RESPOND

DRAFT RESEARCH PROTOCOL WP5 - UNIVR

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

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PU=Public, CO=Confidential, only for members of the consortium (including the Commission Services), CI=Classified, as referred to in Commission Decision 2001/844/EC

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1. List of abbreviations and relevant definitions

ARM	**Asylum seekers, Refugees, Migrants**
CSQ	**Client Satisfaction Questionnaire**
CSRI	**Client Service Receipt Inventory**
DSM	**Diagnostic and Statistical Manual of Mental Disorders**
DWM	**Doing What Matters**
EQ-5D-5L	**EuroQol five dimension five level checklist for quality of life** **EU European Union**
GAD-7	**Generalized Anxiety Disorder checklist (consisting of 7 items)**
GCP	**Good Clinical Practice**
IC	**Informed Consent**
K10	**Kessler Psychological Distress Scale (ten item version)**
BTQ	**Brief Trauma Questionnaire**
MIMIS	**Mainz Inventory of MIcrostressorS**
PCL-5	**PTSD Checklist for DSM-5 (consisting of 20 items)**
PFA	**Psychological First Aid**
PM+	**Problem Management Plus**
PHQ-9	**Patient Health Questionnaire for depression scoring each of the 9 DSM-5 criteria**
PHQ-ADS	**Patient Health Questionnaire – Anxiety and Depression (sum score of PHQ-9 and GAD-7)**
PTSD	**Posttraumatic Stress Disorder**
RESPOND	**pREparednesS of health systems to reduce mental health and Psychosocial concerns resulting from the COVID-19 paNDemic**
RCT	**Randomized Controlled Trial**
WHO	**World Health Organization**

2. SUMMARY

Rationale: The ongoing COVID-19 pandemic has a major and potentially long-lasting effect on mental health and wellbeing across populations worldwide. Vulnerable groups, such as asylum seekers, refugees and migrants, are disproportionally affected by the COVID-19 pandemic. There is a high need for psychosocial interventions that can target the most prevalent mental health problems as a result of the COVID-19 pandemic, addressing the needs of many people in a way that maximizes the use of resources. The World Health Organization (WHO) has developed two scalable, low-intensity psychological interventions: Doing What Matters in times of stress (DWM; a self-help intervention) and Problem Management Plus (PM+; a face-to-face intervention). DWM and PM+ can be delivered by paraprofessionals, are applicable to a variety of mental health problems (depression, anxiety and PTSD), and can be adapted to different populations, cultures and languages. Both DWM and PM+ have been proven to be effective on their own. In this study, DWM and PM+ will be combined into a stepped-care intervention. This study is part of the larger EU H2020-RESPOND project, which aims to improve the preparedness of the European mental health care system in the face of future pandemics.

Objective: The main objective is to evaluate the implementation and (cost-)effectiveness of the culturally and contextually adapted DWM/PM+ stepped-care programs amongst asylum seekers, refugees, and/or migrants living in Italy during the COVID-19 pandemic in terms of mental health outcomes, resilience, wellbeing, health inequalities, and costs to health systems. The main hypothesis is that the stepped-care DWM/PM+ intervention together with psychological first aid (PFA) in addition to care-as-usual (CAU) will be more effective in decreasing psychological distress and symptoms of mental health problems than PFA and CAU alone. We aim to conduct a randomized controlled trial (RCT) to assess the (cost-)effectiveness of the stepped-care DWM/PM+ intervention, and to identify (a) barriers and facilitators to treatment engagement and adherence and (b) opportunities for scaling up the implementation of the DWM/PM+ intervention within the existing health care system in Italy.

Study design: pragmatic implementation trial with a single-blinded, randomized, parallel-group design. The final phase of the trial will consist of a qualitative process evaluation with individual interviews and focus group discussions (FGDs). The qualitative phase will include some participants in the randomized trial who completed DWM (n=2/4;), who completed PM+ (n=2/4), who dropped-out during DWM (n=2/4), and who dropped-out during PM+ (n=2/4); (b) local stakeholders (n=10/15) (c) facilitators of the DWM and PM+ intervention (both helpers and trainers/supervisors).

Study population: Adult asylum seekers, refugees or migrants with self-reported elevated psychological distress (K10 >15.9) (n=212).

Intervention (if applicable): All participants (in both the treatment and the comparison group) will receive Psychological First Aid (PFA) and CAU. In addition to PFA and CAU, the treatment group will receive the stepped-care intervention (DWM with or without PM+). The stepped-care intervention consists of DWM (step 1), and conditionally PM+ (step 2) if participants still meet criteria for psychological distress (K10 >15.9) 2 weeks after having received DWM. DWM, i.e. a self-help book with pre-recorded audios, has been adapted as an online intervention (phase 1). PM+ consists of five sessions and will be delivered by trained peer-support helpers in person or via teleconferencing in individual or group format. In addition to PFA, the comparison group will receive CAU which ranges from community care to specialized psychological treatments, according to the needs and clinical characteristics of participants.

Main study parameters/endpoints: Screening for inclusion and exclusion criteria will be interviewer-administered, in-person or through (video) calls. For all participants, online assessments will take place at baseline, at 2 weeks after having received DWM, at 1 week and at 2 months after having received PM+. The primary outcome will be the decrease in symptoms of anxiety and depression from baseline to two-month follow-up, measured through the sum score of the Patient Health Questionnaire (PHQ-9) and General Anxiety Disorder-7 (GAD-7), i.e. the PHQ-Anxiety and Depression Score (PHQ-ADS). We expect to detect a Cohen's *d* effect size of 0.3 in the DWM/PM+ group at 2 months post-treatment. Additional health outcomes include level of anxiety (GAD-7) and depression (PHQ-9), symptoms of posttraumatic stress disorder (PCL-5), resilience (Mainz Inventory of Microstressors MIMIS), quality of life (EQ-5D-5L), and cost of care (CSRI). Additional study parameters will include demographic data, COVID-19 related (exposure) variables, treatment fidelity, satisfaction and acceptability of the intervention program, and implementation indicators (such as reach, dose, resource use, intervention related costs). Through FGDs and interviews at the end of the trial, the

feasibility of scaling-up the implementation on the stepped-care DWM/PM+ intervention within asylum seekers, refugees, and migrants in Italy.

3. INTRODUCTION AND RATONALE

Impact of pandemic and containment measures

The ongoing COVID-19 pandemic has a major and potentially long-lasting effect on mental health and wellbeing across populations in Europe and worldwide. The pandemic has affected every country in the world, with some of the most deeply affected countries in Europe, including Italy (John Hopkins University and Medicine, 2020). Early reports regarding the levels of psychological distress associated with the COVID-19 crisis are highly concerning (McGinty, Presskreischer, Han & Barry, 2020) and led to the UN releasing a policy briefing on the mental health impacts of COVID-19 warning that a 'long-term upsurge in the number and severity of mental health problems is likely' (United Nations, 2020).

European governments installed epidemic control measures to contain the spreading of the virus, which include lockdown restrictions and closures (amongst others) that have created a great impact on society (Blavantnik School of Government, University of Oxford, 2020). Physical distancing and staying at home orders have led to elevated loneliness in many people, which is in turn associated with depression and suicidal ideation (Stickley & Koyanagi, 2016). Despite social protection programs, many individuals have directly been impacted financially by the economic consequences of the containment measures, and have seen their income decline, especially people with short-term or part-time contracts, or those being self-employed. Economic estimates show that the lockdown will directly affect sectors amounting to up to a loss of 2 percentage points in annual GDP growth for each month of containment (OECD, 2020). Following economic recession, mental health problems have been shown to increase (Garcy & Vagero, 2013).

Focus on vulnerable groups

Although the COVID-19 pandemic has affected the whole population, consequences are not distributed equally. COVID-19 has had a larger effect on people living under fragile circumstances, and on socio-economically disadvantaged and minority populations across Europe. The risk of dying from COVID-19 is higher among people in socio-economically deprived areas than among people in the least deprived areas (Public Health England, 2020). Furthermore, historically, following recession higher increases in mental health symptoms of younger working-age people have been found (Thomson & Katikireddi, 2018). Thus, the COVID-19 pandemic and the associated containment measures are expected to lead to an exacerbation of health inequalities in Europe and beyond. In May 2020, the WHO already stated that particular attention should be given to vulnerable groups, including asylum seekers, refugees, and migrants (ARM)(WHO, 2020b).

ARM resettled in high-income countries are exposed to multiple health-related risks and vulnerabilities than the general population, due to their exposure to complex traumatic events before and during transition, and to additional traumatic events once resettled in a hosting country (Turrini et al, 2017). In particular, in the COVID-19 pandemic ARM may lack biosecurity measures as basic protection equipment due to insufficient information. They are also at high risk of infection because of proximity, lack of sanitation, and poor living conditions. There is evidence of discrimination and social exclusion amongst resettled ARM living in areas associated with COVID-19 (IASC, 2019; WHO, 2020). These reports are in line with previous evidence indicating that discrimination has been a key concern even in the general population in relation to other viral outbreaks and epidemics (Person et al, 20014). In addition, asylum seekers, refugees, and migrants are often left out of disaster preparedness planning, and may experience lack of access to information delivered in a culturally appropriate way, with problems in adapting their behaviors to protection measures and social rules such as social distancing.

The Box 1 below reports the definitions of asylum seekers, refugees, and migrants (ARM) according to the UNHCR (UNHCR, 2018).

Asylum seekers	Asylum seekers are persons fleeing armed conflict or persecution, but whose request for sanctuary has yet to be processed.
Refugees	Refugees are persons fleeing armed conflict or persecution. Their situation is often so perilous and intolerable that they cross national borders to seek safety in nearby countries, and thus become internationally recognized as "refugees" with access to assistance from States, UNHCR, and other organizations. They are so recognized precisely because it is too dangerous for them

	to return home, and they need sanctuary elsewhere. These are people for whom denial of asylum has potentially deadly consequences.
Migrants (economic)	Migrants choose to move not because of a direct threat of persecution or death, but mainly to improve their lives by finding work, or in some cases for education, family reunion, or other reasons. Unlike refugees who cannot safely return home, migrants face no such impediment to return. If they choose to return home, they will continue to receive the protection of their government.

Scalable psychological interventions to improve resilience, mental health and wellbeing

There is a high need of psychosocial interventions for at-risk groups, such as ARM, affected by traumatic events and additionally by the COVID-19 pandemic to address the most prevalent mental health problems, most notably symptoms of distress, anxiety, depression, and posttraumatic stress disorder (PTSD). Telehealth has proven to be effective for delivery of individual or group-based mental health and psychosocial support interventions (Banbury, Nancarrow, Dart, Gray & Parkinson, 2018), and has great advantages over regular mental health care delivery in terms of its feasibility under lockdown restrictions, scalability, and reducing costs. This can be particularly useful for ARM resettled in Italy who experience various barriers to (mental) health care. However, it is yet unclear whether it has met the needs of more vulnerable people with specific needs, who are illiterate, older, or people without internet access (EuroHealthNet, 2020).

The World Health Organization (WHO) has developed a number of scalable psychological interventions for populations affected by adversity (WHO, 2017). They include -amongst others- Doing What Matters in Times of Stress (DWM) and Problem Management Plus (PM+). A core feature of all WHO scalable interventions is that they can be trained to and delivered by non-professional helpers, such as a trained peer, or helper at the workplace, or a psychosocial worker (task-shifting) (WHO, 2017; Epping-Jordan et al., 2016). They have also been designed to be widely applicable to a variety of mental health problems (depression, anxiety and PTSD) and easily adaptable to different populations, cultures and languages. Finally, the interventions and their implementation materials are freely available on the WHO website.

