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ORIGINAL ARTICLE

Naturopathic Treatment of Rotator Cuff Tendinitis Among Canadian Postal Workers: A Randomized Controlled Trial

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Objective. **To explore the effectiveness of naturopathic care (NC) on rotator cuff tendinitis using a prospective randomized clinical trial design.**

Methods. **Canadian postal workers with rotator cuff tendinitis for a duration of >6 weeks were randomized to receive NC (n = 43) or standardized physical exercises (PEs; n = 42) over 12 weeks. Participants in the NC group received dietary counseling, acupuncture, and Phlogenzym (2 tablets 3 times/day). The PE intervention group received passive, active-assisted, and active range of motion exercises and matched placebo. The primary outcome measure was the Shoulder Pain and Disability Index (SPADI), and secondary outcomes were the pain visual analog scale (VAS), Short Form 36 (SF-36), Measure Yourself Medical Outcomes Profile (MYMOP), and shoulder maximal range of motion. Participants and assessors were blinded to group and placebo allocation.**

Results. **Seventy-seven participants (87%) completed ≥8 weeks of the trial. Final total SPADI scores decreased by 54.5% ($P < 0.0001$) in the NC group and by 18% ($P = 0.0241$) in the PE group. Between-group differences in changes to SPADI scores showed statistically significant decreases in shoulder pain and disability in the NC group compared with the PE group ($P < 0.0001$). Significant differences between groups were also observed in the pain VAS, MYMOP, SF-36, and shoulder extension, flexion, and abduction, with the NC group showing superiority in each outcome. No serious adverse reactions were observed.**

Conclusion. **NC and PE provided significant improvements, with greater improvement in shoulder function in the NC group compared with the PE group. Statistically significant improvements in quality of life measures were observed in the NC group as compared with the PE group.**

INTRODUCTION

Shoulder pain is the most common extraspinal symptom encountered in primary care clinics, and in clinical frequency is exceeded only by low back and neck pain (1). The incidence has been estimated at 11.2 per 1,000 person-years (2). In a number of work place health studies, shoulder pain was second only to back pain in workers' compensation insurance claims, chronicity, and work impact (3–5). It carries a high social cost by increasing worker absenteeism, decreasing employees' quality of life and productivity, and contributing to a lower level of job satisfaction (6).

Many shoulder conditions are associated with dysfunction of the rotator cuff (7–9). Rotator cuff tendinitis is caused by inflammation of one of the supraspinatus, infraspinatus, subscapularis, and teres minor muscle tendons (10). Conventional treatments for rotator cuff tendinitis without complete tears include rest, muscle strengthening, pain management, physiotherapy, corticosteroid injections, and surgery (11,12). These therapies exhibit limited or inconsistent long-term success, and are often viewed by patients as a last resort (13,14). Alternative strategies range from physical therapies such as massage and manipulation to energy-based interventions such as acupuncture. Naturopathic medicine combines several approaches and is commonly used for this condition.

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We sought to evaluate the potential for the combined efficacy of a naturopathic approach including acupuncture, dietary advice, and hydrolytic enzymes in the treatment of rotator cuff tendinitis.

PATIENTS AND METHODS

Recruitment. The study took place from March to June 2007, and involved Canadian postal employees who were members of the Canadian Union of Postal Workers. Information sheets were distributed throughout eligible Canadian postal sites. Interested employees received an information package that included an informed consent form, background information explaining the purpose of the study, a description of the care to be provided, a question and answer sheet regarding study participation, and contact information for study enrollment.

Participants were primarily from a central letter processing plant in Toronto, Ontario, Canada; however, a minority of the study population came from the surrounding Toronto area mail delivery depots. Participants included day, evening, and night shift letter and package sorters, as well as outdoor letter carriers and drivers.

Intervention. Naturopathic medicine is a system of medicine with a primary goal of identifying and treating the cause of illness (15). It is a regulated and licensed profession in 5 Canadian provinces and 15 states in the US. Naturopathic doctors practicing in the province of Ontario receive training in and utilize the following therapies: dietary interventions, herbal and nutritional supplements, physical therapy, counseling, acupuncture, and intravenous therapies after specialized training. This study evaluated the combined use of acupuncture, dietary changes, and the use of a supplement as a semistandardized naturopathic intervention for the treatment of rotator cuff tendinitis.

