

## Changes in stress and coping from a randomized controlled trial of a three-month stress management intervention

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**Objectives** The aim of this study was to investigate whether a group-based stress management intervention, based on principles from cognitive behavior therapy, can reduce stress and alter coping strategies in an occupationally diverse population with extensive symptoms of work-related stress.

**Methods** Using a randomized wait list control design, 102 participants were divided into two groups: intervention and wait list control. The intervention was a three-month group-based stress management program. Outcomes measures were the Perceived Stress Scale (PSS-10, range 0–40 points) and five dimensions from the Brief COPE questionnaire (range 2–8 points) at baseline and three-, six- and nine-months follow-up. Data were analyzed with a univariate analysis of variance.

**Results** On the PSS-10 from baseline to three months, the intervention group changed -6.45 (95% CI -8.25–-4.64) points, compared to -1.12 (95% CI -2.94–0.70) points in the wait list control group. The between-groups difference was -5.32 (95% CI -7.89– -2.76) points, equalling a standardized mean difference of -0.84 (95% CI -1.27– -0.42) favouring the intervention. One coping dimension, “positive reframing”, differed between the two groups. Here the intervention group changed -0.86 (95% CI -1.25– -0.48) points from baseline to three months, compared to -0.18 (-0.58–0.22) points in the wait list control group. We found a between-groups difference of -0.67 (95% CI -1.24– -0.11) points, equalling a standardized mean difference of -0.48 (95% CI -0.89– -0.07) favouring the intervention. The gains achieved during treatment were maintained when followed up three months later.

**Conclusions** Treatment is superior to the control condition in positively affecting perceived stress and positive reframing. When followed up, the gains achieved are maintained.

**Key terms** brief COPE; cognitive behavior therapy; follow-up; group treatment; positive reframing; Perceived Stress Scale (PSS-10); wait list control.

Stress has been found to be associated with heart disease (1) and depression (2), but the nature and strength of these associations have been debated (3). Work-related stress, defined by symptoms of sustained animation and reactivity to demands at work, has been identified as a significant occupational health problem and constitutes a major source of staff absenteeism (4). Common treatment for work-related stress is, at present, often characterized by a passive strategy of extended sick leave. In an attempt to provide a proactive approach, interventions applying psychological stress management often focus on teaching participants alternative coping strategies.

Stress and coping have been linked since the work of Lazarus & Folkman (5, p.31), in which the stress reaction was divided into a primary cognitive appraisal of the situation in terms of “Am I in trouble. . .?” and a secondary cognitive appraisal of the situation in terms of “What if anything can be done about it?”

Stress management programs can be divided into preventive or curative interventions. We found only four studies evaluating curative interventions (6–9), compared to a large number of preventive intervention studies. This division compares well with that shown in a recent review by van der Klink et al (10), in which

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none of the 48 studies identified had a curative scope. Another dimension of stress management programs is the nature of the intervention. Van der Klink et al (10) identify four categories of interventions: (i) cognitive behavior therapy, (ii) physical exercise, (iii) relaxation/meditation, and (iv) organizational interventions, all of which can appear alone or in combination. In comparing these approaches, the authors conclude that cognitive behavior therapy is the more effective intervention and already an established evidence-based treatment for clinical depression and anxiety (11).

Searching the literature, we did not identify any studies that (i) were randomized controlled trials, (ii) recruited participants from the general population, (iii) were curative, and (iv) utilized group-based cognitive behavior therapy. One study by Gardner et al (12) used a wait list control design to investigate the effect of a stress management training program on healthcare professionals, but includes participants both with and without elevated stress. Another study by Nickel et al (7) used a randomized design with a placebo control condition, but was limited only to men. A third study by de Jong & Emmelkamp (13) used a randomized controlled design, but recruited participants through an employment agency.

In summary, our study focused on a curative three-month group-based stress management intervention targeted at individuals in the general working population with highly elevated symptoms of work-related stress. The goal of the stress management program was to encourage participants to reflect on their current coping strategies, assess their usefulness and introduce more functional coping strategies. Our study aimed to evaluate the effectiveness of this approach on perceived stress and coping of participants.

This is the first paper reporting on the so-called MARS (measures against work-related stress) trial in which stress and coping have been predefined as the main psychological outcome measures.

