Aus der Klinik und Poliklinik für Palliativmedizin

Klinik der Ludwig-Maximilians-Universität München

Direktorin: Prof. Dr. med. Claudia Bausewein PhD MSc

Caregivers of Palliative Patients: Measurement of Burden and Psychological Intervention

Dissertation

zum Erwerb des Doktorgrades der Humanbiologie

an der Medizinischen Fakultät der

Ludwig-Maximilians-Universität zu München

vorgelegt von

Martina Kühnel

aus

Stuttgart

2021

Mit Genehmigung der Medizinischen Fakultät
der Universität München

Berichterstatter:	Prof. Dr. rer. biol. hum. Martin Fegg
Mitberichterstatter:	Prof. Dr. med. Jochen Gensichen
	Prof. Dr. med. Frank Padberg
Dekan:	Prof. Dr. med. Thomas Gudermann

Tag der mündlichen Prüfung: 04.10.2021

Eidesstattliche Versicherung

Ich erkläre hiermit an Eides statt, dass ich die vorliegende Dissertation mit dem Thema

Caregivers of Palliative Patients:
Measurement of Burden and Psychological Intervention

selbständig verfasst, mich außer der angegeben keiner weiteren Hilfsmittel bedient und alle Erkenntnisse, die aus dem Schrifttum ganz oder annähernd übernommen sind, als solche kenntlich gemacht und nach ihrer Herkunft unter Bezeichnung der Fundstelle einzeln nachgewiesen habe.

Ich erkläre des Weiteren, dass die hier vorgelegte Dissertation nicht in gleicher oder in ähnlicher Form bei einer anderen Stelle zur Erlangung eines akademischen Grades eingereicht wurde.

München, den 09.10.2021

Martina Kühnel

Table of contents

Abbreviations

CBT	Cognitive Behavioural Therapy
EBT	Existential Behavioural Therapy
RCT	Randomised controlled trial
sEBT	Short-term Existential Behavioural Therapy
MBI	Mindfulness based intervention
ZBI	Zarit Burden Interview

Publications included

Publication I

Kühnel, M.B., Ramsenthaler, C., Bausewein, C., Fegg, M., Hodiamont, F. (2020) Validation of two short versions of the Zarit Burden Interview in the palliative care setting: a questionnaire to assess the burden of informal caregivers. *Supportive Care in Cancer*, 28(11): p. 5185-5193. https://doi.org/10.1007/s00520-019-05288-w

Published online: 15 February 2020

Journal Impact Factor 2018: 2.754

Publication II

Kühnel, M.B., Marchioro, L., Deffner, V., Bausewein, C., Seidl, H., Siebert, S., and Fegg, M. (2020). How short is too short? A randomised controlled trial evaluating short-term existential behavioural therapy for informal caregivers of palliative patients. *Palliative Medicine*, 34(6): p. 806-816. https://doi.org/10.1177/0269216320911595

Published online: 29 April 2020

Journal Impact Factor 2018: 4.956

1 Introduction

The following introduction is divided into three sections. The first section clarifies the term ‘informal caregiver’, illustrates the role of caregivers and describes consequences of caregiving (1.1). In the second part, instruments that measure effects of caregiving are outlined and exemplified by the Zarit Burden Interview (1.2). The last section describes interventions for caregivers and elucidates mindfulness-based interventions through the example of Existential Behavioural Therapy and its short-term version (1.3).

1.1 Caregivers of palliative patients

Palliative care, as defined by the World Health Organisation (WHO), aims to treat the symptoms of patients who suffer from diseases and conditions which are potentially life threatening.[1] While worldwide an estimate of 40 million people need palliative care every year, only around 14 % have access to it and as chronic diseases are increasing and populations are aging, the need for palliative care is predicted to grow even further.[2] Providing adequate palliative care is a challenging task for national health systems. In a ranking of countries on the basis of their integration of hospice and palliative care services into mainstream health service provision, Germany is ranked in the top group of countries with advanced integration.[3] Since 2007, every health insurant in Germany is legally entitled to receive specialised palliative care.[4] According to the German Association for Palliative Medicine there were 345 palliative care wards in Germany in 2019.[5] Due to the life-threatening condition, both patients and their families can be faced with physical, psychosocial or spiritual difficulty.[2] Therefore, the WHO defined that the aim of palliative care is to improve the quality of life of not only palliative patients and but also of their families.[1] This includes providing emotional support during the illness and for the bereaved [1] – a remarkable aspect of this branch of medicine, as it means to expand care to the caregiver and to provide support even after the patient has passed away.

The term “caregiver” has a variety of meanings. The subject matter of the publications included in this thesis are informal caregivers[1]. In contrast to nursing staff in hospitals and staff of out-patient nursing services, informal caregivers can be defined by not being financially rewarded for the care they provide.[6] They can be family members or people who are not related to the patient, such as friends or neighbours. Informal caregivers often unexpectedly take over responsibilities due to the poor health of another person. One way to

[1] If the term ‘caregiver’ is not specified it refers to informal caregivers.

become the informal caregiver of a patient is being given power of attorney by the patient. This is usually documented in the living will or in an advance health care directive of a patient. If the patient has made no such provision, informal caregivers can be installed as legal guardians by court. When the patient is admitted to hospital, caregivers can be named as emergency contact, which is often the only information about a caregiver available to hospital staff. The caregiver listed could not only be contacted in case of emergency but also by social services when planning the discharge. Helping the hospital staff with discharge planning is one of a variety of caregivers' potential responsibilities, which include financial procuration, health care decision making, taking care of the patient's home, children or pets, visiting or offering emotional support for the patient.

By taking over responsibility for the patient, caregivers support the medical treatment of a patient, they are "key partners" [7] to the health care system. Many care situations are possible only due to caregivers' efforts [8]: A lot of palliative patients wish to die at home [9] and this wish can only be granted when caregivers are able and willing to organise the professional treatment of patients at home. Caregivers can slip out of focus as a palliative care team's task of treating the patient can be time consuming. Overseeing caregivers, however, and not including them in treatment decisions can reduce the adequacy of the treatment: While the professional team bring their expertise to the table, only caregivers know about factors in the home environment, which could improve the care or which might put the patient's care at risk. Caregivers' own instability might be a reason for refraining from discharging a patient to the home setting.

The concept of "total pain" introduced by Cicely Saunders [10], the founder of the modern hospice movement, can serve as a guideline to palliative care and raises awareness to the different facets of struggles a patient can face. "Total pain" includes a person's physical, psychological, spiritual, practical and social struggles [10], which also comprises the importance of social relations, such as relationships with caregivers. The implementation of the "total pain" concept should raise awareness for the physical and mental state of patients' caregivers. When patients are distressed, it is likely that caregivers are distressed – and vice versa.[11]

Some studies described positive aspects of caregiving and cited caregivers who reported that caregiving had a positive impact on their relationships, increased their wellbeing and gave them a sense of accomplishment.[12] Understanding positive aspects and identifying

predictors of positive outcomes may identify caregivers who are less likely to need support.[13]

However, studies on positive aspects of caregiving are rare and majority of studies on effects of caregiving focus on negative aspects and several negative effects of caregiving have been found.[14, 15] Especially palliative caregivers are affected, as results of a study show, in which end-of-life caregivers were compared to short-term and long-term caregivers. The authors found that caregiving at the end of life is probably the most intense type of caregiving and potentially causes the highest caregiver burden.[7]

A recent retrospective study showed a prevalence of psychological morbidity for end-of-life caregivers of 83% compared to 15% in the general population.[16] Previous studies had already found that, compared to the general population, caregivers have an increased risk for anxiety [17] and depression [18], lower quality of life [19] and higher mortality even [20]. Adverse effects of caregiving have been found to increase progressively with the number of hours devoted to care.[21] Reasons for adverse effects may be that caregivers have neither the time, nor the ability, the knowledge or the resources to maintain their own health and quality of life while taking care of another person.[7] The concept of learned helplessness, developed by Seligman [22] could also explain adverse psychological effects of caregiving. According to Seligman's theory, people who perceive events as uncontrollable will develop the belief of being helpless which can promote the development of mental disorders. Caregivers could regard the terminal illness of the patient as uncontrollable because they have no influence on the progression of the disease or on the effects of therapies. This could lead to helplessness, resignation and symptoms of depression or anxiety.[22]

While findings on psychological health are rather consistent, differences of physical health between caregivers and the general population are less unanimous. In some studies, caregivers report worse mental and physical health than the general population.[23, 24] Other studies show that caregivers of patients staying at home have better or similar physical health than non-caregivers.[17, 25] A reason for this might be self-selection, resulting in only physically healthy caregivers shouldering the burden of homecare.

Caregiving can also interfere with caregivers' paid work. Some caregivers take unpaid leave which can lead to in financial difficulties, they could miss out on career opportunities or even risk losing their job.[7, 26] In particular younger caregivers reported great ambivalence about

the choice between caregiving and professional pursuits.[27] Additionally, job insecurity is highly associated with poorer mental health.[28]

1.2 Measuring effects of caregiving

Concepts of mental disorders and their specific symptoms are results of psychological research. Instruments for measuring symptoms of depression, anxiety or distress were originally developed in psychological studies and are used in the scientific context or for diagnostics in clinical psychology.

The choice of measurement instruments varies with the specific application and depends, among others, on the type of hypotheses proposed, the type of data that should be yielded (i.e. qualitative or quantitative), specific characteristics of the sample (i.e. age, ability to read, educational level, ability to concentrate) and the amount of available resources (i.e. funding, human resources). Researchers need to balance interests and may even make a cost-quality trade-off: A structured interview, for example, may yield the preferred type of data and reduced the rate of missing data but is more costly than a self-administered questionnaire [29] due to additional personnel expenses for the interview, for the data preparation (i.e. transcription) and for the data analysis.[30] Depending on the reason for the measurement, the choice of instrument may also vary. A quick assessment may call for a short interview or a screening questionnaire. In contrast, the monitoring of progress over a long period of time requires standardisation to be unaffected by high turnover of staff which is best achieved with standardised questionnaires.[31]

Different types of measurement instruments can be used to measure the effect caregiving has on caregivers. However, these instruments may not measure outcomes adequately if they were originally developed for a different aim or target group. Measurement errors might occur if for example the participants' understanding of the items differs from the original target group. To avoid such measurement errors, it is necessary to validate instruments for the designated group of users. Caregivers of dementia patients started getting scientific attention in the 1970s [32, 33] and consequently, the first measurement instruments specifically for caregivers were developed for the dementia setting. Research in the field of palliative caregivers is a relatively recent development and hence validation studies are still needed.

The situation of palliative caregivers differs from that of dementia caregivers [34]: In 2017, 80,4% of patients treated in palliative care facilities in Germany patients had cancer.[35] The mean age of patients and caregivers in dementia care and palliative care differs as dementia is

usually diagnosed at an older age.[36] Cancer diagnoses can hit people of all ages, even though the prevalence increases with age.[37] The specific symptoms that patients show result in different care situations and the diseases show diverse timelines regarding onset and diagnosis. Caregivers and patients are often caught off guard by a cancer diagnosis and can instantaneously be confronted with existential questions due to the rapid development of some types of cancer. This surely contributes to end-of-life caregivers being one of the most highly burdened groups of caregivers [38], if not the most burdened [7].

One of the first measurement instruments designed for caregivers is the Zarit Burden Interview (ZBI).[39] The Zarit Burden Interview (ZBI) was developed in English for carers of patients with dementia. The ZBI consists of 22 items covering physical, psychosocial and financial burden of caregivers and was developed as a structured interview conducted by the researcher.[40, 41] While the name "interview" was kept, the interview style was replaced by the more economical paper-and-pencil questionnaire. As answering 22 items can be time consuming, shorter versions of the ZBI for caregiver burden were established using only certain items of the 22-item version.[42, 43] There was no adequate and validated shorter version of the ZBI for carers of palliative care patients. Therefore, Higginson et al. compared short version of the ZBI and developed the seven-item version ZBI-7 version for the palliative care setting.[44] Their ZBI-7 showed very good validity, internal consistency and discriminatory performance and the ultra-short, one-item ZBI-1 showed suitability for screening purposes.[44]

In 2010, the ZBI-22 was translated into German and validated in a study addressed at female caregivers of patients with dementia [45] but no German version of the ZBI had been validated for the palliative care context. The validity of a measurement instrument is its capability to measure what it claims to measure and is regarded as one of the most important qualities of a measurement instrument.[46] The first study included in this thesis is a validation study with the aim of validating the ZBI-7 in the palliative context.[47]

1.3 Interventions for palliative caregivers

Informal caregivers' role in providing vital care for end-of-life patients has gained appreciation since the 1980s.[48] Research shows that health care for the patient can have positive effects on caregivers. Hospice care for patients, for example, is suggested to mitigate the increased mortality of the caregivers after becoming widowed.[49] While this approach is respectable, a direct impact on caregivers' well-being should be more effective. Hence, there is a growing number of interventions aimed directly at caregivers.[14, 50-53] They are

gradually not only perceived as providers of care but also as "users of services" which recognises that caregivers have health and social needs themselves.[54] Due to this dual position, ensuring appropriate support for caregivers presents challenges.[51] Obstacles in the access of interventions might lie in caregivers' ambivalence regarding their own needs, as a qualitative study suggests [27]: Informal caregivers often do not identify as caregivers because they see their caregiving role as a part of the relationship with the patient. To some caregivers it seems abnormal to have a professional nurse take over caregiving, which prevents them from making use of professional help. Many caregivers feel more comfortable contacting nursing staff on behalf of the patient than for themselves and postpone their needs to a point after caregiving, aware that they will "fall apart".[27] Taking part in an intervention programme usually means to spend time away from the patient, which can be ambivalent to some caregivers who report being torn between the desire for time away from the duty of care and an unwillingness to leave the patient.[27]

Different types of interventions have been developed and meta-analyses or reviews on caregiver interventions have defined different categories of interventions.[55-57] So-called respite services take over care for the patient which should result in a period of rest for the caregiver.[55, 58] However, these programmes can lead to adverse effects if the caregiver performs other tasks instead of relaxing or if the substitute care is not adequate.[55, 58] Given the fact that for some caregivers leaving the patient is a serious obstacle to participation, there are also interventions designed for patient/caregiver dyads.[59, 60] Low-threshold support for caregivers can be provided in form of psychoeducational talks or presentations.[56, 57] A more intense option is therapeutic counselling, which is usually conducted in an individual setting similarly to a therapy session.[56] Skills-based interventions, in contrast, are typically offered in a group-setting. Although they often focus on improving physical care provided by caregivers, a number of programmes also include self-care skills.[57]

While the need for effective caregiver support is recognised and different kinds of supportive programmes have been developed [55-59], the range of models remains narrow in relation to caregivers' needs and preferences [59]. It has been criticised that many interventions have had a 'repair' approach and that more emphasis should be on proactive approaches to prevent adverse effects in the first place.[51]

Mindfulness-based interventions (MBIs) could close this gap as they offer an empowering, participatory approach to help caregivers cope better.[53] MBIs are often delivered in a group setting and participants learn to be present in the current moment by watching it, without

trying to change it.[61] Mindfulness, along with acceptance and questions of meaning and values, has been part of the "third wave" of cognitive behavioural therapy (CBT) declared in 2004.[62, 63] Since studies have found that MBIs can contribute to coping better with stress brought upon by daily life as well health problems [64, 65], mindfulness could also be well applicable to informal caregivers. Increased self-efficacy involves perceiving oneself as more capable to cope with a certain situation [53] which, based on Seligman's theory [22], should reduce the belief of being helpless and could consequently prevent negative effects of caregiving.

The third wave of CBT and its impact on psychotherapy inspired Fegg and colleagues to develop a new intervention programme for caregivers of palliative patients.[66] Due to caregivers' confrontation with death, they included not only third wave elements but also approaches of existential therapy [67] and therefore called the intervention Existential Behavioural Therapy (EBT).[66] EBT is a manualised group intervention aimed at caregivers of in-patients on a palliative ward. It provides a space for the exchange on existential questions of death and bereavement, in combination with mindfulness practice, stress management, self-care and the finding of meaning. The programme consists of six sessions with a total of 22 hours. EBT was tested in a randomised controlled trial (RCT) and compared with a control group receiving the usual support offered at the institution (e.g. specialist palliative care physicians and nurses, chaplains, social workers, psychologists and bereavement group). Compared to the control group, the authors found medium to large effects on anxiety and quality of life and medium effects on depression.[66] As the inclusion rate for the intervention was only 13.6%, the authors suspected the reason to be a self-selection process resulting in only caregivers in need participating.[66] It is also possible that the number of appointments, the group setting or the waiting time until the start of the intervention could have discouraged caregivers to participate.

