

Spiritual healing as an intervention to relieve late effects of cancer and cancer treatment
A randomized clinical trial

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Abstract

Many cancer survivors experience late effects in a broad range of mental, emotional and bodily symptoms. This “hidden” delayed disease burden is growing with increasing numbers of survivors and brings with it a need of relieving treatment or support which is largely unmet. Many seek complementary/alternative treatments on an individual basis. This study evaluated the usefulness of a specific type used by many survivors, spiritual healing. In a randomized controlled trial. 30+30 cancer survivors were allocated to either a series of healing treatments, or similar control intervention with calming music. Effects were evaluated through a late effects symptoms score combining five validated symptom load scales: fatigue, depression, pain, sensory disturbances and cognitive functioning - measured at baseline and after 4 and 9 treatments. Improved scores were seen in both groups after 4 and 9 treatments, but the healing group improved significantly more than the control group (statistically as well as clinically). This main result of the study is promising for the usefulness of spiritual healing and perhaps other complementary treatments for late cancer effects. Given the trial design, the study does not address questions of explanation and mechanism – in particular, the existence of an “energy” component – but the results clearly support the notion that such treatments may be useful for many patients in practice. However, the result opens several important questions for future studies: the sustainability of the ameliorating effect over time, the optimal dosage and timing of treatments, and the role of self-selection by “believers”.

Introduction

Cancer survivorship is often associated with various late effects such as insomnia, fatigue, cognitive difficulties, sensory disturbances, pain, fear and depression (Treanor 2013). These late effects can be a long lasting, serious burden on the quality of life and general health for the growing number of cancer survivors who may feel abandoned by a health system geared to focus on acute and specific problems (Treanor 2014). Public health institutions, caregivers and patient organizations increasingly realize that unmet needs of relief and support linger after many cancer treatments, but there is limited knowledge of helpful interventions (Kjaer 2011).

In the absence of other forms of help, many cancer survivors seek a wide range of alternative and complementary therapies, pharmacological as well as nonpharmacological. These patients, as well as the nurses and other health professionals that they often turn to for advice, are in need of reliable knowledge to guide decisions. A number of previous studies have attempted to document relieving effects of complementary and alternative modalities on late cancer effects. These studies generally do show that patients who choose such treatments find them helpful (Henneghan 2015, Lengacher 2006). Yet it has remained controversial whether this perceived benefit reflects a “real” treatment effect or some combination of trust, belief, positive communication, attention and related psycho-social aspects traditionally considered “placebo” factors. Research in the field is often poorly funded, and there is an ongoing debate of how to best use the limited resources to produce knowledge about complementary therapies – a complex question that involves the methodology of trial design as well as the conceptual delimitation of what may be active ingredients vs. “package” and delivery in this case. (Fischer 2014).

“Spiritual healing” and the more or less overlapping term “energy healing” signify a family of treatments comprising no other remedy than the patient-therapist relation, sometimes experienced and described in terms of “energy” and often involving practices of meditative presence as well particular sequences of spatial configuration. For instance, the therapist may be touching or holding hands close to particular body parts (Kaptchuk 2001). These therapies are often considered strongly alternative in the sense that widespread ideas of mechanism of action (energies or fields between the bodies) are controversial from the viewpoint of natural science (Feinstein 2008). The sense of controversy may have been paradoxically amplified through a long tradition of attempts to make these therapies more acceptable through various models of scientific underpinning, dating back at least to Anton Mesmer’s magnetism (Oschman 2000, Kaptchuk 2009), and with recent expressions in terms of quantum entanglement etc. (Walach 2005). Nonetheless, this family of healing practices remains one of the most widespread types of complementary medicine, and is also used by many cancer survivors (Nissen 2012, Eardley 2012). One particularly widespread energy / spiritual healing modality is “therapeutic touch” which is often practiced by trained nurses (Tabatabaee 2016).

Controversy about the existence of an “energetic” substrate sometimes seems to obstruct the discussion of pragmatic helpfulness of the real-world therapeutic work – which may or may not be

better understood through models very different from basic physics – e.g. social psychological theories of trust, ritual, etc. (Benedetti 2011, Ostefeld 2012, Kaptchuk 2011).

