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Original Research

The effects of a group based stress treatment program (the Kalmia concept) targeting stress reduction and return to work. A randomized, wait-list controlled trial.

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Abstract

Objective: The aim of this study was to evaluate the effects of a group based multidisciplinary stress treatment program on reductions in symptom levels and the return to work (RTW) rate.

Methods: General practitioners referred 199 patients with persistent work related stress symptoms to the project. The inclusion criteria included being employed and being on sick leave. Using a randomized wait- list control design, the participants were randomized into three groups: the intervention group (IG, 70 participants) was treated using the Stress Therapy Concept of Kalmia, which consists of an integrative approach of group psychotherapy for 2.5 hours per week and Basic Body Awareness Therapy (BBAT) with mindfulness meditation for 1.5 hours per week, which runs in a parallel process supplemented with workplace dialogue; the treatment-as-usual control group (TAUCG, 71 participants), who received 12 consultations with a psychologist; and the wait-listed control group (WLCG, 58 participants). Treatment in the IG and the TAUCG lasted 10 and 12 weeks, respectively.

Results :Reductions in symptom levels (as measured by scores on the SCL92) were significantly larger in the IG (Cohen´s d= 0.73) and TAUCG compared to the WLCG . Further, the prevalence of depression declined significantly in the IG and the TAUCG compared to the WLCG. Regarding the RTW rate, 66% of the participants in the IG had returned to full time work after three months. This rate was significantly greater than the percentage in the TAUCG (36%) and the WLCG (24%).

Conclusion : The stress treatment program significantly reduced symptom levels and increased the RTW rate in the IG compared to the TAUCG and the WLCG.

INTRODUCTION

Interventions to alleviate job stress have multiplied rapidly over the last two decades [1,2]. The results of the interventions are difficult to compare, as they are characterized by great heterogeneity in terms of 1) *intervention type and form* (information only, workshops, advice and training, treatment/therapy, one treatment component vs. multimodal, practitioner's professional background, individual vs. group therapy), 2) *the volume of the intervention* (number of sessions/consultations), 3) *intervention level* (individual, organizational or both), 4) r*ecruitment of participants* (general practitioner (GP), workplaces, union social workers, direct inquiry) and 5) *outcome variables* (psychological, physiological, and/or organizational).

Focusing on reviews that only include studies in which the interventions were generally directed at members of the working population, we found two reviews, specifically, van der Klink, et al. [3] and Richardson and Rothstein [2], which provided results from meta-analyses of the effects of the included studies. In the meta-analysis by van der Klink, et al., all experimental or quasi-experimental design studies involving a no-treatment control group were included, whereas Richardson and Rothstein only included randomized control studies (RCT) studies in their meta-analysis. As there was heterogeneity in the included studies, effect

sizes were reported separately for cognitive behavioral therapy (CBT) interventions, relaxation techniques, multimodal programs, organization focused interventions, and other alternatives.

Both meta-analyses found a significant overall effect size, indicating that stress management interventions are effective compared to no treatment.

Work-related stress is related to the development of common mental disorders and long-term sick leave [4]. The latter is a major risk factor for early withdrawal from the labor market. Only 50% of people who are on sick leave for more than 6 months due to poor mental health return to work [5]. This finding has resulted in a growing interest in the evaluation of the effects of stress management interventions on the return to work rate (RTW). Reviews and evaluation studies find positive effects on the RTW rate through interventions based on CBT and significant effects of interventions directed both at the worker and the workplace [6-8]. However, study results are inconsistent. In the Netherlands, guidelines for treatment of mental health problems by occupational physicians and general practitioners (GP) have been developed based on cognitive behavioral principles and aim to enhance the problem-solving capacity of patients in relation to the work environment [8]. In an RCT, no significant effect of the use of these guidelines was found on the RTW rate [9]. In a process evaluation study, it was concluded that the guidelines for the management of common mental health problems and return to work should focus on regular contact with the worker and the work organization [10]. The findings imply that the amount of contact and number of consultations is also important for the effects of the intervention. Accordingly, a RCT found no effect on self-reported symptoms or on the duration of sick leave following a "minimal intervention" treatment for stress-related mental disorders, with sick leave consisting of a maximum of 3 consultations of 10-20 minutes with a GP [11,12], and no effect on sickness absence was found following the use of brief, preventive stress reduction programs consisting of four one- hour sessions [13]. Additionally, no evidence has been found for the effects of purely solution-focused therapy on the RTW rate, supporting the argument that the RTW rate is a complex and multi-factorial process involving personal, health related, and job-related factors, as well as negative and positive experiences of the past and present, and dynamically interrelated anticipation of the future [5,14].

