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Effectiveness of multifactorial and single interventions on safety climate and safe patient handling and movement practices: a cluster randomized controlled trial

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Objective Evidence regarding the effectiveness of safe patient handling and movement (PHM) programs is limited. This study compared the effectiveness of a multifactorial and a single intervention for safe PHM in the Swedish healthcare sector.

Methods This cluster randomized controlled trial included 46 healthcare units (HCU) from Swedish hospital care units and nursing homes, randomized to a multifactorial or single safe PHM intervention. Primary outcomes were changes in safety climate (NOSACQ-50) and PHM specific practices (SafePHM-14) over 12 months, analyzed using mixed models at aggregated HCU level, adjusting for organization type.

Results Overall intervention-group differences were observed for management of safety justice [dimension 3, P=0.048] and workers' safety commitment (dimension 4, P=0.026). However, no significant time × intervention group interactions were observed for any of the seven NOSACQ-50 dimensions or the 14 SafePHM-14 items. Significant time effects were observed in NOSACQ-50 management safety priority and ability (dimension 1, P=0.001), management safety empowerment (dimension 2, P=0.001), workers' safety priority and risk non-acceptance (dimension 5, P=0.008), and peer safety communication, learning, and trust (dimension 6, P<0.001). SafePHM-14 practices improved over time in collaborative effort (item 1, P=0.005), equipment use (item 4, P=0.004), policy and guideline use (items 5–7, all P<0.001), risk assessment (item 8, P<0.001), patient mobility assessment (item 11, P=0.036), training (item 13, P<0.001), and injury prevention discussions (item 14, P<0.001).

Conclusions A multifactorial intervention was not more effective than a single intervention in improving safety climate related to PHM. However, safety climate and PHM practices improved over time in both groups. Given the minimal additional benefit observed, the value of implementing the more resource-intensive multifactorial intervention may be questioned.

Key terms healthcare personnel; occupational health; organizational intervention; patient safety; RCT; safety culture.

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A high prevalence of work-related musculoskeletal disorders (WMSD) has been reported among several healthcare workers (HCW), particularly nurses, assistant nurses and physiotherapists across different countries and healthcare settings (1–4).Work tasks involving patient handling and movement (PHM), such as lifting and repositioning patients, are well known work-related risk factors for WMSD (5–7).

Evidence regarding the effectiveness of safe PHM programs in preventing WMSD remains limited. Studies indicate that programs for safe PHM, particularly those combining assistive equipment with organizational support, may reduce injury rates (8, 9). Practical training in PHM is important, but systematic reviews have shown that training alone is ineffective in preventing WMSD among HCW (10–12). Assistive devices may reduce spinal load and improve handling posture during patient handling (13), while appropriate education and training are needed to support their use (9, 11, 14). This also requires a culture of safety. Visible and committed leadership may play an important role in shaping a positive safety climate, with direct implications for HCW and patient safety outcomes (15, 16). Recent results suggest that interventions incorporating risk assessments may have a positive effect on WMSD (10, 11). HCW and manager engagement and collaboration are also stressed as important components of safe PHM (11). Safe PHM initiatives may benefit from combining educational and ergonomic components, while organizational factors may also be important to consider in future intervention development (14).

Previous research suggests that improving occupational safety and health in healthcare requires attention to organizational-level factors such as work organization, employment conditions, organizational culture, values, and the ethical environment, as these may influence work-related risks and HCW' ability to perform their work at a level of quality they consider acceptable (17). However, the evidence base for the effect of multifactorial PHM interventions is uncertain. Systematic reviews indicate that most previous evaluations of PHM interventions have applied observational or quasi-experimental designs, such as pre-, post-, or single-arm studies with short-term follow-ups (8, 10, 11, 14, 18), limiting both generalizability and the ability to draw causal inferences. Additionally, since moving an intervention from efficacy trials to real-world practice in healthcare workplaces is challenging, evaluations of complex interventions need to incorporate implementation process evaluations within the trial (19, 20).

To address these limitations and contribute to the evidence base, we conducted a cluster randomized controlled trial (RCT) focusing on changes in safety climate over time in safe PHM interventions. This study compared the effectiveness of a multifactorial and a single intervention for safe PHM in the Swedish healthcare sector. Healthcare units (HCU) were the clusters, and the primary outcomes were at the HCU level, including safety climate and PHM practices.

Method

Trial design and setting

This multicenter cluster RCT used a hybrid type 2 design (21) to evaluate the implementation and effectiveness of interventions promoting safe PHM in healthcare settings. The study protocol (22) was registered at ClinicalTrials.gov (NCT05276180). This article reports the effectiveness findings, and was written according to the Consolidated Standards of Reporting Trials (CONSORT) 2010 extension for cluster randomized trials (23). Evaluation of the implementation will be presented elsewhere. In Sweden, regional healthcare mainly comprises hospital care, while municipal healthcare includes nursing homes and other forms of elderly care. The present study included regional hospital care units and municipal nursing homes located in different regions of Sweden. HCU within hospitals and nursing homes were randomly allocated to either a multifactorial intervention or a single intervention. These HCU were defined as clusters.

Sample size calculations were focused on the primary outcome of safety climate, assessed using the Nordic Safety Climate Questionnaire (NOSACQ-50) (24). Assuming a moderate effect size (Cohen's d=0.4), an intracluster correlation coefficient of 0.05, and a significance level of 0.05, we determined that approximately 12 clusters with an average of 15 participants per cluster were required to achieve 80% power. This meant a total of 180 participants. The calculation accounted for potential cluster-level variation and anticipated loss to follow-up, drawing upon prior PHM studies in similar settings and adjusting for the design effect due to clustering.

Participants

HCU were eligible for inclusion if they operated within a hospital or a nursing home and employed HCW who regularly carried out PHM tasks. Hospital inpatient units employing ≥15 HCW qualified for inclusion. Similar, only nursing homes for older adults that met the same minimum staffing threshold were considered eligible. HCU were excluded from participation if they primarily delivered outpatient home nursing services, pediatric care, psychiatric care, or specific branches of emergency care. Additionally, HCU undergoing major

organizational transitions or those already engaged in comparable interventions focusing on safe PHM practices were not eligible for inclusion.

All HCW employed at an included HCU at the time of baseline data collection were invited to participate in the study, regardless of profession, without additional inclusion or exclusion criteria at the individual level. HCW were not required to be the same individuals at each measurement point. All eligible HCW within the participating HCU were invited at each data collection, allowing for normal staff turnover during the study period. All participants received oral and written information about the study and gave informed consent prior to enrollment.

Recruitment and randomization

HCU were identified and recruited in close collaboration with hospital and nursing home managers. Recruitment took place between 1 October 2022 and 15 January 2023. A larger number of HCU were initially contacted about possible participation, but not all proceeded to enrollment. Once an HCU had agreed to participate, HCW received written study information and were informed in person by either the HCU manager or a member of the research team. A statistician produced a data-generated randomization list, stratifying clusters by organization type (hospital care units vs. nursing homes). Allocation was carried out at the cluster level. Blinding was not feasible given the nature of the interventions.