DWM was originally designed for flexible implementation either in a group or individual format including an online format. People participating in DWM also receive support from a briefly trained helper. DWM is based on acceptance and commitment therapy (ACT), a modern form of cognitive-behavioral therapy with a strong focus on mindfulness practices and includes exercises which aim to enhance stress reduction and build social support, adaptive coping and resilience (Epping-Jordan et al., 2016). It has been implemented with different populations of asylum seekers and refugees in Europe, Turkey (Purgato et al., 2019) and Northern Uganda (Tol et al., 2020). In RESPOND, the DWM pre-recorded audios and an illustrated stress management guide called “Doing What Matters in Times of Stress: an illustrated guide” (WHO, 2020a), has been culturally adapted to an online application tool. This way, people can use the self-help intervention in their own time. The five weekly sessions of the intervention will follow the five chapters of the book (grounding, unhooking, acting on your values, being kind and making room). Participants will receive a weekly call from a so-called “helper” to support them accessing the intervention sessions, and to shortly revise the contents of each session.

PM+ is a transdiagnostic intervention (Banbury et al., 2018) for reducing symptoms of depression, anxiety, PTSD, and related conditions, is delivered by trained non-specialized workers or lay people, and is available in individual and group delivery formats for face-to-face or online delivery. PM+ comprises five weekly sessions using evidence-based techniques: of (a) problem solving, (b) stress management, (c) behavioral activation, and (d) accessing social support. PM+ has been successfully implemented in Kenya (Bryant et al., 2017) and Pakistan (Rahman et al., 2016b). Both DWM and PM+ have been implemented through two large EU H2020 funded projects, STRENGTHS (733337) and RE-DEFINE (779255). For this study, we adapted both the DWM and the PM+ intervention to the COVID-19 pandemic and to the context and culture of the target population, i.e. we adapted examples and pictures used in the intervention.

RESPOND Project

This study is embedded in the larger, EU H2020 CORONAVIRUS-funded RESPOND (PREparednesS of health systems to reduce mental health and Psychosocial concerns resulting from the COVID-19 paNDemic) project. The RESPOND project

aims to improve the preparedness of the European mental health care system in the face of future pandemics. In order to do that a consortium of eight countries (BE, DE, ES, FR, NL, IT, SWE, UK) will collaborate in:

1) Identifying risk groups for poor wellbeing and mental health related to the COVID-19 pandemic by analyzing longitudinal epidemiological data and identifying resilience factors related to the COVID-19 pandemic;
2) Examining the impact of the COVID-19 pandemic on long-term health and mental health services use, and the associations between health and mental health care use and socio-economic factors across European countries with different control measures and pandemic course (Sweden, Italy and Spain);
3) Performing rapid and recurring holistic assessments of policies and measures across Europe that have and will address different phases of the COVID-19 pandemic to protect the mental health and wellbeing of groups at high-risk for COVID-19 related mental health issues
4) Examining the necessary health system and wider contextual and policy conditions for successful implementation and scaling-up of remote-delivered stepped-care using existing, scalable World Health Organization (WHO) programs to improve resilience, wellbeing, overall functioning and mental health, across frontline workers and other high-risk groups for COVID-19 related poor mental health, including ARM.
5) Providing regional and national health care authorities, including relevant public health and long-term care authorities, with transferable evidence-based practices, methodologies and guidance for scaling up mental health and broader social and economic support measures for frontline workers and other risk groups for COVID-19 related mental health symptoms, including ARM.

This study(-protocol) contributes to aim number 4; examining the feasibility and cost-effectiveness of remote-delivered scalable interventions for targeting COVID-19-related psychological distress and mental health issues. Both DWM and PM+ have been found to be effective (Purgato et al., 2019; Tol et al., 2020; Bryant et al., 2017; Rahman et al., 2016b), but it is unknown if they are also effective when combined as a stepped-care program compared to care-as-usual. Within Italy, the targeted vulnerable group to examine the effectiveness of the stepped-care intervention, will be asylum seekers, refugees, and migrants. The treatment group will be compared to an enhanced care-as-usual (CAU) group in terms of a number of health and implementation outcome variables.

4. OBJECTIVES

4.1. PRIMARY OBJECTIVE

To evaluate the (cost-)effectiveness, feasibility, and acceptability of the culturally and contextually adapted DWM/PM+ stepped-care program among ARM resettled in Italy during the COVID-19 pandemic in terms of mental health outcomes, resilience, wellbeing, health inequalities, and costs to health systems.

4.2. SECONDARY OBJECTIVE

To identify barriers and facilitators to treatment engagement and adherence and opportunities for scaling up among the target population in Italy (qualitative part of the study).

5. STUDY DESIGN

The study consists of a single-blind randomized controlled trial (RCT), that will include a qualitative analysis in its final phase. As a preliminary work, we conducted a qualitative study to assess the needs of ARM resettled in Italy and to inform the adaptation of the DWM/PM+ interventions. The preliminary phase has been completed and was described in a separate protocol for which ethical approval was granted by the Comitato di Approvazione della Ricerca sulla Persona – CARP – of the University of Verona.

Randomized controlled trial (stepped-care DWM/PM+ intervention with Psychological First Aid and care-as-usual vs. Psychological First Aid and care-as-usual alone). The final phase of the RCT will include a process evaluation with qualitative interviews and focus groups to assess barriers and facilitators of engagement and adherence to the stepped-care intervention and opportunities for scaling up the implementation of the intervention.

Box 2. Summary of the present research.

Randomized controlled trial: the DWM/PM+ programs will be evaluated in a RCT. Participants will be screened for elevated distress (K10; see Figure 1). We will conduct a RCT in ARM with increased psychological distress to determine whether the stepped care intervention (i.e. DWM/PM+) leads to stronger decreases in mental health outcomes, and increase in wellbeing among compared to care-as-usual (CAU). This phase is designed as a randomized, single-blind parallel-group trial with one treatment group (n=105) and one comparison group (n=105). All participants in both the treatment and the comparison group will receive Psychological Frist Aid (PFA) and CAU. In addition to PFA and CAU, participants randomized into the treatment group will receive the DWM/PM+ stepped-care intervention, while participants randomized in the comparison group will receive PFA and CAU only.
All participants in the treatment group (i.e. those who receive DWM and PM+ and those who only receive DWM because symptoms subside) will be followed for a period of 2 months after the end of the PM+ session (see Figure 1 for assessment points).
The final part of the RCT will include a qualitative study, consisting of interviews and/or focus group discussions among key stakeholders (identified as reported below) to evaluate barriers and facilitators to treatment engagement and adherence to the DWM/PM+ stepped-care intervention, as well as opportunities for scaling up the implementation of the intervention within the existing healthcare system in Italy. This will inform partners in RESPOND of the synthesis and dissemination of the DWM/PM+ stepped-care intervention for vulnerable groups during a pandemic.

The qualitative study will include the following key stakeholders (a) participants in the RCT who completed DWM (n=2/4; improved and not improved), who completed PM+ (n=2/4; improved and not improved), who dropped-out during DWM (n=2/4), and who dropped-out during PM+ (n=2/4)); (b) local stakeholders (n=10/15); (c) facilitators of the DWM and PM+ intervention (both helpers and trainers/supervisors).

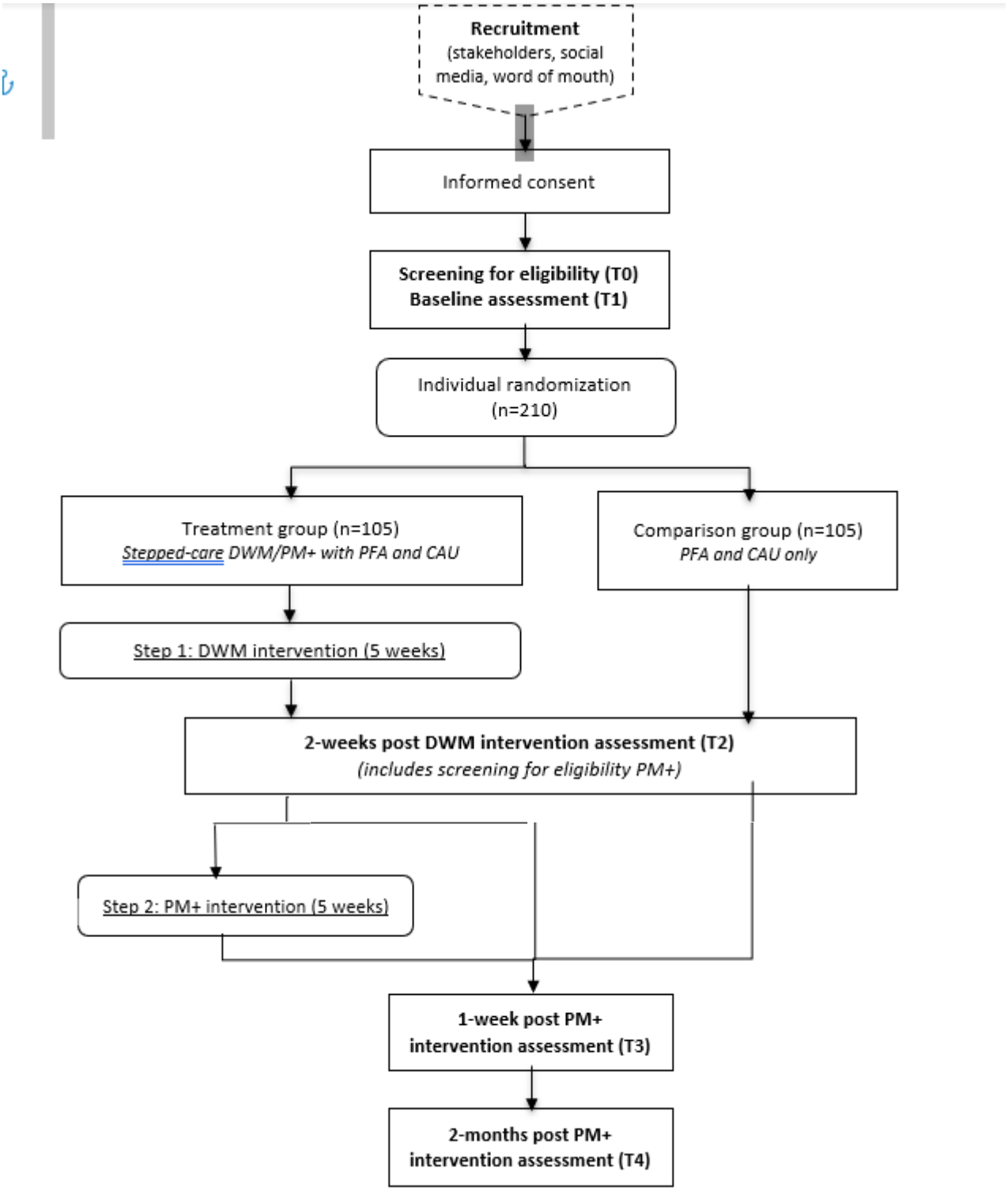

Figure 1. Flowchart of randomized controlled trial

6. STUDY POPULATION

6.1. POPULATION

Participants for the RCT will be ARM resettled in Italy. Participants will be recruited through (a) targeted social media recruitment, (b) key stakeholders as NGOs located in Italy, and (c) other community-based organizations offering legal and/or social and/or psychosocial support for this vulnerable group.
Participants for the qualitative process evaluation will be key informants, such as participants who took part in the RCT; DWM/PM+ facilitators (helpers and supervisors); local stakeholders (recruited through participating centers in the RCT phase). For participants who took part in the RCT, we aim to include both those who took part only in DWM and those who took part in PM+ as well. Also drop-outs from both the DWM and PM+ intervention will be asked to participate in the qualitative process evaluation.

