

STUDY PROTOCOL

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Protocol of a randomized controlled multicenter trial investigating process and effectiveness of a participatory organizational approach for preventing work-related mental health problems among employees: vital@work

Luuk Bouwens^{1,2,3*} , Johannes R. Anema^{1,2} , Trees T. Juurlink^{1,2} , Aartjan T. F. Beekman^{2,4} and Roosmarijn M. C. Schelvis^{1,2}

Abstract

Background Evidence links psychosocial work factors to work-related mental health problems, which affect productivity and highlight the need for workplace interventions. In order to establish sustainable change, a participatory strategy that considers the behavioral, organizational, and contextual (BOC) determinants when selecting and implementing interventions is needed. The objective of the current study, Vital@Work, is to prevent and reduce work-related mental health problems by using an evidence based Participatory Approach (PA) as strategy to compose a set of intervention activities tailored to BOC determinants. While the PA has proven effective in other contexts, in this study we examine the impact of contextual factors on the effectiveness of intervention activities delivered through the PA strategy.

Methods and analysis The PA is evaluated as a strategy to implement intervention activities to prevent and reduce unfavorable psychosocial work factors in a multicenter cluster randomized controlled trial, including an intervention and control group in four different organizations. These four organizations are characterized by unique BOC determinants and differ in sector, size (small and large organizations), type of organization (private or public) and type of work. Employees in the intervention group receive the PA alongside usual practice, while the control group receives only the usual preventive measures. Effectiveness will be assessed through questionnaires administered at baseline, and 6 (T1) and 12 months (T2) after baseline. According to a power analysis, we strive to include a total sample of 1,040 persons at baseline. As primary outcome, stress will be measured using DASS-21. In addition, various secondary outcomes (sense of community, presenteeism and absenteeism) will be assessed. Longitudinal

*Correspondence:

Luuk Bouwens

l.bouwens@amsterdamumc.nl; luuk.bouwens@tno.nl

Full list of author information is available at the end of the article



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mixed model analyses, including subgroup analyses, will be conducted, along with a process evaluation to assess implementation.

Discussion The current study will evaluate the PA as a strategy to develop and implement a set of mental health intervention activities tailored to the organizational context, in order to prevent and reduce work-related mental health problems. By doing this, we aim to identify common and sector-specific challenges, contributing to knowledge on tailoring workplace interventions.

Trial registration number The trial has been retrospectively registered at ClinicalTrials.gov on 31 May 2024 (NCT06445101).

Keywords Mental health, Health workforce, Psychosocial intervention, Implementation science, Randomized controlled trial

Introduction

Work-related mental health problems are a serious issue among workers. In 2020, mental health problems, consisting of stress, depression, and anxiety, were the second most common work-related health problem at the EU level [1]. Moreover, 44.6% of individuals in the European Union reported exposure to work-related risk factors that could negatively impact their mental health [1]. To illustrate, the meta-review conducted by Niedhammer et al. (2021) [2] presented compelling evidence regarding the associations between psychosocial work factors (such as workload, psychological demands and decision latitude, social support, effort-reward imbalance and job insecurity) and mental health problems (including outcomes related to depression, sleep problems, anxiety, or burnout). These outcomes not only affect individuals' personal lives but also have broader implications for their productivity, engagement, and overall performance at work [3–5]. Reduced productivity, higher absenteeism, and the associated costs are harmful consequences for and place a burden on society, through reduced workforce participation and higher social welfare costs [3, 6, 7]. To illustrate, a large proportion of workers' sick leave can be attributed to mental health problems [8]. Sickness absence associated with mental health problems is characterized by a long duration and frequent recurrences [9–11] making them one of the most costly types of sickness absences [12, 13]. The prevalence and impact of work-related mental health problems on individuals, employers, and society underscore the importance of a preventive approach to reduce absenteeism, as emphasized by the WHO [14].

Effective workplace interventions for mental health

According to the framework by Mrazek & Haggerty (1994) [15], prevention activities are classified as universal (targeting the general population) selective (targeting high-risk groups) and indicated (targeting high-risk individuals or groups already displaying symptoms) prevention. Research on mental health in the workplace has shown that universal interventions (targeting all employees, regardless of mental health status) generally lead to

small to moderate effects, while selective and indicated interventions (targeting at-risk individuals or those with symptoms) produce more substantial benefits [16]. A recent synthesis of literature reviews by Aust et al. (2023) [17] found high-quality evidence supporting interventions targeting burnout reduction, while interventions aimed at improving broader health and wellbeing outcomes showed moderate-quality evidence. This underscores the greater potential of indicated interventions over broader, universal strategies. Additionally, this synthesis of literature provided evidence for the effectiveness of organizational-level interventions in enhancing both the psychosocial work environment and employees' mental health outcomes [17]. Regarding intervention types, a substantial level of evidence was presented for the effectiveness of “changes in working time arrangements,” “influencing work tasks or organizational structure,” “changes in health care approaches,” and “improving the psychosocial work environment” [17]. Despite the greater prevention potential of job and organization redesign compared to individual-focused interventions, there is also evidence supporting individually targeted interventions. For example, several individual-level stress management interventions, such as mindfulness programs or assertiveness training, showed favorable effects on employees' mental health, including reductions in perceived stress, alleviation of emotional exhaustion, and a decrease in anxiety symptoms [18, 19]. These individual-level interventions exemplify indicated prevention, focusing specifically on those already showing early signs or heightened risk of mental health challenges. Given the potential benefits of interventions at both the organizational and individual levels, it is advantageous for enhancing employee mental health to focus on implementing strategies at multiple levels [17, 20].

