

**Optimising Outcome for Achilles Tendinopathy:  
An Exploration into Cognitive and Contextual  
Factors**

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# Summary of Thesis

## Optimising Outcome for Achilles Tendinopathy: An Exploration into Cognitive and Contextual Factors

Achilles tendinopathy is a debilitating condition for both active and sedentary people. Clinically it is characterised by a painful response felt in and around the tendon predominantly during tasks involving plantarflexion load; hopping for example. Whilst exercise appears to be a promising intervention for the condition, it remains unclear how exercise influences outcome. Hence, in order to optimise outcomes for our patients, further research is required to better understand factors which may influence exercise-led interventions.

It is acknowledged that further research is required to understand the 'specific' influences of exercise, for example, the ideal exercise type, number of sets and repetitions remain uncertain. However, this thesis aimed to develop insight into optimising outcomes by considering factors not previously investigated in tendinopathy research; the 'non-specific' influences of psychological, cognitive and contextual variables.

To achieve this insight, this thesis comprises a systematic review investigating the association of psychological variables and tendinopathy. Overall, the review's findings were contradictory, suggesting the need to consider further factors which may underpin psychological variables. Consequently, a further narrative review was undertaken. This review considers how the cognitive and contextual factors of working alliance, adherence, self-efficacy and outcome expectation might interact with psychological variables and potentially influence outcome from exercise-led interventions for people with tendinopathy. This is then highlighted as an area in need of research.

Developed from this series of reviews, this thesis reports the feasibility of a study utilising a bespoke online platform for data collection to investigate the association of working alliance, self-efficacy, adherence and outcome expectation with clinical outcome for people with Achilles tendinopathy. The feasibility study comprised of a multi-centre, longitudinal cohort study (n=24) which was conducted in the UK. As part of the development for this study, a final narrative review was undertaken to evaluate the usefulness of the most commonly used patient reported outcome measure used for people with Achilles tendinopathy; the Victorian Institute of Sport- Achilles. Concerns over the measure's validity, reliability and readability, led to the use of an alternative measure, the Lower Extremity Functional Scale.

The feasibility study reports quantitative assessment of recruitment and retention rates alongside a qualitative study to identify obstacles and enablers to engagement with the untested online platform. The results suggest a future large cohort study is warranted and feasible; a basis from which future research has been developed, alongside an enhanced understanding of cognitive and contextual factors which may influence optimal outcome for people with Achilles tendinopathy and hence new knowledge has been generated.

## Contents

Glossary of Terms.....	10
Chapter 1: Setting the Scene .....	11
Summary .....	11
1.0 Introduction .....	11
1.1 Burden of Achilles Tendinopathy and the Role of Exercise .....	14
1.2 Rationale Underpinning Further Study.....	18
1.2.1 Aim and Objectives .....	20
Chapter 2: Literature Review .....	22
Summary .....	22
<i>Part One: The Association of Psychological Variables and Outcome in Tendinopathy: A Systematic Review</i> .....	22
2.0 Introduction .....	22
2.1 Methods .....	24
2.1.1 Protocol .....	24
2.1.2 Data Sources and Search Strategy .....	24
2.1.3 Eligibility Criteria .....	25
2.1.3.1 Population.....	25
2.1.3.2 Outcome .....	25
2.1.3.3 Study Design.....	25
2.1.3.4 Language.....	26
2.1.4 Quality Assessment .....	26
2.1.5 Data Extraction .....	26
2.1.6 Data Synthesis.....	27
2.2 Results .....	28
2.2.1 Study Selection.....	28
2.2.2 Newcastle-Ottawa Scale Assessment.....	29
2.2.3 Study Characteristics .....	30
2.2.4 Study Design .....	37
2.2.5 Participants .....	37
2.2.6 Findings .....	37
2.2.6.1 Psychological Variables (Catastrophisation, Distress, Anxiety and Depression and Kinesiophobia) and Tendinopathy .....	37
2.2.6.2 Catastrophisation .....	38
2.2.6.3 Distress.....	38
2.2.6.4 Anxiety and Depression .....	38
2.2.6.5 Kinesiophobia .....	39



2.2.6.6 Psychological Variables (Catastrophisation, Distress, Anxiety and Depression and Kinesiophobia) and Prognosis.....	39
2.2.6.7 Catastrophisation .....	40
2.2.6.8 Distress.....	40
2.2.6.9 Anxiety and Depression .....	40
2.2.6.10 Kinesiophobia .....	41
2.2.6.11 Summary of Key Findings .....	41
2.2.6.12 Lateral Epicondylalgia .....	41
2.2.6.13 Rotator Cuff Tendinopathy .....	41
2.2.6.14 Patella Tendinopathy .....	42
2.2.6.15 Achilles Tendinopathy .....	42
2.3 Discussion .....	42
2.4 Limitations.....	45
2.5 Future Directions .....	46
2.6 Conclusions.....	47
<i>Part Two: Cognitive and Contextual Factors to Optimise Clinical Outcomes in Tendinopathy .....</i>	<i>49</i>
2.6 Introduction .....	49
2.7 Psychosocial Impact.....	50
2.7.1 Working Alliance .....	55
2.7.2 Developing an Effective Working Alliance .....	55
2.7.3 Goal Setting and Goal Attainment.....	57
2.7.4 Efficacy Expectations .....	59
2.7.5 Outcome Expectations.....	60
2.8 Enhancing Self-Efficacy.....	61
2.9 Conclusion.....	63
Chapter 3: Measuring Clinical Outcomes in People with Achilles Tendinopathy .....	64
Summary .....	64
3.0 Introduction .....	65
3.1 Development of the VISA-A Questionnaire .....	72
3.1.1 Identification of a Specific Patient Population .....	73
3.1.2 Item Generation .....	73
3.1.3 Item Reduction and Content Validity .....	74
3.1.4 Construct Validity .....	75
3.1.5 Reliability .....	76
3.1.6 Interpretability .....	80
3.1.7 Responsiveness.....	81

3.2 Summary .....	82
3.3 Implications for Future Research .....	82
Chapter 4: Research Methodology.....	85
Summary .....	85
4.0 Introduction and Overview .....	85
4.1 Research Paradigm .....	85
4.2 The Design of 'The Map Study' .....	87
Chapter 5: The MAP Study .....	90
Summary .....	90
5.0 Introduction .....	90
5.1 Study Aim and Objectives .....	92
5.1.1 Ethical Approval .....	92
5.2 Methods / Design .....	93
5.2.1 Study Design .....	93
5.2.2 Study Setting .....	93
5.2.3 Eligibility Criteria .....	93
5.2.4 Care Pathways and Physiotherapy .....	94
5.3 Variables.....	94
5.3.1 Working Alliance Inventory Short-Form.....	95
5.3.2 Global rating of change for outcome expectation .....	95
5.3.3 Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence.....	96
5.3.4 Pain Self-Efficacy Questionnaire .....	97
5.3.5 Clinical Outcome Measures .....	97
5.4 Sample Size.....	98
5.4.1 Participant Selection, Recruitment and Informed Self-Consent .....	99
5.4.2 Collection of Clinical Outcome Measures and Variables .....	101
5.4.3 Adverse Events.....	101
5.4.4 Data Management .....	102
5.4.5 Statistical Analysis .....	102
5.5 Patient and Public Involvement .....	103
5.6 Results.....	104
5.6.1 Feasibility Analysis - Recruitment and Retention.....	104
5.6.2 Correlation Analysis .....	107
5.7 Discussion .....	116
5.7.1 Feasibility Outcomes - Recruitment and Retention.....	116
5.7.2 Correlation Outcomes .....	117
5.8 Limitations.....	119

5.9 Conclusion .....	120
Chapter 6: The Process Evaluation .....	121
Summary .....	121
6.0 Introduction .....	121
6.1 Methodological Approach.....	123
6.2 Methods.....	123
6.2.1 Patient Participant Selection and Recruitment .....	126
6.2.2 Physiotherapist Selection and Recruitment .....	126
6.2.3 Data Collection.....	127
6.2.4 Data Analysis .....	127
6.2.4.1 Familiarisation.....	130
6.2.4.2 Identifying an Initial Thematic Framework .....	130
6.2.4.3 Indexing and Sorting .....	131
6.2.4.4 Charting .....	132
6.2.4.5 Mapping and Interpretation .....	133
6.3 Findings .....	137
6.3.1 Acceptability of The MAP Study Procedures from The Physiotherapists' Perspectives .....	138
6.3.1.1 Key Themes.....	139
6.3.1.2 Obstacles.....	139
6.3.1.2.1 Theme 1: Access to Participants .....	139
6.3.1.2.2 Theme 2: Recall .....	140
6.3.1.2.3 Theme 3: Visibility .....	142
6.3.1.2.4 Theme 4: Time.....	144
6.3.1.3 Enablers.....	145
6.3.1.3.1 Theme 5: Training .....	145
6.3.1.3.2 Theme 6: Motivation.....	146
6.3.1.3.3 Theme 7: Incentives.....	147
6.3.1.3.4 Theme 8: Simplicity .....	148
6.3.2 Acceptability of The MAP Study Procedures from The Patient Participants' Perspectives .....	150
6.3.2.1 Key Themes.....	151
6.3.2.2 Obstacles.....	151
6.3.2.2.1 Theme 1: Information from The Physiotherapist.....	151
6.3.2.2.2 Theme 2: Follow Up .....	153
6.3.2.3 Enablers.....	155
6.3.2.3.1 Theme 3: Motivation.....	155
6.3.2.3.2 Theme 4: Website .....	156

6.3.2.3.3 Theme 5: Questionnaire.....	157
6.3.2.4 Consequences.....	158
6.3.2.4.1 Theme 6: Positive Experience.....	158
6.4 Discussion .....	159
6.4.1 Involvement with the Study .....	161
6.4.2 Inviting a Patient .....	162
6.4.3 Discussing the Study .....	164
6.4.4 Willingness to be Involved.....	165
6.5 Strengths and Limitations.....	165
6.6 Conclusion .....	166
Chapter 7: Discussion, Contributions, Strengths and Limitations and Recommendations for Future Research.....	167
Summary .....	167
7.0 Aim of This Thesis .....	167
7.0.1 Objective One .....	168
7.0.2 Objective Two .....	168
7.0.3 Objective Three.....	169
7.0.4 Objective Four.....	169
7.1 Strengths and Limitations.....	170
7.2 Recommendations for Future Research.....	171
Chapter 8: Conclusion.....	172
References .....	173
Appendix 1 – Published Systematic Review.....	197
Appendix 2 – PRISMA Checklist .....	204
Appendix 3 – Newcastle Ottawa Assessment .....	207
appendix 4 – Published Narrative Review .....	217
Appendix 5 – Published Narrative Review.....	219
Appendix 6 – STROBE Checklist .....	221
Appendix 7 – HRA Ethical Approval Letter .....	223
Appendix 8 - Postcard.....	231
Appendix 9 – Physiotherapists’ Training .....	232
Appendix 10 – Participant Information Sheet .....	254
Appendix 11 – Participant Consent Form .....	256
Appendix 12 – Emails for Follow Up.....	258
Appendix 13 – GRIPP 2 Checklist.....	260
Appendix 14 – Published Process Evaluation .....	261
Appendix 15 – COREQ Checklist.....	272

Appendix 16 – Invitation Email for Interview .....	275
Appendix 17 – Participant Information Sheet .....	276
Appendix 18 – Consent Form.....	278
Appendix 19 – Invitation Email to Physiotherapists .....	280
Appendix 20 – Participant Information Sheet .....	281
Appendix 21 – Consent Form.....	283
Appendix 22 – Topic Guide .....	285

## Glossary of Terms

**Working alliance** - the working rapport or positive social connection between the patient and the therapist

**Efficacy expectations** - beliefs about one's ability to perform a given task

**Outcome expectations** - a person's estimate that a given behaviour will lead to certain outcomes

**Adherence** – commitment to the action agreed from a shared decision-making process between the patient and therapist

**Catastrophisation** - the tendency to magnify the threat value of pain and to feel helpless in the context of pain

**Anxiety** - a physiological state characterized by cognitive, somatic, emotional, and behavioural components producing fear and worry

**Depression** - a pervasive low mood, loss of interest in usual activities and diminished ability to experience pleasure

**Kinesiophobia** – a debilitating fear of physical movement and activity through a feeling of susceptibility to painful injury or re-injury

**Distress** - an aversive state in which a person shows maladaptive behaviours

**Minimal Detectable Change (MDC)** - the smallest change that falls outside the measurement error in the score of an instrument used to measure a construct

**Minimal Important Difference (MID)** - the smallest differences in the construct to be measured between patients that is considered important

**Minimal Important Change (MIC)** - the smallest change in score in the construct to be measured which patients perceive as important

# Chapter 1: Setting the Scene

## Summary

This chapter sets the scene for this PhD thesis. The aim of this thesis is to better understand how to optimise exercise-led interventions for people with Achilles tendinopathy (AT). To achieve this, the thesis focuses on factors not previously investigated in tendinopathy research; cognitive and contextual factors. The purpose of this chapter is to introduce relevant terminology as well as providing an overview of the burden of AT as a clinical entity. Specifically, the role of exercise-led management by physiotherapists is explored in depth. Justification for undertaking further work is considered before the aim and objectives of the PhD are presented.

## 1.0 Introduction

The Achilles tendon originates from the merging of the soleus muscle with the two bellies of the gastrocnemius and inserts distally onto the calcaneus [1]. The Achilles tendon is reported to be the strongest and longest tendon in the body [2] and, as is common to all tendons, its function is to transmit force from the muscles described above to its insertion on the calcaneus (figure 1.1).

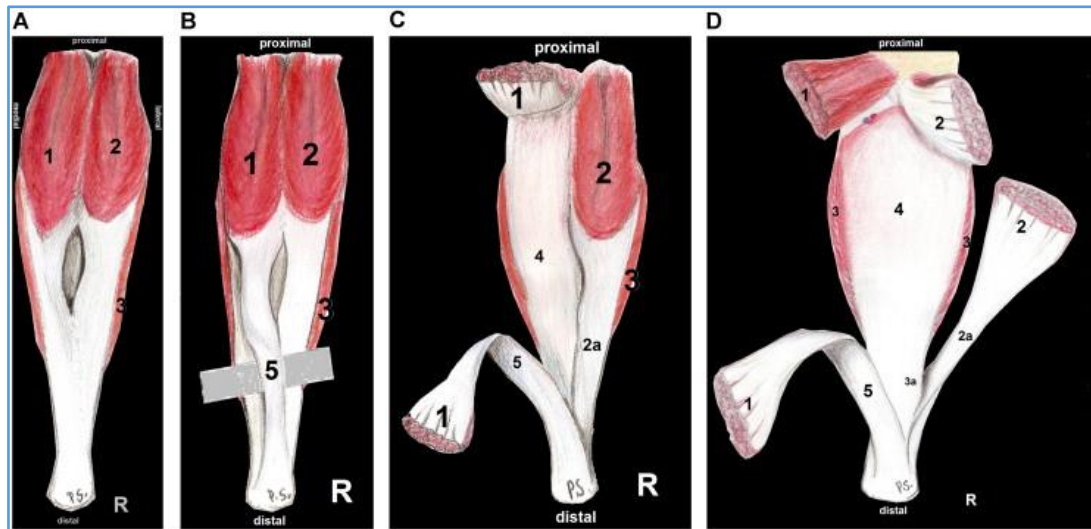


Figure 1.1 Anatomy of the (right) Achilles tendon, posterior view (A–D) [3]. The (1) medial head of the gastrocnemius muscle, (2) lateral head of the gastrocnemius muscle, (2a) fibres from the lateral head of the gastrocnemius, (3) soleus muscle, (3a) fibres from the soleus muscle, (4) aponeurosis of soleus muscle and (5) fascicle from the medial head of the gastrocnemius muscle

The Achilles tendon is prone to load-based injuries and as such is a location for musculoskeletal pathology and a site of patient-reported pain [4]. Tendon-related pain and its associated functional limitations, termed tendinopathy, can be traumatic or insidious in onset and short-lasting or persistent in nature [5]. Tendinopathy can be characterised by a reduced ability of the tendon to sustain tensile load [6]. People with AT present with activity-related pain located 2-7cm proximal to the calcaneal enthesis [7]. Whilst symptoms may occur at the calcaneal insertion (termed insertional Achilles tendinopathy), this is far less common [8]. In recent years, clinical and scientific communities have gained abundant yet incomplete knowledge regarding the underlying processes involved in the development of tendinopathy.



Whilst several models exist proposing to explain the underlying processes concerned with tendinopathy, the most commonly cited model is the ‘continuum model’ (figure 1.2) [6,9]. The continuum model suggests excessive loading causes a loss of tissue homeostasis resulting in a cell mediated reaction in absence of an inflammatory reaction [6,9]. Whilst other models disagree and suggest the involvement of an inflammatory component [10,11], common to all models is the link to the rate of wear being greater than the rate of repair [12,13]. Further examination of the current models for tendinopathy is undertaken in chapter two, *part two*.

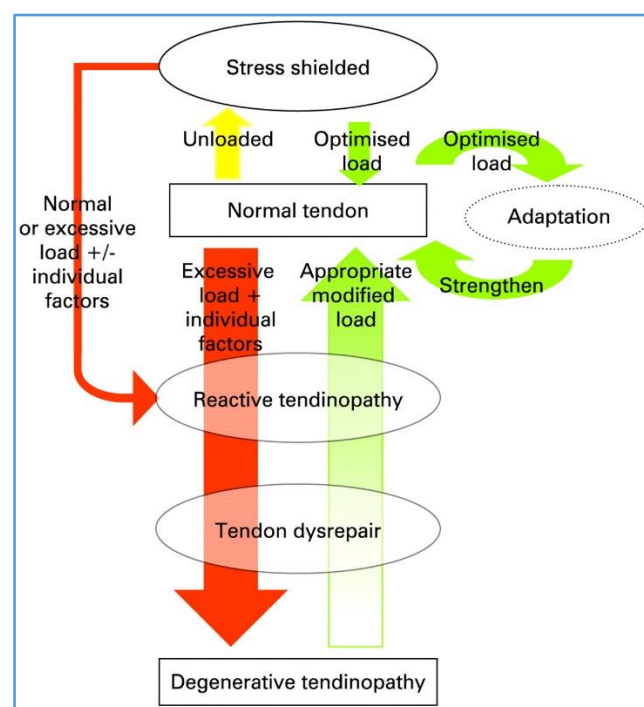


Figure 1.2 The continuum model of tendinopathy [6,9]

Regardless of the pathology underpinning AT, its impact on the sufferer is well documented. For people with AT, it results in decreased activity participation, working ability and quality of life [14]. As will be discussed further in chapters

two and three, factors influencing this impact are poorly understood. Little is known about mechanisms driving pain and the response (or lack of) to rehabilitation [15–18]. Furthermore, despite structural changes being the focus of tendinopathy models [6,9] current evidence suggests that structural changes on imaging of tendinopathic tendons do not explain the response to exercise-led interventions [19]. Whilst recognising that advancements in imaging techniques may yet contribute to improved outcome by enhancing diagnosis [20], current evidence suggests that clinical outcome for people with musculoskeletal conditions is influenced by similar factors across different musculoskeletal presentations [21]. Factors such as pain intensity, association of psychological distress and high functional disability, appear of key influence and the addition of a specific structural diagnosis is not [22,23]. As current strategies appear incomplete, the need to investigate factors beyond the specific effects of exercise on peripheral tissue appears to be one way of potentially optimising outcomes in AT.

### 1.1 Burden of Achilles Tendinopathy and the Role of Exercise

There is little doubt that AT is a social burden. AT has an estimated incidence rate of 2.35 per 1000 person-years for the general adult population [24,25]. Likewise, 52% of top level runners will suffer with AT during their lifetime [26] and may contribute to premature retirement in up to 5% of professional athletes [27]. AT, however, is not only a problem that impacts sports participation. It affects the sedentary population also, negatively affecting the ability to work [25]. For anyone with AT, overall quality of life is impacted [25], potentially leading to significant physical and psychological burden [28].

Whilst AT can be challenging to manage clinically in some [6], and although much uncertainty remains, there is a growing body of evidence advocating an exercise-led management approach [29–31]. Current best practice guidelines include strength training and load-management as core ingredients [32–34], supplemented by additional interventions such as shock wave therapy or laser therapy [35,36], although the evidence supporting their addition is lacking [36,37]. The principal exercise-based management approach recommended to treat AT is eccentric loading [38–40]. Originally described by Alfredson et al [41], eccentric loading for AT comprises of 12 weeks of eccentric heel-drops on the injured limb, with the use of the uninjured limb to concentrically return to the start position (figure 1.3). Exercises are performed twice daily, for three sets of 15 repetitions, both with a straight and bent knee (i.e. 180 repetitions each day). Non-disabling pain during the exercises is permitted, and load is added gradually in a backpack (in steps of 5 kg) when exercises can be performed without pain.

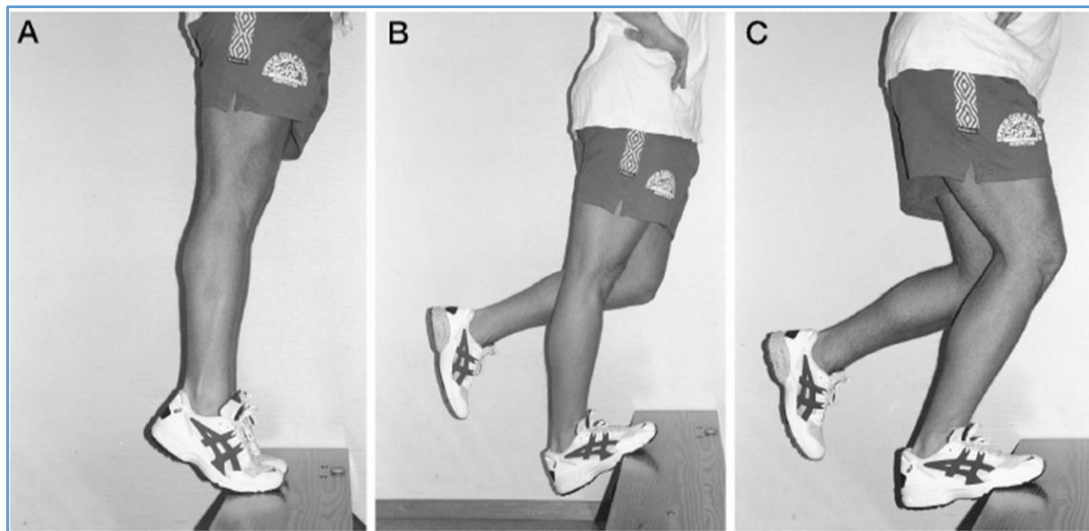


Figure 1.3 The Alfredson protocol [41]. From an upright body position and standing with all body weight on the forefoot and the ankle joint in plantarflexion lifted by the non-injured leg (A), the calf muscle is then loaded eccentrically by lowering the heel with the knee straight (B) and with the knee bent (C)

Despite the initial promising results of this intervention demonstrating a 100% success rate of returning participants to preinjury levels [41], more recent studies have shown up to 45% of individuals do not respond favourably to eccentric loading [42]. Consequently, alternative loading strategies including; heavy slow resistance, concentric-eccentric and concentric-eccentric progressing to eccentric loading, have been investigated [38,43–46]. Similar to eccentric loading, studies into the effects of these interventions have also yielded inconsistent findings [33] and the individual response is also variable [38]. Such inconsistent and variable findings have led to recommendations that clinicians take an approach that enables tolerable repetition volumes to be completed, rather than those recommended by strict programmes [39]. Several explanations may explain this inconsistency; these may relate to our current lack of understanding of the specific and non-specific effects for the optimal delivery of the exercise programme.

Specific explanations relate to exercise parameters and our current lack of knowledge regarding optimal exercise prescription, such as; load magnitude, sets, repetitions, frequency and restitution between loading sessions [38]. For example, eccentric loading is taught to patients to be performed twice a day (morning and evening) yet heavy slow resistance exercises are taught to patients to be performed three times a week [38]. The consideration of such vastly different approaches to exercise within research highlights our existing lack of understanding of why someone with AT may respond favourably to a load-based exercise programme. Most clinical improvement does not correspond with the timeframe for structural tendon adaption to occur [47] raising the probability of other mechanisms being responsible for clinical improvement. To date, such mechanisms that have been considered include; changes to tendon length, neurovascular ingrowth, neuro-chemical alterations, fluid movement and neuromuscular tissue adaption [15]. Whilst much uncertainty remains regarding the specific mechanism of action of exercise on tissue for tendinopathy, an alternative explanation might be to investigate other, non-specific, influences on the effectiveness of exercise.

Non-specific effects of treatments are multi-factorial, and have been described as cognitive and contextual in nature; including the attention of the health care provider, the desire to get better and social variables such as a reduction in anxiety, increased optimism and improved coping [48]. These factors have been considered to significantly influence the success of a range of medical interventions. For example, Roberts et al [49] reviewed the literature relating to five medical interventions that were once considered to be efficacious

(glomectomy for the treatment of asthma; gastric freezing for treatment of duodenal ulcers; and levamisole, photodynamic activation, and organic solvents for treating herpes simplex virus), but later were shown to have no efficacy based on controlled trials. Despite the later evidence that these treatments lacked efficacy, prior published clinical trials showed that out of 6,931 subjects enrolled, 70% of the patients reported good to excellent results from these five interventions. Roberts et al [49] concluded that under conditions of heightened expectations, the power of non-specific effects far exceeds that commonly reported in the literature. Whilst the majority of research indicates biological plausibility that there are specific effects of exercise for AT, it is clear that further research is required to gain a more informed understanding of these processes. Furthermore, given that AT can be resistant to treatment in some cases, and the abundant presence of non-specific effects in other medical conditions, addressing influences beyond the peripheral tissue is also likely to be required [18].

## 1.2 Rationale Underpinning Further Study

As presented in this introduction, exercise-led management of AT is justified as the first line intervention despite the wide variation in current delivery of this. Given that this variation doesn't appear to significantly impact outcome, with no single approach demonstrating superiority over another [33,38], it is paramount that in order to optimise outcomes in AT, the mechanisms underpinning this require urgent exploration. Although, it is acknowledged that a greater understanding of the specific exercise parameters (such as sets, reps and load magnitude) and adaptations (such as neuromuscular adaptations and changes to

tendon length) is also required to optimise outcomes for AT, understanding influences beyond the peripheral tissue might also help to focus our interventions for the benefit of patients [50,51].

In attempt to add significance to this understanding, the thesis is presented as follows. Initially, a systematic review investigating the association and predictive nature of psychological variables and tendinopathy is presented. This review highlights contradictory findings, with conflicting results from high quality studies regarding the significance of factors such as depression, anxiety and kinesiophobia. A subsequent narrative review is then presented exploring possible explanations for this, specifically the cognitive and contextual factors which may underpin psychological factors. These factors include 1) self-efficacy, 2) the relationship between the patient and the therapist, and 3) the role of expectations which are considered in full. From this body of work, the Managing Achilles Pain (MAP) study was developed. The MAP study was a multi-methods study designed to evaluate the feasibility of the protocol for a future large longitudinal cohort study that would investigate the association and predictive relationship of working alliance, outcome expectations, adherence and self-efficacy with clinical outcome in the management of AT. In addition, to further inform the design of the MAP study, a critical evaluation of the most commonly used patient-reported outcome measure in AT was also undertaken.

### 1.2.1 Aim and Objectives

In the context of further research being required to better understand how to optimise exercise-led interventions for people with AT, this thesis aims to develop a greater insight by focusing on factors not previously investigated in tendinopathy research; cognitive and contextual factors and consider how they could contribute to optimising exercise-based interventions.

Underpinning this aim are several objectives:

- i. To systematically review current research evidence to determine if there is an association between outcome and psychological variables for people with tendinopathy (chapter two, *part one*)
- ii. To critically review potential underpinning mechanisms of the identified variables and consider how they can influence outcome for people with tendinopathy (chapter two, *part two*)
- iii. To critically review the most commonly used patient reported outcome measure (PROM) for people with Achilles tendinopathy; the VISA-A and determine suitability for the longitudinal cohort study (chapter three)
- iv. To evaluate the feasibility of conducting a future large longitudinal cohort study utilising an online platform for data collection to investigate the association and predictive relationship of working alliance, outcome expectations, adherence and self-efficacy with outcome in the management of Achilles tendinopathy, exploring methodological issues that may underpin future implementation of a



large longitudinal cohort study, reporting both quantitative and qualitative perspectives (chapters four, five and six)

## Chapter 2: Literature Review

### Summary

This chapter presents two literature reviews. *Part One* is a systematic review which explores the association and prognostic influence of psychological variables and tendinopathy. *Part Two presents a* narrative review, building upon the previous systematic review, which discusses potential cognitive and contextual factors that may influence the outcome for people receiving treatment for tendinopathy.

### *Part One: The Association of Psychological Variables and Outcome in Tendinopathy: A Systematic Review*

***Based upon Mallows A, Debenham J, Walker T, et al. Association of psychological variables and outcome in tendinopathy: a systematic review. Br J Sports Med 2016; bjsports-2016-096154. doi:10.1136/bjsports-2016-096154 (Appendix 1)***

### 2.0 Introduction

Chapter one discussed the complexities and current gaps in knowledge surrounding AT. In addition to these complexities, the chapter also highlights common ground; current recommendations for an exercise-led management approach through strength training and load-management [32,33]. The importance of load management may relate to the role loading history plays in the pathogenesis of AT. Significant change in load is considered a major contributing factor for the development of tendinopathy [9]. In a Delphi study of risk factors for AT, returning to sport following the 'off-season' was cited as the primary extrinsic risk factor for the development of AT in active individuals and trying to get fit as the number one risk factor for sedentary individuals [52]. In addition, many non-mechanical factors are considered to modulate load,

rendering an individual more or less likely to develop tendinopathy. These factors include diabetes mellitus [53], obesity [54,55], high cholesterol [54,56] and hypertension [53,57], with such factors considered as influential to the tendon's capacity to repair. For example, diabetes mellitus may alter the glycation of collagen within the tendon, affecting the tendon's structural integrity and therefore reduce the ability of the tendon to tolerate load [58]. Given such wide ranging possible influences on a person's presentation with AT, current management programmes need to tailor to individual presentations [6].

Tailoring management strategies to individual presentations has been suggested for other conditions which can also be resistant to treatment resulting in persistent pain states [59]. Strategies adopted include not only addressing physical factors such as loss of muscle strength or co-ordination, but also cognitive and psychological factors. Factors such as fear, anxiety, depression, stress and catastrophisation are all known to further affect the pain experience and disability levels [60]. To date, the association of such psychological factors has yet to be established in tendinopathy. Given the novelty of the review, initial scoping suggested there was limited primary research in this area specifically to AT. As such, as a hypothesis generating review, it was decided to expand this review to consider tendinopathy more broadly, offering individualised insight where relevant.

The purpose of this review was therefore to determine;

- 1) Are psychological variables, such as anxiety, depression and kinesiophobia, associated with tendinopathy?

- 2) Are outcomes from non-surgical management of tendinopathy associated to the presence of such psychological variables?

## 2.1 Methods

### 2.1.1 Protocol

A systematic review was performed using a predetermined protocol in accordance with the PRISMA statement (appendix 2) [61].

### 2.1.2 Data Sources and Search Strategy

An electronic search of MEDLINE, CINAHL, SPORTDiscus, EMBASE, PsycINFO and PsycARTICLES was undertaken from their inception to April 2016 by AM. The keywords used are displayed in table 2.1. The electronic search was complemented by hand searching the reference lists of the papers identified. Citation searching using the identified papers was also carried out and recognised experts in the field of tendinopathy were consulted via email in an attempt to identify any further published or unpublished studies. The search, including the application of the selection criteria, was conducted independently by two reviewers (AM & TW – a clinical physiotherapist and named author on the published paper) with any discrepancies resolved by discussion with a third reviewer (CL).

Search Terms	
1	Tendin* or tendon* or jumper's knee or lateral epicondy* or rotator cuff or subacromial pain or subacromial impingement or tennis elbow
2	Psycholog* or fear or depression or emotion* or anxiet* or catastroph* or distress
3	1 & 2 Combined

Table 2.1 Keywords used in the study selection process

### 2.1.3 Eligibility Criteria

#### 2.1.3.1 Population

Adult participants with a diagnosis of a tendon-related disorder, including tendinosis, tendinitis, tendinopathy or synonyms e.g. tennis elbow. In keeping with previous reviews, minimal diagnostic criteria of a largely preserved range of motion with pain provoked by loading of the tendon was required [62]. Studies with mixed or non-specific diagnoses, those concerned with the risk of developing tendinopathy or concerned with tendon rupture or post-surgical recovery were also excluded. In line with previous reviews [36], studies investigating tendinopathy considered to be as a result of an intervention e.g. fluoroquinolone and studies using participants with a known specific disease present (e.g. spondyloarthropathy) were also excluded.

#### 2.1.3.2 Outcome

Self-reported psychological measure(s) measuring emotional and cognitive variables known to be associated with persistent pain. These were namely; depression, anxiety, catastrophisation, fear and distress [60]. Measurements of pain and disability, plus any other clinical outcomes were included.

#### 2.1.3.3 Study Design

Any study design that incorporated measurement of psychological status and clinical measures of pain and / or disability. These included case study, case series, case-control, cohort, cross sectional, uncontrolled trials, quasi-experimental studies and randomised controlled trials (RCT). Narrative reviews, editorials or other opinion-based publications were excluded.

#### 2.1.3.4 Language

Studies published in any language were included.

#### 2.1.4 Quality Assessment

Quality assessment of the included studies was undertaken independently by two authors (AM & TW) using the Newcastle-Ottawa Scale (NOS). The NOS is a tool designed for cohort and case-control studies, which is reliable and valid for assessing quality of non-randomised studies [63]. Criteria evaluate potential bias based on selection of participants, comparability of study groups and attainment of exposure (case-control studies) or outcome of interest (cohort studies) [63]. The NOS uses a star rating system (semi-quantitative) where one star is awarded for each criterion of appropriate methods that are reported, with the exception of comparability of cohorts where two stars are awarded if a study controls for more than one comparison factor [63]. The scale ranges from zero to nine stars [64]. Discrepancies in the awarding of a star were resolved by discussion with a third reviewer (CL). As the effectiveness of an intervention was not of interest to the review, but rather the association of other measures, the NOS case-control scale and NOS cohort study scale were also used to evaluate included cross-sectional, case-series and intervention studies, respectively [65].

#### 2.1.5 Data Extraction

All data were extracted by a single reviewer (AM) and verified by a second reviewer (TW). Data included study characteristics, participant characteristics, source, sample size, intervention details, comparison group characteristics and

results. Quantitative data relating to psychological measures, pain and disability were also extracted.

#### 2.1.6 Data Synthesis

There was considerable heterogeneity within the included studies with regard to study design, patient populations and measures of psychological variables [66]. As meta-analysis should only be considered when a group of studies is sufficiently homogeneous in terms of participants, interventions and outcomes to provide a meaningful summary [67], a qualitative synthesis was deemed the most appropriate means to analyse the data. A qualitative synthesis refers to synthesis of findings from multiple studies that relies primarily on the use of words and text to summarise and explain the findings of the synthesis [68]. As threshold scores to differentiate between 'good' and 'poor' studies using NOS have yet to be established [63] the qualitative synthesis of data was informed by a scoring system to rate studies included in this review. The score for each study was calculated by dividing the number of stars achieved by the number of items. For example, if a study was awarded eight stars, this number would be divided by nine (the number of items on the NOS) to achieve a score of 0.88. Each study was graded as low, moderate or high quality based on this score. Cut-off points were designated *a priori* as: 0.00-0.44 low methodological quality, 0.45-0.70 moderate quality, and 0.71-1.00 high quality. Such cut-off points are often used to determine reference values for level of association / agreement by researchers and have been acknowledged as acceptable by experts in research methods [69,70] and utilised by previous reviews [71]. In accordance with previous reviews in the tendinopathy field [72], in order for

both quality and quantity of the available evidence to be taken into account, a rating system for levels of evidence was used to summarise data relating to psychological factors, tendinopathy and outcome (table 2.2) [73].

Strong evidence	Consistent findings in high-quality studies (n≥2)
Moderate evidence	Consistent findings among lower-quality studies (n>2) and / or one high quality study
Limited evidence	≤ relevant low quality studies
Conflicting evidence	Inconsistent findings amongst multiple studies
No evidence	No studies

Table 2.2 Levels of evidence [73]

## 2.2 Results

### 2.2.1 Study Selection

Figure 2.1 represents the results of the study identification process. Initially, 1243 citations were identified once duplications were removed. After screening, 27 articles were considered for full review. Applying the eligibility criteria, 10 articles, describing 9 studies were included for quality assessment. No identified studies published in a non-English language met the criteria for full review and no unpublished studies were identified.



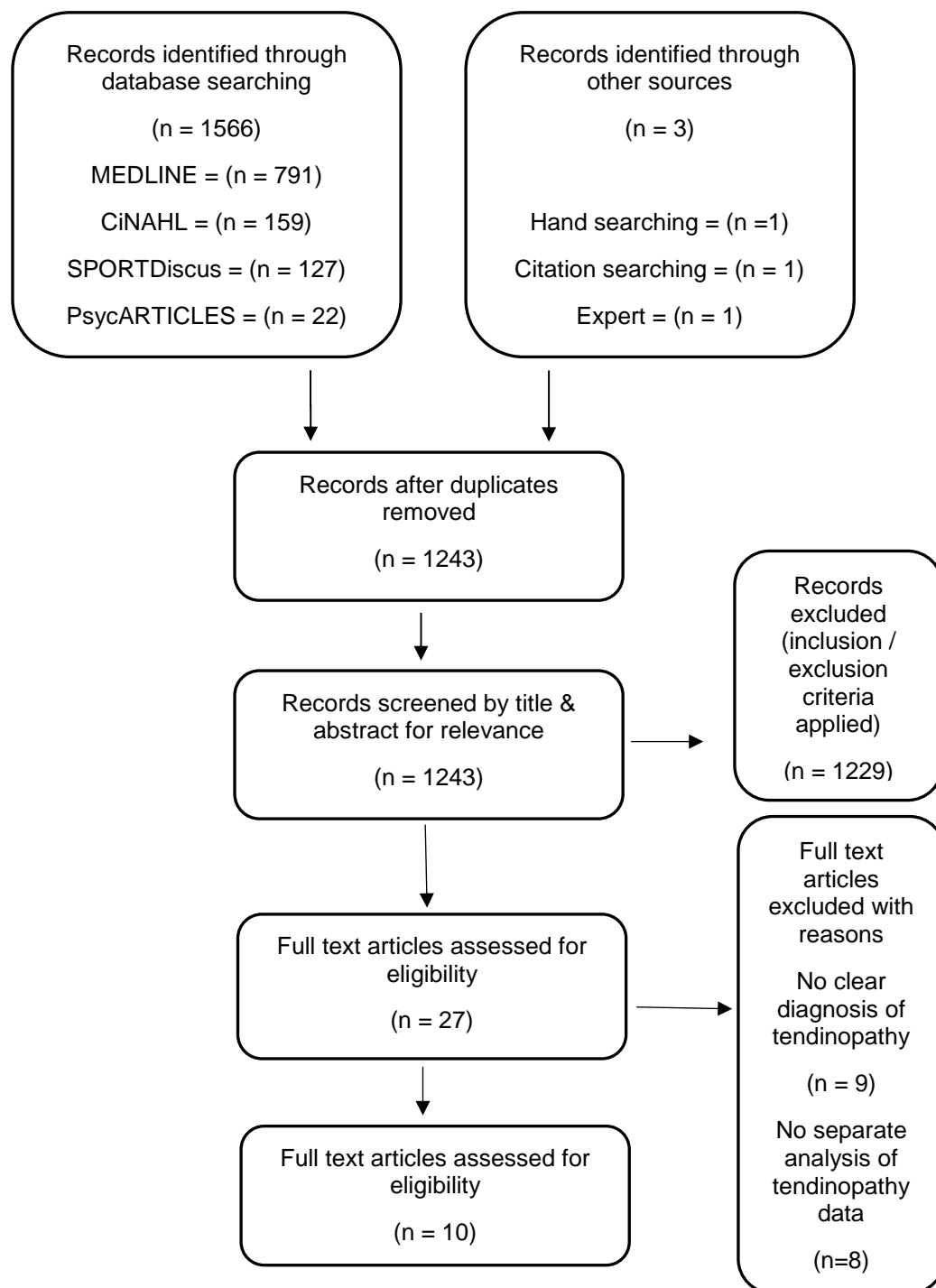


Figure 2.1 Study selection flow diagram

### 2.2.2 Newcastle-Ottawa Scale Assessment

The results of the quality assessment are shown in table 2.3. From the possible nine stars available, five studies were awarded eight stars [74–78] and deemed

of high quality, three studies were awarded seven stars [79–81] and also deemed of high quality and two studies were awarded six stars [82,83], deemed moderate quality (appendix 3).

