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Does a brief work-stress intervention prevent sick-leave during the following 24 months? A randomized controlled trial in Swedish primary care

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Abstract.
BACKGROUND: Work-related stress (WRS) presents a risk for sick leave. However, effective methods to identify people at risk for sick leave due to WRS at an early stage are lacking in primary health care.
OBJECTIVE: To evaluate whether a systematic early identification of WRS can prevent sick leave over 24 months after the intervention.
METHODS: Study participants ($n = 132$ intervention; $n = 139$ control) were employed, non-sick-listed persons seeking care at primary health care centres. The intervention included early identification of WRS by a validated instrument, general practitioner (GP) awareness supported by a brief training session, patients' self-reflection by instrument completion, GP giving the patient feedback at consultation and GP identifying preventive measures. The control group received treatment as usual. Outcome data were retrieved from the Swedish Social Insurance Agency.
RESULTS: The intervention group had less registered median sick leave days ($n = 56$) than the control group ($n = 65$) but the difference was not statistically significant.
CONCLUSIONS: The brief intervention was not proven effective in preventing sick leave in the following 24 months compared to treatment as usual. Further research on how to identify, advice and treat those at high risk for sick leave in primary health care is needed.

Keywords: Preventive intervention, Work stress questionnaire (WSQ), common mental disorders, musculoskeletal disorders, sick leave days

1. Introduction

Gainful employment is generally associated with increased physical and mental health and well-being [1, 2]. In spite of this positive effect of work, research

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shows that exposure to an unfavorable psychosocial and organizational work environment can be detrimental to mental health, and be a risk factor for the occurrence of stress-related disorders [3, 4]. Work-related stress has been found to be associated with mental disorders such as depression and anxiety [5, 6] and musculoskeletal disorders in neck/shoulder and lower back [7]. These two types of disorders are also common causes for an increase in sick leave [8, 9]. Research has shown that people with these types of disorders consult their general practitioner [GP] in primary health care [10, 11] long before they consider going on sick leave [12, 13]. For example, a retrospective study [11] in primary health care showed that patients with exhaustion disorder had consulted their GP on numerous occasions with stress-related complaints during the two years preceding their diagnosis. In a qualitative study by Holmgren and Dahlin Ivanoff [12] including 20 women on sick leave owing to work-related stress, the women described having lost control over their everyday life including their work situation. In spite of experiencing ill-health for a long period of time they had continued working. According to the results of the focus-group discussions, factors at the workplace as well as individual factors resulted in-sick leave. Going to work while being ill has been termed sickness presenteeism [14]. A review [14] of quantitative research concluded that sickness presenteeism is a risk factor for poor self-rated health and future sick leave. Furthermore, short-term sick leave has shown to be associated with subsequent and long-term sick leave [15, 16], which in turn is associated to unemployment [17] and disability pension [17, 18], both of which causing financial consequences for the employee, productivity-related losses, and a considerable financial burden on society [19]. Consequently, an early identification of persons at risk for sick leave due to work-related stress is imperative to enable preventive measures.

The Work Stress Questionnaire (WSQ) [20], was developed in the context of primary health care and designed to identify persons at risk for sick leave due to work-related stress. The WSQ comprises both work-related factors and personal characteristics. The results of a prospective study applying the WSQ in a Swedish primary health care context [13] showed that sick leave was more than twice as high at a 12-months follow-up for women perceiving high stress due to poor organizational climate when compared to those who did not. Moreover, a combination of perceiving high stress owing to indistinct organization and perceiving individual demands and commitment was associated with a four-fold risk for sick leave at the 12-month follow-up.