6.2. INCLUSION CRITERIA

Participants will be eligible to participate in the study if they meet all of the following criteria:

- 18 years or older;
- Living in Italy as asylum seeker, refugee, or migrant
- Having elevated levels of psychological distress (Kessler Psychological Distress Scale (K10) >15.9).
- Sufficient mastery (written and spoken) of one of the languages the DWM/PM+ intervention is being delivered in (e.g. English, Italian).
- Oral and written informed consent before entering the study.

6.3. EXCLUSION CRITERIA

Potential participants who meet the inclusion criteria will be excluded from participation in this study if they meet any of the following criteria:

- Planning to permanently move back to their home country before the last quantitative assessment at 2 months after PM+;
- Having acute medical conditions (requiring hospitalization);
- Imminent suicide risk, or expressed acute needs or protection risks that require immediate follow-up;
- Having a severe mental disorder (e.g. psychotic disorders, substance-dependence);
- Having severe cognitive impairment (e.g. severe intellectual disability or dementia);
- Currently receiving specialized psychological treatment (e.g. EMDR, CBT);
- In case of current psychotropic medication use: being on an unstable dose for at least 2 months.

6.4. SAMPLE SIZE CALCULATION

A total number of 212 participants will be included. Based on prior studies on a PM+ intervention (Bryant et al., 2017; Rahman et al., 2016b), we aim to detect a small to medium effect size Delta (defined as as the square root of the ratio of the variance of the tested effect to the comparison error variance) of 0.3 in the PM+ group at 2 months post-treatment based on the primary composite outcome PHQ-ADS (Kroenke et al., 2016; 2019). The PHQ-ADS is the combined sum score of depression and anxiety symptoms of the PHQ-9 and GAD-7, respectively and has shown good internal consistency (α = .88 to .92) (Kroenke et al., 2016; 2019). A power calculation for an ANOVA repeated

measurement design with two time-periods to identify the effect of treatment at the last endpoint suggests a minimum sample size of N=74 per group (power=0.95, alpha=0.05, two-sided, rho=0.9). Taking into account 30% attrition, we aim to include a total number of 212 participants (106 in the stepped-care DWM/PM+ treatment group - with PFA and CAU - and 106 in the PFA and CAU comparison group).

7. TREATMENT OF SUBJECTS

Psychological First Aid (PFA)
All participants, both in the treatment and the comparison group, will be offered individual Psychological First Aid (PFA) through a face-to-face or teleconferencing meeting. PFA is a WHO developed support strategy that involves humane, supportive and practical help for individuals suffering from serious humanitarian crises. PFA does not necessarily involve a discussion of the event(s) that cause the distress but aims particularly at five basic elements that are crucial to promote in the aftermath of crises, i.e. a sense of safety, calm, self- and community efficacy, connectedness, and hope (Hobfoll et al., 2007). PFA consists of a (telephone) conversation (approximately 30-45 minutes) that a helper has with a participant. PFA has various themes; in PFA, the helper provides non-intruding practical care and support, assesses needs and concerns, helps people to address basic needs (e.g. information), listens to people without pressuring them to talk, comforts people and helps them to feel calm, helps people to connect to information, services, and social support, and protects people from further harm (WHO, 2011).

Care-as-usual (CAU)
In addition to PFA, both the treatment and the comparison group will receive care-as-usual (CAU); they will be allowed to receive any usual care. CAU may include community care, social/legal support, and psychoeducation.

Because ARM may have a lack of knowledge of the Italian health care system and therefore may not utilize health care (Aanjaagteam Bescherming Arbeidsmigranten, 2020), we will inform them on the Italian health care system as well. Additionally, participants will receive information about locally available referral options. We will record for all participants whether they have a general practitioner (when they consent to having this recorded). In case the participant gives approval, we will record name and contact details.

7.1. INVESTIGATIONAL PRODUCT/TREATMENT

Treatment group: Stepped-care Doing What Matters/Problem Management Plus (DWM/PM+)
Stepped-care models assume to provide health care in the most efficient and cost-effective way: the first step of care is readily available for all those in need and more costly treatments are reserved only for those not improving. Evidence suggest that stepped-care models are modestly effective (van Straten, Hill, Richards & Cuijpers, 2014; Ho, Yeung, Ng & Chan, 2016) although there is a high heterogeneity of such models (number of steps, duration of steps, rules about stepping up) and their effects. Interestingly, research in clinical practice has shown that results improve when care providers switch from a matched care to a stepped-care approach (Boyd, Baker & Reilly, 2019).
The treatment group will receive the stepped-care program consisting of Doing What Matters in Times of Stress (DWM) (step 1) and Problem Management Plus (PM+) (step 2) in addition to Psychological First Aid (PFA) and care-as-usual (CAU) (for details of CAU, see: '*Care-as-usual (CAU)'* below). Step 2 will only be provided if the participant still has elevated levels of psychological distress (K10 > 15.9) at 2 weeks after DWM, i.e. during the second quantitative assessment.

Step 1: Doing What Matters in Times of Stress (DWM)
The DWM program has been developed by WHO and collaborators working in the humanitarian field. DWM was designed to be relevant for large segments of adversity-affected populations: it is intended to be transdiagnostic, easily adaptable to different cultures and languages, and both meaningful and safe for people with and without mental disorders. DWM is based on acceptance and commitment therapy (ACT), a form of cognitive-behavioral therapy, with

distinct features (Hayes, Levin, Plumb-Vilardaga, Villatte & Pistorello, 2013). ACT is based on the concept that ongoing attempts to suppress unwanted thoughts and feelings can make these problems worse, so instead it emphasizes on learning new ways to accommodate these thoughts and feelings without letting them dominate. ACT has been shown to be useful for a range of mental health issues (Tjak et al., 2015) and has been used successfully in a guided self-help format (Hayes et al., 2013).

The DWM program consists of a self-help guide that is complemented with pre-recorded audio exercises. The audio material imparts key information about stress management and guides participants through individual exercises. Additionally, participants are guided by a briefly trained helper.

DWM includes five sections (or modules), each of which focuses on a specific skill:

- **Section 1:** *Grounding:* Bringing attention back to the present moment when caught up in distressing emotions.
- **Section 2:** *Unhooking:* Noticing difficult thoughts and feelings, naming difficult thoughts and feelings, and refocusing on what you are doing.
- **Section 3:** *Acting on your values:* Identifying personal values and then taking small or big actions to live in line with these values.
- **Section 4:** *Being kind:* Enhancing and encouraging kindness towards oneself and towards others.
- **Section 5:** *Making room:* Learning how to tolerate stress while still acting consistently with values.

In this study, the DWM program will be delivered as an online intervention. The DWM intervention, i.e. both the audios and the self-help guide, have been adapted for use on a smartphone or other device with internet access. The format of DWM is innovative in that it seeks to ensure that key intervention components are delivered as intended through the use of pre-recorded audio, without the burden of extensive training and supervision. In the online application tool a new module (i.e. section) is released every week so participants will be asked to go through the entire DWM intervention within five weeks with weekly guidance from a helper. Due to its format, the DWM program does not require much time from experts for implementation. The delivery mode for the support from the helper will be flexible and in line with COVID-19 regulations. The potential of using a psycho-educational course to access hard-to-reach populations has been demonstrated previously (Cuijpers, Munoz, Clarke & Lewinsohn, 2009). Additionally, research has found that guided self-help programs produce much better results than “pure” (unguided) self-help, and the effects produced by guided self-help are surprisingly similar to face-to-face psychological treatment (Fledderus, Bohlmeijer, Pieterse & Schreurs, 2012).

Protocol adherence

We will assess DWM protocol adherence at post-intervention based on meta-data collected during the intervention (i.e. by tracking participants usage of the DWM app such as who accesses what page, how often, how much time participants spend on the app etc.). We will only use this meta-data during the intervention to remind each participant (e.g. through e-mail) after finishing each module to let them know that they should start a new module. Additionally, participants receive a weekly phone call from a helper to see how they are doing and to check on their progress.

Step 2: Problem Management Plus (PM+)

PM+ is a new, brief, psychological intervention program based on cognitive behavioral therapy (CBT) techniques that are empirically supported and formally recommended by the WHO (Dua et al., 2011). The manual involves the following empirically supported elements: problem solving plus stress management, behavioral activation, facing fears, and accessing social support. Figure 2 shows a brief outline of the five sessions. In these 60-minute sessions participants may talk to trained non-professional helpers (who are supervised by registered (clinical) psychologists). We will follow this outline, except that we excluded all assessment instruments from the manual, since they are administered at the assessments instead of at the intervention sessions. PM+ has four core features: it is brief (five sessions); delivered by para-professionals; transdiagnostic thereby addressing depression, anxiety, PTSD, stress and problems as defined by people themselves; originally designed for people in low-income country communities but easily adaptable to different (vulnerable) populations, cultures and languages.

In this study, the delivery mode of the PM+ intervention will be flexible, with remote delivery in phases of the pandemic when physical distancing rules apply. The PM+ intervention has been culturally and contextually adapted. This is a future-oriented attempt towards a more holistic mental health care system that can flexibly switch between modes of delivery (e.g. remotely (e.g. Zoom) or face-to-face), depending on the needs and the specific containment measures

that apply, and the specific preferences and needs of the participant.

Protocol adherence

Protocol adherence will be ensured by weekly supervisions provided by the PM+ trainers/supervisors as well as the fidelity checklist (Dawson et al., 2016). In addition to these, audio records of the sessions will be used for fidelity checks. The sessions will be audio recorded with professional equipment only if the participant gives consent to be recorded.

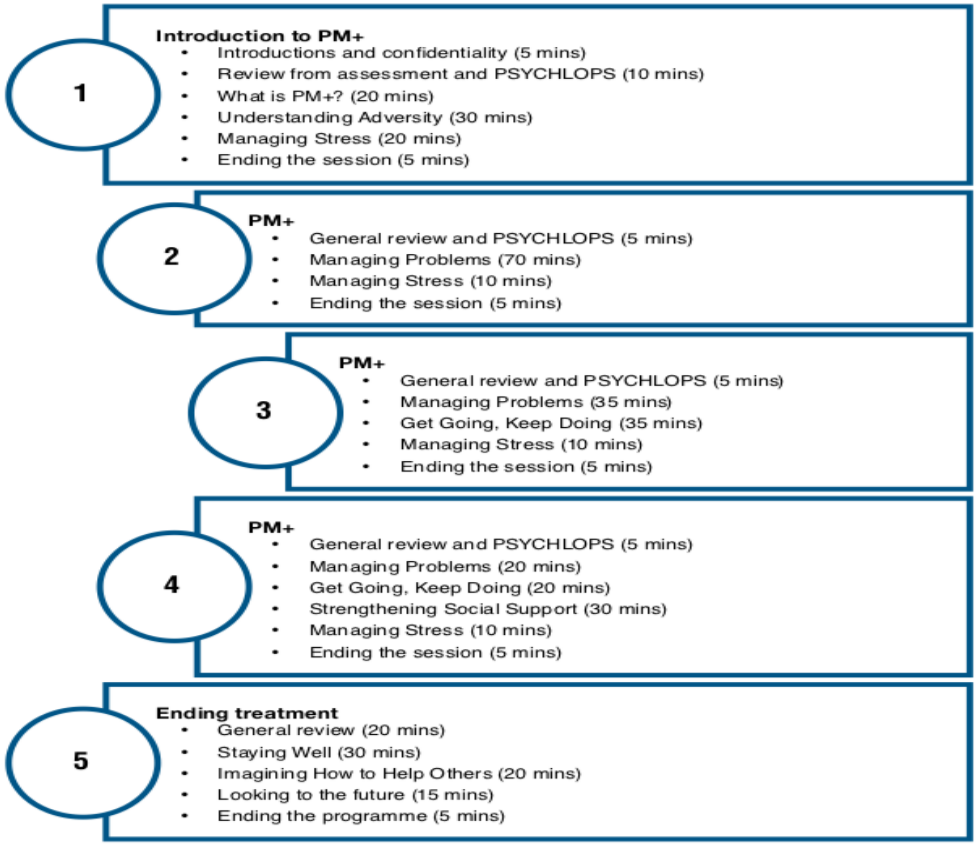

Figure 2. Outline of five PM+ sessions (figure from PM+ Manual, WHO, 2016). We will follow this outline, apart from the PSYCHLOPS assessment which is excluded.