In view of these considerations, EBT was shortened and adjusted to an individual setting to make the intervention more compatible with caregivers' daily life. The EBT short version (sEBT) incorporated the components that participating caregivers had reported most useful in an accompanying qualitative study: strengthening resources and mindfulness practice. The resulting sEBT consisted of two one-hour sessions in a one-on-one setting with a psychologist. The second study included in this thesis is a randomised controlled trial testing the effectiveness of sEBT in comparison to an active control group.[68]

1.4 Contribution to publications

Contribution to publication I

As first author of this study, I wrote the publication to this study, which was then read, commented on and approved by all co-authors. *Farina Hodiamont* had initially obtained funding and had concepted the study together with *Claudia Bausewein*, additional advice was provided by *Martin Fegg*. My responsibilities were the recruitment of informal caregivers in three settings: the two inpatient settings of palliative ward and palliative support team and in the outpatient setting of the palliative home care team; communication with the latter was supported by *Farina Hodiamont.* Further, I was in charge of communicating with the participants, handing out or posting questionnaires as well as entering paper-pencil data into the statistical database. On my initiative, the original wording of the questionnaire was challenged, the new wording discussed and finally approved by all authors. I conducted the statistical data analyses which included the descriptive statistics and the validation analyses such as the confirmatory factor analysis and its prerequisite conditions. *Christina Ramsenthaler* provided statistical advice and conducted the Rasch analysis.

Contribution to publication II

As first author of this study, I wrote the publication to this study, which was then read, commented on and approved by all co-authors. A main part of my work was the implementation of the study designed by *Martin Fegg*. With my appointment, the study was re-launched after it had been suspended for five months. Between July 2016 and February 2018, I contacted informal caregivers on the palliative ward and recruited two thirds of the participants. *Claudia Bausewein* provided advice for recruitment. While the interventions were conducted by *Sarah Siebert*, it was my responsibility to randomise participants, make appointments, assign and post the correct questionnaires at the designated time, to ensure the return of questionnaires and to enter paper-pencil data into the statistics database. *Linda Marchioro* and *Veronika Deffner* provided statistical advice and designed the general linear mixed regression model. I implemented this model for the specific outcome measures and conducted all other statistical data analyses, including the descriptive statistics, the binary logistic regression model for the decliners' follow-up and the analysis of direct health care costs, for which *Hildegard Seidl* provided additional advice.

2 Summary

This thesis includes two studies on informal palliative caregivers with the first study concerning the measurement of caregiver burden [47] and the second study introducing a short-term intervention for caregivers [68]. In this thesis, the term 'informal caregivers' covers all persons whose care for the patient is not financially rewarded, such as family members, friends or neighbours.[6]

The first study is a validation study for two short versions of the outcome measure Zarit Burden Interview (ZBI), which measures caregiver burden and originally comprises 22 items.[39, 47] The ZBI and the short-version ZBI-7 are valid instruments for measuring caregiver burden in advanced cancer and dementia [44] but there has not yet been a validation for a wider palliative care setting with non-cancer diseases. Therefore, in this prospective, cross-sectional study, the two ZBI short versions ZBI-1 and ZBI-7 were validated for informal caregivers in inpatient and outpatient palliative care settings.[47] The methods of this validation study included the analysis of response distribution and missing items to test content validity and acceptability; confirmatory factor analysis and Rasch analysis to assess the structural validity of the ZBI-7; internal consistency and inter-rater reliability were used to assess reliability; and known-groups comparisons as well as a-priori hypotheses on correlations with Brief Symptom Inventory [69], Short Form-12 [70], Distress Thermometer [71] were used to test construct validity.[47] The results showed, that the structural validity assessment confirmed the unidimensional structure of ZBI-7, that the item on overall burden was the best item for the ultra-short version ZBI-1 and that higher burden was recorded for women and for participants with poorer physical health.[47] While internal consistency was good, inter-rater reliability was moderate as proxy ratings estimated caregivers' burden higher than caregivers' self-ratings.[47] In conclusion, ZBI-7 is a valid instrument for measuring caregiver burden in palliative care and the ultra-short ZBI-1 can be used as a quick and proxy assessment when considering higher staff ratings.[47]

The second study is a randomised controlled trial (RCT) testing the effectiveness of short-term Existential Behavioural Therapy (sEBT) in comparison to an active control group.[68] Since informal palliative caregivers have an increased risk for psychological morbidity compared with the general population [16], sEBT aims at lowering psychological symptoms using mindfulness practice and resource activation.[68] sEBT is based on the group intervention EBT which originally comprised 26 hours.[66] The short-term version sEBT comprises only two one-hour sessions which are conducted by psychologists in an individual setting and should therefore be more compatible with caregivers' day to day life.[68]

Shortening the intervention aimed at increasing inclusion rate compared to the original EBT.[66, 68] The primary outcome of this study 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.[68] There were four times of investigation, before (pre) and after the intervention (post) as well as four weeks and three months after the intervention. General linear mixed models were used which allow various measurements for each participant and take change over time into account.[68] The main analysis was based on data of 127 participants and the results showed that the level of post-treatment depression and the secondary outcomes were not significantly associated with participation in either sEBT or the control intervention, instead most of the outcomes were significantly associated with the time of the investigation and the individual pre-intervention level.[68] 54 caregivers who had declined the intervention were included in a follow-up of decliners which showed that the following factors contributed significantly to the decision to decline: self-efficacy, scepticism of the benefit of the intervention, belief of better coping alone and support by family and friends.[68] In conclusion, by shortening the intervention, inclusion rate was traded for effectiveness and the intervention could not impact caregivers' psychological state.[68] It is suggested, that sEBT should be included in early integration of palliative care, that individual and group setting could be combined and that an optimal length for caregiver interventions should be investigated since the intervention used in this study was apparently too short.[68]

3 Zusammenfassung

Diese Arbeit enthält zwei wissenschaftliche Studien, in deren Mittelpunkt Angehörige von Palliativpatienten *(informal caregivers)* stehen. Während die erste Studie die Messung der Belastung Angehöriger behandelt [47], ist die zweite Studie einer Kurzzeit-Intervention für Angehörige gewidmet [68]. Unter Angehörigen von Palliativpatienten werden in dieser Arbeit alle Personen verstanden, deren Betreuung, Unterstützung oder Pflege des Patienten nicht finanziell entschädigt wird, wie z.B. Familienmitglieder, Freunde oder Nachbarn.[6]

Die erste Studie ist eine Validierungsstudie für zwei Kurzversionen des Messinstruments Zarit Burden Interview (ZBI), welches die Belastung *(burden)* von Angehörigen misst und in der ursprünglichen Fassung 22 Items umfasst.[39, 47] Das ZBI und die Kurzversion ZBI-7 sind valide Instrumente, um Belastung bei Angehörigen von Patienten mit fortgeschrittenen Krebserkrankungen oder Demenz zu messen.[44] Bisher wurde das Instrument jedoch noch nicht im palliativen Setting und für Angehörige von Patienten mit einem breiten Spektrum an Erkrankungen validiert. Daher wurden in der vorliegenden prospektiven Querschnittstudie die ZBI-Kurzversionen ZBI-1 und ZBI-7 mit einer Stichprobe von Angehörigen aus dem stationären und dem ambulanten palliativen Setting validiert.[47] Die Methoden der Studie umfassten die Analyse von Antwortverteilung und fehlenden Werten, um Inhaltsvalidität und Akzeptanz des ZBI-7 zu testen; anhand der konfirmatorischer Faktorenanalyse und der Rasch-Analyse wurde die strukturelle Validität getestet; interne Konsistenz und die Interrater-Reliabilität wurden als Maße der Reliabilität verwendet; und es wurden Vergleiche mit bekannten Gruppen *(known-group comparisons)* angestellt sowie A-priori-Hypothesen zu Korrelationen mit den Messinstrumenten Brief Symptom Inventory [69], Short-Form-12 [70] und Distress Thermometer [71] geprüft, um die Konstruktvalidität des ZBI-7 zu testen.[47] Die Ergebnisse zeigten, dass die Analyse der Strukturvalidität die unidimensionale Struktur des ZBI-7 bestätigte, dass das Item zur Gesamtbelastung sich als bestes Item für die Ultra-Kurzversion ZBI-1 erwies und dass eine höhere Belastung bei Frauen und bei Teilnehmern mit schlechterem physischen Gesundheitszustand gemessen worden war.[47] Während die interne Konsistenz gut war, ergaben sich für die Inter-Rater-Reliabilität mittlere Übereinstimmungen, da die Fremdeinschätzung der Belastung höher war als die Selbsteinschätzung durch die Angehörigen.[47] Zusammenfassend zeigte sich, dass der ZBI-7 ein valides Instrument ist, um die Belastung Angehöriger im palliativen Kontext zu messen und, dass das ultra-kurze ZBI-1 für eine kurze Einschätzung und als Fremdeinschätzung verwendet werden kann, wenn eine mögliche Überschätzung der Belastung durch die Fremdeinschätzung berücksichtigt wird.[47]

Die zweite Studie ist eine randomisiert-kontrollierte Studie (RCT), in der die Kurzzeit-Intervention Short-term Existential Behavioural Therapy (sEBT) auf ihre Wirksamkeit im Vergleich mit einer aktiven Kontroll-Intervention getestet wurde.[68] Da das Risiko für psychische Erkrankungen bei Angehörigen von Palliativpatienten im Vergleich zur Normalbevölkerung deutlich erhöht ist [16], soll sEBT, durch die Vermittlung von Achtsamkeit und die Aktivierung von Ressourcen, psychische Symptome von Angehörigen mindern.[68] sEBT basiert auf der Gruppen-Intervention EBT, die ursprünglich insgesamt 26 Stunden umfasste.[66] Die Kurzzeit-Version sEBT umfasst nur zwei einstündige Sitzungen, die im Einzelsetting von Psychologinnen durchgeführt werden, und soll daher alltagskompatibler für Angehörige sein.[68] Durch die Kürzung der Intervention sollte eine höhere Teilnehmerquote erreicht werden als bei der Vorgänger-Version EBT.[66, 68] Das primäre Outcome der vorliegenden Studie war Depression, sekundäre Outcomes waren Angst, subjektiver Distress, geringfügige psychische Störungen, positiver und negativer Affekt, Lebenszufriedenheit, Lebensqualität und direkte Gesundheitskosten.[68] Die Messzeitpunkte der Studie lagen vor (prä) und nach der Intervention (post) sowie im Abstand von vier Wochen und drei Monaten nach der Intervention. Es wurden allgemeine lineare Modelle verwendet, um mehrere Messungen pro Teilnehmer zuzulassen und Veränderungen über die Zeit hinweg sichtbar zu machen.[68] In die Hauptanalyse wurden die Daten von 127 Teilnehmern einbezogen und die Ergebnisse zeigten, dass es keinen signifikanten Zusammenhang zwischen den Werten von Depression zum Post-Messzeitpunkt und der Teilnahme an sEBT oder der aktiven Kontrollgruppe gab, stattdessen zeigten die meisten Outcomes einen signifikanten Zusammenhang mit dem Messzeitpunkt sowie dem individuellen Ausgangswert vor Beginn der Intervention.[68] 54 Angehörige, die die Teilnahme an der Intervention abgelehnt hatten, wurden in eine zusätzliche Befragung eingeschlossen, welche ergab, dass die folgenden Faktoren eine signifikante Rolle bei der Ablehnung der Intervention spielten: Selbstwirksamkeitserwartung, Skepsis gegenüber dem Nutzen der Intervention, die Überzeugung, besser allein zurecht zu kommen und Unterstützung von Familien und Freunden.[68] Zusammenfassend zeigte sich, dass durch die Kürzung der Intervention zwar eine höhere Einschlussquote erreicht wurde, dafür aber die Effektivität der Intervention beeinträchtigt wurde und sie den psychischen Zustand der Angehörigen nicht beeinflussen konnte.[68] Es wird angeregt, sEBT in die frühe palliative Versorgung *(early integration)* einzubinden, das Einzel-Setting mit dem Gruppen-Setting zu verknüpfen sowie weiter an der optimalen Länge für Angehörigen-Interventionen zu forschen, da die hier angewendete Intervention wohl zu kurz war.[68]

4 Publication I

Validation of two short versions of the Zarit Burden Interview in the palliative care setting: A questionnaire to assess the burden of informal caregivers

Authors
Martina B. Kühnel, Christina Ramsenthaler, Claudia Bausewein, Martin Fegg, Farina Hodiamont

Institution
Department of Palliative Medicine, Munich University Hospital, Ludwig-Maximilians-University, Munich, Germany

Supportive Care in Cancer
https://doi.org/10.1007/s00520-019-05288-w

ORIGINAL ARTICLE

Validation of two short versions of the Zarit Burden Interview in the palliative care setting: a questionnaire to assess the burden of informal caregivers

Martina B. Kühnel[1] · Christina Ramsenthaler[1] · Claudia Bausewein[1] · Martin Fegg[1] · Farina Hodiamont[1]

Received: 5 June 2019 / Accepted: 29 December 2019

Abstract

Purpose Several validated outcome measures, among them the Zarit Burden Interview (ZBI), are valid for measuring caregiver burden in advanced cancer and dementia. However, they have not been validated for a wider palliative care (PC) setting with non-cancer disease. The purpose was to validate ZBI-1 (ultra-short version and proxy rating) and ZBI-7 short versions for PC.

Methods In a prospective, cross-sectional study with informal caregivers of patients in inpatient (PC unit, hospital palliative support team) and outpatient (home care team) PC settings of a large university hospital, content validity and acceptability of the ZBI and its structural validity (via confirmatory factor analysis (CFA) and Rasch analysis) were tested. Reliability assessment used internal consistency and inter-rater reliability and construct validity used known-group comparisons and a priori hypotheses on correlations with Brief Symptom Inventory, Short Form-12, and Distress Thermometer.

Results Eighty-four participants (63.1% women; mean age 59.8, SD 14.4) were included. Structural validity assessment confirmed the unidimensional structure of ZBI-7 both in CFA and Rasch analysis. The item on overall burden was the best item for the ultra-short version ZBI-1. Higher burden was recorded for women and those with poorer physical health. Internal consistency was good (Cronbach's $\alpha = 0.83$). Inter-rater reliability was moderate as proxy ratings estimated caregivers' burden higher than self-ratings (average measures $ICC = 0.51$; $CI = 0.23–.69$; $p = 0.001$).

Conclusion The ZBI-7 is a valid instrument for measuring caregiver burden in PC. The ultra-short ZBI-1 can be used as a quick and proxy assessment, with the caveat of overestimating burden.

Keywords Caregivers · Caregiver burden · Palliative care · Validation studies · Zarit burden interview · Psychometrics

Introduction

According to the WHO definition, palliative care (PC) addresses the needs of patients and offers a support system to help the family cope during the patients' illness and in bereavement [1]. Not only family members but also friends or neighbours can be involved in taking care of a patient, and as long as their support is not financially rewarded, they can be defined as informal caregivers [2].

Informal caregivers can become "patients" themselves, as their psychological morbidity is substantially higher compared with the general population [3]. There is a close relationship between the patient's perceived burden and that of the caregiver [4, 5], often leading to higher caregiver burden in the later stages of the patient's illness and a corresponding increase in need for physical and emotional support for caregivers [6, 7].

There is a growing number of intervention programmes [8, 9] aiming at caregiver outcomes, such as reducing caregivers' burden, improving caregivers' coping, or their quality of life. However, quantifying the impact of interventions is impossible without validated outcome measures for caregivers. A systematic review by Michels et al. showed that the majority of studies measuring informal caregiver outcomes in PC use

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00520-019-05288-w) contains supplementary material, which is available to authorized users.

✉ Martina B. Kühnel
martina.kuehnel@med.uni-muenchen.de

[1] Department of Palliative Medicine, Munich University Hospital, LMU Munich, Munich, Germany

Published online: 15 February 2020

carer-specific measures, primarily measures of caregiver burden [10]. According to Michels et al. the Zarit Burden Interview (ZBI) [11] is one of the two most frequently used measures of burden [10], the other one being the caregiver reaction assessment (CRA) [12]. The ZBI, originally comprising 22 items [11, 13, 14], has several short forms including between four and twelve items, and the overall burden is assessed by the total score of all items, with a higher score representing greater caregiver burden [15–17]. Higginson et al. validated ZBI short versions in advanced conditions with caregivers of patients with advanced cancer, dementia, and acquired brain injury (ABI) [18]. The authors recommended using ZBI-6 and ZBI-7 (ZBI-6 plus ZBI-1) in the PC setting as they showed good validity, internal consistency, and discriminatory performance. Additionally, it was reported that the ZBI-1 might be suitable for screening [18].

However, although the ZBI is well-known and used, a formal validation of ZBI short versions in the PC setting using psychometric testing and Rasch analysis, and complementing the results Higginson et al. [18], is still lacking. Furthermore, the German ZBI 22-item version was validated by Braun et al. [19] for female caregivers of dementia patients, but not validated in a German PC setting yet.