Materials and methods

In order to contribute to a better understanding of the potential usefulness of complementary and alternative therapies in everyday life with late cancer effects, this study compared a healing modality with an active control intervention. The control intervention was designed to have a similar setting and course in as many aspects as possible except for the interaction during the act of spiritual healing itself that was replaced by a period of relaxation and listening to music.

With this design the study was focused on the difference made by the concrete person-to-person presence at the core of the healing procedure. This design deliberately circumvented questions of the existence of a separate dimension of energetic interactions, but could contribute importantly to the question whether the effect of a healing intervention is similar to a combination of psychosocial support, or if it is a more effective ritual, thereby assessing its pragmatic usefulness (Schwartz 2009) for cancer survivors. Furthermore, the study was designed to test a hypothesis of broad effect on late effects symptoms. This was defined as a global score combining measures of different aspects of late effects burden, by comparing changes (delta values, see below) in this combined measure, between an energy healing group and an active control group, after 4 and again after 9 treatments.

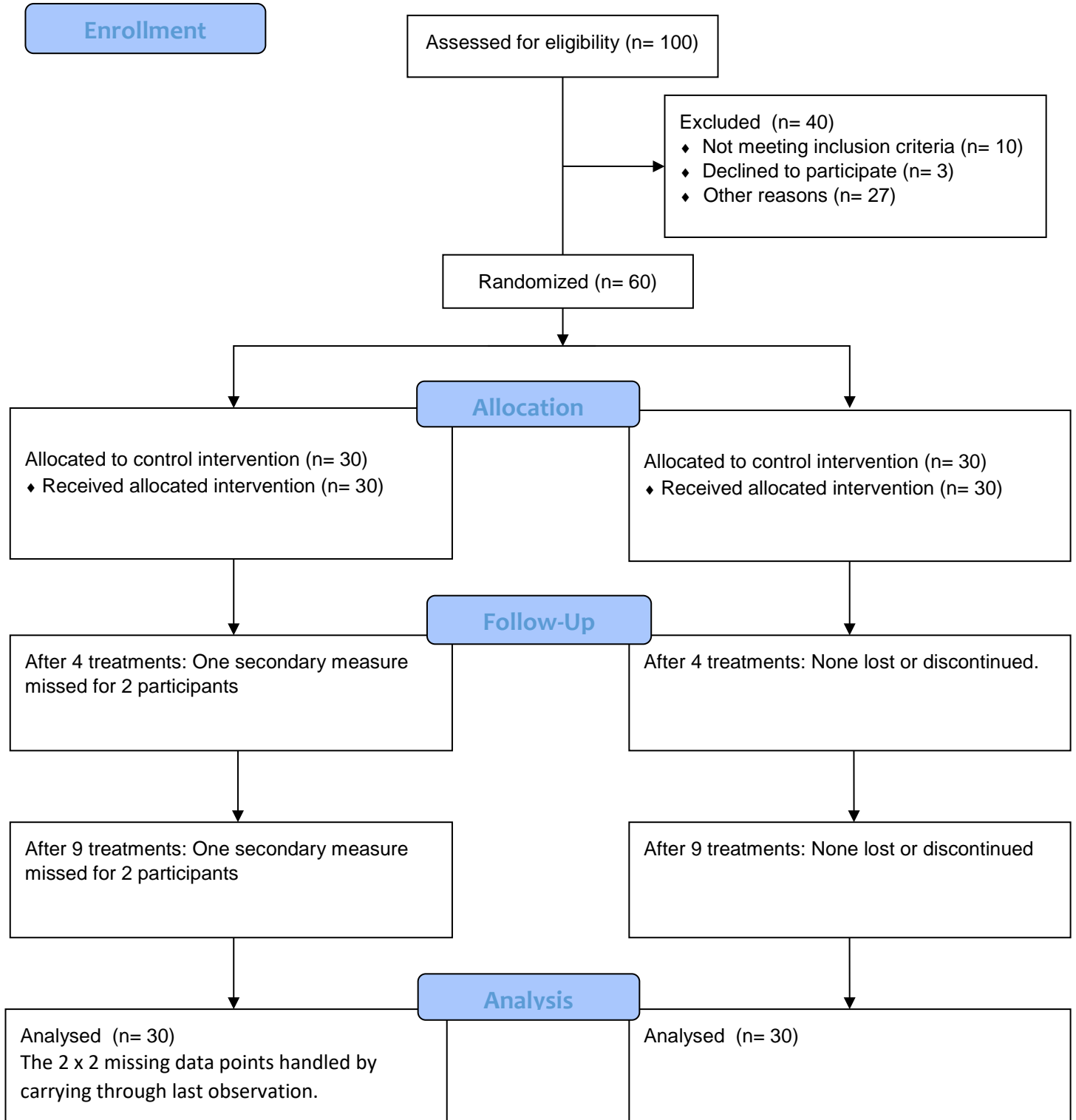
In preparation, a small uncontrolled feasibility trial was run with 12 participants, in order to secure the feasibility of recruitment, intervention and data collection procedures and obtain a rough estimate of the effect measure distribution for use in sample size calculation. Adding moderate requirements of statistical power (significance level 0.05, statistical power 0.8), a dimension of 60 (2 x 30) participants was found to be adequate for the controlled trial.