On its own, acupuncture has been shown to be effective in numerous musculoskeletal syndromes (16,17) and for shoulder pathologies, including rotator cuff tendinitis (18). Kleinhenz et al demonstrated that acupuncture treatment provided significant improvement over placebo on measures, including upper extremity pain, range of motion, strength, and impact on daily activities (19.2 versus 8.4 on the Constant-Murley score) (19).

An antiinflammatory diet may be beneficial in the treatment of rotator cuff tendinitis. Inflammation characterized by the production of inflammatory cytokines contributes to a range of acute and chronic human diseases (20,21). Omega-3 polyunsaturated fatty acids found in oily fish decrease the production of these inflammatory markers (22). Encouraging the consumption of fish high in n-3 polyunsaturated fatty acids may be beneficial to patients with rotator cuff tendinitis (23). Other dietary suggestions include the addition of soybeans and cherries, which can also have pain-decreasing effects, possibly due to their antiinflammatory properties (24). A diet high in plant flavonoids has also been shown to decrease inflammatory processes (25).

Along with acupuncture and an antiinflammatory diet, the naturopathic intervention also evaluated the safety and efficacy of Phlogenzym (Mucos Pharma, Puhonice, Czech Republic) in the treatment of rotator cuff tendinitis. Phlogenzym is composed of the hydrolytic enzymes bromelain and trypsin, and the bioflavonoid rutin. European pharmacologic and medical literature cites the mechanisms of action of oral hydrolytic enzymes as fibrinolytic, antiedematous, antiinflammatory, and analgesic (26–30). Hydrolytic enzymes activate macrophages and natural killer cells by breaking down immune complexes interleukin-1β and interleukin-6 (31). Rutin has been shown to normalize pathologically increased vascular permeability (32). Phlogenzym also contributes to the degradation of plasma proteins that invade the interstitial space during acute inflammation. Following injury, Phlogenzym has been shown to decrease fibrin deposits (fibrinolysis) and restore microcirculation (32).

Trypsin has antioxidant properties that can result in a decrease of the inflammatory response to injury (32). Both bromelain and trypsin can reduce platelet aggregation, lymphocyte adherence, and decrease activation of protease-activated receptor 2, causing vasodilation and prevention of platelet, leukocyte, and erythrocyte adherence (32). Bromelain also exhibits fibrinolytic activities in dissolving fibrin clots (32). Combined, these effects have been shown to decrease pain, reduce inflammation and swelling, and be as effective as the nonsteroidal antiinflammatory drug (NSAID) diclofenac in several musculoskeletal symptoms (27–29,33).

Recruitment and initial visit. All potential participants were scheduled for a 1-hour assessment with 1 of the 2 trial investigators, both of whom are naturopathic doctors. During this initial visit, any outstanding questions were answered, an informed consent form was signed and witnessed, and the intake interview and physical examination were conducted to evaluate participant eligibility.

Physical measurements assessed during the initial visit included height, weight, body mass index, sitting left arm blood pressure, shoulder range of motion, and orthopedic tests. The range of motion tests included flexion, extension, abduction, adduction, internal rotation, and external rotation of both the affected and unaffected shoulder. Ranges were measured using a goniometer/inclinometer (Universal Inclinometer U101; Performance Attainment Associates, Lindstrom, MN) and performed by a second coordinator blinded to the patient's history. Orthopedic tests included the Neer Impingement, Speeds, Apprehension, and Subscapularis Lift tests, and were also performed by the intake physician and blinded coordinator. The diagnosis of rotator cuff tendinitis was confirmed by the blinded coordinator.

The intake interview included family history, patient history, review of systems, and assessment for inclusion and exclusion criteria. Participants also received a diary sheet to document their diet, medication, and concurrent therapy use at home. All women of reproductive age were screened for pregnancy via a human chorionic gonadotropin urine test. At the end of the initial visit, potential participants completed the Shoulder Pain and Disability

Index (SPADI), the Short Form 36 (SF-36), and the Perceived Benefit Questionnaire.

To be considered for inclusion, participants must have been between 18 and 65 years old, judged as able to adhere to the given protocol, had pain in at least 1 shoulder for the previous 6 weeks or more, and had symptoms consistent with rotator cuff tendinitis.

