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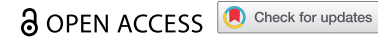


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RESEARCH REPORT



Which self-reported bio-psychosocial variables predict recovery in rotator cuff tendinopathy? An international prospective cohort study

Mehmet Delen PhD^{a,b}, Abdulhamit Tayfur PhD^{a,c}, Halime Gulle PhD^{a,d}, Aleksandra Birn-Jeffery PhD^e, and Dylan Morrissey PhD^{a,f}

^aSports and Exercise Medicine, William Harvey Research Institute, Barts and the London School of Medicine and Dentistry, Queen Mary University of London, UK; ^bOrthopaedics Physiotherapy and Rehabilitation, Ankara Yıldırım Beyazıt University, Ankara, Turkey; ^cPhysiotherapy and Rehabilitation, Kırşehir Ahi Evran University, Turkey; ^dSchool of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, USA; ^eSchool of Sport, Rehabilitation and Exercise Sciences, University of Essex, UK; ^fPhysiotherapy department, Barts Health NHS Trust, London, UK

ABSTRACT

Introduction: It is unclear what baseline factors predict recovery from rotator cuff (RC) tendinopathy, making evidence-based prognostic estimates difficult. The study aimed to identify predictors of RC tendinopathy recovery to guide clinical decision-making.

Methods: People with RC tendinopathy were recruited to an international prospective cohort study. Participants completed a detailed baseline survey in which 41 plausible bio-psychosocial and demographic factors were measured. Recovery was established via the Global Rating of Change scale at monthly follow-ups for a year. Univariate and multivariate Cox proportional-hazards regression analyses were conducted to identify predictors and to build models. Model performance (internal validity) was evaluated using bootstrapping.

Results: Seventy-three people with RC tendinopathy (43.9 ± 14.0 years; Shoulder Pain and Disability Index = 37.7 ± 24.4; 45 females) were recruited, providing 15,284 days at risk (208 ± 129 days). The recovery rate was 47%. Participants typically recovered around month seven. Being moderately active (hazard ratio (HR) = 2.23) and having higher health status (HR = 1.03) were associated with recovery. Demographic and shoulder severity variables did not improve the model performance nor individually predict recovery. The final model partially predicted recovery with near acceptable performance (optimism-corrected Harrell's C discrimination = 0.66 and Calibration Slope = 0.99).

Conclusion: The inadequate recovery rate in RC tendinopathy (under 50%) indicates a necessity for enhancements in treatment strategies for this condition. Demographic variables and shoulder pain severity are not useful factors to predict RC tendinopathy recovery. However, clinicians may consider assessing baseline health status and activity level to guide decision-making as these variables partially predict recovery. Strategies to include these factors in intervention development should be considered.

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Introduction

Prognosis indicates the forecast of disease trajectory and possible consequences, whereas prognostic factors correlate with these outcomes. These often include age, gender, or condition-specific metrics. Prognosis provides essential information from a general perspective; however, individual prognosis varies (Riley, van der Windt, Croft, and Moons, 2019). Prognostic factors help clinicians to comprehend personalized risk profiles and individual prognosis. If clinicians detect early which patients will have persistent symptoms, healthcare resources can be better targeted (Hemingway et al, 2013; Moons et al, 2009; Riley et al, 2013; Traeger, Hubscher, and McAuley, 2017).

Moreover, all prognostic factors are not modifiable, such as age and gender. Nonmodifiable factors are intrinsic characteristics that cannot be changed or influenced by interventions, but they play an important role in shaping disease prognosis and outcomes. Therefore, understanding the interplay between modifiable and non-modifiable factors is critical for developing tailored prognostic models and optimizing patient care.

Shoulder pain is common, likely to explain why many outcome predictors have been considered. There are, however, some published models, albeit typically with insufficient explanatory variables to be clinically useful (Chester, Jerosch-Herold, Lewis, and Shepstone, 2018; Karel et al, 2017; Kuijpers et al, 2006a; Kuijpers et al, 2006b, Kuijpers et

CONTACT Dylan Morrissey  d.morrissey@qmul.ac.uk  Mile End Hospital, Bancroft Road, London E1 4DG, UK

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al, 2007). No model has been validated with external validation studies (Kuijpers et al, 2007; Mintken et al, 2017). A limited number of cohort studies (Braun, Hanchard, Handoll, and Betthäuser, 2018; Brox and Brevik, 1996; Chard, Sattelle, and Hazleman, 1988; de Witte et al, 2016; Engebretsen et al, 2010; TaheriAzam, Sadatsafavi, and Moayyeri, 2005) have focused on improvement in shoulder disability as an outcome for RC tendinopathy. Improvement is distinct from recovery, and no previous studies have evaluated a wide range of bio-psychosocial factors as potential predictors of recovery in rotator cuff (RC) tendinopathy (Bonde et al, 2003; Garrison et al, 2011; James et al, 2005). Consequently, although studies focusing on developing prognostic models have become increasingly popular, there are no useful prognostic models to guide RC tendinopathy management.

Prediction of improvement, but not recovery, of shoulder pain and disability has been studied (Table 1) (de Witte et al, 2016; Reilingh, Kuijpers, Tanja-Harfterkamp, and Van der Windt, 2008). Recovery in musculoskeletal injuries is conceptually complex as it is dependent on patients' expectations and a diversity of bio-psychosocial factors (Carroll, Lis, Weiser, and Torti, 2016; Stubbs et al, 2020). Improvement in shoulder severity does not mean full recovery. Improvement is typically defined by the minimal clinically important difference (MCID) (Roy, MacDermid, and Woodhouse, 2009). This is 13 for the Shoulder Pain and Disability Index (SPADI) (Roy, MacDermid, and Woodhouse, 2009), so if a patient has severe shoulder symptoms of 90 on a 100-point scale, the MCID will represent only partial and likely unsatisfactory improvement. Moreover, Ekeberg et al (2010) and Bot et al (2005) showed a different relationship between shoulder severity and recovery or improvement. Therefore, improvement cannot be considered as being synonymous with recovery.

