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## THE VISA-A (SEDENTARY) SHOULD BE USED FOR SEDENTARY PATIENTS WITH ACHILLES TENDINOPATHY: A MODIFIED VERSION OF THE VISA-A DEVELOPED AND EVALUATED IN ACCORDANCE WITH THE COSMIN CHECKLIST.

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3 **TITLE: THE VISA-A (SEDENTARY) SHOULD BE USED FOR SEDENTARY PATIENTS WITH ACHILLES**  
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5 **TENDINOPATHY: A MODIFIED VERSION OF THE VISA-A DEVELOPED AND EVALUATED IN**  
6  
7 **ACCORDANCE WITH THE COSMIN CHECKLIST.**  
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3 1 **ABSTRACT**  
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6 2 **Objective:** To develop and evaluate a modified version of the Victorian Institute of Sport Assessment  
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8 3 - Achilles (VISA-A) questionnaire, for use in sedentary patients with Achilles tendinopathy, using the  
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10 4 Consensus-based Standards for the selection of health Measurement Instruments (COSMIN)  
11  
12 5 recommendations.  
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15 6 **Methods:** Twenty-two sedentary patients with Achilles tendinopathy completed the VISA-A and  
16  
17 7 provided feedback regarding the relevance, comprehensiveness and comprehensibility of each item,  
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19 8 response options and instructions. Patient and professional feedback was used to develop the VISA-A  
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21 9 (sedentary) questionnaire. Reliability, validity, and responsiveness of the VISA-A (sedentary) was  
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23 10 evaluated in 51 sedentary patients with Achilles tendinopathy: 47.1% women, mean age 64.8 (SD  
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25 11 11.24).  
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30 12 **Results:** Factor analysis identified two dimensions (symptoms and activity) for the VISA-A (sedentary).  
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32 13 Test-retest reliability was excellent for symptoms (ICC = 0.991) and activity (ICC = 0.999). Repeatability  
33  
34 14 was 1.647 for symptoms and 0.549 for activity. There was a significant difference between the VISA-  
35  
36 15 A and VISA-A (sedentary) scores both pre- and post-treatment. There was stronger correlation  
37  
38 16 between the pre- to post-treatment change in the VISA-A (sedentary) scores ( $r=0.420$  for symptoms,  
39  
40 17  $r=0.407$  for activity) and the global rating of change than the VISA-A scores ( $r=0.253$  for symptoms,  
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42 18  $r=0.186$  for activity).  
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47 19 **Conclusion:** The VISA-A (sedentary) demonstrates adequate reliability, validity, and responsiveness in  
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49 20 sedentary patients with Achilles tendinopathy. The VISA-A (sedentary) is a more appropriate measure  
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51 21 than the VISA-A for this cohort and is recommended for clinical and research purposes.  
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3 24 What is already known on this topic?  
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5 25 The VISA-A is the most widely used patient reported outcome measure (PROM) for Achilles  
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7 26 tendinopathy (AT) but the psychometric properties of the questionnaire in sedentary individuals are  
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9 27 unknown.  
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14 29 What this study adds.

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16 30 The VISA-A (sedentary) demonstrated adequate reliability, validity, and responsiveness in sedentary  
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18 31 patients with AT, whereas the VISA-A lacked structural validity, was less responsive and demonstrated  
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20 32 a floor effect in this cohort.  
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25 34 How this study might affect research, practice, or policy.

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27 35 The VISA-A (sedentary) represents a more appropriate PROM for sedentary patients and will better  
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29 36 enable clinicians and researchers to assess the impact of AT and efficacy of specific interventions.  
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## 48 INTRODUCTION

49 Achilles tendinopathy (AT) is the preferred term for persistent Achilles tendon pain and loss of  
50 function related to mechanical loading(1). Achilles tendinopathy is frequently seen in runners(2) but  
51 only 35% of patients presenting to general practice describe symptoms related to sporting activity(3).  
52 Athletic and sedentary patients may therefore represent subgroups of AT, with differing aetiologies(4)  
53 and varying degrees of impact on physical activity, function, and quality of life(5, 6).

54 Patient reported outcome measures (PROMs) quantify an individual's perception of the impact of a  
55 pathology that cannot be captured with clinical tests or diagnostic imaging(7). The Victorian Institute  
56 of Sport Assessment - Achilles (VISA-A) questionnaire is one of the most widely used PROMs for  
57 patients with AT(8), covering the domains of symptoms, function and physical activity(9). However,  
58 the VISA-A was developed with an athletic population and the psychometric properties of the  
59 questionnaire in sedentary individuals are unknown(10). Athletic and sedentary patients are likely to  
60 value different outcomes and PROMs must therefore reflect the issues that are important to these  
61 specific populations(6). Without appropriate measurement properties, it is difficult to determine the  
62 impact of a pathology or efficacy of specific interventions using a PROM(5).

63 The aim of this study was to develop and evaluate a modified version of the VISA-A that can be used  
64 in sedentary patients with AT. This questionnaire: the VISA-A (sedentary), was developed to measure  
65 the severity of AT using the Consensus-based Standards for the selection of health Measurement  
66 Instruments (COSMIN) recommendations(11, 12). We hypothesised that there would be a significantly  
67 larger change in pre- to post-treatment scores for the VISA-A (sedentary), and a stronger correlation  
68 between the change in VISA-A (sedentary) and global rating of change (GROC) scores.

## 70 METHODS

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3 71 This was a prospective study involving patients referred to two National Health Service (NHS)  
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5 72 Foundation Trusts. The study was approved by the University and NHS ethics committees and  
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7 73 conducted in accordance with the ethical standards of the World Medical Association Declaration of  
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10 74 Helsinki (2002).

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13 75 **Equity, diversity, and inclusion statement:**

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16 76 Patients were included if they were aged 18 years or older with a clinical diagnosis of AT but did not  
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18 77 participate in Achilles tendon loading sports, inclusive of all genders, race/ethnicities, socioeconomic  
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20 78 levels, and occurrence in a marginalised community. Patients were excluded if they were unable to  
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22 79 understand the English language or complete the questionnaires, thus findings may not be  
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24 80 generalisable to these cohorts. Our author team consisted of two women and four men, with junior,  
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26 81 mid-career and senior physiotherapy clinician/researchers, four from the United Kingdom and two  
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28 82 from Australia.

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33 83 Development of the VISA-A (sedentary)

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37 84 Consecutive patients presenting to an outpatient's physiotherapy department for non-surgical  
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39 85 management of AT were used as the study population for the development of the VISA-A (sedentary)  
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41 86 questionnaire. All patients were referred with clinically and MRI-confirmed AT by four lower-limb  
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43 87 orthopaedic surgeons working in a secondary care musculoskeletal outpatient's clinic. The clinical  
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45 88 criteria used to diagnose AT was localised Achilles tendon pain during loading (e.g., calf raise) and  
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47 89 palpation. This patient sample was representative of the target population in which the PROM was to  
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49 90 be administered and evaluated (table 1), with regards to the referral pathway to physiotherapy.