The controlled trial was designed as a randomized, two-arms comparison with 1:1 allocation ratio, comparing the healing treatment with a control intervention. An active control was chosen as an attempt to assess the hypothetical effect of healing per se, apart from accompanying psychosocial backgrounds such as attention, relaxation, trust and social interaction – so-called placebo factors.

Participants were recruited through open announcements, newsletters and folders in the Danish Cancer Society's patient support centers, and through a smaller organization for cancer survivors. As criteria of eligibility, participants were required to be cancer survivors (no limitation to specific cancer forms) who had undergone a completed cancer treatment, and all of them reported late, adverse effects of the cancer disease and/or treatment. Exclusion criteria were relapse of cancer, comorbidity with diabetes or cardiovascular disease which might also cause neuropathic disturbance in hands or feet, earlier diseases such as apoplexy or epidemic meningitis where symptoms could be indistinguishable from late cancer effects, and lymphedema as the only symptom.

A total of 60 cancer survivors were included through a procedure involving written (pamphlet) and oral (lecture or telephone) information about the character of the randomized trial, the interventions and the data collections. The decision of including a participant in the study was made through a personal interview to secure inclusion criteria and informed consent. Randomization was performed immediately after inclusion. The random allocation method was by means of closed, indistinguishable envelopes, to secure concealed allocation – each new participant would draw an envelope which would then be opened and the contained note on group allocation read aloud and registered. Participants were randomized into two groups of 30, to receive either the healing or the control intervention.

CONSORT FLOW DIAGRAM



Because of the psychosocial nature of the intervention, blinding of participants regarding treatment arm was not possible and relevant in this case. The consultant who carried out the statistical calculations and comparisons was blinded regarding the treatment allocation between the two groups compared.

All interventions – healing as well as control – and all data collection took place in the patient support centers of the Danish Cancer Society who kindly offered this in support of the project, free of charge.

The healing intervention consisted of a series of 9 healing sessions, one every second week. In addition, each treatment included a 30 minutes' conversation before the healing session, and a short rest and follow-up conversation afterwards. The control treatment comprised the same number of treatments at the same intervals, with a similar structure, but with the central healing session replaced by restful listening to music.

During each healing session, the patient would be in a reclining or sitting position while the healer performed a spiritual / energy healing practice as described and trained in the tradition of a particular spiritual healing teacher, Bob Moore, a tradition which emphasizes spiritual / meditative care and presence. Moore shares underlying assumptions and practice elements with a larger family of spiritual and energy healing schools (Mauther 1992, Perrett 2012). Specifically, the procedure involved the therapist holding or slowly moving her hands at a short distance (about 0-100 cm) from the patient's body.

