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Optimising physiotherapy treatment for people with lateral elbow tendinopathy: development and pilot/feasibility testing of an evidence-based treatment approach.

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A thesis submitted for the degree of Doctor of Philosophy

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Declaration:

I, Marcus Bateman, declare that this thesis was composed by myself, that the work contained herein is my own except where explicitly stated otherwise in the text, and that this work has not been submitted for any other degree or professional qualification.

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Foley Bateman (1931-2024)

Abstract:

Background:

There are a wide range of physiotherapy treatment options for people with lateral elbow tendinopathy (LET), however previous studies have reported inconsistent approaches to treatment and a lack of evidence demonstrating clinical effectiveness. The aim of this thesis was to develop an optimised physiotherapist-led treatment package before testing the feasibility of conducting a future, fully powered, multi-site randomised controlled trial (RCT) to compare the clinical and cost-effectiveness of the new intervention against usual physiotherapy treatment for adults diagnosed with LET.

Methods:

The OPTimisE intervention was developed via consensus, using research evidence combined with the opinions of expert stakeholders. A mixed-methods pilot and feasibility RCT was then conducted, with patients receiving usual physiotherapy treatment or the OPTimisE intervention. Feasibility was assessed by meeting pre-specified thresholds for: consent rate, intervention fidelity, attendance rate of scheduled sessions, outcome measure completion at six months, as well as acceptability of the OPTimisE treatment package from both the perspective of patients and physiotherapists (qualitative investigation).

Results:

The OPTimisE treatment package consisted of three elements: advice/education, an exercise regimen and counter-force orthosis. The pilot and feasibility RCT recruited to target and all feasibility progression criteria were met. Patients and physiotherapists found the OPTimisE treatment package to be acceptable but suggested improvements to the trial design. Analysis of secondary outcomes showed improvements in both groups over time with no signal that the OPTimisE intervention might be more effective than usual physiotherapy treatment.

Conclusions:

It is methodologically feasible to conduct a fully powered RCT to compare the clinical and cost-effectiveness of the OPTimisE intervention against usual physiotherapy treatment. However, both groups showed similar improvements over time, questioning whether a future comparative main trial would be a priority. Future research might instead compare diagnosis, reassurance and comprehensive self-help advice against usual physiotherapy care.

Publications & Presentations from this Thesis:

Journal Publications:

Bateman M, Saunders B, Littlewood C, Hill JC. Development of an optimised physiotherapist-led treatment protocol for lateral elbow tendinopathy: a consensus study using an online nominal group technique. BMJ Open. 2021;11(12):e053841.

Bateman M, Saunders B, Littlewood C, Davis D, Beckhelling J, Cooper K, Foster NE, Vicenzino B, Hill JC. Comparing an optimised physiotherapy treatment package with usual physiotherapy care for people with tennis elbow — protocol for the OPTimisE pilot and feasibility randomised controlled trial. Pilot and Feasibility Studies. 2022;8(1).

Bateman M, Hill JC, Cooper K, Littlewood C, Saunders B. The lived experience of people with lateral elbow tendinopathy – a qualitative study from the OPTimisE pilot & feasibility trial. BMJ Open 2023;13(8):e072070.

Bateman M, Saunders B, Cooper K, Littlewood C, Hill JC. Exploring the feasibility and acceptance of an optimised physiotherapy approach for lateral elbow tendinopathy: a qualitative investigation within the OPTimisE trial.

Bateman M, Skeggs A, Whitby E, Fletcher-Barrett V, Stephens G, Dawes M, Davis D, Beckhelling J, Cooper K, Saunders B, Littlewood C, Foster NE, Vicenzino B, Hill JC. Optimising physiotherapy for people with tennis elbow – results of a mixed-methods pilot and feasibility randomised controlled trial (OPTimisE).

Oral Presentations:

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- British Elbow & Shoulder Society Conference 2021 – Virtual Podium
- Physiotherapy UK 2021 – Virtual Podium

Bateman M, Skeggs A, Whitby E, Fletcher-Barrett V, Stephens G, Dawes M, Davis D, Beckhelling J, Cooper K, Saunders B, Littlewood C, Foster NE, Vicenzino B, Hill JC. Optimising Physiotherapy for People with Tennis Elbow – Results of a Mixed-methods Pilot and Feasibility Randomised Controlled Trial (OPTimisE).

- Keele Postgraduate Faculty Symposium 2023
- British Elbow & Shoulder Society Conference, Newport 2023
- Chartered Society of Physiotherapy Conference, Birmingham 2023
- International Scientific Tendinopathy Symposium, Valencia 2023

Bateman M, Saunders B, Cooper K, Littlewood C, Hill J. The Lived Experience of Patients with Lateral Elbow Tendinopathy – a Qualitative Study from the OPTimisE Pilot & Feasibility Trial.

- British Elbow & Shoulder Society Conference, Newport 2023

- International Scientific Tendinopathy Symposium, Valencia 2023

Poster Presentations:

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- Keele Postgraduate Conference 2021
- NIHR Academy Online Conference 2021 (Poster and video presentation)

Bateman M, Saunders B, Cooper K, Littlewood C, Hill J. The Lived Experience of Patients with Lateral Elbow Tendinopathy – a Qualitative Study from the OPTimisE Pilot & Feasibility Trial.

- International Conference of Shoulder & Elbow Surgery, Rome 2023
- Chartered Society of Physiotherapy Conference, Birmingham 2023

Summary of Chapters

Chapter 1. Background and literature review

This chapter describes the pathology of LET, evidence for available treatments and context of this research project.

Chapter 2. Aims, objectives and research methods

This chapter states the aims and objectives of this project, describes an overview of the project design and the research methods used.

Chapter 3. Development of the OPTimisE intervention

The process undertaken to develop the OPTimisE intervention. This chapter describes how published research evidence was combined with the opinions of patient, physiotherapist and healthcare management stakeholders to form a consensus on what the OPTimisE intervention should contain.

Chapter 4. OPTimisE pilot & feasibility RCT – Quantitative Element

Details of a pilot and feasibility randomised controlled trial comparing the OPTimisE intervention against usual physiotherapy treatment, in a real-world clinical setting, across three different sites. Feasibility was assessed using pre-defined criteria including patient consent rate, fidelity to intervention, attendance rate of scheduled sessions and outcome measure completion at six months. Options for patient identification (via primary care or physiotherapy referral screening) and outcome measure delivery (via postal or online methods) were piloted.

Chapter 5. OPTimisE pilot & feasibility RCT - Qualitative Element

The outcomes of the qualitative study of patients and physiotherapists, embedded within the OPTimisE pilot and feasibility RCT, that assessed the acceptability of the OPTimisE intervention and feasibility of conducting a full-scale RCT to assess its clinical and cost-effectiveness.

Chapter 6. Mixed Methods Analysis and Recommendations for Future Research

A summary of the overall project outcomes, bringing together the results of the two elements of the RCT, to contextualise the findings and provide recommendations for future research.

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Chapter 1 Background and Literature Review

This chapter provides an introduction and overview of Lateral Elbow Tendinopathy (LET) and a narrative literature review of the evidence for the range of physiotherapy treatments available. Publications prior to September 2020 are included. At that time, 19 systematic reviews were available on physiotherapy treatments for LET, including a comprehensive review of systematic reviews commissioned by the National Institute for Health & Care Research.[1] Due to the wealth of systematic review evidence available, a narrative review was undertaken to synthesise the information into this chapter.

1.1 Background and nomenclature

Lateral elbow tendinopathy is currently the recommended terminology, agreed by international consensus, to describe "persistent tendon pain and loss of function related to mechanical loading of the (…) lateral elbow tendons".[2] Possibly the earliest references to the condition were described by Runge in 1873 as "writers' cramp" (originally "schreibers krampfes" in German)[3] and subsequently by Morris in the 1882 Lancet journal as "Lawn Tennis Arm",[4] now commonly shortened to Tennis Elbow (TE). It has since been known by several other names such as lateral epicondylitis, lateral epicondylosis, lateral epicondylalgia or more simply: lateral elbow pain.[5] For the purposes of this thesis, it will be referred to as LET, with the exception of any patient-facing documentation that will refer to TE as recommended by the project's Patient and Public Involvement and Engagement group.

1.2 Pathoanatomy

LET, as the name suggests, describes a tendon pathology affecting the extensor tendon origin of the lateral elbow. More specifically it is thought that the extensor carpi radialis brevis (ECRB) tendon that is most commonly affected.[6,7] It was historically thought to be related to inflammation of the ECRB tendon but histopathological studies from patients with chronic

symptoms have found no evidence of inflammatory white blood cells, rather a degenerative angiofibroblastic hyperplasia, or tendinosis, defined by the presence of fibroblasts, vascular hyperplasia, and disorganized collagen.[6] The presence of tendinosis is thought to be indicative of a failed healing response due to repeated microtrauma.[6-8] Nirschl categorized the severity of pathology based upon structural microscopic appearance into four stages with stage two being the most common clinical presentation[6,9]:

- Stage one - an early and reversible stage of acute inflammation
- Stage two - evidence of tendinosis
- Stage three - more severe tendinosis or tendon rupture
- Stage four - tendinosis and the presence of calcification

Coombes et al[10] have postulated, though, that the pathology may not be always isolated to the tendon itself due to poor correlation between imaging findings and severity of symptoms. Increased concentrations of neurotransmitters such as glutamate, calcitonin and substance P are suggested to be the cause of hyperalgesia often seen in patients with LET so altered pain processing, or central sensitisation may also be involved.

1.3 Aetiology & Epidemiology

The adaptation of human tissue to the forces it is subject to, is long established. Wolff's Law, from the 19th century, describes the changes in bone density related to mechanical stress whereby density increases under stress. The opposite is also true with density reducing under a lack of mechanical stress, otherwise described as stress-shielding.[11] Similar adaptions occur in the skin during wound healing[12] and this principle has been applied to explain tendon pathology also. The Cook & Purdam model of tendinopathy[13], from 2009, recognises the multifactorial nature of the pathology including genetic and lifestyle factors, mechanical overuse and stress-shielding. It describes a continuum of three phases that correlate to Nirschl's findings where phase one is reactive tendinopathy (akin to the Nirschl stage one), phase two is tendon disrepair or failed

healing (akin to Nirschl stage two) and phase three is tendon degeneration (akin to Nirschl stage three and four). The Cook & Purdam model attributes causation to excessive load upon the tendon relative to its baseline tolerance and other associated factors. The baseline tolerance is unique to the individual patient, with a sedentary person (whose tendons are relatively stress-shielded) having lower tolerance compared with a professional athlete at the opposite end of the spectrum. It has been proposed that if an individual performs activities that cause relative overload of their ECRB tendon then they are at risk of developing a reactive tendinopathy. Should that fail to heal, perhaps due to on-going overload or associated risk factors then tendon disrepair or degeneration may result. A large UK population study of 4998 patients with LET, from 2012, identified that risk factors for developing LET included tobacco smoking (Odds Ratio 1.2), oral corticosteroid therapy (OR 1.68), rotator cuff pathology (OR 4.95), De Quervain's tenosynovitis (OR 2.48) and carpal tunnel syndrome (OR 1.5).[14] A similar large study from Finland also identified tobacco smoking as a factor (OR 3.6), in addition to type two diabetes (OR 2.1) and occupations involving lifting loads of 20kg for more than eight years (OR 1.9-2.6) or performing repetitive hand and wrist movements for more than two hours per day for more than one year to be risk factors for developing LET (OR 1.6-2.8).[15] Regular exercise two or three times per week reduced the likelihood of developing LET (OR 0.8).[15] There also appears to be a genetic component as individuals with the BstUI A1 allele (OR 1.40) and DpnII B2 allele (OR 1.65) of the COL5A1 gene, associated with collagen production, are more likely to develop LET.[16]

It has been reported that patients with LET have reduced strength of gripping, wrist extension, wrist flexion and also shoulder abduction, internal rotation and external rotation, though it is uncertain whether this relates to cause or effect of LET.[17] Likewise, is the presence of higher rates of depression and anxiety, compared with healthy controls.[18,19]

LET is common and affects adults most often between 40 and 60 years of age, with higher rates in females than males.[14,15,20] The prevalence has been reported to be between 1% to 2.8% of the

population.[15,20,21] Despite the lay nomenclature of TE, tennis players only make up about 5% of all cases.[7]

1.4 Economic and individual impact

Whilst the condition is self-limiting for many patients, 8.5% to 25% of individuals will have persistent symptoms, lasting more than 12 months based upon trials that include a wait-and-see control group.[22-25] A UK population study of 636 people with elbow pain reported that 27% of patients with LET found simple daily tasks such as dressing, carrying, sleeping and driving 'impossible'.[26] In the same study 5% of patients had taken time off work of a median duration of 29 days.[26] Based upon these figures, population data and median wage value, Hopkins et al calculated that, in 2012, absenteeism from work due to LET cost the UK economy £27m.[27]

1.5 Diagnosis

The diagnosis of LET is usually established by the location of pain in the region of the lateral epicondyle and the clinical examination, rather than utilising imaging modalities.[7,28,29]

1.5.1 Clinical assessment

Examination typically reveals a normal appearance to the elbow with no swelling or deformity and a full range of joint motion unless the patient's movement is inhibited by high levels of pain.[28] Tenderness on palpation of the lateral epicondyle of ECRB tendon origin is a key feature and in the majority of studies discussed in this introduction is combined with one or more pain provocation tests to establish the diagnosis.[28,29] Numerous pain provocation tests have been described that involve stretching of or the application of load to the digit and wrist extensor muscles, such as Cozen's Test, Mills' Test and Maudsley's Test, but none of these have been assessed for sensitivity or specificity.[30,31] This is likely due to the lack of a 'gold standard' method of diagnosis, other than the clinical pain provocation tests themselves, combined with the subjective history.[32] Only grip strength testing has been assessed for diagnostic accuracy, using a battery of clinical tests on which to base the diagnosis (ECRB tenderness and two out of three

positive results from the Cozen's Test, Mills' Test and Maudsley's Test).[31] Dorf et al identified that an 8% reduction in maximum grip strength when measured with the elbow extended compared to when the elbow was flexed at 90° was indicative of LET with a sensitivity of 80% and specificity of 85%.[33] The requirement of a grip strength dynamometer to perform the test makes it impractical for widespread use.

1.5.2 Imaging

Diagnostic imaging is not routinely used in the initial diagnosis of LET and is only indicated to exclude other pathology, such as arthropathy, if suspected from the history or clinical assessment.[7,28] Two retrospective clinical studies have shown that plain x-ray is unlikely to alter the course of management unless the patient presents with elbow stiffness or instability.[34,35] Two systematic reviews have found diagnostic ultrasound imaging to have moderate sensitivity and high specificity, with reference to clinical diagnosis and healthy controls, suggesting that the technique may yield false-positive results, and concluding that it was operator-dependent.[36,37] Magnetic Resonance Imaging (MRI) similarly can identify structural tendinopathy changes with good intra-observer reliability (0.732) and higher sensitivity than ultrasound but may still show false-positive results given the high prevalence (18.75%) of such changes in asymptomatic individuals.[7,32,38] MRI findings have though been shown to correlate highly with patient-reported pain and disability (r=0.92).[32] MRI is recommended when symptoms persist despite appropriate conservative management but initial diagnosis is based upon clinical assessment only.[7]

1.6 Measurement of outcomes

Measuring the outcome of an intervention is key to understanding the effectiveness of the intervention in question. There is great heterogeneity of outcome measure selection in LET trials.[39] With no clear consensus on which outcome measures most accurately determine a patient's health status, meta-analysis of data between trials has been limited with recommendations made to address this issue.[1]

In 2019, the results of an international consensus exercise on outcome measures for tendinopathy were published.[40] Nine core domains were identified that should form the basis of a minimum outcome set for future research related to tendinopathy to allow for direct comparison between trials. These domains were: patient rating of condition, participation in life activities, pain on activity or loading, function, psychological factors, physical function capacity, disability, quality of life and pain over a specified time. The next step was to identify appropriate measures of each domain for each specific tendinopathy to produce a Core Outcome Set (COS). A protocol for the LET COS was designed following the Core Outcome Set Standardised Protocol Statement.[41,42] Following a systematic review of outcome measures used in clinical trials related to LET, a quality assessment was performed alongside an international Delphi study involving clinicians, researchers and patients to determine the components of the COS.[43] The recommendations were to use the Patient-Reported Tennis Elbow Evaluation (PRTEE) questionnaire to measure disability but this was the only firm recommendation that could be made. The patient rating of condition, quality of life and psychological factors domains lacked any recommendations. Interim recommendations were made to use PRTEE sub-scales, length of time off work, pain-free grip strength and a Numerical Rating Scale measuring pain on gripping as measures of function, pain over a specified time, participation in life activities, physical function capacity and pain on activity/loading.

1.7 Treatment guidelines and current physiotherapy practice

There is currently no established guideline in the UK regarding the most appropriate treatment for LET. The National Institute of Health and Care Excellence (NICE) have published a Clinical Knowledge Summary [44], last updated in November 2017, recommending initial management of activity modification and analgesia. For patients with persistent symptoms, physiotherapy, corticosteroid injection, and orthotics are advised before referral to an orthopaedic surgeon if problems persist after six to 12 months of primary care management. If the clinical diagnosis is uncertain then MRI or ultrasound imaging is recommended. It is suggested that physiotherapy

interventions may include stretching and strengthening exercises, massage and ultrasound therapy.

A regional UK study that reviewed NHS hospital data from two Trusts, from 2016, and a national UK survey of surgeons and therapists treating LET, from 2017, reported that, in addition, a wide range of other physiotherapy interventions were provided to patients with LET including ice, acupuncture, taping, laser, cervical spine mobilisation, manual therapy and shockwave therapy.[45,46] In the context of such variety in treatments provided, there is rationale to explore the potential for an optimised approach with the aim of improving clinical outcomes for patients and reducing unwarranted variation in treatment.

1.8 Initial Management Strategies

The NICE Clinical Knowledge Summary[44] suggests that initial management should include the use of analgesia such as paracetamol or topical non-steroidal anti-inflammatory drugs (NSAIDs), with a subsequent prescription of oral NSAIDs if ineffective. It is recommended to give advice to avoid heavy lifting, avoid forceful gripping and twisting activities, favour palm-up lifting rather than palm-down, and modify work by taking more rest breaks, alter work patterns and change practice regarding lifting.

1.8.1 Evidence for simple advice

Similar advice has been used as part of a wait-and-see control arm in five trials, along with simple reassurance that for the majority the symptoms of LET will settle over time.[22,24,47-49] In all five, patients in the wait-and-see group improved with short-term patient-rated successful treatment ('completely recovered' or 'much improved' on a Global Rating of Change scale) ranging from 26.3% to 48% and longer-term success at one year ranging from 75% to 90%. It is unclear whether this represents the natural course of the condition or whether the advice improved outcomes, given that there have been no studies of advice versus a true wait-and-see approach.

Epidemiological studies suggest that there may also be a place for advice related to stopping smoking, improving diabetes control, and promoting regular exercise two to three times per week based upon risk factors for developing the condition.[14,15]

The Kings Fund, in 2015, set ten priorities for UK NHS commissioners that included self-management at number one, with the aim of promoting increased physical function and self-confidence.[50] Self-management "refers to activities which promote health but also prevent deterioration by gaining skills which can be applied to new problems as they arise to increase self-efficacy in managing the condition as it progresses."[51] Some systematic reviews of the musculoskeletal literature, whilst not specific to LET, have reported moderate to strong evidence for the use of exercise and psychological interventions, such as pain coping skills, as physical activity and pain catastrophising are strong mediators for outcome in studies of self-management.[52-54] It is recommended that self-management education is delivered to patients by healthcare clinicians and includes follow-up sessions rather than one-off advice, should include self-help materials, help patients to identify problems specific to themselves, assist the patient to form personalised coping strategies and enhance their self-efficacy by empowering them to take responsibility for their lifestyle choices.[51,55,56] Applying such methods, in addition to the basic advice given in the LET trials previously mentioned, may further improve outcomes.

1.8.2 Evidence for the use of analgesia

Systematic review evidence of five placebo-controlled trials investigating the use of topical NSAIDs suggests that this can offer short-term pain relief up to four weeks but the evidence was judged to be of low quality and therefore inconclusive.[57] The evidence for oral NSAIDs was conflicting. No trials have specifically investigated the use of paracetamol or opioid medication.

1.9 Evidence for use of physiotherapy interventions

In this section the evidence for treatments provided by a physiotherapist will be reported:

1.9.1 Manual therapies

Manual therapy includes a range of different 'hands-on' treatment techniques that, in the case of LET, can be grouped into Cyriax manual therapy, Mobilisation with Movement (MWM) and regional mobilisations.[58] The Cyriax method involves a 10-minute session of deep transverse friction massage to the painful tendon followed by a Mills' Manipulation whereby the patient's elbow is forcibly extended to end range whilst the wrist is fully flexed and the forearm pronated.[59] MWM combines manual therapy with active exercise, typically a lateral glide to the elbow whilst the patient performs an isometric gripping exercise.[60] Regional mobilisations include all other types of manual therapy used more generally in the upper limb, rather than focussed on the elbow, and mobilisation of the cervical spine.[58]

The most-recent systematic review and meta-analysis of manual therapy for LET by Lucado et al[58] concludes that "there is compelling evidence that joint mobilizations directed at the elbow improve both pain and functional grip scores across all time frames compared to control groups in the management of LET." This conclusion must, however, be questioned based upon methodological errors and reporting bias in the review. Three large randomised controlled trials (RCTs) are included in the meta-analyses that investigate manual therapy as part of a multimodal physiotherapy treatment package compared with a control of wait-and-see (including advice).[22-24] It is impossible to determine the effect of the manual therapy component of these studies which should not have been included in the meta-analyses for that reason. With these studies removed the meta-analysis of Mills' Manipulation (Cyriax manual therapy) would not be possible for pain as only one study would remain. The meta-analysis of pain for MWM would only include one small pilot study of 10 patients and a small non-randomised study of 34, with no analysis possible for follow-up beyond four weeks.[61,62] Grip strength would not be possible as only one study would remain.[61]

Reviewing the remaining evidence descriptively, Cyriax manual therapy was found to be no more effective than Bioptron polarised light therapy based upon no significant difference in any outcome measures or time points apart from pain visual analogue scale (VAS) at 28 weeks.[63] This 3-arm RCT involving 75 patients included an exercise intervention arm and found that exercise was more effective than Cyriax manual therapy at all time points and all outcome measures up to 28 weeks.[63] Similarly, Viswas et al's[64] small RCT of 20 patients compared Cyriax manual therapy against the same exercise intervention designed by Stasinopolous[65] and found similar results in favour of exercise. In contrast, an RCT of 60 patients by Nagrale et al[59] found Cyriax manual therapy to be superior to a combination diclofenac gel phonophoresis and Stasinopoulos exercises at eight weeks.

Two randomised repeated measures studies have investigated the immediate effect of MWM on pain free grip strength (PFGS) and pressure-pain threshold (PPT) after a single treatment session.[60,66] The studies were small, totalling 41 patients, but had robust methodologies that included a placebo and control procedure, and blinded both the patient and the outcome assessor to the intervention. Both found statistically significant immediate improvements in PFGS after treatment (46% and 47.5% respectively) compared to a sham MWM group and a no intervention group. There are few studies, however, that investigate longer-term effect: two studies investigated the addition of MWM to multimodal physiotherapy including heat, massage and ultrasound therapy. Amro et al[61], in a study of 34 patients, found in favour of the MWM group at four weeks follow-up but the method was non-randomised and, as such, at high risk of bias. Kim et al[62] also concluded that the addition of MWM improved outcome immediately after 10 days of treatment but only included 10 patients. Afzal et al[67] found that patients treated with MWM and ultrasound therapy had significantly improved pain and function at four weeks follow-up compared to those treated with ultrasound alone but the study was limited by a small sample size (n=30) and a lack of blinding. A novel study by Martinez-Cervera et al[68] investigated the mechanism by which MWM might have an effect. Twenty-four patients were randomised into

two groups that both received MWM three times in a week. Half of the patients were told that MWM was a very effective treatment and the other half were given neutral expectations that it may or may not be effective. Patients given high expectations gained significantly better outcomes immediately after treatment suggesting that patient expectation might be an important factor in treatment selection.

Regional mobilisations can be divided into wrist mobilisation and cervical spine mobilisation. The evidence for wrist mobilisation is limited to two small un-blinded studies of similar methodology compared against multi-modal physiotherapy.[69,70] Both found short-term benefit in favour of wrist mobilisation at three weeks but Struijs et al[70] also followed-up patients to six weeks and found no difference between groups at that time point. The evidence for cervical mobilisation is based upon three small randomised trials totalling 43 patients and one low-quality retrospective study.[71-74] Vicenzino et al found immediate improvements in PFGS, pain VAS and PPT with mobilisation of the C5/6 cervical levels compared to a sham technique or control.[74] Fernandez-Cervaro et al conducted two studies where cervical manipulation was firstly compared with a sham technique and secondly compared with thoracic manipulation.[72,73] Both reported immediate improvement in PPT but conflicting results for PFGS. The retrospective study by Cleland et al[71] concluded that there was a high long-term success rate for multimodal physiotherapy with or without cervical mobilisation. Small differences were seen in favour of cervical mobilisation group but given that the patient demographics and treatments received as part of the multimodal physiotherapy between groups were different the attribution of this effect to manual therapy alone is unjustified.

Overall, there is low quality evidence to suggest short-term benefit of manual therapy but also that it may be less effective than exercise.

1.9.2 Orthoses and Taping

1.9.2.1 Orthoses

Orthoses for LET are widely available for general public sale and are also provided via the UK NHS on the recommendation of clinicians.[45] Different forms of orthotics are available but the two main principles of treatment are either to immobilise the wrist, thus reducing the activity of the wrist extensor muscles, or to alter the mechanical forces along the extensor muscles of the forearm by use of a 'counter-force brace'. Counter-force bracing involves fastening a tight cuff around the forearm containing a padded section that is sited over the ECRB muscle. Cadaveric studies have shown that this reduces the force on the ECRB tendon origin when a load is applied distally, suggesting that *in vivo* the aggravating load on the ECRB might be reduced when performing gripping activities whilst using the brace.[75] This has been demonstrated in a small LET patient population where 31 patients were randomised to either wear the brace correctly as a tight cuff or to wear it loosely to minimise the effect.[76] Those wearing the brace correctly experienced significant pain relief in the short term compared to those wearing it loosely. Likewise, a cross-over study investigating two different types of counter-force brace (one a standard design and another incorporated into an elbow compression sleeve) found that these gave immediate pain relief and improved grip strength compared to no brace.[77]

The use of a wrist immobilising splint has been shown to improve pain and grip strength after three weeks when used in combination with physiotherapy treatment and compared to physiotherapy treatment alone.[78] Two studies have compared the use of counter-force bracing to wrist immobilisation, with different conclusions drawn: Akkurt et al[79] found no difference between the different types of splint up to six weeks follow-up of 82 patients whereas Garg et al[80] concluded that wrist immobilisation was superior at the same time point when studying 42 patients. This conclusion is questionable however, as it was only demonstrated in one sub-domain of the American Shoulder and Elbow Society (ASES) Elbow Assessment Form when all other outcome measures showed no difference. Both studies showed that patients with LET improved over time

regardless of which orthosis was used. Van De Streek et al[81] compared the use of a counter-force brace to both the counter-force brace and wrist immobiliser worn together and found no difference in outcome between groups at six weeks.

Whilst there is some evidence of short-term effect of orthotic use, there may be no effect in the long-term. A large study of 110 patients with LET by Nishizuka et al[82] compared a counter-force brace worn daily for six months in addition to exercises with exercises alone. There were no differences in outcomes between groups at any time point up to one year, but both groups improved significantly suggesting the brace gave no additional benefit to exercises alone. Similarly, a large study of 185 patients compared the use of a counter-force brace against an exercise programme and found in favour of exercise at all time points up to a minimum of 12-month long-term follow-up.[83] Indeed, a large retrospective population study of 4614 patients receiving treatment for LET and medial elbow tendinopathy (MET) in the USA found that those using orthoses of any type had higher healthcare usage, longer treatment duration and longer time off normal work than those that did not use orthoses. Other factors may though confound this conclusion as it was unclear whether the baseline symptoms (such as pain severity) were similar between those using orthoses and those not. Higher baseline pain is an established predictor of poorer outcome in patients with LET[29] so the differences between groups may not be due to orthotic use alone.

1.9.2.2 Taping

Kinesiology tape (or K-tape) is an adhesive elasticated tape that is purported to reduce the load on the wrist extensor tendons when applied longitudinally over the dorsal forearm muscles.[84,85] It is not commonly used in UK practice.[45] Studies of the use of K-tape to treat LET are of low quality and of small sample size.[84,86-90] Cho et al[85] found that the application of K-tape to patients with LET gave some immediate pain relief for up to 15 minutes but for longer follow-up the majority of studies show that the use of K-tape is no more effective than sham taping techniques or offers no increased benefit when used in addition to other physiotherapy modalities such as exercise.[84,86,89]

The exception is a study by Giray et al[90] but with only 10 patients per group the result may have been due to chance (type 1 error).

Diamond taping uses a non-elastic adhesive tape applied in four strips pulled tightly around the location of lateral elbow pain to form a diamond, resulting in the encompassed skin having an orange-peel appearance.[91] Similarly to K-tape it is purported to reduce mechanical load on the wrist extensor tendons.[91] A recent systematic review identified four studies of diamond taping each only measuring the immediate effect after application or up to 30 minutes afterwards.[92] All four studies showed improvements in either pain or grip strength compared to controls. It is unclear however whether this has any useful clinical benefit as longer-term effects have not been studied.

1.9.3 Acupuncture

Acupuncture is used by some physiotherapists in the UK as a treatment for LET.[45] It involves the insertion of fine needles into specific anatomical points on the body as defined in Traditional Chinese Medicine (TCM). These points are then stimulated in a variety of ways such as by twisting the needles (manual stimulation), applying an electrical current (electro-acupuncture) or by heating the needles (moxibustion).[93,94] The purpose is to induce a pain-relieving effect on the nervous system although the evidence for this effect has not been firmly established.[94]

The evidence for the use of acupuncture in the treatment of LET is of low or very low quality based upon several systematic reviews.[1,93,95,96] Of the included RCTs, only four compare acupuncture with a supposed placebo or sham treatment. It might be argued, though, that in three of these studies the control arm still included acupuncture treatment: Fink[97] and Irnich[98] both used a similar method whereby acupuncture needles were still inserted but at least 5cm away from the sites recommended by TCM; in the study by Haker[99] needles were still inserted at acupuncture sites but only superficially rather than to the recommended depth, and were not stimulated. In the fourth study, Molsberger[100] used a sham control method where pressure was

applied to an acupuncture point on the patients' thoracic spine with a pencil-shaped probe instead of a needle being inserted but patients could not be blinded from this as the 'real' acupuncture group did not have any needles inserted in the thoracic region. Despite this, in all four of these studies outcomes favoured 'real' acupuncture immediately post-treatment or up to two weeks' follow-up. A limitation of the majority of acupuncture studies is the lack of longer-term follow-up, lack of blinding, lack of randomisation and heterogeneity of outcome measures that prevents meta-analysis of data.[93] Few studies measure the impact on disability and function, just focussing on pain severity.[96] Fink[97] and Haker[99] both followed-up patients for one year but no significant differences were seen between 'real' acupuncture and sham acupuncture beyond two weeks. Improvements were seen in both groups following the natural trend for improvement in LET symptoms over time. The evidence for acupuncture treatment for LET is therefore uncertain but it may offer some short-term benefit for pain for up to two weeks.

1.9.4 Electrotherapies

Electrotherapy was established as one of the four pillars of UK physiotherapy practice when the Society of Physiotherapy was granted its Royal Charter in 1920. Over the century that followed electrotherapies changed with evolving technology but the principle of the purported mechanism of effect remained the same: when energy is focussed on injured tissue it can improve the healing response.[101-105] Electrotherapy is still used in the management of LET in the forms of laser, ultrasound and shockwave therapy (SWT).[45,46]

1.9.4.1 Laser

Laser treatment uses light energy applied locally to the area of pathology to stimulate a physiological response such as reducing inflammation or promoting collagen production.[106] The reaction is dose-dependent with collagen production at lower doses and anti-inflammatory effects at higher doses.[106] For this reason Low Level Laser Therapy (LLLT) is most commonly used in the treatment of LET to promote collagen repair in the absence of significant inflammation.[6]

Laser light can be generated at different wavelengths dependent on the elements used: gallium arsenide 904nm, helium neon 632nm, gallium aluminium arsenide 820nm and neodymium-doped yttrium aluminium garnet 1064nm.[101,107,108] These different wavelengths penetrate human soft tissues differently with 904nm having the deepest effect.[109] The use of laser was popular in the 1990s but has since declined in both usage and availability.[110] Recent studies of UK practice showed that it was now scarcely used in the treatment of patients with LET.[45,46]

A systematic review of the effectiveness of LLLT in the treatment of LET published in 2008, Bjordal et al[106] concluded that it offered favourable short-term improvements in both pain and function when compared to placebo. In a previous review, Bisset et al[111] had concluded that laser was no more effective than placebo but in this study the analysis was not broken down into different treatment wavelengths. Bjordal et al[106] sub-classified studies by treatment wavelength in their meta-analysis to find that the 904nm wavelength provided an effective response (when applied over the extensor tendons rather than when applied over acupuncture points) immediately after the course of treatment and up to eight weeks of follow-up. The 820nm and 1064nm showed no benefit and the 632nm wavelength was inconclusive but might be effective based upon one study.[112]

1.9.4.2 Ultrasound

Ultrasound therapy delivers energy locally to the tissues via high frequency sound waves. The evidence for ultrasound is conflicting and of low or very-low quality.[1,95,105,113] Smidt et al[113] in a systematic review published in 2003 pooled data from two RCTs to conclude that ultrasound was effective for pain relief in the medium-term up to 13 weeks but the trials were not powered sufficiently to detect a moderate treatment effect (standardised mean difference (SMD) of 0.5). Indeed, considered separately these two trials show conflicting results: Binder et al[114] demonstrated significant benefit from ultrasound over placebo whereas Lundeberg et al[115] found no difference. A subsequent RCT of similar methodology by D'Vaz et al, comparing ultrasound

against placebo also found no difference in outcome.[103] Subsequent reviews in 2014 and 2015 have concluded that ultrasound is no more effective than placebo in the short-term.[105,116] However, Dingemanse et al[105] still concluded that there was moderate evidence in favour of ultrasound over placebo in the medium-term despite this being based on the outcome of the Binder et al trial that could not be replicated by Lundeberg or D'Vaz.

1.9.4.3 Shockwave therapy

Shockwave therapy provides energy to the tissues via pulsed acoustic waves, but the mechanism of any therapeutic effect is unclear.[104] Shockwave therapy can be administered in different ways: by use of a radial shockwave device or an extracorporeal shockwave device, and with or without the addition of local anaesthetic. One method has not been shown to be superior to the others.[116] The continued clinical use of SWT is surprising given the conclusions of a 2006 systematic review stating that based upon "platinum-level evidence that shock wave therapy provides little or no benefit in terms of pain and function in lateral elbow pain."[104] A more recent review published in 2015 pooled data from the 2006 review with subsequent studies to draw similar conclusions: that SWT was no more effective than placebo for pain or pain on resisted wrist extension up to six weeks follow-up.[116] Despite this, it continues to be used in UK practice for the treatment of LET by 11% of respondents to a recent nationwide survey.[45]

1.9.5 Exercise therapy

Exercise is the mainstay of current physiotherapy treatment of LET in the UK.[45,46] A limitation of the evidence regarding exercise is the heterogeneity of exercise type, treatment duration and dosage used in clinical trials.[117] Many trials have used bespoke exercise programmes but there are four specific exercise protocols that have been studied multiple times:

1.9.5.1 The Pienimaki protocol

The Pienimaki protocol was first described in 1996 in a trial of exercise versus ultrasound therapy.[118] It consisted of stretches of the forearm muscles and a four-stage progressive loading regime starting with isometric contractions, then isotonic resisted uniplanar exercises using a Theraband, followed by isotonic resisted biplanar exercises using a Theraband, and finally functional repetitive movements involving gripping. Patients were advised to perform exercises four to six times per day for six to eight weeks. Each exercise was done in two to three sets of 10 repetitions. The findings of the trial showed that the exercise protocol was statistically more effective in terms of pain, sleep quality and grip strength, than ultrasound immediately after eight weeks of treatment. The trial was however limited by a small sample size of 39 patients.

The same exercise protocol was subsequently used with deep transverse friction massage and ultrasound as part of a multimodal physiotherapy treatment package by Smidt et al, in a large high-quality RCT.[48] The multimodal package gave the highest chance of recovery (91%) at 12 months compared to corticosteroid injection (69%) or wait-and-see (83%).

It was also used by Tonks et al[119] in a low-powered RCT involving 12 patients per group. Improvements were seen at seven-week follow-up in pain and grip strength compared to controls but failed to reach statistical significance.

1.9.5.2 The Stasinopoulos protocol

Stasinopoulos et al[63,65] described a four-week supervised exercise protocol consisting of one stretching exercise and a progressive eccentric loading exercise. A stretch of the wrist extensor muscles was performed with the elbow extended, forearm pronated and wrist passively flexed with ulnar deviation to the end of the available range. The position was maintained for 30-45 seconds and repeated three times before and after the eccentric loading exercise. Eccentric loading was performed with the elbow fully extended and forearm pronated whilst supported on a treatment couch. The wrist was passively positioned into full extension then slowly lowered to

full flexion over 30 seconds with the addition of a load individualised to the patient. The load was applied using a weight or Theraband and determined by the pain response. Mild pain was acceptable but disabling pain meant that the load was too great. Eccentric exercises were performed in three sets of 10 with a one-minute rest period in-between sets.

The Stasinopoulos protocol has been used in seven trials.[59,63,64,120-123] It has been directly compared to the Pienimaki protocol in an RCT of 60 patients and found to give statistically greater benefit in terms of pain relief and function at 12 and 24-week follow-up.[122] Patients performed supervised exercises once per day, five days per week for four weeks compared with home exercises four to six times per day for eight weeks in the Pienimaki protocol. Adherence to home exercise was not measured but the authors hypothesise that adherence may have been the deciding factor in why the Stasinopoulos protocol was more effective. An alternative reason could be the different types of exercise used.

Three RCTs have compared the Stasinopoulos protocol to Cyriax manual therapy.[59,63,64] As described earlier, the two trials that used the protocol as a stand-alone treatment found it to be superior to Cyriax manual therapy[63,64] but Nagrale et al[59] combined it with diclofenac gel phonophoresis and found it to be less effective.

Manias et al[120] investigated whether the addition of ice massage to the exercise protocol was more effective than the exercises alone in a small RCT involving 40 patients, finding no difference in outcome. Sethi et al conducted an RCT of 26 patients to investigate whether the addition of shoulder strengthening exercises to the Stasinopoulos protocol improved outcomes when compared to the Stasinopoulos protocol alone.[121] A similar trial was subsequently conducted with 48 patients by Mostafaee et al.[124] Both trials demonstrated statistically greater improvements in pain and patient-reported function up to four months with the addition of shoulder strengthening, although there were clinically important improvements in both groups. Likewise, the addition of concentric and isometric strengthening exercises was reported to show superior

short-term results when compared to the original protocol but these findings were based upon a very small 3-arm RCT involving 34 patients, so is likely to be subject to type 1 error.[123]

1.9.5.3 The Solveborn protocol

The Solveborn protocol[83] consisted of 10-second isometric wrist extension contractions followed by stretches of the forearm extensor muscles held for 15-20 seconds. Isometric contractions were performed three to five times followed by a similar number of stretches. Then, similar exercises were performed for the wrist flexors. Pain during exercise was avoided. Exercises were performed twice daily. In a large non-randomised trial of 185 patients, the exercise protocol was compared with the use of a counterforce brace.[83] All patients received activity modification advice plus their allocated intervention. Both groups gained clinically meaningful improvements but the exercise group had statistically significant better outcomes at all time points up to and beyond a year follow-up in terms of self-reported levels of pain and treatment success (good or excellent result).

The protocol was used in three other trials.[125-127] Nilsson et al[126] taught the exercise protocol for home use along with ergonomic advice and a counterforce brace in a non-randomised trial versus a control of usual care. The intervention group had significantly better outcomes at four and 16-week follow-up but there was a high drop-out rate in the control group (only 44% attended the final follow-up) that may invalidate the results. Haahr et al[125] conducted a large RCT involving 266 patients randomised to a one-off education session, including general advice and instruction in the Solveborn protocol, versus a control group of usual care. They found that both groups improved up to one year but with no between-group difference. Svernlov et al[127] compared the Solveborn protocol to a combination of stretching and progressive eccentric loading in a pilot RCT involving 38 patients. The same stretching dose was used in both groups but the isometric exercises used in the Solveborn protocol were substituted in the intervention group with three sets of five repetitions of pain-free eccentric loading exercises using a weight. Each repetition was

performed over 10 seconds. The weight was progressively increased by 10% each week from a starting point of 1 kilogram for males and 0.5 kilograms for females. Both groups exercised at home for 12 weeks. Similar improvements were seen in both groups, in terms of pain and treatment success, at all time points up to one year. The eccentric exercise group gained statistically significant grip strength improvements at six months compared to the Solveborn protocol group, possibly suggesting a faster recovery of strength with eccentric loading, though by one year the differences were no longer significant. This difference may also have been due to type I error, given the small sample size.

1.9.5.4 The Vicenzino protocol

The Vicenzino protocol[128] has been used in three large high-quality RCTs totalling 483 patients.[22,23,129] In all three trials it has been used as part of a multimodal approach along with manual therapy and taping. The exercise component required patients to perform pain-free exercises of the hand, wrist and forearm starting with simple controlled active movements not incorporating additional load. Load was then progressively added using Therabands of increasing resistance during concentric and eccentric actions of the wrist. The focus was on wrist extension with exercises performed slowly over six to eight seconds. The dose was dependent on the symptom reaction with pain avoided during and after the exercises. As symptoms improved with gripping no-longer painful, additional strengthening exercises of the whole upper limb were prescribed, including bench press, shoulder press, bent-over rows, biceps curls and tricep curls using weights. In two trials, patients attended eight times over six to eight weeks[22,23] and in one trial four times over four weeks.[129] Significant improvements were seen at short-term follow-up across the trials compared to controls. For example, Bisset et al demonstrated that the Vicenzino protocol provided statistically and clinically differences in pain and function compared to advice only at 6 and 12 weeks but not at 6 or 12 months.[22] Yelland et al found statistically significant improvements in pain and function at 12 weeks compared to prolotherapy and advice but, similarly, no difference at 6 or 12 months.[129] Likewise, Coombes et al found clinically and

statistically important differences in favour of the Vicenzino protocol compared to placebo injection and advice at four weeks, with economic evaluation from the trial showing it to be a cost-effective treatment for LET, despite no differences between intervention and control at 6 or 12 months.[130]

1.9.5.5 Isometric exercises

Isometric exercise as an initial treatment for the management of acute tendinopathy is currently *en vogue.*[131] Two RCTs have investigated isometric exercises specifically for the treatment of LET.[49,132] Park et al[132] randomised 31 patients to early pain-free isometric wrist extensions or the same exercises started after four weeks. The contractions were held for 10 seconds and repeated 50 times, four times a day. Statistically significant improvements were seen in the first four weeks in the early exercise group. Vuvan et al[49] compared a single session of isometric exercise instruction versus wait-and-see in a trial of 40 patients. Patients were taught to perform the exercises at 20% of the Maximum Voluntary Contraction (MVC) of the unaffected arm increasing to 35% MVC by week seven. They performed three repetitions of 45 second holds or four repetitions of 30 second holds once daily for eight weeks. Outcomes measured using the PRTEE showed statistical significance in the exercise group at eight weeks but other measures did not show a significant difference. The authors concluded that isometric exercise alone was not sufficient to treat LET but may form part of a treatment package.

Stasinopoulos et al[123] compared their own protocol of eccentric and stretching exercises to the addition of concentric exercises and both concentric and isometric exercises in an RCT. A small and insignificant difference was seen with the addition of concentric exercises but the further addition of isometric exercises resulted in significant improvements compared to eccentric and concentric/eccentric exercises. The study was, however, limited by a small sample size of 34 so the results should be interpreted with caution.

1.9.5.6 Eccentric exercises

The most commonly studied form of exercise for LET is eccentric exercise.[117] A 2020 systematic review by Chen et al[133] showed a large effect of eccentric exercise over other treatment modalities or other forms of exercise but noting that in many studies the eccentric exercise was used as part of a multimodal treatment. There are several studies though that have investigated eccentric exercise in isolation. Tyler et al[134] compared a multimodal approach with and without eccentric exercise using a Theraband Flexbar device. It was a small RCT of 21 patients but the addition of eccentric exercises significantly improved outcomes after six weeks of treatment. The same technique was used by Tiwari[135] and compared to concentric and eccentric exercises using a weight, performed daily. After the three weeks of treatment, PRTEE outcomes showed statistical significance in favour of the Theraband Flexbar technique but the difference may be attributable to dosing rather than technique as patients using the Theraband Flexbar performed 45 repetitions per day compared to 20 repetitions in the other group. The RCT was larger than the original Tyler et al trial, including 40 patients, but lacked any follow-up beyond three weeks.

In contrast, Martinez-Silvestrini et al[136] compared wrist extensor stretching against stretching with the addition of either concentric or eccentric exercises in a three-arm RCT of 94 patients. They found that all groups improved a similar amount at six-week follow-up although the eccentric exercise group suffered fewer exacerbations of symptoms.

Soderberg et al[137] randomised 42 patients in an RCT using a counterforce brace with or without the addition of eccentric wrist extension exercises. A simple method was employed where patients exercised at home holding a bucket with increasing amounts of water to increase load. After six weeks of follow-up the group performing eccentric exercises had significantly better grip and wrist extensor strength, however both groups experienced similar improvements in pain with no statistical difference between groups.

A higher quality study by Crosier et al[138] randomised 92 patients to a multimodal physiotherapy treatment package of ice, TENS, ultrasound and stretching exercise versus multimodal physiotherapy plus eccentric exercises. The eccentric exercises involving wrist extension and forearm supination were performed using a Cybex isokinetic machine three times a week for a total of 25 to 26 sessions. Two sets of 10 exercises were performed for each movement with gradually increasing velocity and resistance over the treatment period up to 90° per second and 80% MVC. Statistically significant improvements were seen in the eccentric exercise group in terms of strength and pain at the end of treatment (mean 9 weeks) but the practicality of an intervention requiring high levels of patient attendance must be questioned.

1.9.5.7 Other exercise protocols

Peterson et al[47] used a similar method to Soderberg et al[137] teaching patients to exercise at home using a bucket filled with water in an RCT comparing exercise to a wait-and-see approach. The exercise protocol used concentric and eccentric wrist extension with progressive load, starting with 2kg for males and 1kg for females. Patients performed three sets of 15 repetitions daily and increased the load by 0.1kg each week for three months. Patients in the exercise group had statistically significant improvements in pain compared to wait-and-see at three-month follow-up but interestingly, disability was not different between groups (measured using the Disability of Arm, Shoulder and Hand questionnaire). The same authors then performed a second RCT of 120 patients splitting the protocol into eccentric exercise only versus concentric exercise only.[139] The eccentric exercise group achieved a faster improvement in pain and strength but similarly, there was no difference in disability score at any time point between groups.

Selvanetti et al[140] used a home exercise combination of contract/relax stretching and eccentric loading of the wrist extensors in a 62-patient RCT against a control intervention of ultrasound and advice. Only the abstract is available in English, but at minimum six-month follow-up a large treatment effect was seen in the exercise group (treatment success 76% versus 3% in the control

group). Without understanding the detail of the trial from the full text manuscript it is impossible to interpret the quality of the trial, so the results should be judged with caution.

Barratt et al[141] conducted a large service improvement project involving 182 patients. Firstly, usual care was assessed before a shift of focus was made towards strengthening exercises and finally a specific progressive loading protocol implemented. The protocol began with moderate to high load isometric exercises progressing to concentric and eccentric exercises with increasing load. Although the study was limited by its non-randomised design and loss to follow-up there was evidence that the specific progressive loading protocol was more effective than other care with the difference attributed to the higher load progressions of the specific protocol. The patients receiving the specific progressive loading protocol attended fewer times (mean 2.95) with higher numbers reporting treatment success (73%) compared to usual care (mean 5.1 treatment sessions, 64% success). Indeed, a systematic review of tendon adaption to loading concluded that it was the progression to high load exercise that is the key factor in stimulating a tissue response rather than the type of muscle contraction used during exercise, though this review only included studies of lower limb tendinopathy.[142]

1.9.5.8 Exercise dosing

Raman et al[117] conducted a review of the literature in 2012 regarding the choice of exercise and dosing used to treat LET. The findings demonstrated great heterogeneity in numbers of repetitions, sets of exercises, frequency of exercise and duration of the exercise course with no clear conclusion on the optimum level. In a more recent 2020 review focussed upon eccentric exercise only, Chen et al[133] found that exercises were typically performed in three sets of 10 to 15 repetitions separated by 30 seconds to a minute's rest between each set. Exercise frequency ranged from three days per week to daily and the duration of treatment from three weeks to 12 weeks. Based upon theoretical healing times for tendon pathology and assessment of treatment effect size of high dose versus low dose trials the authors' recommendation was to perform

eccentric exercises at least once per day, in three sets of 10-15 repetitions, for a minimum period of six weeks.

1.9.5.9 Painful versus pain-free exercise

A systematic review of pain-free exercises versus exercises that allowed some level of pain, published in 2017, found a short-term benefit in favour of painful exercises up to three months.[143] The review does not contain any trials related to LET, however six of the nine included trials related to tendinopathy though the extent to which these findings may be transferrable to patients with LET is unclear. Pain-related fear can lead to central sensitisation of the nervous system resulting in higher perceived pain levels, so an exercise approach that focusses on avoiding pain may exacerbate this response.[144] Central sensitisation is a common feature in patients with LET, as identified by 10 studies included in a recent systematic review so needs to be considered in any intervention design.[145] Methods of addressing central sensitisation and pain-related fear have been proposed for clinical practice and can be applied to exercise interventions for LET.[144,146] These include education of the patient, addressing anxiety related to activity or exercise to reduce the threat response and graded exposure to painful activities. The Stasinopoulos protocol permits mild pain during exercise below 4/10 on a numerical rating scale (NRS) and includes graded exposure to a painful stimulus (loading of wrist extension using a weight) with gradual progression of increasing load. It was consistently effective in treating LET in seven trials, so might be a basis of this theory if applied to practice with additional patient education.[63-65,120-123]

1.9.5.10 Exercise Summary

Eccentric loading is the most frequently studied form of exercise for LET and appears effective, with some certainty in the short-term based upon trials of moderate quality. There is additional evidence for the supplementation of eccentric loading with isometric and concentric exercises to amplify the effect. Based upon modern understanding of pain science and previous trials

involving pain-provoking exercise there is justification to encourage exercise into low levels of pain if supported by appropriate patient education.

1.9.6 Corticosteroid injections

The use of corticosteroid injection (CSI) to treat patients with LET is controversial with calls to stop made as long ago as 2010.[147] Despite this, a survey conducted in 2011 still showed that 48% of UK specialist clinicians used CSI as a primary treatment.[148] Whilst this number had declined in a similar UK survey conducted in 2017, 36% of respondents still used CSI as a first or second-line treatment.[45] The controversy stems from the conclusions of several large RCTs that showed worse outcomes at one year follow-up compared to patients treated without CSI.[22,23,48] Numerous studies consistently showed a significant reduction in pain up to six weeks following CSI with a large effect size.[149] This significant short-term effect may be attractive to patients as it can provide fast alleviation of symptoms and allow early return to work but the longer-term implications need to be considered. Mardaini-Kivi et al[150] found that the symptoms of 34.7% of patients had already returned 12 weeks after CSI. Bisset et al[22] compared CSI to multimodal physiotherapy or a wait-and-see approach that included general advice. At six weeks, CSI produced the greatest improvement but by 12 months had the worst outcome, even when compared to wait-and-see. The CSI group had a 72% recurrence rate at 12 months compared to just 8% with physiotherapy and 9% with wait-and-see. Coombes et al[23] compared CSI with a saline placebo injection and multimodal physiotherapy versus no physiotherapy in a 2 x 2 factorial design study. The two CSI groups showed the greatest improvements at four weeks but the worst outcomes at 12 months, even when compared to the placebo injection and no physiotherapy. The recurrence rate at 12 months was 54% across the CSI groups. A subsequent economic evaluation from the same study concluded that CSI was not a cost-effective treatment for LET.[130] Smidt et al[48] compared CSI to multimodal physiotherapy or a wait-and-see approach. Again, CSI produced the greatest improvement at four weeks but by 12 weeks was no better than wait-and-see. At six months and one year the outcomes for those patients receiving CSI were worse than

wait-and-see. Of the large RCTs of CSI for LET, it is only Hay et al[151] and Olaussen et al[24] that did not show a detrimental effect at one year follow-up. Hay et al[151] compared CSI to naproxen tablets or placebo vitamin C tablets. Olaussen et al[24] compared CSI plus multimodal physiotherapy with a placebo injection plus multimodal physiotherapy and a third wait-and-see group. By 12 months all groups had achieved a similar outcome but after an initially favourable response the CSI plus physiotherapy group had worse outcomes between 12 to 26 weeks compared to the other groups. Overall, the evidence would suggest therefore that CSI should be used with caution as despite strong evidence of short-term beneficial effect, the medium-term and long-term effect may be negative.

1.9.7 Multimodal physiotherapy

Many studies use a combination of treatments as part of a multimodal package of physiotherapy treatment. In particular, there are five large RCTs totalling 845 patients, four of which had wait-and-see control groups, that have investigated a multimodal approach with a long-term follow-up of one year.[22-24,48,129] Three of these trials used the same multimodal approach proposed by Vicenzino in 2003.[22,23,128,129] Patients were educated regarding avoiding painful activities involving repetitive activity or gripping with the forearm pronated and elbow extended. A trial of MWM and taping was performed to establish if there is an immediate reduction in pain on gripping and patients were taught an exercise routine of posture correction, progressive forearm strengthening and general upper limb strengthening. Patients were then seen eight times over six to eight weeks in two trials[22,23] and four times over four weeks in one trial.[129] At these visits MWM and taping was repeated if found to be beneficial and the exercises were repeated under supervision and progressed as able. Exercises were continued at home. All three trials found significant short-term improvement with multimodal physiotherapy between four to six-week follow-up compared in two trials to a control of wait-and-see, and in one trial to prolotherapy. Additionally, Yelland et al[129] found multimodal physiotherapy superior to prolotherapy at 12 weeks. All three studies found that by 12 months the difference between control or prolotherapy was no-longer

significant due to the fact that LET symptoms tend to improve in the majority of patients over time. Bisset et al[22], though, performed an area under the curve analysis to evaluate that, compared to CSI or a control of wait-and-see, multimodal physiotherapy was superior. It was also associated with the lowest symptom recurrence rate and lowest analgesic use.

Olaussen et al[24] compared multimodal physiotherapy with CSI or placebo injection against a control group of wait-and-see. The multimodal physiotherapy consisted of six sessions over six weeks of Cyriax manual therapy, passive stretches of the forearm extensor muscles and a home exercise programme of forearm extensor muscle stretching and eccentric strengthening. The wait-and-see group were given education regarding activity modification and were prescribed NSAIDs. At six-week follow-up multimodal physiotherapy was superior to wait-and-see but at subsequent assessments at 12, 26 and 52 weeks there was no difference between groups.

Smidt et al[48] compared multimodal physiotherapy against CSI and a control group of wait-and-see in a large high-quality RCT involving 185 patients. The multimodal approach consisted of ultrasound, deep transverse friction massage and the Pienimaki exercise programme of stretching and progressive strengthening for six weeks.[118] The highest probability of recovery at six-month follow-up was found in the multimodal physiotherapy group. At 12-months the success rate of the CSI group was 69% compared with 91% and 88% respectively in the multimodal physiotherapy and wait-and-see groups.

Overall, the evidence would suggest a positive short and mid-term effect of multimodal physiotherapy compared with control or comparator treatments but the key components of an optimum multimodal physiotherapy treatment package have not been established.

1.10 Summary

A wide range of treatment techniques have been investigated for LET, highlighting the variability in current practice and a lack of clarity regarding the best treatment approach. Much of the evidence available is derived from trials with low methodological quality, however there appears

to be evidence to suggest that manual therapy, laser, acupuncture, diamond taping and orthotics may give a short-term beneficial effect. The evidence for exercise-based interventions and multi-modal physiotherapy is of higher quality, including several large high-quality RCTs, consistently showing short-term benefit over control or placebo interventions. There remains uncertainty, however, regarding the optimum composition of multi-modal interventions and the type/dosing of exercise. Long term outcomes appear to be influenced by the often-self-limiting nature of the condition. Multiple trials have shown that many patients improve with simple advice and time, but there is potential to improve this self-management support further with the addition of psychological and behavioural interventions to improve patient self-efficacy.

Chapter 2 Aims, Objectives and Summary of Research Methods

This chapter provides the aims and objectives for the thesis, an overview of the project design, and the research methods used.

2.1 Aims and Objectives

Chapter 1 highlighted the current lack of a consistent treatment approach for people with LET and lack of certainty from the evidence base to guide clinicians. The aims of this PhD, therefore, were to design an optimised physiotherapy treatment package for people with LET, suitable for use in a publicly-funded healthcare system. This was achieved by obtaining agreement from key stakeholders through a consensus process based upon best available evidence, practicality and cost, with a subsequent evaluation of the newly designed treatment package using a pilot and feasibility randomised controlled trial.