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53 91 **Patient and public involvement:**

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57 92 Eligible patients completed a paper copy of the VISA-A at their initial physiotherapy assessment and  
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59 93 were asked to write comments regarding the relevance, comprehensiveness and comprehensibility of

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3 94 each item, response options and instructions. Patients were then encouraged to offer alternative  
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5 95 suggestions (item generation) based on their perception of their condition during a one-to-one,  
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7 96 informal interview conducted by one of the authors (RN). Patient feedback was discussed with the  
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10 97 referring orthopods and expert panel (RN, JC, JG, SO) to determine whether this was representative  
11  
12 98 of other sedentary AT patients. The expert panel consisted of four physiotherapists, all of whom have  
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14 99 a special interest in tendinopathy and multiple publications on the topic in peer reviewed journals.  
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16 100 These professionals were also asked to provide input regarding item relevance and  
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18 101 comprehensiveness of the VISA-A for this patient cohort based on clinical experience and the existing  
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20 102 literature. A provisional version of the VISA-A (sedentary) was created, evaluated, and adapted until  
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22 103 no further changes were recommended by patients or professionals (figure 1). In total, 30 individuals  
23  
24 104 (22 patients and eight professionals) were consulted during the development process; points raised  
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26 105 are listed in supplementary table 1.  
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31 106 **INSERT FIGURE 1 HERE**  
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37 108 The VISA-A (sedentary) was developed using a reflective model where all items of the PROM are  
38  
39 109 intended to be a manifestation of the same underlying construct. The construct to be measured by  
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41 110 the VISA-A (sedentary) was the severity of AT in sedentary patients, with eight questions covering  
42  
43 111 symptoms and their impact on activity (appendix A). The structure and item weighting remained  
44  
45 112 consistent with the VISA-A with lower scores indicating greater severity of AT(9). Based on feedback  
46  
47 113 during the development phase, the scoring scale was reversed so 'no pain' was positioned to the left  
48  
49 114 of the scale; the VISA-A scale was also reversed for the evaluation phase to ensure any differences in  
50  
51 115 VISA scores could not be attributed to scale reversal (appendix B). Scale reversal has been utilised in  
52  
53 116 previous studies to avoid patient misinterpretation and support self-administration of the VISA-A(13).  
54  
55 117 The intended application of the PROM is for clinical and research purposes, with the PROM  
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57 118 administered on paper.  
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### 119 Evaluation of psychometric properties

120 For factor analysis to be considered 'adequate', the COSMIN checklist recommends a sample size of  
 121 at least five times the number of items and >100 patients, or at least six times the number of items  
 122 but <100 patients. The VISA questionnaires contain eight items, therefore a minimum sample size of  
 123 48 is recommended but for other elements on the COSMIN checklist to be deemed 'adequate', a  
 124 minimum sample size of 50 was required. To account for potential dropouts, a sample size of 55 was  
 125 chosen to adequately evaluate the psychometric properties of the VISA-A (sedentary).

126 Patients were recruited, assessed, and treated by three of the authors (JR, SO and RN) with each  
 127 patient completing paper copies of the VISA-A and VISA-A (sedentary) questionnaires at their initial  
 128 face-to-face appointment (table 1). The VISA-A (sedentary) was repeated 3-days later via telephone  
 129 call, by the treating physiotherapist who was blinded to the initial results, before commencing  
 130 treatment. This timeframe was considered suitable as the interval between measures should be long  
 131 enough to prevent recall, but short enough to ensure the patient's presentation remains stable. The  
 132 median duration of symptoms prior to treatment was 24 weeks, with a maximum of 520 weeks. Thirty-  
 133 seven patients presented with first-episode AT, with the remaining 14 reporting recurrent symptoms.  
 134 No modification to the treatment/intervention was made as part of this study.

Patient demographics	VISA-A (sedentary) development	VISA-A (sedentary) evaluation
Gender, n (%)		
Female	14 (63.6)	24 (47.1)
Age (years)		
Mean (SD)	60 (7.35)	64.8 (11.24)
Range	48-73	40-85

135 **Table 1:** patient demographics for development and evaluation of the VISA-A (sedentary). SD: standard deviation.

136 The VISA-A and VISA-A (sedentary) were administered in paper format at discharge to determine the  
 137 pre- to post-treatment change in scores. The GROC questionnaire (appendix C), which is a valid,

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3 138 reliable, and clinically relevant measure that is not condition specific(14), was also administered at  
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5 139 discharge to determine the patient's overall perception of change following treatment. Patients were  
6  
7 140 instructed to complete the GROC with specific reference to their Achilles tendon to ensure responses  
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9 141 were relevant(14). The median time to discharge was 12.0 weeks (IQR 6.0 [10-16]). Patients with  
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11 142 incomplete data sets were removed from the study.  
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#### 15 143 **Statistical analysis:**

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19 144 Data analysis was performed by two of the authors (TM and RN). All statistical analyses were  
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21 145 performed using SPSS 25.0 (SPSS Inc, Chicago, Illinois, USA) and R (R version 3.2.0, The R Foundation  
22  
23 146 for Statistical Computing). Continuous variables were assessed for their distributions using graphical  
24  
25 147 analysis (construction of histograms and normal Q-Q plots) and through the Kolmogorov-Smirnov and  
26  
27 148 Shapiro-Wilk tests. Statistical analysis and presentation are consistent with the CHecklist for statistical  
28  
29 149 Assessment of Medical Papers (CHAMP)(15).  
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#### 33 150 Internal consistency:

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36 151 Internal consistency of the VISA-A (sedentary) was determined by calculating Cronbach's alpha ( $\alpha$ ),  
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38 152 including the change to  $\alpha$  when items were deleted. Internal consistency was considered acceptable  
39  
40 153 for Cronbach's  $\alpha$  coefficients between 0.70 and 0.95(16). Kaiser-Meyer-Olkin (KMO) and Bartlett's  
41  
42 154 Test of Sphericity (BTS) were calculated and considered acceptable if KMO values were above 0.5 and  
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44 155 BTS  $p < 0.05$ . Exploratory factor analysis (EFA), using principal component analysis based on the  
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46 156 correlation matrix with varimax rotation, was performed to assess the structural validity of the VISA-  
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48 157 A (sedentary). Eigenvalues were used to identify underlying factors; if more than one factor with an  
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50 158 eigenvalue  $> 1$  was identified, the questionnaire was reviewed and split into subscales that only loaded  
51  
52 159 onto one factor with an eigenvalue  $> 1$ .  
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#### 56 160 Test-retest reliability:

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3 161 Three-day test-retest reliability was assessed through calculation of the intraclass correlation  
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5 162 coefficient (ICC) with 95% confidence intervals (CI), using a two-way mixed-effect model (with raters  
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7 163 considered fixed and participants random) for absolute agreement based on single ratings (ICC  
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9 164 3,1)(17), and Bland-Altman plots. Proportional bias was assessed through linear regression of the  
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11 165 difference in scores on the mean of scores, with the null hypothesis that the slope of this line equals  
12  
13  
14 166 zero.

17 167 Measurement error:

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20 168 Measurement error was expressed as within-subject standard deviation ( $s_w$ ) and calculated as  $s_w^2 = \frac{1}{2n}$   
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22  
23 169  $\sum d_i^2$  where  $n$  is the number of subjects and  $d_i$  is the difference between an individual's pre-treatment  
24  
25 170 and 3-day retest VISA-A (sedentary) scores(18). Repeatability was calculated as  $s_w \times 1.96 \times \sqrt{2}$ (18). The  
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27 171 minimal clinically important difference (MCID) was determined using distribution (0.5 x SD of the  
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29 172 mean difference in the pre-post treatment scores) and anchor-based analyses (difference between  
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31 173 the change in scores of responders and non-responders on the GROC)(19).

