings acknowledged through this project, emerges as a crucial way to inform and improve clinical practice accordingly (Guyatt et al., 2011; Djulbegovic and Guyatt, 2017). Clinicians could, thus, integrate and implement these evidence-based practices specifically developed for

the context in their clinical practice and keep themselves professionally updated more easily, consequently enhancing their competencies and clinical efficacy (Krystallidou et al., 2024; Nyikavaranda et al., 2023; Peñuela-O'Brien et al., 2023). Policymakers are also highly encouraged to collaborate with researchers to develop and then adopt these guidelines to better address migrants' needs also from a higher decision level (Laverack, 2018; Aliev et al., 2023). Nevertheless, common agreements between researchers and policymakers need to be established to better align research and enable comparability across sectors. The first step would be to adopt a consistent definition of migrant and of its sub-types; as an example, the definition of "economic migrants" is particularly problematic from a research and an ethical perspective, given that it comprises both forced economic migrations pushed by climate change and increasing levels of poverty and economic instability in the Global South, as well as well-educated students or employees who decide to live and work abroad, with a work permit, a job, and proper housing.

Methodological quality of future research is then a fundamental point to be addressed by researchers, being an ethical responsibility to improve quality and reporting of randomized studies. The starting point would be to better specify inclusion criteria (i.e., type of migrants) and methods, which would be then reflected in higher quality systematic reviews, leading to a larger impact and contribute of research to the real-world implementation of these mental health interventions (Uphoff et al., 2020).

Another aim of research is to enhance research practice itself, therefore, researchers could use findings from the present project to develop and conduct new studies to fill current gaps. Finding from this project could also help developing an ideal trial, as well as an ideal psychosocial intervention model, which endorses all important and most effective elements. In Table 6 below a PICO table with main suggested elements to consider for the development of an ideal trial is presented, based on gaps emerged from the database. Nevertheless, given the complexity of migrant populations and migration-related factors, as well as interventions, further analyses need to be conducted. In particular, statistical analyses on the effectiveness of included studies in the database are required for developing ideal intervention program and trial.

Table 6: Ideal RCT Trial for Migrant Populations

PICO	Characteristics to be addressed
COMPARATOR	
Migration status	• Economic migrants • Internally displaced
Age group	• Older adults • Refugees' children
Origin - Geographical area	• Europe • Latin America • South Asia
Resettlement - Geographical area	• Latin America
Income	• High income for origin • LMICs for resettlement (forced migrants)
symptomatology	• Anxiety • depressive
INTERVENTION*	
Type	• Promotion and (selective) prevention
Format	• Stepped-care approach • Transdiagnostic approach§
Delivery	• online
COMPARATOR*	
Type	• waiting list or CAU/ECAU
OUTCOMES	
Common mental health outcomes	• All CMDs symptoms (anxiety, depression, PTSD) • Well-being
Outcomes related to the migration process	• Post-migration living difficulties • Traumatic events • Resilience

Notes:
*Effectiveness of existing interventions still needs to be tested.
§Main identified elements of transdiagnostic approaches are behavioural activation, emotion regulation, mindfulness, problem management, psychoeducation, relaxation, supportive counselling, and stress management (Schäfer et al., 2023b).

6.5 Conclusions and Future Directions

The present thesis constitutes an evidence base for developing new studies and (re-)directing research to be tailored to the specific and real needs of this population for a better and more focused research. The database, by including all conducted RCTs adopting psychosocial interventions for migrants' mental health across the whole prevention and treatment range, enables to study and analyze a multiplicity of aspects connected to this research field. Based on the living database, systematic

reviews could be conducted using different inclusion criteria and applying strategies to deal with variability of included target populations. One possibility would be to develop different systematic reviews each one focused on single aspects, by keeping separated refugees and asylum seekers from other migrants, prevention studies from treatment, HICs from LMICs, adults from children. A more nuanced approach might be to include these populations in the same review, to investigate population-level characteristics and factors that may act as determinants of intervention effect. In addition, meta-analyses (MAs) on outcome data will be conducted to test the effectiveness of included psychosocial interventions, also by analyzing potential important variables, for instance, types of interventions, population by type, age and gender, delivery modalities and task-shifting approaches, as well as income and settings. Subgroup, sensitivity, and meta-regression analyses are examples of approaches that can help address and explore population-level heterogeneity (Harrer et al., 2021). By conducting subgroup or sensitivity analyses, it will also be possible to test whether the differential exposure to potential risk or protective factors moderates the effect of psychosocial interventions[30]. Therefore, one important step will be to investigate the role of moderators (e.g., population age, trauma exposure, migration history) and mediators (e.g., functioning, psychological symptoms, resilience) through mediation and moderation analyses, to better study and interpret the effectiveness of interventions (Stewart et al., 2012; Debray et al., 2015; Simmonds, 2015; see for example Serra et al., 2023, for the mediation effect of trauma). As a further step, by retrieving IPD data, IPD-MAs could be performed to study moderators and mediators at the person level, thus overcoming the limitation of the database of study-level analyses on aggregated data. For the RESPOND project, the larger

