The association of working alliance, outcome expectation, adherence and self-efficacy with clinical outcomes for Achilles tendinopathy: A feasibility cohort study (the MAP study)

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Introduction

Achilles tendon-related pain and its associated functional limitations, termed tendinopathy, can be traumatic or insidious in onset and short-lasting or persistent in nature (Scott et al., 2013). Achilles tendinopathy (AT) can be characterised by a reduced ability of the tendon to sustain tensile load (Cook & Purdam, 2009), resulting in decreased activity participation, working ability and quality of life (Longo, Ronga, & Maffulli, 2009). Factors influencing this impact are poorly understood; little is known about mechanisms driving pain and the response (or lack of) to rehabilitation (Mallows, Debenham, Malliaras, Stace, & Littlewood, 2017; O'Neill, Watson, & Barry, 2015; Rio et al., 2015, 2014). Furthermore, despite structural changes being the focus of tendinopathy models (Cook & Purdam, 2009; Cook, Rio, Purdam, & Docking, 2016) current evidence suggests that structural changes on imaging of tendinopathic tendons do not explain the response to exercise-led interventions (Drew, Smith, Littlewood, & Sturrock, 2012; Färnqvist, Malliaras, & Pearson, 2019). Whilst recognising that advancements in imaging techniques may yet contribute to improved outcome by enhancing diagnosis (Khan et al., 2003), current evidence suggests that clinical outcome for people with musculoskeletal conditions is influenced by similar factors across different musculoskeletal presentations (Mallen, Peat, Thomas, Dunn, & Croft, 2007). 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 (Chester, Jerosch-Herold, Lewis, & Shepstone, 2016; de Vos Andersen, Kent, Hjort, & Christiansen, 2017). 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. In recent times, cognitive and contextual influences such as self-efficacy, working

alliance and expectations have been highlighted as potentially relevant factors that would benefit from investigation in tendinopathy (Mallows, Debenham, Walker, & Littlewood, 2017; Mallows et al., 2017). 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, Ogrodniczuk, Piper, & McCallum, 2003).

Based on this need, high-quality research in relation to factors associated with outcome is warranted. However, to enhance the success of future large cohort studies, several factors potentially affecting feasibility need to be investigated.

The primary aim of this study was 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. 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.

Ethical Approval

Ethical approval was sought and granted on 14th September 2017 by London - Camden & Kings Cross Research Ethics Committee; REC reference 17/LO/1583 and by the Health Research Authority on 15th September 2017; IRAS project ID: 219457.

Methods / Design

Study Design

A multi-centred, longitudinal feasibility cohort study was conducted to meet the study's aim and was reported according STROBE guidelines for reporting of observational studies (von Elm et al., 2007).

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.

Recruitment Process

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. Training in the study processes was provided to the physiotherapists in line with Good Clinical Practice (GCP) recommendations (NIHR Clinical Research Network Coordinating Centre, 2016). 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 (www.managing-achilles-pain.com), 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 containing password protected information (the participant information sheet, consent form) 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.

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 (Adrian Mallows, Debenham, Walker, & Littlewood, 2016; Martin et al., 2018):

- 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 (Mallows et al., 2016; Martin et al., 2018). The exclusion criteria were:

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

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.

Variables

Factors beyond the specific effects of exercise on peripheral tissue were the focus of this study. As cognitive and contextual factors may be associated with clinical outcome in AT (Mallows et al., 2017), factors investigated by this study were reflective of these.

- Working Alliance measured by the Working Alliance Inventory Short-Form (WAI-SF) (Hall, Ferreira, Maher, Latimer, & Ferreira, 2010; Hanson, Curry, & Bandalos, 2002; Hatcher & Gillaspy, 2006; Tracey & Kokotovic, 1989). The WAI-SF requires the participant to rate their agreement with their therapist 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.
- Outcome expectation measured by the Global Rating of Change (GRC) for Outcome Expectation (Costa et al., 2008). 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 (Kamper, 2009). 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) (Bialosky, Bishop, & Cleland, 2010). 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?' (Bialosky et al., 2010).

- Adherence measured by a retrospective patient self-report scale (Bassett, 2003). While limited, such scales 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) (Brewer et al., 2000; Taylor & May, 1996).
- Self-efficacy measured by the Pain Self-Efficacy Questionnaire (PSEQ) (Asghari & Nicholas, 2001; Miles, Pincus, Carnes, Taylor, & Underwood, 2011; Nicholas, 2007). 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 (Asghari & Nicholas, 2001).

