

1 Study Protocol.....2

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Study Protocol

Efficacy of Tuina combined with Yijinjing for patients with nonspecific chronic neck
pain: a randomized controlled trial

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62 **1. Background**

63 Non-specific chronic neck pain (NCNP) is a serious health and public problem
64 worldwide. Neck pain appears between the occipital condyle and C7 in the neck
65 region [1]. Neck pain can be divided into specific neck pain and non-specific neck
66 pain. Non-specific neck pain is also known as mechanical neck pain which is defined
67 as simple neck pain without specific pathological changes and neurological
68 impairments; it can be diagnosed as non-specific chronic neck pain if the symptoms
69 persist more than 3 months [2]. Two-thirds of the adult population suffer from
70 non-specific chronic neck pain [3]. According to the research, women are more likely
71 to be affected than men [4]. The annual incidence of NCNP is increasing because of
72 sedentary lifestyle and working conditions [5,6]. Patients' quality of life and
73 efficiency of work decrease due to chronic pain, and high treatment expenses also
74 cause a huge burden to society [7].

75 The mechanism of NCNP is still not clear. The researchers explained the
76 mechanism from different aspects, such as the mechanical factors, EMG, and ROM.
77 Altered muscle cross-sectional area, thickness, size, and activity of deep neck muscles
78 have been mentioned repeatedly in the previous [8-10]. Rahnema et al. [11] showed
79 the change of altered EMG activity and the atrophy of deep neck extensor in patients
80 with NCNP which is thought to be the recurrence of NCNP. Barnsley et al. [12]
81 demonstrated that limited ROM aggravates the tightness of the muscles surrounding
82 the neck and joint adhesion which also leads to a decrease in biomechanical function
83 of the neck, and this condition causes non-specific chronic neck pain. In addition,
84 much attention has been paid to the scapular region. Dyskinesia of the scapula and
85 misalignment of the scapula always follow with NCNP [13,14]. In addition, according
86 to the "Bio-Psycho-Social" framework, repetitive and sedentary working conditions
87 and postural abnormalities also contribute to NCNP [15]. Anxiety and depression
88 associated with the existence of higher levels of pain in musculoskeletal pain
89 conditions [16].

90 For most NCNP patients, first-line medication options always include analgesics
91 like acetaminophen or non steroidal anti-inflammatory drugs (NSAIDs), but the
92 effects of these drugs vary from person to person and they often do harm to the
93 digestive, blood, urinary, and other systems because of the long-term use [17-19]. So,
94 various complementary treatments have become more and more popular. Exercise
95 therapy, ultrasound, acupuncture, electrical nerve stimulation, and manual therapy
96 have also been used widely in treating NCNP [20]. However, poor standardization of
97 experiments, small sample size, low-quality control, and insufficient objective index
98 caused controversy about their efficacy.

99 Tuina therapy is also called Chinese massage [21]. Tuina has also been proved to
100 be a feasible way to treat neck pain and has been widely used in China [22]. As an
101 important part of Chinese traditional medicine, Tuina is a manual therapy with
102 anatomical and physiological principles, putting emphasis on meridians and acupoints
103 [23]. Tuina therapy mainly includes two parts: soft tissue manipulation and spinal
104 manipulation. Soft tissue manipulation techniques include stroking, kneading, and
105 drumming, which are also found in some Western massage techniques, and spinal