Author / Year	Selection	Comparability	Exposure / Outcome	Total Stars	Quality of study
Alizadehkhaiyat et al (2007)	****	*	**	7	HIGH
Coombes et al (2015)	****	*	***	8	HIGH
Coombes et al (2012)	****	*	***	8	HIGH
Engelbrechtsen et al (2010)	****	*	**	7	HIGH
Garneval et al (2013)	****	*	**	7	HIGH
Haahr & Andersen (2003)	****	*	***	8	HIGH
Kromer et al (2014)	****	**	**	8	HIGH
Lee et al (2014)	****	*	***	8	HIGH
Silbernagel et al (2011)	***	*	**	6	MODERATE
van Wilgen et al (2013)	***	*	**	6	MODERATE

Table 2.3 Quality assessment using the Newcastle-Ottawa Scale

### 2.2.3 Study Characteristics

A summary of the characteristics of the included studies is presented in table

## 2.4

Study characteristics	Participants characteristic	(Intervention)	Psychological variable & outcome measure	Results
<p>Alizadehkhayat et al (2007)</p> <p><b>Case control</b> study to evaluate association between anxiety and depression and tennis elbow</p> <p>Liverpool, UK</p>	<p>Cases: 16 participants (50% male; mean age = 49 years) with tennis elbow recruited from an upper limb hospital clinic</p> <p>Tennis elbow defined as:</p> <ol style="list-style-type: none"> <li>Duration &gt;3/12</li> <li>Tenderness at the lateral epicondyle</li> <li>Pain with resisted wrist and middle finger extension</li> </ol> <p>Control: 16 healthy students and staff (56% male; mean age = 40 years)</p>	n/a	<p>Anxiety and depression measured using Hospital Anxiety &amp; Depression Scale</p>	<p>Hospital Anxiety &amp; Depression Scale significantly higher in tennis elbow group (sub scores <math>P &lt; 0.001</math>;) Anxiety subscale showed cases as 55% 'probable', 13% 'possible' and 31% 'non-case'. Depression subscale showed cases as 36% 'probable' 31% 'possible' 31% 'non-case'</p>
<p>Coombes et al (2015)</p> <p><b>Cohort</b> study to investigate the predictive capacity of early physical and psychological measures on short-term and long-term outcomes of pain and disability and mechanical hyperalgesia at the affected (tennis) elbow</p> <p>Brisbane, Australia</p>	<p>41 participants from a placebo group of a Randomised Control Trial (58% male; mean age = 49.9 years).</p> <p>Tennis elbow defined as:</p> <ol style="list-style-type: none"> <li>Duration &gt;6/52</li> <li>Unilateral</li> <li>Pain located over lateral epicondyle</li> <li>Severity of at least &gt;30 on a 100mm VAS</li> <li>Provoked by at least 2 of gripping, palpation, resisted wrist or middle finger extension, or stretching of forearm extensors with reduced pain free grip</li> </ol>	<p>Placebo group forming the cohort all (except 1 whom felt had recovered) received a single blinded injection of a negligible volume saline.</p>	<p>Kinesiophobia measured using Tampa Scale of Kinesiophobia.</p> <p>Anxiety &amp; depression measured using Hospital Anxiety and Depression Scale</p>	<p>Levels of anxiety, depression and kinesiophobia were not prognostic of pain and disability or mechanical hyperalgesia at 2 or 12 months.</p>

<p>Coombes et al (2012)</p> <p><b>Cross-sectional</b> study evaluating if sensory, motor, and psychological factors are different in severe lateral epicondylalgia compared with less severe cases and control</p> <p>Brisbane, Australia</p>	<p>Participants taken from a RCT</p> <p>Cases: 164 participants (62% male; mean age = 49.6 years).</p> <p>LE defined as:</p> <ol style="list-style-type: none"> <li>Unilateral elbow pain over the lateral epicondyle for longer than 6/52.</li> <li>Aggravated by a combination of palpation, gripping, and resisted wrist and / or finger extension.</li> </ol> <p>Control: 62 participants (55% male; mean age = 49.6 years)</p>	n/a	<p>Kinesiophobia measured using Tampa Scale of Kinesiophobia</p> <p>Anxiety &amp; depression measured using Hospital Anxiety and Depression Scale</p>	<p>No significant difference between cases and controls for levels of anxiety, depression, and kinesiophobia</p>
<p>Engelbrechtsen et al (2010)</p> <p><b>Cross sectional</b> study to examine influence of determinants of Shoulder Pain and Disability Index (SPADI).</p> <p>Oslo, Norway</p>	<p>200 participants (45.5% male; mean age 49.9 years).</p> <p>Sub acromial shoulder pain defined as- dysfunction or pain on abduction, normal passive gleno-humeral joint ROM, pain with 2 of 3 of following: Abduction at 0 or 30 degrees, external rotation, internal rotation.</p>	n/a	<p>Emotional Distress measured using the Hopkins Symptom Check List</p>	<p>29 % of variance of SPADI explained by combination of pain medication, emotional distress, flexion and hand-behind-back ROM. Emotional distress contributes 7.5% of total variance of SPADI (p &lt;0.01). Emotional distress was not significant when the variables of pain and function were included in the model</p>
<p>Garnevall et al (2013)</p> <p><b>Cross-sectional</b> study examining psychosocial / personality factors and physical measures in tennis elbow</p>	<p>Cases: 54 participants recruited via adverts (30% males; mean age = 48.7 years).</p> <p>Tennis elbow defined as 2 or</p>	n/a	<p>Anxiety measured by Swedish Scales of Personality</p>	<p>Significant difference was found between cases and controls for somatic anxiety (P = 0.009)</p>

<p>correlating them with Nirschl's classification</p> <p>Norwegian primary care setting</p>	<p>more of the following</p> <ol style="list-style-type: none"> <li>Pain on palpation of the epicondyle</li> <li>Pain on passive stretching of the wrist extensor muscles</li> <li>Pain on resisted extension of the wrist</li> <li>Pain on resisted finger extension</li> </ol> <p>Controls: 43 recruited from the region (42% males; mean age = 48.8 years).</p>			
<p>Haahr &amp; Andersen (2003)</p> <p><b>RCT</b> performed to determine whether minimal intervention involving information about the disorder, encouragement to stay active and instruction in graded self-performed exercises could enhance the prognosis of lateral epicondylitis compared with usual treatment, to quantify workforce factors associated with the prognosis, and to consider treatments given in general practice.</p> <p>Ringkjoebing County, Denmark</p>	<p>Participants recruited consecutively from GP practice.</p> <p>Cases: 141 (43% male; 58% age &gt;40 years).</p> <p>Control: 125 (48% male; 65% age &gt;40 years).</p> <p>Tennis elbow defined as:</p> <ol style="list-style-type: none"> <li>Pain in the elbow region</li> <li>Direct and indirect tenderness at or within 2cm of lateral epicondyle on resisted extension of the wrist and / or third finger.</li> </ol>	<p>Cases: advised that lateral epicondylitis is a self-limiting condition with a favourable prognosis. Participants were informed no specific treatment improves the overall long-term prognosis. Advice was given to avoid total rest, stay active and avoid activities that exaggerate the pain. Patients were encouraged to adjust work conditions if possible. Instructions were given by an ergonomist in performing a graded exercise programme.</p> <p>Control: treatment as preferred and agreed upon by the patient and the patient's GP.</p> <p>No blinding to treatment.</p>	<p>Distress measured by Setterlind two-item symptom scale.</p>	<p>Continued high pain score (and low function) with reduction at 1 year of less than 50% was significantly associated with high baseline distress (Odds Ratio 1.9, Confidence Interval 1.0 - 4.0).</p>

		Primary outcome assessment was done independently. Randomisation performed by primary investigator according to a predetermined random sequence of number supplied to GP practices in sealed envelopes.		
<p>Kromer et al 2014</p> <p><b>Cross-sectional and longitudinal</b> study to investigate the associations among pain, catastrophising, fear, and disability and the contribution of fear avoidance beliefs to disability at baseline and at 3 month follow-up (on subacromial shoulder pain).</p> <p>Germany, general practice.</p>	<p>Data taken from a RCT investigating 2 different physical therapy interventions for participants with subacromial pain.</p> <p>Cases: 46 Control: 44</p> <p>Baseline demographics presented for group overall (49% male; mean age 51 years). Block randomisation process.</p> <p>Subacromial pain defined as;</p> <ol style="list-style-type: none"> <li>Symptoms for at least 4 weeks</li> <li>Main complaints in the GHJ region or proximal segments of the arm</li> <li>Presence of one of the following signs; Hawkins-Kennedy, painful arc with active abduction or flexion,</li> </ol>	<p>Both cases and controls: received 10 sessions within 5/52 and continued the home exercises for another 7/52 Supervised stretching and strengthening exercises for the shoulder, shoulder girdle and thoracic spine.</p> <p>Cases: in addition received;</p> <ol style="list-style-type: none"> <li>examination-based manual mobilisations for the shoulder complex and cervical spine</li> <li>individualised education about the pathology</li> <li>instructions for the most provocative ADLs to reduce pain events during the day.</li> </ol>	<p>Kinesiophobia measured by Fear-Avoidance Beliefs Questionnaire and Catastrophisation measured by Pain Catastrophizing Scale.</p>	<p>Disability showed significant correlations with pain (<math>P&lt;0.1</math>; 0.401), catastrophizing (<math>P&lt;0.1</math>; 0.369), and fear-avoidance beliefs (<math>P&lt;0.5</math>; 0.237). Correlations between pain and catastrophizing (<math>P&lt;0.1</math>; 0.318) and between catastrophizing and fear-avoidance beliefs (<math>P&lt;0.1</math>; 0.293) were significant.</p> <p>Hierarchical regression model used to show:</p> <p>Baseline: Fear-avoidance beliefs significantly contributed to disability at baseline.</p> <p>3 Months: Fear avoidance and scores were not predictive of disability at 3 months</p>

	Neer impingement sign d. Pain during one of the following resistance tests; external rotation, internal rotation, abduction or flexion.			
<p>Lee et al 2014</p> <p><b>Cohort</b> study to establish the relationship between positive and negative phrasing and participants' coping with lateral epicondylitis</p> <p>Seoul, South Korea</p>	<p>108 consecutive participants with isolated lateral epicondylitis of less than 6/12 of symptoms. 91 participated at follow up 1 year later (45% male; mean age = 54 years</p> <p>Lateral epicondylitis defined as the presence of all 3 of the following;</p> <ol style="list-style-type: none"> <li>pain located at the lateral aspect of the elbow</li> <li>point tenderness over the lateral epicondyle</li> </ol> <p>pain on resisted wrist extension with the elbow in full extension.</p>	<p>Wait &amp; see policy; self-stretching, counterforce bracing, pain medication and education that the tendon has temporarily weakened and it will run its course over 12-18 months.</p> <p>All followed up at 4/52 and were discharged (n=101) or referred for physical therapy, corticosteroid injection or surgery (n=7 and excluded from follow up at this stage).</p>	<p>Catastrophisation measured by Pain Catastrophisation Scale.</p> <p>Depression measured using Patient Health Questionnaire</p>	<p>Pain Catastrophizing Scale used at baseline and 12/12. Patient Health Questionnaire (depression screening tool) was also used at follow up only</p> <p>Follow up at 12/12 was conducted by telephone and participants were asked to describe the nature of their condition.</p> <p>At 12/12, those who used positive phrasing terms had significantly lower catastrophisation scores (<math>P = 0.005</math>) and a larger improvement in scores (<math>P = 0.039</math>).</p> <p>Multiple analyses showed that negative phrasing (<math>P &lt; 0.001</math>) and depression (<math>P &lt; 0.19</math>) were independently associated with seeking additional treatment</p>

<p>Silbernagel et al 2011</p> <p><b>Case series</b> to evaluate the 5 year outcome of participants (with Achilles tendinopathy) treated with exercise alone and to examine if certain characteristics, such as level of kinesiophobia, age and sex were related to the effectiveness of the treatment.</p> <p>Gothenburg, Sweden</p>	<p>34 cases (53% male; mean age =51 years). Cases were originally recruited into a randomised study evaluating the effect of continuing sporting activity compared with rest for the initial 6 weeks whilst undertaking identical exercise programme. Achilles tendinopathy defined as a combination of;</p> <ol style="list-style-type: none"> <li>Achilles tendon pain</li> <li>Swelling</li> <li>Impaired performance</li> </ol>	<p>Progressive tendon loading programme for 12/52 to 6/12</p>	<p>Kinesiophobia measured by Tampa Scale of Kinesiophobia</p>	<p>Significant (<math>P = 0.005</math>) negative correlation (-0.590) between the level of kinesiophobia and heel-rise work recovery (a battery of tests consisting of 2 jump tests, 2 strength tests, and 1 endurance test).</p>
<p>van Wilgen et al 2013</p> <p><b>Cross-sectional</b> study to investigate whether somatosensory changes represent a plausible explanation for pain in participants with chronic patellar tendinopathies and second to investigate if psychological comorbidities may contribute to pain.</p> <p>The Netherlands</p>	<p>Cases: 12 (100% male; mean age 23.3 years) athletes. Patella tendinopathy defined as:</p> <ol style="list-style-type: none"> <li>History of knee pain in the region related to exercise</li> <li>Tenderness on palpation</li> <li>6 months duration</li> <li>Lower than 70 points on the Victorian Institute of Sports Assessment – Patella (VISA- P)</li> </ol> <p>Controls: 20 (100% male; mean age 24.7 years) recruited from local sports clubs via advertising.</p>	<p>n/a</p>	<p>Phobic anxiety, anxiety, depression, somatization, insufficiency of thinking and acting, interpersonal sensitivity, hostility, and quality of sleep measured by Symptom Check List-90. Negative mood depression (eight items), anger (seven items), fatigue (six items), positive mood vigor (five items), and tension (six items) measured by Profile of Mood States questionnaire.</p>	<p>The Symptom Check List-90 and Profile of Mood States questionnaires demonstrated no significant differences between cases and controls.</p>

Table 2.4 Summary of the characteristics of the included studies



#### 2.2.4 Study Design

The most frequently used study design was cross sectional (n=5) [74,77,80,81,83]. Other study designs were case control (n=1) [79], case series (n=1) [82], randomised controlled trial (n=1) [76], and cohort (n=2) [78,84].

#### 2.2.5 Participants

Two studies reported data utilising one set of participants [74,84]. Thus, the ten articles included for review identified nine studies. The studies included 1108 participants, 580 women and 528 men. The mean age of the participants was 48.8 years, ranging from 18 [81] to 82 years [78]. Six studies included participants with lateral epicondylalgia (LE) [74,76,78–80,84], two studies included participants with rotator cuff tendinopathy (RT) [77,81], one study included participants with Achilles tendinopathy (AT) [82], and one study included participants with patella tendinopathy (PT) [83].

#### 2.2.6 Findings

##### 2.2.6.1 Psychological Variables (Catastrophisation, Distress, Anxiety and Depression and Kinesiophobia) and Tendinopathy

Overall, there is conflicting evidence relating the presence of psychological variables and their association with tendinopathy. Six studies (5 of high quality and 1 of moderate quality) support a statistically significant positive association between the presence of psychological variables and tendinopathy [76–80,82]. Four of these investigated LE, one RT and the other AT. Four studies (3 of high quality and 1 of moderate quality) demonstrated no statistically significant association between psychological variables and tendinopathy [74,83,84]. Two of these investigated LE, one RT and the other PT.

#### 2.2.6.2 Catastrophisation

Two studies investigated the association of catastrophisation and tendinopathy [77,78]. One high quality study investigating RT supported a statistically significant positive association of the presence of catastrophisation and tendinopathy at baseline [77]. The other study investigating LE was also of high quality and showed a statistically significant positive relationship between a reduction in catastrophisation and a reduction in the need for additional treatment [78].

#### 2.2.6.3 Distress

Two high quality studies investigated the association of distress and tendinopathy [76,81]. One study investigated RT and showed no statistically significant association between the presence of distress and pain and function associated with tendinopathy [81]. The additional study investigated LE and supported a statistically significant positive association of the presence of distress and tendinopathy [76].

#### 2.2.6.4 Anxiety and Depression

Four studies investigated anxiety in conjunction with depression [74,79,83,84]. One study investigated anxiety without depression, but instead included aggression and extraversion factors [80]. Two high quality studies [74,84] investigating LE and one moderate quality study [83] investigating PT demonstrated no statistically significant association between the presence of anxiety, depression and tendinopathy. One high quality study investigating LE supported a statistically significant positive association between the presence

of depression and tendinopathy [79]. Two high quality studies both investigating LE supported a statistically significant positive association of the presence of anxiety and tendinopathy [79,80].

#### 2.2.6.5 Kinesiophobia

Three studies investigated the association of fear-avoidance and tendinopathy [74,77,82]. One high quality study investigating LE demonstrated no statistically significant association between kinesiophobia and tendinopathy [74]. Another high quality study investigating RT supported a statistically significant association of the presence of fear-avoidance beliefs and disability at baseline [77]. One moderate quality study investigated AT and showed a statistically significant negative correlation between levels of kinesiophobia and heel-rise work recovery (a battery of tests consisting of two jump tests, two strength tests, and one endurance test), suggesting a negative effect on the effectiveness of treatment [82].

#### 2.2.6.6 Psychological Variables (Catastrophisation, Distress, Anxiety and Depression and Kinesiophobia) and Prognosis

Overall, there is conflicting evidence relating the presence of psychological variables and their association with outcome in tendinopathy. Three studies (2 of high quality and 1 of moderate quality), two investigating LE and the other AT support a statistically significant positive association [76,78,82]. Two studies (both of high quality), one investigating LE and the other RT showed no association [77,84].

#### 2.2.6.7 Catastrophisation

Two studies investigated the association of catastrophisation and outcome in tendinopathy [77,78]. One high quality study, investigated RT and showed high baseline catastrophisation scores were not predictive of disability at three months [77]. The other, also of high quality investigated LE and showed a statistically significant positive relationship between a reduction in catastrophisation and a reduction in the need for additional treatment at twelve months [78].

#### 2.2.6.8 Distress

One high quality study investigated the association of distress and outcome in LE [76]. This study showed a statistically significant association with continued high pain scores and a less than 50% reduction in pain scores at twelve months associated with high baseline distress.

#### 2.2.6.9 Anxiety and Depression

One high quality study investigated the association of anxiety and depression and outcome in LE [84]. This study found no statistically significant association between anxiety, depression and pain and disability scores at twelve months. One high quality study investigated the association of depression and LE [78]. This study showed depression was independently statistically significant for an association with seeking additional treatment at twelve months.

#### 2.2.6.10 Kinesiophobia

Three studies investigated the association of fear avoidance and tendinopathy [77,82,84]. One high quality study investigated LE and found no statistically significant association between kinesiophobia and pain and disability at twelve months [84] and another high quality study investigating RT found high baseline kinesiophobia scores were not predictive of disability at three months [77]. One moderate quality study investigating AT found at five year follow up, increased fear of movement was statistically significant for an association with reduced heel-rise work recovery [82].

#### 2.2.6.11 Summary of Key Findings

#### 2.2.6.12 Lateral Epicondylalgia

There is conflicting evidence from multiple research studies surrounding the association of anxiety, depression and LE [74,78–80,84]. Strong evidence from one high quality cross-sectional study and one high quality cohort study, suggests kinesiophobia is not associated with LE [74,84]. Moderate evidence from one high quality RCT links distress with LE [76]. Moderate evidence from one high quality cohort study links catastrophisation with LE [78].

#### 2.2.6.13 Rotator Cuff Tendinopathy

There is moderate evidence from one high quality cross-sectional study suggesting distress is not associated with RT [81]. There is moderate evidence from one high quality cross-sectional and longitudinal study to suggest that kinesiophobia and catastrophisation are associated with RT at baseline, but are not associated with a suboptimal outcome [77].

#### 2.2.6.14 Patella Tendinopathy

There is limited evidence from one moderate quality cross-sectional study to suggest anxiety and depression are not associated with PT [83].

#### 2.2.6.15 Achilles Tendinopathy

There is limited evidence from one moderate quality case series to suggest kinesiophobia is associated with AT [82].

### 2.3 Discussion

This systematic review suggests overall there is conflicting high quality evidence relating to the association of psychological variables and outcome in tendinopathy. Previous systematic reviews considering features of tendinopathy have investigated structural changes [19] and central nervous system (CNS) changes [85,86], but consideration to psychological variables has not been well evaluated in the tendinopathy literature [87,88]. The review was undertaken in accordance with published guidelines [61]. Whilst it is acknowledged criteria for 'good' and 'poor' studies have yet to be established for the NOS [63], according to the scoring system and cut off points designated *a priori*, the majority of studies were considered to be of a high quality, whilst two studies were considered of moderate quality. The conflicting high quality evidence as to the association of psychological features in tendinopathy could potentially be explained by several factors.

Firstly, the variance in population under investigation. Although most of the participants were around the mean age of 50 years, one study [83] had a mean

age of 23.3 years. Given that increasing age may be a risk factor for developing psychological variables such as depression [89], contrasting results from the comparison of such differing study populations may be attributable in part to age differences. Additionally, participants were recruited from various settings ranging from specialist hospital settings [79] to university populations [83] and general care [76]. Two studies (from three articles) investigated anxiety and depression in LE and utilised the Hospital Anxiety and Depression scale [74,79,84]. One population [74,84] was recruited via advertising from the general population and the other from consecutive attendance at an upper limb clinic [79]. While inclusion criteria for both populations were similar, the study [79] whose population was taken from attendees at an upper limb clinic found a positive association between LE and anxiety and depression whilst the population who self-selected for inclusion did not [74,84]. Reasons behind these contrasting findings may consequently lie in the population studied. Those attending a specialist service may have a longer duration of symptoms or failed previous interventions; cross-sectional associations with low mood may in part reflect distress that occurs as a consequence of longer-term pain [90]. Consequently, this population may represent a separate sub-population of LE which appear more vulnerable to associated psychological variables alongside tendinopathy. Whilst it is acknowledged the variation in population may contribute to discrepancies between the studies, it was considered that the inclusion of all study types represents the evidence base as a whole; thus allowing the clinician to make their clinical reasoning based on a synthesis of all the available evidence [91].

The second potential explanation underpinning these findings reflects anatomical discrepancies. The majority of studies included in this review investigated tendinopathy of the upper limb; six investigated LE [74,76,78–80,84], two investigated RT [77,81], one PT [83] and one AT [82]. The efficacy of treatment, and potential relationship of psychological variables, may be viewed as dependent on the specific tendon's anatomical and biomechanical properties [92]. For example, with AT most commonly manifesting in the mid-portion and LE occurring as an enthesopathy [93,94]. Nonetheless, this review has highlighted conflicting findings both within and between upper limb and lower limb tendinopathies. For example, kinesiophobia may be associated with AT [82], but no psychological variables were associated with PT [83] and the conflicting evidence which exists for the association of depression and anxiety with LE [74,78–80,84]. As such, considerations beyond the geographical location of individual tendon may be useful.

There is growing evidence of changes beyond the tendon exist in people with tendinopathy. Such changes have been identified in the CNS and may contribute to pain and disability in tendinopathy [18,95–98]. To date these changes have been predominately investigated in the upper limb [85,95], with lower limb data limited [83,98] or even negating [99]. Although more research is required, particularly in the lower limb, it appears that there may be an association between persistent tendinopathy and sensitisation of the nervous system [98]. Changes in the CNS or central sensitisation are much more than generalised hypersensitivity to pain and includes increased responsiveness to stress, emotions and mental load [100]. Consequently, differing dominant



states of sensitivity (peripheral or centrally driven) may have influenced the association of psychological variables. A possible area for further study would be to investigate this potential influence.

Finally, differing cognitive factors which may underpin the psychological variables and their amenability to change could also help explain the conflicting results from the high quality studies included in this review. Factors such as hope, beliefs, information and expectations have all been shown to influence the pain experience [101,102]. The relationship between the patient and the practitioner has been shown to be useful in predicting and influencing outcomes in other chronic conditions such as low back pain [103,104] and a positive alliance is seen to have an overall positive influence on rehabilitation [105]. To date, the management models for tendinopathy have not included such factors [9,94,106,107]. Whilst it is recognised that for some tendinopathies in particular, PT and AT, there are a limited number and quality of studies exploring psychological variables and outcome, within the context of the conflicting results from multiple high quality studies in other tendinopathies, further exploration of cognitive processes connected with psychological variables and means of influencing these seems warranted as one avenue of further enquiry. Consequently, these factors are the focus of the discussion in *part two* of this chapter.

## 2.4 Limitations

Whilst the evidence from this review suggests there may be a statically significant association between some psychological variables and the

presence of and prognosis of tendinopathy in some, it remains unclear if this is clinically meaningful. To understand if a change in psychological status is perceived as clinically meaningful it is important to be sure the smallest change in the score is beyond measurement error (knowing the minimal detectable change of the measure) and whether the smallest change in score is perceived as important to patients, clinicians or relevant others (knowing the minimal important difference of the measure) [108]. To date, these values are unknown in the measures used within a population with tendinopathy. As such, it is currently uncertain whether any change in association of a psychological variable would be both statistically significant and clinically important.

## 2.5 Future Directions

The findings of the current review suggest that taken as a whole, there is conflicting evidence as to the significance of psychological variables in tendinopathy. However, this conclusion is based on a limited volume of research. Specific psychological variables may be associated with tendinopathy and suboptimal outcomes from treatment, although the uncertainty surrounding this suggestion is clearly recognised.

While a clear explanation for the response of tendinopathy to therapeutic exercise is lacking, further studies to identify the underlying mechanism(s) are warranted. Theories surrounding the potential influence of the CNS, biochemical and myogenic factors have been proposed [18,95,109–111]. Whilst acknowledging the likelihood of a multifactorial explanation [112], to date psychological response explanations have not been considered and the

findings of this review suggest further research is warranted. Currently it is unclear how psychological variables might be associated with suboptimal outcome, if at all. One possible explanation that has been hypothesised might be those with fear of pain could perform less exercise with less intensity [82]. Appropriate levels of intensity are likely to be required for the exercise to induce a sufficient response from the proposed mechanisms outlined above and reduce associated pain and disability.

## 2.6 Conclusions

Conflicting evidence exists surrounding the significance of the association of anxiety, depression and LE. However, strong evidence suggests LE is not associated with kinesiophobia. Moderate evidence links catastrophisation and distress with LE, with distress being associated with a less than 50% reduction in pain at twelve months. Conflictingly, moderate evidence suggests distress is not associated with RT, but kinesiophobia and catastrophisation are. However, this may not lead to a suboptimal outcome. Limited evidence exists linking psychological variables and AT and PT, but current evidence suggests PT is not associated with anxiety or depression and kinesiophobia may be linked with suboptimal outcomes in AT. As such, when a person is suspected to have tendinopathy, there may be clinical merit in considering using validated screening tools for the presence of psychological variables which may contribute to suboptimal outcomes. These include the Tampa Scale of Kinesiophobia, Pain Catastrophisation Scale and the Hospital Anxiety and Depression Score. These measures may be particularly important when considering more invasive procedures such as surgery, as they are associated

with negatively influencing outcomes [113–115]. Management to address the presence of specific variables might then usefully be incorporated as means of addressing these potentially relevant factors in the treatment package. Clearly, this is a suggestion that requires validation through further testing but theories underpinning this will now be discussed more.

## *Part Two: Cognitive and Contextual Factors to Optimise Clinical Outcomes in Tendinopathy*

*Based upon Mallows AJ, Debenham JR, Malliaras P, et al Cognitive and contextual factors to optimise clinical outcomes in tendinopathy Br J Sports Med Published Online First: 09 October 2017. doi: 10.1136/bjsports-2017-098064 (Appendix 4)*

### 2.6 Introduction

Substantial variety has been a feature of the exercise prescription used in tendinopathy research to date. However, this variation in exercise does not appear to affect the results positively or negatively. Exercise programmes as different as a concentric-eccentric heavy slow loading programme performed three times per week and eccentric only exercises performed twice daily, seven days per week have achieved similar results [38]. Whilst within-group mean severity scores improve, individual responses are wide ranging for the same exercise programme [38] and success rates vary from 44% failing to improve [42] to 100% success [41] for a similar exercise intervention.

It is acknowledged that heterogeneity in the research cohorts (e.g. age, sex, chronicity, co-morbidities) [9] or variations in how the exercise programme was delivered are likely play a role in explaining these findings. For example, the exercise programme may not have been progressed enough or at the correct rate; the progression of rehabilitation is related to symptom response to load and muscular function, both of which also determine return to full function [106]. Alternatively, the person with tendinopathy may continue to perform activities which maintain their symptoms, potentially highlighting inaccurate beliefs and expectations about pain and the need for appropriate education [106]. Additionally, biomechanical requirements, for instance landing with a stiff knee

which has been associated with the development of patella tendinopathy [116], kinetic chain deficits, such as restricted ankle dorsiflexion [117] or quadriceps and hamstring flexibility [118] which can be associated with the development of patella tendinopathy, or systemic comorbidities, such as the presence of diabetes [11] may have not been adequately addressed; such considerations are recommended to form part of a comprehensive programme [106,119]. However, in light of the findings from chapter two *part one*, where conflicting evidence was presented relating to the significance of psychological variables in tendinopathy, here, an added consideration is provided to offer further potential insight into explaining the current equivocal results from vastly differing exercise programmes for tendinopathy - cognitive and contextual factors that affect each individual therapeutic encounter [120,121].

## 2.7 Psychosocial Impact

Beliefs and fears relating to pain and disability have received little attention in current tendinopathy management models. For example, local tissue pathology-pain models, such as the continuum model of tendon pathology [6,9], solely theorise peripheral nociceptive tissue-based (structure and function of the tendon) drivers of pain as guidance for management. Whilst the identity of the nociceptive driver in tendinopathy remains elusive, the suggested interworking of the reactive tendon and dysrepair / degenerative tendon states may implicate paracrine signalling (a form of cell-to-cell communication in which a cell produces a signal to induce changes in nearby cells, altering the behaviour of those cells) by tendon cells (figure 2.2) [17].

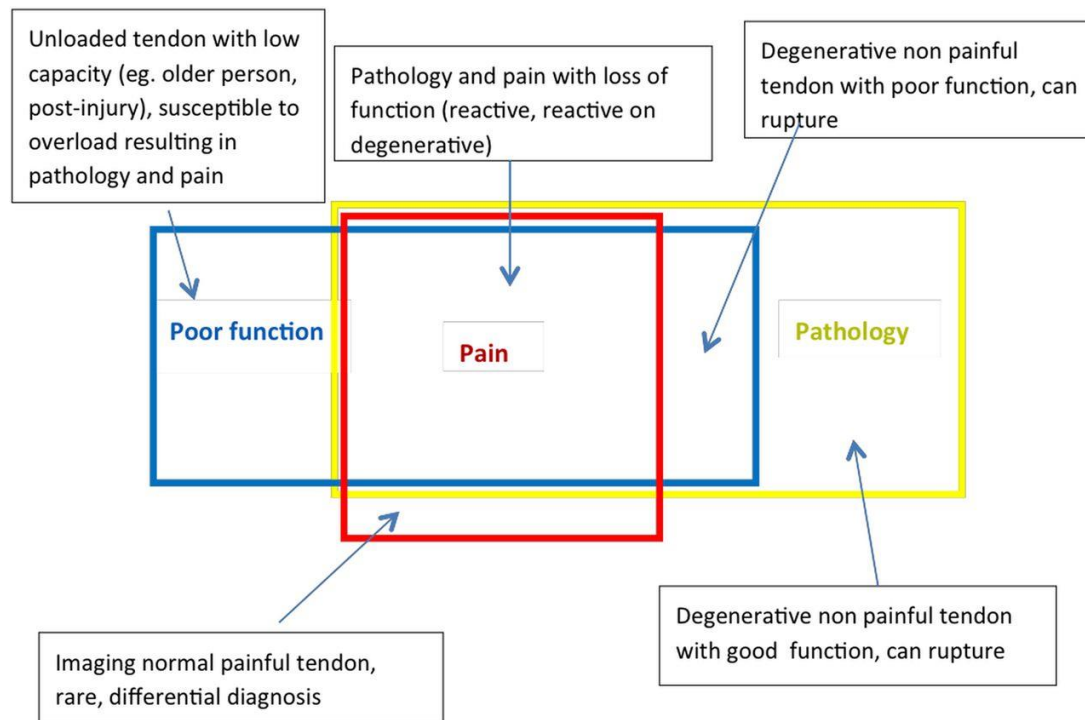


Figure 2.2 Relationship between structure, function and pain according to the continuum model [9]

Whilst the importance of the biologic contribution to tendinopathy is not dismissed, such models are confounded by lack of the association between pathology and pain [19], and as such fail to recognise the important role of mediators beyond the tendon tissue which can affect the painful experience; nociception and pain are neither proportionate nor synonymous terms [122].

Littlewood et al [95] suggest pain associated with tendinopathy, that is lasting longer than anticipated, be considered within a framework that recognises such mediators. Pain is considered as a protective output mechanism of the CNS; serving to guard from further threat [122]. However, this output is influenced by multiple factors, including a person's culture, understanding and behaviours; this influence may result in a magnification or dampening of the pain, resulting in a disproportionate experience to the actual threat (tissue pathology) [123].

For example, a negative perception such as believing pain is a sign of further tissue damage, may lead to fear avoidance and consequently a deconditioned tendon, placing the person at further risk of recurrence [95].

Smith et al [124] have recently revisited the Mature Organism Model [123] to highlight such complexity and overlapping influences (figure 2.3). This model suggests that in addition to pathological and physical status, the clinical status of tendinopathy may also be influenced by factors including, but not restricted to, psychosocial variables, treatment expectations, recall of prior health and pain or health status of the patient at the time of scale administration.

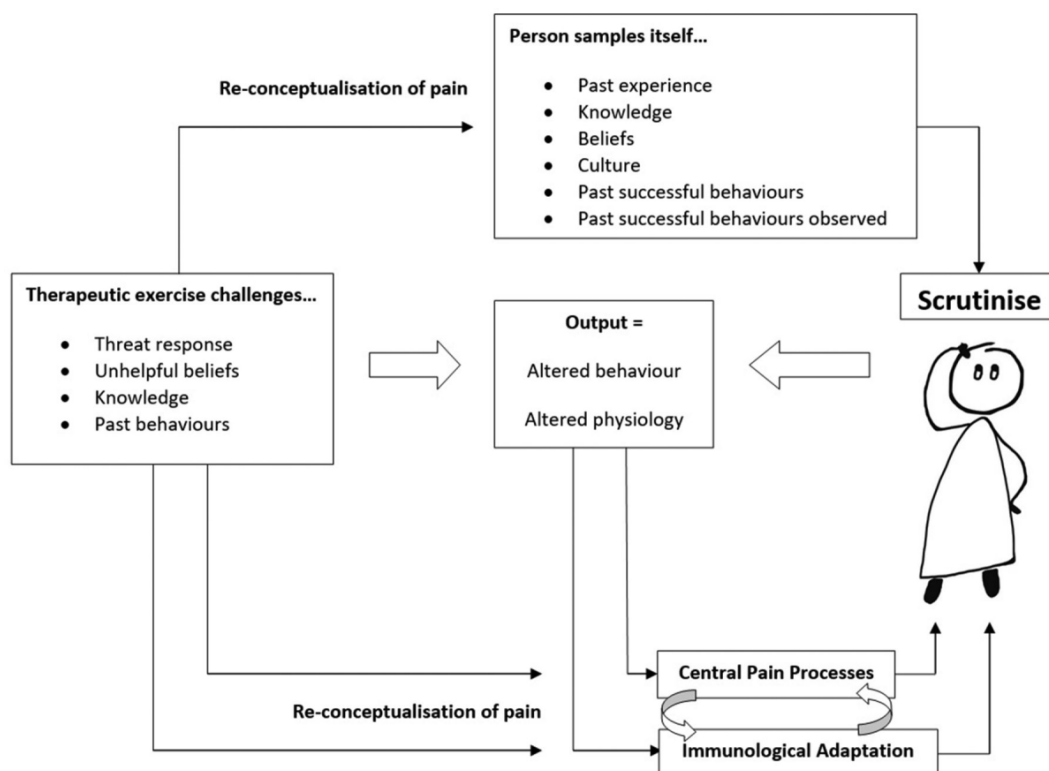


Figure 2.3 The overlapping influences which may mitigate and moderate musculoskeletal pain. Smith et al [124]



Mediation of psychosocial variables may offer another explanation as to the response to commonly used loading programmes for the management of tendinopathy. A confrontational graded exposure intervention, resembling education which aims to address individual cognitive behavioural barriers [125] and to influence hope and positive beliefs [102] combined with a progressive loading programme may serve to reduce fear, anxiety and catastrophisation and consequently enhance performance by reducing pain and disability. Such strategies are required to be tested through further research, but this type of approach has been utilised successfully in other persistent pain conditions [125] where changes in tissue state also do not appear to correlate with reductions in pain and disability [19,126].

Underpinning the amenability of mediation to psychosocial variables to optimise outcome is the concept of ‘working alliance’. Working alliance, also known as ‘therapeutic alliance’ or ‘patient-therapist relationship’, can be defined as “the working rapport or positive social connection between the patient and the therapist” [127]. Decades of research have consistently linked the quality of the alliance between therapist and patient with outcome [105,128,129]. The magnitude of this relation appears to be independent of the type of therapy and whether the outcome is assessed from the perspective of the therapist, client, or observer [128]. Working alliance is positively associated with adherence behaviours and rehabilitation outcomes [130–132] and as such may help explain why clinicians or researchers achieve different outcomes when the prescription of exercises remains the same or similar. Whilst working alliance has been shown to positively correlate with treatment adherence,

outcomes and satisfaction [130–132], a person's level of self-efficacy has the ability to undermine motivation and enhance dissatisfaction, negatively affecting adherence [133,134] and has been shown to be a significant predictor of outcome [22]. Self-efficacy may relate to efficacy expectations or outcome expectations [135]. Efficacy expectations are beliefs about one's ability to perform the task, and are seen as determinants of whether one attempts the task, how persistent one is and ultimately how successful one is [136]. Outcome expectation relates to a person's estimate that a given behaviour will lead to certain outcomes [135]. It seems sensible to suggest that if exercise for AT is going to be effective then adherence to that exercise programme is necessary. Indeed, adherence to therapeutic exercise programmes are associated with outcome in other persistent musculoskeletal conditions [137,138]. Adherence to exercise programmes has generally received little reporting in published studies specifically focusing on tendinopathy [139]. Studies which have published adherence rates report wide ranging values; 27%-92% good adherence (defined as >50% of the exercises performed) [38,140–142]. Given the association of adherence to exercise with outcome, and, as working alliance and self-efficacy are considered to underpin adherence behaviours (figure 2.4), further consideration to these factors in tendinopathy appears justified.

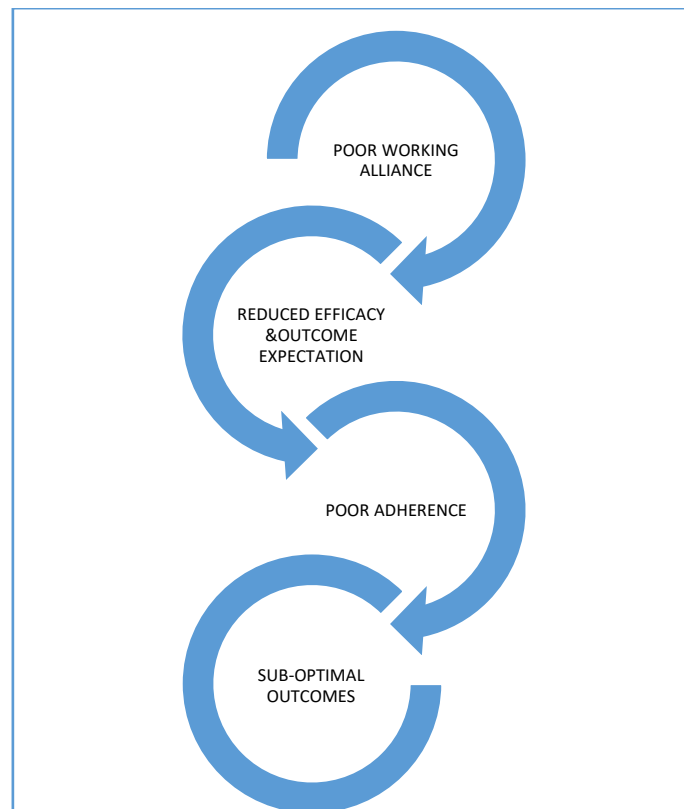


Figure 2.4 Cognitive and contextual factors which may negatively influence clinical outcome

### 2.7.1 Working Alliance

Working alliance (WA), involves technical skill and the reflective capacity of the therapist to respond to the patient, but extends beyond good communication to a sense of collaboration, warmth and support [143,144]. The influences on WA include a mix of interpersonal skills, practical skills and individualised patient centred care [145] and is fundamental to therapeutic process [104].

### 2.7.2 Developing an Effective Working Alliance

Ensuring an effective alliance between the clinician and the person with tendinopathy would seem central to implementing a successful rehabilitation programme for reasons including building trust and adherence. Focusing on a

patient-centred interaction style, related to the provision of emotional support and allowing patient involvement in the consultation processes have been shown to effectively facilitate this [146]. To enable this, a mix of interpersonal, clinical, and organisational factors are important [145]. Such interpersonal skills may include humour, making time for ordinary conversation, appearing socially comparable and giving due attention to the individual [143]. Adopting attitudes which appear paternalistic or arrogant, for example giving the impression the tendinopathy is the patient's *'fault'* because of training errors [106], kinetic chain deficits [117,118] or biomechanical variances [116], should be avoided and clinicians can demonstrate humility by establishing to the patient that they value the importance of both physical and emotional needs [147].

A clinician's verbal and non-verbal skills have the ability to influence an effective WA [121]. Non-verbal skills include the clinician's own non-verbal expressions and the ability to read the patient's non-verbal body language [148]. Affirmative head nodding, forward leaning and suitable body positioning are recommended [148,149]. Verbal skills include the use of positive messages [150,151]; reassurance around perceived damage may be useful *'your tendon might not look good on imaging, but your outlook is still good'* [19]. Additionally, clinicians should avoid interrupting and allow the person with tendinopathy to tell their unique story [145]. At this stage, effective active listening skills, including paraphrasing, language reciprocity and inviting the patient's opinion are necessary as these can significantly impact on outcomes [145,148,152,153].

Further to the establishment of an emotional bond, characterised by liking and trust between the clinician and therapist, Bordin [154] set out two additional constructs; 1) congruence in relation to the goals and purpose of therapy (goal setting) and 2) collaboration on explicit tasks to meet those goals (goal attainment).

### 2.7.3 Goal Setting and Goal Attainment

For long-term conditions, the use of an individualised programme which is based on goal setting, self-monitoring and group support to facilitate engagement and effective self-management has demonstrated efficacy in long term outcomes [155]. At the initial appointment goals should be set collaboratively to enhance a commitment to engage in the tasks required to achieve the goals and to facilitate trust and empathy [156,157]. Since change in tendon pathology does not appear to be linked with outcome [19] and pain intensity does not accurately reflect the state of the tendon tissue [122] functional goals may be most appropriate to set. Activities which induce pain do not have to be avoided, but acceptable pain responses need to be set, including intensity [158] and response over time [106]. Once a meaningful goal has been set, preference should be given to exercises that can be easily progressed to unilateral work [106]. For example, a meaningful goal for a person with patella tendinopathy may be set around jumping ability. Through appropriate questioning the clinician should seek to understand the patient's self-rated ability to perform the task in question and then collaboratively set attainable goals reflecting set amounts or variations. In this example, should the patient rate their ability to perform a task with the stretch-shortening cycle

of the tendon requiring fast energy storage and release unacceptable, breaking the task down into smaller goals which reduce tendon loading through isotonic work (such as leg press, seated knee extension or split squat) might be appropriate. Functional ability can then be monitored by the patient and clinician, discussed at follow-up appointments and new goals set accordingly. Questions aimed at understanding the patient's experience with rehabilitation, hopes for the future and the expected role of exercise have been highlighted [28].

Implementation interventions which spell out the 'when', 'where' and 'how' of the exercise programme have been shown to be effective in enabling goal-attainment, reducing unwanted influences and decreasing disengagement from a planned course of action [159]. An appropriate agreement for a person with rotator cuff tendinopathy, for example, might be *'when I am brushing my teeth in the bathroom I will use the wall to complete my resisted shoulder rotation exercises'* [32]. Here, due consideration needs to be paid to 'social' aspect of the biopsychosocial framework [160]. Although tendinopathy is often considered a sports-related injury, recent research suggested only 29-35% of the cases with lower limb tendinopathy described a relationship with sports [24,25]. Potential barriers to goal-attainment linked to social needs may be transportation problems, child care needs, and work schedules, lack of time, family dependents, financial constraints and convenience [161]. Early consideration should be given to potential barriers as current strategies to enhance adherence to physiotherapist prescribed self-management such as, using an activity monitoring and feedback system, providing written exercise

instructions, utilising a behavioural exercise programme with booster sessions and goal setting require further research before they can be recommended in clinical practice [162]. This further highlights the need to examine potential influences on adherence and strategies to improve it for people with musculoskeletal conditions such as tendinopathy. One possible influence may relate to a person's level of self-efficacy [133,134]. Self-efficacy refers to a person's efficacy expectations or outcome expectations [135], and as such, are discussed in detail below.

#### 2.7.4 Efficacy Expectations

In this PhD thesis, efficacy expectations are referred to as the patient's beliefs about his or her ability to perform the rehabilitation tasks, and to maintain control, engagement and persistence when faced with adversity [136]. As such, efficacy expectations are key determinants of whether the rehabilitation tasks reach their desired outcome [163]. Due consideration must therefore be given to the dosage, levels of pain reproduced and complexity of exercises; what may be considered best for tissue, may not be optimal in terms of efficacy expectations [164]. For example, simple, resistance exercises, completed one at a time may appear sub-optimal from the perspective of exercise physiology, yet may still yield positive clinical results [32,41]. Exercise prescription should promote self-monitoring, and appropriate interpretation of physiological signs is essential [163]. In particular, pain response to a load-based exercise intervention should be self-monitored and adapted by the individual accordingly. Previous guidelines have included using a visual analogue scale of no more than 5/10 [158,165]. However, with sufficient efficacy expectations, the use of a scale might not be required; patients can determine what pain

response is acceptable themselves over time periods that meet their needs, including pain response during exercise, pain response immediately after exercise, pain response overnight and pain response over 24 hours and beyond [32]. This could be judged upon the perceived impact upon sleep, activities of daily living or work, for example. This is important because exercise that contributes to an unacceptable pain response that disturbs sleep, for example, might add a further negative dimension to rehabilitation which serves as a barrier to adherence and engagement.

#### 2.7.5 Outcome Expectations

Outcome expectations relate to a person's estimate that a given behaviour will lead to certain outcomes [135]. Reduced outcome expectations, along with negative expectations, such as a fear, concerns and uncertainty surrounding potential future damage to the tendon have been identified in people with Achilles tendinopathy [28]. Negative outcome expectations might be usefully discussed, challenged and reconceptualised, as they might be an important determinant of engagement with a load-based exercise programme. For example, concerns around the risk of tendon rupture could be explored with the clinician highlighting the disparity between painful tendons preceding a rupture [17]. Consequently, differentiating between a person's ideal expectations (what he or she wants to occur) and the predicted outcome (what is likely to occur) has potential value for directing educational interventions and more appropriate goal-setting [166]. Expectations appear to be embedded in both hopes and fears, suggesting further attention be paid to cognitive factors when setting management plans [167].



## 2.8 Enhancing Self-Efficacy

Self-efficacy depends mostly on the way the person interprets their symptoms, and to what degree they believe that they can exercise control of the outcome of their injury through a series of behavioural choices over time [168]. People with high pre-intervention self-efficacy tend to maintain high self-efficacy levels through rehabilitation [169] leading to more ambitious goals and a faster recovery from setbacks [135]. Consequently, how the patient perceives the problem would appear pivotal. A person may consider their problem as highly complex, perhaps as a result of imaging or internet searching [170]. This may serve as a discourse between the persons' perceived complex problem and the proposed 'simple' exercise of loading. Therefore, addressing inaccurate beliefs and expectations is essential [106]. The aim of verbal persuasion is to allow patients to move beyond their current perceived pain threshold and towards an enhanced capability threshold encompassing a mixture of biological, psychological and sociological factors. For example, if the clinician provides a positive message around the patient's imaging results to reflect the lack of association between structural findings on a scan and pain, it might shift the patient's unhelpful beliefs. For example, from "*I shouldn't do anything that hurts*" to understanding pain during exercise might be helpful in some situations rather than harmful [33]. The choice of words to facilitate this is critical; negative perceptions of tissue health from prior imaging or consultation from prior health care providers may exist and affect the way information is perceived [171]. It may be useful for the clinician to explain pain in terms of sensitivity, ensuring the person in pain understands why hurt does not necessarily equal harm [122] and why pain during rehabilitation should be acceptable [158]. Special

consideration needs to be taken to ensure that experience of the exercises confirms the messages the clinician is conveying and provides the patient with an experience which solidifies their new-found beliefs via successful experiences. In turn, this will expand the patient's locus of control by gently challenging their perceived ability to perform the task without guidance [168]. This concept provides a novel perspective for load-based exercises; providing experienced control for the person with tendinopathy. Experiencing this control will help *'set up for success'* and ensure an understanding upon which a successful partnership can be developed [32]. Understanding should be revisited regularly using simple questions such as: *"What do you understand is the cause of your pain?" "Why could exercises help?"* A summary of suggested cognitive and contextual considerations to optimise clinical outcomes in tendinopathy is offered in figure 2.5.

