REPORT AND LAY SUMMARY FOR TOT TRIAL

The ToT Study: Helping with Touch or Talk (ToT): A pilot randomised controlled trial to examine the clinical effectiveness of aromatherapy massage versus cognitive behaviour therapy for emotional distress in patients in cancer/palliative care.

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BACKGROUND:
There is a significant psychological distress in people with cancer with depression and/or anxiety being the most common reactions being experienced in at least a third of people with cancer. People with cancer have an impaired quality of life and those with significant psychological distress are high utilisers of health service resources. Depressive and anxiety symptoms often go undetected and even when detected are not treated. The National Institute of Health and Clinical Excellence has identified cancer as a treatment priority and recommends: "…psychological, social and spiritual support" for people with cancer.

Although antidepressants are often used for depression in cancer patients they may interfere with other physical treatments and are unlikely to resolve complex psychological issues. Alternative approaches are therefore desirable.

A number of different talking therapies have been used for distress. One of the most widely evaluated and effective treatments for depression and/or anxiety is called cognitive behaviour therapy, otherwise known as CBT. This intervention aims at challenging a number of assumptions people may make; they may think excessively negatively. Cognitive behaviour therapy also looks at what people do and whether this is helpful in improving their distress. Of the other treatments used, aromatherapy massage is both popular and appears beneficial at reducing distress and worrying in the short term. Although there is evidence which suggests that these treatments are better than a patents usual care, there have been no studies comparing these two treatments with each other.

The aims of this study were to see first, whether we could identify and recruit patients to a trial and obtain a measure of likely dropout. Secondly, to determine whether both our CBT and AM package can be delivered and what modification may be required Thirdly, generate data to determine what the numbers required for a definitive trial. Fourthly conduct a cost analysis.

METHODS USED:

Screening and recruitment We considered all patients who had a clinical diagnosis of cancer and in whom the treating clinician expected them to survive more than 6 months. Patients were recruited from cancer outpatient clinics. The clinics we selected were those treating the main cancers seen in clinical practice; breast, colorectal, lung, lymphoma/myeloma and prostate cancer.

Staff in the clinics notified the researcher who may be suitable and providing people referred were 18 years of age or over, had a diagnosis of cancer and scored 8 or more on a scale called the Hospital Anxiety and Depression Scale (HADS), they were considered for the study. They were however excluded if their predicted survival was 6 months or less as our follow up was up to 6 months and we wished to minimise dropout. We also excluded people if they were currently receiving or had received either AM or CBT in the 3 months prior to being seen as this would make it difficult to compare treatments. We excluded those with severe psychological disturbance or where there was brain involvement of cancer which may cause significant concentration problems. As CBT is a talking based therapy we also excluded those unable to read and write in English.

Ethics
Ethical approval was granted by Camden and Islington Community Local Research Ethics Committee. The study was also approved by the Royal Free Hampstead NHS Trust for research and development projects. We adhered to established research and clinical governance procedures throughout the project.

The interventions:
A number of factors may influence how people respond to treatment. In order to manage this, all people recruited to the trail were required to agree to be allocated to one of the two treatments by chance from a list of numbers generated by an independent trial statistician. This process is called randomisation and aims to balance out factors (such as age, gender, type of cancer), which may influence the findings from our intervention. We also tried to ensure that the researcher assessing patients was not aware of the intervention the patient has received as the researcher may have a particular allegiance to one of the treatments and this may affect their reporting of the results. This process is called blinding. Blinding was necessary as patients were allocated to interventions. Allocation to the intervention arms were made randomly using a computerised method implemented by the statistician. Patients were asked to refrain from informing the research team which intervention they had been allocated to until the final follow up had been completed.

In addition to treatment as usual, participants were offered up to 8 sessions of AM or CBT, each session lasting an hour, delivered weekly within 12 weeks. Of the two interventions used one was CBT. In this intervention an experienced CBT therapists used an adapted version of CBT to take into account existential issue, related to a fear of death and dying. This model was chosen as it is more representative of CBT available in the NHS and we had already piloted it in patients with advanced cancer. The AM was given using a clear treatment protocol adapted for use with cancer patients in our previous work. This was delivered in a specific quiet rooms by trained and qualified aromatherapists, in which talk was kept to a minimum.

Data collected:
We collected information on age, gender, ethnicity, marital status, employment status, type and stage of cancer, cancer treatment, length of illness.

In order to measure how well our interventions worked, we used a number of scales as "outcome measures". The main measure used were the shortened version of the Profile of Mood States (POMS) which are able to measure the severity of distress. This score is made up of 6 subscales which measure depression, energy, anger, anxiety, confusion and fatigue. We also used a scale called the EuroQol 5D to measure level of social functioning; i.e. how well people are coping. Finally we also collected some measures on how helpful people found the interventions and some measures of cost using a scale called the Client services receipt Inventory and the Consultation and emotional Empathy Scale. A number of other measures were also used and are reported elsewhere.

All sessions CBT or AM were subject to audiotape recording and an independent rater will rate a random sample of 1 in 5 therapy sessions.

Timing of data collection:
Data were collected at entry into the trial and at 3 (end of intervention period) and at 6 months (3 months post intervention). Data return was maximised by testing the feasibility of data collection over the phone, or via post if necessary.

PROGRESS OF THE STUDY AND ADAPTATIONS TO THE DESIGN:
A Research Fellow and a Research Assistant were employed to work on the study, commencing on November 1st 2006. Due to unforeseen circumstances (pregnancy), the Research Fellow had to leave the post in February 2007 and so the duties fell to the Research Assistant, with the fixed term contract expiring on October 31st 2008. The costs of maternity were born by UCL and the Research Assistant took up her role to ensure smooth progress of the project.

The study was monitored by a steering group. Supervision of the CB therapist was provided weekly given by Drs. M. Serfaty (MS), K. Mannix (KM) and S. Wilkinson (SW), the grant holders. MS and KM provided CBT supervision, supplemented through email. SW gave AM supervision. One in five sessions were observed by SW to ascertain that correct massage strokes and oils were used. To analyse adherence to therapy all sessions were audio-taped and diary accounts of therapists' interventions were kept.

Supervision of sessions by MS who listened to audiotaped material suggested that the standard of therapy delivered by two therapists employed on the trial was extremely high. However, therapists highlighted that the level of distress in patients recruited to the trial was mild and therefore this was fed back and selection criteria using the HADS were raised to a cut off of 11 or more. SW also confirmed that the standard of AM delivered was high.

RESULTS:

Recruitment for the study occurred over 13 months. Months 3 and 4 saw the highest number of participants recruited to the study. From months 8-11, the number of people both screened and recruited began to fall, probably due to saturation of clinics, whereby people had already been screened. At this point, the research team expanded recruitment to haematology, lymphoma and myeloma clinics, which saw screening and recruitment increase immediately. This would suggest that brief recruitment periods over several sites would provide suitable numbers for a future trial.

Screening packs were distributed to 490 patients, with 170 being returned to the research team (See Figure 1). Of those returned 63 people, (37%) were eligible to participate in the study; 23 did not want to or could not participate in the study. Reasons for this included work commitments, having had a course of AM in the last 3 months, feeling too unwell. Of the remaining 40 participants, 39 were consented and randomised to the study; 1 person dropped out of the study prior to randomisation.

Of the remaining 36, 24 people completed all 8 treatment sessions, with 15 of those having been randomised to AM. Follow up was high with full data sets at 3 and 6 month follow up being obtained for 92% (36/39) and 90% (35/39) of participants respectively (3 participants passed away, 1 was unobtainable) (Table 1).

Table 1

	Baseline	3M	6M
AM	20	19	19
CBT	19	17	17
Total	39	36	36

Flow-Chart summary of recruitment

Figure 1

For convenience, only the results of our main findings only are presented in this report.

Of the people recruited using screening on the HADS, the majority either had anxiety or anxiety plus depression with only one person having depression alone.

TABLE 2

		Depression		
		No	Yes	Total
Anxiety	No	0	1	1
	Yes	18	20	38
	Total	18	21	39

Background of participants:
As shown on table 2, of the 39 patients, 79% (31/39) of participants were female, and almost half the sample had breast cancer (46.2%) (table 3). Of note, that although 8 males recruited to the study, only 1 male participant was randomised to CBT. The age ranged from 36 to 77 years. 60% (24/38) were in an owner occupied house or flat, 27% (11/38) were in local authority or housing association accommodation and 7% (3/38) were privately rented accommodation.

Treatment preference:
Although two fifths had no preference, and significantly fewer people wished for CBT compared to AM. However, both treatments were acceptable, with the mean acceptability of treatment being over 75%.

Treatment received:
The sample population had significantly fewer males in the CBT group (Table 1).
Engagement with treatment was high; 67% (24/36) people completed all 8 treatment sessions; 79% (15/19) of the AM group and 53% (9/17) CBT. However, the mean number of treatment session was significantly more for AM (7.2 sessions) compared to CBT 5.4 (sessions).

TABLE 1

Baseline variables		Trial Arms	
	Total (%) n =39 (100)	AM (%) n=20 (51)	CBT (%) n=19 (49)
Mean age in years (sd)	52.5 (10.9)	51.1(10.6)	54.0 (11.3)
Gender			
Male	8 (21)	7 (35)	1 (5)
Female	31(79)	13(65)	18 (95)
Ethnicity			
White	31 (79.5)	15 (75.0)	16 (84.2)
Black British/African/Caribbean	4 (10.3)	1 (5.0)	3 (15.8)
Asian British/Indian	4 (10.3)	4(20.0)	0 (0.0)
Marital status			
married	19 (48.7)	7 (35.0)	12 (63)
single	7 (17.9)	4 (20.0)	3 (15.8)
divorced	5 (12.8)	3 (15.0)	2 (10.5)
living with partner	5 (12.8)	4 (20.0)	1 (5.3)
in a relationship	1 (2.6)	0 (0.0)	1 (5.3)
widowed	1 (2.6)	1 (5.0)	0 (0.0)
estranged	1 (2.6)	1 (5.0)	0 (0.0)
Type of cancer			
Breast	18 (12.8)	6 (30.0)	12 (63.1)
Colorectal	10 (12.8)	7 (35.O)	3 (15.8)
Lung	5 (12.8)	3 (15.0)	2 (10.5)
Lymphoma/ Myeloma	5 (12.8)	3 (15.0)	2 (10.5)
Prostate	1 (2.6)	1 (5.0)	0 (0.0)
Treatment preference			
Would prefer AM	17 (43.6)	8 (40.0)	9 (47.4)
Would prefer CBT	5* (12.8)	2 (10.0)	3 (15.8)
No preference	17 (43.6)	10 (50.0)	8 (42.1)
Happy with AM (Scale 0-100%)	87.7 (SD 21.1)	93.5 (13.8)	68.9 (26.2)
Happy with CBT (Scale 0-100%)	75.5 (SD 24.6)	82.1 (21.5)	81.6 (25.6)
* P = 0.025			

Data suggests that scores in the two intervention groups were Similar when people were first seen (POMS TMS).