### Study population and methods

#### Design and timeframe

The study used a randomized wait list control design (figure 1). Participants were randomized into either the intervention or wait list control groups. Outcome

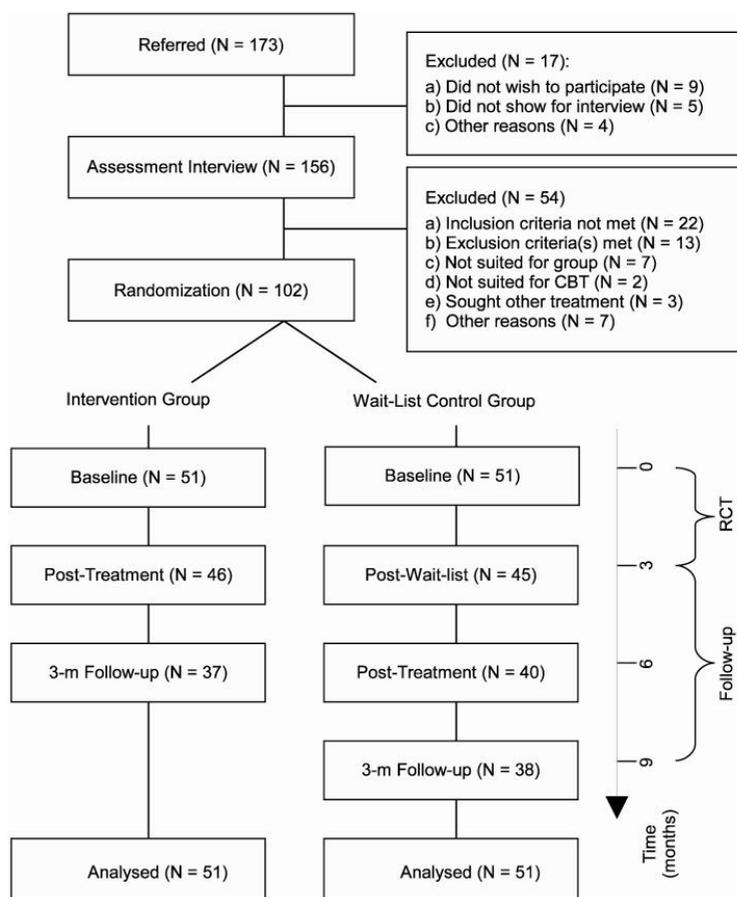


Figure 1. Flowchart of participants' progress through the phases of the trial.

variables were measured at the baseline and at three-, six-, and nine-months follow-up.

A sample size of 90 was needed to detect a between-groups difference of one standard deviation on the Perceived Stress Scale (PSS-10, range 0–40 points). The estimate was based on a significance level of 95%, power 80%, standard deviation of 5 points, an intra-class correlation coefficient 0.15, and an average cluster size of 9. An allowance for a 10% dropout of 102 participants was included.

An external consultant performed a randomization, in blocks of six, using the RANNOR computer algorithm (SAS Inc, Cary, NC, USA). Results were placed in sealed envelopes and handled by the project secretary. To minimize the differences between the groups, we mixed the participants from the intervention and wait list control groups when new groups were formed.

Inclusion and randomization was performed over a period of ten months from December 2006 through September 2007, with groups running in succession from January to December 2007.

### Referral

Participants came from the working population (18–67 years) in the municipality of Aarhus and its surrounding communities. Referral was available for local general practitioners (GP), union social workers and through direct inquiry. All potential participants were assessed by a physician – either their GP prior to referral or a resident occupational physician. The project was promoted via letters sent to local GP, meetings with union social workers, a website, and advertisements in a local newspaper. A total of 173 persons were referred for participation, as illustrated in figure 1. Of this initial number, 156 persons were invited to an assessment interview to determine their eligibility, while 17 potential participants were excluded. On the grounds of the assessment interview, 102 persons were invited and accepted to participate, while 54 persons could not be included. All persons excluded from the study were given advice on other alternatives.

### Eligibility

Inclusion criteria were persistent symptoms of work-related stress, defined as physiological and psychological symptoms of sustained animation lasting more than four weeks and elevated reactivity of symptoms to demands at work. Another criterion for participation in the was a time sequence during which, within the last six months, major organizational or other changes at work (eg, increased caseload, long-term sick leave among colleagues, or no substitutes available to fill in) preceded the stress reaction. Those eligible to participate had to be motivated to remain employed and planned return

to work within four weeks if they were on sick leave. Participants were either on sick leave following a GP assessment or active at their workplace. For the latter, a score of  $\geq 20$  points on the PSS-10 was required, one standard deviation above the population mean reported by Cohen (14).