Despite the evidence for workplace interventions, it appears that effective interventions are rarely deployed by organizations [21–23]. This may be due to unawareness among employers about the existence of effective interventions aimed at preventing work-related mental health problems. Possibly, the wide range of available

interventions hinders the decision-making process of selecting an appropriate intervention. On top of that, available interventions are not tailored to the employers' needs and specific organizational context. In order to establish sustainable change, occupational health interventions need to be aligned and integrated with the strategy and systems of the organization [24]. Ensuring congruence between the contextual elements of organizations with evidence-based interventions has been found critical for successful implementation [20, 24, 25]. Therefore, (researchers of) organizations must carefully consider the specific context and needs of organizations when implementing interventions.

To summarize, effective workplace interventions for the prevention of mental health problems ideally adopt a combination of selective and indicated preventive elements, addressing both organizational and individual levels.

The importance of behavioral, organizational and contextual determinants for the effectiveness of an intervention

Prior research has shown that the effectiveness of an intervention is determined not only by the intervention itself but also significantly by the processes involved in its implementation [26–29]. Internal and external contextual factors have been found to either facilitate or hinder the efficacy of interventions, examples are available resources (e.g. time, financial, mental resources), organizational culture and conditions, resource-demanding parallel change processes, or new project management demands [27, 29]. The importance of context and the manner in which interventions are executed is demonstrated by the observation that the same intervention yielded vastly different outcomes in different contexts [30].

In addition to contextual and organizational factors, individual perceptions and interpretations of participants in the intervention, as well as their subsequent behavior, also affect the effectiveness of interventions [31, 32]. These appraisals and perceptions (referred to as mental models) play a pivotal role in influencing individual's responses to the intervention and its activities.

Due to these specific behaviors, organizational needs, and contextual factors, organizations require tailored solutions to address work-related stress effectively. To optimally align interventions with the specific context, participation from those directly involved is essential to successfully design and implement interventions [28, 29, 33]. This participation ensures that the specific context and needs are adequately taken into account and provides a means to integrate participants' contextual expertise with the general principles and frameworks of interventions [28, 29, 33]. Moreover, preventive interventions target a healthy population, this population often feels less

urgency to participate in preventive measures due to the absence of immediate health problems [34]. Participation of those directly involved in the interventions addresses this issue, as it enhances work control, the sense of fairness and justice, and support for employees, all of which play a significant role in work-related mental health problems [28, 35].

Participatory approach

Given the need for interventions tailored to specific behaviors, organizational needs, and contextual factors, there is a demand for a participatory strategy that considers the behavioral, organizational, and contextual (BOC) determinants when selecting and implementing interventions. A strategy that fulfills this need and has gained considerable interest in recent decades, is the Participatory Approach (PA) [25, 36–39]. This strategy at organizational-level consists of a set of defined process steps, preferably facilitated by a process leader, in which equal and active involvement of all stakeholders is ensured, and in which stakeholders reach consensus on both the key issues for improvement and the solutions [40]. In this context, the PA encompass purposeful collaborative efforts between employees and employers to develop a set of intervention activities that enhance employee well-being through the reorganization, design, and management of work processes [40]. Regarding the prevention of work-related mental problems, PA aims to remove or modify causes of work-related risk factors impacting mental health in a participatory manner [41]. In this regard, the PA is a strategy for development of intervention activities and for the enhancement of their adoption.

In order to focus on implementing strategies at multiple levels, the PA addresses organizational barriers by actively involving employees in the implementation process, helping to lower resistance, improve communication, and better align the intervention with the organization's needs. This active engagement fosters ownership and commitment, making the intervention activities more acceptable and easier to implement [26]. To address individual-level barriers such as resistance to change and lack of believe in the intervention's effectiveness, it is crucial to incorporate peer-to-peer communication and motivation within the PA [26]. The peer-to-peer strategy can be effectively implemented through the deployment of change agents or role models. These individuals are tasked with promoting the widespread implementation of intervention activities within the department, while also ensuring a seamless process that encourages employees to engage with and adopt the intervention activities. The use of change agents during the implementation phase can facilitate the adoption of new practices by acting as role models, addressing concerns, and reinforcing the benefits of the intervention [42].

The effectiveness of PA in organizations depends not only on the intervention activities itself but largely on its implementation at the organizational level and the “dose” received by individual employees [43]. This dose—the frequency and intensity with which employees engage in intervention activities—shapes the intervention’s impact on them and is influenced by factors such as participation frequency and leadership support. Moreover, BOC determinants play a critical role: elements like organizational culture, resource availability, and PA-related policies affect both the dose that employees experience and the overall effectiveness of intervention activities [44]. Together, these factors—the intensity of exposure and the BOC determinants—determine the success of the PA and its positive effects on employees.

Previous research demonstrated that a participatory strategy granting more autonomy and opportunities for employee involvement and participation, enhance employee well-being [45]. This implies that these components are essential factors for enhancing mental health [45]. Employee involvement and participation constitute the core of the PA and emphasize the potential of this strategy. Additionally, previous studies have demonstrated the efficacy of a stepwise PA protocol in facilitating organizations to make informed decisions regarding suitable work-related stress management interventions [39]. This protocol serves as a structured framework that guides organizations in selecting and implementing intervention activities aimed at the prevention of work-related mental health problems in an effective manner. The effectiveness of PA on preventing an increase in work stress in a healthcare institution has been demonstrated [46]. The present study is a new attempt to demonstrate actual prevention of work-related mental health problems and its risk factors across various contexts.

