Randomized Controlled Trials of Non-medical and Non-surgical Therapies for Palliative Care: A Literature Review

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Abstract

A systematic review of randomized controlled trials (RCTs) of non-medical and non-surgical therapies for palliative care was undertaken to provide guidance for best practice palliative care. Nine databases were searched (ERIC, EMBASE, MEDLINE, CINAHL, AHMED, Psychinfo, HealthStar, Sociological Abstracts, and the Cochrane Library, including Central and Systematic Reviews) for RCTs and systematic reviews. Fifteen RCTs, varied in intervention and outcome measures, were identified. Several studies found positive results but the sample sizes were small, the methodological quality of the RCTs did not meet Cochrane Collaboration criteria, and the conclusions were at high risk of bias. Improved planning of the protocols and execution, with the addition of experienced trialists and statisticians, is required to improve the quality of the evidence collected in future studies.

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Key words: palliative care, dying, terminal, randomized controlled trials, experiments, non-medical therapies, non-surgical therapies

Introduction

The goal of this review is to identify all RCTs of non-medical and non-surgical palliative care and systematically review their methodological quality and findings. One previous systematic review of complementary and alternative medicine for the management of symptoms at the end of life (EOL)[1] searched six databases and identified 11 RCTs, but made no assessment of methodological quality. Non-medical is defined as not utilizing medical interventions such as pharmaceuticals, and non-surgical as not utilizing interventions such as surgery or injecting structures to reduce pain. Because many patients wish to try such therapies for palliative care, the goal of this review is to identify therapies that have been rigorously tested. Medical and surgical interventions and drug studies were excluded because a recent Cochrane review of palliative chemotherapy[2] has reviewed medications.

There have been several systematic literature reviews of palliative care,[3-8] which did not compare medical and non-medical therapies. Only Smeenck[8] applied formal methodological criteria and none used Cochrane Collaboration criteria to assess the literature. Hearn[3] identified five RCTs and eight prospective studies of specialist palliative care teams and concluded that patients cared for by a specialist palliative care team spend fewer days in the hospital, have better symptom control, and spend less money, resulting in greater satisfaction among patients and caregivers. Smeenck[8] identified eight RCTs of palliative home care and found two of five studies demonstrated an increase in patient satisfaction, three of seven an improvement in the physical aspects of quality of life, one of six benefit in psychological dimensions, and two of five an improvement in readmission rates.

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Salisbury[7] identified seven RCTs of different models of specialist palliative care and concluded there is limited evidence from methodologically weak studies that pain control is better in the hospital. Kaasa[4] reviewed measures of quality of life in palliative care and concluded measurements had improved, but that a common standard for scoring would improve their usefulness.

Literature Search and Method of Analysis

Nine health databases (EMBASE, MEDLINE, CINAHL, AHMED, Psychinfo, ERIC, HealthStar, Sociological Abstracts, and the Cochrane Library, including the Cochrane Controlled Trials Register and Library of Systematic Reviews) were searched to identify relevant publications using the key words: terminal care or end-of-life care or death or dying or hospice care or palliative care and randomized controlled trial or randomized control or clinical trial. This review focuses on the use of non-medical and non-surgical therapies for palliative care provided to persons who are terminally ill, near death, or dying.

The Cochrane Collaboration criteria for assessing the methodological quality of RCTs were used to assess each RCT of non-medical and non-surgical therapy.[9] These four criteria are:

- **Selection bias.** Bias may arise during the selection and/or allocation of subjects to comparison (i.e., treatment or control) groups. Details of efforts used to prevent selective assigning of subjects, such as blinding and concealment, should be reported to indicate awareness of this threat and efforts to reduce or eliminate it.

- **Performance bias.** Although controlled trials aim to compare treatment and control groups fairly, subjects within groups may be treated differently. As such, the placebo effect or an unintended difference may occur. It is necessary to report details of efforts to prevent or address performance bias. (The authors ascertained whether there was a process analysis documenting that the intervention was observed to have been fully delivered to all participants in the manner planned in the protocol).

