

Improving the mental health of working adults in Dutch small-to-medium-enterprises (SMEs): implementation of WHO*s Doing What Matters in times of stress (DWM)

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Main objectives:a) examine and assess the (cost-)effectiveness of WHO*s Doing What Matters in Times of Stress (DWM) in reducing psychological distress, improving mental health, and enhancing work-related well-being and productivity compared to care-...

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

Summary

ID

NL-OMON57382

Source

ToetsingOnline

Brief title

Implementation of DWM in Dutch SMEs

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym

anxiety, depression, distress, Psychological symptoms

Health condition

psychological symptoms of anxiety and depression

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: European Commission Horizon2020

Intervention

Keyword: digital psychological intervention, Psychological distress, SMEs, workplace mental health

Outcome measures

Primary outcome

Study Phase 4b:

The primary outcome will be the decrease in symptoms of anxiety and depression from baseline to 1-week post-intervention, 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 anticipate a greater reduction in symptoms of depression and anxiety for the DWM group compared to the control group at post-intervention. We expect to observe a Cohen*s d effect size of 0.34 in favour of the DWM group one week after the intervention

Secondary outcome

Study phase 4b:

Secondary outcomes include level of anxiety (GAD-7) and depression (PHQ-9), resilience (Mainz Inventory of Microstressors, MIMIS), burnout (BAT-4), work engagement (UWES-3), absenteeism and presenteeism, self-stigma (SSOH-3), quality of life (EQ-5D-5L), and costs of care (CSRI).

Additional study parameters will include demographic data, treatment fidelity, satisfaction with the intervention program, and implementation indicators (such as reach, adoption, appropriateness, acceptability, feasibility, maintenance, and resource use).

Study phase 5:

Focus group discussions and interviews conducted after the trial will assess the feasibility of scaling up the DWM intervention in Dutch SMEs.

Study description

Background summary

Small-to-medium-sized enterprises (SMEs) often lack the resources to combat the negative consequences of work stressors (e.g., high workplace digitalization). This puts their employees at risk of developing mental health problems. Literature on effective interventions at work for SME employees* mental health is scarce and inconclusive. This project focuses on the implementation of Doing What Matters in Times of Stress (DWM), a scalable, low-intensity, psychological intervention developed by WHO adapted for use in Dutch SMEs. This study is part of the larger EU H2022-ADVANCE project, which aims to improve the mental health of vulnerable populations in Europe.

In the ADVANCE project, two interventions will be tested in Dutch SMEs: (1) DWM: aimed at improving the mental health of SME employees; and (2) the novel WHO-developed supervisor training (ASCEND): aimed at enhancing the supervisors* confidence to manage their supervisees mental health.

Each intervention will be tested separately in a cluster randomized controlled trial (cRCT). Therefore, two cRCTs will be conducted during the ADVANCE project. Additionally, in order to understand whether the combination of ASCEND and DWM is more effective than the implementation of only DWM or ASCEND, the two cRCTs will be conducted sequentially in the same SMEs (see Section 3 of the research protocol).

This protocol specifically relates to the implementation and evaluation of DWM.

The implementation of ASCEND is described in a separate protocol that has been submitted for a non-WMO waiver at the Non-WMO Review Committee of the METC Amsterdam UMC.

Study objective

Main objectives:

- a) examine and assess the (cost-)effectiveness of WHO*s Doing What Matters in Times of Stress (DWM) in reducing psychological distress, improving mental health, and enhancing work-related well-being and productivity compared to care-as-usual (CAU) in employees of Dutch SMEs with increased psychological distress levels. Another objective is to assess the implementation outcomes of DWM (cRCT #2; study phase 4b).
- b) identify barriers and facilitators to intervention engagement and adherence and assess opportunities for scaling up the implementation of the DWM intervention within the context of working adults in Dutch SMEs (process evaluation; study phase 5).

Secondary objectives:

- c) explore whether ASCEND combined with DWM improves mental health, well-being and work-related outcomes among employees of Dutch SMEs in comparison with ASCEND only, DWM only, or CAU only (study phase 4a and 4b combined).
- d) examine the cost-effectiveness of ASCEND combined with DWM on mental health, well-being and work productivity among employees of Dutch SMEs compared to ASCEND only, DWM only, or ECAU only (the economic evaluation informed by the effectiveness study phase 4a and 4b combined)

Study design

The complete ADVANCE study consists of five phases (see below). This proposal concerns study phases 4b and 5.

Study phase 1 and 2 are described in separate non-WMO protocols for which ethical clearance has been sought from the scientific and ethical review board Vaste Commissie Wetenschap en Ethiek (VCWE), of the faculty of Behavioral and Movement Sciences, Vrije Universiteit Amsterdam. Ethical clearance will be sought from VCWE for study phase 3 as well. Study phase 4a is described in a separate protocol that has been submitted for a non-WMO waiver at the Non-WMO Review Committee of the METC Amsterdam UMC.

Study phase 1: Cultural and contextual adaptation of ASCEND and DWM for

supervisors and employees of Dutch SMEs

Study phase 2: Pilot studies investigating the feasibility of the ASCEND and DWM interventions

Study phase 3: Cross-sectional study investigating the relation between digitalization and mental health in employees of Dutch organizations

Study phase 4: Clustered Randomized Controlled Trials (cRCTs) with sequential design

Study phase 4a (cRCT #1): Clustered RCT among supervisors of Dutch SMEs (ASCEND and CAU vs. CAU)

Study phase 4b (cRCT #2): Clustered RCT among employees of Dutch SMEs (DWM and CAU vs. CAU)

Study phase 5: Process evaluation with qualitative interviews and focus groups to assess barriers and facilitators of engagement and adherence to the DWM intervention and opportunities for scaling up the implementation of the intervention.

Intervention

All participants are randomized into a control or intervention group.

The control group receive CAU. The intervention group will receive CAU and also DWM. Namely, participants will receive access to the digital self-help intervention where they will need to complete the 5 modules in 5 consecutive weeks (a new module is made available each week). Additionally, participants will receive weekly support from a trained non-specialist helper.

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. 25 minutes each).

Study phase 4b:

Participants will be assessed online a total of three times over the course of three months. Data will be collected by means of self-administered online questionnaires. Questionnaires will be taken at baseline, 1-week post-intervention, and 3 months follow-up. The six DWM helper support calls, for participants in the treatment group, will be audiotaped for the purpose of monitoring (if participants provide consent for this).

Study phase 5:

The interviews with participants in the target group in phase 4b (both completers and drop-outs) will take approximately 1 hour. The FGDs with DWM facilitators and professionals/representatives of SMEs 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 for the DWM trial must meet the following inclusion criteria:

- 18 years or older.
- Working in a SME in the Netherlands.
- Having elevated levels of psychological distress (Kessler Psychological Distress Scale; K10 >15.9).
- Sufficient literacy and mastery (written and spoken) of one of the languages the DWM intervention is being delivered in (i.e., Dutch or English).
- Having access to an electronic device with internet access to follow the intervention.

- Written informed consent before entering the study.

Exclusion criteria

Employees participating in DWM trial, will be excluded based on the following exclusion criteria:

- Imminent suicide risk, or expressed acute needs or protection risks that require immediate follow-up.
- Currently receiving specialized psychological treatment (e.g., EMDR or CBT) at the time of screening.
- 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.
- Having participated in the ASCEND trial (study phase 4a; cRCT #1; see research protocol) as supervisors.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	568
Type:	Anticipated

Ethics review

Approved WMO

Date: 12-03-2025
Application type: First submission
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	NL87382.018.24