Chapter 7

A workplace intervention for sick-listed employees with distress: results of a randomized controlled trial

Accepted for publication as:
ABSTRACT

Objectives
To evaluate the effectiveness of a participatory workplace intervention compared to usual care for sick-listed employees with distress, with regard to return to work within twelve months follow-up.

Methods
Employees with distress and sick-listed for 2 to 8 weeks were randomized to a workplace intervention (n = 73) or to usual care (n = 72). The participatory workplace intervention is a stepwise process involving the sick-listed employee and supervisor, aimed at reducing obstacles for return to work (RTW) by reaching consensus about an action plan for RTW. Outcome variables were lasting RTW, cumulative sickness absence, and stress-related symptoms.

Results
Overall, a hazard ratio of 0.99 (95% CI 0.70 – 1.39) indicated no effect of the workplace intervention on lasting RTW. However, the workplace intervention significantly reduced the time until lasting RTW for employees who at baseline intended to RTW despite symptoms with a hazard ratio of 2.05 (95% CI 1.22 – 3.45). Employees who intended to RTW despite symptoms returned to work after 55 days in the workplace intervention group and in 120 days in the usual care group. No such effect of the intervention was found for employees without baseline intentions to RTW despite symptoms (hazard ratio = 0.78, 95% CI 0.47 – 1.28).

Conclusion
No overall effect was found of the participatory workplace intervention on lasting RTW. The workplace intervention appeared effective on lasting RTW for employees who at baseline intended to RTW despite symptoms. For employees who showed no baseline intention to RTW, the intervention did not have any effect. Other approaches are needed for this subgroup.
INTRODUCTION

Work absenteeism due to mental health problems results in high costs and a high risk for long term work disability(1-4). Mental health problems account for one third of all disability benefits in the Netherlands(5). Therefore, early intervention is of crucial importance. Return to work (RTW) interventions aim to reduce the burden of work disability for employees, companies and society. However, there is a lack of intervention research with a focus on RTW for common mental health problems(6). Several authors suggested that interventions should be carried out in collaboration with the workplace and should be directed to work adaptations(7-11). Therefore, we developed a participatory workplace intervention for sick-listed employees with distress, based on a successful intervention for sick-listed employees with low back pain (LBP)(12;13). The participatory workplace intervention is unique in the field of mental health problems. It requires a high degree of involvement of both the sick-listed employee and his or her supervisor. It is a stepwise communication process aimed to reduce obstacles for RTW by reaching consensus about an action plan for RTW(14).

Our hypothesis is that active participation and improvement of problem solving skills of both the employee and the supervisor guided by a RTW coordinator increases the likelihood of an early RTW. This expectation is based on positive views from employees, supervisors and occupational health professionals expressed in focus groups(12), and the previous findings from LBP studies(13;15). RTW may be hampered in several ways. First, an employees’ attitude or self-efficacy for RTW may result in a lack of intention to RTW(12). The focus group interviews identified the presence of mental health problems as a potential barrier to RTW. On the other hand, barriers for RTW at the workplace itself may impede a successful RTW, even if an employee intends to RTW. The participatory workplace intervention aims to remove barriers for RTW at the workplace and could increase an employee’s self-efficacy to RTW. Employees, supervisors and occupational health professionals viewed the participatory workplace intervention as a promising intervention strategy for RTW of employees with stress-related symptoms(12).

In a recent publication, the workplace intervention for employees with distress was evaluated to be feasible(16). Employees and supervisors were able to identify obstacles related to mental workload, stress, and communication, to discuss them and to find solutions for these obstacles. Although all stakeholders indicated to be satisfied with the intervention process and the consequential work adaptations, effectiveness still has to be established. The aim of the current study is to assess the effectiveness of the participatory workplace intervention compared to usual care for sick-listed employees with distress, with regard to RTW at twelve months follow-up. In addition, effects of the workplace intervention on stress-related symptoms were investigated.
METHODS

Study design and setting
The study is a randomised controlled trial carried out in three Dutch organisations; the VU University, the VU University Medical Center, and CORUS a steel industry company. Fourteen occupational physicians (OPs) were involved in the study, seven OPs of CORUS occupational health services and seven of the VU and VU Medical Center occupational health services. The Medical Ethics Committee of VU University Medical Center approved the study design and all participants signed informed consent.

