

# Group Psychotherapy of Dysfunctional Fear of Progression in Patients with Chronic Arthritis or Cancer

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## Key Words

Fear of progression · Group psychotherapy · Randomized controlled trial · Rheumatoid arthritis · Cancer · Chronic disease

## Abstract

**Background:** This study investigated the effectiveness of brief psychotherapeutic group interventions in reducing dysfunctional fear of disease progression (FoP). The interventions comprised either cognitive-behavioral group therapy or supportive-experiential group therapy. We tested whether these generic interventions would prove effective in different illness types. **Methods:** Chronic arthritis in-patients (n = 174) and cancer in-patients (n = 174), respectively, were randomized to receive one of the two interventions. The patients provided data before intervention, at discharge, and at 3 and 12 months of follow-up. FoP was the primary outcome, secondary outcomes were anxiety, depression and quality of life. A treatment-as-usual control group provided data on the primary outcome. **Results:** Patients with chronic arthritis indicated higher levels of FoP than cancer patients. The results revealed that, compared with no specialized intervention, both group therapies were effective in reducing dysfunctional FoP, but only among

cancer patients. The effect sizes were 0.54 (cognitive-behavioral therapy) and 0.50 (supportive experiential therapy). The interventions were not differently effective in reducing the secondary outcomes. **Conclusions:** Dysfunctional FoP can be effectively targeted with brief group interventions. Psychotherapeutic interventions for reducing FoP should focus on specific illness characteristics.

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## Introduction

Research has shown that many medical patients suffer from comorbid mental illness [1–6]. However, some researchers and clinicians pointed out limitations of the psychiatric model in medical illness [7–9]. As a consequence, alternative taxonomies were developed [8, 10, 11]. Fears and concerns of medical patients are, mostly, realistic, although they might be exaggerated beyond the actual threat. As such, they differ from typical psychopathological fears [12]. Many of these fears arise from common adaptive tasks that medical patients are facing [13–15].

In our work, we elaborated on fear of disease progression (FoP). Based on results on recurrence fears [16–18],

**Table 1.** Sociodemographic characteristics across diagnosis (chronic arthritis: n = 258; cancer: n = 265)

	Arthritis	Pa- tients	Cancer	Pa- tients
Mean age ± SD, years	46.7 ± 9.5	258	53.7 ± 10.2	265
Sex		258		265
Female	194 (75.2)		220 (83.0)	
Living with partner		253		262
Yes	204 (80.6)		204 (77.9)	
Educational level		258		263
Elementary school	90 (34.9)		96 (36.5)	
Secondary school/ junior high	81 (31.4)		90 (34.2)	
High school	80 (31.0)		68 (25.9)	
Other	7 (2.7)		9 (3.4)	
Employment status		255		256
Full-time	113 (44.3)		83 (32.4)	
Less than full-time	81 (31.8)		51 (19.9)	
Unemployed	35 (13.7)		10 (3.9)	
Homemaker	6 (2.4)		25 (9.8)	
Retired	3 (1.2)		68 (26.6)	
Other	17 (6.7)		19 (7.4)	
Subjective economic situation		253		260
Very good	10 (4.0)		14 (5.4)	
Good	73 (28.9)		73 (28.1)	
Satisfactory	121 (47.8)		123 (47.3)	
Not very good	30 (11.9)		40 (15.4)	
Poor	19 (7.5)		10 (3.8)	

Figures are numbers of patients with percentages in parentheses unless otherwise indicated. Data may not sum to full sample size due to missing data.

we explored FoP in different illnesses [19]. We define FoP as a reactive, nonneurotic fear patients are fully aware of. It is based on the experience of a chronic, life-threatening or incapacitating illness. High levels of FoP cause suffering and reduce the quality of life (QoL) [7]. Thus, there is need for effective treatments of dysfunctional FoP. Most studies investigating effects of psychotherapeutic interventions with medical patients focused on emotional distress and QoL. Group therapies based on cognitive-behavioral principles predominate and seem to be most effective [20–25]. However, such studies did not address FoP. Stress management interventions typically focus on problem-solving strategies in general or in regard to medical procedures [26–28]. Interventions focusing on existential issues may target fears and concerns [29, 30], but they are not based on the concept of FoP. Furthermore, most investigations focus on a single illness, implicating that unique aspects predominate. However, differ-

ent chronic illnesses share many psychosocial characteristics [13, 14, 31], and the prevalence rates of mental disorders are comparable between different diseases [2, 4]. Although there are also differences in consequences [32–35], the lack of generic interventions is striking [see 36 for an exception].