Inherent limitations of studies of work resumption are national differences in labor market regulations and differences in official sick leave policies, weakening the comparability of studies across countries [15,16]. In Denmark, research on the efficacy of job stress interventions is scarce. To date, only one RCT has been published showing significant positive effects on perceived stress and the coping dimension "positive reframing" [17], as well as regarding absenteeism of participants in a three-month, group-based CBT stress management program [16].

In conclusion, both international and national research on the efficacy of job stress interventions finds

1) Significant positive effects on mental health symptoms by individual level interventions based on the principles of cognitive behavioral therapy.

2) Relaxation techniques and multimodal interventions also show significant effects, although they are smaller than those produced by CBT.

3) Organizational interventions generally yield virtually no effect on psychological or organizational measures. When effects are noted, they are both positive and negative.

4) Results indicate that job stress interventions that match the needs of the employees/patients are central to the success and effects of the intervention.

5) Significant positive effects on absenteeism and the RTW rate due to interventions based on CBT are directed at both the worker and the workplace.

The aim of this study is to evaluate the effects of a group based stress treatment program for employees on sick leave due to work-related stress using a randomized wait-list control design. The effects on symptom level reduction and the RTW rate of the program are evaluated compared to no treatment (wait-list controls) and treatment as usual (consultations with a psychologist).

MATERIAL AND METHODS

From June 2010 to September 2010, we invited all general practitioners in the Capital region of Denmark (1.6 million inhabitants) to refer patients with stress symptoms to our project. The purpose of the study and criteria for participation were described in the invitation. Inclusion criteria were as follows: the participant must 1) be on full time or part time sick leave, 2) be employed or self employed, 3) have significant symptoms of work-related stress during months and 4) be motivated to participate. Exclusion criteria were 1) current abuse of alcohol or psychoactive stimulants, 2) major psychiatric disorder and 3) significant somatic disorder assumed to be the primary cause of the stress condition.
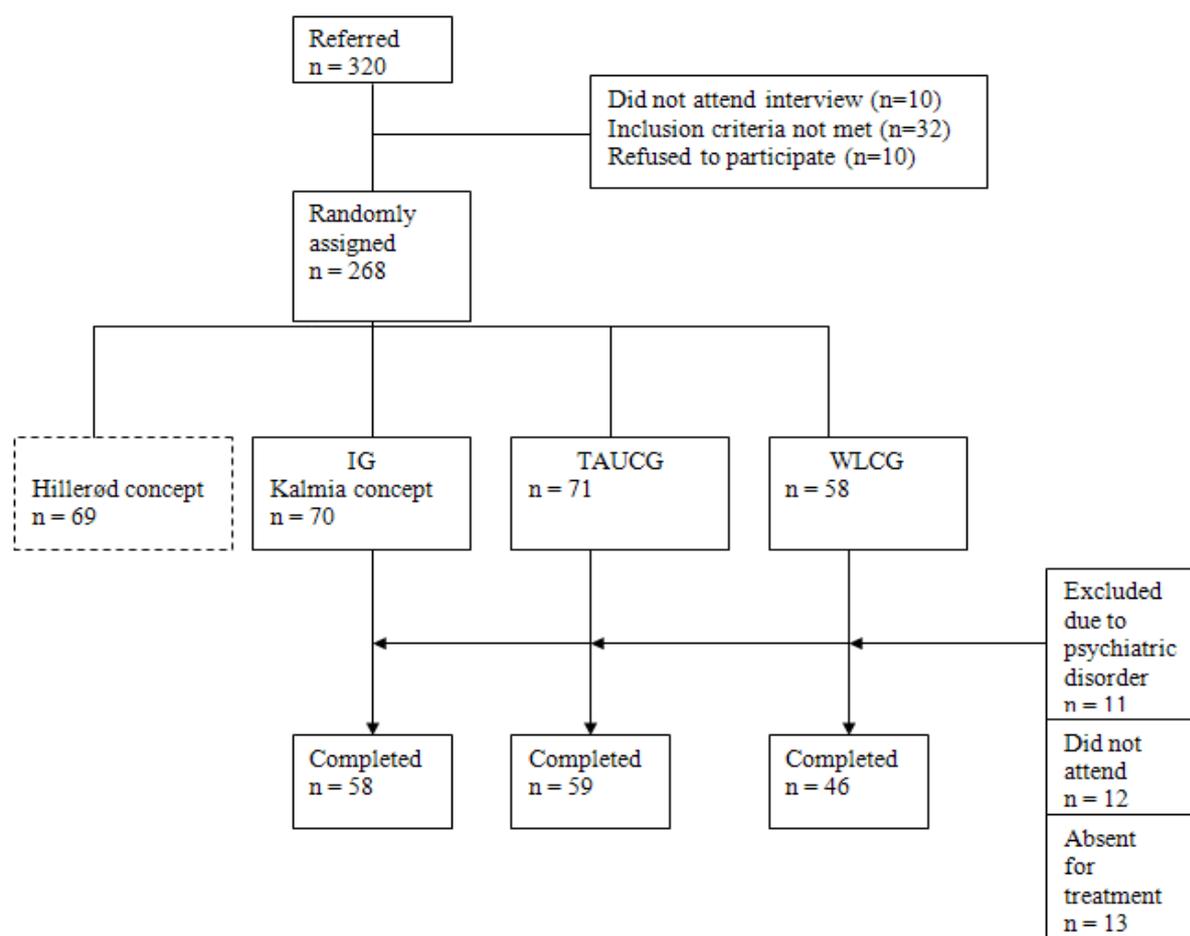
Figure 1. Flow diagram showing how participants were assessed for inclusion in the study