This prospective cohort study aimed to detect what combination of self-reported bio-psychosocial factors predicts RC tendinopathy recovery by constructing an explanatory statistical model. The impact of study success would be improved understanding of RC tendinopathy prognosis and, ultimately, management.

Methods

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline was followed (Cuschieri, 2019). Queen Mary Ethics of Research Committee (QMERC2018/92), the United Kingdom Health Research Authority (264615), and the University of Liège Hospital-Faculty Ethics Committee (2019/182) gave ethical approval.

Participants

Participants with a current RC tendinopathy diagnosis were recruited through social media, private clinics, Barts Health National Health Service (NHS) Trust, and a network of collaborators (Figure 1). After participants gave informed consent, eligibility was checked. Eligibility criteria included being aged at least 18 years and having an RC tendinopathy diagnosis from a clinician. For participants recruited via social media, checks of the diagnostic process were made. Participants were excluded from the study if the diagnosis was made by someone other than a clinician. Recruitment and retention strategies are detailed in Supplement 1.

Measures

The online questionnaire battery was administered using SmartTrial (version 4.0, MEDEI ApS, Aalborg, Denmark). The questionnaire included nine patient-reported outcome measures (PROMs) and a range of questions for demographic, biomedical, social and psychological factors (Table 2, Table 3, and Supplement 2) (Delen et al, 2022). Participants also reported their pain locations, severity, and pain types using Navigate Pain (Version 1, Aglance Solutions, Denmark) (Gulle et al, 2024; Tayfur et al, 2020). The monthly follow-up surveys consisted of questions related to recovery. Severity was also measured with SPADI questionnaires at 3, 6, 9, and 12-month follow-up surveys. Figure 1 presents the journey of a participant in this study. The online questionnaire battery has previously been validated. To test the validity, reliability, and feasibility of the online questionnaire battery, 40 participants completed the online survey with and without assistance in a randomized order. There was no systematic difference between assisted and non-assisted administrations (range of Cohen's $d = -0.25 - 0.15$). The survey completed 25.7 ± 15.3 minutes and had good or excellent reliability (The Intraclass Correlation Coefficient (ICC) = 0.75–0.94) (Delen, 2022).

Primary outcome and selection of measured variables

Recovery was the primary outcome, measured with the Global Rating of Change (GROC) scale (Figure 2). The GROC has good reliability and is commonly used in clinical studies as a relevant concept to interpret meaningful improvements in perceived overall condition change and recovery (Bobos et al, 2020). Among its strengths, GROC scales are praised for their simplicity, efficiency, and flexibility in clinical and research settings, allowing for quick assessments of patient

Table 1. Table summarizing how previous studies defined outcome and what the studies found.

Variables	Association	Result & Outcome	Reference
DEMOGRAPHICS			
Younger age	was associated with	better outcome (improvement in DASH)	Kennedy et al. (2006)
Higher BMI		poor outcome (improvement in Constant-Murley)	Araya-Quintanilla et al. (2021)
Being women		poor outcome (improvement in Constant score)	Charousset et al. (2008)
Dominance side involvement		poor outcome (improvement in WORCI)	de Witte et al. (2016)
Black ethnicity		staying in hospital longer after shoulder surgery	Yin et al. (2019)
Marital Status (married)		better outcome (satisfaction)	Tashjian et al. (2007)
BIOMEDICAL			
Worse baseline shoulder severity	was associated with	poor outcome (improvement in SPADI)	Chester, Jerosch-Herold, Lewis, and Shepstone, (2018)
Lower disease activity in rheumatoid arthritis		better outcome (improvement in DASH)	Ishikawa et al. (2008)
Increasing number of additional health problems		poor outcome (improvement in SPADI)	Chester, Jerosch-Herold, Lewis, and Shepstone, (2018)
Having a previous shoulder injury		poor outcome (SPADI at 1 year)	Engelbrechtsen et al. (2010)
Having multiple tendon involvement		poor outcome (tendon defect)	Nho et al. (2009)
Current condition duration		poor outcome (improvement in SPADI)	Chester, Jerosch-Herold, Lewis, and Shepstone, (2018)
Bilateral arm injury		poor outcome (improvement in WORCI)	de Witte et al. (2016)
Dominant arm injury		poor outcome (improvement in WORCI)	de Witte et al. (2016)
Family tendon disorder history		overall healing failure	Tashjian et al. (2016)
Having comorbidities (No: Yes)		poor outcome (recurrence)	Morales et al. (2019)
Lower pain level		better outcome (improvement in SPADI)	Chester, Jerosch-Herold, Lewis, and Shepstone, (2018)
Pain in the specific shoulder area		poor outcome (persistent symptom)	Macfarlane, Hunt, and Silman, (1998)
Injury mechanism (trauma)		poor outcome (persistent symptom)	Van der Windt et al. (1996)
Stiffness		poor outcome (recurrence)	Chung, Huang, Kim, and Oh, (2013)
Medicine (e.g. Statin, Steroid or Fluoroquinolone)	was associated with	poor outcome (recurrence)	Morales et al. (2019)
Tobacco consumption		poor outcome (improvement in Constant-Murley score)	Araya-Quintanilla et al. (2021)
Activity effect on pain (get worse)		poor outcome (persistent symptom)	Kuijpers et al. (2006a)
Neck pain presence		poor outcome (persistent symptom)	Van der Windt et al. (1996)
Gradual onset		poor outcome (persistent symptom)	Kuijpers et al. (2006a)
Referral to medical professional		poor outcome (pain level)	Solomon et al. (2001)
Getting physiotherapy		poor outcome (persistent symptom in a short time)	Van der Windt et al. (1996)
Getting injection		better outcome (persistent symptom in a short time)	Van der Windt et al. (1996)
SOCIAL			
Lower socioeconomic status	was associated with	more serious morbidity in musculoskeletal conditions	Brekke, Hjortdahl, and Kvien, (2002)
Lower education level		poor outcome (SPADI at 1 year)	Engelbrechtsen et al. (2010)
Higher activity level		poor outcome (improvement in SPADI)	Chester, Jerosch-Herold, Lewis, and Shepstone, (2018)
Doing repetitive activity		poor outcome (persistent symptom)	Kuijpers et al. (2006a)
Heavy manual labor		poor outcome (return to work)	Collin et al. (2015)
Change in work participation due to shoulder problem		poor outcome (improvement in SPADI)	Chester, Jerosch-Herold, Lewis, and Shepstone, (2018)
PSYCHOLOGICAL			
Lower quality of life	was associated with	poor outcome (SPADI at 1 year)	Engelbrechtsen et al. (2010)
Lower pain catastrophizing		better outcome (improvement in pain level)	Reilingh, Kuijpers, Tania-Harferkamp, and Van der Windt, (2008)
Higher self-efficacy score		better outcome (improvement in SPADI)	Chester, Jerosch-Herold, Lewis, and Shepstone, (2018)
Lower fear avoidance		better outcome (recovery with improvement in WORCI)	Woollard et al. (2017)
Sleep disturbance		poor outcome (sickness absence)	Ali, Nyman, Hillert, and Svartengren, (2015)
Positive patient expectation of recovery		better outcome (improvement in SPADI)	Chester, Jerosch-Herold, Lewis, and Shepstone, (2018)