As shown (table 2), the total POMS Mood score reduces in both groups and the CBT group appears to continue after the therapy has ceased. Subscales of depression-dejection scores and tension-anxiety scales suggest a sustained reduction with CBT but not AM. POMS scores for total Mood State (TMS) scores (fig 2), Depression-Dejection (fig 3) and tension anxiety (fig 4) are also represented graphically. We conducted a statistical analysis to see if there were any particular factors which determine how people do, and the only predictor was how severely disturbed when originally seen (POMS TMS at baseline). Similarly Euroqol scores suggest an improvement with both interventions, but the improvement continues after the treatment has ceased in the CBT group.

Table 2. Main outcome data: Profile of Mood States and subscales for ToT study

Completers data		Intervention	
Measure	**Time point**	**AM Mean (SD)**	**CBT Mean (SD)**
TMS Total Mood Score on POMS	Baseline	44.5 (21.7)	46.3 (21.6)
	3 Month follow up	29.0 (27.1)	26.0 (21.0)
	6 Month follow up	34.0 (27.2)	26.5 (18.5)
POMS subscale Depression-Dejection	Baseline	11.2 (6.5)	13.4 (6.0)
	3 Month follow up	8.1 (7.3)	7.9 (6.1)
	6 Month follow up	9.4 (7.9)	7.7 (5.1)
POMS subscale Vigor-Activity	Baseline	10.3 (5.6)	9.6 (4.1)
	3 Month follow up	11.0 (4.4)	11.6 (4.5)
	6 Month follow up	10.5 (6.0)	9.5 (4.2)
POMS subscale Anger-Hostility	Baseline	9.3 (5.4)	9.2 (5.3)
	3 Month follow up	7.6 (7.2)	5.1 (4.1)
	6 Month follow up	7.8 (6.9)	5.4 (5.2)
POMS subscale Tension-Anxiety	Baseline	12.9 (5.0)	12.3 (5.8)
	3 Month follow up	8.6 (4.9)	7.9 (5.3)
	6 Month follow up	9.4 (5.3)	7.0 (4.2)
POMS subscale Confusion-Bewilderment	Baseline	9.1 (3.9)	8.1 (4.0)
	3 Month follow up	6.8 (4.0)	6.1 (4.0)
	6 Month follow up	6.8 (4.1)	6.1 (4.0)
POMS subscale Fatigue-Inertia	Baseline	12.2 (5.6)	12.8 (5.6)
	3 Month follow up	8.9 (6.0)	10.6 (5.7)
	6 Month follow up	11.2 (5.7)	10.1 (4.9)
Euroqol score	Baseline	0.65 (0.26)	0.61 (0.24)
	3 Month follow up	0.67 (0.07)	0.67 (0.21)
	6 Month follow up	0.67 (0.30)	0.75 (0.16)
Euroqol thermometer	Baseline	57.7 (20.0)	50.8 (17.4)
	3 Month follow up	64.2 (20.0)	66.0 (15.8)
	6 Month follow up	68.1 (18.1)	63.5 (14.5)

Figure 2: Total POMS mood score for AM and CBT

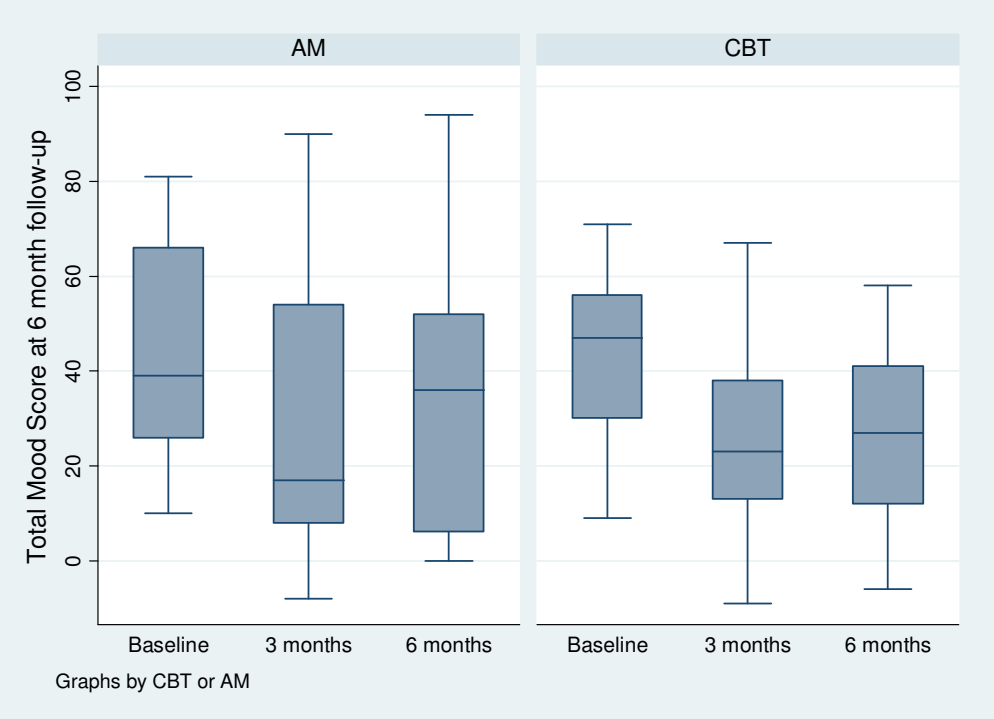


Figure 3: POMS depression-dejection score for AM and CBT

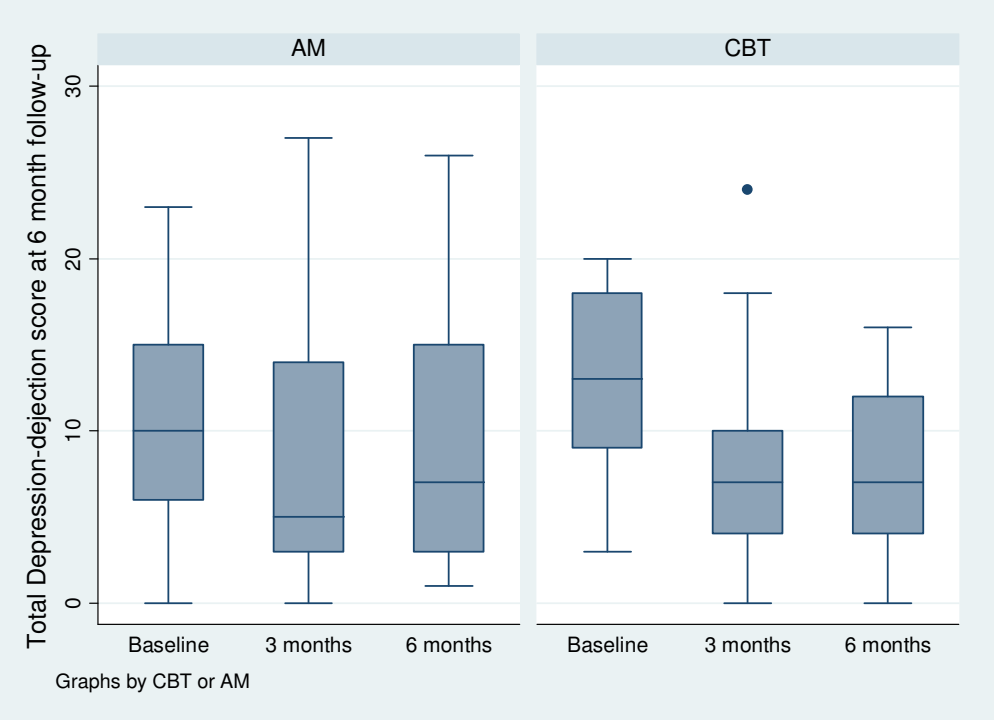
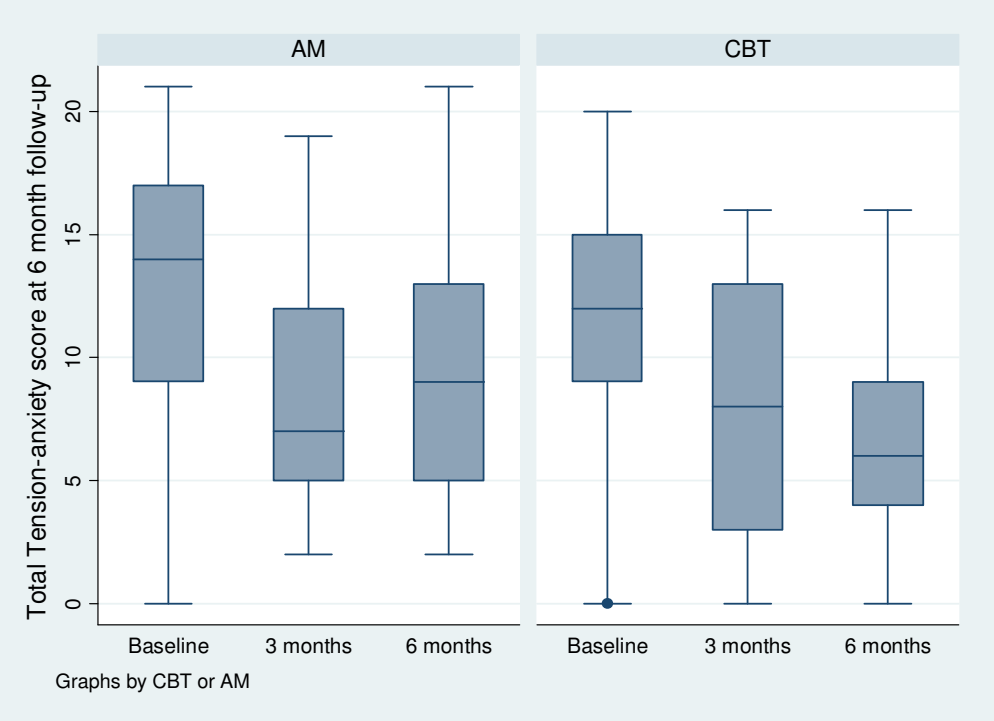


Figure 4: POMS tension-anxiety score for AM and CBT



Comment on the study:

Were the aims of the study achieved?

1. Recruitment and follow-up issues:

The first aim of this study was to determine whether we could identify and recruit patients to a trial and obtain a measure of likely dropout. It is notable that of all screening packs handed out 8% (39/490) of packs generated someone for the study. What we also observed was that when the threshold of the HADS was raised from 8 to 11, the number of people suitable fell to about half during a similar period. There are two likely reasons for this. The first is that the proportion of people who are distressed is about half. The second reason was that as the study proceeded the researcher observed that the same people would present in the clinic during their course of treatment. Our target population was therefore finite and indeed, if anything people's distress would lessen with time. We expanded our recruitment methods to incorporate myeloma/haematology clinics and this generated the additional numbers required for the study. It is striking how good our followup rate was with over 90% of data points being collected at 6 months. This was most likely because of the diligence of our researcher who had a charming but thorough manner. It is also evident that collecting information by phone is helpful.