Phase 1: Design an optimised physiotherapy treatment package for people with LET	
Phase 2a: a multi-centre pilot and feasibility randomised controlled trial comparing the optimised treatment package against usual physiotherapy treatment	Phase 2b: a qualitative study of patients and physiotherapists involved in the pilot and feasibility trial

Table 2-1: A summary of the project design

Phase 1 objectives:

To bring together published research evidence with the opinions of patient, physiotherapist and healthcare management stakeholders to form a consensus on what the optimised physiotherapy treatment package (OPTimisE intervention) should contain.

Phase 2 objectives:

To assess whether it was feasible to conduct a fully powered RCT to compare the clinical and cost-effectiveness of the OPTimisE intervention against usual physiotherapy treatment. Specifically, Phase 2a compared the OPTimisE intervention against usual physiotherapy treatment provided at three different clinical sites, in a pilot and feasibility RCT, using pre-determined thresholds for success. Phase 2b examined the feasibility and acceptability of the OPTimisE intervention, via qualitative interviews with trial patient and physiotherapist participants.

2.2 Summary of Research Methods

Physiotherapy interventions are complex. They typically involve a number of component parts that may interact and are usually tailored to individual patients based upon factors such as pain severity, exercise tolerance, comorbidities and personal circumstances. The UK Medical Research Council have published guidance for the development of such complex interventions, that describes an over-arching four-phase cyclical process of development, feasibility and pilot testing, evaluation, and implementation.[152] This PhD aligns to the first two phases in this process.

In Phase 1, the OPTimisE intervention is developed by consensus using a Nominal Group Technique (NGT) method. It was chosen in preference to other consensus methods, such as Delphi, for reasons of practicality and to promote greater discussion between stakeholders. NGT allows individuals to generate ideas, express opinions, discuss and clarify ideas prior to anonymous voting. If voting outcomes are inconclusive the process can be repeated with further discussion and voting until a conclusion is drawn; all of this typically achieved in one or more two-hour meetings.[153,154] Participants can be primed with information to read prior to meetings as a means of pre-elicitation: to facilitate understanding of the NGT process, provide background information (such as a summary of the research evidence of efficacy for physiotherapy treatments for people with LET) and prompt early consideration of the task proposed.[155] This allows greater discussion between stakeholders and can achieve a consensus in a much shorter time than multiple Delphi rounds. It is crucial that when a complex intervention is developed, that early consideration is given to the implementation of the intervention into real-world practice.[152] For this reason, the stakeholder group included not only clinicians but also patients and physiotherapy service managers, to ensure that patient burden was minimised and that the intervention was practical to implement in a publicly-funded health service.

In Phase 2, the OPTimisE intervention is tested in a real-world mixed-methods pilot and feasibility RCT with nested qualitative study. RCTs are considered the 'gold standard', or best method of

evaluating whether an intervention is effective.[156,157] At the simplest design level, they involve the random allocation of participants to receive either a new intervention or a control intervention (e.g. the standard of care) and effectiveness is then assessed using pre-defined hypotheses.[157] They are, however, costly and time-consuming to conduct, so it is therefore recommended that pilot and feasibility testing is undertaken before a full-scale RCT to ensure that the proposed interventions and research methods can actually be conducted in real-world scenarios.[152] Pilot testing involves testing the trial procedures, such as randomisation systems and data collection methods, whereas feasibility testing predicts the deliverability of a main trial by assessing quantitative feasibility measures, such as patient recruitment, retention and safety, and qualitative measures, such as acceptability and equipoise.[158] Unlike in full-scale RCTs, pilot and feasibility trials do not include hypothesis testing to analyse differences in treatment outcomes between groups, as they are not sufficiently powered to answer those questions[157].

Mixed-methods research is well-suited to the assessment of feasibility as it combines quantitative and qualitative data collection.[159,160] Feasibility has historically been determined by pre-defined quantitative thresholds, such as recruitment rate, but qualitative evidence is increasingly being used and recommended as an adjunct, to provide valuable insight into how the trial can be done in the best possible way, not just whether the trial can be done at all.[160,161]

There are three basic designs of mixed methods research: exploratory sequential, explanatory sequential, and parallel convergent.[162] In an exploratory sequential design the qualitative phase analysis is completed first, to inform the subsequent quantitative phase and vice-versa for explanatory sequential designs.[159,162] This PhD utilised a parallel convergent mixed methods design where data from both phases were collected concurrently so that one could influence the other. For example, this approach might enable the addition of further questions to the qualitative interviews to try to understand reasons behind a low consent rate identified from the quantitative phase. The parallel convergent method was chosen as it is time-efficient (the funder

placed a 12-month limit on recruitment) and can be used to understand whether the qualitative results confirm the quantitative results.[159] This had particular relevance to some of the secondary outcomes that were more challenging to measure using quantitative methods, such as understanding differences between the OPTimisE intervention and usual physiotherapy treatment, or treatment fidelity.

This PhD combines both pilot and feasibility testing in a small-scale RCT, as well as using a parallel convergent mixed-methods design, comparing and relating both the quantitative and qualitative analysis to determine whether a full-scale RCT is feasible.[159] The qualitative interviews were conducted alongside monthly review of the quantitative data, so that interview questions could be tailored to understand particular short-comings (e.g. understanding why some patients had not returned their outcome questionnaires and ways that outcome data collection could be improved). The advantage of this combined approach is that insight is provided in relation to all aspects of feasibility and piloting in real-time, so is an efficient way to refine the trial processes or treatment delivery in order to maximise the impact of a main trial.

Full details of the methods used for both phases will be described in subsequent chapters.

Chapter 3 Development of the OPTimisE Intervention

This chapter outlines the integration of the research evidence, described in Chapter 1, with the insights of patients, physiotherapists and healthcare management stakeholders, culminating in a consensus on the composition of the OPTimisE intervention.

3.1 Context

There are no established treatment guidelines for LET. In the United Kingdom (UK) the National Institute for Health & Care Excellence (NICE) have published a clinical knowledge summary providing advice for clinicians on how to manage patients with the condition.[44] The initial management is advice to use heat or ice for pain relief, take relative rest from aggravating activities, use an orthosis, use paracetamol or ibuprofen topical gel for symptomatic relief and if there is no improvement after six weeks, refer to a physiotherapist.

An Australian group of researchers have proffered a more detailed, stratified algorithm for treatment, taking into account symptom severity and environmental risk factors, although this is theoretical and has not yet been tested in clinical practice.[29] For patients with low baseline severity, defined by a PRTEE score* less than 33, the recommended treatment is aligned with the UK clinical knowledge summary, excluding the provision of an orthosis. For those with moderate risk, defined as a PRTEE score of 33 to 54 or additional environmental risks such as a job involving heavy, repetitive or unmodifiable tasks, or concomitant elbow pathology, immediate referral for 8-12 weeks of multimodal physiotherapy is advised. This might include manual therapy, provision of an orthosis, electrotherapy, progressive strengthening and endurance exercises. For those at high risk, defined as a PRTEE score above 54 or co-existing neck / shoulder pain or evidence of central sensitisation, physiotherapy is recommended alongside drug therapy (e.g. anti-depressants). The rationale for drug therapy being aimed at addressing central sensitisation is

* The Patient-Rated Tennis Elbow Evaluation (PRTEE) is a measure of pain and disability. 0 represents no pain or disability; 100 represents maximum pain and disability.

uncertain, particularly as the authors acknowledge a lack of evidence to support the prescribing of this medication in the LET patient population. In the high-risk group, exercise therapy is recommended and involves starting with low load pain-free isometric wrist extension exercises, before advancing to progressive loading, if symptoms allow.

3.2 Establishing the clinical problem

Physiotherapists, in real-world practice, offer a wide array of different treatments for LET, including advice, exercise therapy, manual therapy, acupuncture, electrotherapies, orthotics and taping.[45,46] This heterogeneity can be attributed to multiple factors such as variations in training, variations in healthcare funding and personal or patient preference. As highlighted in Chapter 1, many of these treatment modalities are either poorly researched or lack evidence of effectiveness. With wide variations in practice, that include provision of treatments of limited effectiveness, there is opportunity to incorporate current best available evidence with opinions of relevant stakeholders to develop a consensus-based physiotherapy treatment package ready for evaluation in a future randomised controlled trial. Indeed, even more commonly used treatments, such as exercise therapy, lack a consistent approach to delivery with no consensus on the types of exercise to include, dose of exercise to prescribe, or whether exercise should provoke pain or be pain-free.[45,46,117,133,163] Physiotherapy treatment packages are complex interventions involving verbal and non-verbal communication, patient education and delivery of therapeutic modalities. They often involve multiple interventions in combination, such as a range of exercises with supporting advice, and rely upon the recipient engaging with those interventions as intended. Interventions also are often adapted for individual patients based upon factors such as symptom severity, comorbidities, exercise tolerance and understanding of language. When designing complex interventions, the purpose should be clear, and the intervention should be informed by evidence prior to pilot and feasibility testing.[152] In addition to treatment modality selection, consideration needs to be given to any additional factors that may contribute to success of the treatment delivery (e.g. patient burden, modes of delivery, adherence, behaviour change

techniques) as well as determining how patient outcomes will be assessed.[152] More recent guidance, from O'Cathain et al, encourages stakeholder involvement including those that deliver the intervention and those that may benefit from it.[164] Thought must also be given to how the intervention will be evaluated in terms of its effectiveness and how it might be implemented into clinical practice.[164]

The current best-practice intervention development process begins with identification of the clinical problem, planning the timeline of work, securing funding, establishing an appropriately skilled team, and establishing an active Patient and Public Involvement and Engagement (PPIE) group. As part of the preparation for the National Institute for Health and Care Research Doctoral Fellowship application, some of these elements had begun to be addressed prior to commencement of this PhD project. The in-depth review of existing research evidence was presented in Chapter 1, and so the next steps include: the identification of key stakeholders, new data collection to understand the contextual factors, development of a programme theory, and designing and refining the new LET intervention.[164] The programme theory is a rationale for how the treatment may achieve its desired effect from its component parts and in different contexts. It can be a combination of theory and prior knowledge, evolving as new information arises, and can be presented as a logic model that depicts the programme theory in a visual model.[164] This chapter explains how the intervention development process was undertaken, resulting in the OPTimisE intervention.

3.3 Aims and Objectives

The aim of this work package was to develop an optimised physiotherapy protocol for treating people with LET, using a consensus approach that combined information from a previous synthesis of the best available evidence (see Chapter 1) with the perspectives of key stakeholders. The agreed treatment protocol would then be assessed in a forthcoming pilot and feasibility trial to determine if it could be delivered in a large-scale randomised controlled trial (RCT).

3.4 Method

The study gained stakeholder consensus for an optimised LET treatment protocol using Nominal Group Technique (NGT). Consensus methods are used in healthcare research to reach agreement in topics that are controversial, due to lack or supporting evidence or conflicting supporting evidence. In this context, and as described in Chapter 1, a plethora of treatment options are available for people with LET but there is currently a lack of evidence for the best approach. Three main approaches are available for consensus agreement, including: the Delphi technique, consensus development conference and NGT.[165] The Delphi technique involves stakeholders responding to questions or providing opinions remotely, without direct interaction with other stakeholders. The process typically includes several cycles, with the results of each cycle being presented to the stakeholders to influence their responses to the next round of questions. Each cycle may take several weeks to complete, so the time required to reach a consensus may be lengthy. Consensus development conferences involve stakeholders meeting together to discuss evidence and agree a consensus over a short timeframe, usually one day. Whilst the speed of the method is advantageous, it may be logistically challenging to convene such a meeting, with additional uncertainty over the length of time that might be required. NGT is somewhat similar but broken down into shorter interactive meetings with a defined process structure to facilitate participation. It is a method that is, by design: dynamic, iterative, creative and open to change – four of the key principles in intervention design.[164] NGT is usually conducted in face-to-face meetings, about two hours long.[153] For topics that are broad, it is recommended that participants are sent information to read prior the meeting as a means of pre-elicitation: to facilitate understanding of the NGT process, provide background information (such as a summary of the research evidence of efficacy for physiotherapy treatments for people with LET) and prompt early consideration of the task proposed.[155] During the meeting, an explanation of the task is then followed by a period of silent idea generation where participants note down their opinions related to the topic or question. These ideas are then shared with the group until no more ideas

are forthcoming. There is opportunity to discuss these ideas to gain understanding of individuals' perspectives and clarify definitions, prior to an anonymous vote on whether to include each of the ideas in the final consensus. If voting outcomes are inconclusive the process can be repeated with further discussion and voting until a conclusion is drawn.[153,166] The process is summarised in *Figure 3-1*.

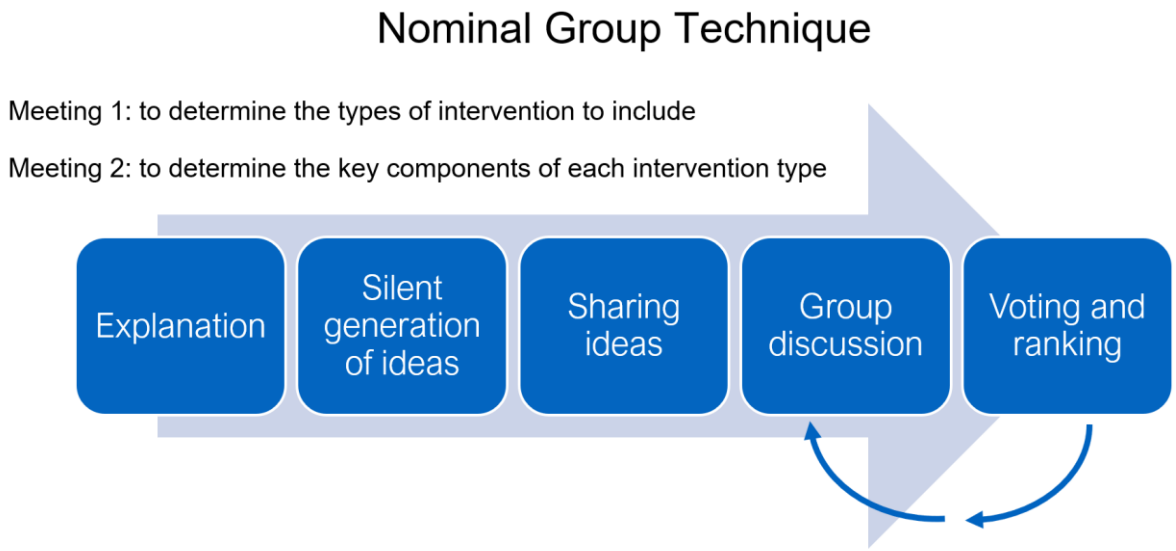


Figure 3-1: A summary of the Nominal Group Technique process.

This work was undertaken during the COVID-19 pandemic, so face-to-face meetings were prohibited. The NGT consensus approach was chosen as the most appropriate method as it could be adapted for online data collection with meetings hosted on the Microsoft Teams video-conference platform. Short online meetings were deemed preferable to a day-long consensus development conference and were easier to organise during evenings, outside of working hours. NGT was also preferred over the Delphi technique as it allowed greater interaction between stakeholders, ensuring that the patient participants' opinions could be heard, and a consensus could be achieved in a shorter timeframe. Whilst the output of any consensus can be influenced by various factors (including the beliefs of the individual participants, the cues provided to those participants, the method of interaction and way that agreement is determined)[167], care was taken

to reduce bias by selecting a broad stakeholder group, present information based upon scientific evidence and use anonymous methods of voting that might mitigate against peer-pressure. These methods are described below.

3.4.1 Identification of stakeholders

Physiotherapists with a special interest in LET were approached to take part via an email advertisement to members of the British Elbow and Shoulder Society (BESS) and by direct contact with clinicians who had agreed to be recruitment and delivery sites for the subsequent pilot and feasibility RCT. The email invitation (Appendix 3.1) provided a brief description of what would be involved and was accompanied by a participant information sheet (Appendix 3.2) containing more detailed information. BESS members were targeted as they were deemed to be experts in the field. Patients volunteered from an existing PPIE group[†] developed by the research team and physiotherapy service managers were identified from the future trial sites. Each were sent the email invitation and participant information sheet. A combination of physiotherapists, physiotherapy service managers and patients were included to provide a broad range of opinions related not only to treatment effectiveness but also practicality of implementation.

All participants were required to give written consent to participate (see Appendix 3.3), including additional consent to meetings being video-recorded. Ethical approval was granted from Keele University Faculty of Medicine Ethics Committee (see Appendix 3.4) and the UK Health Research Authority (see Appendix 3.5).

3.4.2 Presentation of existing evidence

Prior to the first meeting, participants were sent a summary of the evidence synthesis for the full range of LET physiotherapy treatments (see Appendix 3.6). The information was summarised in the form of an evidence flower – a visual display designed for conveying best evidence summaries

[†] Further detail related to the role of the PPIE group is provided in Chapter 4.

to professional and lay audiences (see *Figure 3-2*).[168] The quality assessment was taken from five previous systematic reviews, the majority of which used the GRADE system of quality assessment.[1,95,96,133,169] The GRADE system provides a clear and succinct summary of research evidence quality.[170] This was used in combination with the evidence flower to provide our stakeholders with a simple visual interpretation of the evidence supporting each treatment option, to ensure that those unaccustomed to reading research documents could understand the evidence. A narrative literature review was also included for those interested in further details about the evidence used (see Appendix 3.7). A comprehensive list of papers was included in the review using systematic search results from a concurrent project (development of a Core Outcome Set for LET), supplemented by hand-searching of paper references.[42]

3.4.3 Data collection

The purpose of the first meeting was to determine the broad types of treatment to include. During the first meeting participants were asked: 'Which treatments should be included in the optimised physiotherapy treatment package for people with LET?' They were also asked to consider the evidence presented in the summary documents, whether there were any other treatments that were not in the summary and if any treatments were not feasible for use in their specific UK NHS context. After silent generation of ideas and group discussion, an anonymous vote was conducted using an online voting platform (www.mentimeter.com) with answers only revealed once everyone had voted. Participants were asked to signal "yes" or "no" for the inclusion of individual treatment types in the optimised physiotherapy treatment package. The Outcome Measures in Rheumatology (OMERACT) handbook was used to determine the thresholds for agreement.[171] The OMERACT thresholds have been used in similar areas of research, including consensus projects for clinical terminology in tendinopathy research, tendinopathy Core Outcome Sets and clinical practice guidelines for rotator cuff tendinopathy.[2,40,43,172] Ratings were averaged across the group, and those with ≥70% agreement were included. Those with less than 30% agreement were excluded. Treatment types with 30-

69% agreement were discussed further, followed by a second round of voting, to allow for changes of opinion, with those not reaching 70% agreement excluded after the second vote. Finally, the agreed treatment types were anonymously ranked by participants in order of importance using the Mentimeter online platform.

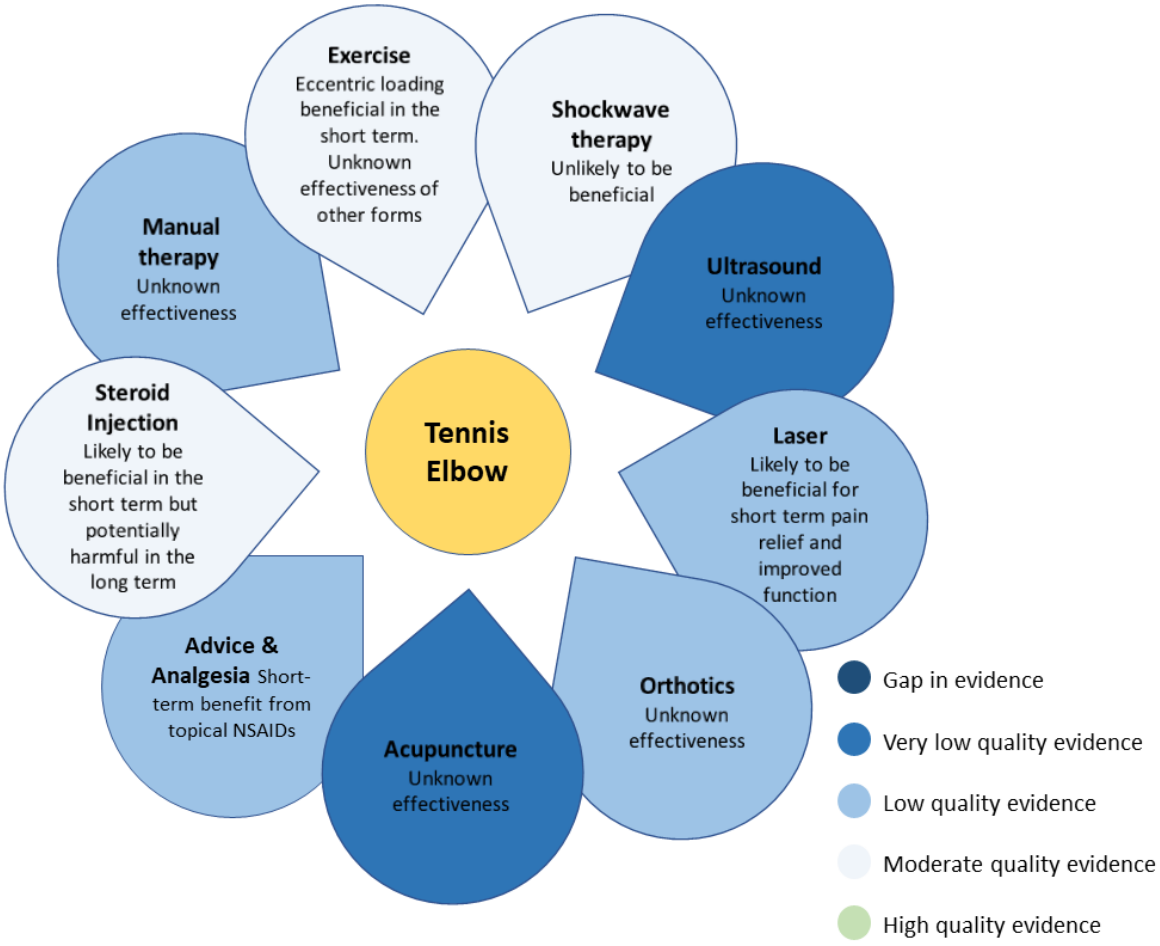


Figure 3-2: An evidence flower summary of the scientific evidence for the full range of physiotherapy treatments available for people with LET, provided to participants prior to NGT meeting 1.

3.4.4 Refinement of the intervention

The purpose of the second NGT meeting was to reach consensus on the key components of the treatment types agreed in meeting 1. Prior to the second meeting, the same participants were sent a summary of the decisions made in the first meeting along with a two-page evidence

summary of the component variables related to each of the treatment types selected (for example, the evidence of efficacy for different exercises to be included within the 'exercise therapy' treatment). Participants were also encouraged to read the more-detailed narrative literature review to gain a deeper understanding of the evidence available. The second meeting followed the same format to the first, with idea generation, discussion and voting on the individual components to be included within each of the treatment type categories. Following the agreement of the key components to be included for each treatment type, further detail related to each component was developed by the research team and the PPIE group.

3.4.5 Development of a programme theory

Following the agreement of the treatment types and their key components, a programme theory was developed by the research team. This was done reflectively using the evidence available for the included treatments (for example: where studies showed improvements in grip strength following exercise) and by incorporating mechanisms proposed by stakeholders during the NGT process where no established evidence was available. The resultant programme theory would then be used to identify relevant outcome measurement instruments that could be used in the future pilot and feasibility trial when testing the OPTimisE intervention.

3.5 Results

The consensus groups comprised 10 physiotherapists with special interest in LET (mean 18.7 years qualified, range 8-30), 2 NHS physiotherapy service managers and 3 patients (mean age 47). Two of the physiotherapists and one of the managers had also experienced LET themselves. There were 8 male participants and 7 females. One patient was unable to attend the first meeting due to illness and all participants attended the second meeting.

The treatment types proposed and discussed in meeting one were: acupuncture, advice & education, exercise therapy, hyaluronic acid injection, laser, manual therapy, orthotics, shockwave therapy, steroid injection, taping, transcutaneous electrical nerve stimulation (TENS)

and therapeutic ultrasound. 14 participants voted on whether to include these treatment types in the optimised physiotherapy treatment package, meaning 10 "yes" votes were required to exceed the 70% threshold and 5 "yes" votes required to exceed the 30% threshold. The voting results from the first round of voting are displayed in *Figure 3-3*.

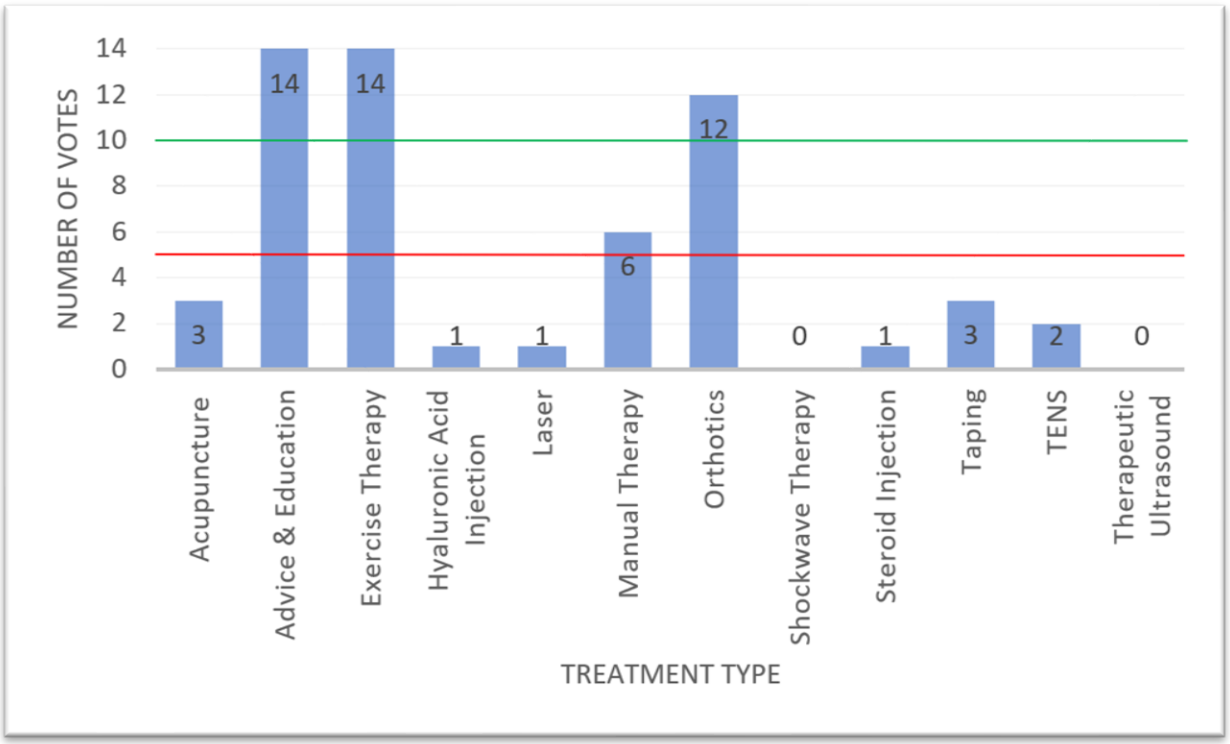


Figure 3-3: Results of the first voting round from meeting one – to decide which treatment types will be included in the optimised physiotherapy treatment package. 10 votes were required for inclusion and 5-9 votes required for further discussion and a second vote

Advice & education, exercise therapy and orthotics surpassed the 70% threshold for inclusion. Manual therapy received 43% of the vote so was discussed again. Following a second vote, the result remained the same (43%) so manual therapy was excluded. All other treatment types failed to reach the 30% threshold, so were excluded after the initial vote. The three included

treatment types were then ranked in order of perceived importance by anonymous vote, with the following outcome:

1. Advice & education
2. Exercise therapy
3. Orthotics

During the discussion stage of the NGT process, the recommendation from the physiotherapy service managers was that the intervention needed to be adaptable for online consultations, due to recent service changes resulting from the COVID-19 pandemic and future uncertainties around face-to-face consultations in the longer term; and that numbers of follow-up sessions should be minimised to improve efficiency. Patients highlighted the importance of practicality, reducing burden on the patient, and were amenable to online consultation.

In meeting two, the components of the advice & education treatment were proposed and voted upon. The voting results are shown in *Table 3-1*.

Component	Vote 1	Vote 2
Advice & Education		
Activity modification	93%	
Pacing	87%	
Promotion of self-efficacy	93%	
Basic pain science	87%	
Medication advice	80%	
Sleep advice	47%	100%
General exercise advice	80%	
Stress management advice	53%	67%
Diabetes management	67%	87%
Ergonomics for work or sport	93%	
Smoking cessation	87%	
What Tennis Elbow is	93%	
Diet advice	67%	100%
Dietary supplements	N/A	60%
Exercise therapy		
Forearm stretches	67%	80%
Spine stretches	27%	
Isometric loading	93%	
Concentric loading	93%	
Eccentric loading	100%	
Functional exercise	100%	
Shoulder girdle strengthening	67%	Grouped and re-classified as 'Shoulder girdle exercises'
Shoulder girdle stability	80%	
Shoulder girdle exercises	N/A	80%
Orthotics		
Counterforce elbow clasp	80%	
Wrist immobilisation splint	7%	
Tubular compression sleeve	13%	

Table 3-1: Voting results from meeting 2, showing the key components of each treatment category. Green = included, Amber = discussed again and re-voted, Red = excluded.

Sleep advice, diet advice, diabetes management and stress management advice failed to meet the 70% threshold but were discussed again and voted upon for a second time. During the discussion it was agreed among participants that dietary supplements were listed as a separate option for

the second vote alongside general diet advice. Following the second vote, only stress management advice and dietary supplements failed to reach the 70% threshold for inclusion, hence were excluded. The full list of agreed advice & education components was: 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, sleep advice, general diet advice, diabetes management. The ranking of these components in order of importance is displayed in *Figure 3-4*.

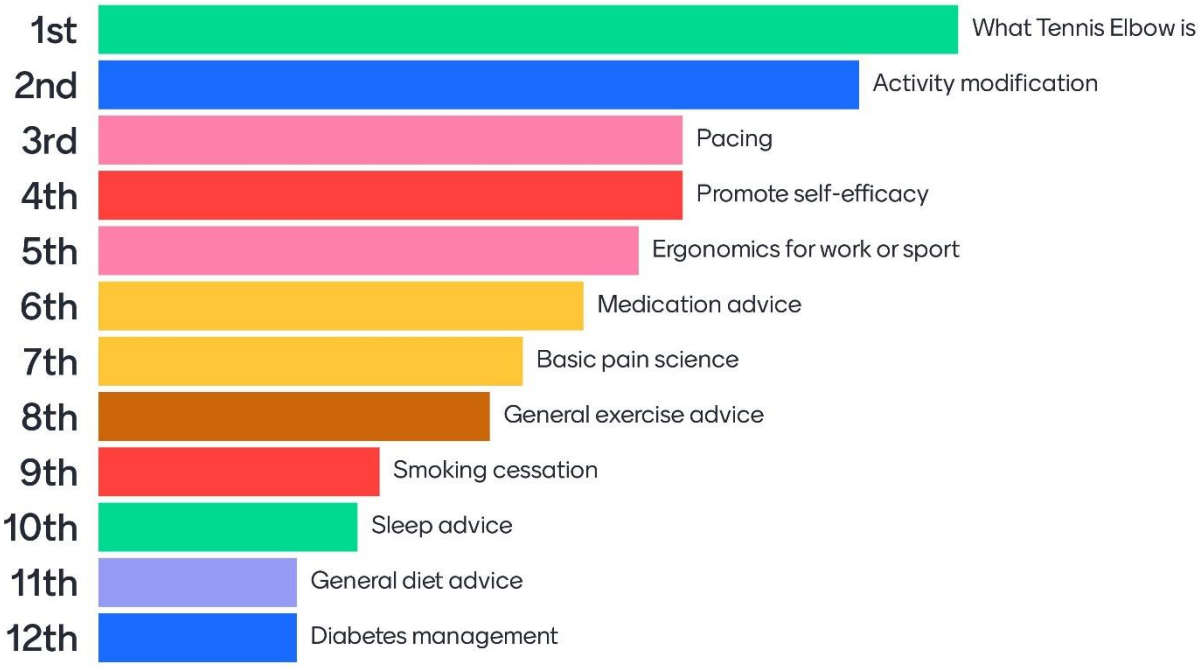


Figure 3-4: Ranking of included advice & education treatment components in order of importance.

The components proposed and voted upon for the exercise therapy treatment were: forearm stretches, spine stretches, isometric loading, concentric loading, eccentric loading, shoulder girdle strengthening, shoulder girdle stability exercise and functional exercise. Spine stretches failed to meet the 30% threshold, so were excluded. Forearm stretches and shoulder girdle strengthening were discussed a second time. It was agreed that, upon reflection, shoulder girdle strengthening and shoulder girdle stability exercises had significant overlap, so were merged into one category: shoulder girdle exercises. Both forearm stretches (80%) and shoulder girdle exercises (80%)

reached the 70% inclusion threshold in a second vote, so the final agreed components were: forearm stretches, isometric loading, concentric loading, eccentric loading, shoulder girdle exercises and functional exercise.

Two further questions were then posed to the participants regarding key components of the exercise therapy intervention:

1. Should exercises provoke pain?

2. What dose of exercise should be used?

Following discussion and voting, it was agreed that exercise should provoke pain to a level that the individual patient deems acceptable to them. Forearm stretches should be held for 30 seconds and repeated three times before and after loading exercises. Isometric exercises should be held for up to 60 seconds and repeated 5 times, once daily. Concentric and eccentric loading should be performed in three sets of 10-15 repetitions, once daily.

For the orthotic treatment, three options were proposed: a counterforce elbow clasp, a wrist immobilisation splint and a tubular compression sleeve. Following voting, the elbow clasp was included (80%) with the other two options excluded (7% and 13% respectively).

3.5.1 Proposed Logic Model

A logic model is proposed for the underpinning programme theory, describing how the content of the intervention may lead to positive treatment outcomes. This is displayed in *Figure 3-5*, with further detail provided in the discussion section (3.6.1).

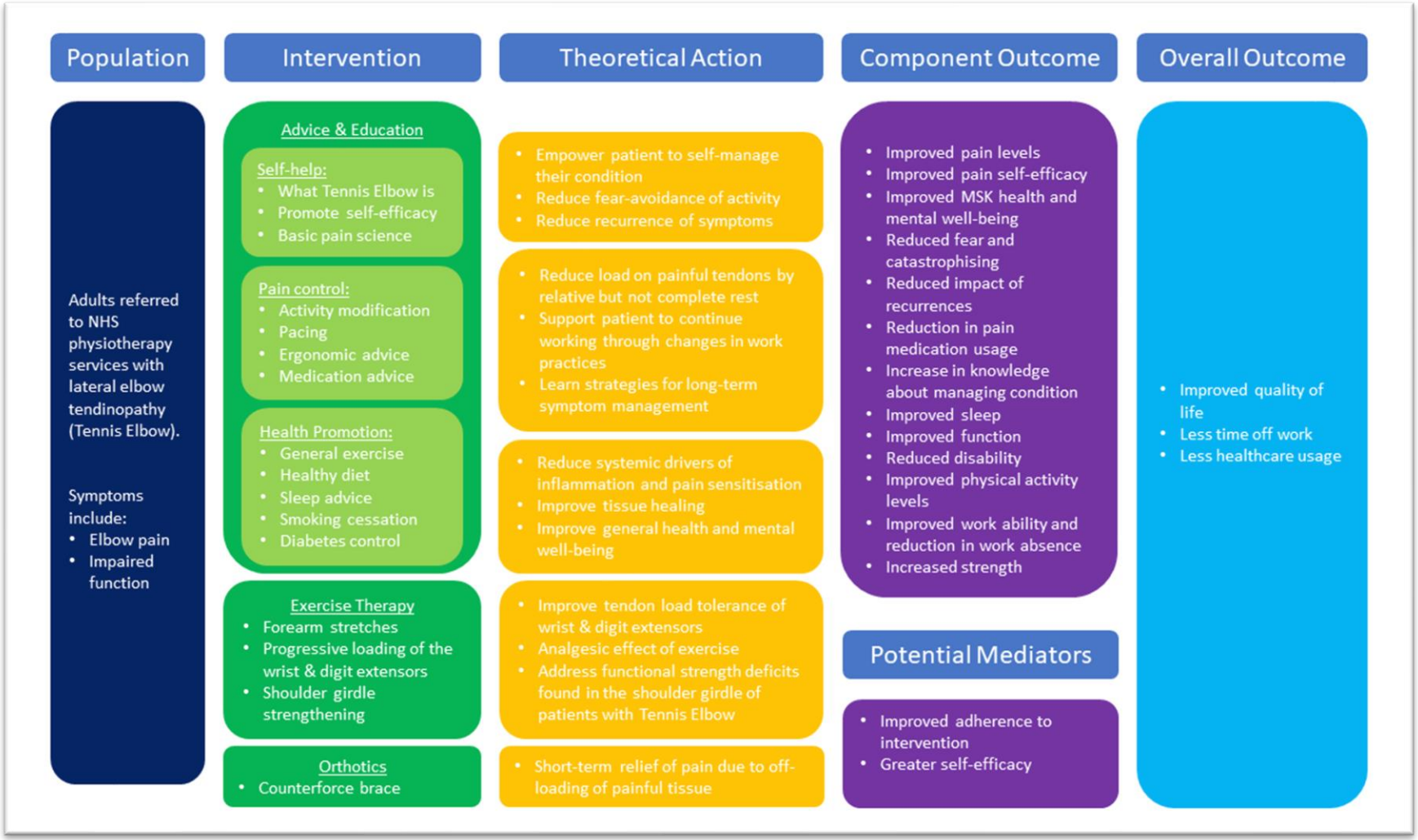


Figure 3-5: The OPTimisE intervention logic model, describing the theoretical action of the three intervention components and potential impact on treatment outcome.

3.5.2 Intervention refinement

Following the NGT process, further detailed content was developed by the research team, the OPTimisE PPIE group and international mentor Professor Bill Vicenzino, who is the most prolific author of LET research in the world. It is described in line with the TIDieR checklist for better reporting of interventions.[173] The OPTimisE Intervention Handbook (Appendix 3.8) was then written as a resource for the musculoskeletal physiotherapists delivering treatments to patients in the subsequent pilot and feasibility RCT. It contained guidance on information to provide as part of the advice and education component of the intervention, structured in order priority, based upon the rankings from the NGT consensus. There was a progressive exercise regimen with a defined dosing structure, ranging from gentle isometric exercises to high-level functional strengthening, and instruction on fitting the counterforce brace. *Figure 3-6* shows the OPTimisE intervention session map, that details how the three intervention elements should be delivered in the initial and subsequent physiotherapy treatment sessions. Follow-up appointments, to review progress, discuss advice/education topics further and review/adjust exercises, were arranged at the discretion of the physiotherapist but guidance was that appointments should be spaced at least four weeks apart, as recommended by patients during the intervention design, with no specific number of visits required. Appointments could be face-to-face, online or by telephone.

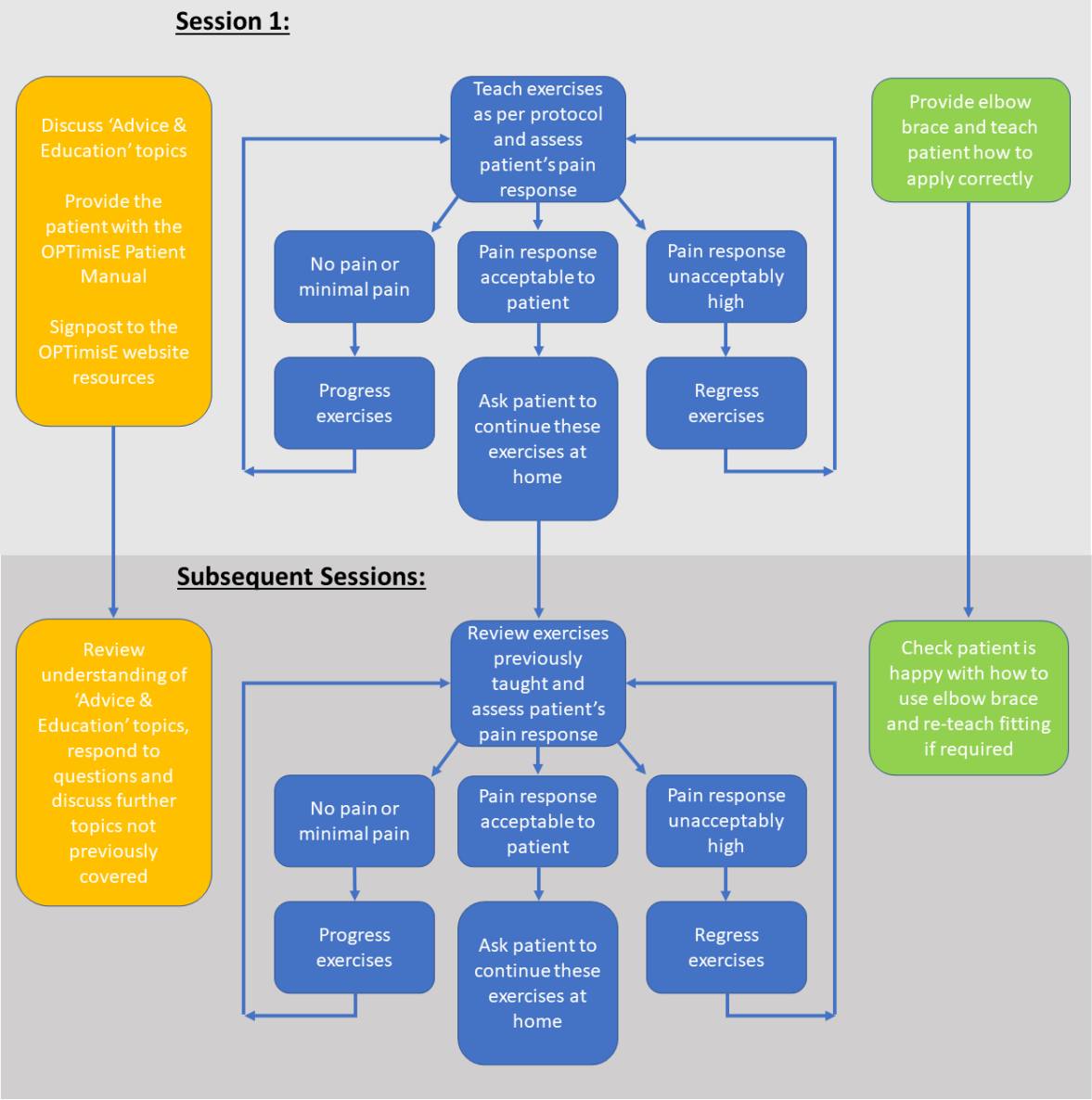


Figure 3-6: The OPTimisE intervention session map

The OPTimisE Patient Manual (Appendix 3.9) and OPTimisE website were then developed as the patient-facing resources to support the information provided by treating physiotherapists. The website resources were only accessible to patients in the OPTimisE intervention group, to avoid contamination, using the following link: https://optimise-trial.uk/patient-login and password: TennisElbow123. The advice and education topics not only related to LET but incorporated

modifiable lifestyle factors that might improve treatment response and reduce risk of recurrence (*Table 3-2*):

Condition-specific advice	**General / lifestyle factor advice**
What Tennis Elbow is	Basic pain science
Activity modification	Promotion of self-efficacy
Pacing	General exercise advice
Ergonomics for work or sport	Smoking cessation (if applicable)
Medication advice	Sleep advice
	General diet advice
	Diabetes management (if applicable)

Table 3-2: The advice and education topics included in the optimised physiotherapy treatment

The OPTimisE Patient Manual and website also provided patients with written and videographic advice and education, plus links to further NHS website resources on smoking cessation, healthy eating, general exercise, sleep, healthy lifestyle and management of chronic pain. The OPTimisE PPIE group provided a list of 'frequently asked questions' that were then answered by the research team and published on the website.

The exercise therapy component consisted of a progressive regimen incorporating stretching, isometric loading, concentric loading and eccentric loading designed to be adaptable to individual patient's functional demands. Dosage was clearly defined based upon best evidence and a novel aspect was that patients were encouraged to exercise into levels of pain deemed acceptable by the individual patient. Painful exercise has been avoided in the interventions tested in the majority of LET trials to date, but recent systematic review evidence from the fields of back pain, shoulder pain and heel pain trials suggests it may offer improved short term pain relief over pain-free exercise.[143] Written instructions and demonstration photographs were provided in the OPTimisE Patient Manual, with videographic demonstrations available on the OPTimisE website secure patient portal.

The choice of counterforce brace was made by three volunteers from the PPIE group. The volunteers inspected and tested a range of available brands/models, taking into account symptom relief when gripping, general comfort and practicality (e.g. if it was washable and if it could be worn under long-sleeved clothing). The EPI-HiT® Classic was chosen as the preferred type.

3.6 Discussion

An optimised physiotherapist-led treatment package for people with LET was successfully developed using an NGT consensus approach. The agreed intervention consists of a) advice & education related to both the condition and wider health-related issues, b) progressive exercise therapy, and c) the provision of an elbow clasp splint. Acupuncture, hyaluronic acid injection, laser therapy, manual therapy, shockwave therapy, corticosteroid injection, taping, TENS and therapeutic ultrasound were excluded.

The NGT consensus approach was easily adapted from the traditional face-to-face format to an online video-conference format without the need for any bespoke software. The online method had the advantage that participants did not have to travel to meetings, allowing for inclusion of a geographically diverse group. A potential disadvantage is that some potential participants could have been put off by the technical aspects of joining a meeting online, or lacked the necessary devices, computer skills or internet connectivity.

This study involved a range of different stakeholders (i.e. physiotherapists and physiotherapy service managers) that would be involved in future roll-out of the proposed intervention and also patients who would stand to benefit from it. It is hoped that this stakeholder involvement will make the agreed optimised physiotherapy treatment package deliverable in a real-life clinical situation. The decision-making process was largely influenced by the scientific evidence, with all of the physiotherapist stakeholders stating that they had read the full evidence review prior to the first meeting, however, the other stakeholders were influential especially when the evidence

was equivocal. Indeed, the input from the physiotherapy service managers shaped the intervention to ensure that all of the elements could be provided via remote online or telephone consultation, should the need arise. Following the result of the first vote in deciding the treatment types to be included, manual therapy was undecided and was discussed again. Some clinicians argued in favour, due to the short-term pain relief that can be achieved with manual therapy, but both the managers and the patients argued against, due to the costs involved with delivering multiple sessions of manual therapy and the burden on the patient of having to attend frequently to receive it. As a result, manual therapy was excluded following a second vote.

The creative nature of the silent generation phase of the NGT process allowed for ideas regarding the advice and education components that differed from previous LET trials. Several trials have included patient education and advice, consisting of explanations of what LET was, reassurance, ergonomic advice, activity modification and medication advice.[22,47-49] None, to date, have considered a more holistic approach to health that was reflected in our results, including advice regarding general exercise, smoking cessation, diet advice, sleep, diabetes management and pain science. This has the potential to improve a patient's overall health alongside influencing the outcome of their LET symptoms.

The components proposed for the exercise therapy intervention were largely in line with previous research evidence, including stretching and strengthening exercises for the wrist and forearm extensors, as described in Chapter 1 and as recommended by the NICE clinical knowledge summary.[44] An exception to this was stretching of the cervical and thoracic spine, proposed by four physiotherapists based on their clinical experience, in the absence of any research evidence, but this did not receive sufficient votes for inclusion or further discussion. Forearm stretches were a topic of debate after receiving 67% of the initial vote. Numerous studies have included forearm stretches as part of an exercise therapy intervention alongside strengthening exercises, making it impossible to assess the efficacy of the stretches alone. Only one, three-armed RCT of

94 patients, has compared forearm stretches against the addition of either eccentric strengthening or concentric strengthening.[136] Outcomes were measured at six weeks, with similar effectiveness across all groups. This evidence, along with testimony from two of the participating patients of the immediate pain-relieving effect of forearm stretches, resulted in a change of opinion for the second vote (80%) and inclusion in the exercise therapy treatment.

For the initial exercise therapy vote, shoulder girdle stability exercises had been proposed as well as shoulder girdle strengthening exercises. Following further discussion regarding the details of what participants understood/meant by the two different terms, this resulted in an agreement that there was overlap across the categories and that, overall, a more generic description 'shoulder girdle exercises' should be used and included in the exercise therapy treatment. This was largely based upon evidence that people with LET have been found to have reduced strength of the shoulder girdle muscles compared to the contra-lateral arm.[17]

It was agreed that the exercise therapy component should be a progressive regimen including a range of exercises to suit patients at different stages of the condition or symptom severity. Previous studies had focussed on a single exercise type, e.g. isometric loading, finding a plateauing of improvement over time, whereas combined regimens appeared more effective.[49,123] By including a progressive regimen, the aim was to avoid this plateau effect and allow patients to return to their normal level of function.

In a departure from the majority of previous LET studies, this consensus group voted unanimously to include exercises that provoke pain. With the exception of the Stasinopoulos protocol[65], that permits exercise into mild pain below 4/10 on a numerical rating scale, all other trials of exercise for people with LET have stated that exercises should be pain-free. Pain-related fear can result in higher perceived pain levels due to stress, so an exercise approach that focusses on avoiding pain may exacerbate this response.[144] Features of sensitisation, such as this hyperalgesia, are a common feature in patients with LET, as identified by 10 studies included in a recent systematic

review.[145] Pain-related fear was recognised as an important factor in this intervention development by all participants as it could be a mediating variable in the effectiveness of the exercise therapy component. The initial vote was split (47:53%) as to whether to limit pain during exercise to the 4/10 level or let the patient decide how much pain was acceptable to them, but following further discussion influenced by the patient participants the final vote rested in favour of pain to a level that the patient deems acceptable (80%).

The choice of dose for the different exercise types included was largely justified upon clinicians' experience and precedents from particular trials. A systematic review of different types of resistance exercises used to treat people with LET, from 2012, found heterogeneity in the dose of exercise prescribed, with no recommendation possible regarding the optimum dose.[117] A subsequent systematic review, from 2020, focussed just on studies of eccentric loading exercises and recommended that three sets of 10-15 exercises be performed daily, for a minimum of six weeks.[133] This dose was agreed by the consensus group for both eccentric and concentric exercises. The dosing of forearm stretches and isometric exercises was chosen based upon what the physiotherapists deemed most pragmatic and the patients deemed most practical/acceptable from examples taken from previous studies showing evidence of efficacy. The agreed dose for forearm stretches was a 30-second stretch performed three times, before and after loading exercises (isometric/concentric or eccentric) as used in the Stasinopoulos protocol.[65] The agreed dose for isometric exercises was maximal resistance, held for 60 seconds and repeated five times, as used by Barratt et al.[141] Two other dosing regimens were considered but the dose prescribed by Park et al[132], of 50 repetitions of 10 second holds, four times per day was considered too burdensome, and contractions based upon percentage of maximum voluntary contraction from 20% increasing up to 35%, used by Vuvan et al[49], too complicated.

For the orthotic treatment, the decision was between a wrist immobilisation splint, a counterforce elbow clasp or an elasticated elbow sleeve. The latter was proposed as a cheap

alternative but due to a lack of trial evidence to support its use was excluded with just 13% of the vote. The evidence would suggest similar levels of efficacy between wrist immobilisation splints and counterforce elbow clasps.[79-81] The practicality of such devices was discussed with the counterforce elbow clasps the clear favourite (80%). Reasons given were that wrist immobiliser splints would easily become dirty or wet during work or daily tasks and that elbow clasps were simpler to provide and stock, as they are universal in terms of fitting the left or right arm and have fewer sizing options than wrist immobilisation splints.

3.6.1 Programme theory

The advice and education component of the intervention involves three elements: self-help, pain control and health promotion. By increasing a patient's understanding of their condition, it may help them manage their symptoms without the reliance on healthcare resources and reduce fear-avoidance behaviours that may be present, as have been identified in other fields of tendinopathy research.[174] Pain control strategies, such as activity modification, may help alleviate symptoms and lessen work absence. Health promotion advice targets the risk factors associated with LET (e.g. smoking) and risk factors for pain chronicity (e.g. poor sleep, lack of exercise), potentially influencing systemic drivers of inflammation and improving tissue healing.[14,15,175,176]

The exercise component includes forearm stretches and progressive loading exercises of the wrist extensor muscles, with evidence to suggest that this may reduce pain and improve both function and strength.[22,23,47,49,163,177] Strengthening exercises for the shoulder girdle are included, to address deficits previously identified in this patient population.[17]

The counterforce orthosis is intended to provide short-term relief of symptoms during pain-provoking activities. Whilst evidence suggests that orthoses do not alter the overall outcome of treatment, they can offer short-term relief of symptoms that may promote greater adherence to the exercise component of the intervention and lessen work absence.[76,77]

The interventions in combination are intended to address the patient's needs holistically, addressing physical, psychological and social aspects related to their condition with the overall aim of improving quality of life, reducing work absence and the reliance on healthcare. The programme theory logic model is depicted in *Figure 3-5*.

3.6.2 Strengths and limitations

The main strength of this study was that a clinical trial intervention was developed using the combination of best-available research evidence and stakeholder opinion. The optimised physiotherapist-led treatment package was designed to be deliverable in the UK NHS, but could be adapted to suit other healthcare systems. Other strengths were: the inclusion of multiple voting rounds to allow for discussion and change of opinion in light of new information, the use of the evidence synthesis to guide decisions based upon the evidence base, that the study used a recommended consensus approach, and that voting thresholds were consistent with established OMERACT guidelines. A limitation is that it is based upon evidence available at the time of the event and the opinions of those involved in the process. The decisions were largely based upon scientific evidence but were influenced, particularly in cases where evidence was equivocal, by each individual's experience. It must be noted also that the effectiveness of the optimised physiotherapist-led treatment package still needed to be assessed against usual physiotherapy care before it could be recommended for use in a clinical setting. Funding and ethical approvals were in place to test this in a feasibility trial involving 50 participants and will be reported in Chapter 4.

3.7 Conclusion

This study successfully developed an optimised physiotherapist-led treatment package for people with LET, that was considered feasible by stakeholders and adaptable for use in online consultations, if required. It included advice & education related to the condition and the patient's general health, progressive exercise therapy that provokes a pain response, and the

provision of an elbow orthosis. This intervention was now ready for testing in a future pilot randomised controlled trial to contribute much needed evidence about the treatment of LET.

Chapter 4 The OPTimisE Pilot & Feasibility Randomised Controlled Trial - Quantitative Element

This chapter describes the mixed-methods pilot and feasibility randomised controlled trial (RCT) comparing the OPTimisE intervention against usual physiotherapy treatment. Whilst the qualitative element is mentioned briefly in this chapter, full detail in provided in Chapter 5. Chapter 6 will then bring together the quantitative and qualitative elements to form the mixed-methods discussion.

4.1 Context:

The OPTimisE intervention was designed in consultation with patients and clinicians to reflect the current evidence base in a way that could be implemented into real-world clinical practice. We combined research evidence with the opinions of patients, physiotherapists with a special interest in LET and physiotherapy service managers, to form a consensus on what the intervention should comprise.[178] The OPTimisE intervention consists of three elements: condition-specific and general health advice that addresses modifiable risk factors, supported by high-quality printed and online resources; an exercise regimen that empowers the patient to progress or regress their rehabilitation based upon limits of pain deemed acceptable by individual patients; and the provision of a counterforce orthosis.[178]

Building from the findings in Chapter 3, the intervention was ready to be tested in order to determine the feasibility of conducting a future, fully-powered randomised controlled trial that would evaluate the clinical and cost-effectiveness of the OPTimisE intervention versus usual physiotherapy treatment.

4.2 Aims and Objectives

The primary aim was to determine feasibility (criteria shown in *Table 4-1*) with reference to the following objectives:

- Consent rate (number consented from those eligible after screening for inclusion/exclusion criteria)
- Intervention fidelity in the intervention group (measured as a binary outcome if participants were given the orthosis, taught the progressive exercise regimen and received advice/education on a minimum of 6 of the 12 specified topics)
- Attendance rate in the intervention group (number of physiotherapy appointments attended from the total appointments booked)
- Outcome measure completion rate at six months post-randomisation

Criteria:	Do not proceed	Proceed with changes	Proceed
Consent rate	<10%	10-25%	≥25%
Fidelity to intervention	<30%	30-60%	≥60%
Attendance rate	<60%	60-70%	≥70%
Outcome measure completion rate	<60%	60-70%	≥70%

Table 4-1: Feasibility criteria for a future main trial

Recruitment feasibility of 25% was selected based upon 50 patients being recruited from 200 patients referred per year – data that the three sites had provided from historic referral patterns. The fidelity criterion was determined by the research team as no precedent has been set. Attendance rate of 70% was set based upon previously published data for physiotherapy outpatient attendance.[179] Outcome measure completion rate of 70% was based upon the TATE trial, a UK physiotherapy trial for LET, that had 69% data returns.[180]

The secondary aims were to assess:

- Outcome measure completion rate at 6 weeks and 12 weeks post-randomisation

- Completion of a grip-strength physical measure at two time points using the Squegg device
- Patient-reported outcome measures (PROMs) at baseline, 6 weeks, 12 weeks and 6 months post-randomisation (analysed descriptively)
- Responsiveness to change analysis of individual PROMs questionnaires compared with patient perceived overall treatment effect, to determine the most appropriate PROMs for a future trial
- Adherence to exercise therapy treatment (measured using a self-reported exercise diary and Exercise Adherence Rating Scale (EARS))[181]
- Acceptability of the optimised physiotherapy treatment package and trial processes, investigated through the nested qualitative study

4.3 Method

4.3.1 Trial design

A parallel two-arm, multi-centre pilot and feasibility randomised controlled trial across three sites was conducted. Recruitment took place between September 2021 and August 2022. The findings are reported following the CONSORT Pilot Trial Checklist.[182]

4.3.2 Study setting

The study was conducted at three National Health Service (NHS) sites in England providing outpatient musculoskeletal physiotherapy for adult patients with Tennis Elbow. Sites were chosen based upon clinic size (small: Royal Orthopaedic Hospital, Birmingham; medium: London Road Community Hospital, Derby; large: Physioworks, Sheffield) to reflect the variations nationally, in readiness for a future main trial.