Clinical Outcome Measures

Due to concerns surrounding the usefulness of the VISA-A to accurately inform a change in a patient's clinical status (Mallows, Littlewood, & Malliaras, 2017), the primary clinical outcome measure chosen was the Lower Extremity Functional Score (LEFS) (Binkley, Stratford, Lott, & Riddle, 1999). The LEFS is a twenty item questionnaire with excellent test-retest reliability and construct validity (Ashby, Grocott, & Haddad, 2008; Binkley et al., 1999), and is recommended in current clinical guidelines to assess activity participation (Martin et al., 2018). The twenty items cover

a range of lower extremity functional activities and 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. A secondary clinical outcome measure was the Numerical Pain Rating Scale (NPRS) (Farrar, Young, LaMoreaux, Werth, & Poole, 2001).

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 online platform (www. managing-achilles-pain.com). Responses from electronic versions of the measures in the form of a questionnaire were collected on three occasions; at baseline, at six and finally at twelve weeks following completion of the first questionnaire. Twelve weeks represents a clinically meaningful timepoint; response to exercise may plateau after this (Murphy et al., 2018), leading to the consideration of a change in treatment for non-responders. Consequently, determining predictive factors early in the rehabilitation (such as baseline and six weeks) would seem important. 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 to encourage them to re-visit the website and complete the questionnaire

Sample Size

Feasibility studies typically do not evaluate the clinical outcome of interest because they do not undertake hypothesis testing and typically are not of a sufficient size to support such statistical testing; the sample size is estimated to enable evaluation of the key feasibility criteria (UK National Institution for Health Research (NIHR), 2017).

To meet the study's objective of evaluating the recruitment rate and retention, a 'recruit to time' approach was used over a period of eleven months to fit within the wider scope of the research programme.

Statistical Analysis

Feasibility outcomes (recruitment and retention rates) were described using descriptive statistics. Primary hypothesis testing is not recommended for this size and type of study (Lancaster, Dodd, & Williamson, 2004; UK National Institution for Health Research (NIHR), 2017), however a preliminary correlational analysis 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) (Cohen, 1988). Statistical analysis was undertaken using SPSS (version 25.0, Armonk, NY: IBM Corp).

Results

Feasibility Analysis - Recruitment and Retention

The physiotherapists were issued 1100 cards to provide to potential patient participants. Of these, 795 were returned on the completion of the study and hence it is assumed that 305 were provided to potential patient participants. 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 3 describes the participants' details. No adverse events were reported by any participants. The study asked participants to complete the same questionnaire on three separate occasions. The questionnaire at baseline was started 63 times and

completed on 60 separate occasions resulting in a 95% conversion rate from those participants who provided initial consent. Full details are listed in figure 1. All three participants who did not complete the questionnaire at baseline aborted when asked for their email address and as such did not consent to join the study. Retainment for completion of the questionnaire for a second time was 83.3% and for the third time was 66.6%. All questionnaires were completed fully without any missing data yielding a missing data indicator of 0%.