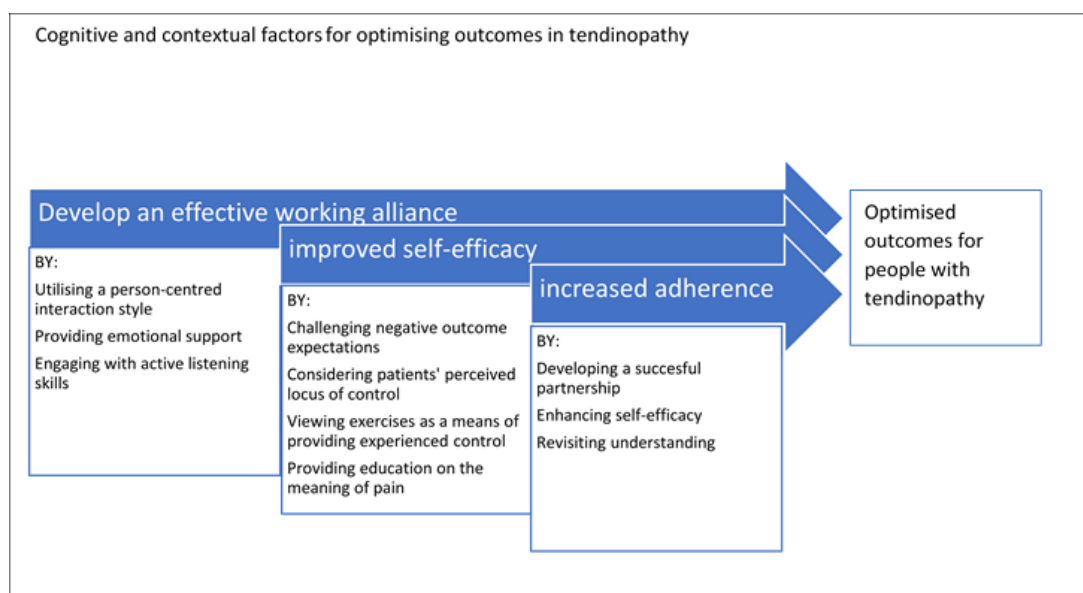


Figure 2.5 Summary of suggested cognitive and contextual considerations to optimise clinical outcomes in tendinopathy

## 2.9 Conclusion

In conclusion, load-based exercise is currently advocated for the management of tendinopathy. However, given the wide-ranging responses from loading exercises in the research, much uncertainty remains. Contextual and cognitive factors may help explain some of the variation. Therefore, a greater understanding of these factors might enhance our treatment outcomes for our patients with tendinopathy. Working alliance and self-efficacy are both associated with adherence behaviours and rehabilitation outcome [130,131], yet measures of these factors are largely absent from the tendinopathy research to date. As such, these factors might usefully be considered further. Based upon this, the next chapter will consider the most suitable primary outcome measure for a study designed to investigate contextual and cognitive factors and outcome in AT (chapter five)

## Chapter 3: Measuring Clinical Outcomes in People with Achilles Tendinopathy

*Based upon Mallows A, Littlewood C, Malliaras P Measuring patient-reported outcomes (PROs/PROMs) in people with Achilles tendinopathy: how useful is the VISA-A? Br J Sports Med Published Online First: 22 June 2017. doi: 10.1136/bjsports-2017-097531 (Appendix 5)*

### Summary

Whilst no current consensus exists regarding the selection of primary outcome measures for research investigating AT, the Victorian Institute of Sport- Achilles (VISA-A) questionnaire is, to date, the most common outcome measure used. The VISA-A is a self-administered questionnaire serving to evaluate the severity of Achilles tendon-related disability in relation to impairment (body structure and function), activity (activity limitations) and participation (participation restrictions) for anyone with AT. As such, the VISA-A would seem to make an obvious selection to include when planning research investigating AT. However, during the planning stages of the cohort study detailed in chapter five, initial inspection of the VISA-A raised concerns over the questionnaire's face validity. Consequently, this chapter goes on to critically examine the ability of the VISA-A to inform decision making; although commonly used, the development of the questionnaire raises questions over its usefulness. The purpose of this examination was to inform the clinical outcome measure selected to meet the aim for the cohort study detailed in chapter five. Chapter five reports on a feasibility study exploring an online data collection method for a longitudinal cohort study investigating the predictive nature of the selected variables identified for people with AT that were identified in chapter two.

### 3.0 Introduction

It is important for clinicians and researchers to measure outcomes. Outcome measures are defined as measurement tools that are used to document change in one or more constructs over time [172]. Reporting of such outcomes can provide benchmarks that assist with interpretation of scores during clinical decision making for individual patient care, assist interpretation of results from research and inform healthcare policy [173,174]. Achieving routine outcome measurement in practice however is challenging [175]. Such challenges include familiarity with the tool, ease of use, time consumed using the measure, and the amount of equipment involved. These factors have all been identified as barriers to measuring clinician-derived outcome measures in physiotherapy practice [172].

Clinician-derived outcome measures in musculoskeletal conditions are measures taken by a clinician and typically focus on imaging for pathology (e.g. ultrasound scanning of the painful tendon [19]) or measurements of impairment (e.g. muscle strength, joint ROM, functional task) [47]. Whilst it is important to select an outcome measure with due consideration given to relevant pathology and impairments, as previously discussed, these findings do not consistently correlate with pain or disability [19]. As such, relying on information from such clinician-derived outcome measures to inform clinical decision making can be problematic. For example, chapter one discussed the current treatment recommendations for AT which focus on load-based exercises, placing emphasis on strengthening the plantarflexors of the ankle [34,176]. This recommendation is based in part on the premise that weakness in the ankle

plantarflexors has been identified as an impairment in runners with AT [177]. However, when re-measuring this impairment at long-term follow up, disparity has been reported between the clinician-derived measure (plantarflexion strength) and the patient's reported experience (pain and disability) [82]. In a five year follow up of participants with AT, now asymptomatic participants who were satisfied with their outcome were still found to have a significant decrease in concentric plantarflexion strength ( $p=0.028$ ) [82]. Examples of such disparity exists in numerous other musculoskeletal conditions. For example, Dayton et al [178] reported that following total hip replacement, performance-based function (timed up and go (TUG), 6 minute walk test (6MW) and stair climbing test (SCT)) declined compared to baseline, whereas self-reported function improved compared with baseline. The results of the correlational analysis from one to six months post-operation indicated there was poor correlation between change in the Hip and Osteoarthritis Outcome Score – Activities of Daily Living subscale and change in TUG ( $r=.32$ ,  $p=0.16$ ), SCT ( $r=.27$ ,  $p=0.24$ ), and 6MW ( $r=0.34$ ,  $p=0.13$ ) performance during this time frame. Likewise, similar findings were reported by Stevens-Lapsley et al [179] for patients following total knee replacement; most self-report measures assessing knee function improved from baseline (figure 3.1), whereas the physical performance measures declined from baseline (figure 3.2).

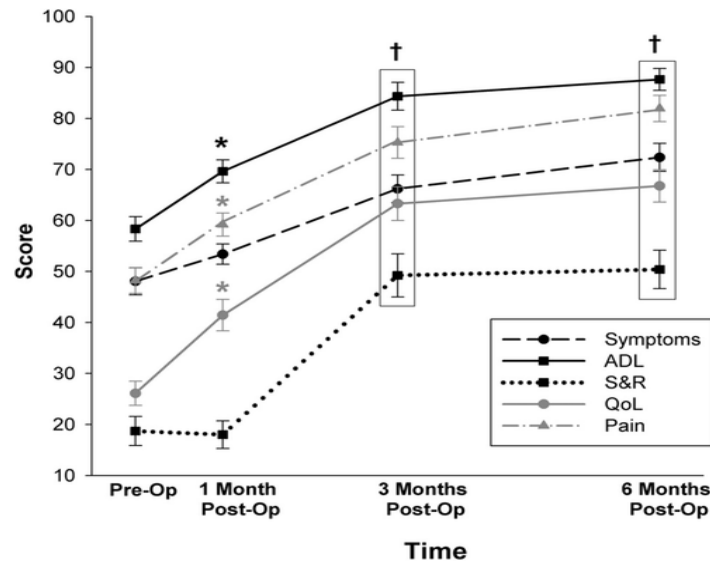


Figure 3.1 KOOS subscale from preoperatively to 6 months postoperatively. Higher scores reflect better outcomes for all subscales. KOOS = Knee Injury and Osteoarthritis Outcome Score; TKA = total knee arthroplasty; ADL = activities of daily living function; S&R = sport and recreation function; QoL = quality of life; SEM = standard error of the mean. \*Significant increase in 1 month postoperative score from preoperative score. †Significant increase in 3- and 6-month postoperative scores from preoperative scores ( $P < .05$ ). Data are mean  $\pm$  SEM [179]

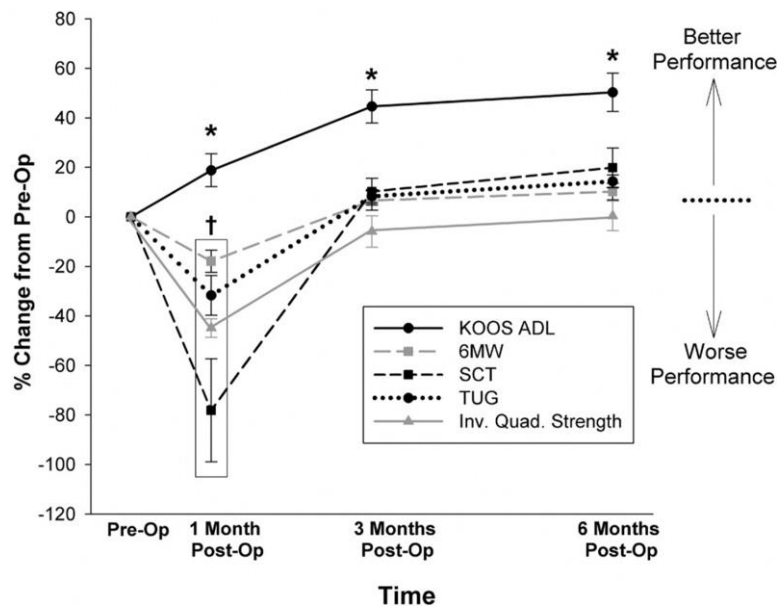


Figure 3.2 Performance measures (6MW, SCT, TUG and involved quadriceps strength) and KOOS ADL percentage change scores preoperatively to 6 months postoperatively. Change scores were calculated by using means for each time point ( $[(\text{initial-final}/\text{initial}) \times -100]$ ) because some individual KOOS values preoperatively were zero. 6MW = 6-minute walk; SCT = stair climbing test; TUG = timed-up-and-go; KOOS = Knee Injury and Osteoarthritis Outcome Score; ADL = activity of daily living; SEM = standard error of the mean. \*Significant increase from preoperative values. †Significant decrease from preoperative values ( $P < .05$ ). Data are mean  $\pm$  SEM [179]

These discrepancies further highlight a) the uncertainty currently surrounding the underlying mechanisms of change in response to intervention and b) the need for clinicians and researchers to consider additional measures to fully understand a patient's response to treatment.

Capturing patient-reported outcome measures (PROMs) offer such an addition [180]. PROMs are questionnaires, which are self-reported and designed to attain a person's perceptions of specified aspects of their health [180]. Conceptually, PROMs are designed to obtain the patient's experience and ideally benefit from a service or intervention and as such can be viewed either as a 'tool for evaluation' or as a 'mechanism for improvement' [174]. For example, data acquired from a PROM can help a clinician quickly evaluate which of their patients experience improvement or deterioration over time and thus suggest refinements to care pathways.

Many different PROMs have been utilised by clinicians and researchers as a tool for evaluation for individuals with AT. A recent systematic review identified eighteen PROMs that have been employed in clinical research for measuring pain and disability in AT (table 3.1) [47]. From these eighteen, the most frequently utilised was the VISA-A Questionnaire (n=28). The VISA-A is not only a widely-used PROM for AT but is also available in seven different languages. Whilst there is no current consensus regarding the selection of primary outcomes for research investigating AT [181], the established popularity of the VISA-A would seem to make the questionnaire an obvious choice. However, initial inspection of the VISA-A raised concerns over the



questionnaire's face validity. Face validity refers to the degree to which the items in the questionnaire indeed look as though they are an adequate reflection of the construct to be measured [182]. The VISA-A assumes that the person completing the questionnaire is an active individual, undertaking tendon-loading sports (figure 3.3; questions 7 and 8, for example). As such, the VISA-A lacks face validity for measuring disability in a non-active population suffering with AT. Given the concern over the VISA-A's face validity, a more detailed examination of ability of the VISA-A to inform decision making was undertaken. The purpose of this examination was to subsequently inform the choice of the primary outcome measure for the cohort study detailed in chapter five. This critical examination will now be discussed in detail.

<b>Outcome Measure</b>	<b>Number of times used in clinical trials of Achilles tendinopathy</b>
Visual Analogue Scale (VAS) of Pain at rest	6 [44–46,183–185]
VAS of Pain with various functional tasks	11 [38,41,189,43,44,158,183,184,186–188]
100mm VAS of Pain with 1KG Squeeze of the Achilles Tendon	3 [44,190,191]
4 Point Scale of Pain with 1KG Squeeze of the Achilles Tendon	1 [192]
Numerical Rating Scale (NRS) of Pain at Rest	2 [193,194]
NRS of Pain over time	5 [140,193–196]
5 Point Likert Scale of Difficulty in Sport	1 [142]
Victorian Institute of Sports Assessment – Achilles	28 [38,42,194–203,45,204–211,82,140,141,158,184,190,193]
Modified Curwin and Stanish Six Level Pain Scale	2 [212,213]
Functional Index of Leg and Lower Limb	1 [183]
American Orthopaedic Foot and Ankle Score Hindfoot Scale	1 [188]
Short Form-36	2 [188,208]
EuroQoL	2 [183,206]
Foot and Ankle Outcome Score	3 [142,185,192]
Numerical Scale of Physical Activity	1 [142]
Numerical Scales of Improvement	8 [82,140,191,192,195,196,198,213]
Treatment Satisfaction	7 [43,45,141,184,199,214,215]
Patient Global Impression of Change	1 [140]

Table 3.1 Outcome measures assessing self-reported pain and function in Achilles tendinopathy. Adapted Murphy et al [47]

The ability of the VISA-A to improve decision making is determined by its reliability, validity and responsiveness to change, as these are essential psychometric properties for any measure (box 3.1) [216,217]. Psychometrics is the name commonly used for the principles and methods of developing valid

and reliable measures of intelligence, attitudes, skills, and other characteristics [218]. This approach is considered appropriate to develop instruments that measure a single construct using multiple items (e.g. depression or anxiety or severity of AT) [219]. Should the measure be directed at measuring multiple constructs with a single index then a clinimetric approach may be considered more appropriate [219]. Clinimetrics is the term introduced by Alvan R. Feinstein in the early 1980s to indicate a domain concerned with indexes, rating scales and other expressions that are used to describe or measure symptoms, physical signs and other clinical phenomena [220]. Whilst the terms psychometrics and clinimetrics have significant overlap (and which term is used may depend on the field of application), any perceived differences are less obvious when evaluating measurement instruments and the characteristics can be considered as clinimetric or psychometric [219].

**Reliability** - The degree to which the measurement is free from measurement error.

**Validity** - The degree to which a PROM instrument measures the construct(s) it purports to measure.

**Responsiveness** - The ability of an outcome measure to detect change over time in the construct to be measured.

### Box 3.1. Definitions of terms [182]

Evidence for an outcome measure's reliability and validity falls along a continuum from no evaluation to full evaluation for the study population; the more evidence that the measure is reliably measuring the specific patient reported outcome, the more confidence is assured. Thus, both reliability and validity are more accurately described as "continuous" rather than

“dichotomous” psychometric indices and claiming that an outcome measure is completely “reliable” or “valid” is inaccurate [217]. The extent of such evidence for the VISA-A will now be evaluated.

### 3.1 Development of the VISA-A Questionnaire

The methodological framework for developing and evaluating a PROM questionnaire is well-described and includes the following steps: (1) identification of a specific patient population, (2) item generation, (3) item reduction and (4) determination of the validity, reliability and responsiveness [221]. A new international consensus for measurement properties for health-related PROMs has been reached [216] and formulated in a Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist [222]. The COSMIN initiative aims to improve the selection of outcome measurement instruments by developing methodological guidelines based on the consensus reached by the international experts [182]. Here a critical review of the evidence that exists for the VISA-A questionnaire is presented utilising the above methodological framework as a tool for review with due consideration given to the recommendations made in the COSMIN checklist [222] as evidenced in the development of a recent PROM; The Copenhagen Hip and Groin Outcome Score (HAGOS) [221]. The work to develop the HAGOS questionnaire [221] by Thorborg et al will be referred to as an exemplar for comparison where appropriate.

### 3.1.1 Identification of a Specific Patient Population

The function of the VISA-A is to evaluate the severity of Achilles tendon-related disability in relation to impairment (body structure and function), activity (activity limitations) and participation (participation restrictions) for anyone (active or sedentary) with AT. The VISA-A is limited in this respect; during the development of the VISA-A, an exclusively active population was utilised (i.e. cases referred to a sports medicine clinic or awaiting surgery and controls representing active individuals from a university population or running club). Given that only 29-35% of the general population with Achilles tendinopathy may describe a relationship to sports activity [24,25], the VISA-A lacks evidence of development and testing not only in non-sporting populations, but also a heterogeneous sporting population.

### 3.1.2 Item Generation

Item generation refers to the development of the items (questions or statements) which may be considered appropriate to be included in the PROM. The item generation process for the VISA-A was developed from a template designed to measure the severity of patella tendinopathy, supplemented by interviewing colleagues, informally interviewing patients about their symptoms, and using a focus group of clinicians and subject experts. One further potential limitation of the VISA-A is that during item generation, the extent of patient inclusion was limited. Patient inclusion at this stage is vital; patients should be considered experts when judging the relevance of the items for their population [216]. As such, the relevance and comprehensiveness of the items in the VISA-A for the target population is questionable. To improve the validity of the VISA-

A further investigation would be required, with additional consideration given to reflect current understanding of the multidimensional nature of the condition [223]. To contextualise this against a recent exemplar, Thorborg et al [221] interviewed a total of 25 patients identified as representative of the identified population. Patients were asked to fill out the preliminary version of the HAGOS questionnaire while commenting on issues related to questions they felt were missing, the questionnaire readability and its ease of comprehension. Data were gathered until data saturation was reached. These steps are missing from the development of the VISA-A, and as such, questions remain regarding the readability and ease of comprehension as these were unexplored. For example, is the unconventional nature of the scoring – ten representing no pain easily understood? Given an average adult in the United Kingdom (UK) has a literacy level comparable to an eleven year-old students [224], these would seem important steps to be missing.

### 3.1.3 Item Reduction and Content Validity

Item reduction is intimately related to content validity; the degree to which the content of the PROM is an adequate reflection of the construct to be measured [180,216]. Item reduction refers to the process of reducing the number of items included to ensure the PROM is effective, but also as short as possible, reducing bias and response in error due to boredom and or fatigue [225]. Although Robinson et al [226] report using a focus group of experts to reduce items, it remains unclear which items (if any) were removed and the process for determining this. Compared again with the exemplar, Thorborg et al [221] used a group of experts to reduce items, with a transparent process for

identifying items for consideration of removal and a voting process clearly described along with a table presenting items removed. The inadequacies in the processes of item generation and reduction described above for the VISA-A raises concerns over its content validity.

#### 3.1.4 Construct Validity

Construct validity is the degree to which the scores of a PROM are consistent with predetermined hypotheses. Construct validity is tested based on the assumption that the PROM validly measures the construct intended to be measured (severity of AT for the VISA-A). Construct validity is evaluated by establishing the degree to which the scores of the PROM are consistent with the predetermined hypotheses [180,216], such as relationships to scores from other instruments. For example, as the VISA-A is designed to measure the severity of AT, scores from the VISA-A would be expected to have higher correlations with the Physical Functioning, Role-Physical and Bodily Pain subscales of the Short-Form 36 (a PROM that contains relevant domains for assessing physically active patients with reduced physical function and pain [227]) than the subscales relating to Mental Health, Vitality, Role-Emotional, Social Functioning and General Health [221]. The more hypotheses which are tested on whether the data correspond to predetermined hypotheses, the more evidence is gathered for construct validity [222]. Whilst Robinson et al [226] tested construct validity against two other measures (convergent validity testing) and controls (divergent validity testing), the formulation and testing of such hypotheses are missing from the VISA-A development, and the potential for the VISA-A to be measuring more than one construct has been identified

[228]. For instance, the physical activity section of the VISA-A weighs heavily in the overall scoring (40 of the 100 points). As such, if a person with AT is functioning at a high level despite pain, the construct of the VISA-A may indicate, incorrectly, that they are less affected by the condition.

### 3.1.5 Reliability

Whilst validity refers to the degree to which a PROM instrument measures the construct(s) it purports to measure, reliability refers to the degree to which the measurement is free from measurement error [182]. In addition to validity, reliability was also tested by Robinson et al [226], measuring test-retest reliability at one week. Test-retest reliability showed no significant difference between scores taken one week apart ( $p=0.58$ ). However, this was tested exclusively in a sporting population; Robinson et al [226] suggest that the VISA-A only be used in homogenous populations, and recognise the limitations of its use in non-sporting populations. In response to questions 3-7 (figure 3.3) a person may never choose to walk more than 30 minutes, use the stairs, perform hops or heel lifts nor be participating in sport; as such, a non-active person's symptoms may resolve, yet they might only score 50/100. As such, people may guess what pain response they might feel when performing these tasks rather than actually carry out the tasks, reducing accuracy. Consequently, the ability of the VISA-A to measure change in a sedentary person with AT is uncertain.



IN THIS QUESTIONNAIRE, THE TERM PAIN REFERS SPECIFICALLY TO PAIN IN THE ACHILLES TENDON REGION

1. For how many minutes do you have stiffness in the Achilles region on first getting up?

100 min

--	--	--	--	--	--	--	--	--	--	--

0 min

0

1

2

3

4

5

6

7

8

9

10

POINTS

2. Once you are warmed up for the day, do you have pain when stretching the Achilles tendon fully over the edge of a step? (keeping knee straight)

strong  
severe  
pain

--	--	--	--	--	--	--	--	--	--	--

no pain

0

1

2

3

4

5

6

7

8

9

10

POINTS

3. After walking on flat ground for 30 minutes, do you have pain within the next 2 hours?  
(If unable to walk on flat ground for 30 minutes because of pain, score 0 for this question).

strong  
severe  
pain

--	--	--	--	--	--	--	--	--	--	--

no pain

0

1

2

3

4

5

6

7

8

9

10

POINTS

4. Do you have pain walking downstairs with normal gait cycle?

strong severe pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	no pain
	0	1	2	3	4	5	6	7	8	9	10	

POINTS

5. Do you have pain during or immediately after doing 10 (single leg) heel raises from a flat surface?

strong severe pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	no pain
	0	1	2	3	4	5	6	7	8	9	10	

POINTS

6. How many single leg hops can you do without pain?

0	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10
	0	1	2	3	4	5	6	7	8	9	10

POINTS

7. Are you currently undertaking sport or other physical activity?

0	<input type="checkbox"/>	Not at all
4	<input type="checkbox"/>	Modified training ± modified competition
7	<input type="checkbox"/>	Full training ± competition but not at same level as when symptoms began
10	<input type="checkbox"/>	Competing at the same or higher level as when symptoms began

POINTS

8. Please complete **EITHER A, B or C** in this question.

- If you have **no pain while undertaking Achilles tendon loading sports** please complete **Q8A only**.
- If you have **pain while undertaking Achilles tendon loading sports but it does not stop you from completing the activity**, please complete **Q8B only**.
- If you have **pain that stops you from completing Achilles tendon loading sports**, please complete **Q8C only**.

A. If you have **no pain while undertaking Achilles tendon loading sports**, for how long can you train/practise?

NIL	1–10 mins	11–20 mins	21–30 mins	>30 mins	POINTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	7	14	21	30	

OR

B. If you have some pain while undertaking **Achilles tendon loading sports**, but it does not stop you from completing your training/practice, for how long can you train/practise?

NIL	1–10 mins	11–20 mins	21–30 mins	>30 mins	POINTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	4	10	14	20	

OR

C. If you have **pain that stops you** from completing your training/practice in **Achilles tendon loading sports**, for how long can you train/practise?

NIL	1–10 mins	11–20 mins	21–30 mins	>30 mins	POINTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	2	5	7	10	

---

<b>TOTAL SCORE ( /100)</b>	<input type="checkbox"/> %
----------------------------	----------------------------

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Figure 3.3 The VISA-A patient reported outcome measure [226]

### 3.1.6 Interpretability

Interpretability is the degree to which qualitative meaning can be assigned to a PROM's quantitative scores or change in scores [229]. The weighting of the scoring of the VISA-A questions the interpretability of the VISA-A. Interpretability includes the distribution of total scores and change scores in the study sample and in relevant subgroups. As such, estimates of minimal important change (MIC) and/or minimal important difference (MID) are key considerations. The MIC is the smallest change in score (within a patient) in the construct that can be measured that patients still perceive as important [229]. The MID is the smallest difference in the construct that can be measured (between patients) that is considered important [229]. Ongoing debate exists in the literature regarding the best way of establishing either the MIC or MID and indeed the COSMIN group failed to reach a consensus on the matter [216]. However, it has been shown that under many circumstances, when patients with a chronic disease are asked to identify minimal change, the estimates fall very close to half a standard deviation [230]. Whilst no MIC has been established for the VISA-A and a wide range of estimates have been used in research (12-20 points) [231], according to the report by Robinson et al [226], the Norman et al [230] rule of thumb estimates a MIC between 9 and 14 points. Finally, a MID for the VISA-A has been cautiously suggested to be 6.5 points [232], albeit tested in a group of patients with insertional AT.

Another important consideration for interpretability are 'floor' and 'ceiling' effects. Floor and ceiling effects are present if the PROM fails to demonstrate a worse score in the patients demonstrating signs of clinical deterioration and

an improved score in patients who show clinical improvement as this can be an indication that a scale is not sufficiently comprehensive [221]. The two examples highlighted above question the comprehensiveness of the VISA-A as they both suggest the PROM has both floor and ceiling effects respectively. Given that patients who have Achilles tendinopathy have never reported a score lower than 24 in the reported research and those who have recovered rarely score higher than 90 [231], this element of interpretability of the VISA-A is one of the tool's limitations.

### 3.1.7 Responsiveness

In addition to the importance of interpretability, responsiveness is also a crucial property to inform clinicians and researchers about change in a patient's status. Responsiveness refers to the validity of a change score in a PROM [216]. As with evaluating construct validity, a PROM responsiveness is required to be tested against hypotheses [216]. Again, this could include testing hypotheses against relationships to scores of other instruments. Thorborg et al [221] selected the Global Perceived Effect where the patients rate their condition in one of seven categories. This relationship (and hypothesis) is then tested at a long enough time to allow time for sufficient clinical improvement [221] and is a crucial measurement quality; in its absence the ability of the PROM to detect when patients are undergoing significant clinical change is missing [233,234]. Unfortunately, there is an absence of longitudinal data to inform responsiveness of the VISA-A [226].

### 3.2 Summary

In summary, the VISA-A was published in 2001, and has now been widely used, offering easy comparison between treatments from various clinics and research studies. In the absence of an alternative PROM, clinicians and researchers might continue to use the VISA-A despite the limited extent of evidence concerning the psychometric properties for this PROM. However, since the original publication of the VISA-A both our understanding of the multidimensional nature of tendinopathy and PROMs have developed, and as such the VISA-A requires updating. This critical review has highlighted the need for future research into the construct and content validity and responsiveness (including interpretability) of the VISA-A. To ensure methodological rigor, this should follow the Consensus-based Standards for selection of health Measurement Instruments (COSMIN) recommendations for terminology and research agenda [216].

### 3.3 Implications for Future Research

Whilst no outcome measure can be considered 100% valid, reliable and responsive, this chapter has highlighted the extent of evidence which is missing for the VISA-A. Given no current consensus exists regarding the selection of primary outcome measures for research investigating AT, this work has been used to inform the selection of the primary outcome measure for a future research study described in chapter five. The future study utilised an online platform for data collection which necessitated participants to complete the outcome measure without any support from a clinician to clarify a question's meaning. Accurate and reliable data could only be obtained if participants were

able to read and understand the questions asked. With an average adult in the UK literacy level comparable to eleven year-old students [224], the chosen primary outcome measure needed to not only be considered of sufficient reliability, validity and responsiveness, but also of sufficient comprehension and readability for the average UK population. Notably the VISA-A has an absence of evidence regarding readability and comprehension testing and coupled with concerns over the validity and responsiveness testing of the VISA-A, an alternative outcome measure was sought. Although table 3.1 provides possible alternatives, only the Foot and Ankle Outcome Score (FAOS) [235] was considered in a review of readability of commonly used PROMs [224]. The FAOS is a 42-item questionnaire and the review concluded that it had a readability age of between 13-15 years old. Given this finding and the potentially burdensome length of the FAOS, a further alternative and more succinct PROM was considered. The Lower Extremity Functional Scale (LEFS) is a self-report questionnaire designed to measure physical function of people with lower extremity dysfunctions, such as AT [232,236–239]. The LEFS is a twenty-item questionnaire developed by Binkley et al [240] in 1999 who suggest it takes two minutes to complete. Items were generated by reviewing existing questionnaires and then surveying thirty-five patients with a variety of lower extremity orthopaedic conditions and experienced clinicians [240]. Similar to the development of the VISA-A, it is unclear how items were reduced. As with the VISA-A, construct validity was tested against the Short-Form 36 physical function subscale. However, in contrast to the VISA-A, construct validity was tested against pre-determined hypotheses. Construct validity was reported as (correlations between the LEFS and the Short-Form 36 physical function

subscale and physical component score [227]) were  $r=.80$  (95% lower limit CI=.73) and  $r=.64$  (95% lower limit CI= .54), respectively [240]. In addition to validity, and similarly to Robinson et al [226], Binkley et al [240] describe excellent reliability ( $r=.94$  [95% lower limit confidence interval (CI)=.89]) when the LEFS questionnaire was repeated 24-48 hours later. Whilst acknowledging the limitations above and, as the LEFS was developed in 1999 it was also not developed to the methodological rigor of the COSMIN recommendations [216], importantly for the online platform of data collection utilised and detailed in chapter five, the LEFS has been reported to have a readability age of around 11-12 years old, meeting the average UK literacy level [241]. As such, whilst, in a similar vain to the VISA-A, the LEFS still possesses developmental concerns, it was considered more suitable for the research study detailed in chapter five.



## Chapter 4: Research Methodology

### Summary

This chapter introduces the methodological approach for the primary research undertaken for this thesis. Initially, the choice of approach is discussed within a relevant paradigm, before justification is offered for the research methods chosen for the MAP study presented in the subsequent chapter.

### 4.0 Introduction and Overview

The Managing Achilles Pain study (MAP study) was a multi-methods study designed to evaluate the feasibility of the protocol for a future large longitudinal cohort study. The aim of the future study is to investigate the association and predictive relationship of working alliance, outcome expectations, adherence and self-efficacy with outcome in the management of Achilles Tendinopathy (AT). Two main phases were conducted over time in a sequential nature. In the first phase, quantitative methods were employed to determine the recruitment & retention rate and to carry out preliminary data analysis of the selected variables and clinical outcomes. In the second phase of the study, the acceptability of the study procedures was explored from the participants' perspectives.

### 4.1 Research Paradigm

This thesis is presented from a post-positivist paradigm. Ontology refers to the nature of reality and what there is to know about the world [242]. A post-positivist paradigm retains the realist ontology of positivism but emphasises that reality is interpreted from different perspectives [243]. As such, this

approach falls broadly within the school of thought generally known as 'critical realism' [244]. Ontologically, this means we see reality as something that exists independently of those who observe it, but it is only accessible through the individuals perceptions and interpretations [242]. Adopting this more holistic approach is reflective of how we currently conceptualise health with the biopsychosocial model [245]. In relation to AT, this may be seen in management of the condition; a person may respond positively to a load-based exercise programme, yet the reasons for the positive response may be interpreted from multiple perspectives [246]. There is clearly an individual aspect which must be considered, which is recognised in the world view of a critical realist, where a constructivist epistemological stance is valued. Epistemology is concerned with the ways of knowing and learning about the world and focuses on issues such as how we can learn about reality and what forms the basis of our knowledge [242]. Constructionism emphasises that knowledge is actively constructed by human beings, rather than being passively received by them. This school of thought focuses on understanding the lived experience from the points of view of those who hold it. Consequently, researchers should also construct meanings and interpretations based on those of participants [242]. From a critical realist perspective, the aim of research is therefore to capture the multifaceted and diverse nature of reality in all its complexity and depth [242]. To meet these needs, it is clear that adopting a solely quantitative or qualitative approach would not fulfil this aim and the need for both approaches is warranted. This approach of combining approaches is discussed next.

## 4.2 The Design of 'The Map Study'

Whether it is viewed as pragmatism or seen as coherent with a critical realist framework, it is argued that it is most important to choose appropriate methods to address the specific research questions than to align with a specific epistemological stance [242]. Such a view allows qualitative and quantitative strategies to be regarded as complementary; viewing the same research problem through different lenses [247]. Still, this view is not shared by all researchers; combining quantitative and qualitative approaches over recent decades has developed a 'paradigm wars'; it has been argued that these two methods are incommensurate in that an objective view of reality need not necessarily correspond with that of a subjective experience [248]. However, the growing trend of combining approaches suggests this view is diminishing within the context of health services research and mixing strategies has become to be seen as a 'good thing' to enhance our understanding of research problems beyond what could be achieved by using either one approach alone [249]. In the context of the current literature, this enhanced understanding seems important. For example, when randomised controlled trials of interventions for AT demonstrate that an intervention is not effective [38], the reasons for this typically remain unknown because strategies to investigate this, for example qualitative interviews of patient experience, are not undertaken.

Qualitative research may precede quantitative enquiry, accompany it, or may be used in some form as a follow up study [242]. Decisions around sequencing will largely depend on the role and status of each method respectively [242]. Mixed method design refers to the incorporation of various qualitative or

quantitative strategies within a single project that may have either qualitative or a quantitative theoretical drive, whilst multi-method design is the conduct of two or more research methods, each conducted rigorously and complete in itself, in one project and the results are then triangulated to form a comprehensive whole [250]. Given the feasibility nature of the MAP study, and the aims aligned with the nature of such a study, using both quantitative and qualitative approaches did not simply provide the opportunity to add depth to data collected. Instead, aligned with a multi-method approach, quantitative and qualitative methods were utilised to answer different questions about the same topic; the feasibility of the MAP study [251]. As such, separate objectives were provided for the quantitative study and the qualitative study, whilst the overall aim still aligned to evaluate the feasibility of the methods utilised in the study. Chapter seven triangulates the quantitative and qualitative approaches to form a comprehensive overall understanding. As the nature of the qualitative study was reliant on the participants having already completed the quantitative study, it was logical to sequence the quantitative prior to the qualitative study (figure 4.1).

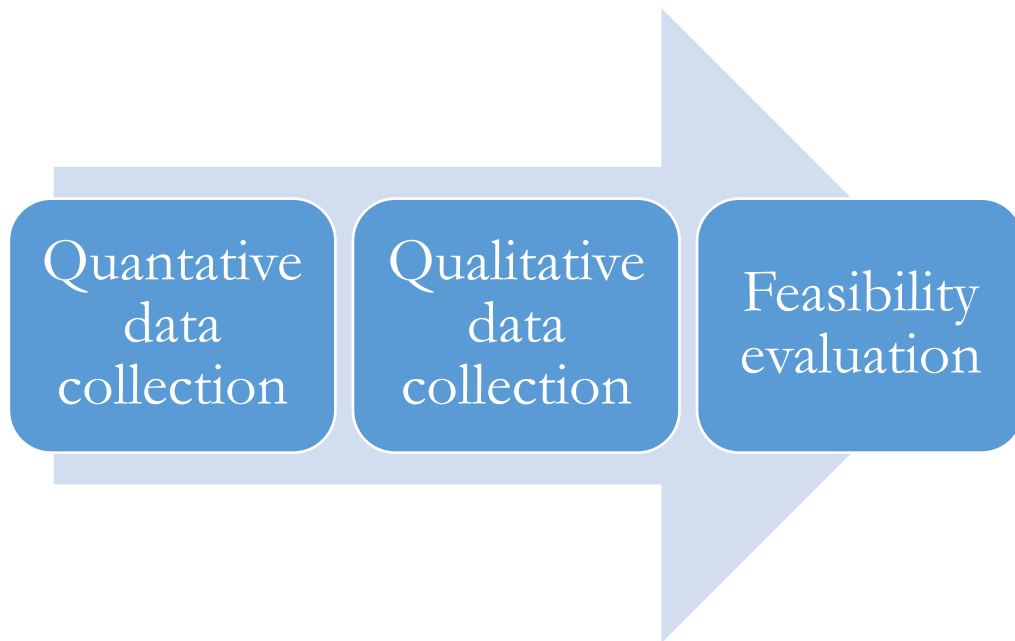


Figure 4.1 The sequential nature of a multi-methods approach for evaluating feasibility of the MAP study

The following chapter will now report upon the methods selected and the development of the protocol for the MAP study.

## Chapter 5: The MAP Study

### Summary

This chapter reports the findings from a feasibility study for a multi-centred longitudinal cohort study. This study involved the development of a bespoke online platform for hosting participant information, data collection and data storage. As part of this feasibility study, twenty-four participants with Achilles tendinopathy (AT) were recruited over an eleven-month period. Data regarding disability from AT, pain, working alliance, outcome expectation, adherence and self-efficacy were collected at baseline, six weeks and twelve weeks via the online platform.

### 5.0 Introduction

Based upon the rationale described in chapter two, the consideration given to effectively measuring outcome in AT in chapter three and the methodological development described in chapter four of this thesis, this thesis chapter describes a study conducted to evaluate the feasibility of a large longitudinal cohort study utilising an online platform to investigate the association and predictive relationship of working alliance, outcome expectations, adherence and self-efficacy with outcome in the management of AT.

Research investigating clinical associations has traditionally been conducted through the administration of 'paper-and-pencil' based PROMs [252]. However, these measures can be burdensome for participants resulting in low completion rates [253,254] and lead to the fear of increased workload for the administrator [255]. In recent years, electronic data collection has been shown to be an

effective alternative [254]. The advantages of using electronic data collection for the administration of PROMs, rather than paper-and-pencil administration, have been well documented [253]; these include reduction in administrative burden, automatic implementation of skip patterns and scoring, avoidance of secondary data entry errors, time and date stamped data, and fewer items of missing data. In addition, the results from a systematic review and meta-analysis investigating the equivalence of electronic and paper administration of PROMs indicated that electronic and paper PROMs across different modes of electronic administration (interactive voice response system, tablet, hand-held device or personal computer) produce equivalent scores across a wide range of scenarios [256]. This suggests that electronic data administration can generally be assumed to be equivalent to paper-and-pencil administration. Consequently, to facilitate electronic data collection an [online platform](#) was constructed which served to host participant information, the selected PROMs and to store the data. Further detail is provided in the methods section below.

Whilst an online platform to facilitate electronic data administration would appear an appropriate method to employ in a research study, as data collection in such a manner was untested for a tendinopathy population, it was uncertain whether it could be done. Distinct from pilot studies, a feasibility study focuses on conducting research to examine whether the study can be done, whereas pilot studies are “smaller versions of the main study used to test whether the components of the main study can all work together” [257]. Given the magnitude and aim of the future large longitudinal cohort study, it was

appropriate to determine if a study designed to utilise an online platform was feasible.

## 5.1 Study Aim and Objectives

The primary aim of this study was to assess the feasibility of conducting a future large longitudinal cohort study utilising an online data collection method to investigate the association and predictive relationship of working alliance, outcome expectations, adherence and self-efficacy with outcome in the management of AT. The objectives were to:

1. To determine the recruitment & retention rate
2. To carry out preliminary data analysis of the selected variables and clinical outcomes
3. Undertake qualitative interviews to explore the acceptability of the study procedures from the patient participants' perspectives
4. Undertake qualitative interviews to explore the acceptability of the study procedures from the physiotherapists' perspectives

The study was reported according STROBE guidelines for reporting of observational studies (appendix 6) [258].

### 5.1.1 Ethical Approval

Ethical approval was sought and granted on 14<sup>th</sup> September 2017 by London - Camden & Kings Cross Research Ethics Committee; REC reference



17/LO/1583 and by the Health Research Authority on 15<sup>th</sup> September 2017; IRAS project ID: 219457 (appendix 7).

## 5.2 Methods / Design

### 5.2.1 Study Design

A multi-centred, longitudinal feasibility cohort study was conducted to meet objectives one and two and is reported in this chapter. A process evaluation was undertaken to meet objectives three and four and is reported in chapter six.

### 5.2.2 Study Setting

Potential participants were recruited from physiotherapy services at a large NHS Foundation Trust site, two NHS musculoskeletal provider services and three private practices within East Anglia from October 2017 to September 2018.

### 5.2.3 Eligibility Criteria

Participants were required to be a minimum of 18 years old, have access to the internet, an available email address, proficient with written and spoken English, and identified as having AT as determined by the attending physiotherapist according to established criteria [32,223]:

- Local Achilles tendon pain reproduced with load-based activity, for example heel raising, for at least ten days duration
- Tenderness on palpation of the Achilles tendon
- Range of movement at the ankle within normal limits

To minimise confounding variables for recovery participants presenting post-operatively, or with lumbar spine related disorders which may refer directly to the Achilles tendon region were excluded [32,223]. The exclusion criteria were:

- Tendon rupture
- Receiving treatment for post-surgical recovery
- Reproduction of pain in the Achilles region on movements of the spine

#### 5.2.4 Care Pathways and Physiotherapy

The care pathway for patients recruited into this cohort study did not change as a result of study participation; physiotherapy treatment, referral pathways and waiting times were unaffected. As discussed in chapter one, treatments provided by physiotherapists may be individualised, but generally include advice and exercise. Furthermore, treatment may have also included supplementary techniques such as manual therapy, electrotherapy or shock wave therapy. Possible biomechanical contributing factors may be assessed and additional treatments such as exercise targeted at proximal structures or orthotics be recommended [259].

### 5.3 Variables

Chapter two identified how cognitive and contextual factors may be associated with clinical outcome in AT. The potential factors investigated by this study were reflective of these:

- Working Alliance
- Outcome expectation
- Adherence

- Self-efficacy

Outcome measures used to evaluate these factors were selected based on their psychometric properties in similar populations, but also to minimise respondent burden. The chosen outcome measures are discussed below.

#### 5.3.1 Working Alliance Inventory Short-Form

The Working Alliance Inventory- Short Form (WAI-SF) has high reliability, with test-retest reliability ( $r=0.93$ ) [260]. With regard to construct validity, the WAI-SF correlates well with other therapeutic alliance measures;  $r = 0.80$  with the California Psychotherapy Alliance Scale and  $r = 0.74$  with the Helping Alliance Questionnaire [261]. It is the most frequently used tool to measure alliance within a physical rehabilitation setting [105]. The WAI-SF is a refined 12-item measure that assesses three key aspects of the therapeutic alliance: (a) agreement on the tasks of therapy, (b) agreement on the goals of therapy and (c) development of an affective bond [262]. The WAI-SF requires the participant to rate their agreement on a numerical rating scale from 1-7 in twelve domains. The total score ranges from 12-84, where a higher score represents a stronger therapeutic alliance.

#### 5.3.2 Global Rating of Change for Outcome Expectation

Global Rating of Change (GRC) scales are utilised to measure a person's response to change with respect to a particular condition over a given time [263]. GRC scales have been shown to demonstrate high test-retest reliability (intraclass correlation coefficient 0.9) [264]. Construct validity is supported by

significant correlations between GRC scales and various construct specific measures; disability (Roland Morris Disability Questionnaire  $r=0.50$ , Shoulder Disability Questionnaire  $r=0.74$ ) [265,266] and pain (Numerical Rating Scale  $r=0.49$ ) [267]. A numerical rating scale from -5 (very much worse) to +5 (very much better) is considered optimal with a change of two or more points considered meaningful [263]. As the literature does not support a standardised measure of expectation, a single question with clear instructions was provided in order to differentiate predicted expectations (what the patient thinks will happen, including negative expectations) from ideal expectations (what the patient wants to happen) [166]. Consequently, participants were asked to 'please indicate what you think will occur, NOT what you want to occur; at the end of your treatment, what do you expect the pain associated with your Achilles tendon to be?' [166].

### 5.3.3 Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence

Currently there is a paucity of reported, validated and reliable self-report measures for unsupervised, exercise-based rehabilitation adherence [268]. Diary data is unlikely to be highly accurate for a given individual [269] and in absence of objectives measures to retrospectively measure adherence, self-report scales represent the simplest way of assessing adherence to the home-based programme [270]. The main limitation of retrospective self-reports is the possibility of inaccurate recall, and a bias toward an overestimation of doing the home-based activities [271]. While limited, such measures are convenient and simple to use. In response to the question, 'if you have been requested by your physiotherapist to do exercises at home, please select the word that

overall best indicates the extent you have followed the instruction', participants responded using a 5-item numerical scale from 0 (not at all) to 5 (as advised) [272,273].