From August 4th, 2010 to April 8th, 2011, 320 potential participants were referred to the study. Each participant was invited to an information consultation at Bispebjerg Hospital within 2 weeks of referral. The invitation letter included the date and place of the consultation, a pamphlet describing participation in a scientific project, a written informed consent form published by the Scientific Ethical Committee, and a layman's edition of the scientific protocol that was approved by the Scientific Ethical Committee. At the information consultation, which was conducted by a medical physician, psychologist or psychology student, the inclusion criteria were immediately evaluated. The exclusion criteria, however, were more difficult to assess during one single consultation, and no potential participants were excluded due to these criteria at the time of the information consultation.

Of the 320 participants that were referred to the study, 10 (3.1%) did not show up to the information consultation, 32 (10%) did not fulfill the inclusion criteria due to unemployment or a return to work during the time between the referral and the

consultation, and 10 (3.1%) did not want to participate.

Therefore, 268 participants (83.8%) of the referred sample were included in the study. A randomization procedure was carried out as follows. The participants were randomized into one of the following four groups: 1) Intervention Group 1 (IG), who were treated with the Kalmia concept, which included 10 weeks of group based psychotherapy for 2.5 hours per week and Basic Body Awareness Therapy (BBAT) with mindfulness meditation for 1.5 hours per week, running in a parallel process complemented with workplace dialogue; 2) Intervention Group 2: Treatment with the Hilleroed concept [18], which consisted of 8 individual stress treatment consultations and a group based mindfulness course lasting 2 hours per week for 8 weeks; 3) Treatment As Usual Control Group (TAUCG), which offered 12 conventional individual sessions with a psychologist in one of two practices with 7 psychologists each; and 4) the Wait List Control Group (WLCG) who had to wait approximately 3 months before receiving the same treatment as Intervention Group 2.

Table 1. Characteristics of participants and dropouts.

	Completed	Drop Outs	p	Total
N	223	33		256
Age, mean	44.3	42.4	0.21	44.0
Women (%)	80.3	66.7	0.05	78.0
Married (%)	62.0	64.2	0.81	62.4
Occupation:			0.04	
Academics, self employed (%)	35.9	45.5		37.1
Medium education (%)	38.6	15.2		35.5
Workers (%)	25.6	39.3		27.4
Moderate/severe depression, (%)	42.1	60.7	0.003	44.2
Mean GSI score	1.2	1.6	0.002	1.3

Table 2. Baseline characteristics for the intervention group (IG), the treatment as usual control group (TAUCG) and the wait list control group (WLCG).