Participants were excluded if they could not comply with the study protocol, had no shoulder pain or range of motion limitations consistent with rotator cuff tendinitis at the time of assessment, had previously identified allergies to any ingredients of Phlogenzym, were receiving corticosteroid injection therapy, were taking daily warfarin or antibiotics, abused substances such as alcohol or illegal drugs, had a severe concurrent illness, or were pregnant or breastfeeding. The use of periodic or ad libitum pain medications was monitored, but was not a reason for exclusion.

Two licensed naturopathic doctors provided onsite delivery of care (OS, KC). This study was a pragmatic randomized controlled trial comparing naturopathic medicine with standard first-line physical exercise treatment for rotator cuff tendinitis. The treatment interventions were planned and carried out for 12 weeks. Upon determination of eligibility and collection of baseline information, participants were randomized using age- and sex-matched computer randomization to either naturopathic care (NC; active group) or physical exercise (PE; control group). Allocation concealment using central randomization was preserved up to the point of treatment and was maintained by the blinded coordinator performing range of motion and orthopedic test assessment. Although the analyst and participants were blinded to allocation and supplements were delivered using identical-looking tablets for all supplements and placebo, it was not possible to mask the interventions from the participants or the clinicians delivering care. Care was taken in the informed consent to ensure that participant blinding was preserved and to keep expectation biases equal within both treatment groups.

Treatment groups. *Naturopathic care.* Participants receiving NC were seen once per week for 30 minutes for a total of 12 weeks to receive specific treatment for rotator cuff tendinitis. Dietary counseling specific to the individual patient was given, with special emphasis on reducing alcohol consumption and increasing consumption of fish, berries, fruits, vegetables, nuts, and whole grains. Standardized acupuncture treatments were performed at each visit, with needle insertion at LI15, SJ14, SI19, SI10–13, and BL41–46, plus up to 4 Ashi points of pain. Acupuncture needles were inserted and briefly stimulated using a perpendicular thrusting technique until the patient reported a dull aching sensation. All needles were left in for a duration of at least 10 minutes, with at least one instance of restimulation using the perpendicular thrusting technique according to the Gunn method (34). Restimulation was done to address the attenuation of sensation and response that can accompany needle insertion. The supplement Phlogenzym containing 90 mg of bromelain, 48 mg of trypsin, and 100 mg of rutin was approved for the study by the Natural Health Products Directorate of Health Canada and provided to participants with instructions to take 2 tablets 3 times per day for the 12-week duration of the trial. Supplements were dispensed to participants every 4 weeks, and compliance was assessed through pill count every 4 weeks for the duration of the trial. Pills were dispensed in blister packs marked only with the study code, subject number, dose instructions, and contact information of the investigators.

Physical exercise. Participants randomized to the control group were seen once weekly for 30 minutes for a total of 12 weeks. Participants received PEs following a protocol shown to be effective for addressing pain consistent with work place–related rotator cuff tendinitis (35). During the treatment visits, participants received a series of passive, active-assisted, and active range of motion muscle strengthening and joint therapy consistent with standard physiotherapy for shoulder injuries (36). Hands-on shoulder muscle and joint therapy was designed to increase shoulder range of motion and assist in recovery and therapy for repetitive strain injuries. Placebo tablets were matched to the Phlogenzym for color, smell, and taste, and consisted of an inert fiber substance. Placebo capsules were dispensed in the same number, container, and schedule as the Phlogenzym given to the NC group.

The control group did not receive dietary counseling, acupuncture, or Phlogenzym, but did receive identical frequency matched supplement placebo, PEs, and hands-on shoulder muscle and joint therapy. Treatment duration and frequency were equal in both groups. Careful consideration was given toward the design and implementation of treatments to provide an effective treatment for rotator cuff tendinitis while creating an adequately matched placebo to the active group. As such, the control group treatment regimen contained elements similar to the NC group consisting of an individualized treatment approach, a well-developed therapeutic doctor-patient relationship, patient motivation, and the consumption of a pill.

