Active stimulation of positive affect and mobilisation of psychological resources during burn out treatment

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The following objectives are examined in a randomized controlled trial whether:1) Person-tailored feedback on appraisals of work-related activities, NA and PA, (as measured with the PsyMate) during CBT has an additional effect in terms of immediate...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Adjustment disorders (incl subtypes)
Study type	Interventional

Summary

ID

NL-OMON35867

Source
ToetsingOnline

Brief title
PsyMate intervention in burn out

Condition

- Adjustment disorders (incl subtypes)

Synonym
Occupational stress, stress-related disorder

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: burn out, ESM, Positive affect, PsyMate

Outcome measures

Primary outcome

Aim 1: Main outcome measures are pre - post intervention change in burn out symptomatology as measured with the UBOS questionnaire and Work Engagement as measured with the UWES questionnaire.

Aim 2: Pre and post intervention changes in PA, NA and person-tailored strategies as measured with the PsyMate are the main outcome measures for this aim.

Aim 3: Follow up measures are changes in burn out symptomatology as measured with the UBOS questionnaire and Work Engagement as measured with the UWES questionnaire.

Aim 4: This economic evaluation will involve a combination of a cost-effectiveness analysis (CEA) and a cost-utility analysis (CUA). In a CEA effects are presented in clinical outcomes (in our study increase of work engagement, decrease of burn out and relapse). The primary outcomes measure for the cost-utility analysis will be Quality Adjusted Life Years (QALYs), based on the EuroQol utility scores, which is measured with the TiC-P, PRODISQ and EQ-5D. The health care consumption and costs are compared between the two groups on base-line and at 12 and 24 weeks follow up.

Aim 5: Changes in daily life experiences and their relation with future burn

out are measured with the Psymate.

Aim 6: not applicable

Secondary outcome

not applicable

Study description

Background summary

People can suffer from burn out complaints as a result of organisational factors and an imbalance of non sufficient coping, increasing demands and/or lack of social support at work which can lead to burn out. Burn out is known as a serious risk for employees who work under chronic stress. The majority of the literature on occupational mental health focused burn out, the underlying mechanisms and methods to prevent high stress-levels. In the recent years there*s increasing attention, under influence of positive psychology, for processes that also may contribute to the overall wellbeing of employees. Several balanced occupational health models include negative (burn out) as well as positive (work engagement) aspects of wellbeing. The potentially positive effects of work are thereby taken into account.

Although burn out is not included as a psychiatric syndrom in current diagnostic classification systems like DSM-IV, it is usually defined as a syndrome of exhaustion, cynicism, and lack of professional ef*cacy. However, accumulating evidence indicates that exhaustion and cynicism are considered the essence or **core** of the burnout syndrome.
In the case positive aspects of wellbeing, the term (work) engagement is often used. Engagement can be defined as a positive, fulfilling, work-related state of mind characterized by vigor, dedication and absorption Rather than a momentary and specific state, engagement refers to a more persistent and pervasive affective-motivational state that is not focused on any particular object, event, individual or behaviour.

Burn out is considered to result from stressors at work, mediated by personal coping or the ability to deal with environmental stressors at a personal level. Work engagement can be seen as a related construct to positive affect (PA). Recent research suggests that more daily positive experiences lead to an

increase of work engagement and less occupational stress. Translated in emotional terms, this will result in higher levels of PA en decreased levels of NA. On the other hand daily negative events can lead to great amounts of negative affect (NA) and reduction in positive affect (PA) which gives a high risk for development of burn out symptoms.

Measurement of emotion and emotional responses must take place at those moments in which an individual interacts with his environment to provide ecological valid information. The Experience Sampling Method (ESM) is suitable for this purpose. Several studies of depression have been performed with the ESM paradigm, and this procedure is not only ecologically valid but proves to have a good validity and reliability. The validity and reliability of ESM for the measurement of direct effects of daily stressors on mood has also been demonstrated. New technology to electronically monitor the patients* dynamic daily life responses to their personal context for extended periods (4-6 weeks) has recently become available and is patented by our group under the name *PsyMate*. This device is not only suitable for ESM, but it can also electronically summarize the information of daily life situations, behaviour, cognitions and feelings. This creates the possibility to provide feedback to subjects on their patterns of emotional responses to daily life (working) situations. Receiving feedback on behaviour can result in emotional and behavioural change, as is already known from the field of behavioural therapy. Feedback may create an active and possibly therapeutic context for the burn out patient and people at risk. Feedback can be given to both patient and therapist. For the patient, feedback can result in an increased insight in personal functioning, awareness of small improvements leading to more control over possible causes of burn out, and finally an increased use of the patient*s personal resources. For the therapist, feedback can result in a better monitoring of both compliance and the effect of the treatment. Additionally the application of detailed, ecologically more valid feedback on daily life behaviour, as measured with the PsyMate, may improve therapeutic efficacy with an active resource-mobilizing therapeutic context.

