

Existential behavioural therapy for informal caregivers of palliative patients: a randomised controlled trial

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Abstract

Background: Existential behavioural therapy (EBT) was developed to support informal caregivers of palliative patients in the last stage of life and during bereavement as a manualised group psychotherapy comprising six sessions. We tested the effectiveness of EBT on mental stress and quality of life (QOL).

Methods: Informal caregivers were randomly assigned (1:1) to EBT or a treatment-as-usual control group using computer-generated numbers in blocks of 10. Primary outcomes were assessed with the Brief Symptom Inventory (subscales somatisation, anxiety and depression), the Satisfaction with Life Scale (SWLS), the WHOQOL-BREF and a numeric rating scale for QOL (QOL-NRS, range 0–10). Data were collected at baseline, pre-treatment, post-treatment and follow-ups after 3 and 12 months. Treatment effects were assessed with a multivariate analysis of covariance.

Results: Out of 160 relatives, 81 were assigned to EBT and 79 to the control group. Participants were 54.5 ± 13.2 years old; 69.9% were female. The multivariate model was significant for the pre-/post-comparison ($p = 0.005$) and the pre-/12-month comparison ($p = 0.05$) but not for the pre-/3-month comparison. Medium to large effects on anxiety and QOL (SWLS, WHOQOL-BREF, QOL-NRS) were found at post-treatment; medium effects on depression and QOL (QOL-NRS) emerged in the 12-month follow-up. No adverse effects of the intervention were observed.

Conclusion: Existential behavioural therapy appears to exert beneficial effects on distress and QOL of informal caregivers of palliative patients. Further longitudinal evidence is needed to confirm these findings.
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Received: 13 July 2012

Revised: 22 January 2013

Accepted: 27 January 2013

Objective

Informal caregivers of palliative patients are exposed to various stresses. Their support of the patients can be extremely stressful, both mentally and physically, and may cause them to require care themselves. High prevalences of mental disorders have been reported in this population: according to self-ratings in the order of 20–30% and in advanced stages of disease up to 30–50% [1,2]. The mental stress of the patient and that of the relative appear to correlate and increase continually with the duration of the disease [3]. The aim of palliative care is to provide patients and their relatives with the maximum quality of life (QOL) possible [4].

Only few psychosocial interventions for relatives of palliative patients have been developed [5–8]. Harding and Higginson identified 22 interventions with nine of them being delivered solely to carers. Only six of the carers' interventions had been evaluated, two of these in a randomised controlled trial (RCT) [9]. Hudson and colleagues found a slight increase in quantity and quality of interventions in the last decade: 14 studies comprised five RCTs, two prospective, five pre-/post-comparisons and two qualitative studies [10].

A survey of relatives showed that professional support was most needed immediately before the patient's death

and for some time afterwards [11] with the importance of support continuity being emphasised [12]. In a Cochrane Review, 11 RCTs for relatives in the palliative care sector were identified, nine of them aimed directly at the carers [13]. However, the methodology of the trials was reported inadequately, and only small effects were achieved. Thus, there is currently only low-quality evidence that some interventions significantly reduce psychological distress in a short term and may marginally improve QOL. So far, long-term effects have not been investigated adequately.

The cognitive behavioural therapies have been developed considerably in recent years: questions of values and meaning, mindfulness and acceptance were integrated in the 'third wave' of behavioural therapy [14]. Initial meta-analyses substantiate the effectiveness of these approaches, even though there has been no application in palliative care yet [15]. In the situation of informal caregivers, in their confrontation with death, it is particularly meaningful to integrate approaches of existential psychology [16].

We have therefore conceptualised existential behavioural therapy (EBT), a new intervention to provide support to informal caregivers of palliative care patients (six meetings, 22 h in total). The objective of the study

was to investigate the applicability of EBT to informal caregivers of palliative care patients and its effectiveness with regard to psychological distress and QOL compared with a treatment-as-usual control group.

Methods

Study design

This study has a parallel-group design (with equal randomisation 1:1) with five assessments (baseline, pre-treatment, post-treatment and follow-ups after 3 and 12 months). Relatives were recruited at three institutions in Munich (see Affiliations 1, 4, 5). Munich is the capital city of Bavaria; with a population of about 1.35 million, it is the third largest city in Germany. The annual number of deaths has been constant in recent years, and in 2007, it was 10 372 [17]. Exhaustive recruitment was attempted at the two palliative care wards, and patients deemed palliative by their doctors were approached at the Radiation Oncology Department. To control for possible expectancy effects, baseline findings were collected prior to randomisation.

