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

Submission date Recruitment status Prospectively registered 15/02/2007 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 28/03/2007 Completed [X] Results [] Individual participant data Last Edited Condition category 03/09/2009 Mental and Behavioural Disorders

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Orest Szczurko

Contact details

353 Thrace Ave Mississauga Ontario Canada L5B 2B2

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 threapy 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. Fatique 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?
Results article	results	31/08/2009		Yes	No