Stress management interventions in the workplace improve stress reactivity: a randomised controlled trial

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Abstract

Objective To examine the long-term effects of a stress management intervention (SMI) based on the effort-reward imbalance (ERI) model, on psychological and biological reactions to work stress. Methods 174 lower or middle management employees (99% male) were randomly assigned to an intervention or a waiting control group. The programme comprised 24×45 min group sessions (2 full days followed by two 4×45 min sessions within the next 8 months) on individual work stress situations. The primary endpoint was perceived stress reactivity (Stress Reactivity Scale, SRS), while secondary endpoints were salivary cortisol and α-amylase, anxiety and depression, and ERI. Assessments were repeated in 154 participants 1 year later. Results SRS score decreased in both groups. A two-factor ANOVA with repeated measures showed a significant time×group effect ($F=5.932$; $p=0.016$) with the greater reduction in the intervention group. For SRS, the effect size (Cohen`s d) after 1 year was $d=0.416$ in the intervention and $d=0.166$ in the control group. α-Amylase as a measure of sympathetic nervous system activation, decreased more strongly in the intervention group (area under the daytime curve and daytime slope: time×group effect $p=0.076$ and $p=0.075$). No difference was observed for cortisol. For depression, anxiety and ERI, improvements were higher in the intervention group but did not reach statistical significance. Conclusions SMI based on work stress theory, is effective in reducing perceived stress reactivity and sympathetic activation in lower and middle management employees. Other mental health parameters and ERI show a tendency towards improvement. These beneficial effects are present 1 year later.

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ABSTRACT

Objective To examine the long-term effects of a stress management intervention (SMI) based on the effort–reward imbalance (ERI) model, on psychological and biological reactions to work stress.

Methods 174 lower or middle management employees (99% male) were randomly assigned to an intervention or a waiting control group. The programme comprised 24×45 min group sessions (2 full days followed by two 4×45 min sessions within the next 8 months) on individual work stress situations. The primary endpoint was perceived stress reactivity (Stress Reactivity Scale, SRS), while secondary endpoints were salivary cortisol and α-amylase, anxiety and depression, and ERI. Assessments were repeated in 154 participants 1 year later.

Results SRS score decreased in both groups. A two-factor ANOVA with repeated measures showed a significant time×group effect ($F=5.932$; $p=0.016$) with the greater reduction in the intervention group. For SRS, the effect size (Cohen's d) after 1 year was $d=0.416$ in the intervention and $d=0.166$ in the control group. α-Amylase as a measure of sympathetic nervous system activation, decreased more strongly in the intervention group (area under the daytime curve and daytime slope: time×group effect $p=0.076$ and $p=0.075$). No difference was observed for cortisol. For depression, anxiety and ERI, improvements were higher in the intervention group but did not reach statistical significance.

Conclusions SMI based on work stress theory, is effective in reducing perceived stress reactivity and sympathetic activation in lower and middle management employees. Other mental health parameters and ERI show a tendency towards improvement. These beneficial effects are present 1 year later.

What this paper adds

- Occupational stress is considered a major risk factor for a wide range of health outcomes.
- A stress management intervention based on the effort–reward imbalance model of work stress and using modified techniques of group psychotherapy reduces perceived stress reactivity and biological stress indices after 1 year.
- Depression, anxiety and work stress showed a tendency towards improvement.
- The majority of the target population, men in lower or middle management positions in the production industry, can be reached with this programme.
- Stress management interventions in the setting of industrial workplaces should be encouraged as a strategy for primary prevention of diseases caused by work stress, and should supplement, not replace, necessary improvements in working conditions.

INTRODUCTION

Occupational stress is considered a major risk factor for a wide range of health outcomes.[1 2] It is also linked to staff turnover, absenteeism, poor morale and reduced performance.[3] Given the enormous burden caused by occupational stress, there is a need for primary prevention strategies to reduce job stress and its negative impact on health. Specifically, using the advantage of a work setting approach, stress management interventions (SMI) in the workplace have received increased attention from employers and research personnel.[4–6]

The broad range of stressful working conditions have been successfully conceptualised in work stress models; the 'demand–control' model, the 'injustice' model and the 'effort–reward imbalance' (ERI) model of work stress have emerged as the most dominant since they have been shown to predict an increased long-term risk for ill health.[7–9]

Here we focus on the ERI model which claims that, for the maintenance of health, equilibrium is necessary between the effort required from a worker and the reward from work for this person.[10] Effort, for example, arises from work overload, time pressure or disturbance of work flow. Lack of reward can be due to social conflicts, low social support, and lack of esteem and justice (especially from superiors), career opportunities and job security. ERI is measured with a questionnaire which has various statements on required efforts and received rewards and seeks the individual's perspective on perceived stress due to efforts and lack of reward by asking for agreement or disagreement with each statement and an indication of the level of distress.[11]

A recent meta-analysis on the effectiveness of SMI using random assignment in occupational settings found an overall weighted effect size (Cohen's d) for 55 independent interventions within 36 studies of $d=0.526$ (95% CI 0.364 to 0.687).[4] However, this meta-analysis also revealed considerable heterogeneity of effects. In addition, only eight out of 36 studies attempted to alter the sources of stress at work.[4] Typically, an SMI takes place over a period of 1–11 weeks, is aimed at the individual, and involves instruction in techniques to manage and cope with

stress. Examples for the most common SMIs are cognitive behavioural skills training, meditation, relaxation, deep breathing, exercise, keeping a journal, time management and goal setting.[4] Interventions based on psychodynamic principles in a worksite setting were not evaluated in this meta-analysis; to our knowledge there are no such studies at all. Several other knowledge gaps became apparent during the meta-analysis: (1) little is known about the long-term effects of SMI weeks after the intervention; (2) studies rarely measure outcomes on different levels, for example psychological, physiological and organisational; (3) there appear to be very few SMIs for professional groups (apart from health care, education and office workers), especially groups that are traditionally hard to reach such as employees in industrial production companies, especially male workers; and (4) most SMIs for stress at work are not based on theories of occupational stress.[4] The findings and conclusions from this meta-analysis have recently been corroborated by a comprehensive study carried out on behalf of the British government.[12]

Based on these considerations we designed an intervention for production line employees with leadership responsibility in the metal production industry, that aimed at (1) improving individual capacity to recognise potential stressors in the workplace, (2) enhancing individual ability to cope with typical stressful situations, (3) thereby—in the long run—empowering the individual to influence workplace conditions, and (4) enhancing mutual social support in the workplace. The SMI was based on the ERI model, that is it focused on stressors, resources and personality traits contained in the model. A precursor of the programme had been successfully evaluated in a pilot study.[13 14] We adopted and modified the programme to better fit the needs and the organisational framework for our target group. Therefore, participants were trained to recognise the factors that contribute to high effort and low reward and to deal with them in a constructive manner.