#### 5.3.4 Pain Self-Efficacy Questionnaire

Levels of self-efficacy appear to be an important determinant of adherence [161], and so this was captured via the Pain Self-Efficacy Questionnaire (PSEQ) [274]. The PSEQ is the the most extensively studied tool to measure pain self-efficacy [275]. The PSEQ has been shown to have a high degree of reliability in a mixed population with persistent pain conditions; test-retest ( $r=0.73$  ( $p<0.001$ )) from initial assessment to three months later [274]. The PSEQ construct validity is reflected in high correlations (in the expected directions) with measures of pain-related disability and different coping strategies; Pain Belief Questionnaire ( $r=0.74$   $p<0.001$ ), Beck Depression Inventory ( $r=-0.59$   $p<0.001$ ), Coping Strategies Questionnaire subscales catastrophisation ( $r=-0.55$   $p<0.001$ ), coping statements ( $r=0.48$   $p<0.001$ ), ignore ( $r=0.46$   $p<0.001$ ), increase behaviour ( $r=0.45$   $p<0.001$ ) and control pain ( $r=0.56$   $p<0.001$ ) [274]. The PSEQ requires the participant to state their confidence, despite pain, on a numerical rating scale of 0-6 in ten domains; the total score ranges from 0-60, where a higher score represents stronger self-efficacy beliefs [276].

#### 5.3.5 Clinical Outcome Measures

As discussed and detailed in chapter three, the primary clinical outcome measure was the Lower Extremity Functional Score (LEFS) [240]. The LEFS is a self-report questionnaire designed to measure physical function of people

with lower extremity dysfunctions, such as AT. Twenty items covering a range of lower extremity functional activities are scored on a numerical rating scale from zero (extreme difficulty or unable to perform activity) to four (no difficulty). This provides maximum scale points of eighty, with zero representing maximum dysfunction. To detect both a minimal detectable change and a minimal clinically important difference a change of nine scale points is needed [240]. One item required the distance to be converted from an American distance of 'a block' to the equivalent in the United Kingdom of 150 metres; participants were asked to rate their difficulty in walking 150 metres.

A secondary clinical outcome measure was the Numerical Pain Rating Scale (NPRS) [277]. The NPRS for pain is a unidimensional measure of pain intensity in adults [278,279]. The NPRS is an 11-point scale designed to measure self-reported pain intensity on a scale ranging between 0 (no pain at all) and 10 (the worst pain ever possible) [280]. High test–retest reliability has been observed in both literate and illiterate patients ( $r = 0.96$  and  $0.95$ , respectively) [281]. In addition, construct validity has been shown against the Visual Analogue Scale with high correlations in a population with mixed pain-related diseases [282]. A change on the NPRS of 20% between two time-points of an assessment is regarded as clinically significant [277,283].

## 5.4 Sample Size

Feasibility studies typically do not evaluate the clinical outcome of interest because they do not undertake hypothesis testing; the sample size is estimated to enable evaluation of the key feasibility criteria [284]. To meet the study's

objective of evaluating the recruitment rate and retention, a 'recruit to time' approach was employed where the recruitment period of eleven months duration was pre-specified for this purpose and to align with the timelines of this PhD. It is recognised that an a priori sample size can be presented but given that the main feasibility criteria were around recruitment, such an approach was deemed useful and appropriate for this study.

#### 5.4.1 Participant Selection, Recruitment and Informed Self-Consent

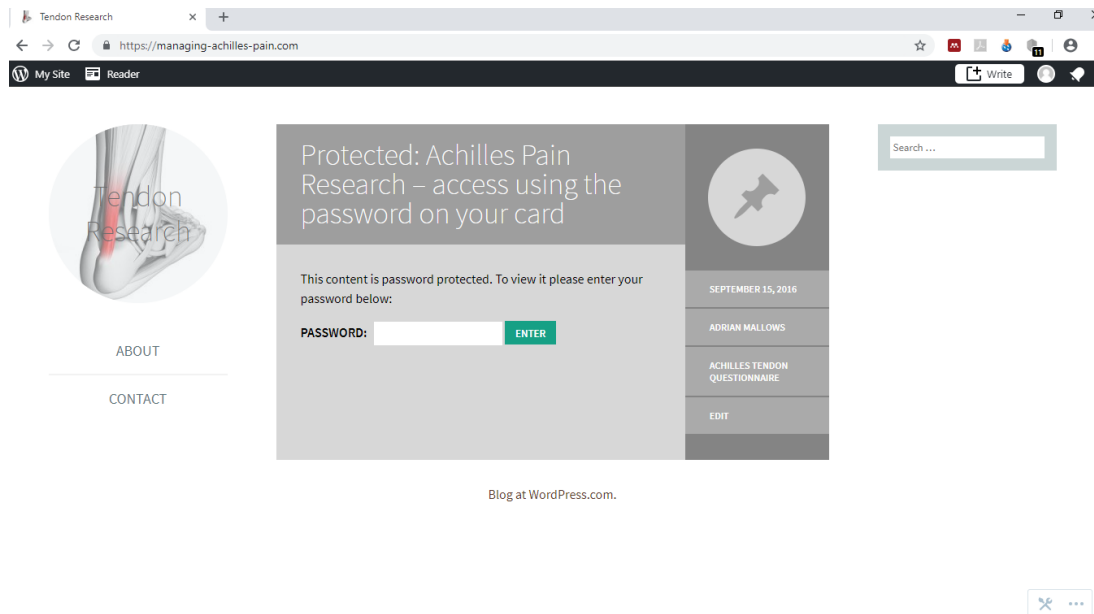
Potential participants were identified at each site by their treating physiotherapist. To minimise burden on the physiotherapist, the physiotherapist explained the purpose of the study, the methods involved, and then provided a card detailing a website which hosted further information (appendix 8). Training in the study processes was provided to the physiotherapists in line with Good Clinical Practice (GCP) recommendations [285]. Key features of the training included providing background information to the MAP study, objectives of the study, eligibility criteria, the design of the study and approaching recruitment through a stepped approach (appendix 9). The stepped approach encourages clinicians to view recruitment in a six-stepped process; 1) explain the condition, 2) reassure they will be receiving the best treatment, 3) explain there is uncertainty what makes it the best, 4) explain the purpose of the study, 5) balance the risks and rewards, 6) explain the procedures [286].

Once identified and provided with a card, potential participants were then able to consider whether they would like to participate or not. If potential participants

decided not to participate in the study while still in the clinic there was the option to provide a reason as to why on the reverse of the card and leave this anonymously in a marked box in the reception area.

On the card, the potential participant was directed to [a website](#), which was designed as a part of the bespoke online platform for the purposes of this study. The website hosted a landing page and blog post (picture 5.1) containing password protected information (the participant information sheet (appendix 10), consent form (appendix 11) and the outcome measures in the form of an online questionnaire). The participant could freely read the participant information sheet and consent details without time constraint, and decide to participate or not. Participants were free to leave the website without having completed the consent form. This information clearly stated that involvement was voluntary, participants were free to withdraw at any time and information would not be shared with their physiotherapist. It also included contact details to provide the opportunity for questions. If the participant consented to take part, they were then able to access the online questionnaire.





Picture 5.1. The landing page and blog post for the MAP study's website

#### 5.4.2 Collection of Clinical Outcome Measures and Variables

Clinical outcome measures (LEFS and NPRS) were collected together with the other outcome variables (GRC, PSEQ, WAI-SF and patient self-report scale) via the password-protected landing page. Responses from electronic versions of the measures in the form of a questionnaire were collected at baseline, and then again at six and twelve weeks following completion of the first questionnaire. The participant did not have access to the responses they provided previously. To maximise response rates, non-responders to follow up were sent two email reminders (appendix 12) to encourage them to re-visit the website and complete the questionnaire.

#### 5.4.3 Adverse Events

It was not expected that any adverse events would occur as a result of this study. Given its observational nature, any adverse events related to treatment were directed to the treating physiotherapist. However, participants were

provided the opportunity to contact the author, a supervisor of the study or an expert external to the study should they have wished.

#### 5.4.4 Data Management

Data were collected through a protected online questionnaire provided by Qualtrics [287]. Qualtrics host a password-protected website to which only the author had the password to for accessing data once participants had completed the questionnaire. Although email addresses from participants were collected in the questionnaire, Qualtrics itself only collected Internet Protocol addresses (IP addresses) by default and made no attempt to identify anyone from these and did not save this information within their data set. All data collected from participants completing the questionnaire were stored in a single secure European data centre. These data were then exported from Qualtrics to a Microsoft Excel database on a password protected file store. Handling of all personal data was done in compliance with the Data Protection Act [288]. The dataset held for an individual participant was pseudo-anonymised meaning that a unique identifier linked a participant's data to their personal details. Personal details were required by the author to send follow up questionnaires at six and twelve weeks.

#### 5.4.5 Statistical Analysis

Feasibility outcomes (recruitment and retention rates) were described using descriptive statistics. As hypothesis testing is not recommended for this size and type of study [284,289], a preliminary correlational analysis only was conducted to assess 1) the overall relationship between the variables of

working alliance, outcome expectation, adherence and self-efficacy and the clinical outcome measures of pain and function and 2) between baseline and the twelve week follow-up time point. The value of the correlation coefficient was interpreted as small (.10 to .29); medium (.30 to .49); and large (.50 to 1.0) [290]. Statistical analysis was undertaken using SPSS (version 25.0, Armonk, NY: IBM Corp).

## 5.5 Patient and Public Involvement

Patient and public involvement in the research process is critical, with repeated calls having been made to engage and involve the public and patients and place them at the centre of healthcare [291]. Patient and public involvement (PPI) in research has been defined as “experimenting with” as opposed to “experimenting on” patients [292] and serves to ensure that patient benefit is not simply based on the views and options of research professionals and clinicians. It has been suggested that PPI in research can improve the relevance and overall quality of research, by ensuring that it focuses on the issues of importance to patients [293]. In the UK, the Department of Health’s national strategy puts patients at the centre of all National Health Service-related activity. This national strategy highlights the importance of involving patients, carers and the public at all stages of the research process.

Two physiotherapists and two local physiotherapy service users were identified through an established working relationship with one recruitment site and invited to be involved in the development of the research design and participant facing material. The physiotherapists and service users were emailed a digital

version of the postcard and a link to the website and asked to review both. The aim of this was to maximise recruitment and retention by determining the acceptability of the documents and the design and flow of the website and questionnaire. Feedback from the physiotherapists and physiotherapy service users was provided through email. PPI involvement was reported according to the GRIPP 2 short form checklist for reporting of patient and public involvement in research (appendix 13) [293].

One paragraph of the participant information sheet was revised following feedback from one physiotherapist; *'I think you can make this a bit more succinct as it is currently a difficult read'*. The other physiotherapist provided a positive overview; *'looks good – no problems envisaged'*. The postcard was amended in response to one service user's comment; *'the web site address needs to be closer to the first paragraph, the position, as it is looks like it's the title line for not doing the survey'*. The other service user provided positive feedback on the process from visiting the website to completing the questionnaire; *'to be honest, it was pretty straightforward and no issues completing it at all'*. Both service users were invited to continue to be involved in the development of any future revisions of participant facing material, with one agreeing but no further revisions were made.

## 5.6 Results

### 5.6.1 Feasibility Analysis - Recruitment and Retention

The physiotherapists were issued 1100 cards for recruitment of participants. Of these, 795 were returned on the completion of the study. One card was

returned with a reason given for a potential participant not wishing to take part; 'didn't want to' was marked. The traffic through the website recorded a total 55 views of the blog post containing the information about the study. These 55 views resulted in 24 participants (11 males) consenting to join the study. Table 5.3 describes the participants' details. No adverse events were reported by any participants. The questionnaire was started 63 times and completed on 60 separate occasions resulting in a 95% conversation rate from those participants who provided initial consent. Full details are listed in table 5.1. All three participants who did not complete the questionnaire did so when asked for their email address and as such did not consent to join the study. All questionnaires were completed fully without any missing data yielding a missing data indicator of 0%. Figure 5.1 shows the participants' journey through the study.

Participant	Response 1	Response 2	Response 3
1	✓	✓	✓
2	✓	✓	✓
3	✓	✓	✓
4	✓	✓	✗
5	✓	✓	✓
6	✓	✓	✗
7	✓	✗	✗
8	✓	✓	✗
9	✓	✓	✓
10	✓	✓	✓
11	✓	✓	✓
12	✓	✓	✓
13	✓	✓	✓
14	✓	✓	✓
15	✓	✗	✗
16	✓	✓	✓
17	✓	✓	✓
18	✓	✓	✓
19	✓	✓	✗
20	✓	✗	✗
21	✓	✗	✗
22	✓	✓	✓
23	✓	✓	✓
24	✓	✓	✓
<b>TOTAL</b>	<b>24</b>	<b>20</b>	<b>16</b>
<b>Retention</b>	<b>100%</b>	<b>83.3%</b>	<b>66.6%</b>

Table 5.1 Number of responses from participants

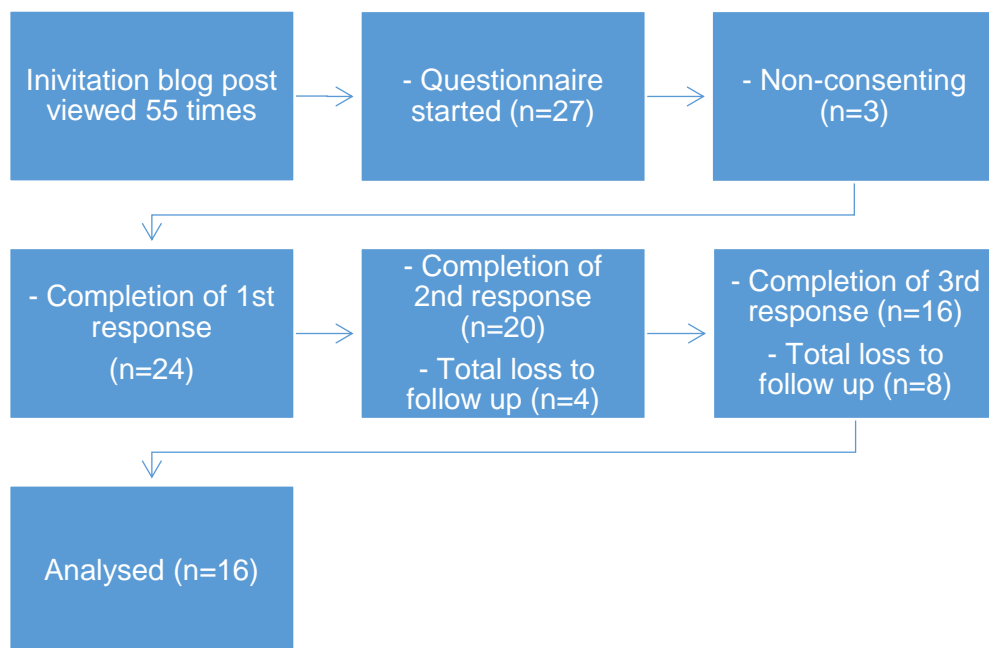


Figure 5.1 Participants flow through the MAP study

### 5.6.2 Correlation Analysis

Initially the data was tested for normality. The results are presented in table 5.2 and in figure 5.2 and indicate that the data from the WAI-SF, GRC, NPRS and Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence were not normally distributed as the value of significance is  $p < 0.05$  [294]. Accordingly, baseline characteristics for all participants shown in table 5.3 reports median and range values and offers comparison between those who returned full data sets (responders) and those who were lost to follow up (non-responders). As data were not normally distributed a non-parametric test (Mann-Whitney Test) was used to assess for differences between the responders and non-responders [294]. Statistically significant differences were found between the median values of the WAI-SF ( $p = 0.003$ ), the PSEQ ( $p = 0.004$ ) and the LEFS ( $p = 0.011$ ).

To describe the strength of the relationship and direction between the variables and the clinical outcomes at baseline and twelve weeks, scatterplots were used (figures 5.3 and 5.4). Figures 5.5 and 5.6 describe the overall strength of the relationship and direction across all time points between the variables and the clinical outcomes.

	Shapiro-Wilk		
	(n)	Statistic	Level of significance
WAI-SF	24	.904	.026*
GRC	24	.856	.003*
PSEQ	24	.947	.238
NPRS	24	.914	.043*
LEFS	24	.959	.428
Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence	24	.693	<.001*

Table 5.2 Shapiro-Wilk test for normality of baseline data

\* Indicates non-normal distribution of data ( $p < 0.05$ )

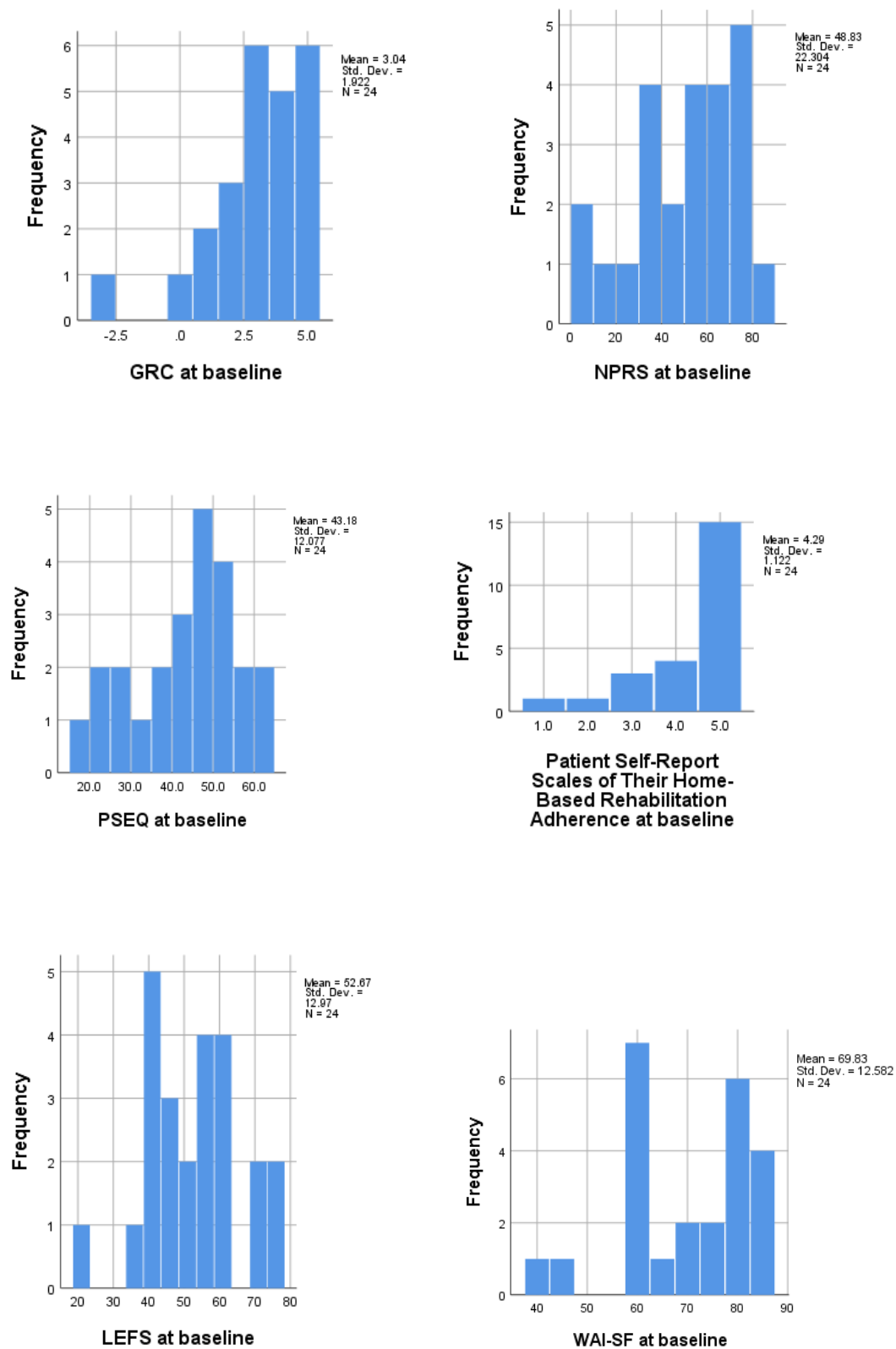


Figure 5.2 Histogram plots of baseline variables and clinical outcome measures



Baseline	Participants included in analysis: responders	Participants lost to follow up: non-responders	Overall
	(Median) Range	(Median) Range	(Median) Range
<b>Age range+ (years)</b>	19% 30-39 25% 40-49 31% 50-59 19% 60-69 06% 70-79	38% 30-39 25% 40-49 25% 50-59 12% 60-69 00% 70-79	25% 30-39 25% 40-49 29% 50-59 17% 60-69 04% 70-79
<b>Sex (% female)</b>	56%	50%	54%
<b>WAI-SF</b>	(78.5) 47-84	(60)* 40-70	(73) 40-84
<b>PSEQ</b>	(50.5) 24.8-60.0	(35)* 19-45.8	(45.8) 19-60
<b>GRC</b>	(3) 0-5	(3.5) -3-4	(3) -3-5
<b>LEFS</b>	(57) 21-75	(43)* 38-60	(53.5) 21-60
<b>NPRS</b>	(45) 5-71	(57.5) 38-81	(50) 5-81
<b>Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence</b>	(5) 1-5	(5) 3-5	(5) 1-5

Table 5.3 Baseline participant characteristics

WAI\_SF- Working Alliance Inventory – Short Form (score ranges from 12-84, where a higher score represents a stronger therapeutic alliance).

PSEQ - Pain Self-Efficacy Questionnaire (score ranges from 0-60, where a higher score represents stronger self-efficacy beliefs).

GRC - Global rating of change for outcome expectation (scale from -5 (very much worse) to +5 (very much better)).

LEFS - Lower Extremity Functional Score (score ranges from 0-80, with 0 representing maximum dysfunction).

NPRS - Numerical Pain Rating Scale (scale ranging between 0 (no pain at all) and 10 (the worst pain ever possible)).

Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence (5-item numerical scale from 0 (not at all) to 5 (as advised))

\* Statistically significant difference ( $p < 0.05$ ) between responders and non-responders using Mann-Whitney Test

+ Age range was captured only

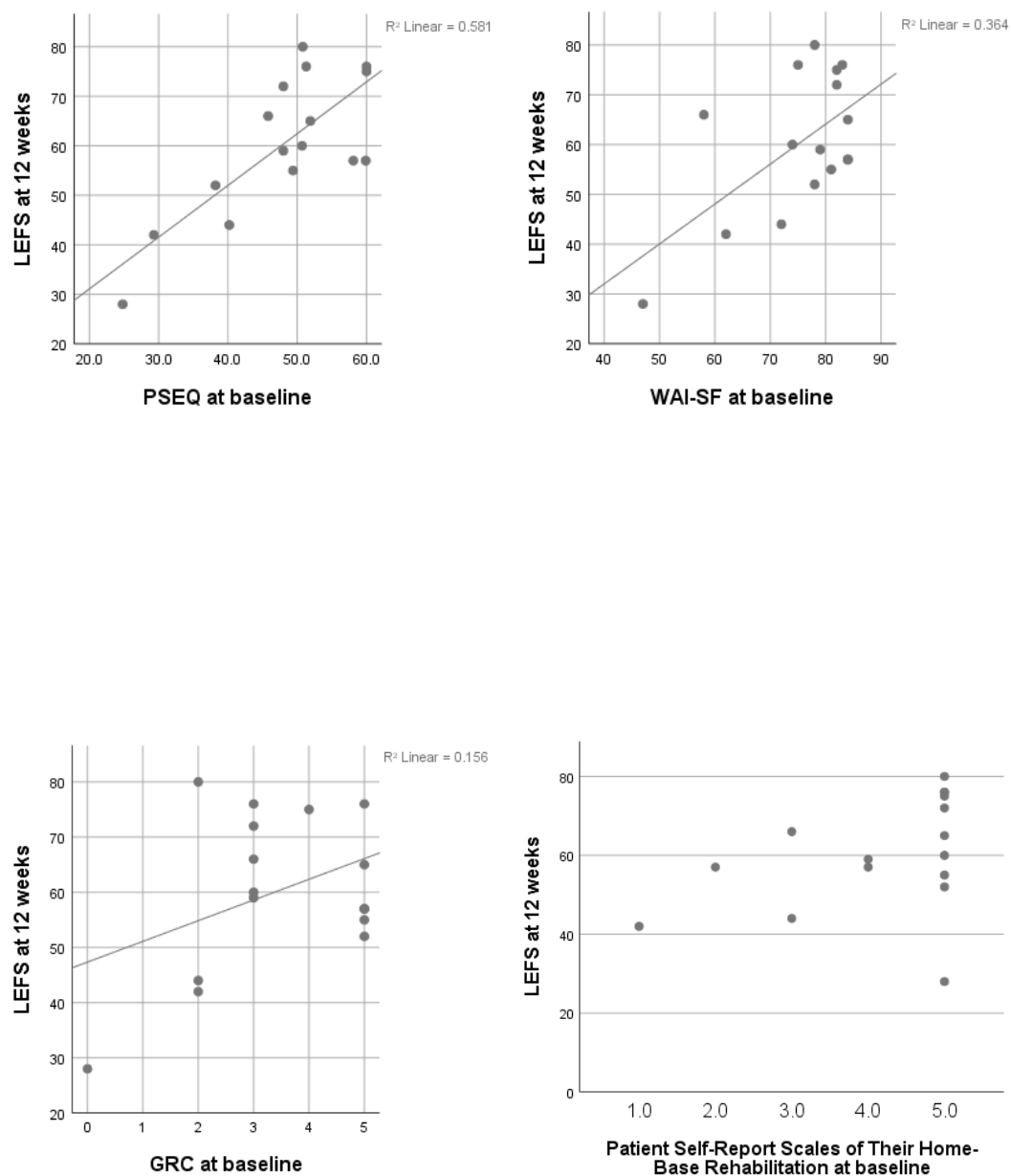


Figure 5.3 Scatterplots exploring interrelationship between baseline variables and clinical outcome (disability) at 12 weeks

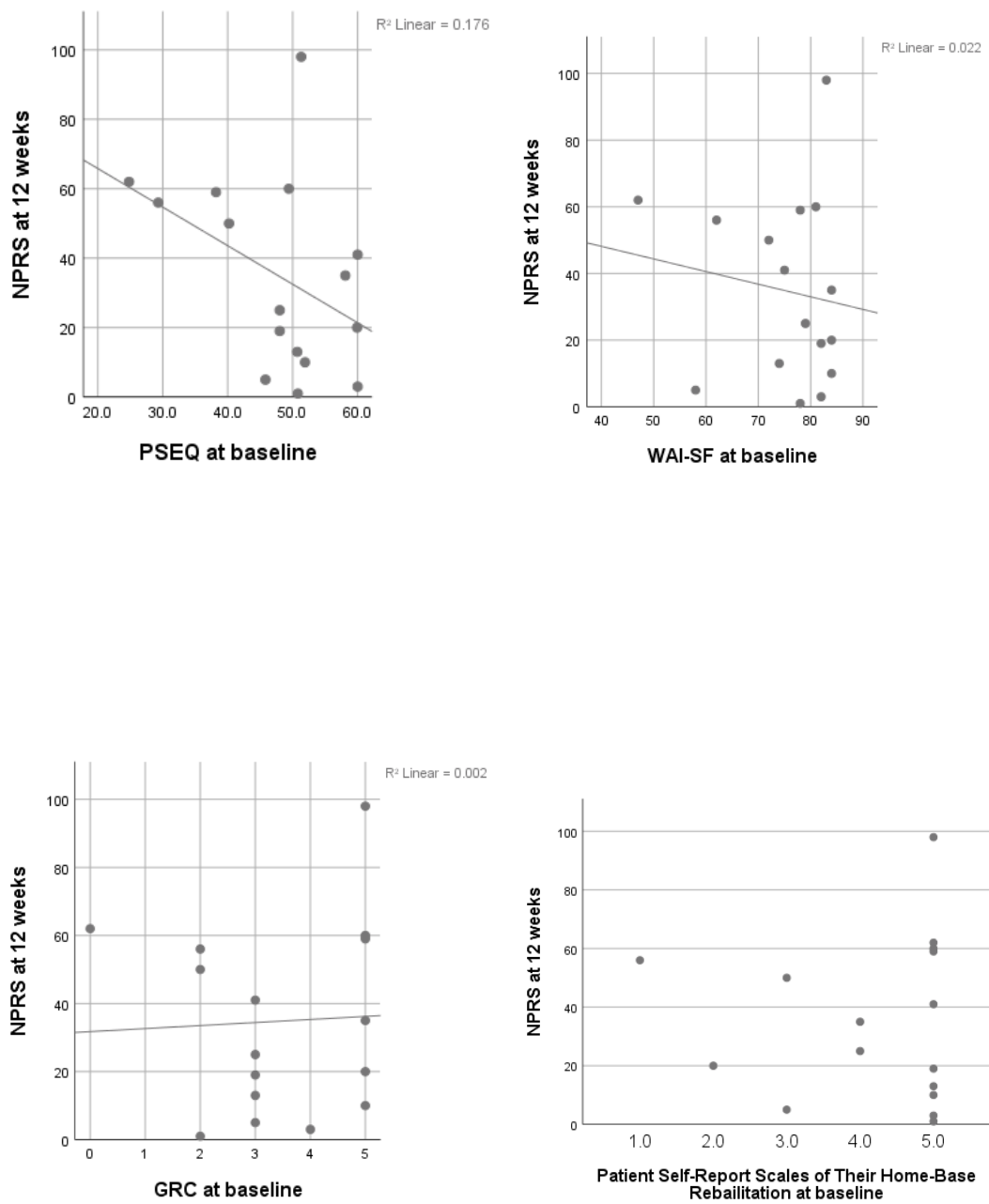


Figure 5.4 Scatterplots exploring interrelationship between baseline variables and clinical outcome (pain) at 12 weeks

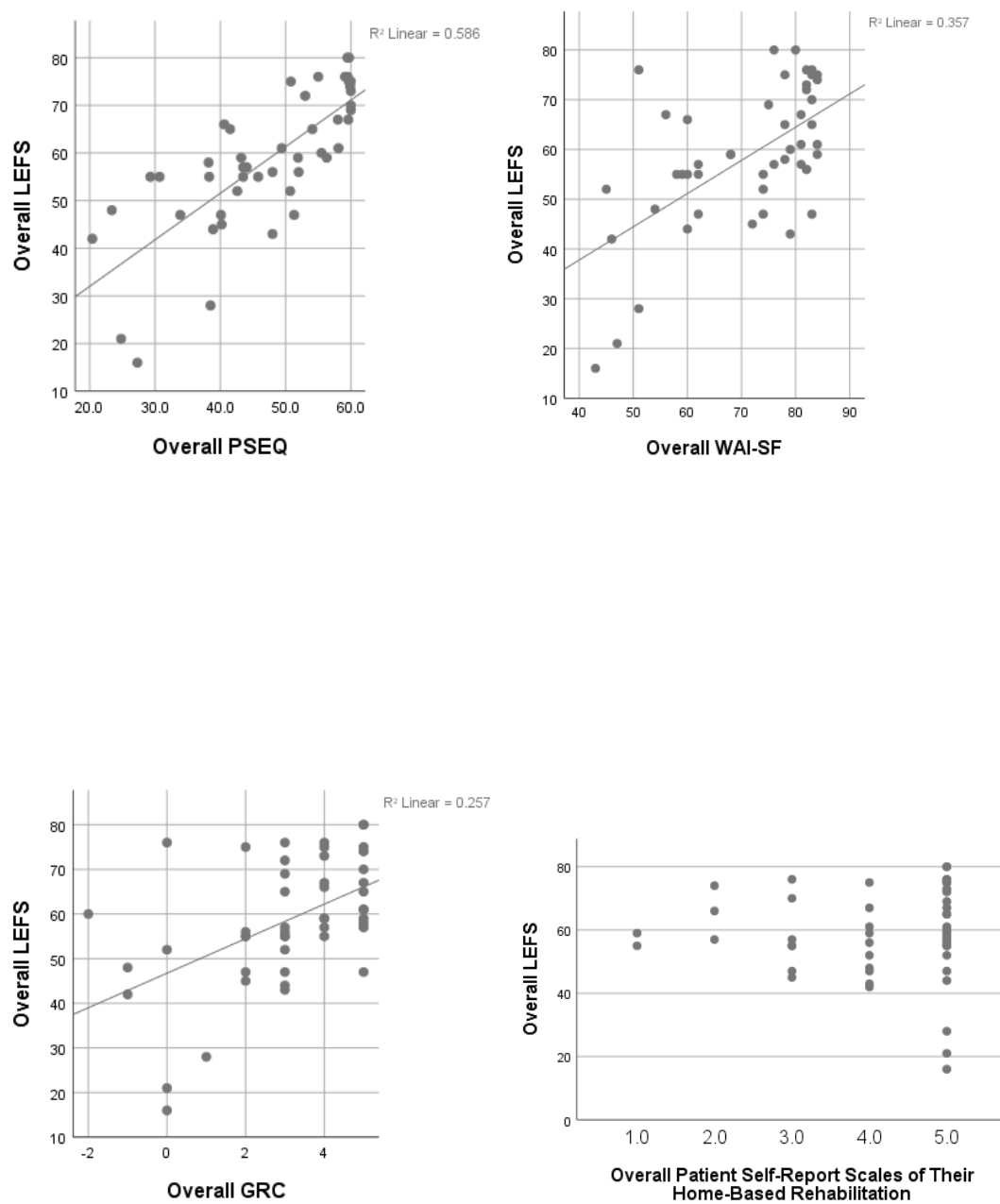


Figure 5.5 Scatterplots exploring the overall interrelationship between variables and clinical outcome (disability) across all time points

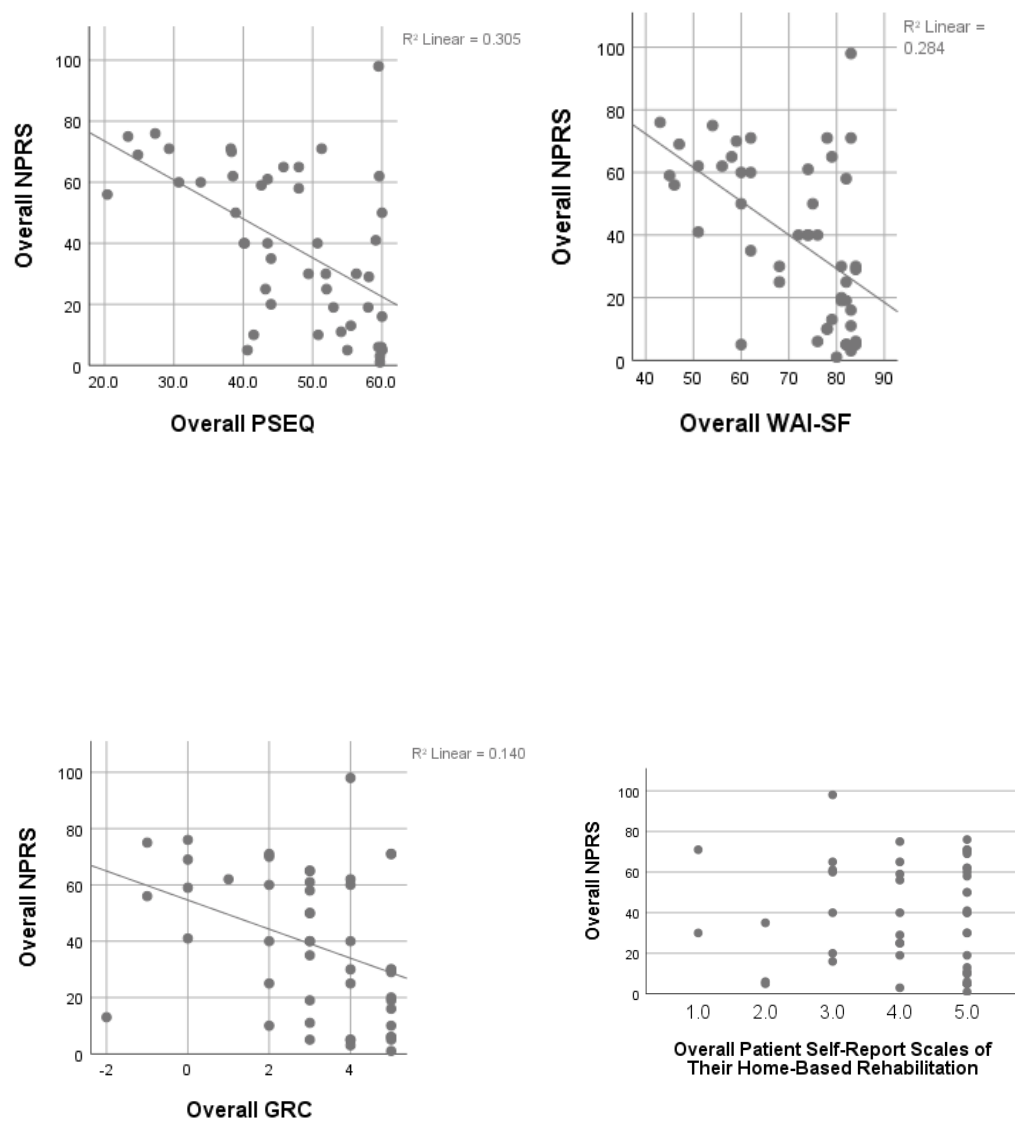


Figure 5.6 Scatterplots exploring the overall interrelationship between variables and clinical outcome (pain) across all time points

Table 5.4 details the results of the overall correlation between variables and clinical outcomes across all time points. The relationship was investigated using Spearman's rho correlation coefficient as preliminary analyses (figure 5.2, table 5.2) indicated there was a violation of normality in distribution of data. Overall, the measures of working alliance (WAI-SF) ( $\rho=-.527$ ,  $p<0.001$ ), and pain self-efficacy (PSEQ) ( $\rho=-.580$ ,  $p<0.001$ ) have a large negative correlation with pain measured by the NPRS. Overall, outcome expectation measured by the GRC ( $\rho=-.417$ ,  $p=0.003$ ) has a medium negative correlation with NPRS measurement of pain. In addition, the WAI-SF ( $\rho=.551$ ,  $p<0.001$ ), PSEQ ( $\rho=.800$ ,  $p<0.001$ ) and GRC ( $\rho=.507$ ,  $p=0.001$ ) overall all have a large positive correlation with disability measured by the LEFS.

	PSEQ	GRC	Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence	LEFS	NPRS
WAI-SF	.669	.634	0.051	.551**	-.527**
PSEQ	-	.492	0.092	.800**	-.580**
GRC	-	-	0.005	.507**	-.417**
Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence	-	-	-	0.121	-0.051
LEFS	-	-	-	-	-.677

Table 5.4 Spearman's rho correlations between measures of the variables and clinical outcome measures across all time points

\*\* Correlation is statistically significant ( $p<0.01$ )

	Baseline Pain self- efficacy	Baseline GRC	Baseline Patient Self- Report Scales of Their Home-Based Rehabilitation Adherence	LEFS at 12 weeks	NPRS at 12 weeks
<b>Baseline WAI-SF</b>	.686	.795	.143	.325	-.157
<b>Baseline PSEQ</b>	-	.521	.220	.650*	-.401
<b>Baseline GRC</b>	-	-	.160	.146	.078
<b>Baseline Patient Self-Report Scales of Their Home- Based Rehabilitation Adherence</b>	-	-	-	.428	.005

Table 5.5. Spearman's rho correlations between measures of the baseline variables and clinical outcome measures at 12 weeks

\* Correlation is statistically significant ( $p < 0.05$ )

Table 5.5 details the results of the correlation between baseline variables and clinical outcomes at 12 weeks. The relationship was investigated using Spearman's rho correlation coefficient as preliminary analyses performed (figure 5.2, table 5.2) indicated there was a violation of normality in distribution of data. There was a large, positive correlation between baseline pain self-efficacy as measured by the PSEQ and disability measured by the LEFS at 12 weeks ( $\rho = .650$ ,  $p < 0.06$ ). There was a medium, positive correlation between baseline working alliance measured by the WAI-SF ( $\rho = .325$ ,  $p < 0.219$ ) and adherence measured by the Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence ( $\rho = .428$ ,  $p < 0.98$ ) and the LEFS at 12 weeks. There was a medium, negative correlation between baseline PSEQ and NPRS at 12 weeks ( $\rho = -.401$ ,  $p < 0.124$ ).

## 5.7 Discussion

To the author's knowledge, this is the first study to utilise a protocol incorporating an online platform as a data collection method for a longitudinal study involving a population with AT. Accordingly, the objectives of this study were: 1) to determine the recruitment & retention rate and 2) to carry out preliminary data analysis of the selected variables and clinical outcomes.

### 5.7.1 Feasibility Outcomes - Recruitment and Retention

Internet-based questionnaires provide an attractive alternative to postal and telephone questionnaires, but they raise important technical and methodological issues. The major obstacle here is external validity; specifically related to how a representative sample and adequate response rate is achieved [295]. Such obstacles were seen in this study. Although 305 cards were not returned, it is not possible to determine how many of these cards were provided to patients. Recruitment difficulties detailed in a subsequent chapter (chapter six) suggests many of these non-returned cards may have been lost or simply not returned. Over an eleven-month duration, the traffic through the website recorded a total 55 views of the blog post containing the information about the study. It is not possible to determine how many of the 31 people who viewed the blog post but did not take the survey had been directed to the website by an invitation card and how many were simply 'traffic'. On average of 2.2 participants were recruited per month. Of these participants 66% were retained and completed all three questionnaires. Whilst the difference in the attrition rates between feasibility studies and their associated full trial demonstrates high variability [296], strategies to maximise retention are



explored in chapter six. Utilising the median scores of the non-responders may suggest these strategies are especially targeted to those who report a WAI-SF score of  $<60$ , PSEQ score of  $<35$  or LEFS score of  $<43$ . Only three people started but did not complete the initial questionnaire resulting in a 95% conversion rate. Internet-based questionnaires allow the option of utilising a 'forced response' to a question; the participant is not allowed to submit the questionnaire without completing all the required details. This option would appear potentially meaningful in facilitating a missing data indicator of 0%.

### 5.7.2 Correlation Outcomes

Overall, there was a large positive correlation between the WAI-SF ( $\rho=.551$ ,  $p<0.001$ ), PSEQ ( $\rho=.800$ ,  $p<0.001$ ) and GRC ( $\rho=.507$ ,  $p=0.001$ ) and the LEFS, and a large negative correlation between the WAI-SF ( $\rho=-.527$ ,  $p<0.001$ ), PSEQ ( $\rho=-.580$ ,  $p<0.001$ ) and the NPRS. These results suggest higher levels of perceived working alliance, outcome expectation and pain self-efficacy were statistically significantly associated with less disability and pain. In addition, there was a large positive correlation between baseline pain self-efficacy measured by the PSEQ and disability measured by the LEFS at 12 weeks ( $\rho=.650$ ,  $p<0.06$ ) and a medium positive correlation between baseline working alliance measured by the WAI-SF ( $\rho=.325$ ,  $p<0.219$ ), adherence measured by the Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence ( $\rho=.428$ ,  $p<0.98$ ) and disability measured by the LEFS at 12 weeks. Finally, there was a medium, negative correlation between baseline PSEQ and pain measured by the NPRS at 12 weeks ( $\rho=-.401$ ,  $p<0.124$ ). These results suggest higher levels of pain self-efficacy are

statistically significantly associated with reduced disability at 12 weeks. Working alliance and adherence at baseline are associated with reduced pain and disability at 12 weeks, but not at statistically significant levels. Whilst the level of statistical significance does not indicate how strongly variables are associated (this is determined by the rho in these results), it instead indicates how much confidence can be placed in the results obtained [294]. In addition, the significance of the rho is strongly influenced by the sample size. A small sample size, such as  $n=16$ , will increase the data variability, lowering the probability of replication and as such data may be unusual simply by chance. Whilst, the statistical method of imputation could have been utilised to replace the missing the data from the 'non-responders' with values created by the statistical package [297], the resultant increase would still leave a small sample size ( $n=24$ ) and given the preliminary nature of the analysis this was decided against. Consequently, these findings should be interpreted cautiously and a future study will require a larger sample size. Tabachnick and Fidell [298] provide a formula for calculating sample size requirements by taking into account the number of independent variables that will be used:  $N > 50 + 8m$  ( $m$ = number of independent variables). Utilising the number of independent variables investigated in this feasibility study ( $n=4$ ; working alliance, outcome expectation, adherence, self-efficacy), the sample size required for a future study which would allow for determining prediction in addition to correlation would be  $50 + (8 \times 4) = n > 82$ .

As the data were not normally distributed, non-parametric testing for correlation was performed and it should be noted that non-parametric tests tend to be less

sensitive, potentially failing to detect relationships that do actually exist [294]. Whilst this appears not to be the case for the results presented here (although alternative explanations have been presented and caution urged with their interpretation), this requires further consideration for planning of a future fully powered study. Because parametric testing requires a minimum level of interval data, the Patient Self-Report Scale of Their Home-Based Rehabilitation Adherence provides ordinal level of data and therefore would not have met assumptions for parametric testing [294]. Furthermore, potential problems of assuming that ordinal level ratings (e.g. Likert scales such as NPRS and the GRC) approximate interval level scaling are increasingly being recognised. As such, further consideration is required to the level of data produced by the responses in the questionnaire to ensure matching with the planned statistical tests [294].

