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Optimising physiotherapy for people with tennis elbow

Submission date	Recruitment status	[X] Prospectively registered
19/07/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/06/2025	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims

Physiotherapy is commonly provided by the NHS for people with Tennis Elbow. The type of treatment given by physiotherapists varies widely, however, with many treatment techniques lacking evidence of effectiveness. We have developed an optimised physiotherapy treatment package based upon a combination of best research evidence and expert opinions of specialist physiotherapists, NHS physiotherapy service managers and patients that we hope will improve the outcomes for people with Tennis Elbow. The aim of this study is to test the feasibility of delivering this new treatment package in the NHS and determine whether a large-scale research trial is justified to assess its effectiveness.

Who can participate?

Adults (aged 18 years or over) with Tennis Elbow, and physiotherapists.

What does the study involve?

People will be randomised to receive the new optimised physiotherapy treatment package or the usual physiotherapy treatment that they would have received normally. Participants will complete questionnaires prior to treatment and for up to six months after starting, to measure the effect of treatment. A selection of patients and physiotherapists will be interviewed regarding the treatment package, research procedures, information provided to patients and training provided to physiotherapists to assess if a large-scale trial is justified and if so, how the processes could be improved. Other measures, such as the amount of people participating, the number of people completing treatment and how successfully the optimised treatment was delivered, will also be used to assess whether this is justified.

What are the possible benefits and risks of participating?

There are no significant disadvantages or serious risks to taking part in this research. Both groups of patients will still receive physiotherapy treatment for their Tennis Elbow.

It is expected that participants will gain benefit from the treatment they receive, in terms of pain reduction and improved function, but we cannot promise the study will help everyone. The information we get from this study may help inform future research and direct future treatment to other people with a similar complaint.

Where is the study run from?
Royal Derby Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2020 to March 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK).
Chartered Society of Physiotherapy Charitable Trust (UK).

Who is the main contact?
Mr Marcus Bateman, marcus.bateman@nhs.net

Study website
http://www.optimise-trial.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
297637

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 49564, Grant Codes: NIHR300704, IRAS 297637

Study information

Scientific Title
Optimising Physiotherapy for people with Tennis Elbow – a mixed methods pilot & feasibility randomised controlled trial

Acronym
OPTimisE - Pilot & Feasibility RCT v1.0

Study objectives
To undertake a multi-centre pilot and feasibility RCT to determine whether a newly-designed optimised physiotherapy intervention for LET is deliverable and whether a future main RCT comparing the clinical and cost-effectiveness of the optimised physiotherapy treatment versus usual NHS physiotherapy treatment is feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/06/2021, Yorkshire & The Humber - Sheffield Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8131; sheffield.rec@hra.nhs.uk), ref: 21/YH/0121

Study design
Interventional randomized controlled trial with qualitative element

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Tennis elbow

Interventions
Once consented and prior to randomisation, participants will complete a baseline set of patient-reported outcome measures and demographic data.

Patients will then be randomly allocated to receive either the optimised physiotherapy treatment package, by physiotherapists specifically trained to deliver this, or usual

physiotherapy care delivered by other physiotherapists not trained in the optimised intervention but trained in the trial procedures. Usual physiotherapy will not be standardised in this pragmatic study but the details of the content and number of treatments given will be captured at the end of a patient's course of physiotherapy. Usual physiotherapy may involve a range of different treatments including advice and education, exercise, taping, manual therapy, acupuncture, ice therapy, orthotics and massage. Evidence suggests that there is inconsistency of approach and a wide range of variation within treatment categories, for example the dosing of exercise therapy. Whilst the optimised physiotherapy treatment package also includes patient advice and education, exercise therapy and provision of a counterforce brace, it will differ from usual care by providing a detailed and consistent approach to treatment based upon best available evidence and omitting treatments lacking evidence of efficacy. The advice and education component is detailed and supported by high-quality written and videographic materials, developed in consultation with patients.

The topics covered not only relate to Tennis Elbow but incorporate modifiable lifestyle factors that may improve treatment response and reduce risk of recurrence:
• What tennis elbow is
• Activity modification
• Pacing
• Promotion of self-efficacy
• Ergonomics for work or sport
• Medication advice
• Basic pain science
• General exercise advice
• Smoking cessation (if applicable)
• Sleep advice
• General diet advice
• Diabetes management (if applicable)

The exercise therapy component consists of a progressive regime of exercise designed to be adaptable to individual patient's functional demands. They will also be provided with an elbow brace, chosen from a selection of available models by our PPIE group based upon comfort, fit and ease of application. It is expected that patients in both treatment arms will receive similar numbers of treatment sessions (approximately four).

Patients will be offered the choice of two data collection methods: 1) a paper questionnaire with follow-up questionnaires delivered and returned by post; or 2) an online system where the questionnaires are completed online using a smartphone, tablet or personal computer with automated follow-up questionnaire links delivered by email and SMS text message. Patients will be asked to complete questionnaires at 6 weeks, 3 and 6 months. Patients failing to return the paper questionnaires within two weeks will receive reminder telephone calls and emails (according to patient preference) on up to two occasions from the research team. Those failing to respond to the online questionnaires will receive automated reminders by email and SMS text message at one week and two weeks. Adherence to treatment will be measured in both treatment arms using a patient reported exercise diary that is returned to the treating physiotherapist at each session and stored in the physiotherapy clinic notes. Additionally the 6-week, 3- and 6-month outcome questionnaires will include the Exercise Adherence Rating Scale.