(Abbreviations: SPADI= Shoulder Pain and Disability Index; WORCI= Western Ontario Rotator Cuff index; DASH= Disabilities of the Arm, Shoulder and Hand).

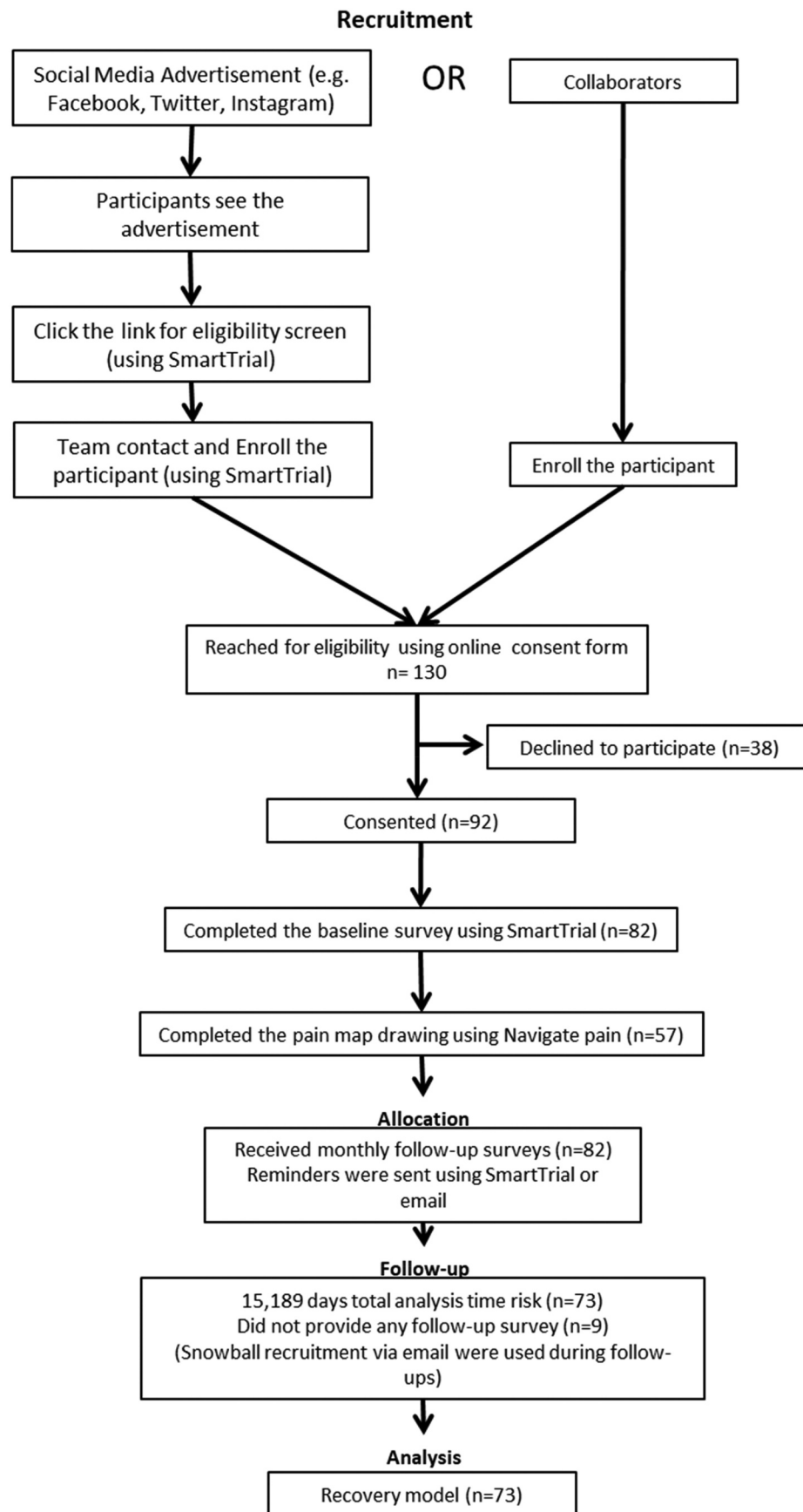


Figure 1. Participants journey presenting screening and enrollment process.

Table 2. Baseline characteristics of participants with RC tendinopathy.