Study population and recruitment procedures
Between April 2006 and May 2008, all employees sick-listed for more than one week received a letter from their OP with a screening questionnaire. The screening questionnaire was based on the distress scale of the Four-Dimensional Symptom Questionnaire(17-19). All employees who had returned the screening questionnaire and who met the distress and sick leave criteria were contacted by the researchers to check the inclusion and exclusion criteria, regardless of the primary reason for their sickness absence. Employees on sick leave from regular work for 2 to 8 weeks were included. Exclusion criteria were 1) a conflict between the employee and the employer with legal involvement; 2) working less than 12 hours a week; 3) pregnancy; 4) any other episode of sick leave within one month before the current episode; 5) inability to complete questionnaires written in the Dutch language. The OP was responsible to prevent employees with severe psychiatric disorders (mania, psychosis or severe risk on suicide) and employees with a terminal illness from starting the workplace intervention.

Randomization and blinding
An independent statistician prepared the randomisation scheme by using a computer-generated randomisation. To prevent unequal randomisation, employees were pre-stratified by the organisation (VU, VU Medical Center or CORUS) and whether they were on full or part-time sick leave, this resulted in six strata. Block randomisation (with blocks of four) was applied to ensure equal group sizes within each stratum. Based on the randomisation scheme, sealed envelopes were prepared before the start of the study containing either a referral to the workplace intervention group or the usual care group. After completing the baseline questionnaire each employee opened a sealed envelope provided by the research assistant.

The participants and occupational health professionals were not blinded for the group assignment. Sick leave data were extracted from the computerized registrations of the occupational health services and self-reported data were entered into the computer by a research assistant, which ensured blinded analysis of the data by the researcher. Recruitment procedures, randomization procedures, and sample size calculations have been described in detail elsewhere(14).
Interventions

Usual care

The employees who were allocated to the usual care group, received the usual care from their OP according to the evidence-based guideline of the Dutch Association of OPs (NVAB) published in 2000 and updated in 2007(20). This guideline aims to facilitate optimal functioning of employees with mental health problems and to prevent long-term sick leave and frequent recurrences.

Participatory workplace intervention

The employees allocated to the workplace intervention, received usual care from their OP and were referred to a RTW coordinator (company social worker or a labour expert) for the workplace intervention. Prior to the study, RTW coordinators had been trained in guidance of employees and supervisors according to the workplace intervention. The participatory workplace intervention consisted of a stepwise communication process to identify and solve obstacles for RTW. The participatory workplace intervention is based on consensus between the sick-listed employee and his or her supervisor. About three weeks after baseline, three meetings took place with the employee and/or the supervisor and the RTW coordinator. In the first meeting, the employee performed a task analysis and identified obstacles for RTW in a structured conversation with the RTW coordinator. These obstacles were ranked according to priority, based on their frequency and perceived severity. At the second meeting, the supervisor and the RTW coordinator were present and identified obstacles for RTW from the perspective of the supervisor. In the third meeting, the employee, the supervisor and the RTW coordinator were all involved in a brainstorm for solutions. The solutions were ranked according to priority, based on feasibility, solving capability and short-term applicability of the suggested solution. After this, a plan for implementation of the suggested solutions was formulated, in terms of the person responsible for the implementation, how the solution was planned, and when it should be implemented. This plan was based on consensus. In the weeks following the meetings, the solutions should be implemented. If required, the RTW coordinator planned a visit to the workplace to instruct and advise the employee. One month after the meetings, actual implementation of the solutions and contributions to RTW were evaluated by the RTW coordinator with the employee and the supervisor. Information about the duration and content of the workplace intervention is described elsewhere(16).