Approximately 16 patient participants will also be interviewed. Patients will be selected from both treatment arms and also from those that were eligible but did not consent to the trial but were willing to be interviewed. Two months following initial assessment and randomisation, patients who have consented to further contact will be sent an invitation letter and patient

information sheet before receiving a follow-up telephone call or email to confirm interest and arrange a suitable interview date. Patients will be able to decline participation in the interviews yet continue to be involved in the pilot and feasibility trial.
Similarly, approximately 9 physiotherapists involved with delivering the optimised physiotherapy intervention will be recruited from different sites.

Interviews will be conducted with patient participants at least two months following randomisation either face-to-face, via video-conference or via telephone, depending on participant preferences. Physiotherapists will be interviewed following the end of their involvement with patients in the pilot and feasibility trial to allow time to reflect on their experiences of delivering the intervention to a number of patients. Consent will be obtained at the start of the interview, either in writing if the interview is face-to-face, or audio-recorded if the interview is over the telephone or video-conference, and checked again at the end. Interviews will be audio-recorded and transcribed verbatim before the data is analysed.

Patient involvement in the trial will finish after completion of the six-month outcome questionnaire.

Intervention Type
Behavioural

Primary outcome measure
Feasibility outcome measures:
1. Consent rate - measured as a percentage of eligible patients approached to participate
2. Intervention fidelity in the intervention group - measured using data from CRF03. Fidelity to the intervention will be defined by delivery of at least 6 of the prescribed advice/education topics, evidence of exercise prescription and progression in line with the protocol and provision of an elbow clasp splint. Results will be expressed as a percentage of the patients in the intervention group who received treatment assessed as being faithful to the protocol.
3. Follow-up rate in the intervention group - the actual number of visits (excluding the baseline visit) divided by the maximum number of possible visits
4. Outcome measure completion rate at 6 months – measured as a percentage of outcome measures completed across both the intervention and usual care groups

Secondary outcome measures
1. NRS pain on gripping (baseline, 6 weeks, 3 months, 6 months)
2. Patient rated tennis elbow evaluation PRTEE (baseline, 6 weeks, 3 months, 6 months)
3. Tampa scale of kinesiophobia TSK-11 (baseline, 6 weeks, 3 months, 6 months)
4. Pain self-efficacy questionnaire PSEQ (baseline, 6 weeks, 3 months, 6 months)
5. Quality of life EQ5D (baseline, 6 weeks, 3 months, 6 months)
6. Pain free grip strength (dynamometer) (baseline, 6 weeks, 3 months, 6 months)
7. Maximum grip strength (dynamometer) (baseline, 6 weeks, 3 months, 6 months)
8. Global rating of change GROC (6 weeks, 3 months, 6 months)
9. Exercise adherence rating scale EARS (6 weeks, 3 months, 6 months)

Overall study start date
01/07/2020

Completion date
03/03/2023

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Lateral elbow pain
3. Pain reproduced on palpation of the common extensor origin and on gripping
4. Positive Cozen's, Mills' or Maudsley's tests (at least one positive)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment
50

Key exclusion criteria
1. Recent history of significant trauma to the affected limb e.g. a fall on an outstretched hand
2. Previous diagnosis of inflammatory arthritis or gout
3. Previous diagnosis of osteoarthritis of the affected elbow
4. Neurological symptoms in the affected limb correlating with onset of elbow pain e.g. loss of sensation in the hand
5. Co-existing neck pain and stiffness that started at a similar time to the elbow symptoms
6. Unable to understand English or lacking capacity for informed consent

Date of first enrolment
09/09/2021

Date of final enrolment
17/08/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Derby Hospital
University Hospitals of Derby and Burton NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Royal Orthopaedic Hospital
The Woodlands
Bristol Rd South
Northfield
Birmingham
United Kingdom
B31 2AP

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
United Kingdom
S5 7AU

Sponsor information

Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

Sponsor details
Royal Derby Hospital
Uttoxeter Road
Derby
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United Kingdom
DE22 3NE
+44 (0)1332 724710
teresa.grieve@nhs.net

Sponsor type
Hospital/treatment centre

Website
https://www.uhdb.nhs.uk/

ROR
https://ror.org/04w8sxm43

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: NIHR300704

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Chartered Society of Physiotherapy Charitable Trust

Alternative Name(s)
CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/08/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v0.5	06/07/2021	19/07/2021	No	Yes
Protocol article		11/08/2022	12/08/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	qualitative study	29/08/2023	30/08/2023	Yes	No
Results article		30/12/2023	12/02/2024	Yes	No
Results article			12/02/2024	Yes	No
Results article	Feasibility and acceptability	13/03/2024	30/06/2025	Yes	No