Most therapy approaches of individual burn out treatment are based on cognitive behavioural principles such as stress-management and cognitive therapy. In the current study we form two groups of subjects in a randomized controlled trial. The control group receives CBT and the experimental group CBT and an additional PsyMate intervention. The experimental group receives during 6 weeks person-tailored feedback on (positive) affect and appraisals of situations in a work-related context and other daily life situations. The feedback aims to increase insight into what specific patterns of activities are associated with what level of positive (work) experiences. This may help create effective person-tailored strategies to reshape daily life behavioural (work) patterns to those that lead to more positive emotions and work engagement, The feedback is therefore focused on PA and activity patterns that are positively associated with aspects of work engagement, such as making successful use of job

resources.

Study objective

The following objectives are examined in a randomized controlled trial whether:
1) Person-tailored feedback on appraisals of work-related activities, NA and PA, (as measured with the PsyMate) during CBT has an additional effect in terms of immediate decrease of burn out symptomatology (as measured with the UBOS) and increase of the work engagement level (as measured with the UWES).

2) the use of Psymate feedback on (work-related) situations leads to an increase in Positive Affect (PA), a decrease in Negative Affect (NA) and more effective person-tailored strategies in work-related contexts.

(3) Person-tailored feedback on daily life (work) situations (as measured with the PsyMate) reduces symptoms and relapse risk for future burn out (as measured with the UBOS) and a higher level of work engagement (as measured with the UWES) at follow up.

(4) Additional person-tailored feedback on relevant dynamic daily life emotional experiences in work-related contexts (as measured with the PsyMate) during CBT is cost-effective. The cost effectiveness of the PsyMate intervention is measured with the TiC-P, PRODISQ and EQ-5D.

(5) Changes in daily life experiences such as increasing levels of PA (both in the experimental and the control condition) predict future outcome (in terms of relapse risk and symptoms).

6) As part of a larger data collection of momentary assessment data and genetic information it will be examined how genetic differences are associated with prospectively measured momentary emotional experiences in interplay with daily life contexts.

Study design

A randomized controlled trial will be conducted with two intervention arms:

- The experimental arm (PsyMate intervention; n=30) receives receives 5-day pre- and post PsyMate assesments and continuous Psymate assessment (each week 3-days PsyMate measurement during a 6- weeks period) with feedback (to both patient and therapist) during treatment as usual (TAU= Cognitive Behavioural Therapy) with the aim of stimulating PA and Work Engagement. This is the experimental group.

- The control group (n= 30) receives 5-day pre- and post PsyMate assessments but no additional intervention during TAU.

Intervention

The Psymate intervention contains feedback about activities that lead to an increase of the different aspects of Work Engagement, namely vigor, dedication and absorption.

The first and second session are focused on building up PA and the energy level (vigor) by giving feedback on activities, sleeping pattern, relaxation but also the amount of tiresome or stress-inducing activities. Feedback is given about the relation between the content of activities and the amount of positive emotions and their energy level. The focus lies on activities which lead to an increase in energy and/or positive emotions and decrease in stress level.

The third and fourth session are focused on mastery experiences. Successes build a robust belief in one's personal efficacy, absorption and higher dedication to work. Feedback is given about the amount of appreciation they feel at their current activity. Little successes and activities in which they feel appreciation of others for their effort, lead to positive emotions. It also reinforces ones professional efficacy and result in higher dedication to work (when the situation took place in a work-related context).

Session five and six are focused on positive emotions in social work interactions. Behaving friendly, sharing good news and success with others, investing in social contact with colleagues and friends leads to positive emotions, vigor, improved self-efficacy and higher dedication to work. Information is given on the amount of momentary positive emotions in relation to the different kind of social contacts and their progress in initiating contact over time in social situations at work and at home. Again, at the end, they also receive information on their energy level and (sessions 1 & 2) and progress in mastery experiences (sessions 3 & 4) accompanied by visual aids.

The therapist communicates this information in such a way that the participant understands what it means and how it relates to his/her daily life behaviour. Furthermore, the therapist and subject look at ways the participant can change his/her daily life activities in a way that would lead to more positive emotions. The therapist can additionally support the participant in modifying his/her working behaviour towards situations of more positive emotions, work engagement and adjust therapeutic strategy or advice.

Study burden and risks

There are no health risks associated with the research.

Burden for the patients is investment of time. They have to fill out some

questionnaires, and also have to spit some saliva in a tube. In addition, all subjects participate twice (before and after the intervention period) in the PsyMate measurements (5-day period of filling in dairies concerning daily life events and mood). PsyMate measurement takes places in the actual living environment of the patient during which they engage in their normal daily activities, and as such reduces the burden for the patient. Before the start of the PsyMate measurements receive specific instructions related to this procedure and the PsyMate by their therapist. On top of this, subjects in the experimental group additionally have to complete the PsyMate measurements for 3 days a week during a 6-week period (3 days a week, 10 times a day, each time approximately 2 minutes), and have weekly contact with the therapist to receive feedback from the PsyMate during this 6-weeks period. After a screening procedure (3 hours), the time investment for subjects is approximately 4 hours comprising self-report questionnaires (distributed over 7 meetings), beside the time spend on filling in questions on the PsyMate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(i) 18-65 years, (ii) meeting the criteria of burn out using the UBOS questionnaire (iii) adequate vision, and (iv) sufficient Dutch language skills.

Exclusion criteria

diagnosis of non-affective psychosis (e.g. schizophrenia), schizoaffective disorder (current) or a bipolar disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-09-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2011

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26760
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL35703.068.11
OMON	NL-OMON26760