Helpers in PFA, DWM and PM+ interventions

In general, helpers selected to provide support to users should have at least primary school level literacy as well as good knowledge and skills in providing psychosocial support. Delivering PFA, DWM or PM+ can be learned by both professionals and non-professionals who are in a position to help people impacted by (very) distressing events. Helpers should speak the same language as the participant (as well as being able to communicate in English). It is not necessary for helpers to have a psychosocial or mental health background in order to be able to offer these interventions. Necessary skills include foundational helping skills, such as effective community and rapport-building skills, and experience supporting people in distress. For DWM but particularly PM+ helpers, it is also recommended that helpers experience receiving support using the stress management guide (i.e., practice using the stress management guide as a user with a colleague acting as the helper). If support is provided remotely, it is preferable that helpers have experience with remote support and receive training in this approach (e.g., EQUIP REMOTE). Practice sessions (e.g., providing support to other helpers, practice supporting persons with impairments) can help identify issues that may arise prior to working with users and build helper capacity. Helpers need to sign a confidentiality agreement and need to show a

certificate of conduct. Helpers may deliver either PFA, DWM and/or PM+, if they are trained (and supervised) in each intervention delivered.

Training PFA helpers

Before providing PFA, helpers will receive training to enhance knowledge and gain better understanding of appropriate psychosocial responses and skills in providing support to individuals exposed to adversity (Sijbrandij et al., 2020). This half- or one-day training (WHO, 2013) will include explanations of the basic concepts and PFA principles, how to support (very) distressed people, and how not to cause further harm by using participatory learning (i.e. role-play).

Training DWM helpers

Similar to PFA-helpers, the role of the coach in DWM is to provide brief motivational support to the participants; not provide specialized mental health services. Helpers should be empathetic and motivated to do this. Before working as a helper, helpers will receive a short training by academics and/or mental health-care professionals. Helpers will be trained in providing support using the stress management guide (i.e., practice using the stress management in role-plays with other helpers) and practice to deliver support remotely (i.e. practice providing support in role-play settings). Helpers will receive a written manual as a guide for the brief support sessions.

Training PM+ helpers

PM+ helpers will receive eight days of training, followed by three practice cases, on-the-job training, and close supervision during the whole trial by the PM+ trainers/supervisors. Audio records of PM+ sessions will also be used for supervision. The training program comprises of education about common mental disorders, basic counseling skills, delivery of intervention strategies and self-care (Rahman et al., 2016a). The additional criteria for PM+ providers include having completed a high-school education and complete the EQUIP 'Delivering Remote Services' training.

Trainers/supervisors

All DWM/PM+ helpers will be actively trained and supervised by registered (clinical) psychologists and will be continued to be monitored throughout the process. These clinicians will also independently assess and monitor treatment sessions at-random in order to ensure treatment adherence and fidelity. Furthermore, these expert clinicians will supervise the entire assessment and therapeutic process to reduce the burden on and risks for participants.
DWM/PM+ trainers/supervisors will be approximately five licensed mental health care professionals such as health-care psychologists or psychiatrists. They will be trained by a Master Trainer via a training-of-trainers (TOT) program, consisting of the same elements as the training for helpers, but also of training and supervision skills (Rahman et al., 2016a). The PM+ trainers/supervisors will be responsible for close supervision of the PM+ helpers. Therefore, as a next step, they will train DWM/PM+ helpers. Figure 3 shows how the TOT of PM+ is planned. Such training with continued supervision by professionals has been successfully used for (lay-)counselors before (Murray et al., 2011).
The research team at UNIVERSITY OF VERONA will be responsible for arranging the trainings and supervision for the lay helpers. Supervision of the helpers by the trainers/supervisors will take place on a weekly basis (Dawson et al., 2016). This will be done remotely or face-to-face, depending on the preference of the trainers/supervisors and accounting for COVID-19 regulations. The trainers/supervisors will also receive supervision by the Master trainer when necessary.

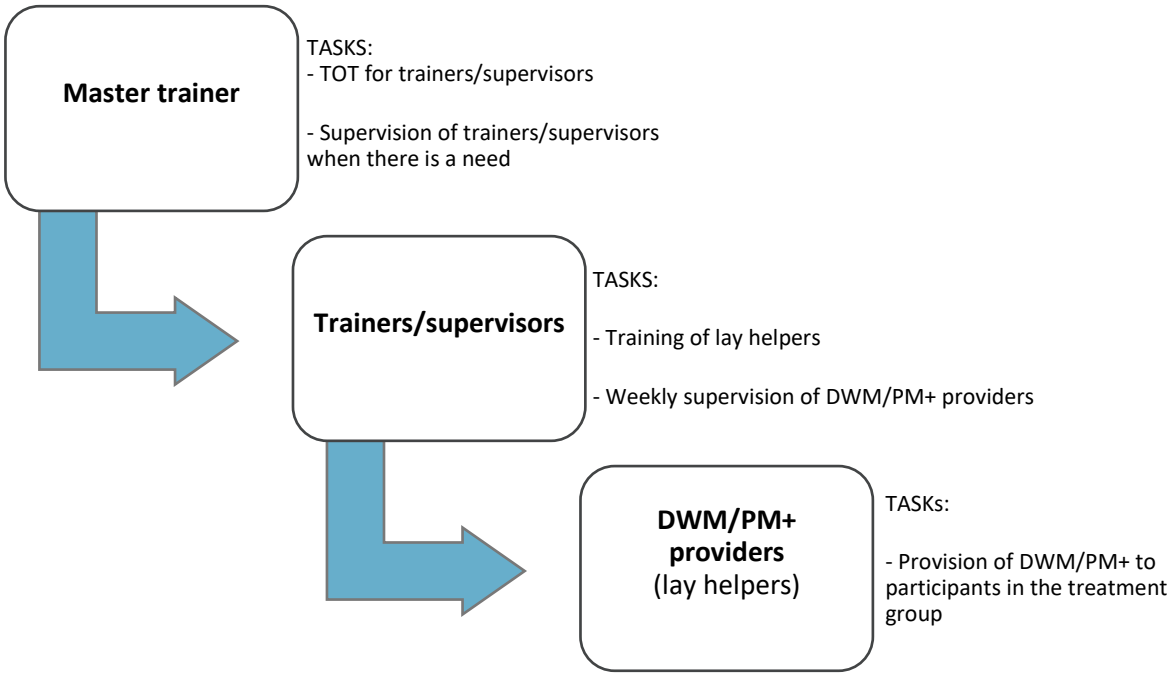

Figure 3. Training of Trainers/Supervisors and DWM/PM+ Helpers

7.2. USE OF CO-INTERVENTION (IF APPLICABLE)

Not applicable

7.3. ESCAPE MEDICATION (IF APPLICABLE)

Not applicable

8. METHODS

8.1. STUDY PARAMETERS/ENDPOINTS

All participants will have five assessments (T0-T4), mostly by filling out online questionnaires. The five assessments take place at the following time-points (see also Figure 1):

T0: Screening for eligibility including psychological distress

T1: Baseline assessment

T2: 2 weeks post DWM intervention assessment

T3: 1-week post PM+ intervention assessment

T4: 2-months post PM+ intervention assessment

8.1.1. Main study parameter/endpoint

The primary endpoint will be the decrease in symptoms of depression and anxiety from baseline to two-month follow-up after the PM+ intervention ended, measured through the combined sum score of the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder (GAD-7) previously validated as the PHQ-ADS (Kroenke et al., 2016; 2019). A description of the measure(s) can be found under 'Study Procedures'. Based on prior studies on PM+ in Pakistan and Kenya (Rahman et al., 2016b; Bryant et al., 2017) where PM+ was administered as a standard treatment, we expect to detect a Cohen's *d* effect size of 0.3 in the PM+ group at 2 months post-treatment.

8.1.2. Secondary study parameters/endpoints (if applicable)

1. Level of depression (PHQ-9)
2. Level of anxiety (GAD-7)
3. Severity of posttraumatic stress disorder (PCL-5)
4. Resilience based on exposure to stressful (general- and COVID-19 related-) events (MIMIS)
5. Quality of life (EQ-5D-5L)
6. Cost of care: impact on use of health system, other services, time out of employment and other usual activities and need for informal care (CSRI schedule)

The measurement instruments are described under 'Study procedures'.

8.1.3. Other study parameters

The measurement instruments are described under 'Study procedures'.
1. Demographic data
2. Exposure to adverse life-events (BTQ)
3. Treatment fidelity (DWM: tracking app usage based on meta-data, PM+: audio records, checklists)
4. Level of self-identified complaints during PM+ ("Psychological Outcomes Profiles" (PSYCHLOPS))
5. Satisfaction (qualitative assessment in study phase 3)

6. Acceptability of the program (qualitative assessment in study phase 3)
7. Implementation indicators: reach, dose, resource use, costs of recruiting, training and retaining staff delivering the stepped-care program, program costs, adaptation, the process, quality.

8.2. RANDOMIZATION, BLINDING AND TREATMENT ALLOCATION

After the screening and the baseline assessment, participants will be randomized to either the treatment group (n=105) or the comparison group (n=105), with an equal probability of assignment to each group (allocation ratio 1:1). The trial is a single-blind RCT (i.e. outcome assessors are blind to treatment allocation). Randomization will be carried out through computerized software (e.g. Castor) using limited block size (e.g. 6-12 participants per block) and will be performed by an independent person who is not involved in the assessment of participants. If participants are randomized into the treatment group, they will be allocated to a DWM helper. This is also done blind by an independent person who is not involved in the assessment. The allocated helper will send an e-mail to the participant to set up a time and date for a first acquaintance telephone call before the intervention starts. During this call, the weekly support calls of the DWM helper will be discussed and planned. If participants still meet the inclusion criteria 2 weeks after the DWM program ended, they will be contacted by the PM+ helper (might be the same helper as for DWM) to plan five consecutive (tele-conferencing) meetings of 60 minutes with the participant. The first session will be scheduled within a few days and not longer than one week after the pre-intervention assessment.

8.3. STUDY PROCEDURES

Screening (T0)
Following informed consent (see TEMPLATE TO BE PREPARED), participants will be invited to complete step 1 of the first assessment: screening. Screening consists of using several (self-administered) measurement instruments to see if people meet the inclusion criteria (6.2 Inclusion criteria). Also, specific questions are asked to check whether participants should be excluded because of fulfilling exclusion criteria.