Study objectives

The objective of the current study, Vital@Work, is to prevent and reduce work-related mental health problems. Therefore, we test an evidence based Participatory Approach (PA) to compose a set of intervention activities tailored to behavioral, organizational & contextual (BOC) determinants. We evaluate the PA as a strategy to develop and implement a set of mental health intervention activities tailored to the organizational context (including related behavior & environmental determinants), in order to prevent and reduce work-related mental health problems. This PA is expected to reduce implementation barriers and increase the implementation and adoption of intervention activities on organizational level. Role models increase the implementation and adoption of intervention activities on the individual level. We hypothesize that the PA as strategy is more effective for prevention of mental health problems

compared to usual (HR-)practice. The PA is investigated in intervention (PA) and control groups (HR-practice as usual) across four different organizations, which differ in sector, size (small and large organizations), type of organization (private or public) and type of work. The varied organizations, each characterized by unique BOC-determinants, provide an opportunity for researching the PA as strategy to effectively prevent and reduce work-related mental health problems. By doing this, we come closer to opening the black box of how and why interventions work and thus closer to tailoring interventions to needs of both individuals and organizations. The study protocol was developed in accordance to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist [47].

Methods and analysis

This paper describes the protocol for the evaluation of PA as a strategy to implement intervention activities to prevent or reduce work-related mental health problems by a multicenter cluster randomized controlled trial, including an intervention and control group. Employees in departments allocated to the intervention group receive the PA in addition to the existing range of preventive mental health measures within the organization. Departments assigned to the control group receive standard HR-practice for mental health and therefore only the preventive interventions already available in the organization will be communicated to the employees in these departments.

The PA strategy consists of six steps: (1) *preparation*: create prerequisites and initiate the PA; (2) *risk assessment*: analysis of bottlenecks and risks; (3) *solutions*: analysis of potential solutions; (4) *action planning*: jointly formulating a plan of action to realize solutions; (5) *implementation*: implementing measures by change agents according to the action plan; and (6) *evaluation*: evaluation of the approach.

Study population

Individual participants

Participants are employed in departments across four different organizations in the Netherlands. The inclusion criteria for individual participation in the study comprise being at least 18 years of age, holding an employment contract with the participating organization and being able to complete a questionnaire in Dutch, with the option of assistance if needed.

The participating organizations represent a diverse array of employee characteristics, including individuals from both low and high socioeconomic status (SES) backgrounds. These include organizations from different sectors (aviation, cleaning, hospital care and psychiatric health care), different target groups (e.g., unskilled,

practically trained or theoretically trained) and different types of organizations (e.g., public versus private).

Prior to the study, the higher management of each organization confirmed their participation by signing an declaration of intent. In their declaration of intent, higher management agreed that their employees on specific departments could allocate work hours to participate in the research and consented to the financial and organizational implications of the intervention. In collaboration with the Vital@Work project coordinator within the organization, potential teams for participation are identified. Subsequently, the managers of these teams were approached for participation in the study and informed by the researchers about the design and content of the intervention.

Sample size

Sample size calculation was performed for a mixed-effects model using nQuery, following several assumptions. These assumptions were based on the StressPrevention@Work study [38], which reported a mean within-subject difference of 1.57 (SD=4.47) on the DASS-21 stress subscale between groups after six months. To detect a small effect (Cohen's $d=0.35$) with 80% power and an alpha of 0.05, 1,040 participants (520 in the intervention condition and 520 in the control condition) are required, accounting for a 25% loss to follow-up. The StressPrevention@Work study [38] closely aligns with our research design and therefore provides the best available estimate of the expected effect. It is important to note that significant contextual factors, such as personnel shortages, turnover, and organizational restructuring, likely influenced the StressPrevention@Work results. Without these adverse conditions, the observed effect might have been greater, as was described in the discussion of the StressPrevention@Work study [38].

Random allocation and matching teams/departments

Randomization will be done on cluster level (e.g. team or department). Eligibility implies the willingness of teams/departments (hereafter referred to as: teams) to participate in the trial and to enable employees to participate in the working group conducting the PA. The objective is to ensure comparability between teams and an equal distribution of participants in both the intervention and control groups. The maximum size of a participating team/department is 150 employees. This is to ensure that employees feel engaged and represented in the PA and that the challenges and proposed solutions are also recognizable and relevant to their daily work. Once the participating teams have been determined, random allocation to the respective conditions will be conducted by an independent researcher who has no prior information about the teams. Randomization is carried out at the

cluster level to prevent contamination between employees assigned to the intervention group and those in the control group. Within an organization, it is possible to have multiple intervention groups simultaneously. The matching and randomization procedure is conducted with all participating teams within the organization, in a manner that guarantees the presence of at least one intervention group and one control group within each organization. The intervention and control groups are matched based on number of full-time equivalent (FTE), type of roles and type of tasks. Since not all organizations start at the same time, we are able to change – if necessary – the randomization scheme from 1:1 to 1:2 (IG: CG) before the last clusters start, to include more control groups to overcome the often encountered issue of high loss to follow-up in control groups.