Findings from this study for future research therefore suggest that when recruiting cancer patients one should aim at a large recruitment base using multiple centres and a wide range of different cancer clinics. In order to avoid saturation people should be recruited over a short time period. Although we achieved excellent followup rates, we believe that this was because of the personality of the researcher. This highlights the need for careful consideration of who is appointed to the research post.

2. Delivery of the intervention packages:

Judging by our level of engagement and followup, it is clear that both CBT and AM could be delivered. Although reported elsewhere, patients indicated that they found the interventions useful. Although the Cognitive Behaviour Therapists have been very highly trained in CBT they had not had prior experience with working with cancer patients. However therapists were able to adapt very quickly to working with such patients and discussion of existential issues was felt to be helpful. It was also particularly helpful for them to ensure that targeted areas of concern were addressed. We will plan to conduct an independent rating of the taped CBT sessions to confirm that the therapy delivered is consistent with recognised good practice in CBT. AM was clearly well received and there were no difficulties encountered with the procedure.

3. Generation of data to determine what the numbers required for a definitive trial:

We also conducted a post hoc power calculation based on the data presented in this study. This helps us determine how many people will be required for a definite trial. Normally we choose an arbritrary cut off if 95% that we can be sure that sure that findings will not have occurred by chance. We have to be cautious when to extrapolate our data to predict the numbers required because of differences between the measures of mood in our participant. Using our 6 month followup data (alpha=0.05, power=0.90, for a 2-sided test) in order to detect an advantage of CBT over AM for the POMS TMS, the depression subscale and the anxiety subscale, 183, 69 or 426 participants respectively will be required in each group.

The above data suggests that if we conducted a multicentre trial to compare AM and CBT, we should probably specifically focus on looking for a change in the depression subscale as the smallest numbers of participants would be required and this would ensure completion of the trial. If we chose only those with depressive symptoms, then 138 participants would be required to complete the trial. We suspect that the follow up rate at 6months was unusually high. If we assume a more realistic rate of 80% followup then 172 participants would be required. It also needs to be noted that of the people we recruited, 54% (21/39) had depressive symptoms using the HADS. It follows that we would need to boost the numbers we need to screen to generate sufficient people for the trial. 490 screening packs generated 21 participants with depressive symptoms. Allowing for 80 % dropout, in order to generate 138 participants, then we would need to hand out 0425 packs (490 x 100/80 x 138/21).

4. Cost analysis findings:

This study demonstrates that t is possible to collect useful health economics data on cancer patients. Preliminary data suggests that there are significant reductions in POMS scores with both AM and CBT. Although higher direct cost of CBT were observed, there may be an economic advantage of CBT once other measures of cost are taken into account.

Other issues:

Thanks to the study the researcher CF went on to secure a clinical psychology post with Camden and Islington Primary care trust in her area of chosen interest, child and adolescent psychology. The two Cognitive Behaviour therapists have gained considerable experience in the management of complex issues associated with cancer and would be willing to help with research and training for a future multicentre trial.

The ToT Study: Helping with Touch or Talk (ToT): A pilot randomised controlled trial to examine the clinical effectiveness of aromatherapy massage versus cognitive behaviour therapy for emotional distress in patients in cancer/palliative care.

Serfaty M, Wilkinson S, Freeman C, Mannix K, King M.

Abstract:
BACKGROUND:
Significant psychological distress can occur in people with cancer, with depression and/or anxiety being the most common reactions. CBT, one of the most effective treatments for depression and anxiety, also appears to be beneficial in cancer patients. Complementary therapies, used by one third of patients with cancer, with aromatherapy massage (AM) being a popular intervention, also appears to alleviate distress. No studies have directly compared the effectiveness of these two treatments.
Aims: to 1) test the feasibility of recruitment into a randomised controlled trial of AM versus CBT in patients with cancer; 2) to test and modify the intervention where necessary; and 3) to determine whether changes in outcomes were consistent with existing published data.
Methods: Patients at all stages of cancer were recruited from oncology outpatient clinics (breast, colorectal, lung, haematology, prostate) in a north London university NHS Trust. They were screened for anxiety and/or depression using the HADS and those scoring above threshold were randomised to Treatment as usual (TAU) plus up to 8 session of weekly of either AM or CBT, offered within 3 months . The POMS was the main outcome measure taken baseline, 3 months (end of therapy) and 6 months (follow up) post baseline.
Results: Participation was high with 39 out of 63 (62%) of suitable patients agreeing to participate. Twenty were randomised to AM and 19 to CBT. Significantly more people desired AM, although at least 75% indicated they would be happy with either intervention. Of the 8 sessions offered, significantly more AM sessions were taken up; [7.2 (SD 2.0) for AM and 5.4 (SD 3.1) CBT, $p<.05$]. Both packages were well both received. Significant improvements in total POMS mood scores, POMS depression and anxiety subscales and Euroqol scores occurred with both interventions, with a non-significant trend towards a greater improvement in anxiety with CBT.
Conclusions: Recruitment was feasible in cancer patients, either intervention was deemed acceptable and engagement with treatment was high. Preliminary data suggests a trend to improvements in the POMS and Euroqol scores with both AM and CBT, with a sustained effect with CBT.

Background

Adjustment disorder, anxiety and depression are the most common psychological disorders in cancer (Maguire et al, 1991; Chichinov et al, 1994). One third of cancer patients experience psychosocial distress and this increases with disease progression (Butler et al, 2003; Zabora et al, 2001). However, psychological distress is often missed, depressive symptoms frequently go undiagnosed and/or untreated (Berard, 2001). Furthermore, antidepressants and tranquilisers, which are often used in cancer (Johnston, 1972; Costa et al, 1985; Holland et al, 1999), may interfere with other physical treatments and are not particularly effective for distress,that involves complex psychological issues (Sutherland et al, 2002).

The National Institute of Health and Clinical Excellence (NICE, 2004) recommends 4 levels of psychological intervention, and at the higher level, suggests counselling/anxiety management (level 3) or specialised therapies (level 4). The effectiveness of interventions for treating cancer (Newell et al, 2002) and advanced cancer is reviewed by Edwards and Hulbert-Williams, 2009; Akechi et al 2009; Price and Hotopf, 2009. Despite the variety of interventions (Fradheim et al, 2001), their effectiveness is often difficult to interpret because of the methodological quality of the trials (Newell et al, 2002; Fawzy et al, 1996). Of the most widely used and popular conventional and complementary interventions, CBT and Aromatherapy Massage respectively are the most commonly chosen.

A number of cognitive behavioural approaches have been used to ameliorate distress in cancer (Sandgren et al, 2000; Moorey et al, 1998; Greer et al, 1992; Roseberger et al, 1992;, Linn et al, 1982; Weissman et al, 1980; Evans et al, 1995; Bottomly et al, 1996; Edelman et al, 1999). Adjuvant Psychological Therapy (APT), a modified form of CBT especially developed for cancer patients (Greer and Mooray, 1992) is helpful, but does not necessarily use CBT trained therapists. However, in CBT, which is increasingly available as a specialised psychological intervention in the NHS therapist training is predictive of outcome (de Rubeis et al, 2005; Hollon et al, 2005) and CBT.. Despite the popularity of CBT, however, it may not always be the preferred option. One third of patients with cancer use a complementary therapy (Bernstein and Grasso, 1995; Ernst 2000; 1998) and aromatherapy massage (AM) is one main chosen (Rankin-Box, 1997) and delivered (Kohn, 1999). It has been suggested that AM promotes relaxation and releases tension through massage. It is claimed that the circulation of blood and lymph is enhanced resulting in increased oxygen supply and removal of waste products. Direct mechanical pressure and effects mediated by the nervous system may beneficially affect areas of increased muscular tension. The massage is enhanced by the use of essential oils as it is thought that the smell from the oils triggers the limbic system, which governs emotional responses and is involved with the formation and retrieval of learned memories (Tisserand and Ballacs, 1995). Essential oils are also absorbed via the dermis and subcutaneous fat into the blood stream (Ernst et al, 2001). AM appears beneficial in alleviating psychological distress (Wilkinson et al, 1999; 2007). A recent systematic review of ten trials (Wilkinson et al, 2008) indicates that massage might reduce anxiety in patients with cancer in the short term and may have a beneficial effect on physical symptoms of cancer, such as pain.

We wished to conduct a pilot trial to 1) test the feasibility of recruitment into a randomised controlled trial of AM versus CBT in patients with cancer; 2) to test and modify the intervention where necessary; and 3) to determine whether changes in outcomes were consistent with existing published data. CBT, a talking therapy, aims at improving emotional wellbeing by modifying thoughts and behaviours, whereas AM, a touch therapy, aims at improving wellbeing by directly accessing feelings. No studies have compared talk (CBT) versus touch (AM). We present the first randomised controlled pilot study of CBT versus AM for people with cancer and- distress to:

1. Determine whether patients can be identified and recruited to a trial and obtain an estimate of likely attrition

2. Determine whether both our CBT and AM packages can be delivered and what modification may be required for this patient population.

3. Examine trends and generate possible numbers required for a full scale trial.

4. Conduct a cost analysis (data to be presented elsewhere).

Hypothesis:
Treatment as Usual (TAU) plus CBT or AM are equally as clinical effective at three months, but the improvements are more likely to be maintained at 6 months with TAU plus CBT.

METHODS:
This pilot study is a parallel group, single-blind, randomised controlled trial, conducted over 2 years. Outpatients were recruited from oncology clinics associated with a central London teaching hospital.

Clinic staff asked people aged 18 or over, who had known about their diagnosis for cancer for at least a month and had a predicted survival of at least 6 months whether they would be willing to see a researcher. The researcher provided them with verbal and written information about the study. They were given 48 hours to think about it and if agreeable to participate asked to return an indication of interest slip in a self stamped addressed envelope. Patients were then screened using the Hospital Anxiety and Depression scale; a score of at least 8 or more for either anxiety or depression were included, although four months into the trial the cut off was increased to 11 as the therapists provided feedback that participants did not seem excessively distressed. The researcher excluded people if they were unable to read and write in English, had a Mini-Mental State Examination score under 24 (Folstein, 1994), had received CBT or AM within the last 6 months or were currently undergoing counselling through oncology services. Participants were then consented to participate in the trial.

Participants were randomised to one of two interventions using random numbers generated by computer. The researcher making assessments of participants was masked to the treatment allocation.

Interventions: Both groups were offered up to 8 one hour sessions of the intervention delivered over 10 weeks.

CBT plus TAU: Therapists who were accredited with the British Association of Behavioural and Cognitive Psychotherapists and had at least 10 years experience of using CBT were trained by MS to modify their practice for cancer patients using the model described by Mannix et al (2006).This model was adapted to take existential issues into account (see appendix). It was also chosen as it was more representative of CBT available in the NHS and had been shown to be beneficial in a palliative care setting (Mannix 2003).

