

1 CONTRIBUTION OF DRY NEEDLING TO INDIVIDUALIZED PHYSICAL THERAPY  
2 TREATMENT OF SHOULDER PAIN: A RANDOMIZED CLINICAL TRIAL.

3

4 AUTHORS Sara Pérez-Palomares. PT. <sup>1, 2, 3</sup>

5 Bárbara Oliván-Blázquez. PhD. <sup>3, 4, 5</sup>

6 Ana Pérez-Palomares, PhD. <sup>6</sup>

7 Elena Gaspar-Calvo. PT <sup>1, 3</sup>

8 Elena López-Lapeña. PT <sup>1, 3</sup>

9 Marina Pérez-Benito. PT. <sup>1, 3</sup>

10 De la Torre- Beldarraín ML. PT. <sup>1, 3</sup>

11 Rosa Magallon-Botaya. Phd. <sup>1, 3, 5, 7</sup>

12

13

14 1. Primary Care Aragonés Health Service (Spain).

15 2. University San Jorge. Faculty of Health Science. Zaragoza (Spain).

16 3. Health Research Institute IIS Aragon (Spain).

17 4. Department of Psychology and Sociology. University of Zaragoza, Spain.

18 5. Preventative Activities and Health Promotion Network (REDIAPP)  
19 (RD06/0018), Health Institute Carlos III (Spain).

20 6. Department of Statistical Methods. University of Zaragoza, Spain.

21 7. Department of Medicine and Psychiatry. University of Zaragoza, Spain.

22

23

24 Corresponding author:

25 Bárbara Oliván-Blázquez

26 Department of Psychology and Sociology.

27 University of Zaragoza.

28 Violante de Hungría 23.

29 50.009 Zaragoza, Spain

30 Phone: 34 976 761000 ext 4547

31 Fax: 34 976 254006

32 Mail: barbaraolivan@gmail.com

33

34 Word count: 3.887 words.

35 Number of pages: 12

36 Number of tables: 3

37 Number of figures: 1

38

39 - Trail Registration: ISRCTN Number: 30907460

40 - The Study Protocol was approved by the Clinical Research Ethics  
41 Committee of Aragon (01/2008).

42 - All authors have read and corrected draft versions and approved the final  
43 version.

44 - Contribution of each author: SP, BO, and RM, are the principal researchers  
45 and developed the original idea for the study. The study design was further  
46 developed by SP, LR, EG, EL, and MP. AP developed the statistical methods.  
47 All authors have read and corrected draft versions and approved the final  
48 version.

49 - There not have been any previous presentation of these data.

50 - The authors declare that they have no conflicts of interest.

51 - The research group that designed and developed this study is financed by  
52 the Carlos III Institute of Health,- (Grant ID number n° PI07/90924) which  
53 is attached to the Spanish Ministry of Science and Innovation.

54

55 Acknowledgements:

56 The study was funded through a grant from the Spanish government's Ministry of  
57 Health (PI07/90924). We wish to thank "Red de Investigación en Actividades de  
58 Prevención y Promoción de la Salud" (Research Network on Preventative Activities  
59 and Health Promotion) (REDIAPP-GRD06/0018/0020), Nodo de Aragón, for its  
60 support in the development of this study. We also wish to thank "project  
61 MTM2014-53340-p of MINECO, Government of Aragón and the European Social  
62 Fund (consolidated research group Modelos Estocásticos) for its support.

63

64 **ABSTRACT**

65 **STUDY DESIGN:** Multi-center, parallel randomized clinical trial.

66 **BACKGROUND:** Myofascial trigger points (MTrP) are implicated in shoulder pain and  
67 functional limitations. An intervention intended to treat MTrP is dry needling (DN).

68 **OBJECTIVES:** To investigate the effectiveness of dry needling in addition to evidence-  
69 based personalized physical therapy treatment in the treatment of shoulder pain.

70 **METHODS AND MEASURES:** 120 patients with non-specific shoulder pain were  
71 randomly allocated into two parallel groups: 1) personalized, evidence-based  
72 physiotherapy treatment; and 2) trigger point dry needling in addition to personalized  
73 evidence-based physiotherapy treatment. Patients were assessed at baseline, post-  
74 treatment and 3 months follow-up. The primary outcome measure was the pain assessed  
75 by visual analog scale (VAS-pain) at 3 months, and secondary variables were joint  
76 range-of-motion limitations, Constant-Murley Score for pain and function, and number  
77 of active MTrPs. Clinical efficacy was assessed using intention-to-treat analysis.

78 **RESULTS:** Of the 120 enrolled patients, 63 were randomly assigned to the control  
79 group and 57 to the intervention group. There were no significant differences in  
80 outcome between the two treatment groups. Both groups showed improvement over  
81 time.

82 **CONCLUSION:** Dry needling does not offer benefits in addition to personalized  
83 evidence-based physiotherapy treatment for patients with non-specific shoulder pain.

84 **TRIAL REGISTRATION:** Retrospectively registered 2009, ISRCTN30907460

85 **LEVEL OF EVIDENCE:** Therapy, level 2b

86

87 **KEY WORDS:** Myofascial trigger points, dry needling, personalized physical therapy  
88 treatment.

## CONTRIBUTION OF DRY NEEDLING IN PHYSICAL THERAPY TREATMENT OF SHOULDER PAIN: A RANDOMIZED CLINICAL TRIAL.

### BACKGROUND

The prevalence of shoulder pain in primary care (PC) is quite high, with almost half of the general population consulting physicians at least once due to shoulder pain.<sup>7,20</sup> It is the third most common cause of musculoskeletal-related PC consultations.<sup>46</sup> Shoulder pain may continue for one year or more in 60% of cases<sup>33</sup> and in 65% of these cases, it requires regular pharmacological treatment over extended periods of time.<sup>20</sup> Extracapsular soft tissue is believed to be implicated in over 90% of shoulder pain.<sup>16</sup> The most prevalent extracapsular soft tissue lesions, both in active and non-active populations, are disorders of the rotator cuff<sup>51</sup> (RC) and related tissues<sup>55</sup> associated with subacromial impingement syndrome (SIS).<sup>6,8,60</sup>

Some studies<sup>3,28</sup> have suggested the existence of myofascial trigger points (MTrPs), as one of causal agents of shoulder pain and functional limitations. Despite the extensive literature on the role of trigger points<sup>9,19,22,23,24,44,62,63</sup> the appropriate diagnostic criteria<sup>4</sup> and, indeed, their very existence remain controversial.<sup>52-53</sup> As there is no confirmatory test to objectify their existence, the diagnosis is exclusively clinical.<sup>62,65</sup> Although there is not considerable knowledge regarding the specific mechanisms involved in the clinical phenomenon of trigger points, a trigger point is considered to be a hypersensitive spot in taut bands of skeletal muscle that is painful upon stimulation and that elicits a referred pain.<sup>44,65</sup>