Figure 1 shows the trial flow, with 46 initially randomized HCU. At baseline, 44 HCU (comprising 1214 HCW) completed a questionnaire, reflecting an individual-level response rate of 67%. By the end of the 12-month follow-up, 35 HCU (with 709 HCW) had completed the study, reflecting an individual-level response rate of 50%.

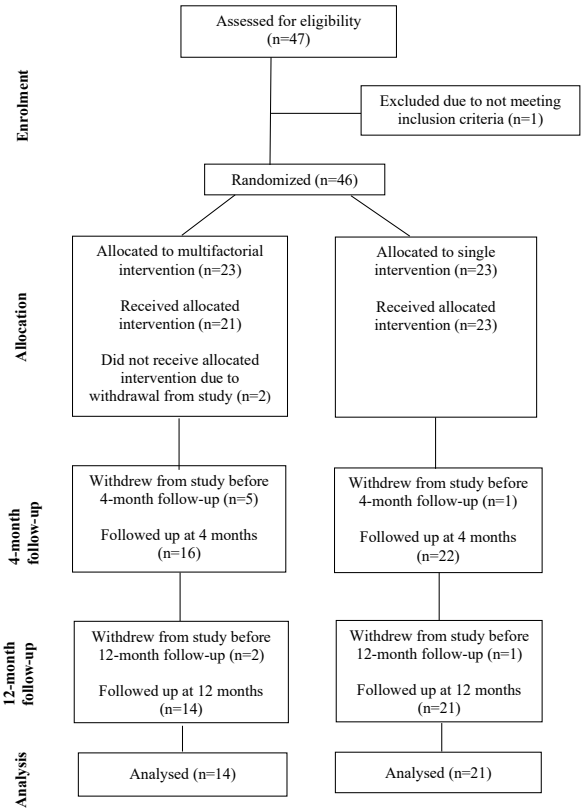


Figure 1. CONSORT diagram showing the flow of care units (clusters) through each stage of the randomized trial.

Interventions

Implementation of the interventions. All participating HCU, regardless of their allocation to the multifactorial or single intervention, began the study with an initial meeting to introduce the interventions and study procedures. The implementation strategy in both intervention arms was based on internal and external facilitation supported by the Integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) framework (25, 26). Each HCU formed an implementation team of 4–8 members, typically including the unit manager, HCW, and safety representatives. These teams were responsible for implementing the intervention locally and supporting adherence to study procedures.

Key persons (external facilitators) employed within the HCU organizations provided ongoing guidance and hands-on support to the implementation teams, helping them work with the safe PHM intervention and address challenges in their own context. The research team primarily provided support to the internal facilitators and was also available to answer study-specific questions from the HCU.

The Swedish research-based guide *Safe patient handling and movement – A research-based guide for a better work environment* was used in both intervention groups. The guide takes a systems and work environment perspective and describes a five-step process including preparation, assessment and analysis, risk assessment, implementation of measures, and follow-up. It focuses on organizational and work environment conditions for safe PHM practices rather than solely on lifting technique (27). All measures identified through the research-based guide were handled within the existing organizational structures of each HCU.

The HCU were encouraged to carry out more activities during the initial phase of the study. Both intervention groups were encouraged to apply the knowledge and recommendations from the guide throughout the 12-month study period. The implementation teams were

instructed to meet at least once a month to plan and carry out activities in accordance with the Swedish research-based guide and the intervention specific instructions described below.

Multifactorial intervention. The intervention comprised five components:

1. Dissemination of the Swedish research-based guide for safe PHM (27): This was facilitated by (i) a pre-recorded digital introduction to the guide, providing all HCW and managers with theoretical knowledge about safe PHM and systematic work environment management; and (ii) two participatory workshops involving the implementation team in each HCU, the external facilitators, and a member of the research team. The workshops focused on systematically identifying and assessing risks related to PHM and jointly developing unit-specific action plans. These plans outlined concrete measures to address identified hazards and improve both the physical and psychosocial work environment, ensuring that interventions were tailored to the organizational context and integrated into existing safety management structures.

2. Risk assessment with the TilThermometer (28, 29): This was conducted once per month during the first four months to assess physical workload and categorize patient mobility levels.

3. Risk assessment with the Downton Fall Risk Index (30): This was conducted once per month during the first four months to identify patients' fall risks.

4. Digital modules and hands-on practical training for safe PHM for all HCW: This included (i) theoretical education on occupational safety and health, risk assessment, and interventions promoting safe PHM, provided by the research group; and (ii) hands-on practical training based on needs identified by the implementation group, typically comprising a half- or full-day session. Practical training was provided by internal staff with competence in PHM and ergonomics or by externally hired professionals. Occupational health services could also be involved at some HCU. The amount of training therefore varied depending on the identified needs of each unit.

5. Use of the Structured Multidisciplinary Work Evaluation Tool (SMET) (31, 32): This tool was used to assess physical, psychosocial, and organizational conditions at the unit, with written feedback on the results provided to and discussed with the manager after each data collection.

Single intervention. The single intervention consisted of dissemination of the research-based guide for safe PHM (27). This was facilitated through a digital introduction, administration of the SMET, and written feedback on the SMET responses, corresponding to the first two sub-steps of the multifactorial intervention.

Outcome measures

The interventions were delivered at the HCU level, and outcomes were assessed through repeated questionnaire measures at baseline, 4 months, and 12 months.

The questionnaire included individual background questions on age, sex, profession, type of employment (full- or part-time), and length of time at the current workplace. It also included questions about daily work routines related to PHM, such as how often the participants performed PHM tasks, if they did them alone or with a colleague, and how often proper equipment was used.

The primary outcome was safety climate, measured using the NOSACQ-50 (24). This validated tool includes 50 items distributed across seven dimensions (i): management safety priority and ability, (ii) management safety empowerment, (iii) management safety justice, (iv) workers' safety commitment, (v) workers' safety priority and risk non-acceptance, (vi) peer safety communication, learning, and trust in co-workers, and (vii) workers' trust in the efficacy of safety systems.

To capture safety aspects and practices specifically related to safe PHM, 14 study-specific items were developed and referred to as the SafePHM-14. The items were informed by existing research, national guidelines, and expert consultation, and were developed using the structure and response format of the NOSACQ-50 as a basis. Each item is rated on a 4-point Likert scale ranging from 1 ("strongly disagree") to 4 ("strongly agree"), consistent with the NOSACQ-50 (24). Higher scores indicate more favorable perceptions or practices related to PHM safety.