Aromatherapy massage (AM) plus Treatment Usual:
Treatment followed a clear treatment protocol adapted for use with cancer patients which had been used in our previous work (Wilkinson et al1999; 2007). The protocol included a choice of 20 essential oils, standardised massage strokes and timings. After an initial assessment, and In accordance with good aromatherapy practice, the therapist prescribed the treatment she considered most appropriate for the patient's symptoms . The treatment was delivered in a quiet room and talk by the therapist was kept to a minimum. The aromatherapist had an aromatherapy Diploma training, which was accredited by the International Federation of Professional Aromatherapists.

All patients received TAU from oncology teams and their GP. This mainly consisted of routine support, such as appointments with GP's, Clinical Nurse Specialists or Oncologists. The patient's physical health and medication would be reviewed and treatment modified according to symptoms such as pain. Psychotropic medication would be prescribed as necessary. Patients were not exempt from receiving external psychological support (other than CBT or AM), but it was agreed that they would not be referred for counseling through oncology services if participating in the trial.

OUTCOMES:
The primary outcome measure was the total score on the Shortened version of the Profile of Mood States (POMS Shackam, 1983, McNAir et al, 1992). This scale consists of a total mood score made up of 6 subscales.

Secondary outcomes were:
a). Psyclops (StaRNet 2003), a 6 point Likert scale collected before and once the intervention period (AM or CBT) had finished. The Psycholps asks respondents about 2 main problem areas in terms of level of distress, duration and impact. The post intervention Psyclops posed the same questions but also how therapy may have affected them on a 5 point Likert scale; low scores are positive and high scores negative.
b). EuroQol (EQ-5D; Brooks 1996), a health-related quality of life measure.
c). Did Not Attend (DNA) rates for therapy sessions were recorded.
d). Client Event Recall Form Elliot and Shapiro, 1988) asked patients about their experience of the therapy.

Other: measures:

a) Treatment preference: At initial assessment the researcher asked patients about their treatment preference, their views on its effectiveness and how satisfied they would be if given AM or CBT (Bokovec and Nau, 1972).

b) At follow-up, the Consultation and Relational Empathy (CARE) scale (Mercer et al, 2002) was used to measure patients' perceptions of relational empathy at first contact with the therapist. This scale, which provides information on the degree of warmth and empathy they experienced at initial interview with their therapist, is reported to be a stable and reliable measure (Mercer, 2004).

c) Assessment of blindness: this was made by asking the researcher undertaking follow-up assessments to guess the participant's trial group (yes, no, don't know). Data were also collected on prescribed psychotropic medication, other psychological treatments and other touch therapies (such as reflexology).

Timing of data collection: Baseline, post intervention (3 months post baseline) and 3 months follow-up (6 months post baseline). Data collection was maximised by testing the feasibility of data collection over the phone and by post.

Analysis:

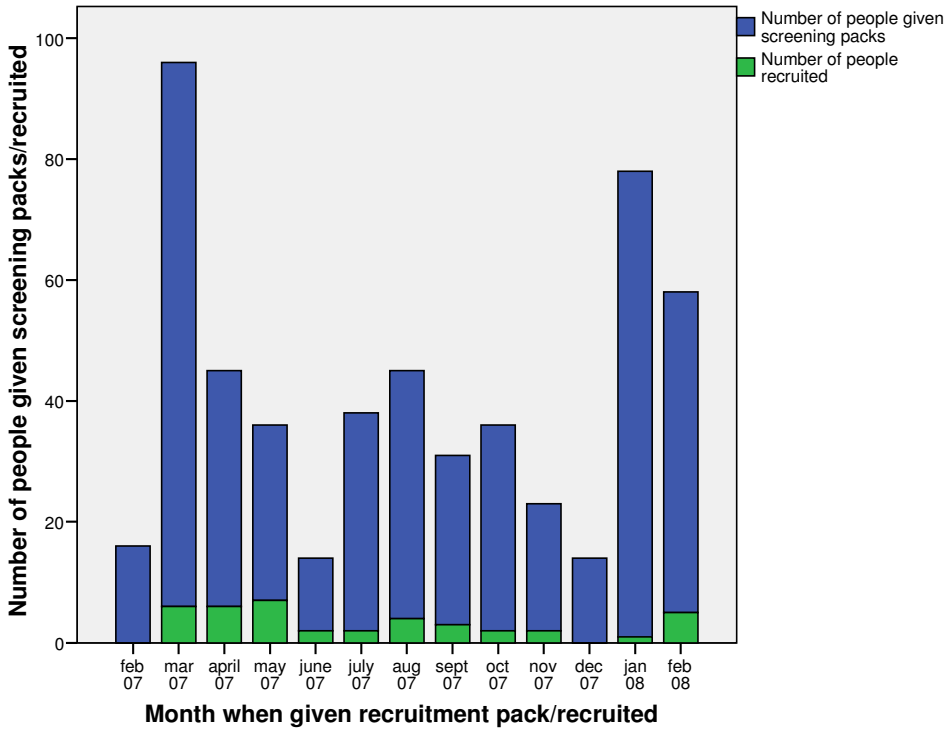
*Clinical data**:***

Given this was a pilot trial our main approach is descriptive and concerned response to recruitment, adherence to therapy and attrition. A description of data is provided and as data were normally distributed, means and standard deviations for the main outcome data are presented. As attrition was low, data imputation was not necessary and complete data is presented. Between group differences at baseline were explored using Students t-test and further analysis of potential changes in outcomes over time were investigated using general linear modelling using SPSS (version 15.0). However, as the sample size is small, caution is required in the interpretation of our findings on outcomes. We conducted a post hoc calculation from means and standard deviations on the sample size that would be required in a large scale trial.

RESULTS:

The number of recruitment packs distributed and the number of people recruited is shown (fig 1). The number screened was initially high and falls off with time. The increase in January 2008 is associated with the addition of haematology clinics to recruitment sources. Two troughs are shown; June 2007 and December 2007 when the researcher was on leave. Feedback from therapists suggested that patients appeared to be at the mild end of distress. The threshold on the HADS was raised in May 2007 from 8 or more to 11 or more for depression or anxiety. The proportion of people recruited after this fell.

Fig 1: Number of patients given recruitment packs and recruited



At the end of May 07 cut off on HADS changed from ≥8 to ≥ 11 for anxiety or depression.
At the end of December 2007 haematology/myeloma clinics added for recruitment.

Participant flow:

As shown on the flow diagram (fig 2), a third of screening packs were returned. Just under a third (63/170) achieved the cut off on the HADS. No one satisfied exclusion criteria, however just over a third (23/63) felt unable to commit to the study requirements and one patient died. Over 90% of participants were followed up at 3 and 6 month follow post baseline.

Fig 2. Flow-Chart summary of recruitment

Number of patients with anxiety and/or depression scores on HADS of at least 8 at screening is shown (Table 1):

Table 1.

HADS > 8 for anxiety and/or depression		Depression		
		No	Yes	Total
Anxiety	No	0	1	1
	Yes	18	20	38
	Total	18	21	39

Due to poor physical health in two cases and death in one case, 3 of the 39 patients randomised did not commence therapy sessions.

Demographics:
Our sample consisted mainly of women of which almost half of these had breast cancer. Only 1 man was randomised to CBT (table 2).

Treatment preference:
Although two fifths had no preference for either treatment arm, significantly fewer people indicated a preference for CBT over AM (X^2 = 7.4, df = 2, P= 0.025) (Table 2). However, both treatments were acceptable, with the mean acceptability of treatment being over 75%.

Treatment received:
Engagement with treatment was high; 67% (24/36) completed all 8 treatment sessions; 79% (15/19) of the AM group and 53% (9/17) CBT. However, the mean number of treatment sessions was significantly more for AM (7.2 SD 2.0) than CBT (5.4 SD 3.1) (t = 2.03, df = 34, p =0.05).

TABLE 2. Description of participants in each of the arms of the study.

Baseline variables		**Trial Arms**	
	Total (%) n =39 (100)	**AM (%) n=20 (51)**	**CBT (%) n=19 (49)**
Mean age in years (SD)	52.5 (10.9)	51.1(10.6)	54.0 (11.3)
Gender			
Male	8 (21)	7 (35)	1 (5)
Female	31(79)	13(65)	18 (95)
Ethnicity			
White	31 (79.5)	15 (75.0)	16 (84.2)
Black British/African/Caribbean	4 (10.3)	1 (5.0)	3 (15.8)
Asian British/Indian	4 (10.3)	4(20.0)	0 (0.0)
Marital status			
married	19 (48.7)	7 (35.0)	12 (63)
single	7 (17.9)	4 (20.0)	3 (15.8)
divorced	5 (12.8)	3 (15.0)	2 (10.5)
living with partner	5 (12.8)	4 (20.0)	1 (5.3)
in a relationship	1 (2.6)	0 (0.0)	1 (5.3)
widowed	1 (2.6)	1 (5.0)	0 (0.0)
separated	1 (2.6)	1 (5.0)	0 (0.0)
Type of cancer			
Breast	18 (12.8)	6 (30.0)	12 (63.1)
Colorectal	10 (12.8)	7 (35.0)	3 (15.8)
Lung	5 (12.8)	3 (15.0)	2 (10.5)
Lymphoma/ Myeloma	5 (12.8)	3 (15.0)	2 (10.5)
Prostate	1 (2.6)	1 (5.0)	0 (0.0)
Treatment preference			
Would prefer AM	17 (43.6)	8 (40.0)	9 (47.4)
Would prefer CBT	5* (12.8)	2 (10.0)	3 (15.8)
No preference	17 (43.6)	10 (50.0)	8 (42.1)
Satisfied with AM (Scale 0-100%)	87.7 (SD 21.1)	93.5 (13.8)	68.9 (26.2)
Satisfied with CBT (Scale 0-100%)	75.5 (SD 24.6)	82.1 (21.5)	81.6 (25.6)

* P = 0.025

Means and standard deviations for the Consultation and Relational Empathy (CARE), collected at the first contact with the therapist generated similar responses. There were no differences in total CARE scores with 31.0 (SD 7.6) for AM and 29.6 (SD 8.6) for CBT. There was no difference in warmth, with mean patient experience being rated between good and very good. Out of a maximum score of 5 for the therapist made the individual feel at ease: 3.61 (0.6) for AM and 3.1 (SD (1.1) for CBT. There was no correlation between the number of therapy sessions taken up and the care score at initial meeting.

Outcome data on POMS and EuroQol:

Baseline data suggest that the two intervention groups were balanced for total POMS score, POMS depression-dejection and POMS tension-anxiety (Table 3).

Table 3 Mean scores (standard deviations) for outcomes at baseline and post intervention periods for CBT and AM. Data were available at baseline (n=20) for AM and (n=19) for CBT. At 3 and 6 months post baseline (n=19) for AM and (n=17) for CBT.