106 manipulation also combined with high-velocity low-amplitude thrust manipulation
107 techniques [23]. Two systematic reviews had shown that Tuina therapy can reduce
108 pain and muscle tension for patients with non-specific neck pain [24, 25]. Tuina
109 therapy acts on soft tissue and connective tissue that may lead to local biochemical
110 changes that regulate local blood circulation, improve muscle flexibility, enhance
111 lymph movement, and loosen connective tissue adhesion, which may alternately
112 improve local injury and inflammation of the reuptake mediator [26]. Chinese
113 traditional exercise is also a kind of exercise therapy which puts attention on the
114 coordination of posture, meditation, and breathing [27]. Exercise therapy has been
115 proved to be good for non-specific chronic neck pain [28]. Yijinjing is an ancient
116 Chinese traditional exercise which has been widely practiced for keeping fit and
117 treating diseases. Yi means change, Jin refers to muscles and sinews, and Jing means
118 methods, so Yijinjing means a series of exercises to change the muscle and sinews
119 literally. Yijinjing is a low-intensity, noncompetitive, and non-impact exercise. TCM
120 doctors often apply Yijinjing as a complementary therapy to NCNP. Yijinjing can
121 reduce neck pain and disability, as well as reduce stress, anxiety, and depression by
122 unique movements [29–31]. Based on previous researches, people can improve
123 sub-health, reduce pain, and promote immune cell by practicing Yijinjing regularly
124 [32, 33]. However, to confirm these findings, more studies with larger sample sizes,
125 standardized trials, and adverse event reports are needed.

126 Studies have shown that a single treatment plan is not effective, so the
127 combination therapy has received more attention and is recommended by related
128 scholars [34, 35]. There is quite a little evidence for the efficacy of Tuina on
129 non-specific chronic neck pain, especially when combined with Yijinjing. We
130 hypothesize that Tuina and Yijinjing have beneficial effects on nonspecific chronic
131 neck pain because that is a case with subacute and long-lasting neck pain [36]. We
132 want to further explore whether Tuina combined with Yijinjing exercises can play a
133 better role in pain, disability, and negative emotions. Thus, we designed a randomized
134 controlled trial (RCT) to prove our hypothesis. This trial will provide a solid clinical
135 foundation for the efficacy of Yijinjing combined with Tuina. It will be served as a
136 prospective experiment as well.

137 **2.Study objectives**

138 This study is a randomized, evaluator and statisticianblinded, parallel-controlled,
139 superiority trial. The purpose of this trial will be to assess the following: 1) Whether
140 Tuina combined with Yijinjing is not inferior to Tuina regarding pain, disability, and
141 negative emotions for patients with NCNP.

142 **Specific primary objective**

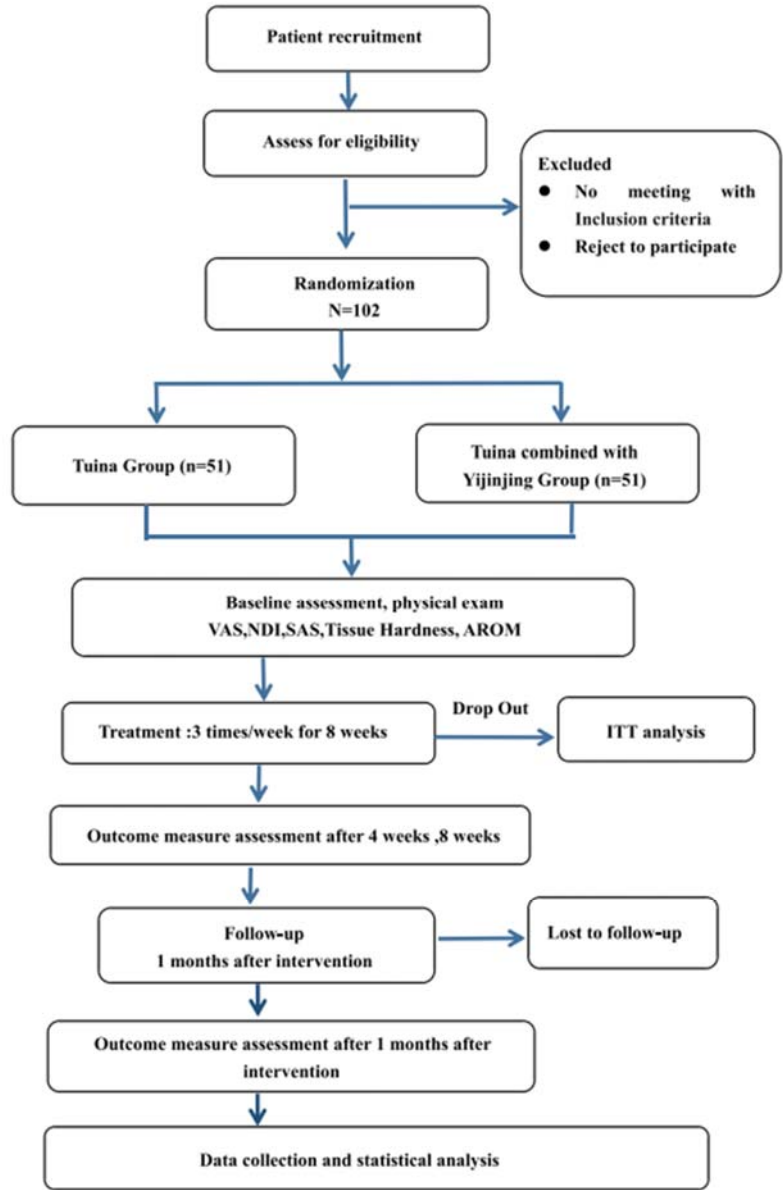
143 The specific primary objective is to determine the change in the visual analog
144 scale (VAS) pain scores from baseline, 4 weeks during the intervention, at the end of
145 the intervention(8 weeks), and 1 month after the intervention within and between the
146 two groups.In particular, the change from baseline in VAS at week 8 was used as the
147 primary outcome.