Following this line of research, an RCT study [21] was developed to test a preventive intervention at primary healthcare centres (PHCC). The study included non-sick-listed employed women and men, aged 18 to 64 years, who had mental and physical health complaints. The screening of work-related stress at baseline showed that the prevalence of overall perceived stress due to high work commitment was 48% for the intervention group and 44% in the control group, and perceived stress due to indistinct organization and conflicts was 21% and 19% respectively [22]. At the12-month follow-up [22] there were no statistically significant differences between the intervention and the control group. The non-significant results were possibly due to a type II error. The results of a further study [23] investigating differences in pharmacy dispensing of prescription medications, for a period of 12 months following study inclusion, showed that the proportion of individuals who collected more than 10 different medications was higher in the control group than in the intervention group ($p = 0.002$). Similarly, the proportion of individuals filling prescriptions issued from more than three different clinics was higher in the control group than in the intervention group ($p = 0.007$). Yet another study [24] showed that over the 12 months following inclusion in the RCT study the intervention participants with high stress had significantly ($p < 0.05$]) more visits to psychologists/psychotherapists (20%, $n = 87$) compared to corresponding controls (7%, $n = 97$). Moreover, collaborative care measures were more common among intervention participants with high stress (23%) post-inclusion compared to the stressed controls (11%) ($p < 0.05$). This gives an indication that the WSQ can assist in identifying risk for sick leave owing to work-related stress in persons seeking primary health care and contribute to GPs' recommendations of appropriate rehabilitative measures at an earlier stage compared to treatment as usual. However, empirically it is well-known that preventive and rehabilitative measures take time. A qualitative study [25] of women, working or on sick leave, participating in a primary health care stress-management programme reported findings supporting that rehabilitative measures for this group warrants time. As preventive and rehabilitation measures for stress-related ill health can take time it is possible that the effects of the RCT's preventive intervention were not visible after 12 months. Therefore exploring if the preventive intervention had an effect on sick leave

between the intervention- and control group in the longer perspective of 24 months is warranted.

1.1. Aim

The aim of this study was to evaluate the effect of a preventive intervention, compared to treatment as usual, among both the entire study population and the sub-group of participants with registered sick leave. Main outcome measures were 1) the number of registered sick leave days (i.e. 14 days or more) 24 months on, 2) the number of registered sick leave days (i.e. 14 days or more) categorized into three levels: low (15–90 days), medium (91–180 days) and high (181 days and above) 24 months on.

2. Methods

2.1. Study design

The study is part of TIDAS, a randomized controlled trial [21] with a follow-up at 24 months. TIDAS is a study in the research programme New Ways. The preventive intervention is described below under the heading Intervention and control. The outcome measure was the difference between the intervention group and the control group regarding registered sick leave days over 24 months after study inclusion. The registered sick leave data were obtained from the Swedish Social Insurance Agency (SSIA) register. The intervention and recruitment of participant were conducted May 2015 through January 2016.

2.2. Recruitment and randomization

Seven PHCCs participated in the data collection, and each PHCC had intervention and control patients simultaneously. The purpose for this was to promote participation by engaging the whole PHCC, and to minimize the risk for differences in socioeconomic factors between participating patients in intervention and control [21]. Researchers, who were not involved in the study, carried out the randomization of the GPs by taking, one out at a time, folded slips of paper with the written names from a non-transparent bowl. A research assistant assigned to the PHCC consecutively recruited patients meeting the inclusion criteria in the study with assistance from the reception-personnel. Inclusion criteria for participants were being non-sick-listed at the time of the visit to the PHCC, employed, being 18 to 64 years old, and attending the PHCCs for mental and/or physical health complaints. Exclusion criteria were having been off work due to sickness for a total of 7 days or more during the last month and receiving full or part-time disability pension [21]. A total of 271 patients participated in the study, 132 of which were allocated to the intervention and 139 patients were allocated to treatment as usual.

2.3. Intervention and control

The WSQ brief intervention procedure was standardized and comprised of a) a GP training, for in total two hours, in the use of the WSQ and GP receiving evidence-based information of the association between work-related stress and health, b) written information to the GPs to be kept on hand regarding access to preventive measures by the services of the primary health care specialists and occupational healthcare, c) the completion of the WSQ by the enrolled participants before the GP consultation, d) the compilation of the result and analysis of the WSQ by a research assistant and provision of the result to the GP before consultation, e) the provision of feedback by the GP to the participant on WSQ results at the consultation, and f) a non-systematic discussion between GP and participant and suggestions on measures to be taken. The intervention was expected to be carried out within the ordinary time limit for the GP-consultation. The study procedure was followed up by a study protocol filled out by the GP after each patient consultation.

