

1           **Efficacy of combined physical and occupational**  
2           **therapy treatment of patients with sub acute**  
3           **neuralgic amyotrophy:**  
4           **a proof of principle pilot-study**

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11   Master thesis

12   Author: Jos IJspeert

13   Student number: 3352234

14   Utrecht University, Master Clinical Health Sciences

15   Program: Physical therapy science

16   Target journal: Physical Therapy

17   Word count body of manuscript: 4414

18   Date: June 26<sup>th</sup> 2012

19   Target paper: Physical Therapy

20

21   Course instructor: dr. M.F. Pisters

22   Project supervisor: dr. N. van Alfen

23   Research location: Radboud University Nijmegen Medical Centre, the Netherlands

## 24 **1. Structured Abstract (264 words)**

### 25 **Introduction**

26 Currently no evidence is available for a multidisciplinary intervention helping people with  
27 upper extremity complaints who are recovering from neuralgic amyotrophy (NA). These  
28 patients encounter numerous difficulties in daily life and are often not able to resume work  
29 activities. We have developed a multidisciplinary treatment program for these patients,  
30 combining physical therapy and occupational therapy. We have tried to establish a proof of  
31 principle for this treatment program

### 32 **Design**

33 Proof of principle pilot study

### 34 **Methods**

35 Eight patients recovering >6 months after NA, recruited from our outpatient clinic, have been  
36 structurally measured 3 months before and during the treatment period. All patients received  
37 eight sessions of occupational- and physical therapy over a period of 16 weeks. Including  
38 proprioceptive shoulder training, strength training, behavioral therapy and teaching of energy  
39 conservation techniques.

### 40 **Results**

41 Patients showed no significant change in patients, three months prior to entering the program.  
42 At the end of program, patients show large and statistically significant improvements  
43 ( $p < 0.025$ ) on the canadian occupational performance measure (COPM) (+2.0 points) and  
44 shoulder rating questionnaire (SRQ) (+46%) measurements. The majority of patients also  
45 show large improvements in disability of arm shoulder and hand (DASH) scores and increase  
46 of serratus anterior muscle strength (6 of 8 patients). Checklist individual strength (CIS)-  
47 fatigue scores did not change significantly.

### 48 **Conclusion**

49 Results clearly show that therapy has not damaged or disadvantaged participants. They show  
50 a big improvement in efficacy in our patients. Patients learn to adapt to their complaints and  
51 limitations, are able to function better and reach higher satisfaction. Further research into a  
52 multidisciplinary approach for people recovering from NA is advised.

## 53 **2. Keywords**

54 Neuralgic amyotrophy, scapula kinesis, physical therapy, occupational therapy, self  
55 management.

### 56 **3. Dutch Summary (283 words)**

#### 57 **Inleiding**

58 Momenteel is geen bewijs beschikbaar voor een multidisciplinaire paramedische interventie  
59 voor mensen met problemen in het functioneren van de bovenste extremiteiten na  
60 neuralgische amyotrofie (NA). Deze patiënten ervaren grote functionele problemen in het  
61 dagelijks leven. We hebben een multidisciplinair behandelprogramma, waarin fysiotherapie  
62 en ergotherapie gecombineerd worden, ontwikkeld voor mensen herstellende van NA. Het  
63 doel van deze studie is het stellen van een proof of principle voor deze behandelmethode.

#### 64 **Design**

65 Proof of principle pilot studie

#### 66 **Methoden**

67 Acht patiënten herstellende van NA minstens zes maanden na hun aanval zijn gerecruteerd via  
68 de “plexuspoli”. Deze patiënten zijn structureel gemeten 3 maanden voor en gedurende de  
69 behandelperiode. Alle patiënten hebben acht behandelingen fysiotherapie en ergotherapie van  
70 een uur elk ondergaan, in een periode van 16 weken. De behandeling omvatte schouderblad  
71 stabiliteitstraining, krachtraining, gedragstherapie en het aanleren van energie besparende  
72 strategieën.

#### 73 **Resultaten**

74 Patiënten lieten geen verschil zien in scores vanaf 3 maanden voor de behandeling tot aan het  
75 begin van de behandeling. Aan het eind van de behandeling maten we grote en statistisch  
76 significante ( $P < 0.025$ ) verschillen met de canadian occupational performance measure  
77 (COPM) (+2 punten) en de shoulder rating questionnaire (SRQ) (+46%). De meerderheid van  
78 de patiënten liet ook een grote verbetering in de disabilities of arm shoulder and hand (DASH)  
79 score zien en een vergrote kracht van de musculus serratus anterior. Checklist individual  
80 strenght (CIS)-fatigue scores verbeterden niet significant.

**81 Conclusie**

82 De resultaten laten duidelijk zien dat onze patiënten niet geschaad zijn tijdens de behandeling.  
83 Meetresultaten veronderstellen een grote verbetering zien in efficiëntie van onze patiënten.  
84 Patiënten lijken te leren hoe ze met fysieke en functionele beperkingen om moeten gaan, ze  
85 kunnen beter functioneren en zijn meer tevreden. Verder onderzoek naar paramedische  
86 interventies na NA wordt aangeraden.

