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

Submission date
15/02/2007

Recruitment status
No longer recruiting

Registration date
28/03/2007

Overall study status
Completed

Last Edited
03/09/2009

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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

Primary study design
Interventional

Study design
Randomised controlled parallel group study

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