Inclusion and exclusion criteria

Inclusion criteria were the patient's palliative situation (life expectancy ≤ 6 months according to the patient's physician), minimum 21 years of age and sufficient knowledge of the German language. Only one relative per patient took part with the next of kin being selected. Exclusion criteria were severe mental illness that would adversely affect the ability to give informed consent and to participate in the intervention (e.g. dementia, delirium, acute psychosis and alcohol or drug dependence). The screening was carried out by psychologists with clinical experience.

Randomisation and masking

Potential participants were given information on the trial orally and in writing. After giving informed consent and completing the baseline questionnaire, participants were randomised in a ratio of 1:1 by means of externally created, computer-generated randomisation lists kept in a locked cupboard (in blocks of 10, each with five EBT and five control allocations in random sequence). Sequentially numbered opaque sealed envelopes were used, on which the study participant's name and date of birth were noted before they were opened.

Because there is no 'gold standard' for support of informal caregivers, the control group did not receive any special comparative treatment. However, they were free to use the spectrum of available support at the institution or elsewhere (e.g. specialist palliative care physicians and nurses, chaplains, social workers, psychologists and bereavement group). The use of other support was recorded and incorporated in the analyses as covariates (cf. Table 1). The study was approved by the Ethics Committee of Ludwig-Maximilians-University Munich.

Treatment

The EBT treatment consisted of six group sessions totalling 22 h:

First meeting: Becoming acquainted and introduction into mindfulness.

Second meeting: Death, bereavement and mindfulness.

Third meeting: Activating resources and finding meaning.

Fourth meeting: Self-care and stress management.

Fifth meeting: Personal values for (re-)orientation.

Sixth meeting: Saying goodbye and new steps.

At the beginning of each session, ample time was provided for discussing the relatives' individual *existential issues* such as the impending or recent death of the patient, their own mortality, dealing with loneliness and isolation, questions about meaning in life and the necessity of giving one's own life a (new) direction.

To promote *group cohesion*, the first two meetings were half-day sessions on consecutive days. The focus was on *mindfulness*, which was practised throughout all treatment sessions. In this context, mindfulness means the ability to accept and observe all inner processes calmly and without making judgments—to distance oneself from ruminative thoughts and aversive feelings and to adopt an attitude of acceptance towards reality [18]. The participants were given a CD and were asked to practise mindfulness at home twice daily for at least 5 min. The third meeting was about *strengthening resources* by imagination and *finding meaning* to cope with the present situation. At the fourth and fifth meetings, establishment of *self-care* and orientation towards the participants' *personal values* for their future was developed. The first steps in the direction of new goals were elaborated for each participant [14]. Finally, the participants were prepared for group dissolution and *saying goodbye*.

The sessions were conducted at the Interdisciplinary Centre for Palliative Medicine, Munich. First, the EBT intervention was outlined in detail in a therapy manual. Before the trial started, a pilot group was carried out in 02/2008 to evaluate and adapt the manual. EBT uses closed groups with a maximum of 10 participants. The six different group leaders (one per group, all behavioural therapists) received 20-h training, learning the therapy manual, and were supervised regularly between the sessions. Scientific staff performing the evaluation were independent of the therapists. Treatment integrity was evaluated via video recordings by six independent raters using coding guidelines and check lists (range 0–4: '0' intervention element missing to '4' fully consistent with the manual). Discussions among the coders for clarification purposes took place where necessary.

Measuring instruments

Before starting the study, six primary outcomes were established. The severity of symptoms was recorded with the Brief Symptom Inventory (BSI, sub-scales of somatisation, depression and anxiety) [19]. Raw scores were transformed into gender-specific *T*-values ($T \geq 60$ is clinically striking). QOL was recorded using the Satisfaction with Life Scale (SWLS) assessing its cognitive aspects [20], WHOQOL-BREF comprising

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Table I. Demographic characteristics