The WSQ comprises 21 questions in four categories: perceived stress owing to indistinct organization and conflicts and to individual demands and commitment, and influence at work and work interference with leisure time. The reliability and face validity of the WSQ has been found to be satisfactory [20, 26].

The control GPs were not informed about, or aware of, their patient being a study participant. The participants in the control group received treatment as usual at the GP consultation, which can consist of medical investigation, diagnostics, treatment, and discussion about preventive and rehabilitating measures. The patients filled out the WSQ after the GP consultation and were also asked for background characteristics.

Oral and written study information was given and informed written consent was obtained from all participants, including consent for linking records to registers during follow-up. The Regional Ethical

Table 1
Baseline characteristics of the participants ($N = 271$)

Characteristics	Intervention group $n = 132$ (%)	Control group $n = 139$ (%)
Gender		
Female	88 (67)	97 (70)
Male	44 (33)	42 (30)
Age groups:		
19–30 years *n*	21 (16)	26 (19)
31–50 years *n*	58 (44)	76 (54)
51–64 years *n*	53 (40)	37 (27)
Marital status[1]:		
Single *n*	33 (25)	25 (18)
Married/cohabitant *n*	91 (70)	106 (77)
In a relationship *n*	7 (5)	7 (5)
Educational level[2]:		
Compulsory school *n*	13 (10)	15 (11)
Secondary school *n*	61 (46)	59 (42)
University or higher *n*	57 (44)	65 (47)
Reasons for seeking care:		
Musculoskeletal *n*	62(47)	44 (32)
Mental health *n*	75 (57)	69 (50)
Other *n*	29 (22)	27(19)
Occupational class:		
Skilled/unskilled manual	49 (37)	58 (42)
Medium/low non-manual	60 (46)	56 (41)
High-level non-manual	23 (17)	24 (17)
Number of health complaints at the time of seeking care, median (min-max)	2 (1–9)	1 (1–9)

Note: [1]Two missing values. [2]One missing value.

Review Board at the University of Gothenburg, Sweden, approved the project (reference no. 125–15).

2.4. Study population

The majority (∼70%) of the participants were female, Table 1. About 70% were married or cohabitant. Age ranged between 19 and 64 years old, and about half of the group were between 31–50 years old. The proportion of participants aged 51–64 years was significantly larger in the intervention group ($p = 0.018$). The main reasons for seeking primary care were mental health and musculoskeletal complaints. The proportion of participants seeking care for musculoskeletal disorders was significantly higher in the intervention group ($p = 0.010$). The number of complaints an individual sought care for ranged between 1 and 9, and the number of complaints were significantly higher in the intervention group ($p = 0.005$) (Table 1).

2.5. Sample size

The power calculation (with a two-sided test, statistical significance of $p < 0.05$ and 80% power) that was performed for the 12-months outcomes showed that 135 participants were needed in each group in order to be able to identify a 15% difference between the intervention and the control group regarding the number of sick leave days from the Swedish Social Insurance Agency (SSIA) (i.e. > 14 days) during 12 months after inclusion [21]. No separate power calculation was performed for the 24 months follow-up.

2.6. Outcome measures and data management

The outcome measure was the number of registered sick leave days. Data, i.e. registered gross sick leave days (number of sick leave days, irrespective of part-time or full-time sick leave) and registered net sick leave days (number of sick leave days converted into whole days; 1 day = 100% = 8 hrs) during 24-months following baseline, was procured from the SSIA's Micro Database for Analyzing Social insurance (MiDAS). For people with employment the first 14 days of sick leave (except for one qualification day) are covered by their employer, and after that period benefits are granted from the Social Insurance Agency. The entitlement to continued sickness benefit (≥14 days) is assessed at standardized time limits according to a rehabilitation chain. These time limits or intervals are referred to as short-term, medium-term and long-term in the aim of this study. The specific time limits are at 90 days, 180 days, 364 days, and 365 days and continued sickness benefits. The first three intervals, with the addition of measurements at 18 months and 24 months are applied in the descriptive analyses of sick leave days and presented in Table 3. The analyses regarding 24 months solely are presented in Tables 2 and 4. Data from the MiDAS register was structured on sick leave spells. Each individual's study period was defined as 730 days from that individual's intervention date. Spells that began within the individual's study period were included, but if the spell included sick leave days that occurred after the individual's study period had ended, then those days were excluded. For each individual, data on the total number of gross and net sick leave days from all included spells were summarized.

