ORIGINAL ARTICLE

Naturalistic study on the effectiveness of psycho-oncological interventions in cancer patients and their partners

J. Barth · S. Delfino · A. Künzler

Abstract

Background There is evidence for the efficacy of psycho-oncological interventions (POI) in randomized controlled trials for cancer patients. Our objective was to explore, under naturalistic conditions (using propensity score matching), whether POI are effective to decrease anxiety, depression, distress and overall psychopathological symptoms within cancer patients and their partners.

Methods This study was conducted in the Oncology and Hematology Center of a University clinic in Switzerland with a group of 186 patients and 117 partners. Outcome measures of mental health were the Hospital Anxiety and Depression Scale and the Symptom Checklist (SCL-9-K). Repeated-measures ANOVAs were used to analyze change over time and group effects between individuals with POI vs. without POI.

Results Highly distressed patients and their partners participating in POI reported better mental health over time. Among moderately distressed patients, a decrease over time emerged in depression and distress independent of POI. No effectiveness of POI could be demonstrated in moderately distressed patients and partners.

Conclusion Most of the highly distressed patients receive additional POI and therefore conclusions about the efficacy of POI are difficult. For moderately distressed individuals, POI as implemented in Switzerland does not improve mental health in such patients and their partners, which may be caused by very time limited POI treatments. Studies with more intense POI treatments are needed.

Keywords Anxiety · Cancer · Depression · Effectiveness · Psycho-oncological interventions · Propensity score

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Introduction

Over the past two decades, numerous psycho-oncological interventions (POI) have been developed to support patients and partners in coping with cancer [1–6]. Psycho-oncological interventions comprise a range of options, from single consultations, psycho-education, and supportive interventions to individualized psychotherapeutic treatments for specific problem areas. Important target areas of POI are anxiety, depression, and overall distress, as well as illness-related quality of life. Meta-analyses on the efficacy of POI have consistently shown moderate effects on anxiety ($d=0.42$), depression ($d=0.36$), distress ($d=0.31$) and quality of life ($d=0.31$) [7, 8]. Larger effect sizes were reported in studies with a longer duration of POI (i.e., more than seven sessions) [7].

To gain clear conclusions about the efficacy of psychological interventions, randomized controlled trials (RCT) are regarded as the gold standard of outcome research [9]. The general purpose of this research design is to ensure internal validity, so that unbiased causal effects of specific treatments can be deduced. However, some authors have raised concerns about the external validity of RCT [10]. RCT select participants according to eligibility criteria, which raises concerns that participants differ from nonparticipants [11, 12] and generalization of the findings would therefore be limited. Moreover, RCTs create artificial treatment conditions [13], because in clinical routine the therapy duration is more flexible and treatment strategies are corrected in

case of lack of improvement. In addition, patients make decisions in favor of or against specific psychological interventions [14] depending on their own preferences and personal needs. For the evaluation of the effectiveness of POI a pre–post design might give only insufficient evidence, self-selected control conditions might be prone to biased results, and RCTs have problems regarding generalizability. A method through which to take these aspects into account and increase internal validity without neglecting external validity in non-randomized studies is the application of propensity score matching [15], which guided us in this study. A propensity score is a balancing score [16] between two groups of patients, in our case patients with POI vs. patients without POI. Baseline characteristics of patients are used to generate the propensity score which reflects the probability to receive POI given a specific baseline characteristic. Propensity score matching takes these aspects into account and increases internal validity without neglecting external validity in non-randomized studies. In a different approach, baseline characteristics can also be used in multivariable models, but the number of characteristics included in the model is limited due to the low statistical power of most studies. A disadvantage of all matching procedures is the restriction of the dataset to patients with a successful matching partner in the other treatment condition which limits generalizability. However, internal validity increases with propensity score matching and causal conclusions can be drawn more appropriately.

The purpose of this study was to explore, under naturalistic conditions, the effects of POI on anxiety, depression, distress and general psychopathological symptoms. The effects of POI were studied separately in highly and moderately distressed cancer patients and their partners.

Methods

Design and procedure

Participating patients and their partners were recruited at an interdisciplinary University hospital in Switzerland between 2004 and 2007 for a larger study examining the mental health of patients with cancer, psycho-oncological treatments, and long-term coping after being diagnosed with cancer [17]. The study was approved by the regional ethics committee and participants gave informed consent before data acquisition. For the present study, a cohort of patients and their partners were recruited to explore the effects of POI. Patients and partners were referred to the psycho-oncological service by the hospital physicians. This referral was based on a clinical decision by the responsible physician and was not done randomly. The physician's impression that the patient or the partner might benefit from POI guided referral.