The aim of this randomised controlled trial (RCT) was to test the long-term effect of this SMI on acute perceived reactions to stress at work (stress reactivity) after 1 year, as the primary endpoint. Stress reactivity, as conceptualised in the current study, refers to the extent to which a person is likely to respond to stressors with immediate, intense and long-lasting emotional or physical stress response characteristics.[14] Within a range depending on individual disposition, the actual reaction to a stressor depends on the stressor and the person's ability to cope, a reaction which is acquired and can be modified. This makes stress reactivity susceptible to change.[15] Biological stress indices (salivary cortisol, salivary α-amylase), mental health (depression and anxiety) and work stress (ERI) were secondary endpoints.

METHODS

Participants and procedures

A randomised parallel-group controlled trial was conducted in an international manufacturing plant located in Southern Germany. All lower and middle level managers (n=262), each responsible for a specific unit within production and for the management of 50 workers, on average, were eligible. Lower and middle management at the interface between higher management (engineers, business economists) and production is stressful due to the different people and situations that have to be managed. International market conditions contribute to the workload as there is constant demand to continuously increase productivity (by approximately 10% per year at the time of the study).

The outcome parameters were assessed at baseline (the beginning of 2006) and 1 year later. After an information workshop for the target group, 189 subjects agreed to participate. All participants were invited to a 1.5 h medical and psychological examination by an experienced team consisting of a psychologist (HL) and a physician (MH). Written informed consent was obtained. All volunteers were required to complete a battery of questionnaires, participate in a basic physical examination with blood sampling and collect saliva samples the next working day. This initial health check included feedback to each participant a few days later. If necessary, specific medical treatment was recommended.

The inclusion criteria for the study were: (1) lower or middle level manager in the production department with leadership responsibility and (2) aged 18–65 years with more than 2 years left before retirement. Exclusion criteria were application for early retirement, planned surgery or other serious disease potentially leading to more than 30 sick leave days annually. Eligible participants were randomised after the initial evaluation to one of two groups: the intervention group was offered a SMI which the control group (waiting control group) would receive 1 year later. The Ethics Committee of the University of Munich approved the study.

Intervention

The SMI consists of interventions addressing the needs of individual employees as well as strategies focussing on the organisational sources of stress.

A specifically tailored group-orientated prevention seminar (eight teaching units lasting 90 min each, over 2 consecutive days) was conducted, based on a previous successful worksite stress prevention programme.[13] It used psychodynamic, conflict- and emotion-focused principles, but also included cognitive behavioural techniques. The programme was specifically designed (1) to foster awareness of and insight into stress situations in the workplace and (2) to provide tools to better deal with typical stressful situations such as work overload, social conflicts, problems with social evaluation and failure at work. In addition, identifying and strengthening individual resources, for example social networking and social support between the participants, was encouraged. More specifically, participants remembered individual situations of stress in the workplace, shared them with another group member who responded ('empathy exercise') and reported them to the whole group. With the help of the experienced trainer, the group searched for the best possible solutions. During this group process, several tools to cope with difficult and stressful situations were introduced by the trainer: how to deal with negative emotions such as anger, how to cope more effectively with interpersonal conflict, how to improve social competence, and especially how to reduce feelings of isolation by creating a social network.

As an example, a participant spoke of a situation that caused him stomach pains, sweating and sleep disturbance during a period when he put a lot of effort in a challenging job. In analysing the course of events, it turned out that symptoms started following criticism of his work by his manager which upset him. In the group he recognised this fact, received social support from his colleagues, discussed ways to better communicate with his manager, and developed strategies to prevent future mismatch between effort and reward.

The seminar was followed by two refresher courses ('booster sessions') within 3–6 months, comprising two lessons/teaching units each (ie, 180 min per session), to enhance the effect.

A manual was developed to standardise the SMI. The seminars were provided by two trainers each, with extensive psychotherapeutic and medical experience. The SMI was offered to the intervention group within a few weeks following the initial evaluation.

Assessment

Sociodemographic data and answers to job-specific questions concerning professional status and working time were recorded. Socio-economic status (SES) was estimated by current professional status. For the assessment of health behaviour, we enquired about physical activity, especially sports, sleeping and smoking, and measured participants' BMI and waist circumference. Blood pressure was measured at least twice within 30 min, each time with the subject in sitting position after 5 min of rest with a digital blood pressure instrument (Boso, Jungingen, Germany). The average of two readings was obtained. A reading ≥140/90 mm Hg was defined as high blood pressure.

A self-assessment of basic work conditions was obtained with the Short Questionnaire for Work Analysis (Kurz-Fragebogen zur Arbeitsanalyse, KFZA) which, in German speaking countries, is an established screening tool for working conditions. It is based on a 5-point Likert scale based on agreement with factual descriptions of the participants' observable working conditions.[15]

The 11 scales cover nearly all relevant stressors and resources in the workplace and are presented in table 1.