Completers data		**Intervention**	
Measure	**Time point**	**AM Mean (SD)**	**CBT Mean (SD)**
TMS Total Mood Score on POMS	Baseline	44.5 (21.7)	46.3 (21.6)
	3 Month follow up	29.0 (27.1)	26.0 (21.0)
	6 Month follow up	34.0 (27.2)	26.5 (18.5)
POMS subscale Depression-Dejection	Baseline	11.2 (6.5)	13.4 (6.0)
	3 Month follow up	8.1 (7.3)	7.9 (6.1)
	6 Month follow up	9.4 (7.9)	7.7 (5.1)
POMS subscale Vigor-Activity	Baseline	10.3 (5.6)	9.6 (4.1)
	3 Month follow up	11.0 (4.4)	11.6 (4.5)
	6 Month follow up	10.5 (6.0)	9.5 (4.2)
POMS subscale Anger-Hostility	Baseline	9.3 (5.4)	9.2 (5.3)
	3 Month follow up	7.6 (7.2)	5.1 (4.1)
	6 Month follow up	7.8 (6.9)	5.4 (5.2)
POMS subscale Tension-Anxiety	Baseline	12.9 (5.0)	12.3 (5.8)
	3 Month follow up	8.6 (4.9)	7.9 (5.3)
	6 Month follow up	9.4 (5.3)	7.0 (4.2)
POMS subscale Confusion-Bewilderment	Baseline	9.1 (3.9)	8.1 (4.0)
	3 Month follow up	6.8 (4.0)	6.1 (4.0)
	6 Month follow up	6.8 (4.1)	6.1 (4.0)
POMS subscale Fatigue-Inertia	Baseline	12.2 (5.6)	12.8 (5.6)
	3 Month follow up	8.9 (6.0)	10.6 (5.7)
	6 Month follow up	11.2 (5.7)	10.1 (4.9)
Euroqol score	Baseline	0.65 (0.26)	0.61 (0.24)
	3 Month follow up	0.67 (0.07)	0.67 (0.21)
	6 Month follow up	0.67 (0.30)	0.75 (0.16)
Euroqol thermometer	Baseline	57.7 (20.0)	50.8 (17.4)
	3 Month follow up	64.2 (20.0)	66.0 (15.8)
	6 Month follow up	68.1 (18.1)	63.5 (14.5)

As shown (table 3), the total POMS Mood score declines in both groups but the decline in the CBT group appears to persist after the therapy has ceased. Subscales of depression-dejection scores and tension-anxiety scales suggest a sustained reduction with CBT but not AM. POMS scores for total Mood State (TMS) scores (fig 3), Depression-Dejection (fig 4) and tension anxiety (fig 5) are also represented graphically. A generalised linear model was undertaken using total POMS mood score at each outcome and entering baseline score as a covariate. Intervention group was entered as between subject factors. The only predictor of outcome was the POMS TMS at baseline (d.f. = 1, F =9.5 and P = 0.004). Similarly EuroQol scores suggest an improvement with both interventions, but the improvement continues after the treatment has ceased in the CBT group.

Figure 1: POMS Total Mood Score for AM and CBT

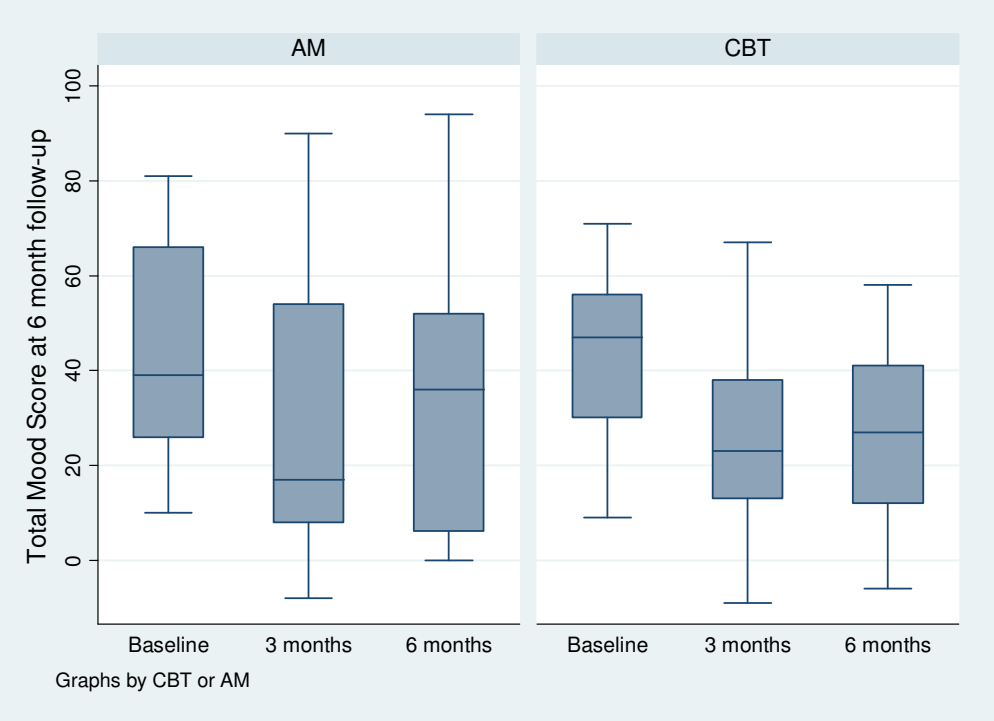


Figure 2: POMS depression-dejection score for AM and CBT

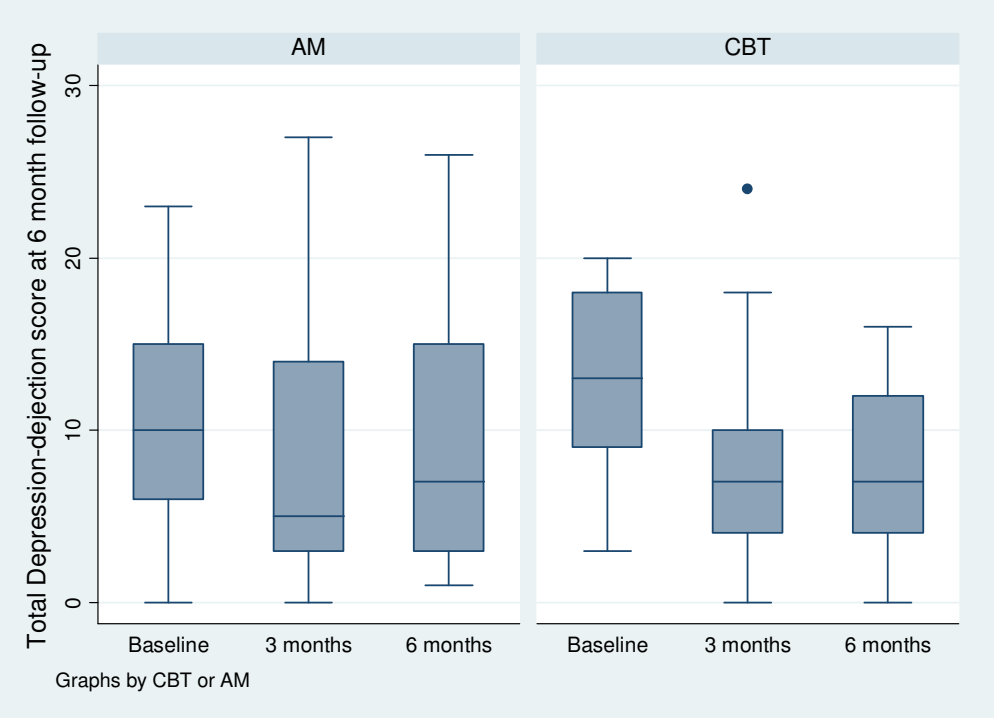
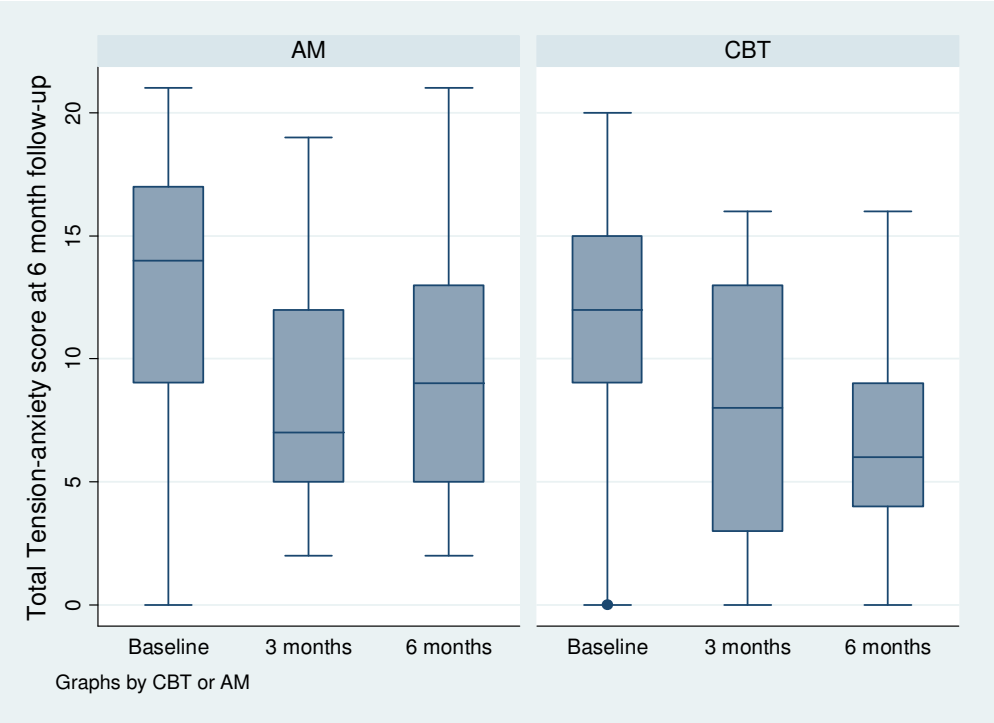


Figure 3: POMS tension-anxiety score for AM and CBT



Secondary outcome data:

Psyclops:

The Psyclops asks people to identify the problem area, and provide a score raging from "felt much better", (a score of 0) to "felt much worse (a score of + 4). Half of respondents cited the main problem as being cancer related (e.g. cancer causing pain, mobility problems, worrying about whether it would reoccur etc) Table 6. Where the main problem was identified at least 49% (19/39) were cancer related and of which 84% (16/19) were psychological, usually existential issues. A small but significant advantage was found for AM in the way in which people felt generally; otherwise no significant differences were found.