**87 4. List of Abbreviations**

88	NA	Neuralgic Amyotrophy
89	HNA	Hereditary Neuralgic Amyotrophy
90	INA	Idiopathic Neuralgic Amyotrophy
91	NRS	Numeric Rating Scale
92	ADL	Activities of Daily Living
93	RUNMC	Radboud University Nijmegen Medical Centre
94	OT	Occupational Therapy
95	PT	Physical Therapy
96	MI	Motivational Interviewing
97	COPM	Canadian Occupational Performance Measure
98	DASH-DLV	Disabilities of the Arm, Shoulder and Hand – Dutch Language Version
99	SRQ-DLV	Shoulder Rating Questionnaire – Dutch Language Version
100	SBBT	Sugar, Bag and Bottle Test
101	HHD	Hand-held dynamometry
102	CIS	Checklist Individual Strength
103	SF-36	Short Form (36) health survey
104	MCID	Minimal Clinically Important Difference
105	VAS	Visual Analogue Scale

## 106 **5. Introduction and rationale**

107 Neuralgic Amyotrophy (NA) is a peripheral nerve disorder which affects the brachial plexus.

108 The disease is also known as Parsonage Turner Syndrome or Brachial Plexus Neuritis<sup>1</sup>.

109 NA has two distinct types: idiopathic NA (INA) and hereditary NA (HNA)<sup>2</sup>. INA is the most  
110 common variant with a reported incidence rate of approximately 500 new cases per year in the

111 Netherlands<sup>3</sup>. However, the disorder is underrecognized and the true incidence of INA is

112 suspected to be (much) more common<sup>3</sup>. The median onset for INA and HNA is in

113 respectively the fourth- and second life's decade<sup>3,4</sup>

114 The etiology of INA is still not fully known, but the current assumption is that the disease is

115 caused by a combination of genetic, mechanical, auto- immune and environmental factors<sup>2,5</sup>.

116 Although there are promising results of prednisolone treatment in the acute phase of NA<sup>6</sup>,

117 there is no strong evidence to support any medical intervention for this disease<sup>7</sup>.

118         The onset of NA usually consists of excruciating pains (numeric rating scale (NRS) 8-  
119 10) which on average last three weeks, mostly accompanied by loss of neurological function  
120 of the upper extremities and neck-shoulder girdle. In some cases the lumbar plexus is also  
121 affected, resulting in pain and loss of neurological function of the lower extremities.

122 Sometimes the phrenic nerve is also damaged, resulting in diaphragm dysfunction<sup>4,8,9</sup>. The

123 diagnosis NA is usually established between three and nine months after onset. This delay is

124 expected to be mostly due to unawareness of the disorder, resulting in failure of detection of

125 NA in primary care<sup>8</sup>.

126         People with NA have long been assumed to have a very optimistic prognosis with near  
127 full recovery<sup>10,11</sup>. Recent research within the Dutch NA population has shown a different

128 perspective<sup>3,12</sup>. Three years after the onset of symptoms, 61% of patients report

129 musculoskeletal pains, 29% report therapy resistant continuous pains<sup>3,12</sup>. One study found

130 that after one year, 50% of patients are unable to work, after three years this number is still

131 22%. Sixty seven percent of patients report problems with household activities and 47% had  
132 difficulties with activities of daily life such as personal hygiene and grooming<sup>13</sup>. In a recent  
133 study of 248 patients more than 6 months after the onset of NA, only 38% of patients report  
134 no pain at all, 60% of patients reported pain in the affected shoulder during movement or  
135 lying down on it and 56% reported continuous mainly “nagging” pains. Pain has shown to  
136 cause restrictions in daily life in 54% of patients and 86% of patients experience increased  
137 fatigability of the affected arm. Forty-five percent of patients reported not being able to use a  
138 computer keyboard for more than 30 minutes<sup>14</sup>.

139 The persistence of complaints even when the peripheral nervous system is  
140 recovering is suggested to be related to the loss of motor function and movement sensation of  
141 the scapula-glenohumeral complex<sup>13</sup>. Patients are described as having dynamic and static  
142 instability of the scapula caused by a dysfunction of the serratus anterior, trapezius, and  
143 rhomboid muscles<sup>7</sup>. These muscles are responsible for stabilizing the scapula against the chest  
144 wall during the complex scapulothoracic movement, especially during daily overhead  
145 activities requiring an anteflexion/abduction movement<sup>15-18</sup>. During clinical examination  
146 patients with NA also show a dysfunction of primary cervical stabilizers, myofascial  
147 triggerpoints in mainly proximal scapular musculature and neural stretching pains of mainly  
148 the brachial plexus. These physical problems combined with adaptational problems decrease  
149 NA patients’ potential for functional recovery<sup>7,13</sup>.

150 Although allied health service interventions are advised, there is currently no evidence  
151 available to support such an intervention in patients recovering from NA. There are  
152 indications that standard physical therapy interventions, such as rotator cuff training or  
153 glenohumeral mobilization techniques, are ineffective or even counterproductive in a  
154 significant proportion of the patients treated<sup>7,13,14,19</sup>.

155 The departments of Rehabilitation and Neurology, of the Radboud University

156 Nijmegen Medical Centre (RUNMC), have started a multidisciplinary outpatient clinic in  
157 2009 called “the plexus clinic”, which serves as the national referral centre for NA in the  
158 Netherlands. In this plexus clinic patients are assessed by a neurologist, a rehabilitation  
159 physician, a physical therapist and an occupational therapist. Also an allied health treatment  
160 program has been developed for patients recovering from NA.

161 Patients with NA are comparable to patients with other chronic conditions because  
162 they encounter problems in adequate use of pain medication, physical functioning,  
163 participation in work and social environment and sports<sup>14</sup>. Thus, interventions used in chronic  
164 disease approaches might be useful in the treatment of problems experienced after NA.  
165 Functional capacity is impaired by pain, fatigue and state of decreased emotional well-being<sup>14</sup>,  
166 <sup>20,21</sup>. To improve daily functioning and reduce pain and fatigue in patients recovering from  
167 NA, they need to find balance in daily activities and their functional capacity. This may be  
168 achieved by the increase of disease knowledge, adaptation of behavior and improvement of  
169 upper extremity control. Self-management interventions have been successfully used in  
170 different chronic disease groups<sup>22-24</sup>. The plexus clinic treatment approach combines self-  
171 management skills with other relevant factors.