[30] In the OSF protocol of the MARD project pre-specified subgroup analyses were defined for type of migrant populations (different categories of migrants), age group (children, adolescents, adults, elderly) intervention setting (community settings, primary health care services, home), format (individual, pairs, family, group), prevention intervention (universal, selective, indicated), interventionists (primary health workers, community health workers, professionals), and comparisons (active control group, no treatment, wait-list, usual care, psychological placebo) (Purgato et al., 2023).

sample size deriving from the three different RCT trials will give the possibility to further analyze specific moderators and mediators with more advanced statistical analyses, such as IPD-MAs. This will enable a better understanding of vulnerability factors across different high-risk populations, enhancing generalizability of findings. As a matter of fact, despite the general effectiveness of these WHO interventions, a careful analysis needs to be carried out before applying them to other migrant populations (i.e., children and adolescents, migrants with mental disorders) or other different vulnerable populations.

Based on the MARD database, scientific papers have been published or are being prepared, in particular a network meta-analysis (NMA) evaluating the effectiveness of psychosocial interventions for adult migrants symptoms of CMDs (Turrini et al., 2025 for published results; Turrini et al., 2023 for protocol registration) and another NMA on children migrants (in preparation). The results from the recently published NMA by Turrini and colleagues (2025) showed that, compared to TAU, trauma-focused interventions (NET and EMDR) were effective in reducing PTSD symptoms, but also counselling, and creative expressive interventions. For depressive symptoms, integrative therapy[31] was the most effective intervention, whereas for anxiety symptoms, NET, integrative therapy, and WHO interventions (PM+/SbS) were more effective compared to TAU. Nevertheless, these findings were supported by a low level of confidence, and TAU interventions were heterogeneous (Turrini et al., 2025).

All these things considered, specific steps need to be taken to better implement future research projects and trials, considering all the aspects of the PICO framework, with a particular focus on interventions.

Firstly, starting with the population, research should focus on assessing and addressing the specific needs of migrants based on the different sub-populations. As a matter of fact, different types of migrants deal with different needs, migration journeys and stressors; consequently, mental health interventions should be tailored on addressing the real needs of migrants, which change over time, also depending

[31] "Integrative therapy is an approach in which mental health providers are guided by a repository of general principles, knowledge, and skills integrating various evidence-based components as opportunity and resources allow." (Turrini et al., 2025).

on the post-migration phase and time since resettlement. It is thus fundamental to specify more clearly the inclusion criteria of studies giving information on the population sub-type and migration journey; this to better study the characteristics of the specific migrant populations and adapt interventions accordingly, as well as to enable the comparability of studies in terms of populations and interventions. Contextually, by considering the global population ageing, research should also focus on long-term effectiveness of interventions and on following migrant populations on the long run (Jagroep et al., 2022; Bhatia et al., 2024). In addition, also other categories of migrants need to be investigated, for instance international students, and circular migration (i.e., migrants who come back to their country) is another key facet of migration to be accounted (IOM, 2022, 2024).

Secondly, for interventions, also promotion studies need to be considered to reach a clearer picture of the whole prevention continuum (see limitations' paragraph 6.3.1 above). This is strictly linked to the need of better classifying trials on the promotion-treatment continuum, especially the sub-types of prevention, by using a quantitative approach. To this end, a new classification tool is being developing by some research groups (Purgato and Albanese et al., 2024). The widespread of the migration phenomenon suggests the need to act also on the pre-migration phase, addressing potential traumatic exposures by developing and implementing promotion and preventive interventions focused on resilience and protective factors, as well as enhancing mental health services, directly in countries of origin mainly involved in migration flows (Uphoff et al., 2020; Singla et al., 2017, Barbui et al., 2020). Given the global representation of migrant populations, cross-cultural adaptation of interventions, as well as instruments and diagnostic categories is needed. As a matter of fact, only culturally adapted interventions (Rathod et al., 2018; Heim and Kohrt, 2019; Spanhel et al., 2021) could adequately account for the needs and specificities of these populations, and transdiagnostic interventions (Schäfer et al., 2023b) could overcome the issue of cultural differences in mental diagnoses (Fusar-Poli et al., 2019). To this regard, also the call for future research to address mental health challenges faced by migrants with full-blown psychiatric diagnoses and to study pre-existing serious mental health conditions emerges as a priority (Brandt et al., 2019; Moore et al., 2021; O'Donoghue et al., 2021; Morinaga

et al., 2021; Gao et al., 2022). For example, Brandt and colleagues (2019) found that the average incidence of psychosis was 43% higher in refugees compared with the non-refugee population. This brings the attention also to the need to better define and conduct the diagnostic process, which has to be a cultural diagnosis (Pancheri et al., 2024; Fusar-Poli et al., 2019). As stated by Chowdhary and colleagues (2014), "particular consideration should be given to the use of diagnostic categories in culturally diverse groups, where the use of diagnostic categories may be problematic due to different symptom constellations that do not necessarily correspond to the diagnostic categories specified in Western diagnostic manuals".