TABLE 6. Results for Psyclops

Psyclops	AM	CBT	ANOVA or t-test.
Main problem (taken at baseline):	n = 20	n = 19	
Cancer related physical	1	1	
Cancer related psychological	7	9	
Cancer related social	1	0	
Physical, not specified	4	1	
Psychological, not specified	1	3	
Social, not specified	6	5	
Length of concern (taken at baseline)			
<1 month	0	1	
1-3 months	5	2	
4 - 12 months	5	8	
1-5 years	8	7	
> 5 years	2	1	
How much has the problem affected you over the last week?			NS
At baseline	3.55 (SD 1.54)	3.58 (SD 1.22)	
Post therapy	2.79 (SD 1.01)	2.47 (SD 1.01)	
How hard it is to do things because of the identified problem			NS
At baseline	3.70 (SD 1.50)	3.53(SD 1.01)	
Post therapy	3.00 (SD 1.37)	2.63 (SD 1.50)	
How have you felt in the last week?			F=8.12, df=1,P< 0.01
At baseline	3.30(SD 1.38)	2.87(SD 1.08)	
Post therapy	1.89(SD 1.29)	2.47 (SD 1.28)	
Now that you have finished therapy how would you describe yourself?	0.79 (SD 0.71)	1.19 (SD 1.11)	NS

Discussion

The first aim of this study was to examine recruitment and participant flow. Eight percent (39/490) of people approached were recruited, suggesting that large numbers of cancer patients need to be approached in order to enter sufficient numbers of participants into a clinical trial. Nevertheless, just over one fifth (39/170) of patients who returned screening packs was suitable for and agreed to participate in the study. Furthermore, once people had been recruited to the study, engagement was high with almost 90% being followed up at 6 months.

There was an initial surge in people who may be approached, but these decreased with time as the same people re-attended clinics. Expanding the recruitment base and keeping the recruitment period brief will minimise this problem. Therapists commented that not all patients recruited into the study with HADS scores of 8 were sufficiently distressed to warrant therapy and thus the threshold on the HADS for entry was raised from ≥ 8 to ≥ 11. This meant that the proportion of people recruited to the study more than halved. and greatly increased the numbers needed for screening Although it has been usual to screen for illness using cut offs on either of the two subscales, anxiety or depression, Walker et al (2007) recommend using a combined score of 15 or more. This approach would certainly facilitate recruitment. Alternatively, an short screening tool, the Distress Thermometer (DT), developed in the USA by the National Comprehensive Cancer Network, has

good psychometric properties and may be more appropriate. The DT is increasing recommended for use in a clinical setting (Low et al, 2009).

Westcombe et al (2003) suggests that a control arm may be a barrier to recruitment. This problem was minimised here by offering all participants an intervention and indeed engagement in the trial was high with over 60% of eligible patients agreeing to participate. Our participant flow was also consistent with findings by Moorey (1998) who offered modified CBT to a similar population. The low attrition is testimony to the high level of engagement with the interventions, with almost 90% of follow-up data obtained at 6 months. This challenges the assumption that cancer patients are sometimes difficult to engage in clinical trials. Indeed, even the complementary therapy trial by Wilkinson et al which included a usual care control arm managed to follow up 77% of patients

More patients reported a preference for AM at recruitment, possibly because CBT requires the individual to engage actively in psychological work. Nevertheless, once allocated to CBT the mean level of satisfaction with this treatment was high at 75%. Thus, particular attention to how patients are informed about each treatment may be required when recruiting people to such trials.

Our second aim was to determine the feasibility of delivery of the treatment and what modifications, if any, should be made. We anticipated that the number of treatments taken up may provide a proxy measure of engagement. Empathy is considered to be a basic component of all therapeutic relations (Reynolds et al, 1999) and a key factor in patients' definition of quality of care (Rees-Lewis, 1994). First impressions are associated with engagement in therapy and do not change significantly as therapy proceeds (Oetzel et al, 2003). The CARE suggested that ratings of therapists' initial contact with patients were good to very good. However, we did not find a correlation between the CARE scores and the number of therapy subsequently taken up.

Two thirds of patients completed all 8 sessions offered which suggests the interventions were well received. Few papers report the number of therapy sessions taken up by cancer patients. Moorey et al (1998) suggests that 8 weekly sessions should be offered, but found that some patients required more sessions, with the median number of sessions for APT, a modified form of CBT, being 10. In a study by Wilkinson et al (2007) 86% (124/144) received 2-4 of the 4 sessions of AM offered.

The number of sessions of AM attended was significantly more than for CBT, however caution is advisable if using the number of sessions as a proxy measure of engagement. A number of patients in the CBT group discontinued therapy before 8 sessions as they reported that they had improved. Verbal feedback from patients for CBT was positive and supports surveys of cancer patients which suggest that they prefer individual therapy on a 1 to 1 basis over group therapy, or computerised therapy or bibliotherapy (Semple et al, 2005). Our trial also demonstrated that the CBT intervention

developed by Mannix was well received and could be applied to cancer patients.

The third aim of this study was to examine trends and generate possible numbers required for a definitive trial. People were not entered into the trial unless they were aware of their diagnosis of cancer for at least a month. It is possible that observed improvements are related to the natural adjustment to a diagnosis of cancer. However, the superiority of CBT and AM against TAU respectively has already been demonstrated and the purpose of this trial was to examine the feasibility of comparing CBT and AM. Examination of the pattern of change in POMS total mood score (and its subscales), suggests that CBT may be more effective for emotional distress in cancer in the longer term than AM. This is consistent with a previous trial suggesting that AM appears to be an option for short term management of anxiety for patients with cancer (Wilkinson et al 2007 2008). It is also consistent with the rationale behind CBT, notably that improvements in mood can be effected by changing thoughts and behaviours whereas AM is mainly palliative and provides people with a temporary sense of wellbeing.

As there were falls in POMS scores in both groups, a large sample size would be required to demonstrate either a significant difference or clinical equivalence between AM and CBT. A post hoc power calculation based on the data presented in this study was undertaken. Caution is required when interpreting these findings as estimates of sample size based on power calculations from small numbers may be unreliable because of the variability of the samples. Means and standard deviations from the 36 patients who completed the 6 months follow-up measures were used to calculate numbers to demonstrate a significant advantage (alpha=0.05, power=0.90, for a 2-sided test) of CBT over AM. For the POMS TMS, depression and anxiety subscales 183, 69 or 426, respectively would be required in each group. For anxiety large numbers of people would need to be treated to demonstrate a superiority of CBT. AM may be as clinically effective and is less costly. In the longer term, and possibly for patients with a better prognosis, CBT may be preferable for depression.

In conclusion, this pilot trial demonstrates that it is possible to recruit cancer patients to a trial of CBT versus AM, that the interventions are well received and that follow-up is high. Preliminary results suggest that both CBT and AM may be beneficial for psychological anxiety in the short term, but that CBT may have an advantage over AM for treating depression in the longer term. A full scale trial is now required to compare CBT with AM.

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The ToT Study: Helping with Touch or Talk (ToT): A pilot randomised controlled trial to examine the cost effectiveness of aromatherapy massage versus cognitive behaviour therapy for emotional distress in patients in cancer/palliative care.

Serfaty M, Holman A, Wilkinson S, King M.

Abstract:

BACKGROUND:

There is a significant psychological distress in people with cancer, with depression and/or anxiety being the most common reactions. People with psychological distress utilise more health service resources than their less distressed counterparts. CBT is one of the most widely evaluated and effective treatments for depression and anxiety and there is some evidence of benefit in cancer patients. Complementary therapies are used by one third of patients with cancer, with aromatherapy massage (AM), being one of the most common and popular interventions in the UK with some evidence for alleviation of distress. There are no studies comparing the cost effectiveness of the two interventions.

Aims: To compare the cost effectiveness of AM versus CBT for the alleviation of emotional distress in patients with cancer, using data from a pilot randomised controlled trial.

Methods: Recruitment from oncology outpatient clinics. Screened for anxiety and/or depression using the HADS and randomised to treatment as usual (TAU) plus AM, or TAU plus up to 8 sessions of CBT given weekly over 3 months, with follow up at 3 and 6 months from baseline. Health service use was collected at two time points over the 6 month period using the Client Service Receipt Inventory (CSRI). The primary outcome was the POMS total mood score (TMS), though quality of life was also assessed using the EQ-5D. Cost-effectiveness of the two interventions is assessed at both 3 months and 6 months from baseline. Only patients with complete cost and outcome data at all time points were included in the analysis.

Results: Of the 18 people randomised to AM and 17 to CBT, substantial reductions in total POMS mood scores, POMS depression and anxiety subscales and improvements in EuroQol scores occurred in both interventions, although the sample size was too small to detect a significant difference between the two intervention groups. Reductions in health service use were observed across both groups from baseline. Incremental cost effectiveness analysis showed CBT costs an additional £14 to gain an additional point change in TMS score per patient, and an additional £4,196 to gain an additional quality-adjusted life year for each patient.

Conclusions: Preliminary data suggests that there are significant reductions in POMS scores with both AM and CBT. A greater change in quality of life was observed for patients treated with CBT compared with patients treated with Aromatherapy. This pilot analysis suggests that CBT is likely to be considered a cost effective treatment in relation to Aromatherapy, though a larger study is needed to confirm the results.

BACKGROUND

One third of cancer patients experience psychosocial distress and this increases with disease progression (Butler et al, 2003; Zabora et al, 2001), with adjustment disorder, anxiety and depression being the most common presentations. Anxiety and depression may also lead to an increased utilisation of healthcare resources (Hawley and Wolfe, 1988; Katz and Yelin 1993; Vali and Walkup, 1998; Manning and wells, 1992) and heavy healthcare users are more likely to suffer from generalised anxiety disorder, depression and panic. A number of studies have demonstrated the clinical effectiveness of psychological therapies in cancer (Sheard and Maguire, 2000; Newel et al, 2002). Psychosocial interventions are often seen as simply adding cost to usual care without considering potential savings. A meta-analysis of psychological interventions, not specifically to cancer, resulted in average savings of about 20% (Chiles et al, 1999). There have been few trials reporting the use of health service resources with economic analyses of psychological therapies in cancer. Using the total mood score on the POMS, a non significant decrease in costs for 82 out of 125 patients with metastatic breast cancer randomised to supportive-expressive group support compared to standard care alone was observed (Lemieux et al, 2006). The effects of psychosocial interventions on survival is less conclusive (Meyer and Mark, 1995; Smedslund and Ringdal, 2004); Altering the coping response through psychotherapy (Greer, 2002; Baider et al, 2001) may in turn may have modulating effects on the disease and thus reduce resource use.

We present a pilot study into the cost effectiveness of aromatherapy massage (AM) compared with cognitive behaviour therapy (CBT), in the management of emotional distress (depression, anxiety or mixed anxiety and depression) in people with cancer.

METHODS

The methodology and background of the pilot parallel group, single-blind, randomised controlled trial has been described in the previous paper by Serfaty et al (reference).