172 The treatment program encompasses training of body functions by improvement and  
173 adaptation of body functions such as movement and position sense of the affected shoulder  
174 girdle and improving functional endurance<sup>19,25-27</sup>. The combined program also relies on  
175 teaching patients problem solving skills similar as described in the model of D’zurilla and  
176 education combined with role management skills as described by Lorig et al.<sup>28,29</sup>. The  
177 program combines physical therapy with occupational therapy and is supported by a  
178 rehabilitation physician.

179 Patients are encouraged to cope with life on a daily basis and become self-managing.  
180 We hypothesize that an increased disease knowledge, a new behavioral approach to activities



181 and greater control over body functions will decrease pain and fatigue. Self-efficacy is  
182 expected to improve when body functions and activities are adjusted to balance each other. It  
183 is theorized that patients who experience an increase in self-efficacy will continue using  
184 acquired skills to their benefit and therefore become self-managing<sup>29</sup>. This leads to a new  
185 patient adaptive treatment model (figure 1)



186

187 Figure 1: patient adaptive NA treatment model

188 The model should be used as a patient adaptive chart, the model varies with each patient and  
189 shows areas of attention in the opinion of the therapist. This can be used for patient and  
190 therapist feedback purposes. During the treatment pain and fatigue should be reduced. The  
191 occupational therapist works mainly in the outer two circles but also on improving behavior  
192 and knowledge of the disease. The physical therapist mainly works on improvement of body  
193 functions, adaptation of behavior and the conveying of knowledge about the disease.  
194 The aim of this study was to establish a proof of principle considering the efficacy of our  
195 allied health services treatment approach in patients with sub acute NA

## 196 **6. Methods**

### 197 *Participants*

198 Patients were recruited by the neurologist or rehabilitation physician by convenience sample  
199 from our multidisciplinary plexus clinic based at the department of Rehabilitation of the  
200 Radboud University Medical Centre in Nijmegen (RUNMC).

201 Patients were included if they fulfilled the following criteria; 1) diagnosed with NA by a  
202 neurologist; 2) uni- or bilateral complaints with a NRS pain score  $>5$ ; 3) recovering from  
203 subacute NA  $> 6$  months after onset of the disease; 4) aged between 18 and 65 years; 5)  
204 understanding of Dutch written and spoken language.

205 Patients were excluded if they had: 1) a Beck depression inventory score  $>20$ <sup>30</sup>; 2) history of  
206 cerebro vascular accidents or other central neurological disease; 3) cervical radiculopathy; 4)  
207 previous surgery of the affected neck and or shoulder; 5) other neuromuscular disease.

208 Informed consent of each patient was obtained before the first treatment session.

209 Descriptive data of subjects were collected: age, sex, affected shoulder, duration of  
210 complaints before entering treatment.

### 211 *Ethical considerations*

212 This study was approved by the ethics committee of the RUNMC, with reference number:  
213 2011/481.

214

### 215 *Intervention*

216 Patients were treated in eight, two-hour, sessions. These sessions were spread out over 16  
217 weeks. The first four weeks, patients were treated weekly. Week four to eight, patients were  
218 treated once every two weeks. Week 8 to 16, patients were treated once every four weeks.

219 After this period patients were expected to have (re-)gained the possibility for self

220 management and the program was ended. Every treatment session consisted of one hour of

221 physical therapy and one hour of occupational therapy.

222 The physical therapy intervention addressed the training of body functions, education about  
223 the disease and its symptoms and behavioural change; see below. The occupational therapy  
224 intervention addressed behavioural change and analysis and adaptation of activities or the  
225 environment (external factors) and obtaining a balance between activities during the day or  
226 week in order to reduce the complaints. The rehabilitation physician supervised the program  
227 and supported when needed with advanced diagnostics or glenohumeraal steroid infiltration.  
228 Treatment consisted of main and optional interventions.

229

### 230 *Main physical therapy interventions*

231 Every patient was trained in regaining scapular muscular balance as described by Cools et.  
232 al.<sup>26</sup>. Further in the program, patients also received progressive resistance training of rotator  
233 cuff- muscles<sup>31</sup>. The rotator cuff training was carried out after the scapular muscular balance  
234 training because it was recognized that scapular stability is essential for the functioning of  
235 arm positioning muscles<sup>32, 33</sup>. In both interventions the focus lied on recovery of sensomotory  
236 function, and all exercises were supposed to be carried out without or with minimal pain and  
237 no or minimal pain after the exercise. The behavioural change was addressed by use of  
238 motivational interviewing techniques as described by Miller et al.<sup>34, 35</sup>.

239

### 240 *Optional physical therapy interventions:*

241 If patients had difficulties detecting an appropriate scapula position during exercise,  
242 and were not able to successfully implement learned scapula control movements in daily life  
243 after the second treatment session. These patients received scapular proprioceptive taping as  
244 described by Morissey and Host<sup>36, 37</sup>.

245 Some patients with NA experienced neural stretching pains of the brachial plexus.

246 These were likely caused by decreased space between the ribs, scapula and clavicle in the  
247 presence of a habitually protracted and adducted scapula because of serratus anterior  
248 weakness and compensatory activation of the pectoral and trapezius muscles. When present,  
249 this complication was treated by use of neural mobilisation techniques<sup>38</sup>. For this purpose we  
250 utilized movements designed for the “Upper Limb Tension Test”<sup>39</sup>. Patients were instructed  
251 to grab hold of the doorway and stretch out the arm until they experienced mild neurological  
252 sensations such as tingling or radiating pain. This stretching exercise was done three times a  
253 day with a duration of 20 to 30 seconds and repeated three times.