Another fundamental point to be addressed by future research is to extensively test the effectiveness of the "new" intervention approaches, namely, scalable interventions through stepped-care and task-shifting approaches (Bryant, 2023; WHO, 2022a; Singla et al., 2017; Koesters et al., 2018; Purgato et al., 2020). Those strategies, firstly developed to address research need in LMICs, showed to be effective and feasible also in high-income countries, like in the RESPOND trial (Purgato et al., 2025). Stepped-care models enable to differentiate intervention levels based on the psychological needs of the population; to this end, a future step would be to study the variables that moderate or mediate the eventual advance to the subsequent levels. For task-shifting, on one hand, the aim would be to better study the level of training and the characteristics of trained people, assessing the impact of the education level and expertise related to the different categories of non-specialists in mental health (i.e., lay people, HCWs, CHWs). This also to investigate whether having some basic knowledge of mental health could impact interventions' effectiveness and implementation, for instance being trained non-specialized workers or lay people with mental health background, like bachelor university students in psychology or related fields or midwifes. Differences in the level of training need to be studied to establish better practices and guidelines, and standardized assessment methods to check competencies are required, for instance the Enhancing Assessment of Common Therapeutic Factors (ENACT) rating scale (Kohrt et al., 2015). Another focus would be to study specific aspects related to the country in which task-shifting is implemented, to assess possible differences between LMICs and HICs. Related to this, another research direction would be to

evaluate the impact of training and intervention delivery on the mental health of personnel itself, both quantitatively (i.e., questionnaires on mental health symptoms) and qualitatively (i.e., focus group, implementation outcomes). This could be of particular interest in the case of peer-to-peer delivery, by people with a migration background themselves. Recent years were characterized by the emergence of online and digital interventions, especially prompted by the Covid-19 pandemic, but a comprehensive understanding of the different modalities (i.e., self-app, smartphone based, online face-to-face synchronous or asynchronous) and their effectiveness is still lacking (Uphoff et al. 2020; El-Haj Mohamad et al., 2022; Cuijpers et al., 2010). Then it would also be important to evaluate whether e-mental health interventions are feasible in low-resourced contexts, related in particular to Internet connection and privacy issues (WHO, 2022c). As a matter of fact, e-health barriers, such as low levels of technological literacy, inadequate supplies of resources and infrastructures, lack of privacy, pre-existing inequalities, lack of experience and confidence, and communication obstacles prevented full implementation and acceptability of remote interventions in the pandemic context, despite their cost-effectiveness and acceptability, especially a more flexible scheduling of services (WHO, 2022c; Witteveen et al., 2022). To comprehensively evaluate new intervention approaches another key step would be to extract and analyze cost-effectiveness data, but also to include them as part of the assessment plan in future studies (Park et al., 2024; Böge et al., 2022; for the RESPOND trial a secondary publication is planned).

A relevant aspect to consider when analysing and improving the effectiveness of psychological interventions is the theoretical background from which they were developed, as this could get new insights into their components and mechanisms of action. Apart from psychotherapies, in global mental health research many trials use psychological support interventions, which can share with psychotherapies the theoretical approach and techniques, by adapting and integrating them with other specific or transdiagnostic elements (Schäfer et al, 2023b). For instance, WHO interventions are almost all CBT-based, with a focus on third wave approaches (i.e., ACT) (see the detailed description in 34.4). However, a focus only on the theoretical background informing intervention development is not resolutive. Many different

forms and approaches of psychotherapy share common roots, as outlined by the 'Nottingham classification of psychotherapies' (Roberts et al., 2019), the first attempt made to develop an agreed classification of psychotherapies, and a fundamental step towards a shared background in research and clinical practice (Roberts et al., 2019). Nevertheless, the main issue in psychotherapy research and practice remains the dominant perspective considering psychotherapies in terms of brands, without a deeper understanding of their active ingredients (Singla et al., 2017). This has led to issues related to 'allegiance bias'[32], and to an unbalanced investigation of psychotherapy approaches in research (Cuijpers and Cristea, 2016; Cuijpers, 2017). To overcome this problem, different strategies have been used so far. Firstly, the development of dismantling or component studies which investigate the same intervention in different groups by adding or removing elements considered essential for the therapy (Ahn and Wampold, 2001; Bell et al., 2013; Furukawa et al., 2021; see Cuijpers et al., 2019c for a systematic review of these studies for depression). Secondly, the 'Distillation and Matching Model' (DMM) (Chorpita et al., 2005, 2007) was the first attempt to systematically meta-analyze components from a pool of studies, by counting the representativeness of each component also in relation to possible moderator variables (see Chorpita et al., 2009, for an applicative example on studies targeting children and adolescents' mental health). Its application to 'winning' treatments only and analyses based on a frequency count, limit the interpretation of results given that most represented components in the trials are not necessarily related to their absolute efficacy. A promising approach to study the active ingredients of multiple interventions overcoming previous limitations, is currently represented by the component-NMA (Furukawa et al., 2021; Cuijpers et al., 2019b; Papola et al., 2024). This innovative methodology has its theoretical basis in a seminal paper of 2009 (Welton et al., 2009), but only statistical advances made possible its development and application. In cNMA interventions are decomposed into their fundamental elements and the effectiveness of each component, alone or in combination, is studied within a

[32] 'Allegiance bias' is the tendency of researchers (and clinicians) to favor interventions for which they have a strong belief of efficacy, by demonstrating a higher effectiveness in trial results (Cuijpers and Cristea, 2016).