The first assessment took place within 4 weeks after diagnosis (T1), the second after 6 months (T2), and the third after 12 months (T3) after initial assessment. All cancer patients ($N=186$) and their partners ($N=117$) with available baseline data (T1) on anxiety, depression, distress, and general psychopathology were included in the present study. Patients without sufficient knowledge of the German language or with a lack of physical capacity to complete the questionnaire were excluded. Furthermore, patients who died during the follow-up period of 12 months ($n=25$) and their respective partners were not considered in this analysis.

Participants

The response rate for patients during follow-up was 77.4 % ($n=144$) after 6 months and 69.4 % ($n=129$) after 12 months. Of the 117 partners, 72 % ($n=85$) returned completed questionnaires for the second assessment and 60.6 % ($n=71$) for the third assessment. Non-responding patients were more often male ($\chi^2=3.79$, $p=0.05$). Correspondingly, non-responding partners were more often female ($\chi^2=11.86$, $p=0.001$). In both groups, responders had a higher education level than non-responders (patients: Mann–Whitney U test $U=2,947$, $p=0.05$; partners: Mann–Whitney U test $U=1,888$, $p=0.02$).

Psycho-oncological treatment

Patients were treated in a Center for Oncology and Hematology which is part of a University clinic in Switzerland. Oncological care, as well as POI, was delivered primarily to outpatients. In some cases, however, hospitalization (for medical reasons) was necessary. In such cases, POI consultations were delivered in the patient's room.

Patients and their partners were referred to POI according to their oncologist/hematologist's clinical evaluation and recommendation. The psycho-oncology unit consisted of four experienced psycho-oncologists (two male, two female) with heterogeneous psychotherapy training (i.e., psychodynamic, humanistic, systemic, body-oriented). Session format (individual/couple/family) was decided mutually between patient and psycho-oncologist in accordance with patients' and partners' needs. The POI was delivered in a non-standardized way (i.e., neither length nor content was pre-specified); however, common intervention strategies were: psycho-education about psychological responses to cancer; cognitive-restructuring, emotion-regulation and behavior-control techniques (working with dysfunctional cognitions, self-instruction, guided imagery, relaxation), resource activation, training couple communication skills, increased meaning-making, and death and grief counseling.

Outcome measures

Anxiety, depression, and distress

The German version of the Hospital Anxiety and Depression Scale (HADS) [17] was used to assess the extent of anxiety, depression and overall distress. The 14-item HADS was specifically developed for use with physically ill patients. It consists of two subscales of seven items, each of which is rated on a four-point Likert scale, resulting in a score ranging from 0 to 21 on the anxiety and depression subscales. Overall distress is determined by adding the scores of the two subscales and thus ranged from 0 to 42. Sound psychometric properties of the HADS have been established [18, 19]; for our sample, the internal consistencies were 0.84 (patients) and 0.85 (partners) for anxiety, 0.80 (patients) and 0.83 (partners) for depression, and 0.89 (patients) and 0.91 (partners) for distress.

General psychopathology

To assess general psychopathology, a validated German short-form [20] of the Symptom Checklist SCL-90-R [21] was applied. The SCL-9-K is a nine-item questionnaire that assesses nine symptom dimensions (anxiety, depression, hostility, interpersonal sensitivity, obsessive–compulsiveness, paranoid ideation, phobic anxiety, psychoticism, somatization) and an overall psychopathology index, the Global Severity Index (GSI). All items can be evaluated on a five-point scale: (0) not at all, (1) a little bit, (2) moderately, (3) quite a bit, (4) extremely. The GSI represents the mean score of all items (range from 0 to 4, with higher scores indicating severe general psychopathology). Internal consistencies of the GSI in our study were 0.85 for patients and 0.88 for partners.

Medical and sociodemographic information

Oncologists provided diagnostic data, including cancer type and stage [22], and classification of curative vs. palliative care. Additionally, cancer localizations were classified in major categories [23]. Sociodemographic information includes age, gender, education, revenue, and relationship status were based on participants' self-reports.