The palliative care context differs from dementia due to often rapidly progressing diseases, and caregiving at the end of life causes the greatest caregiver burden. [20]

Therefore, the aim of this study was (1) to test the ZBI-7, the ZBI-6, and the ZBI-1 short versions for content validity, structural validity, construct validity, and reliability in the PC setting; (2) to confirm findings using Rasch analysis; (3) to evaluate the suitability of ZBI-1 as a proxy assessment for staff members; and (4) to evaluate the suitability of ZBI-1 item as an ultra-short instrument for quick assessment based on validity, reliability, and Rasch analysis.

Methods

Design

This is a prospective, cross-sectional validation study. Psychometric properties are reported according to the Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) guidelines [21, 22] and the quality criteria for measurement properties of health status questionnaires by Terwee et al. [23]. The Ethics Committee of the Ludwig-Maximilians University Munich approved the study (REC-No 772–16).

Setting and population

The study was conducted in the Department for Palliative Medicine at Munich University Hospital. Informal caregivers of patients treated by the hospital support team, and the home care team were consecutively recruited.

In the inpatient PC unit, questionnaires were included in the pre-intervention assessment of a randomized controlled trial evaluating an intervention for informal caregivers (Clinical.Trials.gov registration NCT02325167). The combination of the two studies was approved by the university's ethics committee.

Inclusion criteria were being an informal caregiver of a palliative patient, a minimum age of 18 years, proficiency in written and spoken German, and the ability to give written informed consent. Caregivers with poor general condition, caregivers of patients who had been admitted to PC the same day, or who were imminently dying were excluded. Eligibility for inclusion was assessed by a staff member.

All participating caregivers and patients provided written informed consent. Consent of a legal guardian was sought for those patients unable to give consent.

Data collection

Data were collected between February 2017 and February 2018 using self-assessed questionnaires. Demographic data included age, sex, ethnicity, religion, highest academic qualification, profession, and marital status. Information on type of relation to the patient, role in caring for the patient, and the living status was collected for caregivers. Patient data were collected from medical notes and included age, date of PC admission, symptom burden at day of admission (via routinely collected Integrated PC Outcome Scale [24]), diagnosis, and date of discharge or death.

A member of the attending PC team assessed caregiver burden as a proxy using the ZBI-1 for inter-rater agreement. Staff members were asked for written informed consent and the following demographic data: age, sex, profession, work setting, and years of experience in PC.

Caregivers, who appeared highly burdened personally or in the assessments, were offered additional supportive talks by the multidisciplinary team.

Measurement instruments

Zarit Burden Interview-7 (ZBI-7): 7-item version of the original 22-item version measuring caregivers' physical and psychosocial burden on a five-point Likert scale [13, 18]. From the German translation by Braun et al. [19], we chose the seven items (see Table 1) recommended for use in PC by Higginson et al. [18]

Brief Symptom Inventory (BSI): measuring psychological distress and psychiatric disorders with 53 items on a five-point rating scale [25].

Distress thermometer: one-item measure with a 0–10 scale ranging from "No distress" to "Extreme distress" [26].

Short form 12:12-item version of the Short Form Health Survey measuring subjective health status on three- and five-point Likert scales [27].

Analysis

Descriptive statistics were used to describe sample distribution and distribution of responses. Missing data were imputed using expectation-maximization technique as data was missing completely at random, as indicated by the non-significant chi^2 statistic in Little's MCAR test performed in SPSS [28].

Sample size

Two sample size calculations were conducted to power the study for detecting moderate reliability scores and to allow the detection of medium differences between known subgroups regarding the extent of burden ($d = 0.3$ at a power of 80% and at a significance level of 95%). Sample size estimates ranged from 64 to 144 participants, with a minimum of 90 participants needed to detect known-group differences.

Validity analysis

Content validity and acceptability comprised the analysis of ceiling and floor effects, indicated if more than 15% of responses are in the highest or lowest category [23], as well as assessment of acceptability by analysis of missing items and user comments.

Structural validity: confirmatory factor analysis (CFA) were run to confirm that all items load on one latent factor, excluding the existence of subscales [29]. CFA was run with maximum likelihood estimation as it is robust to minor deviations from normality and accounts for missing data [30, 31]. Evaluation of model fit was based on fit indices and on the chi^2/df-ratio rather than on chi^2, as the latter reacts sensitively to sample size [32]. A chi^2/df-ratio between 2 and 3 was regarded as indicative of acceptable data-model fit [32, 33]. Fit indices of CFI/TLI ≥ 0.90 were regarded acceptable, and root mean square error of approximation (RMSEA) < 0.08 was regarded as showing good fit [31].

Construct validity: we tested a priori hypotheses on scale-to-scale correlations with other measures, assuming that high correlations imply high convergent validity and suggest that the two scales measure similar concepts [34]. BSI, Distress Thermometer, and SF-12 were chosen, as they are well-known and established measurement instruments and, while not explicitly validated for caregivers in palliative care, have all been used in studies on this population [35, 36].

Twelve a priori hypotheses were formulated on ZBI-1, ZBI6, and ZBI-7—each correlating significantly with the BSI subscales depression and Global Severity Index, with the Distress Thermometer and the SF-12 subscale Mental Health Composite. Moderate correlations (0.4–0.7) were assumed, as all measures represent different aspects of burden-related caregiver outcomes. The family-wise alpha error rate was Bonferroni-corrected to a value of 0.05/12 = 0.004.

Construct validity was also determined through known-groups comparisons [34]. Eight hypotheses were formulated. We hypothesised that burden would be higher for female caregivers, due to studies suggesting sex differences [37, 38].

Table 1 Short versions, item wording, and distribution of responses ($n = 84$)

Short versions				Responses (%)					
ZBI 7	ZBI 6	ZBI 1	Items	0	1	2	3	4	Miss
Y	Y		1. Do you feel you do not have enough time for yourself?	*17.9*	21.4	41.7	14.3	4.8	0
Y	Y		2. Do you feel stressed between caring and meeting other responsibilities?	*19.0*	26.2	28.6	20.2	6.0	0
Y	Y		3. Do you feel your relative affects your relationship with others in a negative way?	*56.0*	21.4	16.7	3.6	1.2	1.2
Y	Y		4. Do you feel strained when are around your relative?	*34.5*	27.4	27.4	9.5	1.2	0
Y	Y		5. Do you feel your health has suffered because of your involvement with your relative?	*32.1*	20.2	35.7	8.3	3.6	0
Y	Y		6. Do you feel you have lost control of your life since your relative's illness?	*48.8*	17.9	20.2	9.5	2.4	1.2
Y		Y	7. Overall, how burdened do you feel in caring for your relative?	6.0	17.9	27.7	44.6	3.6	1.2

Y: yes

Italic: responses > 15%; indicating floor-effects

Miss: percentage of missing items

Possible responses to item 1–6: 0, never; 1, rarely; 2, sometimes; 3, quite frequently; 4, nearly always

Possible responses to item 7: 0, not at all; 1, a little; 2, moderately; 3, quite a bit; 4, extremely

Furthermore, a block of hypotheses referred to (a) the relationship between caregivers and patient. It was hypothesised that burden would be higher for (i) parents or partners as losing a child conflicts with life cycle expectations, and losing a partner is ranked as one of the most stressful life events [39]; (ii) those living with the patient as studies suggest that there are more negative consequences for caregivers when caregiving in-house [40]; (iii) those giving physical care to the patient, and (iv) those who had power of attorney or legal guardianship for the patient as we suspected a relationship to burden, since caregivers are neither trained nurses nor legal guardians.

A second block of hypotheses referred to (b) caregivers who felt physically strained which can impact on caregivers' distress [38]. It was hypothesised that ZBI outcomes would be higher for (i) those who scored high on the SF-12 Physical Health Composite (via median split); those who due to physical health in the past 4 weeks (SF-12) (ii) had accomplished less or (iii) had been limited in work or activities. Parametric tests were used for all comparisons, complemented by non-parametric tests to account for non-normal distribution (*t*-test and Kruskal-Wallis H-test for hypothesis (a, i); *t*-test and Mann-Whitney-U tests for all other hypotheses). Hypotheses were tested using non-imputed data to avoid misleading results due to imputation.

The first block of known-group comparisons was tested to a Bonferroni-corrected alpha of 0.05/8 = 0.006; and the last block to a corrected alpha of 0.05/3 = 0.017.

Reliability analysis

Internal consistency was assessed as an aspect of reliability [41]. Cronbach's $\alpha = 0.7–0.9$ indicated internal consistency without item redundancy.

Inter-rater reliability between self-rating of burden and proxy rating by a staff member was examined with the Intraclass Correlation Coefficients (ICC) [21] and a two-way mixed model of the type consistency [42]. ICC < 0.5 indicated poor reliability, ICC of 0.5–0.75 moderate, 0.75–0.90 good, and ICC > 0.90 excellent reliability [42].

Rasch analysis

Rasch analysis complemented the validity analyses and tested items for use as an ultra-short version. The Rasch measurement model tests validity of unidimensional measures. It assumes that the response to a ZBI item is determined by the level of burden a person experiences (person fit) and the level of burden that the item represents (item fit). The Partial Credit Model was used which does not require equidistant categories and is suitable for ordinal-level data. ZBI-7 and ZBI-6 were compared with each other, and for ZBI-1 the self-rating data was compared with the one-item proxy rating by staff members.

Best-performing item candidates for the ultra-short version ZBI-1 were determined by item fit residuals (<and> 2.5), a summary mean item and person fit close to 0 (with SD = 1), ordered Likert response scale weightings for individual answer categories for each item, and the overall floor and ceiling effect for item parameters to person parameters. Overall model fit was assessed using the X^2-test [43, 44].

CFA was run using IBM SPSS Amos 25 [45]. Rasch analysis was conducted using RUMM 2030 [46]. For all other analyses, SPSS version 25 was used [47]. A p value of < 0.05 was considered significant.

Results

Acceptability

Overall, 123 informal caregivers participated. Acceptability was assessed after 39 participants had completed the questionnaires. In open-response text fields, problems with the German translation of "care" were noted. Two participants commented "I don't nurse" and "No nursing" and 2.6–7.7% of items were missing. We therefore decided to change the wording of the German translation and employed the revised version on a sample of 84 participants. Percentage of missing items dropped to 0–1.2%, and overall, the revised version showed better characteristics than the first version. All following analyses in this study were conducted with data of the revised German version only ($n = 84$).

Characteristics of participants

Data of 84 participants who received the revised ZBI-7 were included in the analyses. Figure 1 shows the participant flow of the three settings. Most participants were female (63.1%; see Table 2); the mean age was 59.8 years (standard deviation (SD) 14.4). Approximately, one third of the participants held a university degree (32.1%), and the majority were married (76.2%). Participants were mostly partners (including wives or husbands) (53.6%) or children (32.1%) of the patients. Cancer was the prevailing diagnosis of the patients (79.8%). For characteristics of participating staff members see electronic supplementary material 1.

Structural validity

Scores were non-normally distributed for items 3, 6, and 7, with skewness of 1.215 (standard error (SE) = 0.264), 0.842 (SE = 0.264), and −0.582 (SE = 0.264), respectively; the latter left-skewed, all others right-skewed. Floor effects were observed for all items except item 7 on overall burden (see Table 1).

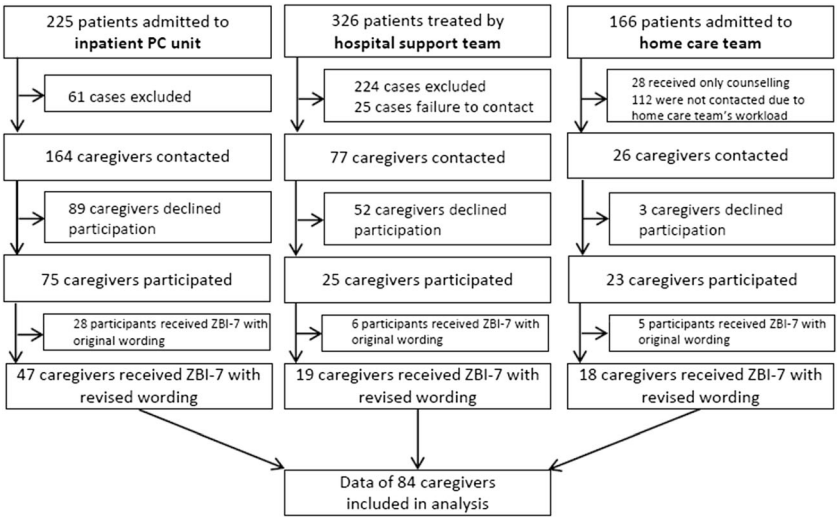

Fig. 1 Flow-chart of participants

The CFA analyses showed a good to moderate fit of a unidimensional model, meaning that all items in the ZBI short versions measure one construct, caregiver burden, only. Fit indices were good (CFI = 0.938, TLI = 0.907, standardized RMR = 0.0643), and RMSEA was moderate (RMSEA = 0.100, 90% confidence interval (CI) = 0.033–0.161). The chi^2/df-ratio was 1.84, also indicating a good fit to a unidimensional model. Overall, the fit indices and other measures (absence of Heywood cases, meaning negative variances or implausible values for variances and factor loadings) of fit confirm a unidimensional model of caregiver burden and the potential to shorten the ZBI further. All factor loadings were above 0.30, indicating good yet variable ability of individual items in the ZBI to measure the underlying construct of caregiver burden. Factor loadings varied between 0.41 for item 3 and 0.81 for item 7 on overall burden. Item 7 loaded highest onto the latent variable "burden" and showed the highest level of explained variance (see Table 3). ZBI-6 showed lower factor loadings and explained variance, as it lacks the overall item 7. The following results are therefore reported for ZBI-1 and ZBI-7 only.

Convergent validity

Correlations between the ZBI-1 and ZBI-7 scales and individual Zarit items with the Distress Thermometer, the SF-12 Mental Health subscale, the BSI global scale, and BSI depression subscale were analysed. Of the 12 a priori hypotheses nine, 75%, had hypothesised the correct direction of correlations (Bonferroni-corrected alpha level of 0.004; see Table 4).

Known-group comparisons

Caregiver burden measured with ZBI-7 was significantly higher for female caregivers The results for the outcome ZBI-1 did not reach statistical significance, based on the Bonferroni-corrected alpha level of 0.006 (ZBI-1 $t = 2.32$, $p = 0.023$; ZBI-7 $t = 2.96$, $p = 0.004$). No hypothesis in block (a) regarding relationship between carers and patient was significant.

In block (b), one of the three hypotheses concerning caregivers who felt physically strained was significant (b ii): Caregiver burden was significantly higher measured with ZBI-7 for those who had indicated on SF-12 that they had accomplished less in the past 4 weeks due to their physical health. The results for the outcome ZBI-1 did not reach statistical significance, based on the Bonferroni-corrected alpha level of 0.0017 (ZBI-1 $t = 2.01$, $p = 0.048$; ZBI-7 $t = 3.32$, $p = 0.001$). Comparisons were also run using non-parametric tests, yielding the same pattern of significant and non-significant results.

Reliability

Cronbach's α for the ZBI-7 scale was 0.83 and was reduced with removal of any item. Item 7 on overall burden (ZBI-1) correlated highest with the whole ZBI-7 scale ($r = 0.73$) and if deleted reduced Cronbach's α most (ZBI-6, Cronbach's $\alpha = 0.78$).

ICC was significant for the 1-item ratings by staff members and informal caregivers. Agreement, however, was moderate for average measures (ICC = 0.51; CI = 0.23–.69; $p = 0.001$). ICCs for the 1-item ratings of staff members and caregivers' ZBI-7 self-rating were not significant ($p = 0.211$; single measures, ICC = 0.09; CI = −0.13–0.31; average measures ICC = 0.17; $CI = -0.31$–0.47).

Rasch analysis

All three models (ZBI-7, ZBI-6, and ZBI-1) showed good model fit. Mean of ZBI-7 item difficulty was 0.00 (SD = 0.63). Item 3 "affecting relationships" measured the highest

Table 2 Descriptive characteristics of participants ($n = 84$)

Characteristic	*n*	Percentage
Setting		
Palliative care unit	47	56.0%
Hospital support team	19	22.6%
Home care team	18	21.4%
Age	59.8[a]	14.4[b]
Sex		
Female	53	63.1%
Religion		
Catholic	36	42.9%
None	31	36.9%
Protestant	17	20.2%
Other		
Nationality		
German	82	97.6%
Other	2	2.4%
Education		
University degree	27	32.1%
Upper secondary	12	14.3%
Intermediate secondary	30	35.7%
Lower secondary	13	15.5%
Missing	2	2.4%
Marital status		
Married	64	76.2%
In relationship	13	15.5%
Single	4	4.8%
Divorced/separated	2	2.4%
Widowed	1	1.2%
Relationship with patient ("Patient is my…")		
Wife/husband	43	51.2%
Partner	2	2.4%
Mother/father	27	32.1%
Sister/brother	7	8.3%
Grandmother/grandfather	1	1.2%
Friend	2	2.4%
Other	2	2.4%
Procuration for patient		
Procuration or legal guardianship	72	85.7%
No procuration or guardianship	12	14.3%
Diagnosis of patient		
Digestive tract cancer	17	20.2%
Genito-urinary cancer	12	14.3%
Brain cancer	8	9.5%
Lung cancer	7	8.3%
Gynaecological cancer	4	4.8%
Breast cancer	3	3.6%
Hemic cancer	3	3.6%
Other cancer	13	15.5%
Neurological disease	8	9.5%
Cardiovascular disease	2	2.4%
Other disease	7	8.3%

[a] Mean

[b] SD

Table 3 Factor loadings of confirmatory factor analyses with EM-imputed data of ZBI-7 and ZBI-6

	ZBI-7		ZBI-6	
ZBI Item	λ	SMC	λ	SMC
1	0.64	0.41	0.66	0.43
2	0.77	0.60	0.79	0.62
3	0.49	0.24	0.51	0.26
4	0.51	0.26	0.48	0.23
5	0.76	0.58	0.75	0.56
6	0.51	0.26	0.50	0.25
7	0.81	0.65	-	-

SMC, squared multiple correlation

λ standardized regression weight (factor loading)

levels of burden, while item 7 "overall burden" measured the lowest levels. There was no major deviation from the Rasch model as no item showed residuals of ± 2.5 and all chi^2 measures were non-significant (Bonferroni-corrected, $p < 0.001$, see electronic supplementary material 2).

