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Patient-reported efficacy 6 months after a 4-week rehabilitation 1 intervention in individuals with chronic ankle instability

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1 **Patient-reported efficacy 6 months after a 4-week rehabilitation** 2 **intervention in individuals with chronic ankle instability**

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4 **Objective:** To track the patient-reported efficacy of a 4-week intervention [wobble board (WB)
5 or resistance tubing (RT)] in decreasing symptoms of Chronic Ankle Instability (CAI) at 6
6 months post-intervention (6PI) as compared to immediately post-intervention (IPI). **Design:**
7 Randomized controlled trial. **Participants:** Fourteen out of 21 participants (66.7%) responded to
8 an electronic 6 month follow-up questionnaire (age: 19.6 ± 0.9 years, height: 1.63 ± 0.18 m, weight:
9 70.5 ± 16.3 kg, 2 males, 12 female, 5 WB, 9 RT). All participants met CAI criteria at enrollment,
10 including a history of ankle sprain and recurrent episodes of giving way. **Interventions:**
11 Participants completed either RT or WB protocols, both 12 sessions over 4 weeks of progressive
12 exercise. WB sessions consisted of five 40 second sets of clockwise and counter-clockwise
13 rotations. RT sessions consisted of 30 contractions against resistance tubing in each of 4 ankle
14 directions. **Main Outcome Measurements:** Patient reported symptoms of giving-way pre-
15 intervention and at 6PI, Global rating of change (GRC) frequencies at IPI and 6PI, and re-sprains
16 at 6PI were reported descriptively. Changes in Global rating of function (GRF) and giving-way
17 were compared using Wilcoxon tests, while GRC was compared with Fisher's exact test.
18 **Results:** All participants reported giving-way pre-intervention, only 57.1% reported giving-way
19 at 6PI. Re-sprains occurred in 21.4% of participants. Giving-way frequency ($P=0.017$), but not
20 GRF or GRC ($P>0.05$), was significantly different at IPI versus 6PI. **Conclusions:** Simple 4-
21 week interventions maintained some but not all improvements at 6PI. Importantly, at least
22 42.9% of participants would no longer meet the current study's CAI inclusion criteria due to a
23 reduction in giving-way.

24 **Introduction**

25 Ankle sprains are one of the most common injuries associated with physical activity, with
26 a prevalence of 42-70%.^{1,2} Developing following initial sprain in 32±9% of patients, chronic
27 ankle instability (CAI) is characterized by sensations of giving-way of the ankle, repeated sprains
28 and instability.³⁻⁶ The residual symptoms of CAI can limit physical activity and activities of
29 living for years post-injury,^{3,7,8} and have been reported to decrease health related quality of
30 life.^{9,10}

31 Thus, treatment that improves the long-term outcomes of this pathology is very important
32 to clinicians. Currently, there is limited data available on long-term (defined as ≥6 months)
33 maintenance of improvements seen after rehabilitation interventions for CAI. For example, of
34 14 controlled interventions targeted at CAI reviewed by O'Driscoll and Delahunt in 2011¹¹, only
35 1 reported follow-up of 6 months or greater;¹² instead most studies recorded laboratory measures
36 (e.g. strength, force plate variables, muscle latency) immediately following the intervention. Eils
37 and Rosenbaum¹² reported a 60% reduction in frequency of ankle inversion episodes (giving-
38 way) 1 year after a 6 week multi-station proprioceptive exercise program. Recent studies are
39 more likely to include important patient-oriented outcomes measures in addition to clinician-
40 oriented and laboratory measures, but still largely lack long-term follow-up.¹³⁻²²

41 While there is limited long-term data on interventions specifically targeted towards
42 decreasing symptoms of CAI in currently symptomatic patients, a larger evidence base exists
43 regarding interventions aimed at preventing acute lateral ankle sprains and/or the incidence of
44 CAI post-acute ankle sprain. Specifically, prophylactic balance and coordination training
45 (including wobble board training) in a general athletic population can decrease injury incidence,
46 especially in those with a previous history of ankle injury.²³ Additionally, balance and
47 coordination training following an acute lateral ankle sprain reduces the risk of re-injury in the

48 next 8-12 months by 54-76%,^{24, 25} and prevented felt instability of the ankle in all training group
49 participants (compared to an incidence of 25% in the control group).²⁵ Despite its common
50 clinical use, the efficacy of ankle joint strengthening using resistance tubing at reducing CAI or
51 repeated sprains has not been previously reported in the literature (although it has been shown to
52 increase strength²⁶).²⁷