Exclusion criteria included the following: (i) being on sick leave for more than 26 consecutive weeks, (ii) having substantial psychosocial strains outside of work, (iii) bullying as the main problem, (iv) a severe psychiatric condition or history of repeated psychiatric conditions, and (v) current abuse of alcohol or psychoactive stimulants.

When determining caseness for work-related stress, it was not possible to ascertain retrospectively whether the cause of stress experienced by the individual was purely work-related, but work was, in all cases, a contributing factor in sustaining the present state.

### Assessment

A clinical psychologist with more than five years training assessed all potential participants in an interview based on a semi-structured format covering the criteria for participation outlined earlier. The psychologist completed a structured form during every interview.

In addition to the interview, the study used four questionnaires [PSS-10 (14), Life Events (15), the Nordic Basic Sleep Questionnaire (16) and the Outcome Rating Scale (17)] to assess eligibility.

### Allocation

Upon completing the baseline measurement, an independent person opened the envelope containing the participant's allocation. Following randomization, a total of 51 participants comprised the wait list control group and 51 participants made up the intervention group. In the first three months after the baseline, five and six participants dropped out from the intervention and wait list control groups respectively (figure 1). No systematic differences were found regarding the characteristics of participants who dropped out of the study.

### Intervention

There were nine participants per group, spanning eight three-hour sessions over a period of three months. An experienced clinical psychologist led each group. The groups met for weekly sessions the first four weeks, and then every fortnight for the remaining four sessions. The themes of the eight sessions were the following: (i) introduction to cognitive behavior therapy, (ii) psychoeducation on stress, (iii) identification of dysfunctional thinking, (iv) modification of dysfunctional thinking,

(v) communication and stress, (vi) communication skills training, (vii) implementation of strategies at work, and (viii) review of techniques.

### Outcome measures

The PSS-10 (14) is a self-reported measure of global stress and measures the extent to which people find their life unpredictable, uncontrollable, and overwhelming. It consists of ten questions rated on a 5-point Likert scale ranging from “never” to “very often” (range: items 0–4, total 0–40). The scale has a Cronbach’s  $\alpha$  of 0.78 (14). A Danish translation of the PSS-10 was used. In our study, the PSS-10 had a Cronbach’s  $\alpha$  of 0.81.

The Brief COPE questionnaire (18) measures the use of different coping strategies. It is a 28-item questionnaire that measures 14 dimensions of coping. Each item

is rated on a 4-point Likert scale ranging from “a lot” to “never” (range: items 1–4, dimensions 2–8).

Five of the 14 dimensions represented in Brief COPE were of special interest in this study, these include: (i) emotional support (seeking support and comforting from others), (ii) instrumental support (seeking advice and help from others), (iii) active coping (taking action to change the situation), (iv) planning (considering future steps and strategies), and (v) positive reframing (changing perspective and focusing on positive aspects). All five dimensions have Cronbach’s  $\alpha$  of 0.64–0.73 (18). The study used a Danish translation of Brief COPE, translated and back-translated by a group at the Department of Occupational Medicine, Herning Hospital. In the present translation and study sample, the five dimensions of Brief COPE had Cronbach’s  $\alpha$  in the 0.70–0.82 range.

**Table 1.** Demographics and baseline characteristics.<sup>a, b</sup>

Characteristics	Intervention		Wait list control	
	N	%	N	%
Gender				
Female	41	80.4	43	84.3
Male	10	19.6	8	15.7
Referred by				
GP	24	47.1	29	56.9
Union	4	7.8	6	11.8
Phone	23	45.1	16	31.4
Sick leave				
Full	20	39.2	20	39.2
Partial	14	27.5	16	31.4
Contacted GP	49	96.1	50	98.0
School education				
9 years	10	9.8	11	10.8
12 years	41	40.2	39	38.2
Further education				
Short (<3 years)	18	17.6	14	13.7
Medium (3–4 years)	28	54.9	29	56.9
Long (>4 years)	5	9.8	7	13.7
Occupation (by field)				
Social	14	27.5	15	29.4
Health	7	13.7	9	17.7
Teaching	9	17.7	5	9.8
Administration	10	19.6	3	5.9
Other	10	19.7	13	25.5
Taking medication	21	41.2	25	49.0
Medication (by type)				
Anti-depressive	15	29.4	10	19.6
Hypertensive	2	2.0	5	4.9
Hypothyroidism	4	3.9	4	3.9

<sup>a</sup> Mean age for the intervention group was 44 years (range 28–61 years) and for the wait list control group 46 years (range 24–58 years), respectively.

