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Tailored cognitive-behavioral therapy in early rheumatoid arthritis for patients at risk: a randomized controlled trial

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Abstract

Recent developments in chronic pain research suggest that effectiveness of cognitive-behavioral therapy (CBT) may be optimized when applying early, customized treatments to patients at risk. For this purpose, a randomized, controlled trial with tailor-made treatment modules was conducted among patients with relatively early rheumatoid arthritis (RA disease duration of <8 years), who had been screened for psychosocial risk profiles. All participants received standard medical care from a rheumatologist and rheumatology nurse consultant. Patients in the CBT condition additionally received an individual CBT treatment with two out of four possible treatment modules. Choice of treatment modules was determined on the basis of patient priorities, which resulted in most frequent application of the fatigue module, followed by the negative mood, social relationships and pain and functional disability modules. Analyses of completers and of intention-to-treat revealed beneficial effects of CBT on physical, psychological and social functioning. Specifically, fatigue and depression were significantly reduced at post-treatment and at the 6-month follow-up in the CBT condition in comparison to the control condition, while perceived support increased at follow-up assessment. In addition, helplessness decreased at post-treatment and follow-up assessment, active coping with stress increased at post-treatment, and compliance with medication increased at follow-up assessment in the CBT condition in comparison to the control condition. Results indicate the effectiveness of tailor-made CBT for patients at risk in relatively early RA, and supply preliminary support for the idea that customizing treatments to patient characteristics may be a way to optimize CBT effectiveness in RA patients.

Keywords: Cognitive-behavioral therapy; Rheumatoid arthritis; Chronic pain; Risk profile; Tailor-made; Recent onset

1. Introduction

In recent decades, the multiple disturbing effects of chronic pain on patients' physical, psychological and social functioning, such as increased functional disability and fatigue, heightened levels of anxiety and depression, and impaired social and economic functioning, has been widely recognized (e.g. Anderson et al., 1985; Chapman and Gavrin, 1999; Maniadakis and Gray, 2000; Gatchel, 2001). Medical treatment only partly alleviates these consequences of chronic pain, and psychosocial interventions – particularly cognitive-behavioral therapy (CBT) – have been shown to be a possibly effective adjunctive treatment for reducing the unfavorable effects on patient functioning (see e.g. McCracken, 1991; Hawley, 1995; Morley et al., 1999; van Tulder et al., 2000).

In spite of the encouraging effects of psychosocial interventions in chronic pain disorders, the variability in outcomes between patients and the magnitude and maintenance of effects in the long run is a point of continuing discussion (e.g. Turk, 1990; McCracken, 1991; DeVellis and Blalock, 1993; Keefe and van Horn, 1993; Hawley, 1995; Turk and Okifuji, 1998; Gatchel, 2001). Specifically, in patients with rheumatoid arthritis (RA), a chronic disabling disease that primarily affects the joints, meta-analyses have indicated that psychosocial interventions in general, and more specifically CBT and behavioral treatments also, have non-significant to small effects on indicators of physical and psychological functioning at post-treatment, and non-significant effects at follow-up assessments (Hawley, 1995; Riemsma et al., 2002; see also, McCracken, 1991; Riemsma et al., 1999). Meta-analyses of CBT for various chronic pain disorders, such as chronic low back pain or osteoarthritis, have revealed more promising effects, but improvement in magnitude and maintenance of effects is still desired (Hawley, 1995; Morley et al., 1999;

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van Tulder et al., 2000). The limited effects of CBT for RA and other chronic pain disorders have frequently been ascribed to the heterogeneity of patients. Not all patients may receive benefits from generic treatments. Instead, customizing treatments more closely to patient characteristics, in terms of patient selection and types and timing of treatment, has been repeatedly suggested as a way to optimize treatment effectiveness (e.g. Turk, 1990; McCracken, 1991; Devellis and Blalock, 1993; Turk and Okifuji, 1998; Gatchel, 2001; van Tulder et al., 2000).

In view of the individual variability between patients with chronic pain, various attempts have been made to classify patients into more homogeneous subgroups and identify patients that may benefit from psychosocial interventions. For example, it has been repeatedly shown in various chronic pain disorders that subgroups of patients are relatively well-adjusted and might only receive limited benefits from CBT. Instead, it has frequently been suggested that the repeatedly identified group of patients with heightened distress levels and dysfunctional cognitive-behavioral factors benefit most from CBT (e.g. Turk and Rudy, 1988, 1990a; Turk, 1990; Main et al., 1992; Klapow et al., 1993, 1995; Strong et al., 1994; Turk and Okifuji, 1998; Gatchel, 2001). Retrospective analyses of CBT effects in fibromyalgia patients provided preliminary support for this view, indicating that patients characterized by high distress levels and dysfunctional cognitive-behavioral factors benefited more from CBT than those relatively well-adjusted or whose impairment was mainly related to social functioning (Turk et al., 1998). In RA, it is a well-known fact that subgroups of 20–40% of the patients suffer from heightened anxiety and depression levels (e.g. Frank et al., 1988; Murphy et al., 1988; Hawley and Wolfe, 1993; Evers et al., 1997, 2002; Dickens et al., 2002). In addition, heightened distress levels in RA patients are directly related to cognitive-behavioral factors of illness cognitions, coping and social support, and these factors have in turn repeatedly been shown to prospectively predict the RA disease outcome. Specifically, there is evidence from prospective studies that illness cognitions of more helplessness and less acceptance, more passive coping with pain or stress, and lower levels of social support predict decreased physical, psychological and social functioning in RA patients in the long run (e.g. Brown and Nicassio, 1987; Brown et al., 1989a,b; Keefe et al., 1989; Smith and Wallston, 1992; Smith et al., 1994, 1997; Evers et al., 1997, 1998a, 2001a, 2002; van Lankveld et al., 1999, 2000; Scharloo et al., 1999). In terms of patient selection, CBT treatment for RA patients is consequently likely to show increased magnitude and maintenance of effects for subgroups of patients with a psychosocial risk profile, including heightened distress levels and more dysfunctional cognitive-behavioral factors of illness cognitions, coping and social support.

