

Evaluation of an aromatherapy service on a leukaemia unit

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/05/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0063054436

Study information

Scientific Title

Study objectives

1. To evaluate the aromatherapy/massage service offered to patients on the Adult Leukaemia Unit (ALU) of the Christie Hospital NHS Trust
2. To assess whether massage with essential oils is more effective than massage with base oil or time for peace and calm at reducing physiological and psychological symptoms of stress and perception of pain

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cancer: Leukaemia

Interventions

1. Arm A: No massage
2. Arm B: Massage with essential oil
3. Arm C: Massage without essential oil

Those randomised to either of the two experimental arms will receive a part body massage once a week for the duration of their stay as an in-patient on the ALU (with or without essential oils depending on which arm they are in).

Those in the control arm will rest on their beds for an equivalent length of time.

All study participants will rest on their beds for twenty minutes prior to treatment after which blood samples will be taken for hormone levels. Once this has been done patients will be asked to fill in the quality of life questionnaire. Following completion, those patients in the experimental groups will receive their massage. Following the therapy session the patients will be allowed to rest for 10 minutes then more blood samples will be taken for hormone levels. This sampling will be repeated half hourly for two hours. At this final session a semi-structured interview will be conducted to aid evaluation of the effect the therapist may have on the patient. The patient will also be asked to fill in pain and quality of life measures at this point. The questionnaires and blood sampling will be repeated after 24 hours.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Reducing cortisol and prolactin levels

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/2001

Completion date

15/08/2003

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

189 NHS patients maximum

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/05/2001

Date of final enrolment

15/08/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Adult Leukaemia Unit

Manchester

United Kingdom

M20 4BX

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Christie Hospital NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2008		Yes	No