RESPOND: Improving mental healthcare for labour migrants in the Netherlands during the COVID-19 pandemic: implementation of a stepped care program (DWM/PM+)

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Primary Objective: To evaluate the (cost-)effectiveness, feasibility, and acceptability of the culturally and contextually adapted DWM/PM+ stepped-care program among labor migrants in the Netherlands during the COVID-19 pandemic in terms of mental...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54380

Source
ToetsingOnline

Brief title
Implementation of DWM/PM+ in labour migrants during the COVID-19 pandemic

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
anxiety, depression, distress, Psychological symptoms

Health condition

psychological symptoms of anxiety, depression and (posttraumatic) stress

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Europese Commissie;Horizon2020

Intervention

Keyword: COVID-19, Implementation and evaluation, Psychological distress, Scaling-up psychosocial interventions

Outcome measures

Primary outcome

Study Phase 2:

The primary outcome will be the decrease in symptoms of anxiety and depression from baseline to two-month follow-up (week 20), 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 PM+ group at 2 months post-treatment (week 20).

Secondary outcome

Study phase 2:

Secundary outcomes include level of anxiety (GAD-7) and depression (PHQ-9), symptoms of posttraumatic stress disorder (PCL-5), resilience (Mainz Inventory of MIcrostressors, MIMIS, Positive Appraisal Style Scale - content focused, PASSc), quality of life (EQ-5D-5L), and costs of care (CSRI). Additional study parameters will include demographic data, traumatic and COVID-19 related (exposure) variables (Brief Trauma Questionnaire, BTQ), hair biomarkers

(cortisol concentrations (HCC), cortisone, dehydroepiandrosterone (sulfate) (DHEA(S)), progesterone, and testosterone concentrations), digital markers, treatment fidelity, satisfaction and acceptability of the intervention program, and implementation indicators (such as reach, dose, resource use, intervention implementation related costs).

Study phase 3:

Through FGDs and interviews at the end of the study, the feasibility of scaling-up the implementation on the stepped-care DWM/PM+ intervention within the Netherlands will be examined.

Study description

Background summary

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 labour 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 arising from the COVID-19 pandemic, addressing the needs of many people in a way that maximises 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 non-specialist helpers, 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 (DWM/PM+). This study is part of the larger EU H2020-RESPOND project, which aims to improve the preparedness of European mental health care systems in the face of future pandemics.

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.

Study objective

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

Secondary Objective:
To identify (a) barriers and facilitators to treatment engagement and adherence and (b) opportunities for scaling up among the target population in the Netherlands (study phase 3).

Study design

This study consists of 3 phases.

Study phase 1: qualitative study consisting of individual interviews and a focus group discussion (FGDs) to adapt the DWM/PM+ manuals to the culture and context of labour migrants (protocol approved by VCWE).
Study phase 2: pragmatic implementation trial with a single-blinded, randomised, parallel-group design.
Study phase 3: qualitative process evaluation consisting of individual interviews and FGDs.

The current protocol focuses on phases 2 and 3.

Intervention

Participants will be randomized into a treatment and a comparison group.
- All participants (in both the treatment and comparison groups) 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) one week after having received DWM.
- DWM, i.e. a self-help book with brief audio exercises to support practice, will be adapted into a digital tool or application (phase 1) and delivered as a guided self-help intervention with support from a briefly trained non-specialist helper via teleconferencing.
- PM+ consists of five sessions and will be delivered by trained non-specialist

helpers in person or via teleconferencing in individual (or group) format. In addition to PFA, the comparison group will only receive CAU which ranges from community care to specialised psychological treatments.

Study burden and risks

The burden and risks resulting from participation in this study are minimal in view of the naturalistic design, inclusion of only participants with mild to moderate functional impairment and psychological distress and minimal duration of the various questionnaire measurements (approx. 45-60 minutes).

Study phase 2: participants will be assessed online a total of four times over the course of six months. Data will be collected by means of self-administered online questionnaires. Questionnaires will be taken at baseline (week 0), week 6, week 12, and week 20. The six DWM helepr support calls, for participants in the treatment group, will be audiotaped for the purpose of monitoring. The five PM+ sessions, for participants in the treatment group who still meet inclusion criteria after DWM, will be videotaped for the purpose of monitoring and for analysis of digital markers. hair sampels are taken to examine stress-related hormones such as cortisol, cortisone, dehydroepiandrosteron(sulphate), progesterone, and testosterone.

Study phase 3: The interviews with participants in the target group in phase 2 (both completers and drop-outs), their family members/close persons, and professionals will take approximately 1.5 hours. The FGDs with DWM/PM+ facilitators will take approximately 2 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Participants will be eligible to participate in the study (phase 2 (and 3)) if they meet all of the following criteria:
- 18 years or older;
- Living in the Netherlands as labour 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, Polish, Romanian).
- Having access to an electronic device with internet access and webcam to follow the intervention
- Oral and written informed consent before entering the study.

Exclusion criteria

Potential participants who meet the inclusion criteria will be excluded from participation in this study (phase 2 (and 3)) if they meet any of the following criteria:
- Planning to move abroad, e.g. back to their home country or to another country, before the last quantitative assessment at 2 months after PM+;
- Having acute medical conditions (requiring hospitalisation);
- 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 specialised psychological treatment (e.g. EMDR, CBT);
- In case of current psychotropic medication use: being on an unstable dose for

at least 2 months.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-05-2022
Enrollment:	265
Type:	Actual

Ethics review

Approved WMO Date:	31-08-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-07-2023
Application type:	Amendment

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77644.029.21