In connection with the healing session, the healer would typically briefly explain the procedure in terms that may involve the notion of non-physical energies. However, patients are not asked to relate to this explanation in any particular manner, but rather to simply "receive".

Two healers performed all healing as well as control interventions. The course of the healing / control intervention session, including the interview parts, was based on a protocol established beforehand. The interview guide was the same in the healing and control groups. It covered a range of overall wellness questions involving bodily, emotional and existential experiences. The protocol allowed for the healer to individualize the treatment accordingly. In order to further secure treatment homogeneity and quality, the healers received supervision from an expert healer and healing teacher throughout the intervention part of the study. The inclusion of individualized treatment elements was allowed in order to keep the intervention close to the actually occurring practice (organic validity) at some cost in terms of standardization and homogeneity, in accordance with the intention and research question of a pragmatic trial (Schwartz 2009).

Outcomes were assessed by way of a battery of validated psychometric scales, assembled in order to cover the five dimensions of the load of late cancer disease and treatment effects laid out in the project description: fatigue, emotional functioning, pain, neurotoxic sensibility disturbances and cognitive functioning. The battery of questionnaires included EORTC-QLQ-C30 (Aaronson et al., 1993), Patient Neurotoxicity Questionnaire (PNQ) (Shimozuma et al., 2009) and Hospital Anxiety

and Depression Scale (HADS) (Zigmond & Snaith, 1983). In both study arms, each participant completed questionnaires before the first treatment and after the 4th and 9th treatment. For the PNQ scale, 32 of the participants reported at onset to have never had neurotoxicity-related experiences, these participants did not fill in the PNQ questionnaire but were rated with a zero at all three times of measurement.

Outcomes in the two groups were compared using SPSS software to perform ANOVA analysis to test for treatment effect in five psychometric dimensions corresponding to the five components of late effects symptom load mentioned above, as well as the primary effect measure. This measure, a combined global symptom load score, was constructed and calculated according to standard principles laid out in the literature (Ferreria et al., 2007, Song et al., 2013) in order to secure that each of the five dimensions was given equal weight in the central effect comparison.

Results

The recruitment of 60 participants was completed according to the design during the period November 2011 – December 2012. They were randomly assigned to the two study arms, 30 in each.

No participants dropped out of the study after randomization. However, two of the 30 participants in the control group missed out in the measurements of one of the five component effect parameters, neuropathic pain. This happened because the PI later discovered that these patients had misunderstood the definition of neuropathic symptoms and should not have been rated in the first instance – according to the procedure described above. These two participants were kept in the analysis of the primary outcome and all other secondary outcomes. The influence of this partial exclusion on the primary outcome is unbiased (in the sense that the average contribution of participants' baseline measures in this variable is zero) because of the method of constructing the main outcome as a combined score with normalized contributions from each sub-score. Furthermore, the neuropathic symptoms measure is characterized by a very small change, particularly in the control group (see table 3 and figure 5 below) making it even more improbable that the absence of these measures makes any difference.

Table 0: participant background information		Healing group	Control Group	Total	
Sex	Male	3	3	6	
	Female	27	27	54	
	Age (years, average)	52	52	52	
Cancer diagnoses	Breast	21	21	42	
	Gastrointestinal	3	1	4	
	Gynecological	2	0	2	
	Hæmatological	3	0	3	
	Lung	1	1	2	
	Neck	0	2	2	
	Liver	0	1	1	
	Testicle	0	1	1	
		Time between end of treatment and inclusion in this study (months, average)	22	30	26
		Relapses	5	3	8
	Multiple diagnoses	3	1	4	
Cancer treatments	Surgery	28	28	56	
	Neurotoxicity associated chemotherapy	23	25	48	
	Other chemotherapy	4	1	5	
	Herceptin	4	5	9	
	Radiation therapy	24	22	46	
	Antihormon	15	19	34	
	Negative change in employment status	15	21	36	

Table 0.