4.3.3 Participants

Two methods of participant identification were used to determine which was the most efficient method:

a) by screening all patient referrals for elbow pain at one of three NHS physiotherapy sites, in either Birmingham, Derby or Sheffield. Prior to attendance in the physiotherapy clinic, all patient referrals were screened by a physiotherapist, as per normal practice, and those patients who were potentially eligible were sent a patient information sheet (PIS) (see Appendix 4.1). The physiotherapist then telephoned the patient (typically 1-2 weeks later) to discuss the trial, check eligibility and book an appointment for clinical assessment screening with a research physiotherapist, if they were interested in taking part.

b) by screening the SNOMED CT NHS database for patients in those three catchment areas with a diagnostic coding of Tennis Elbow in primary care within the last 3 months. Potentially eligible patients were identified from the SNOMED CT database by a member of staff at participating GP practices in the locality. They were sent a PIS by post along with a screening questionnaire and letter of introduction by the practice administrator. If interested and meeting the screening criteria they were invited to contact the research team via the OPTimisE Trial website (https://optimise-trial.uk). The Principal Investigator (PI) at the local trial site and their GP were then informed of their interest to participate and the GP was requested to refer the patient to physiotherapy. The PI then telephoned the patient (typically 1-2 weeks later) to discuss the trial, check eligibility and book an appointment for clinical assessment screening with a research physiotherapist.

4.3.4 Inclusion criteria

Adults aged 18 or over; physiotherapist-diagnosed LET, which included pain on palpation of the common extensor origin and on gripping; either a positive Cozen's, Mills', or Maudsley's test.[31]

4.3.5 Exclusion criteria

A recent history of significant trauma to the affected limb, e.g. a fall on an outstretched hand; previous diagnosis of inflammatory arthritis or gout; previous diagnosis of osteoarthritis of the affected elbow; neurological symptoms in the affected limb correlating with onset of elbow pain, e.g. loss of sensation in the hand; co-existing neck pain and stiffness that started at a similar time to the elbow symptoms; inability to understand English or lacking capacity for informed consent; currently enrolled in another health-related research trial.

4.3.6 Recruitment

Following clinical assessment screening, patients meeting the eligibility criteria were invited to participate in the RCT and consent was gained as per Good Clinical Practice guidelines including an explanation of the condition, reassurance about receiving treatment, establishment of uncertainty as to the optimum physiotherapy treatment approach, an explanation of the study purpose, a balanced view of the two interventions, rights to withdraw and an explanation of study procedures. There was opportunity to discuss and ask questions before providing written consent via the Trial Consent Form (Appendix 4.2). Patients who declined to take part in the pilot and feasibility trial were invited to be interviewed as part of the qualitative feasibility component (described in Chapter 5). Those willing to be interviewed were required to provide written consent to be contacted in relation to the interviews.

4.3.7 Randomisation

Following consent, patients were invited to complete baseline questionnaires (Appendix 4.3) and they were then randomised via an online service (Sealed Envelope™) using 1:1 allocation in mixed blocks, stratified by site. Site stratification was used, to ensure that there was an even group allocation across each site, so that the feasibility aims regarding treatment fidelity and acceptability could be adequately assessed whilst minimising bias that could have occurred if the

allocation was skewed. Mixed blocks were utilised to reduce the predictability of the randomisation allocations and minimise selection bias.

4.3.8 Sample size

The recruitment target was 50 participants, within a maximum recruitment window of 12 months. The original funding application had planned for 60 participants, based upon the median of 30 per arm for trials with continuous outcome measures, identified in a previous review of UK pilot and feasibility trials.[183] A reduction of the sample size to 50 was a condition stipulated by the funder due to concerns regarding the deliverability of the proposed trial in the time available.

4.3.9 Interventions

Patients were randomly allocated to receive either the OPTimisE intervention, by physiotherapists specifically trained to deliver this, or usual physiotherapy care delivered by other physiotherapists not trained in the OPTimisE intervention but trained in the RCT procedures. This was done to minimise the use of the OPTimisE intervention content in the usual care group.

4.3.9.1 Usual care

Usual NHS physiotherapy was not standardised in this pragmatic study but the details of the content and number of treatments given were captured at the end of a patient's course of physiotherapy. The site PI, or delegated person at site, reviewed each patient's physiotherapy notes and completed a case report form (Appendix 4.4). Usual physiotherapy might have involved a range of different treatments including advice and education, exercise, taping, manual therapy, acupuncture, ice therapy, orthotics and massage, based upon previous studies of UK practice.[45,46] Physiotherapists providing usual care treatment had no restrictions on the treatments they could offer.

4.3.9.2 OPTimisE intervention

The OPTimisE intervention included patient advice and education, exercise therapy and provision of a counterforce brace for short term symptomatic relief, as described in Chapter 3.5.2. All

physiotherapists delivering the OPTimisE intervention received detailed in-person training at site from MB and could contact the trial team for further support if required.

4.3.10 Blinding

Due to the nature of the interventions, neither participants nor physiotherapists could be blinded. Outcome measure data were collected and analysed by the research team, who were not blinded to treatment allocation due to the mixed-methods design. On-going monthly review of quantitative data, sorted by treatment allocation, was required to inform the purposive sampling and topic guide for the concurrent qualitative interviews, so blinding was not possible. Risk of bias from non-blinding of outcome assessment was low, as treatment outcomes were not part of the primary data analysis.

4.3.11 Data collection

Once consented and prior to randomisation, participants completed a baseline set of patient-reported outcome measures (PROMs) and demographic data including age, gender, ethnicity, duration of symptoms, occupation, education level, hand dominance and comorbidities (Appendix 4.3). The PROMs contained the recommended Core Outcome Set for LET: the Patient-Rated Tennis Elbow Evaluation (PRTEE)[3], time off work (measured in days), pain-free grip-strength and a Numerical Rating Scale (NRS)[4] measuring pain on gripping.[43] In addition, the Tampa Scale of Kinesiophobia (TSK-11)[5],[184] Patient Self-Efficacy Questionnaire (PSEQ)[6],[185] maximum grip strength and Exercise Adherence Rating Scale (EARS)[7] [181] questionnaires were included, as these factors were identified in the logic model as being potential moderators or mechanisms behind any

[3] *PRTEE = Patient-Rated Tennis Elbow Evaluation, ranging from 0 (normal) to 100 (very high pain and disability). It has a minimal clinically important difference (MCID) of 11 points*
[4] *NRS = Numerical Rating Scale (0-10)*
[5] *TSK-11 = Tampa Scale of Kinesiophobia (11 question version), ranging from 11 (no kinesiophobia) to 44 (very high kinesiophobia)*
[6] *PSEQ = Patient Self-Efficacy Questionnaire, ranging from 0 (very low self-efficacy) to 60 (high self-efficacy)*
[7] *EARS = Exercise Adherence Rating Scale, ranging from 0 (very low exercise adherence) to 24 (very high)*

treatment effect. The Global Perceived Effect scale (GPE-11)[8] [186] was included as a measure of overall outcome but also for use as an anchor to assess external responsiveness of the individual questionnaires. This was done to assess the correlation between the effect of treatment and individual factors, such as kinesiophobia or patient self-efficacy, to establish whether these theoretical factors proposed in the logic model might indeed have an effect on treatment outcome. The EuroQol 5D5L[9] was also included as it would be the basis for health economic evaluation in a future main trial.[187] For the grip-strength measurements, we piloted the use of an electronic grip-measuring device (Squegg™, https://mysquegg.com) that connects to an application on the participant's smartphone or tablet. The Squegg™ is a US Food and Drug Administration approved dynamometer. We gave participants in the OPTimisE group a Squegg™ after randomisation, to capture grip-strength data at all time points. However, to ensure that usual care participants did not use it as part of their treatment, they were only sent the Squegg™ by post in advance of their final six-month follow-up questionnaire. The steer from the PPIE group was to minimise burden on patients and avoid excessive face-to-face appointments. The Squegg™ was therefore included as a means of capturing physical assessment data without the need for patients to attend in person. The OPTimisE Follow-up Questionnaire (Appendix 4.5) prompted participants to use the Squegg™ device and document three measures each of maximum grip strength and pain-free grip strength.

Participants were given the choice of receiving the OPTimisE Follow-up Questionnaire by post or online, using the Amplitude Pro-One™ system (https://amplitude-clinical.com/). They were sent questionnaires at 6-weeks, 12-weeks and 6-months post-randomisation, as shown in *Table 4-2*. Participants using the postal service were telephoned or sent reminders by email if they failed to return their questionnaires after two weeks. The Amplitude system sent automated email and

[8] *GPE-11 = Global Perceived Effect 11-point scale, ranging from -5 (very much worse) to +5 (completely better)*
[9] *EQ5D5L = EuroQol questionnaire (5 dimension, 5 level version)*

SMS text reminders to users of the online system after one and two weeks if data was not returned. The protocol was amended mid-way through the trial to allow the site PI to telephone participants who had not returned questionnaires, to collect minimum data about adverse events and the PRTEE responses. This was implemented at 6-month follow-up, due to low data returns at 6-weeks and 12-weeks. Participants in the OPTimisE intervention group were asked to complete a daily exercise diary (Appendix 4.6) to collect data about exercise adherence. The diary was a simple daily tick-sheet to record whether exercises had been performed, or not, over a 13-week period, with adherence calculated as a percentage (number of ticks/91 days x100).

Outcome Measure	Baseline	6 weeks	3 months	6 months
Numerical Rating Scale of pain on gripping	X	X	X	X
Patient rated tennis elbow evaluation PRTEE [188]	X	X	X	X
Tampa scale of kinesiophobia TSK-11 [184]	X	X	X	X
Pain self-efficacy questionnaire PSEQ [185]	X	X	X	X
EQ5D5L [187]	X	X	X	X
Pain free grip strength (lbs)	OPTimisE Group X	OPTimisE Group X	OPTimisE Group X	OPTimisE Group X
	Usual Care Group X	Usual Care Group	Usual Care Group	Usual Care Group X
Maximum grip strength (lbs)	OPTimisE Group X	OPTimisE Group X	OPTimisE Group X	OPTimisE Group X
	Usual Care Group X	Usual Care Group	Usual Care Group	Usual Care Group X
Global Perceived Effect GPE-11 [186]		X	X	X
Exercise adherence rating scale EARS [181]		X	X	X

Table 4-2: Outcome measures and time-points for data collection (denoted by X).

4.3.12 Treatment fidelity

Fidelity of the optimised physiotherapy intervention was measured retrospectively by reviewing clinical report form data (Appendix 4.7) to establish whether the treatments provided matched the pre-defined protocol. Fidelity was calculated as a percentage based upon the number of participants in the OPTimisE group receiving the full intervention package. This was defined as receiving a progressive exercise regimen, a minimum of six of the advice and education topics and a counterforce brace. Similarly, CRF data were used to review the treatment of patients receiving usual physiotherapy (Appendix 4.4) to assess for key differences and similarities between the interventions and determine whether there was contamination between the interventions. Adherence to treatment was measured in both treatment arms using a patient-reported exercise diary that was reviewed by the treating physiotherapist at each session and returned to the Chief Investigator by the patient after 3 months, via a stamped addressed envelope. Additionally the 6-week, 3- and 6-month outcome questionnaires included the Exercise Adherence Rating Scale.[181] Participants received a £20 voucher after completing the study questionnaires at 6 months.

4.3.13 Quantitative Data analysis

Descriptive statistics were used to summarise the distribution of baseline variables across each of the randomisation groups. The continuous baseline variables (e.g. age) were reported with means and 95% confidence intervals (95% CI), if shown to be normally distributed, otherwise were reported with medians and Interquartile Ranges (IQR). The categorical variables (e.g. gender) were reported with frequencies & percentages. Similarly, we analysed data descriptively to explore the outcome measure scores in the intervention and control groups at baseline and follow-up, to explore changes in LET health status over time. The study was not powered for analysis of results between groups. We also assessed external responsiveness to change of patient-reported outcome measures using Spearman's rank correlation, with GPE-11 scores as the anchor. SPSS Statistics software (version 27) was used for the analysis.

4.3.14 Safety

All Adverse Events (AEs) and Serious Adverse Events (SAEs) were recorded and reviewed from the time of written informed consent until six months following the first intervention.

All AEs and SAEs occurring during the duration of the study were recorded by the site PI and sent to the Chief Investigator within 48 hours for review.

4.3.15 Data Management

Data were collected using a mix of paper and electronic methods. Where possible a patient ID number was used rather than identifiable information. Data from paper forms were transcribed into an electronic database in Microsoft Excel stored on secure NHS servers. Paper hard copies were stored at Derby CTSU and in the relevant Investigator Site Files (ISF). Study documentation was stored securely to maintain participant confidentiality and study data integrity.

Electronic data captured at trial sites was uploaded to a secure electronic ISF on Microsoft Sharepoint. Online outcome data collection was managed by Amplitude Clinical in ISO27001 Tier 3+ data centres approved for use by the NHS.

4.3.16 Approvals:

Approvals were received from the Yorkshire & The Humber - Sheffield Research Ethics Committee (Appendix 4.8) and the UK Health Research Authority (Appendix 4.9) on 22nd June 2021.

4.3.17 Trial registration:

OPTimisE was registered with the ISRCTN database on 19th July 2021.

https://www.isrctn.com/ISRCTN64444585

4.3.18 Patient and Public Involvement and Engagement:

The OPTimisE PPIE group was established prior to commencement of this PhD, at the funding application stage. The group comprised of eight people who had experienced LET themselves and had volunteered after reading advertisements at University Hospitals of Derby & Burton NHS

Foundation Trust or on social media. The group were involved with the design of the OPTimisE intervention, selection of the orthosis from a range of available products, generation of trial website frequently asked questions and review of trial patient-facing resources. One member, Karin Cooper, also sat on the Trial Management Group and contributed to the interpretation of the qualitative data, as well as public dissemination.

4.4 Results:

The target of 50 patients was recruited within the allocated 12-month time-period. Recruitment opened on 30th September 2021 and completed on 17th August 2022, with study closure on 3rd March 2023 after the last patient had returned their final questionnaire. Baseline data are displayed in *Table 4-3*.

SUMMARY OF BASELINE DATA		**OPTimisE Intervention** (n=24)	**Usual Care Treatment** (n=26)
Age mean (SD)		51 (9.4)	46 (8.4)
Body Mass Index median (interquartile range values)		26.30 (24.47-30.72)	26.43 (23.49-29.16)
Duration of symptoms months median (interquartile range values)		7 (4-12)	7 (4.75-12)
Gender n (%)	Male	12 (50)	16 (62)
	Female	12 (50)	10 (38)
	Other	-	-
	Preferred not to say	-	-
Ethnicity n (%)	White British	21 (88)	19 (73)
	White Other	-	2 (8)
	Mixed	-	1 (4)
	Indian	1 (4)	2 (8)
	Pakistani	-	1 (4)
	Sri Lankan	1 (4)	-
	Filipino	-	1 (4)
	Kosovar	1 (4)	-
Hand Dominance	Right	23 (96)	24 (92)

SUMMARY OF BASELINE DATA		**OPTimisE Intervention** (n=24)	**Usual Care Treatment** (n=26)
n (%)	Left	1 (4)	2 (8)
Affected Side n (%)	Right	17 (71)	17 (65)
	Left	6 (25)	9 (35)
	Bilateral	1 (4)	-
Smoking Status n (%)	Smoker	4 (17)	4 (15)
	Non-smoker	11 (46)	10 (39)
	Ex-smoker	9 (38)	11 (42)
	Occasional smoker	-	1 (4)
Questionnaire Delivery Preference n (%)	Paper	6 (25)	5 (19)
	Online	18 (75)	21 (81)

Table 4-3: Summary of Baseline Data.

The CONSORT diagram is shown in *Figure 4-1*

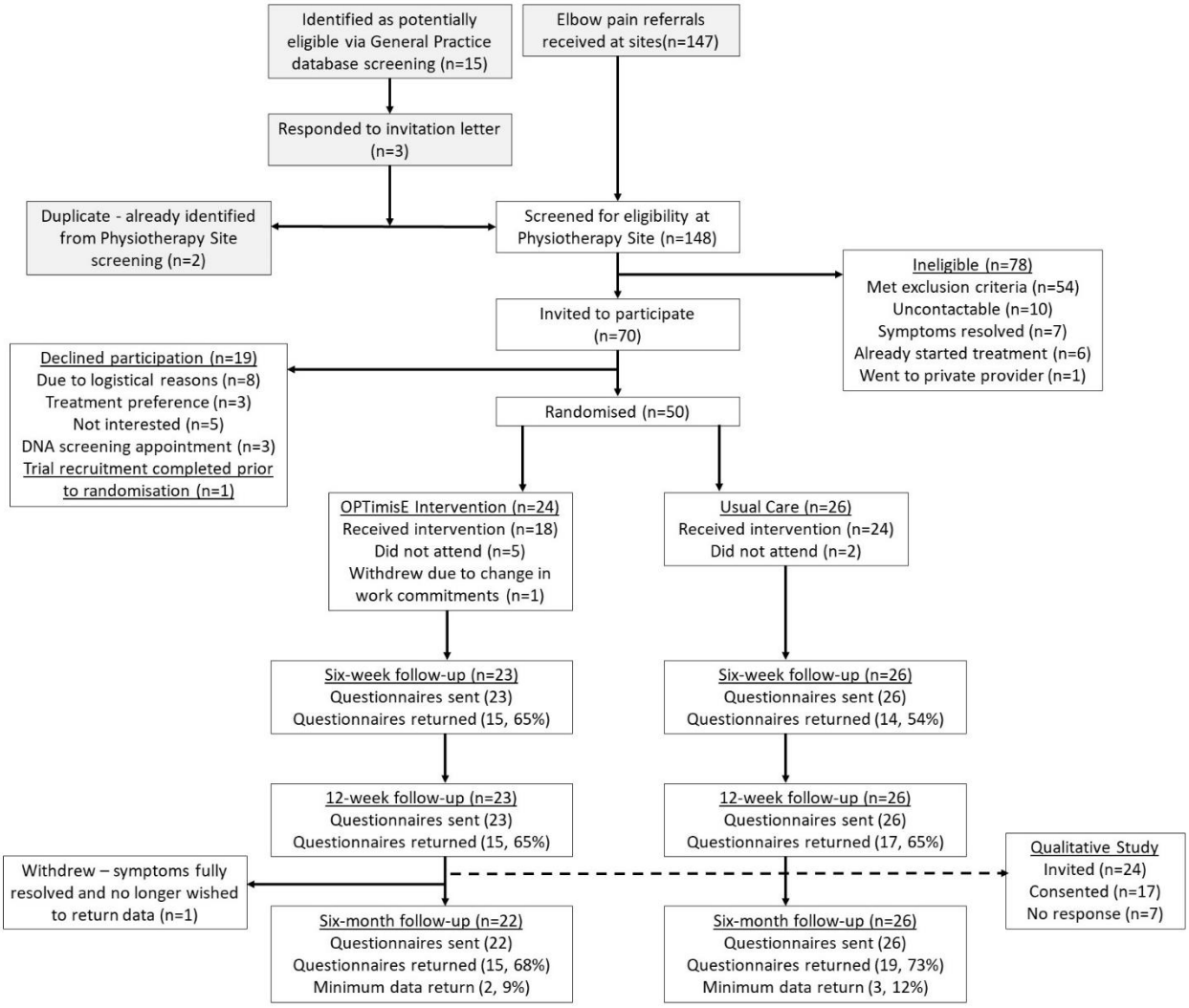


Figure 4-1: CONSORT diagram

4.4.1 Primary analysis

The target of 50 participants was met six weeks ahead of schedule (as shown in *Figure 4-2*), from a pool of 70 identified eligible participants, giving a consent rate of 71%. Two participants in the OPTimisE group subsequently withdrew: one prior to commencing treatment, due to moving away from the area because of a change of work; another after returning their 12-week questionnaire, stating that their symptoms had fully resolved but they did not wish to return the

final questionnaire. The attendance rate at all planned sessions in the OPTimisE intervention group was 82% (55 attendances from 67 booked appointments), with five participants not receiving the intervention, compared with 85% (56 attendances from 66 booked appointments) in the usual care group. Patients typically waited between 2 to 8 weeks from consent to receive their first treatment. Patients in the OPTimisE group attended a mean of 3.1 sessions, compared to 2.3 sessions in the usual care group. All participants in the OPTimisE group that attended received the intervention in full, except for two, who received the orthosis and progressive exercise but only 5 of 12 advice/education topics instead of the 6 required to satisfy the pre-defined criteria for fidelity, resulting in intervention fidelity of 89% (16/18). The secure patient portal of the website was viewed 69 times since recruitment opened, with a mean of 4 minutes and 39 seconds spent viewing the page but the technology did not permit more detailed analysis of how many of the 24 OPTimisE group patients had accessed it. Outcome measure completion, using PRTEE as the minimum data collection tool, was 81% (39/48) at six-month follow-up.

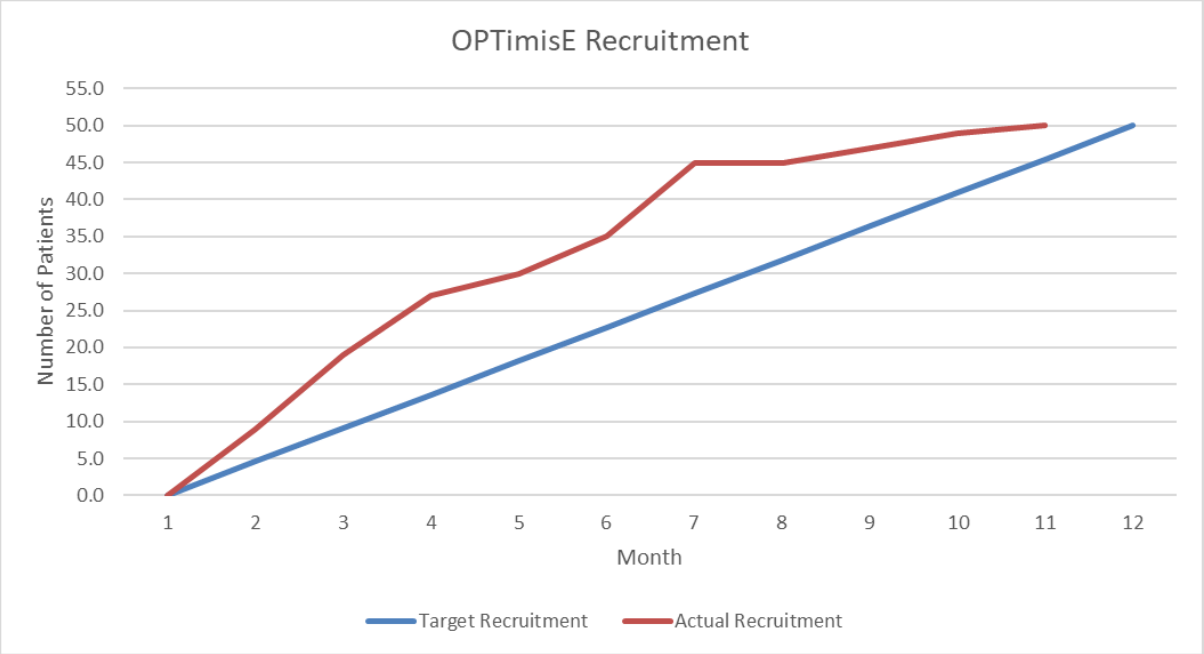


Figure 4-2: Recruitment graph

In terms of the pre-defined feasibility criteria, all the results surpassed the "proceed" criteria (see *Table 4-4* below).

Criteria:	Do not proceed	Proceed with changes	Proceed	**Results**
Consent rate	<10%	10-25%	≥25%	**71%**
Fidelity to intervention	<30%	30-60%	≥60%	**89%**
Attendance rate	<60%	60-70%	≥70%	**82%**
Outcome measure completion rate	<60%	60-70%	≥70%	**81%**

Table 4-4: The results in relation to the feasibility criteria

4.4.2 Secondary analysis

Of the two patient recruitment methods, physiotherapy referral screening provided 49 participants, whereas only 1 participant was recruited from GP record screening (having identified 15 potentially eligible people).

The outcome measure return rate at six weeks was 59% (66% online vs 36% paper); at 12 weeks was 65% (68% online vs 55% paper); at six months was 81% (28/38 online versus 5/10 paper, plus four minimum data telephone collections and two paper returns after requests from participants who had originally opted for online). 27/39 (69%) of 6-month data returns included grip-strength measurements using the Squegg™ device.

The descriptive analysis of the patient-reported outcome measures is presented in *Table 4-5*.

Secondary ANALYSIS Median (interquartile range values) Sample size n	**Baseline**		**6 weeks**		**12 weeks**		**6 months**	
	OPTimisE Group	**Usual Care Group**	**OPTimisE Group**	**Usual Care Group**	**OPTimisE Group**	**Usual Care Group**	**OPTimisE Group**	**Usual Care Group**
PRTEE	*46.25 (40.5-69.625) n=24*	*45 (36.5-62.125) n=26*	*42.5 (24-71) n=15*	*40 (17.75-55.5) n=13*	*30 (10.5-53.5) n=15*	*20.5 (10.25-59.75) n=17*	*12.5 (5.5-37.25) n=17*	*8.5 (3-27.625) n=22*
% Achieving MCID on PRTEE	-	-	-	-	*7/15 (47%)*	*9/17 (53%)*	*12/17 (71%)*	*20/22 (91%)*
Pain on gripping (NRS)	*6.50 (4.25-8) n=24*	*7 (4-7.25) n=26*	*5 (4-8) n=15*	*5 (2.75-6.5) n=14*	*4 (1-6) n=15*	*4 (1.5-6) n=17*	*2 (1-3.75) n=16*	*2 (1-3.5) n=21*
GPE-11	-	-	*1 (0-2) n=15*	*0 (-0.5-2.5) n=13*	*2 (1-4) n=15*	*1 (0-4) n=17*	*3 (1.25-5) n=16*	*4 (1-5) n=20*
% Scoring +4 or +5 on GPE-11	-	-	-	-	*4/15 (27%)*	*6/17 (35%)*	*7/16 (44%)*	*12/20 (60%)*
TSK-11	*25.5 (19.5-28.75) n=24*	*25.5 (22-31) n=26*	*23 (19-27) n=15*	*25 (20-28.5) n=13*	*19 (17-25) n=15*	*24 (19-27) n=17*	*19 (14-25.25) n=14*	*20 (16-26) n=19*
PSEQ	*41.5 (37-53) n=24*	*38.5 (31.25-48.25) n=26*	*51 (36-59) n=15*	*45 (41-55.5) n=13*	*52 (48-59) n=15*	*47 (30-59.5) n=17*	*56 (47.5-60) n=13*	*56 (37-60) n=19*
EQ5D5L index	*.800 (.570-.864) n=24*	*.806 (.717-.866) n=26*	*.768 (.624-.837) n=15*	*.768 (.579-.816) n=13*	*.795 (.736-.837) n=15*	*.706 (.535-.816) n=17*	*.795 (.704-.888) n=13*	*.837 (.704-1.000) n=19*
EQ5D5L Health status	*80 (71.25-90) n=24*	*77.5 (63.75-81.25) n=26*	*84 (79-90) n=15*	*75 (62-81) n=13*	*89 (70-94) n=15*	*78 (69-89.5) n=17*	*89 (74.5-91.5) n=13*	*89 (70-90) n=19*

Secondary ANALYSIS Median (interquartile range values) Sample size n	**Baseline**		**6 weeks**		**12 weeks**		**6 months**	
	OPTimisE Group	**Usual Care Group**	**OPTimisE Group**	**Usual Care Group**	**OPTimisE Group**	**Usual Care Group**	**OPTimisE Group**	**Usual Care Group**
EARS	*-*	*-*	*15.5* *(12-22.5)* *n=14*	*19* *(16-24)* *n=13*	*15.5* *(9.5-21.5)* *n=14*	*16* *(12-20.75)* *n=16*	*13* *(8-21)* *n=13*	*16* *(12-23)* *n=19*
Pain free grip-strength (lbs)	*25* *(15-39)* *n=24*	*27* *(20-48)* *n=26*	*39* *(34-58)* *n=13*	*-*	*44* *(34-55)* *n=13*	*-*	*44* *(32-58)* *n=11*	*44* *(27-54)* *n=16*
Maximum grip-strength (lbs)	*48* *(36-58)* *n=24*	*50* *(40-59)* *n=26*	*52* *(43-64)* *n=12*	*-*	*52* *(47-62)* *n=13*	*-*	*52* *(40-65)* *n=11*	*52* *(43-57)* *n=16*
Time off work (days)	*0* *(0-0)* *n=24*	*0* *(0-0)* *n=26*	*0* *(0-0)* *n=14*	*0* *(0-0)* *n=13*	*0* *(0-0)* *n=12*	*0* *(0-0)* *n=16*	*0* *(0-0)* *n=15*	*0* *(0-0)* *n=19*

Table 4-5: Descriptive analysis of patient-reported outcome measures.

The external responsiveness of individual outcome measures, correlated against the GPE-11 anchor, is displayed in *Table 4-6*. The PRTEE and NRS for pain on gripping demonstrated the highest correlation with perceived treatment effect at both 12-week and six-month follow-up. Only four participants reported taking time off work at baseline and only one at six-month follow-up, so this domain was not analysed due to lack of data.

	12 weeks	**6 months**
PRTEE	-0.800 (p<0.001)	-0.839 (p<0.001)
NRS: Pain on gripping	-0.781 (p<0.001)	-0.852 (p<0.001)
TSK-11	-0.516 (p=0.002)	-0.540 (p=0.001)
PSEQ	0.673 (p<0.001)	0.714 (p<0.001)
EQ5D5L (index)	0.583 (p<0.001)	0.691 (p<0.001)
EQ5D5L (health status)	0.544 (p=0.001)	0.366 (p=0.040)
Pain Free Grip-strength		0.499 (p=0.008)
Maximum Grip-strength		0.410 (p=0.034)

Table 4-6: External responsiveness of outcome measures to GPE-11 anchor.

Exercise adherence score (median (IQR values)), measured using the EARS questionnaire, at 12 weeks was 15.5 (9.5-21.5) in the OPTimisE group compared to 16 (12-20.75) in the usual care group; at six months 13 (8-21) and 16 (12-23) respectively. Only 6/18 (33%) participants who received the OPTimisE intervention returned their exercise diaries, reporting median adherence of 81% (IQR 74-93).

The review of clinical report forms from the usual care group showed that all patients received basic advice about LET and were taught exercises. Few were provided with advice related to lifestyle factors or modifiable risk factors. Exercises often lacked a clear dosing strategy or progression. Three patients received manual therapy treatment from their physiotherapist, and one was taught to perform self-administered manual therapy. No patients were provided with an

orthosis, although two patients requested advice on how to fit orthoses that they had previously purchased themselves. Further information regarding the differences between the OPTimisE and usual care groups is provided in the qualitative study (see Chapter 5).

No related adverse events were reported. One participant was involved in a road traffic collision during their period of treatment. They did not sustain serious injuries and were able to continue their trial participation.

4.5 Discussion

The results suggested that it was feasible to conduct a full-scale trial to compare the clinical and cost-effectiveness of the OPTimisE intervention compared with usual NHS physiotherapy care. The trial successfully recruited to target ahead of schedule, but the number of eligible patients identified was lower than that was predicted based upon site referral data at the planning stage of the project. This was offset by consent rates being far greater (71%) than the conservative feasibility target (25%) set *a priori*. The low eligibility numbers may have been in part due to the COVID-19 pandemic and also that due to the rollout of FCP services across the English healthcare system. The attendance rate at all planned sessions in the OPTimisE intervention group was 82% (55/67 sessions), with five participants not receiving the intervention. This compared to 85% (56/66 sessions) in the usual care group, with two participants not receiving any treatment. It is possible that those who did not attend were dissatisfied with their group allocation resulting in their non-attendance. Alternatively, the wait of 2 to 8 weeks from consent to receiving their first treatment might have been a factor.

In terms of fidelity, the OPTimisE intervention was delivered as intended to the majority of patients (89%). The pre-defined quantitative criteria for fidelity were binary (i.e. fidelity was achieved or not) but in two cases, fidelity was not achieved because physiotherapists only delivered five of the twelve advice/education topics instead of the six required to satisfy the

fidelity criteria. The other remaining criteria, related to exercise prescription and provision of the counterforce brace, were all satisfied.

Of the two patient identification methods, the screening of referrals at physiotherapy clinics was most successful, accounting for 49/50 patients recruited. The database screening at GP practices only generated three expressions of interest, with two of those already identified from referral screening, so this method is unlikely to be worthwhile within a future main trial.

Questionnaire returns were low at six-week follow-up (59%). The follow-up questionnaires were sent at time points determined from the date of randomisation. Some patient participants may not have returned the questionnaire because they had not yet started treatment or only recently started treatment at the time the questionnaire was sent, due to waiting times for initial physiotherapy appointments. Returns increased by 12-week follow-up to 65% but did not meet the feasibility threshold. A protocol amendment was introduced to allow telephone reminders and minimum data collection at this stage which, coupled with the pre-agreed £20 voucher incentive for six-month data return, resulted in an 81% response, surpassing the feasibility threshold.

When the responsiveness of the different PROMs included was examined, the PRTEE measure of function and NRS for pain on gripping showed the highest correlation with patient perceived overall treatment effect. The PRTEE is the recommended primary outcome measure in the Core Outcome Set for LET and the NRS for pain on gripping is recommended for interim use, pending psychometric evaluation.[43] The findings suggest that it has similar external responsiveness to the PRTEE and therefore would be an appropriate way to monitor treatment effect. Two psychological measures were included: the TSK-11 measure of fear of movement and PSEQ questionnaire to capture pain self-efficacy, finding that the PSEQ was more highly correlated with treatment outcome. Similarly, both pain-free grip-strength and maximum grip-strength were included but the former was more highly correlated with treatment outcome. This is consistent

with previous studies comparing the two methods.[189] Therefore, the TSK-11 and maximum grip-strength measures could be removed from a future main trial.

A method of grip-strength self-measurement using the Squegg™ device was successfully piloted. Grip-strength data were provided in 77% of questionnaire returns, suggesting not all participants could/would use the device. A previous UK study that used an analogue spring balance for similar self-measurement, reported 73% data return suggesting that other factors were involved, such as non-adherence, rather than the choice of device or technical difficulties.[190]

Adherence to exercise remains a challenge in physiotherapy trials and is difficult to measure.[191] The daily exercise diary that was piloted was only returned by a third of participants, so failed to provide meaningful data. The EARS questionnaire provided a complete dataset from questionnaires returned, so would be the preferred method of assessment of exercise adherence in a main trial.

Although the focus of this pilot and feasibility trial was not on between-group differences (and statistical tests were not conducted to compare outcomes), the descriptive analysis of the data showed improvements in both groups in health outcomes over 6 months. In some outcomes, the trend was towards greater improvement in the usual care group than the intervention group for disability and perceived overall treatment effect, which was not expected. This may be explained by the usual care provided by the research-active sites involved in the trial being of higher quality than that provided by non-research-active centres more generally. It may also have been due to changes in working practices after the COVID-19 pandemic, with repeat appointments minimised in favour of a more patient self-directed treatment approach and therefore greater similarity between the treatment arms of the trial than expected at the planning stage. The review of the clinical report forms showed that only 3 patients out of 24 (13%) received passive treatments (only manual therapy) in the usual care group from a physiotherapist, compared with 22% (combinations of manual therapy, taping, acupuncture, ultrasound, laser) in data published pre-

pandemic, reinforcing this theory.[46] Similarly, patients in the usual care group attended a mean of 2.3 sessions, whereas pre-pandemic data showed a mean follow-up of 3.7 sessions.[46]

Whilst a fully-powered future RCT would help ascertain whether the intervention is more clinically- or cost-effective than usual care, a future trial using the same intervention approach is unlikely to be desirable given the results of this pilot. There is potential to adapt the OPTimisE intervention to become a comprehensive self-management treatment, supported by hardcopy, web-based and application-based resources. Previous trials including placebo or wait-and-see control arms, that provided very basic advice without online resources, suggested that following enrolment in a clinical trial, patients experience improvements over time without any active treatment, regardless of symptom duration prior to enrolment.[192] This calls into question the current UK recommendation for physiotherapy when symptoms persist beyond six weeks.[44] Future randomised trials might instead want to consider comparing whether physiotherapy is more clinically- and cost-effective than a single appointment to assess the patient, confirm diagnosis and provide self-help advice in the form of the modified OPTimisE intervention. This will be discussed further in Chapter 6.4.

4.5.1 Strengths and limitations

The strengths of this study were that different methods of participant identification, data collection and outcomes questionnaires were piloted, with clear findings that allow the method of a future main trial to be refined. Patient and public experience was included in the intervention development and trial design, which improved the deliverability of the intervention.

The sample size of 50 was smaller than the 60 originally proposed, due to constraints applied by the funder. Recent sample size modelling, proposed by Lewis et al, would suggest that the pre-defined fidelity to intervention feasibility criterion was adequately powered but the other three domains (consent rate, attendance rate & outcome measure completion rate) were under-powered and might have benefitted from a wider margin between the red and green thresholds,

given the specified sample size.[193] Nevertheless, having surpassed the green threshold in all feasibility domains, the conclusions remain valid.

One oversight was the lack of an adherence measure for the use of the orthosis. Whilst the provision of the orthosis was subject to patient demand, it would have been useful to understand whether those who received an orthosis did use it, when, and for how long. This might have provided insight into how integral the orthosis was to the OPTimisE intervention overall.

The trial design was also limited by the lack of translation services, potentially resulting in fewer underserved communities being represented, but this could be addressed in the main trial design.

4.6 Conclusion

The feasibility of conducting a fully powered RCT to compare the clinical and cost-effectiveness of the OPTimisE treatment protocol against usual physiotherapy treatment was established. However, similarities in intervention and usual care group improvements over time, questions the importance of a future comparative main trial. Instead, the OPTimisE intervention might be adapted to become a comprehensive self-management treatment that could be compared to usual physiotherapy care in terms of clinical and cost-effectiveness.

Chapter 5 The OPTimisE Pilot & Feasibility Randomised Controlled Trial - Qualitative Element

This chapter describes the qualitative element of the mixed-methods pilot and feasibility randomised controlled trial (RCT) comparing the OPTimisE intervention against usual physiotherapy treatment, having previously reported the quantitative findings in Chapter 4. A pragmatic research paradigm is followed, where knowledge is derived from the combination of action and reflection.[194] Pragmatism allows for multiple 'truths' and lends itself well to the complex and multi-factorial nature of physiotherapy interventions, as well as mixed-methods research.[195] The qualitative element, reported in this chapter, provides reflections from patients and physiotherapists involved in the trial, that are then integrated with the quantitative findings in the mixed-methods discussion in Chapter 6.

5.1 Context

The qualitative study was embedded within a two-arm multi-centred pilot & feasibility randomised controlled trial (RCT) investigating whether the OPTimisE intervention could be tested against usual care in a real world healthcare setting.[196] In addition to quantitative measures of feasibility, trial participants were interviewed to explore their views and experiences related to the trial design and intervention protocol.

5.2 Aims and Objectives

This study explored the acceptability of delivering/receiving the OPTimisE intervention from the perspectives of participants and physiotherapists, and views on the processes employed in the pilot trial to inform the feasibility findings from the quantitative results. Acceptability is defined by Sekhon et al. as "a multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention."[197] They propose an Acceptability of Healthcare Interventions Framework describing seven components that can be

used to assess the acceptability of an intervention: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy. In order to implement a new intervention into real-world practice, there needs to be evidence that clinicians are willing to adapt their behaviour in favour of the new intervention. Patients need to engage with the new intervention, especially when it is designed to empower patients to self-manage their condition, as in the case of the OPTimisE intervention. The COM-B model can be used to assess this behaviour change.[198] The model defines three key components:

1. Capability - the individual's psychological and physical capacity to engage in the activity.
2. Opportunity - factors that lie outside the individual that make the behaviour possible or prompt it.
3. Motivation - brain processes that energise and direct behaviour.

The key objective of this study, therefore, was to explore participants' views and experiences through the lens of the COM-B model as a means of evidencing changes in behaviour and assess acceptability using Sekhon et al.'s framework, to provide supportive evidence that the OPTimisE intervention can be adopted into real-world clinical practice and inform a future main trial, as well as highlighting potential changes to the intervention or trial processes.

5.3 Method

5.3.1 Context of the study setting, within a Pilot & Feasibility Trial Design

The OPTimisE Pilot & Feasibility Trial opened in September 2021, recruiting 50 participants across three UK National Health Service physiotherapy clinics within a 12-month period, as described in Chapter 4. Patients were randomised to receive the OPTimisE intervention or usual physiotherapy treatment and all patients were asked to complete outcome questionnaires at six-week, 12-week and six-month follow-up.

5.3.2 Qualitative sampling & recruitment

Patients consenting for the trial were asked whether they gave permission to be contacted for an individual interview, following their course of physiotherapy treatment. Those who gave permission were purposively sampled to include people with varied ages, gender, ethnicity, deprivation index (identified by postcode) and treatment allocation within the trial, as far as was possible within the sample recruited to the trial. Patients were sent a participant information sheet (PIS) (Appendix) by post three months after randomisation, accompanied by a letter of invitation (Appendix 2) and followed up by email or telephone two weeks later, to ask if they wished to be interviewed. All physiotherapists involved as site Principal Investigators or treating clinicians delivering the OPTimisE intervention were emailed a letter of invitation and PIS (Appendix), asking them to reply if they wished to volunteer. Participants were given the option of face-to-face, telephone or video-conference calls (via Microsoft Teams) at a mutually convenient time. All patient participants opted for telephone interviews and all physiotherapists video-conference calls. All interviews were audio-recorded and participants provided recorded verbal consent after being read a consent form. Participants were sent a £20 gift voucher to thank them for their time.

5.3.3 Data collection

All interviews were conducted by myself (MB), a male consultant physiotherapist who has qualitative research training, between February 2022 and January 2023. The interviewer was not known to the patient participants, but they were aware that he was the Chief Investigator for the OPTimisE pilot & feasibility RCT. The physiotherapists at one trial site have worked with MB and those at other sites knew him from site initiation visits and trial communication/meetings. Participants were encouraged to speak freely about their opinions, whether positive or negative.

Interviews were semi-structured, using a topic guide developed by MB and Dr Benjamin Saunders (BS) (see Appendix 5.4) and reviewed a patient volunteer from the OPTimisE PPIE group, Karin

Cooper (KC). The topic guide was iteratively revised based on early analysis. 60 minutes were allocated for each interview but the mean duration for patients was 28 minutes (range 18-42) and physiotherapists was 28 minutes (23-35). Interviews were not repeated. Following the interviews, the recordings were uploaded via an encrypted web portal to an independent transcription service (https://www.universitytranscriptions.co.uk/) to be transcribed verbatim and returned via encrypted download. All transcriptions were checked for accuracy by MB and any uncertainties were resolved by relistening to the original audio recording. Transcripts were not returned to participants as there were no unresolved transcription issues.

5.3.4 Data analysis

Anonymised interview transcripts were analysed using inductive thematic analysis.[199] Thematic analysis is recommended for relatively small samples and when researchers are new to qualitative research.[200] The processes are more clearly defined and less complex than other methods, such as grounded theory approaches, allowing the work to be completed within a shorter timeframe.[200] In this instance, there was no intention to develop theory from the qualitative analysis, as done in grounded theory methods,[199] but identify common themes from the data provided from the participant interviews related to the acceptability of the intervention and the trial processes. MB coded all of the transcripts using NVivo 12 software. Codes were explored both within and across interview transcripts, then indexed into areas of relevance, based upon patterns within the data, to form provisional codebooks for each participant group (Appendix 5.5 and Appendix 5.6). MB, BS, KC and lead supervisor, Professor Jonathan Hill (JH), then met in person to review the patient data and finalise the codebook. MB, BS and JH reviewed the physiotherapist data and finalised the codebook, before both codebooks were compared. Codes were grouped according to similar topics (or sub-themes) and, from these, themes were developed that overlapped both codebooks. These themes and sub-themes were then examined through the lens of the three core components of the COM-B model to provide evidence of behaviour change, deliverability of a main trial and identification of processes that can be

improved.[198] Similarly, the codes were mapped to the Acceptability of Healthcare Interventions Framework to provide evidence of intervention acceptability.[197]

5.4 Results

From a total of 50 patients recruited to the OPTimisE Pilot & Feasibility Trial, 45 gave permission to be contacted to discuss taking part in a qualitative interview. Following purposive sampling, 24 of these patients were invited to be interviewed and 17 participated. One other patient initially agreed to be interviewed but later changed their mind due to busy work and personal schedules. The other six did not respond to email and telephone follow-up. The median age of patient participants was 47 (range 37-62) with an even split related to sex and treatment group allocation within the trial. Individuals from a range of ethnic and social backgrounds were included, representative of the demographic of the general population. Demographic data from patient participants is provided in *Table 5-1*. In addition, all eight of the site principal investigators and physiotherapists who delivered the OPTimisE intervention to patients during the trial agreed to be interviewed. Physiotherapist participant demographics are shown in *Table 5-2*.

Identifier	Age	Gender	Ethnicity	Deprivation Score*	Duration of Symptoms (Months)	Baseline PRTEE Score**
BHX003	47	Male	White British	1	6	42
BHX004	47	Male	Kosovar	1	36	47
DER001	52	Male	White British	6	2	80
DER002	39	Female	Pakistani	1	12	69.5
DER003	54	Male	White British	8	3	37.5
DER004	55	Female	White British	2	12	62.5
DER006	39	Female	White British	4	12	31
DER008	54	Male	White British	7	6	44.5
DER011	40	Female	Sri Lankan	10	6	82
SHE001	42	Female	White British	1	3	68.5
SHE004	52	Female	White British	10	8	62
SHE005	48	Female	White British	8	3	93
SHE011	37	Male	White British	2	5	30
SHE013	62	Male	White British	7	10	44.5
SHE014	43	Female	White British	7	3	57.5
SHE016	54	Male	White British	5	4	24.5
SHE018	47	Male	White Other	10	24	18.5

Table 5-1: Patient Participant Demographics

*Deprivation score is measured in deciles, where 1 is the highest level of deprivation and 10 is the lowest level of deprivation.

**The baseline Patient Reported Tennis Elbow Evaluation (PRTEE) score is a measure of pain and function at the time of recruitment to the OPTimisE trial. The scale ranges from 0-100, with 100 being the highest level of pain and functional impairment.

Identifier	Gender	Role	Grade	Years Qualified
PT1	Male	Treating Physiotherapist	Band 7	7
PT2	Male	Temporary Site Principal Investigator and Treating Physiotherapist	Band 7	21
PT3	Male	Site Principal Investigator	Band 6	8
PT4	Female	Treating Physiotherapist	Band 7	35
PT5	Female	Site Principal Investigator	Band 6	12
PT6	Female	Treating Physiotherapist	Band 6	25
PT7	Female	Site Principal Investigator	Band 8a	30
PT8	Male	Treating Physiotherapist	Band 7	15

Table 5-2: Physiotherapist Participant Demographics

Four themes were identified from the data: experiences of the OPTimisE intervention; differences between the OPTimisE intervention and usual care; feedback related to trial processes; and feedback related to the trial resources. Detailed coding trees are shown in *Figure 5-1* and *Figure 5-2* below, showing the themes in orange and sub-themes in pale blue. *Table 5-3* shows the four themes with related sub-themes, matched to the domains of the Acceptability of Healthcare Interventions Framework.[197]

Additional themes, unrelated to the aims and objectives of this chapter, were also identified. These are reported in a separate peer-reviewed publication and relate to the lived experience of people with LET.[201]

Figure 5-1: Coding tree related to patient interviews

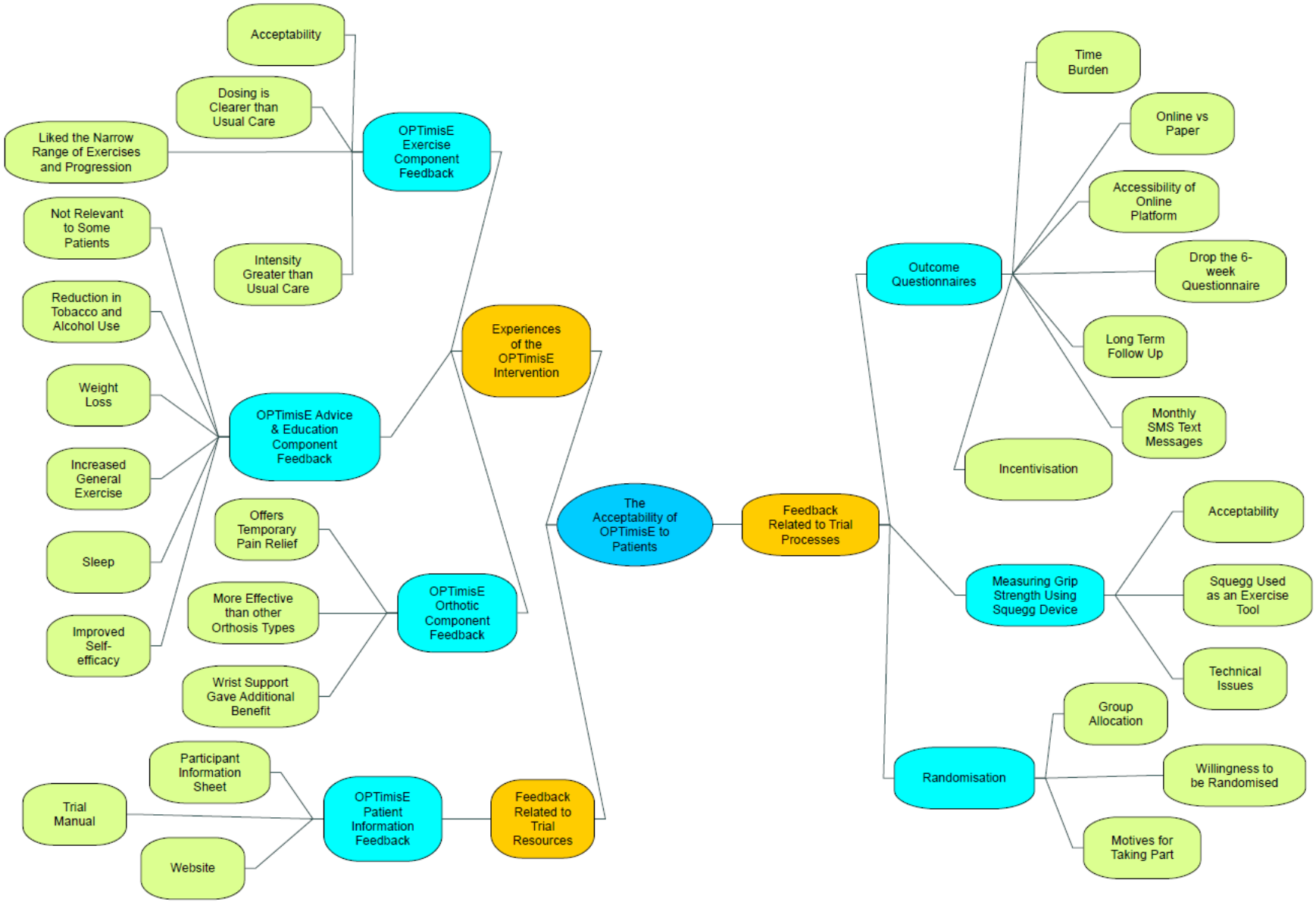
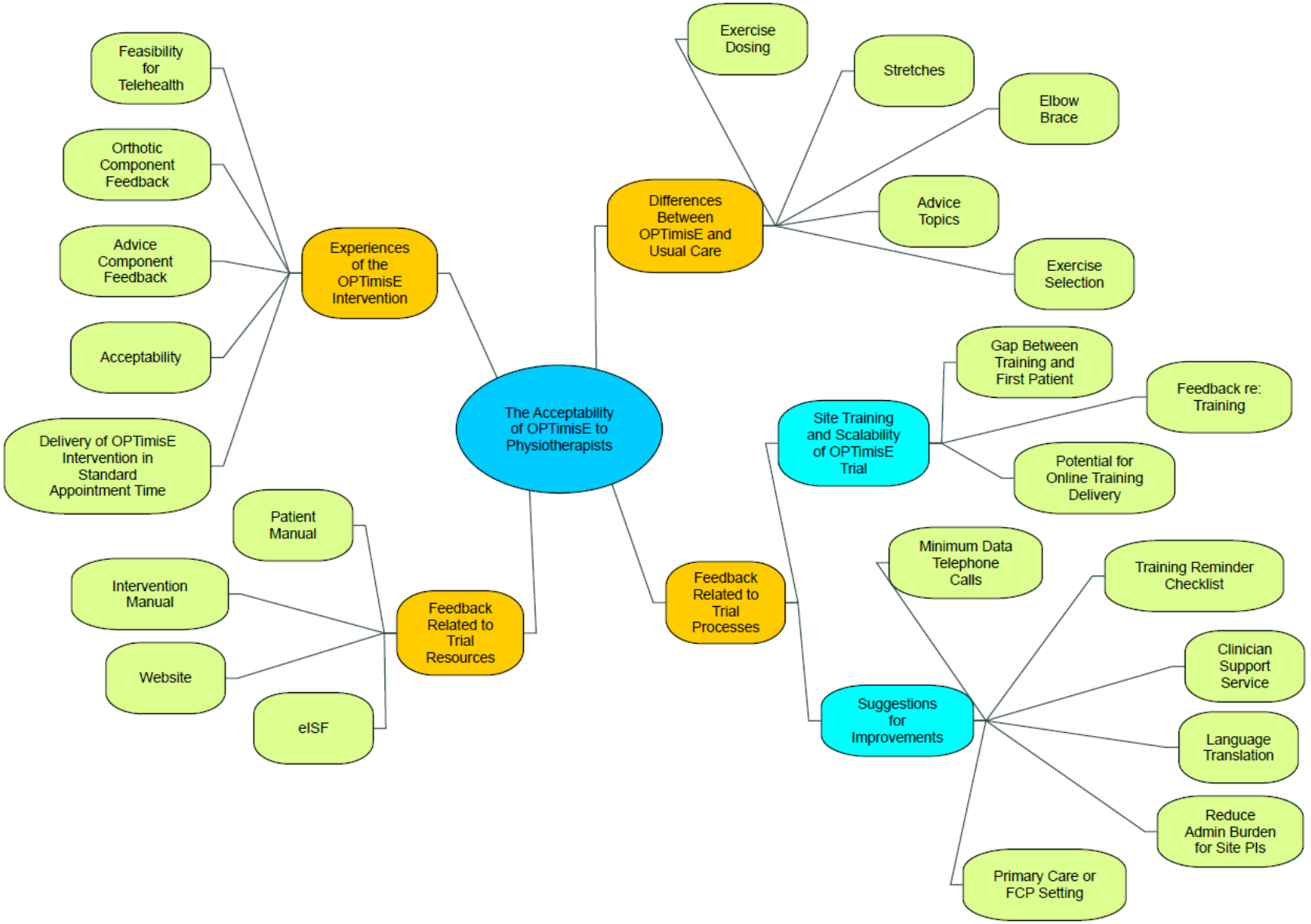


Figure 5-2: Coding tree related to physiotherapist interviews



Themes	Sub-themes	Framework of Acceptability Domain(s)
Experiences of the OPTimisE intervention	Patients' views on the advice & education component	Perceived effectiveness, opportunity costs, burden
	Patients' views on the exercise component	
	Patients' views on the orthotic component	
	Physiotherapists' experience of delivering the OPTimisE intervention	
Differences between the OPTimisE intervention and usual care		Affective attitude, ethicality
Feedback related to trial processes	Patients' experience of the outcome questionnaires	Ethicality, burden
	Views on patient treatment randomisation	
	Use of the Squegg device	
	Physiotherapists' views on the site training and trial scalability	
	Suggestions for improvements	
Feedback related to the trial resources	Patients' feedback on the trial website, Participant Information Sheet (PIS) and patient manual	Intervention coherence, self-efficacy
	Physiotherapists' feedback on the intervention manual, patient manual, electronic investigator site file (eISF) and trial website	

Table 5-3: Map of themes and sub-themes

5.4.1 Theme 1: Experiences of the OPTimisE intervention

The OPTimisE intervention was received positively by both patients and physiotherapists. From the perspective of delivery, physiotherapists reported that it was practical to provide patients with the three treatment components within a standard 30-minute session and that the suggested follow-up times of approximately four weeks could be accommodated. Some found that follow-up sessions could be performed by telephone, without the need of a face-to-face consultation, given that patients could refer to the visual aids in the patient handbook or trial website. Indeed, due to its comprehensiveness and clarity, some felt that the intervention could be delivered in a single session, with patients advised to self-manage using the resources provided.

"It was fairly straightforward to deliver. That was the nice thing about it. I only had a positive experience... The one thing that it really did make me reflect on is just how the information was packaged and how it was brought together and the breadth of the information. That was the really lovely thing about doing it. You did it and just felt why aren't all physiotherapy interventions a bit like this? It's really clear." PT2

"It's almost quite a nice self-management programme… because there was so much information at the start with it, it almost made follow ups a little bit redundant." PT3

In relation to the advice and education component of the OPTimisE intervention, physiotherapists fed back that the holistic health content they were asked to teach was familiar, as it was common practice to provide this for certain conditions, such as chronic low back pain, despite not usually providing it for people with LET. Patients reported that whilst not all the topics were relevant to all people, for some the advice resonated, causing them to address certain lifestyle factors. Examples were reducing alcohol and tobacco use, losing weight, increasing general exercise levels and getting more sleep.