53 In summary, while there is good evidence for the effectiveness of rehabilitation
54 interventions to prevent initial and recurrent sprains of the ankle, there is insufficient evidence
55 regarding the long-term effectiveness of interventions specifically targeting stability in
56 individuals who have already developed CAI. The immediate effect of an intervention is
57 important and helpful in understanding the mechanisms by which an intervention either is or is
58 not effective.¹³⁻²² However, if benefits obtained through rehabilitation do not last, the utility of
59 the intervention is limited. Although potentially costly and logistically difficult to obtain, long-
60 term follow-up data provides essential information to clinicians about the efficacy of treatment.
61 Thus, it was the purpose of the current research to track the patient-reported efficacy of a 4-week
62 intervention aimed to decrease symptoms of CAI at 6 months after the completion of the
63 intervention.

64

65 **Methods**

66 **Participants**

67 Twenty-one physically active individuals with CAI were recruited from a university
68 undergraduate population. These individuals are a subset of a larger two-site randomized
69 controlled trial²⁷; all participants from 1 clinical site were recruited for this 6 month follow-up.
70 Inclusion criteria included a history of ≥ 1 inversion ankle sprain which required protected weight
71 bearing, immobilization, and/or limited activity for ≥ 24 hours.²⁸ The initial sprain must have

72 occurred greater than 1 year prior to study enrollment.²⁹ Additionally, subjects had to self-report
73 recurrent episodes of giving-way, and have a Cumberland Ankle Instability Tool (CAIT) on the
74 involved side of ≤ 25 .³⁰ In the case of bilateral instability, the subjectively reported worse ankle
75 was considered the involved ankle.

76 Participants were excluded if they had a history of fracture or surgery to the involved
77 knee, lower leg or ankle, or if they participated in <1.5 hours of moderate-vigorous physical
78 activity per week. Participants were also excluded if they had any acute symptoms of lower
79 extremity musculoskeletal injury on the day of testing. The University Institutional Review
80 Board approved the study.

81 **Testing Procedures**

82 Participants reported to the testing facility for enrollment procedures and baseline
83 evaluation. Following informed consent, participants completed an injury history questionnaire,
84 the CAIT and a global rating of function (GRF). The injury history questionnaire collected
85 information about the initial ankle sprain, symptoms of giving way and re-sprains, and
86 rehabilitation history (see Table 1). A customized computer program (Access, Microsoft
87 Corporation, Redmond, WA) recorded and scored the CAIT and GRF. The GRF is a single-item
88 question: “On a scale from 0-100, what would you rate your ankle use as if 0 = no use of your
89 ankle (cannot put weight on it at all) and 100 = full use of your ankle (not limited at all)?” The
90 CAIT evaluates perceived ankle instability, has excellent test-retest reliability (intraclass
91 correlation coefficient [ICC]_{2,1} = 0.96), and is scored on a 30-point scale, with lower scores
92 indicating decreased stability.^{30, 31}

93 Next, the investigator measured and recorded participant height, weight, and ankle laxity.
94 Ankle laxity testing procedures have been previously described,^{32, 33} but in brief, consisted of a
95 standardized anterior drawer test and talar tilt test. Both tests were graded on a scale of 1 to 5

96 per the methods of Ryan³³ then condensed into clinically-relevant categories of positive (>3) and
97 negative (≤ 3). Intra-rater reliability of these methods has been reported as ICC>0.80 and
98 standard error of the measure <0.25 points.³⁴ Participants completed baseline testing that
99 included completion of several additional patient-oriented questionnaires and clinical tests,
100 which are reported elsewhere.²⁷ Following all baseline testing, the participant was block
101 randomized to either the resistive tubing (RT) or wobble board (WB) training group. The WB
102 protocol^{16,27} has been previously reported, in brief it consisted of five repetitions of standing
103 balance on a wobble board while rotating clockwise and counterclockwise for 40 seconds each
104 repetition. The RT protocol has also been previously reported,^{26,27} and in brief consisted of
105 resistance tubing exercises in each of four ankle movements (dorsiflexion, plantarflexion,
106 eversion and inversion) for 3 sets of 10 repetitions. Both protocols were progressed
107 systematically as previously described. The participant received instruction for his or her
108 training group and completed the first exercise session on the enrollment day. Each participant
109 then continued to complete 3 supervised sessions each week for 4 weeks (total of 12 sessions).³⁵⁻
110 ³⁷

