Original Article

PALLIATIVE MEDICINE

Palliative Medicine
2020, Vol. 34(6) 806–816

DOI: 10.1177/0269216320911595
journals.sagepub.com/home/pmj


How short is too short? A randomised controlled trial evaluating short-term existential behavioural therapy for informal caregivers of palliative patients

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Abstract

Background: Informal caregivers of palliative patients show higher levels of depression and distress compared with the general population. Fegg's (2013) existential behavioural therapy was shortened to two individual 1-h sessions (short-term existential behavioural therapy).

Aim: Testing the effectiveness of sEBT on psychological symptoms of informal caregivers in comparison with active control.

Design: Randomised controlled trial.

Setting/participants: Informal caregivers of palliative in-patients.

Methods: The primary outcome was depression; secondary outcomes were anxiety, subjective distress and minor mental disorders, positive and negative affect, satisfaction with life, quality of life and direct health care costs. General linear mixed models allow several measurements per participant and change over time. Reasons for declining the intervention were investigated by Rosenstock's Health Belief Model.

Results: Overall inclusion rate was 41.0%. Data of 157 caregivers were available (63.1% females; mean age: 54.6 years, standard deviation (SD): 14.1); 127 participants were included in the main analysis. Participation in sEBT or active control was not significantly associated with post-treatment depression. Outcomes showed prevailingly significant association with time of investigation. Self-efficacy, scepticism of benefit of the intervention, belief of better coping alone and support by family and friends were significant factors in declining participation in the randomised controlled trial.

Conclusion: Inclusion rate was tripled compared with a previously evaluated longer EBT group intervention. By shortening the intervention, inclusion rate was traded for effectiveness and the intervention could not impact caregivers' psychological state. Early integration of sEBT and combination of individual and group setting and further study of the optimal length for caregiver interventions are suggested.

Keywords

Family caregiver, palliative care, existential behavioural therapy, randomised controlled trial

What is already known about the topic?

- Informal caregivers of palliative patients are prone to higher levels of depression compared with the general population.
- Fegg et al. (2013) developed existential behavioural therapy (EBT) for caregivers as a group intervention comprising 22 h.
- EBT showed medium to large effects on anxiety and quality of life and medium effects on depression, reaching 13.6% of all eligible caregivers.

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What this paper adds?

- EBT was shortened to two individual 1-h sessions (sEBT) to fit better into caregivers' daily lives.
- This randomised controlled trial tests the effectiveness of sEBT on psychological symptoms of informal caregivers in comparison with an active control.

Implications for practice, theory or policy

- Shortening the intervention tripled inclusion rate to 41.0% reaching more caregivers.
- Inclusion rate was traded for effectiveness and the intervention could not impact caregivers' psychological state.
- Early integration of sEBT and combination of individual and group setting are discussed.
- This study's results suggest further study of the optimal length for caregiver interventions.

Introduction

Informal caregivers are family members and other persons whose support of the patient is not financially rewarded.[1] Supporting informal caregivers is an essential part of palliative care, as defined by the World Health Organization.[2]

Informal caregivers are prone to higher levels of depression, anxiety, strain and burden than the general population,[3,4] and the number of interventions to support them is growing.[4,5] However, a review of caregiver interventions identified a lack of proactive interventions and supposed that caregivers would prefer interventions that improve the ability to care.[6]

Mindfulness-based interventions for caregivers could potentially close this gap. Despite the challenges for caregivers to access interventions due to scheduling difficulties and them having to leave the patient alone, mindfulness showed positive influences on depression, strain and quality of life.[7]

Fegg et al.[8] developed existential behavioural therapy (EBT), an intervention aimed at informal caregivers of palliative patients. EBT was implemented in a group setting with a total of 22 h focusing on mindfulness practice, strengthening resources, finding meaning, establishing self-care and developing personal values. Medium to large effects on anxiety and quality of life and medium effects on depression were demonstrated. A weakness of this study was the low uptake of the intervention with 13.6%.

Short-term existential behavioural therapy (sEBT) aimed to be more compatible with caregivers' daily life. A qualitative study embedded in the Fegg study had identified two EBT elements regarded as most helpful by caregivers: social support in the group and self-regulation via strengthening resources and practicing mindfulness.[9] Despite the support provided by the group, an individual setting was chosen for sEBT to ensure a quicker start of the intervention. To condense EBT for the individual setting, sEBT focused on the two elements of self-regulation, shortening it to two 1-h sessions.

A feasibility study indicated that sEBT was feasible and accepted by caregivers.[10] Although sEBT is not a treatment applied for a disorder, the term 'therapy' was kept to mark the affiliation with EBT.

This study's aim was to evaluate the effectiveness of the sEBT intervention in comparison with a usual, non-directive psychological intervention using a randomised controlled trial study design.

