

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

Source

NTR

Brief title

RESPOND

Health condition

Common mental disorders;
Depression;
Anxiety;
Posttraumatic stress disorder

Sponsors and support

Primary sponsor :	Vrije Universiteit Amsterdam
Source(s) of monetary or material Support :	EU Horizon 2020

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

- PHQ-9: depression (PHQ-9; subscale of PHQ-ADS)
- GAD-7: anxiety symptoms (GAD-7; subscale of PHQ-ADS)
- PCL-5: PTSD Symptoms
- PSYCHLOPS: self-identified problems
- MIMIS: resilience
- EQ-5D-5L: quality of life
- CSRI schedule: cost of care

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+).

The main objective is to evaluate the implementation and (cost-)effectiveness of the culturally and contextually adapted DWM/PM+ stepped-care programs amongst labour migrants living in the Netherlands during the COVID-19 pandemic in terms of mental health outcomes, resilience, wellbeing, health inequalities, and costs to health systems.

Study participants include adult labour migrants with self-reported elevated psychological distress (K10 >15.9) (n=212).

The primary outcome will be the decrease in symptoms of anxiety and depression from baseline to two-month follow-up, measured through the PHQ-Anxiety and Depression Score (PHQ-ADS), i.e. the sum score of the Patient Health Questionnaire (PHQ-9) and General Anxiety Disorder-7 (GAD-7).

Study objective

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 design

- 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

Intervention

The study has two arms:

1. Control group: participants receive care-as-usual (CAU) and Psychological First Aid (PFA).
2. Treatment group: participants receive care-as-usual (CAU), Psychological First Aid (PFA), and a stepped care intervention consisting of Doing What Matters in times of stress (DWM) (step 1) and conditionally, if participants still meet criteria for psychological distress (K10 >15.9) 2 weeks after having received DWM, Problem Management Plus (PM+). PFA is given at the start of the RCT, which means that participants in the treatment group receive it before the start of the stepped-care DWM/PM+ intervention.

Care-as-usual (CAU):

All participants are allowed to receive any care-as-usual. CAU ranges from community care to specialized psychological treatments, but only care provided by the general practitioner or the assistant of the general practitioner with a specialization in mental health care (POH-GGZ) is fully covered by the basic health insurance package; it does not completely cover mental health service costs. Labour migrants who signed up for the basic health insurance package (which is obligated for everyone who plans to stay for more than 4 months or who needs to pay wage taxes due to work conducted in the Netherlands) have access to the health system like any other Dutch citizen with a standard insurance package.

Psychological First Aid (PFA):

All participants will be offered individual Psychological First Aid (PFA) through teleconferencing. PFA is a WHO developed support strategy that involves humane, supportive and practical help for individuals living in a serious humanitarian crisis. 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; Sijbrandij et al., 2020). PFA consists of a conversation (approximately 30-45 minutes) that a helper has with a participant which can be provided remotely (e.g. videoconferencing or telephone).

PFA has various themes; in PFA, the helper provides non-intruding practical care and support, listen to 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).

Doing What Matters in times of stress (DWM):

DWM is a self-help, stress management, illustrated guide that is part of Self-Help Plus (SH+), a psychosocial intervention developed by the WHO (Purgato et al., 2019). The illustrated DWM guide comprises the core information from the SH+ course and is accompanied by audio files to support regular practice of exercises which enhance stress reduction and adaptive coping and resilience (WHO, 2020).

SH+ and DWM are based on acceptance and commitment therapy (ACT), a modern form of cognitive-behavioural 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).

SH+ has been implemented with different populations of refugees in Europe, Turkey (Purgato et al., 2019) and Northern Uganda (Tol et al., 2020). DWM can be delivered individually with support from a briefly trained, non-specialized helper.

In RESPOND, the DWM pre-recorded audios and the illustrated stress management guide will be adapted to an online application (app) (in a previous, qualitative phase). This way, people can use the self-help online app in their own time. The five weekly sessions in the app will follow the 5 chapters of the book (grounding, unhooking, acting on your values, being kind and making room). Participants will receive a weekly, 15-minute call from a non-specialized helper, trained to support and motivate individuals using the app.

Problem Management Plus (PM+):

PM+ is a brief, transdiagnostic, scalable, psychological intervention program, developed by the WHO, that aims to reduce symptoms of depression, anxiety, PTSD, and related conditions (Dawson et al., 2015). It is based on problem-solving and cognitive behavioural therapy (CBT) techniques that are empirically supported and formally recommended by the WHO (Dua et al., 2011).

PM+ comprises 5 weekly, 90-minute sessions delivered by a trained, non-specialized helper. PM+ is available in individual and group delivery formats. It was originally designed for in-person delivery, but similarly to other psychological interventions, it can be adapted for delivery over the telephone or through video-conferencing. In RESPOND, PM+ will be delivered individually through video-conferencing.

Individual PM+ has been successfully implemented in Kenya (Bryant et al., 2017) and Pakistan (Rahman et al., 2016). Although PM+ was mainly developed for low and middle income countries, it is also being evaluated among refugees in the Netherlands (de Graaff et al., 2020).

For this study, we will adapt 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 will adapt examples and pictures used in the intervention (in a previous, qualitative phase).

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female refugees in Uganda: a cluster randomised trial. The Lancet Global Health, 8(2), e254-e263.

WHO (2011). Psychological first aid: Guide for field workers. Geneva: WHO

WHO (2020). Doing what matters in times of stress: an illustrated guide. Geneva: WHO

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Eligibility criteria

Inclusion 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. Polish, English).

Exclusion 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 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 or a change in dosage over the past 2 months.

Study design

Design

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

Recruitment

NL	
Recruitment status :	Pending
Start date (anticipated) :	01-09-2021
Enrollment :	212
Type :	Anticipated

IPD sharing statement

Plan to share IPD :	Yes
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Plan description

This dataset will be merged with similar data collected in the larger RESPOND project to perform IPD meta-analyses that are planned as part of the work of RESPOND. After completion of the RESPOND project, datasets can be made available to external parties upon requests.

Ethics review

Not applicable	
Application type :	Not applicable

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
NTR-new	NL9630
Other	METc VUmc : METc Protocol No: NL77644.029.21

Study results