Mental Health Promotion and Intervention in Occupational Settings (MENTUPP): a cluster-Randomized Controlled Trial

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

Summary

ID

NL-OMON51385

Source
ToetsingOnline

Brief title
MENTUPP: a cluster RCT

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
as well as stigma related to mental illness., Mental health promotion and prevention of developing mental health problems, mood disorders, stress and burn- out, such as anxiety disorders

Health condition

werkgerelateerde stress

Research involving
Human

Sponsors and support

Primary sponsor: National Suicide Research Foundation, School of Public Health, University College Cork
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: depression, intervention, Mental health, workplace

Outcome measures

Primary outcome

A set of validated scales will measure the main study parameters related to psychosocial work environment, mental well-being, quality of life, burnout, and reduced depression, anxiety, suicidal behaviour and stigma towards mental health issues.

Secondary outcome

A set of self-developed questionnaires aims to assess the secondary study parameters: the outcomes related to the assessment of productivity (losses), more specifically presenteeism and absenteeism. Additionally, two types of focus groups will offer a platform where employers as well as employees can discuss their experiences with both the implementation and the intervention, with special focus on barriers and facilitators related to the implementation and the intervention. Lastly, possible confounding variables (e.g. specific sociodemographic parameters) are assessed.

Study description

Background summary

Depression and anxiety are the most common mental health difficulties in the workplace in the EU, causing immense suffering and costing the global economy ¤1 trillion each year in lost productivity. Research has consistently shown that in the construction, healthcare and Information and Communication Technology (ICT) sectors, a relatively large number of employees suffer from mental health difficulties and have an elevated risk of developing more severe mental health problems, such as suicidal ideation, depression and comorbid anxiety or stress related symptoms. Those working in small and medium enterprises (SMEs) are particularly vulnerable, as available studies indicate elevated levels of depression, psychological distress, burnout, absenteeism and presenteeism among SME employers and employees, compared to large enterprises. Overall, SMEs comprise more than 90% of all EU businesses, meaning there is a huge potential to influence population health through the implementation of the proposed intervention programme.

Study objective

The primary objective of the MENTUPP research project is to improve mental health in the workplace by developing, implementing and evaluating the effectiveness of a multicomponent intervention (MENTUPP) targeting mental health difficulties (non-clinical and clinical) in the workplace in SMEs across construction, health and ICT sectors. A secondary aim is to reduce depression, anxiety and suicidal behaviour, as well as stigma related to mental health problems. The main aim of the current research project is to conduct a multi-country clustered Randomized Controlled Trial (cRCT), in order to assess effectiveness and cost-effectiveness of the MENTUPP intervention, in nine implementation countries, among which the Netherlands.

Study design

The multi-country cRCT will use a mixed-methods approach, in which both qualitative and quantitative outcomes are collected during the thirteen-month study period (June 2022 - July 2023). Within each of the nine intervention countries, among which the Netherlands, a total of 6 SMEs will be recruited (two from the construction, two from the health care and two from the ICT sector). Per sector, the recruited SMEs will be randomly assigned to either the intervention or the delayed intervention control group, in order to allow an evaluation of the (cost-)effectiveness of the MENTUPP intervention compared to the control group. Quantitative and qualitative measures will be collected at baseline, upon completion of the intervention (9 months post-baseline) and at a four-month post-intervention follow-up (13 months post-baseline).

Intervention

The MENTUPP intervention will contain three intervention components:
Component A focuses on promoting mental wellbeing and targeting non- and pre-clinical mental health aspects including stress, burnout, and depressive symptoms.
Component B focuses on depressive disorders, anxiety, and co-morbid physical health difficulties (clinical in accordance with ICD-10).
Component C targets destigmatisation of mental health problems in the SMEs workplace Interventions.
All three components will be developed for the MENTUPP project and are primarily delivered through the online MENTUPP Hub which contains educational materials, such as information packages in textual form, interactive assignments, leaflets and videos. Participants are able to login to the MENTUPP Hub and follow the intervention components of their choice, using their own account and going at their own pace. In addition, workshops will be organized where possible. The MENTUPP intervention targets three interconnected levels: the individual, the peer and the organizational level.

Study burden and risks

Participation in the workshops and online materials of the MENTUPP intervention are voluntarily. Online materials, related to the three components of the MENTUPP intervention, are offered in the MENTUPP Hub, but participants are not obligated to complete a certain set of specific materials or workshops. The materials are freely accessible to all participants and they are free to use any of the materials at any time and in any order depending on individual interests and/or needs. However, participants are required to complete several questionnaires during baseline and follow-up assessments, and participants are only able to access all MENTUPP materials after they completed the baseline assessment. Completion of these questionnaires will take approximately 30 minutes per assessment. Participation in qualitative focus groups is also voluntarily. Outcome data will be processed and managed in accordance with Dutch and European GDPR guidelines. As the MENTUPP intervention will be implemented within the SMEs, anonymous participation of employees related to their employers and leaders cannot be guaranteed, but it might be possible if they choose to only participate in the online intervention materials. Given the potential stigma and risk associated with mental health issues, particular care will be taken when members of the project team engage with employees and employers with mental health issues after informed consent has been received. Although the target groups comprise individuals who may be vulnerable, in previous research projects of several consortium partners, the interventions offered have been shown to have beneficial effects on mental health without any adverse effects. Therefore, the benefits of participating are expected to outweigh any potential risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

employees and/or managers (including subcontractors) within the participating SMEs; >= 18 years; willing to participate in research; able to give informed consent

Exclusion criteria

Participants are not: 1. children or minors; and 2. healthy volunteers for other medical studies

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2022
Enrollment:	138
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-08-2022
Application type:	First submission
Review commission:	METC NedMec

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	NL81411.041.22