comprehensive statistical model (Furukawa et al., 2021; Petropoulou et al., 2021). So far, it has already been applied to some CMDs in the general population, focused on the CBT approach: internet-based CBT (Furukawa et al., 2021) and face-to-face CBT (López-López et al., 2019) for depression, CBT for panic disorder (Pompoli et al., 2018), as well as iCBT for chronic insomnia (Furukawa et al., 2024). One cNMA for bipolar disorder considered different psychotherapeutic approaches (Miklowitz et al., 2021), and another relevant cNMA, especially for global mental health, focused on interventions addressing PTSD and comorbid mental health problems after complex traumatic events (Coventry et al., 2020). Currently, there are other ongoing projects applying this methodology to task-shifting preventive interventions in LMICS (Papola et al., 2023, for the study protocol) and to severe mental disorders (i.e., eating disorders (anorexia and bulimia), psychosis, addiction (cocaine and amphetamine), borderline personality disorder, and bipolar disorder) (https://cordis.europa.eu/project/id/101042701)[33]. In general, cNMAs conducted so far showed that 1) some components are common across different approaches and have similar effects, 2) not all components of the same approach have the same efficacy and 3) usefulness and efficacy of components can vary depending on the clinical characteristics of the population (as the matching variables in the DMM) and the disorder studied. For example, iCBT for depression showed that behavioural activation was the most effective component, combined with human and automated encouragement (Furukawa et al., 2021), whereas, in iCBT for chronic insomnia cognitive restructuring, third wave components, sleep restriction, and stimulus control was the more effective combination, while finding relaxation to be ineffective and/or detrimental (Furukawa et al., 2024). On the other hand, the cNMA of CBT for depression in adults did not prove effects of any component alone or in combination (López-López et al., 2019). In CBT for panic disorder face-to-face and interoceptive exposure were effective components, while excluding

[33] The first project is 'Re-shift: dismantling, redialing, personalizing, and implementing task sharing psychosocial interventions for common mental disorders in low-resource settings' (RE-SHIF), funded by the European Union's HORIZON-MSCA-2021-PF-01. The second project is 'Disentangling psychological interventions for mental disorders into a taxonomy of active ingredients' (DECOMPOSE), funded by the European Research Council (ERC).

muscle relaxation and virtual-reality exposure (Pompoli et al., 2018). Nevertheless, this cNMA highlighted the difference between efficacy and acceptability, with some components enhancing treatment acceptability while not having an impact on efficacy (Pompoli et al., 2018). While depression is one important common disorder to address in migrants, the cNMA of Coventry and colleagues (2020) specifically focused on PTSD symptoms on vulnerable populations, showed that multicomponent interventions, including cognitive restructuring and imaginal exposure were the most effective. One main limitation in these cNMAs is the assumption of additivity of components, leading to the risk of losing their interactive effect, which need to be addressed by future research (Petropoulou et al., 2021). Another important issue to address is the need of a common language to describe components, especially when analysing different therapeutic approaches together. As a matter of fact, dissimilar terms are used by different approaches while essentially addressing the same components, with a risk of a biased language depending on the theoretical approach. Therefore, developing operational definitions of components and comparing them across approaches to find communalities and discrepancies, would be a first important step. This would enable the creation of a comprehensive taxonomy of ingredients, both specific and common, by identifying, for each therapeutic approach, essential and unique active ingredients, transversal, and 'proscribed' components. The first extensive taxonomy developed so far is the 'Behaviour Change Technique Taxonomy', focused on behavioral interventions (Michie et al., 2013). The focus on active components also brings the attention to the need to manualize interventions by describing them in detail to enhance replicability and to better develop and implement interventions (Bryant, 2023). In parallel, fully accessibility and availability of those manuals should be ensured, so the intervention (Blithikioti et al., 2025).

Thirdly, in terms of comparators, a future direction would be to deeper investigate the different types of control groups, with a particular focus on care-as-usual (and its enhanced version), which could differ greatly depending on the study context, as highlighted also by Cuijpers and colleagues (2020b).

Then, for outcomes, as emerged also in the umbrella review by Uphoff and colleagues (2020), post-traumatic stress disorder and trauma-related symptoms are the main focus of research, with less consideration for depression and anxiety disorders. On the other hand, research should also focus on positive mental health, studying and addressing protective factors such as resilience and social support, as well as post-traumatic growth and psychological wellbeing (Apers et al., 2023; Tol et al., 2015). As traumatic events potentially experienced in relation to the migration journey could determine not only negative mental health consequences (Tol et al., 2015; see also background), it is important to study the resilience factors and trajectories that lead to one outcome with respect to the other, by conducting longitudinal observational studies, but also by adding specific assessments within the RCTs. Additionally, future research needs to better focus on stigma and mental health literacy, as well as help-seeking behaviors, giving their role as potential risk or protective factors, as outlined also in the Cochrane systematic review by Baumesister and colleagues (2023) on interventions for improving health literacy on migrants.