The primary outcome was informal caregivers' level of depression, as the Fegg study had shown long-term effects on depression. Secondary outcomes were informal caregivers' levels of anxiety, subjective distress and minor mental disorders, positive and negative affect, satisfaction with life, quality of life and direct health care costs.

Furthermore, we analysed caregivers' reasons to decline participation in the randomised trial as more research in this field had been suggested.[7]

Method

Design

This randomised controlled trial has a parallel-group design with equal 1:1 randomisation and four assessments: pre-treatment, post-treatment and follow-ups after 4 weeks and 6 months. We embedded a follow-up of those informal carers who declined to participate. The study was approved by the Ethics Committee of Ludwig-Maximilians-University of Munich (No: 545-12) and was registered with Clinical.Trials.gov (NCT02325167).

Sample and setting

Informal caregivers were recruited from the Munich University Hospital palliative care unit, Germany. Inclusion criteria were minimum age of 21 years and fluency in German. One caregiver per patient was included, preferably the person closest to the patient. Excluded were professional legal representatives and caregivers with severe mental illness (e.g. dementia, acute addiction).

The sample size was calculated according to Fegg's study:[8] psychotherapy research reports treatment effects between 0.67 and 0.75 standard deviation (SD).[11] To achieve a power of 0.8 at 5% significance level using Dupont

and Plummer's[12] sample size calculation and considering a dropout rate of 25%, 55 participants were needed in every arm of the study.

Recruiting procedure and randomisation

Caregivers were approached earliest after the day of the patient's admission. They were screened for the inclusion criteria by psychologists with clinical experience. Potential participants were contacted in person or by phone and informed orally and in written form about the study. Caregivers who did not want to participate were asked to take part in the decliners' follow-up. All participating caregivers and patients provided written informed consent. Consent of a legal guardian was sought for patients unable to give consent.

Immediately after making the first appointment and receiving the first questionnaire, participants were randomised by a randomisation list which was computer-generated with blocks of 10, each containing five control and five sEBT assignments in random order. Participants were informed about their allocation in the first session.

The study was conducted on weekdays between January 2015 and February 2018. Recruitment was suspended for 5 months due to staff change (March 2016–August 2016) and three times due to staff vacation (21 December 2016–9 January 2017; 2 August 2017–8 September 2017; 22 December 2017–8 January2018).

Intervention

sEBT and control intervention both comprised two sessions in an individual setting lasting 45–60 min; appointments were arranged individually. The interventions took place in a separate room in the palliative care unit and in a psychotherapeutic practice. Three psychologists with several years of experience in behavioural psychotherapy were trained using video feedback. sEBT and control group sessions were audiotaped and rated for treatment integrity using coding guidelines and checklists (range 0–4: '0' = element missing to '4' = fully consistent with the manual).

Control group. The active control group was oriented towards Carl Rogers'[13] client-centred therapy, characterised by acceptance, congruence and empathic understanding, as recommended in supporting informal caregivers in a palliative setting.[14] There was no mention of mindfulness or resources.

sEBT group. The first sEBT session focussing on mindfulness included: introduction, psychoeducation about mindfulness, 2-min body scan, 10-min mindful breathing exercise, addressing questions and motivation to practice mindfulness every day using a CD provided.

The second sEBT session focussing on resources included: introduction, psychoeducation on psychological meaning of resources, encouragement to express strengthening areas and activities (based on Schedule for Meaning in Life Interview[15]), imaginative exercise of the inner image of the strongest resource addressing all five senses, choice of a symbol as reminder and prime, addressing questions, motivation to practice mindful breathing and imaginative exercise using the CD.

Data collection

Caregivers' demographic data and patients' medical data were collected through self-report and clinic chart review. Participants of the randomised controlled trial completed standardised questionnaires at the time of study entry (t1), after the second intervention session (t2) and 4 weeks (t3) and 6 months (t4) after the second intervention session.

Participants of the decliners' follow-up received three questionnaires: at t1 and follow-ups 4 weeks (t3) and 6 months (t4) after t1, with no decliner questionnaire at t2.

Measurement instruments

All measurement instruments were used in a validated German version.

Primary outcome. Level of depression was measured with Patient Health Questionnaire, 9 items; a score >15 is associated with clinical levels of depression, and scores are sums ranging from 0 to 27.[16,17]

Secondary outcomes. Generalised anxiety disorder was assessed using the Generalised Anxiety Disorder Questionnaire, 7 items; a score >10 indicates general anxiety disorder, and scores are sums ranging from 0 to 21.[18,19]

Subjective distress was measured using the National Comprehensive Cancer Network's Distress Thermometer; a score >5 indicates a clinically relevant level of distress, scale range 0–10, from 'No distress' to 'Extreme distress'.[20]

Minor mental disorders were assessed using the General Health Questionnaire, 12 items, with higher scores indicating higher level of mental disorder; scores are sums of item values ranging from 0 to 36.[21,22]