Measurement of stress and stress reactions

Stress reactions

Self-reported stress reactivity was measured with the 29-item Stress Reactivity Scale (SRS). The SRS quantifies general stress reactivity and stress reactivity in specific domains (social conflict, social evaluation, failure at work and work overload). Two scales evaluate stress reactivity before and after stressful events in general. A total (summary) score can be generated.[15] Stress reactivity, measured with the SRS, was previously shown to be increased in stress associated chronic dermatological diseases.[16] In our sample high self-perceived stress reactivity was associated with other measures of chronic psychosocial stress, depression and anxiety.[17]

Effort–reward imbalance

The effort–reward imbalance (ERI) model was used.[10] This model is measured with a standardised questionnaire containing three unidimensional scales: 'effort' (six items), 'reward' (11 items) and 'overcommitment' (six items).[11 16] In addition to single scales, a summary measure, the ratio of effort and reward, was constructed to give a quantitative estimate of the imbalance, where higher values indicate a higher degree of stressful experience at work. If necessary, a cut-point of 1.0 was introduced to distinguish between exposed (>1.0) and non-exposed individuals, although evidence indicates harmful effects at lower thresholds as well.[11 16]

Biological stress indices

Biological stress indices were measured using levels of salivary cortisol as an indicator of hypothalamic-pituitary-adrenal axis activity,[17] and salivary α-amylase, reflecting basal activity of the sympathetic nervous system.[18 19] Saliva for measuring cortisol and α-amylase was collected using a small cotton swab with no additives (Salivette; Sarstedt, Numbrecht, Germany). Participants were instructed to chew the swab for 3 min, put the swab into the Salivette tube, note the time of sampling, keep the samples at ambient temperature, and return them within 3 days. All samples were processed and frozen at −20°C. Participants were instructed to take seven samples over a single working day: upon waking, 30 and 60 min later, and then at defined times throughout the day (08:00, 11:00, 15:00 and 20:00 h). Salivary-free cortisol was analysed using a commercial chemiluminescence immunoassay (IBL, Hamburg, Germany). α-Amylase was determined with the automatic analyser Cobas Mira and assay kits obtained from Roche (Basel, Switzerland).[20]

Table 1 Subject characteristics: demographic, professional and health behaviour variables of the total sample, intervention group and control group at baseline

Characteristic	Total (n=154)	Intervention group (n=75)	Control group (n=79)
Demographic variables			
Age (years)	40.9 (±7.72)	40.67.56 (±7.62)	41.06 (±7.86)
Males	152 (99%)	75 (100%)	77 (97%)
Education			
Low	87 (57%)	41 (55%)	46 (58%)
Middle	33 (21%)	19 (25%)	14 (18%)
Master's degree	34 (22%)	15 (20%)	19 (24%)
Professional variables			
Professional status			
Team leader	65 (42%)	34 (45%)	31 (39%)
Team leader's deputy	27 (18%)	10 (13%)	17 (22%)
Group leader	27 (18%)	15 (20%)	12 (15%)
Other	35 (23%)	16 (21%)	19 (24%)
Leadership responsibility	52.79 (81.49)	49.79 (74.87)	55.63 (97.70)
Shift work	95 (62%)	49 (65%)	46 (58%)
Hours of overtime per month (h)	1.47 (±4.22)	1.61 (±4.58)	1.34 (±3.88)
Daily break time (min)	36.8 (±10.41)	37.2 (±10.76)	36.2 (±10.35)
Self-reported sick leave days			
0	87 (57%)	43 (57%)	44 (56%)
1–10	49 (32%)	25 (33%)	24 (30%)
Over 10	18 (12%)	7 (9%)	11 (14%)
KFZA work conditions			
Decision latitude	3.70 (±0.71)	3.68 (±0.73)	3.72 (±0.68)
Variety of work	3.90 (±0.66)	3.89 (±0.64)	3.91 (±0.68)
Task identity	3.61 (±0.90)	3.63 (±0.90)	3.59 (±0.92)
Social support	3.80 (±0.69)	3.76 (±0.71)	3.83 (±0.67)
Team work	3.76 (±0.62)	3.71 (±0.65)	3.80 (±0.59)
Work load, qualitative	2.16 (±0.85)	2.07 (±0.77)	2.23 (±0.92)
Work load, quantitative	3.23 (±0.87)	3.24 (±0.84)	3.22 (±0.90)
Interruption of work	2.77 (±0.69)	2.76 (±0.68)	2.78 (±0.70)
Environmental stress	2.46 (±01.02)	2.51 (±01.02)	2.42 (±01.03)
Information and co-determination	3.46 (±0.73)	3.41 (±0.77)	3.50 (±0.68)
Company benefits	3.31 (±0.76)	3.32 (±0.73)	3.29 (±0.80)
Health status			
BMI	27.97 (±4.10)	28.40 (±4.55)	27.56 (±3.61)
Waist (cm)	99.38 (±11.06)	100.5 (±12.26)	98.3 (±9.71)
Hypertension RR (≥140/90 mm Hg)	80 (52%)	40 (53%)	40 (51%)
Health behaviour			
Intensive sports (hours per week)	1.32 (±2.04)	1.32 (±2.13)	1.32 (±1.96)
Smoking behaviour			
Smoker	44 (29%)	17 (23%)	27 (34%)
Never smoked	56 (36%)	25 (34%)	31 (39%)
Stopped smoking	54 (35%)	33 (44%)	21 (27%)
Sleeping behaviour			
No sleeping problems	79 (51%)	43 (66%)	36 (52%)
Some sleeping problems	40 (26%)	16 (25%)	24 (35%)
Major sleeping problems	15 (10%)	6 (9%)	9 (13%)

Values are mean (±SD) or numbers (%).
KFZA, Kurz-Fragebogen zur Arbeitsanalyse (Short Questionnaire for Work Analysis).

Assessment of anxiety and depression

Anxiety and depression were assessed with the German version of the Hospital Anxiety and Depression Scale (HADS).[21] This scale is widely used to measure psychological morbidity. The HADS

contains 14 items and consists of two subscales: anxiety and depression. Values between 8 and 10 for each of the two scales are judged as signs of clinical anxiety and depression, respectively, while values over 10 suggest the need for professional treatment.

Statistical analyses

Participants who completed both the baseline assessment and the 1-year follow-up were included in the analysis, performed according to intention-to-treat principles.[22] Compliance with the SMI was defined as participation in at least six of 12 teaching units.

