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MENTUPP: Mental health promotion and intervention in occupational settings

Submission date
03/06/2022

Recruitment status
No longer recruiting

Registration date
12/07/2022

Overall study status
Completed

Last Edited
02/10/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Depression and anxiety are the most prevalent mental health difficulties in the workplace in the EU, causing immense suffering and costing the global economy €1 trillion each year in lost productivity. Certain sectors, in particular construction, health and information and communications technology (ICT), have an elevated risk of mental health difficulties, with those working in Small and Medium Enterprises (SMEs) being particularly vulnerable. However, most SMEs have limited capacity to address mental health promotion and provide mental health interventions to staff. As SMEs comprise more than 90% of all EU businesses, there is a huge potential to influence population health.

The MENTUPP project aims to improve mental health and wellbeing in the workplace by developing, implementing, and evaluating a comprehensive, multilevel intervention (known as the 'MENTUPP Hub') targeting both clinical (depressive, anxiety disorders) and non-clinical (stress, burnout, depressive symptoms) mental health issues, as well as promoting mental wellbeing and combating the stigma of mental (ill-) health. The central aim of the cluster Randomised Controlled Trial is to conduct an outcome, process, and economic evaluation of the MENTUPP intervention. The outcome evaluation examines whether the MENTUPP intervention is effective to induced changes in employees and leaders in terms of wellbeing, symptoms of mental illness, stigmatising attitudes, and productivity loss. In that regard, employees and employers in the intervention and control SMEs will be invited to complete at baseline and at 9- and 13-month follow-up, a selection of six validated scales and two self-developed surveys measuring the long-term, intermediate, and proximate outcomes of MENTUPP. The process evaluation will collect data related to the implementation process of the MENTUPP intervention including the adoption, reach, feasibility, implementation, appropriateness, and maintenance of the intervention. Therefore, a combination of qualitative and quantitative measures will be used (Glasgow, Klesges, Dzewaltowski, Estabrooks, & Vogt, 2006; Proctor, Silmere, Raghavan, Hovmand, Aarons, Bunger, et al., 2011). Finally, the economic evaluation will weigh the costs and outcomes related to MENTUPP to examine whether MENTUPP gives a good value for money.

Who can participate?
The study will involve SMEs which are defined as organisations with 250 employees or less within the healthcare, construction, and ICT sectors. Employees and employers aged 18 years

and older working in the healthcare, construction, and ICT sectors have given written informed consent for participation in the study may participate.

What does the study involve?
Participants will be asked to complete a survey about their mental health, wellbeing, work productivity and psychosocial constructs and participants who are in managerial roles will also be asked to answer additional questions in relation to the organisational culture.
Participants will gain access to the MENTUPP Hub following the completion of the baseline survey. The Hub will host intervention components A, B and C.
Intervention component A is designed to promote wellbeing, stress, burnout and depressive symptoms (non-clinical). Intervention component B addresses the clinical symptoms of depression and anxiety. Intervention C is designed to promote anti-stigma in the workplace in relation to mental health difficulties.
Participants will be asked to complete surveys again at 9 months and 13 months after the baseline survey.

What are the possible benefits and risks of participating?
Some individuals may experience improvements in their mental health and wellbeing. Each participant will be required to answer questions about their mental health, which may cause a degree of discomfort. If participants respond to certain questions that in a manner that indicates they may be at risk to themselves, they will be encouraged to seek help from their GP. All participants will be encouraged to seek appropriate support if they are worried about their mental health. The materials and psychoeducational tools used in the MENTUPP Hub are evidence-informed following several systematic reviews and are not known to be associated with any adverse effects. However, in the event of a participant experiencing a high degree of distress, they will be encouraged to seek help from their GP or an appropriate source of support.

Where is the study run from?
University College Cork (Ireland) is overseeing the implementation of the cRCT and KU Leuven (Belgium) is overseeing the evaluation of the cRCT.

When is the study starting and how long is it expected to run for?
January 2022 to July 2023.

Who is funding the study?
European Union’s Horizon 2020 Research and Innovation Programme

Who is the main contact?
Professor Ella Arensman (ella.arensman@ucc.ie)
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Dr Cliodhna O’Connor and Dr Mallorie Leduc (mentupp@ucc.ie)

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
848137

Study information

Scientific Title
Mental health promotion and intervention in healthcare, construction, and ICT sectors: a cluster randomised controlled trial.