- **Attrition bias**. When subjects drop out of an RCT, systematic differences may occur or be accentuated between the treatment and control groups, and test results may be affected. Details of efforts to proactively and/or reactively manage attrition are thus needed to ensure it does not bias the integrity of the RCT. (The authors recorded an attrition analysis was present only if the researchers reported an analysis showing the intervention and control arms were not differentially affected by attrition, and it was recorded as not present if the researchers only stated the numbers of participants who began and completed the study).

- **Detection bias.** Since determining the outcomes of one or more interventions is often the focus of RCTs, the assessment of outcomes must not be biased. One method of preventing detection bias is to blind the assessors, a particularly important method when the outcome measurement is subjective in nature (e.g., stress level measurement). It is thus important to report details about efforts to prevent detection bias.

This review assessed three additional potential sources of bias:

- Whether a power computation was used to determine the required sample size to avoid type II errors. (A type II error occurs when an intervention is found to have no effect, but the sample size is too small to detect this effect.)

- Whether an intention-to-treat analysis was planned *a priori*. (The authors recorded it as not present if a study with a small sample retained all the participants until the end of the trial and thus completed an intention-to-treat analysis without having planned it.)

- Whether the data were analyzed using appropriate statistical tests.

▼ Each article was independently assessed for potential bias by two reviewers, with continued discussion until differences were resolved.

Results

The authors identified 37 potential RCTs (Figure 1). Four were excluded from further consideration because on closer inspection they were not RCTs,[10-13] 17 because they were RCTs about cancer patients who were not palliative,[14-30] and one that had not yet reported outcomes,[31] leaving 15 RCTs in 17 citations[32-48] for further analysis. The methodological quality of many of the remaining 15 RCTs did not meet most of the Cochrane Collaboration methodological criteria, resulting in a high risk of bias in most of the currently available RCT studies; a few RCTs met more of the criteria and thus had a lower risk of bias (Table 1). Part of the risk of bias may be due to the failure of authors to recognize the need to avoid as many causes of bias as possible. Rinck,[6] in a review of 11 comprehensive palliative care RCTs, also identified many methodological problems that need to be overcome in the conduct of research on measuring the outcomes of EOL treatment or care. The RCTs in this article were systematically reviewed for country where the research was conducted, interventions, data collection measures, subjects, numbers at baseline and end of the project, and results (Table 2).

Figure 1. Trial Flow for RCTs of Non-medical and Non-surgical Therapies in Palliative Care