The age distribution of participants was 35-70 y (mean 52, std. 7.2). 54 were women, 6 men. 43 participants had suffered from breast cancer, the remaining 17 were distributed on 13 other cancer forms. 40 participants had undergone one operation, 17 more than one, 3 no surgical treatment. 38 participants had received taxotere, 19 cyclophosphamide, 5 cisplatin, and 35 patients other chemotherapies. 48 participants had received radiation therapy. At the time of inclusion in the study, 13 had a full-time job, 45 were married or in a relation. 37 participants reported that their job situation had changed after their cancer disease and treatment. Time passed since end of cancer treatment was between 0.5 and 6 years (mean 2.2). Comparison of the randomized groups with respect to these background variables revealed no significant differences except for the time passed since end of treatment – mean 1,8 years in the healing group, 2,6 years in the control intervention group. Although this difference is statistically significant ($p=0.04$) it may not be clinically important, especially since baseline late effects load tends to be slightly heavier in the group with the longer time passed since treatment (controls).

Baseline data for the effect measures are given in Table 1, in absolute measures of the components (the units of the psychometric instruments they were measured by). The normalized baseline data (in the units of the Song et al. composite score method) can be found in Table 2 and Figures 1-6.

Table 1: Primary and secondary effect measures at baseline	Healing		Control	
	Mean	STD	Mean	STD
Secondary:				
Fatigue (QLQ: FA)	51.48	22.69	55.37	19.60
Emotional functioning (HAD combined)	14.60	7.22	16.37	8.34
Pain (QLQ: pain)	35.00	25.28	38.89	26.02
Neuropathic symptoms (PNQ combined)	5.93	6.03	5.60	6.31
Cognitive functioning (QLQ: CF – polarity is reverse)	57.22	24.64	42.78	24.24
Primary: Global late effects score, normalized and pooled	-0.57	3.11	0.57	3.12

Table 1.

At baseline, participants randomized to the healing intervention group suffered from fewer or milder symptoms than the control group in all effect measures, but as one should expect in randomized groups this imbalance is generally small compared to within-group variation (also illustrated in the confidence intervals shown in Figures 1-6 below). There are no post-randomization dropouts and the hypotheses tested compared only score changes over time. Therefore, this difference in baseline scores does not weaken the validity of the conclusion.

Data sets from all of the 30+30 participants included in the study were available and included in the following analysis with the above mentioned exception of data missing from 2 control group participants in one secondary effect measure. For the reasons given above this has negligible influence on the changes in the subscale concerned, and even less on the combined main outcome.

For the primary outcome, the global late effects symptom score, the observed treatment effect was calculated as the change from baseline after 4 treatments, and after 9 treatments. The comparison of this change after 4 treatments, and again after 9 treatments, is the test of the main effect hypothesis in this study. The results are shown in Table 2.

Table 2: primary effect measure: global symptom score	Healing		Control		P (t-test)
	Mean	STD	Mean	STD	
Baseline (N=30+30)	-0.57	3.11	0.57	3.12	
After 4 treatments (N=30+30)	-1.99	2.66	0.26	3.28	
Change	-1.43	1.74	-0.31	1.51	<0.001
After 9 treatments (N=30+30)	-3.09	3.16	-0.45	3.48	
Change	-2.52	1.55	-1.02	1.73	<0.0001

Table 2.

After 4 as well as 9 treatments the global symptom score had improved in both treatment groups, but the improvements were significantly larger in the healing intervention group. This pattern of positive treatment effect compared to control intervention is outspoken at the first follow-up measurement after 4 treatments, and even more so after 9 treatments. This supports the study's main hypothesis of a positive healing intervention effect. This central finding is shown graphically in figure 1.