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35 174 Construct validity and responsiveness:

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38 175 The difference between VISA-A and VISA-A (sedentary) scores, both pre- and post-treatment, was  
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40 176 evaluated using the Wilcoxon Signed Rank test. Agreement between the VISA-A and VISA-A  
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42 177 (sedentary) scores, both pre- and post-treatment, was assessed with Bland-Altman analysis and  
43  
44 178 through calculation of the ICC using a two-way random-effect model (with raters and participants  
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46 179 considered random) for absolute agreement based on single ratings (ICC (2,1)).  
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49 180 The correlation between the pre- to post-treatment change in VISA-A and VISA-A (sedentary) scores  
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51 181 and the GROC was calculated using Spearman's Rank correlation coefficient. Effect size and  
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53 182 standardised response means were calculated based on responders (4 to 7 on GROC) and non-  
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55 183 responders (-7 to 3 on GROC). Where relevant, a  $p$  value  $<0.05$  was considered significant for all  
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57  
58 184 analyses.  
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185 Floor and ceiling effects were determined by calculating the percentage of patients recording the  
 186 highest or lowest possible scores at baseline or discharge. If more than 15% of patients achieved these  
 187 scores, floor or ceiling effects were considered present(20).

## 188 RESULTS:

189 Fifty-five patients were recruited to evaluate the psychometric properties of the VISA-A (sedentary).  
 190 Four patients were excluded due to incomplete data, therefore full data sets were available for 51  
 191 patients (figure 2), which meets the COSMIN requirements for adequate evaluation(11).

192

193 INSERT FIGURE 2 HERE

194

195 The mean pre- to post-treatment change in scores were 14.24 for the VISA-A and 31.04 for the VISA-  
 196 A (sedentary) (table 2). The mean GROCC at discharge was 4.75 (SD 2.11).

	PROM	Symptoms					Activity			Scores		
		Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q1-5	Q6-8	Q1-8
Pre-Rx	VISA-A	6.04 (1.90)	5.16 (2.24)	5.96 (1.93)	5.59 (1.76)	2.92 (2.20)	1.49 (1.68)	0.00 (0.00)	0.00 (0.00)	25.67 (6.94)	1.49 (1.68)	27.16 (7.76)
	VISA-A (sedentary)	5.92 (1.85)	5.45 (1.96)	5.57 (1.62)	5.43 (1.91)	5.04 (2.45)	2.76 (2.18)	3.57 (2.02)	6.90 (5.09)	27.41 (6.45)	13.24 (7.35)	40.65 (12.17)
3-day re-test	VISA-A (sedentary)	5.90 (1.91)	5.53 (1.95)	5.53 (1.57)	5.47 (1.97)	4.98 (2.51)	2.80 (2.23)	3.57 (2.02)	6.90 (5.09)	27.41 (6.40)	13.27 (7.39)	40.69 (12.15)
Post-Rx	VISA-A	7.98 (1.78)	7.57 (2.14)	7.84 (1.94)	7.78 (2.06)	6.84 (2.97)	3.37 (2.86)	0.00 (0.00)	0.00 (0.00)	38.02 (9.46)	3.37 (2.86)	41.39 (10.70)
	VISA-A (sedentary)	7.71 (1.95)	7.43 (2.30)	7.90 (1.72)	7.73 (1.65)	8.31 (2.09)	6.53 (3.04)	7.18 (2.28)	18.90 (8.12)	39.08 (8.41)	32.61 (11.92)	71.69 (19.31)
Pre- to post-Rx change	VISA-A	1.94 (1.36)	2.41 (1.92)	1.88 (1.48)	2.20 (1.89)	3.92 (3.38)	1.88 (2.34)	0.00 (0.00)	0.00 (0.00)	12.35 (6.76)	1.88 (2.34)	14.24 (7.99)
	VISA-A (sedentary)	1.78 (1.33)	1.98 (1.52)	2.33 (1.75)	2.29 (1.72)	3.27 (2.88)	3.76 (3.09)	3.61 (2.50)	12.00 (6.72)	11.67 (6.62)	19.37 (10.07)	31.04 (15.74)

197 **Table 2:** mean pre- and post-treatment scores for the VISA-A and VISA-A (sedentary) questionnaires. Data are presented as mean values  
 198 with standard deviations in parentheses. Rx: treatment.

## 199 Internal consistency:

200 The overall Cronbach's  $\alpha$  for the VISA-A (sedentary) was 0.724 (table 4). All inter-item correlations for  
 201 the questions were  $<0.70$ , with all items having at least one inter-item correlation  $>0.3$ . The

questionnaire's corrected item-total correlations ranged from 0.27 to 0.65, with Cronbach's  $\alpha$  decreasing to 0.719 or less with the removal of any item, indicating all items should be retained.

Exploratory factor analysis indicated that the VISA-A (sedentary) has a multidimensional structure with two factors demonstrating an eigenvalue  $>1$ . The questionnaire was split with items 1-5 (symptoms) loading onto one factor and items 6-8 (activity) loading onto the other (table 3 and supplementary figure 1). For Q1-5 and Q6-8, KMO values were 0.627 and 0.652 respectively. For Q1-5 and Q6-8, BTS values were both  $p < 0.001$ .

		Initial Eigenvalues		
	Component	Total	% of variance	Cumulative %
Symptoms	1	2.165	43.294	43.294
	2	0.999	19.972	62.266
	3	0.916	18.327	81.593
	4	0.544	10.875	92.468
	5	0.377	7.532	100
Activity	1	1.743	58.090	58.090
	2	0.644	21.467	79.557
	3	0.613	20.443	100

**Table 3:** Eigenvalue factor loading for each component.

Cronbach's  $\alpha$  for symptoms and activity was 0.663 and 0.563 respectively (table 4); the  $\alpha$  value did not increase with removal of any item. For both subscales, the inter-item correlations were  $<0.70$ , with all items having at least one inter-item correlation  $>0.3$ . Corrected item-total correlations ranged from 0.31 to 0.58 for symptoms and 0.42 to 0.46 for activity.

	Cronbach's $\alpha$ [95% CI]	ICC (95% CI)	$S_w$	Repeatability
Q1-8	0.724 [0.593-0.825]	0.994 (0.989-0.997)	0.642	1.779
Q1-5 (symptoms)	0.663 [0.491-0.790]	0.991 (0.985-0.995)	0.594	1.647
Q6-8 (activity)	0.563 [0.261-0.720]	0.999 (0.999-1.000)	0.198	0.549

**Table 4:** internal consistency and reliability values for the VISA-A (sedentary).  $S_w$ : within-participant standard deviation.

The overall Cronbach's  $\alpha$  for the VISA-A (Q1-8) was 0.705, with  $\alpha$  values increasing to 0.720 when items seven or eight were removed, indicating these items should not be retained. Factor analysis was

217 not possible for the VISA-A, therefore subsequent analyses were performed using the same  
218 dimensions as the VISA-A (sedentary). Cronbach's  $\alpha$  for Q1-5 was 0.724, increasing to 0.800 with the  
219 removal of item five, indicating this item should not be retained. Cronbach's  $\alpha$  was not calculable for  
220 Q6-8 as all patients scored zero for Q7 and Q8.

#### 221 Test-retest reliability:

222 The ICC for agreement between the 3-day retest and pre-treatment VISA-A (sedentary) scores was  
223 excellent for symptoms and activity (table 4). There was no significant difference between the  
224 repeated measures for symptoms ( $p=0.99$ ) or activity ( $p=0.32$ ). Bland-Altman analysis (supplementary  
225 figure 2) showed no bias of 0.0 (95% CI -0.24 - 0.24) for symptoms, with narrow limits of agreement  
226 from -1.66 to 1.66 and no significant evidence of proportional bias ( $P=0.66$ ). There was a very small  
227 mean bias of 0.039 (95% CI -0.040 - 0.117) for activity with the confidence interval crossing zero,  
228 narrow limits of agreement from -0.51 to 0.59 and no significant evidence of proportional bias  
229 ( $P=0.33$ ).