Primary outcome. Administered at baseline and at 4, 8, and 12 weeks, the SPADI was the primary outcome measure. It is a validated self-report questionnaire measuring the pain and disability associated with shoulder pathology (37). The SPADI consists of 13 items; participants rate how their shoulder function is affected by 2 subscales: pain (5 items) and disability (8 items). Scores can range from 0 to 50 on the pain scale, from 0 to 80 on the disability scale, and from 0 to 130 on the total scale. An increasing score indicates increasing pain or disability.

Secondary outcomes. Secondary outcomes were performed at baseline and at 4, 8, and 12 weeks.

The SF-36 is a self-administered, 36-item questionnaire that measures health-related quality of life in 8 domains. Each domain is scored separately from 0 (worst score) to 100 (best score). Two summary scores can be calculated from the information obtained in the 8 domains: the physical function and mental health summary scores (38).

The pain visual analog scale (VAS) is a self-adminis-

Table 1. Baseline characteristics of the participants starting treatment*

	Treatment group		
	Naturopathic care (n = 43)	Physical exercise (n = 42)	*P*
Age, years	50.7 ± 8.16	50.9 ± 7.86	0.98
Sex, no. (%)			0.85
Men	18 (42)	17 (40)	
Women	25 (58)	25 (60)	
Total SPADI score	77.64 ± 29.38	69.61 ± 24.11	0.83
Flexion range of motion†	122.15 ± 35.91	124.78 ± 37.09	0.96
Extension range of motion†	36.29 ± 11.71	39.03 ± 11.97	0.87
Abduction range of motion†	101.17 ± 44.24	104.47 ± 44.73	0.96
Adduction range of motion†	35.76 ± 11.00	35.83 ± 12.60	0.99

* Values are the mean ± SD unless otherwise indicated. SPADI = Shoulder Pain and Disability Index.
† Maximum active range of motion.

tered single-item questionnaire that asks the participant to assess their average degree of shoulder pain experienced over the last week. Scores range from 0 to 7, where 0 = no pain at all and 7 = severe pain.

The Measure Yourself Medical Outcomes Profile (MYMOP) is a patient-centered outcome questionnaire with internal consistency and construct validity (39,40). It is used in primary care settings as a means of garnering and quantifying qualitative patient experiences. At baseline, patients choose 2 personally relevant symptoms of greatest importance to their health and rate these symptoms on a 7-point VAS. The same 2 symptoms are then reevaluated at each data-gathering followup visit. Ranging from 0 to 6, higher scores correspond to a lower satisfaction (i.e., worse) level of health.

The flexion, extension, abduction, adduction, internal rotation, and external rotation of the affected shoulder were assessed by a coordinator blinded to treatment and using a goniometer/inclinometer. Participants were instructed to actively move the shoulder in the required direction as far as possible.

Statistical analysis. All analyses were performed by a statistician (QZ) under blinded conditions using SAS/STAT, version 9.1 (SAS Institute, Cary, NC). Baseline visit and week 12 visit data were summarized by the mean ± SD. When missing data occurred at week 12, its value was replaced by the value at week 8 as part of the intent-to-treat analysis. For each group, the treatment effect at week 12 was compared with that at baseline and assessed by the paired *t*-test. The mean difference and its 95% confidence interval and *P* value were reported. The independent *t*-test was used to compare the difference in treatment effect between the active (NC) and control (PE) groups. The mean differences of the treatment effects, 95% confidence intervals, and *P* values are reported below.

To determine a 20% reduction in SPADI scores, and assuming a population SD of 20%, a sample size of 37 in each treatment arm was calculated, providing 80% power and a 5% alpha level (41). A commitment to enroll at least 80 participants was made to supplement expected loss to followup.

All patients with available data were analyzed according to the arm to which they were randomized. We summarized the baseline data and the data at week 12 by the mean ± SD. The means over the 12-week period were plotted separately for the outcomes of the SPADI, SF-36, VAS, and range of motion. To assess the treatment effect for each group, we calculated the mean change in scores between groups at week 12 and baseline. We also calculated the mean changes between groups to examine the group effect. The statistical significance of the changes for each group was tested using the paired *t*-test; the exact 2-sided *P* value is reported. The 2 sample *t*-tests were performed to compare the change scores between groups.

The outcomes reported from these analyses include total, pain, and disability SPADI scores; pain VAS, MYMOP, and SF-36; and range of motion.