	IG	TAUCG	WLCG	Total
Randomized	70	71	58	199
Excluded due to psychiatric disorder	6	3	2	11
Did not attend treatment	0	4	8	12
Excluded by being absent during treatment	6	5	2	13
Completed	58	59	46	163
Age ($\bar{x}$)	45.0	44.8	44.8	44.9
Women (%)	84.5	78.0	84.4	82.1
Married (%)	62.1	59.3	65.2	61.8
Occupation:				
Workers	22.8	30.5	11.1	22.2
Medium education	37.9	44.1	37.8	40.1
Academics	39.7	25.4	51.1	37.7
Sick leave fulltime (%)	72.4	71.2	76.1	73.1
Sick leave, number of days ($\bar{x}$)	69.7	64.7	77.9	70.2
Moderate/severe depression, (%)	46.3	45.5	42.2	44.8
Antidepressant medication (%)	16.7	15.1	17.1	16.2
GSI ($\bar{x}$)	1.26	1.31	1.21	1.26
Work ability index ($\bar{x}$)	2.8	2.6	2.2	2.5
Stress index ($\bar{x}$)	3.8	3.7	3.8	3.8

The randomization procedure (drawing lots) was conducted by a secretary a different hospital. The outcome of the procedure was stated in the referral document and was sent to Bispebjerg Hospital where the information consultation took place. Consultations involving participants randomized to the WLCG were conducted by a trained medical physician or psychologist who could respond to any disappointments exhibited by the participants and who could try to prevent any bias in the participant's responses to the questionnaires. The participants were informed of the results of the randomization only <u>after</u> they had agreed to enter the project and the written informed consent form had been signed.

Four of the participants randomized to the TAUCG and eight to the WLCG did not show up for treatment. We have only basic data (name, address and civil personal number (CPR)) for these participants.

Of the remaining 256 participants who enrolled in the project, 223 completed the treatment (87.8%).

Of the 33 dropouts, 17 were excluded due to major psychiatric disorder during the first weeks of treatment. Of these 17 participants, 15 were evaluated by a psychiatrist who proposed other kinds of treatment to the referring GP. Sixteen participants were excluded because they did not complete the treatment or were absent more than 2 times during the duration of

treatment.

As shown in Table 1, the dropouts were predominately female, were less educated and had higher symptom level scores than those who completed the treatment.

The aim of the randomization was to allocate 70 participants to each of the four groups. However, due to a lack of resources, it was necessary to terminate the treatment of participants by the end of June 2011. Therefore, recruitment to the WLCG was stopped in December 2010, resulting in only 58 participants in this group. Recruitment for the other groups continued until April 2011. One participant randomized to group 2 was mistakenly allocated to the TAUCG.

This publication only addresses the results of the Intervention Group 1 (IG) (Kalmia concept), the treatment as usual control group (TAUCG) and the waitlisted control group (WLCG).

Six of the 70 IG participants were excluded due to major psychiatric disorder, and six did not complete the treatment (Table2). In the TAUCG, 3 participants were excluded due to psychiatric illness, 4 did not attend treatment, and 5 did not complete the treatment. Two WLCG participants were excluded due to psychiatric illness, 8 participants did not attend treatment, and 2 did not complete the treatment.

The Stress Therapy Concept in Kalmia

For each participant, the therapy program began with a comprehensive interview to uncover and clarify the elements of a participant's life that brought them to their current position. This history was discussed at an interdisciplinary conference with the participation of psychiatrists and therapists. The program consisted of an integrative approach of group psychotherapy for 2.5 hours per week and Basic Body Awareness Therapy (BBAT) with mindfulness meditation for 1.5 hours per week running in a parallel process. Each group therapy session had 6 participants and two therapists. The length of the program was 10 weeks. If needed, the treatment was complemented with workplace dialogue.