2.7. Statistical analyses

Differences between the intervention and control groups concerning baseline characteristics were explored by means of the Chi-square test, and the Mann Whitney U-test for differences in number of complaints (Table 1). The data concerning sick leave

Table 2
Number of net sick leave days over 24 months in a population of primary health care center patients in Västra Götaland Region, Sweden. Data were collected between 2015 and 2018

	Intervention group			Control group			*p*-value*
	n	median	Q1, Q3	*n*	median	Q1, Q3	
Net sick leave days	132	0	0.0, 62.7	139	0	0.0,78.0	0.713

Note: **p*-value from the Mann-Whitney U-test.

Table 3
Number (n) and proportion of participants with different levels of sick leave days in net days over 24 months in the study population per intervention group ($n = 132$) and control group ($n = 139$)

Sick leave days in net days	Intervention group		Control group		95% C.I.*
	n	percent	*n*	percent	
0 days	76	57.6	73	52.5	(–0.068,0.169)
15–90 days	31	23.5	37	26.6	(–0.134,0.072)
91–180 days	13	9.8	16	11.6	(–0.09,0.057)
181–365 days	8	6.1	6	4.3	(–0.035,0.07)
366–548 days	2	1.5	7	5.0	(–0.077,0.007)
549–730 days	2	1.5	0	0	n.a.

Note: *95% confidence interval for the difference between the groups' proportions of participants with sick leave days.

days was heavily skewed, thus non-parametric statistics were applied. The Mann Whitney U-test was used to analyse the outcome measure, i.e. differences between the intervention and control groups concerning number of registered sick leave days, in the entire study population and the sub-group of participants with registered sick leave. The 95% confidence intervals (CI) for the difference between the intervention group's and the control group's proportions of participants with sick leave days at different levels were calculated.

3. Results

3.1. Sick leave days in the total study population at 24 months

During the 24 months following baseline, 42.4 percent ($n = 56$) in the intervention group and 47.5 percent ($n = 66$) in the control group had at least one registered sick-leave day in a spell longer than 14 days registered sick leave days. The 95% confidence interval (CI) for the difference between the groups in the proportion of participants with sick leave days was –0.068–0.169, i.e. not significant.

Table 2 shows descriptive statistics, and the result of the Mann-Whitney U-test comparing the intervention group with the control group regarding net sick leave days (number of sick leave days converted into whole days) over 24 months. The analysis of gross sick leave days showed similar results (not shown in table).

The number of individuals with different levels of net sick leave days during the 24 months following baseline are presented per intervention- and control group in Table 3. There were no significant differences between the intervention- and control group. The analysis of gross sick leave days showed similar results (not shown in table). Most participants in both the intervention group and the control group had 15 to 90 sick leave days. There were, however, a few individuals in both groups with a very high number of sick leave days (Table 3).

3.2. Sick leave days among the participants who had 15 sick leave days or more over 24 months

Fifty-six (42.4%) of the participants in the intervention group and 65 (47.5%) of the participants in the control group had registered sick leave days (> 14 days) during the 24 months following baseline. As shown in Table 3, there were no significant differences between the intervention group and the control group in net sick leave days regarding any of the intervals over the 24-month period.

Table 4
Descriptive statistics of net sick leave days at 24 months in the sub-population with registered sick leave days (> 14 days) over 24 months in a population of primary health care center patients in Västra Götaland Region, Sweden. Data were collected between 2015 and 2018

	Intervention group			Control group			*p*-value*
	n	median	Q1, Q3	*n*	median	Q1, Q3	
Net sick leave days	56	71.6	15.5, 166.3	65	80.7	37.0, 158.5	0.717

Note: *p-value from the Mann-Whitney U-test.