111 Upon completion of the 4 week protocol, all baseline measures were post-tested and
112 participants completed a global rating of change (GRC) survey. The GRC asked participants to
113 rank on a 13-point scale any change in the condition of their ankle. Participants selecting any of
114 the nine responses ranging from “a very great deal worse” to “somewhat better” were
115 dichotomously categorized as not improved, whereas the four responses ranging from
116 “moderately better” to “a very great deal better” were categorized as improved. Participants did
117 not formally continue ankle exercises after the 12th session. It is possible (but unlikely)
118 participants continued these exercises on their own as they were not given the rehabilitation
119 equipment nor was it easily accessible to them. Then at 6 months post-completion, a single

120 email was sent to all participants requesting that they complete a simple 7-question online
121 survey. This survey recorded ankle sprain incidence, the presence and frequency of episodes of
122 giving-way, GRC and GRF at 6 months post-intervention.

123 **Data Analysis**

124 Patient-reported symptoms of giving-way pre-intervention and at 6 month post-
125 intervention, and GRC frequencies immediately post-intervention and at 6 months post-
126 intervention are presented descriptively (Table 2). A Wilcoxon signed rank test was used to test
127 differences between (1) GRF immediately post-intervention and at 6 months post-intervention,
128 and (2) giving-way frequency pre-intervention and at 6 months post-intervention. GRC was
129 compared immediately post-intervention to 6 months post-intervention using Fisher's exact test.
130 Data is presented separately by treatment group and combined across treatment groups; however,
131 due to small sample size statistical analysis was only performed on combined data. To assess for
132 bias in follow-up survey responders versus those lost to follow-up, characteristics of both groups
133 were also compared: continuous variables (such as height, age, etc.) were compared using paired
134 t-tests, all categorical variables (such as gender, laxity, etc.) were compared using Fisher's exact
135 test except for initial injury severity which was compared using a chi-squared test. All alpha
136 were set a priori at $\alpha=0.05$.

137

138 **Results**

139 Fourteen out of 21 participants (66.7%) responded to an electronic 6 month follow-up
140 questionnaire. Respondent demographics and injury characteristics are shown in Table 1. Four
141 recurrent ankle sprains were reported in 3 separate participants; all other patient reported
142 outcomes are shown in Table 2. GRF did not change significantly between measurement

143 immediately post-intervention and 6 months later ($Z = -1.185, P = 0.236$). However, episodes of
144 giving-way per month were significantly decreased at 6 months post-intervention compared to
145 pre-intervention ($Z = 0.121, P = 0.034$). The frequency of participants whose GRC indicated they
146 were improved was not different between immediately post-intervention and 6 months later
147 (Fisher's exact test $P = 0.559$). Individuals who were lost to 6 month follow-up were not
148 significantly different than survey participants in any variable except whether or not they had
149 previously completed some type of ankle rehabilitation (Table 3). Specifically, individuals lost
150 to follow-up reported a prior history of ankle rehabilitation at a greater frequency than follow-up
151 survey participants.

152

153 **Discussion**

154 Twenty-one ankle rehabilitation participants were invited to complete a 6 month follow-
155 up survey, and 14 (66.7%) responded. In these participants, the simple 4-week WB and RT
156 interventions used in the current study maintained improvements in GRF and GRC at 6 months
157 post-intervention, decreased total number of participants reporting episodes of giving-way to
158 43%, as well as decreased the monthly frequency of these episodes of giving-way. However, re-
159 current ankle sprains were still experienced by 3 (21.4%) participants.

160 **Effect on symptoms of giving-way**

161 To our knowledge, this is the first time that long-term follow-up has been completed on a
162 simple single-exercise protocol like our WB and RT. The limited existing literature on long-
163 term results for individuals with CAI only provides evidence regarding a comprehensive multi-
164 exercise program.¹² Eils and Rosenbaum¹² reported a 60% reduction in episodes of giving-way 1
165 year post-intervention, which is similar to the magnitude of reduction found in the current study

166 (61%). Additionally, previous research using the same WB and RT protocol documented
167 improvements in patient- and clinician-oriented outcomes immediately post-intervention.²⁷
168 Interestingly the magnitude of those differences was similar to that reported in previous multi-
169 exercise interventions.²⁷ This indicates that immediately post-intervention, the RT and WB
170 protocols are at least as effective as more complex interventions, while potentially saving time
171 and resources. The current research adds additional evidence that a single-exercise protocol can
172 also be effective at reducing symptoms of CAI for least 6 months post-intervention.