148 **3.Methods/design**

149 **3.1Study design**

150 This study is a single-center, randomized, and analyst-blinded controlled trial
 151 with two arms: Tuina group (control) and Yijinjing combined with Tuina group
 152 (intervention). The study protocol has been approved by the Regional Ethics Review
 153 Committee of Yueyang Hospital of Integrated Traditional Chinese and Western
 154 Medicine affiliated with Shanghai University of Traditional Chinese Medicine
 155 (project number: 2020-018). A total of 102 eligible NCNP patients will be recruited
 156 and assigned in a 1:1 ratio randomly. Written informed consent will be provided by all
 157 patients. Independent researchers who are blinded to the patient assignment will
 158 collect and analyze the outcome assessment and related data. The study design is
 159 illustrated in the flow chart in Fig1.

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Fig1.Trial flowchart

164 **3.2 Participants and recruitment**

165 Eligible participants include patients diagnosed with NCNP according to the base
166 guideline for the chiropractic treatment of adults with neck pain which is summarized
167 by GDC of Canada [37]. Patients with non-specific neck pain for more than 3 months
168 (no relief for more than 2 weeks) for the first time in the Tuina Department of
169 Yueyang Hospital of Integrated Traditional Chinese and Western Medicine affiliated
170 with Shanghai University of Traditional Chinese Medicine will be informed about this
171 trial. If the patient expresses interest in this trial, a clinical trial communicator will
172 make a contract with him/her immediately and make a brief introduction about the
173 trial. If the patient decides to take part in this trial, he/she will have a face-to-face
174 interview in a reception room of the Shanghai University of Traditional Chinese
175 Medicine. Patients who meet the inclusion criteria will join the trial after they sign the
176 informed consent form.

177 **Inclusion criteria**

178 Participants who meet all the following criteria can be enrolled:

179 1) Aged 20–50 ,2) Individuals from either sex ,3) Current neck pain (localized to
180 the cervical or bilateral scapular region) ,4) Negative sign of neck distraction test,
181 Spurling’s neck compression test, and Adson’s test ,5) Have neck pain symptoms of at
182 least 3 months’ duration ,6) Visual analog scale (VAS) ≥ 3 and Neck Disability Index
183 (NDI) score ≥ 10 at recruitment time ,7) No previous shoulder or neck surgery and no
184 accompanying shoulder problems 8) Willingness to participate.