There are diverse physiotherapeutic treatments available for the treatment of shoulder pain.<sup>27</sup> Some studies have highlighted the prevalence of MTrPs in different pathologies of shoulder.<sup>3,5,28,31,34</sup> Trigger point dry needling (DN) has become recognized as an intervention targeting the treatment of MTrPs.<sup>26,44,50</sup> The objective of the dry needling intervention (repeated needle insertion) is to deactivate (remove the peripheral source of their persistent nociceptive input) the trigger point via mechanical interruption as a region accumulating multiple sensitized nociceptors,<sup>18</sup> after initially causing a local twitch response.<sup>61,65</sup> Insertion of a needle in the skin and subcutaneous cell layer leads to responses provoked by the very needle insertion,<sup>12</sup> which activate pain control responses at the level of the posterior horn of the spinal cord<sup>50</sup> (also obtained by superficial needling,<sup>1</sup> another method described for the treatment of myofascial pain). Always assuming that a local twitch response is obtained,<sup>32</sup> the mechanical effect as therapy through a connective tissue remodeling, plasticity and decreasing of inflammatory mediators on the MTrP to interrupt its pathogenic mechanisms.<sup>61</sup> There is no evidence to suggest an increased effectiveness with the injection of substances such as local anesthetics in MTrP,<sup>14</sup> as compared to needling with no substance.<sup>59</sup> Clinical trials that have conducted on subjects with shoulder pain up until now, have used conservative techniques and compare the results with those from a control group of wait and see or placebo.<sup>3,28</sup>

The aim of this study was to investigate the effectiveness of DN in addition to personalized, evidence-based physiotherapy treatment versus personalized, evidence-based physiotherapy treatment alone in the treatment of non-specific shoulder pain.

### METHODS

#### Design Overview:

140 Multi-center, parallel randomized clinical trial with follow up at three months following  
141 treatment completion.

142

143 Patients were randomized into two parallel groups: A control group receiving  
144 personalized, evidence-based physiotherapy treatment and an intervention group receiving, in  
145 addition to personalized treatment, myofascial trigger point DN.

146

147 This study is a randomized clinical trial performed according to the Initiative on  
148 Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT),<sup>21</sup> which  
149 recommends the inclusion of a set of core outcome domains in clinical trials of pain  
150 treatments. The recommendations established by the Consolidated Standards of Reporting  
151 Trials (CONSORT) statement<sup>10,47</sup> for randomized controlled trials were also followed. The trial  
152 was retrospectively registered in February 2009 with the ISRCTN registry: ID number  
153 ISRCTN30907460. Participant recruitment took place from 10/2008 to 08/2010. The protocol  
154 of this study has previously been published.<sup>49</sup> Some modifications have been made to the  
155 protocol in terms of the number of sessions held in order for the treatment to be as similar as  
156 possible, to actual clinical practice carried out in physiotherapy departments of PC centers.  
157 There was also a slight decrease in sample size as compared to that published in the protocol,  
158 since this size was recalculated based on effectiveness studies with conservative techniques  
159 that were published after the publication of the original protocol.<sup>5</sup> Additional measures of  
160 outcome were also added.

161

## 162 **Setting and Participants**

163

164 Patients with shoulder pain who visited a general practitioner (GP) in any of 5 primary  
165 health care centers in Zaragoza, Spain, were recruited for inclusion in the study. Potential  
166 participants were informed and provided consent to participate in the study were considered  
167 eligible if they met the following selection criteria: age 18 or older; with non-specific shoulder  
168 pain considered by the GP to be consistent with RC tendinopathy or SIS; and keeping a range  
169 of movement above the 50% of full range (180°) of flexion, abduction or scapular plane  
170 elevation, that is, over 90° of range of motion.

171

172 Participants were included in the study according to the clinical symptoms that they  
173 presented, representing non-specific shoulder pain consistent with clinically suspected RC  
174 tendinopathy or SIS, however, 91% of the sample underwent a diagnostic imaging test  
175 (ultrasound) and 50% underwent a resonance magnetic image (MRI) in order to confirm the  
176 inclusion and exclusion criteria.

177

178 The exclusion criteria were the following: prior surgery for subacromial syndrome;  
179 disability, pain or sudden loss of strength after an injury that could suggest another condition;  
180 glenohumeral instability, symptoms that could indicate a systemic disease; impossibility of  
181 attending intervention sessions or refusal to participate; and any illnesses or circumstances  
182 that, in the researcher's judgment, could interfere with trial completion or cases in which  
183 inclusion in the study could be harmful to the patient.

184

185 Informed consent was obtained from participants before they were aware of their  
186 group assignment and before any assessment. Before giving their consent, patients were  
187 offered a general overview of the aims and characteristics of the study and interventions. They  
188 were informed that they would be participating voluntarily and that they could withdraw at  
189 any time with the guarantee that they would continue to receive the treatment considered  
190 most appropriate by their doctor. Data gathering involved no risks for the subjects  
191 participating in the study. A patient was considered to have withdrawn from the trial if he or

192 she withdrew their informed consent, if the researcher felt that he or she should withdraw  
193 from the study for safety reasons or if the researcher felt it to be in the best interest of the  
194 patient.

195  
196 The study was conducted in accordance with Helsinki Convention norms. The Study  
197 Protocol was approved by the Clinical Research Ethics Committee of Aragon (01/2008).

#### 198 **Role of the Funding Source**

199 The study was funded by a grant from the Spanish government's Ministry of Health  
200 (Grand Number PI07/90924). The role of the financing source was to verify that the study was  
201 conducted as requested and in compliance with regulations for research and the obtaining of  
202 public funding as well as with legislation regarding ethical aspects in the study implementation.

#### 203 **Sample size**

204  
205 We calculated the sample size based on the clinically important improvement of VAS-  
206 pain of 1.5 points,<sup>38</sup> on a scale of 0-10, with a standard deviation of 2 points. Assuming a 95%  
207 confidence interval and power of 90%, the resulting sample size was 38 participants per group,  
208 for a total of 76 individuals. Based on previous studies, an attrition rate of 10% may be  
209 expected, therefore, the required number of patients for recruitment was 86. We aimed to  
210 exceed this sample size and recruiting 132 subjects (66 randomized in each treatment group)  
211 to ensure the reliability of the study.<sup>49</sup> The protocol did not include any interim analyses or  
212 stopping rules.

213

214

#### 215 **Randomization**

216

217 Patients were admitted by general practitioners of the primary care centers and  
218 verification of the inclusion and exclusion criteria was carried out by physical therapists from  
219 the involved physical therapy units.

220

221 Each patient was assigned to one of the two groups using a computer-generated  
222 random number sequence with no restrictions. The information for the random allocation  
223 sequence was implemented by phone, from an independent researcher, who said the type of  
224 treatment assigned for each new patient. The sequence was concealed throughout the study.  
225 Group assignment was carried out by the independent researcher.

226

227 Due to the nature of the study, it was impossible to maintain the blinding on both sides  
228 (physical therapist and patient). All of the assessments were performed by an evaluator  
229 blinded to group allocation.

230

#### 231 **Interventions**

232 The interventions were as follows:

233 *Control group:* All participants underwent a clinical examination process, by the treating  
234 physiotherapist beginning with a thorough background history, followed by a physical  
235 examination of the shoulder girdle<sup>43,57,58</sup> and shoulder joints.<sup>37</sup> All joints were manually  
236 assessed with active movements and with a translatory test according to Kaltenborn therapy<sup>37</sup>

237 (Online Only Appendix 1). Personalized physiotherapy treatment based on the most  
238 appropriate manual therapy techniques, after physical evaluation of the patient. This consisted  
239 of manual therapy treatment based on articular gliding or restoration of the glenohumeral<sup>37</sup>  
240 and scapula-thoracic<sup>43</sup> translatory joint movement, stretching of the shortened periarticular  
241 muscle tissue directly or indirectly involved in the shoulder joint movement,<sup>57,58</sup> isometric  
242 exercises, exercises for proprioceptive re-education and scapular control,<sup>43,48</sup> range-of-motion  
243 stretching at home and postural recommendations for everyday activities<sup>25,27,29,58</sup> (Online Only  
244 Appendix 1). All of these therapies were applied in an individualized manner based on patient  
245 state.<sup>40,41</sup> Training sessions were held with the research group to standardize the protocol, as  
246 well a written procedural manual was used, where the applied techniques, the number of  
247 sessions and the content thereof were recorded (Online Only Appendix 1). Ten personalized  
248 physical therapy treatment sessions were conducted, consisting of 30 minutes per session and  
249 distributed twice weekly.

250  
251 *Treatment group:* Participants assigned to this intervention group all received the  
252 physiotherapy treatment described above, as well as DN of active MTrPs identified by the  
253 treating physiotherapists in the participants' supraspinatus, infraspinatus, subscapularis  
254 (lateral, superior and inferior), teres minor, and deltoid (anterior, medial and posterior)  
255 muscles. Needling was performed using the Hong technique<sup>32</sup> ("fast-in, fast-off"), accompanied  
256 by the subsequent application of cold spray to diminish the post-needling pain sensation.<sup>45,65</sup>  
257 Acupuncture needles measuring 0.25 x 25 mm, 0.30 x 50 mm and 0.30 x 75 mm with guide  
258 tube were used. A total of three needling sessions were conducted, distributed over the 1<sup>st</sup>, 4<sup>th</sup>  
259 and 7<sup>th</sup> sessions respectively, in order to have eight days between each dry needling,<sup>17</sup> and  
260 needling the active MTrPs once in each session.

261  
262

## 263 **Outcomes and Measurements**

### 264 *Baseline assessment*

265 Sociodemographic variables were collected at baseline (age, gender and occupation) as  
266 well as history of pain, timing of clinical evolution, background history, prior treatments,  
267 medication (drug type, time administered and evolution with medication).

268  
269

### 269 *Primary outcome variable*

270

271 The primary outcome variable was patient-reported pain perception, assessed using  
272 the Pain Visual Analogical Scale (VAS-pain). The VAS-pain was designed to permit a thorough  
273 and understandable subjective assessment of pain. The visual analogue scale typically consists  
274 of a 10-cm horizontal line, with perpendicular lines on the edges, defined as the extreme limits  
275 of the pain experience. Anchor points at each edge are characterized by verbal expressions,  
276 such as "no pain" (accompanied by the number 0) at one end and "maximum pain ever  
277 experienced" (accompanied by the number 10) at the other end. Higher scores indicate  
278 greater pain. In the study, patients were asked to evaluate the overall pain that was the cause  
279 of their visit. The psychometric usefulness of VAS in pain measurement has been widely  
280 demonstrated.<sup>64</sup> Clinically important improvement of VAS-pain is considered to be 1.5 points.<sup>38</sup>

281  
282

### 282 *Secondary outcome variables*

283

284 Secondary efficacy variables were: joint range-of-motion limitations, Constant-Murley  
285 Score for pain and function, and number of active MTrPs. They were measured as follows:

285

286 Active articular limitation of the glenohumeral joint in degrees, via digital  
287 inclinometers for flexion and abduction movements (AcumarTM Digital Inclinometer, © 2006  
288 Lafayette Instrument Co). For internal and external rotation, the subscale from  
functional

289 Constant-Murley Score measure was used to determine rotation based on functional  
290 movement (Online Only Appendix 1).

291

292       Functionality was measured with the Constant-Murley Score.<sup>2,39</sup> This test scores from 0  
293 to 100 and includes subscales for subjective pain (0 to 15 points), everyday activities (from 0 to  
294 20 points), and objective subscales on mobility (40 points) and strength (25 points). The  
295 greater the score is the greater the functionality. This test has revealed good reliability<sup>13,56</sup> and  
296 is one of the most frequently used in clinics.<sup>13,56</sup>

297

298       Existence of active MTrPs. Supraspinatus, infraspinatus, subscapularis (lateral, superior  
299 and inferior), teres minor and deltoid (anterior, medial and posterior) muscles were evaluated.  
300 All of these localizations were based on the nomenclature and localization of Travell &  
301 Simons.<sup>65</sup> Diagnosis was made according to updated Travell JG & Simons<sup>3</sup> diagnostic criteria:  
302 presence of a hypersensitive spot in a palpable taut band, palpable or visible local twitch  
303 response on palpatory stimulus and reproduction of referred pain elicited by palpation.<sup>44,65</sup>

304

#### 305 *Additional outcomes*

306       One additional outcome measure, not specified in the trial registration or published  
307 protocol, was added. This was nocturnal pain (determined according to the following  
308 nomenclature: Yes/no).

309

#### 310 *Reassessment periods*

311       Patients were assessed at 3 time points: baseline, post-treatment and 3 months  
312 follow-up. Follow-up assessments (post-treatment and follow up at 3 months) were conducted  
313 by an evaluator blinded to group allocation. The treating physical therapists as well as the  
314 evaluators were physical therapists with over 5 years prior experience in the physiotherapeutic  
315 diagnosis and treatment, including the treatment of the MTrP. They also underwent an  
316 additional 4 sessions of protocol standardization with an expert in DN treatment. Furthermore,  
317 they were provided with a telephone contact to make any necessary consultations regarding  
318 doubts or incidents that may arise during the study period.

319

320

#### 321 **Statistical analysis**

322       Clinical efficacy was assessed using intention-to-treat analysis. The worst observation  
323 carried forward (WOCF) method was used to handle missing data. Baseline comparison of key  
324 variables was made between the groups after randomization to establish baseline  
325 comparability. For each group, the improvement at the end of the treatment and 3 months  
326 later was analyzed using a paired sample t-test for quantitative variables. We used the  
327 McNemar test for the binary outcome of nocturnal pain. Differences between both groups at  
328 the end of the treatment and 3 months later were analyzed using ANCOVA. Thus, for the  
329 primary outcome variable and for each pre-specified secondary outcome variable in each time  
330 point (post treatment and 3 months later) we adjusted a linear model in which the type of  
331 treatment and the corresponding outcome measure at baseline were the independent  
332 variables. For nocturnal pain, in order to compare between the groups, we considered the  
333 patients whose nocturnal pain had improved, (changed from yes to no) and the rest of patients  
334 (whose nocturnal pain did not change or even got worse). We compared the frequencies of  
335 these categories between both groups with the Chi-squared test at the end of the treatment  
336 and 3 months later.

337       Statistical analyses were performed with the SPSS 22.0 statistical software package. *P*  
338 values below 0.05 were considered to be statistically significant.



## 339 RESULTS

### 340 *Participant flow and compliance*

341

342 Figure 1 illustrates the flow of participants during the trial. 142 potential patients were  
343 assessed for inclusion in the study, all of whom had pain and shoulder limitations. They were  
344 sequentially included in the study between October 2008 and August 2010. There were 22  
345 exclusions.

346

347 Of the 120 enrolled patients, 57 were randomly assigned to the dry needling group and  
348 63 were randomly assigned to the control group. All patients received the allocated  
349 intervention and all were analyzed using intention-to-treat (ITT) analyses. Attrition was low: of  
350 the 120 subjects who began the study, 117 (97.5%) completed the treatment and the 3 month  
351 follow-up was filled out by 109 subjects (90.8%). The attrition rate in the two treatment groups  
352 was quite similar: 2 out of 63 (3.17%) patients in the PT group and 1 out of 57 (1.75%) patients  
353 in PT+DN group abandoned treatment over 10 treatment sessions. Considering the 3 month  
354 follow-up, the total attrition rate was 11 subjects, 6 out of 63 (9.52%) in the PT group and 5 out  
355 of 57 (8.77%) in PT+DN group. Due to the low dropout rate, predictors of dropout were not  
356 subjected to further analysis, and WOCF was considered an adequate method for dealing with  
357 missing data for ITT analysis.

358

### 359 *Group baseline characteristics*

360

361 TABLE 1 displays the baseline characteristics of the two study groups. There were no  
362 important differences between groups in any sociodemographic or clinical variable, neither in  
363 the diagnosed pathology via US/MRI, indicating that the two groups were equivalent in regards  
364 to the measured variables.

365

### 366 *Primary outcome variable*

367

368 TABLE 2 displays the data for the assessment of the principal and secondary variables  
369 at baseline, post-treatment and 3 month follow-up for the personalized treatment and  
370 personalized treatment plus dry needling groups. Participants in both groups showed  
371 significant improvement at the end of the treatment period and after 3 months in pain. The  
372 patients assigned to the personalized treatment plus dry needling group showed a slight  
373 improvement (0.86 is the difference estimate with a C.I (0.06, 1.67)) in pain at the end of the  
374 treatment period whereas this difference was not revealed at 3 months follow-up.

375

### 376 *Secondary and additional outcomes*

377

378 Participants in both groups showed significant improvement at the end of the  
379 treatment period and after 3 months, in regards to internal rotation range of motion,  
380 functionality and number of active trigger points. The patients assigned to the personalized  
381 treatment group showed improvement in external rotation range of motion whereas this  
382 difference was not revealed in the personalized treatment plus dry needling group. Comparing  
383 both groups, similar effects were found between the two treatments for all pre-specified  
384 secondary outcome variables, at the end of the treatment period and at 3 months follow-up.

385

386 Results for the additional variable not specified *a priori* are reported in Online Only  
387 Appendix 2. The changes in nocturnal pain (a NO value at baseline and a YES value after the  
388 treatment or a YES at baseline and a NO after treatment) indicated improvements in nocturnal  
389 pain in both groups following treatment and at the 3 month follow-up. The results indicated a  
390 slight between group difference in nocturnal pain improvement at post treatment favoring the

391 personalized treatment + DN group (odds ratio equals 0.41 with a C.I. (0.17, 0.99)), but not at 3  
392 month follow-up.

393

## 394 **DISCUSSION**

395

396 This is the first clinical trial assessing the effectiveness of dry needling when added to a  
397 personalized treatment of shoulder pain, compared with personalized treatment only. There  
398 were no clinically or statistically significant differences in the results between the intervention  
399 groups, in terms of pain or in range of motion, or in terms of functioning or in a decreased  
400 number of MTrPs at 3 month follow-up. The only statistically significant difference found at  
401 post treatment was in pain. This comparison showed a difference estimate of 0.86 and a  
402 confidence interval equals (0.06, 1.67), on VAS-pain. This, according to a-priori defined  
403 minimum difference of 1.5 on VAS-pain, is not a clinically relevant improvement.

404

405 We highlight the improvement in pain that was perceived in both treatment groups,  
406 both at the time of post-treatment as well as three months later. This change is clinically  
407 relevant, with a decrease in the VAS-pain scale of more than 2 points<sup>38</sup> and at 3 months, a  
408 decrease by more than 3 points (the mean for pain at three months is less than half of the  
409 initial level for the PT with DN group). While we are unable to attribute this improvement in  
410 pain to the administered treatments, given that our study lacked a control group, it has been  
411 established in studies in which control groups have been included that manual therapy may  
412 with or without supervised exercises be superior to physician advice, as shown by Kachingwe,<sup>36</sup>  
413 or no intervention as shown by Dickens.<sup>15</sup> Nevertheless, a study with a control group should be  
414 conducted in order to confirm these results.

415

416 As for function; changes in the total Constant-Murley Score,<sup>30</sup> although statistically  
417 significant, did not exceed the minimum clinically important change of 17 points in either of  
418 the two treatments. Virtually no changes were observed for range of motion. Significant  
419 improvement was only observed in a similar manner in internal rotation for both groups, as  
420 well as a significant improvement in external rotation in only the group treated with PT. It is  
421 possible to say that there is little capacity for improvement given the fact that the limitation  
422 level in general is not very high; the mean degree in flexion and abduction is over 75%, in  
423 external rotation it is over 70% and in internal rotation it is somewhat less, but it is over 60% in  
424 overall movement. These results may be consistent with those from other studies in which  
425 manual therapy was assessed for shoulder pain,<sup>35</sup> finding few and varied changes in the  
426 different ranges of motion,<sup>11</sup> and whose increase may be related to the initial level of  
427 restriction<sup>42</sup> and the range in which the joint movement is carried out.<sup>11</sup>

428

429 We chose to use a non-standardized physiotherapy treatment protocol in both  
430 because physical therapists generally use a multimodal treatment approach.<sup>27</sup> Manual therapy,  
431 stretching and/or proprioceptive re-education and control exercises have also been described  
432 to inactivate myofascial trigger points.<sup>44,54,65</sup> This may possibly be the reason for similar  
433 decrease for both groups in our study, as the manual therapy may have indirectly benefitted  
434 the MTrPs. The treatment of shoulder pain through the inactivation of MTrPs has been  
435 previously studied by Bron<sup>5</sup> and Hains,<sup>28</sup> who found significant improvements in pain and  
436 function following conservative treatment as compared to a control group, thereby associating  
437 the improvement to the treatment of the MTrPs.

438

439 With respect to the nocturnal pain variable, our study found that the number of  
440 participants with improved nocturnal pain was slightly higher for the DN group after  
441 treatment. This comparison showed an odds ratio of 0.41 with a confidence interval (0.17,  
442 0.99) which does not reveal important differences with respect to this variable. Moreover, we

443 are unable to assess the clinical meaningfulness of this small improvement due to the nature  
444 of the variable used (yes/no), and no significant difference existed at 3 month follow-up. This  
445 outcome was not a primary or secondary outcome for this study, therefore should not be  
446 considered of consequence; it may have been a chance finding, given no other outcomes  
447 showed important significant differences.