The person-item threshold distribution showed a slight mismatch of item and person parameters (see electronic supplementary material 3). Items measured the medium to higher levels of burden. Person parameters (amount of burden as reported by caregivers), however, showed lower to medium values. For ZBI-1, the distribution of scores indicated lower person parameters for caregivers, indicating lower burden, than was observed for staff members' proxy ratings. Item characteristic curves showed that items 5 "health suffered" and 7 "overall burden" marginally over-discriminated by differentiating well between caregivers with high or low burden. Interval-scale assumption via category probability curves yielded items 2 "meeting responsibilities," and 4 "feeling strained" as most evenly distributed items. Moreover, item 7 "overall burden," the designated item of the ZBI-1 ultra-short version, showed comparatively good fit to the Rasch model.

The fit of the self-rated caregiver version (location = 1.172, SE = 0.136, fit residual = − 0.006) was better than the fit of the staff version (location = − 1.172, SE = 0.153, fit residual = 0.715).

Discussion

Our aim for this study was to close the gap of a formal validation of the ZBI short versions in the PC setting. Additionally, the acceptability of the German ZBI was improved by the change of wording (report in preparation).

Concerning convergent validity, scale-to-scale correlations were significant but moderate, as expected, due to the comparison instruments measuring different aspects of burden-related

Table 4 A priori hypotheses and results for construct validity using spearman correlation coefficients of the ZBI with SF-12 and BSI ($n = 84$)

Hypothesis	Scales correlated	*rho*	*p*
Moderate[a] convergent validity expected:			
Between ZBI scales and BSI (sub-)scale	*ZBI-1 + BSI Global Severity Index*	*0.41*	*0.000*
	ZBI-6 + BSI Global Severity Index	*0.53*	*0.000*
	ZBI-7 + BSI Global Severity Index	*0.53*	*0.000*
	ZBI-1 + BSI depression	0.36	0.001
	ZBI-6 + BSI depression	*0.45*	*0.000*
	ZBI-7 + BSI depression	*0.45*	*0.000*
Between ZBI scales and the Distress Thermometer	*ZBI-1 + Distress Thermometer*	*0.51*	*0.000*
	ZBI-6 + Distress Thermometer	0.35	0.001
	ZBI-7 + Distress Thermometer	0.39	0.000
Between ZBI scales and SF-12 subscale Mental Health Composite	*ZBI-1 + SF12 Mental Health Composite*	*− 0.40*	*0.000*
	ZBI-6 + SF12 Mental Health Composite	*− 0.48*	*0.000*
	ZBI-7 + SF12 Mental Health Composite	*− 0.49*	*0.000*

[a] Expected correlations: *rho* (0.4)–(0.7)

Italics: correlations that were consistent with hypotheses

caregiver outcomes. Two of the eight hypotheses formulated on known groups were significant. As suggested by other studies [37, 38], burden was higher for female caregivers, and for those with poor physical health, which also concurs with other findings [38]. Unlike expected, caregiver burden was not higher for those who were partners or parents, who lived with the patient, physically nursed, or acted as legal guardian.

Our results on reliability for ZBI-7 (Cronbach's α 0.83) were only minimally higher than in Higginson et al.'s validation (α 0.82). [18]

Analysis of structural validity using CFA and Rasch analysis confirmed the unidimensional structure of the ZBI, allowing for use of the overall score as outcome measure. ZBI-7 showed advantages over ZBI-6 in factor loadings, explained variance, and internal consistency as the additional item 7 on overall burden proved to be the best item and the best choice as the ultra-short version ZBI-1.

Our results concerning ZBI-1 differ from Higginson et al.'s validation study where ZBI-1 for cancer caregivers showed the lowest discriminative ability and the lowest correlation with the 22-item version. Higginson et al. obtained 91% sensitivity and 53% specificity for ZBI-1, meaning that ZBI-1 oversensitively rated most caregivers as burdened [18]. In our study, ZBI-1 showed good fit with the Rasch model, which means that it discriminated very well between high and low burden and only when used as a proxy rating by staff members overestimated caregiver burden.

Using ZBI-1 as a proxy rating, staff members rated caregivers' level of burden higher than in caregivers' self-ratings, resulting in mediocre inter-rater reliability. Social desirability could have led to lower self-ratings, as caregivers might have presented themselves as more stable to prevent their ability to care being questioned. A potential consequence of personnel's higher evaluation of burden could be the provision of support to caregivers who would not have asked for support themselves.

Rasch analysis and analysis of content validity suggested that items were constructed to measure higher levels of burden but caregivers reported lower levels. This may suggest a comparatively poor fit between sample and measure, resulting in false negative ratings of burden. However, participation bias could explain floor effects as participating caregivers possibly felt less burdened than those who decided to decline study participation. Dura and Kiecolt-Glaser reported a similar account of caregiver participation bias [48]. Additionally, caregivers included in this study were recruited from three specialized PC settings, which could have resulted in them being less burdened than caregivers who receive less professional support. Similarly, Higginson et al. reported lower levels of burden for advanced cancer caregivers, who had been recruited solely from specialized support facilities, while caregivers of patients with dementia and ABI showed higher levels of burden and had been recruited from diverse settings [18].

A strength of this study is that it is the first validation study of ZBI short versions that focusses on the PC setting alone. Participants were recruited in all three relevant PC settings. Additionally, this validation study was conducted with methods based on classical test theory and with Rasch analysis, which comprises aspects of item-response theory. Reliability of the ZBI-7 was higher than in previous studies and relative reliability was tested using inter-rater agreement. While the ZBI is well-known and used, our study closes the gap of a formal validation in the PC setting.

Limitations include rather low participant numbers in the home care setting due to low home care team staffing situation and high workload. Therefore, initially only few caregivers

had been contacted in this setting, and reasons for exclusion were not recorded consecutively. Inclusion decisions were hence recorded by a member of the study team. Additionally, it must be noted that the recruitment of the biggest part of caregivers was combined with an intervention study, to both preserve resources and spare caregivers, but the approach might have influenced caregivers' self-ratings. This study provides good validity for ZBI-1 as a proxy rating and potential as an ultra-short instrument, but because of lacking resources further analyses, e.g., of sensitivity or specificity, were not possible. Sample size was slightly smaller than the minimum of 90 participants needed to detect known-group differences, and subgroup comparison was infeasible due to unequal proportion of settings. However, results were obtained by combining methods of classical test theory and Rasch analysis and can therefore be regarded as robust.

In conclusion, this study complements earlier results of Higginson et al. [18]. ZBI-1 and ZBI-7 were shown to be valid in the PC context. ZBI-1 shows promising indication for use as an ultra-short instrument for caregiver burden while ZBI-7 could be used for more comprehensive measurement of caregiver burden, for example, when quantifying the impact of interventions aimed at caregivers in clinical trials and evaluation studies.

Acknowledgments The authors thank all informal caregivers and staff members who participated in our study.

Funding information Open Access funding provided by Projekt DEAL. This study was supported by the Verein zur Förderung von Wissenschaft und Forschung an der Medizinischen Fakultät der Ludwig-Maximilians-Universität.

Compliance with ethical standards

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 (No. 772-16). In accordance with ethical approval, all results are in aggregated form to maintain confidentiality and privacy. Data are held at the Klinik und Poliklinik für Palliativmedizin, Klinikum der Universität München, Ludwig-Maximilians University, Munich, Germany.

Conflict of interest The authors declare that they have no conflict of interest.

References

1. World Health Organization. Definition of palliative care. http://www.who.int/cancer/palliative/definition/en/. Accessed April 7 2019
2. Payne S (2010) EAPC task force on family carers white paper on improving support for family carers in palliative care: part 1. Eur J Palliat Care 17(5):238–245
3. Grande G, Rowland C, van den Berg B, Hanratty B (2018) Psychological morbidity and general health among family caregivers during end-of-life cancer care: a retrospective census survey. Palliat Med 32(10):1605–1614
4. Pitceathly C, Maguire P (2003) The psychological impact of cancer on patients' partners and other key relatives: a review. Eur J Cancer 39(11):1517–1524
5. Hodges LJ, Humphris GM, Macfarlane G (2005) A meta-analytic investigation of the relationship between the psychological distress of cancer patients and their carers. Soc Sci Med 60(1):1–12
6. Kurtz ME, Given B, Kurtz JC, Given CW (1994) The interaction of age, symptoms, and survival status on physical and mental health of patients with cancer and their families. Cancer 74(7 Suppl):2071–2078
7. Hashemi M, Irajpour A, Taleghani F (2018) Caregivers needing care: the unmet needs of the family caregivers of end-of-life cancer patients. Support Care Cancer 26(3):759–766. https://doi.org/10.1007/s00520-017-3886-2
8. Chi N-C, Demiris G, Lewis FM, Walker AJ, Langer SL (2016) Behavioral and educational interventions to support family caregivers in end-of-life care: a systematic review. Am J Hosp Palliat Care 33(9):894–908
9. Harding R, List S, Epiphaniou E, Jones H (2012) How can informal caregivers in cancer and palliative care be supported? An updated systematic literature review of interventions and their effectiveness. Palliat Med 26(1):7–22
10. Michels CT, Boulton M, Adams A, Wee B, Peters M (2016) Psychometric properties of carer-reported outcome measures in palliative care: a systematic review. Palliat Med 30(1):23–44
11. Zarit SH, Reever KE, Bach-Peterson J (1980) Relatives of the impaired elderly: correlates of feelings of burden. Gerontologist 20(6):649–655
12. Hudson PL, Hayman-White K (2006) Measuring the psychosocial characteristics of family caregivers of palliative care patients: psychometric properties of nine self-report instruments. J Pain Symptom Manag 31(3):215–228
13. Zarit SH, Orr NK, Zarit JM (1985) The hidden victims of Alzheimer's disease: families under stress. New York University Press, New York
14. Conde-Sala JL, Turro-Garriga O, Calvo-Perxas L, Vilalta-Franch J, Lopez-Pousa S, Garre-Olmo J (2014) Three-year trajectories of caregiver burden in Alzheimer's disease. J Alzheimers Dis 42(2):623–633
15. Bedard M, Molloy DW, Squire L, Dubois S, Lever JA, O'Donnell M (2001) The Zarit Burden Interview: a new short version and screening version. Gerontologist 41(5):652–657
16. Gort A, March J, Gómez X, Mazarico S, Ballesté J (2005) Short Zarit scale in palliative care. Med Clin (Barc) 124(17):651–653
17. Arai Y, Tamiya N, Yano E (2003) The short version of the Japanese version of the Zarit Caregiver Burden Interview (J-ZBI_8): its reliability and validity. Nihon Ronen Igakkai zasshi Japanese journal of geriatrics 40(5):497–503
18. Higginson IJ, Gao W, Jackson D, Murray J, Harding R (2010) Short-form Zarit Caregiver Burden Interviews were valid in advanced conditions. J Clin Epidemiol 63(5):535–542
19. Braun M, Scholz U, Hornung R, Martin M (2010) Caregiver burden with dementia patients. A validation study of the German language

version of the Zarit Burden Interview. Z Gerontol Geriatr 43(2): 111–119
20. Williams AM, Wang L, Kitchen P (2014) Differential impacts of care-giving across three caregiver groups in Canada: end-of-life care, long-term care and short-term care. Health Soc Care Comm 22(2):187–196
21. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, Bouter LM, de Vet HCW (2010) The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. Qual Life Res 19(4):539–549
22. Terwee CB, Prinsen CA, Chiarotto A, Westerman M, Patrick DL, Alonso J, Bouter LM, De Vet HC, Mokkink LB (2018) COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. Qual Life Res 27(5):1159–1170
23. Terwee CB, Bot SDM, de Boer MR, van der Windt DAWM, Knol DL, Dekker J, Bouter LM, de Vet HCW (2007) Quality criteria were proposed for measurement properties of health status questionnaires. J Clin Epidemiol 60(1):34–42
24. Schildmann EK, Groeneveld EI, Denzel J, Brown A, Bernhardt F, Bailey K, Guo P, Ramsenthaler C, Lovell N, Higginson IJ (2016) Discovering the hidden benefits of cognitive interviewing in two languages: the first phase of a validation study of the integrated palliative care outcome scale. Palliat Med 30(6):599–610
25. Derogatis LR, Melisaratos N (1983) The brief symptom inventory: an introductory report. Psychol Med 13(3):595–605
26. Mehnert A, Müller D, Lehmann C, Koch U (2006) [The German version of the NCCN distress thermometer: validation of a screening instrument for assessment of psychosocial distress in cancer patients]. Zeitschrift für Psychiatrie, Psychologie und Psychotherapie (54):213-223
27. Gandek B, Ware JE, Aaronson NK, Apolone G, Bjorner JB, Brazier JE, Bullinger M, Kaasa S, Leplege A, Prieto L, Sullivan M (1998) Cross-validation of item selection and scoring for the SF-12 health survey in nine countries: results from the IQOLA project. International quality of life assessment. J Clin Epidemiol 51(11): 1171–1178
28. Little RJ, Rubin DB (2002) Statistical analysis with missing data, 2nd edn. Wiley, Hoboken, NJ
29. Mokkink LB, Terwee CB, Patrick DL, Alonso J, Stratford PW, Knol DL, Bouter LM, de Vet HC (2010) The COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. J Clin Epidemiol 63(7):737–745
30. Byrne BM (2010) Structural equation modeling with AMOS: basic concepts, applications, and programming. Routledge
31. Brown TA (2010) Confirmatory factor analysis for applied research. Guilford Publications
32. Schermelleh-Engel K, Moosbrugger H, Müller H (2003) Evaluating the fit of structural equation models: tests of significance and descriptive goodness-of-fit measures. Meth Psychol Res 8(2):23–74
33. Ullman J (2001) Structural equation modeling. In: Tabachnick BG, Fidell LS (eds) Using multivariate statistics, 4th edn. Allyn & Bacon, Needham Heights, MA, pp 653–771
34. Fayers PM, Machin D (2015) Scores and measurements: validity, reliability, sensitivity. In: Fayers PM, Machin D (eds) Quality of life: the assessment, analysis and interpretation of patient-reported outcomes. John Wiley & Sons, Chichester, pp 89–124
35. Hudson PL, Trauer T, Graham S, Grande G, Ewing G, Payne S, Stajduhar KI, Thomas K (2010) A systematic review of instruments related to family caregivers of palliative care patients. Palliat Med 24(7):656–668
36. Grande GE, Austin L, Ewing G, O'Leary N, Roberts C (2017) Assessing the impact of a Carer Support Needs Assessment Tool (CSNAT) intervention in palliative home care: a stepped wedge cluster trial. BMJ Support Palliat Care 7(3):326–334
37. Pillemer S, Davis J, Tremont G (2018) Gender effects on components of burden and depression among dementia caregivers. Aging Ment Health 22(9):1162–1167. https://doi.org/10.1080/13607863.2017.1337718
38. Dumont S, Turgeon J, Allard P, Gagnon P, Charbonneau C, Vezina L (2006) Caring for a loved one with advanced cancer: determinants of psychological distress in family caregivers. J Palliat Med 9(4):912–921
39. Osterweis M, Solomon F, Green M (1984) Reactions to particular types of bereavement. In: bereavement: reactions, consequences, and care. National Academies Press (US),
40. Kaschowitz J, Brandt M (2017) Health effects of informal caregiving across Europe: a longitudinal approach. Soc Sci Med 173:72–80
41. Cortina JM (1993) What is coefficient alpha? An examination of theory and applications. J Appl Psychol 78(1):98
42. Shrout PE, Fleiss JL (1979) Intraclass correlations: uses in assessing rater reliability. Psychol Bull 86(2):420–428
43. Rasch G (1960) Probabilistic models for some intelligence and attainment tests. The Danish Institute of Educational Research, Copenhagen
44. Tennant A, Conaghan PG (2007) The Rasch measurement model in rheumatology: what is it and why use it? When should it be applied, and what should one look for in a Rasch paper? Arthritis Care Res (Hoboken) 57(8):1358–1362
45. Arbuckle JL (2017) Amos. 25.0 edn. IBM SPSS, Chicago
46. RUMM 2030 (2010). RUMM Laboratory University of Western Australia,
47. IBM SPSS Statistics for Windows (2017). 25.0 edn. IBM Corp., Armonk, NY
48. Dura JR, Kiecolt-Glaser JK (1990) Sample bias in caregiving research. J Gerontol 45(5):P200–P204

5 Publication II

How short is too short?
A randomised controlled trial evaluating short-term Existential Behavioural Therapy for informal caregivers of palliative patients

Authors

Martina B. Kühnel[1], Linda Marchioro[2], Veronika Deffner[2], Claudia Bausewein[1], Hildegard Seidl[3,4], Sarah Siebert[1], Martin Fegg[1]

Institutions

1 Department of Palliative Medicine, Munich University Hospital, Ludwig-Maximilians-University, Munich, Germany
2 Statistical Consulting Unit StaBLab, Department of Statistics, Ludwig-Maximilians-University, Munich, Germany
3 Helmholtz Center Munich, Institute of Health Economics and Health Care Management, Neuherberg, Germany
4 München Klinik, Quality Management and Gender Medicine, Munich, Germany

Original Article

PALLIATIVE MEDICINE

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

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

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

Martina B Kühnel[1], Linda Marchioro[2], Veronika Deffner[2], Claudia Bausewein[1], Hildegard Seidl[3,4], Sarah Siebert[1] and Martin Fegg[1]

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.