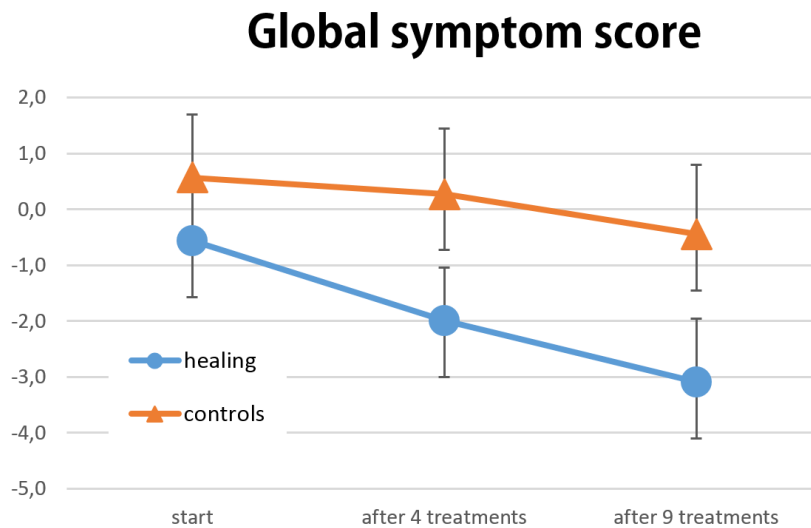


Fig 1.

Between-group difference in change exceeded 0.5 standard deviations of the initial distribution, an effect size conventionally characterized as “moderate to strong” in terms of Cohen’s use of standard deviations as a metric (Cohen 1992). But this apparent effectiveness in terms of a global symptom score seems to reflect a more moderate positive tendency distributed in all of the component scores, seen when each of the five component measures is entered into analysis as secondary effect parameters. An effect hypothesis test was performed for each of these, revealing the same basic pattern: the healing group starts with slightly lighter symptom load, and after 4 as well as 9 treatments they improve more, although both groups tend to improve. In none of the component variables does the between-group difference in change reach the same levels of significance as in the combined score.

Main results are given in Table 3 and Figs 2-6.

Table 3: changes in secondary effect measures (normalized)	Healing		Control		P (t-test)
	Mean	STD	Mean	STD	
Fatigue – change after 4 treatments	-0,26	0,90	0,10	0,84	ns
- after 9	-0,84	0,76	-0,18	0,75	<0.01
Emotional functioning – change after 4 tr	-0,37	0,53	-0,02	0,32	<0.05
- after 9	-0,52	0,57	-0,20	0,36	<0.05
Pain – change after 4 tr	-0,33	0,68	0,15	0,84	ns
- after 9	-0,26	0,89	-0,11	0,64	ns
Neuropathic disturbance – change after 4 tr.	-0,10	0,24	-0,05	0,19	ns
- after 9	-0,22	0,32	-0,07	0,27	ns
Cognitive functioning – change after 4 tr	0,37	0,75	0,48	0,71	ns
- after 9	0,68	0,75	0,46	0,72	ns

Table 3.

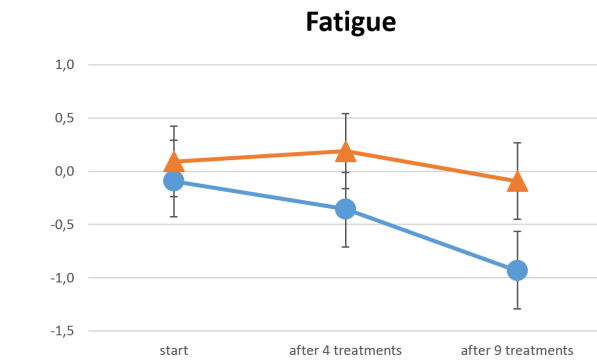


Fig 2.

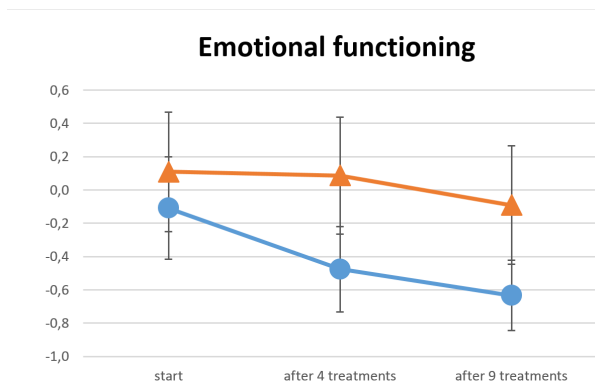


Fig 3.