185 **Exclusion criteria**

186 Participants meeting any of the following criteria will be excluded from this trial:

187 1) Specific disorders of the cervical spine, such as disk prolapse, spinal stenosis,
188 postoperative conditions, cervical radiculopathy, or myelopathy ,2) History of
189 whiplash injury and/or head/neck injuries ,3) Are pregnant or have had a recent
190 delivery ,4) Response to prior treatment (a patient with neck pain radiating into the
191 arm whose arm pain resolved with an injection or medication),5) History of severe
192 trauma, spasmodic torticollis, frequent migraine, fibromyalgia, shoulder diseases,
193 inflammatory rheumatic diseases, tumor, osteoporosis, psychiatric illness, and
194 obvious spinal deformity or neurological disease6) No clinical treatment for neck pain
195 in the past 3 months ,7) Unable to speak or write Chinese in order to complete the
196 questionnaires ,8) Alcohol and drug abuse.9) Have an uncomfortable reaction to
197 Tuina ,10) Subjects with regular practice of Yijinjing, Qigong, or Yoga in the past 3
198 months ,11) Poor cooperation.

199 **3.3 Randomization and allocation concealment**

200 The randomization list will be generated by a random number generator
201 (Strategic Applications Software, version 9.1.3; SAS Institute Inc., Cary, NC, USA).
202 The random numbers will be placed in an opaque envelope which has been numbered
203 in order. Before implementing random assignment, the research team will record the
204 detailed information of each participant in the clinical center, including the new
205 participant (name, date of birth, participant and center code, and date of inclusion)
206 during reporting and preparation of a signed informed consent. The therapist will
207 sequentially open the envelopes and allocate the participants accordingly. Eligible

208 participants will be randomly assigned to the experimental group and the control
209 group according to 1:1 equal proportion rules after the baseline assessment.

210 **3.4Blinding**

211 Patients will be informed of the type of treatment that they will receive. The
212 therapists will know the allocation so they should learn how to communicate with
213 patients to ensure treatment blinding. In order to reduce the risk of bias, evaluators,
214 data managers, and statisticians will be unaware of the group assignments in the result
215 evaluation procedures and data analysis. The blinding procedure will be operated until
216 the data are locked.

217 **3.5Interventions**

218 The Tuina protocol used in this trial is the same as those used in our previous
219 studies [38, 39]. It includes soft tissue manipulation and spinal manipulation, such as
220 rolling, pressing, and tapping. Yijinjing for NCNP patients was designed on the basis
221 of the textbook which has been used for teaching students in the universities of TCM
222 [40, 41].

223 Participants in the Tuina group or the Yijinjing combined with Tuina group will
224 receive Tuina treatment 3 times a week for 8 weeks. The treatment room will be
225 controlled at 23–25°to ensure that the participants feel comfortable. The participants
226 will be asked to rest for 15 min before Tuina treatment. They will be advised to lie in
227 the prone position during the treatment. The intensity level of Tuina is based on
228 physical examination and the therapist’s clinical experience, as well as after careful
229 communication with each study participant. Tuina treatment will last for 25 min.

230 The participants who are in the Yijinjing combined with Tuina group will practice
231 Yijinjing 3 times a week for 8 weeks. The patients will be assembled once a week for
232 practicing Yijinjing together. The Yijinjing teacher will teach them how to practice
233 Yijinjing. The teacher will also correct the wrong movement of patients. The patients
234 will practice Yijinjing another two times per week at home. A digital video disk about
235 the movements of Yijinjing in this trial will be provided to the participants. They can
236 review the movements at home easily. The participants are asked to film themselves
237 and sent it to the teacher by email or WeChat. The teacher will examine the
238 participants’video carefully and give the patients some advice about practicing
239 Yijinjing. Yijinjing treatment will last for 30 min.

240 **Tuina group**

241 In this arm of study, the Tuina therapist will administer a three-step protocol
242 intended to alleviate neck pain and restore neck function by relaxing the soft tissue of
243 the neck and shoulder. The specific protocol used is described below.