#### 230 Measurement error

231 The  $s_w$  for symptoms and activity was 0.594 and 0.198 respectively. Repeatability was 1.647 for  
232 symptoms and 0.549 for activity (table 4). The MCID using a distribution-based analysis was 3.31 for  
233 symptoms and 5.03 for activity; using an anchor-based analysis the MCID was 4.33 and 4.88.

#### 234 Construct validity and responsiveness:

235 There was a significant difference between the VISA-A and VISA-A (sedentary) scores, with the VISA-  
236 A scores being significantly lower both pre- ( $P<0.001$  for symptoms and activity) and post-treatment  
237 ( $P=0.022$  for symptoms,  $P<0.001$  for activity). Bland-Altman analysis (supplementary figures 3 and 4)  
238 showed proportional bias between the questionnaires at both timepoints, with greater differences  
239 observed for higher scores both pre- and post-treatment. The ICC for agreement between scores was  
240 moderate to excellent for symptoms but poor for activity at both time points (table 5).

241 There was stronger correlation between the pre- to post-treatment change in the VISA-A (sedentary)  
 242 scores ( $r=0.420$  [95% CI 0.163 - 0.623] for symptoms,  $r=0.407$  [95% CI 0.148 - 0.614] for activity) and  
 243 the GROC than the VISA-A scores ( $r=0.253$  [95% CI -0.02 - 0.494] for symptoms,  $r=0.186$  for activity  
 244 [95% CI -0.09 - 0.431]). Effect size and standardised response means for symptoms and activity are  
 245 presented in supplementary table 2.

	Q1-5 (symptoms) ICC [95% CI]	Q6-8 (activity) ICC [95% CI]
Pre-treatment	0.834 [0.673-0.911]	0.073 [-0.620-0.256]
Post-treatment	0.894 [0.820-0.938]	0.029 [-0.033-0.127]

248  
 249 **Table 5:** Intraclass correlation coefficient (ICC) for agreement between the VISA-A and VISA-A (sedentary).

250  
 251 Floor and ceiling effects:

252 One patient (1.96%) achieved a maximum score for VISA-A (sedentary) symptoms post-treatment,  
 253 while three patients (5.88%) obtained maximum scores for activity, therefore the VISA-A (sedentary)  
 254 demonstrated no floor or ceiling effect. Twenty patients (39.22%) recorded minimum scores for VISA-  
 255 A activity pre-treatment and ten (19.61%) post-treatment, indicating a floor effect for activity (Q6-8).

256 **DISCUSSION**

257 The VISA-A (sedentary) demonstrated excellent test-retest reliability with very high ICC values and  
 258 narrow 95% confidence intervals. There was stronger correlation between the VISA-A (sedentary) and  
 259 the GROC than the VISA-A, although the correlations were moderate. The VISA-A (sedentary)  
 260 demonstrates no floor or ceiling effect, adequate reliability, validity, and responsiveness and is  
 261 recommended for use in this cohort.

262 Since PROMs measure constructs that can only be reported by patients themselves, no gold standard  
263 exists for these measures(21). The VISA-A is one of the most widely used PROMs in AT studies, but  
264 recent publications have questioned its validity and responsiveness(22, 23). It is felt that internal  
265 validity of the VISA-A was not adequately investigated in the original study(9), likely due to the fact  
266 that it was developed before the COSMIN guidelines were published. However, recent systematic  
267 reviews conclude that whilst the VISA-A demonstrates insufficient evidence for measurement error  
268 there is sufficient evidence for reliability, construct validity and responsiveness (24, 25).

269 In accordance with the COSMIN checklist(11), the VISA-A (sedentary) was developed using an  
270 adequate number of symptomatic patients and professionals from relevant disciplines, indicating that  
271 the questionnaire has content validity. Patient feedback and measures of internal consistency indicate  
272 that items 6-8 of the VISA-A are not relevant to sedentary individuals, with patients unable to score  
273 higher than 60/100 on this PROM. Measures of construct validity and responsiveness also  
274 demonstrate statistically significant differences between questionnaires for the activity dimension  
275 (Q6-8), which is not unexpected as the VISA-A was developed using an active population and is  
276 recommended for use in homogeneous groups(9, 10).

#### 277 Clinical implications:

278 Exploratory factor analysis identified the VISA-A (sedentary) as a two-dimensional PROM; therefore,  
279 each dimension should be scored out of 50 points (Appendix D). The MCID values were similar using  
280 distribution and anchor-based analyses, indicating that a change of 5 points for symptoms and 5 points  
281 for activity is clinically relevant for sedentary individuals with AT. Only 27/51 patients (52.9%) achieved  
282 the MCID of 14 points on the VISA-A(26), despite 49/51 (96.1%) patients recording a perceived  
283 improvement on the GROC.

#### 284 Limitations:

285 It was not possible to perform an EFA for the VISA-A, indicating a lack of structural validity in this  
286 cohort, therefore the VISA-A was split into the same dimensions as the VISA-A (sedentary) to allow



1  
2  
3 287 adequate analyses, as recommended by Comins et al(23). Although Cronbach's  $\alpha$  was acceptable  
4  
5 288 ( $>0.70$ ) for the VISA-A (sedentary) overall, the lower limit of the 95% CI was 0.593, and the  $\alpha$  value  
6  
7 289 was 0.563 for the activity dimension with wide confidence intervals. This may reflect the different  
8  
9  
10 290 scoring format and weighting of response options for items 7-8. Future studies should investigate  
11  
12 291 whether a more consistent and evenly weighted scoring system is warranted or improves the internal  
13  
14 292 consistency of the VISA-A (sedentary).

15  
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17  
18 293 The test-retest reliability of the VISA-A (sedentary) was excellent. Baseline questionnaires were  
19  
20 294 administered face-to-face in paper format, with follow up scores obtained 3-days later via phone call.  
21  
22 295 Although the environment (hospital versus home) and administration (paper versus telephone call) of  
23  
24 296 the two questionnaires were different, this method was employed to minimise patient inconvenience  
25  
26 297 and represents a pragmatic approach given the inherent difficulties in conducting research of this  
27  
28 298 nature amid the COVID-19 pandemic.

29  
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31  
32 299 To promote methodological quality of the study, recommendations from the COSMIN checklist were  
33  
34 300 adhered to where possible. Data from 51 patients were available for this study, indicating adequate  
35  
36 301 sample size. To be categorised as 'very good', at least 100 patients are required, therefore it is  
37  
38 302 recommended that the VISA-A (sedentary) is further investigated in studies with larger sample sizes.

39  
40  
41 303 The study sample contained a comparable number of male and female patients, but all individuals  
42  
43 304 were over the age of 40, which limits the generalisability of findings to younger sedentary patients.

44  
45  
46  
47 305 Several recent publications have identified an association between psychosocial variables and  
48  
49 306 outcomes in tendinopathy(27, 28). Although limited evidence exists for AT, and specific psychosocial  
50  
51 307 variables (e.g., kinesiophobia) were not voluntarily reported by patients in this study, the importance  
52  
53 308 of including a psychosocial domain may become more evident as our understanding of AT evolves.

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56  
57 309 **CONCLUSION:**

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3 310 The VISA-A (sedentary) demonstrates adequate reliability, validity, and responsiveness in sedentary  
4  
5 311 patients with AT. The VISA-A (sedentary) represents a more appropriate measure than the VISA-A for  
6  
7 312 this cohort and is recommended for clinical and research purposes, with each dimension scored out  
8  
9 313 of 50 points.

