

# 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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/05/2018	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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