

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
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 10/05/2018	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

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

Primary study design

Interventional

Study design

Randomised single blind controlled trial

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