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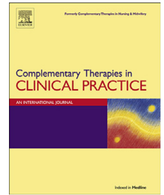

Is reflexology as effective as aromatherapy massage for symptom relief in an adult outpatient oncology population?

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A B S T R A C T

Aim: To test whether reflexology was inferior to aromatherapy massage for ameliorating self-selected problems or concerns.
Design: Non-blinded, randomised study with a 1:1 allocation.
Adult outpatients recruited from a UK cancer centre, randomised by the minimisation method to either four aromatherapy massage or four reflexology sessions.
Outcome measures: MYCaW scores at baseline and completion; VAS (relaxation) pre and post-sessions.
Analysis: Unpaired *t*-test for the primary outcome; analysis of variance tests for repeated measures for VAS (relaxation); descriptive statistics (means and 95% confidence intervals) and content analysis for patient comments.
Results: 115 subjects (58 aromatherapy massage, 57 reflexology) recruited. Reflexology was found to be no less effective than aromatherapy massage for MYCaW first concerns ($p = 0.046$). There was no statistical difference between groups for MYCaW second concerns or overall well-being scores, proportions of patients gaining clinical benefit, VAS scores over time ($p = 0.489$) or between groups ($p = 0.408$) or in the written responses.

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1. Introduction

More than one in three people in the UK will develop some form of cancer in their lifetime. Breast cancer accounts for almost a third (31%) of female cases.[1] There are currently two million people across the UK living with and beyond cancer. This number is likely to grow by over 3% per year, reflecting the increasing incidence of cancer and better survival rates.[2] Cancer is the number one fear for the British public according to a survey commissioned by Cancer Research UK carried out in 2010.[3]

Increasing numbers of these oncology patients choose to access complementary therapies both during and after their treatment in order to help alleviate symptoms caused by their cancer or its treatment.[4] Complementary therapies are widely offered in hospitals, hospices and voluntary centres in the community. In the UK, within the National Health Service, reflexology was found to be available for people with cancer in 62.0% of units, aromatherapy in 59.1%.[5] Reflexology (35.2%) and aromatherapy (30.7%) were the most commonly used therapies by newly diagnosed patients.[6]

A systematic review aimed at critically evaluating all available randomised controlled trials of massage in cancer palliation suggested that massage can alleviate a wide range of symptoms: pain, nausea, anxiety, depression, anger, stress and fatigue. The evidence is encouraging but not compelling due to the poor methodological quality of included studies.[7]

In addition, a systematic review aimed at critically evaluating the data from randomised controlled trials of reflexology concludes that although reflexology is not an effective treatment option for any medical condition, the most promising evidence lies in the realm of cancer symptom palliation.[8]

We were unable to find previous evidence directly comparing reflexology and aromatherapy massage in outpatients with cancer other than a trial considering the psychological effects of reflexology in early breast cancer which used scalp massage as a control for physical and social contact.[9] In this trial there were no significant differences between reflexology and massage.

In this UK specialist cancer centre aromatherapy massage has been available since 1988. It is a very popular therapy both with patients and with the staff who refer their patients. Therefore

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before introducing reflexology we decided to investigate whether it offered the same benefits as aromatherapy massage to our patient group.

This study of outpatients was primarily undertaken to ascertain whether reflexology is as effective as aromatherapy massage for self-selected concerns (using Measure Yourself Concerns and Wellbeing, (MYCaW)). Additionally we sought to assess the difference between groups in MYCaW second concerns, overall well-being scores and levels of relaxation. We also used MYCaW to collect patients' comments on the intervention they received.

2. Hypothesis

We tested the null hypothesis that reflexology is less effective than aromatherapy massage in the outpatient oncology setting for patients' self-selected MYCaW first concern score as indicated by improvement in score for massage minus improvement in score for reflexology is more than or equal to one.

The alternative hypothesis was that reflexology is not less effective than aromatherapy massage as indicated by improvement in score for massage minus improvement in score for reflexology is less than one.