| | EBT (n = 69) | Control (n = 64) | All (n = 133) |
|--|--------------|------------------|---------------|
| Age (years) | 54.3 (13.5) | 54.7 (12.9) | 54.5 (13.2) |
| Sex | | | |
| Female | 50 (72.5%) | 43 (67.2%) | 93 (69.9%) |
| Relation (patient is) | | | |
| Partner | 40 (58%) | 42 (65.6%) | 82 (61.7%) |
| Parent | 18 (26.1%) | 17 (26.6%) | 35 (26.3%) |
| Child | 2 (2.9%) | 2 (3.1%) | 4 (3.0%) |
| Other | 9 (13.0%) | 3 (4.7%) | 12 (9.0%) |
| Religion | | | |
| Catholic | 37 (55.2%) | 30 (47.6%) | 67 (51.6%) |
| Protestant | 14 (20.9%) | 8 (12.7%) | 22 (16.9%) |
| Buddhist | 0 (0%) | 2 (3.2%) | 2 (1.5%) |
| Other | 2 (3.0%) | 1 (1.6%) | 3 (2.3%) |
| None | 14 (20.9%) | 22 (34.9%) | 36 (27.7%) |
| Education | | | |
| None or secondary | 17 (26.2%) | 12 (19.1%) | 29 (22.7%) |
| Vocational secondary | 20 (30.7%) | 22 (34.9%) | 42 (32.8%) |
| Grammar school | 11 (16.9%) | 4 (6.3%) | 15 (11.7%) |
| University degree | 17 (26.2%) | 25 (39.7%) | 42 (32.8%) |
| Employment | | | |
| Full time | 21 (30.4%) | 21 (33.3%) | 42 (31.8%) |
| Part time (<35 h) | 15 (21.7%) | 7 (11.1%) | 22 (16.7%) |
| Houseman/housewife | 5 (7.3%) | 4 (6.4%) | 9 (6.8%) |
| Unemployed | 5 (7.3%) | 1 (1.6%) | 6 (4.5%) |
| Retired | 20 (29.0%) | 25 (39.7%) | 45 (34.1%) |
| Other | 3 (4.3%) | 5 (7.9%) | 8 (6.1%) |
| Diagnosis of patient | | | |
| Cancer—primary site | 56 (81.2%) | 54 (84.4%) | 110 (82.7%) |
| Lung | 8 (11.6%) | 7 (10.9%) | 15 (11.3%) |
| Gastrointestinal | 14 (20.3%) | 12 (18.8%) | 26 (19.6%) |
| Genitourinary | 4 (5.8%) | 8 (12.5%) | 12 (9.0%) |
| Breast | 7 (10.2%) | 6 (9.4%) | 13 (9.8%) |
| Gynaecological | 7 (10.2%) | 5 (7.8%) | 12 (9.0%) |
| Brain | 5 (7.2%) | 7 (10.9%) | 12 (9.0%) |
| Other | 11 (15.9%) | 9 (14.1%) | 20 (15.0%) |
| Neurological diseases | 9 (13.0%) | 8 (12.5%) | 17 (12.8%) |
| Other | 4 (5.8%) | 2 (3.1%) | 6 (4.5%) |
| Patient deceased | | | |
| ≥6 weeks before intervention | 26 (37.7%) | 33 (51.6%) | 59 (44.3%) |
| <6 weeks before or during intervention | 29 (42.0%) | 15 (23.4%) | 44 (33.1%) |
| After intervention | 14 (20.3%) | 16 (25.0%) | 30 (22.6%) |
| Use of other support ^a | | | |
| Yes | 21 (30.4%) | 12 (18.8%) | 33 (24.8%) |

EBT, existential behavioural therapy.

Data are number (%) or mean (SD).

^aA minimum of one support element was taken up at least twice during the last 4 weeks (relating to post-treatment assessment): chaplain, psychologist/psychotherapist, bereavement group and self-help group.

QOL domains [21], and a numeric rating scale on individual, overall QOL experience (QOL-NRS, range 0–10, ‘How do you rate your quality of life at the moment?’).

As a secondary outcome, changes in affect were investigated using the Positive and Negative Affect Scale (PANAS) [22]. Helpfulness ratings of specific intervention elements (range 0–4) were also assessed.

Sample size calculation

With regard to the outcome parameters, effects of 0.6 standard deviation (SD) were expected, as psychotherapy research describes treatment effects of 0.67–0.75 SD [23]. Thus, according to Dupont’s sample size calculation, 44 informal caregivers had to participate in the EBT to achieve a power of 0.8 at $p=0.05$. With an assumed dropout rate of 20%, 55 participants would be needed for each study arm ($n=110$).

Statistical evaluation

All data were entered in two separate files and compared afterwards. After study completion, the data were evaluated independently of the study group; there was no interim analysis. All subjects were compared in the groups to which they were originally randomised (intention-to-treat analysis). The analyses were carried out on all available data using SPSS (v19; IBM Corp., Armonk, NY, USA) and R (v2.13.0; R Foundation for Statistical Computing, R Core Team, Vienna, Austria). The (two-sided) significance level was set at $p=0.05$.

Post-treatment assessments (adjusted for the respective pre-treatment values) were compared separately with the pre-measurement to examine the intervention effect [24]. In the multivariate models, we controlled for age (metric), gender, relation to the patient (partner/child vs parent/other), time of death (≥6 weeks before vs <6 weeks before/during vs after intervention) and use of other support (yes vs no). Conditional normality of the outcome

variables was checked using their residuals. The regression coefficient (*B*-value) and its 95% confidence interval are reported.