314

315

### 316 **Legends for figures and tables**

317 **Figure 1:** development of the VISA-A (sedentary).

318 **Figure 2:** flow of patients for the evaluation of the VISA-A sedentary: Rx: treatment.

319

320 **Competing interests:** None.

321 **Contributorship:** RN and SO contributed to the study design, development of the VISA-A (sedentary),  
322 data collection, data analysis and writing up of the study. JC and JG contributed to the study design  
323 and development of the VISA-A (sedentary). JR contributed to data collection. TW contributed to data  
324 analysis and writing up of the study.

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327 **Funding, grant and award info:** None.

328 **Ethical approval information:** This study was approved by the University research committee and the  
329 NHS Research Ethics Committee.

330 **Data sharing statement:** Full data sets of anonymised VISA-A, VISA-A (sedentary) and GROG scores  
331 are available, upon reasonable request, via email from the corresponding author.

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Confidential: For Review Only

## VISA-A (Sedentary)

Name:

Date:

For each question please mark the box that most accurately describes your usual Achilles tendon symptoms.

1. For how many minutes do you have STIFFNESS in the Achilles region following a period of prolonged inactivity (e.g. when first getting out of bed)?

0	10	20	30	40	50	60	70	80	90	100
10										0

2. Once you have warmed up for the day how much PAIN do you have when stretching your Achilles tendon?

no pain	0	1	2	3	4	5	6	7	8	9	10	strong severe pain
	10										0	

3. How much PAIN do you have when using stairs?

no pain	0	1	2	3	4	5	6	7	8	9	10	strong severe pain
	10										0	

4. For how many minutes does your Achilles PAIN last once you have stopped a painful activity?

0	10	20	30	40	50	60	70	80	90	100
10										0

5. How much PAIN do you have doing 10 double-legged heel raises? If you are unable to do 10, please mark your pain level for the number you can do.

no pain	0	1	2	3	4	5	6	7	8	9	10	strong severe pain
	10										0	

6. How many single-legged heel raises can you do on your affected side without PAIN?

0	1	2	3	4	5	6	7	8	9	10
0										10

## VISA-A (Sedentary)

7. At what level are you undertaking your normal activities due to your Achilles symptoms (e.g. walking, gardening or housework)?

Normal level or higher than when symptoms began (10)

Participating in full activities but not at the same level (7)

Modified activities (4)

Unable to participate (0)

8. Please answer question **A, B or C only**, depending on which section best describes your **PAIN** when walking. Do not complete all sections.

**A.** If you have **no pain when walking** on flat ground, for how long can you walk?

0-5 mins	6-10 mins	11-20 mins	21-30 mins	>30 mins
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	7	14	21	30

**B.** If you have **some pain when walking** on flat ground **but it does not stop you**, for how long can you walk?

0-5 mins	6-10 mins	11-20 mins	21-30 mins	>30 mins
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	4	10	14	20

**C.** If you have **pain that stops you walking** on flat ground, for how long can you walk?

0-5 mins	6-10 mins	11-20 mins	21-30 mins	>30 mins
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	2	5	7	10

---

Total score ( /100)  %

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The VISA-A questionnaire: An index of the severity of Achilles tendinopathy

**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?**

0	10	20	30	40	50	60	70	80	90	100
10										0

- 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)**

no pain	0	1	2	3	4	5	6	7	8	9	10	strong severe pain
	10										0	

- 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, mark box 10 for this question).**

no pain	0	1	2	3	4	5	6	7	8	9	10	strong severe pain
	10										0	



1  
2  
3 **4. Do you have pain walking downstairs with a normal gait cycle?**  
4  
5  
6  
7

8 no pain 

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

 strong  
9 severe  
10 pain  
11 10 0

12  
13  
14  
15  
16  
17 **5. Do you have pain during or immediately after doing 10 (single leg) heel**  
18 **raises from a flat surface?**  
19

20 no pain 

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

 strong  
21 severe  
22 pain  
23 10 0

24  
25  
26  
27  
28  
29  
30  
31 **6. How many single leg hops can you do without pain?**  
32

33  
34  
35  
36 

0	1	2	3	4	5	6	7	8	9	10
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37 0 10

38  
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42  
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44  
45 **7. Are you currently undertaking sport or other physical activity?**  
46

- 47  Not at all (0)  
48  
49  Modified training ± modified competition (4)  
50  
51  Full training ± competition but not at same level as when symptoms began (7)  
52  
53  Competing at the same or higher level as when symptoms began (10)  
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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/practice?

NIL	1-10 mins	11-20 mins	21-30 mins	>30 mins
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
0	7	14	21	30

**OR**

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

NIL	1-10 mins	11-20 mins	21-30 mins	>30 mins
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
0	4	10	14	20

**OR**

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

0-5 mins	6-10 mins	11-20 mins	21-30 mins	>30 mins
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
0	2	5	7	10

---

Total score ( /100)  %

---

## GLOBAL RATING OF CHANGE SCALE (GROC)

Please rate the overall change in your Achilles tendon symptoms from the time that you began treatment until now (tick one box only).

- |   |   |   |
|---|---|---|
| <input type="checkbox"/> A very great deal worse (-7) | <input type="checkbox"/> About the same (0) | <input type="checkbox"/> A very great deal better (7) |
| <input type="checkbox"/> A great deal worse (-6)      |   | <input type="checkbox"/> A great deal better (6)      |
| <input type="checkbox"/> Quite a bit worse (-5)       |   | <input type="checkbox"/> Quite a bit better (5)       |
| <input type="checkbox"/> Moderately worse (-4)        |   | <input type="checkbox"/> Moderately better (4)        |
| <input type="checkbox"/> Somewhat worse (-3)          |   | <input type="checkbox"/> Somewhat better (3)          |
| <input type="checkbox"/> A little bit worse (-2)      |   | <input type="checkbox"/> A little bit better (2)      |
| <input type="checkbox"/> A tiny bit worse (-1)        |   | <input type="checkbox"/> A tiny bit better (1)        |

## The VISA-A (sedentary) questionnaire

Name:

Date:

For each question, please mark the box that most accurately describes your usual Achilles tendon symptoms.

1. For how many minutes do you have **STIFFNESS** in the Achilles region following a period of prolonged inactivity (e.g. when first getting out of bed)?

0	10	20	30	40	50	60	70	80	90	100
10										0

2. Once you have warmed up for the day, how much **PAIN** do you have when stretching your Achilles tendon?

no pain	0	1	2	3	4	5	6	7	8	9	10	strong severe pain
	10										0	

3. How much **PAIN** do you have when using stairs?

no pain	0	1	2	3	4	5	6	7	8	9	10	strong severe pain
	10										0	

4. For how many minutes does your Achilles **PAIN** last once you have stopped a painful activity?

0	10	20	30	40	50	60	70	80	90	100
10										0

5. How much **PAIN** do you have doing 10 double-legged heel raises? If you are unable to do 10, please mark your pain level for the number you can do.

no pain	0	1	2	3	4	5	6	7	8	9	10	strong severe pain
	10										0	

Symptoms total: /50

## The VISA-A (sedentary) questionnaire

6. How many single-legged heel raises can you do on your affected side without **PAIN**?

0	1	2	3	4	5	6	7	8	9	10
0										10

7. At what level are you undertaking your normal activities due to your Achilles symptoms (e.g., walking, gardening, or housework)?

- Normal level or higher than when symptoms began (10)
- Participating in full activities but not at the same level (7)
- Modified activities (4)
- Unable to participate (0)

8. Please answer question **A, B or C only**, depending on which section best describes your **PAIN** when walking. Do not complete all sections.

- A.** If you have **no pain when walking** on flat ground, for how long can you walk?

0-5 mins	6-10 mins	11-20 mins	21-30 mins	>30 mins
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	7	14	21	30

- B.** If you have **some pain when walking** on flat ground **but it does not stop you**, for how long can you walk?

0-5 mins	6-10 mins	11-20 mins	21-30 mins	>30 mins
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	2	5	7	10

- C.** If you have **pain that stops you walking** on flat ground, for how long can you walk?

0-5 mins	6-10 mins	11-20 mins	21-30 mins	>30 mins
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	2	5	7	10

Activity total:      /50

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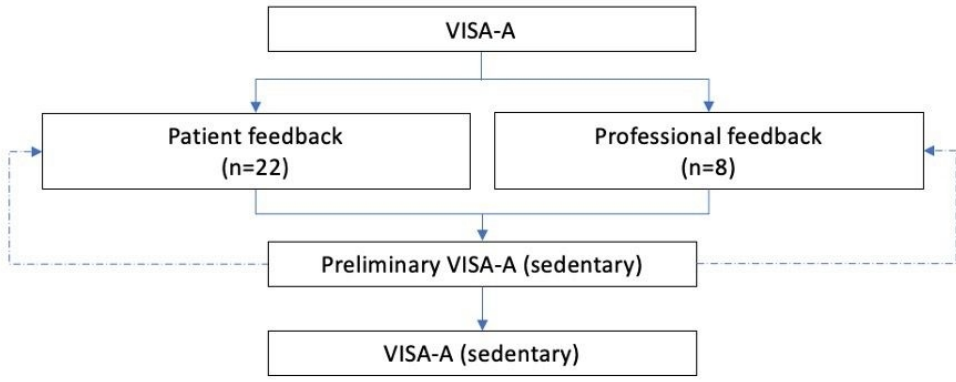


Figure 1: development of the VISA-A (sedentary).

76x33mm (300 x 300 DPI)

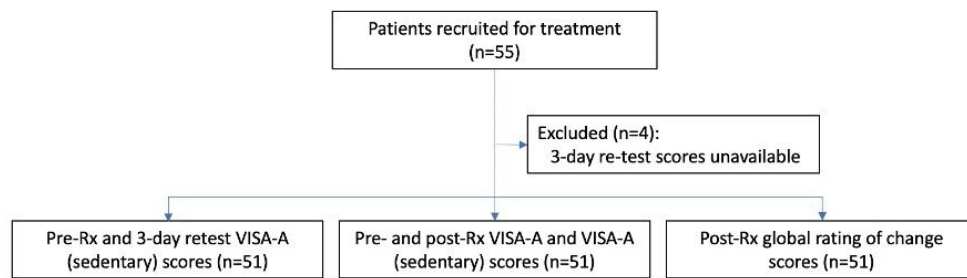


Figure 2: flow of patients for the evaluation of the VISA-A sedentary: Rx: treatment.

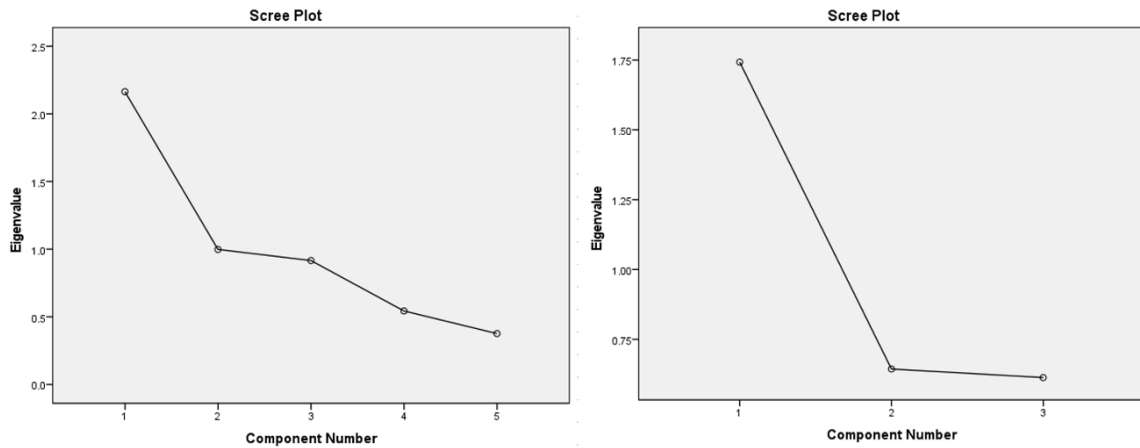
76x23mm (300 x 300 DPI)

## 1 SUPPLEMENTARY MATERIAL:

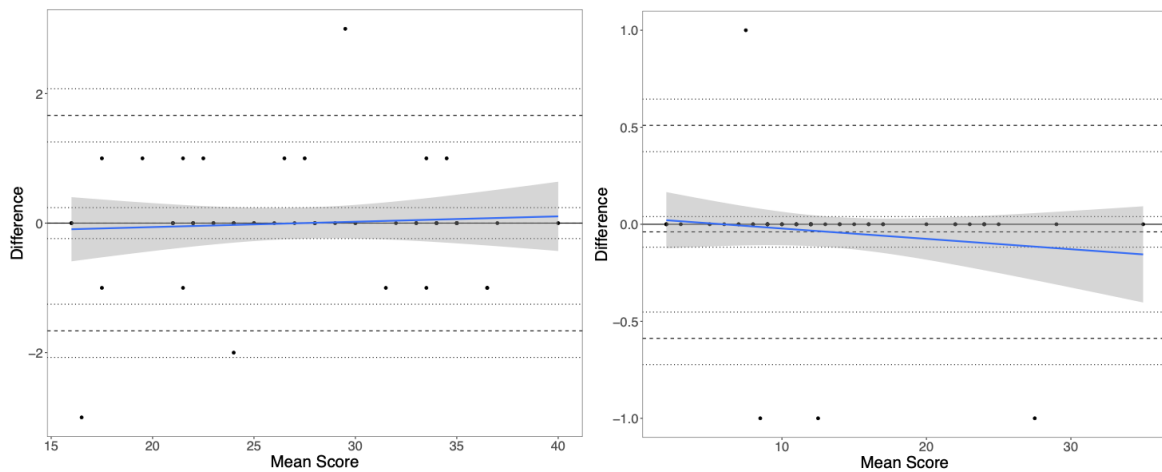
	Summary of patient and professional comments/feedback for the VISA-A	Issues
Q1	<p><b>For how many minutes do you have stiffness in the Achilles region on first getting up?</b></p> <p>Patients agreed that stiffness in the Achilles region is a symptom of Achilles tendinopathy.</p> <p>Patients were unsure whether 'first getting up' referred to the first steps after getting out of bed or after other periods of inactivity (e.g., prolonged sitting).</p> <p>Some patients only reported stiffness after other periods of inactivity, not when getting out of bed.</p>	<p>Comprehensibility</p> <p>Response options</p>
Q2	<p><b>Once you have warmed up for the day, do you have pain when stretching the Achilles tendon fully over the edge of a step? (keeping knee straight)</b></p> <p>Patients agreed that stretching the Achilles can aggravate pain.</p> <p>Some patients did not feel safe performing the test over the edge of a step.</p>	<p>Relevance</p>
Q3	<p><b>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, mark box 10 for this question).</b></p> <p>Patients agreed that walking can aggravate Achilles pain.</p> <p>Patients found it difficult to provide an accurate score due to the complexity of the question.</p>	<p>Comprehensibility</p>
Q4	<p><b>Do you have pain walking downstairs with a normal gait cycle?</b></p> <p>Patients agreed that stairs can aggravate pain.</p> <p>Pain on stairs was often worse, or only present, when ascending stairs.</p>	<p>Comprehensiveness</p> <p>Response options</p>
Q5	<p><b>Do you have pain during or immediately after doing 10 (single leg) heel raises from a flat surface?</b></p> <p>Patients agreed that single leg heel raises can aggravate pain.</p> <p>Several patients were unable to perform 10 single leg heel raises due to fatigue/weakness.</p>	<p>Relevance</p> <p>Response options</p>
Q6	<p><b>How many single leg hops can you do without pain?</b></p> <p>Patients felt hopping on one leg was neither possible, nor a functional task, and all patients reported this as not relevant.</p>	<p>Relevance</p>
Q7	<p><b>Are you currently undertaking sport or other physical activity?</b></p> <p>No patients were participating in 'training' or 'competition'.</p> <p>Other physical activities were impacted including walking, housework, and gardening.</p>	<p>Relevance</p> <p>Response options</p>
Q8	<p><b>Pain during Achilles tendon loading sport.</b></p> <p>No patients were participating in tendon loading sports (training or games).</p> <p>Patients answered more than one part of the question and, although the question states that they should complete EITHER A, B or C, they felt this needed to be emphasised.</p>	<p>Relevance</p> <p>Comprehensibility</p> <p>Instructions</p> <p>Response options</p>
Other	<p>Duration of pain after a provocative exercise is not included in the questionnaire</p> <p>The scale should be reversed so that "no pain" is positioned to the left of the scale and "strong severe pain" to the right.</p> <p>The relevant symptom or instruction for each question should be emphasised, especially question eight.</p>	<p>Comprehensiveness</p> <p>Comprehensibility</p> <p>Instructions</p>