Following the randomization process, the employees belonging to the eligible teams will be sent an email containing the study details, including information about the inclusion criteria, along with the informed consent and the baseline questionnaire. For practical reasons, randomization is conducted before baseline measurements.

Blinding

Due to the PA intervention and associated activities, it is not possible to blind the researchers and department managers. However, employees in the departments randomized to the intervention or control group are not aware of the research design. Only department managers are informed about the research design and the outcome of randomization, and they are asked not to communicate the research design to the employees. We endeavor to prevent participants from knowing whether they are in the intervention or control group by presenting the current range of (HR-) preventive measures for mental health available within the organization to both the intervention and control groups. Furthermore, it is not communicated to employees which condition (the PA or the current range of measures) is the intervention and control condition, making it irrelevant whether they are aware that they are receiving the participatory approach or the currently available set of interventions within the organization. Finally, data analyses are conducted without awareness of group allocation, ensuring blinding of the condition (intervention or control group).

Intervention

Protocol of the participatory approach

With the PA, six consecutive steps are undertaken. Step 1 *Preparation* sets the stage for a successful and well-structured participatory approach. It ensures that all necessary groundwork is in place, enabling the subsequent steps of risk assessment, action planning, implementation, and evaluation to be carried out effectively. This step involves

defining the objectives and securing resources (funding, time, personnel, and expertise) and support for the PA. It is crucial to secure backing for PA and allocate adequate resources for its implementation. As part of step 1, a focus group interview is organized in each organization in order to generate support for the project. Additionally, the goal is to gather insights from various stakeholders and ensure that the program aligns with the specific organizational needs and expectations. By engaging participants in a structured discussion, the focus group aims to identify potential challenges, opportunities, and areas for improvement within the initiative. This knowledge helps to understand the interaction between mental health and BOC-determinants, which should be taken into account to successfully implement interventions within the organization. Simultaneously, the participatory approach will be further developed in collaboration with the organization after identifying the participating departments within each organization and determining the intervention group(s) through randomization (see *allocation and matching teams/departments*).

For each intervention group, a working group will be established, comprising 5–7 employees, a department manager/supervisor, a health and safety coordinator, an HR representative, and a communication specialist. In cases where any of these roles are unavailable within the organization, suitable alternatives will be considered. Additionally, if desired, stakeholders in other roles such as a company doctor or a representative from the occupational health and safety service may be included in the working group. The working group operates in a participatory manner, actively engaging all members in the decision-making process. Each working group is coordinated by a process facilitator who is responsible for preparing the meetings and leading the discussions during the sessions with the working group. To prepare individuals for this role, the process facilitator receives training, provided by researchers experienced in the PA. This 6-hour (train-the-trainer) training aims to enhance the implementation of the approach. Ideally, the process facilitator role is fulfilled by an individual within the organization who possesses expertise in mental health and work, is experienced in facilitating group processes and has some experience in working in projects. By assigning the role of process facilitator to someone working within the organization, it enables the organization to independently carry out the approach after the research project.

The working group will execute steps 2 to 4 of the PA during a one day session. Step 2 within the PA, the *risk assessment*, involves systematically identifying, evaluating, and understanding the various work-related risks and stressors that impact employees' well-being and contribute to work stress. It is a crucial phase that provides a foundation for developing targeted intervention

activities. The starting point for the risk assessment is the results of the baseline questionnaire administered to employees of the participating departments. The baseline questionnaire provides an overview of the mental health status and psychosocial working conditions prior to the PA. During the risk assessment step, one of the researchers presents the results of the baseline questionnaire. Based on these results, the working group collaboratively examines the work environment, job tasks, organizational practices, and interpersonal dynamics to identify and get consensus about most important potential hazards and stress-inducing factors.

Step 3, *solutions*, involves generating and exploring potential strategies and interventions to address the identified work stressors and improve the overall work environment. The working group aims to generate a range of feasible and practical solutions and reach consensus about most important solutions that have the potential to address the identified issues. The solutions should be tailored to the specific context of the organization, taking into account its unique challenges, resources, and workforce characteristics.

Step 4 of the PA, *plan of action*, entails the creation of a thorough and strategic framework to effectively implement intervention activities targeting identified work stressors and fostering a healthier work environment. This step serves as a guiding blueprint for the subsequent implementation phase. During the plan of action step, the working group collectively transforms the outcomes derived from the risk assessment and solutions steps into a tangible action plan. This plan delineates specific goals, objectives, strategies, and activities aimed at addressing the identified stressors. The working group collaborates closely with relevant stakeholders to allocate necessary resources, assign responsibilities, and set timelines for implementing each intervention.

Subsequently, this action plan will be implemented throughout the entire team comprising the intervention group in Step 5 *Implementation*. The step of "implementation" in the PA entails the practical application of the action plan and the active execution of intervention activities aimed at mitigating work stressors and enhancing the work environment. This implementation process will be led by the process facilitator and supported by change agents. Ideally, (some of) the working group members will act as change agents. Change agents or role models have the task of implementing interventions as widely as possible within the department and ensuring a smooth implementation process so that employees actually make use of the innovations. In order to act as catalysts for the implementation process within the department, the change agents and the process facilitator receive a training by researchers experienced in the PA at the beginning of the implementation phase.