254 Patients that lacked of control of the primary cervical stabilizing muscles, tested by  
255 use of the cranio-cervical flexion test using pressure biofeedback<sup>40</sup>, received sensomotory  
256 cervical stability training as described by Murphy et.al.<sup>41</sup>. Patients were treated by muscular  
257 relaxation exercises and myofascial triggerpoint releases as pre-conditioning for sensomotory  
258 scapular and cervical training. This was done when muscle tone was considered high and or  
259 trigger points were found during physical examination by the therapist<sup>42-45</sup>.

### 260 *Occupational therapy interventions*

261 The overall goal of the occupational therapy was to help/facilitate the patient to regain control  
262 over his or her life and attain satisfaction with the achieved situation, even when residual  
263 symptoms are present. The occupational therapy program is based on the energy conservation  
264 course of Packer<sup>46</sup>, the treatment of chronic pain patients<sup>47</sup> and the experiences of the plexus  
265 team within the RUNMC with the NA population. Willingness and readiness to change are  
266 essential for the therapy to be successful. Therefore Motivational Interviewing (MI) was  
267 used<sup>48, 49</sup>. It is important for the therapist to give the patient insight into activities that provoke  
268 pain and to teach self-management strategies to reduce (over)load and gradually increase  
269 abilities. In every therapy session a (or several) topic(s) were addressed including the  
270 implementation of minibreaks, attention for posture, communication with others, analyzing

271 and adapting activities or the environment and finding an balance in activities during the day  
272 and the week.

273 *Outcome measures for physical and occupational therapy*

274 The outcomes for treatment efficacy were the presence and severity of functional shoulder  
275 limitations and quality of life. The Disabilities of Arm Shoulder and Hand Dutch Language  
276 Version questionnaire (DASH-DLV) was used next to the shoulder rating questionnaire  
277 (SRQ), because it is reported to be more sensitive to change and have higher reliability and  
278 validity than the SRQ<sup>50</sup>. The SRQ is a standard screening tool used during the plexus clinic  
279 intake and was also used in this study to control change in functional ability of patients before  
280 they entered the program. The short form 36 questionnaire (SF-36) was used to measure  
281 quality of life as perceived by the patient. The Canadian Occupational Performance Measure  
282 (COPM) is used to evaluate performance and satisfaction of the most important daily  
283 occupations that were identified by subjects as a problem. The Checklist Individual Strength  
284 20 (CIS-20) was used to measure fatigue, the CIS-20 was also used during the plexus clinic  
285 intake and was evaluated for patient change in perceived fatigue before they entered the  
286 program. The properties of the questionnaires are described below.

287 *DASH Dutch Language Version (DASH-DLV)*

288 The DASH Dutch Language Version is a reliable valid and responsive measure for patients  
289 with various shoulder disorders<sup>50-53</sup>. It consists of 30 items, scored on a five point Likert scale,  
290 regarding shoulder, arm and hand disabilities. The items combined provide a score between  
291 24 (no disability) and 124 (maximal disability)<sup>53</sup>. There are also 2 sub scores consisting of 4  
292 items relating to functional disabilities in sports and work related activities. A minimal  
293 clinically important difference (MCID) of 10 points was found in a population with various  
294 shoulder disorders undergoing surgery<sup>52</sup>.

295 *Shoulder Rating Questionnaire-Dutch Language Version (SRQ –DLV)*

296 The Shoulder Rating Questionnaire-Dutch Language Version (SRQ –DLV) is a reliable, valid  
297 and responsive measure for patients with various shoulder disorders<sup>51, 54, 55</sup>. It consists of a  
298 Visual Analogue Scale for global assessment of how well patients are doing with respect to  
299 their shoulder, and 19 multiple choice questions (scoring from 1 = poorest to 5 = best) for  
300 seven subscales (global assessment, pain, daily activities, recreational and athletic activities,  
301 work, satisfaction and areas of improvement). The first five subscales are graded separately  
302 by averaging the scores of the completed questions, multiplied by 2 and a weighting factor.  
303 The sum score for these subscales ranges from minimum 17 to maximum 100 points, higher  
304 scores indicating a better condition. The recommended MCID for the SRQ was set at 9%  
305 (“slightly better” ) or 13,5% (much better ) improvement of the baseline score<sup>56</sup>.

306

307 *Short Form 36 Questionnaire (SF-36)*

308 The SF-36 is a valid and reliable self-report questionnaire to measure general health and  
309 quality of life. The SF-36 consists of 36 questions and assesses eight health concepts: 1)  
310 limitations in physical activities because of health problems; 2) limitations in social activities  
311 because of physical or emotional problems; 3) limitations in usual role activities because of  
312 physical health problems; 4) bodily pain; 5) general mental health (psychological distress and  
313 well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality  
314 (energy and fatigue); and 8) general health perceptions<sup>57, 58</sup>. The MCID of the SF-36 was  
315 reported between a 2,0 and 7,8 points difference in a population lower extremity  
316 osteoarthritis, no MCID for shoulder related complaints was found<sup>59, 60</sup>.

317

318

319

320 *Canadian Occupational Performance Measure (COPM)*

321 The COPM is a semi-structured interview in which the patient is encouraged to identify  
322 problems in self-care, productivity and leisure activities<sup>61</sup>. It detects changes in the patients'  
323 self-perception of their occupational performance over time<sup>61</sup>. It describes activities patients  
324 cannot do, or have problems doing. The patient rates the importance of the problems on a 10-  
325 point scale from 'not important' to 'extremely important'. The five most important problems  
326 are selected and the patient is asked to rate his or her current performance of each of these  
327 activities on a 10-point scale from 'not able to do it' to 'able to do it very well'. Last, the  
328 patient is asked to rate satisfaction with the performance on a 10-point scale from 'not  
329 satisfied at all' to 'extremely satisfied'. Performance and satisfaction can be reassessed during  
330 and after a period of treatment. The average change scores of performance and satisfaction  
331 can be used as outcome measures in rehabilitation<sup>62</sup>. The COPM is reported to be responsive,  
332 reliable and valid<sup>63-65</sup>. The COPM could be used for different diagnose groups, and enables  
333 client-centered practice<sup>65</sup>. The MCID for the COPM was recommended to be 2 points on the  
334 satisfaction and performance subscales<sup>61</sup>.