The psychotherapeutic method of therapy was based on an integrative approach that draws on recent understanding of stress in the relationship between brain function, affect regulation, problem solving and interpersonal relating [19-21]. The group therapy followed the format of Focused Group Therapy, developed within a research project for treatment for worn out patients at the Karolinska Institute, Sweden. The general factors of psychotherapeutic change are categorized into support factors, learning factors and action factors [22,23].

Mindfulness practice is considered beneficial within psychotherapeutic approaches, as it promotes health and reduces stress. The purpose of mindfulness is to develop the ability to be present and aware of the relationship between thoughts, feelings and bodily sensations [19,24,25]. Recent studies have shown that mindfulness is an effective method of psychotherapy in relation to broader issues such as anxiety and depression [26-28]. Along with BBAT, mindfulness promotes the body's abilities for relaxation and restoration, as well as for recovery [19,29-31].

Six therapists with extensive clinical experience and education, who practiced different therapeutic approaches, including relational, dynamic, gestalt and cognitive therapy, performed the treatment therapy.

Control groups

TAUCG participants were offered 12 conventional individual sessions during 3 months with a psychologist at one of two 7-psychologist practices. Therefore, each psychologist treated approximately 5 participants. The treatment varied and might have included cognitive behavioral therapy, narrative methods, and other techniques normally used by psychologists in the Copenhagen area for the treatment of stress symptoms. The WLCG did not receive treatment for 3 months; however, two-thirds of these participants reported that they had received some type of treatment from a psychologist or their GP during this time.

Participants completed a questionnaire regarding demographic variables, including civil status, number of children at home, employment, employer, work hours per week, dates of sick leave, medication use, and baseline smoking and alcohol habits. During the information consultation and after three months (i.e., during the penultimate treatment session for the IG and at the beginning of the treatment for the WLCG), the following questionnaires were administered and were completed by the participants at home: the Symptom Check List 92 (SCL92) [32], the Major Depression Inventory (MDI) [33], the Copenhagen Psychosocial Questionnaire (COPSOQ) and a supplementary questionnaire concerning sleep quality, work ability, stress [34] and supplemental treatments in the previous three months. At the end of treatment, participants and their treating psychologists jointly completed a final questionnaire that examined when sick leave had stopped or increased for those with part-time sick leave, a job change, unemployment, or who were using medication. Finally, this survey evaluated the types of stressors responsible for participant stress.

Outcomes

RTW rate

Sick leave status after treatment was assessed during

the final consultation for IG and TAUCG participants and during the first consultation for WLCG participants. There were 5 possible assessments: 1. Working full time, 2. Increased working hours, 3. Unemployed but available to work, 4. Unemployed but on sick leave, and 5. No change in sick leave. The RTW rate was treated as two binary variables with the following options: A) *Full time work*=1+3 versus 2+4+5 and B) *Increased work* hours from baseline=1+2+3 versus 4+5.

Symptoms

1) The SCL92 was used to calculate the global symptom index (GSI) and its 9 subscales according to [32].

2) Using the MDI score, the degree of depression was categorized into severe, moderate, mild and no depression according to [33]. 3) Workability was measured on a scale ranging from 0 to 10 using the following question: "Assess your work ability as ten points when you are at your best. How do you rate your work ability currently?" 4) The degree of stress was measured using the following question: "'Stress' is a condition characterized by unrest, agitation or anxiety and/or sleeping problems. Do you experience stress at the moment?" There were 5 options for answers ranging from "not at all" to "always".

Statistical analyses

First, a chi-square test compared the RTW rates across the three groups. Then, logistic regression analyses were conducted that compared IG participants with TAUCG and WLCG participants after controlling for age, gender, days of sick leave before treatment and occupation as possible confounders. Finally, degree of depression, stress, the work-ability score (WAS) and the GSI were added to the model.

The GSI and WAS at the end of treatment (or the beginning of treatment for the WLCG) were used as the outcomes. General linear models controlled for age and gender in the first model, and the second model adjusted for the dependent variable at baseline. A third model adjusted for civil status, the number of children at home, occupation and days of sick leave before treatment. Finally, the between-group changes with regard to each SCL92 subscale after the first three months were compared using a GLM that adjusted for the baseline values, age and gender. Cohen's d was used as the effect size [35] .