Finally, step 6 of the PA, *evaluation*, involves a systematic and comprehensive assessment of the implemented intervention activities to determine their effectiveness in reducing work stress and improving the overall work environment. This step is crucial for gathering evidence, measuring outcomes, and informing future decision-making. The working group collaborates with relevant stakeholders, including workers and management, to gather feedback and assess their perceptions and experiences regarding the implemented interventions. This feedback is valuable for assessing the effectiveness and identifying areas for improvement. Additionally, the results of the T1 questionnaire will be shared with the members of the working group. The duration of the entire implementation period is approximately 3 months, but depends on the selected intervention activities.

Considering the assumption that it is advantageous for enhancing employee mental health to focus on implementing strategies at multiple levels [17, 20], existing measures at the individual level are also taken into account in the action plan, alongside the organizational level intervention activities. Therefore, existing measures within the organization related to the prevention of work-related mental health problems are brought to attention and highlighted. HR will highlight the existing interventions during the implementation phase. In the control group(s), highlighting the existing (HR-)measures will be the only activity, whereas in the intervention group(s), this will be an addition to the PA. Therefore, the PA will be evaluated in relation to the usual practice.

Data collection

Data collection will be conducted using online questionnaires. Employees receive an email containing a link to the survey. A pilot study revealed that many of the questions are too complex for employees in the cleaning sector to complete independently. Therefore, in agreement with the organization, it was decided that employees will complete the questionnaires on paper under the supervision of one of the researchers. The researcher will explain each item on the questionnaire, after which the

employees will fill in their responses individually. There will also be an opportunity for employees to ask additional questions if statements or words are unclear. The completed paper questionnaires will be entered into the online survey by an independent researcher.

Approximately one month prior to the first working group meeting, all employees of the involved intervention departments and their corresponding control departments receive a baseline questionnaire. To minimize loss to follow-up, up to three reminders are sent, and each team manager is requested to encourage all employees to complete the questionnaires. Additionally, researchers visit the participating teams at each measurement point, including baseline measurements and follow-up measurements, with the aim to motivate employees to complete their questionnaires. As an additional incentive, the start of every questionnaire is celebrated with a piece of cake.

Effect evaluation

Figure 1 depicts the logic model that illustrates the theoretical assumptions and hypothesized pathways that form the foundation of the PA and its expected outcomes.

Effect evaluation will be done by within person comparisons of scores in the intervention and control groups on questionnaires, administered at baseline (T0), 6 months (T1), and 12 months after baseline (T2). Both the intervention and control groups fill out the questionnaire for the effect evaluation. See Fig. 2 for an overview of the effect evaluation in relation to the PA intervention.

Primary outcome

Stress

Stress will be assessed using the stress subscale of the short version of the Depression Anxiety and Stress Scale (DASS-21) [48], designed to measure the emotional states of depression, anxiety and stress [49]. The stress subscale of DASS-21 comprises seven statements, such as *'I found it difficult to relax'*, *'I tended to over-react to situations'* and *'I found myself getting agitated'*. Participants indicate the extent to which these statements applied to

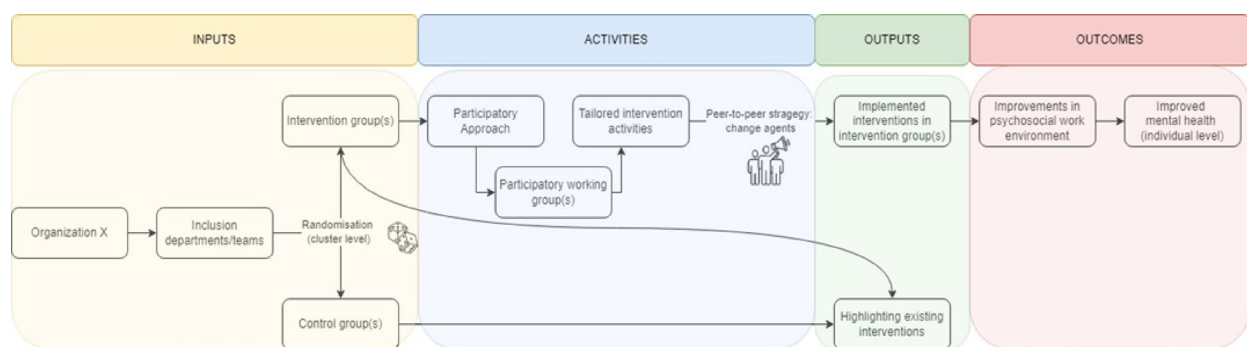


Fig. 1 Logic model with the theoretical assumptions and hypothesized pathways underlying the study design