335

336 *Checklist Individual Strength 20 (CIS-20)*

337 The Checklist Individual Strength 20 (CIS-20) consists of 20 statements in 4 dimensions  
338 (subjective fatigue, reduction in motivation, reduction in activity and reduction in  
339 concentration) for which the person has to indicate on a 7 point scale to what extent it is  
340 applicable. The statements refer to aspects of fatigue experienced during the previous 2  
341 weeks. A CIS total score is calculated by adding the four dimensions, ranging from 20-140.  
342 Higher scores indicate a higher degree of fatigue, more concentration problems, reduced  
343 motivation, and less activity. A total score of > 76 indicates fatigue and a score of  $\geq 35$  on the  
344 CIS-20 fatigue subscale indicates severe fatigue<sup>66, 67</sup>

345 *Maximal isometric strength testing*

346 Maximal isometric strength testing of flexion and extension of the elbow, glenohumeral exo-  
347 and endorotation, and the serratus anterior muscle was performed. This was done by use of a  
348 “hand held dynamometer” (the microfet2<sup>®</sup>) as protocolised by Bohannon et al.<sup>68</sup>, with  
349 exception of the serratus anterior muscle which has been tested in the position advised in a  
350 study of Ekström et. al.<sup>69</sup>. Isometric strength testing of a hand held dynamometer is reported  
351 to be valid, and reasonably reliable<sup>68, 70</sup>. Grips strength was evaluated with a Takei<sup>®</sup> grip  
352 strength dynamometer, which has been reported to be valid and very reliable<sup>71-73</sup>. The  
353 reported minimally detectable difference (MDC) is 17.7 to 35.3 Newton’s for these types of  
354 measurements in patients with shoulder pain and loss of function<sup>74</sup>.

355

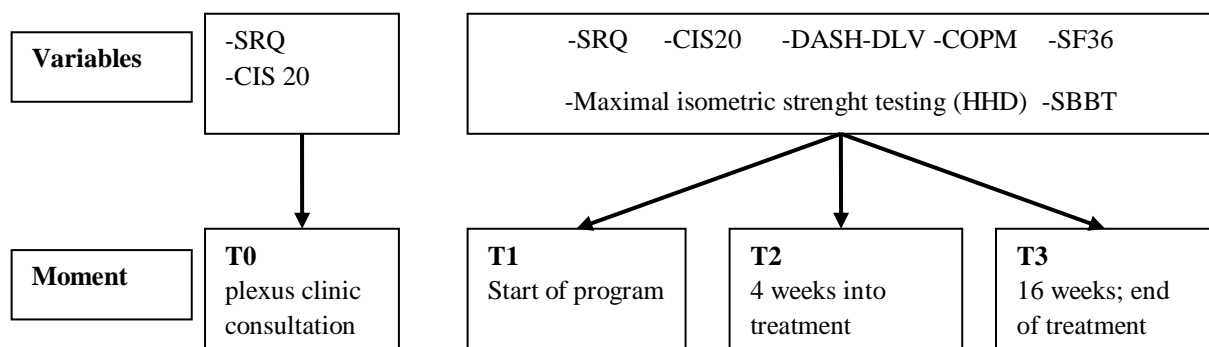
356 *Sugar Bag and Bottle Test (SBBT)*

357 A newly developed functional performance observation was used for the upper extremities.  
358 The test is developed to assess the capacity to perform tasks that are often problematic in  
359 patients with NA such as lifting heavy bags for a short distance and repetitively reach and lift  
360 and unscrew a bottle. The sugar bag and bottle test (SBBT) was developed at our center as a  
361 custom test for NA patients and has not yet been validated. During the test, subjects had to  
362 carry two shopping bags containing eight bags of sugar over a distance of 20 meters. ,Next,  
363 subjects were asked to place eight packs of sugar on surface levels below chest-height and  
364 overhead in a cupboard. After this, they were asked to sit down and unscrew a water  
365 bottle, for testing of functional hand strength and pro- and supination. Every performance was  
366 timed and pain experienced during and after testing was recorded by use of a 10 point  
367 numeric rating scale (NRS).



368 *Study Timeline*

369 Measurements were carried out at the following time points (figure two)



370

371 Figure 2: study procedures timeline

372 SRQ: shoulder rating questionnaire, CIS20: Checklist individual strength 20, DASH:

373 disabilities of arm shoulder and hand, Dutch language version, SF-36: Short form 36, HHD:

374 handheld dynamometry, SBBT: sugar bag and bottle test

375 *Statistical analysis*

376 Before entering treatment patient were measured twice during baseline to control for change

377 in disability, pain, perception of shoulder function and fatigue. This was done by comparing

378 the T0 questionnaires (SRQ global, SRQ Total and CIS-20) with the T1 questionnaires with

379 use of the dependent samples T-test. Difference scores, of T0 to T3 for the SRQ and CIS-20

380 and T1 to T3 for the other outcomes, were controlled for normality by use of a quantile

381 probability plot (qq-plot). Difference scores in outcomes were checked for significance by

382 use of the paired samples T-test, significance was set at 0.05. Ninety-five percent confidence