"I have cut down quite a lot on smoking, so I am pretty chuffed with myself for doing that. And I don't drink like I used to do because me and my husband did like a drink, but we have both cut down loads, which is good because it's a healthier option I suppose, instead of filling your body full of toxins." SHE005

"I mean right now I'm down to fourteen and a half whereas when lockdown started I was over 16 and had quite a bit of a belly kind of thing. And it's all due to trying to hammer exercise whenever I can and get on the cross trainer and stuff." SHE011

"…and I'm trying to get a bit more sleep as well I wasn't doing enough of." SHE016

Whilst the orthosis provided to patients did not help everyone, many reported that it offered short-term pain relief. There were no concerns raised regarding the choice of product. Indeed, some commented that it was superior to others available and the optional wrist support provided additional benefit for some individuals.

"Because I started using the elbow strap and when I was lifting things it was helping with the pain - there was no pain." SHE001

"I wasn't feeling any pain when I had it there, so it was kind of giving a bit of support." BHX004

"They were high quality orthotic devices compared to the sort of things I've seen in the past and participants seem to like them." PT2

"Yes, the brace was much better, I did comment on that, to tell them straight away it made it a lot easier-- I don't wear it all the time but whenever I'm doing any kind of heavy lifting or anything like that, I'll tend to put it on and it does make a real difference that." SHE016

"And there was also like a wrist strap and [physio name] says, he didn't know whether it was to be used and I thought, well it was in the box. So, I have had that on as well while I have been like doing anything, and I've found just that little extra bit of support has helped." SHE005

Patients reported that the exercise component of the intervention could be fitted into their daily routines. There was positive feedback from both patients and physiotherapists regarding the simplicity of exercises and exercise progression.

"Yes, because they don't take a huge amount of time it's been really easy to kind of fit them into a routine. It's been something that I can do, you know, quite easily and it tends to be when I get back from work, that I tend to do it… If I'm at work, they are exercises I can do quite easily at my desk, if I need to, as well… it's a fairly, I'd say, narrow range of exercise - they build up on each other really well I thought." SHE016

"Doing this exercise once a day is quite achievable isn't it, to the patient?... So as a concept I could very much sell it because I believe I could subscribe to that if I was a patient. It was easy to do." PT6

"The exercises themselves are really simple. I think doing something well, if you've got something simple and done well, it often works, doesn't it? So, if you've got a nice simple programme for someone. Some patients liked it because it was really simple." PT8

5.4.2 Theme 2: Differences between the OPTimisE intervention and usual care

As described in Chapter 4, the clinical report form review identified commonalities between usual care and the OPTimisE intervention. Usual care was typically centred around exercise and basic advice; however, in the qualitative study, physiotherapists perceived that usual care lacked consistency and structure, with variations in exercises prescribed and exercise dosing amongst colleagues within their teams. The inclusion of stretches as part of the OPTimisE intervention was highlighted as something that none of the treating physiotherapists would ordinarily use in their practice. Usual care was thought to centre upon progressive loading of the forearm extensor muscles and advice/education based upon a mechanical model of pathology understanding. The OPTimisE intervention, in contrast, was perceived to have a biopsychosocial model, incorporating

holistic health advice/education with a structured rehabilitation programme, which was regarded positively.

"I think it just flags up again what we should be doing as a whole, in regards to all of our MSK [musculoskeletal] patients. Which is the biopsychosocial-type model of care and not forgetting about the extra bits-and-pieces that go alongside tendon healing, like lifestyle changes and all the rest of it. Like I say, you can in a busy clinic and when you've got not enough time to reflect, it's easy to brush over the other bits-and-pieces, rather than, great, I've got a quick lateral epicondyle pain here. I can just give them a quick loading programme and send them on their way. I think it slowed your processing down and think actually look at the bigger picture here, make sure you're addressing the other symptoms or issues that might be affecting this patient." PT1

"…for me the novel thing about it was all of the way it was presented, the structure and having all of that support information all in one place in an easy to follow way for patient participants. I thought it brought down [pause] - it was a lot of these barriers sometimes you get with communicating with patients and feeling like you've got to cram so much into one session. The fact that this was laid out almost as a programme to follow was the nice thing about delivering it. It was a nice intervention to deliver and patients really liked it as well. It was, that felt really and I looked at it and thought why are we not producing more information like this over more conditions for patients and physiotherapists. It was a really high level of support and information around that exercise regime that you were delivering. So, you know the typical exercises themselves weren't, didn't really ring to me because most of those physio exercises are variations on a theme. I thought the novel stuff was how it was all put together and how easy it was to follow." PT2

The exercise dosing in the OPTimisE intervention was perceived to be clearly prescribed, whereas in usual care dosing practice was described as more varied. The promotion of patient self-efficacy by teaching ways to progress and regress exercise difficulty based upon symptom response,

extending to high load and global upper limb strengthening, was another difference that was identified by physiotherapists. Likewise, the inclusion of advice to increase general cardiovascular exercise, combined with addressing other metabolic lifestyle factors.

"For me, the novel thing about it was all of the way it was presented, the structure and having all of that support information all in one place in an easy-to-follow way for patient participants. I thought it brought down a lot of these barriers sometimes you get with communicating with patients and feeling like you've got to cram so much into one session. The fact that this was laid out almost as a programme to follow was the nice thing about delivering it... It was a really high level of support and information around that exercise regime that you were delivering." PT2

"And I guess the other thing with the OPTimisE trial is the advice is more detailed advice so things like sleep, you know, the diabetes, general exercise - they are other things to be advising patients about, whereas perhaps it's not quite done in the same detail with usual care." PT5

The provision of an elbow brace orthosis was not typical of usual care, so this was entirely new to some physiotherapists, whilst others reported that they might suggest that patients purchase their own. Many of the physiotherapists said they would now change their practice as a result of participating in the pilot trial.

"The only thing I wasn't confident on [beforehand] was we didn't have the choice of the splints. So, that was the only thing that I wasn't fully aware of, well got better with practise and things. But that's something I don't tend to normally advise people, because we just didn't have the option really when we treat lots of those. But again, patients seem to like that as well. They like splints or the options to have it as a bit of pain relief for as a management strategy." PT1

"I've had an interesting conversation with two fireman friends of mine who both use elbow clasps now, because they both asked me my opinion and - I think a year ago, I told them I'd have pooh-poohed it, but now I'll give it a go - and actually both of them are climbing now again with using a

clasp. So, I guess it's broadened my horizons slightly to think maybe there's something in this, and if it works for the patient - happy days!" PT6

5.4.3 Theme 3: Feedback related to the trial resources

Patients reported that the PIS was comprehensive and that they felt sufficiently informed about the pilot trial. One participant, who had a mild learning difficulty, suggested that the key information be highlighted and separated from the more detailed aspects, e.g. data protection policy, to make it easier to read.

"Yes, because they also let you know that if you were not interested in doing the research trial that your care would not be stopped. Because obviously when you are, you think to yourself, right if I don't do the research are they going to stop seeing me for my elbow, which it was explained that they don't do that. So I think it gave me everything that I needed to know to make the decision." SHE001

"Yes, I think so. I suppose- Well, she gave me a factsheet and an information sheet which was about three pages long, which I read. Then she had a chat to me about it in the surgery. Yes, I think so, I was quite happy at the time to make that decision and I'm quite happy to continue with it, yes." SHE004

"If you have like really important info to get over… all the blurb about data protection and if you want your data to be used… just really separating that from the main text you want to get across." SHE011

Feedback related to the patient manual and trial website was consistently positive. The website was used by physiotherapists as an additional training resource to initially familiarise themselves with the exercise videos and advice website hyperlinks. Some patients did not feel the need to access the website as they found the patient manual sufficiently comprehensive. Those that did reported having found it useful and some had followed the advice from the linked websites. The

majority used the patient manual as their main resource, commenting that the descriptions of the exercises, dosing and progression/regression were easy to understand.

"We were given a booklet that tells you all about the exercises that we are going to be doing and it explains them all. And it has a proper good description that if I think that I've forgot, I can then look in the booklet and see the exercise that I have been asked to do and I can just, you know, refresh my brain, which is very handy." SHE001

"I think your booklet is outstanding, I do, because I have followed your booklet like religiously, and it's easy to follow, easy to read yes. I'll keep using it until my elbow is completely better, and I don't think it will ever go away completely but I've got the tools here to help me." DER001

"I mean it's very well presented. It looks good, it looks clean, it's easy to understand. It's not too long so it keeps your attention. I wouldn't be looking to tweak it too much." DER008

"The website as well that was really useful initially to be able to make sure I was doing my exercises correctly so yes." SHE016

"As time went on I've gone on [the website] less. I still use the booklet quite a bit, a quick refresher. Not the website." SHE016

"I think the access to the website was very good actually. Having that outlet and that source that patients could go and provide or have the visual feedback for exercises and advice and things, was really useful. It doesn't tend to be something I normally give out with tennis elbow. Other than the verbal advice I would give them or maybe a sheet of exercises that I would print off for them. So I think having the visual outlet of the website was really useful actually." PT1

Having the patient manual, containing details of all the OPTimisE intervention components, in one neatly-packaged booklet was perceived by patients and physiotherapists to add value, save time and allow follow-up consultations to be conducted by telephone if necessary.

"Yes, I mean the handbook was really good. The website, as well - that was really useful initially to be able to make sure I was doing my exercises correctly… both of them combined have been really useful. It helps that the exercises are fairly simple really and because it is a fairly limited range of exercises, you are not constantly shooting on to a new thing. So, I would say the resources have been really good." SHE016

"…if you look at the website, you've got those bits where the patients can click on smoking or exercise or whatever, all the different bits. It's all very straightforward so as the person delivering it, you only have to guide the patient towards some of the education stuff as well as explain it to them that everything's all backed up." PT6

The only critical feedback of the physiotherapists' intervention handbook was a recommendation to add more detail to the basic science section. A new electronic investigator site file (eISF) system, containing all of the administrative resources, was piloted by the trial sponsor with site principal investigators (PIs) finding no technical issues but requesting clearer indexing and a single location for regularly-accessed files.

"So, another thing to idiot proof it would be simple things like at the very start, either having folders set-up, empty but on the e-ISF with all of the labels clearly marked out because initially it was a case of, where do I put this, where do I put that?" PT7

5.4.4 Theme 4: Feedback related to trial processes

5.4.4.1 Patient perspectives

The patients exhibited a positive attitude towards randomisation and did not express strong preferences for their treatment group allocation. They were enthusiastic about the possibility of receiving a novel treatment that could potentially be more effective than standard care but were equally happy to be randomised to either treatment out of a philanthropic inclination to help other people by contributing to the research. Additionally, they appreciated the opportunity to interact with clinicians who were perceived as experts due to their involvement in research.

The Squegg™ device, used to measure grip strength, functioned as intended, apart from one person who was unable to get the device to work and some needed assistance from more technology-aware family members to set it up. In addition to measuring their grip strength for the outcome questionnaires, some patients reported that they used the games built into the application as a way of improving strength and others stated that family also used the device.

"It does work all right on my phone, yes. Sometimes I have to get my daughter to look into it because it doesn't always start up, but she's quite good at sorting that for me. But it generally works, yes it does." DER004

"It's just in this little box, charge it up and yes, it's easy to use. Videos and information on the app is pretty straight forward, so you know, I can obviously do it as and when throughout the day. So it's really good." SHE005

"I've noticed with the Squegg™ and the games I play, and then it calculates at the end how many grips you've done and my grips have been like between 300 and 350 at a time, so I think with these little games it helps, and it also gives you a bit of entertainment while you're doing a bit of physiotherapy." DER001

There were mixed opinions regarding the outcome questionnaires and a feeling from some patients that there were too many questions, which was burdensome for those with busy work and family commitments. It was proffered that highlighting the monetary incentive for returning the questionnaire might encourage more timely completion. The first follow-up questionnaire was sent six weeks after randomisation but some patients had only just, or not yet started their treatment due to waiting lists. It was therefore suggested that the six-week questionnaire could be removed in a future main trial, although patients would be amenable to completing a 12-month follow-up questionnaire.

"But yes, what I found was quite a few questions feel like they're asking about the same thing. So unfortunately, I can't remember those questions, maybe what I can do is the next time I do go through it I'll try and maybe note down some of the things I felt were asking about the same thing or felt a bit repetitive in a certain sense, but it felt like there was a lot overlap, which I think is the normal thing you would do in a survey anyway. I mean you would want to verify the answers that are given are correct, or it's a true representation of what the respondent sort of feels, so with similar sort of questions. But because the questionnaire is quite long, you can easily lose people." DER011

"Very easy. It sort of flowed very easily through the web portal or website whatever it is. And, it was nice and easy, clean, easy to understand. You didn't have to put too much thought in to it and it's probably best that you don't, otherwise you're not going with your gut feeling on each question. Literally, just took a few minutes." DER008

"I definitely think that would be a good idea because sometimes in six months you can be - for example, for me, I've had no pain so you'd think, Okay, I'm fine now. I'll drop the exercise. I'll just go back to my normal life. But then, I think, with these kinds of things they have a tendency sometimes to come back. So, it would be good to see if it, in terms of your research project, did it come back?" DER002

We also proposed the addition of a monthly text message, that was positively received. Patients felt that it would act as a reminder that they were still part of the trial, be easy to respond to and provide the trial team with additional insight into how their symptoms might fluctuate over time.

"I think for convenience it's probably easier to yes, just fill in a single answer text… I think the questionnaire was useful because it does focus your mind on, you know, thinking 'Is it feeling better than last time?' because it's a wider spread of questions, so for me, probably, combining the two would work." SHE016

"…obviously using technology now with mobile phones and where you can reply with a text message from one to 10 which you can select average one. Yes, that's a good idea." BHX004

Patients were given the option of completing questionnaires online or on paper. Those who opted for paper stated that they could have completed them online if that were the default method. The majority using the online service had no problems. The only issues raised were a display issue on a smartphone and feedback to improve the wording of the communication email from the third-party provider to make it clearer that it was related to the trial.

5.4.4.2 Physiotherapist perspectives

From the perspective of the physiotherapists, there were no major concerns regarding the trial processes. The site training sessions were well-received and deemed to be sufficiently comprehensive. Physiotherapists agreed that if the trial were to be delivered at scale, across multiple geographical areas, then the training sessions could be conducted via video-conference, provided that all of the site hard resources had been posted in advance. Most physiotherapists experienced a gap of several weeks between the intervention training and treating their first trial patient. It was suggested that a five-minute refresher video or treatment process summary sheet could be produced to help remind physiotherapists of what to do, or hosting an online discussion forum where physiotherapists could seek advice from the trial team.

An observation from all three trial sites was that recruitment rates declined over the latter half of the recruitment period. It was speculated that this was due to an increasing number of physiotherapists being employed as First Contact Practitioners (FCPs)[$] in Primary Care nationally, with patients with LET managed more in community settings, rather than in hospital outpatient physiotherapy services. It was therefore suggested that a future main trial target these clinical settings as the intervention, being well resourced and straight-forward to deliver, could be easily delivered in Primary Care.

"I mean this would lend itself really nicely to an FCP clinic because you've got all the information out there for the patient to use and access for self-management so that they'd need to know about it as well." PT5

"I think this sort of programme is ideal for that sort of FCP land[scape]... It's simple. They can signpost them straight to it, teach them the exercises quite quickly and manage these patients in primary care probably." PT8

The only other feedback related to reducing some of the administrative burden placed on the site Principal Investigators by transferring the responsibility of minimum data telephone calls and electronic Investigator Site File document monitoring to the trial team. It was also highlighted that for a future trial, provision should be considered for language translation to widen accessibility for underserved patient groups.

"…just in terms of thinking about the future of it - certainly for like if it was going to go in community care, you know, somewhere like Birmingham there's certainly different ethnicities but, you know, with things like, you know, most of our literature, most of [our] literature has to be translated into Urdu, Punjabi, Polish for it to get out in the first place. So, there will be some considerations there around the literature but in our population and the people I saw, you know, it was one of the real strong points but that's I would say just be a consideration for the future trial." PT2

5.5 Discussion

In this chapter, the acceptability of the OPTimisE intervention and pilot trial processes was investigated, to determine whether it is feasible to conduct a full-scale clinical trial. The OPTimisE intervention was found to be deliverable in a publicly-funded healthcare setting and patients engaged with it. The quality of the resources provided to patients was viewed positively, and deemed to add value compared to usual care. The OPTimisE intervention was found to differ from usual care in four important aspects: the provision of an orthosis, holistic advice/education

regarding biopsychosocial influences on pain, addition of forearm stretches and general upper body strengthening, and a more prescriptive exercise dosing regimen that included progression or regression based upon symptom response. It was suggested that the OPTimisE intervention could be delivered at a single clinic visit with patients encouraged to self-manage using the resources as a guide. There were no concerns regarding the processes of patient recruitment, randomisation or treatment delivery but changes to outcome measure collection will need to be incorporated into a main trial design. These include reducing the length of the outcome questionnaire, removal of the six-week and addition of a 12-month follow-up questionnaire, incentivisation of all questionnaires, and addition of a monthly text message question. In a full-scale trial, the intervention training could be delivered remotely but required the addition of a walk-through checklist or refresher video to help physiotherapists prepare for their first trial patient consultations. The administrative burden on physiotherapists could also be reduced by re-assignment of some duties to the trial team. Language translation will also need to be incorporated, to reach underserved communities. It was also proposed that a future trial might be sited in a primary care setting.

The inclusion of qualitative research in feasibility studies is now recognised as an important method of gaining additional insight into how an intervention or trial processes may be improved and consequently increase the impact of a main trial. O'Cathain et al describe a range of questions that can be used in a feasibility study for an RCT, the majority of which were applicable to this study, particularly around the subjects of intervention delivery, trial processes, selection of outcomes and completion of outcome measures.[161] These were used to identify important differences between the OPTimisE intervention and usual care that will allow for a meaningful comparison in a real-world trial, and highlight processes within the trial design that require refinement.

5.5.1 Implementation

From the perspective of implementing the OPTimisE intervention, there was evidence that patients and physiotherapists were able to change their behaviour. If we consider the findings through the lens of the three core components in the COM-B model (capability, motivation and opportunity), we can demonstrate that the intervention is likely to be deliverable in practice and that the trial can be delivered at scale with some additional support for physiotherapists.[198]

5.5.1.1 Capability

Patients were able to engage with the OPTimisE intervention but physiotherapists found that there was an initial period of learning to adapt their practice before they were able to deliver the intervention efficiently. This could be mitigated by providing them with a training refresher video or walk-through checklist in a future full-scale trial.

5.5.1.2 Motivation

Patients were motivated to take part in the trial as the intervention was perceived as something new and potentially more effective than usual care, with access to specialist physiotherapists involved in research. There was also a sense of taking part for the benefit of the greater good, in order to help other people with LET. Physiotherapists appeared motivated by learning new skills and provided evidence that they had adopted some of the treatment components of the OPTimisE intervention into their practice beyond their involvement in the trial.

5.5.1.3 Opportunity

Patients were involved in the design of the OPTimisE intervention in an attempt to maximise the opportunity for engagement with the intervention. The exercise programme was simplified to take a maximum of 15 minutes per day, follow-up clinic visits were kept to a minimum of four weeks in-between visits if required, and resources were presented in hardcopy and online formats with written, pictorial and videographic content to suit a variety of learning styles. Feedback was therefore positive from the patients interviewed but opportunity could be widened

by targeting underserved communities and translating resources into other languages. The intervention was also designed during the COVID-19 pandemic to be deliverable remotely and we found evidence of follow-up consultations being delivered by telephone, for convenience of patients and physiotherapists.

5.5.1.4 Acceptability

Study findings about the acceptability of the OPTimisE intervention and feasibility of comparing it to usual care in a randomised controlled trial are presented in Figure 5-3, mapped to the constructs within the Acceptability of Healthcare Interventions Framework. All seven domains have been satisfied, suggesting that the OPTimisE intervention was acceptable.

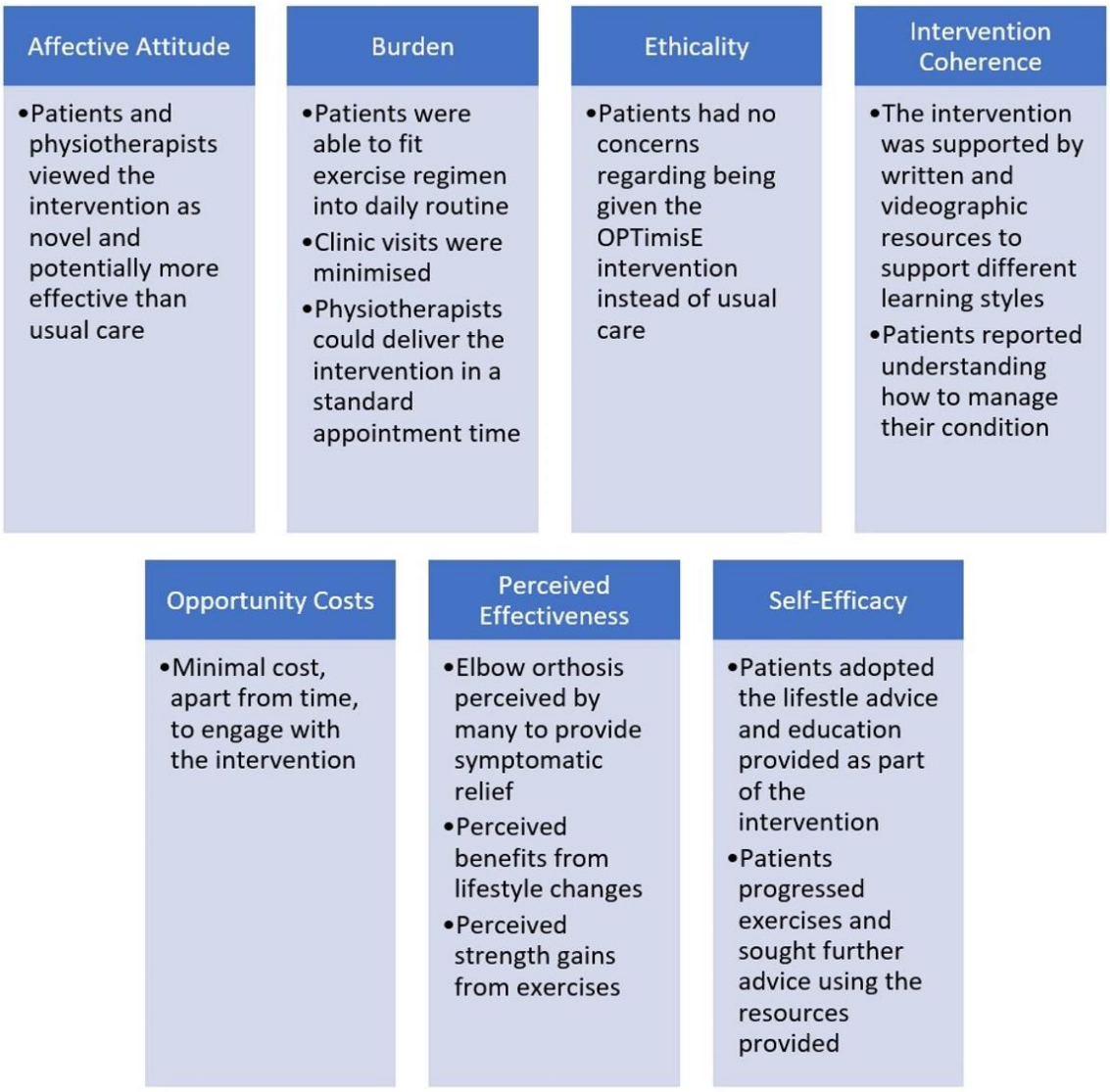


Figure 5-3: Findings mapped to the constructs within the Acceptability of Healthcare Interventions Framework

5.5.2 Strength and limitations

Strengths of this qualitative study are that it included individuals from a range of backgrounds and used established models/frameworks to assess behaviour change and acceptability. It must be acknowledged though that these interviews are the opinions of people accessing healthcare for LET and so may not reflect the views of those who do not access healthcare for LET, including some underserved groups. It was also not possible to interview some patients that failed to attend their allocated treatment sessions, as they failed to respond to interview invitations, so

may not have captured a full range of views. Reflexivity must also be acknowledged.[202] The power dynamic between interviewer (MB, Chief Investigator for OPTimisE) and the interviewees (patients) potentially may have resulted in interviewees providing responses that they thought the interviewer wanted to hear, despite instructions to be open and honest about their opinions. Likewise, the interviewer may have subconsciously asked questions that led the interviewee to provide favourable responses. To mitigate against this, the first three interview transcripts were reviewed by academic supervisor Dr Benjamin Saunders to assess the interview style and ensure that non-leading open questions were used where possible. During data analysis, a patient representative (Karin Cooper) was involved, to check the interpretation of the interviewees statements and minimise interpretation bias, prior to the codebooks being agreed.

5.6 Conclusion

Overall, the OPTimisE intervention was found to have differences to usual physiotherapy care and was acceptable to both patients and physiotherapists. The study highlighted the need to refine trial processes and resources prior to a full-scale trial, to reduce administrative burden, provide additional support for physiotherapists, improve the return rate of outcome questionnaires, and provide language translation.

Chapter 6 Final Discussion and Recommendations for Further Research

This chapter brings together the findings from the quantitative and qualitative elements of the OPTimisE pilot and feasibility RCT to form the mixed methods discussion.

6.1 Context

Mixed methods research combines quantitative data with qualitative data, drawing upon the strengths of each of the two methods to reach an overall conclusion.[159] In the context of a pilot and feasibility trial, quantitative analysis can provide an answer to closed questions, such as whether recruitment targets can be achieved, but the addition of subjective opinions, obtained through qualitative methods, can add valuable insight into short-comings within the trial design or acceptability of a new intervention and how they might be addressed to improve the conduct of a future main trial. They may also serve to validate quantitative results and justify decisions made.[159,162,203]

6.2 Aims and Objectives

The aim of this chapter was to combine the quantitative results from the OPTimisE pilot and feasibility RCT with the qualitative results, to give a comprehensive assessment of the feasibility of conducting a fully-powered RCT comparing the OPTimisE intervention with usual physiotherapy care for people with LET.

6.3 Discussion

The results from the quantitative analysis satisfied all four of the pre-defined objective feasibility criteria related to: consent rate, intervention fidelity in the intervention group, attendance rate in the intervention group and outcome measure completion rate at six months post-randomisation. At face-value therefore, this suggests that, from a methods perspective, it is feasible to conduct a full-scale trial to compare the clinical and cost-effectiveness of the OPTimisE intervention

compared with usual NHS physiotherapy care. However, the secondary analysis of patient-reported outcome measures, despite not being adequately powered for statistical analysis, failed to show a trend towards greater improvement in the OPTimisE intervention, calling into question the merit of such a trial.

The consent rate of 71% was far higher than the feasibility target of 25% but the number of eligible patients (70) identified from screening was far lower than the 200 estimated at the planning stage. That figure was based upon the numbers of patients with LET seen at the three participating sites prior to the COVID-19 pandemic. Although the UK had lifted all pandemic restrictions by the time recruitment opened, working practices in the NHS had not returned to pre-pandemic normality. Physiotherapists interviewed as part of the qualitative phase also proffered that lower numbers of eligible patients being referred might also be due to the expansion of FCP[†††] services widely across the country. Their feedback was that increasing number of patients with LET were being managed solely by FCPs, rather than being referred to the traditional types of outpatient physiotherapy services that were included in the trial. A key implication from this finding is that future studies on this patient population might therefore be better to target recruitment of LET patients at FCP services.

In terms of treatment fidelity, the OPTimisE intervention was delivered as intended to the majority of patients (89%). The pre-defined quantitative criteria for fidelity were binary (i.e. fidelity was achieved or not) and in two cases, fidelity was not achieved because physiotherapists only delivered five of the twelve advice/education topics instead of the six required to satisfy the *a priori* fidelity criteria. The other remaining criteria, related to exercise prescription and provision of the counterforce brace, were all satisfied. The qualitative study suggested that physiotherapists did not have issues delivering the intervention as intended within a standard

[†††] First Contact Practitioners (*FCPs) are primary care healthcare professionals, typically physiotherapists in the context of musculoskeletal conditions, who assess and manage patients instead of a General Practitioner.*

appointment time, but due to some patients not feeling that all of the advice topics were relevant to them, explaining perhaps why fewer topic areas were delivered in those two cases. The topics related to general health and lifestyle advice (smoking cessation, diet, general exercise, diabetes management, sleep hygiene, promotion of self-efficacy and basic pain science) may not have applied to all. Indeed, one of the two patients highlighted was themselves as a medical doctor so would have already had knowledge in these areas.

The attendance rate at all planned sessions in the OPTimisE intervention group was 82% (55/67), with five participants not receiving the intervention. This compared to 85% (56/66) in the usual care group, with two participants not receiving any treatment. The patients interviewed in the qualitative study had positive views about randomisation and did not express strong preferences for their treatment group allocation. They also perceived that the physiotherapists providing the treatments must be experts due to their involvement in research. A limitation and potential source of bias within the qualitative study is that none of the patients who failed to attend for treatment agreed to be interviewed, despite being approached. It is possible that those who did not attend were dissatisfied with their group allocation resulting in their non-attendance. Alternatively, the wait of 2 to 8 weeks from consent to receiving their first treatment might have been a factor.

There were concerns discussed during Trial Management Group meetings early in the trial regarding the low rate of questionnaire returns at six-week follow-up (59%). The qualitative interviews explained that some patients had not yet started treatment or only recently started treatment at the time the questionnaire was sent, due to long waiting times for initial physiotherapy appointments. This suggested that the first follow-up time-point was too soon and could be removed from a future main trial. Returns increased at 12-week follow-up to 65% but did not meet the feasibility threshold. During the interviews some patients reported finding the questionnaires too lengthy and overburdensome with work/family commitments. They also

suggested that financial incentives would be a motivator to respond. A protocol amendment was therefore introduced to allow telephone reminders and brief telephone minimum data collection comprising the PRTEE and reporting of any adverse events. After incorporating this change and combined with the £20 voucher incentive for six-month data return already included in the protocol, this resulted in an 81% response rate at final follow-up, surpassing the feasibility threshold and highlighting the value of the qualitative patient feedback.

By examining the external responsiveness of the different PROMs included in the outcome questionnaire it was possible to identify the measures that were most sensitive to detecting a change in symptoms. This analysis provided evidence that some of the measures with low responsiveness could be removed in a future main trial to reduce unnecessary burden on patients. The PRTEE measure of function and NRS for pain on gripping showed the highest correlation with patient perceived overall treatment effect. Both are recommended in the Core Outcome Set for LET, adding validation to the findings.[43] The idea of measuring the NRS for pain on gripping via a monthly SMS text message was proposed to patients being interviewed. This was perceived favourably as they felt it might act as a reminder that they were still part of the trial and be a quick way to measure how their symptoms might fluctuate over time. An international consensus has recommended nine domains to measure in tendinopathy research including psychological factors and physical function capacity.[40] This trial included two psychological measures: the TSK-11 and PSEQ questionnaires, finding that the PSEQ was more highly correlated with treatment outcome. Similarly, both pain-free grip-strength and maximum grip-strength were included to measure physical function capacity but the former was more highly correlated with treatment outcome. This is consistent with previous studies comparing the two methods.[189] Therefore, the TSK-11 and maximum grip-strength measures could be removed from a future main trial to reduce the burden on patients.

The challenge for measuring physical function capacity is that it typically involves a patient attending for a face-to-face assessment with a physiotherapist. With the aim of reducing burden and to mitigate for any further pandemic lockdowns, a method of grip-strength self-measurement was piloted at home using the Squegg™ device. Grip-strength data were provided in 77% of questionnaire returns with only one person interviewed stating that they had difficulty in using the device, suggesting this was due to a lack of adherence rather than technical issues. Indeed, some patients not only used it for completing the questionnaires but also to monitor their grip strength on a more regular basis and for playing the games included within the Squegg™ App as a way of exercising their arm. It was anticipated that the device might be used in this way, hence the reason for only providing the device to those in the usual care group at six-month follow-up. Exercise using a Squegg™ is not typical of usual care, so would have represented a deviation from protocol if it had been used during the treatment period by patients in the usual care arm.

The OPTimisE intervention received positive feedback from physiotherapists and patients. The physiotherapists interviewed commented that the three intervention components were neatly packaged with clear supporting resources that helped the physiotherapist deliver the intervention within a single appointment. Indeed, some commented that it could be delivered in a one-off appointment without the need for further follow-up. The patients also complemented the OPTimisE patient manual and website. The secure patient portal of the website was viewed 69 times since recruitment opened, with a mean of 4 minutes and 39 seconds spent viewing the page. Unfortunately, the technology did not permit more detailed analysis of how many of the 24 OPTimisE group patients had accessed it. The interviews suggested that some patients felt sufficiently informed by the patient manual not to use the website, whilst others preferred the videographic media online and referred back to it several times.

There were common treatment components shared across both the OPTimisE intervention and usual care, namely condition-specific advice and exercise. Usual care did not include the provision

of a counterforce brace, but some patients interviewed from the OPTimisE group described this as providing effective short-term pain relief and being superior to other types of orthoses they had tried previously themselves. Physiotherapists stated that it was unusual to provide general health and lifestyle advice to people with LET, despite doing this routinely for people with other musculoskeletal conditions, such as low back pain. Some patients engaged with this advice with examples of reducing tobacco use, losing weight, increasing general exercise levels and getting more sleep provided during the interviews. Although this was not captured in quantitative measures this could have a wider effect on the patient's general health in the longer term. Exercise regimens varied in usual care with little consistency in dosing or choice of exercises. Physiotherapists described the exercise regimen and dosing of the OPTimisE intervention to be very clear, empowering the patient to self-manage and progress to a level that would meet their expected levels of normal function. Indeed, patient feedback was that it was easy to incorporate into their daily routine. All physiotherapists found it an acceptable intervention to deliver with some commenting that they had changed their practice as a result of the pilot and feasibility trial.

Having established that the OPTimisE intervention was acceptable to patients and physiotherapists and satisfying all four of the pre-defined feasibility criteria, a future main trial to compare the clinical and cost-effectiveness of the OPTimisE intervention with usual physiotherapy care would appear feasible. The secondary quantitative analysis however failed to identify trends of improvements in pain, function, and perceived treatment effect from the intervention. Indeed, at six-month follow-up the PRTEE and GPE-11 scores appeared to show greater improvement in the usual care group than the OPTimisE intervention group. However, this finding should be treated with caution due to a lack of power (i.e. this may be down to chance rather than reflecting the 'truth'). Nevertheless, without any signal of effect from the OPTimisE intervention over and above the effect of usual physiotherapy care, it is difficult to justify a full-scale trial.

6.4 Recommendations for future research

6.4.1 Active treatment, beyond reassurance and advice, may not be needed for most patients with LET

The findings from this PhD showed a trend away from the traditional usual physiotherapy care model of repeated follow-up appointments and hands-on treatment, in the research-active centres involved in the OPTimisE pilot & feasibility RCT, with patients still reporting improvements in symptoms over time. The usual physiotherapy treatment that patients received was more closely aligned to the newly-developed OPTimisE intervention than was anticipated at the trial design and funding application stage. The findings of the secondary analysis, of similar improvements in both groups, is therefore unsurprising. A future project might take this trend a step further, to investigate whether follow-up physiotherapy is required at all. Physiotherapists interviewed during the RCT proffered that the OPTimisE intervention could be delivered in a single appointment an could be used as a stand-alone self-management package for patients with LET. Indeed, a recent systematic review and meta-analysis of LET trials calls into question the need for active treatment for the majority of people with the condition.[192] RCTs that included a placebo or wait-and-see control arm were meta-analysed to determine the trajectory of symptoms over time. The findings suggested that following enrolment in a clinical trial, patients experience improvements over time without any active treatment, regardless of symptom duration prior to enrolment.[192] The four included studies described as having wait-and-see control arms, that this conclusion was based upon, still included clinical assessment, a diagnosis of LET and provision of reassurance and very basic advice. Patients interviewed during the OPTimisE trial qualitative phase described how they were reluctant to follow self-management advice until they had received a diagnosis from a healthcare professional, therefore offering a possible reason as to why patients had failed to experience natural improvements prior to enrolment in these four trials regardless of the duration of their symptoms.[201] Given that current UK guidance[44] recommends physiotherapy for people that remain symptomatic six weeks after initial advice and

use of analgesia, some may therefore question if any physiotherapy treatment beyond reassurance and advice is worthwhile for these patients.

6.4.2 A potential paradigm shift towards a 'self-directed approach' for managing patients with LET

A useful next step would, therefore, be to test whether a potential paradigm shift towards a self-directed approach for managing patients with LET might be a better use of already stretched healthcare resources. For example, a future RCT could test whether a self-directed approach (e.g. a single appointment) to assess the patient, confirm the diagnosis, provide reassurance, and offer self-management advice, was a cost-effective way of managing these patients.

6.4.3 A cluster RCT with FCPs in primary care

As identified from the OPTimisE clinician interviews, in the UK patients with LET are being increasingly managed by FCPs in primary care, rather than by physiotherapists in outpatient settings, so a future trial could seek to recruit patients directly from primary care via FCP services. The potential challenge with recruiting patients via FCP services, is the lack of time for FCPs to recruit patients in busy primary care clinics. However, one solution would be to utilise a cluster-randomised control trial design, as it reduces the burden on clinicians to perform consent and randomisation procedures prior to treatment.

A further pilot trial (potentially as an internal pilot within a main trial) is needed to test the feasibility of recruitment of patients via FCP services, as the feasibility outcomes from the design used in this PhD, cannot be directly applied. FCP clinic sites could be either randomised to provide usual FCP care including referral to traditional physiotherapy outpatient services where appropriate, or a self-directed approach to treatment where the diagnosis of LET is established and the patient is provided with education about the condition and advice on self-management.

6.4.4 Using the OPTimisE advice and education package as a self-management resource

The advice/education and exercise components of the OPTimisE intervention could be utilised as a self-management resource for patients in the proposed future trial. They are more comprehensive than the advice packages provided in the four previous trials[192] and were developed with patient involvement to ensure relevance. Indeed, the qualitative study found that patients felt that the OPTimisE website and patient manual provided comprehensive advice in formats that were easy to understand. Recent trials in the fields of hip, knee, spine and shoulder pain have explored the delivery of 'blended' physiotherapy interventions, utilising smartphone applications as an interactive resource for self-directed care following an initial direct clinician consultation.[204-206] The OPTimisE resources might similarly be adapted, with the assistance of patients and the technology industry, to provide a comprehensive self-management application.

6.4.5 Broadening the accessibility of the self-management resources

The findings of the OPTimisE patient and clinician interviews suggested that the advice and education material needs to be broadened for accessibility, for example, by captioning videographic content and providing written information in languages other than English. Automated accessibility features could be embedded within a website or smartphone application.

6.4.6 Monitoring patient progress using online systems by default

While online systems may not be accessible for everybody, the OPTimisE trial found that the highest rates of return on outcome measures to monitor patient progress came from patients who used online data collection. In addition, online data collection reduces the burden on clinicians/researchers. Patients unable to use online data systems could be provided with a telephone or paper alternative, upon request.

6.4.7 Outcome measures for minimum data collection

Based on the analysis of the responsiveness of different outcomes used within the OPTimisE trial, it is recommended that, as a minimum, patient progress should be monitored using the PRTEE

(including the use of telephone data collection for non-responders). In addition, NRS scores for pain on gripping were shown to have similar responsiveness to the PRTEE and patients reported that the monthly collection of this measure via SMS text messages was both feasible and might improve engagement with a research trial.

A limitation of many of the published trials of physiotherapy interventions for LET is the lack of long-term follow-up, meaning that the effect of the intervention could not be evaluated against the natural course of the condition.[1] In relation to the future trial, data collection should be extended to 12 months, with financial incentivisation for data returns at all time points to maximise response.

The proposed future main trial design is summarised in Table 6-1: Summary of changes for a future main trial.

	Original Design	Proposed Future Design
Trial Design	Parallel group RCT	Cluster RCT
Setting	Outpatient physiotherapy services	FCP services
Intervention	OPTimisE intervention with multiple follow-up	Single session: OPTimisE advice/education and self-directed exercise components
Control	Usual outpatient physiotherapy treatment	Usual FCP treatment
Data collection method	Choice of online or paper questionnaire Follow-up 6 months	Online questionnaire by default (Paper or telephone upon request) Monthly SMS text question (NRS for pain on gripping) Telephone minimum data collection of PRTEE for non-responders Follow-up 12 months
Data analysis	Descriptive analysis of feasibility targets and thematic analysis of interviews	Full clinical and cost-effectiveness analysis

Table 6-1: Summary of changes for a future main trial

6.4.8 Feedback on the study findings from conference presentations

The outputs from this PhD have been presented in multiple forums, as described in the preface to this thesis. Following the presentation of the main results at the British Elbow & Shoulder Society conference in June 2023, a collaboration request was received from a UK orthopaedic surgery research group related to an NIHR Programme Grant for Applied Research, the broad aim of which was to conduct a series of trials to establish a clear treatment pathway for people with LET, including those that fail to respond to conservative management. There is potential therefore to incorporate the proposed cluster RCT as a first stage in a more complex adaptive trial design that also investigates the effect of surgery for those with recalcitrant symptoms.

6.5 Conclusion

Whilst the evidence from this PhD does not support the progression to a main trial of a similar format, there is potential for the OPTimisE intervention to be modified for use as a self-management strategy for patients with LET in future research.

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Appendices

Appendices pertaining to Chapter 3: Development of the OPTimisE Intervention

Appendix 3.1: Email invitation to participate in the OPTimisE intervention development NGT meetings.

Subject: Tennis Elbow Research

Dear Sir / Madam,

I am writing to invite you to take part in an online discussion group as part of a research project on Tennis Elbow. The project aims to develop an optimised physiotherapy treatment package for patients with Tennis Elbow for use in the NHS. As part of this I hope to ask the opinions of patients, senior NHS physiotherapists with a special interest in Tennis Elbow and NHS MSK outpatient physiotherapy managers in order to reach a consensus on the content of the treatment package.

You would be required to read a summary of the best available evidence for different treatments for Tennis Elbow and give your thoughts prior to joining at least two video-conferences of approximately 15 people. Each of these video-conference meetings will last around 2 hours. You will have the opportunity to discuss the options and give your opinions by an anonymous vote. There may be a need for further workshops depending on how long the process takes.

Workshops will be conducted in normal office hours so you can claim back costs for your time.

I have attached a copy of the Participant Information Sheet and a Consent Form for you to sign and return by email if you wish to participate. It is possible to sign this electronically using pdf editing software such as the free version of Acrobat Reader DC. Alternatively, you can return a photograph of a signed paper copy by email.

This research is funded by the National Institute for Health Research and the Chartered Society of Physiotherapy Charitable Trust. Ethical approval has been given by Keele University's Faculty of Medicine and Health Sciences Research Ethics Committee (reference: MH-200145).

If you have any further queries please contact me by email.

Yours sincerely,

Marcus Bateman.

Marcus Bateman BSc(Hons) MSc IP MCSP
Upper Limb Consultant Physiotherapist
NIHR & CSP Doctoral Fellow

Appendix 3.2: OPTimisE NGT participant information sheet

Optimising Physiotherapy for Tennis Elbow:

Intervention Development using a Nominal Group Technique Consensus Exercise

PARTICIPANT INFORMATION SHEET

What is the purpose of this project?

The aim of this project is to agree which treatments, and the key details of those treatments, should be included in an optimised NHS physiotherapy treatment package for people with Tennis Elbow.

Why is the project being done?

There are currently a wide range of treatments that are offered by physiotherapists treating patients with Tennis Elbow and some have been shown to be more effective than others. By establishing what the optimal treatment package should be, patients can be given the most effective treatments in future. The first stage of the project is to reach consensus on what this new optimised treatment package should contain.

Why do you want me to take part?

We need a balance of views to make sure that the new treatment package is suitable for use in the NHS and acceptable to both patients and physiotherapists. We therefore need a mix of:

- Patients representatives who have had physiotherapy treatment for Tennis Elbow
- Senior NHS physiotherapists with a special interest in Tennis Elbow
- NHS physiotherapy managers

The only other requirements are that you are able to understand written and spoken English.

Do I need any special equipment?

The workshops will be run as an online video-conference using Microsoft Teams. If you haven't used this before, it is similar to other video-conferencing platforms like Zoom, Skype or Google Meet.

You will need access to a computer with a webcam and microphone. You will also need a broadband internet connection. Due to the small screen size using a smartphone is not recommended. If you have any concerns regarding the technology, a test session can be arranged prior to the workshops to make sure you can connect successfully.

Do I have to take part?

Taking part is entirely voluntary. If you agree to take part you will need to sign a consent form to say that you understand what the project involves and what your commitments are. You have the right to change your mind at any stage and withdraw from the project without giving a reason. Any information or opinions you provide up until the point you withdraw will still be used but anonymised.

What will happen to me if I take part?

You will first be asked to complete a short online questionnaire about yourself. This is anonymous and includes general questions such as your age, sex and whether you are a manager, physiotherapist, or patient representative.

You will then be invited to join two online workshops of around 15 participants. The workshops should last about two hours each. Two weeks before the first workshop you will be sent some information by email to read about the scientific evidence for the different physiotherapy treatments available. It is important that you read this thoroughly and then reply with your thoughts on which treatments should be included in an optimised treatment package. The workshops will begin with an overview of the process. During the workshop everyone's ideas will be presented by the research team and there will be discussions and anonymous voting to decide which treatments will be included. Once the treatments have been agreed a second workshop will be used to agree the finer details of those treatments. You will be sent a more detailed summary of the evidence for those treatments prior to the second workshop. It is important that you read this thoroughly and then reply with your thoughts on which specific details should be included the final optimised treatment package. Similar to the first workshop everyone's ideas will be presented by the research team and there will be discussions and anonymous voting to decide which treatment details will be included. Further workshop(s) may be required if the work cannot be completed in the allotted time.

What are the possible benefits of taking part?

Although you may not experience any direct, personal benefit through taking part, you will be able to contribute to research for Tennis Elbow and hopefully improve future treatments for people with the condition.

What are the possible disadvantages of taking part?

There should not be any disadvantages of taking part except for giving up some of your time.

Will I be reimbursed for my time?

NHS staff can claim back salary costs and patient representatives can claim £20 per hour as a reimbursement of time. You will be provided with a form by email to enable you to claim for these expenses.

Will my information be kept confidential?

Your personal information, such as your email address, will remain confidential and will not be shared with any third parties. The online workshops will be video recorded and stored on secure servers at Keele University. The video recordings will be used by the research team to refer back to when writing up the results and will be deleted after the results are published. The video recordings will not be shared outside of the research team or data archive. Your name and face will be visible to the other participants during the workshops. Participants will be advised not to discuss the workshop content with others outside of the workshops. Any contributions that you make will be anonymised if being used in the final results report.

What happens after the workshop(s)?

The research team will use the results of the workshop to specify a detailed physiotherapy treatment package for people with Tennis Elbow. The new optimised NHS physiotherapy treatment package will then be used to treat patients with Tennis Elbow in a research trial and compared to patients receiving current usual physiotherapy treatment. The results will be published in a scientific journal and presented at medical conferences.

Who has reviewed this research?

This study has been approved by Keele University's Faculty of Medicine and Health Sciences Research Ethics Committee (reference: MH-200145).

Sponsorship and funding:

This research is sponsored by Keele University (reference RG-0319-20) and funded by the National Institute for Health Research and the Chartered Society of Physiotherapy Charitable Trust.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and email address. People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking the research team (e-mail: m.bateman@keele.ac.uk)
- by sending an email to research.governance@keele.ac.uk
- by ringing Marcus Bateman on 01332 789697

Appendix 3.3: OPTimisE NGT consent form

Optimising Physiotherapy for Tennis Elbow:

Intervention Development using a Nominal Group Technique Consensus Exercise

CONSENT FORM

Please initial:

1. I confirm that I have read and understand the NGT Participant Information Sheet (version 1.5, date 1/12/2020). ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. I understand that if I do withdraw, my contribution up until the point of withdrawal will still be used. ☐
3. I understand that my participation in this study involves reading summary documents, contribution of ideas and two or more online consensus workshop(s). ☐
4. I consent to be video-recorded. ☐
5. I am aware that I can claim reimbursement of costs for my time. ☐
6. I am aware that any information and opinions I provide will remain confidential and that if used in any publications or reports that arise from this research will be anonymised. ☐
7. I agree to participate in this study. ☐

Signature ……

Name of participant (print) ……

Date ……

One copy to be kept by the participant. One copy to be returned to the research team.

IRAS Number: 290963 NGT Consent Form v1.4 1/12/2020

Keele University FMHS Faculty Research Ethics Committee
health.ethics@keele.ac.uk

Keele UNIVERSITY

01 Oct 2020

Dear Marcus,

Project Title:	Optimising Physiotherapy for Tennis Elbow: Protocol for Intervention Development using a Nominal Group Technique Consensus Exercise
REC Project Reference:	MH-200145
Type of Application	Main application

Keele University's Faculty of Medicine and Health Sciences Research Ethics Committee (FMHS FREC) reviewed the above project application.

Favourable Ethical opinion
The members of the Committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion
The favourable opinion is subject to the following conditions being met prior to the start of the project.

1.	All relevant NHS approvals should be secured prior to beginning the project.
2.	Participants should be informed as to when videos will be deleted/how long they will be stored in Appendix 2 Participant info.
3.	The Ethics Application Form should explicitly declare that the recordings are Video files from Google Meet.

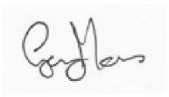
Reporting requirements
The University's standard operating procedures give detailed guidance on reporting requirements for studies with a favourable opinion including:

- Notifying substantial amendments
- Notifying issues which may have an impact upon ethical opinion of the study
- Progress reports
- Notifying the end of the study

Approved documents
The documents reviewed and approved are:

Document	Version	Date
NGT Protocol	1.3	18 Aug 2020
Appendices 1-7	-	18 Aug 2020

Yours sincerely,



Dr Gary Moss
Chair

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Jonathan Hill
School of Medicine
David Weatherall Building
Keele University
ST5 5BG

Email: approvals@hra.nhs.uk

04 December 2020

Dear Dr Hill

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Optimising Physiotherapy for Tennis Elbow: Protocol for Intervention Development using a Nominal Group Technique Consensus Exercise.**
IRAS project ID:	**290963**
Protocol number:	**RG-0319-20**
REC reference:	**20/HRA/5848**
Sponsor	**Keele University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The *"After HRA Approval – guidance for sponsors and investigators"* document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, including:

- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

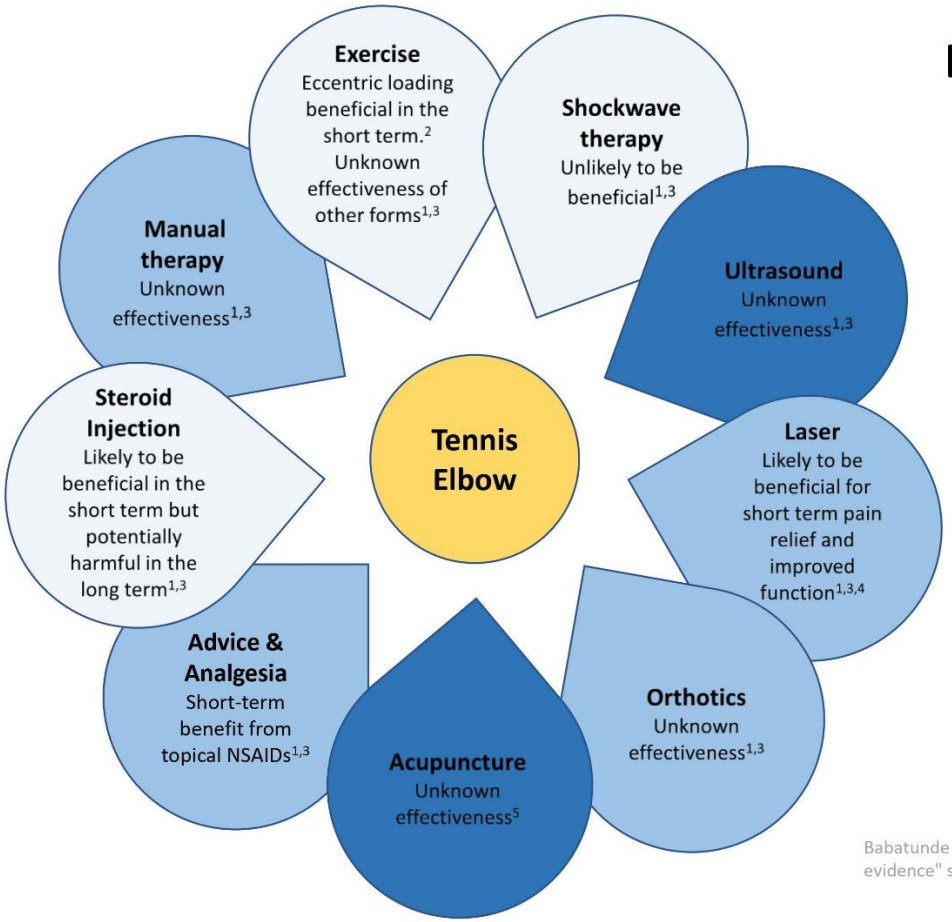
Your IRAS project ID is **290963**. Please quote this on all correspondence.

Yours sincerely,

Rebecca Evans
Approval Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Tracy Nevatte*



Evidence Summary – Treatment Options for Tennis Elbow

- Gap in evidence
- Very low quality evidence
- Low quality evidence
- Moderate quality evidence
- High quality evidence

References

1. Bisset et al. *BMJ Clin Evid.* 2011;2011.
2. Chen & Baker. *J Hand Ther.* 2020.
3. Long et al. *Health Technol Assess.* 2015;19(8):1-134.
4. Mamais et al. *Laser Ther.* 2018;27(3):174-186.
5. Tang et al. *Evid Based Complement Alternat Med.* 2015;2015:861849.

Babatunde OO, Tan V, Jordan JL, et al. Evidence flowers: An innovative, visual method of presenting "best evidence" summaries to health professional and lay audiences. *Res Synth Methods.* 2018;9(2):273-284.

V2.0 15/12/2020

- **Exercise**
  - There are numerous studies that include exercise of different types. The greatest evidence is in favour eccentric exercise (a type of slow controlled strengthening) - this has a large beneficial effect in the short term. The benefit of eccentric exercise in the long term is unclear, but there is evidence to suggest that adding other forms of exercise (stretching, isometric loading, concentric loading and shoulder exercises) may further improve effectiveness.
- **Shockwave therapy** – typically 3 sessions over 3 weeks
  - This is an electrical device that produces energy in the form of shockwaves. It is applied at the location of pain.
  - There are numerous studies of shockwave therapy with the majority showing that it is no better than sham shockwave therapy (where the machine is not working).
- **Ultrasound** – typically 10-15 sessions over 3-4 weeks
  - This is an electrical device that produces energy in the form of sound waves. It is applied at the location of pain.
  - The evidence relating to ultrasound is of very low quality and shows conflicting results. Some studies report that it is effective in the short term up to 13 weeks, but others report that it is no better than sham ultrasound (where the machine is not working).
- **Laser** – typically 10-15 sessions over 3-4 weeks
  - This is an electrical device that produces energy in the form of light waves. It is applied at the location of pain.
  - Based upon the findings of low quality studies laser may give short term improvements in pain and function up to two months when compared to sham laser (where the machine is not working). Beyond two months there is no difference.
- **Advice & analgesia**
  - There is low quality evidence that anti-inflammatory gel can give pain relief up to 4 weeks.
  - It is unclear whether oral anti-inflammatories are effective.
  - The majority of patients given reassurance and simple advice regarding changing daily activities have improved symptoms by 1 year.
- **Acupuncture** – typically 6 sessions over 3 weeks
  - No firm conclusions can be made about effectiveness due to the very low quality of research, but some studies show pain relief for up to 2 weeks.
- **Orthotics**
  - This includes the use of wrist splints, forearm braces and taping techniques.
  - There are numerous studies, mostly of very low quality, that found conflicting results. There is some evidence that wrist splints and forearm braces offer short term pain relief.
  - One large-scale study of 4614 patients with Tennis Elbow found that those using orthotics had more time off work and greater healthcare usage than those that did not.
  - The evidence suggests that the benefit of taping only lasts 15-30 minutes.
- **Steroid injection**
  - Multiple studies show a large beneficial effect up to 6-8 weeks but the effect then wears off.
  - Several studies show that patients are worse on average at 12 months following steroid injection compared to those without injections.
  - Several studies show that symptoms are more likely to return after steroid injections than mixed physiotherapy treatments.
  - There are risks of side effects such as infection, permanent skin discolouration and temporary increase in blood sugar for diabetic patients.
- **Manual therapy** – typically 8-12 sessions over 3-6 weeks
  - This includes massage and 'hands-on' physiotherapy techniques such as Mills' Manipulation and Mobilisations With Movement.
  - Low quality evidence and studies often combine manual therapy with other treatments.
  - The effect of manual therapy is unclear but it may offer short term relief only.
  - Evidence suggests that manual therapy is less effective than exercise.

Literature Review of Physiotherapy Interventions for Lateral Elbow Tendinopathy

Initial Management Strategies

The NICE Clinical Knowledge Summary[1] suggests that initial management should recommend the use of analgesia such as paracetamol or topical non-steroidal anti-inflammatory drugs (NSAIDs), with a subsequent prescription of oral NSAIDs if ineffective. It is recommended to give advice to avoid heavy lifting, avoid forceful gripping and twisting activities, favour palm-up lifting rather than palm-down, and modify work by taking more rest breaks, alter work patterns and change practice regarding lifting.