173 Our CAI inclusion criteria largely aligned with the International Ankle Consortium (IAC)
174 position statement (which was published after data collection began).²⁹ This statement
175 recommends inclusion criteria for CAI include at a minimum (a) a history of 1 significant ankle
176 sprain, and (b) a history of the injured ankle giving-way and/or recurrent sprain and/or feelings
177 of instability.²⁹ More specifically, participants should report at least 2 episodes of giving-way in
178 the past 6 months and self-reported instability would preferably be confirmed with
179 questionnaires such as the CAIT.²⁹ While the first criterion (history of ankle sprain) is non-
180 modifiable, the second criterion can change over time. Perhaps the most significant finding of
181 the current study was that 42.9% of participants would no longer meet CAI inclusion criteria due
182 to lack of giving-way at 6 month follow-up. Unfortunately, we were not able to re-administer
183 the CAIT at 6 month follow-up, thus, it is unknown whether even more participants would have
184 been excluded for exceeding the CAIT cutoff score of ≤ 25 . Even without this data, it is
185 important that almost half of participants had improved sufficiently to no longer be classified as
186 CAI according to IAC criteria.²⁹

187 **Effect on Global Rating of Change**

188 Although not significantly different, the number of participants who self-reported that the
189 condition of their ankle was improved was lower at 6 months than directly after the intervention

190 (71.4% improved immediately post-intervention, 50% improved at 6 months). Thus, by this
191 measure the current protocol demonstrated long term success for approximately half of
192 participants, but failed the other half. Obviously, the ideal intervention would achieve both
193 short-term results and maintain long-term success in 100% of patients. While achieving 100%
194 success may not be realistic, improving on the current results is a realistic goal. Future work
195 should test the long-term efficacy of other rehabilitation protocols or interventions, in an attempt
196 to identify more effective techniques. One specific recommendation would be to test the
197 efficacy of an ongoing maintenance plan following a formal intervention. The individuals in the
198 current study were not instructed (nor provided the resources) to continue rehabilitation after the
199 initial 4 week intervention, making it unlikely that any continued with their rehabilitation
200 program. Based on this study design, it is unknown whether an ongoing maintenance exercise
201 plan would have affected the 6 month follow-up data. However, common clinical reasoning is
202 that some form of maintenance exercise is essential to maintain results. Additionally, it is
203 interesting to note that based on reported GRC immediately and 6-months post-intervention,
204 there may be a difference in maintenance needs for WB versus RT. Future research into the best
205 dose and exercise type for maintenance would aid clinicians in developing evidence based
206 exercise prescription. Additionally, future work should identify which modifiable factors were
207 most predictive of self-reported long-term improvement as measured by the GRC, and then
208 attempt to modify those factors to improve treatment efficacy.

209 **Limitations and Considerations for Future Research**

210 The chief limitation of this study is the small sample size. Unfortunately, due to an IRB
211 limitation at one (of two) clinical sites of the original larger study, we were only able to invite
212 the 21 participants from one clinical site to participate in the follow-up survey. Due to the small
213 sample size we were not able to statistically compare the efficacy of our two interventions (WB

214 or RT). As our sample was recruited exclusively from a small residential university, our 6 month
215 response rate was likely affected when the 6 month follow-up fell over summer break or post-
216 graduation. Although the response rate of 67% was lower than desired, comparison of the
217 characteristics of the individuals lost to follow-up versus those who responded to our survey
218 provided evidence of a representative sample (Table 3). Of sixteen characteristics (including
219 injury severity, giving-way frequency, laxity, etc.) only the frequency of a reported history of
220 prior rehabilitation differed between survey responders and non-responders. It is unclear the
221 meaning (if any) of this singular difference. Future work should document the long-term
222 efficacy of these interventions in a larger sample so that statistical comparisons can be made and
223 conclusions drawn concerning the most effective technique.

224 We defined long-term follow-up as 6 months post-intervention as this seems to be the
225 minimum long-term follow-up period in related literature. Ideally, we would have tracked
226 subjects for a longer time period, however, practical considerations limited follow-up to 6
227 months. Future research should track efficacy at 1 year and further time points. Additionally, if
228 a wash-out effect over time is noted, it would be clinically advantageous to investigate the
229 minimum frequency of exercise required to maintain rehabilitation benefits. For example, would
230 1 rehabilitation session a week be sufficient to maintain improvements?

231 Our follow-up survey asked participants to self-report the incidence of recurrent sprain
232 and frequency of giving-way. Self-reported data is potentially subject to recall bias or error.
233 Specifically, participants could have erred in their definition of what constituted a re-sprain.
234 However, the questionnaire did attempt to address this issue by including the clarification “A
235 sprain is an acute ankle injury, generally resulting in pain, swelling and decreased function”.
236 Future research could require all subsequent sprains to be documented by a healthcare provider,

237 however, given the fact that many people do not seek treatment for ankle sprains³⁸ this may
238 underestimate the true frequency of recurrent injury.