Statistical analyses

Since POI were delivered based on clinical referral, matching of patients with or without POI according to their baseline characteristics was used to estimate treatment efficacy independent of patient characteristics. In a first step, propensity scores [16] 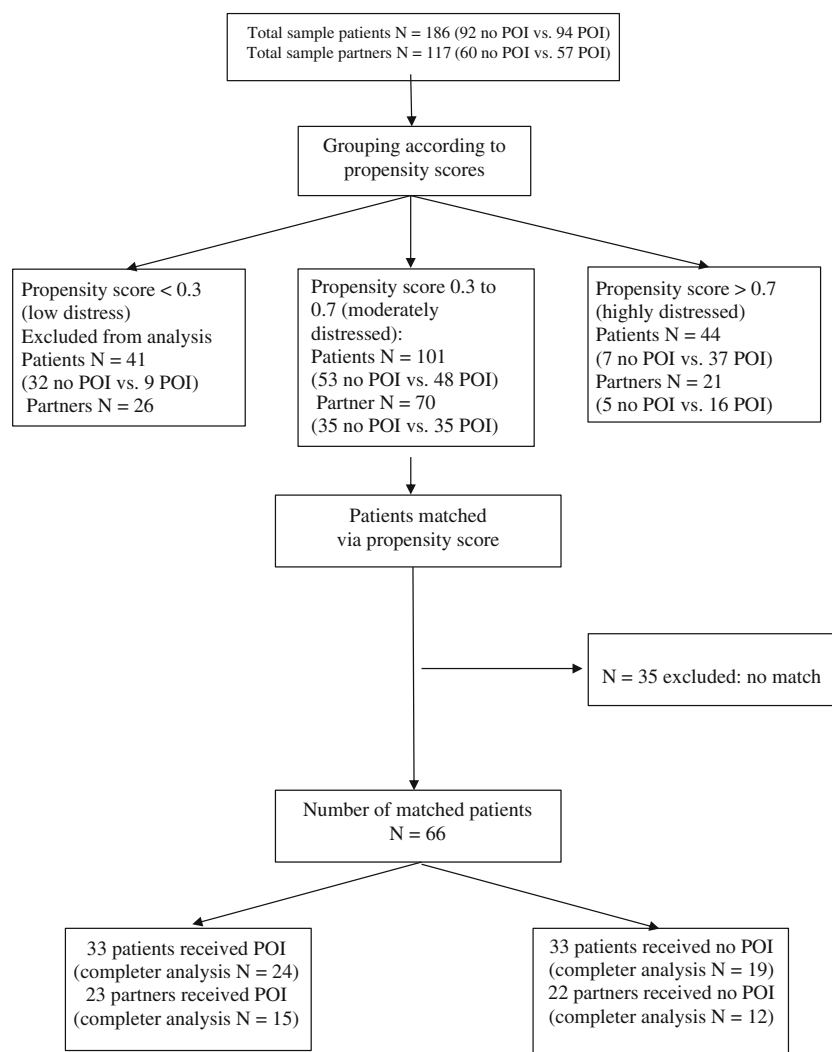were calculated; in a second step, a nearest neighbor matching according to propensity scores was used. Propensity scores ranged from 0 to 1 for each patient and their respective partner and were determined by multivariable logistic regression. A total of nine variables were used as predictors: gender, age, cancer site, stage of disease, cancer treatment approach (curative vs. palliative), social support, mental health-related quality of life, anxiety and depression. The use of POI was included as a dichotomous outcome variable. Patients and partners with a propensity score over 0.70 can be labeled as highly distressed, since mental distress and somatic health status was worse. Equivalently, we labeled patients with a propensity score of 0.30 to 0.70 as moderately distressed (see Fig. 1) and patients with a propensity score of 0.30 and below as suffering from only low levels of distress.

We found that 86 and 79.2 % of highly distressed patients and partners received POI. Therefore, treatment effects on the four outcome measures were analyzed only for persons having received POI. For moderately distressed patients (PS 0.30 to 0.70), we found that 50 % received POI. Differences of baseline characteristics according to POI use were determined by Chi-square test, Mann–Whitney U test or t test depending on the variables scale level.

For moderately distressed patients, an additional matching procedure was used to create a subsample of patients receiving POI and a subsample without this intervention. For the one-to-one matching procedure, the nearest neighbor caliper matching algorithm with a width of 0.05 was used to find the closest control patient (without POI) for each patient with POI. A total of 35 patients were not matched at this step. Effectiveness of the POI was studied by repeated analyses of variance with the factors time and group (POI or not).