The items address areas such as access to work and assistive equipment, workplace policies and guidelines, risk assessment prior to PHM tasks, interprofessional collaboration, training, and preventive discussions related to PHM. The SafePHM-14 has not undergone separate psychometric evaluation and should therefore be considered a study-specific measure of PHM-related practices and safety aspects rather than a validated safety climate measure. The complete item list is provided in the supplementary material (table S1).

Statistical analysis

Descriptive statistics were reported as mean and standard deviation (SD) or frequency and percentage. The inde-

pendent sample t-test was used to compare continuous variables between groups, and the chi-squared test was used to compare categorical variables between groups.

The effectiveness of the multifactorial intervention was evaluated based on improvements in NOSACQ dimensions and SafePHM-14 items. Although the questionnaire responses came from individual HCW, the regression analyses of the NOSACQ-50 and SafePHM-14 were performed at the aggregated level of the HCU, since the data collection did not allow tracking of changes within individuals over time.

The statistical analysis of each study outcome (7 NOSACQ-50 dimensions and 14 SafePHM-14 items) was performed using a linear mixed model with intervention group (multifactorial versus single intervention) and organization type (regional versus municipal) as fixed variables, with occasions nested within HCU, and the two-way interactions between time and intervention and between time and organization type. The regression model was adjusted for the fixed effect of organization type, to control for differences between hospital care and nursing homes.

Intraclass correlation coefficients for aggregated values were calculated to understand how much of the variance was related to the HCU level. Marginal and conditional pseudo R^2 values were used to describe the proportion of variance explained by fixed effects and the full model.

A dropout analysis was performed at the individual and HCU level. The inclusion criterion of ≥15 HCW referred to the number of HCW employed at the HCU at study inclusion, not the number of questionnaire respondents at each measurement point. For the final analyses, only HCU with ≥10 respondents per time point were included to ensure reliability of the aggregated scores. A sensitivity analysis excluding HCU with >15 respondents showed minimal differences in the main results.

All analyses were performed using SPSS v.28 (IBM Corp, Armonk, NY, USA). Confidence intervals (CI) were calculated at the 95% level of significance. All statistical tests were two-sided, and a P-value <0.05 was considered indicative of statistical significance.

Results

Participant characteristics

At baseline, 44 clusters were included in the trial, with a mean of 32 HCW per unit. Most participants were women (89%) and assistant nurses (69%). Of the participants, 42% worked in hospital care units and 58% in nursing homes. The mean age was 45.5 [standard deviation (SD) 13.0] years, 85% worked full-time, and more than half had worked for >5 years at their current workplace. Participant characteristics were broadly similar between the intervention groups at baseline. However, the proportion of individual participants recruited from hospital care units and nursing homes differed between the groups (table 1). This difference at the individual level mainly reflected differences in cluster size between the included HCU. At the cluster level, 6 hospital care units and 13 nursing homes were randomized to the multifactorial intervention, and 11 hospital care units and 14 nursing homes to the single intervention. For participants characteristics in four months follow-up, see supplementary table S2.

Dropout rates differed between intervention types and HCU affiliations. Two HCU withdrew after randomization but before baseline data collection. As no baseline data were available for these HCU, they were not included in analyses requiring baseline data but were included in the overall number of HCU withdrawals. In the multifactorial intervention group, 9 of 23 HCU (39.1%) withdrew during the study, including 2 who withdrew before participating in the intervention and completing the baseline assessment compared with 2 of 23 HCU (8.7%) in the single intervention group (P=0.043). The main reason for dropout was for example, shift in management, in general heavy workload, poor organizational preresquistes and to resource- demanding intervention in the multifactorial intervention.

Cluster-level characteristics include number of clusters, organization type, and HCW per cluster. Individual-level characteristics include gender, age, profession, employment rate, years at workplace, and overtime frequency. P-values are provided for descriptive purposes only, based on chi-square or independent samples t-tests where appropriate. No adjustments for multiple comparisons were made, and no clinically relevant differences were observed between groups.

Primary outcomes

As shown in tables 2 and 3, several dimensions of the safety climate (NOSACQ-50) and safety aspects of PHM (SafePHM-14) demonstrated statistically significant results over the study period.

Safety climate (NOSACQ-50)

Comparing the intervention groups, a significant main effect of group was detected in favor of the multifactorial group in management safety justice (dimension 3, P=0.048) and workers' safety commitment (dimension 4, P=0.026). In the multifactorial group, management safety priority, commitment and competence (dimension 1) improved from a mean of 3.31 (SD 0.18) at baseline

Table 1. Characteristics of participating healthcare workers (HCW) and clusters at baseline and 12 months, divided by intervention group.[a] [SD=standard deviation.]

	Baseline						12 months					
	Total (N=44)		Multifactorial (N=21)		Single (N=23)		Total (N=35)		Multifactorial (N=14)		Single (N=21)	
	N (%)	N (SD)	N (%)	N (SD)	N (%)	N (SD)	N (%)	N (SD)	N (%)	N (SD)	N (%)	N (SD)
HCW per cluster		32 (11.9)		31.4 (13.5)		32.49 (10.4)		21.5 (9.1)		29.4 (11.9)		27.3 (10.0)
Organization												
Municipality (nursing homes)	704 (58.0)		350 (63.6) [b]		354 (53.3) [b]		378 (53.2)		151 (51.7)		227 (54.4)	
Region (hospital care	510 (42.0)		200 (36.4)		310 (46.7)		331 (46.7)		141 (48.3)		190 (45.6)	
Gender												
Male	129 (10.6)		58 (10.5)		71 (10.7)		64 (8.9)		27 (9.2)		37 (8.9)	
Female	1081 (89.0)		489 (88.9)		592 (89.2)		641 (89.7)		262 (89.7)		379 (90.9)	
Prefer not to disclose	4 (0.3)		3 (0.5)		1 (0.2)		4 (0.5)		1 (0.3)		-	
Missing							6 (0.8)		2 (0.7)		1 (0.2)	
Age		44.9 (12.8)		45.5 (13.0)		44.3 (12.7)		45.3 (12.5)		45.3 (13.4)		45.3 (11.8)
Missing			2		7		9		2			
Profession												
Assistant nurse	833 (68.6)		375 (68.2)		458 (69.0)		513 (68.9)		202 (69.2)		311 (74.6)	
Nurse	208 (17.1)		95 (17.3)		113 (17.0)		122 (16.9)		59 (20.2)		63 (15.1)	
Physiotherapist	29 (2.4)		15 (2.7)		14 (2.1)		15 (2.0)		5 (1.7)		10 (2.4)	
Occupational therapist	29 (2.4)		13 (2.4)		16 (2.4)		13 (1.8)		6 (2.1)		7 (1.7)	
Counsellor	2 (0.2)		1 (0.2)		1 (0.2)		2 (0.3)		2		-	
Care assistant	62 (5.1)		33 (6.0)		29 (4.4)		19 (2.7)		10 (3.4)		9 (2.2)	
Other	51 (4.2)		18 (3.3)		33 (5.0)		53 (7.5)		23 (7.9)		34 (8.2)	
Missing	-		-		-		-		-		-	
Employment rate (%)												
0–25	2 (0.2)		2 (0.4)		-		2 (0.3)		-		2 (0.5)	
26–50	20 (1.6)		8 (1.5)		12 (1.8)		11 (1.5)		6 (2.1)		5 (1.2)	
51–75	112 (9.2)		52 (9.5)		60 (9.0)		53 (7.0)		15 (5.1)		38 (9.1)	
76–100	1035 (85.3)		470 (85.5)		565 (85.1)		630 (87.3)		266 (91.1)		364 (87.3)	
Hourly employee,	26 (2.1)		13 (2.4)		13 (2.0)		6 (0.6)		1 (0.3)		5 (1.2)	
Agency staff	19 (1.6)		5 (0.9)		14 (2.1)		7 (1.0)		4 (1.4)		3 (0.7)	
Years at workplace												
0–2	316 (26.0)		141 (25.6)		175 (26.4)		185 (26.1)		77 (26.4)		108 (25.9)	
2–5	259 (21.3)		108 (19.6)		151 (22.7)		147 (20.7)		54 (18.5)		93 (22.3)	
5–10	268 (22.1)		118 (21.5)		150 (22.6)		153 (21.6)		69 (23.6)		84 (20.1)	
>10	371 (30.6)		183 (33.3)		188 (28.3)		224 (31.6)		92 (31.5)		132 (31.7)	
Overtime												
Never	175 (14.4)		92 (16.7)		83 (12.5)		97 (13.7)		38 (13.0)		59 (14.1)	
Occasionally	697 (57.4)		321 (58.4)		376 (56.6)		454 (64.0)		187 (64.0)		267 (64.0)	
Once a month	235 (19.4)		94 (17.1)		141 (21.2)		123 (17.3)		50 (17.1)		73 (17.5)	
Several times per month	83 (6.8)		31 (5.6)		52 (7.8)		26 (3.7)		11 (3.8)		15 (3.6)	
No regulated working hours	13 (1.1)		9 (1.6)		4 (0.6)		9 (1.3)		6 (2.1)		3 (0.7)	
Missing	11 (0.9)		3 (0.5)		8 (1.2)		-		-		-	