RESULTS

Table 2 gives the baseline characteristics for the three groups. There was a non-significant tendency for the

participants in the WLCG to be more educated and to have a longer duration of sick leave before entering the study. No significant differences between the groups were detected. There were significantly more women than men in all of the groups, and 73.1% of the participants were on full time sick leave for an average of more than two months. Almost half of the participants' scores on the MDI indicated moderate to severe depression, while only 16.2% were receiving antidepressant medication.

Figure 2 shows the proportion of the participants in the three groups on full time work and increased working hours compared to baseline. Significantly more participants from the IG were at work full time compared to both control groups. However, the difference in increased number of working hours was not significant compared to the TAUCG.
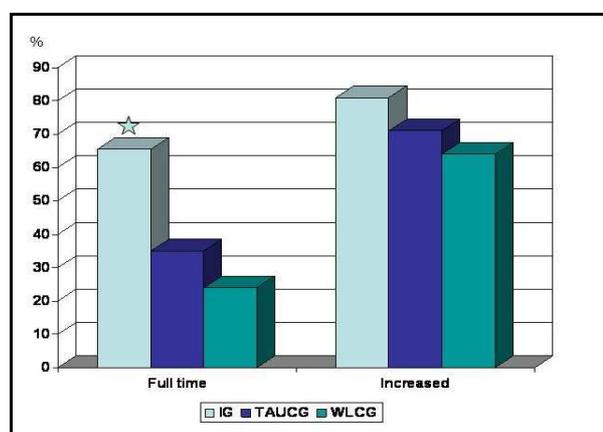
Figure 2. Return to work (percentage at work) in the intervention group (IG), the treatment as usual control group (TAUCG) after treatment and the wait list control group (WLCG) after 3 months on a waiting list.

The odds ratios between the IG and the two control groups regarding the RTW rate are shown in Table 3. The models have increasing numbers of adjustment factors. The odds ratio for full time work in the IG compared to the other groups was highly significant. Adjustments did not affect the relationship, except for a tendency for a stronger association with treatment group after full adjustment when the IG was compared to the WLCG.

No significant difference between the IG and TAUCG could be detected regarding increased working hours. This was the case in the comparison between the IG and the WLCG. The significance disappeared when the comparison was adjusted for other outcome measures, even if the size of the association remained.

The associations between symptoms and treatment

groups are shown in Table 4. No differences were found between the IG and TAUCG regarding the Global Symptom Index (GSI) and the Work Ability Index (WAS). However, the GSI after treatment was significantly higher in the WLCG compared to the other groups, even after controlling for relevant confounders. The WAS was significantly higher in the two treatment groups after treatment compared to the WLCG, but the significance disappeared when confounders were controlled. Cohen´s *d* was 0.67 for the GSI and 0.46 for the WAS in the IG compared to the WLCG, showing a medium effect of the treatment.

Finally, changes in symptom scores were calculated for the IG using a paired t-test (Table 5). All changes were significant. In the GLM, the differences in the scores between the groups were tested. No significant differences were found between the IG and the TAUCG. For all scales except for paranoid anxiety, interpersonal sensitivity and psychoticism, the changes in the WLCG were significantly smaller than for the other groups. The effect sizes for anxiety, depression and all symptoms were medium, as assessed by Cohen's *d*.

Table 3. Odds ratio for return to work after treatment (IG and TAUCG) and after 3 months on a waiting list (WLCG)

Adjustment factors	IG/TAUCG		IG/WLCG	
	Full time work OR (95 % CI)	Increased work OR (95 % CI)	Full time work OR (95 % CI)	Increased work OR (95 % CI)
Model 1	3.47 (1.6-7.5)	1.79 (0.7-4.3)	5.89 (2.4-14.0)	2.40 (1.0-6.0)
Model 2	3.20 (1.5-6.9)	1.70 (0.7-4.2)	6.41 (2.6-15.7)	2.58 (1.1-6.6)
Model 3	3.50 (1.3-9.4)	2.38 (0.6-8.9)	9.51 (2.5-36.4)	2.47 (0.5-11.4)

Model 1: Age and gender
Model 2: Model 1, plus occupation and sick leave days before treatment
Model 3: Model 2, plus grade of depression, stress and work ability at baseline and end of treatment

Table 4. Mean values of the Global Symptom Index (GSI) and the Work Ability Index (WAS) in IG, TAUCG and WLCG adjusted in general linear models. The 95% confidence intervals are noted in brackets.