In this study, we investigated the effects of generic psychotherapeutic interventions on dysfunctional FoP. We assumed that a cognitive-behavioral group therapy (CBT) would be more beneficial in reducing FoP than a client-centered, supportive-experiential group therapy (SET). We examined whether these interventions would show the same effects across different diseases. Finally, we asked whether the 2 group therapies would also lead to a reduction in anxiety and depression and an improvement in QoL, which are the secondary outcomes.

## Methods

### Study Design

This was a multicenter, longitudinal (partially) randomized controlled study. Arthritis patients came from 1 rehabilitation clinic, cancer patients were approached in 2 rehabilitation clinics. The patients were randomized into 2 interventions. The control group received treatment as usual. The study protocol received approval from the local ethics committee. The sample size was determined a priori. We assumed a rather small effect between the 2 different interventions, 80% power and 20% attrition. This resulted in a desired sample size of 164 patients.

### Participants

To be eligible for the study, patients had to be at least 18 years old and had to suffer from dysfunctional FoP, i.e. they had to score above a predefined cutoff (see section ‘Caseness’). Of 548 arthritis patients screened, 252 were eligible; 174 (69.0%) agreed to participate and were randomized. Additionally, 84 patients were sampled into the control group. The sociodemographic and illness-related characteristics are given in tables 1 and 2. The arthritis patients did not differ in sociodemographic characteristics across the 3 groups. However, the proportion of patients who received surgery was lower in the CBT group. Of 457 cancer patients screened, 210 were eligible. Of those, 174 (82.8%) agreed to participate and were randomized. In addition, 91 patients were recruited for the control group (see tables 1 and 2). The only significant difference between the groups was the proportion of patients receiving surgery being lower in the control group.

With regard to the 2 diagnostic groups, the proportion of female patients was lower in the arthritis sample [ $\chi^2(1) = 4.85, p < 0.05$ ]. The arthritis patients were younger [ $t(521) = -8.07, p < 0.001$ ], less often retired [ $\chi^2(5) = 96.56, p < 0.001$ ] and had a longer duration of disease [ $t(190) = 9.31, p < 0.001$ ].

### Treatment Conditions

The patients in the intervention conditions received 4 sessions of group psychotherapy, each lasting 90 min. The CBT interven-

tion was manualized with regard to structure and content, topics and interventions were predefined. The SET intervention was also manualized with regard to structure but less prescriptive regarding the content.

General characteristics of the CBT group were directiveness and specificity, both aiming at confronting patients with their fears and learning to cope with them. The goal was to learn to manage FoP in order not to become overwhelmed by fear in daily life. Specific goals were to strengthen the patients' self-awareness regarding the elicitation and experience of fear, to confront worrying thoughts and to decatastrophize. Educational elements and 'homework assignments' were included.

The SET group intervention was based on a client-centered concept and characterized by nondirectiveness and unspecificity. The main therapeutic goals were emotional expression, mutual support and reassurance, and social comparison. The intervention did not focus on the management of FoP. In each session, the participants decided which topic they would like to discuss. Typically, it was one of the following themes: subjective illness representations and coping with illness, spirituality and life goals, social network and intimate relationships, and autonomy.

Originally, the SET intervention was conceptualized as the control condition. However, to exclude that improvement in FoP was related to overall improvement through the rehabilitation program, a treatment-as-usual control group was sampled.

#### Therapists and Therapist Adherence

The groups were led by psychotherapists who had at least 3 years of clinical experience and/or who had accomplished or were in the final phase of their training. They were trained by 2 of the authors (S.W., G.D.). All sessions were supervised. Meetings were held regularly to ensure treatment integrity, using audiotapes to discuss difficult group situations.

#### Assessment and Measures

The patients from the intervention groups provided data on all measures prior to the initial session (T1), before discharge (T2), as well as 3 months (T3) and 12 months (T4) after discharge. The patients from the control condition only provided data on the primary outcome at T1, T2 and T4.