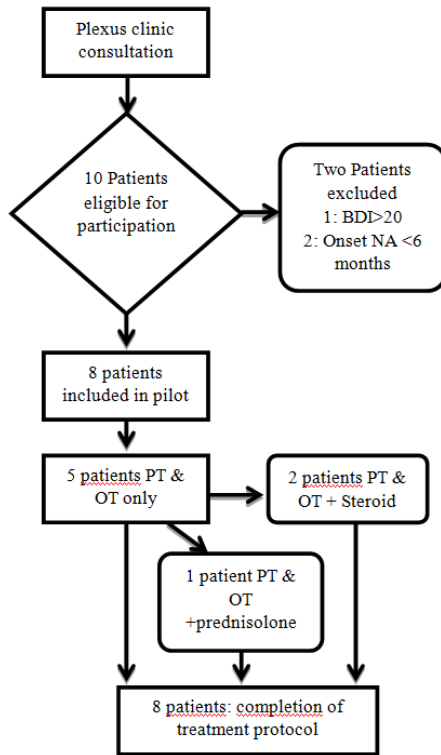
383 intervals were calculated. All statistical analysis were carried out with use of IBM SPSS

384 statistics 18.0 for windows.

385

386 **7. Results**

387 An overview of the inclusion and treatment progress is shown in the flowchart (figure 3)

388  
389 Figure 3: Inclusion and study progress flowchart390 *Patients*

391 Eight patients were included in the pilot. Their mean age was 46,4 years with a standard  
 392 deviation (SD) of 10.4. The mean duration of complaints until start of treatment was 34,5  
 393 months ranging from 7 to 156.

394 Patient characteristics at baseline are shown in table 1.

395

396

397 Table 1: Patient characteristics at baseline

Patient	Sex	Age in years	Time onset NA until treatment start in months	Arm dominance	Dominant side affected?	Baseline CIS_fatigue score	Baseline SRQ total score
1	Female	34	47	Right	Yes	27	63.93
2	Male	39	156	Ambidextrous	Yes	48	51.75
3	Female	58	10	Right	Yes	42	42.42
4	Male	36	15	Right	No	51	45.45
5	Male	52	11	Right	No	39	45.82
6	Male	62	10	Right	Yes	15	44.80
7	Male	41	7	Right	Yes	43	44.50
8	Male	49	20	Right	Yes	46	50.67

398 NA: neuralgic amyotrophy, CIS-fatigue: Checklist individual strength fatigue subscale, SRQ total: shoulder  
 399 rating questionnaire total score

400

401 All patients completed the program. Two patients developed physical therapy resistant  
 402 glenohumeral capsular inflammation. They both were treated by the rehabilitation physician  
 403 with a glenohumeral capsular steroid infiltration once, resulting in a reduction of  
 404 inflammation and pain. One patient experienced prolonged nerve irritation of the middle  
 405 plexus, including the pectoralis nerve, median and radial nerve. Which was treated with oral  
 406 prednisolone. This decreased tinkling sensations and hypo sensibility and seemed to help  
 407 reduce muscle tone in the pectoralis minor muscle.

#### 408 *Results*

409 At baseline, no patient showed significant change in the scores of the SRQ total, SRQ global  
 410 and the CIS-fatigue subscales during the 3-month period before start of the treatment program  
 411 ( $p>0.29$ ).

412 Seven patients improved in the COPM performance subscale, with a range of -0.3 to 3.2  
413 points. The COPM satisfaction shows improvement shows improvement in all patients, with a  
414 maximal improvement of 4.8 points (range; 0.2-4.8). Six patients showed an improvement on  
415 the DASH total scores, with 10 points or higher with a maximal improvement of 36 points.  
416 Two patients deteriorated on this scale with a maximum of ten points. The CIS-fatigue score  
417 shows improvement in scores in six of eight patients with a range of -9.0 to 12.0.  
418 The SRQ change scores are large. The SRQ total score showed a statistically significant  
419 improvement of 46.3 points, which is a substantial improvement of 46%, that exceeds the  
420 MCID of 13.5% for substantial improvement<sup>56</sup>. The SRQ total score improved in all patients  
421 with a minimum of 17.5 and a maximum of 88.7 points. The SRQ global score also showed  
422 improvement in all patients, ranging between 13.5 and 64.5 points. The SRQ pain subscale  
423 improved in all patients with 2 up to 18 points. The SF-36 social functioning scale showed an  
424 improvement up to six points in six patients while the other 2 deteriorated with a maximum of  
425 one point. The SF-36 health change subscale showed a deterioration with a maximum of  
426 three points in seven of eight patients. For the DASH score, six of eight patient showed an  
427 improvement >10 points, exceeding de MCID for the DASH<sup>52</sup>. These results were almost  
428 statistically significant with a drop of 11,3 points and a 95% confidence interval between 0.86  
429 and -23.36 (P: 0.069). The COPM scores also improved in all patients, with a improvement of  
430 1.4 points in performance and 2.3 points in satisfaction. The satisfaction subscale did not only  
431 improve significantly but also exceeded the MCID of 2 points reported for this scale<sup>61</sup>  
432 The SF-36 scores did not improve significantly except for the social functioning (+1.6 points)  
433 and health change (+1.5 points) subscales.  
434 The hand-held dynamometry measurements only show clear improvements for the serratus  
435 anterior muscle strength. Values improved for six of eight patients with a maximum of 187.5  
436 Newton's. The SBBT total scores did not improve significantly, only two patients improved

437 with a maximum of two points. The SBBT pain scores improved in six of eight patients with a  
 438 maximum of 4.3 points on a 10 point scale, significance was not reached.