In relation to treatment specificity, effect studies of CBT usually consist of generic treatments with multiple cognitive and behavioral modules, assuming that the different components are even relevant and effective for patients. However, in view of the various problems from which patients with chronic pain suffer, treatment programs applied modularly and tailored to patients' clinical needs may increase the effectiveness of CBT in chronic pain patients (e.g. Turk, 1990; Fry and Wong, 1991; Turk and Okifuji, 1998; Gatchel, 2001). The most frequently affected areas of pain, functional disability, fatigue, distress and impaired social functioning in RA patients are only moderately correlated (e.g. Huiskes et al., 1990; Evers et al., 1997, 1998b; Huyser et al., 1998; see also McCracken, 1991), and these outcomes have been shown to be differently predicted by specific cognitive-behavioral factors in the long run (e.g. Smith et al., 1994, 1997; Evers et al., 1997, 1998a, 2001a,b, 2002; Scharloo et al., 1999). Consequently, the effectiveness of CBT in RA may be optimized when interventions focus on specific outcomes of impaired functioning and the related cognitive-behavioral factors. In addition, applying treatment modules matched to individual patient profiles and directed to the outcome from which patients suffer most is likely to increase patient satisfaction with treatment and decrease attrition rates (see e.g. Turk and Rudy, 1990b).

It has also been assumed that treatment effectiveness depends on the timing of treatment, specifically the temporal stages of the illness. For example, it has been suggested that patients develop a relatively stable way of coping with chronic pain, and dysfunctional cognitive-behavioral factors may be less established and easier to modify at an earlier stage of the disease than later on, suggesting increased CBT effectiveness for patients suffering for a shorter time from their complaints (e.g. Philips and Jahanshahi, 1985; DeVellis and Blalock, 1993; Peters et al., 2000; Sinclair and Wallston, 2001). In addition, interventions at an earlier stage of the disease have by definition a greater chance of having more long-term benefits and possibly preventing a worse long-term disease outcome, such as irreversible joint destruction in RA patients (Parker and Wright, 1995). Dysfunctional cognitive-behavioral factors' predicting a worse long-term disease outcome in RA patients has been shown to be already established in the initial years of the disease (Evers et al., 1997, 1998a, 2002; Smith et al., 1997). In addition, retrospective analyses of previous CBT trials suggest improved effectiveness in patients with earlier RA, indicating more favorable changes in patients with a shorter duration of disease, particularly within the first 7 years (Kraaimaat et al., 1995; Sinclair and Wallston, 2001). Moreover, a recently conducted CBT trial with early RA patients was the first controlled trial demonstrating beneficial effects on depression at post-treatment and follow-up assessment (Sharpe et al., 2001). Taken together, this provides preliminary evidence that CBT conducted at a relatively early stage of RA may improve effectiveness in the short and long terms.

Recent developments in multidisciplinary treatment for chronic pain increasingly include the regular care of nurse specialists, consisting of providing information and educa-

tion about the medical treatment and counseling and advice on disease-related problems in daily life (e.g. Hill, 1997; Madigan and FitzGerald, 1999; Ryan, 2001; Temmink et al., 2001 for rheumatology). In rheumatology care, there is preliminary evidence supporting various beneficial effects of the care of a nurse specialist on indicators of physical and psychological functioning (Hill et al., 1994). In the Netherlands, regular consultations with a specialized rheumatology nurse – the rheumatology consultant – is a relatively common part of the standard medical care. If customized CBT for RA patients is an effective treatment for use in clinical practice, it is important to show adjunctive effects in addition to the standard care from the rheumatologist and the rheumatology consultant on physical, psychological and social functioning.

In the present study, the effects of tailor-made CBT for patients with relatively early RA who had been screened for a psychosocial risk profile was studied in addition to the standard medical care received from the rheumatologist and a rheumatology consultant. It was hypothesized that, in comparison to the control condition, patients in the CBT condition would demonstrate more favorable changes on indicators of physical, psychological and social functioning with at least small to medium effects at post-treatment and follow-up assessment.

2. Methods

2.1. Patients and procedure

Patients were randomly selected from patient medical records of three rheumatology outpatient clinics in the Netherlands. Inclusion criteria were a diagnosis of RA according to the ACR criteria (Arnett et al., 1988), age above 18 years, and a duration of disease of less than 8 years. Patients with comorbid conditions that might interfere with the CBT treatment (such as malignancy, cardiac, respiratory, hepatic, and renal insufficiency) were excluded. In total, 407 patients who met inclusion criteria received a written invitation to take part in the questionnaire study. Of these patients, 278 (68%) agreed to participate. The participants were predominantly female (71%) and married or living with a partner (75%). The average age of patients was 55.24 (SD 12.20) with a 3.19 year mean duration of disease (SD 1.99). Fifteen percent of the patients had a primary level of education and 68% a secondary educational level (an average of 7 and 12 years of formal education, respectively).

Questionnaires were administered in this sample to screen for previously determined risk profiles. Risk profiles were based on the prevalence of heightened anxiety and negative mood levels in patients with early RA, as well as dysfunctional cognitive-behavioral factors of illness cognitions, coping and social support that have all been shown to prospectively predict the course of physical and psychological functioning in RA patients (Evers et al., 1997, 1998a, 2001a; Scharloo et al., 1999). Cutoff scores were based on findings from previous research, which showed that subgroups of approximately 30% of the patients suffer from subclinical levels of anxiety and depression (Evers et al., 1997, 2002). The cutoff scores for cognitive-behavioral factors were accordingly established at 30% of previous RA patient norm groups (Evers et al., 1997, 1998a, 2001a, 2002). Specifically, patients were classified at risk when scoring in the upper 30% in either anxiety or negative mood in comparison to norm groups of patients with early RA (Evers et al., 1997, 2002), in conjunction with a score in the upper 30% of at least two out of the following six cognitive-behavioral factors: illness cognitions of heightened helplessness and low levels of acceptance (Evers et al., 2001a), a passive manner of coping with stress (Evers et al., 1997, 2002), a passive manner of coping with pain (Evers et al., 1998a) and low levels of social functioning (size of social network and perceived support) (Evers et al., 1997, 1998a). In addition to the questionnaires' addressing the psychosocial risk profile, self-report measures of physical functioning (functional disability, pain and fatigue) were administered in this sample.