Positive and negative affect were measured using the Positive and Negative Affect Schedule, with higher scores indicating higher levels of affect; scores ranging from 1 to 5 are means of positive and negative items, respectively.[23,24]

Life satisfaction was measured using the Satisfaction with Life Scale, with higher scores indicating higher degree of satisfaction; scores are sums of item values ranging from 0 to 36.[25,26]

Quality of life was assessed using the World Health Organization Quality of Life Questionnaire, abbreviated version: scores range from 0 to 100, with higher scores denoting higher quality of life; scores were built according to the manual guidelines, including handling of missing data.[27,28]

Health-related resource use of the past 6 months (number of physician contacts, physiotherapist contacts, hospital days, and rehabilitation days) was collected using the German questionnaire for health-related resource use in an elderly population (at t1 and t4).[29] Individual costs were added up after assigning a cost to each component based on unit prices published by Bock et al.[30]

Three numerical rating scales with one item each measured quality of life, physical impairment and psychological impairment, with scores ranging from 0 to 10, with higher scores indicating higher levels. Of all the used scales, only in the manual of the World Health Organization Quality of Life Questionnaire,[27,28] guidelines on how to treat missing data were provided: Outcomes were only computed if at least 80% of the items in a scale were available and the missing items were imputed with the mean of the available items. Otherwise the whole observation was discarded. For consistency, we applied this approach to all scales.

Factors of the health belief model. Rosenstock's Health Belief Model, designed to predict health-promoting behaviour, was employed in order to understand reasons for declining.[31,32] The following four factors of the Health Belief Model each comprised several variables and were included in questionnaires for decliners and for the randomised controlled trial.

'Modifying factors': age, gender, knowledge about depression (numerical rating scale ranging from 0 to 10) and self-efficacy (German general self-efficacy short scale) scores are means ranging from 1 to 5, with higher scores indicating higher levels.[33]

Factor 'perceived susceptibility and severity': two numerical rating scales with 0–10 ranges on susceptibility for and severity of suffering from depression.

Factor 'perceived benefits and barriers': four numerical rating scales on scepticism of benefit of the intervention (adapted from Patient Questionnaire on Therapy Expectation and Evaluation,[34] 1–5 range), belief in benefit (adapted from German questionnaire for measurement of psychotherapy motivation,[35] 1–5 range), belief one should cope alone (adapted from German questionnaire for psychotherapy motivation,[36] 1–4 range), and belief that the intervention benefit would be greater than the costs (1–4 range). Higher scores indicate higher agreement.

Factor 'cues to action': three numerical rating scales on advice from family/friends to accept psychological support, the extent of support by family/friends and the quality of the relationship with the patient, with higher scores indicating higher levels.

Statistical analysis

Changes in the outcomes over time were evaluated via general linear mixed model with random intercept for subjects. These models allowed several measurements per participant and change over time. A separate regression model was built for each outcome measure.

Outcomes from all three post-treatment questionnaires (t2, t3, t4) were dependent variables. Variables 'group' (sEBT or control group) and 'time of investigation' were independent variables. The interaction effect between 'group' and 'time of investigation' was only included if significantly different from zero. The pre-treatment (t1) value of each outcome measure was included as a predictor variable, capturing individual status before the treatment. In all models, we controlled for age, gender, relationship with the patient (patient is partner/child vs other); patient's time of death (patient alive, unknown, deceased >3 months before measurement, <3 months before measurement); employment (employed/student vs retired/unemployed); the psychologist delivering the intervention (psychologist 1, 2 or 3); and other support used (e.g. social worker, pastoral care, other psychologist; yes, no or unknown).

Besides the main model (model 1), we conducted sensitivity analyses considering the following two subgroups of the study population: only participants (sEBT or control group) who attended both interventional sessions (model 2) and all control participants and only sEBT participants who had practised mindfulness at least once using the CD (model 3). Sensitivity analyses controlling for missing data were also conducted.

Data were analysed according to the principle 'full analysis set' which is as complete and as close as possible to the intention to treat ideal of including all randomised subjects.[37] The regression analyses included only individuals with at least one intervention session and participation in the investigations before (t1) and after the intervention (t2).

A binary logistic regression was conducted to investigate which factors led to declining or accepting the intervention. Based on Rosenstock's[31] Health Belief Model, stepwise inclusion of four factors emulated the process of decision-making for or against the intervention. An overall result was deduced from all four steps. In addition, linear mixed models with repeated measurements were used to model all outcome parameters at t1, t3 and t4 in order to detect differences in outcomes between the participants of the randomised controlled trial and the decliner participants. To analyse differences in direct health care costs, the non-parametric Mann–Whitney *U* test was used due to skewed distribution of the data. Statistical analyses