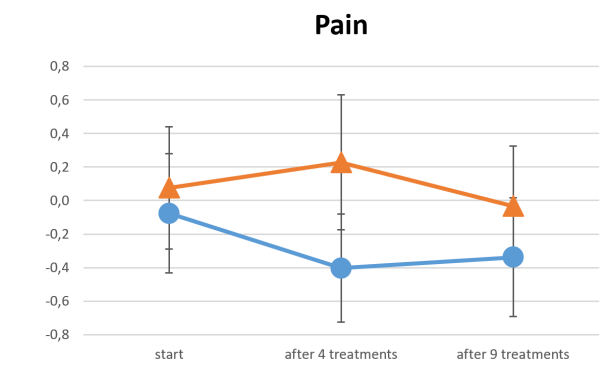


Fig 4.

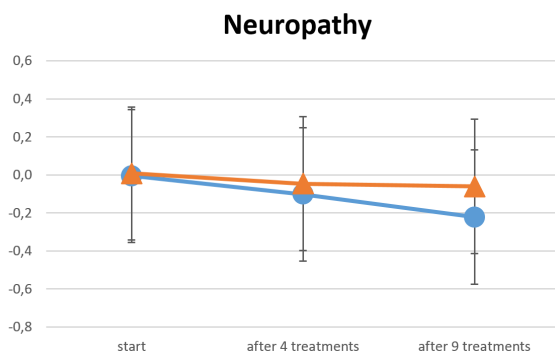


Fig 5.

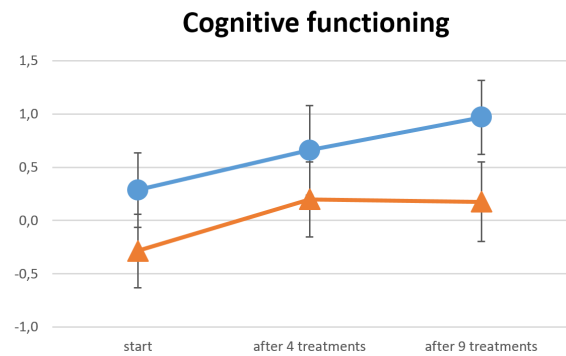


Fig 6.

Notice that the final effect parameter, the cognitive functioning subscale of the EORTC QLQ instrument, is signed so that stronger symptoms are expressed as lower numbers, which is opposite of the other parameters. Thus, this variable repeats the trend pattern of the other variables and the combined score.

The apparently robust existence of a general pattern throughout very different effect measures, which is more outspoken and significant in the combined score than in any of the components, seems to support the idea of a broad-spectrum, non-specific effect profile of spiritual / energy healing. We will return to this in the final discussion.

The a priori construction of a combined global score in this study gave the advantage of fixing one primary effect parameter, thereby avoiding the statistical ambiguities associated with many parallel effect measures. While the method reveals an unambiguous statistically significant improvement in this global effect parameter, it has the disadvantage that the question of clinical significance becomes more complex. The result can be only indirectly related to what is known about the size of changes needed for clinical significance. However, the changes are considerable compared to the natural distributions within the group (“moderate to large effect” in Cronbach’s terms) and at least for two constituent variables that are EORTC subscales (fatigue, cognitive functioning) the magnitude of observed change in each of these contributions alone is a of a clinically valuable dimension (Fayers 2001).

Participants were encouraged to report adverse or uncomfortable experiences in connection with any of the interventions. No serious adverse effects were reported, although several participants in the healing group reported experiences of mild and transient discomfort often described as echoing or repeating experiences of disease and treatment – particularly chemotherapy – in the past. This kind of effect was expected, asked for and interpreted by the healing therapists as a meaningful “energetic balancing of the imbalance”.

