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Evaluation of an aromatherapy service on a leukaemia unit

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 24/05/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J Stringer

Contact details
Adult Leukaemia Unit
Christie Hospial NHS Trust
Wilmslow Road
Withington
Manchester
United Kingdom
M20 4BX

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