FoP was assessed with the Fear of Progression Questionnaire (FoP-Q) [19]. It comprises 43 items relating to 5 dimensions: affective reactions, partnership/family, occupation, loss of autonomy and coping with anxiety. We used the total score, i.e. the sum of the subscales' mean scores excluding the coping scale. The internal consistency in the current sample was  $\alpha = 0.91$ . The 12-item short form, FoP-Q-SF, comprises items pertaining to 4 of the 5 dimensions (excluding coping). Cronbach's  $\alpha$  of this unidimensional scale is 0.87 [37]. We used the FoP-Q-SF as screening device in the current study.

Anxiety and depression were assessed with the German version of the Hospital Anxiety and Depression Scale [38]. The internal consistency in the study sample was  $\alpha = 0.81$  for anxiety and  $\alpha = 0.85$  for depression.

We used the German version of the SF-12 to measure health-related QoL (HRQoL) [39]. Two components, physical and mental, are computed with scores ranging from 0 (worst) to 100 (best). The patients reported on their HRQoL during the past 2 weeks.

Life satisfaction was measured with the Questions on Life Satisfaction (FLZ<sup>M</sup>) [40]. This measure contains 2 modules, of which

**Table 2.** Illness-related characteristics across diagnoses (chronic arthritis: n = 258; cancer: n = 265)

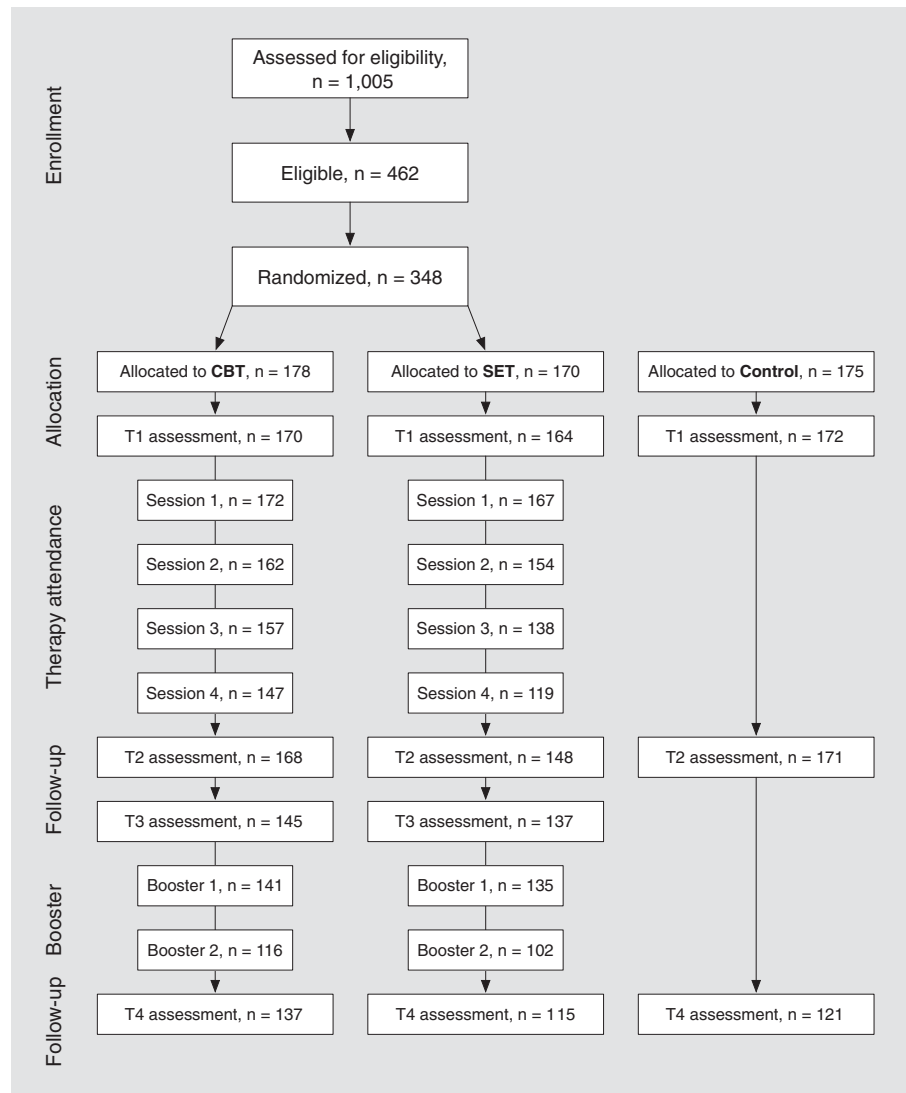
<i>Chronic arthritis</i>	
Mean illness duration $\pm$ SD (n = 172), months	103.3 $\pm$ 115.4
Diagnosis (n = 258) <sup>a</sup>	
Chronic polyarthritis	91 (35.3)
Spondylitis ankylosans	38 (14.7)
Degenerative rheumatic disease	97 (37.6)
Other	99 (38.4)
Affected joints (n = 224)	
1–3	64 (28.6)
4–6	68 (30.4)
7–9	31 (13.8)
>9	61 (27.2)
Other organs affected (n = 243)	71 (29.2)
Treatment: surgery (n = 252)	61 (24.2)
<i>Cancer</i>	
Mean illness duration $\pm$ SD (n = 220), months	19.2 $\pm$ 30.6
Diagnosis (n = 263)	
Breast cancer	155 (58.9)
Colon cancer	21 (8.0)
Bladder/prostate cancer	25 (9.5)
Gynecological cancer	24 (9.1)
Other	38 (14.4)
Treatment (n = 263) <sup>a</sup>	
Surgery	242 (92.4)
Radiotherapy	155 (59.2)
Chemotherapy	167 (63.7)
Disease status (n = 236)	
No activity	185 (78.4)
Recurrence	20 (8.5)
Metastases	31 (13.1)