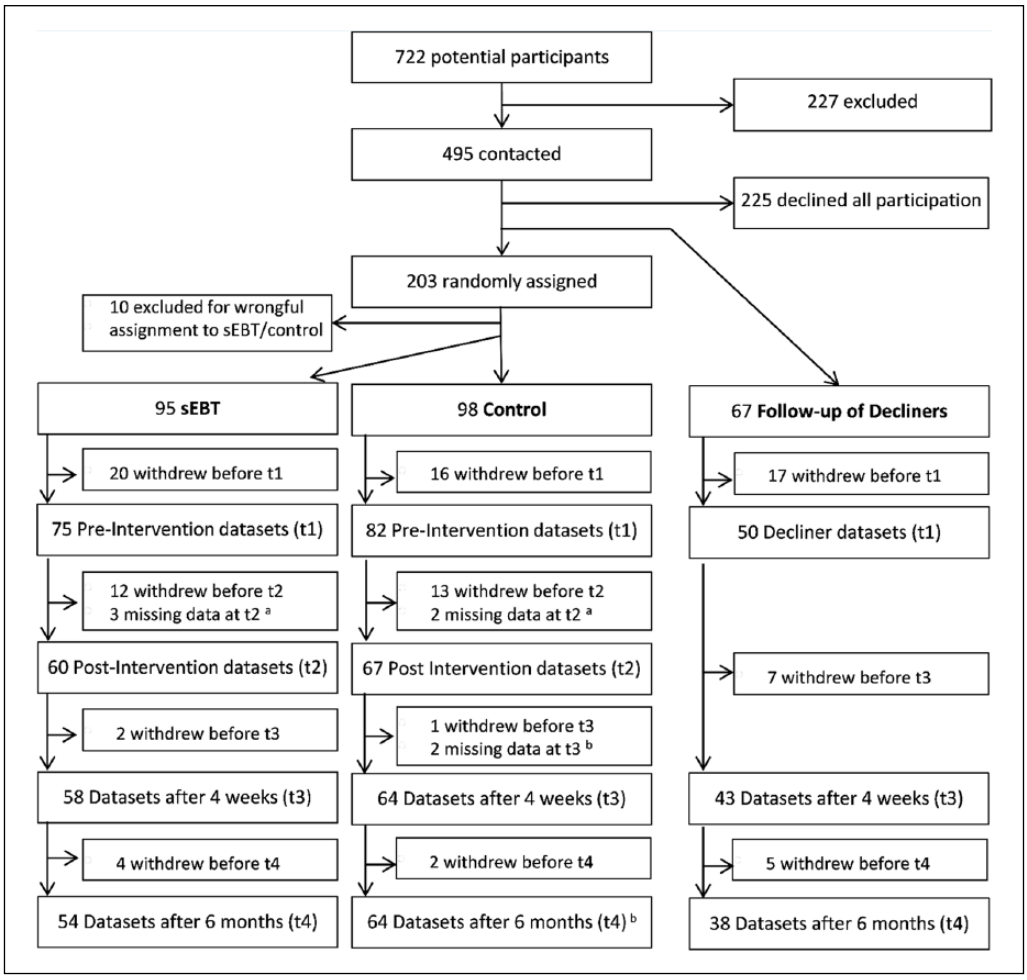

Figure 1. CONSORT diagram of participant flow.
[a]Due to missing data at t2, participants' datasets were excluded from analyses.
[b]Despite missing data at t3, participants' datasets were included in analyses.

were performed using IBM SPSS statistics V.25; a value of $p < 0.05$ was considered significant; a value of $p < 0.1$ was considered a trend.

Results

Results are reported following the CONSORT statement.

Study population

Out of 722 potential participants, 227 were excluded during recruitment (31.4%; see Figure 1), hence 495 caregivers were contacted (68.6%). Of these, 67 participated in the decliners' follow-up and 225 declined any participation. A total of 203 caregivers were randomised into the sEBT or the control group; the inclusion rate was 41.0%. During the study, 10 cases were excluded as they had been wrongfully assigned. After the randomisation, 36 participants dropped out before t1 (20 sEBT, 16 controls).

In total, 157 participants of the randomised controlled trial took part in the pre-intervention examination (t1). At t1, sEBT and control participants showed no significantly different characteristics (see Table 1). The mean age was 54.6 years (SD 14.1) and most participants were female (63.1%). More than one-third of the participants held a university degree (38.2%), more than half were married (59.2%); nearly one-third was retired (29.9%) and two-thirds employed (full time 42.7%, part time 22.0%). Participants were mostly either patients' partners (including wives or husbands; 39.5%) or their children (36.9%). Cancer was the prevailing diagnosis of the patients (79.5%). Two-thirds of participants received interventions by psychologist 3 (66.2%). Most patients were alive at t1 (84.7%; 7.0% deceased $\leqslant$3 months ago; 8.3% unknown; $n = 157$). At t2, patients were mostly alive (49.6%) or had deceased during the last 3 months (43.3%; 7.1% unknown; $n = 127$). At t3, most patients had deceased during the last 3 months (73.7%; 17.2% alive; 4.1% deceased $>$3 months ago; 4.9% unknown; $n = 122$), and at t4, most patients had

Table 1. Participant characteristics by randomised controlled trial and decliners' follow-up.