Adjustment factors	IG		TAUCG		WLCG	
	GSI	WAS	GSI	WAS	GSI	WAS
Model 1	0.61 (0.5-0.7)	5.45 (4.7-6.1)	0.68 (0.6-0.8)	5.79 (5.1-6.4)	0.84* (0.7-1.0)	4.49* (3.7-5.2)
Model 2	0.61 (0.5-0.7)	5.28 (4.6-5.9)	0.63 (0.5-0.7)	5.71 (5.1-6.4)	0.89** (0.8-1.0)	4.71(*) (4.0-5.4)
Model 3	0.58 (0.5-0.7)	5.25 (4.6-5.9)	0.60 (0.5-0.7)	5.86 (5.1-6.5)	0.86 (0.8-1.0)	4.82 (4.1-5.5)

Model 1: Age, gender
Model 2: Model 1, plus dependent variable at baseline
Model 3: Model 2, plus civil status, children, occupation, sick leave days before treatment

 (*):p<0.1
*: p<0.05
**: p< 0.01

Table 5. Changes in SCL92 symptom scores for the IG and both control groups. P values and Cohen´s *d* (effect size) are shown for the IG compared to the WLCG.

	IG* mean (SD)	IG** Mean (SE)	TAUCG mean (SE)	WLCG Mean (SE)	p IG/WLCG	Cohen´s *d* IG/WLCG
Somatization	-0.73 (0.59)	-0.73 (0.06)	-0.77 (0.06)	-0.55 (0.07)	0.04	0.43
Anxiety	-0.82 (0.60)	-0.83 (0.06)	-0.77 (0.07)	-0.50 (0.07)	0.003	0.61
Depression	-0.88 (0.71)	-0.91 (0.08)	-0.87 (0.09)	-0.51 (0.09)	0.003	0.62
Hostility	-0.49 (0.58)	-0.50 (0.06)	-0.41 (0.06)	-0.23 (0.06)	0.009	0.47
Paranoid ideation	-0.50 (0.58)	-0.51 (0.06)	-0.52 (0.06)	-0.29 (0.06)	0.02	0.33
Obsession	-0.87 (0.60)	-0.89 (0.07)	-0.89 (0.08)	-0.63 (0.08	0.03	0.45
Psychoticism	-0.28 (0.74)	-0.28 (0.04)	-0.27 (0.04)	-0.23 (0.04)	0.62	0.22
Phobic anxiety	-0.31 (0.52)	-0.31 (0.08)	-0.39 (0.08)	-0.25 (0.09)	0.48	0.11
Interpersonal sensitivity	-0.59 (0.57)	-0.59 (0.07)	-0.52(0.07)	-0.29 (0.08)	0.08	0.56
GSI	-0.66	-0.67 (0.04)	-0.66 (.05)	-0.35 (0.05)	<0.001	0.73

* Paired t-test
** GLM after adjusting for baseline value, gender and age

The prevalence of moderate to severe depression declined in all groups. The prevalence in the IG was 9.3% and was 7.8% in the TAUCG, which was significantly lower than the 24.4% prevalence observed in the WLCG (p<0.04).

DISCUSSION

This study showed clear effects of the intervention program in terms of the RTW rate compared to the treatment as usual control group and the wait list control group. With respect to improvement of the symptoms, there was a significant effect of treatment versus no treatment. Methodological weaknesses could affect these results. A certain amount of selection bias has probably occurred. For example, there were more low-skilled participants among the dropouts, and dropouts also had more severe symptoms than those who completed the treatment. This selection bias makes it difficult to generalize the results to the working population. The fact that the participants were mainly employed, predominantly as public employees (e.g., social workers and health care workers), and had medium education levels gives the impression that this particular group is more motivated to seek out the kind of treatment applied in the study than other occupational groups. This weakness was also found in another Danish RCT [16]. In the WLCG, participants were generally highly educated and had a relatively longer duration of absenteeism. One reason for this finding could be that the 8 participants who did not begin the treatment after waiting, despite initially agreeing to participate in the study, were relatively more skilled and might have urgently needed treatment and therefore would not accept waiting. The direction of this bias is difficult to assess. An intention to treat analysis to assess directional bias will be performed in the future based on register data comprising absenteeism among all enrolled participants.