Figures are numbers of patients with percentages in parentheses unless otherwise indicated. Data may not sum to full sample size due to missing data. <sup>a</sup> Multiple responses.

only 'general life satisfaction' (LS) was used. The participants rated their LS during the past 4 weeks, with increasing scores indicating higher LS. The reliability of the LS module in this sample was  $\alpha = 0.70$ .

#### Caseness

The cutoff for dysfunctional FoP was derived in an investigation conducted before this study, with 130 arthritis and 150 cancer in-patients. These patients filled in the FoP-Q-SF and indicated whether they felt in need of treatment for FoP. We followed the conventional strategy of using the median score. Next, we stratified the sample according to their self-reported treatment need. Thirty-eight percent of the arthritis patients and 36% of the cancer patients scored above the median and felt in need of treatment. About 10% in both groups scored above the median and did not express a need for treatment, and about 30% scored below the median but expressed treatment need. These results qualified the median as a pragmatic cutoff. The consequence of this approach



**Fig. 1.** Flow of the participants through the study.

was the use of different median scores. Thus, the cutoff scores (median, Md) for this intervention study were Md = 38 for the arthritis patients and Md = 34 for the cancer patients.

#### Procedure

From August 2002 until December 2003, each patient admitted to 1 of the 3 participating rehabilitation clinics was invited to take part in an information session. The patients were asked to fill in the FoP-Q-SF. Those who scored above the cutoff and were willing to participate provided informed consent and were randomized. The patients received a code, which was sent for external randomization, using random numbers. Randomization was stratified by diagnosis, and the patients were blind with regard to group assignment. No patient changed the assigned group. The patients from the intervention groups received booster phone calls 6 and 9 months after discharge. The control group was sampled in the same clinics 1 year after the completion of the inter-

ventions using the same eligibility criteria. The patients' flow through the study is detailed in figure 1.

#### Statistical Analyses

We used an intention-to-treat approach and included all patients who provided baseline scores. Missing data were imputed (SPSS expectation maximization algorithm). Longitudinal changes in FoP were investigated with a repeated-measures ANOVA. We adopted a 3 (group: CBT, SET, control)  $\times$  3 (time: T1, T2, T4)  $\times$  2 (diagnosis: arthritis vs. cancer) approach with time as repeated measure. As the patients from the control group did not provide data on secondary outcomes, we performed a 2 (group)  $\times$  4 (T1, T2, T3, T4)  $\times$  2 (diagnosis) repeated-measures ANOVA. We computed effect sizes for the change between pretherapy assessment and 12-month outcomes using the pooled variance of the complete sample.