A further research perspective would be to establish a set of common data outcomes to be asked in all research trials on migration, to account for relevant mental health predictors and enable comparability across studies. This would imply, for instance, to take into account the impact of postmigration factors (i.e., post-migration living difficulties) beyond mental health outcomes, as well as trauma exposure pre and during migration. To adequately address these aims, research also needs to better focus on questionnaires, which need to be culturally adapted and validated, also based on the educational level of populations (de Graaf et al., 2021). Nevertheless, to enhance research practice, harmonization issues and identification of common and standardized clinical cut-offs have to be adequately considered and addressed.

Another important aspect then, would be to develop studies assessing implementation outcomes to enable a better overview of interventions' real effectiveness. Following the Proctor and colleagues' model (2011), implementation elements to consider would be acceptability, feasibility, fidelity, implementation costs, sustainability, appropriateness, penetration, and adoption. Given the emerging importance of qualitative and feasibility studies to inform RCTs, a first

step would be to collect those kinds of data starting from the already included studies in the MARD database.

A final important element to consider is the setting, as a matter of fact, interventions should be calibrated also on the specific resettlement context, which is related to different needs to be addressed and strategies to be implemented (Dickson et a., 2024). The context itself could be an important vulnerability factor, and some studies on migrant populations could also have been conducted in humanitarian settings (Lee et al., 2019; Tol et al., 2015). Nevertheless, beyond the country income classification, also the specific level of resources within the geographical setting of implementation has to be accounted, given that also in HICs there are deprived contexts and areas where studies are conducted.

Research in global mental health thus requires taking a person-centered care approach given the peculiarity of these vulnerable populations and their contexts (Papola et al., 2025). This gives the path to the concept of 'precision medicine', by prescribing the "right" treatment, (i.e., the most effective and efficacious, as well as feasible intervention) for a certain person in a specific context. The pivotal paper of Singla and colleagues (2017) analysing implementation processes related to the who (personnel), what (components), where (context), and how (modalities) of delivering psychological treatments in LMICs could still be considered as a starting point to familiarize with these issues.

Considering all these factors and perspectives together, the emerging research scenario on migrants' mental health is characterized by complexity, with multiple needs to be addressed and actions to be taken at different levels. Therefore, there is a large potential for future research to overcome current gaps and limitations, also by enhancing its own practices and adopting an integrated approach.

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APPENDICES

Appendices 1: Classification of Psychosocial Interventions

<table>
<tr><th colspan="3">Established psychotherapies</th></tr>
<tr><th>CBT-based/inspired</th><th>Trauma-focused psychotherapies</th><th>Other psychotherapies</th></tr>
<tr><td>• Acceptance and Commitment Therapy (ACT)
• CBT + Basic Body Awareness Therapy (BBAT)
• Cognitive Behaviour Therapy (CBT)
• CBT + pharmacological intervention
• CBT + Bio Feedback (CBT-BF)
• CBT + mindfulness
• Cognitive Processing therapy (CPT)
• internet-based Cognitive Behaviour Therapy (iCBT)</td><td>• Eye Movement Desensitization and Reprocessing (EMDR)
• Imagery Rehearsal Therapy (IRT)
• Narrative Exposure Therapy for Children (KIDNET)
• Narrative Exposure Therapy (NET)</td><td>• Intensive psychotherapy and case management
• Interpersonal therapy (IPT)
• Problem-solving therapy (PST)
• Psychodynamic therapy
• Stabilisation therapy (ST)</td></tr>
<tr><th colspan="3">Counselling and psychosocial support</th></tr>
<tr><th>Counselling</th><th colspan="2">Psychosocial support</th></tr>
<tr><td>• Expressive group counselling
• Supportive counselling
• Value-based counselling
• Trauma counselling
• Psychoeducation + counselling</td><td>• Care management
• Common Elements Treatment Approach (CETA)
• Culture-Sensitive and resource Oriented Peer (CROP) groups
• General psychosocial intervention
• Life skills training
• Mindfulness
• Multilevel strengths-based intervention
• Need-satisfaction intervention</td><td>• Psychoeducation
• Resilience-based intervention
• Stepped Care and Collaborative Model (SCCM)
• Stress management
• Teaching Recovery Techniques (TRT)
• Transdiagnostic group intervention
• Trauma-focused group intervention
• WHO psychosocial interventions</td></tr>
<tr><th colspan="2">Creative-expressive interventions</th><th>Family/parenting interventions</th></tr>
<tr><td colspan="2">• Creative-expressive intervention
• Expressive Writing
• Game-based learning intervention
• Laugher therapy
• Music Therapy Program
• Play Therapy
• Structured sensory intervention</td><td>• Coffee and Family Education and Support (CAFES)
• Family-based intervention
• Parental training
• Parenting and family skills intervention</td></tr>
</table>