244 **Step 1: Soft tissue manipulation**

245 Patients are instructed by the therapist to lie in the prone position and to relax
246 their mind and body naturally. Non-specific chronic neck pain conditions will be
247 carefully examined by postural and palpatory assessment prior to treatment. The
248 therapist will relax soft tissue and stiff muscles of the neck and shoulder by
249 pressingkneading manipulation for 5 min. Then, the therapist will use his palms to roll
250 the trapezius muscle gently so as to relax the back area for 5 min. The aim of this step
251 is to resolve adhesion and increase general circulation.

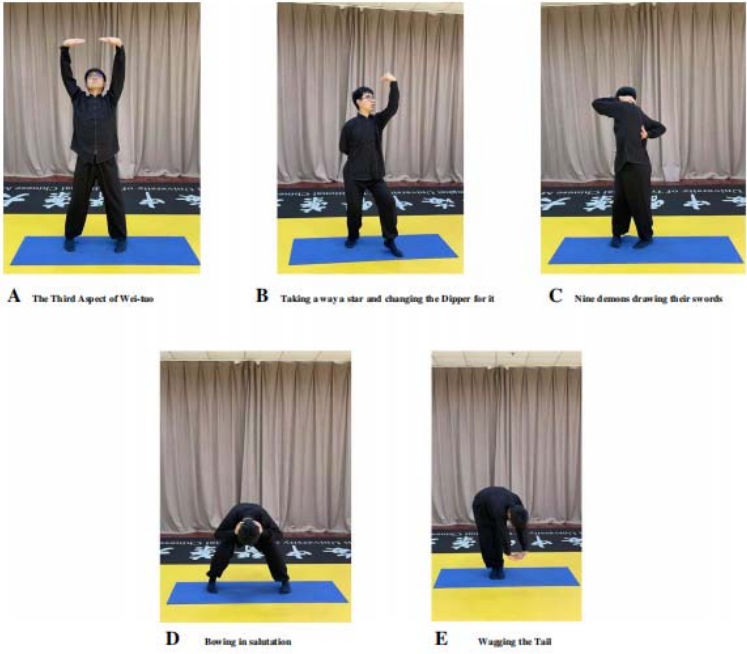
252 Step 2: Clicking on the acupuncture point manipulation
253 The therapist will press and knead GB20, DU16, GB21, SJ14, and SI14 for 2
254 min each. This step is performed to unblock Qi stagnation and remove blood stasis by
255 separating adherent fascicles. The amount of force used is determined by the patient's
256 Deqi sensation, often described as a dull pain, heaviness, numbness, or soreness, and
257 it is commonly regarded as an indicator of manipulation effectiveness in acupuncture
258 and Tuina [42, 43].

259 Step 3: Spinal manipulation
260 The spinal manipulation will be used after the above two steps have relieved the
261 tensions of the muscles and soft tissues. The patient will be instructed to sit in an
262 orthopnea position in order to ensure the safety of manipulation. First, the therapist
263 can exert a gentle torque to align the patient's neck area and use the shake method to
264 relax this area. Then, the therapist will press one thumb on the deviated spinous
265 process while another palm holds the lower jaw. Using gentle tractions and twisting of
266 the neck, the therapist should hold this position for a moment and then made an abrupt
267 pulling motion to advance the stretch by 5 to 10°.

268 **Yijinjing combined with Tuina group**

269 In this arm of study, the steps of Tuina treatment are the same as the Tuina group.
270 The Yijinjing teacher will administer a five-step protocol intended to improve the
271 therapeutic effects and adjust physical and mental conditions. The main movements of
272 Yijinjing are shown in Fig. 2

273 Step 1: The third aspect of Wei-tuo ,Step 2: Taking away a star and changing the
274 Dipper for it,Step 3: Nine demons drawing their swords,Step 4: Bowing in
275 salutation,Step 5: Wagging the tail.



276

277 Fig2. The main movements of Yinjinging

278 **3.6Outcome measurements**

279 **Primary outcome measurement**

280 **VAS**

281 The intensity of NCNP will be measured by a scale of 10-cm horizontal line
282 visual analog scale (VAS) [44]. The patients will be asked “How much pain do you
283 have this moment?”, then the patient will mark on the 10-cm horizontal line visual
284 analog scale. Zero means “absence of pain,” while 10 represent “the worst pain.” VAS
285 has been proved as a valid and reliable outcome measure for recording pain with ICC
286 = 0.96 to 0.98 according to a previous study [45].