**Table 3.** ANOVA results for main effects and interaction effects of intervention, time and diagnosis on FoP total score (intention-to-treat analysis, missing data imputed, n = 506)

	d.f.	MS	F	p
Main effect intervention (int.)	2,500	45.57	2.86	0.058
Main effect time (t)	2,1000	122.46	74.24	<0.001
Main effect diagnosis (diag.)	1,500	626.36	39.26	<0.001
Int. × t	4,1000	2.24	1.36	0.246
Int. × diag.	2,500	23.22	1.46	0.234
t × diag.	2,1000	1.00	0.61	0.546
Int. × t × diag.	4,1000	7.97	4.83	0.001

MS = Mean squares.

## Results

### Preliminary Analysis

At baseline, the 2 intervention groups and the control group did not differ in the primary outcome, and the intervention groups did not differ in the secondary outcomes, in either one diagnostic group (data not shown). Next, we studied differences between the complete arthritis and cancer samples. Patients with chronic arthritis had higher FoP scores [ $M = 12.7$ ,  $SD = 2.5$  vs.  $M = 11.4$ ,  $SD = 2.5$ ;  $t(504) = 5.92$ ,  $p < 0.001$ ], and they expressed lower physical HRQoL [ $M = 35.3$ ,  $SD = 8.2$  vs.  $M = 39.0$ ,  $SD = 8.3$ ;  $t(326) = 4.10$ ,  $p < 0.001$ ] at baseline.

Attrition analysis revealed few significant results. In the arthritis group, not living with a partner [ $\chi^2(1) = 4.18$ ,  $p < 0.05$ ] and educational level [ $\chi^2(3) = 8.11$ ,  $p < 0.05$ ], i.e. less than high school, were associated with dropout. Furthermore, the study group affected attrition [ $\chi^2(2) = 9.11$ ,  $p < 0.05$ ]. Fewer patients from the CBT group than from the SET group and the control condition dropped out of the study. In the sample of cancer patients, those being older [ $t(263) = 2.67$ ,  $p < 0.01$ ] and being retired [ $\chi^2(5) = 14.90$ ,  $p < 0.05$ ] were more likely to withdraw. In addition, experiencing recurrence [ $\chi^2(2) = 8.20$ ,  $p < 0.05$ ] and lower physical HRQoL [ $t(160) = 2.21$ ,  $p < 0.05$ ] were associated with dropping out of the study.

### Longitudinal Analysis

The analysis revealed 2 significant main effects and a significant 3-way interaction with regard to the primary outcome (table 3). The results showed that FoP decreased over time and that diagnosis had an influence on FoP. These main effects should be interpreted in light of the interaction between group, time and diagnosis. Thus,

both interventions were associated with a decrease in FoP over time, but only among cancer patients. The 2 interventions did not differ in reducing FoP. Descriptive data and effect sizes are presented in table 4.

The analyses showed an effect for time for all secondary outcome variables (see table 4 for descriptive data). There was a main effect for illness group regarding depressive symptoms, physical HRQoL and LS. Specifically, cancer patients had lower depression scores and showed better physical HRQoL and higher LS (data not shown). A significant interaction between time and illness group emerged for anxiety [ $F(3,1017) = 4.47$ ,  $p < 0.01$ ], depression [ $F(3,1017) = 3.26$ ,  $p < 0.05$ ] and the mental component of HRQoL [ $F(3,1017) = 4.31$ ,  $p < 0.01$ ], indicating an improvement in cancer patients. There was no effect of the intervention type on any of the secondary outcomes.<sup>1</sup>