3. Methods

3.1. Design

This was a non-blinded, parallel randomised study with a 1:1 allocation conducted with outpatients treated at a UK specialist cancer centre. The primary outcome measure was analysed in a non-inferiority design to test whether reflexology was inferior to aromatherapy massage for self-selected concern scores. The secondary outcomes were analysed in a superiority design to establish if there is a difference between groups for the secondary endpoints.

3.2. Patients

The flow of patients through the study is outlined in Fig. 1. The eligibility criteria for this study were: patients over 18 years old, with a diagnosis of cancer, attending the hospital as NHS outpatients, wishing to access complementary therapy treatment and able to attend the hospital for four, one-hour sessions. The exclusion criteria were: those already receiving (or who had received in the past two months or who were intending to receive during the period of the study) either aromatherapy massage or reflexology from any practitioner and those unable to receive the intervention due to contraindications or precautions for either therapy. Patient withdrawal criteria were if they no longer met the inclusion criteria, if they reported an adverse event to either therapy or if they chose not to continue.

3.3. Sample size

This calculation was based on findings from a study in a similar population. The sample size calculation at 90% power assumed a 2.9-point mean change in the MYCaW first concern score (common standard deviation of 1.63).[10] The aim was to demonstrate that a difference in the mean change between groups in MYCaW first concern was not more than one point in favour of aromatherapy massage. A sample size of at least 47 patients in each group was required to achieve 90% power. We originally sought to include one hundred patients. Due to withdrawal or drop-out a minor amendment approval to the protocol was obtained to allow recruitment of a further fifteen patients in order to maintain intended power.

3.4. Randomisation and interventions

Patients were recruited after responding to posters in outpatient clinics that advertised the study or by hearing of the study from the hospital's health care professionals. After a discussion with the lead researcher (JD) those who were eligible and interested in participating were given a patient information sheet. Those who were not willing or able to participate were instead offered a course of aromatherapy massage as per usual practice. An initial appointment was booked with one of four participating therapists all experienced in delivering both interventions. Appointments took place in quiet treatment rooms in the Therapies Departments. Where possible, patients continued to attend sessions with the same therapist over similar time intervals. At the first appointment informed written consent was obtained; the first form for MYCaW and the pre-treatment VAS (relaxation) were completed with structured guidance and placed in an envelope. All envelopes were collected by the lead researcher (JD) and delivered by hand to the data manager.

The treating therapist called the independent randomisation service at the Clinical Trials and Statistics Unit, Institute of Cancer Research, and patients were allocated to receive four sessions of either aromatherapy massage or reflexology. Randomisation by minimisation was used to balance the two groups.[11] The three factors used were gender (male *or* female), treatment (chemotherapy within previous two months *or* no chemotherapy within previous two months) and pain *or* other as first concern on MYCaW.

Usual practice for new patients was followed. Relevant parts of the patient's medical history were entered on departmental notes and a clinical assessment made by the therapist concerned. The allocated intervention was then given and the post-treatment VAS (relaxation) completed, placed in an envelope by the patient and sealed. The therapists did not see the scores on these post-treatment assessments. The pre and post-session VAS (relaxation) measures were completed at each session and MYCaW follow-up form used at the fourth session. All completed measures were placed in envelopes and sealed by the patients at each visit and collected by the lead researcher (JD). A total of four sessions were offered.

3.5. Interventions

3.5.1. Aromatherapy massage

Aromatherapy massage combines two modalities to produce its effect. Aromatherapy is the systematic, controlled use of essential oils to promote and enhance the health and well-being of the individual, as described in the International Federation of Professional Aromatherapists: Code of Conduct.[12] Essential oils used for aromatherapy are volatile, organic constituents of fragrant plant matter.[13]

Massage therapy involves the administration of combinations of specific physical manipulations applied in a systematic way, with varying intensity, direction, rate and rhythm, to the soft tissues of the body. The application of the manipulations is usually varied to fit the subject's health status and preferences as well as the therapist's eclectic approach.[14]

3.5.2. Reflexology

Reflexology is a therapeutic method that uses manual pressure applied to specific areas, or zones, of the feet (and sometimes the hands) that are believed to correspond to other areas or organs of

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