- Estimations of sample size were based on the SRS total score which was defined as the primary endpoint. Presuming a difference of 5 SRS score points to be relevant, a power of 0.8, a significance level of 0.05, and a standard deviation of 10 score points resulted in an estimated sample size of n=64 for each group.[23]
- Questionnaires: in each scale, missing values were replaced by the mean of the available values. The number of allowed missing values complied with the instructions of the test authors.
- In all between-group comparisons, the significance of differences in means was tested with t tests for normally distributed variables and with Mann–Whitney U tests for variables with skewed distribution; the significance of differences in proportions was tested by χ^2 tests. Group differences in all outcome variables over time were investigated using a two-factor repeated measures ANOVA. This is also the appropriate means to control for regression towards the mean in case there is baseline difference in an outcome measure between intervention and control groups.[24]
- To appraise clinical relevance, effect sizes were calculated as Cohen's d.[25] This effect size is computed as the mean change in score divided by the standard deviation of the baseline score. 95% Confidence intervals (CIs) for the effect size were computed. An effect size of 0.2 is considered a small effect, 0.5 a moderate effect, and 0.8 a large effect of treatment.[25]
- Due to skewed distributions of salivary cortisol and α-amylase concentrations, these measures were logarithmically transformed. Area under the total curve and area under the curve for morning values were calculated for salivary cortisol as well as for α-amylase using the trapezoid formula.[26] Additionally, the cortisol awakening response was computed by subtracting the measurement at the time of waking from the amount after 30 min (both values untransformed). Finally two slopes, reflecting the daytime patterns of salivary cortisol and α-amylase secretion, were computed by estimating a simple linear regression model for each participant, where cortisol and α-amylase values were regressed on four collection time points (08:00, 11:00, 15:00 and 20:00 h).

RESULTS

Participant flow and compliance

A total of 189 employees were enrolled in the study, 15 of whom did not fulfil the inclusion criteria. The remaining 174 employees were randomly assigned to the intervention group or the control group. Ultimately, 154 (88.5%) of the 174 participants completed the follow-up assessments and were analysed according to the available case approach. Eight participants in the intervention group and four in the control group refused to participate any further (figure 1). Reasons for loss to follow-up were parental leave, lack of time and professional reasons. Of the 87 participants in the intervention group, 82 were considered compliant with the SMI (ie, usually attending the basic 2-day seminar plus one refresher session), while 39 completed the entire programme (12 teaching units).

Withdrawal analysis

Twenty of 174 participants only completed the baseline assessments: 12 participants dropped out of the intervention group and eight dropped out of the control group. The drop-outs showed more hours of self-reported overtime per month (5.42 vs 1.47 h; p=0.027) and seemed to be more overcommitted than participating employees (16.50 vs 14.13 score points; p=0.007).

Study population at baseline

A total of 154 subjects were included in the analysis of the outcome, measured after 1 year; 75 belonged to the intervention group and 79 to the control group. At baseline, no significant differences in socio-demographic, professional or health status characteristics between the intervention and the control groups were found (table 1).

Although participants had achieved a professional position with leadership responsibility, more than three-quarters (78%) had a lower educational qualification with fewer than 11 years of formal education. Of the participants, 88% had fewer than 10 sick leave days in the previous year. The average BMI of the total sample indicated overweight, as did waist circumference, 52% had high blood pressure, and 29% were smokers. Mean scores on the effort scale were higher in this sample than in age-comparable groups from the population (reference 12.64±4.93), reward was lower (reference 46.68±7.37) and overcommitment was

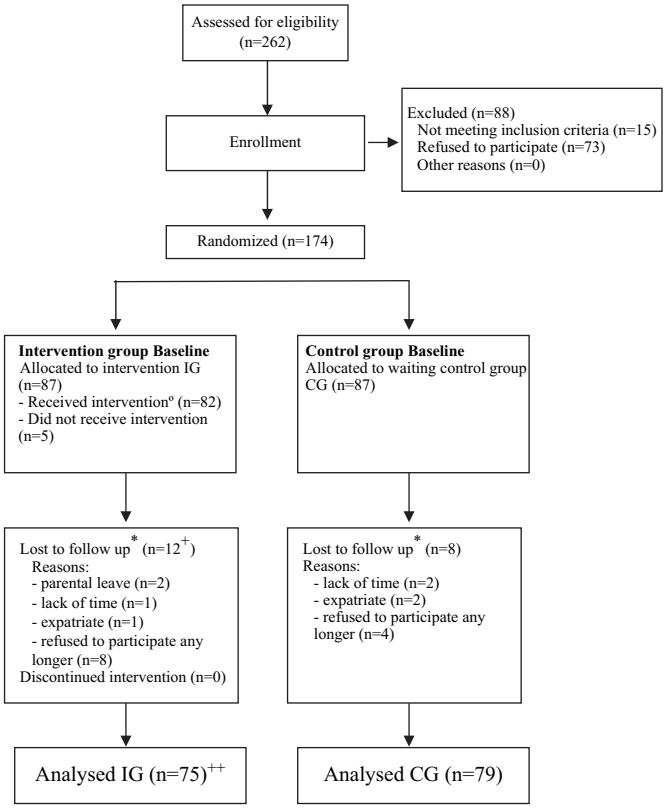

Figure 1 Patient flow during the study according to the CONSORT Statement. °Took part in at least 2 days of basic training or 1 day of basic training and one booster session. *Did not receive a second health check. +Three out of the 12 lost to follow-up did not receive the intervention. ++Two out of the 75 analysed did not receive the intervention.

comparable (reference 14.06±3.53).[11] Sleeping problems were reported by 36% of the participants (table 1).

Between-group differences and effect sizes for the primary outcome (SRS)

As shown in figure 2 and table 2, the effect on the summary score of the SRS was substantial for the intervention and control groups. The reduction in perceived stress reactivity in the intervention group (from 54.5 to 50.2) was significantly higher than in the control group (from 54.5 to 52.7). A two-factor analysis of variance with repeated measures for the primary outcome showed a significant time×group effect (F=5.932; p=0.016).

In all SRS subscales, the reduction in the intervention group was higher than in the control group, with significant time-×group interaction effects for the subscales 'failure at work', 'pre-stress' and 'post-stress'. For the primary study endpoint (SRS summary score), a medium effect size d=0.416 (95% CI 0.078 to 0.753) for the intervention group and a smaller effect size d=0.166 (95% CI −0.153 to 0.485) for the control group were found at the 1-year follow-up (table 2). A between-group effect size d=−0.245 (95% CI −0.569 to 0.078) was calculated.

Changes in effort–reward imbalance

For the ERI questionnaire and its subscales, no significant group×time effects were found, that is changes were not significantly different between groups. However, in the total sample the effort scale score decreased and the reward scale score increased, resulting in an overall decrease in the effort–reward ratio (ie, less work stress). Within the groups, the improvement in the intervention group was at least double that in the control group regarding the reward scale score (effect size: intervention group −0.343 (95% CI −0.665 to −0.021); control group −0.090 (95% CI −0.406 to −0.226)) and the effort–reward ratio (effect size: intervention group 0.320 (95% CI −0.018 to −0.658); control group 0.155 (95% CI −0.166 to −0.476)). Also in the effort and the overcommitment scales, the improvement was greater in the intervention group compared to the control group (table 2).

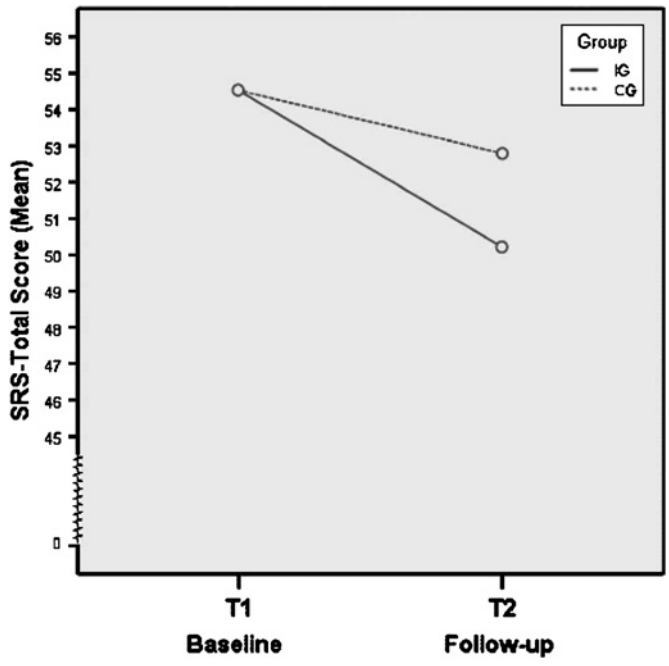

Figure 2 Stress reactivity sum score before and after intervention (1 year apart) according to intervention group.

Changes in depression and anxiety

No significant group×time effects were found for depression and anxiety, that is, any change was not significantly different between groups. However, positive time effects were shown for depression and anxiety. The effect size for depression was d=0.262 (95% CI −0.068 to 0.592) in the intervention group and 0.107 (95% CI −0.209 to 0.423) in the control group; for anxiety the effect size was d=0.194 (95% CI −0.134 to 0.522) in the intervention group and 0.209 (95% CI −0.109 to 0.527) in the control group (table 2).

Changes in biological stress indices (cortisol, α-amylase)

For cortisol, no effect of the intervention was observed. However, for α-amylase, after 1 year the area under the daytime curve and the slope (ie, the steepness of the increase during the day) were markedly lower in the intervention group compared to the control group, the interaction effect almost reaching the predefined statistical significance level (p=0.076 and p=0.075). The change in the area under the morning curve (ie, during the time before work) did not differ between the intervention and control groups. The effect size values for the α-amylase parameters area under the daytime curve and slope were d=0.318 (95% CI −0.070 to 0.706) and d=0.338 (95% CI −0.028 to 0.703) in the intervention group, and d=0.071 (95% CI −0.280 to 0.421) and d=0.031 (95% CI −0.369 to 0.307) in the control group (table 3).

Working conditions

Professional status, leadership responsibility (number of managed workers), shift work, hours worked, and daily break time remained basically unchanged with a small increase in working hours in the intervention group and a small decrease in the control group (group×time effect p=0.07). Among stressors and resources as operationalised by the KFZA, 'variety of work', 'company benefits', 'work load, quantitative', and 'environmental stress' slightly improved while 'information and co-determination' worsened; however, these changes were similar in the intervention and the control groups.

Further analyses

After adjustment for SES and for smoking, the effect of the intervention on the outcome variables as shown in tables 2 and 3 was essentially unchanged. When the—unadjusted—analysis was confined to men (by leaving out the two women), the results remained the same.

DISCUSSION

This RCT evaluated a novel 2-day SMI based on the ERI model of work stress. The target group were healthy but stressed men predominantly working in lower management positions in production area of a heavy truck plant. About two-thirds of the target group participated in the programme. One year after the start of the project, and 4 months after the last 'booster session', perceived stress reactivity was significantly improved by the SMI. Reduction in α-amylase as a measure of basal sympathetic nervous system activation was stronger in the intervention group, and the effect was close to statistical significance. Mental health improved and work stress declined in both groups, with more pronounced changes in the intervention group.

Methodological considerations

Competing influences

Modern industrial companies constantly react to major changes in prevailing conditions with consequent stress and strain for

Table 2 Changes on the Stress Reactivity Scale (SRS) and the ERI questionnaire

Variable	Programme IG: n=75 CG: n=79	Time point		ES (95% CI)	p Value		
		Baseline, mean (SD)	Post intervention, mean (SD)		Group effect	Time effect	Group×time effect
SRS work overload	IG	8.48 (2.34)	7.97 (2.29)	0.219 (−0.115 to 0.552)	0.872	0.004	0.731
	CG	8.44 (2.29)	8.08 (2.28)	0.175 (−0.145 to 0.494)			
SRS social conflicts	IG	12.35 (2.48)	11.51 (2.48)	0.341 (0.005 to 0.677)	0.901	0.000	0.279
	CG	12.23 (2.32)	11.71 (2.64)	0.211 (−0.109 to 0.531)			
SRS social evaluation	IG	8.86 (2.27)	8.23 (2.17)	0.285 (−0.049 to 0.620)	0.620	0.000	0.331
	CG	8.94 (2.22)	8.53 (2.38)	0.178 (−0142 to 0.497)			
SRS failure at work	IG	10.14 (2.16)	9.42 (2.00)	0.346 (0.010 to 0.682)	0.449	0.001	0.031
	CG	10.10 (1.88)	9.93 (1.99)	0.092 (−0.225 to 0.410)			
SRS pre-stress	IG	7.77 (2.04)	7.03 (1.87)	0.381 (0.045 to 0.718)	0.157	0.003	0.048
	CG	7.88 (2.01)	7.74 (2.08)	0.070 (−0.0247 to 0.387)			
SRS post-stress	IG	6.93 (2.14)	6.01 (1.78)	0.465 (0.126 to 0.803)	0.237	0.000	0.003
	CG	6.89 (2.08)	6.78 (2.11)	0.057 (−0.262 to 0.376)			
SRS sum score	IG	54.48 (10.84)	50.16 (9.91)	0.416 (0.078 to 0.753)	0.432	0.000	0.016
	CG	54.48 (10.05)	52.74 (10.99)	0.166 (−0.153 to 0.485)			
Effort scale	IG	14.87 (2.92)	14.24 (2.87)	0.219 (−0.114 to 0.552)	0.960	0.014	0.732
	CG	14.82 (2.65)	14.34 (3.32)	0.160 (−0.159 to 0.479)			
Reward scale	IG	43.11 (7.40)	45.56 (6.89)	−0.343 (−0.665 to −0.021)	0.030	0.012	0.124
	CG	46.14 (6.83)	46.74 (6.28)	−0.090 (−0.406 to 0.226)			
Effort–reward ratio	IG	0.80 (0.28)	0.72 (0.24)	0.320 (−0.018 to 0.658)	0.279	0.005	0.243
	CG	0.74 (0.22)	0.70 (0.23)	0.155 (−0.166 to 0.476)			
Overcommitment	IG	14.28 (3.64)	13.52 (3.61)	0.208 (−0.140 to 0.556)	0.760	0.014	0.614
	CG	13.97 (3.37)	13.47 (4.06)	0.134 (−0.200 to 0.468)			
Depression (HADS)	IG	4.66 (3.58)	3.78 (3.15)	0.262 (−0.068 to 0.592)	0.498	0.007	0.198
	CG	4.06 (2.92)	3.75 (3.02)	0.107 (−0.209 to 0.423)			
Anxiety (HADS)	IG	5.81 (2.79)	5.21 (3.37)	0.194 (−0.134 to 0.522)	0.633	0.009	0.870
	CG	6.06 (3.24)	5.38 (3.25)	0.209 (−0.109 to 0.527)			

CG, control group; ES, effect size (Cohen's d); HADS, Hospital Anxiety and Depression Scale; IG, intervention group.

their employees. Thus all long-term RCTs carried out in the workplace have to deal with competing external factors.[27] In the company in which this RCT took place, there were also continuous changes within the organisation, and steadily increasing productivity (by approximately 16% per year). These conditions would have increased the level of perceived work stress, in contrast to the observed decrease over time in the intervention group. However, at the individual level some self-reported working conditions slightly improved while others worsened. Thus, changes in basic working conditions might in part explain the improvement in stress reactivity seen in both groups. However, it does not explain the significantly larger effect in the intervention group. Another potential influence, regression towards the mean, was—at least for the primary outcome SRS—unlikely as the groups showed almost identical values at baseline. Furthermore, we attempted to minimise the effect of this phenomenon by using ANOVA.

Generalisation

Our results are selective and can be generalised only with caution. First, the sample exhibits a rather high level of work-related stress in terms of the ERI model. Second, as the sample is almost exclusively composed of men, and as men were shown to exhibit higher responsiveness to stressful exposures,[28 29] we have no indication whether the findings apply to employed women as well.

Study design and measurement of outcome

It is widely accepted in psychotherapeutic research that it is impossible to blind participants to their intervention status, and that using a waiting control group is an appropriate method for this type of intervention study. In addition, our primary outcome was a 'soft' endpoint, although measured with the SRS, a well standardised and validated questionnaire. Soft endpoints are common in psychotherapeutic research, since there are virtually no other methods to measure psychological states.[30] Since the control group did not receive a sham intervention, a non-specific treatment effect cannot be ruled out. However, previous RCTs demonstrated beneficial effects on mental health produced by interventions similar to that applied in this study.[31] Furthermore, we may have underestimated the frequency of mild depression and the effect of the SMI by using the HADS as a measure of clinically relevant depression. This more restrictive definition (ie, only asking for symptoms beyond light mood swings) was chosen to minimise common method bias, which otherwise might occur in correlation with measures for stress symptoms.

Interpretation

Effect size

In this study the within-group effect size for the primary outcome in the intervention group was moderate (d=0.416), while in the control group it was small (d=0.166). Thus, a between-group effect size of d=0.245 was calculated. In comparison with the between-group effect sizes of d=0.526 reported by the meta-analysis of Richardson and Rothstein,[4] and of d=0.334 shown by van der Klink *et al*,[5] our differences between the intervention and control groups are lower. This might have several reasons. First, all study members participated in the initial health check which ended with individual feedback during a personal consultation. Medical as well as psychological issues were discussed, according to the needs of the participants. It is possible that this counselling activity may have influenced the stress behaviour in both groups. Consistent improvements in work stress over time, in anxiety and in depression may be partially due to this special treatment of all subjects. Second, we cannot exclude a contamination effect due to

Table 3 Changes in biological stress indices (cortisol and α-amylase)

Variable	Programme IG: n=75 / CG: n=79	Time point		ES (95% CI)	p Value		
		Baseline, mean (SD)	Post intervention, mean (SD)		Group effect	Time effect	Group×time effect
Cortisol (n=130)							
Area under the curve, morning	IG	18.23 (5.26)	15.73 (7.71)	0.379 (0.006 to 0751)	0.303	0.000	0.708
	CG	17.49 (6.09)	14.42 (8.26)	0.424 (−0.074 to 0.774)			
Cortisol awakening response	IG	9.08 (7.10)	8.25 (9.10)	0.102 (−0.261 to 0.465)	0.894	0.083	0.359
	CG	9.85 (8.17)	7.18 (9.19)	0.307 (−0.041 to 0.655)			
Area under the curve, daytime	IG	62.20 (24.82)	57.70 (39.46)	0.136 (−0.241 to 0.513)	0.568	0.002	0.114
	CG	64.03 (23.05)	50.62 (28.73)	0.515 (−0.163 to 0.867)			
Daytime slope cortisol	IG	−0.633 (0.283)	−0.642 (0.436)	0.024 (−0.331 to 0.380)	0.320	0.567	0.746
	CG	−0.575 (0.306)	−0.609 (0.315)	0.092 (−0.243 to 0.428)			
α-Amylase (n=127)							
Area under the curve, morning	IG	46.26 (35.70)	38.59 (25.96)	0.246 (−0.148 to 0.640)	0.924	0.011	0.550
	CG	47.79 (74.17)	35.51 (31.87)	0.215 (−0.150 to 0.581)			
Area under the curve, daytime	IG	1230.1 (919.0)	983.2 (599.5)	0.318 (−0.070 to 0.706)	0.664	0.005	0.076
	CG	1075 (819.6)	1018.8 (776.0)	0.071 (−0.280 to 0.421)			
Daytime slope, α-amylase	IG	0.130 (0.231)	0.048 (0.254)	0.338 (−0.028 to 0.703)	0.479	0.127	0.075
	CG	0.109 (0.197)	0.116 (0.256)	0.031 (−0.369 to 0.307)			