Acronym
MENTUPP

Study objectives
The primary hypothesis states that the multi-country MENTUPP cRCT will show significant improvement in wellbeing and burnout, and reduction in absenteeism among employees and employers in SMEs in the MENTUPP intervention arm compared to employees and employers in the control SMEs.

The secondary hypothesis is that the cRCT will show significant reduction in depressive symptoms and suicidal ideation among employees and employers in SMEs in the MENTUPP intervention arm compared to employees and employers in SMEs in the control condition.

In addition, the cRCT will assess cost-effectiveness and implementation factors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approval pending, Clinical Research Ethics Committee of the Cork Teaching Hospitals, (University College Cork, Lancaster Hall, 6 Little Hanover Street, Cork, Ireland; +353-21-4901901; crec@ucc.ie)
2. Approved 30/05/2022, Griffith University Human Research Ethics Committee (Research Ethics and Integrity, Office for Research, Bray Centre (N54), Nathan Campus, Griffith University, Brisbane, QLD, 4111 Australia; +61 (0)7 3735 2069; research-ethics@griffith.edu.au), ref: 2020/842.
3. Approved 17/05/2022, Ethical Review Board of The Finnish Institute for Health and Welfare (Mannerheimintie 166, Finland PL/PB/P.O Box 30, FI-00271 Helsinki; +358 29 524 6000; no email provided), ref: THL/1273/6.02.02/2022.

4. Approved 16/05/2022, Egészségügyi Tudományos Tanács, Tudományos és Kutatásetikai Bizottság (1051 Budapest, Széchenyi István tér 7-8, Hungary; no telephone number provided; no email provided), ref: 20125-6/2022/EÜIG.
5. Approved 12/04/2022, Kosovo Doctors Chamber Committee on Ethical Issues, (Kosta Novakoviq, Konteineri Nr. 3, Zyra nr. 214, Prishtinë, Kosovo; no telephone number provided; no email provided), ref: none provided
6. Approval pending, Comité de Ética de la Investigación con medicamentos del Parc de Salut MAR (IMIM-Hospital del Mar, Parc de Recerca Biomèdica de Barcelona, Doctor Aiguader, 88, 08003 Barcelona, Spain; no telephone number provided; no email provided)
7. Approval pending, The Medical Research Ethics Committee Utrecht (METC Utrecht) now Medisch-Ethische Toetsingscommissie (METC) NedMec (Netherlands)
8. Approval pending, Ethikkommission des Fachbereichs Medizin der Goethe-Universität Frankfurt am Main (Ass. jur. Anke Schmieder, Leiterin Referat Ethikkomission, Schützenhöhe 16, 01099 Dresden, Germany; no telephone number provided; no email provided).
9. Approval pending, National Ethics Committee (Ministry of Health and Social Protection, Str. Rruga e Kavajes, Nr. 1001, Tirana, Albania; no telephone number provided; no email provided)

Study design
Multicenter cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Mental and behavioural disorders and wellbeing

Interventions
This study will evaluate the effectiveness and cost-effectiveness of the MENTUPP programme for improving mental health in the workplace. The MENTUPP programme will be delivered through the MENTUPP Hub, an online platform that will deliver psychoeducational and wellbeing materials. Nine countries will participate, and each country will recruit SMEs in all three sectors.

The MENTUPP Hub is designed to give tailored content to the construction sector, the healthcare sector and the ICT sector. Within each sector, the Hub provides general material on wellbeing as well as focused material and tools for employees and for leaders/managers.
The MENTUPP Hub will be delivered to participants via three intervention components:
• Intervention Component A focuses on non-clinical mental health including wellbeing, stress, burnout and depressive symptoms. Intervention Component A involves the presentation of materials that develop the participants' general understanding of mental wellbeing, stress and burnout and a mental wellbeing toolkit. Leader-specific materials relate to organisational factors associated with wellbeing and employee-specific materials relate to peer support in the workplace.
• Intervention Component B is focused on depressive disorders and co-morbid anxiety and provides training on suicide prevention.
• Intervention Component C aims to target stigma in the workplace and is comprised of psychoeducational materials for all users including lay helpers and sufferers.