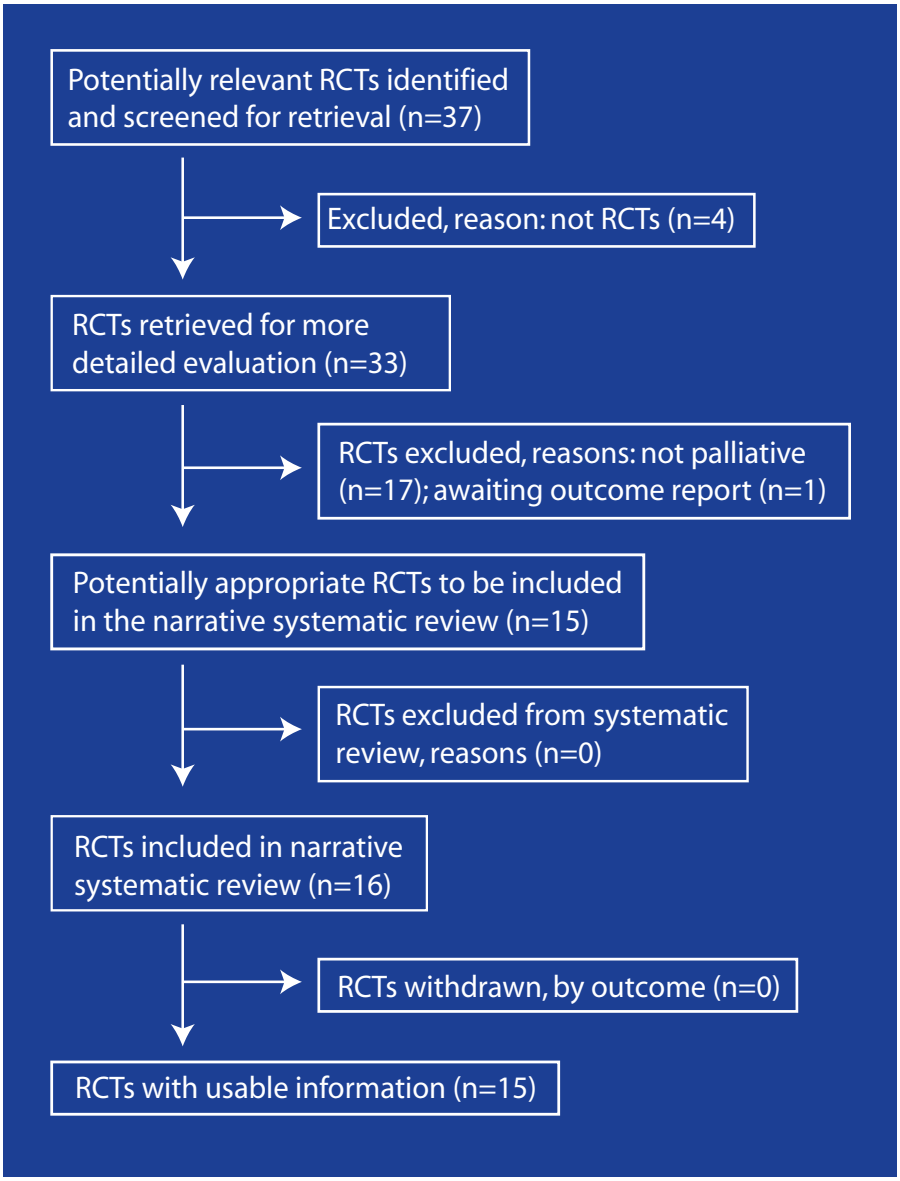

Table 1. The Methodological Quality of RCTs in Palliative Care

	Selection bias		Performance bias				Attrition bias	Detection bias	Intention to treat	Power computation	Appropriate analysis
Study	**Method of randomization**	**Randomization concealed**	**Blinding of participants**	**Blinding of care providers**	**Co-interventions**	**Process analysis**	**Attrition analysis**	**Assessment blinded**	**Intention to treat**	**Power computation**	**Appropriate analysis**
Corner 1996	No	No	No	No	No	No	No	No	No	No	Yes
Curtis 1986	No	No	No	No	No	No	No	No	No	No	Yes
Edmonds 1999	Yes	Yes	No	No	No	Yes	No†	No	Yes†	No	Yes
Gadsby	No	Yes	No	Yes	No	No	No	No	No	No	Too small to analyze
Giasson 1998	No	No	No	No	No	No	No	No	No	No	Yes
Hilliard 2003	No	No	No	No	No	No	No	No	No	No	Yes
Hodgson 2000	No	No	Yes	No	No	No	No	No	No	No	Yes (but N=12)
Linn 1981; 1982	Yes	Yes	No	No	No	No	No	No	No	No	Yes
Liossi 2001	Yes	No	No	No	No	No	No	No	No	No	Yes
Ross 2002	No	Yes	No	No	No	No	No	No	No	No	No analysis
Schofield 2003	No	Yes	No	No	No	No	No	No	No	No	Yes
Soden 2004	No	Yes	No	No	No	No	No	Yes	No	No	Yes
Spiegel 1981	No	No	No	No	No	No	No	No	No	No	Yes
Wilcock 2004	No	No	No	No	No	No	No	No	No	No	Yes
Wilkinson 1999	Yes	No	No	No	No	No	No	No	No	No	Yes

† All 30 intervention patients completed the study

Table. 2a. Summary of the Comparisons, Outcomes, Subjects, and Results of the RCTs