For both highly and moderately distressed patients, the effect size of changes between baseline and 1 year following were calculated using Cohen's d. The confidence intervals of effect sizes were determined by the empirical correlation between pre-scores and post-scores on the outcome measures (intraclass correlations in our sample ranges between $r=0.54$ and $r=0.85$).

To account for missing information at follow-up, both completer analyses and intent to treat analysis (ITT) were conducted in sensitivity analyses. For the intent to treat analysis we used two different procedures, namely the last observation carried forward procedure and a multiple imputation algorithm to fill in missing anxiety, depression, distress, and psychopathological values. Patients dropping out during the follow-up period were more often males and had lower education levels ($p=0.05$). Drop-outs and patients with complete data did not differ on any other characteristic. Analyses were performed with SPSS 18 for Windows, and STATA psmatch2 was used for the propensity score-matching procedure.

Fig. 1 Flowchart


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┌─────────────────────────────────────────────┐
│ Total sample patients N = 186 (92 no POI vs. 94 POI) │
│ Total sample partners N = 117 (60 no POI vs. 57 POI) │
└─────────────────────────────────────────────┘
              │
┌──────────────────────────┐
│ Grouping according to     │
│ propensity scores         │
└──────────────────────────┘
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Propensity score < 0.3
(low distress)
Excluded from analysis
Patients N = 41
(32 no POI vs. 9 POI)
Partners N = 26

Propensity score 0.3 to
0.7 (moderately
distressed):
Patients N = 101
(53 no POI vs. 48 POI)
Partner N = 70
(35 no POI vs. 35 POI)

Propensity score > 0.7
(highly distressed)
Patients N = 44
(7 no POI vs. 37 POI)
Partners N = 21
(5 no POI vs. 16 POI)

Patients matched
via propensity score

N = 35 excluded: no match

Number of matched patients
N = 66

33 patients received POI
(completer analysis N = 24)
23 partners received POI
(completer analysis N = 15)

33 patients received no POI
(completer analysis N = 19)
22 partners received no POI
(completer analysis N = 12)

Results

Sample description

For *highly distressed* patients and partners, the patients' sample consisted of 56.8 % men and 43.2 % women. The average age for highly distressed patients was 50 years (SD= 13.21). Established cutoff criteria of HADS-A and HADS-D scores of 8 or over (moderate level) or a higher threshold of 11 or over (high level) were used to provide a clinical interpretation of anxiety and depression scores. About a quarter of highly distressed patients were depressed (23.1 % moderate level; 12.4 % high level) and anxious (21 % moderate level; 11.3 % high level) to a moderate extent. Highly distressed partners were even more often depressed (56.2 % moderate level; 25 % high level) and anxious (50 % moderate level; 18.7 % high level). Among highly distressed patients, 27 % had hematological cancer, 21.9 % lung cancer, 18.9 % breast cancer, and 16.2 % gastrointestinal cancer; 16.2 % had cancer in other sites. Most of the highly distressed cancer patients

(56.8 %) and 62.5 % of their participating partners faced stage IV cancer. Of all highly distressed patients, 54.1 % received curative and 45.9 % palliative medical care. Among highly distressed partners, curative or palliative treatment was delivered to the patients in a 50/50 split.

The *moderately distressed* subsample consisted of 66 patients (53 % male), 45 of whom had a partner (62.2 % female). Moderately distressed patients and partners were on average 56 years of age (SD=13.6) and 69.4 % had an apprenticeship degree. Predominant cancer sites were gastrointestinal (28.8 %), hematological (27.3 %), lung (16.7 %), and breast (15.2 %). Of moderately distressed patients, 12 % had stage I (early) disease, 22.7 % stage II, 33.3 % stage III, and 31.8 % stage IV (advanced). Concerning the medical treatment goal, 59.1 % of moderately distressed patients received curative and 40.9 % palliative care. Details of the moderately distressed sample are given in Table 1.