RESULTS

Recruitment and followup. Recruitment led to the screening of 103 participants during initial visits. Fourteen of those screened did not qualify: 1 was unknowingly pregnant, and others did not have shoulder pain or had torn shoulder tendons and therefore did not meet inclusion criteria. In total, 89 patients were randomized and enrolled in the study. Four of the 89 patients decided to not start the study after reconsideration or became unreachable before the first treatment visit. None of these 4 participants withdrew with the knowledge of what type of treatment they would be receiving. Of the 85 participants who started treatment, 17 (10 control, 7 active) did not complete the 12-week course of study: 1 participant broke her leg, 6 became unreachable, and 10 could not commit the time or lost interest. Of the 43 participants who started treatment in the NC group, 41 completed week 8 and 36 completed week 12. Of the 42 participants who started treatment in the PE group, 36 completed week 8 and 32 completed week 12.

Baseline characteristics. Randomization was stratified based on age and sex. Both treatment groups had similar characteristics, including baseline SPADI score, range of motion, age, and sex (Table 1).

Table 2. SPADI results for total, pain, and disability subcategory scores in the NC and PE groups before and after treatment*

Outcome	Baseline, mean ± SD	Week 12, mean ± SD†	Change from baseline	95% CI	*P*	Mean difference between groups	95% CI	*P*
Total SPADI						−29.66	−42.35, −16.98	< 0.0001
NC	77.64 ± 29.38	35.30 ± 31.57	−42.34	−49.55, −35.12	< 0.0001			
PE	69.61 ± 24.11	56.24 ± 36.57	−12.68	−23.59, −1.76	0.0241			
Pain SPADI						−13.00	−17.99, −28.00	< 0.0001
NC	34.73 ± 9.11	16.03 ± 13.30	−18.70	−21.65, −15.75	< 0.0001			
PE	31.93 ± 9.49	26.24 ± 14.34	−5.7	−9.92, −1.49	0.0094			
Disability SPADI						−15.64	−23.64, −7.56	0.0002
NC	42.91 ± 21.51	20.34 ± 18.97	−21.64	−26.20, −17.09	< 0.0001			
PE	37.68 ± 16.69	30.97 ± 22.57	−6.00	−12.79, 0.79	0.0813			

* The NC group improved significantly over the PE group in SPADI total, pain, and disability subcategory scores. SPADI = Shoulder Pain and Disability Index; NC = naturopathic care; PE = physical exercise; 95% CI = 95% confidence interval.
† As part of the intent-to-treat analysis, the week 8 value was used for week 12 if the value was missing.

Study treatments. The treatments were well received, as demonstrated by both the pain VAS and good compliance rates in both groups. The mean total of missed supplements was 5.5 pills per week (86% compliance) in the NC group and 7.4 pills (81% compliance) in the PE group throughout the 12-week duration of the trial.

Outcomes. Significant improvements from baseline on the primary outcome measure (total SPADI score) were seen in both the NC (−42.34; $P < 0.0001$) and PE (−12.68; $P = 0.024$) groups (Table 2 and Figure 1). Total SPADI scores improved significantly more in the NC group as opposed to the PE group (−29.7; $P < 0.0001$). The NC group also showed statistically significant differences in SPADI pain and disability subscales. The SPADI pain subscale decreased by −18.70 ($P < 0.0001$) in the NC group and by −5.7 ($P = 0.0094$) in the PE group. The SPADI disability subscale demonstrated this trend with a 21.64 decrease ($P < 0.0001$) in the NC group versus a 6.00 decrease ($P = 0.081$) in the PE treatment group.

The pain VAS showed significant reductions in pain ($P < 0.001$) in the NC group (Table 3 and Figure 2). The improvements reported on the SPADI and VAS questionnaires are supported by range of motion improvements in measured maximal flexion ($P < 0.0001$), extension ($P < 0.0001$), and abduction ($P < 0.0001$) of the affected shoulder in the NC group as compared with the PE group. Maximal adduction was found to have a nonsignificant trend toward improvement between groups ($P = 0.568$) (Table 4).