2 Supplementary table 1: Patient and professional feedback regarding the VISA-A.

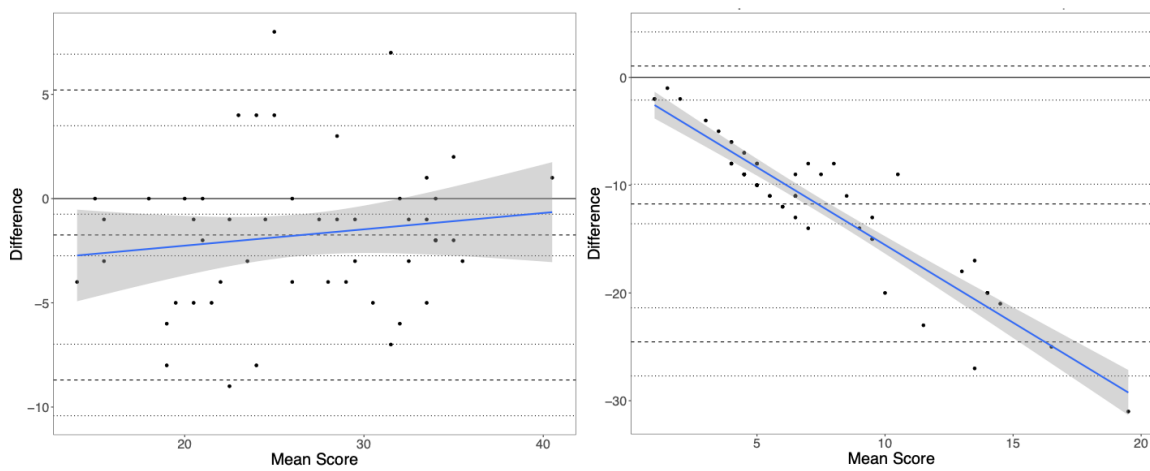




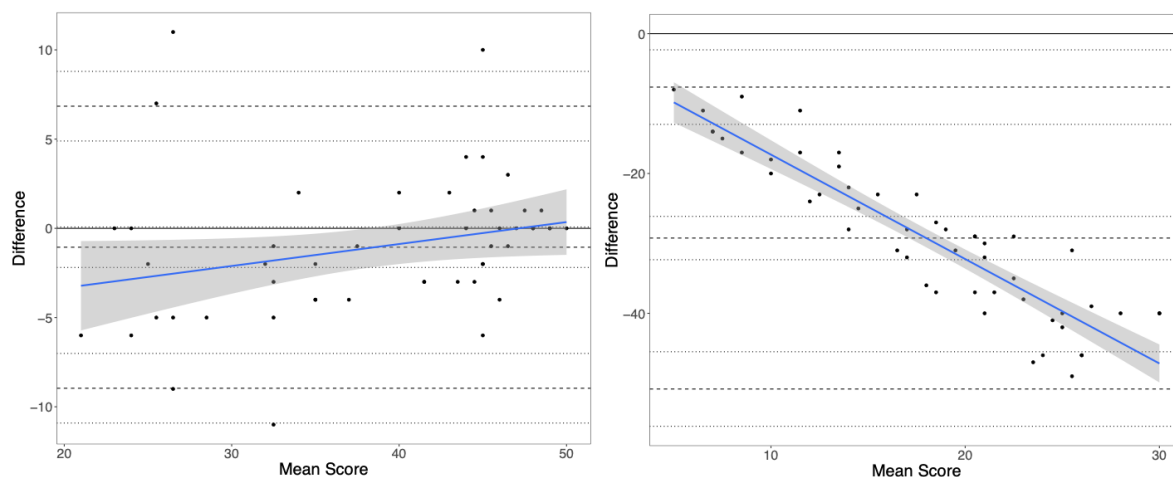
Supplementary figure 1: Scree plots for symptoms (left) and activity (right).



Supplementary figure 2: Bland-Altman plots for VISA-A (sedentary) pre-treatment versus 3-day retest symptoms (left) and activity (right).



Supplementary figure 3: Bland-Altman plots for pre-treatment VISA-A (sedentary) versus VISA-A symptoms (left) and activity (right).



**Supplementary figure 4:** Bland-Altman plots for post-treatment VISA-A (sedentary) versus VISA-A symptoms (left) and activity (right).

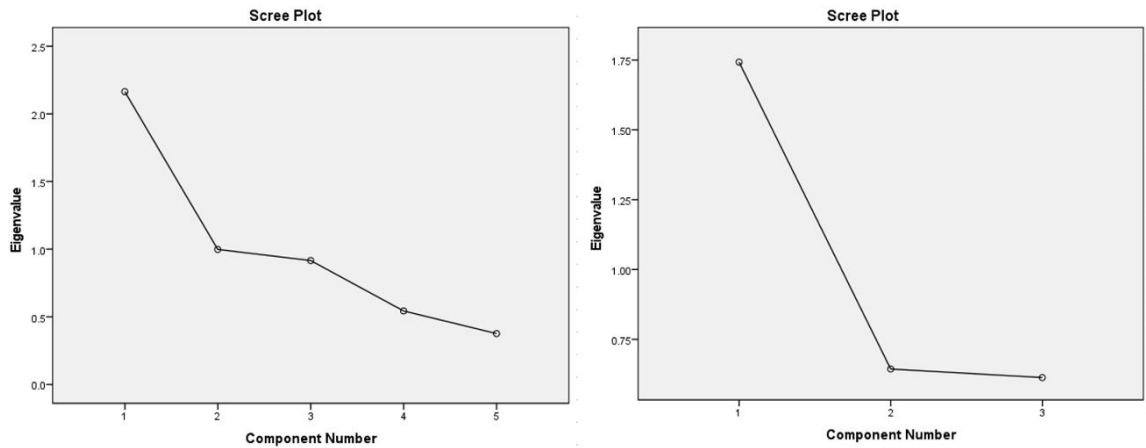
	Mean change	SD of change	SD of pre-Rx scores	SD of post-Rx scores	SD of scores pooled	ES (Cohen)	SRM
VISA-A (sedentary) symptoms - no change	8.27	4.10	7.635	10.147	8.98	0.92	2.02
VISA-A (sedentary) symptoms - change	12.60	6.91	6.013	8.001	7.08	1.78	1.82
VISA-A (sedentary) activity - no change	15.55	10.40	7.737	13.494	11.00	1.41	1.50
VISA-A (sedentary) activity - change	20.43	9.85	7.342	11.432	9.61	2.13	2.07