From the total sample of 278 patients, 112 patients (40%) met the criteria for a psychosocial risk profile (see Fig. 1 for an overview of study participants). In accordance with the psychosocial risk profile criteria, patients at risk were characterized by significantly higher levels of negative mood and anxiety ($t = 16.04$, $P < 0.001$; $t = 15.26$, $P < 0.001$, respectively), as well as more dysfunctional cognitive-behavioral factors of greater helplessness and less acceptance ($t = 9.81$, $P < 0.001$; $t = -7.65$, $P < 0.001$, respectively), more passive coping with pain and stress ($t = 7.24$, $P < 0.001$; $t = 2.51$, $P < 0.05$, respectively), and lower levels of social functioning ($t = -4.89$, $P < 0.001$; $t = -4.81$, $P < 0.001$ for perceived support and the social network, respectively) in comparison to patients not at risk. In addition, patients at risk had a significantly lower educational level ($t = -2.38$, $P < 0.05$) and higher levels of functional disability, pain, and fatigue ($t = 5.61$, $P < 0.001$; $t = 7.06$, $P < 0.001$; $t = 8.94$, $P < 0.001$, respectively). No significant differences were found between the groups with regard to the demographic variables of gender, age, marital status or duration of disease.

Patients screened at risk received a written invitation within 2 weeks to take part in a randomized, controlled CBT trial for RA patients. From the 112 patients selected, 64 patients (57%) agreed to participate in the study. Reasons for refusing to participate related in most cases to practical concerns (63%), such as traveling distance and scheduling difficulties in combining the intervention with work and other daily activities. Twenty-five percent of the patients reported an unwillingness to participate due to a lack of interest, and 12% gave no reason for refusing. When comparing patients willing and unwilling to participate, there were no differences found between the groups in terms of demographic variables (gender, age, marital status,

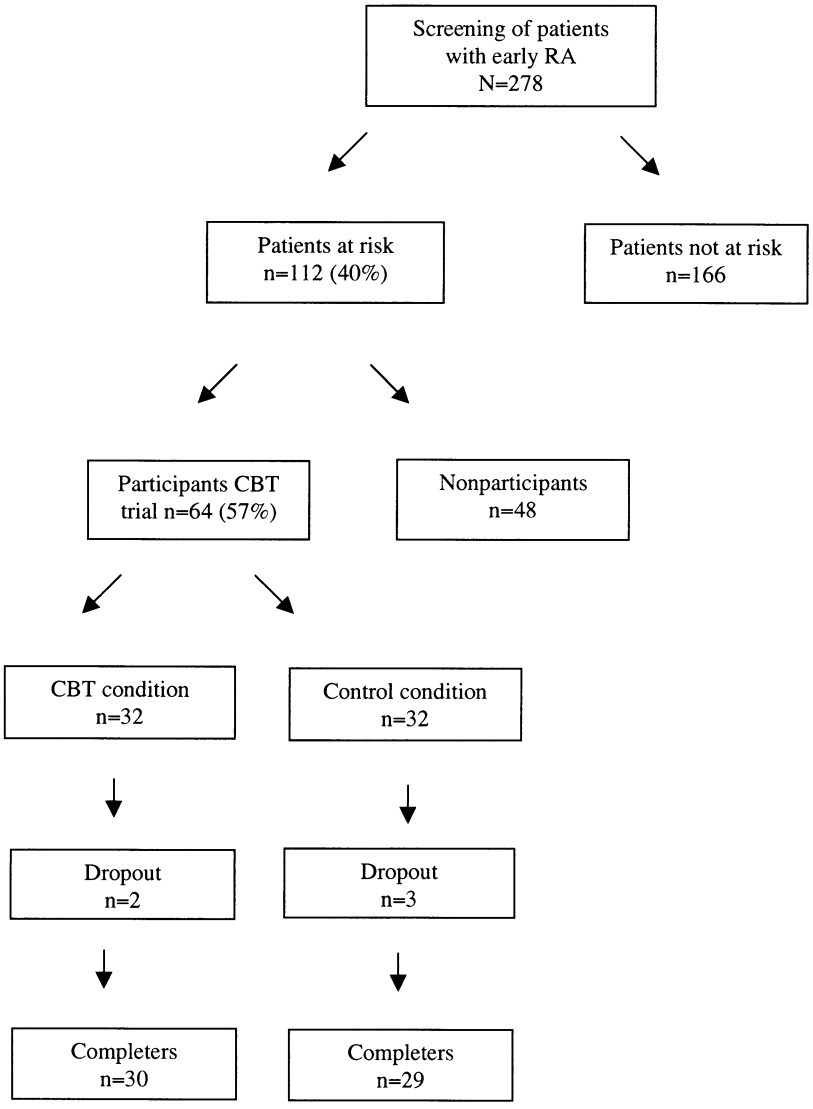

Fig. 1. Overview of study participants.

educational level), duration of disease, indicators of physical (functional disability, pain, fatigue) and psychological functioning (negative mood and anxiety), or any of the cognitive-behavioral factors (illness cognitions, coping with stress or pain, social functioning).

The 64 patients participating in the randomized trial were predominantly female (72%) and married or living with a partner (77%). Their average age was 54.13 (SD 11.17). Nine percent of the patients had a primary educational level and 75% a secondary education level. Mean duration of disease was 3.45 years (SD 2.08) with the following distribution: 13 patients (20%) had a duration of disease of equal to or less than 12 months, 14 patients (22%) 13–24 months, 11 patients (17%) 25–36 months, five patients (8%) 37–48 months, seven patients (11%) 49–60 months, eight patients (13%) 61–72 months, four patients 73–84 months (6%) and two patients 85–90 months (3%). Most patients (72%) were taking a combination of disease modifying drugs (DMARD) and non-steroid anti-inflammatory drugs (NSAID). Twenty and 8%, respectively, exclusively used DMARD and NSAIDs. The 64 patients were randomly assigned to one of the two conditions ($n = 32$, for both conditions) according to a previously determined pattern of random numbers. Patients in both conditions received standard medical care from the rheumatologist as well as quarterly consultations with the rheumatology consultant. Consultations with the rheumatology consultant consisted of providing information and education about the medical treatment and counseling and advice on disease-related problems in daily life. Patients in the CBT condition also received the tailor-made CBT treatment. Assessments of clinical data of disease activity (laboratory Erythrocyte Sedimentation Rate (ESR) data and clinical joint score ratings) and self-report data took place at pretreatment (4–8 weeks after the screening assessment), at 6-month post-treatment and at a 6-month follow-up after post-treatment

during routine medical visits by the rheumatology consultants. Joint score ratings were assessed by four rheumatology consultants who followed the patients over time, i.e. the same consultant scored patients at three times, at pretreatment, post-treatment and follow-up assessment. During these visits, patients also received the questionnaires which they were asked to complete at home. Before starting pretreatment assessment, the rheumatology consultants checked whether patients received any other psychological group or individual treatment. No patient was affected by this exclusion criterion at pretreatment or later.