The cluster randomised controlled trial will take place over a 13-month period, June 2022-July 2023. SMEs will be randomly allocated to the intervention and control conditions. The trial will use a mixed-methods approach, and evaluation data will be obtained using the RE-AIM framework to structure evaluation outcomes from data collected. Quantitative and qualitative measures will be collected at baseline and at two follow-up timepoints, 9 and 13 months. Semi-structured self-report questionnaires addressing client satisfaction will also be administered and focus groups involving research officers' experiences with the intervention will be conducted.

Intervention Type
Behavioural

Primary outcome(s)
1. Mental wellbeing and quality of life is measured using The World Health Organization – Five Wellbeing Index, 5-items (WHO-5; WHO Regional Office in Europe, 1998) at baseline, 9 months, 13 months.
2. Anxiety is measured using Generalised Anxiety Disorder Assessment, 7 items (GAD-7; Kroenke et al, 2016) at baseline, 9 months, 13 months.
3. Burnout is measured using Burnout Assessment Tool, 12 items (BAT; Schaufeli et al, 2019) at baseline, 9 months, 13 months.
4. Absenteeism is measured using a self-developed pre-intervention survey, 34 items at baseline and a self-developed post-intervention survey, 28 items, at 9 months and 13 months.

Key secondary outcome(s))
1. Depression and suicidal behaviour is measured using the Patient Health Questionnaire, 9 items (PHQ-9; Kroenke et al, 2016) at baseline, 9 months, 13 months.

Outcome measures related to the cost-effectiveness and cost-consequence of MENTUPP will be measured by:
Costs:
1. Time spent by employers and employees on activities related to MENTUPP is measured by the post-intervention survey at 9 months and 13 months and the monitoring instrument at baseline, 9 months and 13 months.
2. Time spent by employers and employees on the MENTUPP Hub is measured by Log-data from the MENTUPP Hub at 9 months and 13 months.
3. Absenteeism and presenteeism of employees due to mental health issues is measured by the two self-developed surveys at baseline, 9 months and 13 months.
4. Use of primary healthcare and mental healthcare due to mental health issues is measured by the two self-developed surveys at baseline, 9 months and 13 months.
5. Time investment of research officers to implement MENTUPP is measured by the monitoring instrument at baseline, 9 months and 13 months.
6. Travel costs of research officers to implement MENTUPP is measured by the monitoring instrument at baseline, 9 months and 13 months.
Effects:
1. The validated scales used to measure primary outcomes are used for the cost-effectiveness analysis at baseline, 9 months and 13 months.
2. Support provided by employees facing mental health difficulties is measured by the self-developed surveys at baseline, 9 months and 13 months.
3. Attitudes to search for psychological support is measured by the self-developed surveys at baseline, 9 months and 13 months.

Completion date

30/07/2023

Eligibility

Key inclusion criteria
1. Aged 18 years and older working in the area of health, ICT or construction.
2. Employees and/or managers within construction SMEs, including sub-contractors
3. Volunteers for social or human sciences research
4. Able to give informed consent
5. Individuals and groups who may be vulnerable in terms of mental and physical health difficulties

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Children or minors
2. Patients
3. Healthy volunteers for medical studies

Date of first enrolment
20/06/2022

Date of final enrolment
18/07/2022

Locations

Countries of recruitment
Albania

Australia

Finland

Germany

Hungary

Ireland

Kosovo

Netherlands

Spain

Study participating centre
University College Cork
Western Road
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Study participating centre
National Suicide Research Foundation
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Study participating centre
Finnish Institute for Health and Welfare (THL)
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Study participating centre
Semmelweis University (SEM)
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Budapest
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1085

Study participating centre
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Netherlands
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Study participating centre
Community Centre for Health and Wellbeing (CCHW)
Str. Dibres, Nr. 371
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Albania
1000

Study participating centre
Zyra Per Shendet Mendor Prizren (ZSMKOS)
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Study participating centre
Consorcio Mar Parc de Salut de Barcelona (IMIM)
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Study participating centre
Australian Institute for Suicide Research and Prevention (AISRAP), Griffith University
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Study participating centre
European Alliance Against Depression EV (EAAD)
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Sponsor information

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University College Cork

ROR
https://ror.org/03265fv13

Funder(s)

Funder type
Government

Funder Name
European Commission - DG Research and Innovation

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/09/2023	02/10/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes