



Towards an assessment of psychosocial work factors in a multi-level mental health intervention in the workplace: results from the MENTUPP pilot-study

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Abstract

Background Mental health in the workplace is a growing concern for enterprises and policy makers. MENTUPP is a multi-level mental health intervention implemented in small and medium size enterprises from three work sectors in nine countries. This pilot study aimed to evaluate the feasibility, delivery, and instruments for the MENTUPP intervention to inform the planning of a clustered randomized controlled trial.

Methods We administered items from the Copenhagen Psychosocial Questionnaire and the Danish Work Environment Cohort Study measuring psychosocial workplace factors. The questionnaire was answered by 382 participants at baseline, of which 98 participants also answered after six months at follow-up. We calculated mean scores of 19 psychosocial factors at baseline and conducted repeated measures ANOVAs to assess differences in eight psychosocial factors at follow-up. We also examined whether outcomes differed between work sectors and job positions at follow-up.

Results The construction sector and workers with no or a lower leadership role reported more negative working environment factors at baseline. We observed a statistically significant decline in social support from colleagues and social community at work, and a marginally significant decline in justice at work. For the rest of the constructs, we did not observe statistically significant changes.

Conclusions We found significant differences in psychosocial work environment factors among work sectors and job positions at baseline. Contrary to our hypotheses, three psychosocial work environment factors decreased at follow-up. Possible explanations are the utilization of specific psychosocial factors as resources to cope with psychosocial stressors, high participant expectations that were not met by the intervention, insufficient time for structural changes, or the intervention prompting critical evaluations of the work environment. These findings will inform the design and implementation of the forthcoming clustered randomized controlled trial, where they will also be further investigated to validate their significance.

Keywords Public mental health interventions · MENTUPP · Evaluation · Theory of Change · Workplace mental health

Background

The psychosocial work environment significantly influences employee wellbeing and mental health (Rugulies et al. 2023). High job demands, such as excessive workload, tight deadlines, conflicting priorities and job insecurity can lead to increased stress and burnout among employees (Rugulies

et al. 2023; World Health Organization. WHO guidelines on mental health at work. Geneva 2022). If these demands are not adequately addressed, interventions aimed at improving mental health may be less effective as employees continue to experience overwhelming stressors (Wynne et al. 2014). In addition, interventions typically require time and focus from employees to participate actively. When job demands are too intense or time-consuming, employees may find it challenging to engage fully in the intervention, reducing its potential impact (Aust et al. 2010).

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Job resources encompass the physical, social, and psychological elements within the workplace that aid employees in reaching their work objectives and contribute to their mental health (Bakker and Demerouti 2017). There is a wide array of work elements that can act as job resources such as feeling recognized or being able to have influence, having possibilities to develop and being treated with fairness at work. Job resources may have a buffering effect for the consequences of job demands, and when they are adequately addressed and optimized, they may positively influence the outcomes of mental health interventions (Giusino et al. 2022). Access to job resources can provide employees with the necessary tools and skills to manage stress and navigate challenging situations (Gabriel and Aguinis 2022). This explains why people with such access may exhibit greater resilience when facing difficulties (Ito and Brotheridge 2003), ultimately correlating with improved mental health outcomes (Weitzel et al. 2022). According to the conservation of resources (COR) theory, employees experiencing the benefits of resources will “strive to obtain, retain and protect that which they value” (Hobfoll. 1998) which could increase their willingness to engage themselves in a mental health intervention targeting the decrease of psychosocial stressors and the promotion of mental health in their workplace.

Therefore, integrated approaches to mental health promotion are preferable as they target both psychological and organizational outcomes, such as the improvement of psychosocial risks (LaMontagne et al. 2014; Petrie et al. 2018). By addressing systemic issues and promoting a supportive work environment, these interventions can benefit a larger number of employees and create lasting positive changes as they promote a positive and supportive organizational culture around mental health. In addition, by supporting mental health and by aiming at organizational changes, interventions can improve employee productivity, job performance, and reduce healthcare-related costs, as a healthier workforce is more likely to be focused, creative, and efficient (Leka and Iavicoli 2017).

Studies show variations in psychosocial working conditions affecting workers’ mental health across occupational fields, underscoring the necessity for the customization of workplace mental health interventions, with tailoring of the intervention to the specific needs of the sector in order to promote their effectiveness (Johnson et al. 2005; Derdowski and Mathisen 2023; Langan-Fox and Cooper 2011). Additionally, differences in psychosocial working conditions have been noted between leaders and employees. These variances arise from the unique demands and resources inherent in their respective roles, emphasizing the importance of customizing mental health interventions in the workplace to comprehensively address factors influencing mental health promotion (Skakon et al. 2011; Metzler and Bellingrath 2017; Nielsen et al. 2018).

Despite the significance of integrated approaches to mental health promotion, there is a lack of evaluation on how mental health interventions may result in differential impacts at multiple levels (employees, leaders, organizational levels) (Memish et al. 2017; Skivington et al. 2021) and more research is needed to identify important psychosocial factors for specific work populations (World Health Organization 2022; Dogbla et al. 2023). The evidence is especially scarce about interventions implemented in small and medium enterprises (SMEs) (Greiner et al. 2022; Hogg et al. 2021; Tóth et al. 2023).

MENTUPP (Mental Health Promotion and Intervention in Occupational Settings) is a project funded by Horizon 2020 with the goal of enhancing mental health in workplaces through a complex, evidence-based, multilevel intervention. The intervention aims at both non-clinical (stress, burnout, wellbeing, depressive symptoms) and clinical mental health issues (depression, anxiety disorders), as well as tackling stigma associated with mental illness. The initiative targets SMEs in the construction, healthcare, and information and communication technology (ICT) industries (Tsantila et al. 2023).

Studies consistently demonstrate that individuals employed in specific fields, such as construction and health, exhibit poor mental health and an increased susceptibility to suicide (Tyler et al. 2023; Olfson et al. 2023; Peterson et al. 2016). Furthermore, those engaged in the ICT sector face a heightened risk of experiencing depression, along with concurrent stress-related symptoms and diminished overall wellbeing (Thomson and Grandy 2018). The link between depression and suicidal behaviors, including both suicide attempts and self-harm, is strong. This relationship is further intricate due to co-occurring conditions, such as anxiety and stress-related disorders, that affect both mental and physical health (Hawton et al. 2013). For these reasons, these sectors require particular attention for workplace mental health interventions. However, variability of psychosocial job characteristics and demographic differences of the workforce can be expected between such different work settings (Eurofound. 2017) and designing mental health interventions that can be applied across sectors requires in depth understanding of the differences in psychosocial working conditions and socio-demographics of the workforce.

To assess and improve the design, implementation, and evaluation of the MENTUPP intervention ahead of a clustered randomized controlled trial (cRCT), an uncontrolled six-month pilot study was conducted. The specific objectives of the pilot study include evaluating the delivery of the intervention, examining the implementation strategy, and estimating parameters required for power calculations (Tsantila et al. 2023). The pilot study involved 25 SMEs from nine countries, namely Albania, Australia, Finland, Germany, Hungary, Ireland, Kosovo, the Netherlands, and

Spain. An online platform named the MENTUPP Hub was created to distribute materials and strategies aimed at enhancing mental health. The MENTUPP Hub provided access to resources for managers and employees within the participating SMEs (Arensman et al. 2022). All participants had access to intervention components designed to promote wellbeing, and to reduce burnout, depression, anxiety, and stigma towards mental illness. In addition, the Hub included specific materials for leaders to support them in assessing and improving the psychosocial work environment of their employees, as well as giving guidance in how to support employees with mental problems. Consequently, leaders played a dual role in this intervention: they not only educated themselves about their own mental health, but also worked towards enhancing the workplace environment to positively impact their employees' mental health (Arensman et al. 2022). Further details on the intervention components are described later in this article.

We developed a Theory of Change (ToC) to outline the anticipated causal mechanism of the intervention, allowing the identification of specific outcomes at different levels. In the short term (proximate outcomes), the intervention is expected to enhance the knowledge, skills, and attitudes towards mental health of both leaders and employees. By accomplishing this, the intervention intends to create improved psychosocial working conditions (intermediate outcomes) which will contribute to better mental wellbeing, less symptoms of burnout, anxiety, and depression, less stigmatizing attitudes towards depression and anxiety, and less productivity losses (long-term outcomes) (Tsantila et al. 2023a). It has been previously documented from the MENTUPP pilot study that at follow-up, three long-term outcomes showed improvement: mental wellbeing, symptoms of anxiety, and stigmatizing attitudes towards depression and anxiety (Tsantila et al. 2023). In the present paper, we examine changes in the psychosocial work environment (intermediate outcomes) after the MENTUPP pilot study. We also examine whether the psychosocial factors at baseline differ between the three involved work sectors and between job positions.

This article focuses on addressing five research questions (RQs):

- RQ1. Do psychosocial working conditions differ between the three sectors selected for the MENTUPP intervention (construction, health, ICT) at baseline?
- RQ2. Do psychosocial working conditions at baseline differ between employees' job positions?
- RQ3. Are there changes in psychosocial working conditions (intermediate outcomes defined by the ToC) after six months with access to the MENTUPP intervention tools?
- RQ4. Do the changes in psychosocial working conditions differ between the three sectors?
- RQ5. Do the changes in psychosocial working conditions vary depending on employees' leadership role in the SME?

Method

Design

The pilot study employed both quantitative and qualitative data, incorporating an extensive process evaluation and an uncontrolled pre-post outcome evaluation, which were carried out at baseline and then repeated at the six-month follow-up (Arensman et al. 2022). In this article, we will only present quantitative data related to the assessment of psychosocial factors in the workplace at baseline and at follow-up.

Participating SMEs and employees

The MENTUPP pilot study involved the participation of nine countries, each of which recruited at least one SME from a specified sector. We defined enterprises with ten to 50 employees as small and those with 51–250 employees as medium-sized (European Commission 2020). The breakdown of sectors and countries is as follows:

- *Construction sector*: SMEs were recruited from Albania, Australia, and Ireland.
- *Health sector*: SMEs were recruited from Hungary, Kosovo, and the Netherlands.
- *ICT sector*: SMEs were recruited from Finland, Germany, and Spain.

In each country, Research Officers (ROs) were responsible for recruiting one or more SMEs from their specified sector. The ROs were part of the MENTUPP research team and used a variety of approaches to recruit SMEs, including contacting groups representing SMEs in the sector or using preexisting contacts. The aim was to recruit workplaces with a total of 60 to 70 employees from the designated sector in each country. The sample is detailed in the results section of this article. In an effort to accurately represent the diversity of employees at SME workplaces, all employees were invited to join the study, encompassing individuals in both part-time and full-time roles, as well as those in permanent and non-permanent positions. We also invited subcontractors and agency workers who had contracts extending beyond the follow-up measurement point.

The MENTUPP intervention

The MENTUPP intervention involves providing workplaces with access to an online platform called the MENTUPP Hub (<https://www.mentupphub.eu/en/>) with a range of resources promoting mental health.

The MENTUPP intervention components target individuals (providing coping strategies, psychoeducation), groups (peer-support, de-stigmatization), supervisors (encouraging help-seeking, addressing psychosocial risks), and organizations (promoting positive work environments) (Arensman et al. 2022). The MENTUPP intervention adopts an integrated approach, safeguarding mental health through the mitigation of various risk factors, fostering positive work aspects and personal strengths, and addressing mental health issues, irrespective of their origin (whether work-related or not) (LaMontagne et al. 2014; Arensman et al. 2022).

The resources available on the Hub are designed to serve all participants broadly, while also providing customized materials for each of the three sectors involved. Moreover, there are specialized resources aimed specifically at both employees and leaders within SMEs.

More detailed descriptions of the Hub and the entire intervention can be found in the work by Arensman and colleagues (Arensman et al. 2022) and Tsantila and colleagues (Tsantila et al. 2023a). During the pilot study, the MENTUPP Hub materials were provided in six languages (Albanian, Dutch, English, German, Hungarian, and Spanish) to accommodate and reflect the languages of the participating countries. A translation into Finnish was not necessary as Finland recruited an international enterprise that requested an English translation for their participation in the study.

Procedure

Introductory in-presence sessions were conducted by local Research Officers (ROs) with employees and employers before the intervention. The study's purpose and methodology were clarified, with a strong emphasis on voluntary participation and the assurance of confidentiality. Participants received a link to complete pre-intervention surveys with a subject-generated identification code to ensure anonymity. This code allowed matching participants from baseline with the six-months follow-up survey.

After completing the baseline survey, participants registered with the MENTUPP Hub, which allowed them access to the materials during and outside working hours over the six-month intervention period. The Hub remained accessible from March to September 2021. The follow-up survey was conducted in December 2021. Data collection was performed using Qualtrics (<https://www.qualtrics.com/nl/core-xm/enquetesoftware/>) for validated questionnaires and surveys. More information about the procedure can be found

in Arensman and colleagues (Arensman et al. xxxx) and Tsantila and colleagues (Tsantila et al. xxxx).

Ethical considerations

The pilot study received approval from the institutional ethics committees of each country involved in the MENTUPP project. Additionally, it has been registered with the ISRCTN clinical trial registry under the identifier ISRCTN14582090 (Arensman et al. xxxx).

Assessment of psychosocial factors in the SMEs

A selection of 41 items were taken from the Copenhagen Psychosocial Questionnaire (COPSOQ) version I (one item) (Kristensen et al. 2005), COPSOQ version II (37 items) (Pejtersen et al. 2010), from the Danish Work Environment Cohort Study (DWECS) (three items) (Lund et al. 2005) to measure aspects of the psychosocial work environment at baseline. For a more detailed description of the items that were used, see Appendix 1. We asked all who were employed in the SMEs to fill in the questionnaire. Based on the 41 selected items, we defined the following 19 constructs: (1) quantitative demands, (2) work pace, (3) cognitive demands, (4) emotional demands, (5) influence, (6) possibilities for development, (7) variation in work tasks, (8) recognition, (9) quality of leadership, (10) social support from colleagues, (11) social support from supervisors, (12) social community at work, (13) job insecurity, (14) mutual trust between employees, (15) trust regarding management, (16) justice, (17) mental strain, (18) effort-reward imbalance, and (19) workplace social capital.

Constructs 17–19 are more complex constructs which use a combination of different items to be calculated. According to the Job Demand-Control model (JDC) (Karasek 1979), those who experience high demands with low control are more likely than other employees to experience mental strain in their jobs. The Effort—Reward Imbalance model (ERI) (Siegrist et al. 2004) suggests that stress at work arises from a discrepancy where the effort outweighs the rewards received. The concept of Workplace social capital (WSC) as defined by the Danish Working Environment Council, argues that a workplace rich in social capital, marked by trust, mutual respect, and cooperation among staff and between staff and management, can result in beneficial outcomes including lower stress levels, heightened job satisfaction, and enhanced productivity (Rugulies et al. 2016).

See Appendix 1 for an overview of all constructs and items of the COPSOQ and the DWECS study that were used for the baseline and the follow-up surveys, including the answering categories.

At follow-up, a subset of 21 items measuring the following constructs was used: (1) influence, (2) quality of

leadership, (3) social support from colleagues, (4) social support from supervisors, (5) social community at work, (6) mutual trust between employees, (7) trust in management, and (8) justice. In an effort to shorten the follow-up survey and retain participants, we selected constructs that we deemed more likely to be influenced through the MENTUPP intervention.

Additionally, data on participants' sociodemographic and job-related attributes were gathered, including information about age, gender, education level, nationality, and position of leadership.

The “leadership role” variable was assessed based on participants' responses to a question on an 11-point Likert scale regarding the extent of their leadership responsibilities in their work tasks, with 0 indicating no leadership role and 10 indicating a full-time leadership role. A score of zero was classified as having “no leadership role”, scores from one to three were categorized as a “low leadership role”, four to six as a “medium leadership role”, and seven to ten as a “high leadership role”. We decided to use this scale to capture the perception of respondents' regarding their leadership role instead of a more standardised categorisation as the conceptualisation of leadership differed between the recruited work sectors.

Data analysis

For detailed information on the scoring of the constructs, see Appendix 1.

There was a substantial amount of dropout in the follow-up survey. Of the 382 persons who answered the baseline questionnaire, only 98 answered the follow-up questionnaire, meaning that 25,7% of the original sample answered at follow-up. The rest (74,3%) dropped out of the study. To address this issue, we followed the guidelines provided by Jakobsen et al. (Jakobsen et al. 2017) which offer practical recommendations for handling missing data in longitudinal studies with a high dropout rate (more than 40%). Following their guidance, we chose to conduct a complete case analysis for the data examination. This approach entails including only those participants in the statistical analyses who provided a full set of outcome data, enabling comparison between baseline and follow-up measures. The statistical analyses for this study were carried out using SPSS version 28.0.

Subsequently, a dropout analysis was conducted to compare two groups: the dropout group and the group of respondents who participated at both baseline and follow-up. To perform this comparison, independent sample t-tests were used for continuous variables, while chi-square tests were employed for categorical variables. The use of t-tests and chi-square tests allowed for the identification of any

significant differences between the dropout group and the group of participants who remained in the study.

To measure the effect sizes of the differences found, Cohen's *d* or phi coefficients were calculated. Cohen's *d* provides an effect size measure for continuous variables, indicating the standardized difference between two group means, while phi coefficient is used for categorical variables to determine the strength of association between the variables.

For the analyses of the follow-up data, a repeated measures ANOVA was used to compare the scores of the eight COPSOQ constructs at baseline with the construct scores at follow-up (within-subjects factor time: baseline vs. follow-up). Three two-way repeated measures ANOVAs were also conducted to examine whether the differences between baseline and follow-up differed between sectors (construction vs. health vs. ICT), and leadership roles (no vs. low vs. medium vs. large leadership role). In the results section, we report the F-statistic and accompanying p-value of the main effect of time, and the two two-way interactions time and sector, and time and leadership role. Estimated marginal means (EMs) and standard errors (SEs) of the baseline and follow-up conditions are systematically reported for the main effect of time. For the conditions of the two-way interactions, EMs and SEs are only reported when the interaction reached significance.

Results

Characteristics of participating SMEs

In the pilot study, 25 SMEs from nine different countries were enlisted to participate. Table 1 illustrates how these SMEs are distributed across countries and identifies the sectors they belong to. Among these, 11 SMEs were from the health sector, while the construction and ICT sectors each had seven SMEs participating. The breakdown by enterprise size included 16 small and nine medium-sized enterprises. Additionally, one quarter of the SMEs involved were family-owned businesses.

Characteristics of participating employees and dropout group

A total of 382 respondents completed the survey at the baseline stage, but the number dropped to 98 participants at the follow-up. Table 1 details the characteristics of the participants, including their mean baseline values on the COPSOQ constructs. It also breaks down the number of respondents by sector, leadership role, and country for all respondents at baseline, for those who completed both baseline and follow-up surveys (complete cases), and for those who did

Table 1 Participants' characteristics, baseline mean values on the eight COPSOQ constructs, number of respondents that completed the COPSOQ constructs at baseline, at baseline and at follow-up, and that dropped out, and significant differences

		Participated at baseline (T1) N = 382 Mean (SD)/%	Dropout group N = 284 Mean (SD)/%	Complete cases N = 98 (T2) Mean (SD)/%	Differences between dropout and non-dropout group
Age		36.9 (24.1)	38.6 (11.4)	38.5 (11)	$\chi^2 (5) = 8.6, p = 0.12$
Gender*	Male	60.5%	64.4%	49%	$\chi^2 (1) = 7.3, p < 0.05$
	Female	39.5%	35.6%	51%	
Country*	Albania	15.2%	13%	21.4%	$\chi^2 (8) = 65.5, p < 0.05$
	Australia	15.2%	20.4%	0%	
	Finland	23.8%	19.7%	35.7%	
	Germany	3.7%	3.9%	3.1%	
	Hungary	7.3%	8.5%	4.1%	
	Ireland	4.5%	6%	0%	
	Kosovo	7.6%	3.9%	18.4%	
	Netherlands	7.9%	7%	10.2%	
	Spain	14.9%	17.6%	7.1%	
Sector**	Construction	34.8%	39.1%	22.4%	$\chi^2 (2) = 10.4, p = 0.05$
	Health	22.3%	19.4%	30.6%	
	ICT	42.9%	41.5%	46.9%	
Leadership role	No	16.8%	15.2%	19.4%	$\chi^2 (3) = 1.8, p = 0.61$
	Low	20.9%	20.6%	21.4%	
	Medium	27%	28.5%	22.5%	
	High	35.3%	35.7%	36.7%	
Education level	Primary education	3.4%	3.5%	3.1%	$\chi^2 (3) = 4.7, p = 0.19$
	Lower secondary education	13.4%	15.1%	8.2%	
	Upper secondary or post-secondary education	20.4%	21.8%	16.3%	
	Tertiary education	62.8%	59.5%	72.4%	
Scores in COPSOQ constructs	Influence*	46.5 (19.8)	44.3 (19.9)	52.5 (18.2)	$F (1,416) = 12.5, p < 0.05$
	Quality of leadership	58.3 (23.4)	57 (22.2)	62 (26.1)	$F (1,416) = 2.4, p = 0.12$
	Social support from colleagues*	71.1 (21.2)	69.5 (22.4)	75.5 (16.4)	$F (1,385) = 2.37, p < 0.05$
	Social support from supervisors	65.4 (25.9)	63.9 (26.3)	69.6 (24.3)	$F (1,416) = 2.9, p = 0.08$
	Social community at work	76.4 (18.8)	75.9 (19.1)	77.8 (17.7)	$F (1,416) = 0.8, p = 0.35$
	Trust between employees *	68.6 (20.8)	67.1 (20.6)	72.7 (20.9)	$F (1,416) = 5, p < 0.05$
	Trust in management*	60.8 (23.3)	58.7 (22.8)	66.7 (23.7)	$F (1,416) = 7.65, p < 0.05$
	Justice*	61.5 (20.9)	59.5 (19.9)	67 (22.4)	$F (1,416) = 8.43, p < 0.05$

*A significant difference was found

**A marginally significant difference was found

not continue to the follow-up stage. The average age of the complete cases, meaning those respondents who participated in both the baseline and follow-up surveys, was 38.5 years. The complete cases sample was evenly distributed between genders, and 72.4% had tertiary education. The majority of the participants (46.9%) were employed in the ICT sector, followed by 30.6% in the health sector, and 22.4% in the construction sector. Regarding leadership roles, 19.4% of participants indicated they had no leadership role, 21.4% reported a low leadership role, 22.5% a medium leadership

role, and 36.7% stated they had a high leadership role. The majority of respondents hailed from Finland (35.7%), Albania (21.4%), and Kosovo (18.4%). Notably, there were no complete cases (participants who completed both the baseline and follow-up surveys) from Australia and Ireland.

No significant differences were observed when comparing age, leadership role, and educational level between the complete cases and those who dropped out. However, significant differences were identified concerning gender, country, and sector between the two groups. The effect sizes

of the differences regarding gender and sector was within the small range ($\Phi = 0.138$ for gender, and $\Phi = 0.165$ for sector), while the difference based on country was moderate ($\Phi = 0.414$).

A significant difference was also found between the two groups regarding influence, social support from colleagues, trust between employees, trust in management, and justice. As shown in Table 1, the complete cases had a stronger sense of influence, trust, and justice at their workplace and they felt more supported by their colleagues than the drop out group.

Differences between sectors with regard psychosocial working conditions at baseline (RQ 1)

The one-way ANOVA that was conducted to examine whether the mean values on the construct scores differed between sectors at baseline showed that for most constructs, a significant difference was found. Table 2 provides an overview of the mean values per sector for the significant constructs. Results show that, with respect to demands at work, respondents active in construction and ICT reported a higher level of quantitative demands compared to respondents from

the health sector. Cognitive demands were a little more pronounced in construction and health sectors than in the ICT sector.

With respect to work organization and job content, construction workers responded less favourably on all three constructs compared to health workers and ICT workers, suggesting that they had less influence on their job, less development opportunities, and less variation in their work.

Similarly, with respect to interpersonal relations and leadership, respondents working in construction responded least favourably, while respondents working in health responded most favourably. In construction, respondents felt less recognised and respected for their work, felt less socially supported by colleagues and supervisors, and experienced a smaller sense of community on the work floor. The leadership quality of their supervisors was rated the lowest by construction workers.

Moreover, although respondents in all sectors scored low on job insecurity, indicating that worries about becoming unemployed or being transferred against their will were rare, the feeling of security was higher in people working in health and ICT sectors as compared to people working in construction.

Table 2 Overall and per sector mean values and standard deviations of constructs, and significant differences per sector at baseline

	Overall N=382		Construction N=133		Health N=85		ICT N=164		Significant differences between sectors
Construct	M	SD	M	SD	M	SD	M	SD	F
Demands at work									
Quantitative demands ^{a*}	46.9	12.2	47.8	11.2	44	13.6	47.6	12	$F(2,379)=3.03, p<0.05$
Work pace ^a	59.2	20.1	61.1	18.2	55.9	21.2	59.3	20.9	$F(2,379)=1.74, p=0.17$
Cognitive demands ^{a*}	61.2	20.2	63.2	19.8	66.6	19.3	56.9	20.1	$F(2,379)=1.74, p<0.001$
Emotional demands ^a	39.9	21.4	41.9	21.8	41.9	21.2	37.3	21.1	$F(2,379)=2.18, p=0.11$
Work organization and job content									
Influence ^{b*}	46.5	19.8	41.1	18.6	51.3	22	48.4	18.7	$F(2,379)=8.54, p<0.001$
Possibilities for development ^{b*}	67.9	20	58.7	21.2	70.7	19.3	73.8	16.6	$F(2,379)=24.53, p<0.001$
Variation ^{b*}	59.9	23.4	55.3	25	65.3	21.9	60.8	22.2	$F(2,379)=5.11, p<0.001$
Interpersonal relations and leadership									
Recognition ^{b*}	63	24.3	54	26.5	71.9	23.6	65.6	20.3	$F(2,379)=16.96, p<0.001$
Quality of leadership ^{b*}	58.3	23.4	53.7	24.4	65.4	22.4	58.3	22.2	$F(2,379)=6.64, p<0.05$
Social Support from colleagues ^{b*}	71.1	21.2	61.5	22.1	78	18.1	75.4	19.2	$F(2,349)=22.49, p<0.001$
Social Support from supervisors ^{b*}	65.4	25.9	54.2	27.2	76.5	20.6	68.8	24	$F(2,379)=24.07, p<0.001$
Social Community at work ^{b*}	76.4	18.8	69.9	21.1	82.1	14.1	78.8	17.6	$F(2,379)=14.11, p<0.001$
Work-individual interface									
Job insecurity ^{a*}	21.5	24.1	29.2	26.7	15.6	24.4	18.2	19.9	$F(2,379)=11.51, p<0.001$
Values at the workplace									
Trust between employees ^{b*}	68.6	20.8	62.4	23.2	73.6	17	71	19.6	$F(2,379)=9.8, p<0.001$
Trust regarding management ^{b*}	60.8	23.3	51.2	23.9	74	18.8	61.7	21.5	$F(2,379)=28.43, p<0.001$
Justice ^{b*}	61.5	20.9	57	20.6	66.8	22	62.3	19.8	$F(2,379)=6.06, p<0.05$

^aHigher scores are considered undesirable; ^bhigher scores are considered good and healthy

*A significant difference was found

Finally, values at the workplace were the least positive in construction and the most positive in health. More specifically, in construction, mutual trust among employees, trust in the management, and justice in the workplace were lower.

At baseline, 23.6% of the respondents were categorized as having a high mental strain job (see Table 3). Furthermore, in terms of the ERI, an average ratio of 1.33 was found, indicating that respondents generally exhibited an imbalance with work effort exceeding rewards. The mean value for WSC was 64.5 (SD = 17.6) showing that respondents overall had a good collaboration and trusted each other, trusted the management, and experienced their workplace to be characterized by just decisions.

The prevalence of mental strain, ERI, and the WSC differed significantly between sectors at baseline (Appendix 1). Analyses of the prevalence percentages per sector showed that in construction, more respondents reported to have a high strain job with high demands, and low control, making them more at risk of stress (see Table 3). By contrast, in the health and ICT sectors, the majority of respondents reported having an active job with high demands, combined with high control. Furthermore, the balance between effort and rewards at work was the least favourable in construction workers compared to health and ICT workers, further adding to an increased risk of work-related stress. Finally, the mean value on WSC was found to be highest for health workers, followed by ICT workers, while respondents working in construction scored least favourably. In other words, health workers reported more mutual trust, and a greater sense of justice and collaboration at work, making them less vulnerable for stress; whereas construction workers scored least favourable on these items, increasing their risk of stress.

Differences in baseline psychosocial working conditions with regard to participants job positions (RQ 2)

The study categorized participants into no, low, moderate, and high leadership roles, observing that higher leadership positions were associated with more favorable scores in cognitive demands, work organization, job content, interpersonal relations, and values at the workplace. Notably, job insecurity was low across all groups, but those in stronger leadership roles felt more secure. The one-way ANOVA confirmed significant differences in construct scores among the different levels of leadership, highlighting the influence of leadership responsibility on various psychosocial aspects (Table 4).

The tests that were conducted to examine differences between leadership roles on the mental strain, ERI, and WSC constructs, yielded significance. Analyses of the differences shows that 48.4% of respondents with no leadership responsibilities reported to have a high strain job, with high demands combined with low control (see Table 5). The 32.5% of respondents with a low leadership role reported to have a passive job with low demands and low control. By contrast, respondents with a medium or high leadership role more often had an active job with high demands but also high control. Additionally, respondents with no leadership responsibilities had a larger effort-reward imbalance than respondents with low, medium, and high leadership roles. Finally, the mean value on WSC, measuring mutual trust, sense of justice and collaboration at work, was highest for respondents with a high leadership role and declined with lower leadership role, with respondents with no leadership role having the lowest score for this construct.

Table 3 Overall and per sector mean scores, and significant differences on mental strain, effort-reward imbalance, workplace social capital at baseline

Construct	Overall N = 382	Construction N = 133	Health N = 85	ICT N = 164	Significant differences between sectors χ^2/F
Mental Strain*					$\chi^2(6) = 26.41, p < 0.001$
Low strain job (%)	22.3	13.5	28.2	26.2	
Passive job (%)	20.2	25.6	17.6	17.1	
Active job (%)	34.0	25.6	37.6	39	
High strain job (%)	23.6	35.3	16.5	17.7	
Effort-Reward Imbalance*					$F(2,374) = 13.86, p < 0.001$
M	0.88	1.3	0.4	0.6	
SD	1.3	1.6	1.1	1.2	
Workplace Social Capital*					$F(2,379) = 19.3, p < 0.001$
M	64.5	57.9	72.1	65.8	
SD	17.6	17.4	16	16.8	

*A significant difference was found

Table 4 Mean values and standard deviations per leadership role and significant differences at baseline

Construct	No N = 64		Low N = 80		Medium N = 103		High N = 135		Significant differences between leadership roles F
	M	SD	M	SD	M	SD	M	SD	
Demands at work									
Quantitative demands ^a	46.6	13.8	47.5	11.7	46.2	11.4	47.2	12.3	$F(3,378)=0.23, p=0.09$
Work pace ^a	59.8	20.9	56.7	20.3	59.1	18.9	60.4	20.6	$F(3,378)=0.57, p=0.63$
Cognitive demands ^{a*}	58.4	18.8	52.7	20.2	62.9	19.7	66.4	19.5	$F(3,378)=8.94, p<0.001$
Emotional demands ^a	38.1	22.9	39.5	21.6	38.6	19.5	41.9	22.1	$F(3,378)=0.71, p=0.54$
Work organization and job content									
Influence ^{b*}	32.2	18.6	43.3	20.3	48.4	18.3	53.7	17.3	$F(3,378)=20.78, p<0.001$
Possibilities for development ^{b*}	55.7	23.7	66.7	19.4	69.8	17.1	75.8	16.5	$F(3,378)=20.64, p<0.001$
Variation ^{b*}	51.9	23.7	54.1	21.9	61.4	23.7	65.9	22.1	$F(3,378)=7.63, p<0.001$
Interpersonal relations and leadership									
Recognition ^{b*}	47.9	31.1	56.9	22.3	66.8	22.4	70.8	18.7	$F(3,378)=17.95, p<0.001$
Quality of leadership ^{b*}	49.2	27.5	57.5	22.3	60.9	23.3	61.1	20.9	$F(3,378)=4.43, p<0.05$
Social Support from colleagues ^b	68.1	23.4	67.9	22.6	74.2	20.5	72.1	19.4	$F(3,348)=1.75, p=0.15$
Social Support from supervisors ^{b*}	57.2	30.1	60.9	26.5	68.8	24.4	69.3	23.4	$F(3,378)=4.68, p<0.05$
Social Community at work ^{b*}	71.4	20.9	72.4	22.8	79.6	14.8	78.8	17.2	$F(3,378)=4.57, p<0.05$
Job insecurity ^{a*}	24.1	27.1	25.6	24.1	22.4	24.3	17.1	22.1	$F(3,378)=2.64, p<0.05$
Values at the workplace									
Trust between employees ^b	70.3	19.9	65	25.7	69.7	20.6	69.1	18.1	$F(3,378)=1.05, p=0.37$
Trust regarding management ^{b*}	54.7	30.1	57.5	23.1	60.8	20.9	65.7	20.8	$F(3,378)=4.03, p<0.05$
Justice ^{b*}	56.6	24.6	58.1	20.5	62.1	20.2	65.3	18.9	$F(3,378)=3.44, p<0.05$

^aHigher scores are considered undesirable; ^bhigher scores are considered good and healthy

*A significant difference was found

Table 5 Mean scores per leadership role on mental strain, effort – reward imbalance, and workplace social capital at baseline

Construct	No N = 64	Low N = 80	Medium N = 103	High N = 135	Significant differences between leadership roles $\times 2/F$
Mental Strain*					$\chi^2(9)=62.83, p<.001$
Low strain job (%)	12.5	12.5	27.2	28.9	
Passive job (%)	25	32.5	19.4	11.1	
Active job (%)	14.1	27.5	34	47.4	
High strain job (%)	48.4	27.5	19.4	12.6	
Effort-Reward Imbalance*					$F(3,373)=11.69, p<0.001$
M	1.9	1.3	1.2	1.2	
SD	1.6	0.7	0.6	0.6	
Workplace Social Capital*					$F(3,378)=4.04, p<0.05$
M	59.9	61.3	65.3	67.8	
SD	20.1	18.7	16.3	16.1	

*A significant difference was found

Changes in psychosocial stressors at six-months follow-up (RQ 3–5)

Influence

The main effect of time was not significant,

with $F(1,71)=0.68, p=0.41$. Also, the two-way interactions between time and sector [$F(2,71)=0.99, p=0.37$], and time and leadership role [$F(3,71)=0.06, p=0.98$] did not reach statistical significance.

Quality of leadership

The main effect of time was not significant, with $F(1,71)=0.12$, $p=0.72$. Also, the two-way interactions between time and sector [$F(2,71)=1.08$, $p=0.34$], and time and leadership role [$F(3,71)=1.83$, $p=0.15$] did not reach statistical significance.

Social support from colleagues

The main effect of time reached significance, with $F(1,60)=7.12$, $p<0.05$, and $\eta^2=0.11$, indicating a large size effect. Further exploration showed that the social support from colleagues has been worsened at follow-up (Table 7). However, significance was not observed for any of the two-way interactions, suggesting that social support from colleagues did not differ between sectors [$F(2,60)=0.73$, $p=0.48$], and leadership roles [$F(3,60)=1.27$, $p=0.29$].

Social support from supervisors

The main effect of time was not significant, with $F(1,71)=0.12$, $p=0.72$. Also, the two-way interactions between time and sector [$F(2,71)=0.59$, $p=0.55$], and time and leadership role [$F(3,71)=0.81$, $p=0.49$] did not reach statistical significance.

Social community at work

The main effect of time reached significance, with $F(1,71)=3.93$, $p<0.05$, and $\eta^2=0.05$, indicating a medium effect size. Further exploration showed that the sense of community at work has been worsened at follow-up (Table 7). However, significance was not observed for any of the two-way interactions, suggesting

that social community at work did not differ between sectors [$F(2,71)=1.74$, $p=0.18$], and leadership roles [$F(3,71)=0.48$, $p=0.69$].

Trust between employees

The main effect of time did not reach statistical significance, with $F(1,71)=0.28$, $p=0.59$. In addition, none of the two-way interactions between time on one hand and sector [$F(2,71)=0.71$, $p=0.49$] and leadership role [$F(3,71)=0.36$, $p=0.77$] on the other hand reached significance.

Trust in management

The main effect of time was not significant, with $F(1,71)=0.21$, $p=0.65$. Also, the two-way interactions between time and sector [$F(2,71)=1.02$, $p=0.36$], and time and leadership role [$F(3,71)=0.58$, $p=0.62$] did not reach statistical significance.

Justice

The main effect of time showed a marginally significant difference, with $F(1,71)=3.67$, $p=0.05$. Further analyses showed that the sense of justice in the workplace had worsened at follow-up (Table 6). However, significance was not observed for any of the two-way interactions, suggesting that changes in justice did not differ between sectors [$F(2,71)=0.14$, $p=0.86$], and leadership roles [$F(3,71)=1.67$, $p=0.18$].