[1]Department of Palliative Medicine, Munich University Hospital, Ludwig-Maximilians-University, Munich, Germany
[2]Statistical Consulting Unit (StaBLab), Department of Statistics, Ludwig-Maximilians-University, Munich, Germany
[3]Institute of Health Economics and Health Care Management, Helmholtz Center Munich, Neuherberg, Germany
[4]Quality Management and Gender Medicine, München Klinik, Munich, Germany

Corresponding author:
Martina B Kühnel, Department of Palliative Medicine, Munich University Hospital, Ludwig-Maximilians-University, Marchioninistr. 15, 81377 Munich, Germany.
Email: martina.kuehnel@med.uni-muenchen.de

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

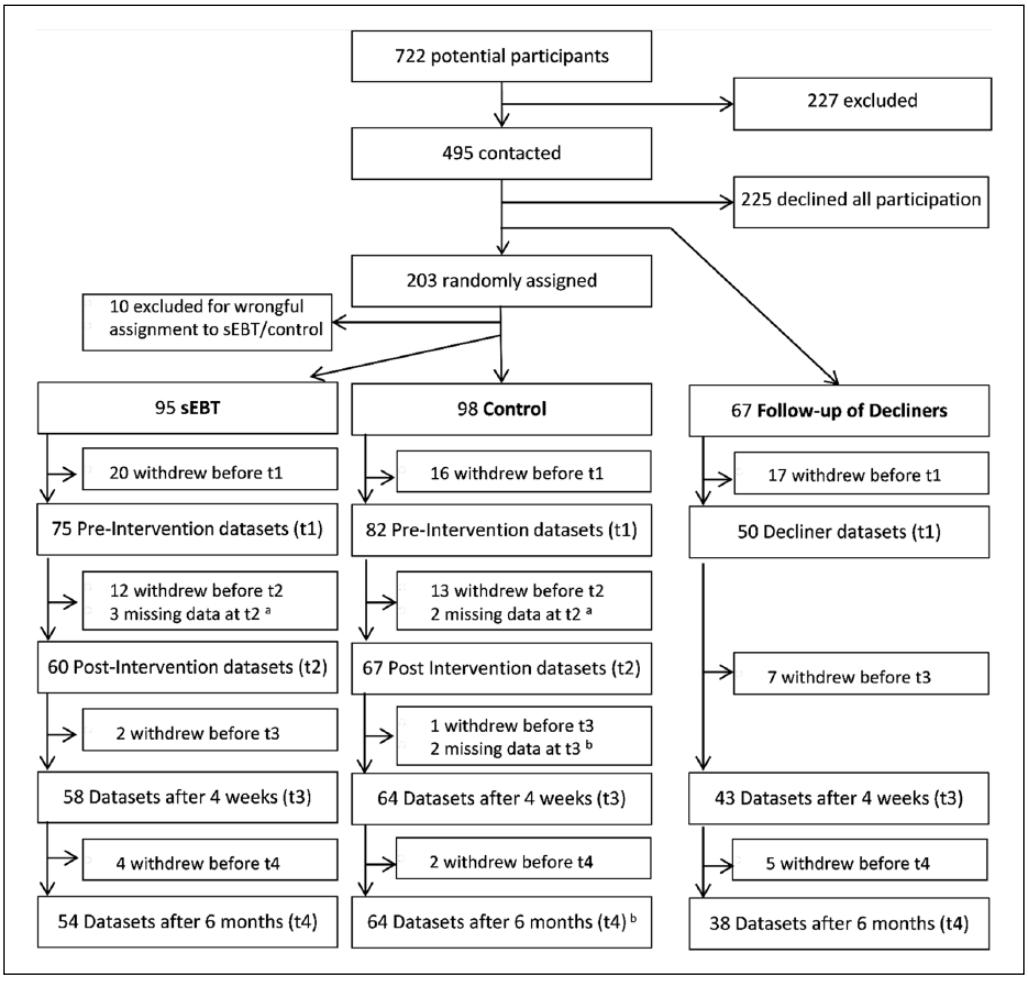

Figure 1. CONSORT diagram of participant flow.
[a]Due to missing data at t2, participants' datasets were excluded from analyses.
[b]Despite missing data at t3, participants' datasets were included in analyses.

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 ⩽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).

ORCID iD

Martina B Kühnel https://orcid.org/0000-0001-5942-8915

Supplemental material

Supplemental material for this article is available online.

References

1. Payne S. EAPC Task Force on Family Carers White Paper on improving support for family carers in palliative care: part 2. *Eur J Palliat Care* 2010; 17: 286–290.
2. World Health Organization, http://www.who.int/cancer/palliative/definition/en/
3. Hudson PL, Aranda S and Hayman-White K. A psychoeducational intervention for family caregivers of patients receiving palliative care: a randomized controlled trial. *J Pain Symptom Manage* 2005; 30(4): 329–341.
4. Pitceathly C and Maguire P. The psychological impact of cancer on patients' partners and other key relatives: a review. *Eur J Cancer* 2003; 39(11): 1517–1524.
5. Knight BG, Lutzky SM and Macofsky-Urban F. A meta-analytic review of interventions for caregiver distress: recommendations for future research. *Gerontologist* 1993; 33(2): 240–248.
6. Grande G, Stajduhar K, Aoun S, et al. Supporting lay carers in end of life care: current gaps and future priorities. *Palliat Med* 2009; 23(4): 339–344.
7. Jaffray L, Bridgman H, Stephens M, et al. Evaluating the effects of mindfulness-based interventions for informal palliative caregivers: a systematic literature review. *Palliat Med* 2016; 30(2): 117–131.
8. Fegg MJ, Brandstatter M, Kögler M, et al. Existential behavioural therapy for informal caregivers of palliative patients: a randomised controlled trial. *Psychooncology* 2013; 22(9): 2079–2086.
9. Kögler M, Brandl J, Brandstätter M, et al. Determinants of the effect of existential behavioral therapy for bereaved partners: a qualitative study. *J Palliat Med* 2013; 16(11): 1410–1416.
10. Stöckle HS, Haarmann-Doetkotte S, Bausewein C, et al. The feasibility and acceptability of short-term, individual existential behavioural therapy for informal caregivers of patients recruited in a specialist palliative care unit. *BMC Palliat Care* 2016; 15(1): 88.
11. Lipsey MW and Wilson DB. The efficacy of psychological, educational, and behavioral treatment: confirmation from meta-analysis. *Am Psychol* 1993; 48: 1181–1209.

12. Dupont WD and Plummer WD Jr. Power and sample size calculations: a review and computer program. *Control Clin Trials* 1990; 11(2): 116–128.
13. Rogers CR. *Counseling and psychotherapy; newer concepts in practice*. Boston, MA: Mifflin, 1942.
14. Heußner P. Gesprächspsychotherapie. In: Fegg M, Gramm J and Pestinger M (eds) *Psychologie und Palliative Care: Aufgaben, Konzepte und Interventionen in der Begleitung von Patienten und Angehörigen*. Stuttgart: Kohlhammer Verlag, 2012, pp. 138–143.
15. Fegg MJ, Kramer M, L'Hoste S, et al. The schedule for meaning in life evaluation (SMiLE): validation of a new instrument for meaning-in-life research. *J Pain Symptom Manage* 2008; 35(4): 356–364.
16. Kroenke K, Spitzer RL and Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001; 16(9): 606–613.
17. Gräfe K, Zipfel S, Herzog W, et al. Screening psychischer Störungen mit dem 'Gesundheitsfragebogen für Patienten (PHQ-D)'. *Diagnostica* 2004; 50: 171–181.
18. Spitzer RL, Kroenke K, Williams JW, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med* 2006; 166(10): 1092–1097.
19. Hinz A, Klein AM, Brähler E, et al. Psychometric evaluation of the Generalized Anxiety Disorder Screener GAD-7, based on a large German general population sample. *J Affect Disord* 2017; 210: 338–344.
20. Mehnert A, Müller D, Lehmann C, et al. Die deutsche version des NCCN distress-thermometers. *Z Psychiatr Psych Ps* 2006; 54: 213–223.
21. Goldberg DP and Williams P. *A user's guide to the General Health Questionnaire*. London: GL Assessment, 2006.
22. Schmitz N, Kruse J and Tress W. Psychometric properties of the General Health Questionnaire (GHQ-12) in a German primary care sample. *Acta Psychiatr Scand* 1999; 100(6): 462–468.
23. Watson D, Clark LA and Tellegem A. Development and validation of the brief measures of positive and negative affect: the PANAS scales. *J Pers Soc Psychol* 1988; 54: 1063–1070.
24. Krohne HW, Egloff B, Kohlmann C-W, et al. Untersuchungen mit einer deutschen Version der 'Positive and Negative Affect Schedule'(PANAS). *Diagnostica* 1996; 42: 139–156.
25. Diener E, Emmons RA, Larsen RJ, et al. The satisfaction with life scale. *J Pers Assess* 1985; 49: 71–75.
26. Glaesmer H, Grande G, Braehler E, et al. The German version of the Satisfaction with Life Scale (SWLS): psychometric properties, validity, and population-based norms. *Eur J Psychol Assess* 2011; 27: 127–132.
27. WHOQOL-Group. Development of the World Health Organization WHOQOL-BREF quality of life assessment. *Psychol Med* 1998; 28: 551–558.
28. Angermeyer MC, Kilian R and Matschinger H. *WHOQOL-100 und WHOQOL-BREF – Handbuch für die deutschsprachigen Versionen der WHO Instrumente zur Erfassung von Lebensqualität*. Göttingen: Hogrefe, 2000.
29. Seidl H, Bowles D, Bock JO, et al. FIMA – Questionnaire for health-related resource use in an elderly population: development and pilot study. *Gesundheitswesen* 2015; 77(1): 46–52.
30. Bock J, Brettschneider C, Seidl H, et al. Calculation of standardised unit costs from a societal perspective for health economic evaluation. *Gesundheitswesen* 2015; 77(1): 53–61.
31. Rosenstock IM. Why people use health services. *Milbank Q* 2005; 83: 1–32.
32. Jones CJ, Smith H and Llewellyn C. Evaluating the effectiveness of health belief model interventions in improving adherence: a systematic review. *Health Psychol Rev* 2014; 8(3): 253–269.
33. Beierlein C, Kemper CJ, Kovaleva A, et al. Kurzskala zur Erfassung allgemeiner Selbstwirksamkeitserwartungen (ASKU). *Methoden Daten Anal* 2013; 7: 251–278.
34. Schulte D. Messung der Therapieerwartung und Therapieevaluation von Patienten (PATHEV). *Z Klin Psychol Psychother* 2005; 34: 176–187.
35. Schneider W, Basler H and Beisenherz B. *Fragebogen zur Messung der Psychotherapiemotivation (FMP)*. Weinheim: Beltz Test, 1989.
36. Nübling R, Schulz H, Schmidt J, et al. Fragebogen zur Psychotherapiemotivation (FPTM) – Testkonstruktion und Gütekriterien. In: Nübling R, Muthny F and Bengel J (eds) *Reha-Motivation und Behandlungserwartung*. Regensburg: Roderer, 2006, pp. 252–270.
37. Lewis JA. Statistical principles for clinical trials (ICH E9): an introductory note on an international guideline. *Stat Med* 1999; 18(15): 1903–1942.
38. Bernard H, Burlingame G, Flores P, et al. Clinical practice guidelines for group psychotherapy. *Int J Group Psychother* 2008; 58: 455–542.
39. Schnur JB and Montgomery GH. A systematic review of therapeutic alliance, group cohesion, empathy, and goal consensus/collaboration in psychotherapeutic interventions in cancer: uncommon factors. *Clin Psychol Rev* 2010; 30(2): 238–247.
40. Carmody J and Baer RA. How long does a mindfulness-based stress reduction program need to be? A review of class contact hours and effect sizes for psychological distress. *J Clin Psychol* 2009; 65(6): 627–638.
41. Klatt MD, Buckworth J and Malarkey WB. Effects of low-dose mindfulness-based stress reduction (MBSR-ld) on working adults. *Health Educ Behav* 2009; 36(3): 601–614.
42. Zimmermann C, Swami N, Krzyzanowska M, et al. Early palliative care for patients with advanced cancer: a cluster-randomised controlled trial. *Lancet* 2014; 383(9930): 1721–1730.
43. Ferrell BR, Temel JS, Temin S, et al. Integration of palliative care into standard oncology care: ASCO clinical practice guideline update summary. *J Oncol Pract* 2017; 13(2): 119–121.
44. Sörensen S, Pinquart M and Duberstein P. How effective are interventions with caregivers? An updated meta-analysis. *Gerontologist* 2002; 42(3): 356–372.

6 References

1. World Health Organisation (2019). *Definition of palliative care.* [cited 06 August 2019]; Available from: http://www.who.int/cancer/palliative/definition/en/.
2. World Health Organization (2018). *Palliative Care Fact Sheet* [cited 8 January 2020]; Available from: https://www.who.int/news-room/fact-sheets/detail/palliative-care.
3. Lynch, T., Connor, S., and Clark, D. (2013). Mapping levels of palliative care development: a global update. *J Pain Symptom Manag*, 45(6): p. 1094-1106.
4. Deutsche Gesellschaft für Palliativmedizin (2018). *Informationen für Patienten und Angehörige* [cited 24 March 2020]; Available from: https://www.dgpalliativmedizin.de/neuigkeiten/informationen-fuer-patienten-und-angehoerige.html.
5. Deutsche Gesellschaft für Palliativmedizin (2019). *Wegweiser Hospiz und Palliativmedizin Deutschland, Einrichtungen für Erwachsene plus Einrichtungen für Kinder und Jugendliche* [cited 11 July 2019]; Available from: www.wegweiser-hospiz-palliativmedizin.de.
6. Payne, S. (2010). EAPC Task Force on Family Carers White Paper on improving support for family carers in palliative care: part 1. *Eur J Palliat Care*, 17(5): p. 238-245.
7. Williams, A.M., Wang, L., and Kitchen, P. (2014). Differential impacts of care-giving across three caregiver groups in Canada: end-of-life care, long-term care and short-term care. *Health Soc Care Comm*, 22(2): p. 187-196.
8. Payne, S. and Hudson, P. (2008). Assessing the family and caregivers, in *Palliative medicine: Expert Consult*, Walsh, D., Caraceni, A.T., and Fainsinger, R., Editors. Elsevier: New York.
9. Tang, S.T. (2003). When death is imminent: where terminally ill patients with cancer prefer to die and why. *Cancer Nurs*, 26(3): p. 245-51.
10. Saunders, C. (2001). The evolution of palliative care. *J R Soc Med*, 94(9): p. 430-432.
11. Northouse, L.L., Katapodi, M.C., Schafenacker, A.M., and Weiss, D. (2012). The impact of caregiving on the psychological well-being of family caregivers and cancer patients. *Semin Oncol Nurs*, 28(4): p. 236-245.
12. Schulz, R., Newsom, J., Mittelmark, M., Burton, L., Hirsch, C., and Jackson, S. (1997). Health effects of caregiving: the caregiver health effects study: an ancillary study of the Cardiovascular Health Study. *Annals of Behavioral Medicine*, 19(2): p. 110-116.
13. Nijboer, C., Tempelaar, R., Sanderman, R., Triemstra, M., Spruijt, R.J., and Van Den Bos, G.A. (1998). Cancer and caregiving: the impact on the caregiver's health. *Psychooncology*, 7(1): p. 3-13.
14. Pitceathly, C. and Maguire, P. (2003). The psychological impact of cancer on patients' partners and other key relatives: a review. *Eur J Cancer*, 39(11): p. 1517-1524.
15. Li, Q. and Loke, A.Y. (2013). The positive aspects of caregiving for cancer patients: a critical review of the literature and directions for future research. *Psychooncology*, 22(11): p. 2399-2407.
16. Grande, G., Rowland, C., van den Berg, B., and Hanratty, B. (2018). Psychological morbidity and general health among family caregivers during end-of-life cancer care: A retrospective census survey. *Palliat Med*, 32(10): p. 1605–14.
17. Grov, E.K., Dahl, A.A., Moum, T., and Fosså, S.D. (2005). Anxiety, depression, and quality of life in caregivers of patients with cancer in late palliative phase. *Ann Oncol*, 16(7): p. 1185-1191.
18. Braun, M., Mikulincer, M., Rydall, A., Walsh, A., and Rodin, G. (2007). Hidden morbidity in cancer: spouse caregivers. *J Clin Oncol*, 25(30): p. 4829-4834.