Results

Inclusion rate, dropouts and applicability

Participants were recruited between 05/2008 and 05/2010. From a total of 1324 patients, 149 relatives could not be

contacted or did not meet the inclusion criteria. From the 1175 relatives approached, the overall inclusion rate was 13.6% (inclusion rates for Interdisciplinary Center for Palliative Medicine: 19.8%, Department of Radiation Oncology: 10.0%, Harlaching Hospital: 7.8%) (Figure 1).

Ten EBT groups consisting of 7.3 ± 1.1 participants were successfully carried out between 06/2008 and 06/2010, the dropout rate was in the expected range ($35/160 = 21.9\%$). Participants took part in 5.5 ± 0.8 sessions. The level of the therapists' adherence to the therapy manual was high

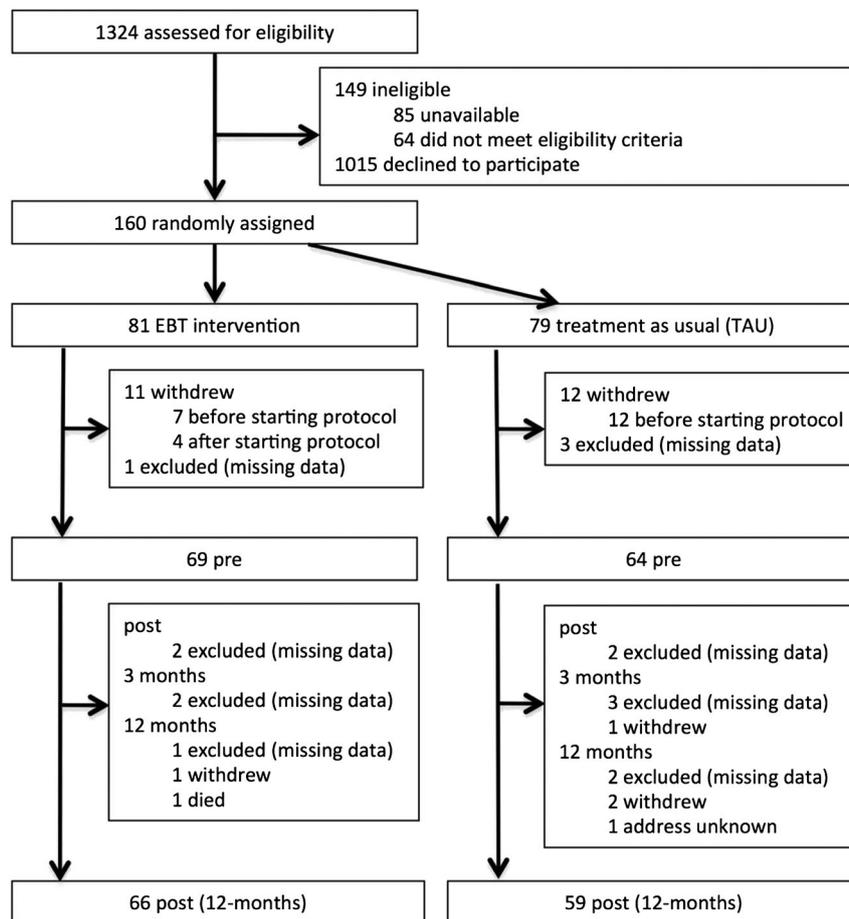


Figure 1. Trial profile

Table 2. Baseline data for primary and secondary outcomes

| | EBT (n = 69) | Control (n = 64) | All (n = 133) |
|----------------------------------|--------------|------------------|---------------|
| <i>Primary outcomes</i> | | | |
| BSI ^a | | | |
| Somatisation | 57.8 (10.9) | 57.5 (10.9) | 57.7 (10.8) |
| Depression | 65.8 (9.4) | 63.5 (10.8) | 64.7 (10.1) |
| Anxiety | 60.7 (12.7) | 58.7 (11.5) | 59.8 (12.1) |
| QOL | | | |
| SWLS (1–7) ^b | 3.9 (1.3) | 4.0 (1.4) | 3.9 (1.3) |
| WHOQOL-BREF (0–100) ^b | 62.2 (12.7) | 63.2 (13.5) | 62.6 (13.1) |
| QOL-NRS (0–10) ^b | 3.8 (2.0) | 3.8 (2.2) | 3.8 (2.1) |
| <i>Secondary outcomes</i> | | | |
| PANAS | | | |
| Positive affect (1–5) | 2.5 (0.7) | 2.4 (0.6) | 2.5 (0.7) |
| Negative affect (1–5) | 2.6 (0.7) | 2.4 (0.7) | 2.5 (0.7) |

EBT, existential behavioural therapy; BSI, Brief Symptom Inventory [19]; SWLS, Satisfaction with Life Scale [20]; WHOQOL-BREF, WHO Quality of Life-BREF [21]; QOL-NRS, QOL Numeric Rating Scale; PANAS, Positive and Negative Affect Scale [22].