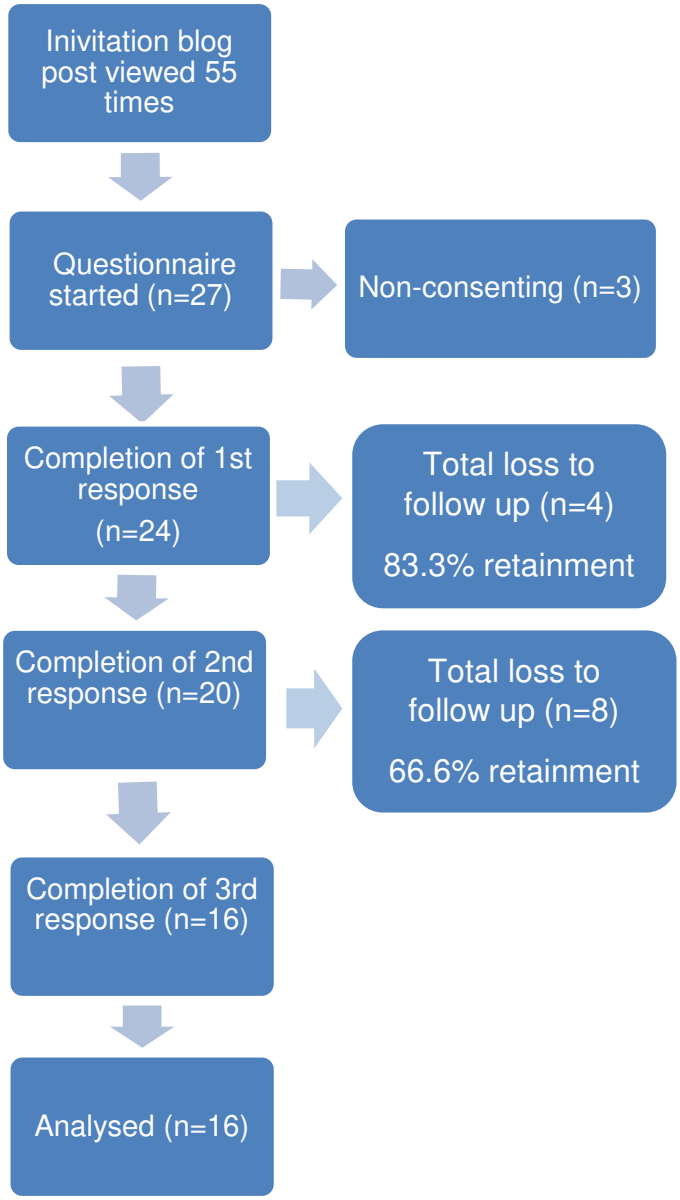

Figure 1 Participants flow through the MAP study

Correlation Analysis

Initially the data were tested for normality. The results are presented in table 2 and indicate that the data from the WAI-SF (p=0.026), GRC (p=0.003), NPRS (p=0.043) and Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence

(p<0.001) were not normally distributed as the value of significance is p<0.05 (Pallant, 2016). Accordingly, baseline characteristics for all participants shown in table 3 are median and range values. 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 (Pallant, 2016). Statistically significant differences were found between the median values of the WAI-SF (responders 78.5, non-responders 60; p=0.003), the PSEQ (responders 50.05, non-responders 35; p=0.004) and the LEFS (responders 57, non-responders 43; p=0.011).

	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 2 Shapiro-Wilk test for normality of baseline data
* Indicates non-normal distribution of data (p<0.05)

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

Table 3 Baseline 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

Table 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 (table 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 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
Baseline WAI-SF	.686	.795	.143	.325	-.157
Baseline PSEQ	-	.521	.220	.650*	-.401
Baseline GRC	-	-	.160	.146	.078
Baseline Patient Self-Report Scales of Their Home-Based Rehabilitation Adherence	-	-	-	.428	.005

Table 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 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 (table 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*).

Discussion

High-quality research in relation to factors associated with outcome in AT is warranted. However, to enhance the success of future large cohort studies, factors potentially affecting feasibility are required to be investigated. 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.

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 (Braithwaite, Emery, de Lusignan, & Sutton, 2003). 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 an accompanying process evaluation suggests many of these non-returned cards may have been lost or simply not returned (Mallows, Littlewood, Jackson, & Debenham, 2019). 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 (Cooper, Whitehead, Pottrill, Julious, & Walters, 2018), strategies to maximise retention were reported in the accompanying process evaluation (Mallows et al., 2019). 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 may have been a contributing factor to the missing data indicator of 0%.

Correlation Outcomes

The small sample size limits inferences from this preliminary analysis. Small sample sizes increase data variability, lowering the probability of replication and as such, correlation data may be unusual simply by chance. As the significance of the rho is strongly influenced by the sample size (Pallant, 2016), these preliminary outcomes should be interpreted cautiously. As such, future studies require a much larger sample size to allow correlation inferences to be made and ascertain dependence through regression analysis. Tabachnick and Fidell (Tabachnick & Fidell, 2007) 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+(8x4)= n>82. Strategies to maximise recruitment were also a focus of the previously reported process evaluation (Mallows et al., 2019). Suggested additional strategies included the use of posters to raise awareness with patients and reminders for staff, the potential need for dedicated clinical time for recruitment purposes and the need for additional communication strategies between the researcher and clinicians – such as the use of a newsletter with recruitment hints and tips.

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.

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, but changes could be useful before proceeding to a much larger study that conceivably could be rolled out across English speaking countries. Changes to consider include; how the study could be better publicised, such as the use of posters in clinical and staffing areas; how verbal recruitment strategies could be optimised, including the potential need for dedicated clinical time for recruitment; and how communication between clinicians and

researchers could be enhanced, such as the use of developing a newsletter as a progress report.

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