2.2. Tailor-made CBT treatment

Patients in the CBT condition received an additional cognitive-behavioral treatment within 6 months, consisting of in total 10 biweekly, 1-h sessions and one final booster session scheduled 4 weeks later. The CBT condition consisted of individual treatment with two out of the four possible treatment modules that targeted the most frequently experienced problems with which RA patients have to cope: pain and functional disability, fatigue, negative mood and social relationships. Choice of treatment modules was determined on the basis of patient priorities. Information about the treatment and the different modules was given in the first session. In the following session, patients chose with the therapist's assistance the treatment module they wanted to start with (first choice), as well as the module with which they wanted to continue (second choice). All treatment modules consisted of cognitive and behavioral interventions with homework assignments of about a half an hour per day. The treatment modules were developed from standardized CBT protocols of RA patients (e.g. Kraaimaat et al., 1995), as well as standardized CBT protocols of pain, fatigue, mood disorders and social functioning problems (e.g. Barlow, 1993; Hawton et al., 1989; Gatchel and Turk, 1996). The pain and function disability module consisted of progressive relaxation, attention diversion, stimulation of physical exercising in daily life in the face of the current physical condition, activity pacing, problem-solving, adjustment of goal-setting to the current physical condition, identification of pain-provoking cues in daily life, and cognitive restructuring of dysfunctional pain cognitions. The fatigue module included activity-pacing, adjustment of goal-setting to the current physical condition, setting priorities and structured planning of daily activities and time off, and cognitive restructuring of activity demands. The negative mood module consisted of problem-solving, cognitive restructuring of depressogenic and anxious cognitions, identification of stress-provoking cues in daily life, stimulating pleasurable activities and restructuring of goal-setting in the face of the current physical condition, emotional processing of the changes RA has brought about in daily life and finding benefits. The social module finally included identification of social stress provoking cues in daily life, cognitive restructuring of social anxious cognitions, stimulating social activities in the face of the current physical condition, and social skills training including help-seeking behavior and communication about RA. In all treatment modules, the final booster session dealt with relapse prevention and further improvement of the attained goals. Patients were treated by two therapists trained in the treatment modules and supervised by a cognitive-behavior supervisor. Sessions were tape recorded and reviewed by the supervising cognitive-behavioral therapist for the accuracy of applying the treatment modules. In addition, an independent cognitive-behavioral therapist uninvolved in the present study reviewed 10% of randomly selected tapes and confirmed the therapists' adherence to the treatment modules.

2.3. Measures

Demographic variables were assessed with a general checklist, assessing patients' gender, age and marital status. In addition, educational level was measured using seven categories that can be classified as primary, secondary and tertiary educational levels, representing on average 7, 12, and 17 years of education, respectively.

Disease activity was assessed in patients participating in the randomized trial with the Disease Activity Score (DAS; Prevoo et al., 1995), which consists of a weighted composite score of Erythrocyte Sedimentation Rate (ESR; 1–140 mm first hour), and clinical joint score ratings (number of painful and swollen joints; Fuchs et al., 1989).

Functional disability was assessed with a composite score of the Mobility and Self-care scales of the Impact of Rheumatic Diseases on General Health and Lifestyle (IRGL) (Huiskes et al., 1990; Evers et al., 1998b), a questionnaire derived from the AIMS (Meenan et al., 1980), which assesses physical, psychological and social health in patients with rheumatic diseases. Previous research has shown that the reliability and validity of the IRGL scales are highly satisfactory (Huiskes et al., 1990; Evers et al., 1998b). The Mobility and Self-care scales, which assess the functional capacities of the lower and upper extremities, respectively, over the last month (15 items) have been shown to be highly comparable to the AIMS physical functioning scales (Evers et al., 1998b). A composite score of the scales was calculated by adding the standardized scores (z-scores) of both indicators. A higher composite score indicates higher levels of functional disability.

Pain was assessed with the IRGL Pain scale (six items), measuring the severity and frequency of painful episodes and swollen joints and duration of early morning stiffness in the last month.

Fatigue was assessed with the Fatigue scale (eight items) of the Checklist Individual Strength (CIS; Vercoulen et al., 1996), measuring patients' level of fatigue for the previous 2 weeks.

Psychological functioning was measured by the IRGL Anxiety and Negative Mood scales. The Anxiety scale is a shortened version of the Dutch State Anxiety Scale (ten

items) (Spielberger et al., 1970; Van der Ploeg et al., 1980), assessing anxiety levels in the last month. The Negative Mood scale (six items) is derived from Zwart and Spooren's questionnaire (Zwart and Spooren, 1982) and assesses various negative mood states over the previous 2 weeks. In addition, depression was assessed with a Dutch version of the Beck Depression Inventory (BDI; Beck et al., 1988) in the patients participating in the randomized trial.

Social functioning in the past 6 months was measured with the IRGL social functioning scales, reflecting a quantitative and qualitative aspect of social support. The qualitative aspect was measured with the Perceived Support scale (five items), inquiring about perceived availability of emotional and instrumental support (availability to share sad and pleasant events, get support when faced with stress and pain, get help for casual work). The quantitative aspect was assessed by the size of the social network, i.e. the number of friends and family members with whom patients associate.

Illness cognitions were measured with the Illness Cognition Questionnaire (Evers et al., 2001b), assessing different ways of cognitive adjustment to a chronic disease. Two scales were used in the present study: helplessness (focusing on the adverse aspects of the disease and generalizing them to daily functioning, six items) and acceptance (recognizing the need to adapt to a chronic disease while perceiving the ability to tolerate and manage its aversive consequences, six items).