Outcome measures and data collection

The baseline measurement took place before randomisation and follow-up measurements were performed 3, 6 and 12 months after baseline. Sick leave data were gathered from continuous registration systems of the occupational health services after the 12 months follow-up.
Primary outcome measure - Return to work
The primary outcome measure in this study is lasting RTW, defined as the duration of sick leave with distress in calendar days from the day of randomization until full RTW in own or other work with equal earnings, for at least 4 weeks without (partial or full) recurrence. Recurrences of sick leave within 4 weeks of full RTW are considered as belonging to the initial period of sick leave, in accordance with the requirements in the Dutch Sickness Benefits legislation. Several medical diagnoses may be distress related, therefore we summed sick leave periods with a diagnosis equivalent with the baseline diagnosis or diagnoses belonging to the same cluster of psychological diagnoses(21). In addition, the total number of days of sick leave in 12 months was calculated.

Secondary outcome measure
Stress-related symptoms were assessed by the Four-Dimensional Symptom Questionnaire at baseline, 3, 6, and 12 months follow-up. This questionnaire consists of 50 items related to the dimensions distress, depression, anxiety and somatization. The items were scored for occurrence during the past week on a 5-point Likert scale ranging from ‘no complaints’ to ‘very often/continuously’. The 4DSQ is a reliable and valid instrument to measure stress-related symptoms in a working population(17;18). Cronbach’s alpha for the 4 subscales ranged from 0.84 to 0.90.

Covariates
All covariates were assessed at baseline. Behavioural determinants for RTW concerned the employees’ attitude, social influence, self-efficacy, and intention towards a RTW despite the existence of symptoms. The questions were measured on five-point Likert scales(22). Four attitude questions were assessed, the response categories varied from ‘very important’ to ‘very unimportant’. Social influence comprised 3 questions about the normative beliefs of the supervisor, colleagues and people in the personal situation regarding a RTW despite symptoms, and 3 questions about the motivation to comply with these beliefs(22). Response categories ranged from ‘totally agree’ to ‘totally not agree’, and ‘very much’ to ‘very little’. The questions about normative beliefs and motivation to comply were multiplied to calculate a scale score for social influence(22). Two self-efficacy questions and one question about the intention to RTW were posed. The response categories of the self-efficacy and intention questions varied from ‘certainly’ to ‘certainly not’. For example, the intention question was formulated like ‘Do you intend to return to work when you still experience symptoms?’.
Decision latitude, psychological (job) demands, and social support were assessed by the Job Content Questionnaire(23). Emotional exhaustion, depersonalization and personal accomplishments were measured by the Utrecht Burnout Scale-General Survey(24). In addition, sick leave in the past year and expectations of the employee about the duration of absence were measured since they are considered to be potentially prognostic variables for RTW.
Statistical analyses
All statistical analyses were performed at employee level, according to the intention-to-treat principle. Baseline characteristics of employees in the two groups were compared using descriptive statistics.

Primary outcome measure
To describe the sick leave duration until lasting RTW in both groups, the cumulative incidence function was used. The Cox proportional hazard model was applied to estimate hazard ratios and corresponding 95% confidence intervals (CI). The shared-frailty procedure was used to account for clustering of employees within OPs(25).
First, unadjusted Cox regression analysis was performed. Second, in an adjusted Cox regression analysis confounding and effect modification were assessed. The potential confounders or effect modifiers were predefined and were all measured at baseline: personal characteristics (age and gender); job characteristics (company, decision latitude, job demands, and social support); sick-leave related characteristics (sick leave in the past year, expectations of the employee about the duration of absence, emotional exhaustion, depersonalization and personal accomplishments); and determinants of RTW (attitude to RTW, social influence on RTW, self-efficacy of RTW, and intention to RTW(12;14)). Continuous variables were checked on linearity and categorical variables were dichotomised based on content. The JCQ scales were dichotomised based on agreement/non-agreement, UBOS scales based on frequency of occurrence never/sometimes and often/always, and ASE variables based on positive and negative categories. Company and sick leave in the past year were analysed as dummy variables.
First, univariate tests for confounding and effect modification were performed. Covariates were considered as confounders if the Beta of the intervention changed more than 10 percent by adding the covariate to the Cox regression model. Effect modification was assessed by including the potential modifier and an interaction term between the potential modifier and the intervention to the Cox regression model. Effect modification was considered to be present when the beta-coefficient of the interactions term had a p<0.05. A forward selection procedure was followed to include interaction effects and covariates. In case of effect modification, separate hazard ratios per subgroup are reported. A test of the proportional hazard assumption was conducted(26).
Differences in total days of sick leave during the year of follow-up were analysed by using Mann-Whitney U tests.