The *low distressed patients* numbered 41 (53 % male), 26 of whom had a partner. These patients were on average

Table 1 Baseline characteristics of moderately distressed patients and partners according to perceived psycho-oncological intervention

	Patients			Partners		
	Control [n^a (%)]	Treatment [n^b (%)]	p	Control [n^c (%)]	Treatment [n^d (%)]	p
Gender			0.49[e]			0.78[e]
Female	18 (54.5)	13 (39.4)		11 (50.0)	17 (73.9)	
Male	15 (45.5)	20 (60.6)		11 (50.0)	6 (26.1)	
Age (years, SD)	57.8 (14.2)	56.5 (13.7)	0.72[f]	56.0 (14.4)	55.6 (12.3)	0.92[f]
Education[g]			0.07[h]			0.59[h]
No graduation	2 (6.1)	4 (12.1)		2 (9.1)	5 (21.7)	
Apprenticeship	21 (63.6)					
University	8 (24.2)	3 (9.1)		0 (0.0)	0 (0)	
Revenue[g]			0.74[e]			0.21[e]
Low < 40,000 Fr	8 (24.2)	8 (24.2)		4 (18.2)	5 (21.7)	
High ≥ 40,000 Fr	23 (69.7)	24 (72.8)		18 (81.8)	18 (78.3)	
Cancer site			0.66[e]			0.76[e]
Head and neck	2 (6.1)	3 (9.1)		1 (4.5)	2 (8.7)	
Gastrointestinal	9 (27.3)	10 (30.3)		6 (27.3)	9 (39.1)	
Breast	7 (21.2)	3 (9.1)		4 (18.2)	2 (8.7)	
Lung	6 (18.2)	5 (15.2)		3 (13.6)	3 (13.0)	
Genital (male)	0 (0.0)	1 (3.0)		0 (0.0)	1 (4.3)	
Hematological	8 (24.2)	10 (30.3)		7 (31.8)	5 (21.7)	
Other	1 (1.3)	2 (6.0)		1 (4.5)	1 (4.3)	
Stage of cancer			0.78[h]			0.68[h]
Stage 1	4 (12.1)	4 (12.1)		2 (9.1)	2 (8.7)	
Stage 2	7 (21.2)	8 (24.2)		4 (18.2)	5 (21.7)	
Stage 3	11 (33.3)	11 (33.3)		10 (45.5)	7 (30.4)	
Stage 4	11 (33.3)	10 (30.3)		6 (27.3)	9 (39.1)	
Cancer treatment			0.47[e]			0.80[e]
Curative	19 (57.6)	20 (60.6)		13 (59.1)	14 (60.9)	
Palliative	14 (42.4)	13 (39.4)		9 (40.9)	9 (39.1)	

CG control group; *TG* treatment group

[a] Total *n* patients = 33

[b] Total *n* patients = 33

[c] Total *n* partners = 22

[d] Total *n* partners = 23

[e] Chi-square test

[f] *T* test

[g] Due to missing data, percentages do not add up to 100

[h] Mann–Whitney *U* test

65.2 years of age (SD=11.5) and 87 % had an apprenticeship degree. Of these patients, 37 % had stage I (early) disease, 53.7 % stage II, 2.4 % stage III, and 7.3 % stage IV (advanced). The cancer sites most often present were breast (39 %), prostate (24.4 %), and ovarian (20 %). The medical treatment aimed at curative (87.8 %) and palliative care (12.2 %).

Dose of psycho-oncological interventions

Of highly distressed patients, 86 % received POI, which started on average 3 weeks after initial cancer diagnosis (range=1 to 10 weeks). A total of 32 % of the highly distressed patients received one session, 37.8 % two to four sessions and 29.7 % five or more sessions. Mean POI intensity for highly distressed patients was 6.62 sessions (SD=10.51; range = 1 to 54 sessions). In all, 76 % of highly distressed partners received POI, starting on average 7 weeks after their partner's initial cancer diagnosis (range = 1 to 28 weeks). Of

highly distressed partners, 12.5 % received one session, 37.5 % two to four sessions and 50 % five or more sessions. Mean treatment intensity for highly distressed partners was 10.56 sessions (SD=13.73; range 1 to 54 sessions).

Among moderately distressed patients 50 % received POI, which began about 11 weeks after initial cancer diagnosis (range=1 to 36 weeks). A total of 30.3 % of the moderately distressed patients received one session, 36.4 % received two to four sessions and 30.3 % received five or more sessions. The mean POI for moderately distressed patients was 4.66 sessions (SD=5.91; range=1 to 26 sessions). A total of 51 % of moderately distressed partners received POI, which began around 13 weeks after their partner's initial cancer diagnosis (range=1 to 36 weeks). Among moderately distressed partners 26.1 % received one session, 30.4 % received two to four sessions and 39.1 % received five or more sessions. The mean treatment intensity for moderately distressed partners was 4.86 sessions (SD=5.10; range=1 to 17 sessions).