Coping with stress was assessed with the Utrechtse Coping Lijst (UCL; Schreurs et al., 1993), a well-documented coping questionnaire in the Netherlands (see e.g. Evers et al., 1997, 2001a, 2002; Scharloo et al., 1999, for use in RA patients), adopted from Westbrook (1979), which measures active and passive coping strategies when dealing with everyday problems. Active coping was assessed with the Problem Focusing scale (seven items), measuring cognitive and behavioral efforts to apply goal-oriented problem-solving strategies. Passive coping was measured with the Avoidance scale (eight items), measuring cognitive and behavioral attempts to avoid, escape from and acquiesce when facing everyday problems.

Coping with pain was assessed by the Pain Coping Inventory (PCI; Kraaimaat et al., 1997; Evers et al., 1998a) measuring active and passive coping strategies when dealing with pain. Active pain-coping strategies reflect three cognitive-behavioral strategies, measuring patients' efforts to distract themselves from the pain (distraction by pleasant activities, five items), to reinterpret and transform the pain (pain transformation, four items) and to function in spite of the pain (reducing demands, three items). Passive pain coping reflects three cognitive-behavioral strategies, assessing behavioral tendencies to restrict functioning (resting, five items), to avoid environmental stimuli (retreating, seven items) and catastrophic cognitions about the pain (worrying, nine items). A composite score of active and passive pain coping can be calculated by summing up the non-weighted scores of the three active and passive coping strategies (Kraaimaat et al., 1997; Evers et al., 1998a).

Compliance with RA medication was assessed on a 3-point scale by a single item, inquiring about the frequency of failing to take the prescribed RA medication during the previous month (1 = once a week or more, 2 = less than once in a week, 3 = never).

2.4. Statistical analyses

Due to slight skewed distributions of scores at negative mood (skewness or kurtosis above 1.5), square root transformation was applied. Social network scores were categorized according to norm classes (Huiskes et al., 1990). Differences between subgroups at the time of screening (patients at risk versus not at risk, participants in the CBT trial versus refusers) and at pretreatment (CBT condition versus control condition, dropouts versus completers) were tested with chi-square analyses for categorical variables and Student's *t*-test for continuous variables with a threshold of $P < 0.05$ (two-tailed). In the event of significant differences or tendencies of differences ($P < 0.10$) between the CBT and control conditions, these variables were taken into account as covariates in the repeated measurement analyses. According to the treatment modules, treatment effects were expected in the primary outcome measures of physical (functional disability, pain, fatigue), psychological (depression, negative mood and anxiety) and social functioning (perceived support, size of the social network). Disease activity and cognitive-behavioral factors of illness cognitions, coping with stress and pain, and compliance were regarded as secondary outcome measures. A general linear model for repeated measurement was used to analyze the effects of CBT on the primary and secondary outcome variables, with time (three levels) as fixed factor. Multivariate analyses were conducted for the primary outcomes of physical, psychological and social functioning, and univariate analyses for the secondary outcomes. In the case of significant group × time interactions, paired *t*-tests between pretreatment and post-treatment and between pretreatment and follow-up assessment were conducted separately for both conditions to gain a better understanding of the nature of the interaction. Effect sizes were calculated by the difference between the means of the assessment points divided by their pooled standard deviations. All analyses were conducted with completers as well as with intention-to-treat analyses, using the last-observation-carried-forward method. Since both methods revealed the same results overall, only analyses with completers will be presented.

3. Results

3.1. Pretreatment condition comparisons

Means and SDs of demographic variables, duration of disease, use of medication, disease activity, indicators of physical, psychological and social functioning and cognitive-behavioral factors are presented for both conditions

Table 1
Means (and SDs) or percentages of demographic variables, duration of disease and medication in the CBT condition (CBT: $n = 30$) and the control condition (CC: $n = 29$) at pretreatment

	CBT	CC
Gender	70%	72%
Married	83%	72%
Age (years)	53.9 (10.3)	53.5 (12.6)
Duration of disease (years)	2.7 (1.9)	3.5 (2.1)
Educational level		
Primary	6%	10%
Secondary	67%	87%
Tertiary	27%	3%
Medication		
NSAID	73%	83%
DMARD	90%	97%

separately in Tables 1, 3 and 4. Pretreatment comparisons of both conditions revealed no significant differences between the groups in relation to demographic variables (gender, age, marital status, educational status), duration of disease, use of medication, disease activity, the indicators of physical, psychological and social functioning or any of the cognitive-behavioral factors. However, a tendency was found for the level of education. Patients in the CBT condition tended to have a higher educational level than patients in the control condition ($t = 1.85$, $P = 0.07$). Consequently, educational level was used as a covariate in all repeated measurement analyses. Finally, patients in the conditions did not differ on medication at post-treatment and follow-up assessment.

3.2. Dropouts

Between pretreatment and follow-up assessment, five patients (8%) dropped out: three patients from the control condition and two patients from the CBT condition. Reasons for dropping out were the occurrence of stressful life events for one patient from both conditions (divorce and a partner's serious medical condition), lack of sustained motivation to participate in the study for two patients in the control condition, and incomplete questionnaire assessment for one patient in the treatment condition. When comparing the dropouts to the completers at pretreatment, no significant differences were found between the groups regarding demographic variables (gender, age, marital status, educational level), use of medication, duration of disease, or the indicators of physical, psychological and social functioning.

Table 2
Frequency of treatment modules applied in the CBT condition ($n = 30$)

	Pain/funct. disability	Fatigue	Negative mood	Social relationships
First choice	5	15	10	0
Second choice	6	4	7	13
Not applied	19	11	13	17

3.3. Treatment modules in the CBT condition

The frequency of treatment modules applied, representing patients' first and second choices, are presented in Table 2, indicating preference differences in treatment modules: the fatigue and negative mood modules were applied to about two-third of the patients as first or second choice (63 and 57%, respectively), while the social relationship and pain and functional disability modules were applied to less than half of the patients (43 and 37%, respectively).

3.4. Outcome in disease activity

The general linear model for repeated measurement regarding disease activity revealed a time effect for both conditions ($F(2, 55) = 3.77$, $P < 0.05$), indicating that disease activity decreased during the study period for both conditions (see Table 3). No significant time × condition effect was found for disease activity ($F(2, 55) = 2.03$, $P < 0.14$).