439 Group results for the initial and follow up measurements are shown in table 2.

440 Table 2: Measurement outcomes

Outcome	Mean Baseline	Mean end of treatment	Paired Differences			Significance*
			Mean difference	95% confidence interval		
				lower	upper	
COPM performance	<b>4.5</b>	<b>5.9</b>	<b>1.4</b>	<b>0.4</b>	<b>2.4</b>	<b>.015</b>
COPM satisfaction	<b>4.3</b>	<b>6.6</b>	<b>2.3</b>	<b>0.9</b>	<b>3.7</b>	<b>.005</b>
DASH total	62.3	51.0	-11.3 <sup>a</sup>	-23.3	0.9	.064
CIS-20 fatigue	38.3	36.0	-2.3 <sup>a</sup>	-8.0	3.5	.263
SRQ total	<b>48.7</b>	<b>63.4</b>	<b>14.7</b>	<b>7.4</b>	<b>22.0</b>	<b>.002</b>
SRQ global	<b>5.9</b>	<b>9.3</b>	<b>3.5</b>	<b>1.9</b>	<b>5.0</b>	<b>.001</b>
SRQ pain	<b>19.5</b>	<b>26.0</b>	<b>4.0</b>	<b>2.4</b>	<b>10.6</b>	<b>.007</b>
SRQ adl	<b>12.2</b>	<b>14.6</b>	<b>2.4</b>	<b>.4</b>	<b>4.4</b>	<b>.025</b>
SF36 social functioning	<b>5.4</b>	<b>7.0</b>	<b>1.6</b>	<b>-1.1</b>	<b>3.4</b>	<b>.040</b>
SF36 health change	<b>2.0</b>	<b>3.5</b>	<b>1.5</b>	<b>0.7</b>	<b>2.3</b>	<b>.016</b>
Energy saving strategies	7.3	7.7	0.4	-0.5	1.4	.263
SBBT Total (seconds)	2.6	1.9	-0.7	-2.6	1.1	.365
SBBT Pain (NRS)	4.2	3.1	-1.1	-3.6	1.2	.277
Pinchgrip affected arm (N)	10.2	8.2	-2.0	-4.5	0.4	.084
Handgrip affected arm (N)	35.2	32.9	-2.3	-7.1	2.6	.313
Exorotation affected arm (N)	94.4	97.2	2.8	-21.8	27.5	.791
Endorotation affected arm (N)	108.4	116.4	8.0	-27.5	43.5	.611
Elbowflexion affected arm (N)	158.5	165.9	7.4	-34.5	49,3	.688
Serratus affected arm (N)	162.7	210.4	47.7	-15.2	110.5	.116

Elbowextension affected arm (N)	125.4	105.6	-19.8	-60.0	20.3	.260
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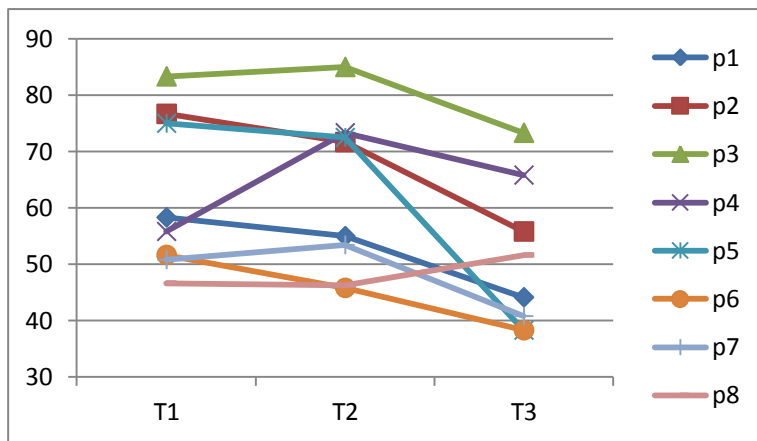
442 \*significance and paired statistics based on paired samples T-test

443 <sup>a</sup>Negative scores relate to functional improvement on scale

444 COPM; Canadian occupational performance measure, DASH; disabilities of arm shoulder and hand, Dutch  
 445 language version, CIS-20; Checklist individual strength 20, SRQ; shoulder rating questionnaire, SF-36; Short  
 446 form 36, SBBT; sugar bag and bottle test, (N); Strength values in Newton force, (NRS); numeric rating scale