19. Weitzner, M.A., McMillan, S.C., and Jacobsen, P.B. (1999). Family Caregiver Quality of Life. *J Pain Symptom Manag*, 17(6): p. 418-428.
20. Schulz, R. and Beach, S.R. (1999). Caregiving as a risk factor for mortality: the Caregiver Health Effects Study. *Jama*, 282(23): p. 2215-2219.
21. Hirst, M. (2005). Carer distress: a prospective, population-based study. *Soc Sci Med*, 61(3): p. 697-708.
22. Seligman, M.E. (1975). *Helplessness: On depression, development, and death*. San Francisco: W.H. Freeman.
23. Chentsova-Dutton, Y., Shuchter, S., Hutchin, S., Strause, L., Burns, K., and Zisook, S. (2000). The psychological and physical health of hospice caregivers. *Ann Clin Psychiatry*, 12(1): p. 19-27.
24. Pinquart, M. and Sörensen, S. (2007). Correlates of physical health of informal caregivers: a meta-analysis. *J Gerontol B Psychol Sci Soc Sc*, 62(2): p. P126-P137.
25. Zapart, S., Kenny, P., Hall, J., Servis, B., and Wiley, S. (2007). Home-based palliative care in Sydney, Australia: the carer's perspective on the provision of informal care. *Health Soc Care Comm*, 15(2): p. 97-107.
26. Koerin, B.B., Harrigan, M.P., and Secret, M. (2008). Eldercare and employed caregivers: A public/private responsibility? *J Gerontol Soc Work*, 51(1-2): p. 143-161.
27. Harding, R. and Higginson, I. (2001). Working with ambivalence: informal caregivers of patients at the end of life. *Support Care Cancer*, 9(8): p. 642-645.
28. Sverke, M., Hellgren, J., and Näswall, K. (2002). No security: a meta-analysis and review of job insecurity and its consequences. *J Occup Health Psychol*, 7(3): p. 242.
29. McHorney, C.A., Kosinski, M., and Ware Jr, J.E. (1994). Comparisons of the costs and quality of norms for the SF-36 health survey collected by mail versus telephone interview: results from a national survey. *Med Care*: p. 551-567.
30. Renner, K.-H. and Jacob, N.-C. (2020). Auswertung von Interviews, in *Das Interview: Grundlagen und Anwendung in Psychologie und Sozialwissenschaften*. Springer: Heidelberg. p. 95-114.
31. Moosbrugger, H. and Kelava, A. (2012). *Testtheorie und Fragebogenkonstruktion*. Heidelberg: Springer.
32. Hudis, I., Zimmer, A., Sainer, J., and Fulchon, C. (1977). *A group program for families of the aging: A service strategy for strengthening natural supports*. 30th Annual Meeting of the Gerontological Society, San Francisco.
33. Sainsbury, P. (1970). The psychiatrist and the geriatric patient. The effects of community care on the family of the geriatric patient. *J Geriatr Psychiatry*, 4(1): p. 23-52.
34. Clipp, E.C. and George, L.K. (1993). Dementia and cancer: a comparison of spouse caregivers. *Gerontologist*, 33(4): p. 534-541.
35. Prütz, F. and Saß, A.-C. (2017). Daten zur Palliativversorgung in Deutschland. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*, 60(1): p. 26-36.
36. Ziegler, U. and Doblhammer, G. (2009). Prävalenz und Inzidenz von Demenz in Deutschland–Eine Studie auf Basis von Daten der gesetzlichen Krankenversicherungen von 2002. *Gesundheitswesen*, 71(05): p. 281-290.
37. The National Cancer Institute (2015). *Age and Cancer Risk - Surveillance, Epidemiology, and End Results Program*. [cited 20 April 2020]; Available from: https://www.cancer.gov/about-cancer/causes-prevention/risk/age.
38. Kim, Y. and Schulz, R. (2008). Family caregivers' strains: comparative analysis of cancer caregiving with dementia, diabetes, and frail elderly caregiving. *J Aging Health*, 20(5): p. 483-503.
39. Zarit, S.H., Reever, K.E., and Bach-Peterson, J. (1980). Relatives of the Impaired Elderly: Correlates of Feelings of Burden. *Gerontologist*, 20(6): p. 649-655.

40. Zarit, S.H., Orr, N.K., and Zarit, J.M. (1985). *The hidden victims of Alzheimer's disease: families under stress*. New York: New York University Press.
41. Conde-Sala, J.L., Turro-Garriga, O., Calvo-Perxas, L., Vilalta-Franch, J., Lopez-Pousa, S., and Garre-Olmo, J. (2014). Three-year trajectories of caregiver burden in Alzheimer's disease. *J Alzheimers Dis*, 42(2): p. 623-33.
42. Bédard, M., Molloy, D.W., Squire, L., Dubois, S., Lever, J.A., and O'Donnell, M. (2001). The Zarit Burden Interview: a new short version and screening version. *Gerontologist*, 41(5): p. 652-7.
43. Arai, Y., Tamiya, N., and Yano, E. (2003). [The short version of the Japanese version of the Zarit Caregiver Burden Interview (J-ZBI_8): its reliability and validity]. *Nihon Ronen Igakkai Zasshi [Japanese Journal of Geriatrics]*, 40(5): p. 497-503.
44. Higginson, I.J., Gao, W., Jackson, D., Murray, J., and Harding, R. (2010). Short-form Zarit Caregiver Burden Interviews were valid in advanced conditions. *J Clin Epidemiol*, 63(5): p. 535-42.
45. Braun, M., Scholz, U., Hornung, R., and Martin, M. (2010). [Caregiver burden with dementia patients. A validation study of the German language version of the Zarit Burden Interview]. *Z Gerontol Geriatr*, 43(2): p. 111-9.
46. Döring, N. and Bortz, J. (2014). *Forschungsmethoden und Evaluation*. Heidelberg: Springer.
47. Kühnel, M.B., Ramsenthaler, C., Bausewein, C., Fegg, M., and Hodiamont, F. (2020). Validation of two short versions of the Zarit Burden Interview in the palliative care setting: a questionnaire to assess the burden of informal caregivers. *Support Care Cancer*, 28(11): p. 5185-5193.
48. Morris, S.M. and Thomas, C. (2001). The carer's place in the cancer situation: Where does the carer stand in the medical setting? *Eur J Cancer Care*, 10(2): p. 87-95.
49. Christakis, N.A. and Iwashyna, T.J. (2003). The health impact of health care on families: a matched cohort study of hospice use by decedents and mortality outcomes in surviving, widowed spouses. *Soc Sci Med*, 57(3): p. 465-475.
50. Knight, B.G., Lutzky, S.M., and Macofsky-Urban, F. (1993). A Meta-analytic Review of Interventions for Caregiver Distress: Recommendations for Future Research. *Gerontologist*, 33(2): p. 240-248.
51. Grande, G., et al. (2009). Supporting lay carers in end of life care: current gaps and future priorities. *Palliat Med*, 23(4): p. 339-344.
52. Schildmann, E.K. and Higginson, I.J. (2011). Evaluating psycho-educational interventions for informal carers of patients receiving cancer care or palliative care: Strengths and limitations of different study designs. *Palliat Med*, 25(4): p. 345-356.
53. Jaffray, L., Bridgman, H., Stephens, M., and Skinner, T. (2016). Evaluating the effects of mindfulness-based interventions for informal palliative caregivers: A systematic literature review. *Palliat Med*, 30(2): p. 117-131.
54. Heaton, J. (1999). The gaze and visibility of the carer: a Foucauldian analysis of the discourse of informal care. *Sociol Health Illn*, 21(6): p. 759-777.
55. Carretero, S., Garcés, J., Ródenas, F., and Sanjosé, V. (2009). The informal caregiver's burden of dependent people: Theory and empirical review. *Arch Gerontol Geriat*, 49(1): p. 74-79.
56. Northouse, L.L., Katapodi, M.C., Song, L., Zhang, L., and Mood, D.W. (2010). Interventions with family caregivers of cancer patients: meta-analysis of randomized trials. *CA-Cancer J Clin*, 60(5): p. 317-339.
57. Ferrell, B. and Wittenberg, E. (2017). A review of family caregiving intervention trials in oncology. *CA-Cancer J Clin*, 67(4): p. 318-325.

58. Jarrott, S.E., Zarit, S.H., Parris-Stephens, M.A., Townsend, A., and Greene, R. (1999). Caregiver satisfation with adult day service programs. *Am J Alzheimers Dis*, 14(4): p. 233-244.
59. Harding, R., List, S., Epiphaniou, E., and Jones, H. (2012). How can informal caregivers in cancer and palliative care be supported? An updated systematic literature review of interventions and their effectiveness. *Palliat Med*, 26(1): p. 7-22.
60. Harding, R., et al. (2012). What are the perceived needs and challenges of informal caregivers in home cancer palliative care? Qualitative data to construct a feasible psycho-educational intervention. *Support Care Cancer*, 20(9): p. 1975-1982.
61. Kabat-Zinn, J. (1994). *Wherever you go, there you are: Mindfulness meditation in everyday life*. New York: Hyperion.
62. Hayes, S.C. and Hofmann, S.G. (2017). The third wave of cognitive behavioral therapy and the rise of process-based care. *World Psychiatry*, 16(3): p. 245-246.
63. Hayes, S.C. (2004). Acceptance and commitment therapy, relational frame theory, and the third wave of behavioral and cognitive therapies. *Behav Ther*, 35: p. 639-665.
64. Ledesma, D. and Kumano, H. (2009). Mindfulness-based stress reduction and cancer: a meta-analysis. *Psychooncology*, 18(6): p. 571-579.
65. Grossman, P., Niemann, L., Schmidt, S., and Walach, H. (2004). Mindfulness-based stress reduction and health benefits: A meta-analysis. *J Psychosom Res*, 57(1): p. 35-43.
66. Fegg, M.J., et al. (2013). Existential behavioural therapy for informal caregivers of palliative patients: A randomised controlled trial. *Psychoocology*, 22(9): p. 2079-2086.
67. Yalom, I.D. (1980). *Existential Psychotherapy*. New York: Basic Books.
68. Kühnel, M.B., Marchioro, L., Deffner, V., Bausewein, C., Seidl, H., Siebert, S., and Fegg, M. (2020). How short is too short? A randomised controlled trial evaluating short-term existential behavioural therapy for informal caregivers of palliative patients. *Palliat Med*, 34(6): p. 806-816.
69. Derogatis, L.R. and Melisaratos, N. (1983). The Brief Symptom Inventory: An introductory report. *Psychol Med*, 13(3): p. 595-605.
70. Gandek, B., et al. (1998). Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. International Quality of Life Assessment. *J Clin Epidemiol*, 51(11): p. 1171-8.
71. Mehnert, A., Müller, D., Lehmann, C., and Koch, U. (2006). [The German version of the NCCN distress thermometer: validation of a screening instrument for assessment of psychosocial distress in cancer patients]. *Zeitschrift für Psychiatrie, Psychologie und Psychotherapie*, (54): p. 213-223.

Acknowledgements

Mein erster Dank gilt meinem Doktorvater *Prof. Dr. Martin Fegg*, der mich von meiner Bewerbung bis zur Fertigstellung der Dissertation unterstützt hat und mir die Weiterführung der randomisiert-kontrollierten Studie und damit das Thema der Dissertation anvertraut und zugetraut hat.

Ein weiterer Dank gilt *Prof. Dr. Claudia Bausewein* für ihre Unterstützung in der Planung der Studien und für ihre Zeit bei den Korrekturen der Publikationen.

Vielen Dank auch an *Dr. Farina Hodiamont* für die kollegiale Zusammenarbeit.

Linda Marchioro gilt mein besonderer Dank für die enge Zusammenarbeit an der Statistik. Ebenso gilt mein Dank sowohl *Dr. Christina Ramsenthaler,* als auch *Dr. Veronika Deffner,* die beide in der jeweiligen Studie ihr statistisches Fachwissen mit mir geteilt haben. Ein weiterer Dank gilt *Dr. Hildegard Seidl* für die hilfreichen Korrekturen der Publikation. *Dr. Michaela Schunk* danke ich für ihre Hilfe beim Problemlösen in meiner Anfangszeit.

Ein Dank geht auch an *Sarah Siebert* für die intensive Zusammenarbeit und ihre motivationale Gesprächsführung zur Studie und zum Leben im Allgemeinen.

Ich möchte mich auch herzlich bei *Alina Hermann* bedanken, für ihre unermüdliche Unterstützung mit Tee und einer offenen Tür.

Dem *AK Forschung* und allen *Kolleginnen und Kollegen* danke ich für ihren hilfreichen Input, die gemeinsamen Mittagessen und die unterstützende Atmosphäre der Abteilung.

Mein großer Dank geht an *meine Familie*. Danke, dass ihr mir alles zutraut, mich motiviert und mich in schwierigen Zeiten auffangt.

List of publications

Publications

Kühnel, M.B., Marchioro, L., Deffner, V., Bausewein, C., Seidl, H., Siebert, S., and Fegg, M. (2020). How short is too short? A randomised controlled trial evaluating short-term existential behavioural therapy for informal caregivers of palliative patients. *Palliative Medicine*, 34(6): p. 806-816. https://doi.org/10.1177/0269216320911595

Kühnel, M.B., Ramsenthaler, C., Bausewein, C., Fegg, M., Hodiamont, F. (2020) Validation of two short versions of the Zarit Burden Interview in the palliative care setting: a questionnaire to assess the burden of informal caregivers. *Supportive Care in Cancer*, 28(11): p. 5185-5193. https://doi.org/10.1007/s00520-019-05288-w

Kühnel, M.B., Ramsenthaler, C., Bausewein, C., Fegg, M., Hodiamont, F. Validierung der 7-Item Kurz-Version des Zarit Burden Interviews – Ein Fragebogen zur Erhebung der Belastung von Angehörigen von Palliativpatienten. *Zeitschrift für Palliativmedizin*, 2018 19(5): P2. https://doi.org 10.1055/s-0038-1669256

Presentations at conferences

Presentation

Kühnel, M.B., Ramsenthaler, C., Bausewein, C., Fegg, M., Hodiamont, F. Validierung der 7-Item Kurz-Version des Zarit Burden Interviews – Ein Fragebogen zur Erhebung der Belastung von Angehörigen von Palliativpatienten. Presented at the 12th conference of Deutsche Gesellschaft für Palliativmedizin (DGP), Bremen, 2018.

Posters

Meesters S., Handtke V., Kühnel M.B., Bausewein C., Schildmann E. Implementation of a Patient and Public Involvement Group in the Context of Palliative Care Research - Experiences from Two Projects on Sedation in Palliative Care. Presented at the 16th conference of the European Association of Palliative Care (EAPC), Berlin, 2019.