Ethics

The clinical trial reported in this article was designed and conducted in accordance with the Helsinki declaration. The protocol was submitted to the research ethics board of Region Zealand, Denmark, who determined that it fell outside of the field of biomedical experiments that need the approval of the ethical committee according to Danish law. The data protection authority accepted the protocol before data collection was initiated. Apart from these formal ethical requirements, the research team felt an obligation towards participants in the control group. Therefore, after the end of the follow-up-period, each of the control group participants was offered the same sequence of nine treatments as the healing intervention group had received in the study.

Discussion

The main result of this trial supports the effect hypothesis it was set up to test. The healing intervention group improved in the main effect parameter. Global symptom scores in both groups improved after 4 and 9 treatments, but significantly better in the healing intervention group. Furthermore, this pattern is generally repeated in all of the secondary and component effect measures, although these observed effects are more modest than that in the global score effect, and only one or two reach statistical significance (cf. table 3). Indeed, the combined picture seems to suggest a nonspecific, general, mild ameliorating effect that may fit well for conditions of nonspecific but persistent suffering such as late cancer effects.

This main result clearly supports the notion that energy healing can be a valuable treatment option for cancer survivors burdened by late effects of disease and treatment. This result is in accordance with the general trend found in the sparse earlier trials recently reviewed by Henneghan (Henneghan 2015). However, the conclusion is subject to several limitations and assumptions.

One obvious limitation to the kinds of knowledge or conclusions that can be drawn from this pragmatic type of study stems from the design's comparison of comprehensive real-world treatment packages rather than particular supposedly active ingredients. For this reason, if a treatment effect is observed, this study will not allow any conclusions on the extent to which it is due to e.g. the interviews or other elements that some may see as inessential to the active healing component – in particular, the putative “energy medicine” components discussed in the introduction (Oschman 2000, Ostenfeld 2012). Also, it is always possible to speculate that an observed effect could be connected with any number of confounding factors associated with differences between the two intervention groups (age, social status, disease history, initial symptom strength, cf. Table 0, or other dimensions not covered by the data collection). However, such potential unknown factors could work either way, and since the observed baseline inter-group differences have the order of magnitude expected in a randomized population of the study's size, this study does not provide opportunity for a substantial discussion of such factors.

The self-selected character of the study population introduces a more substantial kind of bias in the form of more positive interest and expectation associated with energy healing than would be the case in the general population. In combination with the short follow-up period, the fact that all effect measures are self reported, and the impossibility of blinding participants to their group allocation makes it very likely that a large portion of the effect is due to what is commonly understood as “placebo factors”: positive communication, positive expectations, pleasant sensory experiences, meaning-inducing narratives and so on.

In this light, the trial can be said to compare two placebo or ritual-like treatments and show that for persons positively interested in energy healing, its full ritual has significantly better effects than a partial one. In other words, the comparison of two treatments of this character, or perhaps two intensities or degrees of completeness of it, has the advantage of providing some evidence to counter the common objection to complementary therapies: that whatever beneficial effects experienced are “just placebo”. This study at least makes it clear that this field is complex and that all placebos are not equally good. This implies that at least some therapists and/or therapeutic systems are good at inducing or supporting such positive psycho-social-ritual effects. Indeed, to many patients living with burdens such as late cancer effects, the main question may not be how large a fraction of a relief that may be due to psycho-social-ritual factors.

From a scientific viewpoint, the trial design has the disadvantage of neither being optimized for explanatory or pragmatic purposes (Schwartz 2009). The design and research question are half way between the two, but at least sufficiently pragmatic for the result to give some indication of feasibility and usefulness. Given the result of this study, there are important research questions in both directions to pursue. To the explanatory side it would be interesting to compare more different degrees and types of healing and healing-like rituals. To the pragmatic side it would be important to reduce selection biases, to include a trial arm with “treatment as usual” in order to assess the size and value of pragmatic, real-life effect – and perhaps most important, to test the sustainability of treatment effects through follow-up on longer timescales.

Finally, the effect size in this study increased with longer follow-up and more treatments. This points to the value of studies that vary timing and dosage to determine optimal courses of intervention.

Other information

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