Author(s) (Year) Country	EOL Care or Model Comparisons	Measures or Focus of Data Collection	Subjects and Data Collection at baseline (b) and at end of study (e)	Results
Corner (1996) UK	Randomization to 3-6 one hour sessions weekly with a nurse practitioner for counseling, breathing retraining, relaxation, and teaching coping and adaptation strategies, or control	(1) 10 point visual analogue scales to rate breathlessness over the previous week: breathlessness at best; breathlessness at worst; distress caused by breathlessness; (2) Functional Capacity scale to measure ability to walk distances, climb stairs, and perform activities of daily living; (3) Hospital Anxiety and Depression scale; (4) in depth interviews to explore the experience of breathlessness	Patients with small-cell or non-small cell lung cancer who had completed chemotherapy and were suffering from breathlessness; 34 patients were randomized until medical and nursing staff asked for randomization to be stopped as they observed a benefit from the intervention (b) 19 experimental, 15 control; 8 withdrew from the experimental and 6 from the control because of deterioration (e) 11 experimental, 7 control	Distress from breathlessness improved by median 53%, breathlessness at worst by median 35%, functional capacity by median 21%. Significant improvements in breathlessness at best ($p<0.02$), breathlessness at worst ($p<0.05$); distress caused by breathlessness ($p<0.01$), functional capacity ($p<0.02$) and ability to perform activities of daily living ($p<0.03$) compared to control
Curtis (1986) US	Patients were randomized to: A no intervention, B background sound, or C music in two different schedules for 15 minutes twice daily for 2 days	Modified Scott and Huskisson self-reported pain and pain relief graphic rating scale	(b) 17 patients with terminal malignant disease; 8 were eliminated due to scheduling conflicts, worsening symptoms, or need for continuous therapy (e) 9 patients	No significant differences between no intervention, background sound, and music
Edmonds (1999) Canada	Long term (35-week) group psychotherapy versus standard EOL care	Psychological response; measured by Profile of Mood States (POMS); The Functional Living Index for Cancer (FLIC); the DUKE UNC Functional Social Support Questionnaire (DUFSS); Mental Adjustment to Cancer Scale (MAC); Rationality/ Emotional Defensiveness Scale (RED); Marlow-Crowne Social Desirability Scale (M-C); and Defensive Repression scale	432 metastatic breast cancer patients identified at Princess Margaret Hospital, Toronto; N=246 met eligibility criteria (b) n=30 treatment and n=36 control (e) same	No differences in POMS, FLIC, DUFSS, RED or MCSD in experimental compared to control group, but intervention group had more anxious preoccupation (MAC); the therapists noted changes not measured by the scales
Gadsby (1997)	Randomized to 5 daily treatments of acupuncture-like transcutaneous electrical nerve stimulation (ALTENS), or placebo ALTENS, or no ALTENS, plus recognized standard therapies for pain and emesis	EORTC QLQ-C30 on entry and day 6; retrospective review of medication use	All patients with terminal cancer who entered the Leicestershire Hospice August-September 1994 for control of pain and/or nausea and vomiting 15 (b) 5 ALTENS; 5 placebo ALTENS; 5 control (e) 5 ALTENS; 3 placebo ALTENS; 3 control	Pre-post differences in scores for: (1) Global Quality of life: decreases were: ALTENS 5.8; placebo ALTENS 5.33; Control 7.00. The authors claim the OR for ALTENS is 2.67 compared to control; (2) Fatigue: ALTENS 17.78; placebo ALTENS 0.00; Control 0.00; OR for ALTENS = 16 compared to control (3) Nausea and vomiting: ALTENS 0.3; placebo ALTENS 0.167; Control 0.80. (4) Pain: ALTENS 0.00; placebo ALTENS 0.33; Control 1.00

Table 2b. Summary of the Comparisons, Outcomes, Subjects, and Results of the RCTs