- **Screening for inclusion criteria**
  In order to be included in the study, participants need to score above 15.9 on the Kessler Psychological Distress Scale (K10), a 10-item screening questionnaire for common mental disorders (Kessler et al., 2002). This instrument will be self-administered and this way literacy (as inclusion criterion) is immediately accounted for. Because DWM consists of online materials with text, it is important that people are able to read. If indicated, they will be referred to external specialists for potential follow-up. More detailed explanations of all measures are described under *'Measurement Instruments'.*

- **Screening for exclusion criteria**
  If individuals meet inclusion criteria, they will be screened for exclusion criteria (6.3 Exclusion criteria). If they meet one or more exclusion criteria they will be excluded and referred for appropriate treatment and support. We will assess whether individuals: (a) plan to permanently move back to their home country within the next 6 months; (b) have plans to end their life or are in acute need of protection (see *Measurement Instruments)*; c) currently use psychotropic medication of which the dose has been changed in the past 2 months or currently receive specialized psychological treatment and d) suffer from a severe mental disorder (e.g., psychotic disorders, substance-dependence) or severe cognitive impairment (e.g., severe intellectual disability or dementia) (see *Measurement Instruments* for questions/observations in either a face-to-face, telephone or tele-conferencing contact during screening) (WHO, 2016, pp. 87).

- When participants are not selected for the trial because they score below the cut-off scores for the K10 or when they meet the exclusion criteria as described in Exclusion Criteria, they will immediately be provided feedback e.g. on the screening outcomes (including K10 score) and an explanation why they are not eligible for the study (p. 86 of the PM+ intervention manual; WHO, 2016). When participants are excluded because of an imminent suicide risk, expressed acute needs/protection risks (for example, a young woman who expresses that she is at acute risk of being assaulted or killed) or observed (suspicion of) severe mental disorders or severe cognitive impairment they will be referred for appropriate treatment and support such as their general practitioner, and/or a mental health specialized support or to local social service provision, depending upon their clinical characteristics and needs. If the patients agree to be referred, the assessment results will be provided to their general practitioner or the treating mental health professional with permission of the participant.

Baseline assessment (T1)
If participants meet the eligibility criteria and score above the cut-off of the K10, they will continue with the baseline assessment. This step includes administration of questionnaires about socio-demographic characteristics and; PTSD Checklist for DSM-5 (PCL-5), the Patient Health Questionnaire-9 (PHQ-9), General Anxiety Disorders-7 (GAD-7), the Mainz Inventory of MIcrostressorS (MIMIS), Checklist for Quality of life (EQ-5D-5L), and the Client Service Receipt Inventory (CSRI).

Post-intervention and follow-up assessment (T2, T3, T4)
Quantitative assessments will take place four times: at screening (T0) and baseline (T1: before the intervention), at 2 weeks after DWM (T2) and at 1 week (T3) and at 2 months after finishing PM+ (T4). All instruments used in the baseline assessment (T1) will be used for each of the post-intervention and follow-up assessments, see Table 1. The screening instrument K10 (T0) will be re-assessed at T2 only.
In case participants do not respond to a scheduled assessment, they will be called a maximum of five times (on different days) for scheduling a new appointment.

Assessors
Assessments T1 to T4 will be conducted online (collective program CASTOR). Additionally, assessment of suicide risk, mental, neurological or substance use disorders, and the CSRI will be conducted by an assessor, in person or through video/telephone calls.

Assessment of treatment fidelity
DWM: Participants' access to the DWM intervention will be tracked, such as who accesses what page, how often, how much time participants spend on the intervention, etc. This way, we can track protocol adherence to the DWM afterwards, once they finished the intervention. During the intervention, we will only use meta-data to track participants' progress in the sense that participants will receive an e-mail that the next module has been unlocked and is accessible for them to use one week after they finished the previous module. Additionally, participants receive a weekly phone call from a helper to see how they are doing and check on their progress. The metadata of participants' tracked intervention access behavior will not be shared with the DWM helpers.
PM+: Audio tapes of the treatment sessions will be recorded to monitor treatment fidelity. The audio tapes can be used for supervision by the trainers/supervisors and will be used to rate treatment fidelity by UNIVERSITY OF VERONA research assistants.

Measurement instruments
The measurement instruments that will be used for the four quantitative assessments, i.e. at screening (T0) and baseline (T1), post-intervention 1 (T2), and post-intervention 2 (T3), and follow-up (T4), as well as during the DWM/PM+ intervention are depicted in Table 1. All instruments (as well as the intervention) will be administered in English or in Italian, or in the native language of the participants according to their availability.

[PLEASE FIND TABLE 1 below with Overview of the concepts, their measures, the type of study parameter in the study, and the moment of measuring during study phase 2]

Concept	Measures	Type of study parameter	Moment of measuring						
			Screening (T0)	Baseline (T1)	DWM	Post-assessment 1 (T2)	PM+	Post-assessment 2 (T3)	Follow-up assessment (T4)
Psychological distress	K10	Screener	x			x			
Suicide risk:									
- Face-to-face *or*	PM+ tool	Screener	x			x	x		
- Self-administered	Step-by-step question	Screener	x			x		x	x
Mental, neurological or substance use disorders	PM+ tool	Screener	x						
Depression and Anxiety:	PHQ-ADS	Primary							
Subscale depression	PHQ-9	Secondary		x		x		x	x
Subscale anxiety	GAD-7	Secondary		x		x		x	x
Posttraumatic stress reactions	PCL-5	Secondary		x		x		x	x
Self-identified problems	PSYCHLOPS	Secondary		x		x		x	x
Resilience	MIMIS	Secondary		x		x		x	x
Resilience factors	PASSc	Secondary		x		x		x	x
Quality of life	EQ-5D-5L	Secondary		x		x		x	x
Impact on resource use/costs	CSRI	Secondary		x		x		x	x
Socio-demographics		Other		x					
COVID-19 exposure	Questionnaire	Other		x		x		x	x
Exposure to life events	BTQ	Other		x				x	
Treatment fidelity:	Metadata	Other			x				
- DWM									
- PM+	Audio records	Other					x		
Satisfaction DWM	CSQ Interview	Other				x			
Satisfaction PM+	CSQ Interview	Other						x	

Screeners

Screening instruments

K10: psychological distress

Psychological distress will be measures using the Kessler-10 Psychological Distress Scale (Kessler et al., 2002). The K10 is a ten-item self-report questionnaire to screen broadly for psychological distress (e.g. anxiety and depression related distress) experienced in the past 30 days. Items are rated on a five-point Likert scale ranging from *none of the time* to *all of the time*. The sum of the ten items gives a total score ranging from 10 to 50. Higher scores represent higher levels of distress. The K10 has strong psychometric properties and has strong discriminatory power to distinguish DSM-IV cases from non-cases (Kessler et al., 2002). The K10 has been validated in various population samples and is a useful instrument in both primary care (Kessler et al., 2002) and general population samples (Furukawa, Kessler, Slade & Andrews, 2003; Kessler et al., 2005). Moreover, the K10 has been found to not have any substantial bias in regards to education level and gender, thus making it useful for research (Baillie, 2005). The K10 exists in various languages, among which are English and Italian.

There is no standard cut-off score for the K10 present. In addition to a cut-off score of 20, also lower cut-off scores have been found, e.g. a cut-off score of 12 (Lace et al., 2019) or a cut-off score of 14 (Baggaley et al., 2007). When determining the appropriate cut-off point, it is important to take into account the context in which the measurement instrument is used. In order to not miss potential participants, in research a low cut-off score with a low rate of false negatives and a high sensitivity is favored (Smits, Smit, Cuijpers & De Graaf, 2007). In STRENGHTS, a similar study to the RESPOND project, among Syrian refugees in the Netherlands, a cut-off point of 15 was used to indicate moderate to high levels of psychological distress (de Graaff et al., 2020). This was based on a study among Afghan and Kurdish refugees asylum seekers in New Zealand and Australia where they used the following cut-off scores: 10–15.9 (low risk of psychological distress), 16–21.9 (moderate levels of distress consistent with a diagnosis of moderate depression and/or anxiety disorder), 22–29.9 (high level of distress) and 30 or more (possibility of very high or severe levels of distress) (Sulaiman-Hill & Thompson, 2010). As the RESPOND project is conducted in various European countries with various (vulnerable) populations (e.g. health care workers in Spain and migrants in Italy), we will use a cut-off score of 15.9 which we believe is appropriate for this varying target populations.

Screening instruments for exclusion criteria

Suicidal ideation

Suicidality will be explored at several time-points (at T0, at T1, during PM+ and at follow-up assessments) with either the 'assessment of thoughts of suicide' risk tool (from PM+; WHO, 2016, pp. 86) when assessed in face-to-face contact (e.g. in person or remotely through teleconferencing or telephone) or with the self-administered step-by-step suicidality question (Van 't Hof et al., 2021) when assessed with an online questionnaire. People who have plans to end their life (as indicated by an answer of "yes" on the screening question - "In the past week/month, have you had serious thoughts or a plan to end your life?") will be excluded from the study. Participants who answer "yes" to this additional screening question will be considered at imminent risk of suicide (Van 't Hof et al., 2021). In case of imminent suicidal risk, people are excluded from participation. They will be explained (on-screen or by telephone/teleconferencing or in person) that they cannot participate but that they may need additional mental health support with advice to go to an emergency room or to a local psychiatric center (all the details on the available local mental health services will be provided). They will also be presented with suggestions for steps to follow in order to receive mental health care (e.g. contact general practitioner), encouraged to seek help, and provided with additional self-care tips.

Severe mental disorder

(Suspicion of) a severe mental disorder will be assessed by the PM+ tool 'Impairments possibly due to severe mental, neurological or substance use disorders'. This is a tool which is to be filled in by the assessor based on their observations and judgment of the client's behaviors. No questions are asked to the participant. The tool asks 4 questions related to the participant's behavior: 1) does the client understand you (even though they speak the same language or dialect)?; 2) Is the client able to follow what is happening in the assessment to a reasonable extent?; 3) Are the client's responses bizarre and/or highly unusual?; 4) From the client's responses and behaviors, does it appear that they are not in touch with reality or what is happening in the assessment? If the answer is no to question 1 or 2, or yes

to question 3 or 4, the participant will be excluded.

Primary outcome measure
The PHQ-ADS is the sum of the PHQ-9 and GAD-7 scores (details of both instruments summarized below) and thus can range from 0 to 48, with higher scores indicating higher levels of depression and anxiety symptomatology. Two validation studies of the PHQ-ADS in trial data-sets of patients with chronic (musculoskeletal) pain and oncologic diseases have been published (Kroenke et al., 2016; Kroenke et al., 2019). Evidence shows high internal reliability (Cronbach's alpha of 0.8 to 0.9), strong convergent and construct validity, sufficient unidimensionality and evidence for sensitivity to change (i.e. differentiating between individuals classified as worse, stable, or improved by a reference measure at three months post-intervention).