287 **Secondary outcome measurements**

288 **NDI**

289 The Neck disability index(NDI) will be used to measure the patients' limitations
290 in everyday-life activities because of neck function[46]. It is is most commonly used
291 as a self-reported questionnaire in neck pain.It contains 10 questions , each of which
292 comprise 6 potential answers ranging from 0 (no disability) to 5 (full disability) and
293 the total of the NDI score varies between 0 and 50 points.The total NDI scores less
294 than 4 indicate no disability; 5-14, mild disability; 15-24, moderate disability; 25-34,
295 severe disability;more than 35 points “complete disability.”

296 **SAS**

297 The anxiety level of NCNP patient will be measured by Zung self-rating anxiety
298 scale(SAS)[47]. 20 questions are divided into 4 groups:cognitive, autonomic, motor,
299 and central nervous system symptoms. Each section is scored on four levels of anxiety
300 intensity from “1” not at all” to “4”very much” and with a sum score between 20and
301 80. A higher total score indicates a more severe anxiety level. The total raw scores
302 range from 20 to 80. The raw score consequently needs to be converted to an
303 “Anxiety Index”. The primary scores should be interpreted into Anxiety Index. The
304 clinical interpretation of one's level of anxiety is as follows: 20-44 Normal Range;
305 45-59 Mild to Moderate.60-74 marked to severe lever;75-80 extreme Anxiety Level.

306 **Tissue Hardness**

307 Tissue hardness is measured by a digital algometer (OE-220, ITO, Tokyo, Japan)
308 The measurement has been use to test the tissue hardness at previous study[48,49,50].
309 The measuring point is placed between C7 and acromion at the middle point of the
310 upper trapezius muscle. The researcher put the meter on the measuring point
311 perpendicularly and push the force slowly.When hearing the deep sound,the
312 researcher should stop pushing and read the number. To standardize the speed of using
313 this application, the researchers responsible for this measurement will practice one
314 week before the study. They must explain the measurement by demonstrating at the
315 the nar region of the hand. Three soft tissue measurements will be preformed at each
316 point with an interval of 30 seconds between the two measurements,the mean of three
317 measurements will be record.

318 **Active range of motion (AROM)**

319 Cervical active range of motion is measure by Spain ScanTM SH-105 (Ad-Or
320 Medical Technologies Ltd, Israel). The validity and reproducibility of this
321 measurement have been proved by many researchers[51,52]. SH-105 is composed of
322 goniometer and a computer. The data will be transmitted by bluetooth. The patient

323 will be seated with a straight back leaning against the back of a chair. The goniometer
 324 will be placed on the centre of the cranial. The researcher switch the mode and long
 325 press the "start/end" button. When hearing the prompt sounds,the patient will be asked
 326 to flex forward to the limit. The patient will be instructed to stop at the point where
 327 pain symptoms preform. The research press the "Start/end" button again and the
 328 computer will automatically record the data. Each movement(flexion-extension,
 329 lateral flexion as well as rotation) will be measured in this way three time.The mean
 330 of each movement will be recorded.

331 **Safety evaluation**

332 The safety of patients will be monitored in every visit. Any adverse events (AES)
 333 will be evaluated by the researchers. The AES in trail such as changes in pain,syncope,
 334 vertigo,disability and etc. For any AES, no matter it is or not caused by intervention,
 335 the treatment will be stopped immediately. The patient should take any medical aids
 336 to alleviate symptoms. The adverse events should be report to the the relevant
 337 responsible unit and the ethics committee in time.

338 **Follow-up**

339 To evaluate the long-term efficacy and safety of the intervention,we will follow
 340 up the patients after treatments for 1 months. All the specific interventions and
 341 outcome measures assessment process are shown in Fig3.