3.5. Outcome in physical, psychological and social functioning

The general linear models for repeated measurement did not reveal any significant time effects for the conditions for the indicators of physical, psychological and social functioning (see Table 3).

When comparing both conditions, multivariate analyses of the indicators of physical functioning (functional disability, pain, fatigue) revealed a significant time × condition effect, Wilks' $\lambda = 0.73$, $F(6, 51) = 3.16$, $P < 0.05$. Univariate tests indicated a significant time × condition effect for fatigue ($F(2, 55) = 4.17$, $P < 0.05$). Paired t-tests showed that fatigue significantly decreased in the CBT condition at post-treatment and follow-up assessment ($t = 3.09$, $P < 0.01$ and $t = 3.14$, $P < 0.01$, respectively), but not in the control condition ($t = 1.18$, $P = 0.25$ and $t = -1.44$, $P = 0.16$, respectively). Univariate condition × time interactions were not significant for functional disability and pain ($F(2, 55) = 1.82$, $P = 0.17$ and $F(2, 55) = 0.27$, $P = 0.77$, respectively).

With regard to psychological functioning, a significant condition × time interaction was found in the multivariate analyses for the indicators of psychological functioning (depression, negative mood, anxiety), Wilks' $\lambda = 0.73$, $F(6, 51) = 3.20$, $P < 0.05$. Univariate tests showed a significant time × group interaction effect for depression ($F(2, 55) = 5.34$, $P < 0.01$), demonstrating that depression significantly decreased in the CBT condition at post-treatment and follow-up assessment ($t = 3.02$, $P < 0.01$ and $t = 3.10$, $P < 0.01$, respectively), but not in the control condition ($t = -0.57$, $P = 0.58$ and $t = -1.23$, $P = 0.23$, respectively). No significant effects of condition × time

Table 3
Means (and SDs) of disease activity, physical, psychological and social functioning in the CBT condition (CBT: $n = 30$) and the control condition (CC: $n = 29$) at pretreatment, post-treatment and the follow-up assessment

		Pretreatment	Post-treatment	Follow-up assessment
Disease activity	CBT	3.23 (1.45)	2.93 (1.49)	2.92 (1.57)
	CC	3.00 (1.15)	2.85 (1.13)	2.46 (0.88)
Physical functioning				
Funct. disability	CBT	2.41 (0.43)	2.46 (0.47)	2.42 (0.47)
	CC	2.44 (0.36)	2.40 (0.38)	2.37 (0.40)
Pain	CBT	15.40 (3.86)	14.93 (5.32)	14.99 (5.12)
	CC	16.28 (4.83)	15.35 (4.55)	15.79 (4.98)
Fatigue	CBT	40.07 (8.90)	34.70 (10.56)	35.18 (11.51)
	CC	39.38 (9.86)	37.41 (11.35)	41.38 (11.84)
Psychological functioning				
Depression	CBT	12.79 (6.46)	9.98 (4.62)	9.51 (5.35)
	CC	12.18 (6.70)	12.85 (7.87)	13.07 (7.51)
Negative mood	CBT	2.20 (0.86)	1.77 (1.08)	1.81 (0.95)
	CC	2.42 (0.98)	2.33 (1.04)	2.43 (0.98)
Anxiety	CBT	22.23 (5.26)	19.37 (4.72)	20.66 (5.81)
	CT	24.04 (5.56)	22.52 (6.30)	22.55 (5.45)
Social functioning				
Perceived support	CBT	13.30 (4.02)	13.90 (3.49)	14.74 (3.53)
	CC	14.07 (3.75)	13.93 (3.78)	13.45 (3.87)
Social network	CBT	1.87 (0.94)	1.93 (0.74)	1.78 (0.48)
	CC	1.61 (0.56)	1.79 (0.62)	1.86 (0.92)

interactions were revealed for negative mood and anxiety ($F(2, 55) = 1.30$, $P = 0.28$ and $F(2, 55) = 0.67$, $P = 0.52$, respectively). However, due to the significant effects on depression, the course of negative mood and anxiety were additionally explored for both conditions, indicating that negative mood significantly decreased in the CBT condition at post-treatment and follow-up assessment ($t = 2.25$, $P < 0.05$ and $t = 2.02$, $P = 0.05$, respectively), but not in the control condition ($t = 0.43$, $P = 0.67$ and $t = -0.07$, $P = 0.94$, respectively). In addition, anxiety significantly decreased in the CBT condition at post-treatment ($t = 3.46$, $P < 0.01$), but not at the follow-up assessment ($t = 1.63$, $P = 0.11$). However, anxiety also tended to decrease in the control condition at both assessment points ($t = 1.68$, $P = 0.10$ and $t = 1.97$, $P = 0.06$, respectively).

For indicators of social functioning, a nearly significant condition × time interaction was found in the multivariate analyses of social functioning (perceived support, size of the social network), Wilks' $\lambda = 0.84$, $F(4, 53) = 2.55$, $P = 0.05$. Univariate analyses revealed a significant time × group interaction for perceived support ($F(2, 55) = 4.17$, $P < 0.05$), showing that perceived support significantly

Table 4
Means (and SDs) of the cognitive behavioral factors in the CBT condition (CBT: $n = 30$) and the control condition (CC: $n = 29$) at pretreatment, post-treatment and the follow-up assessment