Secondary outcome measure
Linear mixed models were used to assess differences in stress-related symptoms. Linear mixed models can be applied with longitudinal data taking into account clustering on the level of the OP. We applied unstructured covariance matrices to adjust for correlation of the data on the different measurement times. The effect of interest is the interaction between treatment group and measurement time, i.e. the differences between treatment groups at 3, 6 and 12 months adjusted for baseline differences on the outcome variable.
Chapter 7

Intention to treat: Analyzed for administrative data and self-reported data (n=73)

Allocated to Workplace intervention (n=73)
- Received allocated intervention (n=53)
- Did not receive allocated intervention (n=20)
  - Reasons:
    - RTW (n=7)
    - Medical reason (n=4)
    - Decision employee (n=2)
    - Supervisor refused to participate (n=2)
    - Personal situation (n=2)
    - Work conflict (n=1)
    - Exclusion by OP (n=1)
    - Discontinued intervention (n=1)

Allocated to Usual Care (n=72)

Follow-Up
- Administrative data: lost to follow-up (n=0)
- Questionnaires: lost to follow-up (n=0)

Analysis
- Intention to treat: Analyzed for administrative data (n=72)
- Analyzed for self-reported data (n=70)

Enrollment
- 145 randomized

Allocation
- Not meeting inclusion criteria on screening questionnaire (n=3798)
  - Not sick-listed (n=2470)
  - No distress (n=1114)
  - Refused to participate (n=214)
- No enrollment after contact by phone (n=541)
  - Returned to work (n=271)
  - Exclusion (n=50)
  - Refused to participate (n=208)
  - Unable to contact (n=12)
- Administrative data: lost to follow-up (n=0)
- Questionnaires: lost to follow-up (n=2)
  - Reasons:
    - Decision employee (n=1)
    - Unable to contact (n=1)

Assessed for eligibility by screening questionnaire (n=10110)
Figure 1. Flow of employees in the study.

Values of p < 0.05 were considered statistically significant for all analyses. Stata version 10.0 was used to test clustering within OPs in the Cox regression analyses. All other analyses were performed with SPSS version 14.0.

RESULTS

Employee flow
Figure 1 presents the flow of participants in this trial. Based on the response on the screening questionnaire, 686 employees were initially eligible for participation. After telephone contact, 541 employees were not enrolled due to several reasons (Figure 1). Finally, 145 employees fulfilled all inclusion criteria and were randomised to the workplace intervention (n=73) or usual care (n=72). The mean number of days between completing the screening questionnaire and randomisation was 12 days.

Loss to follow-up
The administrative sick leave data were available for all employees for the entire 12 months follow-up period. However, three employees left their company during the follow-up period. Those employees registered their sick leave manually on a monthly calendar and returned the calendar to the researcher. Two employees in the usual care group withdrew from the study. Therefore no follow-up data regarding self-reported outcomes could be collected.

Baseline characteristics
Table 1 shows the baseline characteristics of the participants in the workplace intervention and usual care group. There were only slight differences between the demographic, sick leave, work characteristics and stress-related symptoms.