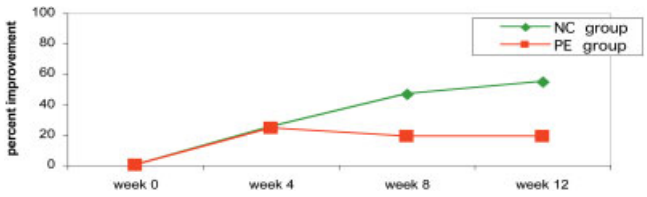

Figure 1. Percent changes in total Shoulder Pain and Disability Index (SPADI) scores. Followup questionnaire results were collected every 4 weeks during the study and calculated as (1 – [total SPADI at followup/total SPADI at baseline]) × 100, where 100 = maximum improvement. NC = naturopathic care; PE = physical exercise.

The MYMOP patient-centered outcome measure was used to allow the patient to evaluate the progression of the 2 health concerns most significant to them. The first symptom showed significant improvement in both the NC (−2.2; $P < 0.0001$) and PE (−1.29; $P < 0.0001$) groups. The second symptom significantly improved in the NC group (−2.52; $P < 0.0001$), whereas the PE group did not achieve significance (−0.66; $P = 0.0443$).

The SF-36 showed statistically significant differences ($P < 0.01$) between the NC and PE groups in all subcategories except social functioning, which showed a trend toward improvement ($P = 0.038$). The NC group showed the greatest improvement over the PE group in role physical ($P = 0.0015$), bodily pain ($P = 0.0004$), and interestingly in role emotional ($P = 0.0020$).

Adverse events. Two adverse reactions were observed in the NC group: 1 patient had loose stool for one day and another reported mild sedation for one day. The PE group reported 1 incident of mild abdominal discomfort, 1 participant reported diarrhea, 1 reported flatulence, 1 reported constipation, and 1 patient briefly experienced moderate skin flushing, burning ears, and a mild tingling sensation. Gastrointestinal upset was most commonly reported in both groups. All reported reactions resolved within 1 or 2 days, and were considered to be mild by the participants reporting them.

DISCUSSION

The results of this clinical trial should be of interest to patients and clinicians alike. This study showed a reduction in rotator cuff tendinitis with the use of standardized physical exercises routinely used by physical therapists. These results are consistent with previous reports of the efficacy of physical exercises and therapies in the treatment of shoulder pain (42). In comparison, naturopathic treatment showed a clinically and statistically significant

Table 3. Pain VAS, MYMOP, and SF-36 outcomes before and after NC and PE treatment*