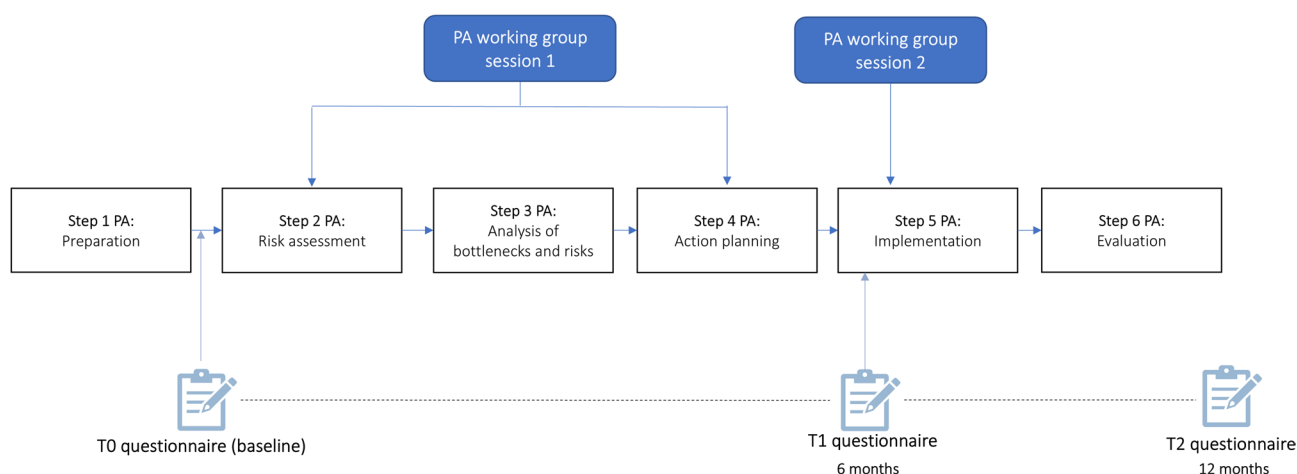


Fig. 2 Overview of effect evaluation in relation to PA intervention

them during the past week, using a Likert scale ranging from 0 ('never') to 3 ('almost always'). This assessment process generate a scale score ranging from 0 to 21, with higher scores indicating elevated levels of stress. Different scale score ranges represented varying degrees of stress severity (0–7 = normal; 8–9 = mild; 10–12 = moderate; 13–16 = severe; 17–21 = extremely severe). The validity of DASS-21 has been established in non-clinical settings [49, 50].

Secondary outcomes

Sense of community

Sense of Community in the workplace will be measured using three items from the validated Dutch version of The Copenhagen Psychosocial Questionnaire (COPSOQ-III) [51, 52] (e.g. 'Is there a good atmosphere between you and your colleagues?').

Presenteeism and absenteeism

Presenteeism will be assessed by two items of the World Health Organization Health and Work Performance Questionnaire (HPQ) [53] and an item obtained from Vänni et al. (2018) [54]. The *absenteeism history* of the employee in the twelve months prior to the survey will be assessed using a set of three questions. Additionally, two questions will be included regarding the most recent absenteeism incident experienced by employees. This most recent incident may potentially have occurred more than twelve months ago, allowing for responses from employees who have not been absent in the past twelve months but were absent before that period. They are asked about the type of complaints that led to their most recent absence and whether these complaints were work-related.

Mediating factors

Work related psychosocial risk factors

Work-related psychosocial risk factors will be assessed, including job demands, autonomy, supervisor support and co-worker support. For measuring job demands, we will utilize the subscales *quantitative demands*, *cognitive demands*, *emotional demands* and *work pace* from the COPSOQ-III [51, 52]. The COPSOQ is a globally recognized and extensively employed tool for assessing a range of psychosocial factors in workplaces [51] and has demonstrated acceptable psychometric characteristics [51, 55]. For each dimension of the COPSOQ-III, 5-point Likert scale-type items are assessed and scaled to the interval of 0 to 100. Response options vary depending on the scale values and scale direction, for example, from 'to a very large extent' (100) to 'to a very small extent' (0) or from 'Always' (100) to 'Never/hardly ever' (0).

Quantitative demands will be measured by three items, for example 'How often do you not have time to complete all your work tasks?'. The cognitive demands subscale consists of four items, such as 'Do you have to keep your eyes on lots of things while you work?'. The concept of emotional demands will be assessed with three items, e.g. 'Does your work put you in emotionally disturbing situations?'. Work pace will be evaluated by two items, e.g. 'Do you have to work very fast?'.

Autonomy is measured with the subscale *Influence at work* of the COPSOQ-III, which consists of four items, for example 'Do you have a large degree of influence on the decisions concerning your work?'.

For the measurement of co-worker and supervisor social support, we will utilize two subscales from the validated Dutch version of the Job Content Questionnaire (JCQ) [56, 57]. Each subscale consists of four items and respondents will provide their ratings on a four-point scale, indicating their level of agreement, ranging from "completely disagree" to "completely agree." The scores

range from 4 to 16, both containing four items each, for example *'People I work with are friendly'* and *'My supervisor is concerned about the welfare of those under him/her'*.

Psychosocial safety climate

At employee level, the Psychosocial Safety Climate (PSC) is assessed using the Dutch translation of the PSC-4, a shortened version of the PSC-12 [58]. The psychometrics and predictive validity of the PSC-4 are just as strong as those of the PSC-12, suggesting support for the use of the concise PSC-4 in both research and practice [58]. The PSC-4 consists of four items (e.g. *'Senior management shows support for stress prevention through involvement and commitment'*) and respondents provide their answers on a 5-point Likert scale, ranging from 1 ("Strongly disagree") to 5 ("Strongly agree"). The total PSC-4 score is derived by summing up the responses to all 4 questions, resulting in a range of scores from 4 to 20. To ensure a more accurate representation of the organizational structure, the questions are tailored to the organizations such that the terminology matches existing roles within the organization (e.g. supervisor/team coach etc.).

Implementation outcomes

To assess implementation outcomes, a series of questions (12 items) will be used concerning existing and recently introduced resources (interventions, measures, policies, and additional support) designed to foster mental health and prevent related issues. These items assess key implementation outcomes, including reach (awareness and knowledge of mental health resources), adoption at both organizational/team level (implementation and uptake within teams) and individual level (personal use of the interventions), dose received (extent of individual engagement with the interventions), and context (organizational support and perceived alignment with workplace needs).

