

# Effect of Naturopathic Treatments On Anxiety Outcomes of Postal Workers, a randomized controlled parallel group study

<b>Submission date</b> 15/02/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/09/2009	<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

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## Additional identifiers

**Protocol serial number**  
02

## Study information

**Scientific Title**

**Acronym**

ENTOAOPW

**Study objectives**

We hypothesise that a treatment utilizing withania somnifera and a multi vitamin along with encouragement to exercise and cognitive behavioral therapy will be more effective than encouragement to exercise and cognitive behavioral therapy plus placebo.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The research ethics board of the Canadian College of Naturopathic Medicine, approved on 12 September 2005

**Study design**

Randomised controlled parallel group study

**Primary study design**

Interventional

**Study type(s)**

Treatment

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

Anxiety

**Interventions**

Herb: withania somnifera and multivitamin vs placebo

**Intervention Type**

Supplement

**Phase**

Not Specified

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

withania somnifera and a multi vitamin

**Primary outcome(s)**

1. Beck Anxiety Inventory
2. Fatigue Questionnaire

**Key secondary outcome(s)**

1. SF-36 Questionnaire
2. Weight
3. Body Mass Index (BMI)

**Completion date**

30/08/2006

# Eligibility

## Key inclusion criteria

1. Males and females aged 18-65 that are Canada Post employees and members of Canadian Union of Postal Workers (CUPW).
2. Mentally competent subjects able to adhere to the given protocol and treatments administered as interventions.
3. Self-selected candidates identifying themselves to suffer from the symptoms of stress and anxiety for a period of 6 weeks or more and a score of at least 10 on the Beck Anxiety Inventory (BAI) at the pre-study intake.
4. Normal on physical examination at the pre-study intake, and in the case of abnormalities the medical practitioner considers them to be clinically insignificant.
5. Written and informed consent.
6. The potential candidate must have a family doctor that they have seen in the last 12 months.
7. A negative pregnancy test for menstruating women and a willingness to practice adequate birth control for the duration of the trial

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Lower age limit

18 years

## Upper age limit

65 years

## Sex

All

## Key exclusion criteria

1. Mentally or physically incapacitated such that informed consent cannot be obtained.
2. Any history or other condition which the study physician regards as clinically significant to the study (including allergies or sensitivities to withanolides or multivitamins, gastritis or peptic ulcer).
3. A major illness considered to be clinically significant by the study physician within 3 months of the study start date.
4. Current participation in another intervention trial.
5. Pregnancy or intent to become pregnant in the next 6 months.
6. Medication at doses that is contraindicated with herb/multi-vitamin. (specifically daily use of benzodiazepene class drugs.)
7. Current alcoholism or substance abuse (sedative)
8. Current history of tumors.

9. Any current serious disorders determined to be clinically significant to the study.

10. Scoring above 20 on the Beck Depression Inventory.

11. Breast feeding women

**Date of first enrolment**

01/01/2006

**Date of final enrolment**

30/08/2006

## **Locations**

**Countries of recruitment**

Canada

**Study participating centre**

353 Thrace Ave

Ontario

Canada

L5B 2B2

## **Sponsor information**

**Organisation**

The Canadian College of Naturopathic Medicine (Canada)

**ROR**

<https://ror.org/03pjwtr87>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Canada Post Corporation (Canada)

**Funder Name**

The Canadian College of Naturopathic Medicine (Canada)

# 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	31/08/2009		Yes	No