### Ancillary Analysis

In a post hoc analysis, we investigated differences in therapy characteristics between the groups. More cancer patients (92.8%) than arthritis patients (62.7%) attended all 4 group sessions [ $\chi^2(4) = 40.46$ ,  $p < 0.001$ ]. Full therapy attendance was higher in the CBT group (82.7%) than in the SET group (69.8%) [ $\chi^2(4) = 11.25$ ,  $p < 0.05$ ]. The combined analysis revealed that only among arthritis patients full attendance differed between the therapy groups (CBT: 72.6%; SET: 52.4%) [ $\chi^2(4) = 16.36$ ,  $p < 0.01$ ]. In the arthritis sample, no group consisted of less than 8 participants, while most cancer patients took part in groups of 3–8 attendants [ $\chi^2(7) = 238.42$ ,  $p < 0.001$ ]. For cancer patients, participating in groups with 8–10 attendants was more frequent in the CBT group than in the SET group (46.2 vs. 31.3%) [ $\chi^2(7) = 41.76$ ,  $p < 0.001$ ]. Diagnosis did not affect participation in the booster sessions [ $\chi^2(1) = 0.08$ , NS]. An ANCOVA with number of sessions attended and group size as covariates did not provide evidence for a different pattern of results (data not shown).

## Discussion

This study has shown that compared to a treatment-as-usual control group, CBT and SET group interventions were effective in reducing dysfunctional FoP, but

<sup>1</sup> A completer analysis, based on the data of patients who participated in all assessments, revealed identical results regarding both primary and secondary outcomes.

**Table 4.** Means  $\pm$  standard deviations and effect sizes (ES) for the primary outcome (FoP-Q) and the secondary outcome parameters anxiety (HADS-A), depression (HADS-D), health-related quality of life (SF-12 physical PCS, SF-12 mental MCS) and general satisfaction with life (FLZ<sup>M</sup>) (intention-to-treat analysis, missing data imputed)

		T1	T2	T3	T4	ES
<i>FoP-Q</i>						
Arthritis	CBT	12.4 $\pm$ 2.6	11.7 $\pm$ 2.6	11.6 $\pm$ 2.7	11.4 $\pm$ 2.8	0.40
	SET	12.5 $\pm$ 2.5	11.8 $\pm$ 2.7	11.8 $\pm$ 2.9	11.8 $\pm$ 2.7	0.28
	control	13.2 $\pm$ 2.2	12.5 $\pm$ 2.5	NA	12.0 $\pm$ 2.6	0.47
Cancer	CBT	11.7 $\pm$ 2.6	11.2 $\pm$ 2.7	10.8 $\pm$ 2.9	10.3 $\pm$ 2.5	0.54
	SET	11.1 $\pm$ 2.7	10.4 $\pm$ 2.7	10.2 $\pm$ 2.5	9.9 $\pm$ 2.3	0.50
	control	11.4 $\pm$ 2.3	10.8 $\pm$ 2.1	NA	11.1 $\pm$ 2.4	0.14
<i>HADS-A</i>						
Arthritis	CBT	9.4 $\pm$ 4.0	8.2 $\pm$ 4.4	9.1 $\pm$ 4.3	8.6 $\pm$ 4.2	0.21
	SET	9.3 $\pm$ 3.6	8.0 $\pm$ 4.3	8.8 $\pm$ 3.9	8.8 $\pm$ 4.0	0.13
Cancer	CBT	9.3 $\pm$ 4.0	8.4 $\pm$ 3.9	8.3 $\pm$ 4.0	7.9 $\pm$ 3.8	0.36
	SET	9.8 $\pm$ 3.9	8.3 $\pm$ 3.9	8.4 $\pm$ 3.9	8.3 $\pm$ 3.6	0.39
<i>HADS-D</i>						
Arthritis	CBT	7.4 $\pm$ 4.3	6.3 $\pm$ 4.1	7.2 $\pm$ 4.3	7.0 $\pm$ 4.5	0.10
	SET	7.4 $\pm$ 3.7	6.3 $\pm$ 3.8	7.5 $\pm$ 4.1	7.5 $\pm$ 4.0	-0.03
Cancer	CBT	7.0 $\pm$ 3.9	5.6 $\pm$ 3.7	6.0 $\pm$ 4.3	5.7 $\pm$ 4.0	0.33
	SET	6.7 $\pm$ 3.9	5.9 $\pm$ 3.9	6.2 $\pm$ 4.0	6.0 $\pm$ 3.1	0.18
<i>SF-12 PCS</i>						
Arthritis	CBT	34.7 $\pm$ 8.3	36.7 $\pm$ 9.1	38.1 $\pm$ 9.4	38.6 $\pm$ 9.8	0.48
	SET	35.8 $\pm$ 7.9	36.4 $\pm$ 8.8	35.5 $\pm$ 8.3	36.3 $\pm$ 7.5	0.06
Cancer	CBT	39.2 $\pm$ 8.2	40.3 $\pm$ 8.4	42.3 $\pm$ 9.8	42.2 $\pm$ 9.4	0.37
	SET	38.6 $\pm$ 8.1	39.9 $\pm$ 8.6	42.3 $\pm$ 8.1	41.0 $\pm$ 9.1	0.30
<i>SF-12 MCS</i>						
Arthritis	CBT	39.8 $\pm$ 10.9	41.4 $\pm$ 10.3	41.4 $\pm$ 10.5	41.6 $\pm$ 9.4	0.19
	SET	38.5 $\pm$ 9.3	41.1 $\pm$ 10.3	41.1 $\pm$ 10.2	40.2 $\pm$ 9.3	0.18
Cancer	CBT	38.3 $\pm$ 8.6	40.9 $\pm$ 9.5	42.2 $\pm$ 10.3	42.7 $\pm$ 10.2	0.47
	SET	37.5 $\pm$ 8.5	40.8 $\pm$ 10.0	42.0 $\pm$ 10.3	43.0 $\pm$ 9.2	0.59
<i>FLZ<sup>M</sup></i>						
Arthritis	CBT	37.3 $\pm$ 32.6	41.4 $\pm$ 35.7	33.7 $\pm$ 35.0	34.5 $\pm$ 33.1	-0.09
	SET	39.6 $\pm$ 34.6	46.8 $\pm$ 35.5	37.7 $\pm$ 33.7	37.7 $\pm$ 31.1	-0.06
Cancer	CBT	44.7 $\pm$ 31.8	49.0 $\pm$ 29.6	48.2 $\pm$ 31.8	46.1 $\pm$ 25.9	0.04
	SET	43.7 $\pm$ 28.6	50.8 $\pm$ 30.1	42.4 $\pm$ 27.5	44.4 $\pm$ 26.4	0.02