Workplace intervention
In total, twenty employees allocated to the workplace intervention did not receive the allocated intervention. Seven employees returned to work before an appointment for the workplace intervention was planned. Twelve employees did not participate in the workplace intervention due to various other reasons (Figure 1). One employee started participating in the intervention, but neither the employee nor the supervisor could identify obstacles for RTW whereupon they decided to discontinue the workplace intervention. Adverse events or side effects were not reported.

All employees in the workplace intervention group consulted their OP in the first 3 months after randomisation, 21 employees (29%) consulted a company social worker (apart from the consultations with a company social worker in the workplace intervention), 36 (49%) were treated by a specialized mental health professional (psychologist, psychiatrist,
psychotherapist), 63 (86%) consulted their GP, 23 (32%) consulted a physiotherapist, and 24 (33%) consulted a medical specialist.

**Usual care**
In the usual care group, 70 employees (97%) consulted their OP in the first 3 months after randomisation, 24 employees (33%) consulted a company social worker, 25 (35%) were treated by a specialized mental health professional, 67 (93%) consulted their GP, 28 (39%) consulted a physiotherapist, and 30 (42%) consulted a medical specialist.

**Table 1.** Baseline characteristics, prognostic variables, and baseline values of outcome measures. Unless indicated otherwise the mean and standard deviation are presented.

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>WI (n=73)</th>
<th>UC (n=72)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>48.6 (7.7)</td>
<td>49.2 (8.6)</td>
</tr>
<tr>
<td>Gender (% male)</td>
<td>76.7</td>
<td>80.6</td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>high [n(%)]</td>
<td>21 (28.8)</td>
<td>20 (28.6)</td>
</tr>
<tr>
<td>average [n(%)]</td>
<td>29 (39.7)</td>
<td>29 (41.4)</td>
</tr>
<tr>
<td>low [n(%)]</td>
<td>23 (31.5)</td>
<td>21 (30.0)</td>
</tr>
</tbody>
</table>

| Sick leave characteristics |            |           |
| Sick leave in the past year |            |           |
| <10 days [n (%)]           | 31 (42.5)  | 37 (51.4) |
| 11 – 30 days [n (%)]       | 23 (31.5)  | 21 (29.2) |
| > 31 days [n (%)]          | 19 (26.0)  | 14 (19.4) |
| RTW expectations           |            |           |
| Within a month [n (%)]    | 18 (25.4)  | 20 (27.8) |
| More than a month [n (%)] | 53 (74.6)  | 52 (72.2) |
| Burnout                   |            |           |
| Emotional exhaustion (0 – 6) | 2.9 (1.7)  | 2.8 (1.6) |
| Depersonalization (0 – 6) | 2.0 (1.3)  | 2.0 (1.2) |
| Personal accomplishment (0 – 6) | 3.7 (1.0) | 3.8 (1.0) |

| Stress-related symptoms   |            |           |
| Distress (0 – 32)         | 20.7 (7.7) | 19.8 (7.7) |
| Depression (0 – 12)       | 3.3 (3.7)  | 3.5 (3.6)  |
| Anxiety (0 – 24)          | 6.5 (6.0)  | 5.2 (5.1)  |
| Somatisation (0 – 32)     | 12.8 (6.8) | 12.9 (6.4) |

| Work characteristics      |            |           |
| Job demands (12 – 60)     | 32.7 (5.37)| 32.0 (4.76)|
| Decision latitude (24 – 120) | 71.0 (10.7) | 69.3 (10.9) |

1 A higher score means a higher level of emotional exhaustion, depersonalization, personal accomplishment, distress, depression, anxiety, and somatisation.
Return to work
After 12 months follow-up, seven employees in the workplace intervention group and six employees in the usual care group did not achieve a lasting RTW. The median time until full and lasting RTW was 96 days (interquartile range IQR 52 - 193 days) in the workplace intervention group and 104 days (IQR 52 - 195 days) in the usual care group. The crude Cox regression analysis showed no overall effect of the workplace intervention compared to usual care. The unadjusted HR was 0.99 (95% CI 0.70 – 1.39).