Table 4 shows the median and the distribution (Q1, Q3) of sick leave days and the result of the analysis comparing the subgroup of participants in the intervention group with the control group who had 15 sick leave days or more during the 24 months. There was no significant difference between the intervention group and the control group. The analysis of gross sick leave days showed similar results (not shown in table).

4. Discussion

The study set out to evaluate the effect on registered sick leave days of the WSQ brief intervention compared to treatment as usual 24 months after baseline, among both the entire study population and the subgroup of participants with registered sick leave days. The study is unique in terms of having a long-term follow-up, and in evaluating an early intervention i.e. before the persons seeking primary health care are on sick leave. At the 24-month follow-up, there were no statistically significant differences between the intervention and the control group. The intervention group, however, had less registered sick leave days than the control group receiving treatment as usual over the 24 months following baseline, and the lack of statistically significant differences between the groups might be due to a type II error (i.e. a false finding is accepted as true) if the study was underpowered.

The study participants were employed women and men who had not been off work due to sickness for a total of 7 days or more during the last month, or having full or part-time disability pension at the time of baseline. Employment is a well-known social determinant of both mental and physical health [2, 27]. The study group as a whole could be considered to be a relatively healthy and resourceful group seeking primary health care. Even so the results showed that 42.4% of participants in the intervention group and 47.5% of the participants in the control group had registered sick leave days [> 14 days] during the 24 months following baseline. This gives an indication that our study group might be more vulnerable than they appear. In a Norwegian study it was estimated that general practitioners (GP) issue a sickness certificate to 11–35 % of patients in primary health care [28]. A longitudinal British study [29] of working-age adults seeking primary health care showed that one in ten patients received a sickness certificate from their GP during the 1-year study period. The rate of sickness certification was greatest for mental health conditions, closely followed by musculoskeletal conditions. However, the present study is unique in terms of having a 24-month follow-up regarding sick leave and to the authors' knowledge there are no other Swedish studies that are comparable, which makes our study unparalleled. Particularly since the results of our study showed that a large proportion of the non-sick listed participants had > 14 sick leave days during the 24 months following study inclusion, and as such is an important group to identify to be able to suggest preventive measures.

Moreover, comparing our findings to other studies is difficult as there are few RCT studies in a primary health care context that address sick leave as an outcome [30, 31]. Another issue is that several studies concern persons already on sick leave at study inclusion [32, 33], whereas the base line-population in the present study where people possibly at risk but not yet sick-listed. Furthermore, most RCTs in primary health-care have shown no, or a modest impact on the sick leave rates [32, 34–37]. Sick leave as an outcome is a rather complicated concept. It is not only an indicator of mental and/or physical ill health, it also reflects health related behavior, personal characteristics, work tasks and the work environment, and the social insurance system [38]. This makes sick leave an issue of importance for other stake holders than primary health care such as the employer, occupational health services and the social insurance agency when striving to take measures to decrease the risk for sick leave and facilitate return to work [39].

In this study the individual's sick leave days were summed over the 24 months. The majority in both the intervention and the control group had between 15 and 90 days, but there were also a few individuals

in both groups with a very high number of sick leave days. The most common reasons for seeking primary health care at study inclusion were mental health and musculoskeletal complaints, which are well-known symptoms that can be caused by stress from work-related factors, increasing the risk for sick leave [8, 40, 41].

The results regarding sick leave between 15 and 90 days can not necessarily be interpreted straightforward. Waddell, Burton and Kendall [42] reported that in the first 15–90 days of sick leave the likelihood of recovery and return to work is high for people with common mental disorders and mild or moderate musculoskeletal conditions, with or without healthcare intervention. In spite of the risk for subsequent and long-term sick leave [15, 16], 15–90 days of sick leave may be appropriate and, possibly together with other taken measures, a necessary intervention for non-sick listed persons seeking primary health care for mental health and musculoskeletal complaints. However, screening for stress among the working age population seeking primary health care for potentially stress-related symptoms is important for an early identification of persons at risk for long-term sick leave [11, 16]. Furthermore, research has shown that GPs rarely bring up the topic of work during the GP consultation [43, 44] and that GPs report limited knowledge about the impact of work-related factors on health and sick leave [45, 46].