	Randomised controlled trial		Decliners (*N* = 50)
	sEBT (*N* = 75)	Control (*N* = 82)	
Age (mean, SD)	53.8 (15.2)	55.3 (13.0)	60.9 (13.1)
Female	51 (68.0%)	48 (58.5%)	33 (66.0%)
Religion			
Catholic	29 (38.7%)	31 (37.8%)	20 (40.0%)
Protestant	17 (22.7%)	19 (23.2%)	10 (20.0%)
Muslim	1 (1.3%)	2 (2.4%)	2 (4.0%)
Other	5 (6.7%)	1 (1.1%)	2 (4.0%)
None	19 (25.3%)	27 (32.9%)	14 (28.0%)
No data	2 (2.7%)	2 (2.4%)	2 (4.0%)
Education			
University degree	26 (34.7%)	34 (41.5%)	13 (26.0%)
Upper secondary	14 (18.7%)	7 (8.5%)	5 (10.0%)
Intermediate secondary	25 (33.3%)	27 (32.9%)	16 (32.0%)
Lower secondary	10 (13.3%)	10 (12.2%)	15 (30.0%)
None/no data	– –	2 (4.9%)	1 (2.0%)
Marital status			
Married	42 (56.0%)	51 (62.2%)	36 (72.0%)
In relationship	16 (21.3%)	16 (19.5%)	8 (16.0%)
Single	8 (10.7%)	5 (6.1%)	1 (2.0%)
Divorced/separated	6 (8.0%)	6 (7.3%)	3 (6.0%)
Widowed	2 (2.7%)	4 (4.9%)	2 (4.0%)
No data	1 (1.3%)		
Employment			
Full time	27 (36.0%)	40 (48.8%)	23 (46.0%)
Part time (<35 h)	18 (24.0%)	15 (18.3%)	6 (12.0%)
Student/vocational	4 (5.3%)	1 (1.2%)	– –
Retired	24 (32.0%)	23 (28.0%)	20 (40.0%)
Homemaker/unemployed	2 (2.7%)	3 (3.7%)	1 (2.0%)
Relationship with patient (Patient is my . . .)			
Wife/husband/partner	29 (38.7%)	33 (40.2%)	27 (54.0%)
Mother/father	27 (36.0%)	31 (37.8%)	18 (36.0%)
Daughter/son	5 (6.7%)	2 (2.4%)	– –
Sister/brother	5 (6.7%)	6 (7.3%)	4 (8.0%)
Friend	5 (6.7%)	4 (4.9%)	– –
Grandmother/grandfather	1 (1.3%)	1 (1.2%)	– –
Other	3 (4.0%)	5 (6.1%)	1 (2.0%)
Diagnosis of patient			
Digestive tract cancer	17 (22.7%)	14 (17.1%)	7 (14.0%)
Genito-urinary cancer	10 (13.3%)	4 (4.9%)	7 (14.0%)
Breast cancer	10 (13.3%)	7 (8.5%)	4 (8.0%)
Brain cancer	6 (8.0%)	7 (8.5%)	2 (4.0%)
Lung cancer	7 (9.3%)	11 (12.6%)	9 (18.0%)
Gynaecological cancer	4 (5.3%)	10 (12.2%)	4 (8.0%)
Other cancer	5 (6.7%)	15 (18.3%)	5 (10.0%)
Neurological disease	7 (9.3%)	6 (7.3%)	9 (18.0%)
Other disease	9 (12.0%)	10 (12.2%)	3 (6.0%)
Psychologist delivering the intervention			
Psychologist 1	14 (18.7%)	14 (17.1%)	– –
Psychologist 2	12 (16.0%)	13 (15.9%)	– –
Psychologist 3	49 (65.3%)	55 (67.1%)	– –

SD: standard deviation.
Data are number (%) or mean (SD).

Table 2. Estimated regression coefficients beta and *p*-values for the independent variables in general linear mixed models with the primary outcome variable post-treatment *depression*.

Variable[a]	Category[b]	Model 1		Model 2		Model 3	
		n = 126		*n* = 114		*n* = 104	
		Beta	*p*-value	Beta	*p*-value	Beta	*p*-value
Gender	Male	–.457	0.407	–.293	0.627	–.588	0.325
Relationship with patient	Partner/child	–.666	0.283	–.553	0.413	–.897	0.185
Employment	Retired/other	–.645	0.443	–.259	0.777	.488	0.601
Support apart from study	Unknown	1.40	0.365	1.32	0.408	2.01	0.231
	Support	.599	0.403	.366	0.631	.789	0.325
Group	sEBT intervention	–.147	0.780	–.273	0.640	–.393	0.515
Time of investigation	t3	–.796	**0.031**	–.957	**0.016**	–.984	**0.021**
	t4	–1.32	***0.085***	–1.72	**0.036**	–1.76	**0.035**
Patients' time of death	Unknown	.574	0.616	.285	0.822	.194	0.871
	Alive	–.381	0.421	–.490	0.335	–.623	0.245
	Deceased >3 months	–1.02	0.183	–.900	0.270	–.882	0.277
Age		.025	0.426	.013	0.695	–.005	0.873
Psychologist	Psychologist 1	–.256	0.743	–.380	0.643	–.608	0.455
	Psychologist 2	.465	0.532	.312	0.695	.678	0.405
Depression at t1		.612	**<0.001**	.618	**<0.001**	.595	**<0.001**

