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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St Thomas' NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration