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1 **A randomised feasibility study using an acupuncture protocol to**
2 **the Achilles tendon in Achilles tendinopathy**

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1 **Abstract**

2 **Background:** The prevalence of Achilles tendinopathy is greatest in activities including middle
3 and long distance running, tennis, badminton, volleyball, and its incidence is increasing.
4 However, currently no gold standard treatment for Achilles tendinopathy exists, although
5 eccentric exercises are commonly recommended.

6 **Purpose:** This study aimed to investigate the changes in clinical scores when administering a)
7 acupuncture and b) sham acupuncture to the Achilles tendon in patients diagnosed with Achilles
8 tendinopathy who did not respond to modified eccentric exercises.

9 **Methods:** Twenty-two patients were randomised and received either acupuncture or the control
10 sham acupuncture treatment. VISA-A, NPRS, EQ-5D and GRC were recorded before
11 treatment at week 0, then at week 2, week 4 with a final follow-up review at week 12.

12 **Main Results:** Acupuncture resulted in significant differences between groups and time points
13 in VISA-A, NPRS, EQ-5D and GRC. The Acupuncture group reached the minimum clinically
14 important difference (MCID) threshold for important difference, when compared to sham
15 acupuncture. The difference between treatments would suggest a beneficial response following
16 the use of acupuncture to the Achilles tendon in Achilles tendinopathy.

17 **Principal Conclusions:** The overall findings suggest the use of a standardised acupuncture
18 protocol to the Achilles tendon is a viable treatment alternative, which could be used as a second
19 line treatment in patients diagnosed with Achilles tendinopathy who did not respond to
20 eccentric exercises. However, in view of the small sample size, the results of this preliminary
21 study should be viewed with caution.

22

23 **Key Words:** Acupuncture, Sham Acupuncture, Achilles tendon, Tendinopathy, VISA-A.

24

25

26 **Introduction**

27 The incidence of Achilles tendon injuries is increasing as more individuals regularly exercise
28 both recreationally, and within sports [1,2]. The prevalence of Achilles tendinopathy is greatest
29 in activities involving endurance running [3-6]. Injuries are also seen in sedentary individuals,
30 De Jonge et al. [7] suggest that 65% of patients diagnosed with Achilles tendinopathy have no
31 link to sport or physical activity.

32

33 The mid-portion of the Achilles tendon is the most commonly injured site accounting for 55-
34 65% of all Achilles tendon injuries [3]. Due to the quality and methodological shortcomings in
35 studies [8], there is still no gold standard treatment for Achilles tendinopathy [9]. At present
36 the greatest amount of evidence supports eccentric exercise as a first line treatment option [10-
37 12], however, this is not always successful. Acupuncture is one of the best known
38 complementary therapy treatments, and is widely used for musculoskeletal disorders and has
39 been shown to offer pain relief [13].

40

41 Pain relief may be related to the spinal acupuncture mechanisms through the effects of counter
42 stimulation, the supraspinal acupuncture mechanisms of pain relief through the diffuse noxious
43 inhibitory control (DNIC), and the stimulation of the descending anti-nociceptive pathway and
44 the limbic regions of the brain [39]. Whereas, increased blood flow and oxygenation to the
45 Achilles tendon following acupuncture may be related to the stimulation of A-Delta and C-
46 afferent fibres and the release of pro-inflammatory neuropeptides, which is mainly mediated by
47 CGRP [36] may initiate a healing response.

48

49 To date one study has explored its use in the treatment of Achilles tendinopathy [14]. An
50 increase from baseline was found in the acupuncture group Victorian Institute of Sports

51 Assessment – Achilles (VISA-A) of 25.8 after 16 week and 28.4 after 24 weeks, whilst the
52 Visual Analogue Scale (VAS) decreased by 3.2 at rest. The results suggested significant
53 functional improvements and decreases in pain, which were greater following the use of
54 acupuncture compared to eccentric exercise. However, when considering clinical outcome
55 measures associated with Achilles tendinopathy treatments in a general NHS population, the
56 Numerical Pain Rating Scale (NPRS) [16], Global Rate of Change (GRC) and Euroqol-5D (EQ-
57 5D) may also assist in identifying change in pain and health status. However, these outcome
58 measures have not been validated for use on the Achilles tendon.

59
60 The aim of this randomised feasibility study was to investigate the changes in clinical scores
61 when administering a) acupuncture and b) sham acupuncture to participants diagnosed with
62 Achilles tendinopathy who were non-responders to a standardised eccentric loading
63 programme.

64

65 **Method**

66 One hundred and fifty-two patients with an Achilles tendon pain were referred to physiotherapy
67 mainly through the GP service. Sixty-three patients were excluded due to; presence of
68 insertional Achilles tendinopathy (24), naturally resolving symptoms (7), did not attend (7),
69 medical co-morbidities (5), lumbar origin (5), other tendinopathies (3), declined intervention (3),
70 ruptures (2), ankle OA (2), plantar fasciitis (2), unable to attend (1), referred for further
71 investigation (1) and previous Achilles rupture (1). Of the eighty-nine eligible patients who
72 consented, eighty-four patients (45 male, 39 female) were recruited, 80 patients (41 male, 39
73 female) completed the modified eccentric exercise phase (conservative treatment including the
74 modified eccentric loading protocol).

75 The modified eccentric exercise protocol used in this study was adapted from Alfredson et al.
76 [17]. Participants performed two types of eccentric exercises, a) with knees straight, b) with
77 the knees bent (within a pain framework – pain no greater than VAS 4/10). Both exercises
78 were performed bilaterally or unilaterally, depending on the level of discomfort not exceeding
79 VAS 4/10 and, using minimal concentric movement, whilst arms were used to return to the
80 starting position. Each exercise included up to 15 repetitions performed in 3 sets (15x3) once
81 per day. The use of minimal pain free concentric movement was chosen due to differing levels
82 of participant fitness.

83
84 Twenty-two patients (8 male, 14 female) aged between; 35 to 72, who were non-responders to
85 conservative care were randomised and received either acupuncture or sham acupuncture
86 treatment. The 22 patients were aged 51.8 years (8.9), height 1.70 meters (0.1), weight 89.3kg
87 (14.1), percentage body fat 34.5% (7.0%) and had a BMI of 30.2 (3.1). Strain gauge weighing
88 scales were used to measure body weight, stature was measured using a standard tape measure
89 against a wall, whilst bioelectric impedance analysis was used to measure percentage body fat.
90 Figure 1 shows the Achilles tendinopathy patient treatment and assessment flowchart. Ethical
91 approval was gained from NRES Committee North West – Greater Manchester South - REC
92 12/NW/0035, the University of Central Lancashire – BuSH 067 with Research and
93 Development approval obtained from Southport and Ormskirk NHS Trust – 2011/059/LTC.
94 All procedures followed during the study were in accordance with the Helsinki Declaration.

95
96 All patients were provided with modified eccentric exercises (within a pain framework – pain
97 no greater than VAS 4/10) that allowed minimal pain free concentric movement. Standard static
98 stretching was also provided coupled with appropriate footwear advice, orthotics, and
99 management advice. During this 6-week phase patients were seen four times, two weeks apart

100 over a 6-week period. The non-responders to modified eccentric exercises and standard
101 treatment were invited to be randomised into two treatment groups, a) acupuncture or b) sham
102 acupuncture. The randomisation was performed using a computer generated random number
103 list. Once consent had been provided for the acupuncture phase, three acupuncture treatments
104 occurred at weekly intervals, at week 0, week 1 and week 2.

105 'Insert Figure 1 here'

106

107 The Acupuncture treatment was provided by a member of the Acupuncture Association of
108 Chartered Physiotherapists (AACCP) and followed AACCP guidelines. The Acupuncture
109 technique used was standardised 9-needle Achilles tendon acupuncture protocol [17], Figure 2.
110 The Achilles tendon was cleaned using alcohol wipe sterets, with participants positioned in
111 prone lying. Nine small plastic rings covered with sterile tape were then attached to the Achilles
112 tendon to enable the Streitberger sham acupuncture needles to remain in place [18,19].
113 Acupuncture or sham acupuncture needles were then inserted into the Achilles tendon, with the
114 needles stimulated for 60 seconds every 5 minutes in a thrusting/twisting motion. The
115 acupuncture session ended 30 minutes after the last acupuncture or sham acupuncture needle
116 was inserted, then needles were removed.

117 'Insert Figure 2 here'

118

119 All patients were assessed using the VISA-A, NPRS, GRC and EQ-5D forms. The GRC has
120 been used as an 11 point Likert scale in numerous studies [20,21] with [22] recommending the
121 use of an 11-point scale for GRC over other scales. The EQ-5D is a standardised measure of
122 health status, and is a quality of life questionnaire which comprises of 5 questions relating to
123 health, mobility, ability to self-care, ability to undertake usual activities, and anxiety and
124 depression, which have been shown to be valid and reliable [23-25]. Although, no data has

125 linked these measures with Achilles tendinopathy. When used as a secondary outcome measure,
126 this may provide a holistic approach to research with Achilles tendinopathy. Scoring for the
127 EQ5D is based on a scale of >0 being death and 1 representing full health. From the 5 health
128 dimensions measured, scores are then inserted into the EQ5D index value calculator. This then
129 provided an index of health – between 0 and 1. Clinical scores were measured before
130 acupuncture and sham acupuncture treatment and assessment at week 0 (session 1), before
131 treatment on week 2 (session 2), before review and reassessment at week 4 (session 3) and
132 before the final follow-up review at week 12 (session 4).

133

134 **Statistical analysis**

135 Differences between the two groups and time points in the VISA-A, NPRS, GRC. VISA-A and
136 NPRS scores were tested for normality of distribution using the Kolmogorov-Smirnov test and
137 were found to be normally distributed and suitable for parametric statistical testing, whereas
138 the EQ-5D scores were found to be non-normatively distributed. A Repeated Measures
139 ANOVAs was used for the VISA-A and NPRS scores and a Mann-Whitney U test was used
140 for the EQ-5D scores. In addition to the Repeated Measures ANOVAs the effect sizes were
141 also calculated, and p values <0.05 were regarded as significant. The differences between
142 groups and time points were further explored using mixed methods ANOVAs. All data analysis
143 was performed using SPSS version 21 (Chicago, IL, USA).

144

145 To determine clinical importance there are two factors involved; the minimum clinically
146 important change (MCIC) from baseline of pre-treatment to a certain time point in a primary
147 endpoint of a treatment, and the minimum clinically important difference (MCID) between
148 treatment groups (Togo et al. [99**]). As the definition of MCIC in the literature has been used
149 interchangeably with MCID, in this study the same value will be used for both the MCIC and

150 MCID. The clinically important thresholds for the outcome measures were based on previous
151 research with 16 points for the VISA-A [26], 2 points for the average pain for the NPRS [27]
152 and an index value of 0.074 for the EQ-5D [28]. The GRC was dichotomised [29,30] into
153 responders and non-responders, the rate of success was expressed as patients who achieved +3,
154 +4 and +5 points, from an 11 point GRC scale (ranging from -5 much worse to +5 much better).

155

156 **Results**

157 Differences between the two groups confirmed a significant difference ($p<0.001$) between
158 acupuncture and sham acupuncture groups. The total change in acupuncture and sham
159 acupuncture EQ-5D from baseline to the final follow-up session in week 12 was 0.16 and 0.01
160 respectively. Overall acupuncture showed a greater increase in EQ-5D score in comparison to
161 sham acupuncture by 0.15. The Repeated Measures ANOVA show a significant mean increase
162 in VISA-A score following both acupuncture and sham acupuncture. Additionally, a significant
163 decrease in NPRS score was seen in the acupuncture group, whilst no significant difference
164 was seen in the sham acupuncture group, table 1.

165

166 'Insert table 1 here'

167

168 Further pairwise comparisons were conducted for the significant main effects, table 2. The
169 acupuncture group showed a significant difference between all weeks/sessions ($p<0.001$ to
170 $p<0.002$), with the exception of week 4 to week 12, where treatment effects stabilised. For sham
171 acupuncture, a significant increase between the baseline in week 0 to week 4 ($p=0.002$), and to
172 the final follow-up session in week 12 ($p=0.016$). For the NPRS scores the acupuncture group
173 showed significant differences between the baseline at week 0 and week 2 ($p<0.001$), and
174 between weeks 4 and 12 ($p<0.003$), table 2. The largest change occurred between baseline in

175 week 0 and week 4, with a decrease of 2.91 points, although this then increased slightly by 0.36
176 points at the final follow up session in week 12.

177

178 'Insert table 2 here'

179

180 The mixed methods ANOVA show no significant difference in NPRS and VISA-A scores over
181 the time points for grouped data ($p=0.152$, $p=0.163$). However, significant differences were
182 seen between treatment groups ($p<0.001$), with the acupuncture group demonstrating a
183 significant difference of 12.42 points ($p=0.001$) in the VISA-A and 1.55 points ($p=0.001$) in
184 the NPRS when compared to sham acupuncture.

185

186 'Insert Table 3 here'

187

188 The GRC was dichotomised [29,30] into responders and non-responders. The acupuncture
189 group demonstrated 73% of patients were responders, whereas the sham acupuncture group
190 demonstrated 36% responders. Dichotomisation showed that there were 73% of responders in
191 the VISA-A score in the acupuncture group, more than double that of the 27% of responders in
192 the sham acupuncture group, when the cut point for clinical significance is a change of 16
193 points. The percentage of responders for VISA-A score is equal to the number of responders
194 for the GRC. For NPRS, 64% of responders in the NPRS score in the acupuncture group, more
195 than triple that of the 18% of responders in the sham acupuncture group, when the cut point for
196 clinical significance is based on a change of 2 points.

197

198 **Discussion**

199 Acupuncture resulted in a statistically and clinically significant increase in VISA-A scores from
200 baseline to session 4 by 27 points. When compared from baseline, the use of acupuncture to the
201 Achilles tendon in Achilles tendinopathy exceeded the 16 point threshold for VISA-A MCIC
202 and MCID at 12 weeks. The greatest increase in VISA-A was noted in session 3 and 4, at week
203 4 and week 12 respectively, following the acupuncture treatment. This suggests that
204 improvement seen following the final acupuncture treatment in week 2 was maintained for the
205 follow-up periods.

206

207 Only one previous study by Zhang et al. has explored the use of acupuncture measured pain
208 and function using the VISA-A [14]. This reported a significant increase in at 8 weeks by 22.1
209 points, at 16 weeks by 25.8 points and at 24 weeks by 28.4 points which supports the findings
210 of this study. However, Zhang et al. used 4 acupuncture needles into a painful area in the
211 Achilles tendon, which could not be kept consistent between treatments or participants; as the
212 painful area can increase or decrease in size between treatment and participants.

213

214 The increase in VISA-A score following acupuncture is similar to that reported by Tumilty et
215 al. [26] and Rompe et al. [31], who found a significant increase from baseline to 18.5 points at
216 the week 4, increasing to 32.4 points at 12 weeks and an increased VISA-A scores in Achilles
217 tendinopathy following eccentric loading and Extra Corporeal Shock Wave Therapy (ESWT)
218 respectively. Eccentric loading increased by 25 points at the 4 month follow-up compared to
219 the ESWT group increase by 20.1 points. [32] also reported increased VISA-A scores in
220 Achilles tendinopathy following both eccentric loading only and eccentric loading coupled with
221 ESWT. The eccentric loading group increased by 22.7 points at 4 months; whereas the
222 combined eccentric with the ESWT group increased by 36.3 points.

223

224 Acupuncture resulted in a 2.5 point NPRS decrease in pain compared to a 0.27 point decrease
225 following sham acupuncture. Therefore, the standardised acupuncture protocol to the Achilles
226 tendon in the Achilles tendinopathy RCT met the MCIC and MCID 2 point threshold for the
227 decrease in pain using the NPRS outcome measure. The greatest decrease in pain occurred at
228 week 4. Similar to the results of the VISA-A, if a greater number of treatments had been
229 administered, this may have resulted in greater reductions in pain. Similarly, Rompe et al. [32]
230 reported a significant decrease in NPRS in Achilles tendinopathy following both eccentric
231 loading only and eccentric loading coupled with ESWT. The eccentric loading group decreased
232 by 3.1 points at 4 months, whereas the combined eccentric with ESWT group decreased by 4.4
233 points. Conversely, Tumilty et al. [26] reported a non-significant decrease in NPRS at 4 weeks
234 when using LLLT to the Achilles tendon which suggests acupuncture to the Achilles tendon
235 may be more useful than LLLT in Achilles tendinopathy.

236

237 The overall difference in average Achilles tendon pain over a one week period using NPRS
238 between acupuncture and sham acupuncture, resulted in a significant difference of -1.55 points
239 (-2 points). No significant difference were seen in the NPRS following sham acupuncture,
240 despite an initial decrease from baseline to session 2 by 1 point. Interestingly by session 4 at
241 week 12, pain returned to baseline values, suggesting sham acupuncture is ineffective in
242 reducing pain. The initial reduction in pain is likely to be related to mixed mechanisms of a
243 placebo response, and the limbic touch response (Lundeberg et al., 2008 [28**]; Lund et al.,
244 2009 [29**]), and suggests any reduction in pain occurring from sham acupuncture may be
245 short lived..

246

247 In addition, the standardised acupuncture protocol to the Achilles tendon in the Achilles
248 tendinopathy exploratory randomised control study exceeded the MCIC and MCID 0.074 point

249 threshold for the improvement in health [28]. This was supported by the positive and
250 statistically significant VISA-A and NPRS data that show all values change in the same
251 direction, suggesting improvement and an effective treatment. Furthermore, GRC data
252 demonstrated that 73% of patients in the Acupuncture group responded to treatment. Therefore,
253 if a patient has less pain, this could result in an increase in function and activities of daily living.
254

255 Potential mechanisms

256 The potential physiological mechanisms behind the effects found in this study could be related
257 to the local and segmental effects of acupuncture reported by Tian et al. [33]. The clinical
258 improvements noted in the acupuncture group, may be related to the local increase in blood
259 flow and oxygenation, through pro-inflammatory effects and the mechanism of axon reflexes
260 and the inhibition of the sympathetic nervous system [34,35]. The stimulation of A-Delta and
261 C-afferent fibres would release vasoactive and pro-inflammatory neuropeptides such as CGRP,
262 substance P, neurokinin and opioids. This would result in peripheral vasodilation in to the
263 Achilles tendon, which is mainly mediated by CGRP [36]. The release of growth factors such
264 as VEGF following acupuncture could promote an increased vascular response following
265 acupuncture and assist in Achilles tendon healing, by the local increase in fibroblasts and
266 tenocytes which result in cellular proliferation and collagen synthesis [37]. The functional
267 improvement seen in the VISA-A could suggest tissue healing may have occurred, which could
268 enable the structure and function of the Achilles tendon to return to its pre-injury status [38].

269

270 The local reduction in pain may also be related to the spinal acupuncture mechanisms through
271 the effects of counter stimulation [39]. The supraspinal acupuncture mechanisms of pain relief
272 through the diffuse noxious inhibitory control (DNIC), could account for a short-term pain
273 relief following treatment in the few patients that experienced this. The reduction in pain may

274 be related to the stimulation of the descending anti-nociceptive pathway and the limbic regions
275 of the brain. This would result in the release of betaendorphins, ACTH and cortisone. Studies
276 using fMRI [33,40] have reported that a strong DeQi stimulation resulted in significant
277 deactivations in the brain, indicating a mechanism for pain relief.

278

279 The standardised Achilles tendon acupuncture protocol [17] on patients with Achilles
280 tendinopathy, is suggested to primarily stimulate the Achilles tendon locally, causing local pro-
281 inflammatory healing and pain relieving effects. The use of acupuncture could also activate all
282 three mechanisms of acupuncture analgesia, locally, segmentally/spinally and supraspinally
283 [39].

284

285 Strengths and Limitations

286 No dropouts were recorded in the 22 patients randomised into the acupuncture or sham
287 acupuncture treatment groups which increases the confidence in the results by reducing the bias
288 that can be introduced through dropouts. The non-specific effects of acupuncture and sham
289 acupuncture [41] were controlled as the same protocol, practitioner, patient-therapist interaction
290 resulted in equal empathy and communication to all patients between groups. However, this
291 was a single blinded exploratory randomised control study where only the participant was
292 blinded, and where the principle investigator in this study was also the acupuncturist and
293 physiotherapist, which could introduce bias.

294

295 Although both needling techniques were uncomfortable, the intensity during a 60 second
296 stimulation of an acupuncture is stronger than the stimulation of a sham needle. However, as
297 no patient had experienced penetrative acupuncture to the Achilles tendon, this was not felt to
298 affect blinding. Improvements in pain may be, in part related to the 4 day relative rest phase

299 between treatment and by following a pain framework of not exceeding VAS 4/10 for general
300 activities. However, as the majority of patients had rested and offloaded unsuccessfully prior to
301 attending the study and followed the pain framework in the modified eccentric exercise phase
302 of the study design, it is unlikely that this could account for the significant difference between
303 groups.

304

305 Due to sample population group not performing hopping actions in daily activity, this was felt
306 to be an unnecessary risk. Therefore, in this study the Hop element comprising of 10 points was
307 omitted from the VISA-A questionnaire. Although this would reduce the risk of Achilles tendon
308 rupture, the VISA-A is designed for sporting athletes rather than for patients that did not partake
309 in regular vigorous exercise that required running or jumping. This possibly distorted the
310 baseline measure and final outcome measure, and increases the difficulty in making
311 comparisons. Patients in the acupuncture group returned to their previous levels functional
312 activities, and were able to self-manage their symptoms on discharge this was supported by the
313 GRC score. This may suggest why the relatively low final score of 60 on the VISA-A was
314 achieved following acupuncture, suggesting acupuncture is a beneficial treatment alternative.

315

316 Recommendation for clinical practice

317 The positive effect of the 6 week modified eccentric loading phase in this study, coupled with
318 standard physiotherapy management advice (within a pain framework – pain no greater than
319 VAS 4/10) on Achilles tendinopathy, is an imperative first line treatment, which is supported
320 by previous studies [10-12]. The results of this randomised feasibility study suggest a minimum
321 of 3 weekly acupuncture sessions may be required to achieve of positive outcome in non-
322 responders to the recommended first line treatment for Achilles tendinopathy. During
323 acupuncture treatments, the recommended 4 days of relative rest between acupuncture sessions

324 is advocated, before gradually progressing loading, exercise and function, within a pain
325 framework.

326

327 **Conclusion**

328 This randomised feasibility study has shown statistically and clinically significant improvement
329 in VISA-A, NPRS, EQ-5D and GRC following acupuncture to the Achilles tendon in patients
330 with Achilles tendinopathy. Acupuncture reached the MCIC and MCID threshold for important
331 change for all clinical scores. Whereas sham acupuncture failed to meet any MCIC or MCID
332 threshold for important change in clinical scores. This study shows that acupuncture can have
333 a positive effect in 73% of non-responders to the first line treatment of Achilles tendinopathy.
334 This suggests that the use of a standardised acupuncture protocol to the Achilles tendon is a
335 viable treatment alternative and an effective second line treatment in patients diagnosed with
336 Achilles tendinopathy who are non-responsive to eccentric exercises.

337

338

339

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438 **Table 1: Mean change from baseline and standard deviation (sd) for VISA-A and NPRS**

439 **and Repeated Measures ANOVA main effects with effect size (η_p^2)**

	VISA-A		NPRS	
	Acupuncture	Sham	Acupuncture	Sham
	Mean (sd)	Mean (sd)	Mean (sd)	Mean (sd)
Week 0	33.73 (15.49)	40.55 (19.12)	5.54 (1.86)	4.54 (1.37)
Week 2	47.91 (16.51)	50.09 (22.92)	3.91 (1.70)	3.54 (2.07)
Week 4	60.36 (16.63)	50.27 (19.45)	2.64 (1.96)	3.36 (1.63)
Week 12	60.73 (19.54)	51.82 (22.22)	3.00 (2.19)	4.27 (2.19)
p-value	<0.001	0.030	<0.001	0.201
effect size	0.670	0.254	0.558	0.141

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442 **Table 2: Repeated Measures ANOVA Pairwise comparisons for significant main effects**
 443 **for NPRS and VISA-A for Acupuncture and Sham groups.**

Repeated Measures ANOVA			
	Mean Difference	p-value	Confidence Intervals of the Differences (95%)
NPRS – Acupuncture Group			
Week 0 – 2	1.64*	<0.001	0.95 to 2.33
Week 0 – 4	2.91*	<0.001	1.98 to 3.83
Week 0 – 12	2.54*	0.003	1.06 to 4.03
Week 2 – 4	1.27*	0.003	0.53 to 2.01
Week 2 – 12	0.91	0.148	-0.38 to 2.20
Week 4 – 12	-0.36	0.596	-1.84 to 1.12
VISA-A – Acupuncture Group			
Week 0 – 2	-14.18*	<0.002	-21.90 to -6.46
Week 0 – 4	-26.64*	<0.001	-36.16 to -17.11
Week 0 – 12	-27.00*	<0.001	-38.89 to -15.11
Week 2 – 4	-12.46*	<0.001	-18.30 to -6.61
Week 2 – 12	-12.82*	0.020	-23.18 to -2.46
Week 4 – 12	-0.36	0.908	-7.19 to 6.46
VISA-A – Sham Group			
Week 0 – 2	-9.54	0.061	-19.65 to 0.56
Week 0 – 4	-9.73*	0.016	-17.23 to -2.22
Week 0 – 12	-11.27*	0.002	-17.13 to -5.41
Week 2 – 4	-0.18	0.969	-10.40 to 10.03
Week 2 – 12	-1.73	0.720	-12.18 to 8.73
Week 4 – 12	-1.54	0.657	-9.06 to 5.97

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449 **Table 3: Mixed methods ANOVA Pairwise comparisons between the Sham and**
 450 **Acupuncture treatment groups.**

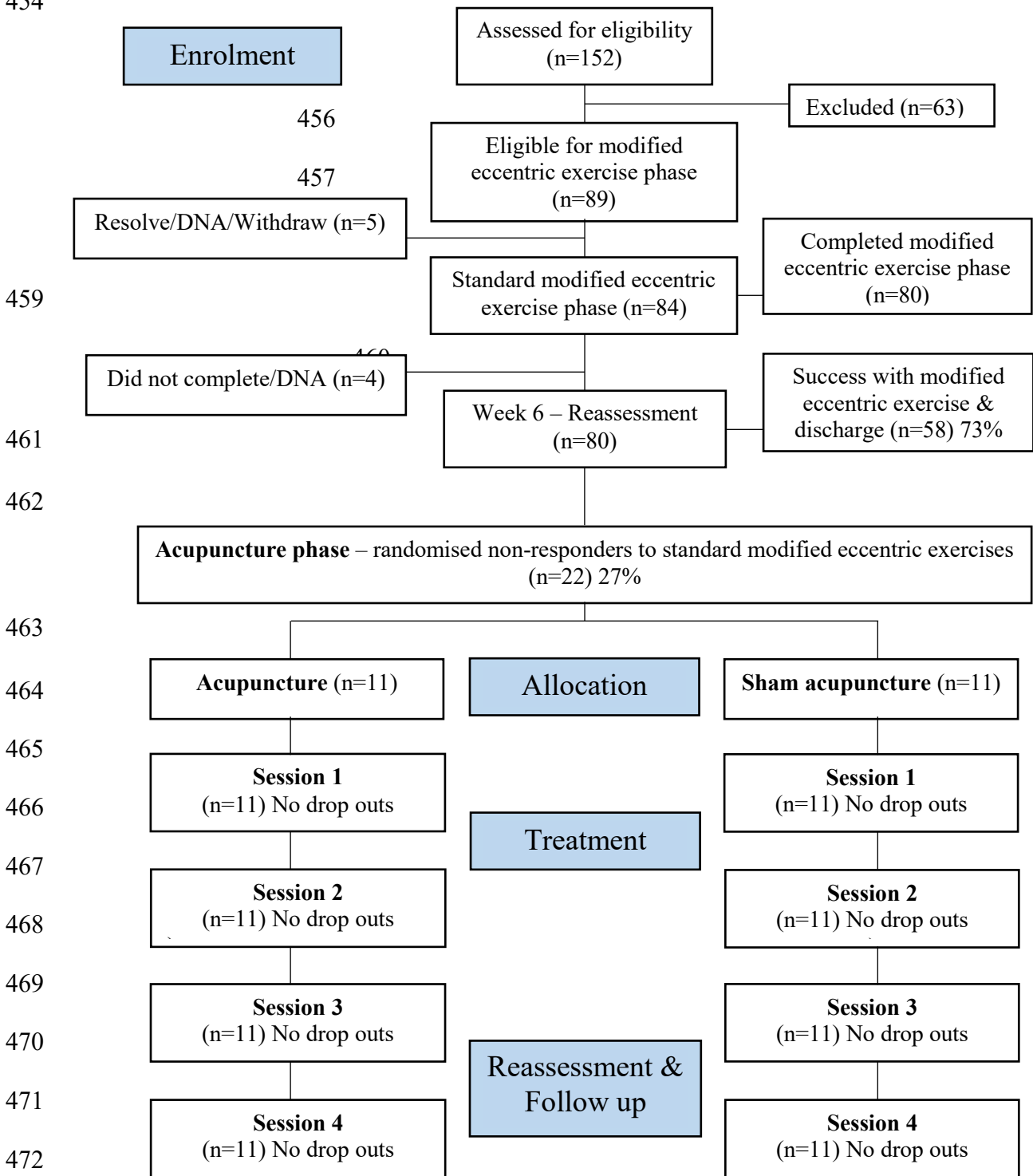
Mixed Methods ANOVA			
	Mean Difference	p-value	Confidence Intervals of the Differences (95%)
NPRS			
Sham vs Acupuncture	-1.545*	<0.001	-2.366 to -.725
VISA-A			
Sham vs Acupuncture	12.424*	<0.001	5.838 to 19.011

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453 **Figure 1: Achilles tendinopathy patient treatment and assessment flowchart**

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473 **Session 1** (week 0) & **Session 2** (week 2)=Physiotherapy assessment, completion of clinical scores prior to
 474 treatment, and NIRS/TI physiological measurements before, during and after acupuncture/sham treatment.

475 **Session 3** (week 4) & **Session 4** (week 12) = Physiotherapy reassessment and completion of clinical scores

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477 **Figure 2: The standardised 9-needle Achilles tendon acupuncture protocol inserted into**
478 **the Achilles tendon (Kishmishian et al, 2012).**



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