Main model: participantsfirst two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations of at least the : model 2 without participants (sEBT and control group) with only one session and model 3 without participants of the sEBT group who did not practise.

[a]Variables are in bold or bold italics depending on the significance of the *F*-test for the whole variable. Bold: significant at *p*-value < 0.05. Bold italics: *p*-value between 0.05 and 0.10 (trend).

[b]Reference categories: gender – female; relationship with patient – other; employment – employment/student; support apart from study – no support; group – control; time of investigation – t2; patient deceased – deceased ⩽3 months; psychologist – psychologist 3.

deceased more than 3 months ago (83.9%; 3.4% deceased ⩽3 months ago; 6.8% alive; 5.9% unknown; *n* = 118; see Supplemental Material Appendix A).

Thirty participants of the pre-intervention examination (t1) were not included in the main data analysis because they dropped out during the intervention or had missing data at t2 (see Figure 1). An independent-sample *t*-test indicated that these drop-outs had higher levels of negative affect at t1 (mean: 2.58, SD: 0.61) than participants included in the main analysis (mean: 2.22, SD: 0.68; *p*-value: 0.010), and they tend to higher levels of minor mental disorders (mean: 1.48, SD: 0.46) than participants included in the main analysis (mean: 1.30, SD: 0.45; *p*-value: 0.058; unequal variances). They did not significantly differ in any other outcome or characteristic.

A total of 127 participants were included in the main regression analysis (model 1) according to the principle of 'full analysis set' as they participated in at least the first two investigations at t1 and t2. These participants showed mild and subclinical levels of depression at t1 (mean: 8.79, SD: 5.20). The sample's average score on anxiety was just under the cut-off for clinically relevant levels (mean: 9.69, SD: 4.77). Their average level of distress was above the score indicating clinical relevance (mean: 7.50, SD: 2.00).

At t3, 122 datasets were available and included in analyses. At t4, 118 datasets were available and included.

The percentage of scales with at least one missing item was 7.49%. By including observations which had at least 80% of items completed, we were able to lower the number of scales that had to be discarded to 3.74%.

Treatment integrity

In total, 291 intervention sessions were held (sEBT and control, including dropouts), 29 participants received only one session. 274 audiotapes of the intervention sessions were available (94.2%), eight were incomplete and not rated; five participants declined consent for audiotaping. 266 audiotapes were rated to evaluate treatment integrity. The therapists' adherence to the intervention manual was high (sEBT mean: 3.80, SD: 0.36; control mean: 3.87, SD: 0.33).

Primary outcome

The level of depression did not differ significantly between sEBT and control group (sEBT beta: –.147; control group as reference category); this was true for all three models (see Table 2). Apart from the impact of pre-treatment depression, there was a trend for the time of investigation being associated with the post-treatment depression level (t3 beta: –.796; t4 beta: –1.32; t2 as reference category),

as depression was on average lower at t3 and t4 than at t2. The interaction effect between the group and the time of investigation was not included in the main model since it was not significantly different from zero.

Secondary outcomes

According to the results of the main models, all post-treatment secondary outcomes did not significantly differ between sEBT and control group (for tables see Supplemental Material Appendix B). The interaction effect between the group (sEBT/control) and the time of investigation was not included in the main models as it was not significantly different from zero, except for psychological impairment. Time of investigation was significantly associated with outcomes anxiety (t3 beta: –1.21; t4 beta: –1.67; t2 as reference category), positive affect (t3 beta: .158; t4 beta: .290) and minor mental disorders (t3 beta: .1.32; t4 beta: 2.96), and was associated by trend with negative affect (t3 beta: .127; t4 beta: .165) and quality of life (numerical rating scale; t3 beta: .444; t4 beta: .574).

Patients' time of death was significantly associated with outcomes negative affect (alive beta: .066; deceased $>$3 months ago beta: –.289; time of death unknown beta: .086; deceased $\leqslant$3 months ago as reference category), satisfaction with life (alive beta: –1.38; deceased $>$3 months ago beta: .984; time of death unknown beta: –1.70), subjective distress (alive beta: .424; deceased $>$3 months ago beta: –1.13; time of death unknown beta: .360) and psychological impairment (alive beta: .615; deceased $>$3 months ago beta: .456; time of death unknown beta: 1.83); patients' time of death showed a trend to be associated with anxiety (alive beta: .011; deceased $>$3 months ago beta: –1.55; time of death unknown beta: .982). Relationship with the patient was significantly associated with quality of life (numerical rating scale; partner/child beta: –.680; other relationship as reference category). Age showed a trend to be associated with subjective distress (beta: .033) and gender showed a trend to be associated with psychological impairment (male beta: –.613 female gender as reference category).