[a] Cluster-level characteristics include number of clusters, organization type, and HCW per cluster. Individual-level characteristics include gender, age, profession, employment rate, years at workplace, and overtime frequency. P-values are provided for descriptive purposes only, based on chi-square or independent samples t-tests where appropriate. No adjustments for multiple comparisons were made, and no clinically relevant differences were observed between groups.

[b] P<0.05

to 3.48 at 12 months, corresponding to a mean difference of +0.17 [95% confidence interval (CI) 0.03–0.30, P=0.015], table 2.

Statistically significant main effects of time across all participants were observed in management safety priority, commitment, and competence (dimension 1, P=0.001), management safety empowerment (dimension 2, P=0.001), workers' safety priority and risk non-acceptance (dimension 5, P=0.008), and safety communication, learning, and trust in co-workers' safety competence (dimension 6, P<0.001). These dimensions showed a positive development across the 12-month follow-up period. No significant time effect was found for management safety justice (dimension 3, P=0.398), workers' safety commitment (dimension 4, P=0.316), or trust in the efficacy of safety systems (dimension 7, P=0.063).

PHM-specific practices (SafePHM-14)

No overall intervention group effect was seen across most of the SafePHM-14 practices, table 3. A significant intervention-group difference was observed for the reported presence of a fixed ceiling lift where needed

Table 2. Nordic safety climate questionnaire (NOSACQ-50) dimensions 1–7 at baseline, 4 months (time 1), and 12 months (time 2), stratified by intervention group (multifactorial versus single intervention) and healthcare organization type (regional versus municipal). [SD=standard deviation; Ref=reference category for baseline comparisons].