<sup>b</sup> Mean years in the workforce for the intervention group was 18 years (range 1–38 years) and for the wait list control group 17 years (range 2–37 years), respectively.

### Statistical analysis

Statistical analysis was performed using the STATA (Stata Corp LP, College Station, TX, USA) and WinPEPI (Brixton Health, London, United Kingdom) software packages. The data were analyzed blinded, by letting an external consultant recode the grouping variable. The blinding was kept unbroken until final conclusions were drawn about the results.

Baseline characteristics were compared using the Chi-squared test of comparable distributions and the Student’s *t*-test. Outcome analyses were performed as intention-to-treat with a mixed model univariate repeated measures analysis of variance. Model validation was performed using Bland-Altman plots, QQ-plots of the residuals and sum-residual plots. To enable comparison between the different measures, effect sizes were calculated using Cohen’s *d* (19). Estimates were reported with their 95% confidence intervals (95% CI).

## Results

### Baseline characteristics

Demographic and baseline characteristics for the intervention and wait list control groups are presented in table 1. No significant differences were found between the two groups.

### Outcome measures

In the present study design, the wait list control group could no longer function as a control group as the timeframe moved beyond three months after baseline. Therefore, the results from the analysis of the outcome

measures fell into two categories. In the baseline 3-month timeframe, the results from the randomized controlled trial were reported. From 3-9 months, the results from the follow-up study were reported.

### Randomized controlled trial

The changes on the outcome measures from 0-3 months are displayed in figure 2. Significant differences were found on the PSS-10 and Brief COPE dimension of positive reframing when comparing changes over time between the groups. Regarding the remaining four Brief COPE dimensions (emotional support, instrumental support, active coping, and planning), no differences were found between the groups; consequently no further results have been displayed for these outcome measures.

In table 2, the results for the PSS and positive reframing dimension scores are presented for the randomized controlled trial. After stating the baseline mean score on the two scales, the difference from baseline 3-months is displayed first as the 0-3 month change for each group in terms of points on the scale, and next as standardized mean differences (Cohen's *d*). In the third row, the intervention effect (the difference between the changes over time in the two groups) is displayed, both as points on the scales and as standard mean deviation.

### Follow-up study

After three months of waiting, participants in the wait list control group were offered the stress management

intervention. From this point on, the two groups were no longer comparable. However, the two groups were still followed up independently and continued to supply information on the effect of the intervention.

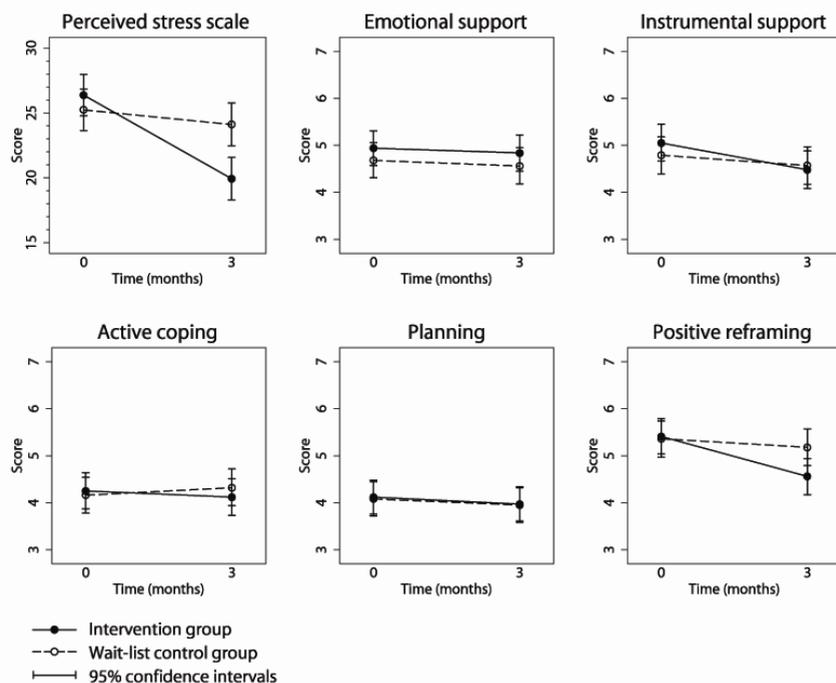
Table 3 shows the analysis of the PSS-10 and positive reframing dimension scores in the 3-6 month timeframe for the intervention group, and for the 3-9 month timeframe for the wait list control group. From 0-3 months, intervention group participants, who had completed their treatment and were only followed up, maintained the gains they had achieved during treatment. The wait list control group, receiving treatment after being on the waiting list, showed a positive response with a significant drop in both the PSS-10 and positive reframing dimension scores.