Kühnel, M.B., Ramsenthaler, C., Bausewein, C., Fegg, M., Hodiamont, F. Validierung der 7-Item Kurz-Version des Zarit Burden Interviews – Ein Fragebogen zur Erhebung der Belastung von Angehörigen von Palliativpatienten. Presented at the 12th conference of

Deutsche Gesellschaft für Palliativmedizin (DGP), Bremen, 2018. (One of the six best abstracts and therefore selected for publication, see above)

Appendix of publication I

Kühnel, M.B., Ramsenthaler, C., Bausewein, C., Fegg, M., Hodiamont, F. (2020) Validation of two short versions of the Zarit Burden Interview in the palliative care setting: a questionnaire to assess the burden of informal caregivers. *Supportive Care in Cancer*, 28(11): p. 5185-5193. https://doi.org/10.1007/s00520-019-05288-w

Supplementary material published online: 15 February 2020

Table 5: Descriptive Characteristics of Staff Members who rated Caregiver Burden using ZBI-1 (n=22)

Characteristic	n (%) or mean (SD)
Setting	
Palliative care unit	13 (59.1%)
Hospital support team	4 (18.2%)
Home care team	5 (22.7%)
Age	36.5 (8.83)
Sex	
Female	16 (72.7%)
Profession	
Nursing staff	15 (68.2%)
Medical staff	7 (31.8%)
Years of professional experience	13.3 (10.5)
Years of experience in palliative care	3.3 (4.6)
Number of Zarit-Ratings	3.6 (2.6)

Table 6: Summary fit statistics of Rasch analysis for scales ZBI-1, ZBI-6 and ZBI-7

Model	Analysis number	n	Overall model fit	Item fit Mean (SD)	Person fit Mean (SD)	Person Separation Index
ZBI-7	1	84	X^2 = 20.255, df = 14 p = 0.122	0.00 (0.63)	-0.91 (1.25)	0.81
ZBI-7 removal of extremes	2	80	X^2 = 23.782, df = 14 p = 0,058	0.00 (0.61)	-0.87 (1.15)	0.79
ZBI-6	3	77	X^2 = 16.418, df = 12 p = 0.173	0.00 (0.43)	-0.84 (0.92)	0.69
ZBI-1	4	84	X^2 = 3.106, df = 4 p = 0.540	0.00 (1.66)	1.23 (1.14)	0.25

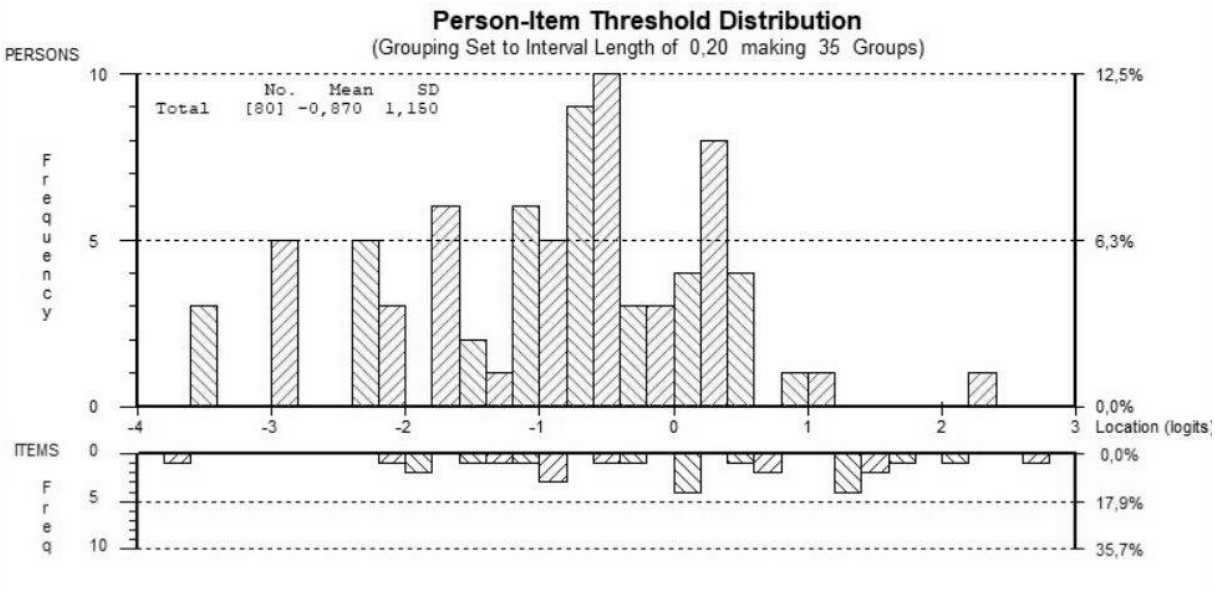

Figure 2: Person-Item Threshold Distribution of Rasch Analysis for ZBI-7

Appendix of publication II

Kühnel, M.B., Marchioro, L., Deffner, V., Bausewein, C., Seidl, H., Siebert, S., and Fegg, M. (2020). How short is too short? A randomised controlled trial evaluating short-term existential behavioural therapy for informal caregivers of palliative patients. *Palliative Medicine*, 34(6): p. 806-816.
https://doi.org/10.1177/0269216320911595

Supplementary material published online: 29 April 2020

Appendix 2.1 Time of death of patients

Table 4

Appendix 2.2 Results of regression analyses for secondary outcomes

Tables 5 - 14

Appendix 2.3 Results of sensitivity analyses regarding missing data

Tables 15 - 25

Appendix 2.1 Time of death of patients

Table 4: Time of death of patients during caregivers' participation in the study.

	RCT		
Time of death of the patient	sEBT	Control	Decliners
At t1	*n* = 75	*n* = 82	*n* =50
Unknown	3 (4.0%)	10 (12.2%)	7 (14.0%)
Alive	66 (88.0%)	67 (81.7%)	37 (74.0%)
Died ≤ 3 months ago	6 (8.0%)	5 (6.1%)	5 (10.0%)
Died ≥ 3 months ago	- -	- -	1 (2.0%)
At t2	*n* = 60	*n* = 67	
Unknown	2 (3.3%)	7 (10.4%)	
Alive	31 (51.7%)	32 (47.8%)	
Died ≤ 3 months ago	27 (45.0%)	28 (41.8%)	
At t3	*n* = 58	*n* = 64	*n* = 43
Unknown	1 (1.7.0%)	5 (7.8%)	11 (22.0%)
Alive	12 (20.7%)	9 (14.1%)	8 (16.0%)
Died ≤ 3 months ago	43 (74.1%)	47 (73.4%)	29 (58.0%)
Died ≥ 3 months ago	2 (3.4%)	3 (4.7%)	2 (4.0%)
At t4	*n* = 54	*n* = 64	*n* =38
Unknown	1 (1.9%)	6 (9.4%)	16 (32.0%)
Alive	4 (7.4%)	4 (6.3%)	2 (4.0%)
Died ≤ 3 months ago	3 (5.6%)	1 (1.6%)	1 (2.0%)
Died ≥ 3 months ago	46 (85.2%)	53 (82.8%)	31 (62.0%)

Note: Data are number (%)
No data for decliners at t2

Appendix 2.2 Results of regression analyses for secondary outcomes

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	p-Value	beta	p-Value	beta	p-Value
Gender	Male	-.783	.184	-.573	.374	-.824	.208
Relationship with patient	Partner/child	.015	.981	.078	.912	-.245	.732
Employment	Retired/other	.125	.888	.407	.672	1.27	.207
Support apart from study	Unknown	1.74	.295	1.85	.285	2.73	.136
	Support	.380	.617	.418	.607	.847	.334
Group	sEBT intervention	-.318	.569	-.580	.346	-.914	.162
Time of investigation	t3	-1.21	**.003**	-1.23	**.006**	-1.40	**.002**
	t4	-1.67	**.022**	-1.76	**.026**	-2.25	**.005**
Patient's time of death	Unknown	.982	.473	.488	.717	.362	.784
	Alive	.011	.983	.105	.856	-.447	.453
	Deceased >3 months	-1.55	**.030**	-1.58	**.040**	-1.27	.103
Age		-.006	.859	-.015	.664	-.039	.278
Psychologist	Psychologist 1	-.109	.895	-.067	.939	-.356	.687
	Psychologist 2	-.504	.517	-.583	.484	-.393	.650
Anxiety at t1		.565	**<.001**	.553	**<.001**	.502	**<.001**

Table 5: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **anxiety**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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.

Variable [a]	Category [b]	Model 1 n= 124		Model 2 n= 112		Model 3 n= 102	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	.323	.313	.497	**.**132	.376	.288
Relationship with patient	Partner/child	.508	.155	.748	**.042**	.310	.428
Employment	Retired/other	.272	.566	.457	.345	.884	.100
Support apart from study	Unknown	-.309	.731	-.490	.575	.617	.529
	Support	.426	.297	.201	.623	.687	.142
Group	sEBT intervention	-.014	.964	-.211	.507	-.084	.814
Time of investigation	t3	-.341	.157	-.447	***.083***	-.441	.117
	t4	-.838	.112	-1.02	***.070***	-.982	.101
Patient's time of death	Unknown	.360	.588	-.053	.939	.003	.996
	Alive	.424	.175	.271	.405	.293	.412
	Deceased >3 months	-1.13	**.032**	-1.02	***.067***	-1.13	***.053***
Age		-.033	***.060***	-.044	**.014**	-.051	**.008**
Psychologist	Psychologist 1	-.451	.309	-.637	.145	-.689	.144
	Psychologist 2	-.007	.987	-.099	.826	-.086	.861
Subjective distress at t1		.405	**<.001**	.385	**<.001**	.450	**<.001**

Table 6: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **subjective distress**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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.

Variable [a]	Category [b]	Model 1 n= 122		Model 2 n= 110		Model 3 n= 100	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.045	.595	-.128	.153	-.098	.312
Relationship with patient	Partner/child	-.094	.311	-.175	***.077***	-.015	.885
Employment	Retired/other	-.072	.566	-.123	.348	-.175	.233
Support apart from study	Unknown	-.186	.421	-.168	.465	-.220	.404
	Support	.097	.384	.164	.153	.190	.153
Group	sEBT intervention	.018	.822	.044	.603	.065	.495
Time of investigation	t3	.158	**.004**	.172	**.003**	.211	**.001**
	t4	.290	**.033**	.317	**.025**	.357	**.017**
Patient's time of death	Unknown	-.016	.927	.047	.791	.022	.904
	Alive	.083	.251	.094	.215	.064	.421
	Deceased >3 months	.110	.413	.045	.741	.105	.464
Age		-.002	.672	.002	.678	-.001	.876
Psychologist	Psychologist 1	.074	.528	.107	.365	.091	.477
	Psychologist 2	.124	.285	.122	.303	.041	.750
Positive affect at t1		.677	**<.001**	.637	**<.001**	.679	**<.001**

Table 7: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment of **positive affect**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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.

Variable [a]	Category [b]	Model 1 n= 122		Model 2 n= 110		Model 3 n= 100	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	.049	.536	.096	.274	.082	.350
Relationship with patient	Partner/child	.119	.163	.160	***.090***	.072	.445
Employment	Retired/other	.147	.213	.176	.171	.304	**.023**
Support apart from study	Unknown	.201	.358	.192	.398	.330	.168
	Support	-.076	.469	-.105	.350	-.014	.905
Group	sEBT intervention	-.080	.288	-.082	.320	-.112	.202
Time of investigation	t3	-.127	**.021**	-.117	**.051**	-.120	**.053**
	t4	-.165	.124	-.188	.111	-.174	.135
Patient's time of death	Unknown	.086	.599	.094	.601	.065	.707
	Alive	-.066	.360	-.058	.464	-.082	.292
	Deceased >3 months	-.289	**.008**	-.263	**.027**	-.278	**.018**
Age		-.005	.237	-.007	.167	-.010	**.035**
Psychologist	Psychologist 1	-.147	.182	-.163	.160	-.199	***.089***
	Psychologist 2	.028	.795	.045	.696	.102	.393
Negative affect at t1		.531	**<.001**	.543	**<.001**	.504	**<.001**

Table 8: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **negative affect.** Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.090	.898	.447	.543	.050	.950
Relationship with patient	Partner/child	1.25	.113	1.79	**.030**	.835	.335
Employment	Retired/other	-1.53	.151	-.896	.413	-.773	.523
Support apart from study	Unknown	1.90	.339	1.75	.368	3.07	.162
	Support	.794	.384	.420	.649	.650	.533
Group	sEBT intervention	-.405	.548	-.683	.349	-.825	.295
Time of investigation	t3	-1.32	**.009**	-1.64	**.003**	-1.62	**.006**
	t4	-2.96	**.010**	-3.30	**.008**	-3.54	**.006**
Patient's time of death	Unknown	-.869	.555	-1.68	.274	-1.44	.366
	Alive	-.915	.165	-1.30	***.059***	-1.32	***.082***
	Deceased >3 months	-1.49	.206	-1.28	.310	-1.35	.293
Age		.032	.431	.001	.989	.014	.750
Psychologist	Psychologist 1	.062	.950	-.062	.950	-.441	.677
	Psychologist 2	-.162	.864	-.296	.757	-.193	.855
Minor mental disorders at t1		.598	**<.001**	.606	**<.001**	.579	**<.001**

Table 9: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **minor mental disorders**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.105	.887	-.356	.654	.176	.824
Relationship with patient	Partner/child	-.226	.781	-.149	.865	.077	.930
Employment	Retired/other	-.605	.583	-.1.39	.238	-2.28	***.063***
Support apart from study	Unknown	-.014	.995	.150	.942	-2.59	.245
	Support	-.372	.693	-.236	.811	-.508	.633
Group	sEBT intervention	-.137	.842	.061	.934	.668	.393
Time of investigation	t3	-.472	.232	-.313	.456	-.269	.549
	t4	-.608	.479	-.357	.698	-.233	.808
Patient's time of death	Unknown	-1.70	.255	-1.23	.444	-1.19	.448
	Alive	-1.38	**.014**	-1.05	***.077***	-1.38	**.031**
	Deceased >3 months	.984	.247	.737	.419	.925	.318
Age		.012	.774	.034	.428	.038	.391
Psychologist	Psychologist 1	.463	.652	.508	.630	1.05	.328
	Psychologist 2	-.118	.902	-.059	.953	-.521	.611
Satisfaction with life at t1		.643	**<.001**	.660	**<.001**	.607	**<.001**

Table 10: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **satisfaction with life**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	p-Value	beta	p-Value	beta	p-Value
Gender	Male	-4.08	.102	-5.69	**.030**	-3.95	.155
Relationship with patient	Partner/child	-1.33	.630	-.904	.752	-1.58	.609
Employment	Retired/other	1.87	.620	-.362	.925	1.23	.777
Support apart from study	Unknown	-4.75	.510	-6.23	.375	-8.53	.285
	Support	-1.05	.743	-1.55	.633	-2.96	.428
Group	sEBT intervention	-2.16	.360	-1.12	.647	-3.13	.266
Time of investigation	t3	.837	.665	1.27	.508	2.13	.297
	t4	-.800	.862	-.083	.986	-.466	.923
Patient's time of death	Unknown	-.833	.873	-.449	.933	.261	.962
	Alive	.186	.941	1.36	.588	.595	.826
	Deceased >3 months	4.75	.314	5.40	.257	5.89	.225
Age		-.141	.324	-.127	.377	-.132	.411
Psychologist	Psychologist 1	-1.74	.622	-3.00	.394	-1.11	.769
	Psychologist 2	-2.99	.369	-3.18	.344	-1.96	.597
Quality of life (World Health Organisation) at t1		.451	**<.001**	.518	**<.001**	.467	**<.001**

Table 11: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **quality of life (World Health Organisation)**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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.

Variable [a]	Category [b]	Model 1 n= 123		Model 2 n= 111		Model 3 n= 102	
		beta	p-Value	beta	p-Value	beta	p-Value
Gender	Male	-.425	.176	-.669	**.047**	-.413	.248
Relationship with pat.	Partner/child	-.680	**.047**	-.804	**.028**	-.459	.235
Employment	Retired/other	-.601	.197	-.876	***.077***	-.907	***.097***
Support apart from study	Unknown	-1.35	.126	-1.29	.143	-1.93	***.051***
	Support	.167	.675	.309	.455	.126	.789
Group	sEBT intervention	-.004	.989	.170	.587	.228	.512
Time of investigation	t3	.444	**.029**	.422	***.053***	.476	**.044**
	t4	.574	.146	.807	***.056***	.761	***.092***
Patient's time of death	Unknown	.366	.571	.313	.647	.278	.691
	Alive	-.049	.862	-.147	.620	.063	.845
	Deceased >3 months	.856	**.032**	.543	.195	.795	***.073***
Age		.014	.424	.024	.182	.017	.373
Psychologist	Psychologist 1	.095	.826	.234	.598	.014	.977
	Psychologist 2	-.091	.825	-.039	.927	-.378	.418
Quality of Life (numerical rating scale) at t1		.206	**.004**	.187	**.012**	.167	**.042**

Table 12: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **quality of life (numerical rating scale)**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.255	.469	-.141	.699	-.262	.509
Relationship with patient	Partner/child	.468	.223	.712	.075	.299	.494
Employment	Retired/other	.628	.231	.369	.507	.691	.266
Support apart from study	Unknown	.593	.550	.392	.689	.432	.699
	Support	-.156	.733	-.256	.582	-.183	.731
Group	sEBT intervention	.006	.986	.028	.935	-.059	.881
Time of investigation	t3	.049	.852	.005	.987	.107	.709
	t4	.728	.171	.548	.327	.526	.364
Patient's time of death	Unknown	.316	.667	.522	.497	.612	.442
	Alive	-.272	.403	-.439	.205	-.269	.458
	Deceased >3 months	-.889	.100	-.860	.130	-.795	.169
Age		-.011	.574	-.016	.423	-.001	.980
Psychologist	Psychologist 1	-.770	.125	-.868	.083	-.775	.156
	Psychologist 2	-.146	.756	-.214	.655	.006	.991
Physical impairment at t1		.518	**<.001**	.543	**<.001**	.517	**<.001**

Table 13: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **physical impairment**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	p-Value	beta	p-Value	beta	p-Value
Gender	Male	-.613	***.092***	-.350	.362	-.475	.251
Relationship with patient	Partner/child	.402	.312	.509	.228	.240	.594
Employment	Retired/other	.445	.415	.613	.288	1.01	.118
Support apart from study	Unknown	.438	.666	.305	.764	1.26	.276
	Support	.144	.757	-.068	.889	.078	.888
Group	sEBT intervention	-.846	**.040**	-.934	**.029**	-.900	.064
Time of investigation	t3	2.15	.146	2.21	.170	2.09	.194
	t4	-1.72	**.005**	-2.11	**.001**	-2.08	**.002**
Time of investigation*Group	t3 * sEBT	-2.39	.265	-2.47	.295	-2.30	.386
	t4 * sEBT	1.14	**.025**	.938	***.075***	.613	.286
Patient's time of death	Unknow	1.83	**.021**	1.74	**.040**	1.80	**.039**
	Alive	.615	.120	.484	.236	.507	.254
	Deceased >3 months	-.456	.467	-.118	.860	-.072	.918
Age		-.010	.604	-.023	.277	-.028	.209
Psychologist	Psychologist 1	-.460	.373	-.540	.304	-.512	.374
	Psychologist 2	.346	.472	.290	.560	.723	.189
Psychological impairment at t1		.446	**<.001**	.440	**<.001**	.418	**<.001**

Table 14: Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **psychological impairment**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Time of investigation*Group – t2*sEBT, t2*Control, t3*Control, t4*Control; Patient deceased – Deceased ≤ 3 months; Psychologist – Psychologist 3.