		Pretreatment	Post-treatment	Follow-up assessment
Illness cognition				
Helplessness	CBT	12.93 (3.61)	11.33 (3.75)	11.79 (3.45)
	CC	12.93 (3.41)	13.04 (3.82)	12.66 (3.41)
Acceptance	CBT	14.13 (4.60)	15.70 (4.12)	16.26 (3.97)
	CC	13.45 (3.63)	14.21 (3.82)	14.28 (3.55)
Coping with stress				
Active	CBT	2.48 (0.51)	2.67 (0.55)	2.60 (0.48)
	CC	2.29 (0.41)	2.23 (0.45)	2.27 (0.44)
Passive	CBT	2.00 (0.56)	1.95 (0.49)	1.96 (0.40)
	CC	2.19 (0.38)	2.18 (0.33)	2.17 (0.36)
Coping with pain				
Active	CBT	2.35 (0.39)	2.27 (0.27)	2.19 (0.37)
	CC	2.31 (0.41)	2.13 (0.40)	2.22 (0.38)
Passive	CBT	2.08 (0.43)	2.04 (0.33)	1.98 (0.34)
	CC	2.01 (0.41)	1.98 (0.45)	1.95 (0.42)
Compliance	CBT	2.67 (0.66)	2.73 (0.52)	2.85 (0.35)
	CC	2.79 (0.49)	2.52 (0.78)	2.59 (0.78)

increased in the CBT condition at follow-up assessment ($t = -3.18$, $P < 0.01$), but not at post-treatment ($t = -1.28$, $P = 0.21$). Perceived support did not significantly change in the control condition ($t = 0.27$, $P = 0.79$ and $t = 1.57$, $P = 0.13$, respectively). No significant time × condition effect was found for the size of the social network ($F(2, 55) = 1.45$, $P = 0.24$).

3.6. Outcome in cognitive-behavioral factors

The general linear models for repeated measurement of the cognitive-behavioral factors of illness cognition, coping with stress or pain, and compliance did not indicate a significant time effect for both conditions (see Table 4). When comparing both conditions, a significant condition × time interaction was found for active coping with stress ($F(2, 55) = 3.85$, $P < 0.05$). Paired t-tests revealed that patients in the CBT condition used significantly more active coping strategies when dealing with stress at post-treatment ($t = -2.88$, $P < 0.01$), but not at follow-up assessment ($t = -1.44$, $P = 0.16$), while active coping with stress did not significantly change in the control condition at both assessment points ($t = 0.80$, $P = 0.43$ and $t = 0.22$, $P = 0.83$, respectively). Moreover, tendencies for condition × time interactions were found for cognitions of helplessness ($F(2, 55) = 2.47$, $P = 0.09$) and compliance with RA medication ($F(2, 55) = 2.51$, $P = 0.09$). Paired t-tests demonstrated that helplessness significantly decreased in the CBT condition at post-treatment and follow-up assessment ($t = 2.98$, $P < 0.01$ and $t = 2.37$, $P < 0.05$, respectively), but not in the control condition ($t = -0.22$, $P = 0.83$; $t = 0.62$, $P = 0.54$). In addition, compliance with RA medication significantly increased in the CBT condition at follow-up assessment ($t = -2.08$, $P < 0.05$), but not at post-treatment ($t = -0.57$, $P = 0.57$), while compliance tended to decrease in the control condition at post-treatment and follow-up assessment ($t = 1.98$, $P = 0.06$; $t = 1.80$, $P = 0.08$, respectively). No significant time × interaction effects were revealed for illness cognitions of acceptance, active and passive coping with pain or passive coping with stress ($F(2, 55) = 1.13$, $P = 0.33$; $F(2, 55) = 2.15$, $P = 0.13$; $F(2, 55) = 0.17$, $P = 0.85$; $F(2, 55) = 0.31$, $P = 0.74$, respectively).

3.7. Effect sizes

Effect sizes of the primary outcome measures with significant effects indicated overall medium effects for the CBT condition at post-treatment and follow-up assessment (Cohen, 1988): effect sizes were 0.55 and 0.48 for fatigue and 0.51 and 0.55 for depression at post-treatment and follow-up assessment, respectively. In addition, small to medium effects were found for negative mood, anxiety and perceived support at post-treatment and follow-up assessment (0.44 and 0.43 for negative mood, 0.57 and 0.28 for anxiety, and 0.16 and 0.38 for perceived support at post-treatment and follow-up assessment, respectively). In contrast, effect sizes on these primary outcomes in the control condition were all negative, except for fatigue and negative mood at post-treatment (0.19 and 0.01, respectively) and anxiety at post-treatment and follow-up assessment (0.26 and 0.27, respectively).

4. Discussion

This trial of customized CBT for patients with relatively early RA indicated that, in addition to the standard care provided by a rheumatologist and a rheumatology consultant, tailor-made treatment offered to individual patients at risk has beneficial effects on primary outcomes of physical, psychological and social functioning, and these effects were generally maintained at follow-up assessment. Specifically, favorable effects on primary outcomes were found for fatigue and depression at post-treatment and follow-up assessment, as well as for perceived support at follow-up assessment. Exploration of secondary outcomes of cognitive-behavioral factors supported additional beneficial effects, including increased active coping with stress at post-treatment, decreased helplessness at post-treatment and follow-up assessment, as well as increased compliance at follow-up assessment in the CBT condition in comparison to the control condition, generally suggesting that offering tailored CBT to RA patients at risk may be a promising way to optimize treatment effectiveness.

Participants in the CBT trial consisted of patients with relatively early RA who had been screened for a psychosocial risk profile. The screening sample was comparable to representative samples of patients with early RA with regard to demographic variables, levels of physical, psychological and social functioning and cognitive-behavioral factors (Meenan et al., 1991; Evers et al., 1997, 1998a, 2002). In accordance with the empirically derived screening criteria (Evers et al., 1997, 1998a, 2001a, 2002; Scharloo et al., 1999), patients at risk were characterized by lower levels of physical, psychological and social functioning and more dysfunctional cognitive-behavioral factors, in comparison to patients not at risk. For patients participating in the CBT trial, results suggest that there was no systematic bias in the selection of patients. Reasons for refusing to take part in the CBT trial were in most cases related to practical concerns, and participants did not differ from non-participants with regard to demographic variables, levels of physical, psychological and social functioning or cognitive-behavioral factors. Finally, dropout rates were generally low for the CBT and the control conditions (6 and 10%, respectively), and statistical analyses of completers and intention-to-treat analyses revealed the same results overall.