Variables (n = 73)	Baseline Characteristics
A) Demographics	
Age (years)	43.9 ± 14.0
BMI (kg/m ²)	26.3 ± 5.4
Sex (Female: Male)	45: 28
Language (English: Turkish: Spanish: French)	52: 11: 5: 5
Ethnicity (White: Arab: Asian: Black: Mixed: Others: Prefer not to say)	56: 0: 7: 4: 1: 1: 4
B) Biomedical	
Shoulder Pain and Disability Index (0 ^a -100)	37.7 ± 24.4
Western Ontario rotator cuff index (0-100 ^a)	56.0 ± 21.6
Single Assessment Numeric Evaluation (0-100 ^a)	57.3 ± 24.3
Patient Acceptable Symptomatic State (No: Yes)	47: 26
Rheumatoid Arthritis Disease Activity Index-5 (0 ^a -10) (n = 8)	5.3 ± 2.8
Previous injury presence (No: Yes)	55: 18
Current condition duration (>1 year: <1 year)	34: 39
Dominant side injured (No: Yes)	21: 52
Family tendon disorder history (No: Yes)	54: 19
Having comorbidities (No: Yes)	61: 12
Pain Onset (Sudden: Gradual)	30: 43
Morning pain duration (hour)	0.9 ± 2.2
Morning stiffness duration (hour)	0.6 ± 1.8
Pain at night (No: Yes)	23: 50
Activity effect on pain (No effect: Get better: Get worse)	16: 17: 40
Neck pain presence (No: Previous: Current)	27: 13: 33
Treatment (N: Y)	16: 57
Physiotherapy	26: 47
Education	63: 10
Provision of information	70: 3
Orthoses	73: 0
Injection	53: 20
Electrotherapy	65: 8
Medication	52: 21
Surgery	60: 13
C) Social	
E-Health Literacy score (8-40 ^a)	30.2 ± 6.7
Education level (High school or lower: Undergraduate: Postgraduate)	18: 35: 20
GPAQ-Activity level (Inactive: Moderately Active: Highly Active)	11: 20: 42
Sporting age (years)	14.1 ± 15.3
Work status (Student or unemployed: Blue collar: White collar: Professional: Athlete)	19: 5: 7: 40: 2
Change in work participation due to shoulder problem (No: Yes)	53: 20
D) Psychological	
EQ-5D-5 L index score (-1 to 1 ^a)	0.7 ± 0.2
EQ-5D-5 L VAS score (0-100 ^a)	69.5 ± 21.0
Pain Catastrophizing score (0 ^a -52)	11.1 ± 10.0
General Self-Efficacy score (10-40 ^a)	33.6 ± 4.2
FABQ (Physical activity) (0 ^a -24)	12.0 ± 7.0
FABQ (Work) (0 ^a -42)	13.8 ± 12.5
Feeling rested Feeling rested (No: Yes)	56: 17
Patient recovery predictions (Stay the same: Get better: Get worse: DNK)	38: 13: 8: 14
F) Pain map drawing (n = 54)	
Number of painful body regions	2.4 ± 2.2
Number of sites around the shoulder	2.4 ± 1.4
Focal pain on anterior area of shoulder (No: Yes)	39: 15

(Abbreviations: HR= Hazard ratio; EQ-5D-5 L= Five-level version of the five-dimensional EuroQol; GPAQ= Global physical activity questionnaire; PCS= Pain Catastrophizing score; FABQ= Fear-Avoidance Beliefs Questionnaire; GSES= General Self-Efficacy score; BMI= Body mass index; kg= Kilogram; cm= centimeter; m= meter).

improvement or deterioration (Carrasco-Labra et al, 2021; Kamper, 2009; Kamper, Maher, and Mackay, 2009). However, weaknesses include potential ambiguities in interpretation, particularly when patients report slight improvements, which may not correspond to clinically significant changes (De Vasconcelos et al, 2024). A particular criticism of the measure is that individuals may not reliably remember previous health states (Kamper, Maher, and Mackay, 2009).

If a participant selected “better” or “worse,” then the degree was asked on a five-point scale (Figure 2) (Kamper,

Maher, and Mackay, 2009). Participants who selected the top two categories (“much better” and “very much better”) were considered recovered (Kiely and Galvin, 2021; Mellor et al, 2016; Negahban, Behtash, Sohani, and Salehi, 2015).

Forty-one plausible variables were derived from literature related to RC disorders and shoulder pain (Brox and Brevik, 1996; Chard, Sattelle, and Hazleman, 1988; de Witte et al, 2016; Engebretsen et al, 2010; TaheriAzam, Sadatsafavi, and Moayyeri, 2005). The factors were examined as independent variables for the regression analysis (Table 1).

Table 3. The univariate cox regression analysis for RC tendinopathy.