Author(s) (Year) Country	EOL Care or Model Comparisons	Measures or Focus of Data Collection	Subjects and Data Collection at baseline (b) and at end of study (e)	Results
Giasson (1998) Canada	Therapeutic touch (3 non-contact therapeutic touch sessions each of 20 minutes) compared with regular care that included three 20-minute rest periods	Personal wellbeing (measured by Giasson's 1994 Well Being Scale for pain, nausea, depression, anxiety, shortness of breath, activity, appetite, relaxation, and inner peace)	Terminal cancer patients in one palliative care unit in one hospital (b) n=10 intervention and n=10 control (e) same	The intervention group had higher well-being scores immediately after the treatments administered on days 2, 3, and 4 (of a four-day schedule)
Hilliard (2003) US	Randomization to routine hospice services and music therapy, or routine hospice services. Each experimental group patient received at least 2 music sessions; one patient received 13	Hospice Quality of Life Index-Revised (HQOLI-R); Palliative Performance Scale of functional status assessed on every visit by the hospice nurse; length of life	(b) 80 patients with terminal cancer with a prognosis of less than 6 months in a north Florida hospice; experimental = 40; control = 40 (e) no stated	There was significant improvement on the psycho-physiological subscale ($p<0.05$) of the HQOLI-R for the experimental group ($p<0.05$) but no significant differences on the functional well-being or social/spiritual subscales; no significant differences on the Palliative Performance scale or length of life
Hodgson (2000) UK	Randomization to three 40-minute sessions of either reflexology or placebo reflexology	Modified Holmes and Dickinson (1987) visual analogue self-assessment of quality of life scale	(b) 22 patients with palliative cancer on surgical or hematological units at a UK NHS district hospital in Lanarkshire; 10 patients were unable to participate (1 died, 3 too weak, 2 refused , 2 previous reflexology , 2 contraindications to reflexology) (e) 12 (6 reflexology; 6 placebo)	The VAS scores were significantly better for the experimental group ($p=0.004$), but only one of the 18 components (breathing) was significantly better for the experimental group ($p=0.026$)
Linn (1981; 1982) US	Comparison of life review counseling	Cumulative Illness Rating Scale; Depression Factor of the Psychiatric Outpatient Mood Scale (POMS); Sherwood Self-Esteem Scale; Cantril Life Satisfaction Scale; Srole Alienation Scale; Rotter Locus of Control Scale; Rapid Disability Rating Scale; time to death	Terminally ill patients in Veterans Administration Hospital in Miami (141), of whom 120 participated (b) 62 experimental, 58 control (e) 9, 12 at 12 months	The experimental group after 3 months had lower scores on depression ($p<0.001$), and alienation ($p<0.05$) and higher scores on life satisfaction ($p<0.01$), and self esteem ($p<0.001$) than the control group. At 12 months they had lower scores than the control group on alienation ($p<0.001$) and high scores on life satisfaction ($p<0.01$), self esteem ($p<0.05$), and locus of control ($p<0.001$); there were no statistically significant differences in days in hospital, readmissions, disability, functional status, or survival, and no differences in response to therapy in those less than 60 years of age compared to a group over 60 years
Liossi (2001) Greece	Standard care versus standard care plus hypnosis (four 30-minute sessions each week) for terminally ill cancer patients	Greek translations of the Rotterdam Symptom Checklist (RSCL); the Hospital Anxiety and Depression Scale (HADS); semi-structured interviews of hypnosis patients	78 patients in a palliative care unit in Athens with advanced terminal cancer, of whom 50 were eligible (b) N=50, numbers in 2 groups not stated (e) N=50, not stated	Significant decrease in anxiety scores ($p<0.01$), depression scores ($p<0.01$), physical distress scores ($p<0.01$) for the treatment group compared to the control group

Table 2c. Summary of the Comparisons, Outcomes, Subjects, and Results of the RCTs