Data are mean (SD). Parenthesised numbers beside the scale names represent the response format.

^aScores are gender-adjusted *T*-values (mean = 50, SD = 10). $T \geq 60$ is clinically striking.

^bHigher scores indicate better QOL.

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(3.3 ± 0.42). No adverse outcomes of the intervention were reported.

Demographic characteristics

The baseline demographic characteristics of the participants were well balanced (Table 1). Their age ranged from 23 to 88 years.

Descriptive results

Table 2 shows means and SDs of the outcomes at baseline. As expected, no differences were found between EBT and controls. In the EBT, there were 31.0 ± 31.2 days (range 2–152 days) between baseline and pre-treatment, and in controls, 34.1 ± 23.1 days (range 5–108 days). Whereas at baseline, 60 (45.1%) patients were still alive (EBT: *n* = 31, 44.9%; control: *n* = 29, 45.3%), at pre-treatment, 93 (69.9%) relatives (EBT: *n* = 49, 71.0%; control: *n* = 44, 68.8%) were in bereavement.

There were no significant expectancy effects between baseline and pre-treatment (controlled for the waiting time) but a trend towards greater anxiety in EBT ($B = -3.23$ (-6.78 to 0.32), $p = 0.07$).

EBT participants were asked how many times per week they had practiced mindfulness for at least 5 min. At post-treatment, participants reported to practice formal mindfulness (e.g. following the breath) 3.4 ± 3.8 times/week and informal mindfulness (in daily activities) 5.7 ± 9.2 times/week.

Intervention effects

First, the pre-specified analyses are reported. The multivariate analysis of the six primary outcomes of the pre-/post-comparison (Table 3) is significant ($p = 0.005$). EBT shows medium to large effects on anxiety (BSI) and QOL (SWLS, WHOQOL-BREF and QOL-NRS). No significant effect was found for somatisation, and a trend was observed for depression.

Table 3. Pre-/post-comparison

| | Mean (SD) | | | | B ^a (95% CI) | p |
|---------------------------|--------------------|--------------------|--------------------|--------------------|----------------------------|--------------|
| | EBT | | Control | | | |
| | Pre | Post | Pre | Post | | |
| <i>Primary outcomes</i> | <i>n</i> = 67 | | <i>n</i> = 62 | | | |
| BSI | | | | | | |
| Somatisation | 58.5 (12.2) | 56.8 (12.3) | 58.4 (11.5) | 56.5 (11.9) | 0.39 (-2.53 to 3.31) | 0.79 |
| Depression | 65.1 (11.1) | 62.5 (11.5) | 64.1 (9.7) | 64.0 (11.1) | 2.36 (-0.39 to 5.10) | 0.09 |
| Anxiety | 62.0 (11.9) | 56.5 (12.6) | 57.7 (12.3) | 57.9 (12.1) | 4.59 (1.34 to 7.85) | 0.006 |
| QOL | | | | | | |
| SWLS | 3.7 (1.2) | 4.2 (1.2) | 3.9 (1.3) | 4.0 (1.3) | -0.39 (-0.69 to -0.10) | 0.009 |
| WHOQOL-BREF | 62.1 (11.4) | 67.1 (11.9) | 63.5 (13.2) | 64.4 (12.1) | -3.68 (-6.34 to -1.02) | 0.007 |
| QOL-NRS | 3.9 (1.8) | 5.6 (2.0) | 4.3 (2.2) | 4.7 (2.2) | -1.17 (-1.78 to -0.56) | <0.001 |
| <i>Secondary outcomes</i> | <i>n</i> = 67 | | <i>n</i> = 64 | | | |
| PANAS | | | | | | |
| Positive affect | 2.6 (0.6) | 2.9 (0.7) | 2.5 (0.6) | 2.6 (0.6) | -0.19 (-0.38 to 0.01) | 0.06 |
| Negative affect | 2.4 (0.7) | 2.3 (0.7) | 2.2 (0.7) | 2.2 (0.6) | 0.29 (0.10 to 0.49) | 0.003 |

EBT, existential behavioural therapy; BSI, Brief Symptom Inventory [19]; SWLS, Satisfaction with Life Scale [20]; WHOQOL-BREF, WHO Quality of Life-BREF [21]; QOL-NRS, QOL Numeric Rating Scale; PANAS, Positive and Negative Affect Scale [22].