Sample size primary outcome: arthritis: CBT = 86, SET = 85, control group = 82; cancer: CBT = 84, SET = 79, control group = 90; sample size secondary outcomes: arthritis: CBT = 86, SET = 86; cancer: CBT = 89, SET = 82; controls did not provide data on primary outcome at T3, thus T3 was not included in the statistical analysis of the primary outcome. NA = Not applicable; HADS = Hospital Anxiety and Depression Scale.

only among cancer patients. The results confirm the effectiveness of CBT group interventions in cancer [22–24]. There is mixed support for the effectiveness of supportive-expressive or experiential group therapy in chronic diseases [41–45], but in our study this approach was effective in reducing FoP in cancer patients. During in-patient stay, there was also a reduction in FoP for the control group of cancer patients, which can be understood as part of a general improvement. However, only cancer patients

who had the opportunity to work on FoP during the in-patient stay continued to improve after discharge, while patients from the control condition deteriorated. This result underlines that, at least among cancer patients, FoP is a specific psychological burden in need of treatment.

Contrary to our hypothesis, the interventions did not reduce dysfunctional FoP in patients with chronic arthritis. Several intervention studies have produced weak results [43, 46, 47], although there is also some evidence for

positive effects, e.g. regarding health care utilization [48]. Kraaimaat et al. [46] argue that the ineffectiveness might be due to the progressive nature of chronic arthritis, allowing only small behavioral changes [see also 49–51]. Furthermore, it is possible that disease characteristics played a significant role in the differential effectiveness of our approach. Though many illnesses share common adaptive tasks, it seems that with regard to chronic arthritis and cancer the differences in disease characteristics override the relevance of common psychosocial features.

Some limitations of our study should be mentioned. The interpretation of the results is limited by the fact that we were not able to realize full randomization. However, all efforts were made to ensure that the control group was not object to systematic bias. Our protocol did not result in differences between the control group and the inter-

vention groups in the selected variables. Clearly, there is no guarantee against unmeasured confounding variables or underlying bias, e.g. cohort effects. Actually, cohort effects seem unlikely as the control group was sampled using the same criteria in the same settings. Furthermore, admission to rehabilitation care is beyond the investigator's control. Another point to consider is the predominance of specific diagnoses, especially in the cancer group. This might restrict the generalizability of our findings.

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