Outcome	Baseline, mean ± SD	Week 12, mean ± SD†	Change from baseline	95% CI	*P*	Mean difference between groups	95% CI	*P*
Pain VAS‡						−1.67	−2.47, −0.88	0.0001
NC	5.09 ± 1.52	2.75 ± 1.77	−2.34	−2.84, −1.85	< 0.0001			
PE	4.85 ± 1.48	4.05 ± 1.69	−0.67	−1.32, −0.02	0.0431			
MYMOP symptom 1§						−0.91	−1.68, −0.13	0.0225
NC	5.62 ± 1.21	3.59 ± 1.72	−2.20	−2.81, −1.58	< 0.0001			
PE	5.48 ± 1.31	4.08 ± 1.76	−1.29	−1.8, −0.78	< 0.0001			
MYMOP symptom 2§						−1.86	−2.73, −1.00	0.0001
NC	5.36 ± 1.36	3.03 ± 1.58	−2.52	−3.13, −1.90	< 0.0001			
PE	5.03 ± 1.52	4.38 ± 1.68	−0.66	−1.29, −0.02	0.0443			
SF-36 aggregate physical component¶						5.71	2.63, 8.79	0.0004
NC	38.44 ± 8.41	46.19 ± 8.88	7.75	5.57, 9.93	< 0.0001			
PE	37.51 ± 8.25	39.97 ± 7.92	2.04	−0.17, 4.25	0.0690			
SF-36 aggregate mental component						5.73	1.37, 10.09	0.0107
NC	44.22 ± 11.66	50.08 ± 10.97	5.85	2.25, 9.46	0.0021			
PE	50.13 ± 11.38	50.05 ± 10.40	0.13	−2.04, 2.29	0.9059			
SF-36 physical functioning						13.52	4.91, 22.13	0.0025
NC	60.13 ± 24.03	74.02 ± 25.2	14.88	8.41, 21.34	< 0.0001			
PE	58.82 ± 20.78	61.29 ± 22.40	1.36	−4.38, 7.10	0.6339			
SF-36 role physical						17.34	6.85, 27.84	0.0015
NC	50.94 ± 25.38	72.71 ± 24.68	21.09	13.56, 28.62	< 0.0001			
PE	56.60 ± 23.14	61.61 ± 22.85	3.75	−3.75, 11.25	0.3165			
SF-36 bodily pain						16.52	7.71, 25.34	0.0004
NC	36.13 ± 14.86	59.60 ± 19.70	24.16	17.77, 30.56	< 0.0001			
PE	40.17 ± 16.39	47.81 ± 19.67	7.64	1.42, 13.86	0.0176			
SF-36 general health						11.62	4.11, 19.12	0.0029
NC	60.37 ± 19.60	70.44 ± 19.08	10.07	4.30, 15.85	0.0011			
PE	58.81 ± 22.00	56.60 ± 24.99	−1.54	−6.27, 3.18	0.5114			
SF-36 vitality						10.16	3.21, 17.12	0.0047
NC	49.39 ± 17.05	63.72 ± 20.55	14.33	8.59, 20.07	< 0.0001			
PE	51.91 ± 19.18	56.08 ± 18.21	4.17	0.42, 7.92	0.0304			
SF-36 social functioning						10.38	0.60, 20.15	0.0378
NC	63.41 ± 20.80	77.44 ± 24.72	14.02	6.27, 21.78	0.0007			
PE	70.49 ± 19.86	74.13 ± 23.54	3.65	−2.21, 9.51	0.2149			
SF-36 role emotional						16.09	6.10, 26.08	0.0020
NC	66.26 ± 25.82	80.08 ± 23.63	13.82	6.46, 21.18	0.0005			
PE	76.39 ± 24.52	74.12 ± 27.24	−2.27	−9.14, 4.60	0.5070			
SF-36 mental health						14.66	5.77, 23.55	0.0015
NC	62.07 ± 21.85	74.51 ± 18.83	12.44	5.09, 19.78	0.0014			
PE	74.03 ± 21.64	71.81 ± 18.83	−2.22	−7.00, 2.55	0.3513			

* VAS = visual analog scale; MYMOP = Measure Yourself Medical Outcome Profile; SF-36 = Short Form 36; NC = naturopathic care; PE = physical exercise; 95% CI = 95% confidence interval.
† As part of the intent-to-treat analysis, the value at week 8 was used for week 12 if the value was missing.
‡ The NC group shows significant improvement over the PE group.
§ Symptom 1 shows significant improvement in the NC and PE groups. Symptom 2 shows significant improvement in the NC group.
¶ Significant differences between the NC and PE groups are present in all subcategories except social functioning.

improvement in shoulder pain and quality of life measures as compared with the control standard.

Antiinflammatory whole-food diets emphasizing omega-3 fatty acids, plant flavonoids, green tea, and cruciferous and yellow vegetables have been shown to reduce inflammation (22,23,43). It has previously been shown that the avoidance of known proinflammatory irritants such as alcohol, smoking, soft drinks, refined grains, and processed meats will lower inflammation (43,44).

Phlogenzym has demonstrated antiinflammatory effects in previous research (26–32,45,46). Trypsin can result in a decrease in the inflammatory response to injury. Combined with bromelain, it can reduce platelet aggregation, lymphocyte adherence, and decrease protease-activated receptor 2 activation. Phlogenzym has been shown to decrease pain, reduce inflammation and swelling, and be as effective as the NSAID diclofenac in several musculoskeletal symptoms.

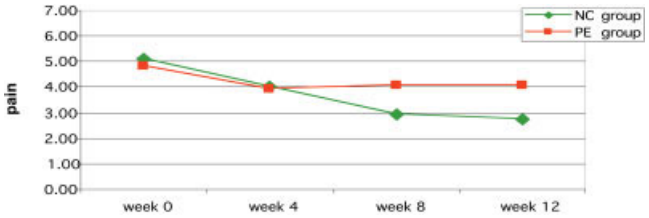

Figure 2. Raw score changes in the pain visual analog scale (VAS). Followup questionnaire results were collected every 4 weeks during the study. The naturopathic care (NC) group shows significant improvement over the physical exercise (PE) group.