Adjusted for age, gender, relation to the patient, time of death, use of other support elements and pre-values. **Bold type:** significant at $p < 0.05$; *italics:* $p < 0.10$ (trend).

^aPositive B-values (regression coefficient with 95% confidence interval) indicate higher, negative B-values lower values in controls compared to EBT.

Table 4. Pre-/3-month comparison

| | Mean (SD) | | | | B ^a (95% CI) | p |
|---------------------------|------------------|------------------|------------------|------------------|-------------------------------|-------------|
| | EBT | | Control | | | |
| | Pre | 3 months | Pre | Post | | |
| <i>Primary outcomes</i> | <i>n</i> = 67 | | <i>n</i> = 60 | | | |
| BSI | | | | | | |
| Somatisation | 58.3 (12.8) | 57.2 (11.6) | 59.4 (11.6) | 57.5 (10.4) | -0.01 (-3.08 to 3.07) | 0.996 |
| Depression | 65.3 (11.1) | 63.3 (10.5) | 64.2 (9.9) | 63.3 (10.1) | 0.83 (-1.84 to 3.50) | 0.54 |
| Anxiety | 62.2 (11.8) | 56.3 (12.3) | 58.6 (12.0) | 56.2 (11.0) | 1.96 (-1.54 to 5.46) | 0.27 |
| QOL | | | | | | |
| SWLS | 3.7 (1.2) | 4.2 (1.2) | 3.9 (1.3) | 4.0 (1.3) | -0.37 (-0.72 to -0.02) | 0.04 |
| WHOQOL-BREF | 62.2 (11.4) | 67.3 (13.2) | 63.1 (13.0) | 65.3 (13.9) | -3.04 (-6.62 to 0.54) | 0.10 |
| QOL-NRS | 3.9 (1.8) | 5.5 (2.2) | 4.2 (2.2) | 5.2 (2.2) | -0.41 (-1.08 to 0.26) | 0.23 |
| <i>Secondary outcomes</i> | <i>n</i> = 68 | | <i>n</i> = 61 | | | |
| PANAS | | | | | | |
| Positive affect | 2.6 (0.6) | 2.9 (0.7) | 2.5 (0.6) | 2.8 (0.7) | -0.04 (-0.26 to 0.17) | 0.68 |
| Negative affect | 2.4 (0.7) | 2.1 (0.7) | 2.2 (0.7) | 2.1 (0.7) | 0.17 (-0.05 to 0.39) | 0.13 |

EBT, existential behavioural therapy; BSI, Brief Symptom Inventory [19]; SWLS, Satisfaction with Life Scale [20]; WHOQOL-BREF, WHO Quality of Life-BREF [21]; QOL-NRS, QOL Numeric Rating Scale; PANAS, Positive and Negative Affect Scale [22].

Adjusted for age, gender, relation to the patient, time of death, use of other support elements and pre-values. **Bold type:** significant at $p < 0.05$; *italics:* $p < 0.10$ (trend).

^aPositive B-values (regression coefficient with 95% confidence interval) indicate higher, negative B-values lower values in controls compared to EBT.

Table 5. Pre-/12-month comparison

| | Mean (SD) | | | | B ^a (95% CI) | p |
|--------------------|--------------------|--------------------|-------------------|--------------------|-------------------------------|--------------|
| | EBT | | Control | | | |
| | Pre | Post | Pre | Post | | |
| Primary outcomes | n = 66 | | n = 59 | | | |
| BSI | | | | | | |
| Somatisation | 58.7 (13.0) | 55.9 (12.4) | 58.1 (11.4) | 55.0 (10.9) | -0.54 (-4.05 to 2.97) | 0.76 |
| Depression | 65.0 (11.0) | 58.9 (10.0) | 63.5 (9.6) | 61.7 (10.4) | 3.27 (0.15 to 6.39) | 0.04 |
| Anxiety | 62.2 (11.8) | 53.7 (11.6) | 57.5 (11.6) | 53.2 (11.6) | 1.44 (-2.26 to 5.13) | 0.44 |
| QOL | | | | | | |
| SWLS | 3.7 (1.2) | 4.4 (1.1) | 3.9 (1.3) | 4.2 (1.4) | -0.31 (-0.68 to 0.06) | 0.10 |
| WHOQOL-BREF | 62.4 (11.5) | 70.7 (10.7) | 64.1 (12.5) | 68.3 (14.4) | -3.60 (-7.32 to 0.11) | 0.06 |
| QOL-NRS | 3.9 (1.8) | 6.5 (1.8) | 4.3 (2.2) | 5.4 (2.4) | -1.18 (-1.90 to -0.45) | 0.002 |
| Secondary outcomes | n = 66 | | n = 61 | | | |
| PANAS | | | | | | |
| Positive affect | 2.6 (0.6) | 3.2 (0.7) | 2.5 (0.6) | 2.9 (0.8) | -0.21 (-0.43 to 0.01) | 0.06 |
| Negative affect | 2.4 (0.7) | 2.2 (0.7) | 1.8 (0.6) | 2.0 (0.7) | 0.33 (0.11 to 0.54) | 0.003 |