## 5.8 Limitations

This feasibility study has some limitations. Firstly, the design of the study did not allow for all feasibility data to provide complete answers; it remains uncertain how many patients were given cards and how many landed on the blog page and then decided not to participate. Secondly, all recruitment sites were within the UK. The online platform allows for future studies to include international collaboration to improve generalisability. Whilst the current study would, however, inform the documentation of standard operating procedures in terms of recruitment and data collection, potential recruitment and retention obstacles from international collaboration remain unknown.

## 5.9 Conclusion

Feasibility studies ask the question 'can this be done'? Based on the data from recruitment and rates and exploratory correlation analysis a future study can be done; this previously untested online platform appears feasible. Future consideration is required to ensure the level of data produced from the responses to the questionnaire matches with the statistical technique required to meet the aim of the study. Additional consideration is needed to enhance recruitment strategies and reduce attrition rates; these strategies are investigated and discussed in chapter six of this thesis.

## Chapter 6: The Process Evaluation

*Based upon Mallows A, Littlewood C, Jackson J, Debenham J Managing Achilles Pain (the MAP study) – a process evaluation of data collection methods. Musculoskeletal Science and Practice 2019; doi.org/10.1016/j.msksp.2019.04.008 (Appendix 14)*

### Summary

This chapter describes the process evaluation from a sample of patient participants (n=7) and physiotherapists (n=6) exploring the acceptability of the study from their perspective. Semi-structured interviews were used to obtain the data and analysed using the Framework Approach.

### 6.0 Introduction

Process evaluations explore the way in which the outcome from a study is implemented and can provide valuable insight into why a failure happens or unexpected consequences, or why a success occurs and how this can be optimised [299]. High quality evaluation is crucial in allowing policy-makers, practitioners and researchers to identify outcomes that are effective, and learn how to improve those that are not [300]. The online platform used for collection methods was untested and as such it was important to identify outcomes from using this method and explore these from the perspectives all of those involved in the study. Hence, this aspect of the study provides complementary data to the findings of the feasibility cohort study and identifies factors that might present as obstacles or facilitate successful wider implementation. Whilst this process evaluation refers to the feasibility of the MAP study, the data generated can provide guidance to researchers developing study protocols for similar studies.

The Medical Research Council (MRC) process evaluation framework [300] sets out guidance which emphasises the relations between implementation, mechanisms, and context (box 6.1). For example, figure 6.1 highlights the success of data collection could be affected by design of the website and the questionnaire (implementation); the motivation of the participants to complete repeated questionnaires (mechanism of impact); and the perceived effort to take part (context).

- Implementation: the structures, resources and processes through which delivery is achieved, and the quantity and quality of what is delivered
- Mechanisms of impact: how intervention activities, and participants' interactions with them, trigger change
- Context: how external factors influence the delivery and functioning of interventions

Box 6.1 Definitions of terms [300]

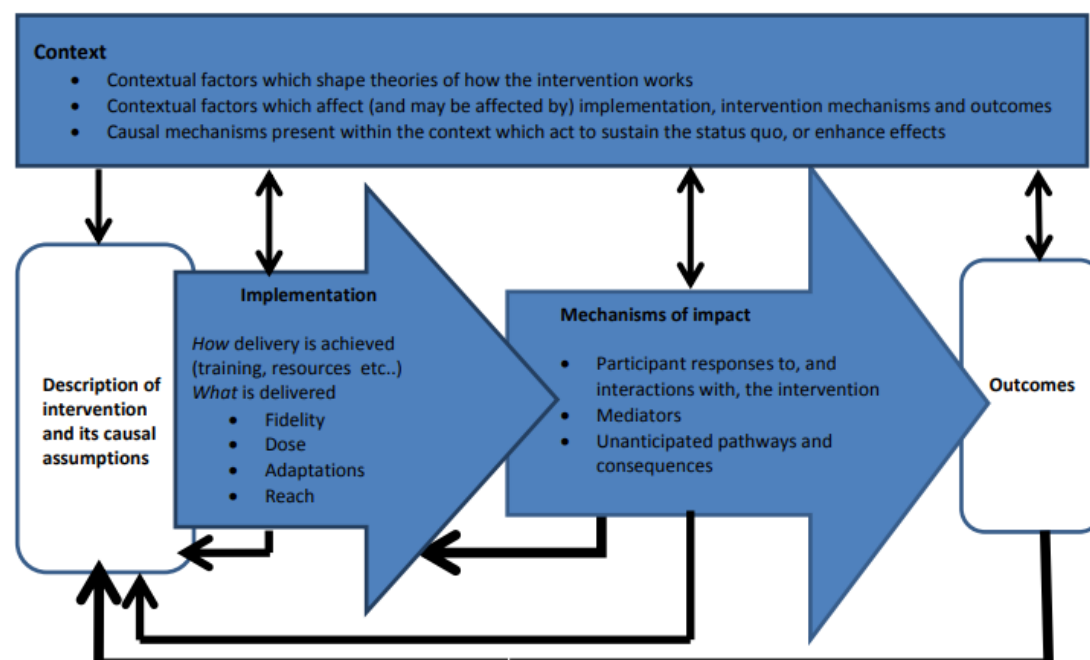


Figure 6.1 Key functions of a process evaluation and relationships amongst them [300]

Utilising the guidance from the MRC [300], the purpose of the process evaluation was to meet predetermined objectives three and four of the MAP study; to explore the acceptability of the study procedures from the patient participants' and physiotherapists' perspectives respectively. The process sought to discover what worked (and did not), for whom, how, why and in what circumstances. The process evaluation is reported according to the COREQ checklist for research using interviews and focus groups (appendix 15).

## 6.1 Methodological Approach

As discussed in chapter four, the qualitative component reported here took a 'critical realist' perspective; to evaluate participant perspectives to realise the critical importance of participants' own interpretations of the issues researched, believing that the varying vantage points of different participants would yield different types of understanding [242]. This perspective was adopted to ensure data collection methods and analytical strategies best met the objectives of the process evaluation [301–303] and focused on accurately describing participants' experiences, staying close to the data, and ensuring subsequent interpretations are transparent [304,305].

## 6.2 Methods

Guidance in the literature exists for conducting a process evaluation. At the feasibility and piloting stage, Moore et al [300] recommend basic quantitative measures of implementation be combined with in-depth qualitative data to provide detailed understandings of outcome functioning on a small scale. To achieve this, the same authors [300] propose combining quantitative data on

key process variables from all sites or participants with in-depth qualitative data from samples purposively selected along dimensions expected to influence the functioning of the outcome.

To generate such in-depth qualitative data, semi-structured interviews were utilised. Such interviews are a powerful method for generating description and interpretation of people's social worlds; researchers talk to those who have knowledge of or lived experience with the problem of interest. Through exploration of experiences, motives, and opinions, the researcher may learn to view the world from another perspective other than their own [242]. Silverman [247] outlines three models of interviewing, each underpinned by a different epistemological standpoint; positivism, naturalism and constructionism (table 6.1). According to positivism, interview data have the potential to give accurate and reliable 'facts' about what is being explored; a standardised interview through a set of questions is used to 'mine' for data which participants already hold independent of the research. However, this model ignores the desire to understand the meaning behind the data generated. To achieve this, more open-ended interviews are required to allow the researcher to 'travel' with the interviewee; therefore, both naturalism and constructionism models require analysis. Naturalism is concerned with eliciting authentic accounts of a subjective experience.



	<b>Status of Data</b>	<b>Methods</b>
Positivism	Facts about behaviour and attitudes	Random samples Standardised questions Tabulations
Naturalism	Authentic experiences	Unstructured, open-ended interviews
Constructionism	Mutually constructed	Close study of how participants produce sense in any research data

Table 6.1 Differing models of interviewing [247]

Given that the interviewer wants to access the lived experience of the interviewee, emotions are central to this model. However, the interview itself is not acknowledged as a contextual and interactive component of shaping this experience, potentially limiting the validity of the data uncovered. Constructionism views the process of the interview itself as a recognised part of the representation of that which it seeks to explore; constructionists are concerned with how interview participants actively create meaning. However, this has led to criticism of a narrow view; 'it would seem to deny the value of treating interview data as saying anything about any other reality than the interview itself' [247]. Consequently, although a constructionist approach was undertaken to interview the two separate stakeholder groups (physiotherapists and patient participants), given the critique of the models discussed above, it was important to not only interpret the interview data, but also the way it was collected. Such considerations are discussed in the strengths and limitations section of this chapter.

### 6.2.1 Patient Participant Selection and Recruitment

To gain maximum variation in terms of age, gender and clinical outcome, as determined by change in LEFS and NRS from baseline to twelve weeks follow-up, all patient participants were invited from the MAP cohort study described in chapter five. Patient participants were contacted by email; sent the participant information sheet, and consent form (appendices 16-18), then provided the opportunity to ask questions and invited to respond. Once any questions were answered, the patient participant was invited to participate in an individual interview at their convenience. Consent to take part in the interviews was audio recorded prior to commencing the interview. To reduce recall bias, selection and recruitment were completed within one month of the patient participant completing the cohort study.

### 6.2.2 Physiotherapist Selection and Recruitment

An invitation by email (appendix 19) along with a participant information sheet and consent form (appendices 20 and 21) was sent to the Lead Physiotherapist at each site. Lead Physiotherapists were asked to share this email with all physiotherapists who have taken part in recruitment for the study. Physiotherapists considering volunteering replied to the email and were then provided the opportunity to ask questions; once any questions were answered, the physiotherapist was invited to participate in an individual interview at their convenience. Consent to take part in the interviews was audio recorded prior to commencing the interview.

### 6.2.3 Data Collection

Face to face interviews have traditionally been the preferred mode of conduct for this type of data collection. However, recent research has highlighted that face to face interviews are not inherently superior over telephone interviews [306]. Consequently, to minimise burden on the patient participant, or physiotherapist respectively, one-on-one interviews were conducted via telephone. There was a pre-existing professional relationship with the physiotherapists from the provision of the training, consequently, the physiotherapists were aware of the reasons for carrying out the research and the author's interest in the research topic. There was no established relationship with the patient participants. Semi-structured interviews were directed by a topic guide (appendix 22) and were recorded at the University of Essex using a digital voice recorder and transcribed verbatim. Training, provided by the University of Essex, in conducting interviews was undertaken prior to data collection and practice interviews were carried out to pilot the topic guide with feedback provided by one of the PhD supervisors (CL).

### 6.2.4 Data Analysis

The data were analysed using the Framework Approach [242]. To facilitate this a computer-assisted analysis software (CAQDS) programme was used; QSR International's NVivo 12 (NVivo Version 12, QSR International, Melbourne, Australia). The Framework Approach has been developed specifically for applied research in which the objectives of the investigation are set *a priori* [307]. The Framework Approach is an analytic tool that supports key steps in the data management process, including the indexing and sorting tasks

common across many different approaches, but adds one further step; data summary and display (figure 6.2) [242]. The framework can be used for indexing, but its distinctive feature is that it forms the basis of a thematic matrix, in which every participant is allocated a row and each column denotes a separate theme. Data are then summarised by case and by theme and the summary entered in the appropriate cell. The thematic matrix was then triangulated with interview notes and sent to all participants to verify source interpretation. Whilst some debate amongst qualitative researchers exists about the extent to which triangulation is in fact useful in checking the validity of data, triangulation during data analysis has been advocated to not only provide diverse ways of looking at the same phenomenon but to also add creditability by strengthening confidence in whatever conclusions are drawn [302]. Different forms of triangulation are advocated based on a conceptualisation from Denzin listed below [308].

- Methods triangulation: comparing data generated by different methods (e.g. qualitative and quantitative)
- Triangulation of sources: comparing data from different qualitative methods (e.g. observations, interviews, documented accounts)
- Triangulation through multiple analysis: using different observers, interviewers, analysts to compare and check data collection and interpretation
- Theory triangulation: looking at data from different theoretical perspectives

This process evaluation utilised triangulation of sources through comparison of interview notes and interview data and source triangulation by taking the research evidence back to the research participants.

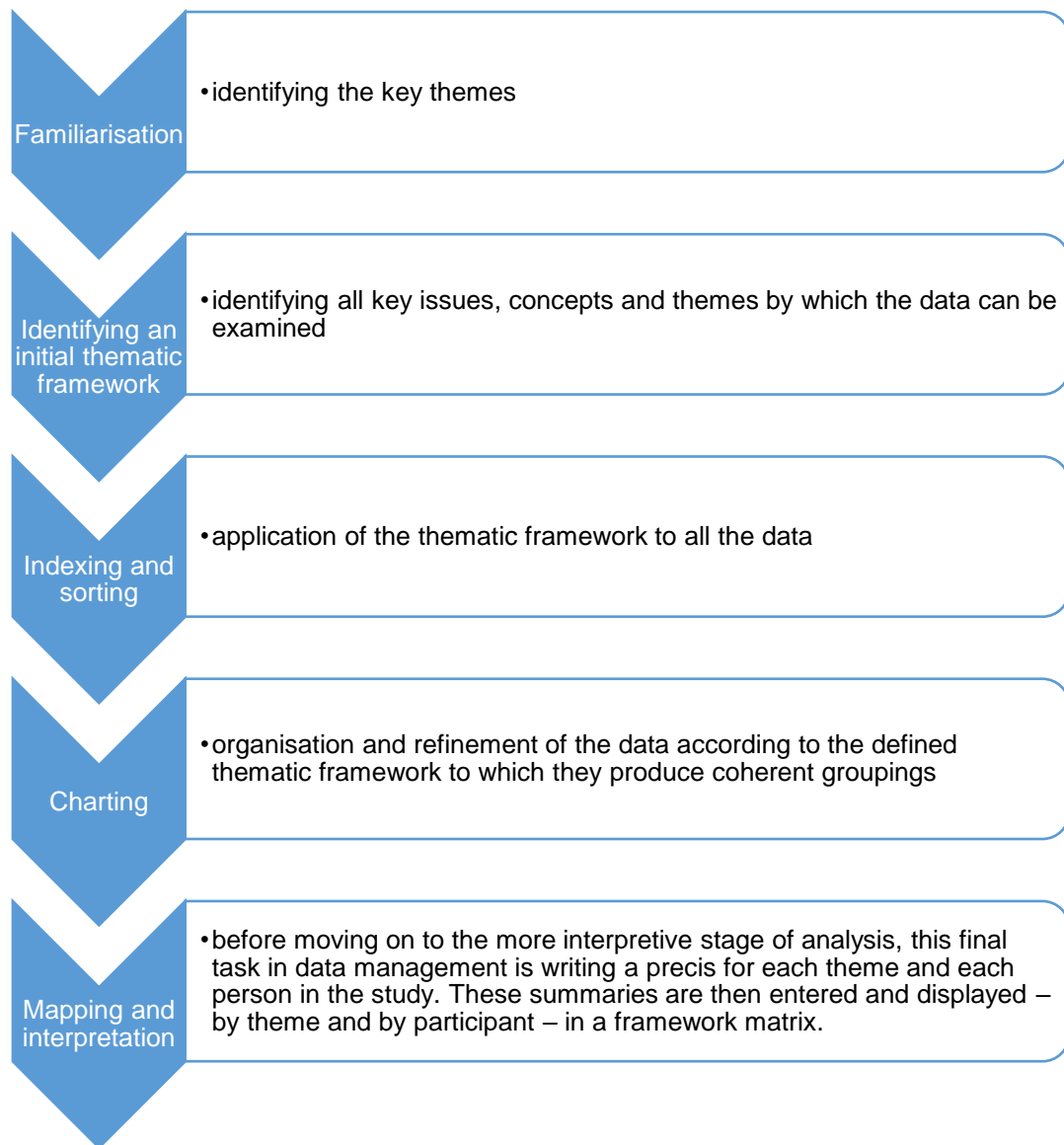


Figure 6.2. The five stages of data analysis associated with the Framework Approach

Given that not all researchers embarking using the Framework Approach go through each of the steps detailed above in figure 6.2 (researchers may need

to adapt the process within the context of any particular study [242]), a detailed description of the steps taken in the analytic process is given below.

#### 6.2.4.1 Familiarisation

Familiarisation of the data began early on with the undertaking of all telephone interviews and notes were made of the interviewees' responses during each interview. Once all interviews were transcribed, recurrent topics of interest were identified and cross referenced against the notes made and topic guide to ensure the list was exhaustive and against the research objectives to confirm their relevance. Whilst the preparatory stage of this was completed using pen and paper, by the end of this stage the themes that were used to label, sort and compare the data were determined and entered into the CAQDAS programme. This can be viewed as the initial thematic framework. The initial thematic framework from data provided by the physiotherapists can be seen in picture 6.1 below.

#### 6.2.4.2 Identifying an Initial Thematic Framework

Themes were sorted and grouped in a hierarchal arrangement of themes and subthemes so that an overall structure could be viewed. This served to ensure no obvious areas of overlap or omission were evident.

Nodes			
	Name	Sources	References
[-]	Barriers	0	0
[-]	Access	4	9
[-]	Recall	5	28
[-]	Visability	5	14
[-]	Time	4	9
[-]	Enablers	0	0
[-]	Motivation	5	16
[-]	Incentives	5	10
[-]	Simplicity	6	14
[-]	Training	5	10

Picture 6.1 Initial thematic framework

#### 6.2.4.3 Indexing and Sorting

In this step the thematic framework was applied to the data in order to locate where particular topics were being discussed. Indexing shows which theme or subtheme is being referred to within a particular section of the data, in much the same way that a subject index in the back of a book works [242]. Each sentence was read and then determined to which part or parts of the framework it applied. Using the CAQDAS programme this is achieved by highlighting the text to be indexed and 'dragging and dropping' into the desired section of the framework. Once indexing has been completed sorting reassembles the 'fractured' data. Using the CAQDAS programme this was straightforward by viewing the data which have grouped together under one theme. An example from the theme 'participants' motivation' is provided in the picture 6.2 below.

DATA ANALYZE QUERY EXPLORE LAYOUT VIEW

Look for  Search In  Nodes Find Now Clear Advanced Find

Nodes			
Name	Sources	References	
Barriers for participants	0	0	
follow up	4	11	
information given by physiothe	6	17	
Barriers for physiotherapists	0	0	
Access	4	9	
Recall	5	28	
Visability	5	14	
Time	4	9	
Consequences	0	0	
Positive experience	6	15	
Enablers for participants	0	0	
participant's motivation	6	14	
questionnaire	6	15	
website	7	11	
Enablers for physiotherapists	0	0	
Motivation	5	16	
Incentives	5	10	
Simplicity	6	14	
Training	5	10	

participant's motivation

Reference 4 - 2.33% Coverage

recognizing that here's something that I'm benefitting other people's research into physio and Achilles

<Internals\\180208\_003> - \$ 1 reference coded [1.97% Coverage]

Reference 1 - 1.97% Coverage

I just felt that I'd like to help.

<Internals\\180525\_1430> - \$ 2 references coded [3.06% Coverage]

Reference 1 - 1.37% Coverage

If it helps other people who have hurt themselves and moves things forward and all that, then that should be what you should do

Reference 2 - 1.69% Coverage

advancing research on such issues is beneficial for everyone, isn't it? So it's something one should do rather than not.

<Internals\\180529\_0800> - \$ 1 reference coded [2.84% Coverage]

Reference 1 - 2.84% Coverage

it was kind of nice to be able to feel that I'm kind of giving something back and helping out.

<Internals\\180717\_1030> - \$ 4 references coded [8.60% Coverage]

Reference 1 - 4.86% Coverage

Probably just that the trust that I had in my physiotherapist, after the disappointment of

Picture 6.2 Sorting of the theme 'participants' motivation'

#### 6.2.4.4 Charting

After the data have been indexed and sorted the data extracts were re-read to gauge the coherency and establish if any important themes were missing from the framework. The final indexed themes are provided in picture 6.3 below.



Nodes			
	Name	Sources	References
⊞	Barriers for participants	0	0
	follow up	4	11
	information given by physiotherapist	6	17
⊞	Barriers for physiotherapists	0	0
	Access	4	9
	Recall	5	28
	Visability	5	14
	Time	4	9
⊞	Consequences	0	0
	Positive experience	6	15
⊞	Enablers for participants	0	0
	participant's motivation	6	14
	questionnaire	6	15
	website	7	11
⊞	Enablers for physiotherapists	0	0
	Motivation	5	16
	Incentives	5	10
	Simplicity	6	14
	Training	5	10

Picture 6.3 Final refinement of indexed themes

#### 6.2.4.5 Mapping and Interpretation

This final stage of data management served to reduce the data to a more manageable level by distilling the essence of the data for representation. Each theme has its own matrix in which each subtheme was allocated a column. The first column describes the physiotherapist / patient participant number. Each physiotherapist / patient participant was then assigned a row so that comparisons can be made across physiotherapists / participants. If a subtheme did not emerge from the discussion with physiotherapist / patient participant then this was recorded as 'not discussed'. A framework matrix displaying a

summary for physiotherapists' and patient participants' data are detailed below in tables 6.2 and 6.3 respectively.

Physio	OBSTACLES					ENABLERS		
	Access to participants	Recall	Visibility	Time	Training	Motivation	Simplicity	Incentives
1	Low numbers on caseload	Busy clinic impacting on recall	Waiting room posters	Less of a priority	Helped to answer questions	Useful in a broad sense	Not discussed	Helpful, but not sure what
2	Telephone triage	Infrequency impacting on recall	Information for patients	Time is valuable	Clarity on their role	Interest to be involved in research	Easy and quick to do	Not discussed
3	Telephone triage	Forgetting due to other priorities	Not discussed	Not discussed	A clear understanding	Help to shape care	Can't think of barriers	More reward for more cards
4	Achilles patients disappeared	Part-time in clinic	Waiting room posters	Extra time needed	Not discussed	Patient's interest at forefront	Didn't faze participants	Opportunity to help others
5	Not discussed	Busy clinic impacting on recall	Not discussed	Not discussed	Improved confidence	Interest to be involved in research	Quick and easy to do	How could you do it?
6	Not discussed	Infrequency impacting on recall	Handy reminders	Running out of time to explain things	Well laid out	Interest to be involved in research	Easy enough to get involved	Not discussed

Table 6.2 Framework matrix for physiotherapists' data

Patient Participant	OBSTACLES		ENABLERS			CONSEQUENCES
	Information from the physiotherapist	Follow up	Website	Motivation	Questionnaire	
1	More explanation would be helpful	Not discussed	Easy to navigate	Important for society	Literally quick	Not discussed
2	Didn't talk about it	Text reminder would be fine	Not discussed	Advancing research	Very simple and reassuring	Revaluated feeling disability
3	Nothing much said	Junk email causing interference. Use text	All the information was there	Trust in the physio	Not so much off-putting detail	Be more interactive
4	Not much detail provided	Not discussed	Nothing frustrating	Benefiting others	Not discussed	reconsider relationship
5	would like to discuss what was being done	Confused- thought had already done it	Not discussed	Physio was asking	Happy to do for free	Made think about progress
6	A heads up is needed	Not discussed	straightforward	Not discussed	straightforward	Not discussed
7	Not discussed	Seemed like already done it	Not discussed	If it helps other people	Not discussed	Validated problem

Table 6.3 Framework matrix for patient participants' data

## 6.3 Findings

Data from seven patient participants and six physiotherapists were analysed. Three patient participants declined to be interviewed without stating a reason, and no response was received from fourteen patient participants. It is unknown how many physiotherapists participated in the MAP cohort study and therefore how many did not respond. Interviews lasted up to 30 minutes. Patient participant and physiotherapist characteristics are given in tables 6.4 and 6.5 respectively.

Patient Participant	Age range*	Gender
1	30-39 years	Male
2	60-69 years	Female
3	40-49 years	Male
4	50-59 years	Male
5	40-49 years	Female
6	40-49 years	Male
7	60-69 years	Female

Table 6.4 Patient participants' characteristics. \*Only age range was recorded

Physiotherapist	Years Qualified	Years of speciality in MSK	Sex	Private or NHS provider
1	7	6	Male	NHS
2	4	3	Male	Private
3	4	4	Male	NHS
4	18	16	Male	Private
5	15	12	Female	NHS
6	3	3	Male	NHS

Table 6.5 of physiotherapists' characteristics

### 6.3.1 Acceptability of The MAP Study Procedures from The Physiotherapists' Perspectives

Figure 6.3 details the initial thematic map developed from the physiotherapists' data. Through indexing, sorting and charting a final thematic map was constructed (figure 6.4).

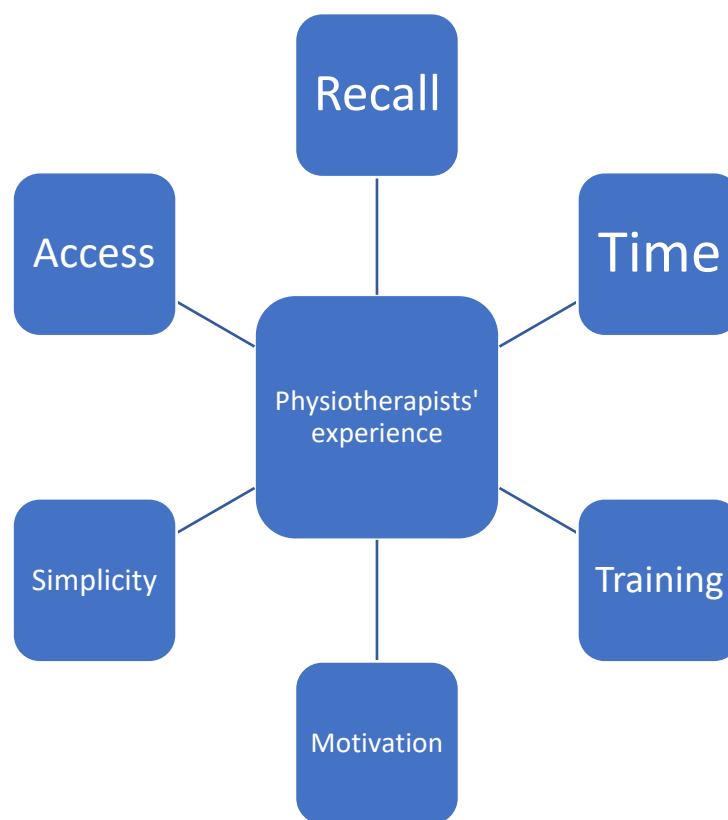


Figure 6.3. Initial thematic map from the physiotherapists' perspectives

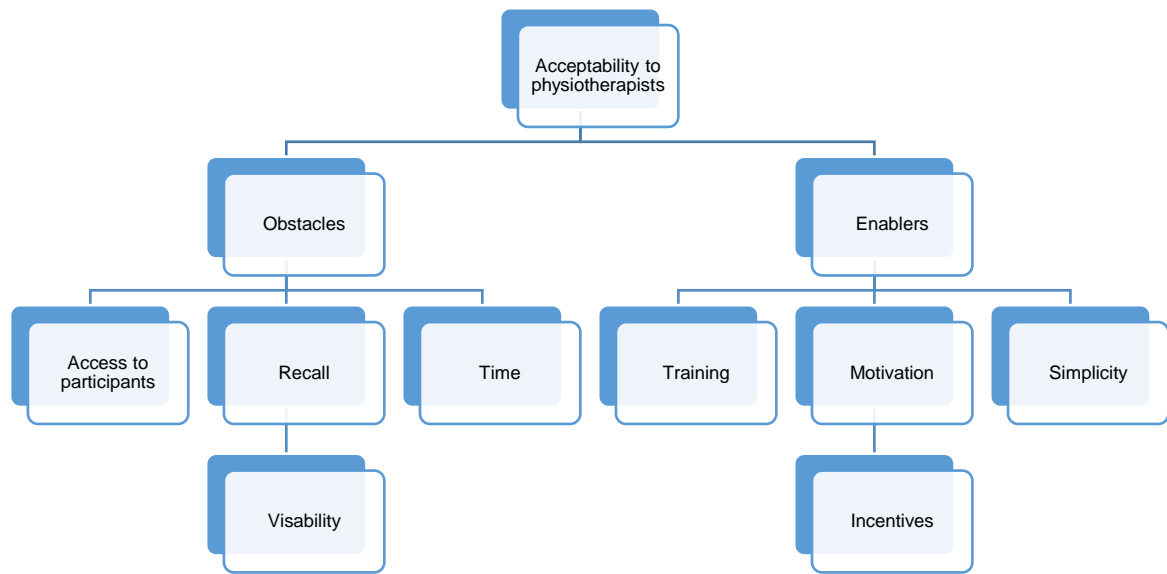


Figure 6.4 Final thematic map from the physiotherapists' perspectives

#### 6.3.1.1 Key Themes

To meet the aim of the process evaluation and interpret acceptability, two main themes were sought from the data after transcription; obstacles and enablers. From these 2 themes a further 8 subthemes were identified; (1) access to participants; (2) recall; (3) visibility; (4) time; (5) training; (6) motivation; (7) incentives; (8) simplicity.

#### 6.3.1.2 Obstacles

##### 6.3.1.2.1 Theme 1: Access to Participants

Difficulties in accessing the target population for the MAP study was often referred in many of the interviews. Potential reasons for this varied. Two physiotherapists felt this was simply serendipitous.

*“The main issue seemed to be that all my Achilles tendon patients seemed to disappear.”* Physiotherapist 4.

“I noticed was that in my particular caseload, I don't have a lot of Achilles tendinopathy patients.” Physiotherapist 1.

Whilst two other physiotherapists felt part of the problem lay with a telephone triage system operated at their place of work.

*“We do telephone triage, and a lot of that emphasis is to give the patient the option of self-management with some exercises, and with tendinopathy despite the complexity that I've mentioned, might be deemed something that actually, you can start someone off with simple exercises. So, there's a possibility that some patients might not have had the opportunity to be recruited.”*  
Physiotherapist 2.

*“I think because whether those patients get better on the phone or not, it definitely means that less of Achilles pain comes through to eventually see in a clinic.”* Physiotherapist 3.

#### 6.3.1.2.2 Theme 2: Recall

A common theme reported by the physiotherapists in the study related to difficulties in remembering to recruit potential participants. Some physiotherapists related this to their workload.



*“In a busy clinic remembering to provide them with the information in the first place.”* Physiotherapist 1.

*“Everybody’s got lots of different pressures in clinic generally, lots of different things to think about. It definitely would be easy to have an Achilles tendinopathy patient and just forget and not hand it out to the patient.”*  
Physiotherapist 3.

*“If you’re seeing sometimes 18 patients in a day, and you get a couple of Achilles ones within that, if that, then is it going to be the thing that you’re going to remember? Probably unlikely.”* Physiotherapist 5.

Other physiotherapists felt that the infrequency of seeing people with Achilles tendinopathy was a contributing factor.

*“But yeah, other clinicians have definitely said that they forgot, and part of the reason for that, I guess, is if you see an Achilles tendinopathy one week and then, two or three weeks later, you see your next new patient.”* Physiotherapist 2.

*“Some of our part-time staff or people that run classes or hydrotherapy and don’t have a massive case load, they’re not going to see one very often and it might not be at the forefront of their mind.”* Physiotherapist 6.

Although training was provided, and a staff meeting was attended one month following to discuss any recruitment queries and then monthly email reminders were sent to the Lead Physiotherapist at each site, physiotherapists were keen to be contacted directly to be reminded of recruitment.

*“To kind of set up a group email and just ping it across because that's just one level of communication that you can then take out where it could fall down if said manager doesn't pass it on.”* Physiotherapist 3.

*“You might receive six or seven or eight emails from the manager, and there might be potential to only skim-read that, whereas if there was an email from a different source that you don't normally see in your email box, that might prompt you to pay more attention.”* Physiotherapist 1.

*“An automated email that - although that might be received as slightly irritating, to have an email every week saying the same thing, equally it may also prompt individuals - if something's repeated on a weekly basis, they're probably going to be more likely to remember.”* Physiotherapist 6.

#### 6.3.1.2.3 Theme 3: Visibility

Participating physiotherapists outlined a common theme of needing to improve the visibility of the study to aid with recruitment. Some felt using posters to inform patients that the study was recruiting participants would be useful.

*“A poster or some visualisation of the study. Maybe something to put in the waiting room that a patient may have some preconceptions, pre-information about the study so that it's not completely something that's maybe sprung on them out of the blue if you like.”* Physiotherapist 1

*“If the information's there for them, the patient, they might actually start that conversation off, kind of like what you just said, rather than the other way around.”* Physiotherapist 2.

*“I don't know whether things like posters and stuff doesn't always work in clinical setting at times because when you've been working in an environment for a period of time, you tend to start to phase out what's around you, I suppose, on a visual side of things, whereas if you're a patient and you're waiting, you're more likely to take in that type of information, perhaps.”* Physiotherapist 4.

Some physiotherapists felt that it was them would benefit from an increased visualisation of the study.

*“Put the information there so it's in plain sight so that, again, from a jogging your memory”* Physiotherapist 2.

*“Whether you have left some out in the area, or some kind of handouts for the physio just as a reminder, more like a poster that we could have popped up in the staffroom just to remind people to keep doing it.”* Physiotherapist 1.

*“There's lots to sort of do and think about every day at work, and it's very easy to get quickly engrossed in what the patient's needs are and what they're telling you and maybe forget that there's a bunch of cards there with a study on it that to talk about. So I think the more sort of handy reminders, the better.”*

Physiotherapist 5.

#### 6.3.1.2.4 Theme 4: Time

Time as an obstacle was often cited by the physiotherapists. Some felt a lack of time with the patient impacted on the success of recruitment.

*“If you got half an hour to get a patient in, treat them, manage them, and document, and then you starting thinking there are other things on top sometimes. So that is then pushed to the less of a priority and such.”*

Physiotherapist 1.

*“It would be good to have an extra five minutes at the end of the consultation to say, on a complete side note to this, one of our colleagues at the university is doing this, this is what it entails. But it always felt a bit more rushed than that and difficult to really give out the information that was needed alongside.”*

Physiotherapist 4.

*“We're pushed for time. So if you're running short on time in an appointment session and then had to go and explain everything that could have been difficult.”*

Physiotherapist 6.

Physiotherapists viewed time as a precious commodity; something that they valued with their patients. Two physiotherapists felt that they would have

benefitted from more reassurance that recruiting patients shouldn't impact greatly upon this.

*"Yeah, I guess it's always going to be valuable, isn't it, to know that it's not going to take much time."* Physiotherapist 2

*"I guess, kind of how long would it take? Again, I guess, with physio you don't want to lose time."* Physiotherapist 6.

### 6.3.1.3 Enablers

#### 6.3.1.3.1 Theme 5: Training

A common theme reported by the physiotherapists referred to the recruitment training which was provided for them. The training served to provide clarity on the role of the physiotherapists and installed a sense of confidence in the procedures which were described.

*"I felt very confident and capable of recruiting participants after that session itself and the information given across from that."* Physiotherapist 5

*"From my point of view I think the information that was delivered was appropriate and enabled me to have a clear understanding of what I needed to do."* Physiotherapist 3.

*"I think all the information was there. I think it was well laid out from the beginning to finish."* Physiotherapist 6.

*"As far as I was concerned, my role was simply to identify patients that were appropriate for the study and give them the information, give them the handout*

*that I was given for them to then look at the website and participate if they chose to, or not.”* Physiotherapist 2.

The training enabled physiotherapists to answer questions from the participants.

*“Yes, I could answer most of it for them and just direct them towards the website if they have any other queries before getting involved.”* Physiotherapist 1.

#### 6.3.1.3.2 Theme 6: Motivation

Motivation to be involved in the MAP study was commonly referred to by the physiotherapists interviewed. Some physiotherapists felt that the impact this might have on their care of patients was an important motivating factor.

*“I think the study was very much with the patient's interest at the forefront.”*  
Physiotherapist 4.

*“We treat Achilles tendinopathy. So the more information eventually we can get from research, it better shapes our care.”* Physiotherapist 3.

*“I certainly think the aim of what was being looked at is probably useful for all other physiotherapy intentions, although it won't be able to be generalized that easily.”* Physiotherapist 1.

Physiotherapists were also motivated by the opportunity to be involved in a research project.

*"It's always interesting to get involved with any research or the data collection side of things that may turn up for our department. And it's important, I think, from a physio side of things to engage with that."* Physiotherapist 4.

*"I think it's just if you're aware of a research project or anything from that side of things going on, you tend to want to engage with that as much as you can."* Physiotherapist 5.

*"It's something that I'm interested in, research and evidence, so if in any way I can help with that, even if it's in a small way, then I'm normally more than happy to do so."* Physiotherapist 2.

#### 6.3.1.3.3 Theme 7: Incentives

Physiotherapists discussed the potential need for incentivising the MAP study. Some physiotherapists felt a reward for the efforts of the physiotherapists might be warranted, although they were not sure what that could be.

*"I think incentives always helps, doesn't it? And I don't think it really should be necessary for it. And like I said people always like to think they are getting something from it, but I wouldn't have any suggestions on what."* Physiotherapist 1.

*"Whether you give out 10, 20 cards to appropriate patients, then you're-- not get a reward, that sounds wrong, but you're more likely to be able to-- I don't know. It encourages clinicians to do more from that side of things."* Physiotherapist 3.

*“But then, how do you incentivise clinicians about effecting or influencing results around that?”* Physiotherapist 5.

It was also highlighted that the non-onerous nature of the recruitment task be more clearly made.

*“But I guess you could highlight it, or emphasize how simple it is, or how little time it actually takes. It may help with the physios doing it”.* Physiotherapist 1.

Questions were also raised with regard how participants felt incentivised. Some physiotherapists felt the answer lay in the opportunity to help others who are experiencing what they are.

*“It's difficult to know whether patients thought that was a worthwhile reason for completing the study.”* Physiotherapist 1.

*“There's always the question of the patient thinking, “What am I getting out of doing this?””* Physiotherapist 3.

*“And eventually, treat people that were suffering with what they've been suffering with. That seemed to be quite a key thing that people were interested in.”* Physiotherapist 4.

#### 6.3.1.3.4 Theme 8: Simplicity

A common theme discussed during the interviews with the physiotherapists was the simplicity of the MAP study. Most felt this was a key issue to raise to the potential participants in order to maximise recruitment.



*“I think it was quite clear and that seemed to be the case when speaking to patients, they weren't too fazed by the simplicity and the process they're about to undertake.”* Physiotherapist 4.

*“If someone has to go through something that takes them half an hour, then they're going to, generally speaking, not really want to fill that out or complete it. So if they know it's going to be fairly quick and easy to do, then most people will try to engage.”* Physiotherapist 5.

*“The ease or speed of which they can complete it because – it turns people off.”* Physiotherapist 2.

Others highlighted how, overall, straightforward they found being involved in the MAP study.

*“It wasn't difficult as all of that actually sounded. I thought it was quite easy to do. There were just, if I would say, small bumps in the road along the way, rather than any big barriers to actually putting the study into action. So it might- there's quite a few negative points there, but it wasn't like that in reality.”*  
Physiotherapist 6.

*“I don't suppose I think there are too many barriers to the study, I think it's an easy enough one to get involved in or get the data you need from.”*  
Physiotherapist 3.

### 6.3.2 Acceptability of The MAP Study Procedures from The Patient Participants' Perspectives

Figure 6.5 details the initial thematic map developed from the patient participants' data. Through indexing, sorting and charting a final thematic map was constructed (figure 6.6).

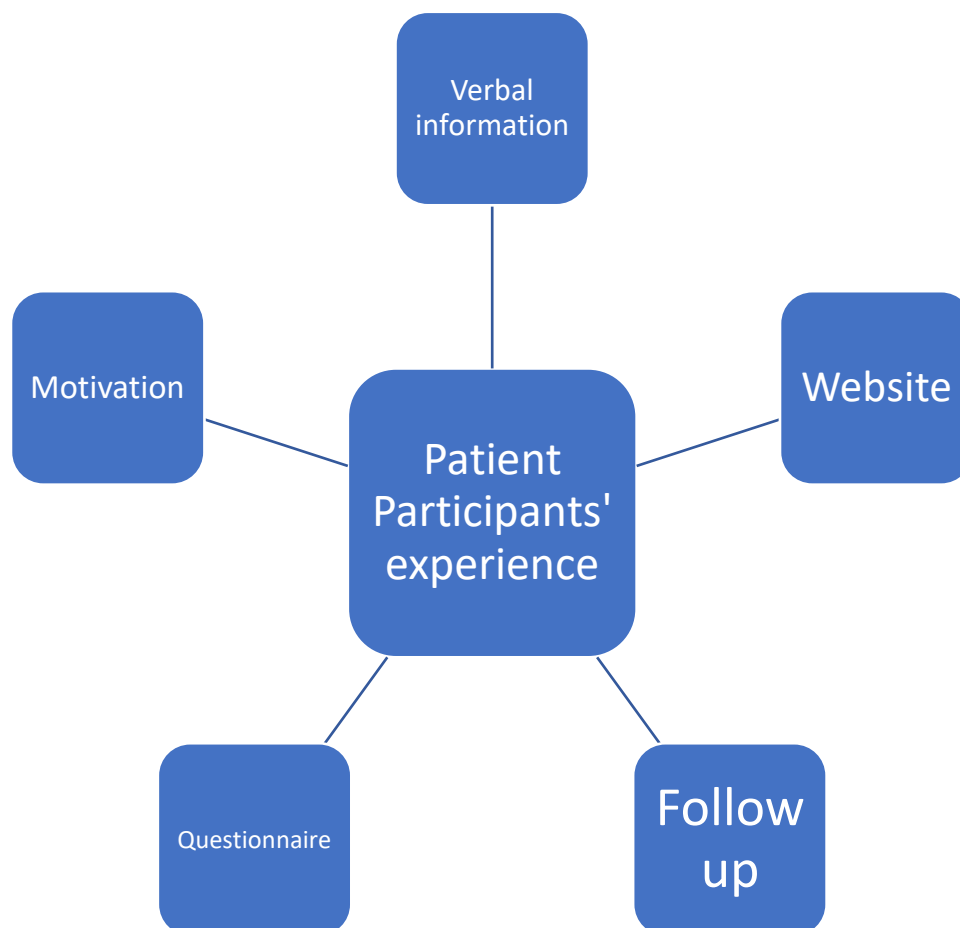


Figure 6.5 Initial thematic map from patient participants' experience

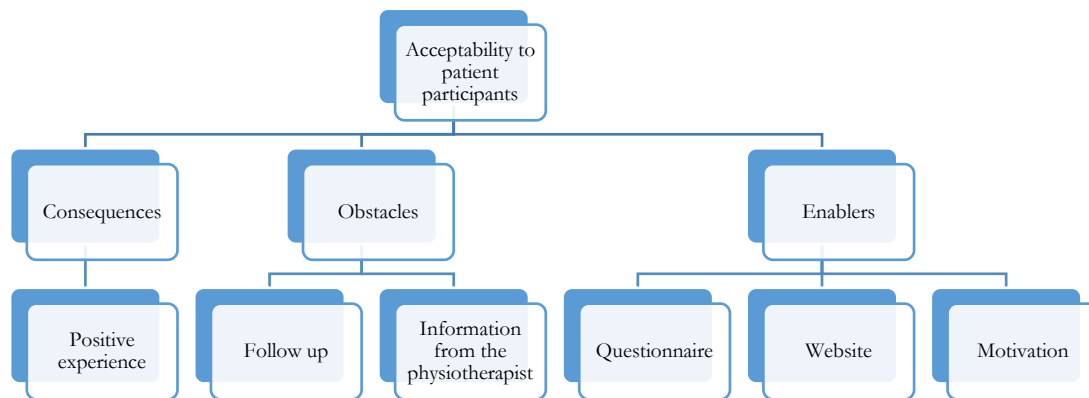


Figure 6.6 Final thematic map from patient participants' experience

#### 6.3.2.1 Key Themes

To meet the aim of the process evaluation and interpret acceptability, three main themes were sought from the data after transcription; consequences, obstacles and enablers. From these 3 themes a further 6 subthemes were identified; (1) information from the physiotherapist; (2) follow up; (3) motivation; (4) website; (5) questionnaire; (6) positive experience.

#### 6.3.2.2 Obstacles

##### 6.3.2.2.1 Theme 1: Information from The Physiotherapist

The patient participants interviewed often referred to the need for more quality verbal information from the physiotherapists at the time of recruitment.

*"If I hadn't been quite so spontaneously happy to do it, I might have benefitted with a little bit more explanation as to what they were trying to get out of it."*

*Patient participant 1.*

*“He didn’t really say anything. He was quite neutral about it.”* Patient participant 3.

*“I think he gave me a card and asked me how I felt about being part of the study, but we didn’t talk about it at all.”* Patient participant 2.

*“She said that you required someone for the study and would I be prepared to do it, to which I said I would, and at that point I took the card. And I think that was pretty much it really. We didn’t go into too much detail at that stage.”*  
Patient participant 4.

Some of the patient participants felt more information would be helpful to prepare potential participants about the question topics.

*“It would have been perhaps nice just to have discussed it through a bit what kinds of things were being done.”* Patient participant 5.

*“Just give me a bit of a heads up about what the questions were going to be about. That would have been interesting, I think. I wasn’t sure what the questions were going to be about.”* Patient participant 6.

Most patient participants viewed the postcard as a positive tool, enhancing engagement in the study.

*“Had she just told me about it, chances are I would have forgotten about it, even though I was very eager to do it. But I think it was a business card, or like*

*a little flyer that she gave me, but I then found later. So obviously, that was really helpful in kind of jogging my memory to actually doing it.”* Patient participant 6.