When followed up three months after termination of their treatment, in the 6-9 month timeframe, wait list control group participants also maintained the gains achieved during treatment.

Table 4 is an alternative version of tables 2 and 3 combined.

### Study homogeneity

To assess homogeneity, analyses were performed to check whether any of the following factors influenced the study's outcome: (i) participation in different treatment groups, (ii) referral route, or (iii) group leader. No significant effects were found.



**Figure 2.** Changes on outcome measures from baseline (0-3 months).

**Table 2.** Baseline scores and within-group changes over time from the randomized controlled trial. The effect of the intervention is estimated as the between-groups difference of the changes from 0-3 months. Effect sizes are reported using Cohen's d (standardized mean difference). (95% CI = 95% confidence intervals, SD = standard deviation)

	Baseline			0-3 months			Effect size (d)	95% CI
	Score	SD	95% CI	Within-group change	P-value	95% CI		
<b>Perceived stress scale</b>								
Intervention	26.37	5.80	24.79-27.97	-6.45	0.000	-8.25--4.64	-1.11	-1.42--0.80
Wait list control	25.23	5.81	23.64-26.83	-1.12	0.226	-2.94-0.70	-0.19	-0.51-0.12
Intervention effect	.	.	.	-5.32	0.000	-7.89--2.76	-0.92	-1.36--0.48
<b>Positive reframing</b>								
Intervention	5.41	1.37	5.04-5.79	-0.86	0.000	-1.25--0.48	-0.62	-0.91--0.33
Wait list control	5.36	1.38	4.98-5.74	-0.18	0.376	-0.58-0.22	-0.13	-0.42-0.16
Intervention effect	.	.	.	-0.67	0.019	-1.24--0.11	-0.49	-0.90--0.08

**Table 3.** Scores at three months and within-group changes over time from the follow up study. (95% CI = 95% confidence intervals)

	3 months		3-6 months			6-9 months		
	Score	95% CI	Within-group change	P-value	95% CI	Within-group change	P-value	95% CI
<b>Perceived stress scale</b>								
Intervention	19.93	18.29-21.57	-1.03	0.305	-3.00-0.94	.	.	.
Wait list control	24.11	22.46-25.76	-3.99	0.000	-5.91--2.06	-1.02	0.343	-2.98-0.94
<b>Positive reframing</b>								
Intervention	4.56	4.17-4.94	0.07	0.747	-0.37-0.51	.	.	.
Wait list control	5.18	4.79-5.57	-0.44	0.043	-0.87--0.01	-0.34	0.123	-0.77-0.09

**Table 4.** Alternative version of tables 2 and 3 combined: baselines scores and within-group changes over time. The effect of the intervention is estimated as the between-groups differences of the changes from 0-3 months. Effect sizes are reported using Cohen's d (standardized mean difference). (95% CI = 95% confidence intervals, SD = standard deviation, SE = standard error of the mean)

	Baseline		Randomized controlled trial				Follow-up study					
	Score	SD	0-3 months <sup>a</sup>	SE	P-value	Effect size (d)	3-6 months <sup>a</sup>	SE	P-value	6-9 months <sup>a</sup>	SE	P-value
<b>Perceived stress scale</b>												
Intervention	26.37	5.80	-6.45	0.92	0.000	-1.11	-1.03	1.00	0.305	.	.	.
Wait list control	25.23	5.81	-1.12	0.93	0.226	-0.19	-3.99	0.98	0.000	-1.00	1.05	0.343
Intervention effect	.	.	-5.32	1.31	0.000	0.92	.	.	.	.	.	.
<b>Positive reframing</b>												
Intervention	5.41	1.37	-0.86	0.20	0.000	-0.62	0.07	0.22	0.747	.	.	.
Wait list control	5.36	1.38	-0.18	0.20	0.376	-0.13	-0.44	0.22	0.043	-0.34	0.22	0.123
Intervention effect	.	.	-0.67	0.29	0.019	-0.49	.	.	.	.	.	.

<sup>a</sup> Within-group change.