VARIABLES (n = 73) Recovery (Non-recovered: Recovered)	Univariate Cox Proportional-Hazards	
	39: 34 (Recovery rate: 47%)	
A) Demographics	HR (95% CI)	Prob>chi2
Age (years)	1.02 (0.99–1.05)	0.12
BMI (kg/m ²)	1.02 (0.96–1.09)	0.74
Sex (Female: Male)	1.14 (0.57–2.27)	0.72
Language (English: Turkish: Spanish: French)	Turkish: 1.01 (0.41–2.47)	0.99
Ethnicity (White: Arab: Asian: Black: Mixed: Others: Prefer not to say)	NA	NA
B) Biomedical		
Shoulder Pain and Disability Index (0 ^a –100)	0.996 (0.98–1.01)	0.54
Western Ontario rotator cuff index (0–100 ^a)	1.01 (0.99–1.03)	0.31
Single Assessment Numeric Evaluation (0–100 ^a)	1.003 (0.99–1.02)	0.65
Patient Acceptable Symptomatic State (No: Yes)	1.48 (0.75–2.94)	0.26
Rheumatoid Arthritis Disease Activity Index-5 (0 ^a –10) (n = 8)	NA	NA
Previous injury presence (No: Yes)	0.66 (0.28–1.54)	0.34
Current condition duration (>1 year: <1 year)	2.04 (0.98–4.25)	0.06⁺
Dominant side injured (No: Yes)	0.71 (0.35–1.45)	0.35
Family tendon disorder history (No: Yes)	0.69 (0.30–1.59)	0.38
Having comorbidities (No: Yes)	0.62 (0.22–1.78)	0.38
Pain Onset (Sudden: Gradual)	0.60 (0.30–1.19)	0.15
Morning pain duration (hour)	1.01 (0.85–1.20)	0.89
Morning stiffness duration (hour)	1.07 (0.90–1.27)	0.45
Pain at night (No: Yes)	0.69 (0.34–1.39)	0.30
Activity effect on pain (No effect: Get better: Get worse)	Get better: 1.15 (0.42–3.18)	0.79
	Get worse: 0.91 (0.38–2.19)	0.83
Neck pain presence (No: Previous: Current)	Previous: 0.60 (0.22–1.66)	0.33
	Current: 0.53 (0.25–1.13)	0.10
Treatment (N: Y)	1.10 (0.48–2.52)	0.83
Physiotherapy	1.04 (0.51–2.11)	0.92
Education	0.53 (0.16–1.73)	0.29
Provision of information	NA	NA
Orthoses	NA	NA
Injection	0.77 (0.34–1.79)	0.55
Electrotherapy	NA	NA
Medication	1.11 (0.52–2.33)	0.79
Surgery	1.50 (0.65–3.45)	0.35
C) Social		
E-Health Literacy score (8–40 ^a)	0.96 (0.91–1.02)	0.19
Education level (High school or lower: Undergraduate: Postgraduate)	Undergraduate: 1.11 (0.46–2.72)	0.81
	Postgraduate: 1.54 (0.58–4.08)	0.39
GPAQ-Activity level (Inactive: Moderately Active: Highly Active)	Moderately: 3.74 (1.05–13.41)	0.04[*]
	Highly: 2.17 (0.64–7.41)	0.22
Sporting age (years)	1.06 (0.998–1.13)	0.06⁺
Work status (Student or unemployed: Blue collar: White collar: Professional: Athlete)	Professional: 1.29 (0.26–6.26)	0.76
Change in work participation due to shoulder problem (No: Yes)	0.57 (0.24–1.32)	0.19
D) Psychological		
EQ-5D-5 L index score (–1 to 1 ^a)	1.14 (0.19–6.84)	0.89
EQ-5D-5 L VAS score (0–100 ^a)	1.02 (1.003–1.05)	0.03[*]
Pain Catastrophizing score (0 ^a –52)	0.97 (0.93–1.01)	0.16
General Self-Efficacy score (10–40 ^a)	1.04 (0.95–1.13)	0.39
FABQ (Physical activity) (0 ^a –24)	1.01 (0.96–1.06)	0.67
FABQ (Work) (0 ^a –42)	0.98 (0.95–1.01)	0.17
Feeling rested Feeling rested (No: Yes)	2.08 (1.003–4.29)	0.049[*]
Patient recovery predictions (Stay the same: Get better: Get worse: DNK)	Get better 1.21 (0.49–3.02)	0.68
F) Pain map drawing (n = 54)		
Number of painful body regions	0.43 (0.25–0.75)	0.003[*]
Number of sites around the shoulder	0.72 (0.52–1.01)	0.06⁺
Focal pain on anterior area of shoulder (No: Yes)	0.17 (0.04–0.73)	0.02[*]

(Abbreviations: HR= Hazard ration; EQ-5D-5 L= Five-level version of the five-dimensional EuroQol; GPAQ = Global physical activity questionnaire; PCS= Pain Catastrophizing score; FABQ= Fear-Avoidance Beliefs Questionnaire; GSES= General Self-Efficacy score; BMI= Body mass index; kg= Kilogram; cm= centimeter; m= meter.)

Sample size calculation

To obtain a robust sample size calculation, the primary outcome measure was calculated using the area under the receiver operating characteristic curve (AUC) and checked with events per variable (EPV). An excellent score (>0.8) was specified for a useful model with

a power of 80% and an alpha of 5% in order to generate robust data for clinical approaches (Hosmer and Lemeshow, 2010). To our knowledge, there is no data to detect the strongest single variable prediction of RC tendinopathy for recovery. However, we judged that to be 0.7 based on Moore (2013), who reported AUC

With respect to your shoulder pain, how satisfied are you with your condition?

☐ Better

☐ No change

☐ Worse

How much better?

☐ Slightly better

☐ Somewhat better

☐ Moderately better

☐ Much better

☐ Very much better

How much worse?

☐ Very much worse

☐ Much worse

☐ Moderately worse

☐ Somewhat worse

☐ Slightly worse

Figure 2. The global rating of change to examine recovery. The circle in the figure refers to the top two categories of the scale, used to define participant status as “recovered”.

values of outcome predictors for shoulder pain. The ratio of sample sizes in negative (non-recovery)/positive (recovery) groups was considered 0.43 (30%:70%) based on recovery rates from a previous RC tendinopathy study (Holmgren et al, 2012). MedCalc software (version 18.6) was used to calculate the required sample size of 201 participants. A twenty percent drop-out rate was assumed based on previous cohort studies (Bot et al, 2005; Feleus et al, 2006), giving a final sample size of 251.

Statistical analysis

Statistical analysis was conducted using STATA (version 16.0, StataCorp LP, College Station, TX, USA). Data visualization and calculation of descriptive statistics were used to profile the results for participants with RC tendinopathy (Table 2, Table 3, and Supplement 2). Longitudinal survival time analysis was conducted with univariate Cox proportional-hazards regression to calculate time to event, examining individual predictive associations between (outcome) recovery and plausible independent variables at baseline.