Psycho-oncological treatment effects for highly distressed patients and partners

Highly distressed patients showed a significant decrease in psychological distress over time. Anxiety, depression, distress, and psychopathology (all $p<0.05$) were reduced after the psycho-oncological treatment (see Table 2). The highest treatment effect was detected for depression ($d=0.52$) and the lowest for psychopathology ($d=0.30$). Within highly distressed partners, a decrease in all outcomes was found, although only anxiety ($p=0.01$) and distress ($p=0.02$) reached the level of statistical significance. The largest intervention effect was observed for anxiety ($d=0.45$) and the lowest for psychopathology ($d=0.22$).

Equivalence of moderately distressed participants according to use of psycho-oncological treatment

Before the matching procedure, moderately distressed patients receiving POI were more anxious, depressed and distressed, and showed more psychopathological symptoms (all $p<0.01$) compared to patients without POI at baseline (see Table 3). Partners receiving POI were also more anxious ($p=0.01$) and distressed ($p=0.02$), and showed more psychopathological symptoms ($p=0.04$) compared to partners without POI at baseline (see Table 3). Comparable score were found for depression. After propensity score matching, patients' mental health status on all measures (anxiety, depression, distress, and psychopathology) was equal regardless of POI use. The same situation was realized for partners with equal scores on anxiety, depression, distress, and psychopathology measures.

Effectiveness of psycho-oncological interventions on moderately distressed patients and partners

Results of completer analysis on the effect over time (pre–post) and of the POI on mental health outcome measures are

shown in Table 4. Time effects within patients' groups showed significant decreases over time for depression ($p=0.03$) and distress ($p=0.05$), but not for anxiety ($p=0.13$) and psychopathology ($p=0.30$). It was hypothesized that the interaction between time and group would be significant, but completer analyses indicated no group effects on anxiety ($p=0.82$), depression ($p=0.83$), distress ($p=0.99$), or psychopathology ($p=0.17$). Additionally, in partners, no change over time was found on any outcome measure (anxiety, $p=0.62$; depression, $p=0.93$; distress, $p=0.83$; psychopathology, $p=0.76$). Completer analyses showed no significant effect of POI on anxiety ($p=0.88$), depression ($p=0.53$), distress ($p=0.68$), or psychopathology ($p=0.22$).

ITT analyses on anxiety, depression, distress, and psychopathology showed the same pattern of results for patients and partners as the completer analyses (see Table 5). For patients, results for depression and distress converged with the completer analyses by demonstrating a significant reduction over time ($p<0.05$). There were no significant effects of POI on anxiety ($p=0.66$), depression ($p=0.79$), distress ($p=0.90$), and psychopathology ($p=0.31$). None of the partners' outcome measures changed over time (anxiety, $p=0.71$; depression, $p=0.75$; distress, $p=0.97$; psychopathology, $p=0.86$). Within partners there were no significant differences between POI groups on anxiety ($p=0.67$), depression ($p=0.23$), distress ($p=0.40$), and psychopathology ($p=0.18$).

Discussion

Highly distressed cancer patients and their partners showed a decrease in distress. Such a decrease in psychological distress in the first year for initially highly distressed patients and relatives may justify the implementation of psycho-oncological services for clinical reasons since patients use this service regularly which can be seen as a need for such an intervention [24, 25]. Our data cannot

Table 2 Psycho-oncological treatment effects for highly distressed patients and partners (pre–post change)

	Baseline [M (SD)]	12 months [M (SD)]	F	p	ES	[95 % CI]
Patients[a]						
Anxiety	8.48 (3.79)	7.18 (4.24)	6.26	0.01	0.32	0.05–0.58
Depression	7.45 (3.69)	5.38 (4.18)	13.58	0.001	0.52	0.21–0.83
Distress	15.94 (6.61)	12.56 (7.89)	12.04	0.001	0.46	0.18–0.74
Psychopathology	1.18 (0.68)	0.97 (0.71)	3.84	0.05	0.30	0.00–0.59
Partners[b]						
Anxiety	11.56 (4.70)	9.47 (4.45)	7.15	0.01	0.45	0.07–0.83
Depression	7.87 (3.86)	6.63 (3.94)	4.03	0.06	0.31	−0.01–0.65
Distress	19.43 (7.78)	16.09 (7.81)	6.20	0.02	0.42	0.05–0.80
Psychopathology	1.45 (1.06)	1.21 (1.10)	2.65	0.12	0.22	−0.05–0.50

M mean, SD standard deviation, F F value, p p value, ES effect size, CI confidence interval