Author(s) (Year) Country	EOL Care or Model Comparisons	Measures or Focus of Data Collection	Subjects and Data Collection at baseline (b) and at end of study (e)	Results
Ross (2002) UK	Randomization to weekly reflexology for 6 weeks or basic foot massage	Hospital Anxiety and Depression Scale (HADS); rating of 10 symptoms	(b) 26 patients in Edinburgh with advanced cancer; (7 died within 6 weeks of entry to the study, one could not attend, and there were no base-line measures for one) (e) 17	No differences over time and between groups on HADS or symptoms (no significance levels stated)
Schofield (2003) England	Randomization to two one-hour sessions in a multisensory room (Snoezelen) or a normal quiet room	Depression measured by the Hospital Anxiety and Depression Scale (HADS), and quality of lifemeasured by the EORTC C-30	Patients in one hospice day unit who scored 8 or more on the Hospital Anxiety and Depression Scale (HADS) and with no evidence of psychosis. The potential pool was 45 patients. (b) N=26, n=13 (treatment) and n=13 (control) (e) same	Treatment group had significant reduction in anxiety in week 1 ($p<0.01$) and week 2 ($p<0.02$), as measured each week
Soden (2004) England	Comparison of aroma-therapy and massage; massage; and standard care (no massage)	Pain was measured by a Visual Analogue Scale and a modified Tursky Pain Descriptors Scale; sleep by the Verran and Snyder-Halpern (VSH) sleep scale; depres-sion by the Hospital Anxiety and Depression Scale (HAD); and symptoms by the Rotterdam Check List (RSCL)	Patients in three palliative care units in the South Thames region (b) N=42, 19 received aromatherapy and massage, 13 received massage alone, and 13 in control group. (e) N=36, as 3 died and 3 too ill to continue	No statistically significant differences or changes in pain, sleep, depression, anxiety, symptoms, and quality of life for any group; the massage groups had significantly better sleep than the control ($p<0.04$)
Spiegel (1981) US	Randomized to weekly 90-minute supportive group meetings with a social worker and a patient with breast cancer in remission as leaders	Health Locus of Control (HLC) scale; Profile of Mood States (POMS); Janis-Field self-esteem scale; 9 self-asssessed maladaptive habits; 14 item phobias checklist; 9 item denial measure of an individual's usual method of coping with problems	(b) 109 women with metastatic breast cancer referred by oncologists; 86 completed the first questionnaire; 18 refused to participate; 5 died prior to contact; of those assigned to the treatment group, 14 were too ill to participate and 2 moved away; in the control group 4 were too ill to partici-pate, 2 died, 4 refused, and 2 were not contactable (e) treatment n=34; control n=24; (16 of the treatment and 14 of the control groups completed 4 adminis-trations of the test package)	Those who participated in weekly group sessions had lower POMS scores ($p<0.01$); with lower scores on subscales of tension-anxiety ($p<0.01$), more vigour ($p<0.01$), less fatigue ($p<0.01$) and less confusion ($p<0.05$); fewer maladjusted coping responses ($p<0.01$); and fewer phobias ($p<0.05$)

Acupuncture

Gadsby[32] randomized 15 patients in the Leicestershire Hospice, UK, with terminal cancer who needed control of pain and/or nausea and vomiting, to five daily treatments of acupuncture-like transcutaneous electrical nerve stimulation (ALTENS), placebo ALTENS, or no ALTENS; all patients received recognized standard therapies for pain and emesis. The study was too small to report results but demonstrated the feasibility of using the ALTENS machine.

Aromatherapy

Two RCTs of aromatherapy yielded conflicting results. Wilkinson[33,34] randomized 103 patients attending a palliative care center to either massage or massage with aromatherapy. Sixteen patients were lost from the study. She found the group receiving three massages with aromatherapy had significant improvements on the Rotterdam Check List scales of physical symptoms (p=0.001), psychological symptoms (p=0.01), quality of life (p=0.001), severe physical symptoms (p=0.001), and severe psychological symptoms (p=0.01) compared to baseline; and both the massage with aromatherapy and massage groups had a significant decrease in anxiety (p=0.0001). It was not stated whether they also received medical care for physical symptoms.

Wilcock[35] randomized 46 patients attending a palliative day care in Nottingham, UK, to day care plus weekly aromatherapy or day care only for four weeks. Seventeen patients were lost from the study. For the 29 who completed all four weeks there were no significant differences on the Profile of Mood States (POMS), patient-rated intensity and bother caused by two physical symptoms most important to the patient, or patient-rated quality of life compared to baseline. The differing conclusions of these studies may be due to the use of aromatherapy with massage by Wilkinson, or the large number of drop outs (37%) from Wilcock's study.