A manual forward model development process that was similar to Chester, Jerosch-Herold, Lewis,

and Shepstone (2018) and a recent case-control study (Delen et al, 2022) was employed. Full details of model development are in Supplement 3. Data imputation was not used in this study as the follow-up surveys were very short (2–3 minutes), and participants either completed them or did not respond. To evaluate the time to occurrence, a Cox proportional-hazards regression model was built with the number of days at risk as the time variable (Riley, van der Windt, Croft, and Moons, 2019). For the model fit of the final model, the proportional-hazards assumption was tested by estimating the Schoenfeld residuals (estatphtest >0.05) (Xue et al, 2013). Visualization methods were also used to test the assumptions; 1) the survival time proportional-hazards plot curves should be parallel for each category, and 2) predicted and observed curves in Kaplan-Meier survival plots should be close (di Valmarino, 2005). The individual hazard ratio values of each factor were used to interpret the model. The predictive performance of the final model was evaluated with discrimination, calibration analysis, and bootstrapping. The optimism-corrected calibration slope was used as a uniform shrinkage factor to correct the regression coefficients of the variables for potential overfitting or underfitting (Harrell,

2015). Full details of model performance tests are in Supplement 3.

Results

A total of 130 participants with RC tendinopathy were recruited between April 5, 2019 and May 18, 2021. Ninety-two participants consented to the study, and 82 of them (completion rate = 89%) completed the baseline survey. Nine participants did not complete any follow-up surveys (Figure 1). Therefore, they

were excluded from the cohort analysis. The retention rates for 3, 6, 9, and 12-month (the major milestones) surveys were 71%, 62%, 57%, and 68%, respectively. Seventy-three participants (43.9 ± 14.0 years, 45 females, SPADI = 37.7 ± 24.4 , WORCI = 56.0 ± 21.6) (Table 2, Table 3, and Supplement 2) provided 15,189 days of total analysis time at risk (208 ± 129 days per person, minimum 30 days, median 181 days, and maximum 407 days) in the survival analysis. The recovery rate was 47%, occurring mainly around the 7-month follow-up point (Figure 3).

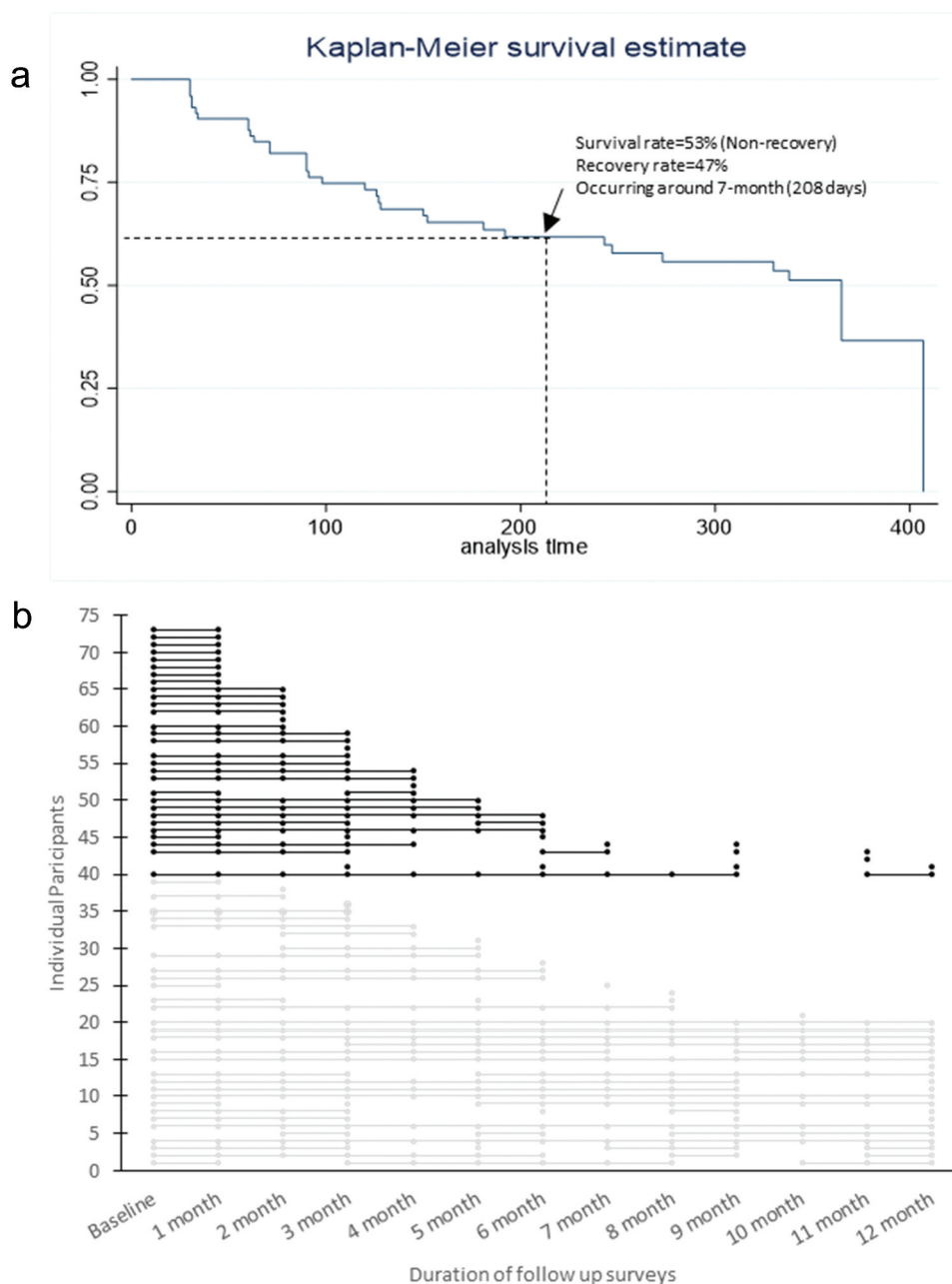


Figure 3. (a) Kaplan-Meier survival estimate graph. (b) individual participants' journey showing how many follow-ups surveys a participant completed before reaching full recovery or before dropping out this study similar to the Kaplan-Meier survival graph. Keys: black represents participants who recovered and were then censored, while gray represents participants who did not recover.