447 Results for individual outcome measures are shown in figures four to seven.

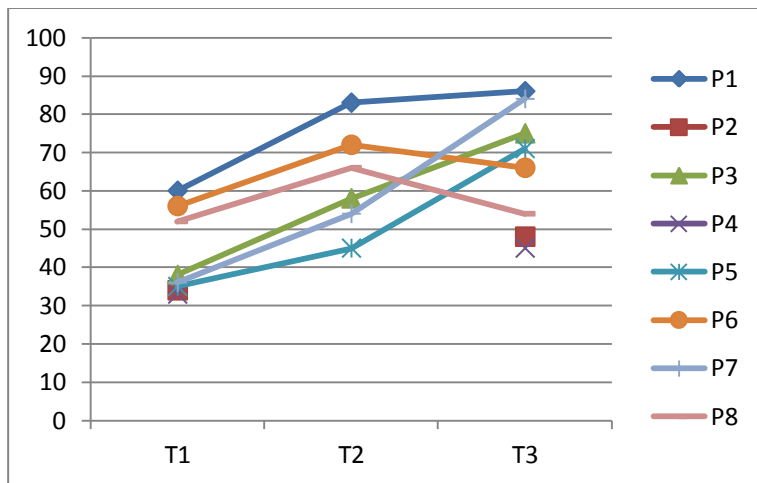
448



449

450 Fig 4: DASH-DLV scores

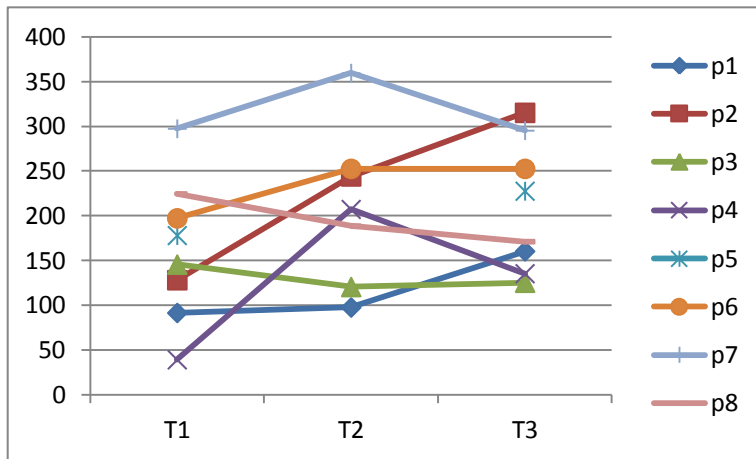
451 P: Patient



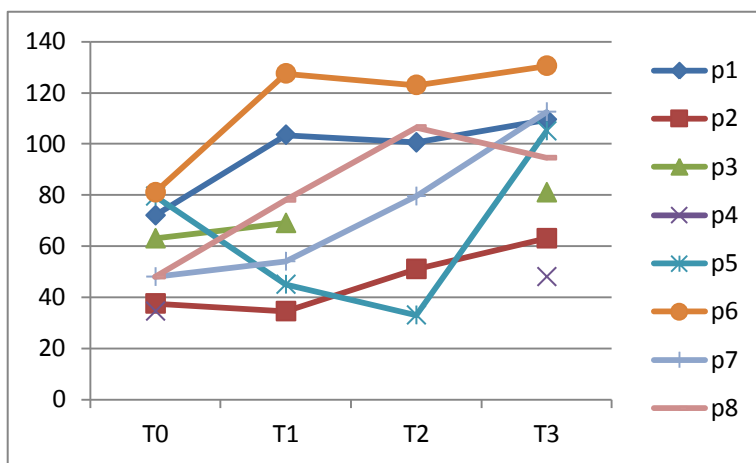
452

453 Fig 5: COPM satisfaction

454 P: Patient



455  
456 Fig 6: Serratus anterior muscle strength, affected shoulder isometric muscle strength HHD (newton force)  
457 P: Patient



458  
459 Fig 7: SRQ global perception scores  
460 P: Patient

461

462 **8. Discussion**

463 The aim of this study was to establish a proof of principle considering the efficacy of our  
464 allied health services treatment approach in patients with sub acute NA

465 The vast majority of patients showed improvement in functioning, but more so in satisfaction  
466 in the COPM scores. All patients showed large improvement in the SRQ subscales, and the  
467 majority in the DASH total score. Even the lower limits of the 95% confidence interval relate  
468 to a 26.3 points and 20.4 points increase on respectively the SRQ-total and SRQ-global  
469 subscales, showing a clear clinically relevant improvement. These improvements are notable  
470 even when there was no clear change in physical strength of the affected nerves and muscles.

471 Strength values of the upper extremities obtained by hand-held dynamometry showed no  
472 significant change during the treatment period. Some mean changes support an increase in  
473 strength larger in number than the reported minimally detectable difference (MDC) of 17.7 to  
474 35.3 Newton's for these types of measurements in patients with shoulder pain and loss of  
475 function<sup>74</sup>. However, these differences were not found statistically significant with quite  
476 broad 95% confidence intervals indicating that, although the measurements were carried out  
477 by one physical therapist, the performed measurements in our subjects might not have been  
478 very reliable. The CIS-fatigue sub scores did not improve significantly and in fact only  
479 showed improvement in two of eight patients, this shows us that there was no positive effect  
480 found on the perceived fatigue of the patients treated.

481 This study was designed as a proof of principle pilot study, and has its limitations. The  
482 physical measurements were carried out by the treating physical therapist and the treating  
483 occupational therapist. This was due to practical limitations in this phase of research. Another  
484 limitation is the group size, though we are enthusiastic about finding rather large and  
485 significant differences even in this small study. Two patients have received optional treatment  
486 consisting of glenohumeral steroid infiltration, sub analysis without these two subjects  
487 showed no large differences as to the whole group analysis.

488 Overall we feel that the observed group of patients showed us that our treatment has not  
489 harmed or negatively influenced the physical and social functioning of our patients. On the  
490 contrary, the perceived global status in the SRQ and patient satisfaction in the COPM  
491 improved quite well during the treatment period. Muscle strength did not increase  
492 significantly, which shows us that improvement in this population is primarily caused by  
493 functional and behavioral adaptation to nerve damage and corresponding loss of function of  
494 the affected shoulder. Therefore, patients' behavior in relation to complaints, smart alternative  
495 ways of carrying out (heavy) activities and acceptance of limitations appear to be the key



496 issues for treatment of these patients. Patients seem to learn to adapt to their limitations and  
497 achieve higher efficacy without big improvements of body functions. This is why we think a  
498 multidisciplinary intervention aimed at control of shoulder movements, adaptation of  
499 behavior and convening of knowledge provide empowering ingredients for patients to deal  
500 with their limitations.

501 We strongly emphasize the need for a further controlled study in a larger population to  
502 provide this multidisciplinary program with a firmer evidence base. Also qualitative studies  
503 are recommended to give better insight and understanding of the treatment ingredients that  
504 helped patients to deal with the problems as a result of NA.

## 505 **9. Acknowledgements**

506 The author would like to thank dr. Nens van Alfen, dr. Edith Cup and Renske Janssen (OT)  
507 for their onsite and practical support during the research project and the department of  
508 rehabilitation of the RUNMC for facilitating the study. Also our gratitude goes out to dr.  
509 Martijn Pisters, for supporting the project from within the Clinical health science organization  
510 of the Utrecht University.

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