Appendices 2: Definitions of Psychotherapies

Established psychotherapies	Definition
CBT-based/inspired	
Cognitive Behaviour Therapy (CBT)* **internet-based CBT (iCBT)**	"In CBT the therapists focus on the impact that a patient's present dysfunctional thoughts have on current behavior and future functioning. CBT is aimed at evaluating, challenging and modifying a patient's dysfunctional beliefs (cognitive restructuring). In this form of treatment the therapist mostly emphasizes homework assignments and outside-of-session activities. Therapists exert an active influence over therapeutic interactions and topics of discussion, use a psycho educational approach, and teach patients new ways of coping with stressful situations. The most used subtypes are CBT according to Beck's manual (Beck et al., 1979) and the "Coping with Depression" course (Lewinsohn et al., 1984)."
Acceptance and Commitment Therapy (ACT)	"Acceptance and commitment therapy (ACT) is a cognitive behavioral approach that promotes psychological flexibility. Psychological flexibility is the aptitude of adjusting to any situational demand which in turn allows for living a meaningful life. ACT targets psychological flexibility through advancing 6 core skills: acceptance (experiences of both pleasant and unpleasant thoughts, emotions, and feelings instead of trying to avoid or control them), defusion (stepping back and observing thoughts as thoughts), contact with the present moment (consciously engaging in any moment and being mindful of thoughts, feelings, and actions), self-as-context (awareness and self-perspective), values (being clear about what matters), and committed action (taking actions that are guided by one's values)" (Vahabi et al., 2022)
Cognitive Processing therapy (CPT)	"Cognitive Processing Therapy (CPT), an evidence-based intervention developed for survivors of assault" (Greene et al., 2021)
CBT + Basic Body Awareness Therapy (BBAT)	"As a mind-body intervention we were interested in studying basic body awareness therapy (BBAT), a mild, body-awareness-oriented physiotherapeutic method. Improved body awareness has been suggested to be a potential mechanism for the therapeutic effect of mind-body therapies, such as BBAT" (Nordtbrandt et al., 2021)
CBT-Bio Feedback (CBT-BF)	"A promising approach is a biofeedback-based cognitive behavioral intervention (CBT-BF) treatment for pain management in traumatized refugees. This intervention focuses on hyperarousal as the key factor in the chronifi- cation of PTSD and pain and facilitates the development of strategies for coping with pain and PTSD symptoms. The manualized CBT-BF protocol consists of 10 weekly 90-minute sessions covering psychoeducation, relaxation strategies, and cognitive restructuring. Findings from a pilot study (N = 11) support the feasibility of CBT-BF in trauma- tized refugees with PTSD and chronic pain. Results showed high acceptance of the intervention and substan- tial effects on cognitive and behavioral coping with pain." (Liedl et al., 2011)
CBT + mindfulness*	"Third wave therapies are a heterogeneous group of therapies that introduce several new techniques to cognitive behavior therapies. They have in common that they abandon or only cautiously use content-oriented cognitive interventions, and the use of skills deficit models to delineate the core maintaining mechanisms of the addressed disorders (Kahl, Winter, & Schweiger, 2012). Well-known therapies that we clustered in this category include Acceptance and Commitment Therapy, Mindfulness-based CBT, and meta-cognitive therapy."
CBT + pharmacological intervention	"CBT emphasized the following elements: (1) information on the symptoms and nature of PTSD from a cognitive-behavioral perspective