Confounding factors

At baseline, we will investigate several prognostic factors to gain insight into the differences between the intervention and control teams.

Personal and socio-demographic characteristics

To control for individual differences that potentially affect work-related mental health outcomes, we incorporate various socio-demographic characteristics (i.e. age, gender, marital status and household composition, education) [59].

Work characteristics

Previous research suggested that occupation, tenure [60], job insecurity [61] and working hours [62] affect work-related mental health. Therefore, occupation, the number

of years working for the organization, whether or not on a permanent contract, contractual hours per week and overtime hours will all be measured at the employee level.

Process evaluation

In addition to the effect evaluation, a process evaluation is also being conducted following Nielsen and Randall's (2013) [29] model for assessing organizational-level interventions, the framework proposed by Linnan and Steckler (2002) [63] and the RE-AIM model [64]. This process evaluation utilizes quantitative data collected through the T0, T1, and T2 questionnaires filled out by the participants from the intervention group. In the control group, these questions will assess the extent to which existing interventions were highlighted and whether participants utilized them. In addition to implementation outcomes (see above), *readiness for change* and *stress mindset* will be measured. *Readiness for change* will be measured by five items based on the Organizational Change Questionnaire–Climate of Change, Processes, and Readiness (OCQ–C, P, R) [65]. The Stress Mindset Measure (SMM) [66] is a self-report 8-item instrument, and will be used to assess the extent to which an individual believes that the effects of stress are either enhancing or debilitating. In addition, qualitative data obtained through interviews and data logs will be used for the process evaluation. The interviews are conducted with participants involved in the design and implementation of the intervention activities such as members of the working group (e.g. HR-officers, occupational physician and employee representatives), and will take place during steps 5 and 6 of the PA in between T1 and T2. These interviews pertain to the design and implementation of intervention activities, the implementation strategy, the context and feasibility and sustainability. The data logs pertain to the same topics and will occur throughout all steps of the PA based on observations by the researchers and information provided by the contact person within the organization. For an overview and the goals of the process evaluation, see Table 1.

Statistical analyses

Both intention-to-treat and per-protocol analyses will be conducted. Descriptive statistics, including means, standard deviations, or frequencies, will be computed for all measured variables and compared between the intervention and control groups. Within-persons longitudinal mixed model analyses will be performed for the intervention and control groups, including subgroup analyses for low SES groups and other relevant subgroups. In these analyses, stress, sense of community, presenteeism, and absenteeism will be used as dependent variables. Work-related psychosocial risk factors, psychosocial

Table 1 Components of the process evaluation based on implementation factors and their corresponding goals, operationalization and data source

Implementation factor	Goal	Operationalization	Source		
			Questionnaire	Interviews	Re-search Logs
Reach					
<i>Representation</i>	All target groups are reached	Measuring representation by comparing demographics of participants Attendance of members in the participatory working group	X	X	X
<i>Accessibility</i>	No barriers to access exist (location, cost, time, technology)	Measuring accessibility barriers and solutions by stakeholder feedback	X	X	
<i>Communication effectiveness</i>	Potential participants are fully aware of the intervention and engaged.	Measuring awareness and engagement The manner in which the project was communicated to the participants	X	X	X
Effectiveness					
<i>Health outcomes achieved</i>	Significant improvements are observed in mental health, indicating the intervention's effectiveness in meeting its goals	Measuring mental health outcome	X		
<i>Participation</i>	Stakeholders at all levels are actively engaged in the intervention. Higher participation leads to better outcomes.	Composition of group and procedure was in line with protocol Measuring the extent the employees feel represented by the members of the participatory working group Keeping track of involvement of stakeholders during implementation phase		X	X X
<i>Contextual moderators</i>	External factors such as work pressure or personal circumstances have minimal impact on outcomes.	Identify contextual factors that may affect outcomes. Track these factors and assess their impact on the intervention		X	X
Adoption					
<i>Organizational willingness</i>	Organizations are willing to adopt the intervention.	Measure reasons for middle and senior management to participate (initiation) Keeping track of decisions and actions that demonstrate organizational support.		X	X
<i>Leadership support</i>	Leaders show active and visible support for the intervention.	Keeping track of decisions and actions that demonstrate organizational support.		X	X
<i>Fit with organizational culture</i>	The intervention aligns with organizational values and goals.	Measure alignment through participant feedback.		X	
Implementation					
<i>Fidelity</i>	The intervention is implemented as originally designed.	The extent to which the process facilitator complied with PA protocol, according to the facilitator and researcher		X	X
<i>Dose delivered</i>	The full planned scope of the intervention is delivered.	Monitoring the delivery of intervention components		X	
<i>Dose received</i>	Participants actively engage with and fully participate in the intervention.	Measuring the extent participants know that interventions are implemented Measuring whether participants engaged in the intervention activities	X X		
<i>Quality of delivery</i>	The intervention is delivered with high quality	Rate process facilitator competence and effort The use of change agents: amount and efforts			X X
Maintenance					
<i>Institutionalization</i>	The intervention is integrated into organizational policies	The amount of trained process facilitators within the organization The extent intervention activities will be available for non-participating departments within the organization		X	X X

Table 1 (continued)