Period Assessment Measure Point	Inclusion baseline 0 week after inclusion	First 4 weeks after inclusion	Treatment Second 8 weeks after inclusion	Follow-up Third 12 weeks after inclusion
Inclusion confirmed	✓			
Informed consent	✓			
Physical exam	✓	✓	✓	✓
Disease history	✓			
Treatment history	✓			
Comorbidity	✓	✓	✓	✓
Current treatment	✓	✓	✓	✓
Visual analogue scale (VAS)	✓	Pain condition and neck function assessment		✓
Neck Disability Index (NDI)	✓	✓	✓	✓
Self-Rating Anxiety Scale(SAS)	✓	✓	✓	✓
Time hardness	✓	✓	✓	✓
Active Range Of Motion(AROM)	✓	✓	✓	✓
Adverse event		Data collection and statistical analysis		✓
Causes of dropout		✓	✓	✓
Safety analysis		✓	✓	✓
Compliance analysis		✓	✓	✓

342

343 Fig3. All interventions,measurements and measuring time points

344 **3.7Sample size calculation**

345 The following two hypotheses are related to the differences between the two
 346 groups.

347 $H_0: \mu_1 - \mu_2 \leq \Delta$

348 $H_1: \mu_1 - \mu_2 > \Delta$

349 where μ_1 is the VAS score for treating 8 weeks in Tuina group, and μ_2 is the VAS
 350 score for treating 8 weeks in the Tuina combined with Yijinjing group.According to a
 351 previous clinical study in China[53], the mean and standard deviation of VAS in Tuina
 352 group(n=34) after intervention was 5.5 and 1.1.The the mean and standard deviation
 353 of VAS in Tuina combined with neck exercise group(n=34) after intervention was
 354 4.7 and 1.3.The following formula as used to calculate the sample size in this trial:

$$n = \frac{2(z_{\alpha/2} + z_{\beta})^2 \times \sigma^2}{(\mu_2 - \mu_1 - \Delta)^2}$$

355

356

$$n = \frac{2(0.025 + 0.2)^2 \times 1.3^2}{(4.7 - 5.5 - 0)^2} = 42$$

357

358 ($\alpha=0.025$ $\beta=0.2$, superiority design, $\Delta=0$)Considering a dropout rate of 20%, each
359 group will require 51 cases. Therefore, a total of 102 participants should be recruited
360 for this randomized controlled trial (RCT).

361 **3.8Statistical analysis**

362 All statistical analyses will be performed with SPSS Software (SPSS, version
363 24.0, SPSS Inc., Chicago, IL, USA) by statisticians who are independent of the
364 research team and blinded to the group allocation. Data analysis will be based on the
365 intention-to-treat (ITT) principles. The statistical significance was accepted for values
366 of $p < 0.05$. Participants who fail to complete the study will be treated as having no
367 change from baseline at all times. Descriptive statistics will be used to compare
368 demographic and baseline information and evaluate the credibility of the groups. The
369 normality of data will be tested by Kolmogorov–Smirnov test. Parametric statistics
370 (Tukey test) or non-parametric statistics (Wilcoxon rank sum test) will be used for the
371 within- and between-group according to the results of homogeneity and normality
372 analysis. If the data does not conform to a normal distribution, a covariance analysis
373 will be used. The efficacy will be measured at four time points. A repeated measures
374 analysis of variance will be conducted to analyze dependent variables (from baseline
375 and follow-up). Bonferroni and Dunn tests will be used for multiple comparisons.
376 The intra-group comparison (comparison between baseline and follow-up) will be
377 tested by two-sided paired t test. The difference of categorical
378 variables (VAS, NDI, SAS, PPT, AROM) and adverse effects between groups will be
379 analyzed by using Chi-square test or Fisher's exact test. All numerical data will be
380 presented as the mean \pm SD and categorical variables will be described with
381 percentages (%). If it is necessary, post hoc analyses will be performed. The
382 confidence interval will be established at 95% and the significance level at 0.05.

