

The role of omega-3 fatty acids in the management of rotator cuff tendinopathy.

Submission date 03/06/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/06/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/11/2019	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

The rotator cuff is a group of muscles and their tendons in the shoulder. Rotator cuff tendinopathy is defined as pain and dysfunction of one or more of those tendons (called supraspinatus, infraspinatus, subscapularis and teres minor). Exercise is the most common and relatively effective treatment. However, although the results are comparable to surgery, not everyone responds positively or completely. There is a definitive need to identify new methods to support current practice and in order to improve outcomes. Nutritional supplements are marketed to people suffering musculoskeletal symptoms, such as joint degeneration and tendinopathy. Omega-3 poly unsaturated fatty acids (PUFAs) have been recommended for people suffering from tendinopathy, with one potential benefit being a reduction in inflammation which may be present in tendinopathy. The aim of this study is to compare exercise and PUFAs to exercise and placebo supplements.

Who can participate?

Adults diagnosed with Rotator cuff tendinopathy.

What does the study involve?

Participants are randomly allocated to one of two groups: exercise and PUFAs group or exercise and dummy supplements group.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

3 sites in London (UK): Guy's and St Thomas' NHS Foundation Trust, St George's Foundation NHS Trust and Health at the Stowe, Westminster PCT / Central London Community Healthcare NHS Trust

When is the study starting and how long is it expected to run for?

June 2008 to December 2012

Who is funding the study?
Seven Seas (UK)

Who is the main contact?
Ms Fiona Sandford
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
A randomised single blinded placebo controlled study investigating the role of poly unsaturated fatty acids in addition to exercise in the management of rotator cuff tendinopathy

Study objectives
Poly unsaturated fatty acid supplementation will result in significant improvement in disability (as measured by the Oxford Shoulder Score) or the experience of pain when compared to placebo when assessed at 2 months, 3 months, 6 months and one year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Main REC: NRES Committee London-Bromley, ref: 08/H0805/21

Primary study design
Interventional

Study design

Multi-centre interventional randomised placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rotator cuff tendinopathy

Interventions

The active supplements used in this trial were MaxEPA supplements (Seven Seas Ltd, Hull, UK). They are gelatine coated capsules, oval in shape and brown tan in colour, containing 170mg EPA, 115mg DHA, 100 units/g vitamin E and 10 units/g vitamin D. The placebo supplement looked identical but contained mixed inert oil in place of the EPA and DHA. Participants in both groups were asked to take 9 soft shell capsules per day for a total of 2 months. Both groups also attended an exercise group once a week for a total of 8 weeks.

Intervention Type

Supplement

Primary outcome(s)

The Oxford shoulder score questionnaire was used at baseline, 2 months, 3 months, 6 months and 12 months.

Key secondary outcome(s)

1. Numerical rating score for pain
2. Shoulder Pain and Disability Index (SPADI)
3. Patient specific functional score (PSFS): a questionnaire used to quantify activity limitation and measure functional outcome in areas chosen by the patient specifically
4. EuroQol D5-3L (EQ-D5-3L) health questionnaire: a measure of health related quality of life
5. Short Form (SF)-36
6. Global perception of change
7. Range of glenohumeral range of motion (flexion/abduction/internal and external rotation, hand behind back)
8. Shoulder strength (shoulder flexion/abduction/internal and external rotation and biceps strength).

All taken at baseline, 2 months, 3 months, 6 months and 12 months.

Completion date

12/12/2012

Eligibility

Key inclusion criteria

The study aimed to recruit men and women aged 18 to 80 years, who were referred for physiotherapy to one of four physiotherapy departments with a diagnosis of unilateral RC tendinopathy.

1. Unilateral shoulder pain of more than 3 months duration (anterior &/or antero-lateral)
2. Pain produced or increased during flexion and/or abduction of the symptomatic shoulder
3. Failure of conservative management (manual therapy, exercises, injections, electrotherapy)

NSAIDS)

4. At least 4 of the following:

4.1 Positive Neer's impingement sign

4.2 Positive Hawkins & Kennedy test

4.3 Pain & weakness reproduced on full & empty can test

4.4 Pain & weakness on resisted shoulder external rotation

4.5 Pain on palpation over greater tuberosity of humerus

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

73

Key exclusion criteria

1. Outside age range of 18-80 years

2. Known allergy to fish or fish products

3. Unwilling to take fish oils

4. Currently taking high dose fish oils (over 1g daily).

5. Diabetes

6. Pregnancy or breast feeding

7. Reproduction of shoulder symptoms during active cervical spine movements

8. Post traumatic onset of symptoms

9. Radiographic or clinical evidence of shoulder instability (sulcus, anterior/posterior draw, relocation test, apprehension test)

Date of first enrolment

18/12/2008

Date of final enrolment

18/01/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Guy's and St Thomas' Foundation NHS Trust

London

United Kingdom

SE1 7EH

Study participating centre

St George's Foundation NHS Trust

London

United Kingdom

SW17 0QT

Study participating centre

Health at the Stowe, Westminster PCT / Central London Community Healthcare NHS Trust

London

United Kingdom

SW1E 6QP

Sponsor information

Organisation

Guy's and St Thomas' NHS Foundation Trust

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Industry

Funder Name

Seven Seas provided the supplements and placebos

Funder Name

St Georges's charitable foundation- medical research

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/10/2018	27/11/2019	Yes	No