Evidence for simple advice

Similar advice has been used as part of a wait-and-see control arm in four trials, along with simple reassurance that for the majority the symptoms of LET will settle over time.[2-5] In all four, patients in the wait-and-see group improved with short-term patient-rated successful treatment ranging from 26.3% to 32% and longer-term success at one year ranging from 83% to 90%. It is unclear whether this represents the natural course of the condition or whether the advice improved outcomes, given that there have been no studies of advice versus a true wait-and-see approach.

Epidemiological studies suggest that there may also be a place for advice related to stopping smoking, improving diabetes control and promoting regular exercise two to three times per week based upon risk factors for developing the condition.[6,7]

The Kings Fund, in 2015, set ten priorities for UK NHS commissioners that included self-management at number one, with the aim of promoting increased physical function and self-confidence.[8] Self-management "refers to activities which promote health but also prevent deterioration by gaining skills which can be applied to new problems as they arise to increase self-efficacy in managing the condition as it progresses."[9] Systematic reviews of the musculoskeletal literature, whilst not specific to LET, show moderate to strong evidence for the use of exercise and psychological interventions, such as pain coping skills, as physical activity and pain catastrophising are strong mediators for outcome in studies of self-management.[10-12] It is recommended that self-management education is delivered to patients by healthcare clinicians and includes follow-up sessions rather than one-off advice, should include self-help materials, help patients to identify problems specific to themselves, assist the patient to form personalised coping strategies and enhance their self-efficacy by empowering them to take responsibility for their lifestyle choices.[9,13,14] Applying such methods, in addition to the basic advice given in the LET trials previously mentioned, may further improve outcomes.

Sport-related advice

In racquet-sports players, it has been hypothesised that changing grip size on the racquet may help to reduce symptoms by altering the grip force required to hold it, but a laboratory study found no difference in muscle activity with different grip sizes.[15] Racquet string tension has though been found to relate to changes in force transmission across the elbow during backhand tennis groundstrokes, with higher string tension resulting in higher force.[16] Similarly, a tighter grip on the racquet combined with below-centre strikes on the racquet face result in higher eccentric wrist extension torque.[17] Whilst these two studies were performed in laboratory experimental conditions,

the biomechanical findings could be transferrable to real-world sport with advice to de-tension strings, grip the racquet less firmly and seek coaching to improve ball-strike technique.

Evidence for the use of analgesia

Systematic review evidence of five placebo-controlled trials investigating the use of topical NSAIDs suggests that this can offer short-term pain relief up to four weeks but the evidence was judged to be of low quality and therefore inconclusive.[18] The evidence for oral NSIADs was conflicting. No trials have specifically investigated the use of paracetamol or opioid medication though it stands to reason that these may offer short-term symptomatic pain relief only rather than affecting the overall course of the condition, as found with other musculoskeletal disorders, such as back pain and shoulder pain.[10]

Evidence for use of physiotherapy interventions

In this section the evidence for these treatments will be analysed and discussed:

Manual therapies

Manual therapy includes a range of different 'hands-on' treatment techniques that, in the case of LET, can be grouped into Cyriax manual therapy, Mobilisation with Movement (MWM) and regional mobilisations.[19] The Cyriax method involves a 10-minute session of deep transverse friction massage to the painful tendon followed by a Mills' Manipulation whereby the patient's elbow is forcibly extended to end range whilst the wrist is fully flexed and the forearm pronated.[20] MWM combines manual therapy with active exercise, typically a lateral glide to the elbow whilst the patient performs an isometric gripping exercise.[21] Regional mobilisations include all other types of manual therapy used more generally in the upper limb, rather than focussed on the elbow, and mobilisation of the cervical spine.[19]

The most-recent systematic review and meta-analysis of manual therapy for LET by Lucado et al[19] concludes that "there is compelling evidence that joint mobilizations directed at the elbow improve both pain and functional grip scores across all time frames compared to control groups in the management of LET." This conclusion must, however, be questioned based upon methodological errors and reporting bias in the review. Three large studies are included in the meta-analyses that investigate manual therapy as part of a multimodal physiotherapy treatment package compared with a control of wait-and-see (including advice).[2,22,23] It is impossible to determine the effect of the manual therapy component of these studies which should not have been included in the meta-analyses for that reason. With these studies removed the meta-analysis of Mills' Manipulation (Cyriax manual therapy) would not be possible for pain as only one study would remain. The meta-analysis of pain for MWM would only include one small pilot study of 10 patients and a small non-randomised study of 34, with no analysis possible for follow-up beyond four weeks.[24,25] Grip strength would not be possible as only one study would remain.[24]

Reviewing the remaining evidence descriptively, Cyriax manual therapy is no more effective than Bioptron polarised light therapy based upon no significant difference in any outcome measures or time points apart from pain visual analogue scale (VAS) at 28 weeks.[26] The same study included an exercise intervention arm and found that exercise was more effective than Cyriax manual therapy at all time points and all outcome measures up to 28 weeks.[26] Similarly, Viswas et al[27] compared Cyriax manual therapy against the same exercise intervention designed by Stasinopolous[28] and found similar results in favour of exercise. In contrast, Nagrale et al[20] found Cyriax manual therapy to be superior to a combination diclofenac gel phonophoresis and Stasinopoulos exercises at eight weeks.

Two studies have investigated the immediate effect of MWM on pain free grip strength (PFGS) and pressure-pain threshold (PPT) after a single treatment session.[21,29] The studies were small, totalling 41 patients, but had robust methodologies that included a placebo and control procedure, and blinded both the patient and the outcome assessor to the intervention. Both found significant immediate improvements in PFGS compared to a sham MWM group and a no intervention group. There are few studies, however, that investigate longer-term effect: two studies investigated the addition of MWM to multimodal physiotherapy including heat, massage and ultrasound therapy. Amro et al[24], in a study of 34 patients, found in favour of the MWM group at four weeks follow-up but the method was non-randomised and at high risk of bias. Kim et al[25] also concluded that the addition of MWM improved outcome immediately after 10 days of treatment but with just 10 patients the study was under-powered. Afzal et al[30] found that patients treated with MWM and ultrasound therapy had significantly improved pain and function at four weeks follow-up compared to those treated with ultrasound alone but the study was limited by a small sample size (n=30) and a lack of blinding. A novel study by Martinez-Cervera et al[31] investigated the mechanism by which MWM might have an effect. Twenty-four patients were randomised into two groups that both received MWM three times in a week. Half of the patients were told that MWM was a very effective treatment and the other half were given neutral expectations that it may or may not be effective. Patients given high expectations gained significantly better outcomes immediately after treatment suggesting that patient expectation might be an important factor in treatment selection.

Regional mobilisations can be divided into wrist mobilisation and cervical spine mobilisation. The evidence for wrist mobilisation is limited to two small un-blinded studies of similar methodology compared against multi-modal physiotherapy.[32,33] Both found short-term benefit in favour of wrist mobilisation at three weeks but Struijs et al[33] also followed-up patients to six weeks and found no difference between groups at that time point. The evidence for cervical mobilisation is based upon three small randomised trials totalling 43 patients and one low-quality retrospective study.[34-37] Vicenzino et al found immediate improvements in PFGS, pain VAS and PPT with mobilisation of the C5/6 cervical levels compared to a sham technique or control.[37] Fernandez-Cervaro et al conducted two studies where cervical manipulation was firstly compared with a sham technique and secondly compared with thoracic manipulation.[35,36] Both reported immediate improvement in PPT but conflicting results for PFGS. The retrospective study by Cleland et al[34] concluded that there was a high long-term success rate for multimodal physiotherapy with or without cervical mobilisation. Small differences were seen in favour of cervical mobilisation group but given that the patient demographics and treatments received as part of the multimodal physiotherapy between groups were different the attribution of this effect to manual therapy alone is unjustified.

Overall, there is low quality evidence to suggest short-term benefit of manual therapy but also that it may be less effective than exercise.

Orthoses and Taping

Orthoses

Orthoses for LET are widely available for general public sale and are also provided via the UK NHS on the recommendation of clinicians.[38] Different forms of orthotics are available but the two main principles of treatment are either to immobilise the wrist, thus reducing the activity of the wrist extensor muscles, or to alter the mechanical forces along the extensor muscles of the forearm by use of a 'counter-force brace'. Counter-force bracing involves fastening a tight cuff around the forearm containing a padded section that is sited over the ECRB muscle. Cadaveric studies have shown that

this reduces the force on the ECRB tendon origin when a load is applied distally, suggesting that *in vivo* the aggravating load on the ECRB might be reduced when performing gripping activities whilst using the brace.[39] This has been demonstrated in a small LET patient population where 31 patients were randomised to either wear the brace correctly as a tight cuff or to wear it loosely to minimise the effect.[40] Those wearing the brace correctly experienced significant pain relief in the short term compared to those wearing it loosely. Likewise, a cross-over study investigating two different types of counter-force brace (one a standard design and another incorporated into an elbow compression sleeve) found that these gave immediate pain relief and improved grip strength compared to no brace.[41]

The use of a wrist immobilising splint has been shown to improve pain and grip strength after three weeks when used in combination with physiotherapy treatment and compared to physiotherapy treatment alone.[42] Two studies have compared the use of counter-force bracing to wrist immobilisation, with different conclusions drawn: Akkurt et al[43] found no difference between the different types of splint up to six weeks follow-up of 82 patients whereas Garg et al[44] concluded that wrist immobilisation was superior at the same time point when studying 42 patients. This conclusion is questionable however, as it was only demonstrated in one sub-domain of the American Shoulder and Elbow Society (ASES) Elbow Assessment Form when all other outcome measures showed no difference. Both studies showed that patients with LET improved over time regardless of which orthosis was used. Van De Streek et al[45] compared the use of a counter-force brace to both the counter-force brace and wrist immobiliser worn together and found no difference in outcome between groups at six weeks.

Whilst there is some evidence of short-term effect of orthotic use, there may be no effect in the long-term. A large study of 110 patients with LET by Nishizuka et al[46] compared a counter-force brace worn daily for six months in addition to exercises with exercises alone. There were no differences in outcomes between groups at any time point up to one year, but both groups improved significantly suggesting the brace gave no additional benefit to exercises alone. Similarly, a large study of 185 patients compared the use of a counter-force brace against an exercise programme and found in favour of exercise at all time points up to a minimum of 12-month long-term follow-up.[47] Indeed, a large retrospective population study of 4614 patients receiving treatment for LET and medial elbow tendinopathy (MET) in the USA found that those using orthoses of any type had higher healthcare usage, longer treatment duration and longer time off normal work than those that did not use orthoses. Other factors may though confound this conclusion as it was unclear whether the baseline symptoms (such as pain severity) were similar between those using orthoses and those not. Higher baseline pain is an established predictor of poorer outcome in patients with LET[48] so the differences between groups may not be due to orthotic use alone.

Taping

Kinesiology tape (or K-tape) is an adhesive elasticated tape that is purported to reduce the load on the wrist extensor tendons when applied longitudinally over the dorsal forearm muscles.[49,50] It is not commonly used in UK practice.[38] Studies of the use of K-tape to treat LET are of low quality and of small sample size.[49,51-55] Cho et al[50] found that the application of K-tape to patients with LET gave some immediate pain relief for up to 15 minutes but for longer follow-up the majority of studies show that the use of K-tape is no more effective than sham taping techniques or offers no increased benefit when used in addition to other physiotherapy modalities such as exercise.[49,51,54] The exception is a study by Giray et al[55] but with only 10 patients per group the result may have been due to chance.

Diamond taping uses a non-elastic adhesive tape applied in four strips pulled tightly around the location of lateral elbow pain to form a diamond, resulting in the encompassed skin having an orange-peel appearance.[56] Similarly to K-tape it is purported to reduce mechanical load on the wrist extensor tendons.[56] A recent systematic review identified four studies of diamond taping each only measuring the immediate effect after application or up to 30 minutes afterwards.[57] All four studies showed improvements in either pain or grip strength compared to controls. It is unclear however whether this has any useful clinical benefit as longer-term effects have not been studied.

Acupuncture

Acupuncture is used by some physiotherapists in the UK as a second-line treatment for LET.[38] It involves the insertion of fine needles into specific anatomical points on the body as defined in Traditional Chinese Medicine (TCM). These points are then stimulated in a variety of ways such as by twisting the needles (manual stimulation), applying an electrical current (electro-acupuncture) or by heating the needles (moxibustion).[58,59] The purpose is to induce a pain-relieving effect on the nervous system although the evidence for this effect has not been firmly established.[59]

The evidence for the use of acupuncture in the treatment of LET is of low or very low quality based upon several systematic reviews.[58,60-62] Of the included studies, only four compare acupuncture with a supposed placebo or sham treatment. It might be argued, though, that in three of these studies the control arm still included acupuncture treatment: Fink[63] and Irnich[64] both used a similar method whereby acupuncture needles were still inserted but at least 5cm away from the sites recommended by TCM; in the study by Haker[65] needles were still inserted at acupuncture sites but only superficially rather than to the recommended depth, and were not stimulated. In the fourth study, Molsberger[66] used a sham control method where pressure was applied to an acupuncture point on the patients' thoracic spine with a pencil-shaped probe instead of a needle being inserted but patients could not be blinded from this as the 'real' acupuncture group did not have any needles inserted in the thoracic region. Despite this, in all four of these studies outcomes favoured 'real' acupuncture immediately post-treatment or up to two weeks' follow-up. A limitation of the majority of acupuncture studies is the lack of longer-term follow-up, lack of blinding, lack of randomisation and heterogeneity of outcome measures that prevents meta-analysis of data.[58] Few studies measure the impact on disability and function, just focussing on pain severity.[62] Fink[63] and Haker[65] both followed-up patients for one year but no significant differences were seen between 'real' acupuncture and sham acupuncture beyond two weeks. Improvements were seen in both groups following the natural trend for improvement in LET symptoms over time. The evidence for acupuncture treatment for LET is therefore uncertain but it may offer some short-term benefit for pain for up to two weeks.

Electrotherapies

Electrotherapy was established as one of the four pillars of UK physiotherapy practice when the Society of Physiotherapy was granted its Royal Charter in 1920. Over the century that followed electrotherapies changed with evolving technology but the principle of the purported mechanism of effect remained the same: when energy is focussed on injured tissue it can improve the healing response.[67-71] Electrotherapy is still used in the management of LET in the forms of laser, ultrasound and shockwave therapy (SWT).[38,72]

Laser

Laser treatment uses light energy applied locally to the area of pathology to stimulate a physiological response such as reducing inflammation or promoting collagen production.[73] The reaction is dose-dependent with collagen production at lower doses and anti-inflammatory effects at higher doses.[73] For this reason Low Level Laser Therapy (LLLT) is most commonly used in the treatment of LET to promote collagen repair in the absence of significant inflammation.[74] Laser light can be generated at different wavelengths dependent on the elements used: gallium arsenide 904nm, helium neon 632nm, gallium aluminium arsenide 820nm and neodymium-doped yttrium aluminium garnet 1064nm.[67,75,76] These different wavelengths penetrate human soft tissues differently with 904nm having the deepest effect.[77] The use of laser was popular in the 1990s but has since declined in both usage and availability.[78] Recent studies of UK practice showed that it was now scarcely used in the treatment of patients with LET.[38,72]

A systematic review of the effectiveness of LLLT in the treatment of LET published in 2008, Bjordal et al[73] concluded that it offered favourable short-term improvements in both pain and function when compared to placebo. In a previous review, Bisset et al[79] had concluded that laser was no more effective than placebo but in this study the analysis was not broken down into different treatment wavelengths. Bjordal et al[73] sub-classified studies by treatment wavelength in their meta-analysis to find that the 904nm wavelength provided an effective response (when applied over the extensor tendons rather than when applied over acupuncture points) immediately after the course of treatment and up to eight weeks of follow-up. The 820nm and 1064nm showed no benefit and the 632nm wavelength was inconclusive but might be effective based upon one study.[80]

Ultrasound

Ultrasound therapy delivers energy locally to the tissues via high frequency sound waves. The evidence for ultrasound is conflicting and of low or very-low quality.[60,61,71,81] Smidt et al[81] in a systematic review published in 2003 pooled data from two studies to conclude that ultrasound was effective for pain relief in the medium-term up to 13 weeks but the studies were low-powered. Indeed, considered separately these two studies show conflicting results: Binder et al[82] demonstrated significant benefit from ultrasound over placebo whereas Lundeberg et al[83] found no difference. A subsequent study of similar methodology comparing ultrasound against placebo also found no difference in outcome.[69] Subsequent reviews in 2014 and 2015 have concluded that ultrasound is no more effective than placebo in the short-term.[71,84] However, Dingemanse et al[71] still concluded that there was moderate evidence in favour of ultrasound over placebo in the medium-term despite this being based on the outcome of just one study that could not be replicated.

Shockwave therapy

Shockwave therapy provides energy to the tissues via pulsed acoustic waves, but the mechanism of any therapeutic effect is unclear.[70] Shockwave therapy can be administered in different ways: by use of a radial shockwave device or an extracorporeal shockwave device, and with or without the addition of local anaesthetic. One method has not been shown to be superior to the others.[84] The continued clinical use of SWT is surprising given the conclusions of a 2006 systematic review stating that based upon "platinum-level evidence that shock wave therapy provides little or no benefit in terms of pain and function in lateral elbow pain."[70] A more recent review published in 2015 pooled data from the 2006 review with subsequent studies to draw similar conclusions: that SWT was no more effective than placebo for pain or pain on resisted wrist extension up to six weeks follow-up.[84] Despite this, it continues to be used in UK practice for the treatment of LET by 11% of respondents to a recent nationwide survey.[38]

Exercise therapy

Exercise is the mainstay of modern physiotherapy treatment of LET in the UK.[38,72] A limitation of the evidence regarding exercise is the heterogeneity of exercise type, treatment duration and dosage used in clinical trials.[85] Many trials have used bespoke exercise programmes but there are four specific exercise protocols have been studied multiple times:

The Pienimaki protocol

The Pienimaki protocol was first described in 1996 in a trial of exercise versus ultrasound therapy.[86] It consisted of stretches of the forearm muscles and a four-stage progressive loading regime starting with isometric contractions, then isotonic resisted uniplanar exercises using a Theraband, followed by isotonic resisted biplanar exercises using a Theraband, and finally functional repetitive movements involving gripping. Patients were advised to perform exercises four to six times per day for six to eight weeks. Each exercise was done in two to three sets of 10 repetitions. The findings of the trial showed that the exercise protocol was significantly more effective than ultrasound immediately after eight weeks of treatment.

The same exercise protocol was subsequently used with deep transverse friction massage and ultrasound as part of a multimodal physiotherapy treatment package by Smidt et al.[4] The multimodal package gave the highest chance of recovery at six months compared to corticosteroid injection or wait-and-see.

It was also used by Tonks et al[87] in a low-powered randomised controlled trial (RCT) involving 12 patients per group. Improvements were seen at seven-week follow-up in pain and grip strength compared to controls but failed to reach statistical significance.

The Stasinopoulos protocol

Stasinopoulos et al[26,28] described a four-week supervised exercise protocol consisting of one stretching exercise and a progressive eccentric loading exercise. A stretch of the wrist extensor muscles was performed with the elbow extended, forearm pronated and wrist passively flexed with ulnar deviation to the end of the available range. The position was maintained for 30-45 seconds and repeated three times before and after the eccentric loading exercise. Eccentric loading was performed with the elbow fully extended and forearm pronated whilst supported on a treatment couch. The wrist was passively positioned into full extension then slowly lowered to full flexion over 30 seconds with the addition of a load individualised to the patient. The load was applied using a weight or Theraband and determined by the pain response. Mild pain was acceptable but disabling pain meant that the load was too great. Eccentric exercises were performed in three sets of 10 with a one-minute rest period in-between sets.

The Stasinopoulos protocol has been used in seven trials.[20,26,27,88-91] It has been compared to the Pienimaki protocol and found to give greater benefit in terms of pain relief and function at 12 and 24-week follow-up.[90] Patients performed supervised exercises once per day, five days per week for four weeks compared with home exercises four to six times per day for eight weeks in the Pienimaki protocol. Adherence to home exercise was not measured but the authors hypothesise that adherence may have been the deciding factor in why the Stasinopoulos protocol was more effective. An alternative reason could be the different types of exercise used.

Three studies have compared the Stasinopoulos protocol to Cyriax manual therapy.[20,26,27] The two studies that used the protocol as a stand-alone treatment found it to be superior to Cyriax manual

therapy[26,27] but Nagrale et al[20] combined it with diclofenac gel phonophoresis and found it to be less effective.

Manias et al[88] investigated whether the addition of ice massage to the exercise protocol was more effective than the exercises alone and found no difference in outcome. Both Sethi et al[89] and Mostafaee et al[92] added shoulder strengthening exercises to find that these further improved outcomes when compared to the Stasinopoulos protocol alone. Likewise, the addition of concentric and isometric strengthening exercises resulted in superior short-term results when compared to the original protocol.[91]

The Solveborn protocol

The Solveborn protocol[47] consisted of 10-second isometric wrist extension contractions followed by stretches of the forearm extensor muscles held for 15-20 seconds. Isometric contractions were performed three to five times followed by a similar number of stretches. Then, similar exercises were performed for the wrist flexors. Pain during exercise was avoided. Exercises were performed twice daily. In a large trial of 185 patients, the exercise protocol was compared with the use of a counterforce brace. Both groups improved but the exercise group had significantly better outcomes at all time points up to and beyond a year follow-up.

The protocol was used in three other trials.[93-95] Nilsson et al[94] taught the exercise protocol for home use along with ergonomic advice and a counterforce brace in a non-randomised trial versus a control of usual care. The intervention group had significantly better outcomes at four and 16-week follow-up but there was a high drop-out rate in the control group that may invalidate the results. Haahr et al[93] conducted a large RCT involving 266 patients randomised to a one-off education session, including general advice and instruction in the Solveborn protocol, versus a control group of usual care. They found that both groups improved up to one year but with no between-group difference. Svernlov et al[95] compared the Solveborn protocol to a combination of stretching and progressive eccentric loading. The same stretching dose was used but the isometric exercises used in the Solveborn protocol were substituted with three sets of five repetitions of pain-free eccentric loading exercises using a weight. Each repetition was performed over 10 seconds. The weight was progressively increased by 10% each week from a starting point of 1 kilogram for males and 0.5 kilograms for females. Both groups exercised at home for 12 weeks. Improvements were seen in both groups but the eccentric exercise group gained significantly improved grip strength at six months compared to the Solveborn protocol group.

The Vicenzino protocol

The Vicenzino protocol[96] has been used in three large RCTs totalling 483 patients.[2,22,97] In all three trials it has been used as part of a multimodal approach along with manual therapy and taping. The exercise component required patients to perform pain-free exercises of the hand, wrist and forearm starting with simple controlled active movements not incorporating additional load. Load was then progressively added using Therabands of increasing resistance during concentric and eccentric actions of the wrist. The focus was on wrist extension with exercises performed slowly over six to eight seconds. The dose was dependent on the symptom reaction with pain avoided during and after the exercises. As symptoms improved with gripping no-longer painful, additional strengthening exercises of the whole upper limb were prescribed including bench press, shoulder press, bent-over rows, biceps curls and tricep curls using weights. In two trials patients attended eight times over six to eight weeks[2,22] and in one trial four times over four weeks.[97] Significant improvements were seen between four and 26 weeks follow-up across the trials compared to controls and economic evaluation from the trial by Coombes et al found it to be a cost-effective treatment for LET.[98]

Isometric exercises

Isometric exercise as an initial treatment for the management of acute tendinopathy is currently *en vogue.*[99] Two studies have investigated isometric exercises specifically for the treatment of LET.[5,100] Park et al[100] randomised 31 patients to early pain-free isometric wrist extensions or the same exercises started after four weeks. The contractions were held for 10 seconds and repeated 50 times, four times a day. Significant improvements were seen in the first four weeks in the early exercise group. Vuvan et al[5] compared a single session of isometric exercise instruction versus wait-and-see in a trial of 40 patients. Patients were taught to perform the exercises at 20% of the Maximum Voluntary Contraction (MVC) of the unaffected arm increasing to 35% MVC by week seven. They performed three repetitions of 45 second holds or four repetitions of 30 second holds once daily for eight weeks. Outcomes measured using the PRTEE improved significantly in exercise group at eight weeks but other measures did not show a significant difference. The authors concluded that isometric exercise alone was not sufficient to treat LET but may form part of a treatment package.

Stasinopoulos et al[91] compared their own protocol of eccentric and stretching exercises to the addition of concentric exercises and both concentric and isometric exercises. A small and insignificant difference was seen with the addition of concentric exercises but the further addition of isometric exercises resulted in significant improvements compared to eccentric and concentric/eccentric exercises. The study was, however, limited by a small sample size of 34 so the results should be taken with caution.

Eccentric exercises

The most commonly studied form of exercise for LET is eccentric exercise.[85] A 2020 systematic review by Chen et al[101] showed a large effect of eccentric exercise over other treatment modalities or other forms of exercise but noting that in many studies the eccentric exercise was used as part of a multimodal treatment. There are several studies though that have investigated eccentric exercise in isolation. Tyler et al[102] compared a multimodal approach with and without eccentric exercise using a Theraband Flexbar device. It was a small study of 21 patients but the addition of eccentric exercises significantly improved outcomes after six weeks of treatment. The same technique was used by Tiwari[103] and compared to concentric and eccentric exercises using a weight, performed daily. After the three weeks of treatment outcomes significantly favoured the Theraband Flexbar technique but the difference may be attributable to dosing rather than technique as patients using the Theraband Flexbar performed 45 repetitions per day compared to 20 repetitions in the other group.

In contrast, Martinez-Silvestrini et al[104] compared stretching against stretching with the addition of either concentric or eccentric exercises. They found that all groups improved a similar amount at six-week follow-up although the eccentric exercise group suffered fewer exacerbations of symptoms.

Soderberg et al[105] treated 42 patients using a counterforce brace with and without the addition of eccentric wrist extension exercises. A simple method was employed where patients exercised at home holding a bucket with increasing amounts of water to increase load. After six weeks of follow-up the group performing eccentric exercises had significantly better outcomes.

A higher quality study by Crosier et al[106] randomised 92 patients to a multimodal physiotherapy treatment package of ice, TENS, ultrasound and stretching exercise versus multimodal physiotherapy plus eccentric exercises. The eccentric exercises involving wrist extension and forearm supination were performed using a Cybex isokinetic machine three times a week for a total of 25 to 26 sessions.

Two sets of 10 exercises were performed for each movement with gradually increasing velocity and resistance over the treatment period up to 90° per second and 80% MVC. Significantly improved results were seen in the eccentric exercise group at the end of treatment but the practicality of an intervention requiring high levels of patient attendance must be questioned.

Other exercise protocols

Peterson et al[3] used a similar method to Soderberg et al[105] teaching patients to exercise at home using a bucket filled with water in a trial comparing exercise to a wait-and-see approach. The exercise protocol used concentric and eccentric wrist extension with progressive load, starting with 2kg for males and 1kg for females. Patients performed three sets of 15 repetitions daily and increased the load by 0.1kg each week for three months. Patients in the exercise group had significantly better outcomes than wait-and-see at three-month follow-up. The same authors then performed a second study of 120 patients splitting the protocol into eccentric exercise only versus concentric exercise only.[107] The eccentric exercise group achieved a faster and greater improvement in pain.

Selvanetti et al[108] used a home exercise combination of contract/relax stretching and eccentric loading of the wrist extensors in a trial against a control intervention of ultrasound and advice. Only the abstract is available in English, but at minimum six-month follow-up a large treatment effect was seen in the exercise group, significantly greater than controls.

Barratt et al[109] conducted a large service improvement project involving 182 patients. Firstly, usual care was assessed before a shift of focus was made towards strengthening exercises and finally a specific progressive loading protocol implemented. The protocol began with moderate to high load isometric exercises progressing to concentric and eccentric exercises with increasing load. Although the study was limited by its non-randomised design and loss to follow-up there was evidence that the specific progressive loading protocol was more effective than other care with the difference attributed to the higher load progressions of the specific protocol. Indeed, a systematic review of tendon adaption to loading concluded that it was the progression to high load exercise that is the key factor in stimulating a tissue response rather than the type of muscle contraction used during exercise, though this review only included studies of lower limb tendinopathy.[110]

Exercise dosing

Raman et al[85] conducted a review of the literature in 2012 regarding the choice of exercise and dosing used to treat LET. The findings demonstrated great heterogeneity in numbers of repetitions, sets of exercises, frequency of exercise and duration of the exercise course with no clear conclusion on the optimum level. In a more recent 2020 review focussed upon eccentric exercise only, Chen et al[101] found that exercises were typically performed in three sets of 10 to 15 repetitions separated by 30 seconds to a minute's rest between each set. Exercise frequency ranged from three days per week to daily and the duration of treatment from three weeks to 12 weeks. Based upon theoretical healing times for tendon pathology and assessment of treatment effect size of high dose versus low dose trials the authors' recommendation was to perform eccentric exercises at least once per day, in three sets of 10-15 repetitions, for a minimum period of six weeks.

Painful versus pain-free exercise

A systematic review of pain-free exercises versus exercises that allowed some level of pain, published in 2017, found a short-term benefit in favour of painful exercises up to three months.[111] The review does not contain any trials related to LET but six of the nine included trials related to tendinopathy so the findings may be transferrable. Pain-related fear can lead to central sensitisation of the nervous system resulting in higher perceived pain levels, so an exercise approach that

focusses on avoiding pain may exacerbate this response.[112] Central sensitisation is a common feature in patients with LET, as identified by 10 studies included in a recent systematic review so needs to be considered in any intervention design.[113] Methods of addressing central sensitisation and pain-related fear have been proposed for clinical practice and can be applied to exercise interventions for LET.[112,114] These include education of the patient, addressing anxiety related to activity or exercise to reduce the threat response and graded exposure to painful activities. The Stasinopoulos protocol permits mild pain during exercise below 4/10 on a numerical rating scale (NRS) and includes graded exposure to a painful stimulus (loading of wrist extension using a weight) with gradual progression of increasing load. It was consistently effective in treating LET in seven trials, so might be a basis of this theory if applied to practice with additional patient education.[26-28,88-91]

Exercise Summary

Eccentric loading is the most frequently studied form of exercise for LET and appears effective, with some certainty in the short-term based upon trials of moderate quality. There is additional evidence for the supplementation of eccentric loading with isometric and concentric exercises to amplify the effect. Based upon modern understanding of pain science and previous trials involving pain-provoking exercise there is justification to encourage exercise into low levels of pain if supported by appropriate patient education.

Corticosteroid injections

The use of corticosteroid injection (CSI) to treat patients with LET is controversial with calls to stop made as long ago as 2010.[115] Despite this, a survey conducted in 2011 still showed that 48% of UK specialist clinicians used CSI as a primary treatment.[116] Whilst this number had declined in a similar UK survey conducted in 2017, 36% of respondents still used CSI as a first or second-line treatment.[38] The controversy stems from the conclusions of several large randomised controlled trials that showed worse outcomes at one year follow-up compared to patients treated without CSI.[2,4,22] Numerous studies consistently showed a significant reduction in pain up to six weeks following CSI with a large effect size.[117] This significant short-term effect may be attractive to patients as it can provide fast alleviation of symptoms and allow early return to work but the longer-term implications need to be considered. Mardaini-Kivi et al[118] found that the symptoms of 34.7% of patients had already returned 12 weeks after CSI. Bisset et al[2] compared CSI to multimodal physiotherapy or a wait-and-see approach that included general advice. At six weeks, CSI produced the greatest improvement but by 12 months had the worst outcome, even when compared to wait-and-see. The CSI group had a 72% recurrence rate at 12 months compared to just 8% with physiotherapy and 9% with wait-and-see. Coombes et al[22] compared CSI with a saline placebo injection and multimodal physiotherapy versus no physiotherapy in a 2 x 2 factorial design study. The two CSI groups showed the greatest improvements at four weeks but the worst outcomes at 12 months, even when compared to the placebo injection and no physiotherapy. The recurrence rate at 12 months was 54% across the CSI groups. A subsequent economic evaluation from the same study concluded that CSI was not a cost-effective treatment for LET.[98] Smidt et al[4] compared CSI to multimodal physiotherapy or a wait-and-see approach. Again, CSI produced the greatest improvement at four weeks but by 12 weeks was no better than wait-and-see. At six months and one year the outcomes for those patients receiving CSI were worse than wait-and-see. Of the large randomised controlled studies of CSI for LET, it is only Hay et al[119] and Olaussen et al[23] that did not show a detrimental effect at one year follow-up. Hay et al[119] compared CSI to naproxen tablets or placebo vitamin C tablets. Olaussen et al[23] compared CSI plus multimodal physiotherapy with a placebo injection plus

multimodal physiotherapy and a third wait-and-see group. By 12 months all groups had achieved a similar outcome but after an initially favourable response the CSI plus physiotherapy group had worse outcomes between 12 to 26 weeks compared to the other groups. Overall, the evidence would suggest therefore that CSI should be used with caution as despite strong evidence of short-term beneficial effect, the medium-term and long-term effect may be negative.

Multimodal physiotherapy

Many studies use a combination of treatments as part of a multimodal package of physiotherapy treatment. In particular, there are five large randomised trials totalling 845 patients, four of which had wait-and-see control groups, that have investigated a multimodal approach with a long-term follow-up of one year.[2,4,22,23,97] Three of these trials used the same multimodal approach proposed by Vicenzino in 2003.[2,22,96,97] Patients were educated regarding avoiding painful activities involving repetitive activity or gripping with the forearm pronated and elbow extended. A trial of MWM and taping was performed to establish if there is an immediate reduction in pain on gripping and patients were taught an exercise routine of posture correction, progressive forearm strengthening and general upper limb strengthening. Patients were then seen eight times over six to eight weeks in two trials[2,22] and four times over four weeks in one trial.[97] At these visits MWM and taping was repeated if found to be beneficial and the exercises were repeated under supervision and progressed as able. Exercises were continued at home. All three trials found significant short-term improvement with multimodal physiotherapy between four to six-week follow-up compared in two trials to a control of wait-and-see, and in one trial to prolotherapy. Additionally, Coombes et al[22] found multimodal physiotherapy superior to wait-and-see at 26 weeks and Yelland et al[97] superior to prolotherapy at 12 weeks. All three studies found that by 12 months the difference between control or prolotherapy was no-longer significant due to the fact that LET symptoms tend to improve in the majority of patients over time. Bisset et al[2], though, performed an area under the curve analysis to evaluate that, compared to CSI or a control of wait-and-see, multimodal physiotherapy was superior. It was also associated with the lowest symptom recurrence rate and lowest analgesic use.

Olaussen et al[23] compared multimodal physiotherapy with CSI or placebo injection against a control group of wait-and-see. The multimodal physiotherapy consisted of six sessions over six weeks of Cyriax manual therapy, passive stretches of the forearm extensor muscles and a home exercise programme of forearm extensor muscle stretching and eccentric strengthening. The wait-and-see group were given education regarding activity modification and were prescribed NSAIDs. At six-week follow-up multimodal physiotherapy was superior to wait-and-see but at subsequent assessments at 12, 26 and 52 weeks there was no difference between groups.

Smidt et al[4] compared multimodal physiotherapy against CSI and a control group of wait-and-see. The multimodal approach consisted of ultrasound, deep transverse friction massage and the Pienimaki exercise programme of stretching and progressive strengthening for six weeks.[86] The highest probability of recovery at six-month follow-up was found in the multimodal physiotherapy group. At 12-months the success rate of the CSI group was 69% compared with 91% and 88% respectively in the multimodal physiotherapy and wait-and-see groups.

Overall, the evidence would suggest a positive short and mid-term effect of multimodal physiotherapy compared with control or comparator treatments but the key components of an optimum multimodal physiotherapy treatment package have not been established.

Summary

A wide range of treatment techniques have been investigated for LET. There is low or very low-quality evidence to suggest that manual therapy, laser, acupuncture, diamond taping and orthotics may give a short-term beneficial effect but the practicalities of using such interventions in a publicly-funded health service are questionable. There are uncertainties regarding the value of treatments that require numerous patient attendances, such as manual therapy, laser, taping or acupuncture. Exercise is supported by a greater evidence base but questions remain as to the optimum exercise choice and exercise dose. Stretching and eccentric exercise show beneficial effects but with the potential for further improvement with the addition of isometric and concentric exercises. Modern understanding of pain theory would suggest that exercise into mild pain might also improve outcomes. Trials have shown that many patients improve with simple advice and time, but there is potential to improve this self-management support further with the addition of psychological and behavioural interventions to improve patient self-efficacy.

Given the current lack of a consistent treatment approach provided in the UK and lack of certainty from the evidence base to guide clinicians, it is necessary to ascertain from clinical, managerial and patient stakeholders which are the most practical treatments for use in UK NHS practice as part of an optimised physiotherapy treatment package.

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Optimising Physiotherapy for Tennis Elbow

Intervention Handbook

Trial overview:

The OPTimisE pilot and feasibility trial is comparing a newly-developed package of physiotherapy treatment against usual physiotherapy care for people with Tennis Elbow. The aim of the trial is to evaluate whether the OPTimisE intervention is acceptable to both patients and physiotherapists, and whether it is feasible to scale-up the project to a fully-powered randomised controlled trial.

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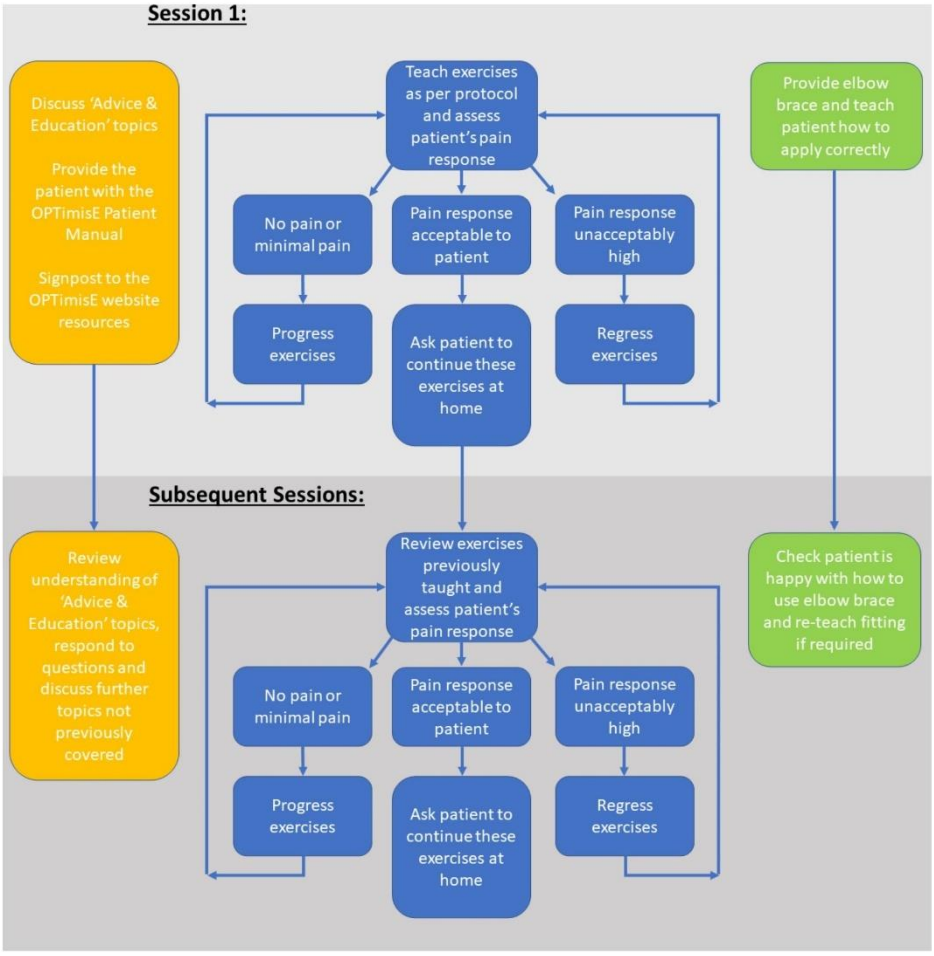
The OPTimisE intervention was developed using a combination of the best available research evidence and stakeholder consensus. It comprises of three treatment categories:

1. Advice and education
2. Exercise therapy
3. Orthotics

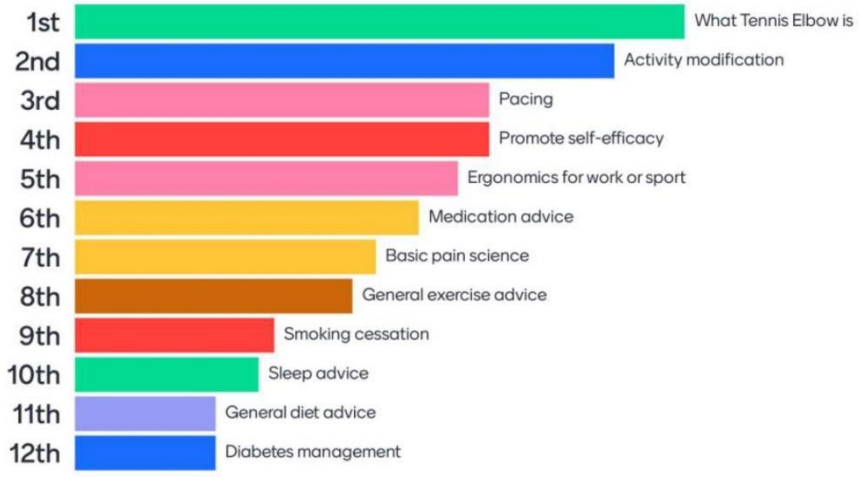
This handbook provides detailed instructions regarding how these treatments should be delivered. If you have any questions related to these instructions, please contact Marcus Bateman via email or Microsoft Teams at marcus.bateman@nhs.net.

Treatment Process Map:



Advice and education

Discuss the following topics, if relevant to the patient, in order of priority, across treatment sessions. Provide patients with the 'OPTimisE Patient Manual' and encourage the patient to also visit the online resources on the OPTimisE website (www.optimise-trial.uk) for further information. Topics and patient understanding should be re-visited at subsequent sessions.



The following table advises on content for each topic:

Topic	Guidance
What tennis elbow is	Describe the condition as being 'pain from the tendons that move your wrist and help you grip'. Avoid using words that imply structural failure such as 'degeneration', 'damage' or 'disease'. Discuss common causes such as an episode of relative overuse, persistent heavy lifting or repetitive work involving the wrist & hands. Discuss age-related changes to metabolism that may be involved, as it most commonly occurs in middle age.
Activity modification	Discuss how painful tendons become very sensitive to the load that they are subjected to. Discourage trying to maintain normal activities despite high pain levels. Encourage modification of activities to reduce pain whilst still allowing function (e.g. palm-up lifting, use of the contra-lateral limb, use of lifting aids). Discuss the concept of relative rest but not complete rest. Encourage conversations with employers to adjust working routine if work is a significant contributory factor.
Pacing	Discuss the concept of pacing i.e. dividing larger tasks into manageable smaller stages interspersed with rest or other activities.

Promote self-efficacy	Self-efficacy is the patient's level of belief that they can overcome a problem. Discuss the importance of the patient understanding their condition, identify areas of their lifestyle that are affected and encourage them to think of solutions or ways of managing those situations. Reassure that those patients who have higher self-efficacy and take responsibility for managing their condition usually do better than those who rely on others.
Ergonomics for work or sport	Identify common work-related tasks that involve using the wrist in deviated positions, involve highly repetitive wrist movements or involve forceful gripping/wrist movements. Work with the patient to identify modifications or solutions. For sports involving racquets, bats or sticks consider trying a larger grip or reducing tension in racquet strings. Try to grip less firmly and consider altering technique to reduce ulnar deviation. Consider a session with a qualified coach to assess/improve technique.
Medication advice	If pain is interfering with the patient's quality of life, advise regarding the use of analgesia based upon the World Health Organisation's analgesic ladder. Paracetamol +/- NSAIDs should be sufficient. Topical NSAID gels have fewer side-effects than oral NSAIDs. Direct the patient to see their pharmacist regarding NSAIDs due to potential contra-indications for use (e.g. asthma, gastric ulcer, anti-coagulation).
Basic pain science	Explain the concepts of acute and chronic pain. Relate chronic pain to systemic factors that influence the nervous system, such as fear, stress, lack of sleep. Reassure that, in chronic pain situations, pain does not equal tissue damage. Encourage patients to work around their pain symptoms rather than avoiding painful activities totally.
General exercise advice	People who take regular exercise 2-3 times a week are 20% less likely to develop Tennis Elbow than those who don't. Encourage regular exercise to help promote healing, improve general health and mental-wellbeing. Further information on NHS Get Active website.
Smoking cessation (if applicable)	Research has shown that smokers are up to 3.6 times more likely to develop tennis elbow than non-smokers. Stopping smoking is likely to improve the chances of recovery. Please direct patients to local smoking cessation services or NHS Quit Smoking website.
Sleep advice	Poor-quality or lack of sleep can cause increased sensitivity to pain and lead to patients experiencing chronic pain. Discuss the patient's sleep patterns and advise regarding avoidance of caffeine, nicotine, opioid medication and alcohol before bed. Promote regular exercise. Encourage regular bedtime and wake-up times for routine. Avoid daytime naps. If sleep is disturbed by background noise consider earplugs or 'white noise' mobile phone apps.
General diet advice	Promote a healthy balanced diet rich in fruit, vegetables and fibre. High energy diets have been associated with inflammation and chronic pain. Obesity is an independent predictor of chronic pain. Obese patients should be advised to seek help from their GP or dietician. Further information on NHS Lose Weight website.

Diabetes management (if applicable)	People with diabetes are up to 2.1 times more likely to develop Tennis Elbow than those without. Poorly controlled diabetes is associated with slower tissue healing. Discuss the patient's diabetes control and advise to consult their diabetes practitioner if concerns are highlighted.

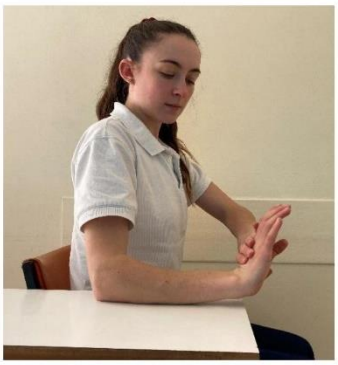
Exercise Therapy

A progressive exercise regime should be taught to all patients. No more than four exercises should be provided at any one time and the total exercise time should not exceed 15 minutes. Patients should aim to perform one session of exercise per day and continue over a minimum period of 12 weeks. Exercises should provoke pain to a level that is acceptable to the patient, both at the time of performing the exercises and during the subsequent 24 hours. The level of exercise should be adapted to the severity of the patient's symptoms but patients should aim to tolerate high level exercises before discharge.

Low level exercises:

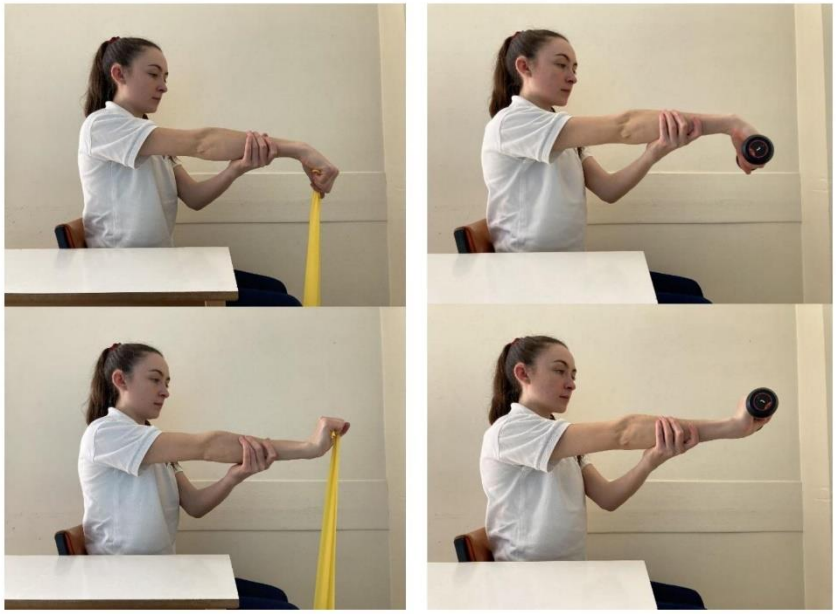
- Forearm stretches – elbow extended, forearm pronated, wrist flexed and ulnar-deviated. Stretch into moderate discomfort as acceptable to the patient. 30s hold x 3, before and after loading exercises.

- Isometric loading – sit with elbow flexed to 90°, forearm supported on a table and pronated. A maximal isometric contraction is performed (based upon acceptable level of pain) in full wrist extension, using the opposite hand to apply the resistance. Hold for 60 seconds and repeat 5 times.



Medium level exercises:

- Combined concentric and eccentric loading – the elbow should be fully extended with the forearm supported and pronated. Starting from a fully flexed wrist position a concentric exercise is performed to the full range of wrist extension. This movement should be done slowly over at least six seconds. A slow eccentric exercise is then performed over six seconds to return to the starting position. Three sets should be performed 10-15 times with a minute's rest in between sets. The amount of load should be varied due to the individual patient's pain response. This may vary day-to-day and patients should be taught to modify the load themselves accordingly. Load can be applied using weights (including household objects) or elasticated exercise bands. *Note: if the exercise is too painful, try repeating with the elbow flexed to 90° rather than fully extended. Also, be aware that loading with a large size object may be more painful than with a smaller object of the same weight.*



High level exercises:

- Functional higher load exercises tailored to the patient's activity demands - For example, plyometric racquet sport simulation with resistance or high load simulation of work activities.
- Higher load general upper body exercise - For example: incline push-ups, kneeling push-ups, full push-ups, shoulder press, bent-over rows.

Orthotics

Patients should be provided with a counterforce brace to use if they wish. They should be instructed in the correct fitting of the brace and to only wear it during activities that regularly provoke significant pain. They should be discouraged from wearing it all of the time or during minimally painful activities to reduce reliance on the device. A video of how to fit the brace is available on the www.optimise-trial.uk website.

Optimising Physiotherapy for People with Tennis Elbow

Patient Manual

IRAS Project ID: 297637

Version 0.1 30/3/2021

Tennis Elbow is very common and can impact on your ability to work, do household activities or play sports. A wide array of physiotherapy treatment options are available, but there is no agreement on the best approach.

We have used the best research evidence and experience of expert physiotherapists to design an optimised physiotherapy treatment package. We now need to test how well it works.

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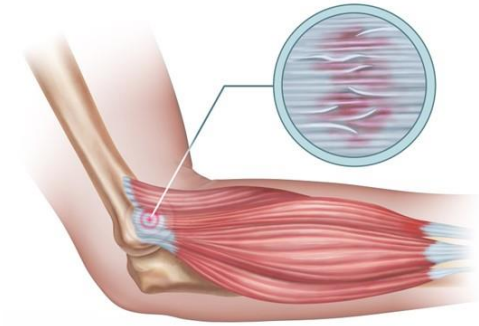
What is Tennis Elbow?

'Tennis Elbow' describes pain from the tendons of your forearm muscles, where they join the outside of your elbow.



It commonly affects people of middle-age and is often caused by repetitive work or over-use. Only about 5% of people with Tennis Elbow actually play tennis! Women are more likely to get Tennis Elbow than men and it is much more common if you smoke or have diabetes.

It can become a stubborn long-term problem so it is important to treat it early.

Advice

Tendons recover slowly, so the key is to optimise your body's healing potential:

- Identify the activities you do that aggravate your symptoms and find ways to make them less painful.
- Do specific exercises that encourage healing and reduce sensitivity to pain.
- Address general health issues that may affect your body's ability to heal itself.

Ways to make activities less painful:

- Change the position of your arm, for example, lift objects with your palm facing upwards.
- Avoid carrying heavy objects in your hands - use shoulder straps or loop bags over your forearms.
- Use power tools rather than hand tools.
- Keep swapping hands to share the load.
- Wear your elbow brace.
- Take regular breaks or switch between different activities.

General Health

For many people, Tennis Elbow is a localised problem but it can be a sign of deterioration in your overall health. Consider these lifestyle factors as they have a big influence on healing and may be relevant to you:

General exercise:

Try to do general exercise for 20-30 minutes, 3 times a week to improve your circulation and help healing.

Smoking:

Smoking reduces the speed of healing so quitting should help your elbow recover.

Sleep:

Sleep is important for our bodies to heal. If we don't get enough good-quality sleep, pain feels worse.

Diet:

Diets high in fat and sugars are associated with inflammation in the body. Try to eat a balanced diet rich in fruit and vegetables.

Diabetes:

If you are diabetic, the body heals less quickly. If your sugar levels are poorly controlled, please see your diabetes specialist.

Useful Resources:

If you think any of these issues may be relevant to you, please visit these websites for further help, or discuss them with your physiotherapist.

Stopping smoking

https://www.nhs.uk/better-health/quit-smoking

Healthy diet

https://www.nhs.uk/live-well/eat-well/

General exercise

https://www.nhs.uk/better-health/get-active/

https://www.nhs.uk/live-well/exercise/

Managing persistent pain

https://www.nhs.uk/live-well/healthy-body/ways-to-manage-chronic-pain/

Sleep

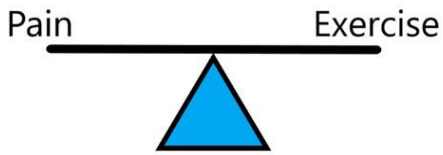
https://www.nhs.uk/live-well/sleep-and-tiredness/

Healthy body

https://www.nhs.uk/live-well/healthy-body/

Exercises for Tennis Elbow:

There is a balance to be found to help your elbow recover. You need to reduce or modify the activities that really aggravate your symptoms, but not rest completely. Your elbow has become very sensitive to the amount of force that is put through it, so we have selected some specific exercises that help to reduce that sensitivity.

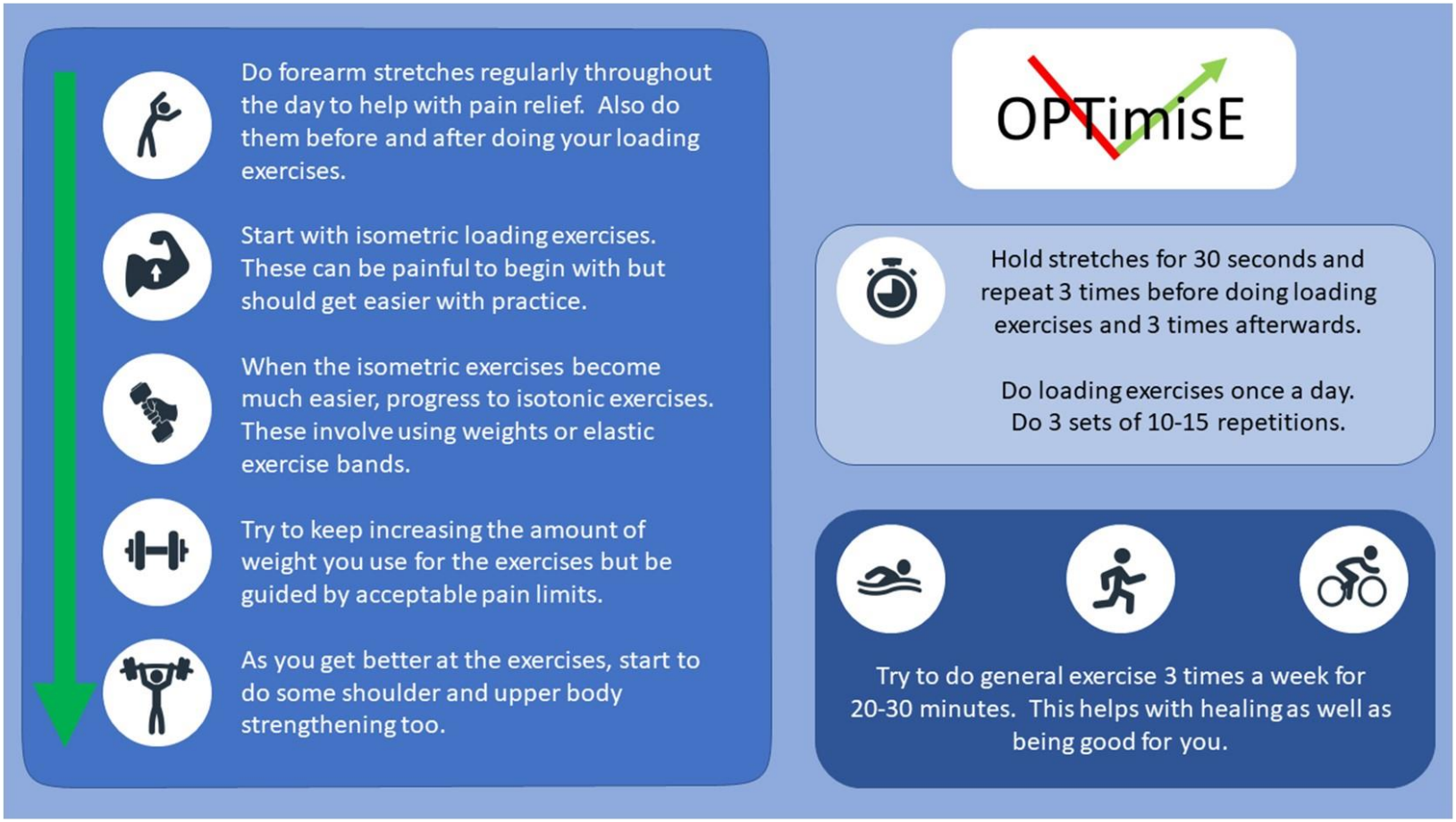


Pain when exercising:

Everyone feels pain differently. It is important to feel some pain or discomfort when you are doing the exercises, otherwise you are not exercising hard enough. Make sure that the level of pain remains acceptable to you at the time you do the exercises and for the rest of the day afterwards. All of the exercises can be modified to make them easier or harder depending on the amount of pain you have that day.