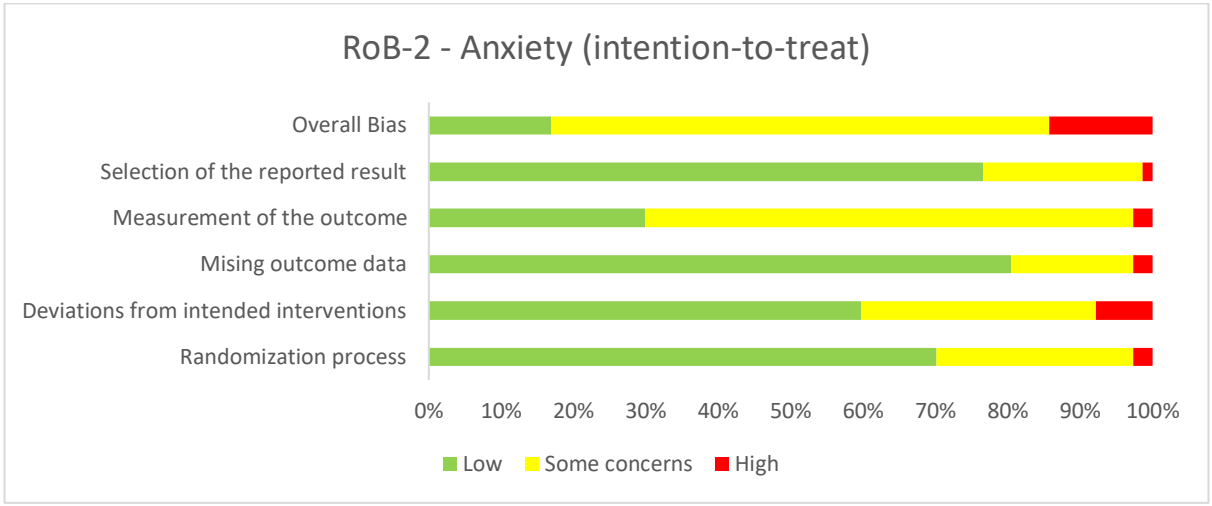
	(Otto, Penava, Pollock & Smoller, 1996), (2) clarification of the difference between PTSD symptoms and culturally-distinct fears of death or disability associated with somatic sensations, (3) exposure to somatic sensations associated with PTSD and anxiety (interoceptive exposure), (4) exposure to memories of specific trauma events with rehearsal of emotional acceptance and cognitive coping strategies, (5) progressive muscle relaxation and diaphragmatic breathing skills, and (6) self-care skills and assignment of pleasant events."; pharmacological treatment was sertraline (clonazepam). (Otto et al., 2003)
Trauma-focused psychotherapies	
Eye Movement Desensitization and Reprocessing (EMDR)[§]	"Eye Movement Desensitization and Reprocessing (EMDR) is a psychotherapy treatment that was originally designed to alleviate the distress associated with traumatic memories. During EMDR therapy the client attends to emotionally disturbing material in brief sequential doses while simultaneously focusing on an external stimulus. Therapist directed lateral eye movements are the most commonly used external stimulus but a variety of other stimuli including hand- tapping and audio stimulation are often used. EMDR therapy facilitates the accessing of the traumatic memory network, so that information processing is enhanced, with new associations forged between the traumatic memory and more adaptive memories or information. These new associations are thought to result in complete information processing, new learning, elimination of emotional distress, and development of cognitive insights."
Narrative Exposure Therapy (NET)[§] **Narrative Exposure Therapy for Children (KIDNET)**	"It is a treatment for trauma-spectrum disorders in survivors of multiple and complex trauma. During the therapy sessions, the patient, assisted by the therapist, constructs a detailed chronological account of his or her own biography. The autobiography is recorded by the therapist in written form and is corrected and elaborated on each subsequent reading. The therapist writes down the biography and reads it aloud at the beginning of each following session for completion and correction. The aim of the therapy is the reorganization of the generally fragmented report of traumatic experiences into a coherent narrative. During the confrontation with the aversive life events, the therapist asks for current and past emotional, physiological, cognitive, and behavioural reactions, and probes for respective observations. During the last session, the participant receives the written report of the biography."
Imagery Rehearsal Therapy (IRT)	"Imagery rehearsal therapy (IRT) is one such adapted CBT where the patient rehearses positive images and, guided by the therapist, writes and rehearses a new and non-disturbing script of a nightmare. The American Academy of Sleep Medicine recommends IRT as first choice psychotherapeutic treatment for PTSD-related nightmare disorders, and IRT is likewise recommended as the preferred treatment in reviews and meta-analyses (Casement & Swanson, 2012; El-Solh et al., 2018; Miller et al., 2020; Waltman et al., 2018; Yücel et al., 2020)."; "Imagery rehearsal therapy was integrated in six sessions of manual-based CBT administered by a psychologist. The IRT treatment consisted of three methods: (1) psychoeducation on disturbing dreams, nightmares and sleep, as well as exercises in cognitive restructuring, (2) imagery education and positive imagery exercises, and (3) imagery rescripting of the disturbing dream or nightmare and rehearsal of a new and non-disturbing dream." (Sandahl et al., 2021)
Other psychotherapies	
Intensive psychotherapy and case management	"Consistent with pragmatic randomized trial design to examine real-world practice with refugees, providers delivering psychotherapy and case management tailored ap- propriate trauma and depression interventions to individual patients. Case management's function was to

	help patients gain access to medical, social, educational, vocational and other necessary services connected to their mental health needs. Case management interventions focused on re- establishing safety and stabilization; facilitating communication, problem-solving and understanding be- tween patients and medical providers; and increasing skill in navigating health and community systems in resettlement. Each patient and his/her case manager de- veloped and worked from an Individual and Community Support Plan (ICSP) that prioritized 3–5 goals, stated in the patient's words (e.g., "I want to work to help my family with bills"; "I want to become U.S. citizen")."; "Psychotherapy functioned to increase patients' coping skills and understanding of their symptoms, as well as to alleviate these symptoms and their impact. Psychotherapists taught mind-body awareness and relaxation skills calibrated to sur- vivors of severe trauma and catastrophic losses."; "Psychotherapists applied evidence-based treatments for PTSD and depression tested on refugee populations, including Narrative Exposure Therapy and Cognitive Behavior Therapy; they also utilised compo- nents of other psychoeducational approaches and trauma- focused treatments, such as Sensorimotor Psychotherapy, and patient-centered methods such as Motivational Interviewing."
Interpersonal therapy (IPT)*	"IPT is a brief and highly structured manual-based psychotherapy that addresses interpersonal issues in depression, to the exclusion of all other foci of clinical attention. IPT has no specific theoretical origin although its theoretical basis can be seen as coming from the work of Sullivan, Meyer and Bowlby. The current form of the treatment was developed by the late Gerald Klerman and Myrna Weissman in the 1980s (Klerman et al., 1984). There is a brief version of IPT, called Interpersonal counseling."
Problem-solving therapy (PST)*	"PST as a psychological intervention in which the following elements had to be included: definition of personal problems, generation of multiple solutions to each problem, selection of the best solution, the working out of a systematic plan for this solution, and evaluation as to whether the solution has resolved the problem (Cuijpers et al., 2018)."
Psychodynamic therapy*	"The primary objective in (short-term) psychodynamic therapy is to enhance the patient's understanding, awareness and insight about repetitive conflicts (intra psychic and intrapersonal). An assumption in psychodynamic therapy is that a patient's childhood experiences, past unresolved conflicts, and historical relationships significantly affect a person's present life situation. In this form of treatment, the therapist concentrates on the patient's past, unresolved conflicts, historical relationships and the impact these have on a patient's present functioning. Furthermore, in psychodynamic therapy the therapists explore a patient's wishes, dreams, and fantasies. The time limitations and the focal explorations of the patient's life and emotions distinguish psychodynamic therapy from psychoanalytic psychotherapy."
Stabilisation therapy§	"The aim of stabilisation is to defined as the establishment of safety in physical, cognitive-behavioural, interpersonal, and social areas of functioning. The first phase or stabilisation phase is aimed at enhancing safety, control over symptoms and socio-psychological competencies through interventions such as emotion regulation and relational skills building, stress management and cognitive restructuring; processing of traumatic memories is left until the second phase."