EBT, existential behavioural therapy; BSI, Brief Symptom Inventory [19]; SWLS, Satisfaction with Life Scale [20]; WHOQOL-BREF, WHO Quality of Life-BREF [21]; QOL-NRS, QOL Numeric Rating Scale; PANAS, Positive and Negative Affect Scale [22].

Adjusted for age, gender, relation to the patient, time of death, use of other support elements and pre-values. **Bold type:** significant at $p < 0.05$; *italics:* $p < 0.10$ (trend).

^aPositive B-values (regression coefficient with 95% confidence interval) indicate higher, negative B-values lower values in controls compared to EBT.

The multivariate analysis of the pre-/3-month comparison (Table 4) is not significant ($p = 0.4$). Univariate analyses show small to medium effects on SWLS and WHOQOL-BREF.

The multivariate pre-/12-month comparison (Table 5) is significant ($p = 0.05$). After 1 year, EBT showed medium effects on depression (BSI) and QOL-NRS, and small effects for WHOQOL-BREF and SWLS. No effect was found for anxiety and somatisation (BSI).

In the secondary outcomes, EBT participants had significantly less negative affect and a tendency towards more positive affect in the pre-/post-comparison. At the 3-month follow-up, differences were in the same direction but not significant. At the 12-month follow-up, there was significantly less negative and by trend more positive affect in EBT compared with controls.

Helpfulness of the group elements

While all intervention elements were rated as either 4 (extremely helpful) or 3 (quite helpful) by most

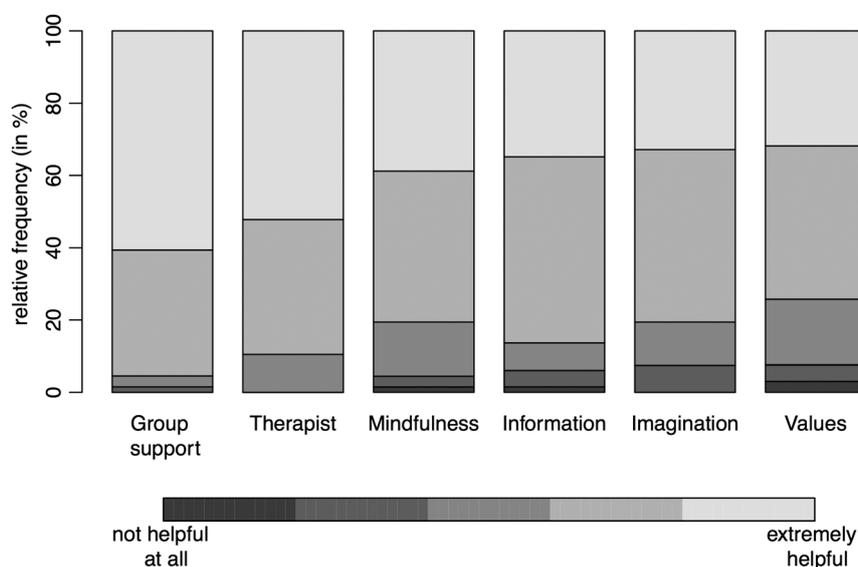
participants, group support and the therapist received the most favourable ratings (Figure 2).

Discussion

In the first RCT investigating a sample of care-giving and grieving relatives, EBT resulted in significant long-term improvements with regard to mental distress and QOL.

Participating informal caregivers appeared to be highly burdened at the beginning of the study: their *T*-levels of anxiety and depression were approximately one SD above the gender-adjusted mean and were more pronounced than those reported by Kissane *et al.* [1]. QOL was clearly lower than in the general population (WHOQOL-BREF) [21]; with regard to life satisfaction (SWLS), relatives were in the dissatisfied range [25]. Relatives had similar levels of positive affect (PANAS) as a student sample but showed considerably more negative affect [26].