	Overall groups		Intervention group				Healthcare unit organization			
			Multifactorial		Single		Regional healthcare		Municipal healthcare	
	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value
NOSACQ-50 dimension 1: management safety priority and ability										
Overall effect of intervention group [a]		0.413								
Overall effect of organization type [a]		0.027 *								
Overall effect of time [a]		0.001 **								
Time × intervention group [a]		0.409								
Time × organization type [a]		0.015 *								
Baseline	3.28 (0.18)	Ref	3.31 (0.18)	Ref	3.26 (0.18)	Ref	3.25 (0.18)	Ref	3.31 (0.19)	Ref
Time 1	3.33 (0.20)	0.523 [b]	3.31 (0.22)	0.965 [b]	3.34 (0.19)	0.064 [b]	3.29 (0.2)	0.590 [b]	3.36 (0.2)	0.198 [b]
Time 2	3.42 (0.22)	0.226 [b]	3.48 (0.14)	0.015 [b,*]	3.39 (0.26)	0.004 [b,**]	3.3 (0.22)	0.478 [b]	3.53 (0.16)	<0.001 [b,**]
NOSACQ-50 dimension 2: management safety empowerment										
Overall effect of intervention group [a]		0.132								
Overall effect of organization type [a]		0.463								
Overall effect of time [a]		0.001 **								
Time × intervention group [a]		0.813								
Time × organization type [a]		0.024 *								
Baseline	3.28 (0.18)	Ref	3.28 (0.17)	Ref	3.27 (0.17)	Ref	3.28 (0.17)	Ref	3.27 (0.17)	Ref
Time 1	3.33 (0.20)	0.16 [b]	3.37 (0.18)	0.077 [b]	3.34 (0.19)	0.06 [b]	3.36 (0.19)	0.111 [b]	3.35 (0.18)	0.038 [b,*]
Time 2	3.42 (0.22)	0.707 [b]	3.45 (0.16)	0.006 [b,**]	3.36 (0.23)	0.018 [b,*]	3.33 (0.23)	0.409 [b]	3.47 (0.17)	<0.001 [b,**]
NOSACQ-50 dimension 3: management safety justice										
Overall effect of intervention group [a]		0.048 *								
Overall effect of organization type [a]		0.87								
Overall effect of time [a]		0.398								
Time × intervention group [a]		0.331								
Time × organization type [a]		0.007 **								
Baseline	3.46 (0.16)	Ref	3.46 (0.16)	Ref	3.46 (0.16)	Ref	3.51 (0.13)	Ref	3.43 (0.17)	Ref
Time 1	3.47 (0.18)	0.579 [b]	3.48 (0.17)	0.999 [b]	3.46 (0.19)	0.949 [b]	3.48 (0.2)	0.565 [b]	3.46 (0.17)	0.541 [b]
Time 2	3.51 (0.30)	0.050 [b,*]	3.62 (0.12)	0.101 [b]	3.45 (0.36)	0.896 [b]	3.43 (0.41)	0.201 [b]	3.59 (0.13)	0.001 [b,**]
NOSACQ-50 dimension 4: workers' safety commitment										
Overall effect of intervention group [a]		0.026 *								
Overall effect of organization type [a]		0.077								
Overall effect of time [a]		0.316								
Time × intervention group [a]		0.988								
Time × organization type [a]		0.38								
Baseline	3.44 (0.15)	Ref	3.47 (0.15)	Ref	3.41 (0.16)	Ref	3.39 (0.15)	Ref	3.46 (0.15)	Ref
Time 1	3.43 (0.17)	782 [b]	3.47 (0.18)	0.926 [b]	3.41 (0.16)	0.987 [b]	3.38 (0.17)	0.804 [b]	3.48 (0.16)	0.703 [b]
Time 2	3.49 (0.28)	0.953 [b]	3.54 (0.14)	0.4 [b]	3.46 (0.35)	0.261 [b]	3.41 (0.4)	0.992 [b]	3.56 (0.11)	0.039 [b,*]
NOSACQ-50 dimension 5: workers' safety priority and risk non-acceptance										
Overall effect of intervention group [a]		0.969								
Overall effect of organization type [a]		0.902								
Overall effect of time [a]		0.008 **								
Time × intervention group [a]		0.314								
Time × organization type [a]		0.004 **								
Baseline	3.11 (0.19)	Ref	3.12 (0.19)	Ref	3.09 (0.19)	Ref	3.16 (0.18)	Ref	3.07 (0.18)	Ref
Time 1	3.18 (0.21)	0.227	3.15 (0.22)	0.933	3.19 (0.21)	0.029 *	3.2 (0.21)	0.685 [b]	3.16 (0.22)	0.068
Time 2	3.25 (0.23)	0.491	3.25 (0.21)	0.199	3.26 (0.26)	<0.001 **	3.18 (0.18)	0.954 [b]	3.31 (0.26)	<0.001 **
NOSACQ-50 dimension 6: peer safety communication, learning, and trust in co-workers										
Overall effect of intervention group [a]		0.085								
Overall effect of organization type [a]		0.011 *								
Overall effect of time [a]		<0.001 **								
Time × intervention group [a]		0.915								
Time × organization type [a]		0.066								
Baseline	3.44 (0.15)	Ref	3.47 (0.13)	Ref	3.42 (0.17)	Ref	3.39 (0.17)	Ref	3.48 (0.14)	Ref
Time 1	3.47 (0.19)	0.476 [b]	3.48 (0.18)	0.658 [b]	3.46 (0.19)	0.248 [b]	3.41 (0.16)	0.618 [b]	3.51 (0.2)	0.276 [b]
Time 2	3.57 (0.2)	0.128 [b]	3.6 (0.14)	0.007 [b,**]	3.55 (0.24)	<0.001 [b,**]	3.47 (0.23)	0.126 [b]	3.66 (0.13)	<0.001 [b,**]
NOSACQ-50 dimension 7: workers' trust in the efficacy of safety systems										
Overall effect of intervention group [a]		0.185								
Overall effect of organization type [a]		0.085								
Overall effect of time [a]		0.063								
Time × intervention group [a]		0.516								
Time × organization type [a]		0.053								
Baseline	3.59 (0.11)	Ref	3.59 (0.12)	Ref	3.6 (0.1)	Ref	3.57 (0.08)	Ref	3.61 (0.12)	Ref
Time 1	3.53 (0.17)	0.126 [b]	3.55 (0.19)	0.604 [b]	3.52 (0.15)	0.022 [b,*]	3.51 (0.15)	0.19 [b]	3.55 (0.18)	0.165 [b]
Time 2	3.6 (0.18)	0.061 [b]	3.62 (0.13)	0.471 [b]	3.58 (0.21)	0.778 [b]	3.53 (0.22)	0.23 [b]	3.66 (0.12)	0.054 [b]

[a] Overall effects of intervention group, organization type, time, and interaction terms (time × intervention group; time × organization type) are based on linear mixed-effects models adjusted for clustering at the healthcare unit level.

[b] Time 1 and Time 2 P-values represent model-based within-group comparisons with baseline as the reference category.

* P<0.05.

** P<0.01.

Table 3. Safephm-14 items at baseline, 4 months (time 1), and 12 months (time 2), stratified by intervention group (multifactorial versus single intervention) and healthcare organization type (regional versus municipal). [Ref=reference category for baseline comparisons, SD=standard deviation]