In the univariate analyses the following variables appeared to be significant effect modifiers: baseline intention to RTW despite symptoms, baseline attitude to RTW despite symptoms, and baseline self-efficacy to RTW despite symptoms. All variables were classified as a confounder in the univariate Cox regression, except gender, social influence on RTW and decision latitude. In the final multivariate model, intention to RTW despite symptoms remained the only effect modifier, and sick leave in the past year and expectations about the duration of absence remained as confounders (Table 2).

For the employees who at baseline intended to RTW despite symptoms, the workplace intervention was associated with a shorter median duration of sick leave until a lasting RTW, compared to usual care. The cumulative incidence functions stratified for treatment group and intention to RTW are presented in Figure 2. The median time until full and lasting RTW for employees who at baseline intended to RTW despite symptoms was 55 days (IQR 27 - 89 days) in the workplace intervention group and 120 days (IQR 47 - 198 days) in the usual care group. For employees who at baseline intended to RTW despite symptoms, the HR was 2.05 (95% CI 1.22 – 3.45) (Table 2).

A HR of 0.78 (95% CI 0.47 – 1.28) was found for employees who had at baseline uncertain intentions to RTW despite symptoms, with a median of 141 days (IQR 78 - 216 days) in the workplace intervention group and a median of 97 days (IQR 61 - 185 days) in the usual care group. The proportional hazard assumption was not violated in any of these analyses.

Total number of days of sick leave in 12 months follow-up was 141 days in both groups and did not differ significantly (p=0.88). Five employees in the workplace intervention group experienced a recurrence of sick leave within 12 months and one employee experienced two recurrences. Six employees in the usual care group experienced a recurrence. Clustering on the level of the OP was not found in these analyses.

Secondary outcome measure
The results on the effectiveness of the workplace intervention on secondary outcomes are presented in Table 3. In both groups the severity of all stress-related symptoms improved significantly over 12 months (p < 0.001). However, no differences were found between the improvements in the workplace intervention group and the usual care group. In total, 46 employees (32%) still reported elevated levels of distress after 12 months follow-up.
Figure 2. Cumulative incidence functions for return to work during 12 months follow-up, by intervention condition and baseline intention to RTW despite symptoms.
Table 2. Differences in RTW between the workplace intervention and usual care group. Cox proportional hazard models with the results of the crude and adjusted Cox regression analyses. Beta coefficients, standard errors (SE), p-values, hazard ratio’s (HR) and 95% confidence intervals (CI) are presented.

<table>
<thead>
<tr>
<th></th>
<th>Crude model¹</th>
<th>Adjusted model – certain intention to RTW despite symptoms²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Beta coefficient</td>
<td>SE</td>
</tr>
<tr>
<td>Intervention</td>
<td>-0.01</td>
<td>0.17</td>
</tr>
<tr>
<td>Intervention – certain intention to RTW despite symptoms</td>
<td>0.72</td>
<td>0.27</td>
</tr>
<tr>
<td>Intention to RTW despite symptoms</td>
<td>0.10</td>
<td>0.27</td>
</tr>
<tr>
<td>Sick leave in the past year (11 days - 1 month vs 0-10 days)</td>
<td>-0.26</td>
<td>0.22</td>
</tr>
<tr>
<td>Sick leave in the past year (&gt; 1 month vs 0-10 days)</td>
<td>-0.61</td>
<td>0.24</td>
</tr>
<tr>
<td>Expectation duration of absence (&lt;1 month vs &gt;1 month)</td>
<td>-0.41</td>
<td>0.21</td>
</tr>
<tr>
<td>Interaction intervention*intention to RTW despite symptoms</td>
<td>-0.97</td>
<td>0.37</td>
</tr>
</tbody>
</table>

¹ The median time until full and lasting RTW was 96 days (IQR 52 - 193 days) in the workplace intervention group and 104 days (IQR 52 - 195 days) in the usual care group.