448  
449 The main strength of this study is that it is the first clinical study to assess the  
450 effectiveness of dry needling when added to personalized physiotherapy treatment in primary  
451 care, with appropriate sample size and representativeness. Furthermore, a follow up at 3  
452 months following treatment completion was conducted, allowing us to analyze patient  
453 evolution after the treatment. But there are several limitations to this study. One of these is  
454 the inclusion based on diagnosis by the family physician based on clinical symptoms (although  
455 a large percentage of the subjects had their pathology confirmed via US or MRI). Finally, the  
456 follow-up period may be considered rather short; longer follow-up periods may be necessary  
457 to confirm the long-term stability of the improvements. Finally, although previous studies have  
458 shown individualized manual therapy and exercise therapy to be superior to a no-  
459 physiotherapy control,<sup>15,36</sup> larger, higher quality studies are necessary to definitively establish  
460 the effectiveness of physical therapy management of non-specific shoulder pain, RC disorders  
461 or SIS.<sup>11</sup>

462

#### 463 **CONCLUSIONS**

464 Dry needling does not offer benefits to personalized treatment in terms of shoulder pain, with  
465 regard to pain, self-reported function, range of motion, or reduction in active MTrPs.

466

#### 467 **Conflicts of interest**

468 The authors have declared that they have no conflicts of interest.

469

#### 470 **Authors' contributions**

471 SP, BO, and RM, are the principal researchers and developed the original idea for the  
472 study. The study design was further developed by SP, LR, EG, EL, and MP. AP developed the  
473 statistical methods. All authors have read and corrected draft versions and approved the final  
474 version.

475

#### 476 **Acknowledgements**

477 The study was funded through a grant from the Spanish government's Ministry of Health  
478 (PI07/90924).

479

#### 480 **Key Points**

481

482 Findings: Dry needling did not offer benefits in addition to personalized physiotherapy  
483 treatment, in patients with non-specific shoulder pain, with regard to pain, self-reported  
484 function, range of motion, or reduction in active MTrPs.

485 Implications: Dry needling is not justified as an adjunct to the management of pain in shoulder  
486 pain by personalized evidence-based physiotherapy treatment.

487 Caution: In the primary care setting of this study, the inclusion of the participants was based  
488 on clinical diagnosis of non-specific shoulder pain considered by the family physician to be  
489 consistent with RC tendinopathy or SIS; and who also had impaired movement of less than  
490 50% of the expected normal range of motion. Although a large percentage of the subjects had  
491 their pathology confirmed via US or MRI, the shoulder pain diagnosis was non-specific. The  
492 evidence-based physiotherapy treatment, although similar between the groups, was  
493 individualized and therefore not exactly replicable.

494

## 495 REFERENCES

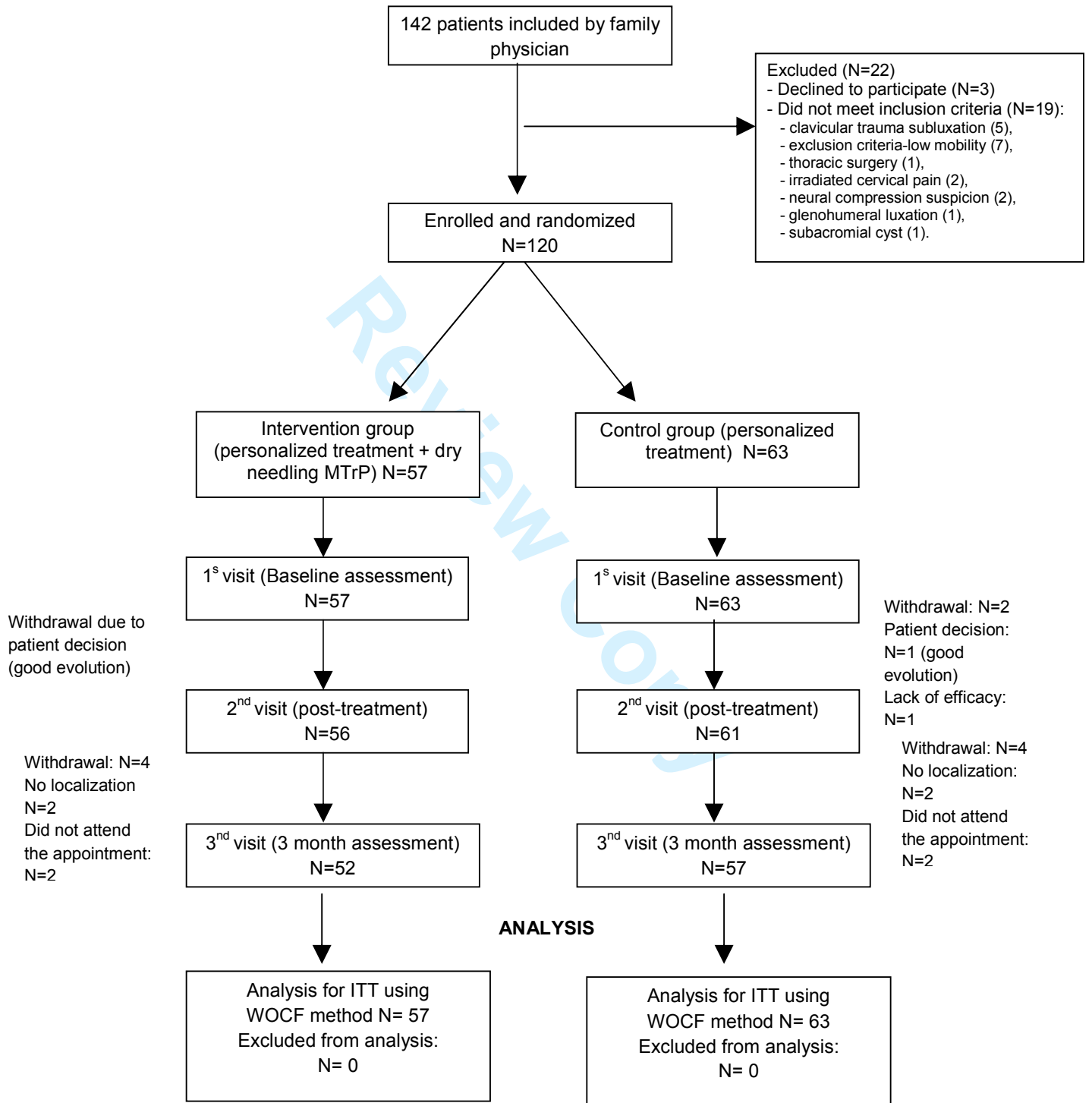
- 496
- 497
- 498 1. Baldry P: Superficial versus deep dry needling. *Acupunct Med.* 2002; 20(2-3):78–81.
- 499 2. Barra López, ME. El test de Constant-Murley. Una revisión de sus características.
- 500 [Constant-Murley Test. A revision of its characteristics]. *Rehabilitación.*
- 501 2007;41(5):228-35.
- 502 3. Bron C, Dommerholt J, Stegenga B, Wensing M, Oostendorp RA. High prevalence of
- 503 shoulder girdle muscles with myofascial trigger points in patients with shoulder pain.
- 504 *BMC Musculoskelet Disord.* 2011;12:39.
- 505 4. Bron C, Franssen J, Wensing M, Oostendorp RA. Interrater reliability of palpation of
- 506 myofascial trigger points in three shoulder muscles. *J Man Manip Ther.* 2007;15:203-
- 507 15.
- 508 5. Bron ,C de Gast A, Dommerholt J, Stegenga B, Wensing M, Oostendorp RA. Treatment
- 509 of myofascial trigger points in patients with chronic shoulder pain: a randomized,
- 510 controlled trial. *BMC Med.* 2011;9:8.
- 511 6. Browning DG, Desai M M. Rotator cuff injuries and treatment. *Primary Care-Clinics in*
- 512 *Office Practice.* 2004;31:4.
- 513 7. Brox JI. Regional musculoskeletal conditions: shoulder pain. *Best Pract Res Clin*
- 514 *Rheumatol.* 2003;17(1):33-56.
- 515 8. Burbank KM, Stevenson JH, Czarnecki GR, Dorfman J. Chronic shoulder pain: part I.
- 516 Evaluation and diagnosis. *Am Fam Physician.* 2008;77:453–60.
- 517 9. Calandre EP, Hidalgo J, Garcia-Leiva JM, Rico-Villademoros F, Gado-Rodriguez A.
- 518 Myofascial trigger points in cluster headache patients: a case series. *Head Face Med.*
- 519 2008;4:32.
- 520 10. Calvert M, Blazeby J, Altman DG, Revicki DA, Moher D, Brundage MD. Reporting of
- 521 patient-reported outcomes in randomized trials: the CONSORT PRO extension. *JAMA.*
- 522 2013;309:814–22.
- 523 11. Camarinos J, Marinko L. Effectiveness of manual physical therapy for painful shoulder
- 524 conditions: a systematic review. *J Man Manip Ther.* 2009;17:206-15.
- 525 12. Ceccherelli F, Rigoni MT, Gagliardi G, Ruzzante L: Comparison of superficial and deep
- 526 acupuncture in the treatment of lumbar myofascial pain: A doubleblind randomized
- 527 controlled study. *Clin J Pain.* 2002;18:149-153.
- 528 13. Conboy VB, Morris RW, Kiss J, Carr AJ. An evaluation of the Constant-Murley shoulder
- 529 assessment. *J Bone Joint Surg Br.* 1996;78(2):229-32.
- 530 14. Couto C, de Souza IC, Torres IL, Fregni F, Caumo W. Paraspinal stimulation combined
- 531 with trigger point needling and needle rotation for the treatment of myofascial pain: a
- 532 randomized sham-controlled clinical trial. *Clin J Pain* 2014;30(3):214-23.
- 533 15. Dickens VA, Williams JL, Bhamra MS. Role of physiotherapy in the treatment of
- 534 subacromial impingement syndrome: a prospective study. *Physiotherapy.*
- 535 2005;91:159–164.
- 536 16. Dinnes J, Loveman E, McIntyre L et al. The effectiveness of diagnostic test for the
- 537 assessment of shoulder pain due to soft tissue disorders: a systematic review. *Health*
- 538 *Technology Assessment.* 2003;7:29.
- 539 17. Domingo A, Mayoral O, Monterde S, Santafé MM. Neuromuscular Damage and Repair
- 540 after Dry Needling in Mice. *Evid Based Complement Alternat Med.* 2013; 2013:260806.
- 541 doi: 10.1155/2013/260806. Epub 2013 Apr 9.
- 542 18. Dommerholt J. Dry needling, peripheral and central considerations. *J Man Manip Ther.*
- 543 2011;19:223-236.
- 544 19. Dommerholt J, Finnegan M, Grieve R, Hooks T. Clinical Review Section. A Critical
- 545 Overview of the Current Myofascial Pain Literature-January 2016. *J Bodyw Mov Ther.*
- 546 2016;20(1):156-67.