	Overall groups		Intervention group				Healthcare unit organization			
			Multifactorial		Single		Regional healthcare		Municipal healthcare	
	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value
SafePHM-14 item 1										
Overall effect of intervention group [a]		0.131								
Overall effect of organization type [a]		0.011 *								
Overall effect of time [a]		0.005 **								
Time × intervention group [a]		0.194								
Time × organization type [a]		0.043 *								
Baseline	3.43 (0.18)	Ref	3.42 (0.2)	Ref	3.45 (0.17)	Ref	3.39 (0.1)	Ref	3.46 (0.22)	Ref
Time 1	3.47 (0.22)	0.915 [b]	3.51 (0.2)	0.19 [b]	3.44 (0.24)	0.969 [b]	3.42 (0.18)	0.581 [b]	3.51 (0.25)	0.397 [b]
Time 2	3.58 (0.34)	0.632 [b]	3.68 (0.17)	0.001 [b,**]	3.52 (0.41)	0.25 [b]	3.42 (0.43)	0.498 [b]	3.72 (0.14)	<0.001 [b,**]
SafePHM-14 item 2										
Overall effect of intervention group [a]		0.658								
Overall effect of organization type [a]		0.018 *								
Overall effect of time [a]		0.374								
Time × intervention group [a]		0.958								
Time × organization type [a]		0.133								
Baseline	3.64 (0.16)	Ref	3.64 (0.14)	Ref	3.64 (0.17)	Ref	3.58 (0.15)	Ref	3.68 (0.15)	Ref
Time 1	3.61 (0.22)	0.937 [b]	3.62 (0.18)	0.922 [b]	3.6 (0.25)	0.603 [b]	3.58 (0.23)	0.93 [b]	3.63 (0.22)	0.456 [b]
Time 2	3.69 (0.34)	0.778 [b]	3.7 (0.18)	0.506 [b]	3.69 (0.42)	0.448 [b]	3.56 (0.45)	0.765 [b]	3.81 (0.15)	0.063 [b]
SafePHM-14 item 3										
Overall effect of intervention group [a]		0.034 *								
Overall effect of organization type [a]		0.163								
Overall effect of time [a]		0.469								
Time × intervention group [a]		0.844								
Time × organization type [a]		0.37								
Baseline	3.06 (0.95)	Ref	2.67 (1.04)	Ref	3.41 (0.72)	Ref	3.34 (0.54)	Ref	2.88 (1.11)	Ref
Time 1	3.05 (0.96)	0.414 [b]	2.66 (1.05)		3.34 (0.79)	0.925 [b]	3.28 (0.54)	0.546 [b]	2.87 (1.18)	0.854 [b]
Time 2	3.16 (0.96)	0.458 [b]	2.76 (1.05)		3.43 (0.81)	0.429 [b]	3.29 (0.61)	0.655 [b]	3.05 (1.18)	0.131 [b]
SafePHM-14 item 4										
Overall effect of intervention group [a]		0.82								
Overall effect of organization type [a]		0.003 **								
Overall effect of time [a]		0.004 **								
Time × intervention group [a]		0.766								
Time × organization type [a]		0.091								
Baseline	3.57 (0.19)	Ref	3.57 (0.18)	Ref	3.57 (0.21)	Ref	3.51 (0.21)	Ref	3.6 (0.18)	Ref
Time 1	3.52 (0.28)	0.332 [b]	3.51 (0.33)	0.351 [b]	3.52 (0.25)	0.427 [b]	3.44 (0.24)	0.241 [b]	3.58 (0.3)	0.612 [b]
Time 2	3.68 (0.23)	0.817 [b]	3.7 (0.18)	0.066 [b]	3.67 (0.26)	0.176 [b]	3.52 (0.2)	0.914 [b]	3.81 (0.15)	0.001 [b,**]
SafePHM-14 item 5										
Overall effect of intervention group [a]		0.911								
Overall effect of organization type [a]		0.001 **								
Overall effect of time [a]		<0.001 **								
Time × intervention group [a]		0.909								
Time × organization type [a]		0.654								
Baseline	3.38 (0.23)	Ref	3.37 (0.21)	Ref	3.39 (0.25)	Ref	3.29 (0.24)	Ref	3.44 (0.21)	Ref
Time 1	3.4 (0.27)	0.976 [b]	3.38 (0.24)	0.764 [b]	3.41 (0.3)	0.594 [b]	3.29 (0.29)	0.911 [b]	3.49 (0.23)	0.31 [b]
Time 2	3.56 (0.22)	0.088 [b]	3.54 (0.17)	0.006 [b,**]	3.57 (0.26)	0.006 [b,**]	3.44 (0.21)	0.038 [b,*]	3.66 (0.18)	<0.001 [b,**]
SafePHM-14 item 6										
Overall effect of intervention group [a]		0.362								
Overall effect of organization type [a]		<0.001 **								
Overall effect of time [a]		<0.001 **								
Time × intervention group [a]		0.639								
Time × organization type [a]		0.194								
Baseline	3.21 (0.39)	Ref	3.26 (0.39)	Ref	3.17 (0.4)	Ref	2.81 (0.26)	Ref	3.46 (0.21)	Ref
Time 1	3.22 (0.39)	0.184 [b]	3.28 (0.42)	0.126 [b]	3.18 (0.38)	0.728 [b]	2.96 (0.3)	0.042 [b,*]	3.44 (0.33)	0.782 [b]
Time 2	3.39 (0.37)	0.003 [b,**]	3.4 (0.27)	0.003 [b,**]	3.38 (0.43)	0.004 [b,**]	3.11 (0.34)	<0.001 [b,**]	3.63 (0.19)	0.024 [b,*]
SafePHM-4 item 7										
Overall effect of intervention group [a]		0.827								
Overall effect of organization type [a]		<0.001 **								
Overall effect of time [a]		<0.001 **								
Time × intervention group [a]		0.87								
Time × organization type [a]		0.834								
Baseline	3.13 (0.35)	Ref	3.14 (0.36)	Ref	3.12 (0.35)	Ref	2.82 (0.25)	Ref	3.32 (0.25)	Ref
Time 1	3.26 (0.39)	0.159 [b]	3.28 (0.38)	0.016 [b,*]	3.24 (0.41)	0.042 [b,*]	2.96 (0.36)	0.064 [b]	3.51 (0.2)	0.008 [b,**]
Time 2	3.45 (0.38)	<0.001 [b,**]	3.43 (0.3)	<0.001 [b,**]	3.46 (0.43)	<0.001 [b,**]	3.2 (0.38)	<0.001 [b,**]	3.66 (0.22)	<0.001 [b,**]
SafePHM-14 item 8										
Overall effect of intervention group [a]		0.589								
Overall effect of organization type [a]		<0.001 **								
Overall effect of time [a]		<0.001 **								
Time × intervention group [a]		0.348								
Time × organization type [a]		0.17								
Baseline	2.81 (0.45)	Ref	2.81 (0.51)	Ref	2.82 (0.39)	Ref	2.41 (0.29)	Ref	3.07 (0.32)	Ref
Time 1	2.98 (0.43)	0.003 [b,**]	2.93 (0.47)	0.021 [b,*]	3.02 (0.4)	0.016 [b,*]	2.75 (0.38)	<0.001 [b,**]	3.17 (0.38)	0.244 [b]
Time 2	3.14 (0.41)	0.001 [b,**]	3.18 (0.38)	<0.001 [b,**]	3.12 (0.44)	0.001 [b,**]	2.85 (0.35)	<0.001 [b,**]	3.39 (0.26)	<0.001 [b,**]
SafePHM-14 item 9										
Overall effect of intervention group [a]		0.191								
Overall effect of organization type [a]		0.002 **								
Overall effect of time [a]		0.26								
Time × intervention group [a]		0.733								
Time × organization type [a]		0.11								

Continues

Table 3. continued.