In addition, we conducted sensitivity analyses regarding missing data (for tables see Supplemental Material Appendix C). Participants without missing items in any of the relevant outcome scales were regarded as having no missing data (n = 45, 35.4%); they were significantly younger than participants with missing data (n = 82). A variable discriminating between these two groups was added to an additional set of regression analyses. These analyses yielded highly similar results compared the analyses described above, apart from the variable missing data being associated by trend with negative affect (no missing data beta: .155).

At t1, a Mann–Whitney U test showed that, at t1, there was no significant difference between the median of direct health care costs for the past 6 months of sEBT participants (median: €450, n = 51, interquartile range: 846.4) and controls (median: €328, n = 62, interquartile range: 558.8).

At t4, there was also no significant difference between the median of direct health care costs for the previous 6 months of sEBT participants (median: €224, n = 54, interquartile range: 560.2) and controls (median: €301, n = 64, interquartile range: 829.9).

Decliners' follow-up

Data of 50 decliners were available at t1, as 17 dropped out before t1. Data of 43 decliners were available for the follow-up at t3 and data of 38 decliners at t4. Declining participants were significantly older (mean: 60.9 years, SD: 13.1) than participants of the randomised controlled trial (mean: 54.6, SD: 14.1) but did not significantly differ regarding gender, relationship status or employment.

Linear mixed models with repeated measurements modelling all outcome parameters at t1, t3 and t4 showed no differences in any outcomes between the participants of the randomised controlled trial and the decliner participants.

The binary logistic regression showed that the preference towards the decliner study significantly depends on 'perceived benefit and barriers' and 'cues to action' (see Table 3). The odds to prefer the decliners' follow-up were 2.45 times higher for caregivers with high self-efficacy (95% confidence interval: 1.06–5.65), 1.71 times higher when being sceptic of the benefit of the intervention (95% confidence interval: 1.12–2.61), 2.21 times higher for caregivers who believed in better coping alone (95% confidence interval: 1.28–3.81) and 1.30 times higher for caregivers supported by family and friends (95% confidence interval 1.01–1.69).

Discussion

Main findings of the study

The purpose of sEBT is to provide a short-term intervention with coping strategies to informal caregivers of palliative patients facing the existential situation of disease and bereavement. This randomised controlled trial studied the impact of sEBT on depression, anxiety, subjective distress, minor mental disorders, positive and negative affect, satisfaction with life, quality of life and direct health care costs. Receiving sEBT sessions or supportive psychological sessions was neither significantly associated with the primary outcome of post-treatment depression nor with the secondary outcomes. The outcomes were prevailingly associated with their respective level before the intervention and with the time of investigation, which leads to the assumption that the time passing was the main reason for changes of outcomes over the course of 6 months. Caregivers who declined the intervention did not differ significantly from participants of the randomised controlled trial in outcomes at any assessment.

Table 3. Preference for decliners' follow-up or participation in the randomised controlled trial explained by 'Health Belief Model' comprising four factors (modifying factors, perceived susceptibility and severity, perceived benefit and barriers, and cues to action).

Factors		Predictors	Odds ratio[a]	*p*-value[a]	95% CI[a]
Modifying factors	First model Nagelkerkes $R^2 = .066$	Age	1.02	.263	.99–1.06
		Sex	1.81	.240	.67–4.89
		Knowledge	.98	.824	.82–1.17
		Self-efficacy	2.45	**.036**	1.06–5.65
Perceived susceptibility and severity	Second model Nagelkerkes $R^2 = .094$	Susceptibility	1.02	.865	.85–1.21
		Severity	.88	.124	.75–1.04
Perceived benefit and barriers	Third model Nagelkerkes $R^2 = .286$	**Scepticism of benefit**	1.71	**.013**	1.12–2.61
		Belief in benefit	.81	.523	.42–1.55
		Belief one should cope alone	2.21	**.005**	1.28–3.81
		Belief that benefit > cost	.77	.346	.44–1.34
Cues to action	Fourth model Nagelkerkes $R^2 = .325$	Advice from family/friends	.98	.751	.84–1.13
		Support by family/friends	1.30	**.044**	1.01–1.69
		Quality of relationship with Patient	.97	.806	.76–1.24

CI = confidence interval.
Binary-logistic regression with stepwise inclusion of factors.
Coding of outcome: preference of decliners' follow-up = 1; preference of randomised controlled trial = 0.
Coding of predictors: gender 0 = male, 1 = female; other predictors 0 = lowest level, 1 = highest level.
Bold values signifies p-value < 0.05.
[a]Data of only the fourth model reported for brevity.