Costs

This analysis was conducted from the perspective of the NHS, considering the cost of the intervention and direct health service costs only. Health service use was recorded retrospectively using patient notes, and transcribed onto on a modified version of the Client Service Receipt Inventory (CSRI; Beecham and Knapp, 1992). Hospitalisations and community health service use including attendances with GPs, physiotherapists, psychiatrists, psychologists, occupational therapists and counsellors were recorded from baseline to three months, and three to six months. Therefore costs presented at six month follow-up are cumulative totals from baseline.

Unit costs were estimated using published NHS Reference Costs (Department of Health, 2007) and Unit Costs for Health and Social Care (Curtis, 2008), which are most likely to represent average costs associated

with a national service. Hospitalisations were not costed according to the specific reason for admission due to the large range of admission types. The majority of admissions were related to the patient's diagnosis of cancer, therefore, a general cost for hospitalisation or outpatient treatment on an oncology ward was applied. A health-specific inflation index was applied to inflate all costs to 2008 estimates (ONS, 2009). Unit costs including those for the interventions are presented in Appendix 1.

Unit costs were multiplied by counts of health service resource use to calculate health service costs for each patient. Heath service costs were added to the cost of the intervention (based on the number of sessions each patient attended) to present total patient level costs.

Outcomes

The primary outcome was change from baseline in total mood score (TMS) using the shortened version (POMS Shacam, 1983) of the Profile of Mood States (McNAir et al, 1992). The EuroQol (EQ-5D; Brooks 1996) was also used as a subsidiary measure to estimate changes in health-related quality of life from baseline. Utility data collected using the Euroqol EQ-5D was converted into quality-adjusted life years by multiplying patient-level utility scores with the length of time between each follow-up point (3/12 months). QALY's presented at six month follow-up are cumulative totals from baseline.

Data Analysis

While cost data by nature is highly skewed, data was scanned and extreme outliers were removed, as well as patients with missing cost or outcome data at any time point. Cost and outcome data were compared between groups at baseline, and then at three and six months from baseline. Non-parametric bootstrapping was used to calculate confidence intervals around estimates. If a trade-off between costs and outcomes was observed, incremental cost-effectiveness ratios were calculated for both outcome measures.

RESULTS

Baseline Analysis

Only 1 patient (group = CBT) was excluded from baseline analysis due to two hospitalisations of more than 20 days each. This left a total of 38 patients for baseline analysis (AM=20, CBT=18).

There was little difference in TMS at baseline between groups (difference 1.8, 95% CI -11.0, 15.3). Health-related quality of life was lower at baseline for CBT compared with AM patients (difference -0.03, 95% CI: -0.18, 0.12). Average health service costs for 3 months prior to baseline were higher for the CBT group (£2315) compared with the AM group (£1888; difference £427, 95% CI: -£852, £1474).

Follow-up Analysis

Follow-up analysis was conducted for complete cases only. Four patients were excluded due to missing cost and quality of life data (CBT=2, AM=2), leaving a sample size of 35 patients (AM=18, CBT=17).

Patients receiving treatment with CBT showed greater change in TMS at both follow-up points, though the difference between groups in TMS from baseline was more marked at 6 months (difference 7.3 points, 95% CI: -9.6, 23), than at 3 months follow up (difference 3.9 points, 95% CI: -10.1,18.5).

Table 2. Change in TMS from baseline

3 month follow-up	Aromatherapy (N=19)	CBT (N=17)	Difference
TMS 1_2	13.6	17.5	3.9
95% CI	4.0, 22.3	7.5, 27.3	-10.1, 18.5
6 month follow-up			
TMS 1_3	10.4	17.7	7.3
95% CI	-1.1, 21.7	6.5, 27.8	-9.6, 23.0

Differences in health-related utility and resulting quality-adjusted life years gained over the trial (QALYs) were indistinguishable between groups until 6 month follow-up (Table 3, Figure 1). By 6 months, CBT patients reported higher utility values, and had accrued more QALYs over the duration of the trial than AM patients (difference 0.025 QALYs, 95% CI: -0.02, 0.08), though this difference was not significant.

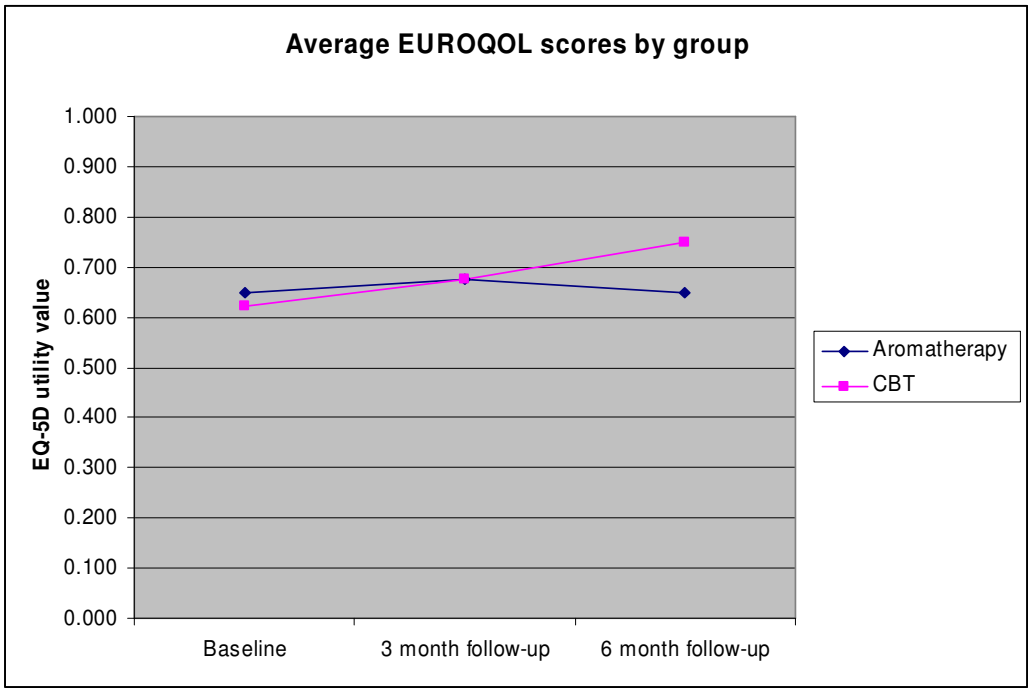

Table 3. QALYs accrued from baseline to follow-up

3 month follow-up	**Aromatherapy (N=18)**	**CBT (N=17)**	**Increment**
QALYs	0.009	0.006	-0.003
95% CI	-0.02, 0.03	-0.01, 0.03	-0.03, 0.03
6 month follow-up	**Aromatherapy (N=18)**	**CBT (N=17)**	**Increment**
QALYs	0.007	0.032	0.025
95% CI	-0.01, 0.03	-0.01, 0.08	-0.02, 0.08

Costs

Table 4 shows the average cost of CBT treatment was £352 per patient, and aromatherapy was £249 per patient (difference £103). This was based on a reported average of 7 aromatherapy sessions per patient, and 5 CBT sessions per patient, delivered over the 3 month period.

There was no significant difference between groups on any items of health service use, so only totals are presented in Table 4 below. Health service costs were substantially lower in both groups for the three month period post baseline, compared with pre-baseline. The difference between groups in health service use also narrowed by 3 months follow-up (difference £243), compared with baseline (difference £427). The relative reduction in health service use in the CBT group compared with the AM group, offset the additional cost of the CBT intervention so that the difference in total costs was only £345 (-£201, £1005) between groups.

At 6 month follow-up, total costs over the duration of the trial remained higher for the CBT group at £2975, compared with £2376 for the AM group. The difference in costs between groups was £600 (95% CI: -500, £1709) over the 6 month trial period, comprising £103 related to the intervention, and £497 related to health service use. Again, this difference in the cost of health service use is virtually indistinguishable from the difference that was present at baseline (£427).

Table 4. Average patient costs from baseline to follow up

Average per patient costs (£)	Aromatherapy (N=18)	CBT (N=17)	Increment
Intervention costs	249	352	103
95% CI	218, 277	260, 434	-1, 196
3 month follow up			
Health service costs	1,134	1,377	243
95% CI	700, 1520	956, 1757	-267, 874
Total costs	1,383	1,729	345
95% CI	950, 1775	1273, 2191	-201, 1005
6 month follow up			
Health service cost	2,127	2,624	497
95% CI	1370, 2924	1957, 3419	-594, 1589
Total costs	2,376	2,975	600
95% CI	1628, 3166	2293, 3801	-500, 1709

Cost-Effectiveness Analysis

As there is no evidence that the interventions influence patterns of health service use differentially, the cost effectiveness analysis should be restricted to costs that vary between the groups, being the intervention alone.

This analysis has demonstrated CBT to be more costly, but also more effective than AM, except with respect to health-related quality of life at 3 month follow up. Because CBT was less effective than AM with respect to health-related quality of life at 3 months, CBT is described as being dominated by AM at this timepoint.

For all other scenarios, the difference in costs between the two interventions (£103) is divided by the difference in outcomes at each follow up point to produce an incremental cost-effectiveness ratio (ICER, Table 5). The ICER reports the incremental costs and outcomes as a ratio, reflecting the cost incurred to obtain the additional benefits from the chosen intervention. At 3 months follow-up, the ICER for CBT compared with AM is £26 per point

change in TMS. By 6 months follow-up, CBT costs an additional £14 per point change in TMS, and £4,196 per QALY gained.

Table 5. Incremental cost-effectiveness (ICER) of CBT compared with aromatherapy (intervention costs only)

Cost effectiveness at 3 months	Mean
Incremental cost (intervention only)	£103
Incremental effectiveness (change in TMS)	3.9
Incremental effectiveness (QALYs)	-0.003
Incremental cost-effectiveness (per point change in TMS)	£26
Incremental cost-effectiveness (per QALY gained)	DOMINATED
Cost effectiveness at 6 months	
Incremental cost (intervention only)	£103
Incremental effectiveness (change in TMS)	7.299
Incremental effectiveness (QALYs)	0.025
Incremental cost-effectiveness (per point change in TMS)	£14
Incremental cost-effectiveness (per QALY gained)	£4,196

Uncertainty around the ICER values at 6 month follow up is reflected by plotting the distribution of ICERs from a bootstrap sample on a cost effectiveness plane (Figure 2 and 3). The plots show the majority of ICERs for the bootstrap sample fall within the northeast quadrants of the planes, reflecting both higher incremental costs and outcomes for CBT in comparison with AM.