	Overall groups		Intervention group				Healthcare unit organization			
			Multifactorial		Single		Regional healthcare		Municipal healthcare	
	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value	Mean (SD)	P-value
Baseline	3.6 (0.16)	Ref	3.62 (0.13)	Ref	3.58 (0.18)	Ref	3.52 (0.16)	Ref	3.65 (0.13)	Ref
Time 1	3.62 (0.22)	0.604 [b]	3.63 (0.23)	0.815 [b]	3.62 (0.21)	0.514 [b]	3.55 (0.19)	0.69 [b]	3.67 (0.23)	0.643 [b]
Time 2	3.67 (0.33)	0.644 [b]	3.74 (0.16)	0.154 [b]	3.63 (0.41)	0.4 [b]	3.51 (0.43)	0.887 [b]	3.81 (0.13)	0.009 [b,**]
SafePHM-14 item 10										
Overall effect of intervention group [a]		0.421								
Overall effect of organization type [a]		<0.001 **								
Overall effect of time [a]		0.149								
Time × intervention group [a]		0.409								
Time × organization type [a]		0.278								
Baseline	3.66 (0.16)	Ref	3.71 (0.13)	Ref	3.62 (0.18)	Ref	3.57 (0.18)	Ref	3.71 (0.12)	Ref
Time 1	3.66 (0.19)	0.171 [b]	3.65 (0.17)	0.528 [b]	3.67 (0.2)	0.22 [b]	3.62 (0.18)	0.514 [b]	3.7 (0.2)	0.792 [b]
Time 2	3.72 (0.2)	0.484 [b]	3.76 (0.17)	0.287 [b]	3.7 (0.21)	0.102 [b]	3.61 (0.21)	0.551 [b]	3.82 (0.12)	0.030 [b,*]
SafePHM-14 item 11										
Overall effect of intervention group [a]		0.421								
Overall effect of organization type [a]		0.012*								
Overall effect of time [a]		0.036*								
Time × intervention group [a]		0.903								
Time × organization type [a]		0.588								
Baseline	3.62 (0.14)	Ref	3.63 (0.14)	Ref	3.61 (0.14)	Ref	3.57 (0.11)	Ref	3.65 (0.15)	Ref
Time 1	3.65 (0.16)	0.703 [b]	3.68 (0.15)	0.33 [b]	3.63 (0.16)	0.595 [b]	3.6 (0.16)	0.505 [b]	3.69 (0.15)	0.375 [b]
Time 2	3.71 (0.2)	0.301 [b]	3.71 (0.17)	0.092 [b]	3.7 (0.22)	0.044 [b,*]	3.63 (0.22)	0.264 [b]	3.77 (0.15)	0.008 [b,**]
SafePHM-14 item 12										
Overall effect of intervention group [a]		0.324								
Overall effect of organization type [a]		0.035*								
Overall effect of time [a]		0.249								
Time × intervention group [a]		0.965								
Time × organization type [a]		0.328								
Baseline	3.68 (0.16)	Ref	3.7 (0.16)	Ref	3.67 (0.16)	Ref	3.66 (0.14)	Ref	3.69 (0.17)	Ref
Time 1	3.71 (0.19)	0.946 [b]	3.72 (0.21)	0.748 [b]	3.7 (0.18)	0.519 [b]	3.66 (0.18)	0.965 [b]	3.74 (0.19)	0.869 [b]
Time 2	3.75 (0.18)	0.956 [b]	3.77 (0.12)	0.248 [b]	3.73 (0.21)	0.225 [b]	3.67 (0.22)	0.903 [b]	3.81 (0.11)	0.28 [b]
SafePHM-14 item 13										
Overall effect of intervention group [a]		0.21								
Overall effect of organization type [a]		<0.001 **								
Overall effect of time [a]		<0.001 **								
Time × intervention group [a]		0.918								
Time × organization type [a]		0.044 *								
Baseline	2.8 (0.53)	Ref	2.82 (0.52)	Ref	2.79 (0.55)	Ref	2.53 (0.46)	Ref	2.97 (0.52)	Ref
Time 1	2.97 (0.54)	0.696 [b]	2.98 (0.49)	0.035 [b,*]	2.96 (0.59)	0.065 [b]	2.6 (0.47)	0.488 [b]	3.27 (0.39)	<0.001 [b,**]
Time 2	3.23 (0.42)	<0.001 [b,**]	3.14 (0.37)	<0.001 [b,**]	3.28 (0.45)	<0.001 [b,**]	3.07 (0.45)	<0.001 [b,**]	3.35 (0.36)	<0.001 [b,**]
SafePHM-14 item 14										
Overall effect of intervention group [a]		0.488								
Overall effect of organization type [a]		<0.001 **								
Overall effect of time [a]		<0.001 **								
Time × intervention group [a]		0.661								
Time × organization type [a]		0.293								
Baseline	2.86 (0.37)	Ref	2.87 (0.36)	Ref	2.84 (0.39)	Ref	2.55 (0.24)	Ref	3.05 (0.31)	Ref
Time 1	3.03 (0.37)	0.035 [b,*]	3.04 (0.41)	0.004 [b,**]	3.02 (0.35)	0.008 [b,**]	2.75 (0.26)	0.011 [b,*]	3.25 (0.28)	0.002 [b,**]
Time 2	3.28 (0.35)	<0.001 [b,**]	3.29 (0.31)	<0.001 [b,**]	3.27 (0.38)	<0.001 [b,**]	3.09 (0.35)	<0.001 [b,**]	3.44 (0.26)	<0.001 [b,**]

[a] Overall effects of intervention group, organization type, time, and interaction terms (time × intervention group; time × organization type) are based on linear mixed-effects models adjusted for clustering at the healthcare unit level.

[b] Time 1 and Time 2 P-values represent model-based within-group comparisons with baseline as the reference category.

* P<0.05.

** P<0.01.

(item 3, P=0.034), with higher scores in the single intervention group.

Several PHM-specific practices such as safety behaviors and routines showed statistically significant improvement over time. Significant main effects of time were found for items related to collaborative effort (item 1, P=0.005), use of equipment (item 4, P=0.004), policy and guideline use (items 5–7, all P<0.001), risk assessment before PHM (item 8, P<0.001), assessment of patient mobility (item 11, P=0.036), training in PHM (item 13, P<0.001), and discussions to prevent injuries (item 14, P<0.001).

Model performance

Model diagnostics showed good overall fit. Intraclass correlation coefficients for aggregated values ranged from 0.13 to 0.56 across models, indicating moderate to substantial clustering of the different outcomes at the HCU level. Marginal R^2 pseudo values (fixed effects) ranged from 0.08 to 0.52, and conditional pseudo R^2 (fixed + random effects) reached as high as 0.94.

Sensitivity analysis

A sensitivity analysis excluding HCU with fewer than 15 participants had minimal impact on the results. The main

findings comparing the multifactorial and single interventions at 12 months remained robust, except that management safety justice (dimension 3) lost statistical significance. The general pattern of change over time persisted, with the largest changes observed in management safety priority, commitment and competence (dimension 1), management safety empowerment (dimension 2), and safety communication, learning and trust in co-workers' safety competence (dimension 6), while workers' trust in the efficacy of safety systems (dimension 7) showed little change. Time effects remained significant for six dimensions ($P<0.05$), and method and interaction effects were generally non-significant, indicating that improvements occurred independently of intervention type.

Discussion

The overall aim of this cluster RCT was to compare the effectiveness of a multifactorial and a single intervention in promoting safe PHM in hospital care units and nursing homes in the Swedish healthcare sector, using safety climate and safety aspects of PHM as primary effectiveness outcomes. Three principal findings emerged. First, statistically significant between-group differences were observed for NOSACQ-50 management safety priority and justice (dimension 3) and workers' safety commitment (dimension 4), favoring the multifactorial intervention. For the SafePHM-14 items, only the reported presence of a fixed ceiling lift where needed (item 3) differed significantly between the intervention groups at both baseline and the 12-month follow-up. No other statistically significant differences between the multifactorial and the single intervention were observed in safety climate outcomes during follow-up. Second, several safety climate dimensions (NOSACQ-50) and safety aspects of PHM (SafePHM-14 items) improved over time, regardless of which intervention the HCU underwent. Third, the findings provide insights into the implementation of a cluster design with two active interventions in routine healthcare settings, including the assessment of safety climate and PHM practices at the organizational level. However, challenges related to cluster retention should be considered.