CG, control group; ES, effect size (Cohen's d); IG, intervention group.

communication concerning stress prevention between members of the intervention and control groups. However, the SMI emphasised individual stress situations and reinforcement of coping skills, aspects which cannot easily be transmitted to non-trained people. In addition, mutual social support within the group setting was exclusively available to the intervention group. Third, the SMI was implemented in the workplace, and thus in the context of a stressful environment with multiple uncontrollable influences. It is possible that increasing overall work pressure within the company may have weakened the specific SMI effects. Conducting a stress prevention programme in a real work setting must be considered a special strength of this study as most intervention programmes are conducted under laboratory conditions.[4]

Implications of a change in stress reactivity

Self-perceived stress reactivity assesses typical cognitive, emotional and physiological reactions to different stressful situations. High stress reactivity scores have been shown to significantly correlate with a variety of other psychological measures of distress such as depression or anxiety (H Limm *et al*, 2010).[23 32] An indication that improved SRS scores signify better management of stressful situations at work is the (non-significantly) stronger improvement in ERI, depression and anxiety in the intervention group. In addition, correlations of the changes in SRS scores with scores for depression, anxiety and ERI (between r=0.4 and r=0.65) point to a relationship between improved stress reactivity and improved mental health; however, this must be confirmed in a future study. On the other hand, these findings are in line with other intervention studies reporting positive effects on chronic stress, depression and quality of life.[33–35]

As expected, the individually focused SMI did not show any major effects on working conditions as measured with the KFZA which also contains the constructs 'demands' and 'control'. Whether in the long run our participants will be able to improve their working environment remains to be shown.

Biological stress indices

Whereas previous research has shown positive effects of cognitive behavioural interventions on psychological well-being,[4 33–35] it is still unclear whether these findings also affect biological measures of stress.[36] Only a few studies have measured physiological outcome variables (mainly blood pressure), with small effects.[4] One such investigation assessed endocrinological and psychological outcomes, but, unlike this study, was targeting a highly selective sample with a more intense intervention.[35]

Cortisol

The association of cortisol excretion with work stress is debated in current research as chronic stress may attenuate as well as enhance hormonal responsiveness.[37 38] Therefore, depending on the duration of exposure, increases or decreases in cortisol may have occurred in our sample, thus precluding a systematic pattern of response. This reasoning is supported, among others, by findings from a recent study in Denmark which found no association between work stress and salivary cortisol.[39]

α-Amylase

Salivary α-amylase reflects the responses of the sympathetic nervous system.[20] Short-term increases in salivary α-amylase following exposure to stressful stimuli were reported, but few studies tested the effects of long-term stressors[18]; our study is probably the first in this regard. After 1 year, we observed a lower summary value and a lower increase, both during the working day, in the intervention group compared to the control group. However, there was no such effect concerning α-amylase excretion in the morning.

There are lessons for future research and practice: (1) interventions for stress prevention should combine the individual behaviour centred approach with an organisational approach to improve working conditions and organisational culture, which is reflected in communication, supervisor support and work climate; (2) extended follow-up is required in order to assess whether the expected positive effect of a SMI on mental and cardiovascular health actually occurs in the long term; and (3) SMIs should be part of a broader approach to health promotion in the workplace if more marked effects on health outcomes are to be achieved.

CONCLUSION

The SMI evaluated in this trial used psychodynamic as well as cognitive behavioural techniques in order to better deal with factors contributing to high effort and low reward at work. Our approach proved to be feasible in the workplace setting, it was well accepted and it produced selected favourable behavioural and physiological effects. However, the effects were only moderate and health effects still have to be demonstrated in longer follow-up studies. This also points to the fact that improving working conditions must remain a primary goal of stress prevention even though this is sometimes hard to attain in practice. Although it is difficult to motivate men working in the production area of an international industrial company to participate in a stress prevention programme, we achieved a high participation rate. In conclusion, this approach may be a promising tool for reducing work stress in an area of increasing work pressure due to the globalised economy.