Implementation factor	Goal	Operationalization	Source		
			Questionnaire	Interviews	Re-search Logs
<i>Stakeholder involvement</i>	Stakeholders remain actively involved in sustaining the intervention.	Number of participatory working groups Attendance of working group members during meetings			X
Overarching factors					
<i>Resource availability</i>	Sufficient time, budget, and personnel are allocated for implementation and sustainability.	Monitor resource use and availability through regular check-ins with stakeholders.	X	X	X
<i>Communication quality</i>	Clear, consistent, and effective communication is maintained throughout the intervention.	Keeping track of all communication activities regarding the project.	X		X
<i>Contextual barriers and facilitators</i>	Barriers are minimized, and facilitators are leveraged for success.	Identify contextual factors that may affect outcomes. Track these factors and assess their impact on the intervention		X	X

safety climate, and implementation outcomes will be considered as mediating variables, while personal and socio-demographic characteristics, as well as work characteristics, will be included as confounding factors. Statistical significance will be determined at a two-tailed significance level of $p < 0.05$.

Patient and public involvement

The participatory role of employees in preventive interventions is generally considered a key factor in shaping both the content and the process of the intervention [67]. In their systematic overview of systematic reviews, Aust et al. (2023) [17] highlight the participatory role of employees in several organizational-level interventions to prevent for unfavorable psychosocial work conditions as well as unfavorable health outcomes. The notion that employees should not be viewed as passive recipients of an intervention is endorsed by the WHO guidelines on mental health at work, which recommend organizational interventions that address psychosocial risk factors, including those employing participatory approaches [14]. Because the PA ensures that employees are involved in the development and implementation of interventions, and these interventions are tailored BOC determinants, this is a particularly suitable approach to prevent for both unfavorable psychosocial working conditions and adverse health outcomes. In our participatory framework, employees possess direct and indirect (via the working group) influence over the scope, substance, and execution of intervention activities throughout the risk assessment, action planning, and implementation phases. This involvement increases the likelihood of acceptance and reduces any resistance of employees and management to change [40]. Also more appropriate solutions are created that are better aligned with the practice, the needs and preferences of those directly involved.

Ethics approval and dissemination

The study protocol was approved by the Medical Ethics Committee of Amsterdam UMC. At the beginning of the questionnaire, each participant is asked for consent to participate and to use their responses for this research. Participants are also asked to provide their work email address so that the data can be coded and linked across different measurements. During the coding process, the email address is connected to a unique numerical code. The responses associated with this email address are assigned the same unique code. Each time the questionnaire is completed, we check if the work email address is already in the database. If it is, the new information retains the same code. If the work email address is not in the database, a new unique code is assigned to the email address and the associated responses. An independent researcher from Amsterdam UMC, who is not involved in the project, performs this coding. The email address is used by the researchers solely for this coding process.

The scientific papers that are planned as a result of this project, will be submitted to top quartile, peer reviewed scientific journals. Throughout the project, intermediary results will be shared by the project team within the scientific community, at international conferences.

Abbreviations

BOC	Behavioral, Organizational and Contextual
CG	Control Group
COPSOQ	Copenhagen Psychosocial Questionnaire
DASS-21	Depression Anxiety Stress Scale-21
EU	European Union
FTE	Full-Time Equivalent
HR	Human Resources
HPQ	Health and Work Performance Questionnaire
IG	Intervention Group
JCQ	Job Content Questionnaire
OCQ-C, P, R	Organizational Change Questionnaire—Climate of Change, Processes, and Readiness
PA	Participatory Approach
PSC	Psychosocial Safety Climate

RE-AIM	Reach, Effectiveness - Adoption, Implementation, Maintenance
SES	Socioeconomic Status
SD	Standard Deviation
SMM	Stress Mindset Measure
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
WHO	World Health Organization

Supplementary Information

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Supplementary Material 1

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Author contributions

LB is the primary executor of the project and the cluster randomized controlled trial presented in this study protocol. LB, HA, TJ, AB and RS will participate in the execution and collection of the project's data. All authors contributed to the study conception and design of the intervention strategy. LB wrote the first draft of the manuscript, and the other co-authors (HA, TJ, AB and RS) were involved in reviewing the manuscript. HA, RS, TJ and AB wrote the grant proposal for this study on which the protocol is based; HA is as a principle investigator the recipient of the grant. All authors have read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Medical Ethics Committee of Amsterdam UMC. At the beginning of the questionnaire, each participant is asked for consent to participate and to use their responses for this research. Participants are also asked to provide their work email address so that the data can be coded and linked across different measurements. During the coding process, the email address is connected to a unique numerical code. The responses associated with this email address are assigned the same unique code. Each time the questionnaire is completed, we check if the work email address is already in the database. If it is, the new information retains the same code. If the work email address is not in the database, a new unique code is assigned to the email address and the associated responses. An independent researcher from Amsterdam UMC, who is not involved in the project, performs this coding. The email address is used by the researchers solely for this coding process.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Author details

¹Amsterdam UMC location Vrije Universiteit Amsterdam, Department Public and Occupational Health, De Boelelaan 1117, Amsterdam 1081 HV, The Netherlands

²Amsterdam Public Health Research Institute location Vrije Universiteit Amsterdam, Amsterdam, The Netherlands

³Netherlands Organization for Applied Scientific Research, Unit Health and Work, Sylviusweg 71, Leiden 2333 BE, The Netherlands

⁴Amsterdam University Medical Centre location VUmc, Department of Psychiatry, De Boelelaan 1117, Amsterdam, The Netherlands

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