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A randomised, controlled, single blind pilot study to evaluate the efficacy of a mindfulness stress reduction intervention as an adjunct therapy in moderate to severe psoriasis

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
30/09/2004	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
10/05/2018	Skin and Connective Tissue Diseases	[_] Record updated in last year

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
N0013137386

Study information

Scientific Title
A randomised, controlled, single blind pilot study to evaluate the efficacy of a mindfulness stress reduction intervention as an adjunct therapy in moderate to severe psoriasis

Study objectives
A randomised, controlled, single blind pilot study to evaluate the efficacy of a mindfulness stress reduction intervention as an adjunct therapy in moderate to severe psoriasis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised single blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Psoriasis

Interventions
Patients with moderate to severe psoriasis will be randomly assigned at a ratio of 1:1 to receive a mindfulness stress reduction audio tape or nothing (control) as an adjunct treatment to their conventional psoriasis treatment plan. The experimental group subjects will be required to listen to the tape and practice the relaxation technique 3 times a week for 8 weeks. Both groups will be seen at week 0, 4 and 8 for psoriasis severity scores, and psychological assessment scores to evaluate effect.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
1. Psoriasis severity measured using the Psoriasis Severity Index (PASI)
2. Mental health using Hospital Anxiety and Depression Scale (HADS)
3. Mental health using Penn State Worry Questionnaire (PSWQ)

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2003

Completion date
01/07/2004

Eligibility

Key inclusion criteria
Approx 50 adult psoriasis patients attending St John's Institute of Dermatology as an out-patient who have had the diagnosis of psoriasis for at least one year.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/12/2003

Date of final enrolment
01/07/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Oral Medicine Department
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St Thomas' 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