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REFERENCES

1. **Kivimaki M,** Virtanen M, Elovainio M, *et al*. Work stress in the etiology of coronary heart disease - a meta-analysis. *Scand J Work Environ Health* 2006;**32**:431—42.
2. **Stansfeld S,** Candy B. Psychosocial work environment and mental health—a meta-analytic review. *Scand J Work Environ Health* 2006;**32**:443—62.
3. **Noblet A,** Lamontagne AD. The role of workplace health promotion in addressing job stress. *Health Promot Int* 2006;**21**:346—53.
4. **Richardson KM,** Rothstein HR. Effects of occupational stress management intervention programs: a meta-analysis. *J Occup Health Psychol* 2008;**13**:69—93.
5. **van der Klink JJ,** Blonk RW, Schene AH, *et al*. The benefits of interventions for work-related stress. *Am J Public Health* 2001;**91**:270—6.
6. **Michie S,** Williams S. Reducing work related psychological ill health and sickness absence: a systematic literature review. *Occup Environ Med* 2003;**60**:3—9.
7. **de Lange AH,** Taris TW, Kompier MA, *et al*. "The very best of the millennium": longitudinal research and the demand-control-(support) model. *J Occup Health Psychol* 2003;**8**:282—305.
8. **Kivimaki M,** Vahtera J, Elovainio M, *et al*. Effort-reward imbalance, procedural injustice and relational injustice as psychosocial predictors of health: Complementary or redundant models? *Occup Environ Med* 2007;**25**:659—65.
9. **van Vegchel N,** de Jonge J, Bosma H, *et al*. Reviewing the effort-reward imbalance model: drawing up the balance of 45 empirical studies. *Soc Sci Med* 2005;**60**:1117—31.
10. **Siegrist J.** Adverse health effects of high-effort/low-reward conditions. *J Occup Health Psychol* 1996;**1**:27—41.
11. **Siegrist J,** Starke D, Chandola T, *et al*. The measurement of effort-reward imbalance at work: European comparisons. *Soc Sci Med* 2004;**58**:1483—99.
12. **Siegrist J,** Benach J, McKnight A, *et al*. Employment arrangements, work conditions and health inequalities. *Marmot Report* 2009. http://www.ucl.ac.uk/gheg/marmotreview/consultation/Employment_arrangements__work_conditions_report (accessed 9 Nov 2009).
13. **Siegrist K,** Silberhorn T. Streßabbau in Organisationen. Ein Manual zum Streßmanagement. *Münster: LIT-Verlag* 1998:1—68.
14. **Aust B,** Peters R, Siegrist J. Stress Management in Bus Drivers: A Pilot Study Based on the Model of Effort—Reward Imbalance. *International Journal of Stress Management* 1997;**4**:297—305.
15. **Cohrs JC,** Abele AE, Dette DE. Integrating situational and dispositional determinants of job satisfaction: findings from three samples of professionals. *J Psychol* 2006;**140**:363—96.
16. **Rödel A,** Siegrist J, Hessel A, *et al*. Fragebogen zur Messung beruflicher Gratifikationskrisen. Psychometrische Testung an einer repräsentativen deutschen Stichprobe. *Zeitschrift für Differentielle und Diagnostische Psychologie* 2004;**25**:227—38.
17. **Kirschbaum C,** Hellhammer DH. Salivary cortisol in psychoneuroendocrine research: recent developments and applications. *Psychoneuroendocrinology* 1994;**19**:313—33.
18. **Nater UM,** Rohleder N. Salivary alpha-amylase as a non-invasive biomarker for the sympathetic nervous system: current state of research. *Psychoneuroendocrinology* 2009;**34**:486—96.
19. **Nater UM,** Rohleder N, Gaab J, *et al*. Human salivary alpha-amylase reactivity in a psychosocial stress paradigm. *Int J Psychophysiol* 2005;**55**:333—42.
20. **Nater UM,** La Marca R, Florin L, *et al*. Stress-induced changes in human salivary alpha-amylase activity - associations with adrenergic activity. *Psychoneuroendocrinology* 2006;**31**:49—58.
21. **Herrmann C.** International experiences with the Hospital Anxiety and Depression Scale - a review of validation data and clinical results. *J Psychosom Res* 1997;**42**:17—41.
22. **Cochrane Collaboration.** Cochrane handbook for systematic reviews of interventions, version 4.2.5. 2005 5. November 2009. http://www.cochrane-handbook.org (accessed 9 Nov 2009).
23. **Schulz P,** Jansen L, Schlotz W. Stress reactivity: Theoretical concept and measurement. *Diagnostica* 2005;**51**:124—33.
24. **Vickers AJ,** Altman DG. Statistics notes: Analysing controlled trials with baseline and follow up measurements. *BMJ* 2001;**323**:1123—4.
25. **Kazis LE,** Anderson JJ, Meenan RF. Effect sizes for interpreting changes in health status. *Med Care* 1989;**27**:178—89.
26. **Pruessner JC,** Kirschbaum C, Meinlschmid G, *et al*. Two formulas for computation of the area under the curve represent measures of total hormone concentration versus time-dependent change. *Psychoneuroendocrinology* 2003;**28**:916—31.
27. **Theorell T,** Karasek RA. Current issues relating to psychosocial job strain and cardiovascular disease research. *J Occup Health Psychol* 1996;**1**:9—26.
28. **Kudielka BM,** Hellhammer J, Hellhammer DH, *et al*. Sex differences in endocrine and psychological responses to psychosocial stress in healthy elderly subjects and the impact of a 2-week dehydroepiandrosterone treatment. *J Clin Endocrinol Metab* 1998;**83**:1756—61.
29. **Traustadottir T,** Bosch PR, Matt KS. Gender differences in cardiovascular and hypothalamic-pituitary-adrenal axis responses to psychological stress in healthy older adult men and women. *Stress* 2003;**6**:133—40.
30. **Eccleston C,** Williams AC, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. *Cochrane Database Syst Rev* 2009: CD007407.
31. **Abbass AA,** Hancock JT, Henderson J, *et al*. Short-term psychodynamic psychotherapies for common mental disorders. *Cochrane Database Syst Rev* 2006: CD004687.
32. **Limm H,** Angerer P, Heinmueller M, *et al*. Self-perceived stress reactivity is an indicator of psychosocial impairment at the workplace. *BMC Public Health* 2010;**10**:252.
33. **Kirby ED,** Williams VP, Hocking MC, *et al*. Psychosocial benefits of three formats of a standardized behavioral stress management program. *Psychosom Med* 2006;**68**:816—23.
34. **Mino Y,** Babazono A, Tsuda T, *et al*. Can stress management at the workplace prevent depression? A randomized controlled trial. *Psychother Psychosom* 2006;**75**:177—82.
35. **Nickel C,** Tanca S, Kolowos S, *et al*. Men with chronic occupational stress benefit from behavioural/psycho-educational group training: a randomized, prospective, controlled trial. *Psychol Med* 2007;**37**:1141—9.
36. **Hanson EK,** Maas CJ, Meijman TF, *et al*. Cortisol secretion throughout the day, perceptions of the work environment, and negative affect. *Ann Behav Med* 2000;**22**:316—24.
37. **Bellingrath S,** Weigl T, Kudielka BM. Cortisol dysregulation in school teachers in relation to burnout, vital exhaustion, and effort-reward-imbalance. *Biol Psychol* 2008;**78**:104—13.
38. **Wirtz PH,** Siegrist J, Schuhmacher A, *et al*. Higher overcommitment to work is associated with higher plasma cortisol but not ACTH responses in the combined dexamethasone/CRH test in apparently healthy men and women. *Psychoneuroendocrinology* 2009;**35**:536—43.
39. **Mikkelsen S,** Hansen A, Thomsen J, *et al*. Work-related stressors and cortisol. Cross sectional study on 3660 persons. In: *29th ICOH International Congress on Occupational Health, 22-27 March 2009*. Cape Town, South Africa; 2009.