Secondary outcome measures

PHQ-9: depression (PHQ-9; subscale of PHQ-ADS)
Depressive symptoms during the past two weeks will be measured using the Patient Health Questionnaire depressive module. It asks how often someone was bothered by each of the nine DSM-5 criteria and scores answers on a four-point Likert scale ranging from 0 (not at all) to 3 (nearly every day) (Kroenke, Spitzer, & Williams, 2001). In addition to the nine items, the PHQ-9 asks: "If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?", which is to be answered with "Not difficult at all", "Somewhat difficult", "Very difficult", or "Extremely difficult". For the current study, we will examine changes in caseness in depression. We will use a cut-off score of 10, which has been found to be a valid cut-off point for diagnosis (Manea, Gilbody & McMillan, 2021).
The PHQ-9 has been translated to and is available in many languages (see https://www.phqscreeners.com/), amongst which are English and Italian. The PHQ-9 has been found to be a reliable and valid instrument to measure depressive severity. Furthermore, due to its brevity, PHQ-9 is a useful instrument for usage in a clinical or research setting (Kroenke et al., 2001).

GAD-7: anxiety symptoms (GAD-7; subscale of PHQ-ADS)
The Generalized Anxiety Disorder (GAD-7) questionnaire is a seven-item, self-report anxiety questionnaire which assesses the degree to which the patient has been bothered by feeling nervous, anxious or on edge over the last two weeks. Items also include other generalized anxiety symptoms such as being unable to stop worrying about multiple things, having trouble relaxing or sitting still, feeling irritable and being afraid of something bad happening at all times (Spitzer et al., 2006). Items are scored from 0 to 3, respectively for experiencing symptoms 'not at all', for 'several days', for 'more than half the days' and for 'nearly every day'. The total score ranges from 0 to 21. Cut-off points for mild, moderate and severe anxiety, are scores of 5, 10 and 15, respectively (Spitzer et al., 2006). A score of 10 has been identified as the optimal cut-off score to balance specificity and sensitivity (Spitzer et al., 2006).
The GAD-7 has been translated to and is available in many languages (see https://www.phqscreeners.com/), amongst which are English and Italian. The GAD-7 has been found to be a valid and reliable instrument in both the psychiatric (Kertz, Bigda-Peyton & Bjorgvinsson, 2013; Rutter & Brown, 2017) and the general population (Löwe et al., 2008; Hinz et al., 2017).

PCL-5: PTSD Symptoms
Posttraumatic stress disorder (PTSD) symptoms during the past week according to the DSM-5 PTSD diagnosis will be measured using the PTSD Checklist for DSM-5 (PCL-5) (Weathers et al., 2013). A shortened 8-item version of the original PCL-5 (a 20-item checklist which correspond with the 20 DSM-5 PTSD symptoms) will be used. Items are rated on a 0-4 scale. Added up, the maximum severity score is 32. Higher scores indicate higher symptomatology. The original 20-item PCL-5 exists amongst others, in English (Weathers et al., 2013).

Since populations in the trials might not all be severely traumatized, we will use the abbreviated 8-item version. In a comparison of two abbreviated version, i.e., the 4-item and 8-item versions of the PCL-5, the PCL-5 8 item version showed a strong correlation with the total scale, greater internal consistency, and allowed for sufficient variability in patient response. Internal consistency of the 8-item version was α 0.90 (comparable to total PCL-5 20-item version) and

accounted for 94.1% (R = 0.97) of the variance in the total PCL-5. There were no significant differences in the sensitivity and specificity between the total 20-item PCL-5 scale and the 8-item scale (Price et al., 2016).

MIMIS: resilience

The Mainz Inventory of Microstressors (MIMIS) was recently developed to measure objective microstressors of modern life in the past 7 days (Chmitorz et al., 2020). In the Dynacore-C study (Veer et al., 2021) this was changed into a period of 2 weeks. The MIMIS uses a definition of resilience as a trade-off between the outcome of mental health and exposure to adversity. Outcome-based resilience will be assessed by relating self-reported changes in mental health problems (i.e. anxiety and depression) over the past 2 weeks (assessed with the PHQ-ADS) to the self-reported exposure to stressors. The MIMIS was adapted in three ways: firstly, it was shortened to reduce the burden on participants, secondly, new items were generated to capture exposure to pandemic-related stressors, and thirdly, the question was changed to cover the past 14 days (rather than 7 previously). With the adapted instrument, stressor exposure is thus measured in RESPOND by a combined list of general stressors (6 items), COVID-19-specific stressors (5 items), general life events (n=3), and population-specific stressors (n=8). Daily stressor items (general, COVID-19, population-specific) are rated on a four-point Likert scale in which participants can indicate the frequency at which a stressor occurred, ranging from 0 (did not happen/almost never) to 3 ((nearly) every day). Life events are rated on a five-point Likert scale to indicate the impact of this event, ranging from 0 (this situation did not happen) to 4 (severe impact).

A high correlation has been found between the ecological momentary assessment (EMA), end-of-day, and end-of-week versions of the MIMIS regarding the occurrence and severity of microstressors, thereby indicating ecological validity of the MIMIS questionnaire (Chmitorz et al., 2020).

EQ-5D-5L: quality of life

The EQ-5D-5L measures quality of life and consists of two parts, the EQ-5D and the EQ VAS. Part 1, the EQ-5D, rates the level of impairment across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The EQ-5D-5L is an adapted version of the EQ-5D(-3L), which only had three response options for each dimensions and was therefore thought to not sufficiently capture milder health issues and small changes between different states of health (Herdman et al., 2011). The EQ-5D-5L has been used widely and is available in over 150 languages, also for laptop, tablet or Castor EDC (https://euroqol.org/eq-5d-instruments/eq-5d-5l-available-modes-of-administration/self-complete-for-use-in-castor-edc/). Country specific utility weights will be attached to data from the EQ-5D-5L and changes in participant quality of life years gained between intervention and control groups will be determined. Part 2, the EQ VAS, is a visual, vertical, analogue scale. The endpoints of the scale are called 'The best health you can imagine' and 'The worst health you can imagine' and the current health status of that day needs to be indicated, after which the number checked on the scale also needs to be written down.

PSYCHLOPS: self-identified problems

The Psychological Outcomes Profiles (PSYCHLOPS) scale is a patient-generated outcome measure as an indicator of change after therapy (Ashworth et al., 2004). PSYCHLOPS consists of four questions. It contains three domains: problems (2 questions), function (1 question), and wellbeing (1 question). Participants are asked to give free text responses to the problem and function domains. Responses are scored on an ordinal six-point scale producing a maximum score of 18 (six points per domain). PSYCHLOPS has been validated in primary care populations across several countries (Czachowski, Seed, Schofield, & Ashworth, 2011; Héðinsson, Kristjánsdóttir, Ólason, & Sigurðsson, 2013).

CSRI schedule: cost of care

The Client Service Receipt Inventory (CSRI) was developed for the collection of data on service utilization (e.g. use of health system, other services, time out of employment and other usual activities, need for informal care) and related characteristics of people with mental disorders, as the basis for calculating the costs of care for mental health cost-effectiveness research. It has been used cross-culturally and is available for Italy (Chisholm et al., 2000).

Other measures

Socio-demographic information

Socio-demographic information will be collected with predefined items based on the REDEFINE and STRENGTHS studies (i.e. age, gender, nationality, years of education, relationship status, and main work-status and additional questions regarding country of birth, household population (incl. children < 18 and elderly people), household income on average, occupational area working, mental health condition and overall current health status and housing (square meters of the house, outdoor space available).

Impact of COVID-19 questionnaire

The COVID-19 questionnaire includes 11 questions related to the impact of COVID-19. The questionnaire is based on other COVID-19 questionnaires (Conway, Woodward & Zubrod, 2020). It may be backward translated from English to other languages and will be administered at each time-point.

Resilience factor(s): positive appraisal style

Resilience factors (i.e. underlying factors that lead to resilience) may also be measured by assessing factors like optimism, positive appraisal style, perceived social support (in general and related to COVID-19), perceived self-efficacy and behavioral coping style. In RESPOND, we will assess positive appraisal style with the "Positive Appraisal Style Scale – content focused" (PASSc). The PASSc is based on positive appraisal style theory of resilience (PASTOR; Kalisch et al, 2015; Kalisch et al, 2021). The PASTOR theory conceptualises resilience as an outcome: the maintenance of mental health after stressor exposure. Positive appraisal style would therefore not be a measure of resilience, but a resilience factor. It intends to capture the underlying mechanism which leads to resilience. The PASSc is currently used in a number of longitudinal studies (Mainz Resilience Study (MARP); Longitudinal Resilience Assessment study (LORA)and several studies of the DynaMORE project). The PASSc was originally developed as a 29 items questionnaire featuring generalized positive appraisals of and attitudes towards difficulties, covering specifically the 3 main dimensions of stressor/threat appraisal - appraisal of threat magnitude/cost (relating to catastrophizing vs. trivialization), of threat probability (relating to pessimism vs. optimism), and of one's coping potential (relating to helplessness vs. overconfidence). Internal validity testing and a factor analysis resulted in a reduced list of 12 items, which is the Positive Appraisal Style Scale (PASSc). A paper (R. Kalish and P. Petri-Ramao) currently being prepared shows internal consistency $\alpha = .87$ and reliability Cronbach's $\alpha = .84$. The PASSc shows convergent validity with other underlying resilience factors as it correlates with optimism .52 (SOP-2), with stress recovery (BRS): .50, with well-being (WHO-5): .42, with trait anxiety (STAI-Y2): -.51 , with neuroticism (from BFI-10): -.49. Discriminant validity is shown in low correlation with I-8 impulsivity subscales urgency, intention <=.13; with openness (from BFI-10): .17, with conscientiousness (from BFI-10): .19.

Brief Trauma Questionnaire

The BTQ is a brief self- report questionnaire that is derived from the Brief Trauma Interview (Schnurr et al., 1995). (Information about the reliability and validity of the BTI is provided in Schnurr et al., 2002). The BTQ was originally designed to assess traumatic exposure according to DSM-IV but specifically asked only about Criterion A.1 (life threat/serious injury) because of the difficulty of accurately assessing A.2 (subjective response) in a brief self- report format. Criterion A.2 has been eliminated from the PTSD diagnostic criteria in DSM- 5, so the BTQ provides a complete assessment of Criterion A. The questionnaire may be used to determine whether an individual has had an event that meets the A Criterion, or to determine the different types of Criterion A events an individual has experienced.

Treatment fidelity

Process monitoring of the full stepped-care intervention includes review of helpers' records of DWM phone calls and PM+ sessions with clients; helpers' supervision records including intervention fidelity monitoring, and supervision of supervisors by intervention trainers. Tracked intervention access information of the DWM app and audio records of the PM+ sessions will be analyzed by UNIVERSITY OF VERONA research assistants and used for treatment fidelity analysis. The data will be collected throughout the intervention delivery (see Table 1) and reviewed as it is collected, leading to an iterative process of intervention monitoring informing intervention delivery.

To monitor treatment fidelity of DWM, participants' usage of the DWM intervention will be tracked (see study procedures - *Assessment of treatment fidelity*). To monitor treatment fidelity of PM+, treatment sessions will be audio-recorded. If participants are randomized into the treatment group, they will be asked to record the sessions. Giving consent to the audio recording is no requirement to receive the PM+ program. Audio records will be coded by research

assistants at UNIVERSITY OF VERONA and used for treatment fidelity analysis. In order to determine whether the intervention-as-implemented does not differ from the intervention-as-designed, fidelity checklists filled out by UNIVERSITY OF VERONA research assistants are completed for a random sample, stratified on helpers, of sessions / participants. The data will be collected throughout the intervention delivery and reviewed as it is collected, leading to an iterative process of intervention monitoring informing intervention delivery. Treatment fidelity will be analyzed as manipulation check.