Table 4. The properties of the final recovery model.

Independent Variables (<i>n</i> = 73)	HR (95% CI)	Beta coef	<i>p</i> > <i>z</i>	Interpretation
General health status	1.03 (1.01–1.05)	0.03	0.02	Higher health status
Moderately active	2.23 (1.08–4.61)	0.80	0.03	Being moderately active ... associated with getting better in RC tendinopathy

Abbreviations: RC = Rotator cuff; HR = hazard ratio; coef = Coefficient.

Univariate cox proportional-hazards regression analysis showed eight factors, each on their own, could predict RC tendinopathy recovery (Table 3 and Supplement 2). These were used to build the final multivariable model which ultimately only included activity level measured using the Global physical activity questionnaire (GPAQ) (for moderately active hazard ratio (HR) (95%CI) = 2.23 (1.08–4.61), *p* = .03) and general health status (HR (95%CI) = 1.03 (1.01–1.05), *p* = .02 (Table 4). Moreover, the Cox proportional-hazards regression assumption was not violated (estatphtest = 0.93 and the final model *p* = .007), and model fit was good.

Model performance, the apparent Harrell's C-statistic was 0.67, and the calibration plot was 1.0. The results demonstrated that the model could detect outcomes for almost 7 out of 10 participants with RC tendinopathy. After bootstrapping (internal validation) was done, the optimism-corrected C-statistics and the slope were 0.66 and 0.99, respectively (Supplement 4 and 5), showing that there was minimal overestimation in the predicted outcome. The calibration slope remained close to 1.0, so the regression coefficients were not adjusted.

Discussion

In this study, it was found that a limited number of factors individually predicted RC tendinopathy recovery, and the developed model partially differentiated recovered participants with RC tendinopathy from those not recovering. The final model consisted of two modifiable variables: general health status and activity level. The recovery rate was 47%, occurring around 7 months. Demographic factors and shoulder severity did not individually predict recovery nor improve model performance. Our explanatory model is also practical from a clinical perspective. The two modifiable variables can be collected via self-reported online survey with associated accessibility, time, and cost advantages (Özcan, Kocak, and Brune, 2013). The statistical causal model could help clinicians and care commissioners predict who is likely to get better, why, and when.

Carefully defining the primary outcome is vital for meaningful cohort analysis. For example, Ekeberg et al (2010) examined the association between baseline

shoulder severity (SPADI) and both recovery and improvement in severity at 6 weeks. They reported a significant association between baseline and 6-week severity, while the baseline SPADI did not predict recovery at 6-weeks. Bot et al (2005) recruited 443 participants who had new shoulder pain and investigated predictors for two different outcomes (recovery and improvement in shoulder disability at 12-month). Baseline shoulder disability was included as an independent outcome predictor for improvement in shoulder disability at 12 months. Otherwise, the baseline factor was not retained in the model predicting shoulder pain recovery. Similarly, in our study, shoulder severity (SPADI and WORCI scores) was not related to recovery; however, the baseline SPADI explained SPADI at 3, 6, 9 and 12-month ($R^2 = 0.64$ *p* < .001, $R^2 = 0.34$ *p* < .001, $R^2 = 0.36$ *p* < .001, and $R^2 = 0.24$ *p* < .001, respectively). Moreover, the Single Assessment Numeric Evaluation (SANE) measures an individual's perception of their shoulder's normalcy (severity) (Baumgarten, 2022). Baseline SANE also was not associated with recovery in our study. It is therefore clear that recovery and improvement in severity are not interchangeable, and clinical translation of findings needs to consider this carefully. Baseline severity is inversely correlated with the likelihood of meaningful improvement but has no association with recovery.

The associations “morning pain” and “activity effect on pain” with recovery in RC tendinopathy are complex and not straightforwardly linked. Morning pain is often associated with stiffness and may not completely indicate the severity of the underlying tendinopathy. It can be influenced by factors such as sleep position (Magarey, 2012). Activity effect on pain can reflect mechanical issues or muscle imbalances rather than the healing process itself. It may persist even as the tendon heals, indicating that pain perception is multifaceted (Hood and Savoie, 2019). In this study, morning pain and activity effect on pain were not associated with recovery in RC tendinopathy. Therefore, the two variables are critical for clinical perspective. For example, if the patient reports that activity has an effect on pain, strengthening exercises may be added to the treatment to address muscle imbalances. However, having the symptom does not mean that the patient will not recover, or vice versa.

Education is crucial for effective management and rehabilitation, as highlighted in various studies; the literacy levels of patients can significantly impact their understanding and adherence to treatment protocols. However, many patient education materials exceed the reading capabilities of a substantial portion of the population (Miskiewicz et al, 2024). This discrepancy suggests that even with higher education, patients may struggle to comprehend essential information, potentially hindering their recovery. Similarly, having higher education (postgraduate or undergraduate) was not associated with recovery in this study. Moreover, lower educational attainment may result in blue-collar employment (Hwang and Lee, 2014). Over fifty percent of the enrolled participants are employed in professional occupations in this study. Therefore, the relationship between employment status and education, as well as its impact on recovery, cannot be analyzed in depth due to low EPV in blue-collar employment.