*“Eager though, I was to do it when my physiotherapist told me about it. It's one of those things that I probably would have forgotten about had I not had the postcard and thought, "Oh, I was going to do that. I need to do that.””* Patient participant 4.

*“It's quite colourful. I was experiencing pain in the very area that was indicated at the time. I think that struck a chord.”* Patient participant 2.

#### 6.3.2.2.2 Theme 2: Follow Up

Some patient participants expressed confusion around the process of being invited to complete the questionnaire for a second or third time.

*“In my head it just seemed like I'd done that bit. So it wasn't until I went on and looked at my emails on the laptop that I actually found it. It might be helpful if it were headed up second of the doc and then third and final of the doc.”* Patient participant 7.

*“I got a bit confused and I thought I'd already filled that one out.”* Patient participant 5.

*"I think the problem lies with the amount of rubbish we all receive over email. And I'm sure you're exactly the same as the rest of us. Sometimes more important things do get lost amongst the dross really, there's just so much of it."* Patient participant 3.

Patient participants offered ways of improving communication, including the suggestion of adding a text message reminder and ensuring communications were clearly headed as to which number survey the correspondence was referring to.

*"I suppose before you answered the first one, you should be absolutely clear that you're going to have to answer a few more afterwards, and that they're all going to be the same questions and the one variable is the time lapse between them."* Patient participant 7.

*"Heading them up and making it clear at the start that there were going to be three and heading them up two and three, I think that would be very helpful."* Patient participant 5.

*"I think for a lot of people they wouldn't mind a text reminder."* Patient participant 3.

*"I don't think for future people taking part it would be that much of an extra step to give their phone number for this service as well."* Patient participant 2.

### 6.3.2.3 Enablers

#### 6.3.2.3.1 Theme 3: Motivation

Almost all the patient participants outlined their motivation for involving themselves in the MAP study. Motivation appeared to be largely altruistic in nature.

*“If it helps other people who have hurt themselves and moves things forward and all that, then that should be what you should do.”* Patient participant 7.

*“Advancing research on such issues is beneficial for everyone, isn't it? So it's something one should do rather than not.”* Patient participant 2.

*“I've had various surveys that have come through about my diabetes condition, and I've done one on aorta, and things like that. So, you know, I've done a few surveys before so, I don't mind contributing because I know research into health-related matters is important for society these days.”* Patient participant 1.

*“Recognizing that here's something that I'm benefitting other people's research into physio and Achilles pain.”* Patient participant 4.

Two patient participants suggested that the relationship that they had with the physiotherapist motivated them to participate.

*“Probably just that the trust that I had in my physiotherapist, after the disappointment of what I had from me GP, and the fact that he was giving me good treatment that was improving the situation, puts you in a good frame of mind.”* Patient participant 3.

*“The fact that he was asking me, made me much more likely to fill it in than if he just sent me a mailshot.”* Patient participant 6.

#### 6.3.2.3.2 Theme 4: Website

A positive experience from using the website was expressed from most of the patient participants. This ranged from providing information which was missed by the recruiting physiotherapist to the ease of navigating the webpage.

*“Once I got to the website page, it gave me all the information I needed.”* Patient participant 3.

*“I don't recall being frustrated by anything. I'm easily frustrated on the Internet.”*  
Patient participant 4.

*“It was easy to navigate. It was clearly laid out, and it was all quite straightforward. So it wasn't an arduous task at all.”* Patient participant 1.

*“That was very straightforward. I didn't have any problems at all.”* Patient participant 6.



#### 6.3.2.3.3 Theme 5: Questionnaire

A positive engagement with the questionnaire was often cited by the patient participants. Particular reference was made to the simplicity and short duration of the questionnaire.

*“For most people now, because everyone seems to lead very busy lives, I think it was very helpful that it was just literally quick. And I think it kind of made it more intuitive as well, I suppose, because you haven't got to sit down and think about, “What am I going to write? What am I going to say?” When you just see the questions, it's kind of like your mind I suppose immediately goes to, “Well, that's an eight. That's a three. That's a seven.” You know?”* Patient participant 1.

*“We've all had questionnaires of customer feedback where they ask you to write so much detail, you give up because it's too painful. So it wasn't like that, which is really good.”* Patient participant 3.

*“I think it was so straightforward. I'm not sure, but I don't think anybody would have a problem completing any of it. And as I said, it's all very-- like I said, it's all so simple. And I mean, I think it says that it will take about 15 minutes, but I think it probably takes less than that. I'm not sure what else there is that could be done to actually encourage people more.”* Patient participant 6.

*“If you'd ask me to fill in a 58-page paper form, I might have been asking a fine to keep doing it every time, particularly if they're the same questions.”* Patient participant 4.

*“It was all very, kind of, reassuring. And I found the actual website, and the logging on, and the actual questionnaire itself is all very, very simple. I found it very simple to use. It's really good.”* Patient participant 2.

#### 6.3.2.4 Consequences

##### 6.3.2.4.1 Theme 6: Positive Experience

Many patient participants stated that their involvement in the MAP study resulted in a positive experience; it made them reconsider their condition and treatment and how they engaged with their physiotherapist.

*“It has made me think actually - maybe asking, this is not making as much progress as we were making. Should we try something different and I've started to think about that actually.”* Patient participant 5.

*“It made me think actually, it's not half bad because I can do all this stuff. There must be people who can't do all those things and therefore, I'm in a pretty good state. So I shouldn't worry or complain too much about the fact that I can't run and play hockey.”* Patient participant 2.

*“Being more interactive rather than just submissive if that's the phrase for in this context.”* Patient participant 3.

*“It made me very aware of all the things we just discussed. The fact that if you don't have a relationship shall we say, a positive relationship, with your physiotherapist, I can see that you may not get the end result that I've been fortunate in the second case to achieve.”* Patient participant 4.

*“It made me take it a bit more seriously really and feel a bit more as though, I wasn't on my own. There were other people obviously who were going through the same kind of problem. So maybe it validated it a bit more, I think, for me, which was good.”* Patient participant 7.

## 6.4 Discussion

The purpose of the process evaluation was to meet objectives three and four of this thesis; to explore the acceptability of the study procedures from the patient participants' and physiotherapists' perspectives respectively. The online data collection method was newly developed and as such it was important to evaluate the processes involved. Likewise, it was important to explore these methods from the perspectives all of those involved in the study. As such, this aspect of the study provided complementary data to the findings of the cohort study and identifies factors that might present as obstacles or facilitate successful wider implementation. From the physiotherapists' perspective four themes were identified which related to obstacles; (1) *access to participants*; (2) *recall*; (3) *visibility*; (4) *time*, and four themes were identified which related to facilitating success; (1) *training*; (2) *motivation*; (3) *incentives*; (4) *simplicity*. From the patient participants' perspective two themes were identified which

related to obstacles; (1) *information from the physiotherapist*, (2) *follow up*, three themes were identified which related to facilitating success; (1) *motivation*; (2) *website*; (3) *questionnaire*, and one theme which related to unintended consequences of participating in the study; *positive experience*.

The NHS Constitution for England pledges to inform all patients about opportunities for involvement with suitable research studies [309]. In this context healthcare professionals play a vital role in clinical research, linking researchers and patients. A variety of challenges may exist in recruiting participants from specialist healthcare services, such as physiotherapy, into cohort studies and little formal research has investigated these challenges [310]. Frayne et al (figure 6.7) have conceptualised a process by which a patient may be referred to a research study when the initial invitation to participate is delivered by a healthcare professional in the clinical setting (rather than being invited by a healthcare provider who has responsibilities and involvement in the whole trial) [311].

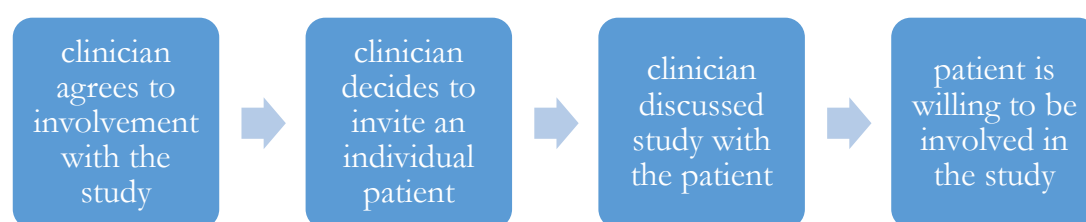


Figure 6.7 Process of a patient being referred to a research study by a clinician (adapted from Frayne et al. [311])

In order to contextualise the findings from this process evaluation with previous research and consider implications for future studies, the discussion is framed by the conceptual process outlined in figure 6.7.

#### 6.4.1 Involvement with the Study

Motivation to be involved in research was a theme identified from patient participants and physiotherapists alike. From the patient participants' perspective, the motivation was largely altruistic in nature; the chance to 'give back', and from the physiotherapists' perspective the drive was the opportunity to be involved in research which was considered to directly influence patient care. Motivation as a driving factor for recruitment wasn't considered in the training provided for the physiotherapists prior to commencing recruitment. Although the training was considered by the physiotherapists as facilitatory for recruitment, the training focused on how to recruit [286] rather than serving to motivate recruitment. Nevertheless, this focus did have benefits; the physiotherapists understood what they were required to do, were happy to answer questions from patients and felt confident in carrying out the recruitment. For example, Cvijovic et al [312] highlighted that pharmacists were reluctant to invite patients when they felt this could prompt questions they could not answer. However, valuing the research has been seen as a key driver of engagement of recruiting healthcare providers previously [313] and as such, training would benefit from tailoring to ensure the physiotherapists not only understood what to do and how to do it, but also developed attitudes towards the research which were as positive as possible. For example, the training could emphasise the positive experience (and absence of negative experience)

which the participants have described from being involved in the study. The *Research changed my life* [314] campaign within the NHS is a further example, where patients across England share stories of how their lives were positively transformed by clinical research. Allowing the physiotherapists to better understand this might serve to act as an incentive, something which the physiotherapists felt was important. Incentivising patients to participate was not possible as the study was unfunded. However, a £10 gift voucher has been shown to more than triple a response rate to an internet-based recruitment system and as such could be considered in future funded studies though automatic email delivery by a voucher supplier [315]. Whilst, the provision of such training has been shown to modify some aspects of recruiters' behaviour, this may still result in clinicians not sufficiently restructuring their recruitment consultations [316]. As such, a process of monitoring and further visits, where necessary, from the researcher to the recruitment sites to ensure recruiters are clear how participation in research varies from clinical practice might be a useful strategy [317]. At this stage, the focus might turn to communication skills facilitated by role play scenarios to highlight common obstacles to recruitment [318].

#### 6.4.2 Inviting a Patient

Pragmatic issues rather than 'gate keeping' concerns [319,320] largely influenced whether a patient was invited to be involved in the study or not. Two main pragmatic issues were identified; remembering to recruit participants and the visibility of the study. Reasons for not remembering to invite a participant ranged from other work pressures to the infrequency of seeing people with

Achilles tendinopathy. French et al [321] identified the clinical work setting as an influence on recruitment; an organisation which has developed a positive research culture is an important facilitator to inviting patients to participate. It was unknown what the research culture was like at each recruitment site prior to commencing recruitment. Fenlon et al [322] utilised a careful pre-screening and selection of participating centres. Although the nature of pre-screening sites and the decisions to work with sites varies according to the given study, it is a useful way to initiate relationships and potentially identify sites at risk of low recruitment [322]. Recognising this complexity, formal methods of evaluation have been developed that identify problems with recruitment and informed consent and develop action plans to address them while recruitment is underway [323]. Increasingly such methods, evaluating processes, need to be integrated into the pilot phases of research work to maximise the chance of success.

To address the second pragmatic issue, physiotherapists suggested recruitment for the study might be enhanced if the study was visualised in some way, such as posters in the waiting room and staff room to act as a reminder to staff and to encourage questions from potential participants. This would incur only a small increase in cost, and also provide a further opportunity to share the positive experience which participants can have from being involved in research [314]. A positive experience from this study was found from the use of the postcard to invite patients to become participants; the design resonated with participants and it served as a tangible reminder to take part. Contrastingly, the use of a follow up via email was sub-optimal. Using email and text message

reminders to encourage questionnaire completion amongst participants appears to be a viable strategy; following two email reminders, a text message reminder appeared to be more effective than another email reminder in a study also utilising an online questionnaire [315].

#### 6.4.3 Discussing the Study

Reporting lack of time as an obstacle to recruiting participants would appear significant. This was also reflected by the participants expressing they were given minimal verbal information by the physiotherapists during the invitation process. Limited time for recruitment resulting in clinicians not prioritising research activities has been seen in previous studies [310,313]. Resources are critical and lack of resources have been seen to negatively influence recruitment at all stages [322]. The absence of dedicated resources, such as clinical time, not only constrains the capacity of clinicians to undertake research activity but can also undermine their belief in the research and lose a sense that their roles are respected [313]. Consequently, research resources must be seen to make a difference. Here, effective communication is considered central to promote respect, reciprocity and maximise recruitment [313,322]. Ensuring that the right information reaches the right people in a timely manner, and that clinicians are provided with progress reports and study findings, is essential [313]. Improved communication from the researcher directly to the physiotherapists involved in recruiting was a finding from this study. To address this, future studies should consider providing progress reports and developing a newsletter which includes 'frequently asked questions' and tips from research sites that have good recruitment rates [322].



#### 6.4.4 Willingness to be Involved

The minimal burden of the study design appeared to be key to both physiotherapists' and participants' willingness to be involved in the study. As previously discussed, time is a precious commodity to physiotherapists. The simplicity of the MAP study was referred to as an enabler to engaging physiotherapists and that this simplicity needed to be highlighted more effectively in the training to provide reassurance on the minimal impact of time to the physiotherapists. Participants described a positive engagement with the website; it appeared to enhance patients' willingness to participate by being easy to navigate and ensuring it gave them all the information they required. In addition, the short duration of the questionnaire appeared a significant factor for participants to be willing to be involved. Previous research shows participants appear to start abandoning questionnaires after around 9 minutes, regardless of whether they are told the survey would take 8-10 minutes or 20 minutes [324].

### 6.5 Strengths and Limitations

This study included physiotherapists from all but one recruitment site and this ensured that the views expressed were as representative as possible of the sites involved. However, the self-selecting nature of recruitment may result in 'volunteer bias'; for example, physiotherapists largely expressed an interest in research, meaning perceptions of physiotherapists who felt negatively or ambivalent towards research were not recruited. Nevertheless, those taking part offered both positive and negative comments towards the MAP study. In addition, five of the six physiotherapists who volunteered were male which,

depending on the gender balance at each site, suggests female physiotherapists' views might be underrepresented.

Whilst those patient participants who dropped out, but had agreed to be contacted for interview, were invited for interview no responses were received. Again, this may have resulted in 'volunteer bias' and therefore alternative views were not captured. While this is a limitation, several of the insights offered by this study relate to facilitators brought about by positive attitudes, affording the opportunity to examine facilitators in more depth.

The prior established professional relationship with the physiotherapists through the provision of training, could have inhibited physiotherapists and discussing negative opinions about the study. Although efforts to reduce this were made through prior training and interview practise with feedback from one PhD supervisor (CL), this could have led to a degree of interviewer bias.

## 6.6 Conclusion

This process evaluation has highlighted some important factors for researchers to consider when planning future research studies. Although clinicians are enthused to be involved in research, organisational factors, such as time, appear to be key drivers of levels of engagement. Publicising the study to all involved; optimising verbal recruitment strategies between the physiotherapists and potential participants; and ensuring clarity in communication to recruiting physiotherapists and the participants all appear key to optimising the potential success of a study.

## Chapter 7: Discussion, Contributions, Strengths and Limitations and Recommendations for Future Research

### Summary

This chapter returns to the aim and objectives stated in chapter one and discusses the extent to which each has been met. Consideration is then given to the implications and impact of the work that has been conducted in relation to each objective. Through triangulation of the results from chapters five and six, the degree to which new knowledge has been generated is discussed alongside suggestions for further research in this field.

### 7.0 Aim of This Thesis

***In the context of further research being required to better understand how to optimise exercise-led interventions for people with Achilles tendinopathy, this thesis aimed to develop new knowledge by focusing on factors not previously investigated in tendinopathy research – cognitive and contextual factors and consider how they could contribute to optimising exercise-based interventions.*** It is suggested this has been met through the enhanced understanding generated from the feasibility study reported in chapters five and six. The study has provided a robust, previously untested, approach to investigating the selected variables generated from the two reviews presented in chapter two. Underpinning this aim were several objectives. The extent to which each one of these has been met and the impact of the work will now be considered in turn.

### 7.0.1 Objective One

***The first objective of this thesis was to systematically review the current evidence-base to determine the association and link to outcome between psychological variables and people with tendinopathy.*** This objective was met in chapter two, *part one*. This was the first systematic review to consider this link. Reported in accordance with the PRISMA statement [61], the review reported the overall conflicting high quality evidence relating to the association of psychological variables and outcome in tendinopathy. The review recognised the limited number and quality of studies regarding Achilles tendinopathy. However, within the context of the conflicting results from multiple high-quality studies in other tendinopathies, it was highlighted that differing cognitive factors which might underpin the psychological variables and their amenability to change, were worthy of further investigation.

### 7.0.2 Objective Two

***The second objective of this thesis was to critically review potential underpinning mechanisms of psychological variables and consider how they might influence prognosis for people with tendinopathy.*** This objective was met in chapter two, *part two*. Here a novel consideration was discussed which had received little attention in current tendinopathy management models -*cognitive and contextual factors*. The review discussed how these factors may help explain some of the variation in results from exercise-led interventions and also present a novel perspective to target for interventions. These key variables were then utilised to inform the variables for the future cohort study.

### 7.0.3 Objective Three

***The third objective of this thesis was to critically review the most commonly used patient reported outcome measure (PROM) for people with Achilles tendinopathy; the VISA-A and determine its suitability for use within the future study.*** This objective was met in chapter three. This review highlighted the extent of evidence which was missing from the development for the VISA-A. This was then used to inform the selection of the primary outcome measure for the future cohort study. Given the future cohort study required participants to complete an online version of the primary outcome measure in isolation from any support of a clinician to clarify a question's meaning, the chosen primary outcome measure required to not only be considered of sufficient reliability, validity and responsiveness, but also be considered of easy readability and comprehension. Notably the VISA-A had an absence of evidence regarding readability and comprehension testing and, coupled with concerns over the validity and responsiveness testing of the VISA-A, an alternative outcome measure was utilised (the LEFS) which met the current literacy standards within the UK.

### 7.0.4 Objective Four

***The fourth objective of this thesis was to conduct and complete a cohort study and report feasibility from both quantitative and qualitative perspectives.*** This objective was met in chapters four, five and six. Triangulating the results from the quantitative and qualitative findings, a future large cohort study appears feasible, but with certain caveats. The results from

the quantitative component suggested further consideration was required to ensure the level of data produced from the responses to the questionnaire matches with the statistical technique required to meet the aim of the study. Additional consideration was needed to enhance recruitment strategies and reduce attrition rates. Such considerations were explored in the qualitative aspect of the study; the process evaluation. The findings from the process evaluation highlighted clinicians were enthused to be involved in research, however organisational factors, such as time, appeared to be key drivers of levels of engagement. In addition, future studies should ensure the study is publicised to all involved and ensure clarity in communication to recruiting physiotherapists and the participants.

## 7.1 Strengths and Limitations

This thesis presents several strengths. Firstly, wherever appropriate the reporting of the research undertaken has been in accordance with the appropriate reporting guideline. A reporting guideline is a tool which provides a minimum list of information needed to ensure a manuscript can be; understood by a reader; replicated by a researcher; used by a health professional to make a clinical decision; and included in a systematic review [325]. The use of such guidelines have been shown to increase the completeness and transparency of health research published in journals [326]. In addition, four of the chapters have been shaped from external peer review through publication. This process has also added robustness and rigour to the thesis. Chapters five and six have highlighted some limitations within both the quantitative and qualitative approaches to feasibility. Firstly, the study did not allow for all feasibility data to

provide complete answers; it remains uncertain how many patients were given cards and how many landed on the blog page and then decided not to participate. Secondly, all recruitment sites were within the UK. As will be discussed below, a strength of the online platform is the ease of transition to international collaboration to improve generalisability.

## 7.2 Recommendations for Future Research

There are a number of areas for future research that could be proposed based upon the focus of the preceding thesis. Chapter three has demonstrated the need for a robustly developed patient-reported outcome measure for people with Achilles tendinopathy. Our knowledge of the condition and outcome measures has evolved significantly since the VISA-A was developed and a newly constructed measure to reflect this is warranted.

Prognostic factors for people with Achilles tendinopathy remain poorly understood but are critically important to informing patient management. The current evidence base however suggests these prognostic factors are unlikely to be reflective of the state of the tissue alone. The triangulation from the quantitative and qualitative investigations into the feasibility of the MAP study, indicate a future large cohort study is feasible to investigate the association and predictive nature of cognitive and contextual factors. The online platform design of the protocol should facilitate potential international collaboration and future studies should consider this to maximise generalisability and recruitment.

## Chapter 8: Conclusion

This PhD thesis has offered new insight into novel considerations to optimise the outcome for Achilles Tendinopathy. Using robust methods, the thesis has explored variables which have previously received little attention in tendinopathy research. Acknowledging the limiting factors discussed above, the high-quality feasibility study suggests a future large cohort study is warranted and feasible. In many respects this thesis leaves as many questions as it provides answers, however, importantly it has provided a platform from which those questions can begin to be answered.



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## Association of psychological variables and outcome in tendinopathy: a systematic review

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### ABSTRACT

**Objective** Fear, anxiety, depression, distress and catastrophisation are all factors known to affect pain and disability levels. To date, the association of such psychological factors has yet to be established in tendinopathy. Therefore, the purpose of this paper was to determine if psychological variables are associated with tendinopathy and whether any such variables may be associated with pain and disability outcomes in conservative management of tendinopathy.

**Design** A systematic review was undertaken and included studies were appraised for risk of bias using the Newcastle-Ottawa Scale. Owing to heterogeneity of studies, a qualitative synthesis was undertaken.

**Data sources** An electronic search of MEDLINE, CINAHL, SPORTDiscus, PsycINFO, EMBASE and PsycARTICLES was undertaken from their inception to April 2016.

**Eligibility criteria for selecting studies** Any study design that incorporated psychological measures and clinical outcomes using participants with tendinopathy.

**Results** Ten articles describing nine studies and 1108 participants were included. Conflicting evidence exists regarding the association of anxiety, depression and lateral epicondylalgia (LE). Strong evidence suggests LE is not associated with kinesiophobia. Moderate evidence links catastrophisation and distress with LE. Moderate evidence suggests distress is not associated with rotator cuff tendinopathy, but kinesiophobia and catastrophisation are. Limited evidence suggests patellar tendinopathy is not associated with anxiety or depression and kinesiophobia may be linked with suboptimal outcomes in Achilles tendinopathy.

**Summary/conclusions** Tendinopathy requires an individualised approach to management. Clinicians should consider using validated screening tools for the presence of psychological variables as a part of their holistic management.

tendinopathy (PT)<sup>7</sup> and for top level runners Achilles tendinopathy (AT) is a 52% lifetime risk.<sup>8</sup>

While tendinopathy is problematic to manage clinically,<sup>1</sup> there is a body of evidence to support a conservative management approach.<sup>9–11</sup> Current conservative management strategies for tendinopathy usually include strength training,<sup>12, 13</sup> but may additionally include other interventions such as shock wave therapy or laser therapy.<sup>14, 15</sup> However, tendinopathy can remain resistant to treatment, and peripheral tissue focused interventions are unlikely to address complex adaptations associated with persistent pain.<sup>16</sup> This suggests the need to include further considerations to management as current strategies appear suboptimal. Load is considered a major pathoetiological component of tendinopathy. However, many factors are considered to modulate load. These include genes, age, circulating and local cytokine production, sex, biomechanics and body composition, with current management programmes suggesting the need to tailor to individual presentations.<sup>1</sup>

Tailoring management strategies to individual presentations has been suggested for other conditions which can also be resistant to treatment resulting in persistent pain states.<sup>17</sup> Strategies adopted include addressing physical factors such as loss of muscle strength or coordination, and cognitive and psychological factors. Initial results from this approach, known as cognitive functional therapy, have been encouraging.<sup>18</sup> Factors such as fear, anxiety, depression, stress and catastrophisation are all known to further affect the pain experience and disability levels.<sup>19</sup> To date, the association of such psychological factors has yet to be established in tendinopathy. Therefore, the purpose of this paper was to determine the following:

1. Are psychological variables associated with tendinopathy?
2. Are outcomes from conservative management of tendinopathy linked to the presence of psychological variables?

### METHODS

#### Protocol

A systematic review was performed using a predetermined protocol in accordance with the preferred reporting items for systematic review and meta-analysis (PRISMA) statement.<sup>20</sup>

#### Data sources and search strategy

An electronic search of MEDLINE, CINAHL, SPORTDiscus, EMBASE, PsycINFO and PsycARTICLES was undertaken from their inception to April 2016. The keywords used are displayed in table 1. The electronic search was

### INTRODUCTION

Tendinopathy is a widely accepted, generic term characterised by reduced loading capacity of a tendon associated with pain.<sup>1</sup> Thirty to fifty per cent of all sports-related injuries are reported to be diagnosed as tendinopathy<sup>2</sup> with clinical symptoms including load-related pain, tenderness, localised swelling and disability.<sup>3</sup> Tendinopathy is frequently reported within the upper and lower limb.<sup>4</sup> Lateral epicondylalgia (LE) or tennis elbow affects up to 3% of the population<sup>5</sup> and while rotator cuff tendinopathy (RT) is considered a common problem, it is uncertain to what extent, with estimates of point prevalence ranging from 2.4% to 21%.<sup>6</sup> Twenty per cent of knee injuries are diagnosed with patellar



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743

## Review

**Table 1** Keywords used in the study selection process

Search terms	
1	Tendin* or tendon* or jumper's knee or lateral epicondy* or rotator cuff or subacromial pain or subacromial impingement or tennis elbow
2	Psycholog* or fear or depression or emotion* or anxiet* or catastroph* or distress
3	1 and 2 Combined

complemented by hand searching the reference lists of the papers identified. Citation searching using the identified papers was also carried out and recognised experts in the field of tendinopathy were consulted in an attempt to identify any further published or unpublished studies, although no unpublished studies were identified. The search, including the application of the selection criteria, was conducted independently by two reviewers (AM and TW) with any discrepancies resolved by discussion.

**INCLUSION CRITERIA****Population**

The review included adult participants with a clear diagnosis of a tendon-related disorder, including tendinosis, tendinitis, tendinopathy or synonyms, for example, tennis elbow. In keeping with previous reviews, minimal diagnostic criteria of a largely preserved range of motion with pain provoked by loading of the tendon was required.<sup>6</sup> Studies with mixed or non-specific diagnoses, or those concerned with the risk of developing tendinopathy were excluded. Additionally, studies investigating tendinopathy considered to be as a result of an intervention, for example, fluoroquinolone, studies using participants with a known specific disease present (eg, spondyloarthropathy), or concerned with tendon rupture or postsurgical recovery were also excluded.

**Outcome**

Self-reported psychological measure(s) measuring emotional and cognitive variables known to be associated with persistent pain were included. These were, namely, depression, anxiety, catastrophisation, fear and distress.<sup>19</sup> Measurements of pain and disability, plus any other clinical outcomes were included.

**Study design**

Any study design that incorporated measurement of psychological status and clinical measures of pain and/or disability was included. These involved case study, case series, case-control, cohort, cross-sectional, uncontrolled trials, quasi-experimental studies and randomised controlled trials (RCT). Narrative reviews, editorials or other opinion-based publications were excluded.

**Language**

Studies published in any language were included; however, no identified studies published in a non-English language met the criteria for full review.

**Risk of bias assessment**

Risk of bias assessment of the included studies was undertaken independently by two authors (AM and TW) using the Newcastle-Ottawa Scale (NOS). The NOS is a tool designed for cohort and case-control studies, which is reliable and valid for assessing quality of non-randomised studies.<sup>21</sup> Criteria evaluate

potential bias based on selection of participants, comparability of study groups and attainment of exposure (case-control studies) or outcome of interest (cohort studies).<sup>21</sup> The NOS uses a star rating system (semiquantitative) where one star is awarded for each criterion of appropriate methods reported, with the exception of comparability of cohorts where two stars are awarded if a study controls for more than one comparison factor.<sup>21</sup> The scale ranges from zero to nine stars.<sup>22</sup> Discrepancies in the awarding of a star were resolved by discussion with a third reviewer (CL). As the effectiveness of an intervention was not of interest to the review, but rather the association of other measures, the case-control scale and cohort study scale were also used to evaluate included cross-sectional, case-series and intervention studies, respectively.<sup>23</sup>

**Data extraction**

All data were extracted by a single reviewer (AM) and verified by a second reviewer (TW). Data included study characteristics, participant characteristics, source, sample size, intervention details, comparison group characteristics and results. Quantitative data relating to psychological measures, pain and disability were also extracted.

**Data synthesis**

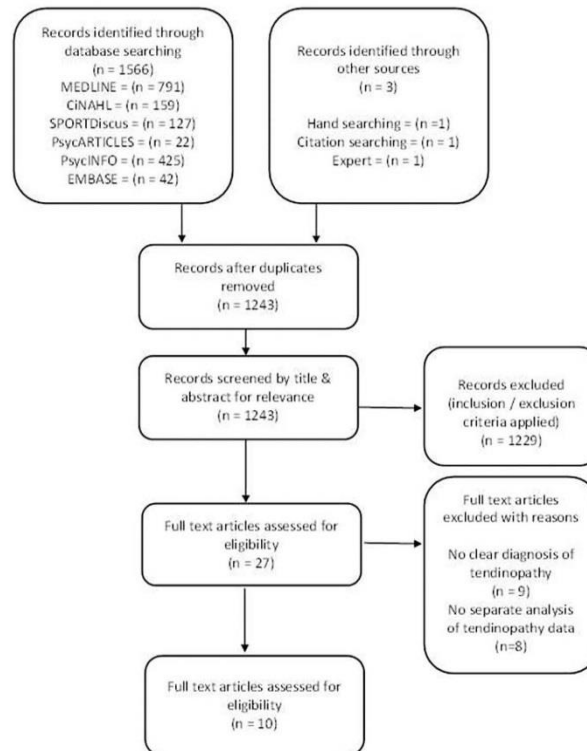
There was considerable clinical heterogeneity within the included studies with regard to study design, patient populations and measures of psychological variables.<sup>24</sup> Therefore, a qualitative synthesis was deemed the most appropriate means to analyse the data. As threshold scores to differentiate between 'good' and 'poor' studies using NOS have yet to be established,<sup>21</sup> the qualitative synthesis of data was informed by a scoring system to rate studies included in this review. The score for each was calculated by dividing the number of stars achieved by the number of items. Each study was graded as low, moderate or high quality based on this score. Cut-off points were designated a priori as: 0.00–0.44 low methodological quality, 0.45–0.70 moderate quality and 0.71–1.00 high quality. Such cut-off points are often used to determine reference values for level of association/agreement by researchers and have been acknowledged as acceptable by experts in research methods<sup>25 26</sup> and used by previous studies.<sup>27</sup> In order for quality and quantity of the available evidence to be taken into account, a rating system for levels of evidence was used to summarise data relating to psychological factors, tendinopathy and outcome (table 2).<sup>28</sup>

**RESULTS****Study selection**

Figure 1 represents the results of the study identification process. Initially, 1243 citations were identified once duplications were removed. After screening, 27 articles were considered for full review. Applying the eligibility criteria, 10 articles, describing 9 studies were included for risk of bias assessment.

**Table 2** Levels of evidence

Strong evidence	Consistent findings in high-quality studies (n≥2)
moderate evidence	Consistent findings among lower-quality studies (n>2) and/or one high-quality study
Limited evidence	≤ relevant low-quality studies
Conflicting evidence	Inconsistent findings among multiple studies
No evidence	No studies

**Figure 1** Study selection flow diagram.**Newcastle-Ottawa Scale assessment**

The results of the risk of bias assessment are shown in table 3. From the possible nine stars available, five studies were awarded eight stars<sup>29–33</sup> and deemed of high quality; three studies were awarded seven stars<sup>34–36</sup> and also deemed of high quality and two studies were awarded six stars,<sup>37–38</sup> deemed moderate quality.

**Study characteristics**

A summary of the characteristics of the included studies is presented in online supplementary appendix 1.

**Study design**

The most frequently used study design was cross-sectional (n=5).<sup>29–32–35–36–38</sup> Other study designs were case-control (n=1),<sup>34</sup> case series (n=1),<sup>37</sup> RCT (n=1)<sup>31</sup> and cohort (n=2).<sup>30–33</sup>

**Participants**

Two studies reported data using one set of participants.<sup>29–30</sup> Thus, the 10 articles included for review identified 9 studies. The studies included 1108 participants, 580 women and 528 men. The mean age of the participants was 48.8 years, ranging from 18<sup>36</sup> to 82 years.<sup>33</sup> Six studies included participants with LE,<sup>29–31–33–35</sup> two studies included participants with RT,<sup>32–36</sup> one study included participants with AT<sup>37</sup> and one study included participants with PT.<sup>38</sup>

**CLINICAL FINDINGS****Psychological variables and tendinopathy**

Overall, there is conflicting evidence relating the presence of psychological variables and their association with tendinopathy. Six studies (five of high quality and one of moderate quality) support a statistically significant positive association between the presence of psychological variables and tendinopathy.<sup>31–35–37</sup> Four of these investigated LE, one RT and the other AT. Four studies (three of high quality and one of moderate quality) demonstrated no statistically significant association between psychological variables and tendinopathy.<sup>29–30–38</sup> Two of these investigated LE, one RT and the other PT.

**Catastrophisation**

Two studies investigated the association of catastrophisation and tendinopathy.<sup>32–33</sup> One high-quality study investigating RT supported a statistically significant positive association of the presence of catastrophisation and tendinopathy at baseline.<sup>32</sup> The other study investigating LE was also of high quality and showed a statistically significant positive relationship between a reduction in catastrophisation and a reduction in the need for additional treatment.<sup>33</sup>

**Distress**

Two high-quality studies investigated the association of distress and tendinopathy.<sup>31–36</sup> One study investigated RT and showed no statistically significant association between the presence of



## Review

**Table 3** Risk of bias assessment using the Newcastle-Ottawa Scale

Author/year	Selection	Comparability	Exposure/ outcome	Total stars	Quality of study
Alizadehkhayat <i>et al</i> <sup>34</sup> (2007)	****	*	**	7	High
Coombes <i>et al</i> <sup>30</sup> (2015)	****	*	***	8	High
Coombes <i>et al</i> <sup>29</sup> (2012)	****	*	***	8	High
Engebretsen <i>et al</i> <sup>36</sup> (2010)	****	*	**	7	High
Gamevall <i>et al</i> <sup>35</sup> (2013)	****	*	**	7	High
Haahr and Andersen <sup>21</sup> (2003)	****	*	***	8	High
Kromer <i>et al</i> <sup>32</sup> (2014)	****	**	**	8	High
Lee <i>et al</i> <sup>33</sup> (2014)	****	*	***	8	High
Silbernagel <i>et al</i> <sup>37</sup> (2011)	***	*	**	6	Moderate
van Wilgen <i>et al</i> <sup>38</sup> (2013)	***	*	**	6	Moderate

distress and pain and function associated with tendinopathy.<sup>36</sup> The additional study investigated LE and supported a statistically significant positive association of the presence of distress and tendinopathy.<sup>31</sup>

### Anxiety and depression

Four studies investigated anxiety in conjunction with depression.<sup>29 30 34 38</sup> One study investigated anxiety without depression, but instead included aggression and extraversion factors.<sup>35</sup>

Two high-quality studies<sup>29 30</sup> investigating LE and one moderate-quality study<sup>38</sup> investigating PT demonstrated no statistically significant association between the presence of anxiety, depression and tendinopathy.

One high-quality study investigating LE supported a statistically significant positive association between the presence of depression and tendinopathy.<sup>34</sup> Two high-quality studies investigating LE supported a statistically significant positive association of the presence of anxiety and tendinopathy.<sup>34 35</sup>

### Kinesiophobia

Three studies investigated the association of fear-avoidance and tendinopathy.<sup>29 32 37</sup> One high-quality study investigating LE demonstrated no statistically significant association between kinesiophobia and tendinopathy.<sup>29</sup> Another high-quality study investigating RT supported a statistically significant association of the presence of fear-avoidance beliefs and disability at baseline.<sup>32</sup> One moderate-quality study investigated AT and showed a statistically significant negative correlation between levels of kinesiophobia and heel-rise work recovery (a battery of tests consisting of two jump tests, two strength tests, and one endurance test), suggesting a negative effect on the effectiveness of treatment.<sup>37</sup>

### Psychological variables and prognosis

Overall, there is conflicting evidence relating the presence of psychological variables and their association with outcome in tendinopathy. Three studies (two of high quality and one of moderate quality), two investigating LE and the other AT

support a statistically significant positive association.<sup>31 33 37</sup> Two studies (both of high quality), one investigating LE and the other RT showed no association.<sup>30 32</sup>

### Catastrophisation

Two studies investigated the association of catastrophisation and outcome in tendinopathy.<sup>32 33</sup> One high-quality study, investigated RT and showed high baseline catastrophisation scores were not predictive of disability at 3 months.<sup>32</sup> The other, also of high quality investigated LE and showed a statistically significant positive relationship between a reduction in catastrophisation and a reduction in the need for additional treatment at 12 months.<sup>33</sup>

### Distress

One high-quality study investigated the association of distress and outcome in LE.<sup>31</sup> This study showed a statistically significant association with continued high pain scores and a <50% reduction in pain scores at 12 months associated with high baseline distress.

### Anxiety and depression

One high-quality study investigated the association of anxiety and depression and outcome in LE.<sup>30</sup> This study found no statistically significant association between anxiety, depression and pain and disability scores at 12 months. One high-quality study investigated the association of depression and LE.<sup>33</sup> This study showed depression was independently statistically significant for an association with seeking additional treatment at 12 months.

### Kinesiophobia

Three studies investigated the association of fear-avoidance and tendinopathy.<sup>30 32 37</sup> One high-quality study investigated LE and found no statistically significant association between kinesiophobia and pain and disability at 12 months,<sup>30</sup> and another high-quality study investigating RT found that high baseline kinesiophobia scores were not predictive of disability at 3 months.<sup>32</sup> One moderate-quality study investigating AT found that at 5-year follow-up increased fear of movement was statistically significant for an association with reduced heel-rise work recovery.<sup>37</sup>

## SUMMARY OF KEY FINDINGS

### Lateral epicondylalgia

There is conflicting evidence from multiple study designs surrounding the association of anxiety, depression and LE.<sup>29 30 33–35</sup> Strong evidence from one high-quality cross-sectional study and one high-quality cohort study, suggests kinesiophobia is not associated with LE.<sup>29 30</sup> Moderate evidence from one high-quality RCT links distress with LE.<sup>31</sup> Moderate evidence from one high-quality cohort study links catastrophisation with LE.<sup>33</sup>

### Rotator cuff tendinopathy

There is moderate evidence from one high-quality cross-sectional study suggesting distress is not associated with RT.<sup>36</sup> There is moderate evidence from one high-quality cross-sectional and longitudinal study to suggest that kinesiophobia and catastrophisation are associated with RT at baseline, but are not associated with a suboptimal outcome.<sup>32</sup>

### Patellar tendinopathy

There is limited evidence from one moderate-quality cross-sectional study to suggest anxiety and depression are not associated with PT.<sup>38</sup>

### Achilles tendinopathy

There is limited evidence from one moderate-quality case series to suggest kinesiophobia is associated with AT.<sup>37</sup>

### DISCUSSION

This systematic review suggests overall there is conflicting high-quality evidence relating to the association of psychological variables and outcome in tendinopathy. Previous systematic reviews considering features of tendinopathy have investigated structural changes<sup>39</sup> and central nervous system (CNS) changes,<sup>40–41</sup> but consideration to psychological variables has been limited to other conditions such as low back pain.<sup>42–43</sup> The review was undertaken in accordance with published guidelines.<sup>20</sup> While it is acknowledged that criteria for 'good' and 'poor' studies have yet to be established for the NOS,<sup>21</sup> according to the scoring system and cut-off points designated a priori, the majority of studies were considered to be of a high quality, while two studies were considered of moderate quality. The conflicting high-quality evidence as to the association of psychological features in tendinopathy could potentially be explained by several factors.

First the variance in population under investigation. Although most of the participants were around the mean age of 50 years, one study<sup>38</sup> had a mean age of 23.3 years. Additionally, participants were recruited from various settings ranging from specialist hospital settings<sup>34</sup> to university populations<sup>38</sup> and general care.<sup>31</sup> Two studies (from three articles) investigated anxiety and depression in LE and used the Hospital Anxiety and Depression scale.<sup>29–30–34</sup> One population<sup>29–30</sup> was recruited via advertising from the general population and the other from consecutive attendance at an upper limb clinic.<sup>34</sup> While inclusion criteria for both populations were similar, the study<sup>34</sup> whose population was taken from attendees at an upper limb clinic found a positive association between LE and anxiety and depression, while the population who self-selected for inclusion did not.<sup>29–30</sup> Reasons behind these contrasting findings may consequently lie in the population studied. Those attending a specialist service may have a longer duration of symptoms or failed previous interventions and consequently represent a separate subpopulation of LE which appear more vulnerable to associated psychological variables alongside tendinopathy. While it is acknowledged the variation in population may contribute to discrepancies between the studies, it was considered that the inclusion of all study types represents the evidence base as a whole; thus allowing the clinician to make their clinical reasoning based on a synthesis of all the available evidence.<sup>44</sup>

Second, the heterogeneity of outcome measures; for example, symptoms of anxiety and depression were measured by five studies and four different outcome measures were used. Although this in itself does not reduce the quality of the individual studies as they are justified choices, comparability between studies is made more difficult. Third, the majority of studies investigated tendinopathy of the upper limb; six investigated tennis elbow,<sup>29–31–33–35</sup> two investigated RT,<sup>32–36</sup> one PT<sup>38</sup> and one AT.<sup>37</sup> The efficacy of treatment, and potential relationship of psychological variables, will likely be dependent on the specific tendon's anatomical and biomechanical properties.<sup>45</sup> For example, with AT most commonly manifesting in the mid-portion and PT occurring as an enthesopathy.<sup>46</sup> In addition, there is growing evidence of CNS changes that may contribute to pain and disability in tendinopathy, but to date these data have been predominately considered in the upper limb,<sup>40–47</sup> with lower-limb data limited<sup>38</sup> or even negating.<sup>48</sup> Changes in the CNS or central sensitisation is much more than generalised hypersensitivity to pain and includes increased responsiveness to

stress, emotions and mental load.<sup>49</sup> Consequently, differing dominant states of sensitivity (peripheral or centrally driven) may have influenced the association of psychological variables. A possible area for further study would be to investigate this potential influence.

Finally, differing cognitive factors which may underpin the psychological variables and their amenability to change could also help explain the conflicting high-quality studies results. Complex mental events such as hope, beliefs, information and expectations have all been shown to influence the pain experience.<sup>50–51</sup> The relationship between the patient and the practitioner has been shown to be useful in predicting and influencing outcomes in other chronic conditions such as low back pain<sup>52–53</sup> and a positive alliance is seen to have an overall positive influence on rehabilitation.<sup>54</sup> The influences on this relationship or 'working alliance' include a mix of interpersonal skills, practical skills and individualised patient-centred care.<sup>55</sup> Working alliance involves technical skill and the reflective capacity of the therapist to respond to the patient, but extends beyond good communication to a sense of collaboration, warmth and support.<sup>56–57</sup> Consideration to the aforementioned mental events and investigation into the influence of working alliance has yet to be explored and may be an area for future study.

For the clinician, being aware that psychological variables may be associated with tendinopathy may assist in optimising management by using strategies to help overcome or reduce their influence. Although future testing by research is required, adopting strategies which aim to influence hope and positive beliefs,<sup>51</sup> place emphasis on neuroscience education<sup>58</sup> or address individual cognitive-behavioural barriers<sup>18</sup> while maximising working alliance<sup>52–54</sup> are all plausible strategies to adopt in conjunction with a graded loaded programme.<sup>13–59</sup> These psychological variables may be particularly important when considering more invasive procedures such as surgery, as they are associated with negatively influencing outcomes.<sup>60–62</sup>

Change in psychological status may offer another explanation as to the response to commonly used loading programmes for the management of tendinopathy. A confrontational graded exposure intervention, resembling education and a progressive loading programme (a combined cognitive and behavioural intervention), may serve to reduce fear, anxiety and catastrophisation and consequently enhance performance by reducing pain and disability. This type of approach has been used successfully in other persistent pain conditions,<sup>18</sup> where changes in tissue state also do not appear to correlate with reductions in pain and disability.<sup>39–63</sup>

### FUTURE DIRECTIONS

The findings of the current review suggest that taken as a whole, there is conflicting evidence as to the significance of psychological variables in tendinopathy. However, specific psychological variables may be associated with tendinopathy and suboptimal outcomes from treatment. As such, clinicians should be vigilant as to the possibility of the presence of such variables and the possibility to need to adapt management accordingly.