[a] n patients = 37

[b] n partners = 16

Table 3 Equivalence of control group (CG) and treatment group (TG) before and after matching procedure

	CG M (SD)	TG M (SD)	p	CG M (SD)	TG M (SD)	p
Patients	Before matching[a]			After matching[b]		
Anxiety	4.84 (3.53)	6.95 (4.12)	0.01	5.70 (3.41)	6.36 (3.75)	0.45
Depression	4.37 (3.56)	5.90 (3.90)	0.01	4.82 (3.31)	5.06 (3.42)	0.77
Distress	9.21 (6.39)	12.85 (7.53)	0.01	10.52 (5.78)	11.42 (6.79)	0.56
Psychopathology	0.64 (0.54)	0.94 (0.64)	0.01	0.77 (0.63)	0.82 (0.57)	0.74
Partners	Before matching[c]			After matching[d]		
Anxiety	7.10 (4.09)	9.56 (4.46)	0.01	8.27 (4.18)	8.87 (3.67)	0.61
Depression	5.78 (4.42)	6.68 (3.99)	0.25	6.45 (4.58)	6.09 (3.83)	0.77
Distress	12.88 (8.16)	16.24(7.94)	0.02	14.73 (8.46)	14.96 (7.27)	0.92
Psychopathology	0.84 (0.62)	1.12 (0.87)	0.04	1.05 (0.70)	1.06 (0.87)	0.97

[a] CG n patients = 92; TG n patients = 94

[b] CG n patients = 33; TG n patients = 33

[c] CG n partners = 60; TG n partners = 57

[d] CG n partners = 22; TG n partners = 23

demonstrate whether POI were efficacious to improve mental health in highly distressed cancer patients, since a control group without POI was not available. A decrease in mental distress over time was found in moderately distressed patients. However, no decrease in psychological distress was observed among partners.

No efficacy of the POI was found in moderately distressed patients and partners. This could be due to the low mean scores on the HADS [17] and the SCL-9-K [20], which indicates clinically meaningful distress for a part of the patients only. Some authors have argued that efficacy of psycho-oncological interventions cannot be expected in moderately distressed patients [24], which is in line with some conflicting results in reviews [26, 27]. As an alternative explanation, low intensity of POI may limit its effectiveness. This view is supported by meta-analyses [7, 8]

Table 4 Psycho-oncological intervention effects of psycho-oncological intervention (TG) compared to persons without treatment (CG) in moderately distressed patients and partners: completer analyses

	Group	Baseline [M (SD)]	12 months [M (SD)]	Time F	Time p	Time×group F	Time×group p	ES	[95 % CI]
Patients[b]									
Anxiety	CG	6.58 (3.48)	5.00 (3.00)	2.38	0.13	0.02	0.82	−0.04	−0.64–0.55
	TG	5.96 (3.83)	4.83 (4.27)					0.27	−0.15–0.71
Depression	CG	4.11 (2.94)	3.63 (3.04)	4.75	0.03	0.04	0.83	0.31	−0.29–0.91
	TG	4.83 (3.55)	4.67 (3.63)					0.04	−0.40–0.49
Distress	CG	10.68 (6.07)	8.63 (5.71)	3.97	0.05	0.00	0.99	0.13	−0.47–0.73
	TG	10.79 (6.94)	9.50 (7.47)					0.17	−0.25–0.61
Psychopath	CG	0.94 (0.76)	0.67 (0.50)	1.08	0.30	1.91	0.17	0.16	−0.44–0.76
	TG	0.73 (0.49)	0.76 (0.61)					−0.05	−0.48–0.38
Partners[c]									
Anxiety	CG	7.17 (3.12)	4.75 (3.16)	0.24	0.62	0.02	0.88	0.77	0.13–1.40
	TG	8.67 (3.75)	6.97 (3.74)					0.45	−0.05–0.96
Depression	CG	4.83 (3.32)	3.25 (2.52)	0.08	0.93	0.40	0.53	0.53	−0.05–1.12
	TG	5.53 (3.44)	4.93 (3.61)					0.17	−0.32–0.66
Distress	CG	12.00 (6.03)	8.00 (5.42)	0.04	0.83	0.16	0.68	0.69	0.08–1.31
	TG	14.20 (7.00)	11.91(7.14)					0.32	−0.17–0.82
Psychopath.	CG	0.80 (0.55)	0.39 (0.30)	0.09	0.76	1.52	0.22	0.92	0.19–1.65
	TG	0.83 (0.53)	0.72 (0.50)					0.21	−0.34–0.76