The WSQ brief intervention provided training for all the GPs working with the intervention group to increase their awareness and knowledge about work-related stress. The GPs were also informed about access to preventive measures by the services of the primary health care specialists and occupational healthcare. No information is available to confirm that this in fact increased the GPs awareness and knowledge. Another study showed that brief training in a structured functional assessment method increased the GPs' knowledge about functional assessments and patient work factors [47]. However, it was found that after training GPs to use a brief intervention for stress-related disorders the adherence to the new routines was limited [47]. A further study showed that training GP s did not improve GPs' registration of work-related problems or patients' expectations concerning their ability to work [48]. The training in our study was short, and it is possible that it was too short to enable the GPs to acquire enough knowledge and competence to provide feedback to the participant on WSQ results and discuss preventive measures.

The demands for access and prompt care is high in primary health care. Therefore, the RCT needed to be pragmatic and fit into the regular care and the health care system. Nevertheless, the brief intervention might have been too brief to have an effect over 24 months. It may also have been too brief to be a contrast to treatment as usual. The study did not collect specific information about the GPs' recommendations for interventions during the GP-patient consultation. This should be looked into in further research to explore if there were any differences between the intervention and the control group.

To the best of our knowledge there are no established methods to identify individuals at risk for sick-leave due to work-related stress at an early stage, and to advise and treat people with work-related stress in primary health care. Consequently, further research on methods to support primary health care professionals in identifying people at risk for concurrent or long-term sick leave, preventing these people from falling ill and to report sick, and facilitating return to work is warranted. Furthermore, future research should explore the feasibility to implement a structured use of a method to early identify people at risk for work-related sick leave from the perspective of primary health care professionals.

4.1. Strengths and limitations

The strengths of the study are the randomized design and the availability of registry data on sick leave for all participants. When using registered data, the risk of drop-outs is very slim, and there is no risk for recall-bias. The sick leave data were very heavily skewed with most individuals having no registered sick leave. In relation to the number of participants the study may have been underpowered. Thus, the lack of statistically significant differences between the groups might be due to a type II error. There is a scarcity of research on preventing sick leave among people at risk seeking primary health care which makes estimation of future sick leave level difficult. A larger RCT-study of the preventive intervention is therefore warranted.

The randomization was done at the PHCC level but we considered the risk for contamination between the two groups to be low as the inclusion period was short and the intervention was incorporated into the ordinary daily practice. Engaging the entire primary healthcare center in recruiting participants has been beneficial for the number of people participating in the study [49].

A few differences were found regarding the study participants: the proportion of participants aged 51–64 was larger in the intervention group, the proportion of participants with musculoskeletal disorders was higher in the intervention group, and the number of complaints seeking care for was higher in the intervention group. We have no reason to believe that this had any bearing on the results.

Finally, the training in our study was short, and it is possible that it was too short to enable the GPs to acquire enough knowledge and competence to provide feedback to the participant on WSQ results and discuss preventive measures.

5. Conclusion

The WSQ brief intervention was not proven effective in preventing sick leave in the following 24 months compared to treatment as usual. The study may, however, have been underpowered and the lack of statistically significant differences between the groups might thus be due to a type II error. The study population as a whole was vulnerable in that a large proportion had > 14 sick leave days during the 12 months following the intervention, which is why an early identification of these people is of great importance to be able to suggest preventive measures. Further research on methods to support primary health care professionals in identifying people at risk for concurrent or long-term sick leave, preventing these people to fall ill and to report sick, and facilitating return to work is warranted.

Conflict of interest

None to report.

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Trial registration

ClinicalTrials.gov. Identifier: NCT02480855.

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