- 547 20. Dorrestijn O, Greving K, van der Veen WJ, van der Meer K, Diercks RL, Winters JC,  
548 Stevens M. Patients with shoulder complaints in general practice: consumption of  
549 medical care. *Rheumatology*. 2011;50:389–395.
- 550 21. Dworkin RH, Turk DC, McDermott MP, Peirce-Sandner S, Burke LB, Cowan P, Farrar JT,  
551 Hertz S, Raja SN, Rappaport BA, Rauschkolb C, Sampaio C. Interpreting the clinical  
552 importance of group differences in chronic pain clinical trials: IMMPACT  
553 recommendations. *Pain*. 2009;146:238–44.
- 554 22. Eng-Ching Y. Myofascial Pain-An Overview. *Ann Acad Med Singapore*. 2007; 36: 43-48.
- 555 23. Fernández-Carnero J, Fernández-de-las-Peñas C, De-la-Llave-Rincón AI, Ge HY, Arendt-  
556 Nielsen L Prevalence of and referred pain from myofascial trigger points in the forearm  
557 muscles in patients with lateral epicondylalgia. *Clin J Pain*. 2007;23:353–360.
- 558 24. Fernández-de-las-Peñas C, Ge HY, Arendt-Nielsen L, Cuadrado ML, Pareja JA (2007d)  
559 The local and referred pain from myofascial trigger points in the temporalis muscle  
560 contributes to pain in chronic tension-type headache. *Clin J Pain*. 2007;23:786–792.
- 561 25. Forthomme B. *Reeducación del hombro. [Re-education of the shoulder]*. Barcelona: Ed.  
562 Paidotribo; 2007.
- 563 26. Furlan AD, Van Tulder M., Cherkin D., Tsukayama H., Lao L., Koes B. and Berman B.  
564 Acupuncture and dry-needling for low back pain: an up dated systematic review within  
565 the frame work of the Cochrane collaboration. *Spine*. 2005;30:944-963.
- 566 27. Green S, Buchbinder R, Hetrick S. Intervenciones fisioterapéuticas para el dolor del  
567 hombro (Revisión Cochrane traducida). En: *La Biblioteca Cochrane Plus*, 2008 Número  
568 1. Oxford: Update Software Ltd. Disponible en: <http://www.update-software.com>.  
569 (Traducida de The Cochrane Library, 2008 Issue 1. Chichester, UK: John Wiley & Sons,  
570 Ltd.).
- 571 28. Hains G, Descarreaux M, Hains F. Chronic shoulder pain of myofascial origin: a  
572 randomized clinical trial using ischemic compression therapy. *J Manipulative Physiol*  
573 *Ther*. 2010;33(5):362-9.
- 574 29. Hakgüder A, Tastekin N, Birtane M, Uzunca K, Zateri C, Süt N. Comparison of the Short-  
575 Term efficacy of physical therapy in subacromial impingement syndrome patiens with  
576 stage I and II magnetic resonance imaging finding. *Turk J Rheumatol*. 2011;26(2):127-  
577 134.
- 578 30. HenselerJF, Kolk A, Van der Zwaal P, Nagels J, Vliet Vlieland TP, Nelissen RG. The  
579 minimal detectable change of the Constant score in impingement, full-thickness tears,  
580 and massive rotator cuff tears. *J Shoulder Elbow Surg*. 2015;24:376-381.
- 581 31. Hidalgo-Lozano A, Fernández-de-las-Peñas C, Alonso-Blanco C, Ge H-Y, Lars Arendt-  
582 Nielsen L, Arroyo-Morales M. Muscle trigger points and pressure pain hyperalgesia in  
583 the shoulder muscles in patients with unilateral shoulder impingement: a blinded,  
584 controlled study. *Exp Brain Res*. 2010;202:915–925.
- 585 32. Hong Cz. Lidocaine versus dry needling to myofascial trigger point. The importance of  
586 local twitch reponse. *Am J Rehabil*. 1994;73(4):256-63.
- 587 33. House J, Mooradian A. Evaluation and management of shoulder pain in primary care  
588 clinics. *South Med J*. 2010;103:1129-35.
- 589 34. Ingber RS. Shoulder impingement in tennis/racquetball players treated with  
590 subscapularis myofascial treatments. *Arch Phys Med Rehabil*. 2000;81:679–682.
- 591 35. Johnson AJ, Godges JJ, Zimmerman GJ, Ounanian LL. The effect of anterior versus  
592 posterior glide joint mobilization on external rotation range of motion in patients with  
593 shoulder adhesive capsulitis. *J Orthop Sports Phys Ther*. 2007;37(3):88-99.
- 594 36. Kachingwe AF, Phillips B, Sletten E, Plunkett SW. Comparison of Manual Therapy  
595 Techniques with Therapeutic Exercise in the Treatment of Shoulder Impingement: A  
596 Randomized Controlled Pilot Clinical Trial. *J Man Manip Ther*. 2008;16:238-47.
- 597 37. Kaltenborn FM. *Fisioterapia Manual: Extremidades*. 2ª edición. Aravaca (España).  
598 Editorial McGraw-Hill/ Interamericana. 2004.