## Discussion

In the randomized controlled trial, intervention was more effective than the no-treatment wait list control condition in reducing perceived stress and strengthening the coping dimension of positive reframing. The effect of the intervention was approximately a five-fold greater change in numerical scores on the two measures. According to Cohen's division of effect sizes (19), the standard mean deviation found on the PSS-10 Stress Scale can be labeled as large ( $>0.8$ ), whereas the difference for positive reframing can be considered small ( $<0.5$ ).

The follow-up study showed that the gains achieved during treatment were maintained three months after termination of treatment. Strengthening the results from the randomized controlled trial, a similar effect of the intervention was replicated for the wait list control group, when they were given the opportunity to participate in the intervention. A limitation of the findings was, however, that in a clinical and occupational perspective, the three-month follow-up period was not sufficient to determine the long-term effects of the intervention.

No significant changes were found in the coping dimensions of (i) emotional support, (ii) instrumental support, (iii) active coping, and (iv) planning, even though these dimensions were integrated in the treatment manual. As a possible explanation, one could differentiate between behavior- and attitude-oriented coping dimensions. Such a distinction would label the aforementioned coping dimensions as behavior-oriented, and positive reframing as an attitude-oriented coping dimension. As such, the intervention may be more effective in changing attitude-oriented than behavior-oriented coping.

Interpreting the overall findings, the results concerning perceived stress can be considered quite robust. Interpretation of the results of the positive reframing dimension requires more caution, considering that five different aspects of coping were investigated, thus increasing the risk of a Type I error, and the probability value for changes on the coping dimension of positive reframing was significant at the 95% confidence interval level but below 99%.

Compared to a conventionally controlled design, the wait list control design imposed limitations regarding the conclusions that can be drawn from the study. Allowing the wait list control group to "cross over" and receive treatment was been an ethical and logistical consideration that attempted to ensure a high degree of motivation in the control group while still maintaining a partially controlled design. It was feared that participants randomized to a control condition throughout the trial would have low motivation to continue participating after their allocation or be prone to seek help elsewhere while acting as controls.

Another methodological constraint lay in the lack of standard measures for both stress and coping. The PSS-10 and Brief COPE questionnaire were chosen as a result of a number of considerations, but were not definitive measures of their subject matter. A common critique against questionnaires is the subjective nature of the data collected – a critique that may also be justified in our study, but it was a choice that reflects the use of the best measures available.

One characteristic of the intervention is that it took place away from the workplace. Interventions that are onsite can perhaps be tailored more precisely to the particular setting, ensuring a tighter integration of the coping strategies learned in the groups and their implementation in everyday routines. To counter this possibility, we emphasized homework assignments and gave the intervention participants an opportunity to implement the strategies learned in the groups at the workplace.

It is important to distinguish between the outcome measures and the concept of work-related stress when interpreting the results. Perceived stress and positive reframing were shown to change, but the degree to which these changes were a direct reflection of changes in work-related stress could not be answered exhaustively in our study. When compared to previous results from similar studies (12, 7, 13), our trial supported the findings that stress management interventions based on cognitive behavior therapy can lower perceived stress. Expanding on what is known from previous studies, our trial suggests that this type of intervention is effective also when applied to a sample recruited from the general population, having symptoms of elevated levels of stress and coming from a wider range of diverse occupations than in previous trials.

Participants were mainly white-collar workers from the social, health, teaching and administrative work fields. Though more diverse in terms of occupation than the aforementioned previous trials, the relative occupational homogeneity may have weakened the external validity of the study, leaving partially unanswered the question of the effectiveness of the intervention when applied elsewhere, ie, blue-collar workers.

With respect to coping, previous studies' findings point in different directions. Both Gardner et al (12) and de Jong & Emmelkamp (13) found that individual coping style did not change as a result of treatment, while Timmerman et al (20) found that one dimension of coping (ie, facing and solving problems) changed, while other dimensions did not. In our study, another dimension of coping (ie, positive reframing) changed during the intervention while other investigated dimensions did not. These results question if coping is measured adequately or if there may be a need revisit the role of coping in stress management interventions.

The stress management program and the accompanying manual was a feasible, effective, and resource-efficient format for offering an intervention to the target group. It was a relatively short program of eight three hour sessions spanning over three months, but still substantial enough to initiate changes. Dropout from the groups was low and verbal feedback from the participants was mainly positive.

In summary, this study has shown that stress management intervention is effective in lowering perceived stress for working individuals who have elevated symptoms of work-related stress and are actively seeking help. A less robust and smaller effect was found for the use of positive reframing to cope with the situation.

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