Acupuncture has been shown to be effective for rehabilitation and pain reduction in various musculoskeletal studies (16,17), and specifically for rotator cuff tendinitis (18). This therapy significantly improved several shoulder-specific pathologies, including pain, range of motion, strength, and impact on daily activities (19).

Our study demonstrates that naturopathic treatments including dietary changes, acupuncture, and Phlogenzym have a significant effect on decreasing the symptoms of rotator cuff tendinitis. In addition, the naturopathic treatments showed secondary effects on quality of life in the work place, including significant improvements in physical function, bodily pain, general health, vitality, emotional and mental health markers, and patient-specific concerns. The benefits from this pragmatic study on providing access to care and ongoing treatment for all of the participants were notable and highly valued in the work place.

This was a pragmatic randomized controlled trial, and as such it is impossible to ascertain the precise effect of the individual component therapies of either the NC or PE treatment packages. Future research trials employing a multifactorial design would allow the characterization of the effects of single and combination treatments used within this study.

Maintaining internal and external validity in pragmatic randomized controlled trials is a challenge (47,48). Our study design attempted to maximize external validity by having few exclusion criteria and including some flexibility or variability in study interventions based on individual needs (e.g., specific advice given in dietary counseling). However, one specific enzymatic supplement was used to treat all study participants in the NC group despite the range of potential antiinflammatory natural health products (49). Treatment decisions made by the naturopathic doctors in the study were limited as a result, thus decreasing the external validity of our study.

Internal validity was achieved by attempting to account for nonspecific effects of treatments in both groups and absence of assessment bias, and by preventing contamination (47). Both the NC and PE groups received therapeutic doctor-patient relationships, patient motivation and education, a physical therapy, and a pill. Assessment and data analysis were conducted by assessors blinded to group allocation. No contamination of the PE group with respect to Phlogenzym use or visits to a naturopathic doctor occurred. The lack of a no treatment control group limits the internal validity of this study; however, given the complex and holistic approach to the care employed, it would be impossible to separate the contextual effects implicit in the interventions used.

Naturopathic treatment including dietary advice, acupuncture, and ingestion of a proteolytic enzyme appears to be safe and effective in providing significant benefit over standard therapy in the treatment of chronic rotator cuff tendinitis in the Canadian postal worker population. Standard therapy including physical therapy and strengthening/stretching exercises was shown to also achieve improvements under the same conditions but not to the same degree as the semistandardized naturopathic treatment approach. Future research is required to examine the effects of the individual components of treatments.

Table 4. Maximal range of motion goniometer readings before and after NC and PE treatment*

Outcome†	Baseline, mean ± SD	Week 12, mean ± SD‡	Change from baseline	95% CI	*P*	Mean difference between groups	95% CI	*P*
Flexion						40.94	28.58, 53.3	< 0.0001
NC	122.15 ± 35.91	159.39 ± 25.97	37.24	28.66, 45.83	< 0.0001			
PE	124.78 ± 37.09	121.08 ± 40.53	−3.69	−12.88, 5.49	0.4196			
Extension						9.68	4.90, 14.46	< 0.0001
NC	36.29 ± 11.71	42.39 ± 11.18	6.10	2.80, 9.40	0.0006			
PE	39.03 ± 11.97	35.44 ± 10.26	−3.58	−7.16, −0.01	0.0495			
Abduction						46.57	31.21, 61.94	< 0.0001
NC	101.17 ± 44.24	148.63 ± 34.73	47.46	37.98, 56.94	< 0.0001			
PE	104.47 ± 44.73	105.36 ± 45.05	0.89	−11.83, 13.61	0.8880			
Adduction						−0.81	−3.63, 2.01	0.5683
NC	35.76 ± 11.00	35.39 ± 7.42	−0.37	−2.67, 1.94	0.7499			
PE	35.83 ± 12.60	36.28 ± 11.05	0.44	−1.11, 2.00	0.5664			

* NC = naturopathic care; PE = physical exercise; 95% CI = 95% confidence interval.
† Maximum active range of motion of the affected shoulder was assessed with a goniometer by a coordinator blinded to treatment. The NC group achieved significant improvements over the PE group in flexion, extension, and abduction.
‡ As part of the intent-to-treat analysis, the week 8 value was used for week 12 if the value was missing.

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AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Dr. Seely had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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