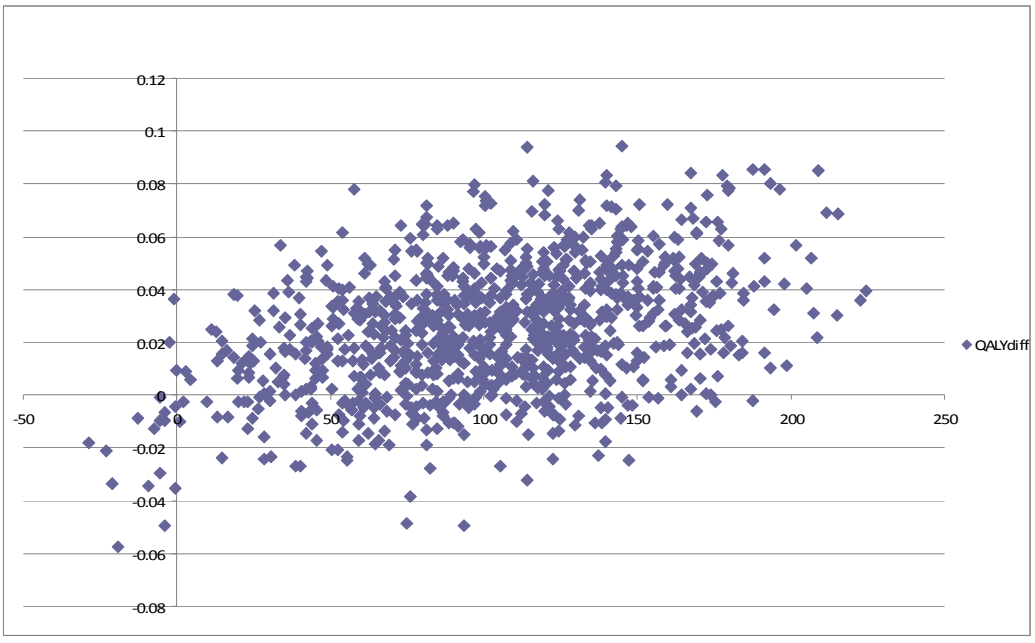

Figure 2. Cost effectiveness plane using QALYs at 6 month follow-up

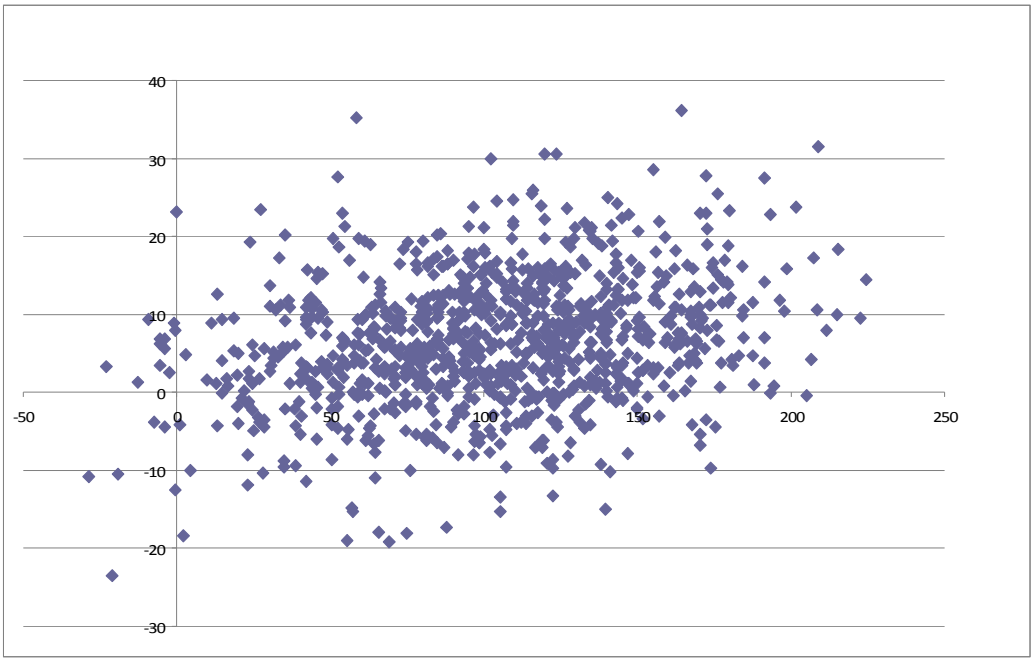

Figure 3. Cost effectiveness plane using TMS at 6 month follow-up

Interpreting whether CBT is likely to present 'value for money' over AM depends on how much one is willing to pay to gain an additional point change in TMS, or an additional QALY. The relationship between willingness to pay and cost-effectiveness of CBT is best illustrated using a cost effectiveness acceptability curve (CEAC). A CEAC shows the probability that CBT will be accepted as cost-effective in relation to the comparator, over a range of threshold cost-effectiveness values. CEACs are presented below for both change in TMS and QALYs at 6 month follow up (Figures 4 and 5).

Figure 4 shows an 82% probability that CBT will be considered cost effective.using a willingness to pay threshold of £30,000 per QALY gained. Figure 5 shows an 81% probability that CBT will be considered cost effective using a willingness to pay threshold of £800 per point change in TMS.

Figure 4. Cost effectiveness acceptability curve using QALYs at 6 months

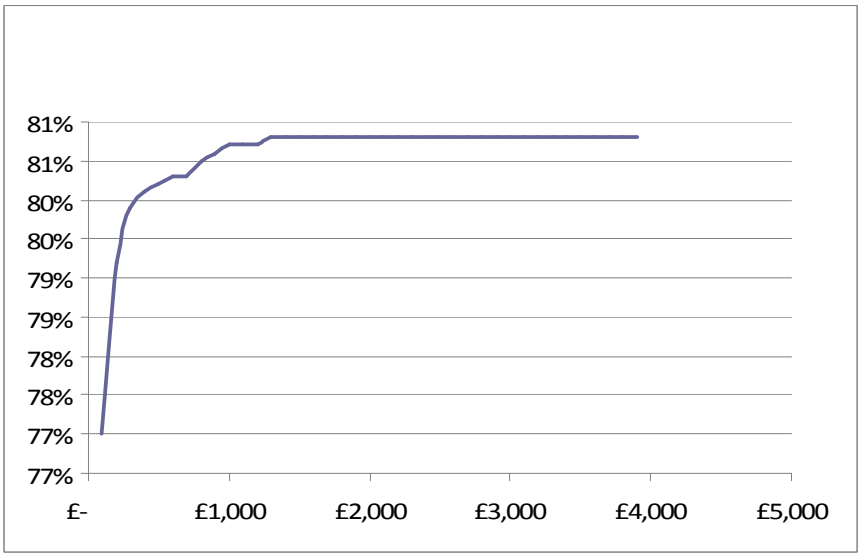

Figure 5. Cost effectiveness acceptability curve using TMS at 6 months

Discussion

Economic analysis showed that CBT was more costly, but also more effective than AM at 6 months follow-up. This analysis aimed to compare the cost-effectiveness of CBT compared with Aromatherapy delivered over a 3 month period, with follow up at 6 months. Results of this analysis are discussed within the limitations of a small sample size and the analysis being restricted to raw unadjusted data.

Although there was no significant difference in clinical outcome (mood) and quality of life for CBT compared with Aromatherapy, this was probably due to the small sample size in this pilot trial. CBT cost an average of £103 per patient more than Aromatherapy. Both interventions were of benefit to patients, though CBT was associated with a larger change in outcomes at 6 months compared with Aromatherapy (7.3 point difference in TMS from baseline; and a 0.025 difference in QALYs). Combining the difference in costs and outcomes into an incremental cost effectiveness analysis shows CBT costs an additional £14 to gain an additional point change in TMS score per patient, and an additional £4,196 to gain an additional quality-adjusted life year for each patient. Whether or not these ratios are acceptable depends on the willingness to pay on part of the funder. Assuming a willingness to pay threshold of £30,000 per QALY gained, there is an 82% probability that CBT will be considered cost effective compared to Aromatherapy. It is more difficult to interpret the cost effectiveness of CBT in relation to changes in TMS, though analysis showed a 81% probability that CBT will be considered cost effective using a willingness to pay threshold of £800 per point change in TMS.

Cost analysis has shown while the treatments were both associated with reduced health service use and costs, the interventions do not appear to have had a differential effect on health service use and resulting costs. These findings are also consistent with those by Lemieux et al (2006) who found a non significant decrease in costs with supportive-expressive group support. Differences in health service use between the groups remained consistent from baseline and through the trial and therefore this cost effectiveness analysis focussed on comparing the costs of the interventions alone.

This study has also enabled us to determine which health service costs are most relevant in the particular patient population. While the CSRI offers an extremely comprehensive estimate of patient costs, it is desirable to modify the form to suit the needs of each particular study. This pilot has enabled us to pick and choose which costs are the most relevant in a future study, so omission of some sections will not necessarily mean the costing is incomplete. And in fact, this analysis suggests that while health service use appears to be influenced by the interventions, reductions appeared no larger in one group over the other. It could therefore be argued that the collection of health service use data is not necessary in a future cost-effectiveness study, as only costs that are likely to differ between the interventions are relevant.

In conclusion, CBT was shown to be more effective than Aromatherapy in reducing distress and improving health-related quality of life, though differences were not significant. Both CBT and Aromatherapy resulted in reduced health service use among cancer patients experiencing emotional distress. This pilot analysis suggests that CBT is likely to be considered a cost effective treatment in relation to Aromatherapy, though a larger study is needed to confirm these results.

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Appendix 1. Unit Costs

Treatment	Cost per day (£, Dec 2006)	Cost per day (£, Dec 2008)	Details	Referer
Inpatient stay (oncology)	262	278	Other admissions related to neoplasms (cancer type not specified). Weighted average of major, intermediate and without complications (WA17V,X,Y)	2006-7 Trusts a Elective (TNEI)
Outpatient visit (Oncology follow-up)	116	123	Medical oncology (Attendance without Treatment) Total Attendances, specialty code 370,	2006-7 Trusts Consult Attenda Face to
Day visit (Chemotherapy, radiotherapy)	176	187	Deliver chemotherapy, excluding drugs (weighted average SB11Z-SB15Z)	2006-7 Trusts Chemot (TCHEM
A&E	100	106	A&E visit; weighted average of category 1-5 treatment received (VB01Z-VB09Z)	2006-7 Trusts Acciden Service Admitte
Ambulance	195	207	Unconscious / Fainting (near) / Passing Out (non-traumatic) code PS31A	2006-7 Trusts Parame Urban A Categor
GP visit		36	Per clinic consultation lasting 11.7 minutes	PSSRU (Estima
Practice nurse		11	Per consultation	PSSRU (Estima
District nurse		26	Per home visit	PSSRU (Estima
Psychiatrist		137	Per patient hour of contact	PSSRU (Estima
Clinical psychologist		41	Per professional chargeable hour.	PSSRU (Estima
Occupational Therapist		66	Average cost for a one to one contact.	PSSRU (Estima
Physiotherapist		42	Average cost for a one to one contact.	PSSRU (Estima
Counsellor/Therapist		40	Per hour of client contact. Counselling services in primary medical care.	PSSRU (Estima

Note: CPI (Health specific) inflation index of 1.06 (Dec06-Jan09) was applied to all Dec 2006 costs.

Source: Office of National Statistics: http://www.statistics.gov.uk/statbase/Product.asp?vlnk=868

Intervention costs	**£ per session**
Aromatherapy massage (AM)	35
CBT	65