- 599 38. Kelly AM. The minimum clinically significant difference in visual analogue scale pain  
600 score does not differ with severity of pain. *Emerg Med J*. 2001;18:205–207.
- 601 39. Kirkley A, Griffin S, Dainty K. Scoring systems for the functional assessment of the  
602 shoulder. *Arthroscopy*. 2003;19(10):1109-20.
- 603 40. Kromer TO, de Bie RA, Bastiaenen CH. Effectiveness of individualized physiotherapy on  
604 pain and functioning compared to a standard exercise protocol in patients presenting  
605 with clinical signs of subacromial impingement syndrome. A randomized controlled  
606 trial. *BMC Musculoskelet Disord*. 2010;11:114.
- 607 41. Kromer TO, de Bie RA, Bastiaenen CH. Physiotherapy in patients with clinical signs of  
608 shoulder impingement syndrome: a randomized controlled trial. *J Rehabil Med*  
609 2013;45:488-97.
- 610 42. Lombardi I Jr, Magri AG, Fleury AM, Da Silva AC, Natour J. Progressive resistance  
611 training in patients with shoulder impingement syndrome: a randomized controlled  
612 trial. *Arthritis Rheum*. 2008;59:615-22.
- 613 43. Ludewig PM, Reynolds JF. The association of scapular kinematics and glenohumeral  
614 joint pathologies. *J Orthop Sports Phys Ther*. 2009;39(2):90-104.
- 615 44. Llamas-Ramos R, Pecos-Martín D, Gallego-Izquierdo T, Llamas-Ramos I, Plaza-Manzano  
616 G, Ortega-Santiago R, Cleland J, Fernández-de-las-Peñas C. Comparison of the short-  
617 term outcomes between trigger point dry needling and trigger point manual therapy  
618 for the management of chronic mechanical neck pain: a randomized clinical trial. *J*  
619 *Orthop Sports Phys Ther*. 2014;44(11):852-61.
- 620 45. Majlesi J, Unalan H. Effect of treatment on trigger points. *Curr Pain Headache Rep*.  
621 2010;14:353-60.
- 622 46. Mitchell C, Adebajo A, Hay E, Carr A. Shoulder pain: diagnosis and management in  
623 primary care. *Clinical review BMJ*. 2005;331:1124-1128
- 624 47. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, Elbourne D,  
625 Egger M, Altman DG. CONSORT 2010 explanation and elaboration: updated guidelines  
626 for reporting parallel group randomised trials. *BMJ*. 2010;340:c869.
- 627 48. Myers JB, Wassinger CA, Lephart SM. Sensorimotor contribution to shoulder stability:  
628 Effect of injury and rehabilitation. *Man Ther*. 2006;11:197–201.
- 629 49. Pérez-Palomares S, Oliván-Blázquez B, Arnal-Burró AM, et al. Contributions of  
630 myofascial pain in diagnosis and treatment of shoulder pain. A randomized control  
631 trial. *BMC Musculoskelet Disord*. 2009;24(10):92.
- 632 50. Pérez-Palomares S; Oliván-Blázquez B; Magallón-Botaya R et al. Percutaneous electrical  
633 nerve stimulation vs dry-needling. Effectiveness in the treatment of chronic low back  
634 pain. *J Musculoskeletal Pain*. 2010;18, (1):23-30.
- 635 51. Pribicevic M, Pollard H, Bonello R. An epidemiologic survey of shoulder pain in  
636 chiropractic practice in Australia. *J Man Phys Ther*. 2009;32:107-117.
- 637 52. Quintner JL, Bove GM, Cohen ML. Response to Dommerholt and Gerwin: Did we miss  
638 the point? *J Bodyw Mov Ther*. 2015;19:394-5.
- 639 53. Quintner JL, Cohen ML. Re: Are peripheral pain generators important in fibromyalgia  
640 and chronic widespread pain? *Pain Med*. 2014;15:718-20.
- 641 54. Renan-Ordine R, Alburquerque-Sendín F, de Souza DP, Cleland JA, Fernández-de-Las-  
642 Peñas C. Effectiveness of myofascial trigger point manual therapy combined with a  
643 self-stretching protocol for the management of plantar heel pain: a randomized  
644 controlled trial. *J Orthop Sports Phys Ther*. 2011;41(2):43-50.
- 645 55. Roquelaure Y, Ha C, Leclerc A, Touranchet A et al. Epidemiologic surveillance of upper-  
646 extremity musculoskeletal disorders in the working population. *Arthritis &*  
647 *Rheumatism*. 2006;55:765–78.
- 648 56. Roy JS, MacDermid JC, Woodhouse LJ. A systematic review of the psychometric  
649 properties of the Constant-Murley score. *J Shoulder Elbow Surg*. 2010;19(1):157-64.

- 650 57. Sahrman SA. *Diagnóstico y Tratamiento de las Alteraciones del Movimiento*  
651 *(Diagnosis and Treatment of Movement Disorders)*. 1ª edición. Badalona (España).  
652 Editorial Paidotribo. 2006.
- 653 58. Sahrman SA. *Movement System Impairment Syndromes of the Extremities, Cervical,*  
654 *and Thoracic Spines*. 1<sup>st</sup> edition. St. Luis (Missouri). Editorial Elsevier Mosby. 2011.
- 655 59. Scott NA, Guo B, Barton PM, Gerwin RD. Trigger point injections for chronic non-  
656 malignant musculoskeletal pain: a systematic review. *Pain Med*. 2009;10:54-69.
- 657 60. Seitz AL, McClure PW, Finucane PW, Boardman ND th, Michener LA. Mechanisms of  
658 rotator cuff tendinopathy: Intrinsic, extrinsic, or both?. *Clin Biom*. 2011;26:1-12.
- 659 61. Shah JP, Gilliams EA. Uncovering the biochemical milieu of myofascial trigger points  
660 using in vivo microdialysis: An application of muscle pain concepts to myofascial pain  
661 syndrome. *J Bodyw Mov Ther*. 2008;12: 371-384.
- 662 62. Simons DG. Review of enigmatic MTrPs as a common cause of enigmatic  
663 musculoskeletal pain and dysfunction. *J Electromyogr Kinesiol*. 2004;14(1):95-107.
- 664 63. Simons DG, Dommerholt J. Myofascial pain syndromes- Trigger points. *J*  
665 *Musculoskeletal Pain*. 2007;15:69-84.
- 666 64. Sriwatanakul K, Kelvie W, Lasagna L. Studies with different types of visual analogue  
667 scales for measurement of pain. *Clin Pharmacol Ther*. 1983;34:234–239.
- 668 65. Travell JG, Simons DG, Simons LS: *Dolor y Disfunción Miofascial.El Manual de los*  
669 *Puntos Gatillo. Volumen 1. Mitad Superior del Cuerpo*. 1ª edición. Madrid (España).  
670 Editorial Médica Panamericana. 2002.  
671  
672

## FLOWCHART





## TABLES

Table 1. Baseline sociodemographic and clinical characteristics of the sample (N= 120)

<b>VARIABLES</b>	Personalized treatment (N=63)	Personalized treatment + Dry needling (N=57)
<b>SOCIODEMOGRAPHIC VARIABLES</b>		
Gender (M/F)	28/35	17/40
Age	54.32 (11.45)	52.74 (11.81)
PAIN (VAS)	6.75 (1.5)	6.58 (1.52)
<b>GLENOHUMERAL ACTIVE ROM (degrees)</b>		
Flexion	136.09 (16.42)	135.97 (20.40)
Abduction	141.74 (27.87)	150.02 (26.03)
External rotation	7.08 (2.96)	7.82 (2.46)
Internal rotation	6.37 (2.67)	6.21 (2.71)
FUNCTIONALITY (CONSTANT-MURLEY SCORE)	47,6 (11.53)	50.3 (11.75)
NOCTURNAL PAIN (NO/YES)	22/41	16/41
NUMBER OF ACTIVE TRIGGER POINTS	4.82 (1.75)	5.07 (1.86)
<b>PATHOLOGY</b>		
TOTAL/PARTIAL TEAR (NO/YES)	51/6	48/4
TENDINOPATHY (NO/YES)	37/20	39/13
ARTHROSIS (NO/YES)	35/22	38/14
BURSITIS (NO/YES)	43/14	46/6
INJURY (NO/YES)	23/34	27/25

Other than gender and pathology, all values are means (SD)

Table 2: Outcome data at baseline, post-treatment and 3 month follow-up.

	P.T.*	P.T.+D.N.*	Between-group differences**
<b>PAIN (VAS)</b>			
Baseline	6.75 (1.50)	6.58 (1.52)	
Post-treatment	4.71 (2.28)	3.81 (2.20)	0.86 (0.06, 1.67)
After 3 months	3.59 (2.61)	3.00 (2.44)	0.52 (-0.37,1.42)
Within group improvement from baseline <sup>+</sup>			
Post-treatment	2.04 (1.44, 2.63) <sup>§§</sup>	2.77 (2.08, 3.46) <sup>§§</sup>	
After 3 months	3.16(2.55, 3.77) <sup>§§</sup>	3.58 (2.82, 4.34) <sup>§§</sup>	
<b>GLENOHUMERAL ACTIVE ROM (degrees)</b>			
<b>FLEXION</b>			
Baseline	136.09 (16.42)	135.97 (20.40)	
Post-treatment	136.17 (18.90)	140.53 (15.47)	4.41 (-1.29,10.10)
After 3 months	141.08 (16.49)	139.32 (17.61)	-1.71(-7.34, 3.92)
Within group improvement from baseline <sup>+</sup>			
Post-treatment	0.08 (-4.58, 4.75)	4.56 (-0.67, 9.79)	
After 3 months	4.99 (0.44, 9.53)	3.35 (-2.06, 8.77)	
<b>ABDUCTION</b>			
Baseline	141.74 (27.87)	150.02 (26.03)	
Post-treatment	149.23 (25.18)	151.17 (25.64)	-0.98 (-9.64,7.68)
After 3 months	148.12 (25.65)	149.89 (25.18)	-0.60 (-9.51, 8.31)
Within group improvement from baseline <sup>+</sup>			
Post-treatment	7.49 (-0.02, 14.99)	1.15 (-6.48, 8.79)	
After 3 months	6.37 (-1.34, 14.09)	-0.13 (-8.43, 8.17)	
<b>EXTERNAL ROTATION</b>			
Baseline	7.08 (2.96)	7.82 (2.46)	
Post-treatment	8.44 (2.20)	8.53 (2.31)	-0.09 (-0.89, 0.69)
After 3 months	8.54 (2.52)	8.53 (2.41)	-0.24 (-1.09, 0.62)
Within group improvement from baseline <sup>+</sup>			
Post-treatment	1.36 (0.64, 2.09) <sup>§§</sup>	0.70 (-0.12, 1.53)	
After 3 months	1.46 (0.75, 2.17) <sup>§§</sup>	0.70 (-0.15, 1.55)	
<b>INTERNAL ROTATION</b>			
Baseline	6.37 (2.67)	6.21 (2.71)	
Post-treatment	7.21 (2.86)	7.86 (2.13)	0.74 (0.02, 1.46)
After 3 months	7.73 (2.37)	8.00 (2.14)	0.34 (-0.36, 1.04)
Within group improvement from baseline <sup>+</sup>			
Post-treatment	0.84 (0.33, 1.35) <sup>§</sup>	1.65 (0.99, 2.31) <sup>§§</sup>	
After 3 months	1.36 (0.75, 1.98) <sup>§§</sup>	1.79 (1.14, 2.44) <sup>§§</sup>	
<b>FUNCTIONALITY (CONSTANT-MURLEY SCORE)</b>			
Baseline	47.39 (11.53)	50.30 (11.75)	
Post-treatment	57.29 (13.74)	61.44 (12.00)	3.04 (-1.36, 7.44)

After 3 months	61.77 (16.18)	62.89 (12.91)	-0.07 (-5.19, 5.04)
Within group improvement from baseline <sup>++</sup>			
Post-treatment	9.68 (6.55,12.81) <sup>§§</sup>	11.14(7.10,15.18) <sup>§§</sup>	
After 3 months	14.39 (10.55,18.22) <sup>§§</sup>	12.60 (8.36, 16.83) <sup>§§</sup>	
<b>NUMBER OF ACTIVE TRIGGER POINTS</b>			
Baseline	4.82 (1.75)	5.07 (1.86)	
Post-treatment	3.97 (1.71)	4.17 (2.01)	-0.001 (-0.39, 0.38)
After 3 months	3.75 (1.94)	4.05 (2.12)	0.10 (-0.39, 0.59)
Within group improvement from baseline <sup>+</sup>			
Post-treatment	0.86 (0.61, 1.10) <sup>§§</sup>	0.89 (0.57, 1.21) <sup>§§</sup>	
After 3 months	1.08 (0.73, 1.43) <sup>§§</sup>	1.02 (0.65, 1.38) <sup>§§</sup>	

Abbreviations: PT, personalized treatment; DN, dry needling.

+ Improvement calculated as the reduction of the variable.

++Improvement calculated as the increment of the variable.

\*For each variable and time point, the first three rows are mean (SD) and the last two rows are mean differences (95% confidence interval).

\*\* For each variable and time point, values are mean differences (95% confidence interval) between both treatments by using ANCOVA (outcome score at different time points is the dependent variable and the corresponding variable at baseline is the covariable).

§ Statistically significant differences with  $p$ -values<0.01.

§§ Statistically significant differences with  $p$ -values<0.001.