383 **3.9Ethical considerations**

384 The study collects data from patients with NCNP. The informed consent are
385 required from the patients. Patients can terminate participation at any time. The results
386 of the trial will be shown in tables and figures only and no individual will be
387 identified. All data collected from this study can only be used for this research. All
388 members of the research team have ethical principles of confidentiality. In addition,
389 we will try our best to deal with ethical issues which arise during the study. We
390 estimate that the benefits of the study far outweigh any possible risks. The trial has
391 been approved by the ethics committee of Yueyang Hospital of Integrated Traditional
392 Chinese and Western Medicine, which is affiliated with Shanghai University of
393 Traditional Chinese Medicine (2020-018) and registered on ChiCTR (2000036805).

394 **4. Discussion**

395 Nonspecific chronic neck pain(NCNP) is a common and high prevalence
396 musculoskeletal problem in the world. It can cause ADL ,work disability and
397 economic cost and psychological stress[54,55]. Because of high recurrence rate, a
398 scientific and reasonable intervention should be explored and promoted. It can not
399 only relieve symptoms and reduce the burden of individual and society, but also
400 decrease complication and improve the quality of life. Yijinjing and Tuina are
401 important components of traditional Chinese medicine. They have been used
402 thousands of years to keep people healthy. Quite a few people know
403 the concrete operating procedure,advantages ,efficacy of such interventions. Therefore,
404 the aim of this study is to investigate whether Yijinjing combined with Tuina has any
405 superiority to than Tuina.

406 According to TCM, a healthy human body depends on the coordination of the
407 internal organs and the harmony of qi and blood. The main reason of pain will be
408 attribute to qi stagnation and blood stasis. In this study , relaxing
409 manipulation,clicking on the acupuncture point manipulation and neck structural
410 rectification are chosen to release adhesion and smooth joint movement so as to
411 alleviate pain improve joint movement condition. By using these manipulations, the
412 circulation of qi and blood will be promoted. Five movements of Yijinjing which are
413 specifically for neck are chosen. These movements include neck flexion, rotation and
414 lateral flexion. The features of Yijinjing is the harmony of body, breath and mind. It
415 puts emphasis on the unity of strength and meditation by using static postures and
416 dynamic movements. It can circulate qi and blood, strengthen muscles and nourish
417 tissues and organs and also arrest spasm[56].Previous study demonstrated that regular
418 and long-term training of Yijinjing can raise the skeletal muscle strength and improve
419 the motor function and ADL[57-58]. A clinical research reported that after 6 month
420 Yijinjing multiple factors of depression and anxiety dropped significantly. It indicated
421 that Yijinjing can improve patients' mental conditions[59] .

422 The present trail is a comparative efficacy of Tuina(control) and Yijinjing combined
423 with Tuina (intervention) for the physical and mental symptoms of NCNP patient. We
424 want to explore whether Yijinjing combined with Tuina is better than Tuina. We will
425 evaluate three aspect of neck pain:pain,physical function and mental function. we will
426 use validated scales and questionnaires and some measuring instrument to assess the
427 clinical outcomes.

428 Pain is the most important symptom of neck pain, so visual analog scale(visual
429 analog scale) will be used as the primary outcome.It. It can evaluate the intensity of
430 neck pain. The secondary outcomes are NDI,which can evaluate the limitation of
431 daily life because of NCNP. Cervical active range of motion (AROM) which can
432 evaluate the neck active range of motion is measure by using a easy
433 equipment.SAS ,which can evaluate the anxiety level of patients.Tissue Hardness will
434 be measured by a tissue hardness meter and expressed in numbers.

435 To the best of our knowledge, no study has proved the efficacy of Yijinjing combined
436 with Tuina for patients with NCNP.

437 High quality clinical data will be collected because of the rigorous experimental
438 design. The efficacy of this specific intervention protocol for treating NCNP will be

439 evaluated by these data. We hope that this study will provide a solid foundation for
440 the treatment of NCNP, as well as Tuina and Yijinjing research.

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