Satisfaction and acceptability

Satisfaction and acceptability of the stepped-care DWM/PM+ intervention is measured through qualitative process evaluation (see Study Phase 3). Additionally, at the first assessment after DWM (T2) and after PM+ (T3), participants will also fill out a questionnaire to measure their satisfaction with the intervention. The CSQ-I for the web-based intervention DWM (Boss et al., 2016) and the CSQ-8 for PM+ Client Satisfaction Questionnaire (CSQ-8; Attkisson & Zwick, 1982).

Implementation indicators

After the intervention has finished, various implementation indicators will be assessed, such as reach, dose, resource use, costs of recruiting, training and retaining staff delivering the stepped-care program, program costs, adaptation, the process and quality of the stepped-care DWM/PM+ intervention.

Additionally part of the cost-effectiveness analysis, we will estimate the incremental cost per change in the primary outcome, as well as quality of life. To do this, estimates of the resource use and costs of implementation are needed, making use of data from implementation indicators. This will involve analysis of records on resources and costs for initial training, as well as use of process and fidelity data on resources used for receipt of interventions, such as the number of PM+ sessions attended and input and support from supervisors.

Qualitative evaluation at the end of the RCT

The aim of this qualitative evaluation is to explore the feasibility, i.e. identifying barriers and facilitators specific to the target population, of scaling-up the implementation on the stepped-care DWM/PM+ intervention within Italy. This will be done by conducting interviews and/or focus group discussions (FGDs) with key informants. In these interviews, participants' satisfaction and acceptability of the program will also be explored.

Key informants will include participants in the treatment group who completed the DWM intervention (n=2/4) or the PM+ intervention (n=2/4), who dropped-out during DWM (n=2/4) or during PM+ (n=2/4). Participants will be asked questions concerning the satisfaction and acceptability of the intervention, barriers and facilitators to adherence, and to what extent they think that the stepped-care program has actually contributed to improving participants' functioning. Recruitment for participants of the treatment group will start at 3 months post-PM+.

Additionally, we will interview local stakeholders of the participating centers, e.g. mental health professionals, Non-Governmental Organizations (NGOs) workers, cultural and linguistic mediators and local policy makers with knowledge on mental health care (10/15participants in total). Policy decision makers will be interviewed to obtain their perceptions of the benefits and challenges of integrating the stepped-care DWM/PM+ intervention into routine service provision. Health care professionals will be interviewed to explore their views on the potential for scaling-up the stepped-care DWM/PM+ intervention and integrating the program into the health system in Italy. Furthermore, we will conduct focus group discussions (FGD) with facilitators (n=2/4) of the DWM/PM+ intervention. Facilitators will include both helpers and trainers/supervisors. Facilitators will be interviewed on their experience in providing the DWM/PM+ intervention and to obtain their ideas in implementing this intervention in Italy.

Interviews and FGDs will be conducted online or in person, depending on the preferences of the participant and will in accordance with COVID-19 regulations. Key informant interviews and FGDs will be audio-recorded, transcribed and coded.

8.4. WITHDRAWAL OF INDIVIDUAL SUBJECTS

Participants can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a participant from the study for urgent medical reasons, e.g. imminent suicide risk. Since only individuals with imminent suicide risk will be excluded, those with suicidal thoughts at inclusion/screening will be followed up by the helpers. When during calls with DWM/PM+ helpers, participants show deterioration with imminent suicidal plans than the helper will discuss this immediately with one of the DWM/PM+ supervising mental health specialists. Also, when there is clear suspicion of worsening of (severe) mental health problems, participants will be asked to withdraw from the study and contact their general practitioner for a referral to specialized mental health treatment.

8.4.1. Specific criteria for withdrawal (if applicable)

Not applicable for this study.

8.5. REPLACEMENT OF INDIVIDUAL SUBJECTS AFTER WITHDRAWAL

No new subjects will be included for each withdrawn subject. In our power calculation for the sample size, we have taken into account 30% attrition.

8.6. FOLLOW-UP OF SUBJECTS WITHDRAWN FROM TREATMENT

If a subject decides to withdraw from the study, the investigator will ask for the reason. It will be enquired whether the subject wishes to withdraw from the study or from a specific time point only and so whether the subject can be re-contacted at a later time. Withdrawal from the study will have no effect on the regular treatment. Subjects who leave the study for medical reasons will be followed until the interfering condition has resolved or reached a stable state.

8.7. PREMATURE TERMINATION OF THE STUDY (IF APPLICABLE)

Not applicable.

9. SAFETY REPORTING

9.1 TEMPORARY HALT FOR REASONS OF SUBJECT SAFETY

The study sponsor (UNIVR) will suspend the study if there is sufficient ground that continuation of the study will jeopardize subject health or safety. The sponsor will notify the Ethics Committee without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the Ethics Committee. The investigator will take care that all subjects are kept informed.

9.2 AES AND SAES

9.2.1 ADVERSE EVENTS (AES)

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to the trial procedure or the stepped-care DWM/PM+ intervention. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

9.2.2 SERIOUS ADVERSE EVENTS (SAES)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalization or prolongation of existing inpatients' hospitalization;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or
- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

The investigator will report all SAEs to the sponsor without undue delay after obtaining knowledge of the events.

9.3 FOLLOW-UP OF ADVERSE EVENTS

All AEs will be followed until they have abated, or until a stable situation has been reached.

Depending on the event, follow-up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist. SAEs need to be reported till end of study. The DWM and PM+ helpers will be supervised and receive weekly supervision by experienced mental health care professionals. If, during the course of the study, participants in the treatment group (PM+/DWM/CAU) or comparison group (CAU only) show severe psychiatric symptoms (e.g., psychosis, imminent suicide risk, etc.), or any other symptoms occur that require immediate specialist treatment and follow-up, they will be referred to specialist staff (e.g. psychiatrists) for immediate follow-up. The researcher from UNIVERSITY OF VERONA will be responsible to monitor this process and make sure the appointment has been made.

9.4 ETHICS AND DATA ADVISORY BOARD (EDAB)

The RESPOND' Ethics and Data Advisory Board (EDAB) will monitor and provide expert advice on data management and all ethical, legal and societal issues that arise within the project, promoting integrity and a better alignment of RESPOND with social needs and expectations that may arise within or as a result of RESPOND. This includes monitoring

the safety, rights, and wellbeing of study participants, and providing input for ethics reports. In addition, the EDAB will provide advice on FAIR data management, including data privacy and adherence to the GDPR. The EDAB will ensure that the trial and data collection in RESPOND are conducted in accordance with the International Conference on Harmonisation (ICH), the WHO Good Clinical Practice standards (GCP), Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013), and (inter)national laws (e.g, Medical Research Involving Human Subjects Act (WMO)). In addition, the ethical, legal of the participants and research staff members will be reviewed and interim analyses will be considered in case safety issues are (suspected to be) violated. Incidental findings within RESPOND refer to an extreme score on study instruments (questionnaires or interviews) that need additional follow-up. Other issues that will be considered include privacy and intellectual property rights. Relevant issues will be discussed in an annual meeting, but if issues arise between these meetings, the EDAB will be requested to plan an additional meeting. Additional meetings will be held before submission of ethics documents for formal approval as well as before submission of ethics reports. The EDAB compromises of independent members having no conflict of interest with the sponsor of the study, i.e. dr. Christopher Dowrick, dr. Victor Perez, and dr. Sonja Rutten, member of the Ethics Review Committee Board member (VUA). For RESPOND principal investigator Prof. dr. Marit Sijbrandij will join the EDAB meetings together with assistant professor Dr. Anke Witteveen. Tom Paffen LL.M (VU) will join for matters of data protection and privacy.

The management team and EDAB will ensure that all necessary actions will be undertaken to minimize risks and suggest necessary measures to counter these risks. Through efficient communication between the EDAB, overall management (Work Package 1), and leader of individual Work Packages, the consortium will ensure that mitigation measures will be undertaken in a timely and effective manner.

The advice(s) of the EDAB will only be sent to the sponsor of the study. Should the sponsor decide not to fully implement the advice of the EDAB, the sponsor will send the advice to the reviewing Ethics Committee, including a note to substantiate why (part of) the advice of the EDAB will not be followed. The EDAB should conclude each review with their recommendations to RESPOND as to whether the study should continue without change, be modified, or be terminated. Recommendations regarding modification of the design and conduct of the study could include: modifications of the study protocol based upon the review of the safety data; suspension or early termination of the study or of one or more study arms because of serious concerns about subjects' safety, inadequate performance, or rate of enrolment; suspension or early termination of the study or of one or more study arms because study objectives have been obtained according to pre-established statistical guidelines.

10. STATISTICAL ANALYSIS

The statistical analyses for the Randomized Controlled Trial are described under section below.

10.1 PRIMARY OUTCOME(S)

The statistical analysis of the RCT will estimate effectiveness of the stepped-care DWM/PM+ with PFA and CAU intervention compared to PFA and enhanced CAU alone, with PHQ-ADS score as the primary study outcome.

The primary outcome will be summarized using number of subjects (*n*), minimum and maximum; and means, standard deviations (*SD*) for normally distributed data, or medians and inter-quartile ranges for non-normally distributed data. To measure comparisons at baseline between the two treatment groups *t*-tests (continuous variables) or chi-squared test (categorical variables) will be conducted for normally distributed data; Mann-Whitney tests will be conducted for continuous non-normally distributed data.
Both intention-to-treat (ITT) analysis, including all randomized participants (*n*=212), and completers' (per protocol - PP) analysis will be carried out. The main conclusion of the trial will be based on the ITT analysis of the primary outcome. A secondary analysis of the primary outcome will also be presented using the PP population.

The statistical analysis will be masked, i.e. the trial statistician will be blinded to the treatment groups until the analysis has been completed. Moreover, the trial statistician will not be involved in determining participants' eligibility, in administering the intervention, in measuring the outcomes or in entering data.
To estimate the treatment effect, a linear mixed model will be employed for the primary endpoint analysis, which will have treatment as fixed effects, baseline measurement of primary endpoint as covariate, and subject as random effects. The mean difference between two treatment arms at each visit/time together with its 95% confidence interval will be derived from the mixed model. Covariate-adjusted mixed model of primary endpoint will also be performed by adding pre-specified covariates at baseline (gender, age, education, prior trauma, COVID-19 related events and stressor list) into the above model.

Missing data

Missing data will be treated as missing at random (MAR). No imputations of missing values will be made, as multilevel models can deal with missing data (Singer, Willett & Willett, 2003).

10.2 SECONDARY OUTCOME(S)

Economic outcomes

Health economic analysis will be conducted to determine the difference in costs and outcomes in the intervention arm as compared to the care as usual group at each time-point. Primary analysis will be the total costs over the 2-month follow-up treatment period. Between-group comparison of mean costs will be completed using standard t-test with ordinary least squares regression used for adjusted analysis, with the validity of results confirmed using bootstrapping. Pseudonymised data will be sent to the London School of Economics and Political Science, partner in RESPOND under Work Package 3, for the health economics analysis of the CSRI.

Analysis of secondary outcomes with repeated measurements

Additionally, a linear mixed model as mentioned for the primary outcome analysis (PHQ-ADS) will be carried out for analyzing the following clinical outcomes measured at baseline, at 2 weeks after DWM, at 1 week and at 2 months after finishing PM+: posttraumatic stress reactions (PCL-5), depressive symptoms (PHQ-9), generalized anxiety (GAD-7), resilience (MIMIS) and quality of life (EQ-5D-5L).

