

Naturopathic Treatment of Rotator Cuff Tendonitis Amongst Postal Workers, a randomized controlled parallel group study

Submission date 15/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/03/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/03/2021	Condition category Musculoskeletal Diseases	<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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

03

Study information

Scientific Title

Naturopathic Treatment of Rotator Cuff Tendonitis Amongst Postal Workers, a randomized controlled parallel group study

Acronym

NTRCTAPW

Study objectives

This study aims to evaluate the difference in efficacy between the treatment of rotator cuff tendonitis with acupuncture, dietary advice and a supplement containing bromelain, trypsin, and rutosin vs placebo supplement with assisted, active, and resisted range of motion exercise

Ethics approval required

Old ethics approval format

Ethics approval(s)

The research ethics board of the Canadian College of Naturopathic Medicine, approved on 30 October 2006

Study design

Randomized controlled parallel group study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Rotator cuff tendonitis

Interventions

Supplement containing bromelain, rutin, and trypsin, and acupuncture vs placebo supplement with assisted, active, and resisted range of motion exercise

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Shoulder Pain And Disability Index (SPADI)

Secondary outcome measures

1. 36-item short form general health questionnaire (SF-36)
2. Shoulder range of movement
3. Orthopaedic shoulder tests

Overall study start date

01/02/2007

Completion date

01/08/2007

Eligibility**Key inclusion criteria**

1. Males and females aged 18-65
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 pain in at least one shoulder for a period of 6 weeks or more
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
8. Symptoms consistent with rotator cuff tendonitis, as determined by medical history or examination at screening

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

80

Total final enrolment

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
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 supplement (specifically daily use of warfarin, high dose aspirin, other blood thinners, or antibiotics)
7. Current alcoholism or substance abuse
8. Current history of tumors
9. Any current serious disorders determined to be clinically significant to the study
10. Breast feeding women
11. No prior shoulder surgeries, or scheduled surgeries of any kind
12. Haemophiliac, suffering from severe liver damage, or suffering from any hemorrhagic disease
13. Major shoulder joint pathology on assessment including full tendon rupture or degenerative joint disease. In these cases, referral for further evaluation and diagnosis will occur
14. Subjects with known sensitivity to any ingredient in the test product or to any member of the Bromeliaceae family, including pineapple
15. Subjects using Natural Health Products (NHPs) for 2 weeks prior to enrolment which affect shoulder pain or inflammation, contain phlogenzym or therapeutic constituents of the diet in supplement form
16. Current use of corticosteroid injection therapy

Date of first enrolment

01/02/2007

Date of final enrolment

01/08/2007

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)

Sponsor details

1255 Sheppard Ave E
Toronto
Ontario
Canada
M2K 1E2

Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Other

Funder Name

Canada Post, The Canadian College of Naturopathic Medicine (Canada)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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		15/08/2009	26/03/2021	Yes	No