Table 6 Estimated marginal means (EMs), Standard Errors (SEs), and Confidence Intervals (CI) at baseline and follow-up for the 8 constructs of the COPSOQ

Measured construct	Scale range	Baseline (N=98)				Follow-up (N=98)			
		95% CI				95% CI			
		EM	SE	LL	UL	EM	SE	LL	UL
Influence	0–100	53.4	2.3	48.7	58.1	53.7	2.4	48.7	58.6
Quality of leadership	0–100	60.6	3.1	54.5	66.7	59.8	2.6	54.5	65.1
Social support from colleagues*	0–100	77.7	2.2	73.2	82.3	67.5	3.1	61.5	73.6
Social support from supervisors	0–100	69.5	3.3	62.7	76.2	67.2	2.5	62.1	72.4
Social community at work*	0–100	80.5	2.3	75.9	85.1	76.4	2.5	71.2	81.5
Trust between employees	0–100	72.3	2.8	66.5	78.1	74.3	2.4	69.3	79.2
Trust in management	0–100	68.6	2.9	62.8	74.4	68.1	3.1	62.1	74.1
Justice**	0–100	68.4	2.8	62.7	74.2	61.5	3.1	55.5	67.5

*A significant difference was found

**A marginally significant difference was found

EM estimated mean, SD standard error, CI confidence interval, LL lower limit, UL upper limit

Discussion

Regarding our first research question (RQ1), the three different work sectors showed very differential profiles with respect to psychosocial working conditions requiring tailored approaches in mental health interventions to target the specific work environment. The results of our study suggest that psychosocial working conditions particularly in the construction sector may require additional attention in workplace mental health interventions. Furthermore, as posited in the article's background section, it is conceivable that work sectors experiencing heightened job demands may encounter greater challenges in participating in an intervention, while those with more job resources can be assumed to have better possibilities to participate. This could explain the observed lower reach and the higher dropout rate of MENTUPP participants in the construction sector compared to the highest reach in the health sector (Tsantila et al. 2023b). Our findings are consistent with previous research observing that the nature and content of occupations are closely connected to the way the working environment is experienced. Sectors with a larger part of blue-collar workers, such as workers employed within the construction sector, experience overall a poorer psychosocial work environment related to heavy workload, job content, interpersonal relationships, job insecurity, values at the workplace, mental strain, and effort-reward imbalance (Williams et al. 1987; Saint-Martin et al. 2018). However, the small and non-representative sample size limits the generalizability of sector-specific conclusions.

However, we did not only find differences in psychosocial factors between the three sectors. Even in the same sector, people can have varying work experiences based on their position in the workplace (RQ2). Our results affirm findings from other studies, highlighting that employees with no or in lower leadership roles experience different psychosocial stressors compared to employees in higher leadership positions (Skakon et al. 2011; Metzler and Bellingrath 2017; Rugulies et al. 2016; Bhui et al. 2016). Also, our results indicate that these distinctions are primarily linked to the fact that individuals with no or in lower leadership positions are confronted with more negative psychosocial working conditions, like high workload and limited recognition, and at the same time with less positive psychosocial working conditions, like influence and possibilities for development (Taouk et al. 2020). In contrast, while employees in higher leadership roles also often have elevated demands associated with the nature of their jobs (e.g., cognitive demands) they typically have greater control over their work tasks. Moreover, people in higher job positions can be assumed to often have more personal resources to cope with the stressors that they face, as they

are more experienced and usually older and in a better socioeconomic status than employees in lower job positions (Bhui et al. 2016; Maqsoom et al. 2018; Ghezzi et al. 2020; Lundahl et al. 2013). These job-related differences highlight the potential difficulty for leaders to understand the psychosocial stressors faced by their employees (Woringer et al. 2020) and underscore the need to involve the latter in the process of organizational changes.

With respect to the third research question (RQ3), the MENTUPP intervention did not achieve improvements in psychosocial working conditions, which were assumed to be the intermediate outcomes in the Theory of Change for this project (Tsantila et al. 2023a). Instead, we observed no improvement in most of the psychosocial work environment aspects, and even a decline in social support from colleagues, social community at work, and justice. There may be several possible explanations for this phenomenon. First, social support from colleagues and social community at work are two constructs that were practically affected by the COVID-19 restrictions in the workplace. Moreover, these two constructs had the higher scores at baseline making them important job resources for the employees participating in MENTUPP during the pandemic. In line with the Conservation of Resources theory, individuals experiencing challenging situations, such as the COVID-19 pandemic, are anticipated to draw upon their resources, potentially resulting in a depletion of these resources (Hobfoll 2002). Second, another explanation might be related to the fact that the participants' scores on the psychosocial factors showed that constructs, which were only assessed at baseline, such as quantitative demands, emotional demands, and job insecurity, were scored a lot lower than those assessed both at baseline and at follow-up, meaning that we may have not selected the most important indicators for psychosocial factors for the SMEs involved in our intervention. The need to reconsider the intermediate outcomes for our ToC is also supported by our study on the long-term outcomes (Tsantila et al. 2023) which showed that the participants of the pilot intervention reported improvements in mental wellbeing, symptoms of anxiety, and stigma towards depression and anxiety despite no changes or the negative effects in the intermediate outcomes. The MENTUPP cRCT, which, unlike the pilot study, is a controlled study and lasts longer than the pilot study (ten months), will provide more insight on our assumptions. Third, Aust and colleagues (Aust et al. 2010) have previously discussed that workplace interventions may result in a worsening of the psychosocial work environment, if employees' expectations regarding the intervention are not met. Therefore, assessing participants' expectations of a workplace mental health intervention is essential to understand their potential association with adverse effects on psychosocial factors at follow-up. Fourth, it is also possible that the MENTUPP intervention encouraged respondents to

think more critically about the psychosocial aspects in their organization, which made them in turn more skeptical in their judgment at follow-up. Third, the short follow-up time of six months may have been too short to achieve organizational-level structural changes. The observed declines in social support from colleagues and justice at work warrant further investigation, as they may be influenced by the COVID-19 pandemic and other external factors during the pilot implementation.

In relation to RQ4 and RQ5, which focused on examining differences in psychosocial working conditions between the various work sectors and leadership roles at follow-up, the study did not find any significant differences. These findings could be attributed to the successful tailoring of the intervention, managing to overcome the differences noticed at baseline and achieve the same results across workplaces and people with diverse mental health and organizational needs. This assumption is also supported by the findings of the MENTUPP pilot process evaluation showing that the intervention received many positive comments regarding its appropriateness and acceptability across leaders and employees of the three work sectors involved (Tsantila et al. 2023b).

Strengths and limitations

A first strength of our study is that it reports on the assessment of psychosocial factors of an intervention that was implemented internationally in three work sectors and includes people with different job positions. The study contributes to fill in the research gap on workplace mental health interventions in SMEs. The assessment of the psychosocial factors between our implementation settings at baseline helped us to understand where changes on the organisational level are needed the most and what kind of intervention components can be utilized to facilitate the achievement of the desired mental health outcomes. The variability of psychosocial stressors between work sectors and job roles confirmed the recommendation that tailoring is required when designing and implementing a mental health intervention in the workplace.

Another strength is the fact that we were able to test the assumptions of our Theory of Change and thereby found that the mechanisms that we assumed with regard to the intermediate outcomes were not confirmed. This knowledge will contribute to a better understanding of the mechanisms that lead to an improvement of some of the long-term outcomes (improved mental health) without “going through” improvements in the intermediate outcomes. Moreover, the fact that we found negative effects on some of the targeted psychosocial factors at follow-up contributed to further optimizing our Theory of Change, taking into consideration that even when specific intermediate outcomes are targeted through an intervention,

backward effects can be noticed for a period of time as participants may exploit specific psychosocial aspects, such as social support, as resources to combat psychosocial stressors.

A significant limitation of the study is the substantial dropout rate observed among respondents when it came to completing the questionnaire at the follow-up stage. Our dropout analyses showed that the dropout was not random but differential by gender, sector, and country, resulting in a highly selective sample. Furthermore, the sample was highly educated with a high proportion of workers with tertiary-level education, which limits the generalizability of results to lower educated workers. The high dropout rate hinders a definitive interpretation of the findings. The high dropout rate in the pilot study could be attributed to various reasons. Firstly, the extensive length of the questionnaire might have discouraged employees from completing it, resulting in lower participation rates. To mitigate this issue, the cRCT has reduced the number of items in the questionnaire for evaluation purposes. Secondly, the disruption caused by the COVID-19 pandemic genuinely affected the implementation process of the MENTUPP pilot study. The original plan of a blended online and face-to-face approach for the implementation of MENTUPP was replaced by a totally online provision of the intervention components and the enhancement of participants' engagement through reminders via emails, which may not have been adequate. Thirdly, the study's findings indicate that males and individuals working in the ICT sector were more likely to drop out, affecting the study's sample composition. Additionally, the dropout analysis revealed that the complete cases had a stronger sense of influence, trust, and justice at their workplace, and they felt more supported by their colleagues at baseline. Perhaps, there was not enough room for improvement, as a lot of people engaged in the intervention were already experiencing a positive work environment. Overall, we aimed to handle the challenges posed by the high amount of missing data appropriately and provided a clear account of the approach taken in dealing with this limitation in our study (Jakobsen et al. 2017; Clark and Altman 2003). In addition, the study recognizes the importance of addressing the dropout issue and acknowledges the preliminary nature of the findings.

Another limitation of this study is the absence of a control group. However, MENTUPP is a complex intervention involving participants and implementation settings with a wide array of individual, organizational, and cultural characteristics. Piloting such interventions is highly recommended before proceeding to a larger-scale trial, as the obtained information through a pilot study can contribute to the refinement of the intervention's development, implementation, and evaluation (Skivington et al. 2021; Thornicroft and Patel 2014). We consider that the findings obtained in this study, as well as the findings of the pilot long-term outcomes evaluation (Tsantila et al. 2023) and the pilot process

evaluation (Tsantila et al. 2023b) contributed significantly to the optimization of our intervention and of the ToC that we developed to evaluate it. These optimizations will be discussed more thoroughly in upcoming articles.

Conclusions

The results show significant differences at baseline between the three work sectors involved in the pilot study. Among the three sectors, participants from the construction sector reported the most negative psychosocial working conditions. This indicates that mental health interventions designed for this sector should especially focus on these aspects which best can be approached through organisational and work-related changes. Additionally, more time might be needed to be able to observe the desired effects. Furthermore, people with no or in lower leadership job roles, face more psychosocial stressors in the workplace compared to people with high leadership roles and low/high leadership is respectively connected to different psychosocial hazards. Our findings, contrary to our expectation from the Theory of change, suggest that the intervention may result in worsening of some psychosocial work environment factors. This may be attributed to participants utilizing these factors as resources to cope with psychosocial stressors, high expectations at baseline resulting in disappointment with the intervention, insufficient time for implementing structural changes, or the intervention motivating participants to reassess their work environment and adopt a more critical perspective. Our study highlights the necessity of tailoring mental health interventions in the workplace, considering sectoral and individual work-related characteristics, and recommends the pre-assessment of organisational aspects ahead of their development and implementation in wide scale studies. Overall, the pilot study offers valuable insights for refining the implementation strategy and evaluation instruments of the MENTUPP intervention. However, significant challenges in participant recruitment and retention render the findings preliminary, necessitating further investigation for validation. The dropout analysis has informed strategies to address these challenges in the upcoming cRCT.

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Data availability The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request. When the project will be completed, all of our data will be saved together in an open access repository. The journal will be informed about the name of the repository as soon as it will be available.

Declarations

Conflict of interest The authors declare no conflict of interest.

Ethical approval The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals (Ireland; reference number ECM 4 (bb) 10/11/2020), Griffith University Research Human Research Ethics Committee (Australia; reference number 2020/842), Ethical Review Board of The Finnish Institute for Health and Welfare (Finland; reference number THL/5316/6.02.01/2020); Egészségügyi Tudományos Tanács, Tudományos és Kutatásétkai Bizottság (Hungary; reference number iV/10156–3/2020/EKU); Professional Ethics Commission of Hospital and University Clinical Service of Kosovo (Kosovo; reference number 2550); Comité de Ética de la Investigación con medicamentos del Parc de Salut MAR (Spain; reference number 2019/8872/1); The Medical Research Ethics Committee Utrecht (The Netherlands; reference number SL/avd/21/500074); Ethikkommission des Fachbereichs Medizin der Goethe-Universität Frankfurt am Main (Germany; reference number 20–1025); and National Ethics Committee, Albania (Albania; reference number 98.8).

Informed consent All participants received information about the study and provided informed consent before starting the survey.

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