Breathing Training

Corner[36] randomized 34 patients in London, UK, with small-cell or non-small cell lung cancer who had completed chemotherapy and were suffering from breathlessness, to 3-6 one-hour sessions weekly with a nurse practitioner. Fourteen patients withdrew

Table 2d. Summary of the Comparisons, Outcomes, Subjects, and Results of the RCTs

Author(s) (Year) Country	EOL Care or Model Comparisons	Measures or Focus of Data Collection	Subjects and Data Collection at baseline (b) and at end of study (e)	Results
Wilcock (2004) UK	Randomization to day care + weekly aromatherapy or day care for 4 weeks	Profile of Mood States (POMS); the patient rated the intensity and bother of two physical symptoms that were most important to the patient from 0 to 7; patient rated quality of life from 0 to 7	(b) 46 patients attending a palliative day care in Nottingham, UK (e) 11 in aromatherapy and 18 in the control group completed all 4 weeks	No significant differences in outcomes
Wilkinson (1999) UK	Comparison of (a) three full body massages with Roman chamomile essential oil (aromatherapy group); and (b) three full body massages with sweet almond oil (massage group)	Rotterdam Symptom Checklist (RSCL); State Anxiety Inventory (SAI); Trait Anxiety Inventory (TAI); semi-structured questionnaire about the positive and negative aspects of massage	103 patients attending a palliative care center and referred either by their GP or center staff (b) 46 to aromatherapy, 57 to sweet almond group (e) 43 and 44	Significant improvements on RSCL scales of physical symptoms (p=0.001), psychological symptoms (p=0.01), quality of life (p=0.001), severe physical symptoms (p=0.001), and severe psychological symptoms (p=0.01) only for the aromatherapy group; significant decease in anxiety (p=0.0001) for both groups after massage

due to clinical deterioration. The sessions included counseling, breathing re-training, and teaching relaxation, coping, and adaptation strategies. Distress from breathlessness improved by a median of 53 percent, breathlessness at worst by a median of 35 percent, and functional capacity by a median of 21 percent. There were significant improvements in breathlessness at best ($p<0.02$), breathlessness at worst ($p<0.05$), distress caused by breathlessness ($p<0.01$), functional capacity ($p<0.02$), and ability to perform activities of daily living ($p<0.03$) compared to the control group.

Hypnosis

Liossi[37] found a significant decrease in anxiety ($p<0.01$), depression ($p<0.01$), and physical distress ($p<0.001$) scores in patients at a palliative care center receiving hypnosis compared to the control group.

Massage

Soden[38] found patients in a palliative care unit receiving massage had no statistically significant differences in pain, sleep, depression, anxiety, other symptoms, or quality of life compared to controls, although the massage group had significantly better sleep than the control group because sleep worsened for the control group ($p<0.04$). (See Aromatherapy section for other studies associated with massage.)

Multisensory Stimulation

Schofield[39] found 26 hospice patients who spent one hour on two occasions in a multisensory room had a significant reduction in anxiety in week 1 ($p< 0.01$) and week 2 ($p<0.02$) compared to those placed in a quiet room. In the multisensory room, colors were projected on the floor from a fiber-optic spray, shapes and colors were projected onto the wall, and music was played.

Music Therapy

There are two RCTs of music therapy with conflicting results. Hilliard[40] randomized 80 patients, with terminal cancer in a north Florida hospice, to receive either routine hospice services and music therapy or routine hospice services alone. There was significant improvement on the psychophysiological subscale of the Hospice Quality of Life Index-Revised (HQOLI-R) for the experimental group ($p<0.05$), but no significant differences on the functional well-being or social/spiritual subscales, and no significant differences on the Palliative Performance scale or length of life.

Curtis,[41] for nine terminally ill cancer patients, found no differences in pain among those who received usual therapy, usual therapy plus background music, or usual therapy plus music therapy for fifteen minutes twice daily for two days. Curtis' study is very small.