The final model, consisting of activity level and general health status, partially predicted RC tendinopathy recovery. Moderately active participants were more likely to recover compared to either sedentary or highly active participants. That is plausible as tendon regeneration requires loading to facilitate growth factor and collagen expression, so an inactive lifestyle might slow down or block the recovery process (Magnusson, Langberg, and Kjaer, 2010). Overloading could also cause the recovery process to be interrupted (Abraham et al, 2021). However, Langberg et al (2007) found long-term effect of controlled loading was positive on the recovery of a tendon. The recent systematic review also showed higher intensity and lower volume were associated with better outcomes for all tendinopathies (Anastasia Vladimirovna et al, 2023). Therefore, clinicians may be able to improve recovery by facilitating optimal activity levels of patients with RC tendinopathy as the factor is modifiable and can be measured with a self-reported questionnaire.

It was expected that participants with better general health at baseline would have a more favorable outcome. A systematic review found moderate evidence that having poor general health was associated with shoulder pain chronicity (Struyf et al, 2016). Therefore, general health status should be examined, and clinicians could focus on improving the factor to facilitate recovery. On the other hand, the degree to which these factors are modifiable should be considered with particular caution. General health is a multifaceted concept influenced by both modifiable and non-modifiable factors, with comorbidity exemplifying the latter. Comorbidity often arises from complex interactions between genetic predispositions

and environmental factors, making it difficult to modify (Cerdá, Sagdeo, Johnson, and Galea, 2010; Klimek, Aichberger, and Thurner, 2016). Moreover, individual behaviors and lifestyle choices (e.g. smoking and exercise) are modifiable parts of general health. Adopting healthy behaviors may enhance recovery (Murray et al, 2020). Therefore, focusing on the modifiable part of the general health may facilitate the RC tendinopathy recovery.

Long-term adherence to treatment and advice is a key factor in achieving recovery (Gilanyi et al, 2024; Hayden, Van Tulder, and Tomlinson, 2005). Recently, Gilanyi et al (2024) conducted a systematic review of 16 barriers and facilitators related to pre-exercise, during exercise, and post-exercise contexts for chronic low back pain. It is complex to facilitate behavior change, and there is a lack of knowledge about barriers and facilitators for RC tendinopathy (Gilanyi et al, 2024; Rhodes and Pfaffli, 2010; Vader, Doulas, Patel, and Miller, 2021). Behavior change intervention approaches may be used to improve adherence to exercise in persistent musculoskeletal problems (Meade et al, 2019; Whittall, Störk, Riegel, and Herber, 2020), albeit the evidence is limited (Meade et al, 2019). Moreover, Vader, Doulas, Patel, and Miller (2021) carried out a qualitative study to investigate facilitators and barriers for participating in exercise and reported barriers such as motivation, access to facilities for exercise, social support, and beliefs. Therefore, social factors could be an important barrier to adherence, and further studies are needed to develop interventions to improve adherence based on behavior change theory for people with RC tendinopathy.

The associations between “morning pain” and “activity effect on pain” and recovery in RC tendinopathy are intricate and not directly established. Morning discomfort may interact with stiffness and may not fully reflect the severity of the underlying tendinopathy. It may be affected by variables such as sleep posture (Zenian, 2010). The impact of activity on pain may indicate mechanical issues or muscular imbalances instead of the healing process itself. The discomfort may continue despite tendon healing, suggesting that pain perception is diverse (Hood and Savoie, 2019; Mihata et al, 2009). In this study, morning pain and activity effect on pain were not associated with recovery in RC tendinopathy. However, these factors might be useful for the management of RC tendinopathy. Morning pain could be an indicator of inflammation (Walker and Williamson, 2009). Pain with activity may reflect RC muscle imbalance (Hood and Savoie, 2019; Mihata et al, 2009). These factors can help determine which physiotherapy agent to use in treatment. Consequently, morning pain and/or

pain during activity does not mean that it will prevent recovery or vice versa.

Limitations

To enable data collection from a large international cohort, this study used self-reported RC tendinopathy diagnosis from a previous consultation with a health professional instead of verifying it via an in-person clinical examination. Moreover, our recruitment was close to that of previous studies but still underpowered due to pandemic restrictions. Collaboration with more clinicians and NHS sites would be useful to boost recruitment and improve the diversity of the sample (Chester, Jerosch-Herold, Lewis, and Shepstone, 2018; Thomas et al, 2005). Another limitation was missing data in the pain map, likely due to questionnaire fatigue and exacerbated by using a second data collection tool.

Although a diverse sample has been recruited and the important but rare attempt to establish participants' ethnicity, sex, and health literacy have been made, analyses could not be performed at the ethnic subgroup level. It was never our intention to do so, with the sampling designed to be open and wide rather than powering for specific subgroups, but it is worth highlighting that the cohort findings are most applicable to digitally literate white people younger than 70 years old (Supplement 6). Further research is warranted that recruits adequately from defined subgroups.

The main limitation was that it could not be tested how clinical examination, imaging, and biomechanical assessments have been associated with recovery. These assessments were commenced but had to be curtailed because of the COVID-19 pandemic but remain recommended in future research.

Conclusion

The results of this self-reported online survey should improve clinicians' understanding of recovery in people with RC tendinopathy who are digitally literate, white individuals, and under 70 years old. A unique international sample was recruited, so the findings are generalizable, though the sample was mainly digitally literate, white individuals, and younger than 70 years old. So, external validation would ideally access a more diverse sample and include physical and imaging assessment. The combination of two bio-psychosocial factors (activity level and health status) partially predicted RC tendinopathy recovery which may be useful to improve interventions as both factors are modifiable. Clinicians may wish to assess these factors to inform clinical

reasoning and shared decision-making with patients presenting with RC tendinopathy.

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Consent to participate

After giving informed consent, all participants completed our survey.

Ethic approvals

This study was approved by the United Kingdom Health Research Authority (264615), Queen Mary Ethics of Research Committee (QMERC2018/92) and University of Liège Hospital-Faculty Ethics Committee (2019/182).

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