**Supplementary table 2:** effect size (ES) and standardised response means (SRM). SD: standard deviation, Rx: treatment.

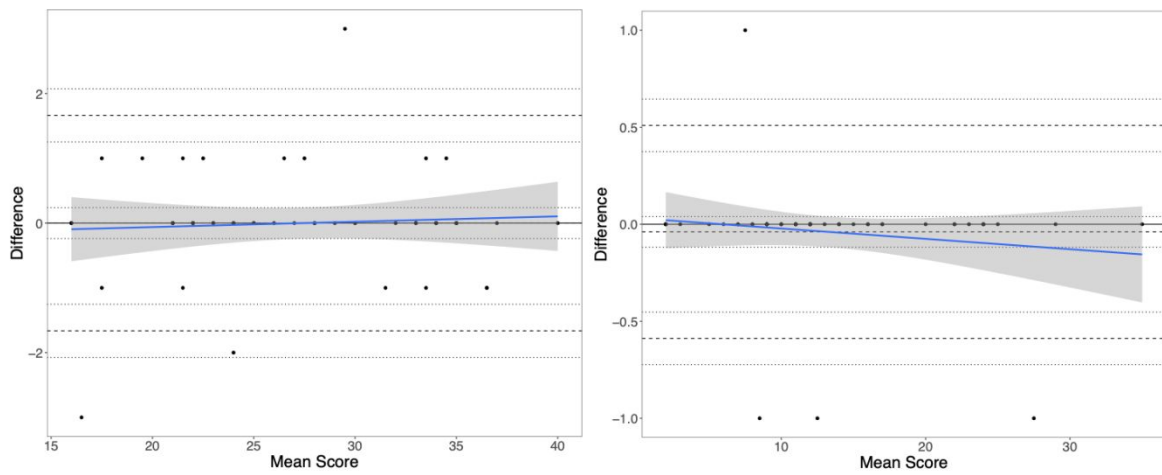
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Other	<p>Duration of pain after a provocative exercise is not included in the questionnaire</p> <p>The scale should be reversed so that "no pain" is positioned to the left of the scale and "strong severe pain" to the right.</p> <p>The relevant symptom or instruction for each question should be emphasised, especially question eight.</p>	<p>Comprehensiveness</p> <p>Comprehensibility</p> <p>Instructions</p>

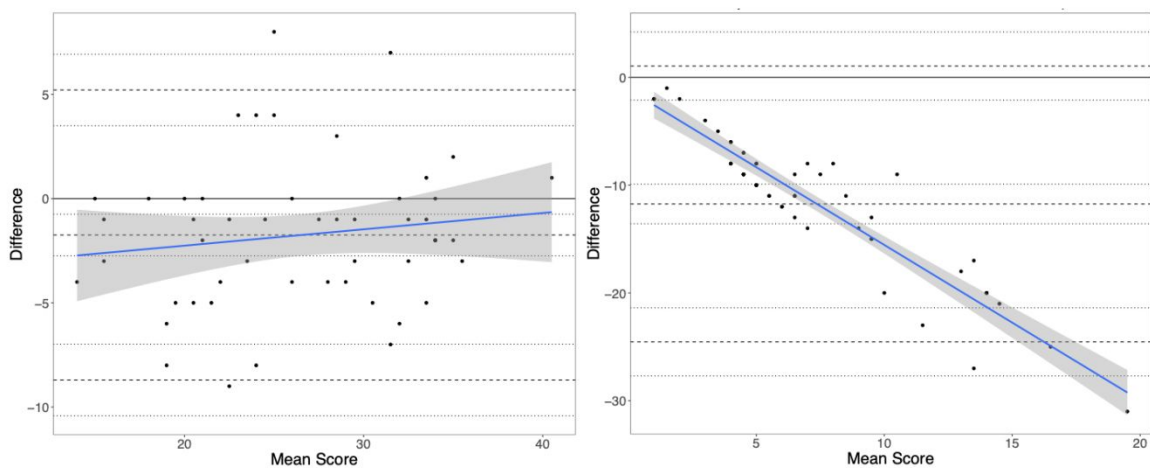
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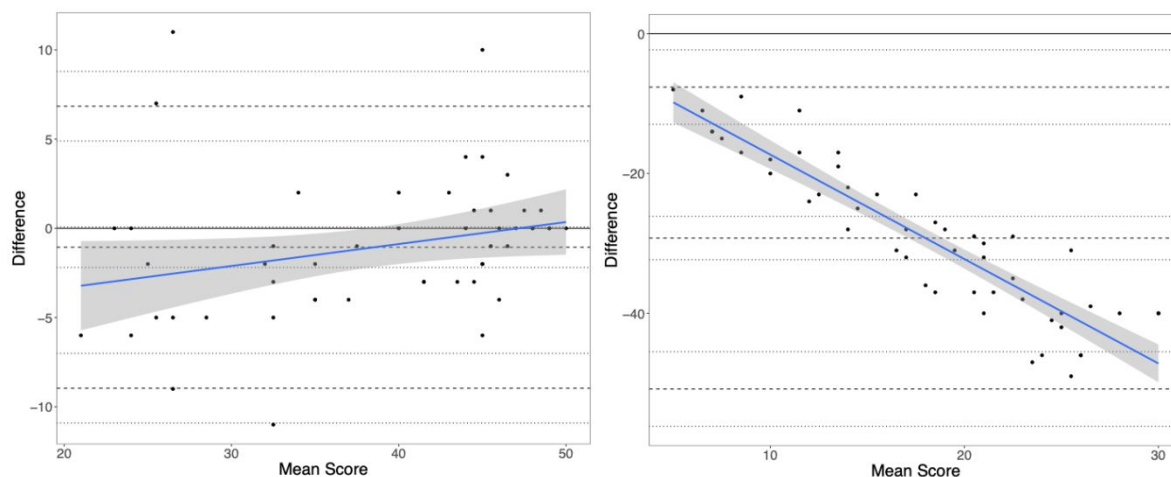
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VISA-A (sedentary) activity - change	20.43	9.85	7.342	11.432	9.61	2.13	2.07

Responsiveness	ES (Cohen)	SRM
VISA-AS(pain) no resp	0.92	2.02
VISA-AS(pain) resp	1.78	1.82
VISA-AS(function) no resp	1.41	1.50
VISA-AS(function) resp	2.13	2.07

Supplementary table 2: effect size (ES) and standardised response means (SRM). SD: standard deviation, Rx: treatment.