Analysis of other secondary outcomes
Changes in caseness of the composite measure anxiety and depression will be calculated using the recommended cut-off of >20 for moderate severity on the PHQ-ADS questionnaire (Kroenke et al., 2016; Kroenke et al., 2019) and will be analyzed using a hierarchical logistic model with the same fixed and random effects as the hierarchical linear models above, from which odds ratio of having a depression together with 95% CI at each time point will be derived.

Corrections for multiple testing

Models will be tested on $\alpha = .05$; to deal with problems associated with multiple testing, for each time point T2-T4 the hypothesis that the experimental intervention has no effect on secondary outcome scores will be tested by performing the Seemingly Unrelated Regression equations model (Zellner, 1962), controlling for baseline values.

10.3 OTHER STUDY PARAMETER(S)

The final phase of this RCT will include qualitative interviews and/or focus group discussions among key stakeholders to evaluate possible barriers and facilitators to treatment engagement and adherence to the PM+/DWMS program. The outcomes of these assessments will be used to make informed-decisions for potential mediators or moderators of PM+/DWMS treatment effectiveness.

Treatment fidelity:

In order to determine whether the intervention-as-implemented does not differ from the intervention-as-designed, fidelity checklists filled out by UNIVERSITY OF VERONA research assistants are completed for a random sample of 10% of all recordings, stratified on peer-refugee PM+ providers, of sessions/participants. Treatment fidelity will be analyzed as manipulation check.

Analyses of qualitative interviews and focus group discussions

Interviews and focus group discussions will be audio-recorded. These recordings will not include any identification of participants by name and will be labelled with an anonymized key only known to the researchers. The information recorded is confidential, and no one else except the members of the research team will have access to it. Once the interview is finished, the recording will be transcribed. The transcribed data will be coded and analyzed through thematic analysis. Once all data is processed, audio-recordings will be deleted.

10.4 INTERIM ANALYSIS

Interim analyses will be considered in case safety issues are (suspected to be) violated. See ‘Safety committee’.

11. ETHICAL CONSIDERATIONS

11.1 REGULATION STATEMENT

This study will fully comply with relevant European and national regulations concerning data protection, privacy regulations, and the procedures for obtaining informed consent. All these procedures will be conducted according to the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013), in accordance with, the EU Good Clinical Practice Directive (2001/20/EC), the International Conference on Harmonization (ICH), the WHO Good Clinical Practice Standards (GCP), and the Medical Research Involving Human Subjects Act (WMO).

11.2 RECRUITMENT AND CONSENT

Recruitment

Eligible trial participants will be adult (18 years or above) asylum seekers, refugees or migrants without acute medical conditions (see inclusion and exclusion criteria in paragraph 4.2 and 4.3). The recruitment strategy for the RCT will be pragmatic and will mainly involve relationships with community organizations and local institutions that implement services/projects for ARM in Italy (e.g. municipalities, NGOs, health care providers, and/or language courses). If necessary, participants will also be recruited through targeted (social) media strategies and snowballing. The qualitative evaluation will include a purposive sampling method called, maximum variation sampling. In this sampling method, the sample is selected based on variations of some key characteristics (Suri, 2011). For the treatment group participants relevant variables will include gender, age, country of origin, and status of completing the intervention program (drop-out or completed). Selection of DWM and PM+ helpers will also be based on maximum variation and the relevant variables will include gender, age, country of origin, and the type of intervention (DWM and/or PM+) provided. Mental health specialists/supervisors involved in the trial will be directly approached if they want to participate in the interviews. Decision makers from the key stakeholders will be approached through available professional contacts.

Informed consent procedure
Before being enrolled in the study, participants will be informed about the nature and scope of the study in a form understandable to them. Participation will be completely voluntary to prevent biased responding – either exaggerating or minimizing problems in the belief that this may help participants obtaining secondary advantages. If a potential participant wants to participate, a research assistant will meet with the potential participant (in person or through video-calling). The research assistant will explain the research to the potential study participant and will provide the information document to the participant.

Persons who decide to participate in the trial will be asked to complete a written consent form to check for eligibility (after a minimum consideration time of one week). If participants meet the eligibility criteria (K10 >15.9 and not meet any exclusion criteria), they can participate in the trial. We will inform participants of the reason why they can or cannot participate in the RCT. In order to participate in the trial, participants will sign a second informed consent form, covering the optional recording of PM+ sessions in case of PM+ administration and the qualitative interviews. Giving consent for the audio recordings and/or for the qualitative interviews is not a condition for participating in the study. Audio recordings will only be used for fidelity assessments and supervisions.
The research assistant will explain the research to the potential participant via telephone or video conference.

Participants are allowed to withdraw from the study at any time after they have given their written consent. If people are eligible for participation in the RCT, we will inform their general practitioner of this.

11.3 OBJECTION BY MINORS OR INCAPACITATED SUBJECTS

Not applicable.

11.4 BENEFITS AND RISKS ASSESSMENT, GROUP RELATEDNESS

Participants randomized into the DWM/PM+ treatment group may benefit from their participation in terms of expected reductions in psychological distress. The risks associated with participation are estimated to be minimal, since DWM and PM+ have shown to reduce psychological distress in previous studies (Purgato et al., 2019; Tol et al., 2020; Bryant et al., 2017; Rahman et al., 2016b). Participants in both the treatment and comparison group will not be withheld care as usual (note: the treatment group receives CAU along with stepped-care DWM/PM+ and psychological first aid (PFA), the comparison group will receive enhanced CAU and PFA only).

It is possible that participants experience (increased) stress/depressive feelings during the PM+ sessions (e.g. by speaking of stressful events happening at work or speaking of their personal (living) situation). The intervention will be supervised and strictly monitored by experienced clinical psychologists. If a participant deteriorates during the intervention period, or has elevated symptoms at follow-up assessments, (s)he will be advised to contact his/her general practitioner (part of the CAU), who may refer the participant for continued or high-intensity treatment, e.g. referral to an external specialist (licensed psychologist or psychiatrist). Whether referral has taken place, will be actively followed up by the researchers.

Participants may also experience some distress during the assessments, as they may think of their situation. These assessments will be conducted online through self-reporting, and/or through video-calling. The interviewer-administered assessments will be administered by assessors who are trained and closely monitored by the University of Verona research team. Administering the instruments is crucial to draw conclusions about the feasibility and credibility of the intervention. In case of an undesirable emotional reaction both during the intervention as well as during the follow-up assessments the researcher or a clinician will be available to provide support if necessary or desirable.

11.5 COMPENSATION FOR INJURY

Participation in the study only carries negligible risks for the research subjects; therefore, the present study is relieved from an insurance that provides cover for damage to research subjects.

11.6 INCENTIVES

If applicable, study participants will receive reimbursements during the study. Participants will receive a reimbursement ranging from 25 to 75 euros (monetary or in their bank account). The amount will vary depending on their involvement in the study (n. of sessions to attend, n. of assessments, etc).

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 HANDLING AND STORAGE OF DATA AND DOCUMENTS

All data will be handled confidentially and will be coded by a code known only by the research team. Processing of personal data will comply to the General Data Regulation ("GDPR") on the protection of individuals regarding the processing of personal data and the free movement of such data.

Data including personal information will be stored in a locked record at the University of Verona to ensure the confidentiality of the study participants. Only authorized research personnel would have access to this data. According to the data management rules of RESPOND, all partners acknowledge and agree that no personal data, as defined in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) ("GDPR"), will be exchanged between the Parties. Moreover, all partners in RESPOND acknowledge and agree that each partner is considered independent controller, as defined in GDPR, for its processing of personal data and will act in accordance with applicable data protection laws (including but not limited to GDPR).

Qualitative data collection

Before commencing a qualitative interview, the date of the interview or of the PM+ session and the participant number will be recorded on a professional audio recording device. No identifying information will be collected during the qualitative interviews, with all data de-identified. Audio files (mp3) will be encrypted and stored in a password protected server at the University of Verona, that can only be accessed by the members of the University of Verona research team. The audio files will be saved separately from their identifiers. The audio files for Study Phase 3 (interviews) will be transcribed in the Microsoft word program (secured with a password known to the research team only) and safely stored at the office of the principal investigator who coordinates the research at the University of Verona. After the completion of the project, the mp3 files will be destroyed.

Quantitative data collection

Quantitative data will be coded and the identifying key (a list connecting names to numbers) will be kept in a separate, secure locked location in the coordinating researcher's office (prof. dr. Corrado Barbui). The data will be entered into a data-analytic computer program (e.g., SPSS), without the identifying key. All data will be stored pseudonymous, and they will be available only to the University of Verona research team members. All pseudonymous data to be stored at the University of Verona will be stored in a data repository. The team will identify an online platform that can be used to share and publish research data in a (semi-)open environment. The University of Verona research group will analyze the data, and both positive and negative trial results will be disclosed. No attributable data will be used in publications. Results will be submitted for publication to peer-reviewed scientific journals. After the completion of RESPOND, the list of participants will be stored in DarkStor, an offline research data archive for sensitive data. Data of the trial are only accessible by authorized persons (principal investigator prof. dr. Corrado Barbui).

12.2 MONITORING AND QUALITY ASSURANCE

Process monitoring is a part of the RCT and more detailly explained under 'Study Procedures'.
Monitoring includes review of Helpers' records of PM+, supervision records including intervention fidelity monitoring and supervision of supervisors by the Master trainers. The supervision of Helpers will be scheduled weekly. The supervision will be given by expert psychologists. The supervising psychologists will also receive supervision from the Master trainers and these supervisions will be scheduled monthly.

This is similar to the procedure used by Rahman and colleagues (2016) for the PM+ trial in Pakistan.

One of the outcome measures of this study is the treatment fidelity. Audio records will be coded by University of Verona research assistants. The data will be collected throughout the intervention delivery (see Table 1). Monitoring of the assessments will be the responsibility of the main investigator of the qualitative assessment.

In case of any concerns about the capacity of the assessors to carry out their roles, psychologists will conduct full assessments to ensure quality. This oversight will help ensure that any potential concerns about the capacity of assessors to carry out their roles is picked up and responded to.

12.3 AMENDMENTS

Amendments are changes made to the research after a favorable opinion by the accredited Ethics Committee has been given. All amendments will be submitted to the Ethics Committee.

12.4 ANNUAL PROGRESS REPORT

The University of Verona research team will submit a summary of the progress of the trial to the accredited Ethics Committee once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events, other problems, and amendments.

12.5 TEMPORARY HALT AND (PREMATURELY) END OF STUDY REPORT

The investigator/sponsor (University of Verona) will notify the accredited Ethics Committee of the end of the study within a period of 8 weeks. The end of the study is defined as the last finished follow-up assessment (T4) of the last participant who joined the RCT. The sponsor will notify the Ethics Committee immediately of a temporary halt of the study, including the reason of such an action. In case the study is ended prematurely, the sponsor will notify the accredited Ethics Committee within 15 days, including the reasons for the premature termination. Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the Ethics Committee.

12.6 PUBLIC DISCLOSURE AND PUBLICATION POLICY

The trial will be registered in a public trial registry before the first patient is recruited. For the RESPOND project, a Communication and Dissemination Plan has been written. This study will lead to publications in international, peer-reviewed journals. Additionally, findings will be shared/presented on the project website, through newsletters, through

regular and social media, at high level dissemination events, through policy briefs, etc. In addition, results will be disseminated through channels of the WHO and through events within the EU. The publication policy of the planned research will be carried out in line with the CCMO statement publication policy (March 2002).

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