While a clear explanation for the response of tendinopathy to therapeutic exercise is lacking, further studies to identify the underlying mechanism are warranted. Theories surrounding the potential influence of the CNS, biochemical and myogenic factors have been proposed.<sup>16–47–64–66</sup> While acknowledging the likelihood of a multifactorial explanation,<sup>67</sup> to date psychological response explanations have lacked consideration and the findings of this review suggest further research is warranted. Currently, it is unknown why people with tendinopathy may



## Review

also present with psychological variables which link with sub-optimal outcome. One possible explanation might be those with fear of pain might perform less exercise with less intensity.<sup>37</sup> Given the conflicting high-quality evidence of psychological variables presented in the review, further exploration of cognitive processes connected with psychological variables and means of influencing these is warranted.

## CONCLUSIONS

Conflicting evidence exists surrounding the significance of the association of anxiety, depression and LE. However, strong evidence suggests LE is not associated with kinesiophobia. Moderate evidence links catastrophisation and distress with LE, with distress being associated with a <50% reduction in pain at 12 months. Conflictingly, moderate evidence suggests distress is not associated with RT, but kinesiophobia and catastrophisation are. However, this may not lead to a suboptimal outcome. Limited evidence exists linking psychological variables and AT and PT, but current evidence suggests PT is not associated with anxiety or depression and kinesiophobia may be linked with suboptimal outcomes in AT.

Tendinopathy requires an individualised approach to management. As such, when a person is suspected to have tendinopathy, clinicians should consider using validated screening tools for the presence of psychological variables which may contribute to suboptimal outcomes. Management to address the presence of specific variables would need to be tailored for the individual's circumstances, but consideration should be given to providing neuroscience education and addressing cognitive-behavioural barriers.

## What are the findings?

- ▶ Psychological variables may be associated with tendinopathy and a suboptimal outcome.
- ▶ Multidimensional factors influence the development and maintenance of pain and disability in tendinopathy.
- ▶ The underlying factors for the presence of these variables and their amenability to change warrant further investigation.

## How might it impact on clinical practice in the future?

- ▶ Tendinopathy management should include an individualised, holistic assessment.
- ▶ Management strategies may need to be adapted to address individual psychological variables and any underlying cognitive barriers.

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## APPENDIX 2 – PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
<b>TITLE</b>			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	19
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	-
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known.	20
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	20
<b>METHODS</b>			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	-
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	22
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	21
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	21



Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	21
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	24
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	24
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	23
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	24
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ ) for each meta-analysis.	-

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	-
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	-
<b>RESULTS</b>			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	26
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	28-33
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	27

Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	-
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	-
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	-
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	-
<b>DISCUSSION</b>			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	38
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	39-43
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	43
<b>FUNDING</b>			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	-

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: [www.prisma-statement.org](http://www.prisma-statement.org).

(Alizadehkhayat et al 2007)

### NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -CASE CONTROL STUDIES –

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

#### Selection

- 1) Is the case definition adequate?
  - a) yes, with independent validation \*☒ *Orthopaedic surgeon made diagnosis + previous diagnosis made separately i.e. taken from a list diagnosed with TE.*
  - b) yes, eg record linkage or based on self reports
  - c) no description
- 2) Representativeness of the cases
  - a) consecutive or obviously representative series of cases \*☒ *Consecutively identified from hospital records*
  - b) potential for selection biases or not stated
- 3) Selection of Controls
  - a) community controls \*☒ *Students and University staff*
  - b) hospital controls
  - c) no description
- 4) Definition of Controls
  - a) no history of disease (endpoint) \*☒
  - b) no description of source

#### Comparability

- 1) Comparability of cases and controls on the basis of the design or analysis
  - a) study controls for \_\_\_\_ GENDER \_\_\_\_ (Select the most important factor.) \*☒
  - b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.) *Age range too spread in controls. Weight & height (?significance of these factors to TE)*

#### Exposure

- 1) Ascertainment of exposure
  - a) secure record (eg surgical records) \*
  - b) structured interview where blind to case/control status \*
  - c) interview not blinded to case/control status
  - d) written self report or medical record only ☒ *Questionnaires completed by participants*
  - e) no description
- 2) Same method of ascertainment for cases and controls
  - a) yes \*☒
  - b) no
- 3) Non-Response rate
  - a) same rate for both groups \*☒
  - b) non respondents described
  - c) rate different and no designation

(Coombes et al 2012)

## NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

### Selection

1) Representativeness of the exposed cohort

- a) truly representative of the average TENNIS ELBOW (describe) in the community  
\*☒ *tennis elbow clearly defined* )

b) somewhat representative of the average \_\_\_\_\_ in the community \*

c) selected group of users eg nurses, volunteers

d) no description of the derivation of the cohort

2) Selection of the non exposed cohort

a) drawn from the same community as the exposed cohort \*☒ *No non-exposed cohort*

b) drawn from a different source

c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure

a) secure record (eg surgical records) \*☒ *Ascertained from a placebo arm of a RCT*

b) structured interview \*

c) written self report

d) no description

4) Demonstration that outcome of interest was not present at start of study

a) yes \*☒ *outcome of interest (pain & disability) were present (as they needed to be) at start*

b) no

### Comparability

1) Comparability of cohorts on the basis of the design or analysis

a) study controls for \_\_\_\_\_ (select the most important factor) \*☒

b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.)

### Outcome

1) Assessment of outcome

a) independent blind assessment \* ☒ *blinded outcome assessor used to complete all questionnaires and assessments*

b) record linkage \*

c) self report

d) no description

2) Was follow-up long enough for outcomes to occur

a) yes (select an adequate follow up period for outcome of interest) \*☒

b) no

3) Adequacy of follow up of cohorts

a) complete follow up - all subjects accounted for \* ☒

b) subjects lost to follow up unlikely to introduce bias - small number lost - > 2 %  
(select an adequate %) follow up, or description provided of those lost) \*

c) follow up rate < \_\_\_\_\_% (select an adequate %) and no description of those lost

d) no statement

(Coombes et al 2015)

## NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

### Selection

1) Representativeness of the exposed cohort

- a) truly representative of the average TENNIS ELBOW (describe) in the community \*☒ *tennis elbow clearly defined.*
- b) somewhat representative of the average \_\_\_\_\_ in the community \*
- c) selected group of users eg nurses, volunteers
- d) no description of the derivation of the cohort

2) Selection of the non exposed cohort

- a) drawn from the same community as the exposed cohort \*☒ *No non-exposed cohort*
- b) drawn from a different source
- c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure

- a) secure record (eg surgical records) \*☒ *Ascertained from a placebo arm of a RCT*
- b) structured interview \*
- c) written self report
- d) no description

4) Demonstration that outcome of interest was not present at start of study

- a) yes \*☒ *Prospective study, so outcome of interest (pain & disability) were present (as they needed to be) at start*
- b) no

### Comparability

1) Comparability of cohorts on the basis of the design or analysis

- a) study controls for \_\_\_\_\_ (select the most important factor) \*☒
- b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.)

### Outcome

1) Assessment of outcome

- a) independent blind assessment \* ☒ *blinded outcome assessor used to complete all questionnaires and assessments*
- b) record linkage \*
- c) self report
- d) no description

2) Was follow-up long enough for outcomes to occur

- a) yes (select an adequate follow up period for outcome of interest) \*☒ *1 year follow up adequate to see change in dependant variables (pain and disability) as measured by Patient-rated Tennis Elbow Evaluation (PRTEE)*
- b) no

3) Adequacy of follow up of cohorts

- a) complete follow up - all subjects accounted for \*
- b) subjects lost to follow up unlikely to introduce bias - small number lost - > 2 %  
(select an adequate %) follow up, or description provided of those lost)
- \*☒ *40/41 subjects able to be contacted at 1 year*
- c) follow up rate < \_\_\_\_\_% (select an adequate %) and no description of those lost
- d) no statement

(Engebretsen et al 2010)

## NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

### Selection

1) Representativeness of the exposed cohort

- a) truly representative of the average Rotator cuff (describe) in the community \*☒  
*diagnostic criteria clearly defined* )
- b) somewhat representative of the average \_\_\_\_\_ in the community \*
- c) selected group of users eg nurses, volunteers
- d) no description of the derivation of the cohort

2) Selection of the non exposed cohort

- a) drawn from the same community as the exposed cohort \*☒ *No non-exposed cohort*
- b) drawn from a different source
- c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure

- a) secure record (eg surgical records) \*☒ *Ascertained from a clinical trial*
- b) structured interview \*
- c) written self report
- d) no description

4) Demonstration that outcome of interest was not present at start of study

- a) yes \*☒ *outcome of interest (pain & disability) were present (as they needed to be) at start*
- b) no

### Comparability

1) Comparability of cohorts on the basis of the design or analysis

- a) study controls for \_\_\_\_\_ (select the most important factor) \*☒
- b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.)

### Outcome

1) Assessment of outcome

- a) independent blind assessment \*
- b) record linkage \*
- c) self report ☒ *SPADI and HSCL.*
- d) no description

2) Was follow-up long enough for outcomes to occur

- a) yes (select an adequate follow up period for outcome of interest) \*☒
- b) no

3) Adequacy of follow up of cohorts

- a) complete follow up - all subjects accounted for \* ☒
- b) subjects lost to follow up unlikely to introduce bias - small number lost - > 2 %  
(select an adequate %) follow up, or description provided of those lost) \*
- c) follow up rate < \_\_\_\_\_% (select an adequate %) and no description of those lost
- d) no statement

(Garnevall et al 2013)

## NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

### Selection

1) Representativeness of the exposed cohort

- a) truly representative of the average \_tennis elbow (describe) in the community  
\*☒ *tennis elbow clearly defined* )

b) somewhat representative of the average \_\_\_\_\_ in the community \*

c) selected group of users eg nurses, volunteers

d) no description of the derivation of the cohort

2) Selection of the non exposed cohort

a) drawn from the same community as the exposed cohort \*☒ *primary care*

b) drawn from a different source

c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure

a) secure record (eg surgical records) \*

b) structured interview \*☒ *by lead author*

c) written self report

d) no description

4) Demonstration that outcome of interest was not present at start of study

a) yes \*☒ *outcome of interest (pain & disability) were present (as they needed to be) at start*

b) no

### Comparability

1) Comparability of cohorts on the basis of the design or analysis

a) study controls for \_\_gender\_\_\_\_ (select the most important factor) \*☒

b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.)

### Outcome

1) Assessment of outcome

a) independent blind assessment \*

b) record linkage \*

c) self report ☒

d) no description

2) Was follow-up long enough for outcomes to occur

a) yes (select an adequate follow up period for outcome of interest) \*☒

b) no

3) Adequacy of follow up of cohorts

a) complete follow up - all subjects accounted for \* ☒

b) subjects lost to follow up unlikely to introduce bias - small number lost - > \_\_\_\_ %  
(select an adequate %) follow up, or description provided of those lost) \*

c) follow up rate < \_\_\_\_% (select an adequate %) and no description of those lost

d) no statement

(Kromer et al 2014)

## NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

### Selection

1) Representativeness of the exposed cohort

a) truly representative of the average rotator cuff (describe) in the community \*☒  
*sub acromial pain clearly defined* )

b) somewhat representative of the average \_\_\_\_\_ in the community \*

c) selected group of users eg nurses, volunteers

d) no description of the derivation of the cohort

2) Selection of the non exposed cohort

a) drawn from the same community as the exposed cohort \*☒ *No non-exposed cohort*

b) drawn from a different source

c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure

a) secure record (eg surgical records) \*☒ *Ascertained from a RCT*

b) structured interview \*

c) written self report

d) no description

4) Demonstration that outcome of interest was not present at start of study

a) yes \*☒ *outcome of interest (pain & disability) were present (as they needed to be) at start*

b) no

### Comparability

1) Comparability of cohorts on the basis of the design or analysis

a) study controls for \_\_\_\_\_ (select the most important factor) \*☒

b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.) ☒

### Outcome

1) Assessment of outcome

a) independent blind assessment \*

b) record linkage \*

c) self report ☒

d) no description

2) Was follow-up long enough for outcomes to occur

a) yes (select an adequate follow up period for outcome of interest) \*☒

b) no

3) Adequacy of follow up of cohorts

a) complete follow up - all subjects accounted for \*

b) subjects lost to follow up unlikely to introduce bias - small number lost - > 2 %  
(select an adequate %) follow up, or description provided of those lost) \*☒

c) follow up rate < \_\_\_\_\_% (select an adequate %) and no description of those lost

d) no statement



**NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -COHORT STUDIES**

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

**Selection**

- 1) Representativeness of the exposed cohort
  - a) truly representative of the average TENNIS ELBOW (describe) in the community \* ☒ *tennis elbow clearly defined. 289 consecutively diagnosed cases utilised.*
  - b) somewhat representative of the average \_\_\_\_\_ in the community \*
  - c) selected group of users eg nurses, volunteers
  - d) no description of the derivation of the cohort
- 2) Selection of the non exposed cohort
  - a) drawn from the same community as the exposed cohort \* ☒
  - b) drawn from a different source
  - c) no description of the derivation of the non exposed cohort
- 3) Ascertainment of exposure
  - a) secure record (eg surgical records) \* ☒ *consulted GP*
  - b) structured interview \*
  - c) written self report
  - d) no description
- 4) Demonstration that outcome of interest was not present at start of study
  - a) yes \* ☒ *All had pain and disability present*
  - b) no

**Comparability**

- 1) Comparability of cohorts on the basis of the design or analysis
  - a) study controls for \_\_\_\_\_ (select the most important factor) \* ☒
  - b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.)

**Outcome**

- 1) Assessment of outcome
  - a) independent blind assessment \* ☒ *primary outcome assessment was done independently, based on patient self-reports in follow up questionnaires*
  - b) record linkage \*
  - c) self report
  - d) no description
- 2) Was follow-up long enough for outcomes to occur
  - a) yes (select an adequate follow up period for outcome of interest) \* ☒ *1 year follow up to assess pain and disability*
  - b) no
- 3) Adequacy of follow up of cohorts
  - a) complete follow up - all subjects accounted for \*
  - b) subjects lost to follow up unlikely to introduce bias - small number lost - > \_\_\_\_ % (select an adequate %) follow up, or description provided of those lost)

\* ☒ *227 of 238 followed up*

  - c) follow up rate < \_\_\_\_% (select an adequate %) and no description of those lost

(Lee et al 2014)

## NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

### Selection

1) Representativeness of the exposed cohort

- a) truly representative of the average TENNIS ELBOW (describe) in the community \* ☒ *tennis elbow clearly defined. 108 consecutive patients utilised.*
- b) somewhat representative of the average \_\_\_\_\_ in the community \*
- c) selected group of users eg nurses, volunteers
- d) no description of the derivation of the cohort

2) Selection of the non exposed cohort

- a) drawn from the same community as the exposed cohort \* ☒
- b) drawn from a different source
- c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure

- a) secure record (eg surgical records) \*
- b) structured interview \* ☒
- c) written self report
- d) no description

4) Demonstration that outcome of interest was not present at start of study

- a) yes \* ☒ *All had pain and disability present*
- b) no

### Comparability

1) Comparability of cohorts on the basis of the design or analysis

- a) study controls for \_\_\_\_\_ (select the most important factor) \* ☒
- b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.)

### Outcome

1) Assessment of outcome

- a) independent blind assessment \* ☒ *2 researchers blinded to patient data or survey results*
- b) record linkage \*
- c) self report
- d) no description

2) Was follow-up long enough for outcomes to occur

- a) yes (select an adequate follow up period for outcome of interest) \* ☒ *1 year follow up to assess pain and disability*
- b) no

3) Adequacy of follow up of cohorts

- a) complete follow up - all subjects accounted for \*
- b) subjects lost to follow up unlikely to introduce bias - small number lost - > \_\_\_\_\_ %  
(select an adequate %) follow up, or description provided of those lost)
- \* ☒ *91 of 108 followed up*
- c) follow up rate < \_\_\_\_\_ % (select an adequate %) and no description of those lost
- d) no statement

(Silbernagel et al 2011)

## NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

### Selection

1) Representativeness of the exposed cohort

- a) truly representative of the average \_\_\_\_ (describe) in the community \*
- b) somewhat representative of the average \_\_\_\_\_ in the community \*☒

Achilles tendinopathy clearly described. Cohort derived from a RCT ( small representative sample n=31)

- c) selected group of users eg nurses, volunteers
- d) no description of the derivation of the cohort

2) Selection of the non exposed cohort

- a) drawn from the same community as the exposed cohort \*☒
- b) drawn from a different source
- c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure

- a) secure record (eg surgical records) \*
- b) structured interview \*
- c) written self report ☒
- d) no description

4) Demonstration that outcome of interest was not present at start of study

- a) yes \*☒ *All had pain and disability present*
- b) no

### Comparability

1) Comparability of cohorts on the basis of the design or analysis

- a) study controls for \_\_AGE\_\_\_\_ (select the most important factor) \*☒
- b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.)

### Outcome

1) Assessment of outcome

- a) independent blind assessment \*
- b) record linkage \*
- c) self report ☒ *VISA-A, TSK & PAS*
- d) no description

2) Was follow-up long enough for outcomes to occur

- a) yes (select an adequate follow up period for outcome of interest) \*☒ *5 year follow up to assess pain and disability*
- b) no

3) Adequacy of follow up of cohorts

- a) complete follow up - all subjects accounted for \*
- b) subjects lost to follow up unlikely to introduce bias - small number lost - > \_\_\_\_ %  
(select an adequate %) follow up, or description provided of those lost)
- \* ☒ *90% followed up*
- c) follow up rate < \_\_\_\_% (select an adequate %) and no description of those lost
- d) no statement

(Van Wilgen et al 2013)

## NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE -COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

### Selection

1) Representativeness of the exposed cohort

- a) truly representative of the average (describe) in the community \*
- b) somewhat representative of the average \_\_\_\_\_ in the community \*
- c) selected group of users eg nurses, volunteers ☒ *Only male subjects asked to participate.*
- d) no description of the derivation of the cohort

2) Selection of the non exposed cohort

- a) drawn from the same community as the exposed cohort \* ☒ *male sports population*
- b) drawn from a different source
- c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure

- a) secure record (eg surgical records) \* ☒ *from attending physician*
- b) structured interview \*
- c) written self report
- d) no description

4) Demonstration that outcome of interest was not present at start of study

- a) yes \* ☒ *outcome of interest (pain & disability) were present (as they needed to be) at start*
- b) no

### Comparability

1) Comparability of cohorts on the basis of the design or analysis

- a) study controls for \_\_\_\_\_ (select the most important factor) \* ☒
- b) study controls for any additional factor \* (This criteria could be modified to indicate specific control for a second important factor.)

### Outcome

1) Assessment of outcome

- a) independent blind assessment \*
- b) record linkage \*
- c) self report
- d) no description ☒ *no blinding evident*

2) Was follow-up long enough for outcomes to occur

- a) yes (select an adequate follow up period for outcome of interest) \* ☒
- b) no

3) Adequacy of follow up of cohorts

- a) complete follow up - all subjects accounted for \* ☒
- b) subjects lost to follow up unlikely to introduce bias - small number lost - > 2 %  
(select an adequate %) follow up, or description provided of those lost) \*
- c) follow up rate < \_\_\_\_\_ % (select an adequate %) and no description of those lost
- d) no statement

## Cognitive and contextual factors to optimise clinical outcomes in tendinopathy

Adrian James Mallows,<sup>1</sup> James Robert Debenham,<sup>2</sup> Peter Malliaras,<sup>3</sup> Richmond Stace,<sup>4</sup> Chris Littlewood<sup>5</sup>

Tendinopathy, a clinical term used to describe 'tendon-related pain', is a heterogeneous clinical presentation, reflected by the wide-ranging pain presentations and functional deficits.<sup>1</sup> For this population, load-based exercise is effective; however, the 'optimal' type of exercise, intensity, frequency and duration are not known.<sup>2,3</sup>

Substantial variety has been a feature of the exercise prescription used in tendinopathy research to date. However, this variation does not appear to have impacted the results. Exercise programmes as different as a concentric-eccentric heavy slow loading programme performed three times per week and eccentric only exercises performed twice daily, 7 days/week, have achieved similar results.<sup>4</sup> While within-group mean severity scores improve, individual responses are wide ranging for the same exercise programme<sup>4</sup> and success rates vary from 44% failing to improve<sup>5</sup> to 100% success<sup>6</sup> for a similar exercise intervention.

Here we discuss a novel consideration to explain such phenomena—cognitive and contextual factors that affect each individual therapeutic encounter. We acknowledge that heterogeneity in the research cohorts (eg, age, sex, chronicity, comorbidities) or variations in how the exercise programme was delivered and progressed likely play a role, but we focus on factors we feel have received little attention.

### PSYCHOSOCIAL IMPACT

Beliefs and fears have received little attention in current tendinopathy management

models. Working alliance and self-efficacy are both associated with adherence behaviours and rehabilitation outcome,<sup>7,8</sup> yet measures of these factors are largely absent from the tendinopathy research to date.

### WORKING ALLIANCE

Working alliance is defined as the positive social connection between the patient and the therapist. A person-centred interaction style, related to the provision of emotional support and allowing patient involvement in the consultation processes, develops working alliance<sup>9</sup>; this underscores the importance of the clinician recognising the patient's physical and emotional needs. To facilitate this, clinicians should practise skills such as active listening, paraphrasing and inviting the patient's opinion; consider initially avoiding interruptions, allowing the patients to tell their story. Within this interaction, the clinician can monitor the patient's self-efficacy indicators via questioning to establish efficacy expectations and outcome expectations. Questions aimed at understanding the patient's experience with rehabilitation, hopes for the future and the expected role of exercise have been highlighted.<sup>10</sup>

### EFFICACY EXPECTATIONS

We refer to efficacy expectations as the patient's beliefs about his or her ability to perform the rehabilitation tasks, and to maintain control, engagement and persistence when faced with adversity. As

such, efficacy expectations are key determinants of whether the rehabilitation tasks reach their desired outcome and due consideration must therefore be given to the dosage, levels of pain reproduced and complexity of exercises; what may be considered best for tissue may not be optimal in terms of efficacy expectations. For example, simple, resistance exercises, completed one at a time may appear suboptimal from the perspective of exercise physiology, yet have shown efficacy in a population with rotator cuff tendinopathy.<sup>11</sup> Exercise prescription should promote self-monitoring, and appropriate interpretation of physiological signs is essential.<sup>12</sup> In particular, pain response to a load-based exercise intervention should be self-monitored and adapted by the individual accordingly to aid efficacy expectations. Previous guidelines have included using a visual analogue scale of no more than 5/10.<sup>13,14</sup> However, with sufficient efficacy expectations, the use of a scale is not required; patients can determine what pain response is acceptable over a 24-hour period themselves.<sup>11</sup> This could be judged upon the perceived impact upon sleep, activities of daily living or work, for example.

### OUTCOME EXPECTATIONS

Outcome expectations relate to a person's estimate that a given behaviour will lead to certain outcomes. Reduced outcome expectations, along with negative expectations, such as a fear, concerns and uncertainty surrounding potential future damage to the tendon, have been identified in people with Achilles tendinopathy.<sup>10</sup> Such negative outcome expectations should be discussed, challenged and reconceptualised, as they will be a critical determinant of engagement with a load-based exercise programme. For example, concerns around the risk of tendon rupture could be explored with the clinician highlighting the disparity between painful tendons preceding a rupture.<sup>15</sup>

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Figure 1 Cognitive and contextual factors for optimising outcomes in tendinopathy.

## Editorial

## ENHANCING SELF-EFFICACY

Self-efficacy depends mostly on the way people interpret their symptoms, and to what degree they believe that they can exercise control of the outcome of their injury through series of behavioural choices over time. The success of a load-based exercise programme depends upon the person interpreting the pain response in a way that facilitates the use of exercise as a management strategy. The aim of verbal persuasion is to allow patients to move beyond their current perceived pain threshold and towards an enhanced capability threshold encompassing a mixture of biological, psychological and sociological factors. For example, if the clinician provides a positive message around the patient's imaging results to reflect the lack of association morphology and pain it may to shift the patient's unhelpful beliefs. For example, from 'I shouldn't do anything that hurts' to understanding pain during exercise might be helpful rather than harmful.<sup>3</sup> The choice of words to facilitate this is critical; negative perceptions of tissue health from prior imaging or consultation from prior healthcare providers may exist and affect the way information is perceived. It may be useful for the clinician to explain pain in terms of sensitivity, ensuring the person in pain understands why hurt does not necessarily equal harm and why pain during rehabilitation should be acceptable. Special consideration needs to be taken to ensure that experience of the exercises confirms the messages the clinician is conveying and provides the patient with an experience which solidifies their new-found beliefs via successful experiences. In turn, this will expand the patients' locus of control by gently challenging their perceived ability to perform the task without guidance. This concept provides a novel perspective for load-based exercises; providing experienced

control for the person with tendinopathy. Experiencing this control will help 'set up for success' and ensure an understanding upon which a successful partnership can be developed. Understanding should be revisited regularly using simple questions such as: 'What do you understand is the cause of your pain?', 'Why could exercises help?'. A summary of suggested cognitive and contextual considerations to optimise clinical outcomes in tendinopathy is offered in figure 1.

In conclusion, load-based exercise is currently recommended for management of tendinopathy. However, given the wide-ranging responses from loading exercises in the research, much uncertainty remains. Contextual and cognitive factors may help explain some of the variation and also present a novel perspective to target for interventions. As such, these factors should be considered further by researchers and clinicians within the field.

**Competing interests** None declared

**Provenance and peer review** Not commissioned; externally peer reviewed.

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## Measuring patient-reported outcomes (PROs/PROMs) in people with Achilles tendinopathy: how useful is the VISA-A?

Adrian Mallows,<sup>1</sup> Chris Littlewood,<sup>2</sup> Peter Malliaras<sup>3</sup>

It is important for clinicians and researchers to measure outcomes. Patient-reported outcome measures (PROMs) are short questionnaires, which are self-reported and designed to capture a person's perceptions of specified aspects of their health status.<sup>1</sup> Conceptually, PROMs can be viewed either as a 'tool for evaluation' or as a 'mechanism for improvement' suited to the many factors that characterise a person's health status that cannot be observed, measured with a device or analysed with even the most sophisticated imaging methods.<sup>2</sup> Such questionnaires are ideally suited to areas such as tendinopathy where disease impact does not correlate consistently with biomarkers.

The Victorian Institute of Sport Assessment - Achilles (VISA-A) Questionnaire is a widely used PROM for Achilles tendinopathy and is available in seven different languages (figure 1). The ability of the VISA-A to improve decision making is determined by its reliability, validity and responsiveness to change, as these are essential psychometric properties for any measure.<sup>3,4</sup> Here we critically review the evidence that exists for the VISA-A questionnaire.

### DEVELOPMENT

The severity of Achilles tendinopathy is the construct of interest for the VISA-A, with validity and reliability first being examined by Robinson *et al.*<sup>5</sup> Content validity is defined as the degree to which the content of the PROM is an adequate reflection of the construct to be measured.<sup>1,3</sup> Content validity for the VISA-A was established from a pre-existing version of the

questionnaire, interviewing colleagues, informally interviewing patients about their symptoms and using a focus group of clinicians and subject experts. The inclusion of patients in this process is limited. Because the focus is on patient reported outcome, patients should be considered experts when judging the relevance of the items for the patient population.<sup>3</sup> As such, the relevance and comprehensiveness of the items in the VISA-A for the target population require further investigation, with additional consideration given to reflect current understanding of the multidimensional nature of the condition.<sup>6</sup>

Construct validity is the degree to which the scores of the PROM are consistent with predetermined hypotheses based on the assumption that the PROM validly measures the construct of interest.<sup>1,3</sup> The formulation and testing of such hypotheses are missing from the VISA-A development, and the potential for the VISA-A to be measuring more than one construct has been identified.<sup>7</sup> The physical activity section of the VISA-A weighs heavily in the overall scoring (40/100). Consequently, if a person with Achilles tendinopathy is functioning at a high level despite pain, the construct of the VISA-A may lead to the view that they are less affected. As high-level function precedes pain, they may be simply 'pushing on'.

In addition to validity, reliability was also tested by Robinson *et al.*,<sup>5</sup> but only in a sporting population; they used cases referred to a sports medicine clinic or awaiting surgery and controls representing active individuals from a University population or running club. Given that only 35% of the general population with Achilles tendinopathy may describe a relationship to sports activity,<sup>8</sup> the VISA-A lacks evidence of reliability in non-sporting populations and a heterogeneous sporting population. Robinson *et al.*<sup>5</sup> suggest that the VISA-A only be used in homogenous populations, and recognise the limitations of its use in non-sporting populations; a non-active person's symptoms may resolve, yet they might only score 50/100.

Responsiveness is the ability of a PROM to detect change over time in the construct to be measured, thus referring to the validity of a change score.<sup>3</sup> As with evaluating criterion validity, a PROM responsiveness is required to be tested against hypotheses.<sup>3</sup> While a minimum clinically important difference for the VISA-A has been cautiously suggested to be 6.5 points,<sup>9</sup> test-retest reliability has only been established at 1 week.<sup>3</sup> Predetermined hypotheses require testing at longer term follow-up to ascertain responsiveness. Longer term follow-up needs to allow time for sufficient clinical improvement, but still be short enough to assume the patients would be able to recall whether any changes in their condition had occurred.<sup>10</sup>

In summary, the VISA-A was published in 2001, and has now been widely used, offering easy comparison between treatments from various clinics and research studies. In the absence of an alternative PROM, clinicians and researchers might continue to use the VISA-A, despite the limited extent of evidence concerning the clinimetric properties for this PROM. However, since 2001, both our understanding of the multidimensional nature of tendinopathy and PROMs have developed, and as such the VISA-A requires updating. This critical review has highlighted the need for future research into the construct and content validity and responsiveness of the VISA-A. To ensure methodological rigour, this should follow the COnsensus-based Standards for selection of health Measurement Instruments recommendations for terminology and research agenda.<sup>3</sup>

**Competing interests** None declared.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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## Editorial

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## APPENDIX 6 – STROBE Checklist

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	86
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	-
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	86-87
Objectives	3	State specific objectives, including any prespecified hypotheses	88
Methods			
Study design	4	Present key elements of study design early in the paper	89
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	89
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	89
		(b) For matched studies, give matching criteria and number of exposed and unexposed	-
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	91
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	91-95
Bias	9	Describe any efforts to address potential sources of bias	90
Study size	10	Explain how the study size was arrived at	95
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	99

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	99
		(b) Describe any methods used to examine subgroups and interactions	-
		(c) Explain how missing data were addressed	101
		(d) If applicable, explain how loss to follow-up was addressed	102
		(e) Describe any sensitivity analyses	-
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	102
		(b) Give reasons for non-participation at each stage	101
		(c) Consider use of a flow diagram	102
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	105
		(b) Indicate number of participants with missing data for each variable of interest	105
		(c) Summarise follow-up time (eg, average and total amount)	111
Outcome data	15*	Report numbers of outcome events or summary measures over time	110-11



## Health Research Authority

Mr Adrian J Mallows  
Lecturer in Physiotherapy & PhD Student

Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)

University of Essex  
School of Sport, Rehabilitation and Exercise Sciences  
Wivenhoe Park  
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CO4 3SQ

15 September 2017

Dear Mr Mallows

Letter of HRA Approval

<b>Study title:</b>	<b>The association of working alliance, outcome expectation, adherence and self-efficacy with clinical outcomes for Achilles tendon-related pain: protocol for a pilot cohort study (the MAP study)</b>
<b>IRAS project ID:</b>	<b>219457</b>
<b>REC reference:</b>	<b>17/LO/1583</b>
<b>Sponsor</b>	<b>University of Essex</b>

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

**Appendix B** provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read Appendix B carefully**, in particular the following sections:

- **Participating NHS organisations in England** – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- **Confirmation of capacity and capability** - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.

- ***Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)*** - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Page **1** of **8**

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from [www.hra.nhs.uk/hra-approval](http://www.hra.nhs.uk/hra-approval).

## Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

## After HRA Approval

The 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.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the ***After Ethical Review*** document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the [HRA website](http://www.hra.nhs.uk), and emailed to [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net).
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the [HRA website](http://www.hra.nhs.uk).

## Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at <http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/>.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

#### 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 Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

Your IRAS project ID is **219457**. Please quote this on all correspondence.

Yours sincerely

Kelly Rowe

Assessor

Email: [hra.approval@nhs.net](mailto:hra.approval@nhs.net)

*Copy to: Ms Sarah Manning-Press, University of Essex, Sponsor Representative  
Craig Mackerness, Southend University Hospital NHS Foundation Trust,  
Lead NHS R&D contact*

#### Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Card given to potential participants]	2.0	18 July 2017
Covering letter on headed paper [Covering letter explaining changes which have been made]		02 August 2017

Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		15 July 2017
HRA Schedule of Events [Validated SOE]	1.0	15 September 2017
HRA Statement of Activities [Validated SOA]	1.0	15 September 2017
Interview schedules or topic guides for participants	2.0	18 July 2017
IRAS Application Form [IRAS_Form_29082017]		29 August 2017
Letter from sponsor		17 August 2017
Letters of invitation to participant [Email invitation for participation in the follow up interview]	1.0	02 August 2017
Non-validated questionnaire [The questionnaire is compiled of validated outcome measures ]	2.0	18 July 2017
Other [CV for collaborator]	2.0	18 July 2017
Other [CV for 2nd collaborator]	2.0	18 July 2017
Other [Interview consent form]	1.0	18 July 2017
Other [Letter from private site]	1.0	02 August 2017
Other [REC letter]	NA	13 July 2017
Other [Email invitation to complete questionnaire for 2nd time]	1.0	13 September 2017
Other [Email invitation to complete questionnaire for 3rd time]	1.0	13 September 2017
Other [response to Camden and Kings Cross PR Sub-Committee]	1.0	13 September 2017
Participant consent form [Online consent form]	2.0	18 July 2017
Participant information sheet (PIS) [Changes are highlighted]	2.0	18 July 2017
Research protocol or project proposal [Changes are highlighted in response to London Central REC and track changes used in response to PR Sub-Committee from Camden]	3.0	13 September 2017
Summary CV for Chief Investigator (CI)		18 July 2017
Summary CV for student		18 July 2017
Summary CV for supervisor (student research)		18 July 2017

## Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in

**England, please refer to the, *participating NHS organisations, capacity and capability and Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) sections in this appendix.***

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Ms Sarah Manning-Press

Tel: 01206873561

### HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	NHS involvement will be through PIC activity.
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	<p>The statement of activities will act as agreement of an NHS organisation to participate. No further agreements expected</p> <p>Although formal confirmation of capacity and capability is not expected of all or some organisations participating in this study (see <b><i>Confirmation of Capacity and Capability</i></b> section for full details), and such</p>

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			<p>organisations would therefore be assumed to have confirmed their capacity and capability should they not respond to the contrary, we would ask that these organisations pro-actively engage with the sponsor in order to confirm at as early a date as possible. Confirmation in such cases should be by email to the CI and Sponsor confirming participation based on the relevant Statement of Activities and information within this Appendix B.</p>

4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No external application for funding has been made, study will be undertaken as part of a PhD The statement of activities confirms that there is no funding available to sites from the sponsor.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC FO dated 14/09/2017
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter	Not Applicable	No comments
<b>Section</b>	<b>HRA Assessment Criteria</b>	<b>Compliant with Standards</b>	<b>Comments</b>
	received		
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

### Participating NHS Organisations in England

*This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.*



There is one site type; participating NHS organisations will be Participant Identification Centres (PIC). An information card is to be given to potential eligible patients by their treating physiotherapist. Patient will then access the website for further information of their own free will. Researcher will conduct interviews with participants via telephone or Skype.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at [hra.approval@nhs.net](mailto:hra.approval@nhs.net). The HRA will work with these organisations to achieve a consistent approach to information provision.

## Confirmation of Capacity and Capability

*This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.*

The HRA has determined that participating NHS organisations in England (PIC Sites) **are not expected to formally confirm their capacity and capability to host this research**, because of their limited involvement in this study.

- The HRA has informed the relevant research management offices that you intend to undertake the research at their organisation. However, you should still support and liaise with these organisations as necessary.
- Following issue of the HRA Approval letter, and subject to the two conditions below, it is expected that these organisations will become participating NHS organisations 35 days after issue of this Letter of HRA Approval (no later than **20/10/2017**):

- You may not include the NHS organisation if they provide justification to the sponsor and the HRA as to why the organisation cannot participate
- You may not include the NHS organisation if they request additional time to confirm, until they notify you that the considerations have been satisfactorily completed..
- You may include NHS organisations in this study in advance of the deadline above where the organisation confirms by email to the CI and sponsor that the research may proceed.
- The document “[Collaborative working between sponsors and NHS organisations in England for HRA Approval studies, where no formal confirmation of capacity and capability is expected](#)” provides further information for the sponsor and NHS organisations on working with NHS organisations in England where no formal confirmation of capacity and capability is expected, and the processes involved in adding new organisations. Further study specific details are provided the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this Appendix.

### Principal Investigator Suitability

*This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).*

A local collaborator is expected at participants NHS organisations. CI will provide guidance on the eligibility criteria to the local collaborator.

GCP training is not a generic training expectation, in line with the [HRA statement on training expectations](#).

### HR Good Practice Resource Pack Expectations

*This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken*

It is anticipated that participant identification will be completed by local staff with existing contractual arrangements with the participating NHS organisation. No further HR good practice arrangements expected.

### Other Information to Aid Study Set-up

*This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.*

The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Interested in taking part in our study? Head to the  
website below for more details



**[www.managing-achilles-pain.com](http://www.managing-achilles-pain.com)**

(Password: essex)

Don't want to take part? Could you let us know why?

18<sup>th</sup> July 2017; Version 2.0, IRAS ID: 219457



University of Essex

# Managing Achilles Pain – the MAP study

Adrian Mallows

## The full title!

**The association of working alliance, outcome expectations, adherence and self-efficacy with clinical outcomes for Achilles tendon-related pain: protocol for a pilot cohort study**



University of Essex

## Background to the study

The explanation to date:

- Research has largely focused on the 'bio'
- Little research considers the 'psycho' or 'social'
- We have carried out two reviews exploring this further



## Background to the study

The problem:

- Load-based exercises can be beneficial for people with Achilles tendinopathy
- But, we don't know why
- Variation in exercises doesn't seem to matter



# Systematic review

BJSM Online First, published on November 16, 2016 as 10.1136/bjsports-2016-096154

Review

## Association of psychological variables and outcome in tendinopathy: a systematic review

Adrian Mallows,<sup>1</sup> James Debenham,<sup>2</sup> Tom Walker,<sup>3</sup> Chris Littlewood<sup>4,5</sup>



# Systematic review

## What are the findings?

- ▶ Psychological variables may be associated with tendinopathy and a suboptimal outcome.
- ▶ Multidimensional factors influence the development and maintenance of pain and disability in tendinopathy.
- ▶ The underlying factors for the presence of these variables and their amenability to change warrant further investigation.



## Critical review

BJSM Online First, published on October 9, 2017 as 11

### **Cognitive and contextual factors to optimise clinical outcomes in tendinopathy**

Adrian James Mallows,<sup>1</sup> James Robert Debenham,<sup>2</sup> Peter Malliaras,<sup>3</sup>  
Richmond Stace,<sup>4</sup> Chris Littlewood<sup>5</sup>



## Critical review

“In conclusion, load-based exercise is currently recommended for management of tendinopathy. However, given the wide-ranging responses from loading exercises in the research, much uncertainty remains. Contextual and cognitive factors may help explain some of the variation and also present a novel perspective to target for interventions. As such, these factors should be considered further by researchers and clinicians within the field.”



## The key players

- Working Alliance
- Efficacy Expectations
- Outcome Expectations

## Working Alliance

- Working alliance, also known as therapeutic alliance or patient-therapist relationship, can be defined as the working rapport or positive social connection between the patient and the therapist.

(Joyce et al, 2003)



## Efficacy Expectations

- Efficacy expectations are beliefs about one's ability to perform the task, and are seen as determinants of whether one attempts the task, how persistent one is and ultimately how successful one is.

(Lee et al, 1984)



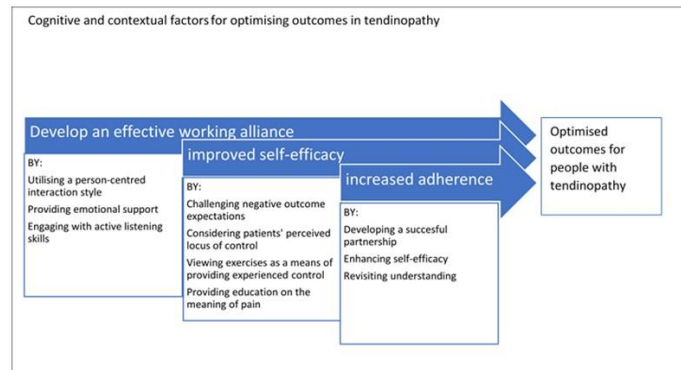
## Outcome Expectations

- Outcome expectation relates to a person's estimate that a given behaviour will lead to certain outcomes.

(Bandura, 1977)



# Summary



## A pilot cohort study

The primary aim of this study is to assess the feasibility of the protocol for a future full longitudinal cohort study that would investigate the association and predictive relationship of working alliance, outcome expectations, adherence and self-efficacy with outcome in the management of Achilles tendon-related pain.

# Objectives

1. Evaluate the recruitment & retention rate for completing all questionnaires
2. Evaluate and refine the data collection procedures
3. Preliminary evaluation of participant responses
4. Explore the acceptability of the study procedures from the participants' perspectives

# Research Design

- Study design

A multi-centred, longitudinal pilot and feasibility cohort study will be used to meet objectives 1-3.

Recruitment will be to time (six months duration)

## Eligibility criteria

Participants must be a minimum of 18 years old, have access to the internet, an available email address and identified as having Achilles tendon-related pain as determined by the attending physiotherapist according to the following criteria:

- Local Achilles tendon pain reproduced with activity, for example heel raising, of at least ten days duration
- Tenderness to palpation of the Achilles tendon
- Dorsiflexion range of movement at the ankle within normal limits



## Exclusion criteria

- Tendon rupture
- Receiving treatment for post-surgical recovery
- Reproduction of pain in the Achilles region on movements of the spine



## Care Pathways

- The participants journey will be unaffected by taking part in the study

## Independent variables

- Working Alliance
- Outcome expectation
- Adherence
- Self-efficacy

## Outcome measures

- **Primary**

Lower Extremity Functional Scale

- **Secondary**

Numerical Pain Rating Scale

(All measures collected 3 times)



## What, no VISA-A?

BJSM Online First, published on June 22, 2017 as 10.1136

**Measuring patient-reported outcomes  
(PROs/PROMs) in people with Achilles  
tendinopathy: how useful is the VISA-A?**

Adrian Mallows,<sup>1</sup> Chris Littlewood,<sup>2</sup> Peter Malliaras<sup>3</sup>



## Recruitment

Interested in taking part in our study? Head to the website below for more details



[www.managing-achilles-pain.com](http://www.managing-achilles-pain.com)

(Password: essex)



## Online Data Collection

[dedicated website](#)



## Statistical analysis

- Recruitment & retention rates will be described descriptively
- A exploratory correlational analysis to establish relationships
- Regression analysis to investigate predictions

## Process evaluation

- The purpose of the process evaluation is to meet objective 4; to explore the acceptability of the study procedures from the participants' perspectives.



## Participants

- Purposefully selected from the cohort study

## Data collection

- Semi-structured interviews, directed by a topic guide and digitally recorded

# Data analysis

- A framework approach:

- 1) Familiarisation – identifying the key themes
- 2) Identifying a thematic framework – identifying all key issues, concepts and themes by which the data can be examined
- 3) Indexing – application of the thematic framework to all the data
- 4) Charting – organisation of the data according to the defined thematic framework to which they relate to form common charts
- 5) Mapping and Interpretation – using the charts to define concepts, map the range and nature of phenomena, create typologies and find associations with a view to providing explanations for the findings.



# Questions?



Please.....