Appendix 2.3 Results of sensitivity analyses regarding missing data

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.468	.396	-.323	.593	-.585	.328
Relationship with patient	Partner/child	-.898	.172	-.799	.266	-1.12	.116
Employment	Retired/other	-.716	.396	-.365	.691	.410	.661
Support apart from study	Unknown	1.39	.371	1.30	.417	2.01	.232
	Support	.701	.331	.503	.516	.857	.287
Group	sEBT intervention	-.174	.741	-.253	.666	-.387	.522
Time of investigation	t3	-.806	**.029**	-.966	**.015**	-.989	**.020**
	t4	-1.35	***.078***	-1.75	**.034**	-1.78	**.032**
Patients' time of death	Unknown	.350	.764	.073	.955	-.041	.973
	Alive[a]	-.406	.391	-.514	.312	-.633	.238
	Deceased >3 months	-.991	.196	-.878	.281	-.858	.290
Age		.026	.417	.014	.679	-.005	.884
Psychologist	Psychologist 1	-.166	.833	-.269	.745	-.551	.500
	Psychologist 2	.448	.547	.312	.695	.654	.423
Missing data	No missing data	-.615	.303	-.647	.324	-.611	.333
Depression at t1		.619	**<.001**	.630	**<.001**	.603	**<.001**

Table 15. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the primary outcome variable post-treatment **depression**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.797	.176	-.595	.357	-.810	.217
Relationship with patient	Partner/child	-.230	.9736	-.144	.847	-.480	.523
Employment	Retired/other	.042	.963	.303	.755	1.19	.241
Support apart from study	Unknown	1.75	.292	1.85	.285	2.74	.135
	Support	.500	.514	.554	.501	.911	.300
Group	sEBT intervention	-.351	.530	-.564	.361	-.915	.162
Time of investigation	t3	-1.22	**.003**	-1.24	**.006**	-1.41	**.002**
	t4	-1.70	**.020**	-1.77	**.025**	-2.27	**.005**
Patient's time of death	Unknown	.637	.611	.281	.838	.091	.947
	Alive	-.017	.974	.086	.881	-.459	.441
	Deceased >3 months	-1.52	**.033**	-1.56	**.042**	-1.24	.108
Age		-.005	.876	-.015	.676	-.039	.284
Psychologist	Psychologist 1	-.108	.993	.042	.962	-.278	.754
	Psychologist 2	-.510	.512	-.568	.496	-.408	.638
Missing data	No missing data	-.679	.286	-.628	.370	-.699	.311
Anxiety at t1		.574	**<.001**	.553	**<.001**	.512	**<.001**

Table 16. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **anxiety**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 124		Model 2 n= 112		Model 3 n= 102	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	.311	.333	.486	**.**143	.370	.298
Relationship with patient	Partner/child	.443	.242	.700	**.074**	.245	.553
Employment	Retired/other	.256	.591	.441	.366	.865	.110
Support apart from study	Unknown	-.311	.731	-.494	.574	.619	.529
	Support	.449	.278	.223	.592	.700	.138
Group	sEBT intervention	-.020	.948	-.202	.529	-.078	.829
Time of investigation	t3	-.345	.153	-.450	***.081***	-.443	.115
	t4	-.852	.107	-1.03	***.067***	-.938	***.098***
Patient's time of death	Unknown	.293	.666	-.093	.894	-.073	.919
	Alive[a]	.416	.185	.266	.416	.291	.417
	Deceased >3 months	-1.12	**.034**	-1.01	***.070***	-1.12	***.057***
Age		-.034	***.060***	-.044	**.014**	-.051	**.008**
Psychologist	Psychologist 1	-.432	.334	-.620	.160	-.676	.155
	Psychologist 2	-.012	.978	-.100	.827	-.088	.858
Missing data	No missing data	-.190	.583	-.143	.689	-.203	.584
Subjective distress at t1		.410	**<.001**	.391	**<.001**	.456	**<.001**

Table 17. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **subjective distress**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 122		Model 2 n= 110		Model 3 n= 100	
		beta	p-Value	beta	p-Value	beta	p-Value
Gender	Male	-.046	.592	-.127	.158	-.102	.289
Relationship with patient	Partner/child	-.074	.448	-.146	.160	.024	.826
Employment	Retired/other	-.064	.611	-.109	.409	-.159	.276
Support apart from study	Unknown	-.188	.419	-.168	.464	-.225	.391
	Support	.086	.445	.146	.215	.178	.182
Group	sEBT intervention	.022	.788	.044	.600	.065	.495
Time of investigation	t3	.159	**.003**	.173	**.003**	.211	**.000**
	t4	.293	**.031**	.321	**.024**	.360	**.016**
Patient's time of death	Unknown	.003	.987	.074	.685	.061	.747
	Alive	.085	.241	.098	.199	.066	.405
	Deceased >3 months	.107	.424	.042	.761	.103	.474
Age		-.002	.651	.002	.706	-.001	.821
Psychologist	Psychologist 1	.065	.585	.092	.440	.079	.537
	Psychologist 2	.121	.298	.115	.332	.035	.788
Missing data	No missing data	.052	.565	.080	.400	.103	.305
Positive affect at t1		.681	**<.001**	.644	**<.001**	.692	**<.001**

Table 18. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment of **positive affect**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 122		Model 2 n= 110		Model 3 n= 100	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	.051	.520	.095	.273	.085	.325
Relationship with patient	Partner/child	.067	.450	.103	.286	.009	.928
Employment	Retired/other	.125	.282	.145	.256	.276	**.037**
Support apart from study	Unknown	.211	.331	.200	.376	.351	.136
	Support	-.048	.648	-.067	.551	.010	.936
Group	sEBT intervention	-.089	.233	-.079	.333	-.113	.188
Time of investigation	t3	-.130	**.019**	-.120	**.046**	-.122	**.049**
	t4	-.175	.102	-.196	***.096***	-.182	.115
Patient's time of death	Unknown	.032	.844	.037	.836	-.001	.997
	Alive	-.074	.307	-.065	.411	-.088	.260
	Deceased >3 months	-.281	**.009**	-.255	**.030**	-.270	**.020**
Age		-.005	.258	-.006	.180	-.010	**.042**
Psychologist	Psychologist 1	-.126	.252	-.136	.239	-.185	.110
	Psychologist 2	.033	.757	.057	.614	.103	.380
Missing data	No missing data	-.155	***.064***	-.177	***.055***	-.183	**.042**
Negative affect at t1		.543	**<.001**	.563	**<.001**	.526	**<.001**

Table 19. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **negative affect.** Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.130	.854	.368	.614	.054	.945
Relationship with patient	Partner/child	.848	.309	1.30	.133	.397	.661
Employment	Retired/other	-1.6	.124	-1.09	.317	-.933	.441
Support apart from study	Unknown	1.87	.345	1.71	.375	3.07	.159
	Support	.962	.295	.701	.452	.782	.453
Group	sEBT intervention	-.440	.512	-.640	.356	-.801	.307
Time of investigation	t3	-1.34	**.008**	-1.66	**.002**	-1.63	**.006**
	t4	-3.03	**.008**	-3.38	**.007**	-3.60	**.005**
Patient's time of death	Unknown	-1.26	.399	-2.13	.168	-1.94	.229
	Alive	-.960	.146	-1.35	***.050***	-1.33	***.078***
	Deceased >3 months	-1.40	.232	-1.19	.344	-1.28	.317
Age		.032	.420	.002	.970	.015	.733
Psychologist	Psychologist 1	.191	.847	.140	.887	-.319	.763
	Psychologist 2	-.214	.821	-.306	.747	-.257	.807
Missing data	No missing data	-1.08	.158	-1.33	**.095**	-1.27	.125
Minor mental disorders at t1		.612	**<.001**	.627	**<.001**	.598	**<.001**

Table 20. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **minor mental disorders**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.088	.906	-.315	.693	.179	.822
Relationship with patient	Partner/child	-.001	.999	.090	.992	.270	.769
Employment	Retired/other	-.548	.620	-.1.29	.276	-2.22	***.072***
Support apart from study	Unknown	-.002	.999	.175	.933	-2.60	.246
	Support	-.491	.606	-.388	.698	-.569	.594
Group	sEBT intervention	-.095	.890	.063	.932	.682	.385
Time of investigation	t3	-.467	.237	-.310	.461	-.267	.553
	t4	-.586	.495	-.342	.710	-.218	.820
Patient's time of death	Unknown	-1.45	.341	-.989	.546	-.958	.550
	Alive	-1.37	**.015**	-1.04	***.081***	-1.38	**.032**
	Deceased >3 months	.960	.259	.719	.430	.908	.326
Age		.012	.769	.034	.428	.038	.389
Psychologist	Psychologist 1	.379	.714	.407	.702	1.00	.352
	Psychologist 2	-.106	.912	-.082	.935	-.521	.615
Missing data	No missing data	.658	.401	.707	.398	.581	.483
Satisfaction with life at t1		.644	**<.001**	.662	**<.001**	.609	**<.001**

Table 21. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **satisfaction with life**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	p-Value	beta	p-Value	beta	p-Value
Gender	Male	-4.09	.103	-5.75	**.029**	-3.93	.159
Relationship with patient	Partner/child	-1.55	.593	-1.29	.668	-1.99	.538
Employment	Retired/other	1.81	.632	.186	.962	1.12	.798
Support apart from study	Unknown	-4.76	.510	-6.26	.375	-8.50	.289
	Support	-.930	.775	-1.28	.699	-2.82	.454
Group	sEBT intervention	-2.20	.354	-1.12	.650	-3.17	.262
Time of investigation	t3	.830	.667	1.26	.509	2.13	.298
	t4	-.852	.853	-.151	.974	-.528	.913
Patient's time of death	Unknown	-1.10	.836	-.854	.876	-.303	.958
	Alive	.168	.947	1.35	.592	.593	.827
	Deceased >3 months	4.81	.309	5.50	.249	5.98	.219
Age		-.143	.322	-.129	.372	-.136	.400
Psychologist	Psychologist 1	-1.63	.646	-2.79	.432	-.999	.794
	Psychologist 2	-2.99	.372	-3.12	.356	-1.92	.607
Missing data	No missing data	-.701	.792	-1.27	.645	-1.38	.637
Quality of life (World Health Organisation) at t1		.452	**<.001**	.519	**<.001**	.471	**<.001**

Table 22. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **quality of life (World Health Organisation)**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 123		Model 2 n= 111		Model 3 n= 102	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.421	.181	-.660	***.051***	-.412	.249
Relationship with pat.	Partner/child	-.558	.123	-.735	***.057***	-.360	.377
Employment	Retired/other	-.569	.224	-.850	***.088***	-.880	.109
Support apart from study	Unknown	-1.32	.134	-1.27	.151	-1.90	***.054***
	Support	.107	.790	.272	.518	.101	.839
Group	sEBT intervention	.008	.977	.163	.603	.226	.517
Time of investigation	t3	.448	**.028**	.424	***.052***	.477	**.044**
	t4	.592	.134	.816	***.053***	.768	***.090***
Patient's time of death	Unknown	.493	.453	.377	.588	.382	.593
	Alive	-.37	.894	-.140	.638	.065	.842
	Deceased >3 months	.836	**.036**	.533	.203	.784	***.078***
Age		.014	.405	.024	.177	.017	.363
Psychologist	Psychologist 1	.052	.906	.205	.646	-.006	.991
	Psychologist 2	-.093	.821	-.050	.908	-.382	.414
Missing data	No missing data	.354	.290	.203	.507	.290	.436
Quality of Life (numerical rating scale) at t1		.215	**.003**	.195	**.010**	.178	**.033**

Table 23: **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **quality of life (numerical rating scale)**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	**p-Value**	**beta**	**p-Value**	**beta**	**p-Value**
Gender	Male	-.260	.460	-.161	.658	-.260	.514
Relationship with patient	Partner/child	.347	.391	.518	.212	.195	.673
Employment	Retired/other	.593	.274	.249	.655	.643	.304
Support apart from study	Unknown	.571	.566	.346	.722	.428	.703
	Support	-.097	.834	-.134	.774	-.148	.781
Group	sEBT intervention	-.023	.946	.036	.917	-.063	.874
Time of investigation	t3	.045	.862	.000	1.00	.105	.713
	t4	.717	.178	.532	.341	.520	.370
Patient's time of death	Unknown	.206	.783	.354	.648	.105	.530
	Alive	-.283	.386	-.456	.189	-.273	.453
	Deceased >3 months	-.878	.104	-.844	.136	-.789	.172
Age		-.011	.593	-.015	.442	-.002	.994
Psychologist	Psychologist 1	-.710	.160	-.756	.132	-.775	.180
	Psychologist 2	-.150	.751	-.200	.674	-.001	.999
Missing data	No missing data	-.346	.366	-.580	.144	-.299	.483
Physical impairment at t1		.524	**<.001**	.557	**<.001**	.525	**<.001**

Table 24. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **physical impairment**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Missing data – Missing data in outcome scales.

Variable [a]	Category [b]	Model 1 n= 126		Model 2 n= 114		Model 3 n= 104	
		beta	p-Value	beta	p-Value	beta	p-Value
Gender	Male	-.630	***.081***	-.384	.312	-.481	.240
Relationship with patient	Partner/child	.197	.635	.280	.522	-.001	.998
Employment	Retired/other	.400	.460	.543	.342	.955	.133
Support apart from study	Unknown	.435	.666	.303	.763	1.27	.266
	Support	.255	.586	.080	.869	.158	.733
Group	sEBT intervention	-.881	**.033**	-.924	**.031**	-.903	.063
Time of investigation	t3	2.14	.148	2.20	.172	2.09	.196
	t4	-1.77	**.004**	-2.14	**.001**	-2.12	**.002**
Time of investigation*Group	t3 * sEBT	-2.39	.266	-2.47	.296	-2.30	.386
	t4 * sEBT	1.15	**.024**	.954	***.070***	.616	.283
Patient's time of death	Unknown	1.61	**.044**	1.53	***.072***	1.53	***.081***
	Alive	.584	.142	.454	.268	.488	.272
	Deceased >3 months	-.414	.507	-.096	.886	-.040	.954
Age		-.011	.578	-.023	.254	-.029	.188
Psychologist	Psychologist 1	-.396	.441	-.466	.373	-.469	.411
	Psychologist 2	.327	.494	.295	.550	.702	.197
Missing data	No missing data	-.626	.106	-.697	***.090***	-.750	***.081***
Psychological impairment at t1		.454	**<.001**	.456	**<.001**	.430	**<.001**

Table 25. **Sensitivity analyses regarding missing data:** Estimated regression coefficients beta and p-values for the independent variables in general linear mixed models with the secondary outcome variable post-treatment **psychological impairment**. Main model: participants of at least the first two investigations (model 1); both sensitivity analyses include participants of at least the first two investigations, model 2 without participants (sEBT and control group) with only one session, 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; Time of investigation*Group – t2*sEBT, t2*Control, t3*Control, t4*Control; Patient deceased – Deceased ≤ 3 months; Psychologist – Psychologist 3; Missing data – Missing data in outcome scales.