² The median time until full and lasting RTW for employees who at baseline intended to RTW despite symptoms was 55 days (IQR 27 - 89 days) in the workplace intervention group and 120 days (IQR 47 - 198 days) in the usual care group.

Table 3. Differences in stress-related symptoms. Results of the mixed models analyses. Means and standard deviations of both groups at baseline, 3, 6, and 12 months are presented, and the p-value of the difference between the groups.

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distress (0 - 32)</td>
<td>WI</td>
<td>20.7 (7.73)</td>
<td>11.9 (8.85)</td>
<td>10.7 (8.68)</td>
<td>9.00 (8.26)</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>19.8 (7.69)</td>
<td>12.3 (8.47)</td>
<td>10.4 (8.05)</td>
<td>8.37 (8.07)</td>
</tr>
<tr>
<td>Depression (0 - 12)</td>
<td>WI</td>
<td>3.32 (3.72)</td>
<td>1.81 (3.36)</td>
<td>1.69 (3.01)</td>
<td>1.30 (2.40)</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>3.50 (3.56)</td>
<td>2.06 (2.96)</td>
<td>1.43 (2.60)</td>
<td>1.04 (1.97)</td>
</tr>
<tr>
<td>Anxiety (0 - 24)</td>
<td>WI</td>
<td>6.49 (6.02)</td>
<td>3.67 (5.60)</td>
<td>2.93 (5.27)</td>
<td>2.55 (4.44)</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>5.19 (5.08)</td>
<td>2.76 (3.81)</td>
<td>1.61 (3.15)</td>
<td>1.50 (3.05)</td>
</tr>
<tr>
<td>Somatisation (0 - 32)</td>
<td>WI</td>
<td>12.8 (6.76)</td>
<td>8.68 (6.78)</td>
<td>7.08 (6.05)</td>
<td>6.81 (6.21)</td>
</tr>
<tr>
<td></td>
<td>UC</td>
<td>12.9 (6.40)</td>
<td>9.20 (6.15)</td>
<td>7.81 (5.65)</td>
<td>7.10 (6.14)</td>
</tr>
</tbody>
</table>

WI baseline n = 73, 3 months follow-up n = 72, 6 months follow-up n = 72, 12 months follow-up n = 73. UC baseline n = 72, 3 months follow-up n = 68, 6 months follow-up n = 70 12 months follow-up n = 70.
DISCUSSION

Main findings
The present study showed no superior effect on lasting RTW of the participatory workplace intervention compared to usual care for sick-listed employees with distress. However, the intervention reduced the time until a lasting RTW for employees who at baseline reported the intention to RTW despite symptoms.

Comparison with other studies
Our study results are not in line with a study for self-employed workers with adjustment disorders, which found a superior effect on RTW of a combined intervention consisting of a brief cognitive behavioural therapy program and advice by a labour expert on work adaptations, compared to usual care and cognitive behavioural therapy(27). Although not measured, it can be assumed that, owing to the immediate (financial) consequences of their absence from work, self-employed will likely intend to RTW despite symptoms. The positive findings of this study are therefore in line with the findings for the subgroup with intentions to RTW despite symptoms in our study. Very recently, a study by Brouwer et al. emphasized the importance of behavioural determinants in the field of RTW(28). That study indicated that work attitude, social support, and a subscale of self-efficacy were predictive for RTW in a cohort of employees with a maximum of 12 weeks of sick leave. Intention to RTW was not measured in that study.

Strengths and limitations
A strength of this study is the primary outcome lasting RTW. Data about RTW were available for all employees and unbiased. Lasting RTW, which considered the sustainability of RTW by allowing for recurrences within 4 weeks is a robust outcome measure. Many studies report the first RTW even though it is generally known that a first RTW is not as relevant as lasting RTW, because it ignores recurrences(29). Furthermore, the generalizability of the results is high due to the pragmatic RCT design and the broad inclusion criteria for the study population. The study had no loss to follow-up for the sick leave data and minimal loss to follow-up for the self-reported outcomes.