One could argue that the IG was given more hours of treatment than the TAUCG, but the treatment was performed in a group setting and therefore cannot be directly compared quantitatively. It was crucial that the treatment duration was of a similar magnitude, 10 to 12 weeks, and was the shortest for the IG. The fact that two thirds of the WLCG underwent some form of treatment while waiting for treatment in our study puts the results in perspective, but still produces a possible underestimation of the effect of the intervention.

It would have been preferable to have a true control group of participants who were not waiting for treatment, with the intended effect that some participants would delay their RTW. However, the large proportion of participants in the WLCG who sought out treatment during the waiting period contradicts this theory.

Although, in terms of symptoms, the participants were similar, participants were not diagnostically well defined. The starting point was the GP's assessment of the condition of the individual. Only 11 participants were excluded due to psychiatric illness, which suggests that the referring physicians selected participants who met the inclusion criteria. Symptom profiles as measured by the SCL92 showed that the participants had adjustment disorders characterized by a variety of symptoms and a significant degree of depressive symptoms.

The strengths of the study are the RCT design with two control groups and a high participation rate (82%). The randomization seemed to be managed satisfactorily, as participants in the three groups were comparable with respect to important variables such as marital status, age, gender, sick leave status, medication and symptom severity.

The fact that the physician or psychologist who obtained informed consent was aware of the outcome of the randomization process could lead to bias in terms of the way information was given to the participants. This may be evidenced by the 4 participants in the TAUCG and the 8 participants in the WLCG who did not show up for treatment even though they met the inclusion criteria (Table 2). However, more likely explanations may be that they preferred other forms of treatment and that the participants in the WLGG did not want to wait 3 months for treatment to begin. It should be noted that the results of the randomization were recorded on the reference papers and it was not possible to change groups. This specific procedure was chosen with regard to the participants assigned to the WLCG. We thought that these participants might get upset, be disappointed or have more questions. Therefore, trained medical physicians or psychologists conducted the information consultations. It is expected that because of this procedure relatively more participants would chose to stay in the program when they were told that they were in the WLCG. It was expected that this procedure would minimalize bias in the baseline questionnaires due to emotions associated with being in the WLCG. As stated above, the three groups were comparable in relation to all relevant parameters.

One might suppose that the improvement of symptoms was greater in the IG than in the TAUCG because the IG increasingly gained full time employment. This is perhaps a key point as the intervention treatment concept included workplace dialogue as an objective, which is in opposition to normal psychological treatment. Focusing on return to work early in the

course of treatment could be the reason for the indicated effect. A one year follow-up of the RTW rate is planned and will determine if there is merely an acceleration of the RTW process, as a previous Danish study [16] has shown, or if there is a lasting effect of treatment.

Compared to normal Danish values, phobic anxiety, hostility, paranoid ideation, psychoticism and interpersonal sensitivity in the treatment groups almost reached the normal values after treatment, whereas somatization, depression, anxiety and obsession mean values were still significantly higher than normal[32].

The results of this study are comparable with those of other randomized studies [8,13,16,36,37]. Differences in the options to remain on sick leave, the risk of losing one's job during sick leave, and economic compensation during sick leave make it difficult to compare results from different countries regarding the RTW rate. A higher motivation to return to work is expected when the risk of getting fired is high or when a substantial decline in income is possible. Compared to the only existing Danish study, which used group based CBT as an intervention, the results on improvement in symptom levels were the same size [16]. Half of the participants in the Willert study were not on sick leave at baseline, and one of the inclusion criteria was that a return to work was expected within 4 weeks from baseline. This finding implies that the participants in that program may have had milder stress conditions than those participating in our research program. The fact that the RTW rate in our study was greater than in the Willert study may indicate that the focus on RTW in the IG was essential for a positive outcome.

CONCLUSION

The Kalmia treatment concept was effective regarding the RTW rate compared to both the treatment as usual and wait-listed control groups. Regarding symptom reduction, the program seems comparable to different kinds of treatment by psychologists but superior to no treatment with a medium effect size.

The work described in this article have been carried out in accordance with *The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans*

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