

# American skullcap (*Scutellaria lateriflora*): a study of its effects on mood in healthy volunteers

<b>Submission date</b> 01/07/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/06/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

UW080921

## Study information

### Scientific Title

An investigation of the psychological, somatic and related social effects resulting from the use of American skullcap (*Scutellaria lateriflora*): a randomised placebo-controlled crossover study in healthy volunteers

### **Study objectives**

Anxiety is a common but potentially serious disorder as it can lead to both somatic and social dysfunction. Orthodox anxiolytics are associated with unpleasant side-effects and dependency. There is therefore an urgent need for safe, well-tolerated and effective alternatives. American skullcap (*Scutellaria lateriflora*) is a popular herb in traditional medicine systems and the western herbal medicine *Materia medica* is used for anxiety, stress, hysteria, tremors, sleep disorders, panic, tension, and related disorders. It is reported to have minimal side-effects and no known toxicity. It is therefore an ideal candidate for providing evidence for its efficacy and safety with a view to its widespread use as a licensed product, for the reduction of anxiety, stress and related co-morbidities.

Research question:

Can *Scutellaria lateriflora* extracts provide an effective treatment for reducing anxiety and stress?

Study hypotheses:

1. *S. lateriflora* will have a superior anxiolytic effect to placebo
2. The safety profile of *S. lateriflora* will be comparable to that of placebo
3. *S. lateriflora* will reduce anxiety without a marked diminution of cognition or energy
4. *S. lateriflora* will decrease salivary cortisol levels in moderately anxious individuals

On 07/09/2009 this record was updated to include a new anticipated start date; the initial start date at the time of registration was 01/09/2009.

On 24/03/2011 this record was updated to include an edited public title, scientific title, inclusion criteria, exclusion criteria, anticipated start and end dates and status of trial.

Previous public title:

American skullcap (*Scutellaria lateriflora*) for anxiety and stress: an efficacy study in healthy volunteers

Previous scientific title:

An investigation of the psychological, somatic and related social effects resulting from the use of American skullcap (*Scutellaria lateriflora*) in the treatment of anxiety and stress: a randomised placebo-controlled crossover study in healthy volunteers with self-reported moderate anxiety

The previous start date was 01/11/2009 and the previous end date was 01/12/2010.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

University of Westminster Research Ethics Sub-Committee, 24/4/2009, ref: 08/09/21

### **Study design**

Interventional randomised double-blind (subjects, investigators/outcome assessors) placebo-controlled crossover study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Moderate anxiety

## **Interventions**

Intervention: organic freeze-dried *Scutellaria lateriflora* capsules 350 mg three times daily

Placebo control: organic freeze-dried stinging nettle leaf (*Urtica dioica* folia) capsules 300 mg three times daily

The study will last for 38 days including a 7-day washout period. Participants will be randomly assigned to receive either freeze-dried *Scutellaria lateriflora* test or freeze-dried *Urtica dioica* folia placebo three times daily for half of the intervention study duration and then, following a washout period of 1 week, will cross over to receive the other for comparison. In other words, participants will be acting as their own controls.

Clinical reporting scales and salivary cortisol measurements will be used to compare anxiety symptoms and quality of life at the beginning, before the end of the first half prior to crossover, and at the end of the clinical study. There have been no reports of toxicity associated with *S. lateriflora*. To confirm its safety profile, all participants will undergo fingerpick blood extraction for liver function analysis pre-, intermediate and post-intervention.

## **Intervention Type**

Drug

## **Phase**

Phase IV

## **Drug/device/biological/vaccine name(s)**

*Scutellaria lateriflora*, *Urtica dioica* folia

## **Primary outcome(s)**

Reduction in anxiety following 2 weeks' intervention in comparison to placebo control, indicated by a significantly reduced score on the Beck Anxiety Inventory, projected to be at least 10 points (0 - 7 = no anxiety-minimal anxiety; 8 - 15 = mild anxiety; 16 - 25 = moderate anxiety; 26 - 63 = severe anxiety).

## **Key secondary outcome(s)**

1. Self-reported changes in quality of life
2. Changes in salivary cortisol measurements to indicate a reduction in stress levels
3. Live blood analysis of liver function by fingerprick blood extraction

Sampling and testing for secondary outcome measures will be conducted prior to commencement of the interventional stage of the study in order to take baseline measurements for comparison with subsequent measurements, during the last 2 days of the first half of the intervention prior to a 7-day washout period and during the last 2 days of the second half of the intervention study following crossover. Pulse and blood pressure will also be assessed at these time-points as a matter of interest.

**Completion date**

30/10/2011

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 24/03/2011:

1. Aged 18 - 75 years, either sex
2. Good general health
3. Males and females
4. Participants will be volunteers and will have given informed consent
5. Agree to undergo a fingerprick blood test for analysis of liver function pre-, intermediate- and post-intervention

Previous inclusion criteria:

1. Symptoms of moderate anxiety, indicated by a cut-off score point for anxiety on the Beck Anxiety Inventory (BAI) between 16 - 25
2. Aged 18 - 75 years, either sex
3. Good general health
4. Males and females
5. Participants will be volunteers and will have given informed consent
6. Agree to undergo a fingerprick blood test for analysis of liver function pre-, intermediate- and post-intervention

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

75 years

**Sex**

All

**Key exclusion criteria**

Current exclusion criteria as of 24/03/2011:

1. Alcohol, tobacco or recreational drug dependence
2. Known hypersensitivity to any herbal medicines when taken orally
3. Current use or use within the past month of antipsychotic medication, e.g., tranquilisers, antidepressants, or sedatives
4. A history of (diagnosed) severe psychiatric disorders, e.g., clinical depression, bipolar disorder or generalised anxiety disorder
5. Neurological, immunological or endocrinological disorders
6. Liver disease, kidney disease, cancer, diabetes mellitus, malignant hypertension or any other serious medical condition
7. Moderate-high depression, i.e., Hospital Anxiety and Depression Scale (HADS) scores 8 - 21
8. Those currently on, or with a recent history of using, synthetic hormones (other than the contraceptive pill), including sprays or topical corticosteroid analogues
9. Those taking herbs or supplements that may have either a direct or indirect effect on the HPA axis (e.g., dopaminergic, serotonergic, gamma-aminobutyric acid [GABA] -ergic)
10. Pregnancy or lactation
11. Those under 18 or over 75
12. Refusal to undergo blood tests

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6. Liver disease, kidney disease, cancer, diabetes mellitus, malignant hypertension or any other serious medical condition
7. Moderate-high depression, i.e., Hospital Anxiety and Depression Scale (HADS) scores 8 - 21
8. Initial scores of above 26 in the BAI, indicating severe anxiety
9. Initial scores below 16 in the BAI, indicating mild anxiety
10. Those currently on, or with a recent history of using, synthetic hormones (other than the contraceptive pill), including sprays or topical corticosteroid analogues
11. Those taking herbs or supplements that may have either a direct or indirect effect on the HPA axis (e.g., dopaminergic, serotonergic, gamma-aminobutyric acid [GABA] -ergic)
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**Date of first enrolment**

01/04/2011

**Date of final enrolment**

30/10/2011

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**University of Westminster**  
London  
United Kingdom  
W1W 6UW

## Sponsor information

**Organisation**  
University of Westminster (UK)

**ROR**  
<https://ror.org/04ycpbx82>

## Funder(s)

**Funder type**  
University/education

**Funder Name**  
University of Westminster (UK) - Institute of Health and Wellbeing

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/05/2014		Yes	No