We recommend that you try to do your elbow exercises every day and keep doing it for 3 months.

Exercise Summary:



Turn the page to learn how to do the different exercises.

8

Forearm stretches:

Fully straighten your arm and turn your thumb towards the ground. Bend your wrist and apply a stretch with the other hand. Hold it for 30 seconds. Do this 3 times before your loading exercises and 3 times afterwards. If you find that it helps give pain relief, do it at other times of the day as well. Stretch before and after your loading exercises.

Isometric Loading Exercises:

Sit with your elbow bent at a right-angle and your forearm supported. Make sure your palm is facing down. Lift your wrist back as far as it will go and then push against the back of your hand with the other hand. You should feel your forearm muscles contract. Do this as hard as you can provided the pain remains at an acceptable level for you. Hold the contraction for 60 seconds. Repeat 5 times, with a short rest in between. If it becomes too painful, push against your hand less hard.

Isotonic Loading Exercises:

Once you are able to do isometric loading exercises without any significant pain, move on to isotonic loading exercises. You will need a light weight (0.5 to 1kg) or elastic exercise band. Alternatively, use a household object, such as a bottle of water.

Straighten your elbow and support your forearm. Start with your wrist fully bent and palm facing down. Slowly lift your wrist backwards as far as it will go. It is important to do this slowly over 6 seconds. Then, slowly lower it back to the starting position over another 6 seconds. Repeat this process 10 to 15 times. Do 3 sets of 10-15 repetitions with a short break in between. Do this every day. Adjust the amount of weight according to acceptable pain limits.

Upper body and shoulder exercises:

As your elbow symptoms improve, you should start to do some general upper body exercises as well. When you haven't used your arm normally for some time the muscles around your shoulder, in particular, get weak.

Bent-over rows:

Lean forward and support your weight on a table. Start with your arm straight towards the floor, holding a weight in your hand. Bend your elbow and lift it back towards the ceiling. Then slowly lower back down. Do 3 sets of 10-15 repetitions.

Shoulder Press:

Hold a weight in each hand and start with them at either side of your head. Straighten your arms fully towards the ceiling, then slowly lower back down. Do 3 sets of 10-15 repetitions.

Incline Push-ups:

Use a solid surface at roughly waist height. The kitchen worktop is usually suitable. Stand 2 steps away and lean on the surface with your hands shoulder-width apart. Perform a push-up, making sure to keep your back and legs straight. Do 3 sets of 10-15 repetitions.

Kneeling Push-ups:

If you can do the incline push-ups easily, try doing kneeling push-ups. Kneel on the floor and perform a push-up, keeping your back straight. Do 3 sets of 10-15 repetitions.

Full Push-ups:

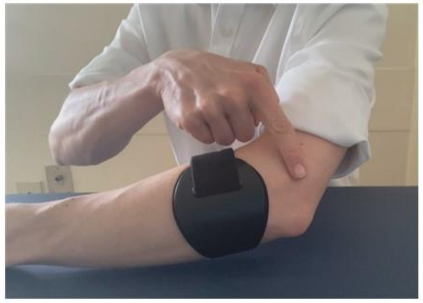
If you can do kneeling push-ups easily, try doing full push-ups on your toes. Do 3 sets of 10-15 repetitions.

How to use your splint:

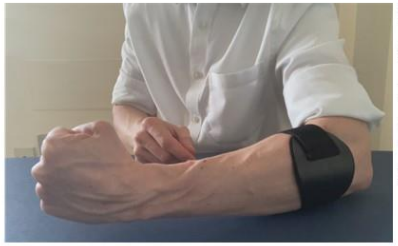
Wear your elbow splint when you are doing activities that aggravate your Tennis Elbow, but not all of the time. Do not wear it at night. The splint will probably not make activities completely pain-free but should make them more comfortable to do.

Fitting the elbow splint:

Take your splint and loosen off the strap. Slide it up your forearm and position the outer cushion in line with the bone of your outer elbow.



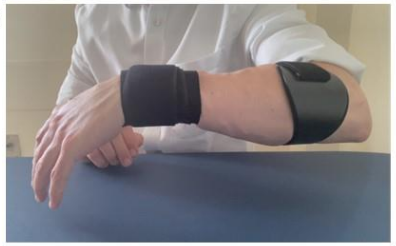
Tighten the strap and fasten the Velcro. Squeeze your fist - it should be more comfortable with the splint on. If not, change the position or tighten the strap more. Just make sure that it isn't restricting the circulation to your hand.



Fitting the optional wrist support:

The splint also comes with an optional wrist support. Try using this if you do activities such as racquet sports that involve a lot of wrist movement. It may give extra relief than just using the elbow splint alone.

Undo the two layers of Velcro and lay it flat on a table. Wrap the inner layer around your wrist as tightly as you can. Then wrap the outer strap and fasten it tightly. Make sure it is not restricting your circulation. The support should partially restrict your wrist movement.



Cleaning your splints:

The elbow splint and wrist support can both be hand-washed and air-dried. The inner layer of the elbow splint can be removed for washing.

Further Information

For further information, including exercise demonstration videos, please visit our website and click on 'Patient Login'.
Enter the password: TennisElbow123

www.optimise-trial.uk

The trial is being co-ordinated by:

Derby Clinical Trials Support Unit,

Medical School Office 5033,

Royal Derby Hospital,

Derby,

DE22 3DT.

Email: helpdesk@optimise-trial.uk

Appendices pertaining to Chapter 4: The OPTimisE Pilot & Feasibility Randomised Controlled Trial - Quantitative Element

Appendix 4.1: OPTimisE Trial patient information sheet

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

Patient Information Sheet

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

Tennis Elbow is a common problem but we do not know the best way of treating it. Physiotherapy is often recommended. This can involve a variety of treatments, for example: exercise, taping, acupuncture, manual therapy, ultrasound or laser. Different physiotherapists prefer different treatments, dependent on how they were trained, but research suggests that the best treatments are not always used. We have designed an optimised physiotherapy treatment package based upon research evidence and expert opinion that we want to test with patients. This is focussed on three elements:

1. Advice and education so that patients can learn to manage the problem themselves
2. A specific exercise regime to improve function
3. A Tennis Elbow brace to control pain

The purpose of this study is to evaluate if it is feasible to run a large-scale study to establish whether this optimised physiotherapy treatment package is more effective than usual physiotherapy in reducing pain and improving function in people with Tennis Elbow. We will look at how willing people were to be involved, how well they engaged with the treatments and how well the treatment effect could be measured. We will also be inviting some people to discuss their experience of being involved to identify what worked well and what could be improved for a large national trial.

Why have I been invited?

You are being invited to take part because you may have Tennis Elbow.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your medical care or legal rights. If you decide not to take part, we will ask you whether you wish to be interviewed as to your reasons why. Again, this is optional but this information will help us to improve our research design. Likewise, you can agree to take part in the physiotherapy trial but decided not to be interviewed. People that are interviewed will receive a £20 Amazon/Love2shop voucher for their time and travel expenses will be reimbursed if the interviews are held in the physiotherapy department.

What will happen to me if I take part?

You will be invited to attend the physiotherapy department to undergo a short examination carried out by a qualified physiotherapist. This is to confirm that you do have Tennis Elbow and see if you are eligible to participate in the study. The examination will last up to 30 minutes and will involve asking questions about the problems you have, as well as an examination of your arm. If you do not meet the criteria you will not be eligible to participate in the study, and your physiotherapy appointments will continue as normal in line with the usual arrangements within the department.

If you are eligible then you will be asked to fill in a questionnaire to help us understand how your elbow pain affects you. This should take 10-15 minutes. You will be asked to complete a similar questionnaire again after 6 weeks, 3 months and 6 months. You will be given the choice of doing this online or on paper. If you choose the paper method, the questionnaires will be posted to you along with a free-return envelope. The online method is provided by Amplitude Clinical. They will send you links to the questionnaires by email or SMS text message and you can complete the questions on a smartphone, tablet or computer. If you choose the online method, we will share your email address and telephone number with Amplitude Clinical. This information will be stored on servers in the UK and will be deleted at the end of the trial. Completing the questionnaires is very important to this research so we will send reminders by email or telephone if you forget. We may also ask you a few questions to capture information about your tennis elbow.

Because we don't know which is the best way to treat patients, we need to compare the different treatments. This is the reason why we perform a randomised controlled trial, where we put an equal number of patients into each group and then compare treatments. To make sure that each group is similar, patients are put into their groups by chance (randomly). So, once you have completed the questionnaires you will be randomly assigned to receive either the optimised physiotherapy treatment package, or usual physiotherapy. There is equal chance you will be treated with one or the other option. Usual physiotherapy treatment may involve a range of different treatments, whereas the optimised physiotherapy treatment package focusses on advice and education, exercise and using an elbow brace. The optimised physiotherapy treatment package does not include other treatments such as acupuncture or electrotherapy. If randomised to the optimised physiotherapy treatment package, you will be asked to attend physiotherapy appointments approximately once per month for at least three months and will be supported to exercise at home. You will be given a detailed treatment booklet and have access to a private website containing advice and exercise videos.

We will also measure your maximum grip strength and the amount of gripping that you can do pain-free using an electronic device called a Squegg. Participants receiving the OPTimisE treatment package will be given a Squegg device to take home and keep. We will ask you to repeat your grip strength measurements at home when you complete the questionnaires at 6 weeks, 3 months and 6 months. If you are allocated the usual physiotherapy treatment, you will be sent a Squegg device by post after 6 months, in time to measure your grip for the 6-month questionnaire. To use the Squegg device you will need to install the Squegg App on an Apple or Android smartphone/tablet and create an account, or log

in using a Facebook or Google account. For data privacy reasons it would be recommended to use an email address rather than Facebook to create a user account, however this is your own personal choice. No data will be shared between the research team and Squegg.

If you are asked to take part in the optimised physiotherapy treatment programme you will be asked to complete a short exercise diary to let us know how much of the exercise you were able to complete. You will be asked to complete the diary daily, and return it at 3 months in a stamped envelope provided.

Some information will be retrieved from your medical records, such as how many physiotherapy treatments you received and the types of treatments given.

During the study we will invite some of the participants to attend a short interview to discuss their experience of the process. The interviews will be relaxed and informal, may last up to 1 hour and can be arranged face-to-face, either in a quiet room at the physiotherapy department or in your own home, or by telephone, or online using video-conferencing.

These interviews are optional and should you wish, you can choose to not volunteer to take part in them while completing the consent form.

Interviews will be audio-recorded and some quotes used in the written-up report. Any quotes or discussions will be anonymised, so no one will know it was you who made the comments. There will be no other use of the recordings.

Expenses and payments

Travel expenses will be reimbursed for the first visit to the physiotherapy department as this research assessment is not part of normal physiotherapy care. Participants will receive a £20 Amazon/Love2shop voucher after completing all of the study questionnaires at 6 months.

Participants that are interviewed will receive a £20 Amazon/Love2shop voucher for their time and travel expenses will be reimbursed if the interviews are held in the physiotherapy department.

What are the possible disadvantages and risks of taking part?

You will have to take time to complete the questionnaires on 3 separate occasions at home and attend the initial research assessment. Apart from that there are no disadvantages or serious risks to taking part in this research. Both groups of patients will still receive physiotherapy treatment for their Tennis Elbow. If invited to take part in the interview, should you feel uncomfortable with any of the discussions, you are free to end the discussion at any point.

What are the possible benefits of taking part?

It is expected that you will gain benefit from the treatment you receive, in terms of pain reduction and improved function. But we cannot promise the study will help you. The information we get from this

study may help inform future research and direct future treatment to other patients with a similar complaint.

What happens when the research study stops?

Your involvement in the study will end when you complete and return your questionnaires at 6 months after starting the study, or after completing the interview if you are invited. Your physiotherapy appointments will end at the discretion of your physiotherapist, in agreement with you. When your involvement in the study ends, if you still require any further treatment for your Tennis Elbow, please consult your GP.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. You may also contact your local Patient Advice Liaison Service (PALS) for any concerns or complains that you might have on {add local PALS details}

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from Keele University and University Hospitals of Derby and Burton NHS Foundation Trust. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Electronic information will be stored on UK servers. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (address, email, telephone number) will be kept for up to 6 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 5 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

How will we use information about you?

We will need to use information from you for this research project.
This information will include your

- Initials
- NHS number
- Name
- contact details (address, email, telephone number)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to uhdb.sponsor@nhs.net
- https://mysquegg.com/privacy-policy/

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your medical care or legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

It is anticipated that the results of the study will be published in scientific journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish.

Who is organising and funding the research?

This research is being organised by University Hospitals of Derby and Burton NHS Foundation Trust and is being funded by the National Institute of Health Research (NIHR) and the Chartered Society of Physiotherapy Charitable Trust.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Sheffield Research Ethics Committee (reference number: 21/YH/0121).

Further information and contact details:

Marcus Bateman
Chief Investigator
marcus.bateman@nhs.net

Dr Jonathan Hill
Academic Supervisor
j.hill@keele.ac.uk

Website: www.optimise-trial.uk

TRIAL CONSENT FORM

Title of Study: Optimising Physiotherapy for People with Tennis Elbow – a mixed methods pilot & feasibility trial

IRAS Project ID: 297637

Please indicate whether you consent to part 1, part 2 or both.

Please initial box

Part 1:

I confirm that I have read and understand the Participant Information Sheet (version 0.6, date 17 February 2022) for the above trial and have had the opportunity to ask questions. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

I understand that data will be drawn from my medical records (such as the types of physiotherapy treatment received). ☐

I understand that data collected in the study may be looked at by authorised individuals from the research team, Derby Clinical Trials Support Unit and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

I understand that the researchers require access to my personal contact details to send questionnaires to me, and that my email address and telephone will be retained for use during the trial. ☐

I agree to take part in the above study. ☐

Part 2:

I give permission to be contacted to discuss my experience in an interview, which will be recorded and I agree that anonymous direct quotations may be used for the purpose of this research. ☐

Email: …….. Telephone……

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Do you wish to receive a summary of the trial results? Yes / No

3 copies: 1 for participant, 1 for the site file and 1 for the physiotherapy records

Appendix 4.3: OPTimisE Trial baseline questionnaire

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

OPTimisE Baseline Questionnaire

Patient ID Number	
Site	
Date	

Thank you for agreeing to take part in this trial. The answers you give in this questionnaire will help us to find out more about your elbow problem.

Please answer all of the questions, and follow the instructions for each section carefully. Please use a **BLACK or BLUE** pen. Please do not use a pencil.

Section 1 **This section asks for general information about you.**

1. Full name .....

2. Address .....
   .....
   .....
   .....

3. Telephone ..... Mobile .....

4. Email address .....

5. Your date of birth

D	D	M	M	Y	Y	Y	Y

6. What is your gender?

   Male ☐

   Female ☐

   Other (please state) _____ ☐

   I prefer not to answer ☐

7. To which of these ethnic groups do you consider yourself to belong? Please cross (X) ONE box.

White British	☐
White Other	☐
Mixed	☐
Indian	☐
Pakistani	☐
Bangladeshi	☐
Black or Black British	☐
Chinese	☐
Other (please state) _____	☐
Prefer not to say	☐

8. Are you left or right-handed? Please cross (X) **ONE** box.

Left-handed	☐
Right-handed	☐
Both	☐

9. For how long (approximately) have you had this problem with your elbow?

☐ weeks or ☐ months

10. Which elbow is affected? Please cross (X) **ONE** box.

Left elbow	☐
Right elbow	☐
Both	☐

11. What is your estimated weight? Please fill in **ONE** box.

Kilograms	☐☐☐
Stones and Pounds	☐☐ ☐☐

12. What is your estimated height? Please fill in **ONE** box.

Metres and centimetres	☐☐☐
Feet and inches	☐ ☐☐

13. Which of the following best describes your current cigarette smoking status? Please cross (X) **ONE** box.

Never smoked	☐
Former smoker	☐
Current smoker	☐

14. If you have ever smoked, on average how many cigarettes do/did you smoke per day?

☐☐☐

Section 2 **This section relates to how you would like to receive future questionnaires.**

During the trial we will ask you to complete 3 more questionnaires: after 6 weeks, 12 weeks and 6 months. These are very important as they will measure how much your elbow problem has changed over the course of your treatment. After completing all of these we will send you a voucher to the value of £20.

You have the option to complete these online or on paper (returning by post). Which would you prefer?

Online ☐ Paper ☐

Section 3 **This section asks questions about your elbow problem affects you.**

In the last month, how many days have you had off work due to your elbow?

☐ days Not applicable ☐

Please rate from 0-10 how much pain you have when gripping strongly.

No pain Worst imaginable

0 1 2 3 4 5 6 7 8 9 10

*The questions below will help us understand the amount of difficulty you have had with your arm in the past week. You will be describing your **average** arm symptoms **over the past week** on a scale 0-10. Please provide an answer for all questions. If you did not perform an activity because of pain or because you were unable ,then you should circle a "10". If you are unsure please estimate to the best of your ability. Only leave items blank if you never perform that activity. Please indicate this by drawing a line completely through the question.*

1. PAIN in your affected arm											
*Rate the average amount of pain in your arm **over the past week** by circling the number that best describes your pain on a scale from 0-10. A **zero** (0) means that you **did not have any pain** and a **ten** (10) means that you had **the worst pain imaginable.***											
RATE YOUR PAIN: No Pain											Worst Imaginable
When your are at rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with repeated arm movement	0	1	2	3	4	5	6	7	8	9	10
When carrying a plastic bag of groceries	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its least	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its worst	0	1	2	3	4	5	6	7	8	9	10

Please turn the page.....

2. FUNCTIONAL DISABILITY											
A. SPECIFIC ACTIVITIES *Rate the **amount of difficulty** you experienced performing each of the tasks listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. A zero (0) means you did not experience any difficulty and a **ten (10)** means it was **so difficult you were unable to do it at all**.*											
	No Difficulty										Unable To Do
Turn a doorknob or key	0	1	2	3	4	5	6	7	8	9	10
Carry a grocery bag or briefcase by the handle	0	1	2	3	4	5	6	7	8	9	10
Lift a full coffee cup or glass of milk to your mouth	0	1	2	3	4	5	6	7	8	9	10
Open a jar	0	1	2	3	4	5	6	7	8	9	10
Pull up pants	0	1	2	3	4	5	6	7	8	9	10
Wring out a washcloth or wet towel	0	1	2	3	4	5	6	7	8	9	10
B. USUAL ACTIVITIES *Rate the **amount of difficulty** you experienced performing your **usual** activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities that you performed **before** you started having a problem with your arm. A **zero** (0) means you did not experience any difficulty and a **ten** (10) means it was so difficulty you were unable to do any of your usual activities.*											
1. Personal activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
2. Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
3. Work (your job or everyday work)	0	1	2	3	4	5	6	7	8	9	10
4. Recreational or sporting activities	0	1	2	3	4	5	6	7	8	9	10

Comments:

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Please circle one response for each question:

	Strongly disagree	Disagree	Agree	Strongly agree
1. I'm afraid that I might injure myself if I exercise.	1	2	3	4
2. If I were to try to overcome it, my pain would increase.	1	2	3	4
3. My body is telling me that I have something dangerously wrong.	1	2	3	4
4. People aren't taking my medical condition seriously enough.	1	2	3	4
5. My accident/problem has put my body at risk for the rest of my life.	1	2	3	4
6. Pain always means that I have injured my body.	1	2	3	4
7. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening.	1	2	3	4
8. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body.	1	2	3	4
9. Pain lets me know when to stop exercising so that I don't injure myself.	1	2	3	4
10. I can't do all the things normal people do because it's too easy for me to get injured.	1	2	3	4
11. No-one should have to exercise when he/she is in pain.	1	2	3	4

Please rate how confident you are that you can do the following things at present, despite the pain. To indicate your answer circle one of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

Remember, this questionnaire is not asking whether or not you have been doing these things, but rather how confident you are that you can do them at present, despite the pain.

	Not at all confident						Completely confident
1. I can enjoy things, despite the pain	0	1	2	3	4	5	6
2. I can do most of the household chores (e.g. tidying-up, washing dishes etc), despite the pain	0	1	2	3	4	5	6
3. I can socialise with my friends or family members as often as I used to do, despite the pain	0	1	2	3	4	5	6
4. I can cope with my pain in most situations	0	1	2	3	4	5	6
5. I can do some form of work, despite the pain ("work" includes housework, pain and unpaid work)	0	1	2	3	4	5	6
6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain	0	1	2	3	4	5	6
7. I can cope with my pain without medication	0	1	2	3	4	5	6
8. I can still accomplish most of my goals in life, despite the pain	0	1	2	3	4	5	6
9. I can live a normal lifestyle, despite the pain	0	1	2	3	4	5	6
10. I can gradually become more active, despite the pain	0	1	2	3	4	5	6

Section 4 **This section is about your general health.**

Under each heading, please cross (X) the **ONE** box that best describes your health **TODAY**.

1. Mobility
   - I have no problems in walking about ☐
   - I have slight problems in walking about ☐
   - I have moderate problems in walking about ☐
   - I have severe problems in walking about ☐
   - I am unable to walk about ☐

2. Self-care
   - I have no problems washing or dressing myself ☐
   - I have slight problems washing or dressing myself ☐
   - I have moderate problems washing or dressing myself ☐
   - I have severe problems in washing or dressing myself ☐
   - I am unable to wash or dress myself ☐

3. Usual activities (e.g. work, study, housework, family or leisure activities)
   - I have no problems doing my usual activities ☐
   - I have slight problems doing my usual activities ☐
   - I have moderate problems doing my usual activities ☐
   - I have severe problems doing my usual activities ☐
   - I am unable to do my usual activities ☐

4. Pain / Discomfort
   - I have no pain or discomfort ☐
   - I have slight pain or discomfort ☐
   - I have moderate pain or discomfort ☐
   - I have severe pain or discomfort ☐
   - I have extreme pain or discomfort ☐

5. Anxiety / Depression

I am not anxious or depressed ☐

I am slightly anxious or depressed ☐

I am moderately anxious or depressed ☐

I am severely anxious or depressed ☐

I am extremely anxious or depressed ☐

6. We would like to know how good or bad your health is **TODAY**.

This scale is numbered from 0 to 100.

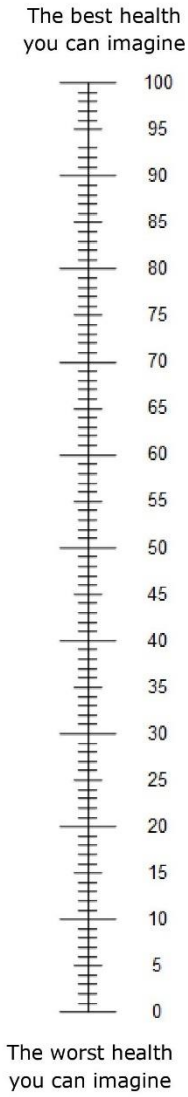
100 means the best health you can imagine.

0 means the worst health you can imagine.

Mark an **X** on the scale to indicate how your health is **TODAY**.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Section 5: **This section is about your strength measurements**

For this section, the physiotherapist will use an electronic device, called a Squegg, to measure your grip strength.

Pain-free grip strength:

Squeeze the Squegg as hard as you can without it causing pain at your elbow. Write down the measurement and repeat this three times.

Measurement 1 ..... lbs

Measurement 2 ..... lbs

Measurement 3 ..... lbs

Maximum grip strength:

Squeeze the Squegg as hard as you can and push through pain. Write down the measurement and repeat this three times.

Measurement 1 ..... lbs

Measurement 2 ..... lbs

Measurement 3 ..... lbs

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

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

CRF02 – Usual Care Treatments

Participant ID Number: Site:

Appointment Date:				
Treatment:	Tick boxes below if delivered			

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

OPTimisE Follow-up Questionnaire

For office use only:

Patient ID Number	
Site	
Time point	6 weeks / 3 months / 6 months

Thank you for continuing to take part in this trial. The answers you give in this questionnaire will help us to find out more about your elbow problem has changed since you started treatment.

Please answer all of the questions, and follow the instructions for each section carefully. Please use a **BLACK or BLUE** pen. Please do not use a pencil.

Please write the date that you completed this questionnaire:

____ / ____ / _____

DD / MM / YYYY

Section 1 **This section asks questions about your elbow problem affects you.**

In the last month, how many days have you had off work due to your elbow?

☐ days Not applicable ☐

Please rate from 0-10 how much pain you have when gripping strongly.

No pain Worst imaginable

0 1 2 3 4 5 6 7 8 9 10

How much has your elbow changed since you began physiotherapy treatment?

(Please circle one option)

-5 -4 -3 -2 -1 0 1 2 3 4 5

Very Much Worse Unchanged Completely Recovered

*The questions below will help us understand the amount of difficulty you have had with your arm in the past week. You will be describing your **average** arm symptoms **over the past week** on a scale 0-10. Please provide an answer for all questions. If you did not perform an activity because of pain or because you were unable ,then you should circle a "10". If you are unsure please estimate to the best of your ability. Only leave items blank if you never perform that activity. Please indicate this by drawing a line completely through the question.*

1. PAIN in your affected arm											
*Rate the average amount of pain in your arm **over the past week** by circling the number that best describes your pain on a scale from 0-10. A **zero** (0) means that you **did not have any pain** and a **ten** (10) means that you had **the worst pain imaginable.***											
RATE YOUR PAIN: No Pain											Worst Imaginable
When your are at rest	0	1	2	3	4	5	6	7	8	9	10
When doing a task with repeated arm movement	0	1	2	3	4	5	6	7	8	9	10
When carrying a plastic bag of groceries	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its least	0	1	2	3	4	5	6	7	8	9	10
When your pain was at its worst	0	1	2	3	4	5	6	7	8	9	10

Please turn the page.....

2. FUNCTIONAL DISABILITY

A. SPECIFIC ACTIVITIES

*Rate the **amount of difficulty** you experienced performing each of the tasks listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. A zero (0) means you did not experience any difficulty and a **ten (10)** means it was **so difficult you were unable to do it at all**.*

	No Difficulty										Unable To Do
Turn a doorknob or key	0	1	2	3	4	5	6	7	8	9	10
Carry a grocery bag or briefcase by the handle	0	1	2	3	4	5	6	7	8	9	10
Lift a full coffee cup or glass of milk to your mouth	0	1	2	3	4	5	6	7	8	9	10
Open a jar	0	1	2	3	4	5	6	7	8	9	10
Pull up pants	0	1	2	3	4	5	6	7	8	9	10
Wring out a washcloth or wet towel	0	1	2	3	4	5	6	7	8	9	10

B. USUAL ACTIVITIES

*Rate the **amount of difficulty** you experienced performing your **usual** activities in each of the areas listed below, over the past week, by circling the number that best describes your difficulty on a scale of 0-10. By "usual activities", we mean the activities that you performed **before** you started having a problem with your arm. A **zero** (0) means you did not experience any difficulty and a **ten** (10) means it was so difficulty you were unable to do any of your usual activities.*

1. Personal activities (dressing, washing)	0	1	2	3	4	5	6	7	8	9	10
2. Household work (cleaning, maintenance)	0	1	2	3	4	5	6	7	8	9	10
3. Work (your job or everyday work)	0	1	2	3	4	5	6	7	8	9	10
4. Recreational or sporting activities	0	1	2	3	4	5	6	7	8	9	10

Comments:

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Please circle one response for each question:

	Strongly disagree	Disagree	Agree	Strongly agree
1. I'm afraid that I might injure myself if I exercise.	1	2	3	4
2. If I were to try to overcome it, my pain would increase.	1	2	3	4
3. My body is telling me that I have something dangerously wrong.	1	2	3	4
4. People aren't taking my medical condition seriously enough.	1	2	3	4
5. My accident/problem has put my body at risk for the rest of my life.	1	2	3	4
6. Pain always means that I have injured my body.	1	2	3	4
7. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening.	1	2	3	4
8. I wouldn't have this much pain if there weren't something potentially dangerous going on in my body.	1	2	3	4
9. Pain lets me know when to stop exercising so that I don't injure myself.	1	2	3	4
10. I can't do all the things normal people do because it's too easy for me to get injured.	1	2	3	4
11. No-one should have to exercise when he/she is in pain.	1	2	3	4

Please rate how confident you are that you can do the following things at present, despite the pain. To indicate your answer circle one of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

Remember, this questionnaire is not asking whether or not you have been doing these things, but rather how confident you are that you can do them at present, despite the pain.

	Not at all confident						Completely confident
1. I can enjoy things, despite the pain	0	1	2	3	4	5	6
2. I can do most of the household chores (e.g. tidying-up, washing dishes etc), despite the pain	0	1	2	3	4	5	6
3. I can socialise with my friends or family members as often as I used to do, despite the pain	0	1	2	3	4	5	6
4. I can cope with my pain in most situations	0	1	2	3	4	5	6
5. I can do some form of work, despite the pain ("work" includes housework, pain and unpaid work)	0	1	2	3	4	5	6
6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain	0	1	2	3	4	5	6
7. I can cope with my pain without medication	0	1	2	3	4	5	6
8. I can still accomplish most of my goals in life, despite the pain	0	1	2	3	4	5	6
9. I can live a normal lifestyle, despite the pain	0	1	2	3	4	5	6
10. I can gradually become more active, despite the pain	0	1	2	3	4	5	6

Section 2 **This section is about your general health.**

Under each heading, please cross (X) the **ONE** box that best describes your health **TODAY**.

1. Mobility
   - I have no problems in walking about ☐
   - I have slight problems in walking about ☐
   - I have moderate problems in walking about ☐
   - I have severe problems in walking about ☐
   - I am unable to walk about ☐

2. Self-care
   - I have no problems washing or dressing myself ☐
   - I have slight problems washing or dressing myself ☐
   - I have moderate problems washing or dressing myself ☐
   - I have severe problems in washing or dressing myself ☐
   - I am unable to wash or dress myself ☐

3. Usual activities (e.g. work, study, housework, family or leisure activities)
   - I have no problems doing my usual activities ☐
   - I have slight problems doing my usual activities ☐
   - I have moderate problems doing my usual activities ☐
   - I have severe problems doing my usual activities ☐
   - I am unable to do my usual activities ☐

4. Pain / Discomfort
   - I have no pain or discomfort ☐
   - I have slight pain or discomfort ☐
   - I have moderate pain or discomfort ☐
   - I have severe pain or discomfort ☐
   - I have extreme pain or discomfort ☐

5. Anxiety / Depression

I am not anxious or depressed	☐
I am slightly anxious or depressed	☐
I am moderately anxious or depressed	☐
I am severely anxious or depressed	☐
I am extremely anxious or depressed	☐

6. We would like to know how good or bad your health is **TODAY**.

This scale is numbered from 0 to 100.

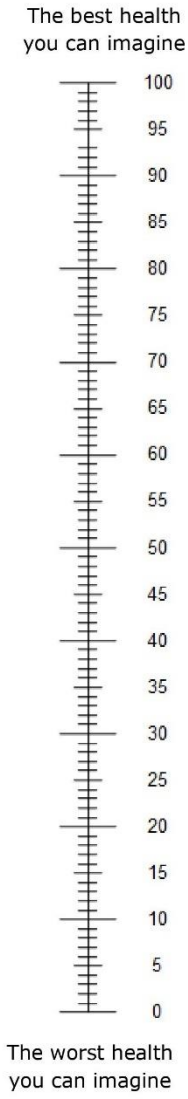
100 means the best health you can imagine.

0 means the worst health you can imagine.

Mark an **X** on the scale to indicate how your health is **TODAY**.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Section 3: **This section is about your physiotherapy treatment**

For each of the following 6 statements, please tick the box which best describes how you do your recommended exercises/activities. When thinking about your answer, please consider any exercises/activities that you have been asked to do as part of your treatment.

	Completely agree				Completely disagree
I do my exercises as often as recommended	0	1	2	3	4
I forget to do my exercises	0	1	2	3	4
I do less exercise than recommended by my healthcare professional	0	1	2	3	4
I fit my exercises into my regular routine	0	1	2	3	4
I don't get around to doing my exercises	0	1	2	3	4
I do most, or all, of my exercises	0	1	2	3	4

Section 4: **This section is about your strength measurements**

For this section you will need to use your Squegg device. If you received usual physiotherapy treatment, you only need to complete this section for the 6-month questionnaire and you will be sent a Squegg device beforehand.

Open the Squegg App on your smartphone/tablet and connect your Squegg by squeezing it 3 times. If you are having difficulty please refer to the instruction manual or the OPTimisE Squegg Information Sheet. Select the 'Measure' icon and make sure that it is set to measure in pounds (lbs).

Pain-free grip strength:

Squeeze the Squegg as hard as you can without it causing pain at your elbow. Write down the measurement and repeat this three times.

Measurement 1 ..... lbs

Measurement 2 ..... lbs

Measurement 3 ..... lbs

Maximum grip strength:

Squeeze the Squegg as hard as you can and push through pain. Write down the measurement and repeat this three times.

Measurement 1 ..... lbs

Measurement 2 ..... lbs

Measurement 3 ..... lbs

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Please return it in the pre-paid envelope provided, to:

Marcus Bateman (OPTimisE Trial)
Orthopaedic Outpatient Department
Royal Derby Hospital
Derby
DE22 3NE

Exercise Diary

Participant ID number:

Please keep a daily record of whether you have completed the exercises prescribed to treat your elbow. Your physiotherapist will not see this information, so please be honest in your record-keeping.

If you have done your exercises, please tick the box for that day. If you have not done any exercises, please leave the box empty.

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Week 1							
Week 2							
Week 3							
Week 4							
Week 5							
Week 6							
Week 7							
Week 8							
Week 9							
Week 10							
Week 11							
Week 12							
Week 13							

When you have completed your diary please return it in the stamped addressed envelope provided, to:

Marcus Bateman (OPTimisE Trial),
Orthopaedic Outpatient Department
Royal Derby Hospital,
Derby,
DE22 3NE.

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

CRF03 – OPTimisE Intervention Treatments

Participant ID Number: Site:

Appointment Date:				
Advice Topic	Tick boxes below if delivered			
What tennis elbow is				
Activity modification				
Pacing				
Promote 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)				
Exercise	Tick boxes below if delivered and indicate amount of load for isometric and con/eccentric exercise			
Forearm stretches (30s x3 before and after loading exercises)				
Isometric loading (hold for 60s and repeat 5 times)				
Combined eccentric & concentric loading (10-15 reps, 3 sets, 12 seconds to complete each rep)				
Higher load functional exercise				
High load general upper body exercise				
Orthotics	Tick boxes below if delivered			
Elbow clasp provided and patient instructed how to use				

NHS
Health Research Authority

Yorkshire & The Humber - Sheffield Research Ethics Committee
NHS Blood and Transplant Blood Donor Centre
Holland Drive
Newcastle upon Tyne
Tyne and Wear
NE2 4NQ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

22 June 2021

Mr Marcus Bateman
Consultant Upper Limb Physiotherapist
Derby Teaching Hospitals NHS Foundation Trust
Orthopaedic Outpatient Department
Royal Derby Hospital
Derby
DE22 3NE

Dear Mr Bateman

Study title:	**Optimising Physiotherapy for people with Tennis Elbow – a mixed methods pilot & feasibility randomised controlled trial.**
REC reference:	**21/YH/0121**
Protocol number:	**UHDB/2019/013**
IRAS project ID:	**297637**

Thank you for your letter of 14 June 2021, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities
The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion
The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:
https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at:
https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at
https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites
NHS/HSC sites
The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to

confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites
I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents
The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Interview schedules or topic guides for participants [OPTimisE Interview Topic Guide]	v0.2	26 April 2021
IRAS Application Form [IRAS_Form_19052021]		19 May 2021
Letter from funder [Funding letter]		23 January 2020
Letters of invitation to participant [OPTimisE Letter of Introduction (from GP practice)]	v0.2	28 April 2021
Letters of invitation to participant [OPTimisE Letter of Introduction (from Physio clinic)]	v0.1	10 March 2021
Letters of invitation to participant [OPTimisE Qualitative Study Invitation Letter]	v0.2	28 April 2021
Non-validated questionnaire [OPTimisE Exercise Diary]	v0.2	13 May 2021
Non-validated questionnaire [OPTimisE Screening Questionnaire]	v0.2	13 May 2021
Other [OPTimisE CRF02 - Usual Care Treatments]	v0.1	10 March 2021
Other [OPTimisE CRF03 - OPTimisE Intervention Treatments]	v0.1	10 March 2021
Other [OPTimisE Intervention Handbook]	v0.4	06 April 2021
Other [OPTimisE Patient Manual]	v0.1	30 March 2021
Other [Short CV Chris Littlewood]	v1.0	02 December 2020
Other [Short CV Benjamin Saunders]	v1.0	02 December 2020
Other [Short CV Jonathan Hill]	v1.0	10 November 2020
Other [Ethical Review - Response to Recommendations]		14 June 2021
Participant consent form [OPTimisE Qualitative Consent Form]	v0.1	08 March 2021
Participant consent form [OPTimisE Trial Consent Form]	v0.4	14 June 2021
Participant information sheet (PIS) [OPTimisE Patient Information Sheet]	v0.4	14 June 2021
Participant information sheet (PIS) [OPTimisE Qualitative Participant Information Sheet (Patients declined trial)]	v0.2	14 June 2021
Participant information sheet (PIS) [OPTimisE Qualitative Participant Information Sheet (Patients in trial)]	v0.2	14 June 2021
Participant information sheet (PIS) [OPTimisE Qualitative Participant Information Sheet (Physiotherapist)]	v0.2	14 June 2021
Research protocol or project proposal [OPTimisE Trial Protocol]	v1.0	18 May 2021
Summary CV for Chief Investigator (CI) [CV Marcus Bateman]		26 April 2021
Validated questionnaire [OPTimisE CRF01 - Baseline Questionnaire]	v0.4	06 May 2021
Validated questionnaire [OPTimisE Follow-up Questionnaire]	v0.4	13 May 2021

Statement of compliance
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback
The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning
We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: 297637 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

pp

Dr Tim Sprosen
Chair

Email:sheffield.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: Dr Teresa Grieve

Lead Nation
England: approvals@hra.nhs.uk

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mr Marcus Bateman
Consultant Upper Limb Physiotherapist
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Email: approvals@hra.nhs.uk
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22 June 2021

Dear Mr Bateman

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Optimising Physiotherapy for people with Tennis Elbow – a mixed methods pilot & feasibility randomised controlled trial.**
IRAS project ID:	**297637**
Protocol number:	**UHDB/2019/013**
REC reference:	**21/YH/0121**
Sponsor	**University Hospitals of Derby & Burton NHS Foundation Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **297637**. Please quote this on all correspondence.

Yours sincerely,

Natalie Marking
Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Teresa Grieve*

Appendices pertaining to Chapter 5: The OPTimisE Pilot & Feasibility Randomised Controlled Trial - Qualitative Element

Appendix 5.1: OPTimisE Trial qualitative participant information sheet (patient version)

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

Qualitative Study - Participant Information Sheet

We would like to invite you to take part in an interview as part of our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

Tennis Elbow is a common problem but we do not know the best way of treating it. Physiotherapy is often recommended. This can involve a variety of treatments, for example: exercise, taping, acupuncture, manual therapy, ultrasound or laser. Different physiotherapists prefer different treatments, dependent on how they were trained, but research suggests that the best treatments are not always used. We have designed an optimised physiotherapy treatment package based upon research evidence and expert opinion that we want to test with patients. This is focussed on three elements:

1. Advice and education so that patients can learn to manage the problem themselves
2. A specific exercise regime to improve function
3. A Tennis Elbow brace to control pain

The purpose of this study is to evaluate if it is feasible to run a large-scale study to establish whether this optimised physiotherapy treatment package is more effective than usual physiotherapy in reducing pain and improving function in people with Tennis Elbow. We will look at how willing people were to be involved, how well they engaged with the treatments and how well the treatment effect could be measured. We will also be inviting some people to discuss their experience of being involved to identify what worked well and what could be improved for a large national trial.

Why have I been invited?

You are being invited to take part because you were a participant in the trial

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your medical care or legal rights. People that are interviewed will receive a £20 Amazon/Love2shop voucher for their time and travel expenses will be reimbursed if the interviews are held face-to-face.

What will happen to me if I take part?

You have been invited to attend a short interview to discuss you experience of the research trial. The interviews will be relaxed and informal, may last up to 1 hour and can be arranged face-to-face, either in

a quiet room at the physiotherapy department or in your own home, by telephone, or online using video-conferencing.

Interviews will be audio-recorded and sent to a UK-based transcription service to be converted into a written format. These will be subject to a confidentiality agreement. Your personal details will not be shared with the transcription service and you should avoid disclosing any information during the interview that you do not wish to be shared. Some quotes may used in the written-up report. Any quotes or discussions will be anonymised, so no one will know it was you who made the comments. There will be no other use of the recordings. Recordings will be deleted following the publication of the results.

Expenses and payments

Participants that are interviewed will receive a £20 Amazon/Love2shop voucher for their time and travel expenses will be reimbursed if the interviews are held face-to-face.

What are the possible disadvantages and risks of taking part?

There are no serious risks to taking part in this research. During the interview, should you feel uncomfortable with any of the discussions, you are free to end the discussion at any point.

What are the possible benefits of taking part?

There are no direct benefits from taking part, but the information we get from this study may help inform future research and direct future treatment to other patients with a Tennis Elbow.

What happens when the research study stops?

Your involvement in the study will end after the interview.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet.

You may also contact your local Patient Advice Liaison Service (PALS) for any concerns or complains that you might have on {add local PALS details}

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

The interview recording and transcription will be looked at by authorised persons from Keele University and University Hospitals of Derby and Burton NHS Foundation Trust. It may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (email address, telephone number) will be kept for up to 6 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 5 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your

- Initials
- Name
- contact details (email, telephone number)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from http://www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to uhdb.sponsor@nhs.net

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your medical care or legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

It is anticipated that the results of the study will be published in scientific journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish.

Who is organising and funding the research?

This research is being organised by University Hospitals of Derby and Burton NHS Foundation Trust and is being funded by the National Institute of Health Research (NIHR) and the Chartered Society of Physiotherapy Charitable Trust.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Sheffield Research Ethics Committee (refence number: xxxxxxxxxx).

Further information and contact details:

Marcus Bateman
Chief Investigator
marcus.bateman@nhs.net

Dr Jonathan Hill
Academic Supervisor
j.hill@keele.ac.uk

Website: www.optimise-trial.uk

Appendix 5.2: OPTimisE Trial qualitative invitation letter

Derby Clinical Trial Support Unit,
Medical School Office 5033,
Royal Derby Hospital,
Derby,
DE22 3NE.

Optimising Physiotherapy for people with Tennis Elbow – Qualitative Study

Dear Sir / Madam,

Thank you for agreeing to be contacted about this part of the OPTimisE trial. As part of this research, we are inviting a selection of patients and physiotherapists to be interviewed. The purpose of the interviews is to find out your opinions about several aspects of the trial, such as what you found good or bad and how it could be improved for a future large main trial.

The interviews are expected to take around one hour and can be done in person at the physiotherapy department where you received your treatment, by telephone or by video-conference. You will receive £20 for your time, and travel expenses will be reimbursed if you choose to be interviewed in the physiotherapy department. The conversations will be audio-recorded and direct quotes may be used when we report the results but these will be anonymised to protect your identity.

I will contact you within the next fortnight by telephone or email to discuss whether you wish to take part in the interviews and if so, arrange a convenient time. Your participation is entirely optional.

Yours sincerely,

Marcus Bateman.
Consultant Physiotherapist / Doctoral Research Fellow

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

Qualitative Study - Participant Information Sheet

We would like to invite you to take part in an interview as part of our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

Tennis Elbow is a common problem but we do not know the best way of treating it. Physiotherapy is often recommended. This can involve a variety of treatments, for example: exercise, taping, acupuncture, manual therapy, ultrasound or laser. Different physiotherapists prefer different treatments, dependent on how they were trained, but research suggests that the best treatments are not always used. We have designed an optimised physiotherapy treatment package based upon research evidence and expert opinion that we want to test with patients. This is focussed on three elements:

1. Advice and education so that patients can learn to manage the problem themselves
2. A specific exercise regime to improve function
3. A Tennis Elbow brace to control pain

The purpose of this study is to evaluate if it is feasible to run a large-scale study to establish whether this optimised physiotherapy treatment package is more effective than usual physiotherapy in reducing pain and improving function in people with Tennis Elbow. We will look at how willing people were to be involved, how well they engaged with the treatments and how well the treatment effect could be measured. We will also be inviting some physiotherapists to discuss their experience of being involved to identify what worked well and what could be improved for a large national trial.

Why have I been invited?

You are being invited to take part because you were

a physiotherapist in the trial

.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your involvement as a physiotherapist in the trial or your legal rights. People that are interviewed will receive a £20 Amazon/Love2shop voucher for their time and travel expenses will be reimbursed if the interviews are held face-to-face.

What will happen to me if I take part?

You have been invited to attend a short interview to discuss you experience of the research trial. The interviews will be relaxed and informal, may last up to 1 hour and can be arranged face-to-face, either in a quiet room at the physiotherapy department or in your own home, by telephone, or online using video-conferencing. You would be expected to participate outside of your working hours.

Interviews will be audio-recorded and sent to a UK-based transcription service to be converted into a written format. These will be subject to a confidentiality agreement. Your personal details will not be shared with the transcription service and you should avoid disclosing any information during the interview that you do not wish to be shared. Some quotes may used in the written-up report. Any quotes or discussions will be anonymised, so no one will know it was you who made the comments. There will be no other use of the recordings. Recordings will be deleted following the publication of the results.

Expenses and payments

Participants that are interviewed will receive a £20 Amazon/Love2shop voucher for their time and travel expenses will be reimbursed if the interviews are held face-to-face.

What are the possible disadvantages and risks of taking part?

There are no serious risks to taking part in this research. During the interview, should you feel uncomfortable with any of the discussions, you are free to end the discussion at any point.

What are the possible benefits of taking part?

There are no direct benefits from taking part, but the information we get from this study may help inform future research and direct future treatment to other patients with a Tennis Elbow.

What happens when the research study stops?

Your involvement in the study will end after the interview.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet.

You may also contact your local Patient Advice Liaison Service (PALS) for any concerns or complains that you might have on 0114 271 5535.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

The interview recording and transcription will be looked at by authorised persons from Keele University and University Hospitals of Derby and Burton NHS Foundation Trust. It may also be looked at by

authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

Your personal data (email address, telephone number) will be kept for up to 6 months after the end of the study so that we are able to contact you about the findings of the study (unless you advise us that you do not wish to be contacted). All other data (research data) will be kept securely for 5 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your

- Initials
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People will use this information to do the research or to check your records to make sure that the research is being done properly.

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We will keep all information about you safe and secure.

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What are your choices about how your information is used?

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Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
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- by asking one of the research team
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What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your medical care or legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

It is anticipated that the results of the study will be published in scientific journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish.

Who is organising and funding the research?

This research is being organised by University Hospitals of Derby and Burton NHS Foundation Trust and is being funded by the National Institute of Health Research (NIHR) and the Chartered Society of Physiotherapy Charitable Trust.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Yorkshire & The Humber - Sheffield Research Ethics Committee (refence number: 21/YH/0121).

Further information and contact details:

Marcus Bateman
Chief Investigator
marcus.bateman@nhs.net

Dr Jonathan Hill
Academic Supervisor
j.hill@keele.ac.uk

Website: www.optimise-trial.uk

Interview Topic Guide

Patient Interviews (those that declined trial participation):

1. Introduction and purpose of the interview
2. Reasons for declining participation in the trial:
    a. What were your thoughts when you were invited to participate in this trial?
    b. Probe any points raised.
    c. Prompts: explanation given about the trial, method of approach.
3. Trial information:
    a. What were your thoughts on the information you received about the trial?
    b. Probe any points raised.
4. Areas for improvement:
    a. What are your opinions about how the trial could be improved?
    b. Prompts: any changes to the patient information?

Patient Interviews (trial participants):

1. Introduction and purpose of the interview
2. Impact of the condition:
    a. What has the impact of having Tennis Elbow been for you?
    b. Probe any points raised
3. Reasons for participating in the trial:
    a. What were your thoughts when you were invited to participate in this trial?
    b. Probe any points raised.
    c. Prompts: explanation given about the trial, method of approach.
4. Trial information:
    a. What were your thoughts on the information you received about the trial?
    b. Probe any points raised.
5. Physiotherapy treatment:
    a. What were your thoughts about the physiotherapy treatment that you received during the trial?
    b. Probe any points raised.
    c. Prompts: frequency of appointments, dosage of exercises, adherence to exercises, acceptability of treatment, have symptoms improved, self-efficacy, feelings re: what treatment aspects contributed most to improvements (if applicable).
6. Outcome measures:
    a. What were your thoughts about the questionnaires used to measure the effect of your treatment?
    b. Probe any points raised.
    c. Prompts: suitability of paper or online systems as applicable, length of questionnaires, frequency of outcome measure collection.
7. Areas for improvement:
    a. What are your opinions about how the trial could be improved?
    b. Prompts: any changes to the patient manual or website.

Physiotherapist Interviews:

1. Introduction and purpose of the interview
2. Trial information and training:
    a. How confident did you feel in treating people with Tennis Elbow before the trial?
    b. What were your thoughts on the information and training you received about the trial?
    c. Probe any points raised.
    d. Prompts: site training sessions, website, site resources.
3. Intervention delivery:
    a. What are your thoughts on delivering the physiotherapy treatment during the trial?
    b. Prompts: challenges, opinions re: deliverability in an NHS clinical setting.
4. Areas for improvement:
    a. What are your opinions about how the trial could be improved?
    b. Prompts: any changes to supporting information e.g. Intervention Handbook.
5. Outlook:
    a. How has being involved in this trial changed how you would treat people with Tennis Elbow in the future?
    b. Probe any points raised.

Trial Acceptability Interview Codebook (Patient Participants)

Contents

Code name	Definition	Example quotes

Randomisation		
Patients willing to be randomised	Descriptions of people's willingness to be randomised to either intervention in the OPTimisE trial	"No, because I was that desperate just to see a physio because there was a bit of a waiting list prior to that. so, no when the call came I was happy to take the opportunity." BHX003 "I wouldn't say I had any strong preferences. My main goal was just to get physio and see where that takes me. I was just hopeful either way that it would help in some way." DER002 "**INT: Okay. When you were, when you came to that first appointment and there was the option of receiving the usual physiotherapy treatment or the optimised treatment, did you have any particular preferences or concerns about being randomised?** RES: Not in the slightest, no. **INT: Good. So if you were randomised to the usual care, that wouldn't have been a problem for you?** RES: No not at all, no. Because it's been good to have the physio as well, so no, not at all." DER004 "Yes, I would have been fine either way as long as it helped me yes I would have gone through it especially because I'm in the optimised trial, I was happy to obviously go through with it, and anyway my background is statistics and I know it's important to get data and information about these sorts of things so I was happy to be part of it either way." DER011 "Either. Either. I mean I don't know what the other treatment option is. It did, obviously I did get an information leaflet and it did say such as it would be electrical therapy and stuff like that. I would have been happy to do either, number one just to get rid of the pain and number two, it just helps you gather information." SHE001 "Oh, I was quite happy. I'm not bothered at all, yes, anything that helps, you know." SHE004 "No, it was fine, no issues at all." SHE013

Group allocation preference	People's preferences towards the OPTimisE intervention or usual care	"I think by nature of its name, optimised. I think my preference was to- I was in discomfort so anything that might expedite the process or equal rotation is obviously going to be attractive. So, yes, my preference was towards the optimised for sure." DER008 "No, not particularly. I think that's one of the things when you do a trial, it's a case of to see the difference. My main hope was for the outcome, you know, for it to be cured and not to be in pain anymore was really the big thing." SHE014 "No, I mean I was told I would be in the usual treatment as opposed to the optimised one but I wasn't told what the optimised one entailed so [laughs], I guess you don't miss what you don't, what you don't know or what you don't have so, no." SHE018
Motives for taking part	Descriptions of people's motivation for taking part in the OPTimisE trial	"My motivation was I thought, *If it can help in any way for someone else who is suffering from tennis elbow*. I think it's good to do these research projects because there's always something that they find that maybe there's an area of weakness, people aren't being diagnosed or the treatment is incorrect. So, hopefully it kind of helping through the treatment of tennis elbow." DER002 "Well, to help out really. It's a funny old diagnosis and doesn't look like we know exactly what to do with it. So, it's to help try and contribute to finding a solution that works better." DER003 "Yes I was quite keen to take part. I always know how important medical research is. We all benefit from it. I mean hopefully I'll never have tennis elbow again in my life but the treatment I've had this time comes from studies that have been done in the past. All of the medicine I take has come from other studies. My Covid vaccine came from studies and so on so you know as long as I can help I'm always willing to." DER006 "And it's helping give information for other people that, you know, obviously because when I saw it was a research thing, it's just it's helping a wider range of people rather than just myself." SHE001 "Well I just, I thought if it can help then it's not really much, it wasn't going to cause an inconvenience to myself because it was still going to see the physio. I thought if it can help people then, yes, it makes sense to do it." SHE014

		"When they said it was research, I was straightaway interested because it helps you gather information that you can use for other people that will help other people who aren't as convinced as what, because I wasn't convinced you see. So if I was a person that had not done this research and I knew a lot of people had done the research and that was the information that you were coming out with, then I wouldn't be so dead set on just having the injection, do you know what I mean? I would be thinking, right well people have done it, they have been there and it's tried and tested." SHE001 "Yes, I'm not bothered at all, it's fine, if I can help somebody else not go through it, that'd be great or to recover quicker." SHE004 "Well actually I thought, brilliant I will be able to hopefully get some kind of physio or some kind of exercises and not have to go down the route of having surgery again. Because I just think, you know, it can be manageable and if I carry on and continue with the exercises given, I do think it's going, it will be improving, start to improve a lot more." SHE005 "After I went to the doctors – I mean she said to me, I got quite scared because she said, "In the worst-case scenarios sometimes you need injections and that's when if it was really, really severe, steroid injections. And in the milder cases, if you do physio correctly it could get better with physio." So, I think I was more determined to go down the physio route and hopefully try and get myself better rather than having to get to that stage, where you need more medical intervention in terms of injections or medicine." DER002 "I was thinking well, maybe it's a higher level they're trying out so, maybe I'll get better quicker, that's what I was thinking in my mind. Because it's a trial maybe it's something more advanced than the physios could do before." BHX003 "I was pleased to be part of the trial mainly because, for selfish reasons if you like, if you're part of a trial you know that there is some additional focus on you. But, that meant that I was confident there was- You know, probably speeded up having the first session with a physio. And, clearly, that was the catalyst to improving the situation. As you've been so consistently uncomfortable for a long time and it only took a short period of activity following the physio that led to some improvement." DER008

		"Beyond just trying to get back to sort of the level of activity that I was doing before I suppose would be the main thing because it had-- I think at the point I went on to the trial to kind of carried on for a long time without really seeming to get much better, so a lot of my motivation for it was you know the previous recommendations hadn't really gone anywhere and I wasn't going to be someone who's going to rely on pain killers to kind of manage it, so, yes. To me it was a really good opportunity." SHE016
OPTimisE Patient Information		
Patient information sheet	People's feedback related to the OPTimisE Participant Information Sheet.	"Yes, I think I did but I'm the kind of person who will take in the information but when it comes to the actual doing, that's when I really learn. But yes, the information was good, it was clear, yes no problem with the information at all." BHX003 "No, I think the information was fully covered to be honest, yes. It was everything in there, yes." BHX004 "Yes, I think the information is easy to read, easy to follow" DER001 "Yes. I thought it was all there, all information that was available, yes." DER003 "Yes definitely, it was very informative, yes." DER004 "Yes, it was very clear. I understood it all." DER008 "Yes I think it gave me enough information but what I probably would have liked a little bit more information on were the questionnaires, because I think when I got the first questionnaire, like the survey that was sent, it had a lot of questions that I didn't expect. I mean it's a good thing you want to get all the information but it probably wasn't, or maybe I just didn't realise it would be quite so time consuming so to say. It's not a complaint but maybe making that quite clear up front would have been a bit better." DER011

		"Yes, because they also let you know that if you were not interested in doing the research trial that your care would not be stopped. Because obviously when you are, you think to yourself, right if I don't do the research are they going to stop seeing me for my elbow, which it was explained that they don't do that. So I think it gave me everything that I needed to know to make the decision." SHE001 "Yes, I think so. I suppose- Well, she gave me a factsheet and an information sheet which was about three pages long, which I read. Then she had a chat to me about it in the surgery. Yes, I think so, I was quite happy at the time to make that decision and I'm quite happy to continue with it, yes." SHE004 "Yes, I've done medical trials before through university. I used to study biomedicine. So everything was kind of the formats I'd been involved in as someone running a trial before. So it was good for me in that way…But if you have like really important info to get over, because I know you guys you have to say a lot of, you know, all the blurb about data protection and if you want your data to be used and stuff, just really separating that from the main text you want to get across. And I know you do that on some bits in the correspondences, you do like the bullet points and bold lettering, just use plenty of that because when you do it, it's good and it's quite easy to pick it out amongst all the standard, you know, if you want to opt out we won't use your data by a certain point, and all that. I mean as I say it's kind of like, I mean my perception on it is a bit different from the average person's as well with me both running medical trials before and me being, having essentially a form of learning difficulty, you know, it's just a different view on it isn't it, yes." SHE011 (Highly functioning autistic spectrum disorder)
Trial manual	People's feedback related to the OPTimisE Patient Manual	"I think your booklet is outstanding, I do, because I have followed your booklet like religiously, and it's easy to follow, easy to read yes. I'll keep using it until my elbow is completely better, and I don't think it will ever go away completely but I've got the tools here to help me." DER001 "I mean it's very well presented. It looks good, it looks clean, it's easy to understand. It's not too long so it keeps your attention. I wouldn't be looking to tweak it too much." DER008

		"Yes. Absolutely and I referred to the booklet quite a few times just to make sure that I was doing it right and the pictures helped and I thought the booklet was good enough actually, so yes I found that useful." DER011 "But also I find that when I am in appointments, I sort of listen to the information but then when I get home I sort of sometimes forget the information. But we were given a booklet that tells you all about the exercises that we are going to be doing and it explains them all. And it has a proper good description that if I think that I've forgot, I can then look in the booklet and see the exercise that I have been asked to do and I can just, you know, refresh my brain, which is very handy." SHE001 "Good, it was fully self-explanatory and very clear so, it was fine." SHE013 "Yes, I mean the handbook was really good. The website, as well - that was really useful initially to be able to make sure I was doing my exercises correctly so yes. Yes, so, both of them combined have been really useful. It helps that the exercises are fairly simple really and because it is a fairly limited range of exercises, you are not constantly shooting on to a new thing. So, I would say the resources have been really good." SHE016 "I was really impressed with the booklet I thought there was enough information in there and there is enough kind of links to other resources as well. To me yes, I think the booklet is just about right, it's not long enough to be kind of intimidating to put people off it's got enough information there yes and enough kind of links to other resources." SHE016
Website	People's feedback related to the OPTimisE trial website	"**INT: Did you have a look at the website? Did you have a look at the videos and the advice?** RES: Oh, not really no…I thought let me do this [treatment] and see how it goes and obviously it was going the right way, so I didn't really feel the need to go to website and get more information about it." BHX004 "**INT: Have you had a look at the website?** RES: No…You've got a website as well?" DER001

		"**INT: Okay. So obviously you have had a look at the sleep information on the website, did you have a look at all of it or just certain parts?** RES: So I have not looked at all of it I have to admit, perhaps I need to look a bit more into it, yes." DER004 "They were pointing me towards a website that I only visited once. I had a look at everything that was on there but the session that I had with the physio and the exercises that she had me doing I continued pretty much to plan." DER008 "**INT: Were you given the details of the website to look at?** RES: Yes. I was but I must confess I haven't looked at it. I did want to look at but I think I managed to clarify what I wanted to check on the second, you know on the second day I met that lady, so I didn't have to go to the site as such." DER011 "**INT: Do you think overall there's anything that we ought to change, anything we could do differently, better or worse.** RES: I don't know maybe an update on the progress of the research. I've no idea of what you're trying to achieve really, I think is the main sort of thing. What the research is trying- I'm assuming it's to try and improve the level of service and look at alternative levels of services and different methods of service. I don't know really, but maybe some updates on how the research is going and what early findings suggest maybe useful." SHE004 "**INT: And have you had a look at the content on the website?** RES: Yes, most of it is just more in depth, just going through the exercises bit that are on there so, yes I did have a look at it in the early part of the trial, yes. **INT: Okay, do you think there's anything on the website that could be you know, changed or more detailed, less detailed, any thoughts?** RES: No, to be fair nothing that springs to mind, as I say it was very much reiterating what [physio name] had shown me or done in the first consultation. The same video obviously the video that she was showing me and reiterating what's in the leaflet. So, it seems pretty clear, pretty easy to understand.