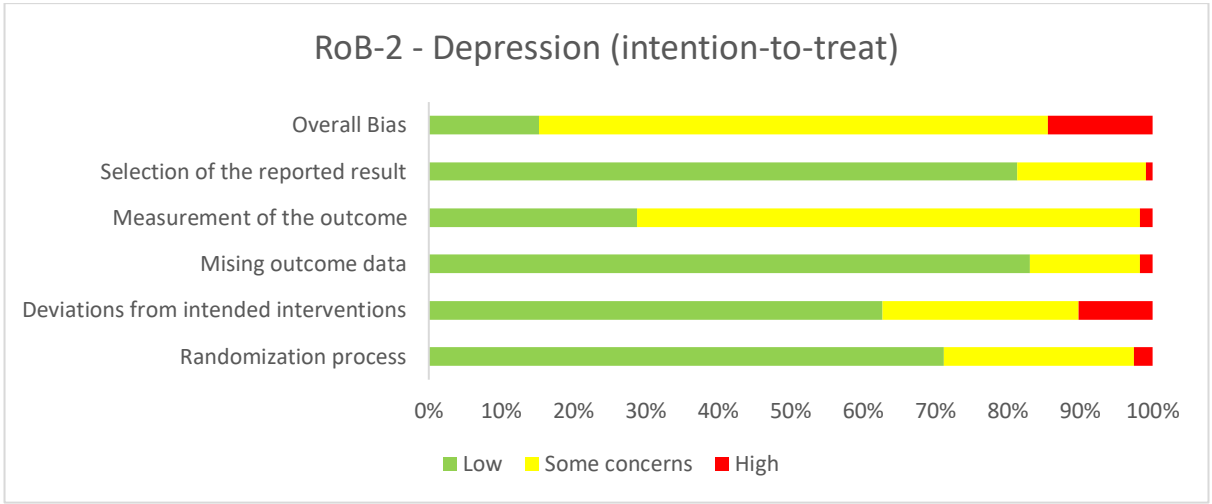
Sources: definitions were directly taken from *Cuijpers and Karyotaki, 2022, §Turrini et al., 2021, and from specific trail papers implementing that specific psychotherapy included in the database.

Appendices 3: ROB-2 Graphs Divided by Outcome

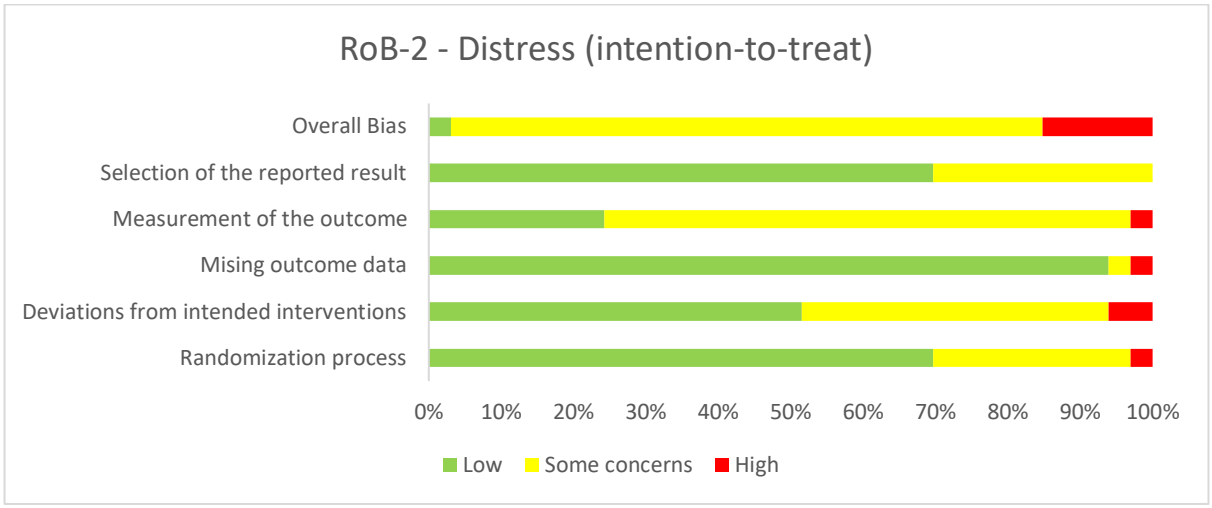
Anxiety



Depression



Distress



PTSD