Interpretation of results

In Fegg et al'.s[8] randomised controlled trial on EBT, the control participants did not receive a control treatment and instead could decline any support or could choose from the spectrum of available support at the palliative care unit (e.g. physicians, nurses, chaplains, social workers, psychologists and bereavement group), whereas this study included an active control group. It is possible that sEBT and control showed no significant difference as both groups received a treatment of similar effectiveness.

Palliative caregivers' capacities for learning new skills like mindfulness might be limited: they face high emotional distress and the responsibilities palliative caregivers typically take over for the patient (i.e. financial decisions, organisation of follow-up hospice care) additionally to their own duties. Fegg et al'.s[8] study provided a group setting which could have facilitated learning the new skill of mindfulness by benefitting from group cohesion, central for beneficial effects in group therapy[38,39] or by relieving participants from the personal responsibility to practice. Participants in sEBT were asked to practice mindfulness by themselves which was possibly too demanding, leading to low compliance to practice and less effectiveness.

Our aim was to create a short-term EBT intervention that fitted better into informal caregivers' daily lives. We reached our goal of increasing acceptability: 41.0% of all contacted caregivers participated in the randomised controlled trial. Shortening EBT and choosing an individual setting tripled the inclusion rate compared with 13.6% in Fegg et al'.s[8] study. However, by shortening the intervention, we traded inclusion rate for effectiveness and the intervention was not intensive enough to impact caregivers' psychological state in comparison to the control group.

Carmody and Baer's[40] review about the optimal length of mindfulness based programmes, with participants ranging from healthy to chronically ill participants, did not evidence that shortened versions of mindfulness-based programmes are less effective compared with the standard format of 26 class hours. The authors suggested that adaptations including less class time may be worthwhile for populations for whom a longer time commitment may be a barrier to participate.

But how short is too short? The study with the fewest sessions in Carmody and Baer's[40] review included 6-weekly 1-h classes,[41] which is three times more instruction time than in this study. Our results lead to the conclusion that the 2-h sEBT version is too short, especially with participants as burdened as palliative caregivers. The optimal length of mindfulness-based interventions for informal caregivers should be investigated further to offer interventions which impact caregivers' psychological status while not overwhelming them.

Strengths and limitations

Strengths of the study include the randomised controlled design, the high adherence of the therapists to the manual and the embedded decliners' follow-ups which allowed a comparison with trial participants and ensured high external validity.

During the study, it became apparent that 10 participants had been assigned to sEBT or control group violating the randomisation protocol. Recruiting was suspended, all data collected up to this point was carefully checked and affected participants' data were excluded from analysis. In addition, appropriate measures of staff change and staff training were taken.

Data of 30 caregivers were removed from analysis as they had missing post-intervention data at t2 or dropped out of the intervention. Comparing their pre-intervention data to the other participants, they had higher levels of negative affect and of minor mental disorders which possibly caused them to drop out. This leads to the assumption that the intervention might be too demanding for highly burdened caregivers.

Implications of our study and future research

Profiting of the 'small window'[6] for recruiting caregivers before they become too burdened by care could be facilitated with early integration of palliative care.[42,43] Early integration of sEBT could help caregivers learn new skills to prepare for stressful times ahead.

Furthermore, sEBT could benefit from mixing the settings. Sörensen et al.[44] suggested combining group and individual setting to improve caregiver affect in the individual setting and help build social networks in the group. Individual sEBT could offer immediate support to caregivers, while a following EBT group could yield higher impact on caregivers' psychological morbidity with more class hours and positive influence of group cohesion[38] on motivation and personal practice.

Acknowledgements

We thank all caregivers, patients and staff members especially Verena Zierl, Marianne Schmidt and Sigrid Haarmann-Doetkotte for their contribution to this study.

Author contributions

M.F. designed the study L.M. and V.D. provided statistical consultation and designed the regression model. M.K. collected the data, carried out the statistical analysis, and drafted the manuscript. H.S. provided consultation on pricing data analysis. S.S. conducted the intervention. L.M., V.D., H.S., S.S., C.B. and M.F. critically commented on, read and approved the final manuscript.

Data management and sharing

Ethical approval precludes the data being provided to researchers who have not signed the appropriate confidentiality agreement. These restrictions are as per the Ethics Committee of Ludwig-Maximilians University Munich which approved the study (REC No. 545-12). In accordance with ethical approval, all results are in aggregated form to maintain confidentiality and privacy. Data are held at the Department of Palliative Medicine, Munich University Hospital, Ludwig-Maximilians-University, Munich, Germany.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship and/or publication of this article: Stifterverband für die Deutsche Wissenschaft e.V. (H420 7218 9999 25214).

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Supplemental material

Supplemental material for this article is available online.

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