[a] Covariate: gender

[b] CG n patients = 19; TG n patients = 24

[c] CG n partners = 12; TG n partners = 15

Table 5 Psycho-oncological intervention effects of psycho-oncological intervention (TG) compared to persons without treatment (CG) in moderately distressed patients and partners: intent to treat analyses (LOCF)

	Group	Baseline M (SD)	12 months M (SD)	Time F	Time p	Time×group F	Time×group p	ES	95% CI
Patients[b]									
Anxiety	CG	5.70 (3.41)	5.09 (2.93)	3.67	0.06	0.19	0.66	0.19	−0.13–0.52
	TG	6.36 (3.75)	5.58 (4.41)					0.19	−0.14–0.51
Depression	CG	4.82 (3.31)	4.33 (3.20)	3.94	0.05	0.06	0.79	0.15	−0.17–0.46
	TG	5.06 (3.42)	5.00 (3.58)					0.01	−0.30–0.34
Distress	CG	10.52 (5.78)	9.42 (5.51)	4.56	0.03	0.01	0.90	0.19	−0.19–0.52
	TG	11.42 (6.79)	10.58 (7.63)					0.11	−0.20–0.44
Psychopath	CG	0.77 (0.63)	0.64 (0.47)	0.82	0.36	1.04	0.31	0.23	−0.08–0.55
	TG	0.82 (0.57)	0.84 (0.67)					−0.03	−0.34–0.28
Partners[c]									
Anxiety	CG	8.27 (4.18)	6.55 (4.12)	0.13	0.71	0.17	0.67	0.41	0.04–0.78
	TG	8.87 (3.67)	7.90 (4.11)					0.24	−0.09–0.59
Depression	CG	6.45 (4.58)	5.00 (4.03)	0.09	0.75	1.42	0.23	0.33	−0.00–0.68
	TG	6.09 (3.83)	5.87 (4.01)					0.05	−0.26–0.37
Distress	CG	14.73 (8.46)	11.55 (7.93)	0.00	0.97	0.71	0.40	0.38	0.03–0.73
	TG	14.96 (7.27)	13.77 (7.90)					0.15	−0.16–0.48
Psychopath	CG	1.05 (0.70)	0.71 (0.61)	0.03	0.86	1.85	0.18	0.51	0.18–0.85
	TG	1.06 (0.87)	0.97 (0.81)					0.10	−0.18–0.39

LOCF last observation carried forward

[a] Covariate: gender

[b] CG *n* patients = 33; TG *n* patients = 33

[c] CG *n* partners = 22; TG *n* partners = 23

which showed that therapy duration is an important predictor of POI efficacy.

A major strength of our study was that threats to internal validity were reduced by propensity score matching [15]. Despite a gain in internal validity, confounders were not controlled in this type of study design. Randomization is still the gold standard in efficacy research, but random allocation is not always feasible or ethical [28]. Propensity score matching allowed coming to more meaningful results with data from naturalistic setting than regular analysis by incorporating baseline differences between individuals. However, some limitations of this study should be noted. Propensity score matching has the disadvantage that large initial samples are needed and, due to missing matches, this initial sample will be reduced dramatically. In our study, we faced the problem that the number of patients in the highly distressed group without POI was low, and an analysis of the efficacy of POI in this group was not possible. The sample size was rather small, and it was not possible to analyze established predictors in psycho-oncological effectiveness studies (e.g., gender, age). The heterogeneity of the

interventions did increase external validity and reflects clinical practice in psycho-oncology [29], but has limits if specific intervention strategies are of interest. The initial assessment of mental distress was carried out in the 4-week period after cancer diagnosis, which might have introduced bias due to the different coping stages of patients and partners. Another bias might be introduced by a higher rate of males and patients with lower education in the drop-outs.

In conclusion, our study showed an improvement of mental health in highly distressed cancer patients and their relatives over time. Since a control group without POI is missing, conclusions about the efficacy of POI in highly distressed subjects cannot be drawn. But the positive change of mental distress shows effects of a comprehensive rehabilitation program. Our results did not provide evidence for the effectiveness of POI in moderately distressed patients and partners, which might be partly explained by two established predictors of low treatment effects, namely low distress and low treatment dose. Our findings indicate that further research should clarify whether POI meet the needs of moderately distressed patients and partners, and if higher

treatment intensity would be required to achieve more beneficial outcomes.

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