It is possible that those relatives who were particularly burdened consented to the trial [27,28]. As reported elsewhere, stressed relatives may benefit particularly from

**Figure 2.** Helpfulness of specific group elements

Existential behavioural therapy

a psychotherapeutic intervention [29,30]. Our inclusion rate could reflect a self-selection process where the consenting relatives are those who are in need and are able to benefit from such group support. To test this hypothesis, a separate study was conducted comparing participants and rejecters as well as their detailed reasons for rejecting. The results will be reported in detail in another paper.

To develop a general support, we intentionally decided not to conduct a pre-screening of the informal caregivers regarding their mental distress. Because not every relative of a palliative patient is in need of psychological treatment, the overall take-up rate seems sufficient. Comparable studies report similar inclusion rates: about 10–30% resorted to professional support to cope with grief [28]. Toseland *et al.* [29] as well as Harding *et al.* [31] report inclusion rates of around 25%, the latter even provided bedside care and transportation to reduce organisational barriers for participants [8]. The inclusion rate of the institution hosting the intervention was highest. Here, participants were already familiar with the setting. Future groups should therefore be held at the institution that cared for the palliative patient.

Unlike previous studies, we examined possible expectancy effects by comparing baseline and pre-treatment values. The trend of higher anxiety in EBT participants could reflect tension about the impending start of the intervention.

In the pre-/post-comparison the effects approximate the expected extent of 0.6 SD. Moreover, the 12-month effects are clinically relevant, as the distress values improved from abnormal to within the normal range. In contrast to previous interventions with relatives [13], long-term effects were evidenced not only on psychological distress but also on QOL. There were no adverse events reported in the study arm that would indicate side effects of EBT.

Although trends in the expected direction were evident 3 months after the intervention, the multivariate model was not significant. This raises the question: what influences could mask the effects shown in the univariate models? It may be that at this time, relatives finally have time for emotional processing after having completed the various tasks that follow the death of their loved one. In addition, it may require some time for group participants to overcome the loss of the support received in the EBT group and reap the long-term benefits from the learned skills by putting them into practice in their own lives.

Dropout rates were in the expected range and considerably lower than in comparable studies [31].

Over the course of the study, there was a decrease in symptom severity and an increase in QOL in both groups. After 1 year, *T*-values in both groups fell within the normal range for somatisation and anxiety, but were still elevated for depression in the control group.

The questionnaires used have good psychometric properties. Participants were selected from different institutions, improving the generalisability of the results. Although many studies are limited to pre-/post-comparisons or short follow-up periods [13], we observed the

treatment effects over a longer period. Study participants were informal caregivers of patients receiving inpatient palliative care; a next step would be to extend and evaluate such support to informal caregivers of outpatients.

A possible limitation is the heterogeneity of the sample. Participating informal caregivers had varying relationships to the patient, with partners being predominant. As almost half of the patients died during their stay at the palliative care unit (average treatment period: 10 days), the majority of relatives were already grieving at the beginning of the intervention. To increase the external validity and generalisability of the results, we admitted both caring and grieving relatives, thus developing a procedure that corresponds to the reality of clinical practice. This entails the risk that relatives in different grief situations may interact in unpredictable ways. Notably, the feedback from participants regarding the 'mixed' group composition was positive. Several authors pointed explicitly to the need for continuous support for relatives in the transition from caring to grieving [11,12]. We considered this by incorporating the time of death and the relation to the patient as covariates in the analyses.

By comparing EBT with standard care, the observed effects could be attributed to non-specific factors such as contact with others in a similar situation, the empathy of the therapist or the supportive structure of the meetings [31,32]. To prove the specific effects of EBT, a comparison with a specific control group (e.g. a self-help group) would be necessary.

Responses to the open-answer questions showed that many informal caregivers regarded the discussion of existential issues with others as particularly helpful: '...seeing other people that have been through something similar and manage to cope with it', 'I am not alone in my situation' or 'I looked forward to the group meeting each time. I went about my daily life strengthened and with confidence.'

Palliative care means the comprehensive care of patients and their caregivers with regard to physical, psychosocial and spiritual dimensions [4]. There has been significant progress with regard to treating physical problems; it is important to also improve the psychosocial and existential well-being of relatives of palliative care patients: EBT is a promising approach to contribute to this complex task.

Acknowledgements

We thank the group leaders for their commitment and readiness to familiarise themselves with the EBT concept. We thank the nursing and ward staff and head physicians of the institutions involved as well as our graduate students for their co-operation and assistance. Last but not the least, we are sincerely grateful to all caregivers who took part in the trial.

This work was supported by the Deutsche Krebshilfe e.V. (no. 107433). The funder had no role in study design, data collection, analysis or interpretation, decision to publish, or preparation of the manuscript.

Conflict of interest

The authors declare that they have no conflicts of interest.

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