Obviously, this study has some limitations. First, although the interaction between the workplace intervention and the baseline intention to RTW despite symptoms was highly significant, the results retrieved from the adjusted analysis need to be interpreted carefully(30). The results of the adjusted analysis have an exploratory nature and should be confirmed in future RCTs with larger sample sizes. Second, the behavioural determinants were measured by questions whose structure was deduced from studies in health promotion and which were applied to RTW. The validity of these questions applied to RTW is unknown. A limitation of the questions is that no time frame for RTW was incorporated. There is thus a need for validated questionnaires with regard to these variables. Third, the guideline for OPs for treatment of workers with mental health problems, which was applied in both groups, recommends workplace accommodations.
Also, employees and supervisors are legally obligated to make a RTW plan (Improved Gatekeeper Act). These elements of usual care may have reduced the contrast between the groups in our study. However, we believe that the contacts between the employee and supervisor in the workplace intervention were certainly more intensive and more structured than in usual care. This assumption is confirmed by the effects of the intervention for employees with a baseline intention to RTW despite symptoms.

**Interpretation of results**
For employees with LBP, the participatory workplace intervention was overall effective in Canada and the Netherlands(13;15). This discrepancy with the results of our study can be explained by the fact that among employees and employers it is more accepted to work with LBP than to work with mental health problems. This explains also the difference in median duration until lasting RTW between LBP and mental health problems. Most employees with LBP returned to work at short-term, while about 34% of the employees with distress did not reach a lasting RTW at 6 months. With regard to stress-related sick leave, stigma is involved; employees, supervisors, and even OH professionals indicated that it is difficult to discuss RTW(12). Focus groups prior to our trial indicated that fear for an increase in stress-related symptoms resulting from early RTW is still common(12). Oomens et al. recently found that the traditional view that employees should take the necessary time to recover completely before they return to work still exists and may impede RTW(31). It is likely that cautiousness connected to stress-related sick leave explains a longer duration until full and lasting RTW.

This is the first study that assessed behavioural determinants regarding RTW of employees with distress. The role of self-efficacy in RTW processes is frequently assessed, but not clear yet(28;32-36). To our knowledge, intention to RTW was not measured before. Our results indicate the importance of the baseline intention to RTW despite symptoms. At first sight intention and self-efficacy seem to measure closely related constructs, but no effects of self-efficacy were found, so apparently these questions tap different constructs. No significant effect was found for the subgroup employees without baseline intentions to RTW despite symptoms. The median number of days until lasting RTW indicated a tendency towards a delayed effect on RTW of the workplace intervention in this group. This is a worrisome finding because this is a most problematic group for OPs. This finding suggests that employees without baseline intention to RTW despite symptoms require a different treatment approach than the employees who intend to RTW despite symptoms. A focus on RTW without adapting their motivation for working despite symptoms may be insufficient for this group. Prochaska’s stages of change model conceptualised the development of motivation for behaviour change(37), which is theoretically applied to RTW by Franche and Krause(32). According to this model, employees without intentions to RTW may be in the precontemplation or contemplation phases of readiness for RTW. Based on this assumption, we hypothesize that employees without intentions to RTW despite symptoms need an (additional) intervention that aims at changing cognitions or motivation regarding RTW with sustained symptoms. Cognitive behavioural interventions
could be applied to change the motivation for RTW despite symptoms, as these interventions were found to be effective on RTW for employees with adjustment disorders (27;38). However, future research is needed to confirm this hypothesis.

**Implications for practice**
With great caution we conclude that the practical implication for OPs is to verify whether an employee intends to RTW despite the existence of symptoms. If that is the case, a workplace intervention is recommended. For employees who have no intentions to RTW despite symptoms, a workplace intervention should not be recommended.
References

(3) Weehuizen RM. Mental Capital; The economic significance of mental health Maastricht University; 2008.