		INT: Fair enough yes, you're right in that it's designed to reinforce everything that's gone before, we're just trying to get an understanding of how much use the website has had. Would you say that you're more of a website person or prefer to have something like a paper leaflet to read? RES: Don't mind, I'll work either way. And as I say having read the leaflet then the website was almost superfluous because I'd read the leaflet, I'd sat with [physio name], seen some of the content on the website already in that consultation so, the website really didn't add anything at that point. But if I hadn't had the leaflet and been directed to the website first then obviously, I'd have done that but I'm quite happy to work either way." SHE013 "The website as well that was really useful initially to be able to make sure I was doing my exercises correctly so yes." SHE016 "**INT: You said you used it several times, the website?** RES: Yes, I've logged into it a few times. **INT: What was that to remind yourself of the exercises or for other things?** RES: Yes, just to remind myself to make sure I was doing the exercises in the right way and just to look at some of the other information on there. As time went on I've gone on less. I still use the booklet quite a bit, a quick refresher. Not the website." SHE016
OPTimisE Advice & Education Component		
Not relevant for some patients	Feedback that not all of the advice topics included in the OPTimisE intervention were relevant to some people	"It was a very good session with the physio, I came away impressed. We might have covered a bit of the lifestyle actually thinking about it but only very minor. There wasn't a lot I needed to really focus on. I'm quite conscious of my diet and alcohol intake and things like that at the moment. I'm generally active even though I have a desk based job. I'm moving around all the time. I stand a lot of the time when I'm working. So, there wasn't a lot I needed to change on that." DER008 "To me they weren't applicable in that I like to think that I generally have an okay lifestyle in like I do get exercise, I don't smoke or anything and so diet wise I have a balance diet and all of it. I think for me it wasn't relevant but I can see why it's important because yes obviously it might be applicable to other people so yes I didn't find it relevant but it's important to have it anyway." DER011

Reduction in alcohol and tobacco use	People reporting that they had reduced their alcohol or tobacco consumption due to the advice provided as part of the OPTimisE trial	"Yes, yes. Interesting, because I know [physio name] did mention like lifestyle and things. And obviously drinking and smoking, which I have cut down smoking and I did dry January and I've tried, not continued it, but obviously I don't drink like I used to do. Which is surprising because that's helped as well, I have noticed a difference in that as well and plus my health. --- So like I say, I have cut down quite a lot on smoking, so I am pretty chuffed with myself for doing that. And I don't drink like I used to do because me and my husband did like a drink, but we have both cut down loads, which is good because it's a healthier option I suppose, instead of filling your body full of toxins. We have been really good, so we are both quite pleased with ourselves on that department." SHE005
Weight loss	People reporting that they had lost weight due to the advice provided as part of the OPTimisE trial	"I mean right now I'm down to fourteen and a half whereas when lockdown started I was over 16 and had quite a bit of a belly kind of thing. And it's all due to trying to hammer exercise whenever I can and get on the cross trainer and stuff." SHE011
Increased general exercise	People reporting that they had increased their general exercise levels due to the advice provided as part of the OPTimisE trial	"And also I was impressed by the physio in that they did recognise that I was trying to, how to put it, almost get the most health, almost like weight loss and exercise benefits out of the exercises that I could, so that I was saying "Oh could I turn the weight up on this so I'm actually burning some calories?" SHE011 "**INT: Did you have a look at the sort of general lifestyle advice? Was any of that relevant to you?** RES: Yes, I have, I try to keep as fit as I can any way, so I do tend to walk quite a lot. My job is fairly active anyway, so, that's a good thing, I tend to spend a lot of time on my feet, doing stuff like that rather than sitting at a screen. But yes, it is useful to have that sort of three times a week, I do try to get that amount of exercise in. **INT: Is that something that you have adapted to since the advice from the trail or is that just you did that anyway?** RES: It's something I really do anyway. I'm probably more focused on it during the trial I think but it's probably something I aspire to. I suppose previously but having the sort of trial, it kind of focused

		it a bit. Yes rather than just resting on my laurels. I'm fairly healthy but I've been trying to get more exercise in" SHE016
Sleep	People reporting that they had adjusted their sleep due to the advice provided as part of the OPTimisE trial	"and I'm trying to get a bit more sleep as well I wasn't doing enough of." SHE016
Improved self-efficacy	People's examples of improved self-efficacy as a result of the OPTimisE trial	"RES: Obviously I had the same kind of pain on my left hand, exactly the same issues but I'm doing the same exercises which are helping. I can see that… **INT: So, it's helping for the other side then, yes?** RES: Yes, it's helping and it's lowering the pressure and all the pain. **INT: Okay, so you feel confident having been through it with your right side, you're now confident that you can treat yourself with the left one?** RES: That's right, yes." BHX004 "**INT: It's interesting that you only needed that one appointment. Did you feel that there was sufficient information in the booklet and on the website to progress the exercises yourself?** RES: Yes, there was for me. **INT: Good. I mean that was our intention when we put these things together. But, it's good to know that they actually worked in practice. So, that's useful to know.** RES: I felt it improving so I just…I'm fairly self-sufficient if you like. **INT: Yes. So, you felt in charge that you could manage the problem yourself.** RES: Once I saw that it was improving, yes." DER008 "I also try and pace out digging a lot more so I try and mix the jobs up between like being on the wheelbarrow or mixing concrete by, you know, trying to have a bit of time dispersal between the tasks." SHE011
OPTimisE Counterforce Brace Component		

Feedback that the brace gave temporary pain relief	Descriptions of temporary pain relief provided by the Epi-Hit orthosis	"**INT: Yes. Did they give you a strap to go round your arm?** RES: Yes, I got a strap as well yes. To be honest I used that only when I was working like heavy during the day, but most of the time I wasn't using it. I don't use it anymore really. **INT: Okay. When you used it at work did it make much of a difference to you?** RES: Yes, reducing the pain basically. I wasn't feeling any pain when I had it there, so it was kind of giving a bit of support." BHX004 "**INT: Were you given a brace to go round your elbow?** RES: Yes, I was. **INT: Did you have much use of that?** RES: I used it a little bit to begin with. I have to say when I was wearing it, it did- I don't know if it altered the way I was working or moving my arm around, but it did, while it was on, create less discomfort. The main reason I did it, if I knocked my elbow when it was particularly bad it would only take the lightest glance on a doorway or something that I was passing and it was really painful. And, of course, wearing that, if I did knock something I didn't even notice it. **INT: But it also took the pain away when you were gripping you say?** RES: I felt it did, yes. **INT: Yes. I mean that's what it's-** RES: I was sort of analysing that because I didn't know whether it was just in my head. You know, if I was doing some work outside or some actions where I knew it would be increasing the pain I'd put it on and it felt like it was better." DER008 **"**RES: Yes, she gave me the yellow band and the elbow guard sort of thing I can use, and the wrist guard too. I didn't use the wrist guard but I did use the elbow guard when I use the laptop and that eased the pain quite a lot. --- **INT: Good. Was that just giving you pain relief whilst you were wearing it and doing the activities or did it sort of give you pain relief once you'd taken it off as well?** RES: It was more the first because it was just painful when I was clicking and this kind of reduced that. Yes, I don't think I could say that it helped me afterwards but I can't say that for sure. But it definitely helped me while I was working to reduce that." DER011

		"Because I started using the elbow strap and when I was lifting things it was helping with the pain - there was no pain. --- And so there were a couple of days when I didn't use it and I lifted up a chair and I was in so much pain when I just lifted the chair up onto the table, because I was mopping a floor. But when I use the strap I don't. And then I would try and pick a chair up. Obviously I am not going to purposefully pick the chair up, but when I was working and I picked the chair up and not thought about it, but the strap has helped there not be any pain there, if you know what I mean? It makes it feel like it's not even there." SHE001 "Yes, they provided me with that which whenever I remember I use. But I've only used it probably half a dozen times and they've been the sessions where I've been out in the garden doing just general work in the allotment. Or just digging, weeding, strimming so, just for those activities. I did wear it for golf once but I found that was actually quite constrictive and more painful wearing it than not wearing it. And as it doesn't really affect me when I play golf so, I took that off. But I do, I have found that when I've used the strap I've certainly not had that particular pain when I've been doing the work in the garden. And afterwards I would say less reaction than I probably would have had without it so, I think it seems to provide some good sort of support for me." SHE013 "**INT: Okay, so you get immediate pain relief do you from that?** RES: Yes, it's certainly-- There is less pain sort of travelling up the arm to where the elbow tendons are, so it did make a difference it made it easier to do a lot of stuff that I was struggling with before. **INT: That's good to know. And have you had any issues with the brace you know after using it for several weeks, does it still work all right or?** RES: It still seems to work fine yes, so it's been in conjunction with the exercise and things like that so that's good, it's slow progress but it does seem to be-- I seem to be in less pain with it now certainly than I was initially. It's made a difference, the brace makes a difference I haven't had any problems wearing it, I don't tend to wear it for any longer than I have to but yes, it's sort of short stints, it's not uncomfortable to wear or anything like that. **INT: Good, okay. Why do you not like wearing it for a long time?** RES: Just to avoid kind of reliant on it I suppose I tend to just wear it while I'm doing stuff where I know it will put a bit more strain on it. Yes, I have worn it for longer periods, yes when we've been

		doing sort of site set ups and things like that as I say it's not uncomfortable to wear, so I could wear it for longer periods, it's more a case of preferring not to rely on it too much." SHE016
Superior to other orthoses participants had used	People' perceptions that the Epi-Hit orthosis provided greater symptomatic relief than other orthoses they had used	"I do think the brace, because I had one before and obviously it wasn't very good, but since I have been given this one it has helped a lot, it does help." SHE005 "**INT: And just describe that to me, was it like a full sleeve for over the elbow or was it--?** RES: Yes, it was over the-- yes, covering the whole elbow – a neoprene sleeve, a bit of texturing on it. It didn't really seem to have much effect. **INT: And I think as part of your treatment in the trial you were given a different sort of brace to use?** RES: Yes, the brace was much better, I did comment on that, to tell them straight away it made it a lot easier-- I don't wear it all the time but whenever I'm doing any kind of heavy lifting or anything like that, I'll tend to put it on and it does make a real difference that." SHE016
Wrist support gave additional pain relief	Perceptions that the use of the Epi-Hit's optional wrist support provided additional symptomatic relief	"RES: And there was also like a wrist strap and [physio name] says, he didn't know whether it was to be used and I thought, well it was in the box. So, I have had that on as well while I have been like doing anything, and I've found just that little extra bit of support has helped. **INT: Okay, that's interesting. The wrist strap is an optional extra, you can wear it if you want, so it's interesting that you found that helpful as well.** RES: Yes, it was, it felt like it was a bit more support rather than just concentrating just like supporting my arm, I felt like it was helping me not to be in so much pain, if you get what I mean? It's kind of, it was like a double strap thing, you know what I mean, arm brace. So I have found that to be quite useful." SHE005
OPTimisE Exercise Component		
Acceptability of the exercise component	People's feedback related to the exercise component of the OPTimisE intervention	"**And you said that you found the exercises beneficial?** RES: Yes, slow progress so you don't-- certainly the really simple stretch exercises the kind of warm up and warm down one, I do find myself still doing that quiet a bit you know at work when I feel a bit of a twinge it's just those simple kinds of stretches are really useful, yes. Certainly, I think when

		we switched to doing the isotonic the loading exercises with the weights, I think that's where I'm really starting to see a bit more improvement." SHE016 "I mean they're not too difficult, too sore. They're not nice but they're not designed to be nice I guess. When I've done the loading one, the lifting one after each session of 15 I put the weight down and I sort of can't bend my arm for only about 20 seconds or so. And after about half a minute it sort of loosens up again, after a minute I'm fine and I can do the next set." SHE013 "Yes, it's all right, yes. I am not the worlds best at exercising but I am trying my hardest to make sure that I do do the exercises if nothing else. I would rather do, I do find them easier than trying to use the Squegg sometimes. It's actually getting comfortable sometimes to be able to do it and finding a space to be able to do the proper exercises. Whether I am doing it right is a different matter. I did point that out to the physiotherapist and so she did point me in the right direction of how to do it better." DER004 "I've been doing the exercises, I must do them about five times a week, there's always two days I don't do them but I have been doing them five times a week and my elbow has been a lot better than it has been in years from doing these exercises. I've been doing the exercises with a band and also a small weight, you know just to get the wrist going. The more I did with the wrist helped a considerable amount with my elbow. I mean I'm still getting twinges now and again but I've still got the bands so I still do the exercises." DER001 "**INT: In the beginning did you have any problems with the exercises or were they okay?** RES: Well, because my elbow was quite sore and I'm quite in pain I wasn't lifting a lot of weight at the beginning. Obviously I started with a lower weight and afterwards I was improving and I was just raising the weights. **INT: Yes, and doing the stretches as well?** RES: Yes, the stretches, palm up and palm down, so yes." BHX004 "Yes it is realistic because it only a takes a half hour to do your exercises with your elbow." DER001

		"I was fairly meticulous about doing it. And I started to ramp it up and do it a little more a little longer when I felt that it was starting to have an effect. And, over the last sort of three weeks, four weeks, maybe I was doing the tick sheet. I felt I was probably doing it and I kind of got rid of all of the discomfort. I still do it now occasionally, if I'm sat on a plane or something." DER008 "Yes, because they don't take a huge amount of time it's been really easy to kind of fit them into a routine it's been something that I can do you know quite easily and it tends to be when I get back from work, that I tend to do it. But it is something that I can-- If I'm at work, they are exercises I can do quite easily at my desk, if I need to, as well." SHE016
Dosing is clearer than usual care	Feedback that the dosing of the OPTimisE exercise component was clearer than the dosing of exercises given in usual care before starting the trial	"**INT: Okay, was those exercises given in the beginning different to the ones that you were given later on?** RES: Not very different actually. I mean one of the exercises he recommended was to just stretch my hand, push my wrist down using my other hand and sort of keep it for a bit. I guess the difference is in terms of timings because the lady I spoke to, I can't remember her name, I can't remember it, I know she was an Italian lady. But she gave me specific exercises to say okay, I need to do this and that for 30 seconds, take a break, do it for another 30 seconds and so on. So that wasn't specified at the start by the other gent I spoke to. **INT: Okay so the specifics of the dose of the exercise were different?** RES: Yes exactly." DER011
Like the narrow range of exercises and progression	Positive feedback related to the narrow range of exercises in the OPTimisE exercise component	" **INT: You said that the range of exercises was quite narrow so do you think that means it's more manageable?** RES: For me it is, yes. That one thing that good because it's a fairly I'd say narrow range of exercise - they build up on each other really well I thought." SHE016
Intensity greater than usual care	Feedback that the dosing intensity of the OPTimisE exercise component was greater than the dosing intensity of exercises given in	"Well, the exercises that I've done on the trial have been more intense, they've been for longer periods of time. Like the first one where you're pushing one hand with the other hand for a minute at a time on five separate occasions, that's quite onerous, quite intense. Whereas, the other ones were more like 10 repetitions or holding it for three seconds either side, things like that. So, there was definitely more intensity in it and the same with the current ones I've been doing for the last 10 weeks. Which are just slowly lifting the weight up 15 times, six seconds up, six seconds down so,

	usual care before starting the trial	they're more intense of the same exercise. Yes, that's the main difference, the time to do it and the time that the pressure is on is much more." SHE013
Measuring Grip Strength Using the Squegg Device		
Acceptability	People's feedback related to the Squegg device used to measure grip strength outcomes during the OPTimisE trial	"**INT: Did that work okay for you?** RES: Yes, I've been using it through daily, just having it for a couple of minutes on my hands, so when I'm lying on the sofa and stuff. But yes I think it was improving my strength day to day and getting better. **INT: Good, so you had no problems getting it to work on your phone or anything?** RES: No, no." BHX004 "It does work all right on my phone, yes. Sometimes I have to get my daughter to look into it because it doesn't always start up, but she's quite good at sorting that for me. But it generally works, yes it does." DER004 "Yes, very straightforward. Of course, you get half way through it and then you realise you need to go and charge it up. So, I've not been doing regular stuff with the Squegg. But, yes, it worked fine. It's quite an interesting gauge isn't it?... I just sort of downloaded the app and it functions nice and easily. I can imagine a few people might struggle with it but I was obviously- I was in a fairly cognitive, active state the day I put it on!" DER008 "RES: The Squegg? Yes. So the last time I did the questionnaire I think it was I don't know a week or so ago, I had a problem just figuring out how I can get the measurement on the app. But then I eventually found that and I like to think that I'm usually tech savvy but I struggled to find out where that was, so yes that was the only problem. I think getting the Squegg on and all of it that's fine, but I think using the app to me it wasn't very clear to see how I could just get the measurement because when you open up the home page you can see all of the different games and things you could do, but it wasn't very obvious that I could just see what the grip thing is. **INT: Okay, perhaps we need to just explain that or include a picture on that questionnaire page then perhaps?**

		RES: Yes. That or even in the Squegg, what do you call it, a little booklet that's in the Squegg box, that just to have a simple instruction on saying this is how you take the measurement or on the questionnaire." DER011 "**INT: Did you manage to get it to work on your phone?** RES: Yes. I used it the first time with the lady, not the one I got, but I used one, I think it was the one I got, I am not sure. But I have noticed that without even using that the grip is a lot better, at first I couldn't even hardly grip because the pain was all up my arm. And it is quite easy to do, it tells you everything you need to know in there, in the little box that it comes in. **INT: Yes, yes.** RES: It tells you how to set it up. How to download the app and all that sort of thing." SHE001 "RES: Yes. It's a good piece of kit. **INT: Good. That was something new that we wanted to try, so I am glad you are getting on well with that.** RES: It's just in this little box, charge it up and yes, it's easy to use. Videos and information on the app is pretty straight forward, so you know, I can obviously do it as and when throughout the day. So it's really good. **INT: Is the Squegg working okay on your phone?** RES: Yes, yes, after a bit of technical help from my son, because I am not very technical, so. But yes, in fact even my children have been using it… It's a little bit more interesting because as well there is more technology, like the Squegg app and things." SHE005
Some participants used it as an exercise tool	Reports that people used the Squegg device as an exercise tool	"I've noticed with the Squegg and the games I play, and then it calculates at the end how many grips you've done and my grips have been like between 300 and 350 at a time, so I think with these little games it helps, and it also gives you a bit of entertainment while you're doing a bit of physiotherapy." DER001 "RES: Yes, and the squeeze ball I thought it was going to be a gimmick at the start- that's still something I can use, that still comes in useful as well. **INT: The Squegg, yes. Do you use that for exercises as well as the measurements?**

		RES: Yes, I've carried on using it. I don't use the—initially, I was using it quite a bit but I've carried on using it for exercises as well as just trying to… as well, checking each time we have to write an update I have to check my grip strength. But it has been useful that, a good way of tracking actually seeing some improvements that you wouldn't necessarily notice you know physically to actually see some improvement in grip strength and stuff like that." SHE016
Technical issues	Technical problems related to using the Squegg device	" **INT: As I said I know you had some issues with the Squegg that was given to you, what happened with that in the end, was it just found to be faulty or was it?** RES: No ,it just doesn't want to pair with my phone for some reason and we tried it in Vanessa's office a couple of times. And it's just, for whatever reason whether it's my software on my phone or whatever, it just didn't seem to want to play. But it's no, for me it was no hardship because it's literally five minutes around the corner to pop in at a time when Vanessa is in between physiotherapy sessions. So, I'm quite happy to pop in any time and do that but no, it just wouldn't pair up at all. **INT: Would it work with her phone?** RES: She couldn't, she tried one with it which she managed to get to work, she tried another one which wouldn't work. She swapped the Squegg, we tried it but it wasn't, it just wasn't doing it. **INT: Okay.** RES: But again, I guess it's down to the, it could be well, it's got to be something to do with the phone software or the Bluetooth location enabled and all the rest of it. Everything is supposed to be lined up to work but it just didn't want to work. **INT: Okay, do you mind me asking what type of phone you have?** RES: It's a Samsung A40." SHE013
Outcome Questionnaires		
Time burden	Feedback related to the time burden of completing the OPTimisE Follow-up Questionnaire	"The exercises, I think itself was – I don't have any issues with that. It was very informative and I don't think I've got any issues with the treatment. But I think just with the study itself, just making it a bit more simplified for people who do have busier lives who are working and have got families. In terms of answering the questions – just simplify it. I think if the questionnaire was just that bit more simplified with the questions it would be quicker for someone to answer it." DER002 "It doesn't take long, 10 minutes or so, it doesn't take long at all." DER003

		"Well I never really timed myself. Maybe five minutes or so. You know not a long amount of time. It's not onerous or anything. It just takes a little bit you know." DER006 "RES: Crikey, five minutes, I've not really timed it. I'd say five minutes, tops. **INT: Great, okay. So, it wasn't a particular burden then?** RES: No, it wasn't. Very easy. I sort of flowed very easily through the web portal or website whatever it is. And, it was nice and easy, clean, easy to understand. You didn't have to put too much thought in to it and it's probably best that you don't, otherwise you're not going with your gut feeling on each question. Literally, just took a few minutes." DER008 "Yes because I think, yes I mean what I found – sorry to interrupt. But yes what I found was quite a few questions feel like they're asking about the same thing. So unfortunately I can't remember those questions, maybe what I can do is the next time I do go through it I'll try and maybe note down some of the things I felt were asking about the same thing or felt a bit repetitive in a certain sense, but it felt like there was a lot overlap, which I think is the normal thing you would do in a survey anyway. I mean you would want to verify the answers that are given are correct, or it's a true representation of what the respondent sort of feels, so with similar sort of questions. But because the questionnaire is quite long, you can easily lose people." DER011 "**INT: And do you think there were too many questions on the questionnaire or was it okay?** RES: No it was just enough. It was perfect I think because it was just enough to find out the pain rating, you know, what movement you have got in the arm as opposed to what you had at the beginning. I think it helps see what progress you are at really." SHE001 "No, no, oh no, no, it's a two minute thing isn't it? A five minute thing, it's nothing." SHE004 "Oh no, no it doesn't take long. Obviously you have just got to make sure you set your Squegg properly and done that. But no it's a good length of questions that obviously you need to go forward with this trial, so I am happy to answer any questions, yes it's fine." SHE005

		“I think a lot of the questions on there are more about state of mind about your health overall. So, I don't necessarily find that the questionnaire is that informative or that helpful because it’s the same questions each time. And when it asks about your overall health, I think I've put 80% every time and that's not necessarily my elbow, it could be my elbow and a little bit of arthritis in a couple of fingers, just general. I mean I’m fairly optimistic, I’m fairly upbeat and I don't feel negative about stuff. But I don't think that that question, a lot of the questions really, my response to them would change much at all. So, probably most of the answers will be the same, I can never quite remember because it’s a point in time. But I don't think there's much, there's be much difference between it. --- As I say I think that the questionnaire we've discussed, I found not particularly helpful because of the repetitive nature of it and the short term between it. And the fact that a lot of the questions relate to a state of mind rather than your condition. I can understand in some people maybe their condition influences their state of mind for their responses but I don't, not in my case it doesn't.” SHE013 “15-20 minutes, tops…I mean obviously the first one you take a bit longer but then the second one you’ve already done it so it’s kind of a bit quicker and yes, you have to be careful because the questions are worded in exactly the same way but it says, in the last month and then in the last week or today. So, I mean the repetition helps but the first time you fill in the questionnaire, because you’re skim reading, you just say, “Oh no, I’ve already answered that, why are they asking me again?” And then obviously by looking into more details you realise that actually the timescale has changed or it’s related to the activity you’ve been doing or something like that. I also found that some of the questions like, you know how much pain do you get when you carry a shopping bag, I was never affected by carrying shopping bags. So, again those were kind of irrelevant for me and I know typically what triggers it in people but because I’m more hands-on, what triggered mine was, was repetitive stress so like, using a drill or using a screwdriver. In terms of putting my clothes on and carrying shopping bags I never really had an issue from the word go. So again those questions, when you’ve answered them for three or four times get a bit frustrating [laughs] but I appreciate you’ve got to get a one-size-fits-all for your questionnaire so, you know. I just wonder how somebody maybe less educated than me would react and whether they would just like dismiss the questionnaire basically because they feel it’s not representative to them, but again that’s always the problem when you put a questionnaire together is to try and make sure that they appeal to everyone isn’t it?” SHE018

Online vs paper	Feedback related to the choice of completing outcome questionnaires by post or online	"**INT: If we'd gone back to the start with you and said that you could only do it online, would you still have been able to do it do you think?** RES: Oh, yes. Yes, I would definitely be able to do it. It's just it was more convenient for the paper, it's as simple as that. There's nothing against me doing it online, it was just more convenient. **INT: Yes. So, it wouldn't have put you off signing up to the trial if it wasn't?** RES: No." BHX003 (paper) "RES: Because I got the paper versions in the post so, obviously when you read something you put it on the side and then you walk off. And then you might be at work and you remember it but it's on the side at home. So, you come home, you don't remember anything, you do what you're doing at home, you go to bed. You wake up in the morning, you go back to work and when you're at work you remember it again. Where if it's online that would be more convenient for me at that time, yes. **INT: Yes, if you had a spare five minutes you could just do it online?** RES: Yes, yes." BHX003 (paper) "**INT: Mm. Good, good. And in terms of the other parts of the trial, we've been measuring how your elbow is changing with the questionnaires. I think you get them on email, don't you?** RES: Yes. **INT: Has that been working okay for you?** RES: Oh, I think yes. Yes, that's fine. It's more convenient that way." DER002 (online)
Accessibility of online platform	Feedback related to the Amplitude Pro-One online outcome questionnaire platform.	"**INT: Yes and you haven't had a problem with the questionnaires that you get on the internet, online?** RES: No, no not really no. I think I filled one online myself, I remember." BHX004 "They've been technologically pretty straight forward to do, yes. So, it feels slightly repetitious but other than that, yes, it's been fine." DER003

		"**INT: In terms of the follow up I know you had some, well it was an issue at our end really, the issue with the electronic questionnaire.** RES: Oh yes, one bit of data was set slightly incorrectly so I couldn't press the verification for access. Very easy mistake. Once I was able to get hold of someone it was fixed very quickly. The chap I spoke to was very nice. We managed to solve it between us quite quickly. It was just again a bit difficult to actually contact someone to get hold of it and say look I'm trying to do your questionnaire but it's not letting me access it. **INT: Yes. What we, when we set up the system we hadn't realised that they checked date of birth to let you access the questionnaire and so yes we've, since that we've learnt from that mistake and we've been double checking the entries for dates of birth to make sure people can get in all right. Following that have you managed to access the subsequent questionnaire okay?** RES: Yes. **INT: Brilliant.** RES: Yes that one all went nice and smoothly." DER006 "**INT: Have you had any sort of technical issues with that or has that worked okay?** RES: Actually I did because the first time I tried to fill in the questionnaire I used my phone and for whatever reason I couldn't fill it in properly. I don't know, I think it was just the display that didn't work properly on my phone. Yes I don't know whether it was just me but usually you know when you create a survey like that you can have like a mobile friendly, laptop friendly sort of thing, it automatically happens, but for whatever reason, the survey on my phone just didn't work well so I went on my laptop and that's the only way I could see it properly and fill it in properly. **INT: It is supposed to be mobile friendly so I'll check that with the company. Do you mind me asking what type of phone you have?** RES: Yes I have one of the newer ones, like the Samsung S22. **INT: Okay.** RES: So it's like one of the new ones. Usually I won't have any problems, well I haven't done a lot of surveys or anything like but yes, usually it's alright but I did find this particularly troublesome on my phone. **INT: What browser does it use, is it a Google browser?**

		RES: Yes I usually use Chrome, so yes." DER011 "They've just come through on an email, yes on an email with a reminder and you then just click on it and it takes straight through to it, they've easy and very quick to fill in." SHE004 "**INT: Have you had any issues with that or is that working out for you?** RES: No that's fine, no it's been fine." SHE005 "**INT: Very good, okay. And in terms of the questionnaires that we've been sending out, have you had any issues with those?** RES: No, no issues with those." SHE014 "I do tend to work on Mac's. Sometimes you do get stuff that doesn't work with brilliantly with the Mac OS but yes, I had no problems with that." SHE016 "**INT: Mm. Good, good. And in terms of the questionnaires that we've used to measure the outcomes, I think you're using the online system-** RES: Yes I did yes. **INT: -has that worked okay for you?** RES: It's worked fine" SHE018 "RES: The only thing I would say is when I got the original email to ask to fill the questionnaire, the reason I didn't complete it straightaway, I thought it was a hoax [laughs], because I- Your name was on it in fairness and it's my fault for not double-checking with the letter that I got from the physio that it was actually you. But I think maybe having an official NHS logo or something making it look more official because there's so much spam and stuff like that going on through the internet, it's actually my wife who said, because I mentioned to her that I got something and I kind of panicked when, when I clicked on the link and then suddenly it was asking me a lot of personal details and I thought, oh is it somebody's trying to, is it a fraudster basically. So I kind of deleted everything and then mentioning it to my wife, she said, "No no [name] is the guy who's doing the study." So, so then I went back into the email and completed it but yes, just- If it happened to me, as I said, it might

		happen to someone else, so maybe making it more official or through an NHS channel or something like that… **INT: -I'm guessing the email comes from Amplitude does it?** RES: Yes it does. So it says, you know, here is your questionnaire, on behalf of [name], can you please complete it. But as I said, because it comes from a third party source it makes you wonder whether it's genuine article or whether somebody had got my...duplicit... then it asks you to confirm like personal details straightaway, which I guess is security thing for them to make sure you're the right person by entering your NHS number and things like that. And it, that's what scared me, it's like whoa the first question they ask you is to actually provide details that they should actually have, they don't specify that it's a security check or anything like that and this is what kind of made me re-think it as I said, at first. Obviously once I'd done it the first one and confirmed that that was the genuine article then the second email I didn't worry at all but it's just that initial one that came in I wasn't sure what that was or whether that was genuine or not. **INT: Okay. I was wondering about, once people sign up to the trial, sending them an email from ourselves rather than from Amplitude just to say, thank you for signing up to the trial and just reinforcing-** RES: -and just maybe mention the fact that the next email will come from Amplitude you know, naming them so they're kind of expecting it. I mean, if it's a third party it could even go into their spam box so you could have a little one liner on there saying please check your, you know your email and expect it within the next week or so, it'll come from this company, thank you for filling it in. **INT: Mm, yes, that-** RES: -that might just, might just add extra reassurance that, well I mean you'll get more response." SHE018
Drop the 6-week questionnaire	Feedback recommending that the 6-week follow-up outcome questionnaire could be removed from a future main trial	"Because you're doing exercises but you're not seeing – it's not an instant result kind of thing, it takes time. And I think in six weeks you're not going to see tremendous results from six weeks." DER002 "**INT: Do you think the six week one might be too soon? I'm trying not to make this a leading question but –** RES: Yes, not a lot had changed. Certainly, by the second one, things had definitely improved, things were definitely on the move. So, there was definitely more of a change I suppose." DER003

		"**INT: One of the thoughts that I had was whether the six week one was too early, I'm not sure, do you have any thoughts on that?** RES: Yes, that would, because I mean I didn't really start to notice much difference, because it was still a couple of weeks after being randomised that I actually got to see the physio. I think it was about three weeks ish I think. So there wasn't a massive amount of difference from six weeks because obviously I'd only been, I'd only seen the physio three weeks beforehand or two weeks beforehand." SHE014 "**INT: The time point starts from when your sign up to the trial so at some places for some patients just depending on their availability and the physios availability, they perhaps don't even start their treatment until four weeks in, so they've only had two weeks before they get their questionnaire, so-- I don't know how long you had to wait?** RES: I think the first one possibly three weeks, it was yes it was fairly soon after the session. I think on the first one there wasn't much of a measurement improvement." SHE016
Long term follow-up	Feedback related to the possible use of a 12-month follow-up outcome questionnaire in a future main trial	"**INT: Okay, and the other thing we wondered about was adding in a 12 month one so we can see like the long term outcome.** RES: Yes, yes I think that's the longevity of it, that's what you want isn't it? You want to feel it's worked and you're pain-free for a period of time and it hasn't come back really." BHX003 "I had this pain for five years, so 12 months still is something I'm still cautious and think might come back again, you know, just in case, you know. So, yes that's a good idea to extend it to 12 months to make sure everything gone to 100% rather than like you say 90% and still is not fully recovered." BHX004 "Yes that would be good yes. That way then you'll understand if all your Optimise trials are working because I'm not going to stop doing the exercises after I've sent my booklet in, I'll still do my exercises until my elbow is better." DER001 "Yes. Oh, I definitely think that would be a good idea because sometimes in six months you can be for example, for me, I've had no pain so you'd think, *Okay, I'm fine now. I'll drop the exercise. I'll just go back to my normal life*. But then I think with these kinds of things they have a tendency sometimes

		to come back. So, it would be good to see if it, in terms of your research project, did it come back? And if it did, did you carry on with the exercise? How did you approach it again? So, yes, I definitely think that would be good." DER002 "**INT: And if we were to expand this to a bigger trial across more hospitals, do you think it would be reasonable to add in a twelve month follow up as well?** RES: I think it probably would actually, yes. I think the patients would think that they are being looked after properly then, definitely, yes I think it probably would." DER004 " **INT: Yes, so had that applied to you, you wouldn't have objected to doing one again after a year?** RES: No, I wouldn't have objected. I think, knowing people as I do, when an email comes through after that much time they might think what the hell's that and just delete it as spam. But, I think if you're preparing people that there will be something that far out, particularly around the time of the six month once, it's less likely to get missed. But, I certainly wouldn't have objected if there was a 12 month one." DER008 "Yes because it feels like this sort of issue, at least in my case, I feel like you know it takes a long time and obviously you know better than I do about the time it actually takes for someone to actually properly come out of it. So yes as far as questionnaires and sort of interview questions it might be good to have the 12 month thing as well, not just limited to six months. If people, I don't know, people would respond to that, you know whether people would be willing but if they could it would help your trial." DER011 "**INT: Do you think if we added a 12 month that you'd be prepared to do it for that length of time?** RES: Oh, yes, yes, not a problem at all. It's not arduous is it? It's not an arduous task, yes." SHE004 "Yes, definitely because after six months you may have got a lot of people say, "Yes, it's all gone," and then the 12 months they may say, "It's not gone, I'm getting it back again." Or vice versa after

		six months in my case it's probably going to be it's not gone. So, after 12 months you want to know whether there's been any change and what's happened in the interim." SHE013
Monthly SMS questions	Feedback related to the possible use of monthly SMS text message questions in a future main trial	"**INT: The other thing we thought of was just something really quick like a monthly text message. Where the message asks you, "Please rate how much pain you've got from your elbow from 0-10." And you just reply with a number from 0-10.** RES: Oh yes, that's quick and easy, simple. **INT: Yes, what do you think to that idea?** RES: Yes, that's a better idea than the paper or online because basically, you're reading the message and it takes what, two seconds to actually press the number and send. Probably another five seconds to read the text [laughs] you know what I mean. So, it's very easy to do it that way, perfect actually." BHX003 "Well, yes I think that's more like it obviously, because obviously using technology now with mobile phones and where you can reply with a text message from one to 10 which you can select average one. Yes, that's a good idea." BHX004 "I think if you're someone who's working and even if it popped up at work, you'd probably quickly just answer it there and then and just be done with it really. But again, I don't know if that would give you the results if you needed more in-depth information." DER002 "**INT: You wouldn't find a monthly text message too intrusive or anything?** RES: I don't think so. I might need to realise who it's from, I guess that's the only thing, is how have you got your phone set up? And do you recognise who it comes from? In the middle of spam and – **INT: Yes, absolutely.** RES: So, yes if you knew it was coming, expecting it to come and it comes from a recognisable name, number, whatever, rather than block it. **INT: Yes. So, if it said OPTimisE Trial on it for example, do you think that would be – just at the top?** RES: Yes, that might be better, yes." DER003

		"RES: Well that might have provided some interesting data because it wasn't a smooth oh it hurts, it hurts less, now it doesn't hurt much, it's gone type thing it would be depending on what I was doing it would be hurting more or hurting less but with the distance between the questionnaires we got plus that fact that I had that Covid bedrest period it just looks like I smoothly got better. Oh it hurts, oh it hardly hurts and on my next questionnaire oh look I'm cured. So it's going to look like I had a very steady decrease in pain but that's not really how it went. You know there were sometimes where it was hurting more, there were sometimes where for a week or so it would just be the odd twinge. So might be valuable data for you. **INT: So you wouldn't object to receiving a monthly text message?** RES: No that would be, I mean it's better than the junk mail I get through the post every day. [laughs] At least it would be useful and it wouldn't be time consuming or anything for me to have to fill in and it would be something I'd be able to do quite quickly and easily when I've got a minute. You know a text message is always quite easy to fire off on a lunch break or whatever." DER006 "**INT: Okay. And another thought that we had to try and keep people engaged so they don't forget about the trial was perhaps a monthly- Just a text message once a month where they respond with a number from nought to 10 rating, how much pain they've had perhaps over the course of that week.** RES: I think that's a really good idea. **INT: Just to keep people's interest and act as a bit of a reminder that they're still in a trial as well as providing us with some information.** RES: Absolutely right, and I can see the benefit on both sides of that, but I think the big one is just reminding people that they're part of something." DER008 "I think that'd actually be quite good because yes it's just a case of reaching out and it's just a simple number just one number which would be easy for people to respond to and you can get a general idea of how it works and yes I think a monthly check in would work and people would be happy to do that I think because it's a little thing and like what you said it will keep them in you know, remind them that this sort of thing is happening in the background and yes, I think that will actually be good rather than having the full blown survey less frequently and having a more frequent single thing. But yes I think it would be good actually." DER011

		"**INT: If we were to ask you one particular question on that text message and with a scale response from 0 to 10 for example. What do you think would be the most suitable question for you?** RES: It would be like, probably something like, "Over the last seven days or last fortnight what level of pain have you experienced from your tennis elbow at any time?" So, it's not activity, it may be not linking it to specific activity i.e. gripping or twisting or lifting but to say the tennis elbow has caused a pain of 6 or 10 or 9 or whatever in that period. So, then you could almost track whether over a period of months you were getting a lower level. So, whatever the activity was that's caused it on a particular day, in that period it was less than the previous period which was less than the previous period. So, you're not pinning it down to activity that doesn't necessarily affect everybody." SHE013 "RES: Yes, I would, because something like that is a quick sort of reminder that you're still in the trial but also you can gauge yourself. You can, you know, be able to just gauge, you can actually, it will actually stop you and make you think, oh actually, how much pain am I in with it? And I think, like you say, if somebody's stopped treatment but you're still checking in on them that would make more sense. **INT: Yes. So you like that idea?** RES: I'd be more inclined to, you know, if somebody sent me that one through I'd go, oh, because it's going to take you a matter of seconds to reply." SHE014 "I think so, you wouldn't get the nice detail you get in the full questionnaire you're breaking it down a bit when you get the other questionnaire as well you are kind of-- It forces you to think a bit more, I guess. So, I think for convenience it's probably easier to yes, just fill in a single answer text but I think certainly with the questionnaire, for me, I think the questionnaire was useful because it does focus your mind on, you know, thinking 'Is it feeling better than last time?' because it's a wider spread of questions, so for me, probably, combining the two would work." SHE016
Incentivisation	Feedback related to monetary incentives for follow-up questionnaire return	"Maybe like my thought is for you guys to get more people to fill them in, is, because I have to say I did forget about the £20 bonus. I was just doing this for the benefit of like free NHS physio sessions as opposed to ones I had to pay for. But yes, maybe get your free £20 voucher if you complete this, this and this and have the questionnaire pretty high on there, I might have got round to it sooner than what I did do." SHE011

		"**INT: And when people return their last questionnaire we're sending them out a 20 pound voucher/card as well. Do you think that's a reasonable amount to give somebody for their time?** RES: I think so because it doesn't take a massive amount of time to go through the questionnaires." SHE014

Trial Acceptability Interview Codebook (Physiotherapists)

Contents

Code name	Definition	Example quotes
Experiences of the OPTimisE Intervention		
Acceptability		"In terms of the, I mean in terms of the intervention can't think of anything off the top of my head that I would think needed to change. You know it was fairly, fairly straightforward to follow as far as I could, I could see so and there's nothing I would obviously think about that I would change about it. So no not like that it was, it was fairly straightforward to deliver. That was the nice thing about it. I only had a positive experience. I will admit it was a fairly limited experience but I only had a positive experience of delivering it. Yes my only, I know with testing this research my own clinical practice I sort of wondered about things like you talk about you know the stretching or the nature of those things and for some aspects of the support intervention would be more specific to some patients than others when it talks about their lifestyle factors and all of these other things but I thought that was the nice thing about it that all the information is in one place and you could steer people towards bits that

		they might find interesting or relevant to them. You didn't have to deliver it as a blanket intervention. So that's why I thought it was well designed and I thought you know it's the way more physio intervention should be, should be delivered. --- The one thing that it really did make me reflect on is just how the information was packaged and how it was brought together and the breadth of the information. That was the really lovely thing about doing it. You did it and just felt why aren't all physiotherapy interventions a bit like this It's really clear - all of the information is in one place. There's clear stages to go through. You know how to increase, you know how to, you know what to do if you get sore and you know how to manage that and it's just really well packaged and brought together and I just thought you know the standard of general information stuff in physio departments and the way we deliver treatment is so scatter gun and you're also often under so much pressure to deliver a lot of that information in a short period of time. Having all of that infrastructure around the treatment with like kind of back up stuff and to have it all in one place was just a really nice experience. It made it just a really nice intervention to be able to deliver. So I was delivering the same types of treatment but it just felt a lot more, don't know what the word is but it just felt very, it felt like kind of concise and you felt like it was easy to deliver just because the whole package around it was there. Does that, does that make sense for the trial?" PT2 "Doing this exercise once a day is quite achievable isn't it, to the patient? They don't need to take anything in particular. So as a concept I could very much sell it because I believe I could subscribe to that if I was a patient. It was easy to do. Well, it's obvious isn't it? It's straightforward, you're giving them a stretch for 60 seconds times whatever and then you're giving them exercises to do and you can explain how to regress and progress them to me, then you get the patient on board doing that. You explain to them that it's okay to have some pain and explain to them how much and you can both be on board with that really. It's quite easy to guide them. And it's easy to leave them on open on the odd occasion if you need to, because they can do it themselves." PT6 "No, I have to say that when I mentioned it in [the other department where the physio works], they all wanted it to be fed back to them because I keep saying, "I love tennis elbows now." PT6

		"It was a case of me just reading the booklet, logging on to the website with the patient log-in, reminding myself what topics you wanted to cover, where the videos were. Then I used those resources straight away with my first patient. I literally just pulled up the website and went through stuff pretty much as it was requested really. It was quite simple. --- Anyone that's been qualified a reasonable amount of time will be aware of all those things. The exercises themselves are really simple. I think doing something well, if you've got something simple and done well, it often works, doesn't it? So, if you've got a nice simple programme for someone. Some patients liked it because it was really simple, "I can do this." It's a bit of a recipe, which obviously some patients like and it works for some of them. I had the odd patient who thought it was a bit too simple, thought they were coming into a big all-singing, all-dancing trial and then it was just, in his words, "Just some exercises." From a physio point of view, it was very easy to implement. --- Yes, because the resources you'd made were really good, loads of information. You've got the videos. You've got the principles. Yes, it was good. I really liked that sort of package that you'd got." PT8 "I find having almost like a paradigm for younger clinicians might be quite useful, being that there's almost like a tick process that you go through that you make sure you encompass your lifestyle advice, your smoking cessation, stress and all the rest of it - to actually incorporate into the programme. So I think that's going to be a good thing to incorporate, in regards to, to younger clinicians, where they might find tennis elbow that they miss out a lot of those things. Which are so highly important in tendon repair and tendon health, rather than just going straight in for it for a graded loading programme. So, I found that really good." PT1
Advice component feedback		"INT: Just thinking about all those different advice topics that we included, I think there were 12 altogether, would those be on your radar normally if treating a patient or were some of those kind of outside of what you'd normally focus on? RES: I think most of them were broadly on my radar of things that potentially have an effect on a persistent musculoskeletal problem but I think probably some of the things we got into we were talking about, don't know why, I'm talking about just purely my own implicit advice, don't know why but things like something like a tennis elbow, whenever I saw a spinal patient for instance so a lot of

		things like these lifestyle practises and sleep it would be quite high on my agenda and things like sleep with an elbow I don't get lots of patients telling me they don't sleep because of their elbow pain if that makes sense. So some of these sorts of other things I would maybe associate with other interventions wouldn't have been so high on my list. I wouldn't have really, don't consider often with somebody who's got with an elbow problem. So some of those things probably made me just question how I weight those things for a peripheral condition like tennis elbow and made me think that maybe I, I'm not as holistic when it comes to like other implicit advice. It means that I'm not as holistic with some peripheral conditions as I would be maybe when I look at a spinal one and made me think I don't, maybe just don't think yes think like that so much as a physio. So that was a nice point of reflection but none of them were like completely out of left field where I wouldn't consider them with a patient. You know most of them were in the realms of what I would, what I would consider with a patient. In fact all of them were. There was nothing there that I thought oh I'm not sure about that or I wouldn't be comfortable to talk about or deliver that. It just did make me think about patients with elbow problems and why maybe I tend to be a bit more you know I guess give more traditional or structured type treatments than you would do for something like a neck or a spine. I guess when you do, when we see more evidence of that full blown central sensitisation type of pattern where you do think much more about lifestyles and things like that. So that was an interesting reflection. INT: It's interesting having done the patient interviews because I mean we, like you say with back pain it's well recognised that people struggle with sleep and it can be regarded as a red flag etc but not at all really in my training, I don't know about you for tennis elbow and yet a lot of the patients that I interviewed said, "Oh sleep is a nightmare. It wakes me up, I can't get to sleep, it's really uncomfortable" so RES: Yes. INT: That was something that came out of the patient interviews and yes I've reflected on that as well I have to say. RES: Yes I mean that, even that now even having done the study it's still a bit of a revelation to me and it actually makes me think that again so my advice is, my gut is you don't feel people talk about it much in elbow pain but I guess that's probably because we're not giving them a chance and asking them the question and again is this a reflection on you know that we make these associations with certain conditions? If someone's got rotator cuff shoulder problem you know that lying on it is often painful, one of the first things they report and it's any text you read about that condition and so you

		tend to feel that even those experiences rather than seeing so many patients maybe should have this algorithmic approach to reasoning where you still follow some of this stuff from my training but I wouldn't consider asking a tennis elbow patient how he slept. You know this is, that kind of thing wouldn't generate as part of my routine. If they brought it up I would probably address it but I probably wouldn't ask the question as part of my routine assessment and that's why, that's why research and taking part in this is really interesting and why it's useful because actually you know you're interviewing patients, they're telling you it's a, it's a problem so that's a nice, that's a nice reflection, something to get out of the study." PT2 "INT: Did you feel that they were receptive to the topics that you were trying to bring up and discuss? RES: Yes, fairly. Fairly. I wonder if they realised the relevance of some of the topics, you know what I mean? And not forget them. INT: Yes, some may not be relevant to all people, obviously. RES: No. No, but, and there again, it's having the time isn't it to talk about, well why is sleep important? Maybe persistent elbow pain you know, it's linking it in isn't it, really in a way that feels valuable for the patient?" PT4 "INT: "one of the more detailed elements was all of the different advice sections. Did you get much engagement back from the patients on that? RES: What do you mean, so when, if they looked at smoking cessation or diet or any of those other bits? INT: Yes. RES: Not a huge amount no. I've had one or two who have definitely interacted with the website and said they did but I didn't really labour it to be honest." PT6 "INT: You were happy with the tick sheet? Did that serve as much of a prompt or was it just a-? RES: Yes, it did actually. It was quite useful. You kind of covered a lot of those things anyway but it just gave you that extra little reminder to maybe touch into how's your sleep, how's your general health, your diet, things that you might not automatically do when you're treating a tendinopathy but maybe we should do more of. So, I found that quite useful as a little prompt and take that into other tendinopathy problems as well.

		INT: Okay. Did you have many patients that responded to those prompts about the general lifestyle? RES: Yes, I did actually, yes. I can think of a couple that acknowledged that some of those issues might be affecting their pain symptoms, healthy lifestyle type advice, smoking cessation. We talked about healing times and pain sensitivity with lack of sleep and that sort of thing. So, it rung a few little bells and light bulb moments for the odd patient here and there." PT8
Orthotic component feedback		"The only thing I wasn't confident on [beforehand] was we didn't have the choice of the splints. So, that was the only thing that I wasn't fully aware of, well got better with practise and things. But that's something I don't tend to normally advise people, because we just didn't have the option really when we treat lots of those. But again, patients seem to like that as well. They like splints or the options to have it as a bit of pain relief for as a management strategy." PT1 "Wouldn't have incorporated the orthotic device which was something that was interesting. So we don't routinely give out orthotics and they were high quality orthotic devices compared to the sort of things I've seen in the, in the past and participants seem to like them so I wouldn't have done that at all and stretching generally wouldn't be high on my list of things to give out to people, only purely for symptom relief. So I wouldn't, but I wouldn't routinely prescribe the stretches. More it would be about doing the resistance stuff and then the education around that." PT2 "INT: Okay. Good. Before you started with the trial, how confident did you feel in treating people with tennis elbow? RES: It's an interesting question that. I felt very confident treating them and completely dismissed though giving them an aid, i.e. an elbow clasp. We never even issued one in my life so I was less confident with that. And then the wrist component threw me completely because I didn't even know that existed and then the more I thought about it, the more I thought well actually that's genius because it's stopping them going into extension and we're telling them to avoid extension. I don't know why I never even considered it as a possibility for some people. So it's kind of made me think slightly differently with some of my tennis elbows. Whatever the outcome might be, the principle behind it to me makes sense to add a potential wrist thing, particularly for those patients who are doing loads and loads of repeated wrist extensions at work. INT: Yes. Not everybody used the wrist part of it and it was designed to be an optional extra. But yes, there were a couple of patients that did and found it useful so.

		RES: And also I think the fact that it gave you the stretch and then you did the exercises and then you went back to the stretch, maybe did change what I do slightly because it kind of emphasised that the stretch they can do whenever in the day, whenever they're feeling it and then they're doing this exercise once a day is quite achievable isn't it, to the patient? They don't need to take anything in particular. So as a concept I could very much sell it because I believe I could subscribe to that if I was a patient. --- I've had an interesting conversation with two fireman friends of mine who both use elbow clasps now, because they both asked me my opinion and - I think a year ago, I told them I'd have pooh-poohed it, but now I'll give it a go - and actually both of them are climbing now again with using a clasp. So, I guess it's broadened my horizons slightly to think maybe there's something in this, and if it works for the patient - happy days!" PT6 "RES: I found the patients in the cohort, some got on well with it, really well, like it was the best thing since sliced bread and others it didn't make a blind bit of difference. INT: Fair enough. RES: One patient found it made it worse as well. She found it just really sore to wear it, obviously quite sensitised around the area. INT: Okay. So I'm guessing they stopped wearing it at that point? RES: Yes, they stopped wearing it." PT8
Feasibility for telehealth		"INT: Do you think moving forward do you think that would be something that you could use as like a tele health intervention over the phone or over a video call? If you were able to RES: Yes. INT: Post out the orthotic and the booklet beforehand? RES: Yes, yes I would think so. Yes I think so. I think the, some people might have a difficulty fitting the brace probably. That might be a bit difficult so actually just talking around that about which way round it goes and where to you know which way to put it on. So that might be a bit confusing for some people but, but I think it could be delivered remotely because it was, yes it's just easy to follow. So yes I, I wouldn't have a problem with doing it remotely. I wouldn't have thought I'd have a problem with many people doing it remotely." PT2

		"INT: Yes, yes. You mentioned before that, with one of the patients you had some telephone follow up as well, so not just face-to-face? RES: Yes. It was on the telephone. Yes. INT: Yes, or did you have any others that were video calls or anything? RES: That were sorry, I didn't hear that, that there were?- INT: That were video calls. RES: No, I didn't do any video calls. INT: But the phone call one, did you feel like you were able to kind of deliver the intervention by phone as well? RES: I don't, I didn't ever have the initial with, by phone call. It may have just been a, I think I had one of the interventions was a telephone call, but it was I think checking up how they were doing and whether they felt they were happy with how they were progressing. INT: But you felt you could - RES: I might, I may have got that wrong because it might have all been face-to-face, I can't quite remember. INT: Yes, not to worry. It's just an idea as to whether you felt that you know, you could follow people up remotely as well. RES: I think, yes I think it would be very possible that in that, once they're self confident with what they were doing and how they could self-progress." PT4 "INT: Did you do any remote consultations then as part of the trial? Any telephone or video? RES: Yes. No video I don't think but yes I did some telephone ones and I can't remember if they were initials and then later did a follow up or if it was, I've definitely done a couple of follow ups with face-to-face because patients just wanted to find out what, you know have a chat and have a pat on the back really, a couple of mine. One of mine moved to Sri Lanka so she was going to have something remotely. INT: Yes, I've actually done a remote interview with her as well. So the ones that you did over the phone, did you feel that you were able to do everything that you needed over the phone? RES: Yes, because once I'd seen them once, they'd already got the booklet. So you can refer back to it. You can have the booklet in front of you and say on this page, and they can be on the same page. So it makes it ten fold easier, doesn't it? To do it, because you're talking about the same thing. They've physically done the exercises with you and if you've shown them any kind of

		isometric resistance or whatever, they know what kind of strength and then if you're progressing them the can only, they can look at the pictures. INT: Yes. RES: So it does make it easier to do." PT6 "INT: Did you do all of those face to face or were some of them by phone or video call? RES: A bit of a blend. Not video but phone, yes. Face to face yes. I'd get them started and give them a bell a couple of weeks later just to make sure things are alright, any major problems and then review them. It's the sort of thing, because it's quite prescriptive you can obviously say, "Have a look at this video online. This is what I'm going to progress you to." So that was the useful thing about the online pack, you can do that via telephone and they can see the exercise." PT8
Delivery of OPTimisE intervention in standard appointment time		"INT: In terms of time, did you feel that you were able to deliver the intervention within the time frames that you normally work to? RES: Yes, I would say that I wasn't able to- I think there were a few things because I think we had a form our [computer system] that would say if you covered all the things about certain aspects of the study each time or in the initial assessment. Obviously some patients need to tell their story and you need to give them that time to go through their journey with it as such. So it depends on the patient I'd say. If you've got a patient who's just there for, I've got this, had it since, then, no further issues outside of work and all the rest of it. Then it's easier to go through the entire bit, but if you've got a patient with a longer story that just needs to vent or needs to explain their story up until now, it gets a little bit harder to put everything in there. But then saying that you can always come back to the things that you missed off in your first assessment in the second one and just let the patient know that there's still some things that we need to go through. We'll revisit those on a follow up appointment as such. INT: Yes, that's how it was intended to be, yes. How long do you have with your patients? RES: We have 45 for a new patient and then half an hour for a follow up. That's been changed for the last few years. We used to have 40 minutes for a new consultation and 20 for a follow up. --- INT: We talked about whether you could fit everything within the allotted time. Did you feel that with your service as it is at the moment that you were able to offer sufficient follow up for the patients?