Effects found on the primary outcomes of fatigue, depression and perceived support corresponded to the three treatment modules most frequently applied in the CBT condition. Application of treatment modules was based on

patients' priorities, which were highest for the fatigue module, followed by the negative mood, social relationships and pain and functional disability modules. In particular, fatigue has only recently received attention as a frequent problem for RA patients and as a possible focus for psychosocial interventions (Belza, 1995; Huyser et al., 1998; Barlow et al., 2000). In accordance with a nearly significant effect found for fatigue in a recently conducted self-management trial (Barlow et al., 2000), our results indicate that fatigue can be significantly reduced by CBT. In addition, psychological functioning was improved by decreased depression and, as in the case of fatigue, these effects were stable at follow-up. Previous CBT trials with RA patients only incidentally reported beneficial effects on depression or other outcomes of psychological functioning (cf. Bradley et al., 1987; O'Leary et al., 1988; Sharpe et al., 2001). As for social functioning, there is only one study that previously reported beneficial effects of CBT on an indicator of social support at post-treatment (O'Leary et al., 1988), while perceived support in our study increased in the treatment condition at follow-up assessment.

Effect sizes found for these primary outcomes supply preliminary support for the idea that tailor-made treatment for patients with relatively early RA can improve treatment effectiveness. Effect sizes for the primary outcome measures indicated overall medium effects for fatigue and depression at post-treatment and follow-up assessment, as well as small to medium effects for perceived support at follow-up assessment (Cohen, 1988). In contrast, a recently conducted meta-analysis of controlled trials of psychosocial interventions for patients with RA revealed non-significant to small effects for physical and psychological functioning at post-treatment, and non-significant effects at follow-up assessment (Riemsma et al., 2002; see also Hawley, 1995; Riemsma et al., 1999). When exclusively CBT trials or behavioral treatments for RA patients are considered (Hawley, 1995; Riemsma et al., 2002), results are about the same. Although comparisons to other trials must be cautiously interpreted due to differences between studies in type of intervention, control groups, designs, outcome measures and settings, these findings generally suggest that increased effect sizes at post-treatment and follow-up assessment may be an adjunctive value of tailor-made CBT in relatively early RA.

Treatment effectiveness could also be optimized when interventions change dysfunctional cognitive-behavioral factors at an early stage of the disease and possibly prevent a worse long-term disease outcome. Our results indicated beneficial changes at follow-up assessment in disease-related cognitive-behavioral factors, such as reduced helplessness in handling RA and its consequences and increased compliance with RA medication. In addition to previous findings of beneficial effects of CBT on helplessness in longstanding RA (Parker et al., 1995), our results indicate that helplessness can be modified at a relatively early stage of the disease, and effects were maintained at follow-up assessment. Taking into account that the findings for compliance should be regarded as explorative due to the single-item assessment, the effects on compliance may be particularly likely to provide a long-term benefit by reducing the risk of an unfavorable disease process (Radojevic et al., 1992) and decreasing the costs of medical treatment (Lorig et al., 1993).

The beneficial effects of CBT were found as an addition to the standard medical care received from a rheumatologist and a rheumatology consultant. In view of the preliminary findings of beneficial effects of the rheumatology consultant on indicators of physical and psychological functioning (see, Hill et al., 1994) and the fact that consultations with the rheumatology consultant have a variety of aspects in common with CBT, such as providing support and empathy, problem-solving related to the limitations of daily activities (e.g. returning to work, helping in housekeeping, adjustment of home facilities), as well as stimulation of favorable health behaviors (e.g. compliance, activity pacing and exercising), the present trial gives a rather conservative estimate of the contribution of tailored CBT.

A low rate of attrition has been suggested as another proxy outcome variable of treatment effectiveness (Turk and Rudy, 1990b). In contrast with dropout rates of about 45% found in a meta-analysis of psychosocial interventions (see Wierzbicki and Pekarik, 1993), the relatively low 6% dropout rate in the treatment condition indicated high treatment acceptance, possibly due to the use of customized treatment modules applied on the basis of patient priorities. In addition, patients with a psychosocial risk profile are likely to be motivated for CBT and pretreatment screening of patients at risk may have a favorable effect on attrition rates.

Despite its relatively promising results, the present study had several limitations. Most importantly, we did not directly test the hypothesis that tailored CBT for patients at risk at an early stage of the disease may be superior to general CBT treatments for all RA patients, and consequently information is unavailable about the specific treatment characteristics to which the beneficial results of the present study can be ascribed. To directly demonstrate the possible superior efficacy of the present approach, future studies will have to compare the effectiveness of CBT trials for patients screened at risk versus those not at risk, for patients with recent versus longstanding RA, and the application of tailored versus generic or mismatched treatments for RA patients. In addition, treatment effects were limited to specific indicators of physical, psychological and social functioning and cognitive-behavioral factors. Most evidently, the present trial was unsuccessful in altering primary disease outcomes of pain and functional disability. Previous CBT and self-management trials, usually focusing more exclusively on pain management, have occasionally found effects on pain and functional disability at post-treatment, although these effects were in most cases not maintained at follow-up (e.g. Parker et al., 1995; see also

McCracken, 1991; Hawley, 1995; Riemsma et al., 1999, 2002). In the present study, the pain and functional disability module was the least frequently chosen and applied treatment module for only 11 patients, which may be the reason for the lack of effects on these outcomes. A recent RA study also suggests that focusing this treatment module on physiologically mediated changes, such as the use of relaxation and biofeedback in patients with high physiological reactivity to pain, could improve its effects on pain outcomes (Evers et al., 2001b). Moreover, higher expectations of patients in the CBT condition or the greater degree of attention patients in the CBT treatment received might have contributed to the beneficial effects of CBT, requiring expectancy assessments and comparisons with an attention control group in future studies. A selection bias could not be detected in our sample. However, information is unavailable about patients who initially refused to take part in the screening study. To avoid any unmeasured selection bias, the screening procedure should be preferably carried out as part of the standard medical care. Further validation of the empirically derived psychosocial risk profile is also desired, e.g. by comparing questionnaire criteria with standardized interviews for diagnosis of subclinical anxiety and depression. Finally, replication of the effects in larger samples as well as maintenance of treatment effects at longer-term follow-ups, preferably accompanied by cost-effectiveness analyses and use of economic outcome measures – such as health care use, drug intake, and occupational status – is desired to further validate the significance of the findings for application in clinical practice (see e.g. Lorig et al., 1993).

In conclusion, the present study demonstrates that customized treatment for RA patients at risk offered at an relatively early stage of the disease is effective for indicators of physical, psychological and social functioning, and suggests that this approach is a promising way to optimize treatment effectiveness in terms of treatment acceptance and magnitude and maintenance of effects.

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