Psychotherapy and Behavioral Therapy

For 432 patients with metastatic breast cancer at Princess Margaret Hospital, Toronto, Edmonds[42] found 246 met the eligibility criteria for the study and enrolled 30 in the treatment group for group psychotherapy and 36 in the control group to receive standard EOL care. At the end of 35 weeks there were no differences in POMS, Functional Living Index for Cancer (FLIC), the DUKE UNC Functional Social Support Questionnaire (DUFSS), the Rationality/Emotional Defensiveness Scale (RED), the Marlow-Crowne Social Desirability Scale (M-C), or the Defensive Repression scale.

Linn[43,44] found after three months terminally ill patients who received "life review" counseling had lower scores on depression ($p<0.001$) and alienation ($p<0.05$), and higher scores on life satisfaction ($p<0.01$) and self esteem ($p<0.001$) compared to the control group.

Spiegel[45] randomized 109 women with metastatic breast cancer to weekly 90-minute supportive group meetings with two leaders (a social worker and a patient with breast cancer in remission). For the 62 who remained in the study, those who participated in weekly group sessions had lower POMS scores ($p<0.01$), with lower scores on the subscale of tension-anxiety ($p<0.01$), more vigor ($p<0.01$), less fatigue ($p<0.01$), less confusion ($p<0.05$), fewer maladjusted coping responses ($p<0.01$), and fewer phobias ($p<0.05$).

Reflexology

Two RCTs of reflexology found conflicting results. Ross[46] randomized 26 patients in Edinburgh, Scotland, with advanced cancer to weekly reflexology or basic foot massage for three weeks. There were no differences at baseline and after therapy between the groups on the Hospital Anxiety and Depression Scale (HADS), but the foot massage group improved significantly (level not stated) in appetite and mobility on a rating of 10 symptoms (the text only mentions appetite, mobility, pain, and nausea).

Hodgson[47] randomized 12 patients, in the palliative stage of cancer on surgical or hematological units at a United Kingdom National Health Service district hospital in Lanarkshire, to either three 40-minute sessions of reflexology or placebo reflexology. The total scores on the Holmes and Dickinson visual analogue self-assessment of quality of life scale were significantly better for the experimental group (p=0.004), but only one of the 18 components (breathing) was significantly better for the experimental group (p=0.026).

Therapeutic Touch

Giasson[48] found that patients with terminal cancer randomized to three 20-minute sessions of non-contact therapeutic touch had significantly increased ratings of well-being on the Giasson Well-Being Scale compared to the control group that received rest periods (p=0.0015).

Discussion

The RCTs identified in this review were mostly small pilot studies. One aromatherapy study found symptoms improved and the other did not. Patients with lung cancer who received breathing training experienced less breathlessness. Patients who received hypnotherapy experienced less anxiety, depression, and distress. Patients who received massage slept better, while patients who received multisensory stimulation had less anxiety. In one study of music therapy, patients had improved scores on a scale of psychophysiological wellness, and the other study found no effects. A study of group therapy with patients with metastatic breast cancer found no improvement in psychological symptoms, whereas another found decreased tension and anxiety, more vigor, and less confusion. Patients who engaged in life review experienced less depression and alienation, more life satisfaction, and better self-esteem. One study of reflexology found no differences in symptoms, and another found improvement in the quality of life. A study of therapeutic touch found improvement in well-being, while a study of ALTENS stimulation found less fatigue.

The details of the interventions and how they were delivered to patients were clearly defined in most of the RCTs, probably because the interventions were part of the authors' professional expertise. Most authors used validated measurement scales, although some did not explain why their choice of a particular scale was the optimal choice.

Withdrawal of patients because of worsening symptoms was frequent, and future researchers should collect data at baseline to ascertain whether withdrawals from the experimental and control groups are comparable.

Most researchers did not systematically plan the design and execution of their research protocol to minimize the risk of bias. No firm conclusions, therefore, can be drawn from the research to date regarding these non-medical and non-surgical therapies.

In terms of future research, improved planning of strategies to avoid bias in planning and execution, and addition of experienced trialists and statisticians to the research teams is necessary before conclusions can be drawn about these therapies. Researchers could consult the Cochrane Handbook[9] and follow the CONSORT[49-51] statement to design research to minimize bias.

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