		RES: At the moment, yes. I think coming out of Covid and things, when there was a lot of pressures on us and actually follow ups were getting a little bit sparse and we had some changes with staffing. On a normal running service that we provide, then yes, I think I'll be fine to do. I don't see any issues with- Yes, I think it would be absolutely fine, to be honest. We didn't have any issues as such with getting them in, because I don't think we needed to see that regularly. I think saw them once every two to four weeks. So yes, I think it's fine to get them at those times to be honest. I didn't have any troubles." PT1 "INT: It felt easy enough to deliver what we asked of you within a treatment session? RES: Yes, yes and that all of the information you normally try and cram into an appointment you knew that it was stages that, you could cover it across all of the sessions. It was all in one place for the patient to review. It was all really structured nicely like the importance is how to progress them so because the patient literature was so good and the supporting information from the website and it was all very you know nicely laid out, easily laid out it just felt that you were delivering the same, well a lot of the similar types of treatments that you would deliver but delivering them in this package that just felt really nice and easy to deliver and easy for the patient to understand that really got buy-in from the you know certainly from the participant I saw this is really straightforward to deliver." PT2 "Probably more because at the minute we struggle for follow ups every four weeks or something like that. So it's kind of you know you get them in and you're hoping that you know you probably can't see them in two weeks whereby you might go right you know you should be ready to move on or something at that point. So you say I know I can't see you till end of November now so I'm giving you the skills to go right you know here I am so the next time I see you you might be over here rather than still back there." PT3 "INT: Yes, okay. So you were able to see them, you know, sufficient times within, I know essentially the health service is busy at the moment, but you felt that you could see them sufficiently? RES: Yes. And that was partly down to how many times they wanted to be seen as well, but yes, I got all the content in within that time, but it was, because I only saw most of them about, at the most, one patient three times, so one telephone call and a face-to-face, but yes, they did, did cover everything needed to yes. And recapping on the exercises could often, despite the manual, they needed to maybe sort of correct a little what people were doing or maybe they weren't doing sort of

		enough of something so, you know it was just making sure. But again that's how clear you make it in the first place I guess, isn't it? And making people want, asking people to refer back to the manual to check they were doing a set amount." PT4 "INT: In terms of actually delivering everything that you were supposed, well asked to deliver, you said 30 minutes was, you know, it was a bit tight. Can you just expand on that? RES: Well, I suppose in a way it was, clarifying it because, you know just getting a little bit of communication with the patient, developing their, a bit of a relationship to start with and that, that often takes a little bit of time really. But then it's, as, in a way it's covering all of those elements and it's, you know because you don't know how many times you're going to see the patient I guess. So it's, or how many times you're going to have contact with them, you know. It depends on whatever they want, doesn't it really as much as anything? Although it can be up to what was it, six sessions, is that correct? INT: Yes, well we left that kind of flexible, up to you really but yes. RES: Yes. Okay, so and some of my patients weren't, there was a few confusions with, one of my patients in fact had had a cuff repair in the meantime and had become confused either it was for the cuff repair or treating the tennis elbow so I had some difficulties with one of the three patients that I saw. And then another patient, it was tricky as well because she was going fairly quickly to live in Australia so we had two sessions, so it was making sure everything was covered within sort of a, it was face-to-face but we needed to cover face-to-face and we just had one telephone call to follow up, so. It did make it a bit tricky because of the complications with a few of the patients but, yes. I mean, it's achievable I would say, within 30 minutes. You're also slicker at doing it. But because it was, it's new it didn't feel quite as fluid the whole process. INT: Okay. Did you feel that you were, across the multiple sessions with your patients, did you manage to sort of get all of the content in? RES: Yes, yes. I did, yes." PT4 "INT: Did you feel that you could do everything within the allotted time? RES: It depends how long I had. So if I had a face-to-face, first patient half an hour no. I'd say my first patient with it I needed the hour because of paperwork and showing them the website and stuff. But once I'd seen them once, it was very easy to do in 20 minutes really.

		INT: Okay. Okay, so maybe we need to think about more time for the first one. RES: Because I think that very first one, particularly the first couple and I don't know how many I did, maybe five or six but you get used to it, but that first one or two you do, you're just trying to measure, you've got the stamped addressed envelope, you've got the diary, you've shown them this, you've shown them the website. Can they get onto it on their phone or whatever, do they know what they're doing? And you want to make sure they've got all the things that, oh then the elbow clasp and all of that, you just want to make sure they're doing it all right and it's quite, it's too big an ask I think to do it in half an hour. With taking a history as well. INT: Yes, so you did the whole history thing - RES: Because one of mine came face-to-face by accident I think, to be fair. But you've got to do it all. It's too swift. INT: Okay, and later on once you'd kind of got used to the whole routine - RES: You can easily do it, really in half an hour because you've got everything you need. I guess it just depends on your patient and how much they talk as well, doesn't it? INT: So it's just those first couple of patients that you did a bit - RES: Yes, just getting used to the extra bits you're doing that are maybe above and beyond your normal therapy, because you don't have the extra forms normally, do you? You just crack on with the tennis elbow, give them the information and off they trot. INT: But later on you could do it within the half an hour? RES: Yes because I got, I only ever use this stuff now. I don't use anything else." PT6 "INT: So how long do you get for a new patient and a follow-up? RES: New ones were 45 minutes, half an hour follow-ups. INT: Okay, so you had an extra 15 minutes to use? RES: Yes. So I had that time so I used it I suppose. INT: Yes. Thinking about the ones where you only had 30 minutes, was that sufficient to get everything across that we'd asked you to? RES: Yes, it was, just without sitting and watching the videos, yes. I didn't cover everything in the first session. On the little tick sheet I covered what I thought was pertinent to that patient as a priority and got them started on the exercises. -----

		Our caseload is just…you might not see someone for a month or six weeks. It did work in that environment as well, not being able to see someone for quite a long time. It worked because they had the resources and they had videos and booklets to work themselves through. So, some self-progressed." PT8
Differences between the OPTimisE intervention and usual care		
Exercise selection		"Yes, and things like the exercise I think is more for me it wasn't the, I guess it's probably just part of my clinical practice, I'm not too hung up on the sort of exercise things like whether we give them stretches or not give them stretches or things like for me the novel thing about it was all of the way it was presented, the structure and having all of that support information all in one place in an easy to follow way for patient participants. I thought it brought down a lot of these barriers sometimes you get with communicating with patients and feeling like you've got to cram so much into one session. The fact that this was laid out almost as a programme to follow was the nice thing about delivering it. It was a nice intervention to deliver and patients really liked it as well. It was, that felt really and I looked at it and thought why are we not producing more information like this over more conditions for patients and physiotherapists. It was a really high level of support and information around that exercise regime that you were delivering. So you know the typical exercises themselves weren't, didn't really ring to me because most of those physio exercises are variations on a theme. I thought the novel stuff was how it was all put together and how easy it was to follow." PT2 "I've always given them stuff over the edge of a table, but I guess I didn't always progress them further on. I've often used the static stuff as well, but that later bit, I'd probably have just discharged them rather than encourage them to keep building free range and going to the next bit. So I quite liked that, don't forget to keep rehabing them even when they're getting better because they're less likely to come back I'm suspecting if you actually rehab them fully through to doing weight bearing or whatever different bits that are just focus away from the elbow a bit really, isn't it?" PT6 "RES: Certain staff are well-read and well-informed and other just stick to the same old, same old that they've always been doing. So we have quite a variety of clinicians, management strategies. INT: So describe same old, same old to me.

		RES: [laughs] Some won't do that much background reading or literature reviewing, they literally will do what they were taught when they first qualified quite a while ago. INT: Yes, so what would that be with the patients then? RES: It would literally just be the eccentric loading, that's pretty much it. --- RES: Yes, some will be quite similar to the optimised scenario and other staff won't be as dynamic, they will literally just do the wrist extension activity and not upper limb activity or general exercise. So there can be quite a disparity between." PT7 "INT: Did you progress many on to beyond the specific elbow and forearm exercise? Did you progress many on to the general strength and conditioning shoulder exercises, upper body exercises? RES: Yes, I did a good handful definitely, yes. I tried to sell that as let's get your whole upper limb robust, strong, efficient. INT: Was that something that you would have focused on previously or was that something a little new? RES: Truthfully, probably I'd include- it depends on the patient. If they had got a heavy manual upper limb based job, yes. If they don't then I probably wouldn't. So not routinely but yes, sometimes." PT8
Exercise dosing		"INT: Okay and in terms of the dosing of the exercises was there anything new there would you say? RES: Well in terms of kind of doing the actual dosing of the exercises yes I think there's so much to, there's so much variability in what people prescribe in terms of exercises. You know we've done most physio regimes look at three times 10 of just doing it you know with something that you can tolerate and it was certainly a move away from that that was, that made it a nice progression from kind of going from that isometric long hold and building it up. So again it was, it was that starting at the, with the isometric long hold and gauging it and moving it forwards was good but I didn't see many who I saw weren't, didn't need, they could move through it quite quickly, I didn't see anybody who was really sore and needed to be long in that very first stage and we could progress it quite quickly but again it was built into it that you could do that, you could you know you could progress it quite quickly. So from what I can, again I'm doing this from recall, it was a while ago since I saw a participant on it but I felt it was all there. There was, the exercise literature was easy to follow and it

		felt like a, I guess it felt like something you know for the patient felt easy to follow and it's on a theme of what I would typically do to really start on something like isometrics and doing long holds and then build up to isotonics but with heavier and heavier weights." PT2 "INT: And did you feel that the usual care dosing of exercise might have been different to the optimised intervention? RES: Yes, I feel like dosing's not well recorded as an intervention in standard treatment but again I think there's probably a lot of kind of start at this and then this is how you progress and this is how you regress. So you know and then leaving it with them to self prescribe in terms of dosage if that makes sense. INT: Yes. RES: And you know progress by slowing down or increasing weight or so on and so forth. So I know that's you know typically my management of tendinopathy would be to start them at a baseline and then say you know sort of 48 hour learning pattern and start at this weight with a pain up to this VAS say four/five out of 10 and then when you can do x amount of reps x amount of sets within that pain tolerance then start progressing the weight or something like that until you are at your objectives. INT: Okay so less clearly defined and more in the patient's own realm to progress it as they see fit. RES: Yes, on a set of qualifying criteria I suppose." PT3 "I guess it's giving more guidance and specificity around the exercises and the exercise prescription. I don't think as a department where we work now we would have used acupuncture or electrotherapy we wouldn't have injected those sorts of things just because we're up to date with that current practise. I'm not sure whether every department is the same over the country. But yeah I think specifically for our department it gave more guidance on the exercises and which ones, because when I'd gone through the usual care the mixture of those dosing, sets, reps that sort of thing does vary quite a lot whereas if it was more specific guidance I guess in the trial." PT5 "RES: Well the dosing strategy was quite interesting to me. Because it's slightly longer than I would normally do. So for me I probably wouldn't have held it for as long and doing it six seconds and controlling it and all that, again it makes sense because you're slowing it down. If I think of other

		things I do with patients, I don't know why I'd be so quick with a tennis elbow compared to a knee, so it's made me actually think, "Okay, I just need to slow this down again for this tendon." Because I would straight away for rotator cuff stuff do it maybe slower, but with my tennis elbows I think, I don't know why I didn't think like that, so I'm not saying it's the only right way, but I seem to get better results by slowing patients down and making them understand what they're doing, why they're doing it and less is best in a way, but doing them with good quality. INT: So that dosing strategy was different to what you've done before. RES: They were slightly yes. It was for me, because I wouldn't necessarily have held for so long and I wouldn't have been really focussed on really control over six seconds if you're doing a graded kind of from extension to flexion or whatever. So it was slightly different to my normal, because I probably would have just been, "Yes do a couple of sets of ten." Not worry about how long it took them." PT6 "INT: Okay, and did you notice anything about dosing of exercise, whether the optimised was different to what people tend to do? RES: Well with the optimised team basically- Well, with [name of physio delivering the OPTimisE intervention] it was quite clear exactly how many exercise, how many reps, how frequently he'd advised them to do things, whereas I think pretty much single other member of staff hadn't written the number of reps or frequency, they'd just put what exercise they wanted them to do." PT7 "INT: The exercises that we asked you to prescribe during the trial, did they differ in any way to what you'd previously- you mentioned that you would add in some supination exercises but in terms of the graded loading and particularly the dosing of the exercises, was that any different or any aspects that stood out to you? RES: Yes. I mean it was very specific because it was very like, "This is what you need to do, six seconds up, six seconds down." One minute was 30 second stretches. So I found it quite prescriptive. I would have liked it a bit more, I suppose go with the symptoms a little bit. So we might be able to accelerate someone else for the programme based on how they respond to an exercise I suppose. I tend to do the graded loading wrist extension. Historically I probably started with a bent elbow through range rather than doing just the isometric stuff. I think people tend to do okay with that actually and then could rest through to straight arm unsupported, loading - extensor tendon loading - given how I normally would treat one. I wouldn't worry too much about counting up

		and down for six seconds. I'd say nice and slow and controlled. I've moved away a bit from stretching it as well. I don't know. Prior to it I'd not really stretched tennis elbows in the last few years. Some people found it sore, sort of moving away from stretching painful tendons. It's around the shoulder that I've been working more so than elbows. The principles of graded loading are what I have done and this is similar, just maybe slightly different positions and different grips as well, maybe different hand positions. Just rather than being prescriptive, being just a bit more tailored I suppose to the patient and what I find. INT: Did you progress many on to beyond the specific elbow and forearm exercise? Did you progress many on to the general strength and conditioning shoulder exercises, upper body exercises? RES: Yes, I did a good handful definitely, yes. I tried to sell that as let's get your whole upper limb robust, strong, efficient. INT: Was that something that you would have focused on previously or was that something a little new? RES: Truthfully, probably I'd include- it depends on the patient. If they had got a heavy manual upper limb based job, yes. If they don't then I probably wouldn't. So not routinely but yes, sometimes. INT: I'm just trying to pick out the key differences between what usual care looks like and what we did in the optimise, so what the characteristics are that are different. So obviously you've said about the stretches were different, the routine giving out of the elbow brace was different, the advice topics were more diverse but yes, any other specific things with the exercises really? RES: I wouldn't necessarily do them every day as well. It depends on irritability patient wise. So someone that's got a highly irritable tendon, I might ask them to do it every other day, a day on, day off. I think the odd person made themself a bit sore trying a bit too hard initially. They had to back off a bit." PT8
Stretches		"The only thing I probably would do less with tendons is the stretching programme. I tend to find that wouldn't normally be the thing that I would go for irritable tendons. I don't know if there's other reasoning behind why you want us to do the stretching programme, in regards to, because I find tendons don't tend to like to be put under tensile compressive forces. So I did do that with the patients to follow the paradigm to give them that stretching programme alongside it. But it's something that I did from the research I've done and from my clinical practise, I tend to avoid in the early stages of rehabilitation of tendons. Is that compressive and tensile force, that people seem to

		like it and seem to get on well with it. So, it was something I incorporated alongside the rehab programme as prescribed. That would be the only thing I would probably question about it was the stretching programme that's introduced into it as well. INT: I was like you actually. So, before we designed the programme those were my thoughts, but when we went through the process of designing the intervention, there is some evidence for stretching. Although it's often combined with other exercises, so it's difficult to tease out what the benefit of stretching is alone. But the inclusion of that was driven by the patients actually. RES: Oh, right. INT: So, we had patients in our intervention design group and they were the ones that felt very strongly that stretches should be in there, because they found- RES: Interesting. INT: -that they gave short term pain relief. So, yes, it wasn't something that I'd anticipated including. But yes, as I say it was driven by them which was interesting. RES: Interesting, yes. That's similar to what I found to be honest when I gave it to the patients. They liked it, it was almost like a warm up or a warm down scenario. Yes, so, I had no problem with them doing it to be honest, because they seemed to enjoy it. So, yes, similar findings with the patients I saw." PT1 " No, no wouldn't usually be part of my practice the stretching. I wouldn't normally give out those. I'd normally give them out as like ad hoc symptom relief so you can do these if it's sore, more if and when it's sore but not necessarily part of every single regime, no." PT2 "I would never have used stretches before… and I probably wouldn't have gone onto the upper body strengthening stuff." PT4 "And also I think the fact that it gave you the stretch and then you did the exercises and then you went back to the stretch, maybe did change what I do slightly because it kind of emphasised that the stretch they can do whenever in the day, whenever they're feeling it." PT6 "I probably wouldn't stretch routinely either, whether I should or not. It's a debate, isn't it?" PT8
Elbow brace		"I wouldn't have incorporated the orthotic device which was something that was interesting. So we don't routinely give out orthotics and they were high quality like orthotic devices compared to the sort

		of things I've seen in the, in the past and participants seem to like them so I wouldn't have done that at all and stretching generally wouldn't be high on my list of things to give out to people, only purely for symptom relief." PT2 "Usual care I mean we don't give them [elbow braces] out in our department but going through doing the CRF forms there was advice about trialling them so people would advise the patient to go and buy a clasp so I guess the patient then has to buy it before they know if it works or not. That was probably 50% of the time in usual care I reckon." PT5 "I felt very confident treating them [people with tennis elbow] and completely dismissed though giving them an aid, i.e. an elbow clasp. We never even issued one in my life so I was less confident with that. And then the wrist component threw me completely because I didn't even know that existed and then the more I thought about it, the more I thought well actually that's genius because it's stopping them going into extension and we're telling them to avoid extension. I don't know why I never even considered it as a possibility for some people. So it's kind of made me think slightly differently with some of my tennis elbows. Whatever the outcome might be, the principle behind it to me makes sense to add a potential wrist thing, particularly for those patients who are doing loads and loads of repeated wrist extensions at work." PT6 "INT: Are orthotics used at all in the usual care? RES: Rarely because I have to say the orthotics that our service has purchased are more like a tourniquet than a useful orthotic." PT7 "I would try it [elbow brace] and if it modifies their symptoms, use it. So I might do a grip test with a Jamar, stick a clasp on. Does it change your symptoms? Do you get better grip with than without? I wouldn't routinely give it out probably." PT8
Advice topics		"RES: I think the access to the website was very good actually. Having that outlet and that source that patients could go and provide or have the visual feedback for exercises and advice and things, was really useful. It doesn't tend to be something I normally give out with tennis elbow. Other than the verbal advice I would give them or maybe a sheet of exercises that I would print off for them. So I think having the visual outlet of the website was really useful actually. ------

		RES: I think it just flags up again what we should be doing as a whole, in regards to all of our MSK patients. Which is the biopsychosocial-type model of care and not forgetting about the extra bits-and-pieces that go alongside tendon healing, like lifestyle changes and all the rest of it. Like I say, you can in a busy clinic and when you've got not enough time to reflect, it's easy to brush over the other bits-and-pieces, rather than, great, I've got a quick lateral epicondyle pain here. I can just give them a quick loading programme and send them on their way. I think it slowed your processing down and think actually look at the bigger picture here, make sure you're addressing the other symptoms or issues that might be affecting this patient. Rather than just doing a slapdash give them a quick loading programme and screen for red flags and then crack on. So I think that, yes, it probably just highlighted to me actually you can always offer a better service if you break things down and look at the bigger picture. ------ INT: It probably comes back to your point there that it's perhaps seen as something quite trivial and quick to treat, but actually we could do better. RES: Yes, yes, I would agree with that, absolutely. I do think like I said earlier is good to have that paradigm of making sure that you tick all the boxes that we normally do with other or certain other pathologies that we know. There's a great instance of psychosocial input with pathology. So, yes, I'd agree. I'd totally agree with that." PT1 "I might have talked about general aerobic exercises, and I probably wouldn't have gone into as much detail with things like smoking, you know all the other aspects or the other general health stuff. I might have covered things like stress and sleep and, but yes it was more of a broader approach I think to the health of the individual." PT4 "And I guess the other thing with the optimised trial is the advice is more detailed advice so things like sleep you know the diabetes, general exercise - they are other things to be advising patients about, whereas perhaps it's not quite done in the same detail with usual care." PT5 "RES: [laughs] Some won't do that much background reading or literature reviewing, they literally will do what they were taught when they first qualified quite a while ago. INT: Yes, so what would that be with the patients then?

		RES: It would literally just be the eccentric loading, that's pretty much it. They won't think about diets, smoking, general activity levels, mental wellbeing, they'll just focus on the one thing." PT7 "RES: Yes. We usually find psychosocial stuff a lot for back pain and persistent pain but why don't I use that as much for tennis elbow and tendinopathies. I don't know. Maybe we should, shouldn't we but I think my bias is towards more the biomedical approach and physically increasing the robustness of the tendons and sell it that way to the patients. INT: So if that wasn't part of your usual practice for tennis elbow, just because we're asking you to do something new, were you happy to deliver that content as part of the trial? RES: Yes. I mean I used the psychosocial general health advice for a lot of conditions but for a lot of patients, more the spinal patients, persistent pain patients rather than the tendinopathy patients that might have had an overloading incident or a change of activity that's brought something on that might not have lots of psychosocial stuff going on in the background but those things like sleep and diet and healthy lifestyles obviously affect healing and any sensitivity, etc. So it's something we should probably consider more." PT8
Site training and scalability of the OPTimisE trial		
Feedback regarding training		"It was useful. Yes, really good. I think it laid out the clarification of why you were doing it and things. So understanding that actually. What took me by surprise was how big a problem it actually is for the nation I think really. So I didn't realise it was actually that big of an effect on the general population, to be honest. So that was very interesting to know how prevalent it is and how much of a disabling factor it is on the nation. Yes, I've no qualms with the training, to be honest. It was it was insightful. It was just get an understanding of the pathology and why that study was there to help the patients and things, so yes, it was fine." PT1 "I thought the training was comprehensive, covered all of the things that you'd need to know I think from delivering the intervention. I thought that it was delivered in an appropriate way so and I also felt well prepared going into the, so after the session. So and obviously most of the, all of the literature we were provided with was all very easy to understand, appropriate. Level of content felt good. So I have to say that I was impressed by the, by the kind of preparatory tools. -----

		I have to admit I think there was a real feeling in the room that it was a trial that everyone really kind of wanted to be part of and felt prepared to do." PT2 "INT: Yes, fairly straight forward exercises. And the fitting of the clasp? RES: Yes, I think a little bit of, it might sound simple, but just a little bit of going through that would be a good idea. Particularly in the wrist bit, because I wasn't aware of a wrist section to be, you know and I know it's, yes just running through that in the training might be quite handy. INT: Yes, so a bit more detail on that. Okay. --- INT: And do you think there's anything that we need to improve either on the training for the physios or the resources or any of the other, you know the sort of the patient flow or the research aspects to the trial? Was there anything that struck you? RES: Well, I think I knew very little about what they were doing with the, is it the Squegg? INT: Okay. RES: I knew very little about that. So when one of the trial participants was talking about it, I felt I couldn't really, they were showing me what they were doing. So I would like to know exactly what that involves, and how that then links in to the rest of it. So that felt very, very separate." PT4 "The training was really good it seems a long time ago now so it was really useful to have written information to back that up and we can look back on for future reference. I know I had the folder and at the beginning certainly I needed to look back at bits and pieces. And it was useful to have the training manual for the therapist and the patient because sometimes the therapist would come and ask me some questions and so obviously we both looked at that together. So definitely having the written information was useful. The training itself was good I was happy at the time so there are no questions or anything that I was unsure of it's just passage of time." PT5 "RES: Well, as it happens, I was actually super pleased because it was straightforward. I was slightly anxious having only really done GRASP before and I found that super complicated. This, the information was straightforward. The book that I got was straightforward and the website I got to then give to patients and then I could use when I wanted to, was straightforward so to me, it wasn't too much to remember. And I liked that. ---

		INT: In terms of the training itself, did you feel that that was comprehensive enough? RES: I think so. I can't truly remember exactly, I just remember going into your office, having a bit of a chat about it, going back through it then I went back through the booklet and it, I don't recall floundering on my first patient, but it was so long ago I can't remember the nitty gritty of it. INT: Okay. And - RES: I think where I struggled was knowing what to do with all the bits of forms. Because Emma wasn't around very often, I was a little unsure at the first couple what I should do with all this paperwork and where I should get it from. And finding the patient numbers, I didn't know what any of the numbers were to write on the forms of what my participant number was for that patient. INT: Ah, got you. RES: So the logistics of it as to, I could physically do my bit of the trial but I wanted to make sure I was making the identification correct for the patients. And I didn't know how to do that at the beginning. And then I found the file on Emma's desk and had to root through them until I found a name that matched. INT: Okay. Somebody else has said actually we could have done with like a walk through guide for that first session so that you know what paperwork you need, what specifically to do each time. Okay. RES: Because I think that's the only bit that was probably lacking for me. The actual what to do with the patient in front of me was fine, it's just the little hidden bits that don't concern the patient per se, but it's the other bits." PT6 "Yes, the training was really helpful. It seemed as though it was going to be quite straight forward to implement from a clinical point of view. You gave some good resources in terms of the website and the booklet. I thought they were helpful and I thought patients might get on well with those so I went into it fairly confident, that I knew I'd be able to implement it, implement what you wanted us to. ----- It came across as very professional as well, you'd got all the leaflets and the website up and running and the videos. It all looked like it was nice and slick and I liked that." PT8
Potential for online training delivery		" INT: One of the things we were thinking about is if we scale this up to sites all around the country, is whether we could deliver the training remotely. I don't know if you have any thoughts on that? RES: Yes, to be honest, I suppose the only thing that would possibly catch people out is the application of the splint if they hadn't seen something- I suppose you could still talk them through it

		virtually and things and have that contact with them by camera. So, yes, I think you could do, yes, absolutely. I don't think it was anything on the top of my head that we did in there that would necessarily warrant you being there in person or I suspect- Go on, sorry? INT: I was thinking about sending out a box in advance with the with all the paperwork, the books and the clasps in. So, people in the room could have a practise with the clasps and have a look through the book, but we could just direct that remotely. Would that work do you thing? RES: Yes, Yes, I think so. Yes, absolutely. I think if they've got the splints there and stuff and you can talk through the application of it, I don't see why not. Yes. I can't remember if there's anything that you did that would warrant face to face to be honest. So yes, no I think that would be fine to honest." PT1 " INT: And do you think it's feasible to do the training, the site training remotely as well? RES: Yes, yes I think it, I think it would be. Can't see any barriers particularly to doing it remotely at all that I can think off the top of my head. I think for mostly I would say that I can't think of a reason why you wouldn't do it remotely because it's fairly straightforward. I think it's, for me it would be more to do with like I say having that, making sure you have something that bridged the gap between the session and when you see your first patient but yes, no I can't see any reason why it couldn't be delivered as an intervention and the training could all be delivered remotely from my perspective." PT2 "Yes, because there's nothing- I suppose if you follow tendinopathy and you're fairly up to date then it all makes sense. If you've got somebody fairly newly qualified in MSK then to be honest I still think unless you're giving a bit of background information on tendinopathy it provides a nice framework by which if somebody referred me a tennis elbow I've got some special tests that you know aren't the most complicated special tests in the world. I've got nice clear diagnostic criteria and I've got a nice structured rehab of okay you know try this exercise if they're tolerant and it's easy then progress and if they're too good at this you know isometric to the isotonic increased weight and then think about considering adding something functional upper limb and then functional generally. So it was a nice kind of structure to a physio intervention which with all the trimmings of activity coaching and lifestyle coaching." PT3 "Yes, I don't think there would be any issue with that at all. No, I think it would be fine.

		----- They're simple aren't they? Very simple things to do so, I wouldn't think that would be a problem at all. And they're not something that people might not be aware of anyhow." PT4 "Yes I think I don't think there was anything that was really important to be face to face in that situation. Having it scaled up what I would say is that it was quite useful to have you on site occasionally so if I did have any queries or questions then it was useful to be able to ask you. So I guess if it was going to be scaled up across the country having somebody that they could all contact if they were unsure." PT5 " RES: Yes. I think it would be very, very easy to do online. Because I think it's mainly what people do anyway with patients, so I think it's not loads and loads of new information is it? So it's quite easy to remember. ----- INT: So if we did a remote training session and sent them all of the, you know the paperwork and the elbow clasps etc., you think that would work okay? RES: Yes, because they could watch the video couldn't they, after the training session to recap on both how to deliver, how to perform the exercises, how to do the elbow clasp plus wrist component if they wanted it. All the education is on there as a quick link access, not too much to go wrong, as long as they're not missing out an exercise diary and the other list. There's only really that, wasn't there?" PT6 "INT: Okay. If we rolled this out to lots of sites around the country, do you think we'd be able to do that site set-up remotely? RES: I don't see why not. INT: Yes, if we sent out all the hard copies by post and then had a Teams meeting or something to do that? RES: Yes, and then just visually show them what the clasps look like and how to apply them and all that sort of thing. I think it should be perfectly easy to do online." PT7
Gap between training and first patients		"INT: Did you feel sufficiently equipped when you saw your first patient to be able to deliver the intervention?

		RES: I think I would of if I received my patient sooner, but I think there was quite a big gap chunk in between me actually seeing a patient and having the training. So, I did have to have a quick chat with Mike and just run myself through the website and the process of it really. So I think it is absolutely fine if I'd have received a patient sooner, but I think there's a bit of a chunk in between. So I tend to lose my train of thought if I sleep more than twice. INT: Yes, some of the feedback from another site was something similar. They wondered whether like just a recording of the training or a short refresher video or a tick sheet, like a reminder sheet that walks you through it, might be useful in that scenario. I don't know what you think? RES: Yes, Yes, I would agree with that would be great. Nothing as in-depth as such as the lecture that you gave us. But Yes, something just like a quick little refresher really just to go through the intervention and the dosing. Would be useful, I'd say yes, I'd agree with that one." PT1 "The, as always in research I think the, the gap between receiving the training and then seeing your first patient is always the issue and so then having to then refresh it at the point of then seeing the patient was the, was the thing and so maybe felt like that a top up or something or you know I know I've been involved in other studies that have done things where they have you know like sessions where you can call in like trouble shooting sessions just where you can call in and just get a top up or ask questions and things like that that you use for that kind of reason you know where you do a drop in session on a Monday lunchtime and anybody who's having issues can, can dial into it and just top up the bits of information you need because the inevitability of clinical practice is that you suddenly get in on Wednesday morning and the first patient is an optimised one and then you've got to you know refresh it quickly as a gap but it was, yes that was the only thing I felt to get that after the session." PT2 "INT: Was there a bit of a gap between the training and you seeing the first patient in the trial? RES: Yes, absolutely. Yes, there was. Maybe that's quite spot on that, you know. Like you say. INT: So maybe, what do you think? Perhaps if we had like a little reminder, presentation or a video that you could just - RES: Yes. INT: Like a five minute video or something that you could watch just to - RES: Yes. Something simple. Very simple, you know, this is what you do, yes. Very simple I would say." PT4

		"INT: Okay. From that training, do you think that you had sufficient information so that when you started to treat those patients, when they started coming through, that you knew what you were doing? RES: Yes, I did but I had a few weeks before I got the first patient through so I had to do a bit of a recap myself and with [the site PI] just to cover it, make sure I was doing it right. If you'd have asked me to do a patient the next day, I'd have probably been pretty fine with it. Just because there was a bit of a gap in the time between doing the training and my first patient, I tried to do a bit of a reminder to myself of what you wanted from us." PT8
Feedback Related to Trial Resources		
Patient manual		"I think having a booklet or something empowers a patient or makes them want to do the exercises more, rather than normal practise of giving them an exercise sheets or just giving them verbally some exercises to do. I think it gives them more onus and empowers the patient a little bit better, to actually want to do the exercises. It would probably help with adherence as well. Rather than, like I say, the normal practises that we do. ----- The world is going so virtual now isn't it? I don't know whether or not having a QR code or something like that, that you could scan with your patients and maybe an information booklet that has that on it. Might be quite nice. Something that's easy access, people can just pick up their phones and literally just scan it, log on to it and then and it takes you to the website or anything. I don't know if that's something? You've probably got in the pipeline already or if it's there already. But that's what we find with a lot of our services that we've been setting up and things, that actually having that quick access via your phone is very useful. But I think in regards to the actual delivering of it and things, I think there wasn't anything that I had any worries about or anything that I would change. Because, yes, it's very similar to the normal practise that I would offer to patients. Then the extra bits and pieces that you've included, which are really useful and helpful. But yes, no, I think maybe the quickness of access to the information electronically or virtually would be really useful." PT1 "Really good. So I really liked it because it did you know in the book it had the exercises and when it was appropriate to progress I think didn't it? -----

		So I really liked it as a resource and they way it talked about other factors that can help to improve tendinopathy or prognosis yes." PT3 "RES: But I think the manual felt very detailed and it felt like I knew exactly what to do from the patient manual... I thought the patient manual was really handy as a therapist actually, yes. INT: Yes, so you sat down with them and talked them through the manual, did you? RES: Yes, yes. --- RES: Pictures, the photographs of the exercises. Very clear. The upper body and shoulder exercises might be interesting to sort of, I don't know state, well why do you need to work on all of your body, upper body strength, I don't know. Maybe that would be relevant for patients to know, you know this is part of a sort of improving your overall health and health of your upper limbs generally. Yes, I'm all right. No, I thought the manual was good. Really clear and it feels really clear to me now, having looked through it a few times. So yes." PT4 "I like the booklet, and I like the fact they can go backwards and forwards on it. Because that's what we teach them anyway, isn't it? But to have that there, and the patient can just flick through, it meant most of my patients seemed to understand and they were compliant." PT6 "I found the booklet was really helpful. Patients tended to use that more than the online stuff." PT8
Intervention manual		"RES: Great. I thought it was great. Yes. I've actually, I actually took some notice of it. No, it is good. It sort of covers, you know all aspects in general health as well. I think sometimes it gets a bit lost so, generally doing an assessment but you know covering things like general exercise and sleep and stuff, and there's an element as well on sort of persistent pain which, you know, I suppose that could be enlarged upon a bit really. Because a lot of people have got chronic issues though, yes maybe a bit, maybe a tiny bit more detail on that. On how people - INT: On the chronic pain section? RES: Yes, persistent pain, because I think it can be tricky for a lot of people to explain, patients to understand. I know it's talked about in terms of sensitivity in the tissues, but I suppose it's the other aspects as well that we all inform the pain process. It's not you know what is making it sensitive and how does that then link into things like you know, stressful environment or sleep etc. so yes.

		Perhaps that link in with it while you're, when you're talking about other stuff as well. I don't know if that's in there, sorry. Something might be in there and I hadn't noticed it." PT4 "And it was useful to have the training manual for the therapist and the patient because sometimes the therapist would come and ask me some questions and so obviously we both looked at that together. So definitely having the written information was useful." PT5
Website		"I think the access to the website was very good actually. Having that outlet and that source that patients could go and provide or have the visual feedback for exercises and advice and things, was really useful. It doesn't tend to be something I normally give out with tennis elbow. Other than the verbal advice I would give them or maybe a sheet of exercises that I would print off for them. So I think having the visual outlet of the website was really useful actually. --- Yes, really useful. Like I say, I think I prefer almost the visual online sources that people can go and watch videos, hear a bit of information about it as well. But, I agree having both sources is really useful." PT1 "INT: Did you, with the patients, did you refer much to the website at all? RES: No. I didn't. Did they? I'm not sure whether they did actually." PT4 "RES: But if you look at the website, you've got those bits where the patients can click on smoking or exercise or whatever, all the different bits. It's all very straightforward so as the person delivering it, you only have to guide the patient towards some of the education stuff as well as explain it to them that everything's all backed up. INT: Yes, that was the idea. Yes. You're saying all the right things! In terms of that website, did you use that much with the patients? RES: I did actually, because it was straightforward and because it came on the back of the booklet, and because we've now got laptops at work, it was easier to just take that, and I grant you I'm not a massive laptop user, but when I had an OPTimisE patient, I did take the laptop so I could go through the website with them, because it was a resource that I really wanted to use with some of my patients elsewhere but I couldn't because they weren't trial ones. INT: Okay. That's interesting.

		RES: Because for me I like having that. I like having the pictures, I like having the videos there and I like the booklet, and I like the fact they can go backwards and forwards on it. Because that's what we teach them anyway, isn't it? But to have that there, and the patient can just flick through, it meant most of my patients seemed to understand and they were compliant. INT: Okay. Did you actually show them the videos whilst you were there with them? RES: No, I showed them how to get onto the, I showed them physically the videos but I didn't sit through them. I sat through them by myself, but then I showed them how to click onto them and showed them how to use them. I don't know whether they did access them after that, but I didn't physically watch the two minutes or whatever with the patient. INT: Okay. It was a bit of a mixed bag actually. Some people did use the website, some people didn't because they felt the booklet had sufficient information in it. But it's interesting that you actually, you know you physically showed them the website because, and again some patients had gone through the consultations and actually had forgotten about the website. But obviously you'd shown them so that's more - RES: The one that was the most useful was the how to put on the splint. The clasp. Because I think people forget how to do stuff like that, so I was wanting to make sure they knew how to put on both components, and to show them that there was a video there, so if they didn't remember after I'd shown them, they could go back and consult it as well. Because the exercises are on the booklet, but the video for the actual clasp, it good because it's information. INT: Okay. Do you think there's anything that was missing off the website or the booklet? RES: I didn't see anything that was missing. Not that I can think of. --- RES: I think so because I actually, because I'm a bit OCD, did look at every single thing that was on there, because I don't like to offer my patients something I haven't seen. So I flicked through every single thing that was on there to make sure that I was fully aware of what I was recommending my patients looked at in case they threw me any curve balls and asked me about them later. But they were all quite self explanatory and comprehensive so that was okay. INT: And they are all NHS resources as well, they're not just random websites so yes, okay. That's good to know. RES: And I think patients like a reliable website." PT6 "INT: Was that a theme with all the patients? Did you look at the website with them all?

		RES: I did for the first few definitely. Then I probably stopped doing that with the latter few. I don't know why, maybe because I was more confident in delivering it because I'd done it numerous times by then and more signposted them to it rather than going through it with them. Whichever way, I don't know if one's right or wrong but it provided the same content I think. I just- INT: Yes, it was, yes. RES: I found the videos helpful for the first few just to make sure I'm doing it right I suppose because that resource was there to use. Then once I'd got it in my head exactly what we need to do, I probably didn't use it as much but then did signpost to it. The first few patients, I sat and watched the videos with them in the session but then not with further patients. Again, probably because in the end I became more familiar with it. Also I think because the initial few patients were put into new patient slots and then following on from that they weren't, they were put into follow-up slots so it was a bit more time pressed. --- I liked the exercises, the videos of the exercises and a couple of patients liked that - to copy it and make sure they were doing it right." PT8
eISF		"INT: In terms of all the processes like the monitoring visits etc and the online site file did that seem to work okay? RES: Yes, it did. If I'm honest I've not entered the online site file that much because we've got [name], our data manager, who sort of does all that. So the main thing I've really been involved in is just the sort of consenting patients off that. So [data manager] will identify all the elbow referrals that come in and then I just do the more sort of investigative call and then the consenting face-to-face. So from my point of view yes it's been absolutely fine I've been able to access all the documentation that I need. So yes, so actually it's not been complicated Sarah hasn't reported any issues to me and then monitoring visits seem to have gone pretty much you know uneventfully. So that's good really just a couple of kind of signatures here and there but other than that okay." PT3 "INT: How did you find the electronic site file? RES: It took me a while to get my head around it there were lots of different files on there and folders and files and bits and pieces that I don't feel that I necessarily used or looked at and may be that's my fault. But then it meant that I wasn't familiar with those things so when I was asked to check site files and [trial manager] was asking me to do things I found it quite laborious to go through and

		check that everything was in there when I wasn't familiar with some of the processes and things that went on in the background. INT: Is that how it was laid out do you think? RES: I think I would use two or three of the folders regularly and I was quite happy dipping in and out of those and I found them really easy to use and really easy to upload stuff to. I don't know if it was the layout or if it was just a lot of the stuff that went on in the background I then wasn't familiar with that paperwork so then when I was being asked to check whether it was there or not I wasn't sure if that was the one that he was referring to or not. INT: Can you see how we could do things differently to make that easier? RES: I suppose the PI role is to make sure that site file is up to date it's just that I felt some of the clinical stuff and then some of the research stuff that was in the background that I didn't know about then I was being asked to check it and it didn't know if it would have been easier for [trial manager] to check that or whether that should of all been my responsibility. --- INT: Yeah okay that's a good point. From a technology point of view did the electronic site file work okay? RES: Yeah that was fine there were no issues with that. INT: And in terms of all of the paperwork and everything that you need to consent the patients and give them the information about the trial etcetera, did you have everything that you needed? RES: Yes that was fine. I found one of them I think it was the consent form it defaulted so it didn't line up on the page but I think that was kind of a glitch from Word or something so I had to email you and ask for the original so I could print it off again for them. INT: Oh yes that was from the shared on the electronic site file wasn't it? RES: Yeah, but that was my only glitch and I think that was probably – I don't know how you would remedy that I think that's Word on its own. INT: Yeah, we'll probably have to save it as a PDF instead of a Word document and then it shouldn't change the format." PT5 "RES: So another thing to idiot proof it would be simple things like at the very start, either having folders set-up, empty but on the e-ISF with all of the labels clearly marked out because initially it was a case of, where do I put this, where do I put that? INT: Okay, for where you put the patient baseline form?

		RES: Data. Yes. INT: Okay, to make that a bit clearer. RES: Then also obviously the form that you'd got for the recruitment sheet, all of the tick boxes weren't actually working. INT: No, that was really annoying, wasn't it? RES: It was a real shame, but I mean we got round that by just- I shaded in the box that was relevant to make it easier for me. INT: They work, if you open it up as a Word document on a normal computer they work but in the online version of Word, tick boxes don't work. So, yes, that's something we'll have to just modify somehow. RES: Yes, I mean if everyone just finds a system like the cell-shading or whatever is useful for you and them, then great. It's just simple things like make you feel a bit stupid. And you're like, why can't I do it? [laughs] --- INT: Yes, and a lot of the documents are there because they need to be there but would a folder of sort of the most frequently needed documents or something make life easier? RES: Or even having them highlighted in set colours so that these are the ones you're likely to be looking at regularly and the rest you can dip into as and when, if you want to. INT: Okay, yes, that's a good idea. Maybe we could- RES: Because I like visual aids and colours can be really, really useful to make sure that people know they're the ones that you need to be looking at most. INT: Okay, I'll see if the technology will let us do that. Yes, that's a good idea. Okay, this is the first time the CTU has ever used an electronic site file. So it was a bit of a pilot from that respect as well. So, yes, all these bits of feedback will be useful. RES: If you've got anyone who's elderly and a bit of a technical luddite like I am, then simple things that make it just really a lot more simple really do work. INT: Okay, and just the fact that you had to upload things onto the electronic file, did that work okay? RES: That's was absolutely fine. That wasn't, that wasn't difficult. But you just simply telling me how to scan things in was something that no one had told me here, and when we had the technology so as soon as you told me how to do it, that was it, I was fine." PT7

Suggestions for improvements		
Primary care or FCP setting		"INT: Okay, good. The recruitment was a little bit slow. I mean towards the end it was slow across all of the sites but I know your site struggled a little bit. I don't suppose you have any reflections on why that might have been or thoughts why that might have been? RES: Yes again what we realised is that we just don't, we're not seeing many tennis elbows reaching secondary care, they're all being managed in, the nature of what we see here is changing at the orthopaedic, we're a specialist orthopaedic hospital and so much of these sort of, many of these sort of conditions like we've noticed a real drop off in the number of these conditions like frozen shoulders, tennis elbows that are coming here. They're tending to be managed in community trusts out in GPs, well in that sort of FCP, APP. We're not seeing that here. Secondary care here is much, so we're seeing more of the patients with osteoarthritis and wanting to convert to surgery but we have noticed in the last six/seven years with the changing FCP and APP roles that not many of them are these conditions. We've had a real drop off in these sorts of conditions that are reaching us in practice so yes things like tennis elbow and frozen shoulder that would have been our real, like a lot of people would, a lot of bread and butter in physio is, is not there so much. So it's just I think it is changing the nature of referrals that are around this FCP and APP and then in future if we did it you know I think we would embed the, try and embed it within our, purely, we tried to run it through physio thinking that we'd get enough referrals from our FCPs and APPs into physio but actually when we've looked at the data we're getting so few tennis elbow referrals making it past that APP barrier, they're managing them in the community, that we would have to embed the trial in that service rather than embed it within our physio service. So that's what we learnt from the trial is that there is a real change in the nature of the referrals that we're getting. INT: Yes and that's something that the other sites have said so like you just mentioned I think if we were to scale this up we'd probably have to embed the trial within the FCP environment in primary care. RES: Yes and if I was doing it you know my first thing if you approached me about the main trial I would say we would look to embed it in FCP or APP but really I'd be putting you in touch with my equivalent at the Birmingham Community Health Care Trust because it just strikes me that they're seeing all of it in that environment. You know we're just noticing a big change in what we see here in secondary care." PT2

		“INT: Did you have any sort of reflections on the patients that you did sort of screen and recruit? The process of screening the referrals approaching the patients recruiting them? RES: Yes, not too bad. I think we were wondering if referrals were drying up because they weren’t necessarily making it to secondary care as a pathology that much unless they were kind of really stubborn or unless we were their local physio place because we do have self-referrals here and GPs can refer to us. So yes, I think that’s one of the reasons why we didn’t get that many because we just kind of thought that most people would probably try and carry on working with tennis elbow and that it makes it difficult to attend physio appointments and things like that. INT: I mean since we sort of came up with the design of this trial and applied for funding they physio landscapes changed there are many more physios in FCP roles so do you think that might have had an impact? RES: Yes, definitely yes because we talked about that didn’t we? Trying to get some referrals in from FCP land and they sounded quite keen on it initially when I just discussed it with an FCP but I don’t think we got a huge, I think we got one or two referrals our way because of that but not that many. So yes, so I wonder if it’s something that maybe they’re just kind of managing within themselves a little bit and holding it. So whether it gets extended out to FCP because it is it’s almost quite a nice self-management programme because I think almost because there was so much information at the start with it, it almost made follow ups a little bit redundant. --- It was a well-designed intervention which meant that actually when you brought somebody in you were just kind of going "how are you getting on?" and "where are you at?" and then you just went "do you know how to progress?" "yes I did" "perfect, what are you up to?" So yes so I almost feel like it could be something you just design as a single arm intervention and then say sorry not single arm but yes just a single appointment and then say if you’re having trouble get back in. INT: Yes, and maybe target the FCP more the primary care side a little bit more. RES: Yes, because that’s how that service is designed isn’t it as a one stop shop really to prevent onward referral.” PT3 “INT: And what are your reflections on the numbers of patients coming through?

		RES: I think we did quite well at the beginning and then it seemed to slow down a bit and I'm not entirely sure why. I know Derby have got a lot more FCPs going at the moment and we've definitely seen the number increase of FCPs out in the community so I don't know whether at the end FCPs hold on to them a little bit more or they treat them in the community and then they don't ever need to be referred through to physio. But yeah certainly it slowed down and that was around the time that our FCP numbers went from about three to about ten. So I don't know if that had something to do with it. INT: Yeah, and this is something that's come from other sites as well. Over the course of the trial recruitment period I think nationally the numbers of FCPs have expanded and having since spoken to a couple of FCPs they would tend to hold on to these patients and treat them themselves rather than referring them through to an outpatient physio service. So yeah that assessment is probably accurate I would think. RES: I mean this would lend itself really nicely to an FCP clinic because you've got all the information out there for the patient to use and access for self-management so that they'd need to know about it as well." PT5 "RES: Well that's what we get. Yes, but it would appear that now the FCPs are doing more of that here, whereas previously they were literally off-loading all of them. INT: So have you seen that over the course of the last year with the trial then, do you think? RES: I would say literally in the last four months, the FCPs are doing more treatment whereas up until then the FCPs were off-loading more. INT: Okay, so- RES: When it came to things like tennis elbow. INT: Okay, because your referrals seemed to drop off towards the end as well, didn't they? RES: Yes, and we've got quite a change in the number of FCPs and their experience, knowledge and, yes, so it's been quite changeable issue." PT7 "Yes. I think this sort of programme is ideal for that sort of FCP land, clinician/patient. It's simple. They can signpost them straight to it, teach them the exercises quite quickly and manage these patients in primary care probably. --- Yes. We're struggling to recruit. Everyone is going into FCP." PT8

Language translation		" Yes, no my only reflection I think one of the things I was aware of is that for whatever reason, I'm not sure considering we live in you know we're in Birmingham, which is a big city, we do have quite a sort of Caucasian population here and most people the reading level is reasonable. It's pretty good and just it was also because there's quite a lot of literature around it, around the intervention the people I saw and participants I saw were just following it and it went really well. I did wonder about delivering it to somebody who maybe English wasn't their first language or somebody who didn't quite have that level of kind of literacy just because of the, whether that would then be the thing I really like about it and found it really easy to deliver might actually become a complication in that instance…And that's why you know delivering it in primary care might put you in touch with them and say deliver it with them would be really interesting because they see a much, very different population to we see here and it may be a different experience. Now hopefully that's a part of doing it in many different sites but yes that was just one thing because it was quite literacy heavy. My only thing that was just maybe on the, you know would somebody on, that didn't speak English as their first language find it as easy as my, the people I saw did who just thought it was fantastic. --- Yes. That would be, no that would be my feedback just in terms of thinking about the future of it certainly for like if it was going to go in community care you know somewhere like Birmingham there's certainly different ethnicities but you know with things like you know most of our literature, most of DCH literature has to be translated into Urdu, Punjabi, Polish for it to get out in the first place. So there will be some considerations there around the literature but in our population and the people I saw you know it was one of the real strong points but that's I would say just be a consideration for the future trial." PT2
Clinician support service		"RES: The, as always in research I think the, the gap between receiving the training and then seeing your first patient is always the issue and so then having to then refresh it at the point of then seeing the patient was the, was the thing and so maybe felt like that a top up or something or you know I know I've been involved in other studies that have done things where they have you know like sessions where you can call in like trouble shooting sessions just where you can call in and just get a top up or ask questions and things like that that you use for that kind of reason you know where you do a drop in session on a Monday lunchtime and anybody who's having issues can, can dial into it and just top up the bits of information you need because the inevitability of clinical practice is that you suddenly get in on Wednesday morning and the first patient is an optimised one and then you've got

		to you know refresh it quickly as a gap but it was, yes that was the only thing I felt to get that after the session. INT: Okay, that's interesting. I've not heard of that before. So how did that work then? The trial team had you know an open session on the Teams calendar and people could call in for advice if they needed to? RES: Yes they just say we're going to do, we're going to do a half and hour open session that will be available on Teams you know on a Thursday at twelve o'clock. Every Thursday we'll guarantee we'll have an open session so that if you've got any queries about the trial or you want to refresh anything about the delivery you can drop in to that session and ask your questions or just refresh it and so you know it might be an opportunity if there is a gap that you can then say well actually well if you call into that session the week before we can do a quick top up before you then have to go on and see your patients. So they'll just do a drop in every, it just seems like quite, sometimes you'll do it and no one will turn up obviously but particularly you know to cover that gap it's quite, I just feel like it's quite a nice, a nice idea because it doesn't matter, if there is a gap it doesn't matter how engaging the session is there is always a bit of a re-skilling that happens in that time because you see it just the one time and you don't get a chance to practise it before you then do it with a patient." PT2 "So I guess if it was going to be scaled up across the country having somebody that they could all contact if they were unsure." PT5
Reduce admin burden for site PIs		"RES: …if there's a change in protocol then I need to be aware of that but some of the stuff was about funding and other things in the background that didn't really affect me being the PI and I was just thinking may be that could be done more by R&D rather than us, but I don't know how you would make that easy may be at the beginning sitting down and going through the site file and just making sure everyone's familiar with what is in there that might be useful if it was all left to the PI. INT: Yeah, I suppose the online site file we introduced quite close to when the trial started didn't we it took a bit of time to get that up and running. RES: I can't think of documents in particular but I know the last check that I did it just took me a good couple of hours to go through and make sure all the documents were there and it just felt like a lot of time and I hadn't looked at over 50% of those documents that were in there because it was all stuff that had happened in the background.

		INT: That was for the monitoring visit wasn't it? RES: That's right yeah. INT: There are pros and cons of how we did I suppose. If we did it in the background it meant less work for you at the time. RES: That's true. INT: But then later on at the monitoring visit you had to double back and check that it's there. RES: Yeah. INT: Okay, I'll raise that with [the trial manager] and we can see if we can reduce the burden on you a little bit or reduce the burden on the PIs for any future trial. RES: If it is done for the PI then so be it but I was just thinking it was quite a lot of clinical time for me to just go through and check it and because I wasn't familiar it just took me longer, whereas you'd say to [the trial manager] I can't find this file and he'd go it's there and he'd find it within about two seconds. So, I think he was probably just more familiar with that site file may be. --- INT: In terms of the numbers of meetings and monitoring visits and time burden etcetera you've already said that the monitoring had a bit more of a time burden than you were expecting, how about the rest of the trial as a whole? RES: No, I found it quite manageable actually. I sometimes had to block out a bit of time but nothing unreasonable. And the meetings monthly they were fine. Once it was in the normal flow it wasn't too much of a burden." PT5 "RES: Well, one of the key things is that even though the managers all signed-up for this they don't seemed to have recognised how much time that it would potentially take, and so when I then say, oh, I've got a further meeting. Like, have you finished already? You've recruited all of the patients and I'm like- [laughs] INT: Yes. RES: So that's been one part. INT: And that's one of the challenges when we're setting up a trial, it's trying to predict how much time is involved. So- RES: I mean obviously because I've recruited 25 of them, it's meant that it's been more input than if it had been fewer. ---

		RES: So the online monitoring is fine and simple because you can get that all sorted but my bosses weren't keen on me attending each and every one of the OPTimisE team meetings. So that's why I haven't attended as many. --- INT: But perhaps if we scale this up we ought to cost in more time for clinicians for meetings and the administrative side because I think we perhaps under-did that? RES: Yes, I think that would be great, especially from my manager's perspective because if ever I then said, "Oh, I've got a meeting," or, "I've got to do some work," they're like, "Really?" [laughs] INT: Right, yes, okay. Yes, we ought to cost that in because we want life to be easy for you so you're not having to battle for everything. The research process should be interesting and enjoyable hopefully. But, yes, not a battle. RES: Well, I always found a way of just trying to morph whatever time I had available to be used, but it would be lovely if it could be accounted for so that the managers are completely aware as to how much time it may take." PT7
Minimum data telephone calls		"INT: Halfway through we introduced this idea that we could phone the patients to do the questionnaire over the phone if they hadn't sent it back. We put that on the site PIs to do. Do you think that's a reasonable thing to do or do you think it would be better if the like the trial team did that? Is that just one extra thing too many? RES: No to be honest I do as I'm told! I'm fairly easy going but no I don't think that's too much to do. I don't know if that's a reflection on how much I'm doing but yes I suppose I'm quite happy to get that done but I'm easy going so I don't know if that's the answer you're looking for." PT3 "INT: And of course halfway through we added in the telephone minimum data set calls to patients who hadn't returned their questionnaires, what are your thoughts on that because we asked you as the PIs to do those phone calls do you have any thoughts on that? RES: Again I think if you can allocate that time if you can factor it in from the offset. I think I only had to ring may be three so it wasn't a huge amount of time to get them. And often then when I managed to speak to the person they weren't keen on giving me the minimum data set there over the phone but it prompted them to then return their questionnaires to you. INT: Right okay.

		RES: So I don't think I actually did a minimum data set over the phone because they all said no I've changed my email address or I've moved address or something had happened that they said can you resend it and once that had happened they returned it. So yeah I didn't mind doing that." PT5 "INT: So, the chasing the patients with the phone call questionnaires, that was something that wasn't costed in. Have you spent a lot of time doing that? RES: Well, I tried phoning several people on repeated occasions and got nowhere, so, yes, it does take time but it's not taking huge amounts of time, it's just trying to fit them in between other things on my list, so, yes. INT: Taking that forward, do you think that would be sort of less of a burden if the trial teams, basically if we did that job rather than you doing that job? RES: That would be fantastic, yes, that would be great." PT7
Training reminder checklist		"Making a checklist. I think maybe, you know possibly having a checklist at the beginning to show that you are, that I know it's a checklist that you're actually ticking there to, but it's almost something a bit broader wasn't it? You know, bits there. You're talking about have you read all the information, you've then I don't know. Something to remind, honestly I'd completely forgotten about it until right at the end and I don't know why that was. So whether it was just not clearer or whether that was just me thinking I knew all aspects of it, because there was quite a few things to consider within it wasn't there, the trial? In terms of yes going through all the things and then making sure you were doing the exercises in the right way, the right format. Yes." PT4 "Yeah, from that training I wrote myself a sort of crib sheet checklist which I used for every patient that I went into just to make sure that I had done everything that I needed to do. So maybe something like that might be useful." PT5 "I think just at the very beginning, when you're getting somebody on board, I guess to do a trial arm of something, it's just making sure you've got access to numbers, sheets or whatever it is you need - a tick-list. Because a tick-list generally helps, doesn't it? Helps someone to get going, a novice starting it, and then once they've done it a few times, they remember. And I think in research it's quite useful just to make sure we've not missed any bits out anyway." PT6