Contrary to our hypothesis that a multifactorial intervention would produce larger improvements, we observed no superiority of the multifactorial intervention over the single intervention in terms of our primary outcome. At the same time, systematic reviews show that multifactorial PHM programs combining ergonomic equipment, structured risk assessments, training, and organizational reinforcement tend to give better and more long-lasting results than single interventions such as stand-alone practical education (8, 10, 11). Detailed information on specific measures and the implementation process was collected as part of the process evaluation and will be analyzed separately. In PHM research, interventions are often complex (equipment, training, local routines, leadership, and follow-up), and systematic reviews emphasize heterogeneity in both components and outcomes, making the benefits of "more components" difficult to demonstrate across contexts (8).

The decision to provide all HCU with at least an evidence-based intervention likely contributed to overall improvements; this was an ethically motivated design choice, but one that narrows contrasts between intervention arms, as previously described (33). An important consideration is the use of the safe PHM guideline (27), which was available to both arms and may have led single-intervention HCU to adopt elements similar to the multifactorial arm and thereby reduced between-group contrasts. Given that safety climate change tends to develop gradually, previous research has found that larger clinical effects might be expected with extended follow-up and continued leadership and organizational reinforcement (34, 35).

Differences in SafePHM practices were observed between hospital care units and nursing homes, indicating that organizational context should be considered when interpreting the findings. For some outcomes, significant time × organization type interactions were also observed, suggesting that patterns of change may differ between healthcare settings.

Safe PHM should be understood from a broader systems perspective, where patient characteristics, healthcare worker capacity, task demands, assistive equipment, the physical environment, staffing, and organizational conditions interact and influence patient handling (36). In addition, physical workload should not be understood simply in terms of being safe or harmful, as responses to physical demands are influenced by individual, psychosocial, and work-related factors (37). This broader perspective is relevant when interpreting PHM practices and their variation across organizational settings.

Safety climate scores and several PHM-specific practices improved over time in both intervention groups. However, as the study did not include a usual-care or no-intervention comparator, these changes cannot be attributed specifically to the interventions. Previous studies of safe PHM programs have reported favorable changes in PHM practices and work-related outcomes, although the evidence remains mixed and varies considerably across study designs and settings (38–41).

Changes in PHM practices should also be interpreted in relation to the organizational context. The use of assistive equipment and safe PHM routines may be influenced by factors such as workload, availability of equipment, local routines, and organizational support

(42, 43). The observed differences between organizational settings in the present study further suggest that local context may be important when implementing and evaluating safe PHM practices. By assessing outcomes at the HCU level, this study also contributes an organizational perspective to a field in which outcomes have often been evaluated at the individual level (10, 11).

Methodological considerations

A strength of this study is the use of NOSACQ-50, a standardized safety climate instrument with evidence of reliability and validity (24). However, PHM is a specific work task influenced by factors at both the individual and organizational levels. Combining a general safety climate instrument with PHM-specific items was therefore considered relevant for capturing changes in PHM practices. Moda et al. (44) used NOSACQ-50 in a cross-sectional healthcare sample, demonstrating its applicability in healthcare, although the study design did not allow changes over time to be assessed. In the present RCT, the NOSACQ-50 enabled longitudinal evaluation of safety climate during the 12 months study period. The NOSACQ-50 was developed as a generic occupational safety climate instrument and captures dimensions such as management safety priority, communication, and learning (24). This is consistent with healthcare safety culture literature emphasizing that safety climate is multidimensional and may be influenced by organizational context and implementation (45).

From a statistical perspective, the study has several limitations. First, analyzing outcomes at the aggregated HCU level reduced the effective sample size and statistical power, as commonly observed in cluster RCT (46, 47). Second, the substantial and differential cluster attrition, particularly in the multifactorial intervention group, may have introduced selection bias and further reduced the power to detect time × intervention group effects. This is a common challenge in complex interventions (48). The HCU that remained in the study may have differed from those that withdrew in terms of organizational readiness, staffing, managerial support, or ability to implement the intervention, which may also limit the generalizability of the findings. Third, the multiplicity of primary outcomes (seven NOSACQ-50 and 14 SafePHM-14 items) increased the risk of type I error (49). Nevertheless, analyzing outcomes at the HCU level was relevant to the organizational focus of the study, as leadership, teamwork, and shared PHM routines are developed and maintained within care units (17).

The study did not include a usual care or no-intervention control group. Therefore, the observed changes over time cannot be attributed specifically to the interventions, and it is not possible to determine what would have occurred in the absence of either intervention. Researcher involvement in supporting implementation may have reduced the degree of independence between intervention delivery and evaluation. This involvement was intended to support implementation fidelity but may also have influenced the implementation process and should therefore be considered when interpreting the findings.

A potential Hawthorne effect should be considered, as study participation and increased attention to PHM may have contributed to the changes observed over time in both groups (50). The observed changes were generally small, and their practical relevance should therefore be interpreted with caution. In addition, the 12-month follow-up may have been too short to capture longer-term effects of the multifactorial intervention.

Clinical implications

In the present study, the limited additional benefit of the multifactorial intervention and the observed differences between organizational settings suggest that PHM practices may be strongly influenced by the inner context and existing work conditions. This is also supported by findings from our previous cross-sectional study, where organizational support, clear guidelines, and ergonomic and psychosocial work factors were associated with a more favorable safety climate, highlighting the importance of local organizational conditions for safe PHM (51). The findings also indicate that using a research-based guide as a less resource intensive approach may be sufficient to support structured PHM work within HCU. This suggests that HCU may be able to identify and manage PHM related work environment issues within their existing organizational structures, with potentially lower implementation resource use.

The effect sizes observed in this study, including the small to moderate increase in management safety engagement in the multifactorial intervention, are comparable to those reported in previous intervention and implementation studies focusing on safe PHM (6, 9, 10, 12).

Concluding remarks

This cluster RCT found that a multifactorial intervention was not more effective than a single intervention in improving safety climate in relation to PHM. Change over time was identified in both intervention groups, however these findings must be viewed with caution as no usual-care comparator was included in the study. The findings support the use of PHM interventions at the HCU level and suggest that organizations may select a research-based guideline intervention with or without multifactorial components. Further research is

needed to better understand the implementation process of the intervention, including a comprehensive process evaluation.

Declarations

This study followed the ethical principles of the Helsinki Declaration. After the workplace managers approved study participation, the HCW were given both oral and written information about the study. Participants gave their informed consent to participate. Ethics approval was received from the national ethical board (Dnr 2021–00578 and Dnr 2022-05334-02).

Availability of data and materials

The data are not publicly available but can be obtained from the research leader (CW) on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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