## Recruitment into the study

Consider in two separate stages

- 1) Diagnostic consultation – usual practice; explain the diagnosis and treatment options
- 2) Recruitment consultation

## Recruitment consultation

Takes place after the diagnostic consultation

- Should enable patients to understand the uncertainty arising from a lack of clinical research evidence about the optimal treatment of Achilles tendinopathy



## Recruitment consultation – 6 steps

- Step 1 – explain the condition
- Step 2 – reassure they will be receiving the best treatment
- Step 3 – explain there is uncertainty what makes it the best
- Step 4 – explain the purpose of the study
- Step 5 – balance the risks and rewards
- Step 6 – explain the procedures



## Step 1 – explain the condition

Reiteration of diagnostic consultation:

- *‘Having a painful Achilles tendon is fairly common. Tendons usually become sensitive when we ask them to cope with more than they can manage.’*

## Step 2 – reassure about treatment

- *‘Exercise treatment, guided by a physiotherapist is the most promising treatment we have for helping people with a painful Achilles tendon.’*

### Step 3 – explain the uncertainty

- *‘However, we aren’t entirely sure why it helps. Recent research suggests how treatment is delivered may be influential on the success of treatment. Based on previous work, we think a person’s expectations, beliefs and who delivers the treatment to them may be important.’*



### Step 4 – explain the purpose of the study

- *‘Exploring these factors has yet to be investigated, and in order to do so we have designed this ‘pilot study’ to help us develop a larger study.’*



## Step 5 – balancing the risks & rewards

- *‘The survey will take around 15 minutes to complete each time. There are no anticipated risks associated with your participation.’*
- *‘There are no direct benefits to you, but we hope the information derived from this study will help improve the future treatment of people with painful Achilles tendons.’*



## Step 6 – explain the procedures

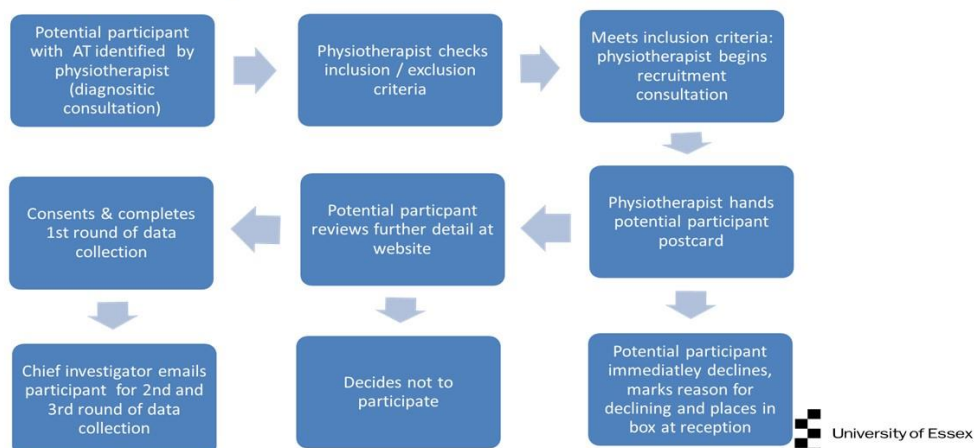
- *‘We are asking people to complete a survey 3 times over a 3 month period. You will be contacted by email to remind you to take the follow up surveys. You may then be invited to participate in a follow up interview about your experience of your of the study.’ Everything is kept confidential – only Adrian at the University of Essex will know your answers.*



## Dealing with questions

- Try to answer questions as they arise
- Point them to the website for further details and my contact details

## In summary





# Questions?



## Participant Information Sheet

### Managing Achilles Pain – a pilot study

Adrian Mallows, PhD Student and Chief Investigator

Professor Jo Jackson, Academic Supervisor

*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. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask us if there is anything that is not clear.*

#### Background to the study

Having a painful Achilles tendon is fairly common. Recent research suggests *how* treatment is delivered may be influential on the success of treatment. Based on previous work, we think a person's expectations, beliefs and who delivers the treatment to them may be important.

#### What is the purpose of the study?

Exploring these factors has yet to be investigated, and in order to do so we have designed this 'pilot study' to help us develop a larger study.

#### Why have I been invited?

You have been invited because you are currently undergoing treatment for a painful Achilles tendon.

#### Do I have to take part?

*No, it is up to you to decide to join the study.* You can change your mind at any time and decide not to participate. The treatment and standard of care you receive will not be affected in any way if you decide not to take part now or if you withdraw from the study later. We are happy to answer any questions you may have before deciding whether you wish to take part in this study.

#### What will I have to do?

We are asking people to complete a questionnaire 3 times over a 3 month period. You will be contacted by email to remind you to take the follow up questionnaires. You may then be invited to participate in a follow up interview about your experience of the study. This interview will take place using a video call over the internet or simply by telephone. The interviews will be audio recorded and transcribed by the Chief Investigator, Adrian Mallows.

#### Expenses and payments

There are no expenses or payments for your participation.

#### What are the possible disadvantages and risks of taking part?

The questionnaire will take around 15 minutes to complete each time. A follow up interview will last around 30 minutes. There are no anticipated risks associated with your participation.

#### What are the possible benefits of taking part?

There are no direct benefits to you, but we hope the information derived from this study will help improve the future treatment of people with painful Achilles tendons.

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

All information collected prior to your withdrawal with your permission will be used, but no further data will be collected.

**What if there is a problem?**

If you have any concerns about any aspect of this study, please contact the Chief Investigator, Adrian Mallows. You can do this by email [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk) or telephone 01206 873847. Alternatively, you can contact his PhD supervisor Professor Jo Jackson at the University of Essex. You can do this by email [jo.jackson@essex.ac.uk](mailto:jo.jackson@essex.ac.uk) or by telephone 01206 874230. They will do his best to answer your questions, however, if you remain unhappy and wish to provide any feedback, or formally complain you can do this by contacting Sarah Manning-Press, the Research Governance and Planning Manager, Research Office, University of Essex, Wivenhoe Park, Colchester, CO4 3SQ or by emailing: [sarahm@essex.ac.uk](mailto:sarahm@essex.ac.uk).

**Will my taking part in this study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence and will not be shared with anyone, including your physiotherapist. The questionnaire will not collect any personally identifiable data, but will ask you for your email address so that you can be reminded to take the follow up questionnaires and potentially be invited for a follow up interview. All data storage will comply with EU data protection regulation. The data collected are stored on a secure, encrypted website called Qualtrics. The website is password protected with only the Chief Investigator having access to the survey's data. If you participate in a follow up interview, the audio recordings will not collect any personally identifiable data and will be stored on a secure computer at the University of Essex. Direct quotes may be used from the recordings and these will be anonymised. Only the Chief Investigator and his academic supervisors will listen to the recordings, and these will be destroyed after they have been transcribed. This transcription will then be stored for 5 years.

**What will happen to the results of the research study?**

It is anticipated the results from the study will be published and presented at scientific meetings. There is no formal plan to make the results available to participants, however if you would like to obtain a copy please contact Adrian Mallows by email [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk) or by telephone 01206 873847.

**Who is organising and funding the research?**

The study is being organised by Adrian Mallows as a part of his PhD at The University of Essex. There is no external funding.

**Who has reviewed the study?**

The NHS Health Research Authority have reviewed the study and given approval for the conduct of the research (IRAS ID: 219457).

**Further information and contact details**

For further information, please contact Adrian Mallows by email [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk) or by telephone 01206 873847.

## APPENDIX 11 – Participant Consent Form

### **CONSENT FORM**

1. I confirm that I have read the information sheet dated 19th May 2017(version 1:1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- ☐ I agree

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

- ☐ I agree

3. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

- ☐ I agree

4. I agree to providing an email address in order for the researchers to send me the 2 further questionnaires

- ☐ I agree

6. I am willing to be invited by email to participate in a follow-up study.

- ☐ I agree
- ☐ I do not agree

If I participate in a follow-up study, I agree for the interview to be audio-recorded and transcribed by the chief investigator. I am aware that this recording will be listened to by the chief investigator and academic supervisors. I am aware this recording will be kept on a secure computer on University premises and will be destroyed after 5 years.

- ☐ I agree
- ☐ I do not agree

I consent to direct quotes being used from the recording of my interview

- ☐ I agree
- ☐ I do not agree

7. If I choose to withdraw from the study, I understand all information collected prior to my withdrawal will be used, but no further data will be collected.

- ☐ I agree

- ☐ I do not agree

I understand that relevant sections of data collected during the study, may be looked at by individuals from the University of Essex, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records“

- ☐ I agree
- ☐ I do not agree

5. I agree to take part in the study.

- ☐ I agree

## APPENDIX 12 – Emails for Follow Up

Dear XXXX

Thank you for taking part in the Managing Achilles Pain study and completing the questionnaire for the first time.

As we are measuring change over time, I would like to ask you to complete the questionnaire for a second time. Here is the link to the website hosting the questionnaire <https://managing-achilles-pain.com/>. The password is essex. Just to remind you, all your answers are kept confidential and are helpful to progressing the future treatment for people with painful Achilles tendons.

If you have any questions please let me know.

Best Wishes

Adrian

### **Adrian Mallows**

Lecturer in Physiotherapy

MSc (pre-reg) Physiotherapy Programme Lead

School of Sport, Rehabilitation and Exercise Sciences

University of Essex

Room 2S2.5.22

**T** +44 (0)1206 873847

**E** [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk)

► <https://www1.essex.ac.uk/sres/>

### **WE ARE ESSEX**

**TOP 20 FOR RESEARCH EXCELLENCE**

**TEF GOLD 2017**



Dear XXXX

Thank you for taking part in the Managing Achilles Pain study and completing the questionnaire for the second time.

As we are measuring change over time, I would like to ask you to complete the questionnaire for the third and final time. Here is the link to the website hosting the questionnaire <https://managing-achilles-pain.com/>. The password is 'essex'. Just to remind you, all your answers are kept confidential and are helpful to progressing the future treatment for people with painful Achilles tendons.

If you have any questions please let me know.

Best Wishes

Adrian

**Adrian Mallows**

Lecturer in Physiotherapy

MSc (pre-reg) Physiotherapy Programme Lead

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**P** <https://www1.essex.ac.uk/sres/>

**WE ARE ESSEX**

**TOP 20 FOR RESEARCH EXCELLENCE**

**TEF GOLD 2017**



## APPENDIX 13 – GRIPP 2 Checklist

Section and topic	Item	Reported on page No
1: Aim	Report the aim of PPI in the study	100
2: Methods	Provide a clear description of the methods used for PPI in the study	100
3: Study results	Outcomes—Report the results of PPI in the study, including both positive and negative outcomes	100
4: Discussion and conclusions	Outcomes—Comment on the extent to which PPI influenced the study overall. Describe positive and negative effects	100
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience	100



## APPENDIX 14 – Published Process Evaluation

### Managing Achilles Pain (the MAP study) – a process evaluation of data collection methods

#### Introduction

The Managing Achilles Pain study (MAP study) had the primary aim of assessing the feasibility of the protocol for a future large longitudinal cohort study that would investigate the association and predictive relationship of contextual influences (self-efficacy, working alliance and expectations) with outcome in the management of Achilles tendinopathy (AT) (see supplementary file 1 for full protocol). In recent times, such factors have been highlighted as potentially relevant factors that would benefit from investigation in tendinopathy [16,327]. The MAP study enrolled twenty-four participants with Achilles tendinopathy; participants were directed to an internet-based data collection method by their treating physiotherapist. Participants completed the same [internet-based questionnaire](#) relating to the contextual factors discussed previously, and the pain and disability relating to their AT at three data collection points over a three month period. Such a data collection method was untested, therefore, to understand more about how the data collection worked, we undertook a process evaluation. Process evaluations explore the way in which a study was conducted and can provide valuable insight into why studies work well or fail as a basis for a future large study [299]. The Medical Research Council (MRC) has provided a framework for process evaluation, arguing that process evaluation can have a vital role in understanding the feasibility and optimising its design and evaluation [300]. The aim of the process evaluation reported here was to investigate factors affecting the implementation, context and mechanisms of impact on the data collection process described above (figure 1). These factors were considered from both the participants' and physiotherapists' perspectives. Whilst this process evaluation refers to the data collection methods of the MAP study, the data generated can provide guidance to researchers developing study protocols for similar studies.

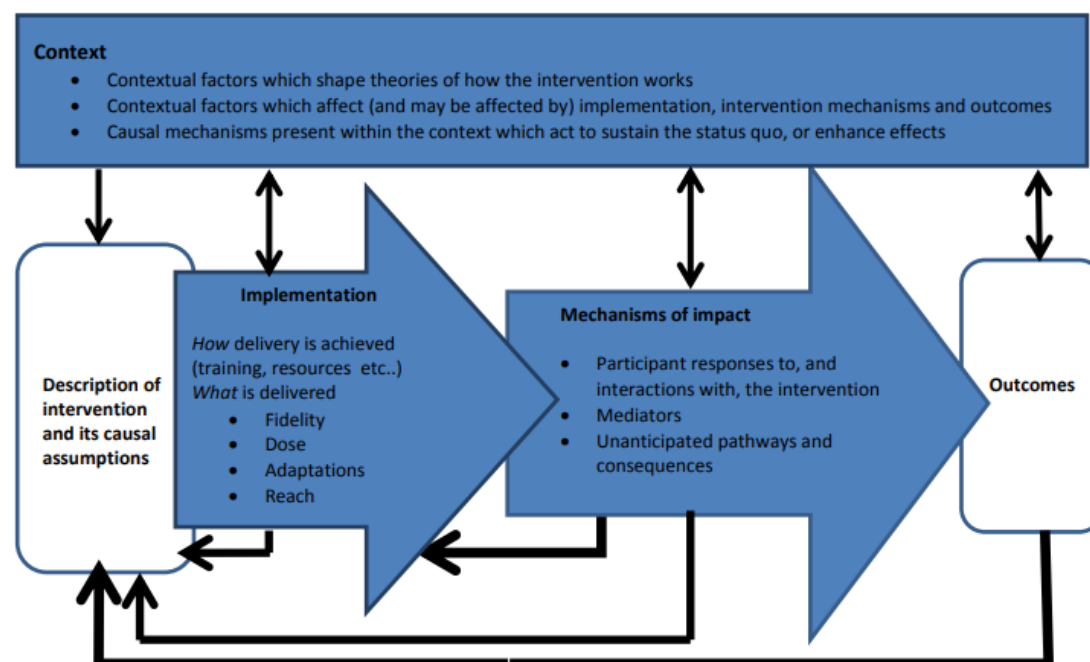


Figure 1. Key functions of a process evaluation and relationships amongst them. Blue boxes represent components of process evaluation, which are informed by the causal assumptions of the intervention, and inform the interpretation of outcomes [300].

#### Ethical Approval

Ethical approval was sought and granted on 14<sup>th</sup> September 2017 (IRAS project ID: 219457, REC reference 17/LO/1583).

### **Methodological Approach**

To realise the critical importance of participants' own interpretations of the issues researched, our process evaluation took a 'critical realist' perspective to evaluate participant perspectives, believing that the varying vantage points of different participants would yield different types of understanding [242]. This perspective was adopted to ensure data collection methods and analytical strategies best met the objectives of the process evaluation [301–303] and focused on accurately describing participants' experiences, staying close to the data, and ensuring subsequent interpretations are transparent [304,305]. The consolidated criteria for reporting qualitative research (COREQ) checklist provided guidance during the reporting of this study [328].

### **Methods**

We utilised the MRC framework outlined in figure 1 to meet the predetermined aim; data was sought to determine factors influencing insights into factors affecting the implementation, context and mechanisms of impact from the data collection procedures during the MAP study [300]. The process sought to discover what worked (and did not), for whom, how, why and in what circumstances.

### **Data collection**

Whilst traditionally face to face interviews have been the preferred mode of conduct, recent research has highlighted that face to face interviews are not inherently superior to telephone interviews [306]. Consequently, to minimise burden on the interviewee (participant or physiotherapist), one-on-one interviews were conducted remotely by the lead author, a PhD candidate, via telephone. To gain maximum variation in responses, all participants who enrolled in the MAP study and all physiotherapists who had taken part in recruitment for the study, were invited to take part in this process evaluation. Participants and lead physiotherapists at each recruitment site were contacted by email and sent the participant information sheet and consent form. Lead physiotherapists were asked to share the email with all physiotherapists who had taken part in recruitment. Anyone considering volunteering then emailed the lead author. Both physiotherapists and participants were provided with the opportunity to ask questions and once any questions were answered, were invited to take part in one-to-one individual interviews at their convenience. Consent to take part in the interviews was audio recorded prior to commencing the interview. To reduce recall bias, selection and recruitment were completed within one month of the participant completing the cohort study. During the interviews the lead author took notes as needed. The lead author was unknown to participants but had provided recruitment training to the physiotherapists prior; consequently, the physiotherapists were aware of the reasons for carrying out the research and the author's interest in the research topic. Semi-structured interviews were directed by a topic guide and were recorded at the University of Essex using a digital voice recorder and transcribed verbatim. The lead author undertook training in conducting interviews prior to data collection and carried out practice interviews to pilot the topic guide with feedback provided by one co-author (CL).

### **Data analysis**

The data was analysed by one author (AM) using the Framework Approach. To facilitate this, a computer-assisted analysis software (CAQDS) programme was used (NVivo Version 12, QSR International, Melbourne, Australia). The Framework Approach has been developed specifically for applied research in which the objectives of the investigation are set *a priori* [307]. Framework Approach is an analytic tool that supports key steps in the data management process, including the indexing and sorting tasks common across many different approaches, but adds one further step; data summary and display [242]. The framework can be used for indexing, but its distinctive feature is that it forms the basis of a thematic matrix, in which every participant is allocated a row and each column denotes a separate theme (Supplementary File 2). The

thematic matrix was then triangulated with interview notes and sent to all participants to verify source interpretation.

## Findings

Data from seven participants and six physiotherapists were analysed. Three participants declined to be interviewed without stating a reason, and no response was received from fourteen participants. It is unknown how many physiotherapists participated and therefore how many did not respond. Interviews lasted up to 30 minutes.

Participant	Age range*	Gender
1	30-39 years	Male
2	60-69 years	Female
3	40-49 years	Male
4	50-59 years	Male
5	40-49 years	Female
6	40-49 years	Male
7	60-69 years	Female

Table 1. Participants' characteristics. \*Only age range was collected from participants

Physiotherapist	Years Qualified	Years speciality MSK	of in	Gender	Private or NHS provider
1	7	6		Male	NHS
2	4	3		Male	Private
3	4	4		Male	NHS
4	18	16		Male	Private
5	15	12		Female	NHS
6	3	3		Male	NHS

Table 2. Physiotherapists' characteristics

## Physiotherapists' perspectives of the study procedures

### Key themes

To meet the aim of the process evaluation, two main themes were sought from the data after transcription; obstacles and enablers. From these two themes a further eight subthemes were identified; (1) access to participants; (2) recall; (3) visibility; (4) time; (5) training; (6) motivation; (7) incentives; (8) simplicity.

### Obstacles

#### Theme 1: Access to participants

Difficulties in accessing the target population for the MAP study was often referred to in many of the interviews. Potential reasons for this varied from the serendipitous to a telephone triage system.

*"The main issue seemed to be that all my Achilles tendon patients seemed to disappear."* Physiotherapist 4.

*"I think because whether those patients get better on the phone or not, it definitely means that less of Achilles pain comes through to eventually see in a clinic."* Physiotherapist 3.

## Theme 2: Recall

A common theme reported by the physiotherapists in the study related to difficulties in remembering to recruit potential participants. Some physiotherapists related this to their workload.

*"In a busy clinic remembering to provide them with the information in the first place."* Physiotherapist 1.

Other physiotherapists felt that the infrequency of seeing people with Achilles tendinopathy was a contributing factor.

*"But yeah, other clinicians have definitely said that they forgot, and part of the reason for that, I guess, is if you see an Achilles tendinopathy one week and then, two or three weeks later, you see your next new patient."* Physiotherapist 2.

Although training was provided, and a staff meeting was attended one month later to discuss any recruitment queries followed by monthly email reminders sent to the Lead Physiotherapist at each site, physiotherapists were keen to be contacted directly to be reminded of recruitment.

*"You might receive six or seven or eight emails from the manager, and there might be potential to only skim-read that, whereas if there was an email from a different source that you don't normally see in your email box, that might prompt you to pay more attention."* Physiotherapist 1.

## Theme 3: Visibility

Participating physiotherapists outlined a common theme of needing to improve the visibility of the study to aid with recruitment. Some felt using posters to inform patients that the study was recruiting participants would be useful. Others felt it would benefit the physiotherapists.

*"If the information's there for them, the patient, they might actually start that conversation off, kind of like what you just said, rather than the other way around."* Physiotherapist 2.

## Theme 4: Time

Time as an obstacle was often cited by the physiotherapists. Some felt a lack of time with the patient impacted on the success of recruitment.

*"If you got half an hour to get a patient in, treat them, manage them, and document, and then you starting thinking there are other things on top sometimes. So that is then pushed to the less of a priority and such."* Physiotherapist 1.

## **Enablers**

### Theme 5: Training

A common them reported by the physiotherapists referred to the recruitment training which was provided for them. The training served to provide clarity on the role of the physiotherapists and installed a sense of confidence in the procedures which were described.

*"I felt very confident and capable of recruiting participants after that session itself and the information given across from that."*  
Physiotherapist 5

#### Theme 6: Motivation

Motivation to be involved in the MAP study was commonly referred to by the physiotherapists interviewed. Some physiotherapists felt that the impact this might have on their care of patients was an important motivating factor.

*"I think the study was very much with the patient's interest at the forefront."* Physiotherapist 4.

Physiotherapists were also motivated by the opportunity to be involved in a research project.

*"It's always interesting to get involved with any research or the data collection side of things that may turn up for our department. And it's important, I think, from a physio side of things to engage with that."* Physiotherapist 4.

#### Theme 7: Incentives

Physiotherapists discussed the potential need for incentivising the MAP study. Some physiotherapists felt a reward for the efforts of the physiotherapists might be warranted, although they were not sure what that could be.

*"Whether you give out 10, 20 cards to appropriate patients, then you're-- not get a reward, that sounds wrong, but you're more likely to be able to-- I don't know. It encourages clinicians to do more from that side of things."* Physiotherapist 3.

Questions were also raised with regard how participants felt incentivised. Some physiotherapists felt the answer laid in the opportunity to help others who are experiencing what they are.

*"And eventually, treat people that were suffering with what they've been suffering with. That seemed to be quite a key thing that people were interested in."* Physiotherapist 4.

#### Theme 8: Simplicity

A common theme discussed during the interviews with the physiotherapists was the simplicity of the MAP study. Most felt this was a key issue to raise to the potential participants in order to maximise recruitment.

*"If someone has to go through something that takes them half an hour, then they're going to, generally speaking, not really want to fill that out or complete it. So if they know it's going to be fairly quick and easy to do, then most people will try to engage."*  
Physiotherapist 5.

### **Participants' perspectives of the study procedures**

#### **Key themes**

To meet the aim of the process evaluation, three main themes were sought from the data after transcription; consequences, obstacles and enablers. From these three themes a further six subthemes were identified; (1) information from the physiotherapist; (2) follow up; (3) motivation; (4) website; (5) questionnaire; (6) positive experience.

#### **Obstacles**

##### Theme 1: Information from the physiotherapist

The participants interviewed often referred to the need for more quality verbal information from the physiotherapists at the time of recruitment.

*"If I hadn't been quite so spontaneously happy to do it, I might have benefitted with a little bit more explanation as to what they were trying to get out of it."* Participant 1.

Most participants viewed the postcard as a positive tool, enhancing engagement in the study.

*"Eager though, I was to do it when my physiotherapist told me about it. It's one of those things that I probably would have forgotten about had I not had the postcard and thought, "Oh, I was going to do that. I need to do that.""* Participant 4.

## Theme 2: Follow up

Some participants expressed confusion around the process of being invited to complete the questionnaire for a second or third time.

*"I think the problem lies with the amount of rubbish we all receive over email. And I'm sure you're exactly the same as the rest of us. Sometimes more important things do get lost amongst the dross really, there's just so much of it."* Participant 3.

Participants offered ways of improving communication, including the suggestion of adding a text message reminder and ensuring communications were clearly headed as to which number survey the correspondence was referring to.

*"Heading them up and making it clear at the start that there were going to be three and heading them up two and three, I think that would be very helpful."* Participant 5.

*"I don't think for future people taking part it would be that much of an extra step to give their phone number for this service as well."* Participant 2.

## **Enablers**

### Theme 3: Motivation

Almost all the participants outlined their motivation for involving themselves in the MAP study. Motivation appeared to be largely altruistic in nature.

*"Advancing research on such issues is beneficial for everyone, isn't it? So it's something one should do rather than not."* Participant 2.

### Theme 4: Website

A positive experience from using the website was expressed from most of the participants. This ranged from providing information which was missed by the recruiting physiotherapist to the ease of navigating the webpage.

*"Once I got to the website page, it gave me all the information I needed."* Participant 3.

*"I don't recall being frustrated by anything. I'm easily frustrated on the Internet."* Participant 4.

### Theme 5: Questionnaire

A positive engagement with the questionnaire was often cited by the participants. Particular reference was made to the simplicity and short duration of the questionnaire.

*"We've all had questionnaires of customer feedback where they ask you to write so much detail, you give up because it's too painful. So it wasn't like that, which is really good."* Participant 3.

## Consequences

### Theme 6: Positive experience

Many participants stated that their involvement in the MAP study resulted in a positive experience; it made them reconsider their condition and treatment and how they engaged with their physiotherapist.

*"It made me take it a bit more seriously really and feel a bit more as though, I wasn't on my own. There were other people obviously who were going through the same kind of problem. So maybe it validated it a bit more, I think, for me, which was good."* Participant 7.

## Discussion

The purpose of this process evaluation was to explore the MAP study procedures from the participants' and physiotherapists' perspectives respectively. From the physiotherapists' perspective four themes were identified which related to obstacles; (1) *access to participants*; (2) *recall*; (3) *visibility*; (4) *time*, and four themes were identified which related to facilitating success; (1) *training*; (2) *motivation*; (3) *incentives*; (4) *simplicity*. From the participants' perspective two themes were identified which related to obstacles; (1) *information from the physiotherapist*; (2) *follow up*, three themes were identified which related to facilitating success; (1) *motivation*; (2) *website*; (3) *questionnaire*, and one theme which related to unintended consequences of participating in the study; *positive experience*.

The NHS Constitution for England pledges to inform all patients about opportunities for involvement with suitable research studies [309]. In this context healthcare professionals play a vital role in clinical research, linking researchers and patients. A variety of challenges may exist in recruiting participants from specialist healthcare services, such as physiotherapy, into cohort studies and little formal research has investigated these challenges [310]. Frayne et al (Figure 2) have conceptualised a process by which a patient may be referred to a research study when the initial invitation to participate is delivered by a healthcare professional in the clinical setting (rather than being invited by a healthcare provider who has responsibilities and involvement in the whole trial) [311].

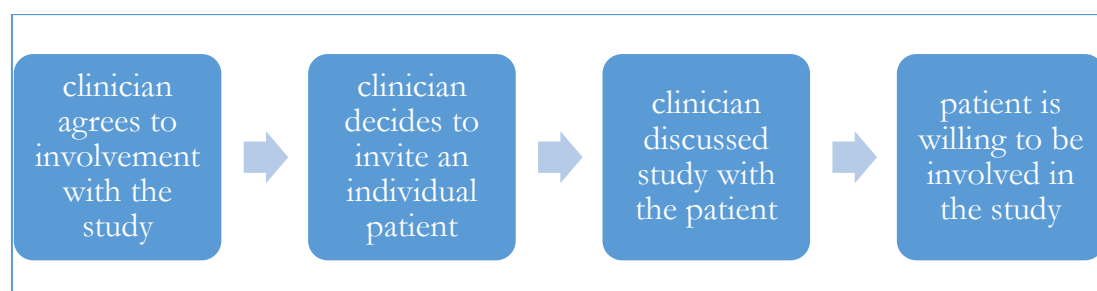


Figure 2. Process of a patient being referred to a research study by a clinician (adapted from Frayne et al [311].)

In order to contextualise the findings from this process evaluation with previous research and consider implications for future studies, the discussion is framed by the conceptual process outlined in figure 2.

### Involvement with the study

Motivation to be involved in research was a theme identified from participants and physiotherapists alike. From the participants' perspectives, the motivation was largely altruistic in nature; the chance to 'give back',

and from the physiotherapists' perspectives the drive was the opportunity to be involved in research which was considered to directly influence patient care. Motivation as a driving factor for recruitment wasn't considered in the training provided. Although the training was considered by the physiotherapists as facilitatory for recruitment, the training focused on how to recruit [286] rather than serving to motivate recruitment. Nevertheless, this focus did have benefits; the physiotherapists understood what they were required to do, were happy to answer questions from patients and felt confident in carrying out the recruitment. Cvijovic et al [312] highlighted that pharmacists were reluctant to invite patients when they felt this could prompt questions they could not answer. However, valuing the research has been seen as a key driver of engagement of recruiting healthcare providers previously [313] and as such, training would benefit from tailoring to ensure the physiotherapists not only understood what to do and how to do it, but also developed attitudes towards the research which were as positive as possible. For example, future training could emphasise the positive experience (and absence of negative experience) which the participants have described from being involved in the study. Whilst, the provision of such training has been shown to modify some aspects of recruiters' behaviour, this may still result in clinicians not sufficiently restructuring their recruitment consultations [316]. As such, a process of monitoring and further visits, where necessary, from the researcher to the recruitment sites to ensure recruiters are clear how participation in research varies from clinical practice might be a useful strategy [317]. At this stage, the focus might turn to communication skills facilitated by role play scenarios to highlight common obstacles to recruitment [318].

### Inviting a patient

Pragmatic issues rather than 'gate keeping' concerns [319,320] largely influenced whether a patient was invited to be involved in the study or not. Two main pragmatic issues were identified; remembering to recruit participants and the visibility of the study. Reasons for not remembering to invite a participant ranged from other work pressures to the infrequency of seeing people with Achilles tendinopathy. French et al [321] identified the clinical work setting as an influence on recruitment; an organisation which has developed a positive research culture is an important facilitator to inviting patients to participate. It was unknown what the research culture was like at each recruitment site prior to commencing recruitment. Fenlon et al [322] utilised a careful pre-screening and selection of participating centres. Although the nature of pre-screening sites and the decisions to work with sites varies according to the given study, it is a useful way to initiate relationships and potentially identify sites at risk of low recruitment [322]. Recognising this complexity, formal methods of evaluation have been developed that identify problems with recruitment and informed consent and develop action plans to address them while recruitment is underway [323]. Increasingly such methods, evaluating processes, need to be integrated in to the pilot phases of research work to maximise the chance of success.

To address the second pragmatic issue relating to the visibility of the study, physiotherapists suggested recruitment for the study might be enhanced if the study was visualised in some way, such as posters in the waiting room and staff room to act as a reminder to staff and to encourage questions from potential participants. This would incur only a small increase in cost, and also provide a further opportunity to share the positive experience which participants can have from being involved in research [314]. A positive experience from this study was found from the use of the postcard to invite patients to become participants; the design resonated with participants and it served as a tangible reminder to take part. Contrastingly, the use of a follow up via email was sub-optimal. Using email and text message reminders to encourage questionnaire completion amongst participants appears to be a viable strategy; following two email reminders, a text message reminder appeared to be more effective than another email reminder in a study also utilising an online questionnaire [315].

### Discussing the study

Reporting lack of time as an obstacle to recruiting participants would appear significant. This was also reflected by the participants expressing they were given minimal verbal information by the physiotherapists during the invitation process. Limited time for recruitment resulting in clinicians not prioritising research activities has been seen in previous studies [310,313]. Resources are critical and lack of resources have been seen to negatively influence recruitment at all stages [322]. The absence of dedicated resources, such as



clinical time, not only constrains the capacity of clinicians to undertake research activity but can also undermine their belief in the research and lose a sense that their roles are respected [313]. Consequently, research resources must be seen to make a difference. Here, effective communication is considered central to promote respect, reciprocity and maximise recruitment [313,322]. Ensuring that the right information reaches the right people in a timely manner, and that clinicians are provided with progress reports and study findings, is essential [313]. Improved communication from the researcher directly to the physiotherapists involved in recruiting was a finding from this study. To address this, future studies should consider providing progress reports and developing a newsletter which includes ‘frequently asked questions’ and tips from research sites that have good recruitment rates [322].

### Willingness to be involved

The minimal burden of the study design appeared to be key to both physiotherapists’ and participants’ willingness to be involved in the study. As previously discussed, time is a precious commodity to physiotherapists. The simplicity of the MAP study was referred to as an enabler to engaging physiotherapists and that this simplicity needed to be highlighted more effectively in the training to provide reassurance on the minimal impact of time to the physiotherapists. Participants described a positive engagement with the website; it appeared to enhance patients’ willingness to participate by being easy to navigate and ensuring it gave them all the information they required. In addition, the short duration of the questionnaire appeared a significant factor for participants to be willing to be involved. Previous research shows participants appear to start abandoning questionnaires after around 9 minutes, regardless of whether they are told the survey would take 8-10 minutes or 20 minutes [324].

### **Strengths and Limitations**

This study included physiotherapists from all but one recruitment site and this ensured that the views expressed were a fair representation of those sites involved. However, the self-selecting nature of recruitment may have resulted in ‘volunteer bias’; for example, physiotherapists largely expressed an interest in research, meaning perceptions of physiotherapists who felt negatively or ambivalent towards research were not obtained. Nevertheless, those taking part offered both positive and negative comments towards the MAP study. In addition, 5 of the 6 physiotherapists who volunteered were male which, depending on the gender balance at each site, suggests female physiotherapists views were underrepresented.

Participants who dropped out, but had agreed to be contacted for interview, were invited for interview but no responses were received. Again, this may have resulted in ‘volunteer bias’ and therefore alternative views were not captured.

### **Conclusion**

This process evaluation has highlighted some important factors for researchers to consider when planning future research studies. Although clinicians are enthused to be involved in research, organisational factors, such as time, appear to be key drivers of levels of engagement. Publicising the study to all involved; optimising verbal recruitment strategies between the physiotherapists and potential participants; and ensuring clarity in communication to recruiting physiotherapists and the participants all appear key to optimising the potential success of a study.

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## APPENDIX 15 – COREQ Checklist

### COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
<b>Domain 1: Research team and reflexivity</b>			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	123
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	123
Occupation	3	What was their occupation at the time of the study?	123
Gender	4	Was the researcher male or female?	123
Experience and training	5	What experience or training did the researcher have?	123
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	123
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	123
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	123
<b>Domain 2: Study design</b>			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	119
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	122
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	122
Sample size	12	How many participants were in the study?	132

Non-participation	13	How many people refused to participate or dropped out? Reasons?	132
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	123
Presence of nonparticipants	15	Was anyone else present besides the participants and researchers?	1223
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	132
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	123
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	no
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	123
Field notes	20	Were field notes made during and/or after the inter view or focus group?	125
Duration	21	What was the duration of the inter views or focus group?	132
Data saturation	22	Was data saturation discussed?	122 (all participants were invited)
Transcripts returned	23	Were transcripts returned to participants for comment and/or	125 (matrix was returned)
<b>Topic</b>	<b>Item No.</b>	<b>Guide Questions/Description</b>	<b>Reported on Page No.</b>
		correction?	
<b>Domain 3: analysis and findings</b>			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	125
Description of the coding tree	25	Did authors provide a description of the coding tree?	127
Derivation of themes	26	Were themes identified in advance or derived from the data?	134
Software	27	What software, if applicable, was used to manage the data?	123
Participant checking	28	Did participants provide feedback on the findings?	125
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Findings

Data and findings consistent	30	Was there consistency between the data presented and the findings?	Findings and discussion
Clarity of major themes	31	Were major themes clearly presented in the findings?	Findings and discussion
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	-

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

## APPENDIX 16 – Invitation Email for Interview

Dear XXXX

Thank you for taking part in the Managing Achilles Pain study and completing the questionnaires.

I would like to ask you to participate in an interview to discuss your experience of the procedures used in the study. The interview can take place over the phone, or using the internet, and would be arranged for whenever is most convenient for you. It is expected to take no more than 30 minutes. More information can be found in the information sheet, along with a consent form which are attached. You don't need to complete the consent form, but you should be aware of what you may be consenting to.

Could you please let me know if you are willing to take part? Please also ask any questions you may have.

Best Wishes

Adrian

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## Participant Information Sheet

### Managing Achilles Pain – a pilot study

Adrian Mallows, PhD Student and Chief Investigator

Professor Jo Jackson, Academic Supervisor

*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. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask us if there is anything that is not clear.*

#### Background to the study

Having a painful Achilles tendon is fairly common. Recent research suggests *how* treatment is delivered may be influential on the success of treatment. Based on previous work, we think a person's expectations, beliefs and who delivers the treatment to them may be important.

#### What is the purpose of the study?

Exploring these factors has yet to be investigated, and in order to do so we have designed this 'pilot study' to help us develop a larger study.

#### Why have I been invited?

You have been invited because you are currently undergoing treatment for a painful Achilles tendon.

#### Do I have to take part?

*No, it is up to you to decide to join the study.* You can change your mind at any time and decide not to participate. The treatment and standard of care you receive will not be affected in any way if you decide not to take part now or if you withdraw from the study later. We are happy to answer any questions you may have before deciding whether you wish to take part in this study.

#### What will I have to do?

We are asking people to complete a questionnaire 3 times over a 3 month period. You will be contacted by email to remind you to take the follow up questionnaires. You may then be invited to participate in a follow up interview about your experience of the study. This interview will take place using a video call over the internet or simply by telephone. The interviews will be audio recorded and transcribed by the Chief Investigator, Adrian Mallows.

#### Expenses and payments

There are no expenses or payments for your participation.

#### What are the possible disadvantages and risks of taking part?

The questionnaire will take around 15 minutes to complete each time. A follow up interview will last around 30 minutes. There are no anticipated risks associated with your participation.

#### What are the possible benefits of taking part?



There are no direct benefits to you, but we hope the information derived from this study will help improve the future treatment of people with painful Achilles tendons.

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

All information collected prior to your withdrawal with your permission will be used, but no further data will be collected.

**What if there is a problem?**

If you have any concerns about any aspect of this study, please contact the Chief Investigator, Adrian Mallows. You can do this by email [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk) or telephone 01206 873847. Alternatively, you can contact his PhD supervisor Professor Jo Jackson at the University of Essex. You can do this by email [jo.jackson@essex.ac.uk](mailto:jo.jackson@essex.ac.uk) or by telephone 01206 874230. They will do his best to answer your questions, however, if you remain unhappy and wish to provide any feedback, or formally complain you can do this by contacting Sarah Manning-Press, the Research Governance and Planning Manager, Research Office, University of Essex, Wivenhoe Park, Colchester, CO4 3SQ or by emailing: [sarahm@essex.ac.uk](mailto:sarahm@essex.ac.uk).

**Will my taking part in this study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence and will not be shared with anyone, including your physiotherapist. The questionnaire will not collect any personally identifiable data, but will ask you for your email address so that you can be reminded to take the follow up questionnaires and potentially be invited for a follow up interview. All data storage will comply with EU data protection regulation. The data collected are stored on a secure, encrypted website called Qualtrics. The website is password protected with only the Chief Investigator having access to the survey's data. If you participate in a follow up interview, the audio recordings will not collect any personally identifiable data and will be stored on a secure computer at the University of Essex. Direct quotes may be used from the recordings and these will be anonymised. Only the Chief Investigator and his academic supervisors will listen to the recordings, and these will be destroyed after they have been transcribed. This transcription will then be stored for 5 years.

**What will happen to the results of the research study?**

It is anticipated the results from the study will be published and presented at scientific meetings. There is no formal plan to make the results available to participants, however if you would like to obtain a copy please contact Adrian Mallows by email [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk) or by telephone 01206 873847.

**Who is organising and funding the research?**

The study is being organised by Adrian Mallows as a part of his PhD at The University of Essex. There is no external funding.

**Who has reviewed the study?**

The NHS Health Research Authority have reviewed the study and given approval for the conduct of the research (IRAS ID: 219457).

**Further information and contact details**

For further information, please contact Adrian Mallows by email [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk) or by telephone 01206 873847.

**Managing Achilles Pain - a pilot study**

Please read the statements below and ask any questions which may have. Your response to the statements below will be audio-recorded prior to starting the interview.

**CONSENT FORM**

I confirm that I have read the information sheet dated 19th May 2017(version 1:1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐ I agree

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

☐ I agree

I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

☐ I agree

I agree for the interview to be audio-recorded and transcribed by the chief investigator. I am aware that this recording will be listened to by the chief investigator and academic supervisors. I am aware this recording will be kept on a secure computer on University premises and will be destroyed after 5 years.

☐ I agree

I consent to direct quotes being used from the recording of my interview

☐ I agree

☐ I do not agree

If I choose to withdraw from the study, I understand all information collected prior to my withdrawal will be used, but no further data will be collected.

☐ I agree

I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Essex, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records

☐ I agree

I agree to take part in the study.

☐ I agree

## APPENDIX 19 – Invitation Email to Physiotherapists

Dear XXXX

I would be most grateful if you could circulate the following to Physiotherapy colleagues who have been identifying participants for the research study 'Managing Achilles Pain':

You have been recently identifying participants for a study about Achilles tendon pain - I have attached the study information sheet as a reminder. Part of the study is looking at how well the processes worked, or otherwise, for those who were identifying participants.

The interview could take place over the telephone at a time convenient to you and would take 20 to 30 minutes.

I would be grateful if you would reply directly to this e-mail letting me know whether you would be willing to be interviewed or not.

Thanks in advance for considering this.

If you have any questions, please let me know.

Best Wishes

Adrian

**Adrian Mallows**

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**P** <https://www1.essex.ac.uk/sres/>

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## Participant Information Sheet

### Managing Achilles Pain – a pilot study

Adrian Mallows, PhD Student and Chief Investigator

Professor Jo Jackson, Academic Supervisor

*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. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask us if there is anything that is not clear.*

#### Background to the study

Having a painful Achilles tendon is fairly common. Recent research suggests *how* treatment is delivered may be influential on the success of treatment. Based on previous work, we think a person's expectations, beliefs and who delivers the treatment to them may be important.

#### What is the purpose of the study?

Exploring these factors has yet to be investigated, and in order to do so we have designed this 'pilot study' to help us develop a larger study.

#### Why have I been invited?

You have been invited because you are a physiotherapist who has been identifying participants for the study.

#### Do I have to take part?

*No, it is up to you to decide to join the study.* You can change your mind at any time and decide not to participate. We are happy to answer any questions you may have before deciding whether you wish to take part in this study.

#### What will I have to do?

We are asking people to participate in an interview about your experience of the study. This interview will take place using a video call over the internet or simply by telephone. The interviews will be audio recorded and transcribed by the Chief Investigator, Adrian Mallows.

#### Expenses and payments

There are no expenses or payments for your participation.

#### What are the possible disadvantages and risks of taking part?

The interview will last around 30 minutes. There are no anticipated risks associated with your participation.

#### What are the possible benefits of taking part?

There are no direct benefits to you, but we hope the information derived from this study will help improve the future treatment of people with painful Achilles tendons.

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

All information collected prior to your withdrawal with your permission will be used, but no further data will be collected.

**What if there is a problem?**

If you have any concerns about any aspect of this study, please contact the Chief Investigator, Adrian Mallows. You can do this by email [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk) or telephone 01206 874252. Alternatively, you can contact his PhD supervisor Professor Jo Jackson at the University of Essex. You can do this by email [jo.jackson@essex.ac.uk](mailto:jo.jackson@essex.ac.uk) or by telephone 01206 874277. They will do his best to answer your questions, however, if you remain unhappy and wish to provide any feedback, or formally complain you can do this by contacting Sarah Manning-Press, the Research Governance and Planning Manager, Research Office, University of Essex, Wivenhoe Park, Colchester, CO4 3SQ or by emailing: [sarahm@essex.ac.uk](mailto:sarahm@essex.ac.uk).

**Will my taking part in this study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence and will not be shared with anyone. All data storage will comply with EU data protection regulation. The audio recordings will not collect any personally identifiable data and will be stored on a secure computer at the University of Essex. Direct quotes may be used from the recordings and these will be anonymised. Only the Chief Investigator and his academic supervisors will listen to the recordings, and these will be destroyed after they have been transcribed. This transcription will then be stored for 5 years.

**What will happen to the results of the research study?**

It is anticipated the results from the study will be published and presented at scientific meetings. There is no formal plan to make the results available to participants, however if you would like to obtain a copy please contact Adrian Mallows by email [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk) or by telephone 01206 874252.

**Who is organising and funding the research?**

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**Who has reviewed the study?**

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**Further information and contact details**

For further information, please contact Adrian Mallows by email [amallows@essex.ac.uk](mailto:amallows@essex.ac.uk) or by telephone 01206 874252.

**Managing Achilles Pain - a pilot study**

Please read the statements below and ask any questions which may have. Your response to the statements below will be audio-recorded prior to starting the interview.

**CONSENT FORM**

I confirm that I have read the information sheet dated **18.06.2018 (version 1.0)** for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

☐ I agree

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

☐ I agree

I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

☐ I agree

I agree for the interview to be audio-recorded and transcribed by the chief investigator. I am aware that this recording will be listened to by the chief investigator and academic supervisors. I am aware this recording will be kept on a secure computer on University premises and will be destroyed after 5 years.

☐ I agree

I consent to direct quotes being used from the recording of my interview

☐ I agree

☐ I do not agree

If I choose to withdraw from the study, I understand all information collected prior to my withdrawal will be used, but no further data will be collected.

☐ I agree

I understand that relevant sections of my data collected during the study, may be looked at by individuals from the University of Essex, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records

☐ I agree

I agree to take part in the study.

☐ I agree



## TOPIC GUIDE FOR SEMI-STRUCTURED INTERVIEWS

### 1. Introduction

- Introduction to researcher and study topic
- Explanation of the aim of the study
- Explain confidentiality and anonymity
- Explain recording length (up to 30 minutes) and nature of discussion
- Go through consent issues and explain they may withdraw at any time and they do not have to answer any interviews they would prefer not to
- Check whether they have any questions
- Check they are happy to continue

### 2. Experience of the study

- Describe overall experience
- Establish any perceived strengths or weaknesses of the process
- Where they feel areas for improvement lie – website (information), questionnaires (data collection procedures), recruitment process (selling or engaging with the study) – why were you interested? How
- Check for any unintended consequences
- Check for any other comments

### 3. In conclusion

- Summarise and check key issues
- Thank the participant for their time.
- Reiterate confidentiality

**END RECORDING**