239

240 **Conclusions**

241 A simple 4-week intervention aimed at reducing the symptoms associated with CAI
242 maintained some but not all improvements at 6 months post-intervention. Importantly, 42.9% of
243 participants no longer experienced giving-way, a hallmark of CAI. Results were achieved using
244 a single-exercise protocol (WB or RT) that involved minimal time and resources, making it
245 easily accessible to patients and clinicians.

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345

Table 1. Participant Demographics and Injury Characteristics

Descriptor	Wobble Board (n=5)	Resistance Tubing (n=9)	Combined (n=14)
Age, y	19.40±0.55	19.67±1.12	19.57±0.94
Height, m	1.61±0.27	1.64±10.93	1.63±0.18
Weight, kg	77.04±19.81	66.81±13.83	70.48±16.26
Time since initial sprain, y	5.80±3.96	6.11±3.98	6.00±3.82
Limited weight bearing, d	18.25±27.90	13.83±14.66	15.60±19.60
Lifetime number of re-sprains	1.80±2.05	1.67±1.50	1.71±1.64
Episodes of giving-way, month	4.20±4.49	9.01±19.30	7.29±15.53
Gender	2 (40%) male 3 (60%) female	0 (0%) male 9 (100%) female	2 (14%) male 12 (86%) female
Initial ankle sprain evaluated by a medical professional?	4 (80%) Yes 1 (20%) No	6 (67%) Yes 3 (33%) No	10 (71%) Yes 4 (29%) No
Severity of initial ankle sprain	1 (20%) Mild 2 (20%) Moderate 1 (20%) Severe 1 (20%) Unknown	1 (11%) Mild 3 (33%) Moderate 2 (22%) Severe 3 (33%) Unknown	2 (14%) Mild 5 (36%) Moderate 3 (21%) Severe 4 (29%) Unknown
Rehabilitation performed?	1 (20%) Yes 4 (80%) No	1 (11%) Yes 8 (89%) No	2 (14%) Yes 12 (86%) No
Rehabilitation supervised by therapist?	1 (100%) Yes 0 (0%) No	1 (100%) Yes 0 (0%) No	2 (100%) Yes 0 (0%) No
Anterior drawer laxity	2 (40%) positive 3 (60%) negative	6 (67%) positive 3 (33%) negative	8 (57%) positive 6 (43%) negative
Talar tilt laxity	2 (40%) positive 3 (60%) negative	4 (44%) positive 5 (56%) negative	6 (43%) positive 8 (57%) negative

Values are presented as either mean ± standard deviation or n (percent).

Table 2. Participant reported outcomes at 6 months post-intervention

Outcome	Wobble Board (n=5)	Resistance Tubing (n=9)	Combined (n=14)
Episodes of giving way, yes or no?			
Pre-intervention	5 (100%) Yes 0 (0%) No	9 (100%) Yes 0 (0%) No	14 (100%) Yes 0 (0%) No
6 mo. Post-intervention	1 (20%) Yes 4 (80%) No	7 (78%) Yes 2 (22%) No	8 (57%) Yes 6 (43%) No
Episodes of giving way per month			
Pre-intervention	4.20±4.50	9.02±19.30	7.29±15.53 ^a
6 mo. Post-intervention	6.00±13.42	1.09±1.26	2.84±7.89 ^a
Global rating of change			
Immediately post-intervention	5 (100%) improved 0 (0%) not improved	5 (56%) improved 4 (44%) not improved	10 (71%) improved 4 (29%) not improved
6 mo. Post-intervention	3 (60%) improved 2 (40%) not improved	4 (44%) improved 5 (56%) not improved	7 (50%) improved 7 (50%) not improved
Global rating of function			
Immediately post-intervention ^b	95.50±2.52	89.75±6.90	91.67±6.33
6 mo. Post-intervention	90.00±16.96	90.89±11.21	90.57±12.89
Re-sprain incidence			
6 mo. Post-intervention	1 (20%)	2 (22%)	3 (21%)

Numbers are presented as mean ± standard deviation, or n (percent).

^a Significant difference between pre-intervention and 6 months post-intervention

^b Total N = 12 due to missing data for 2 subjects (1 wobble board, 1 resistance tubing)

Table 3. Characteristics of Survey Responders versus Non-responders

Descriptor	Responders (n=14)	Non-responders (n=7)	P-value
Age, y	19.57±0.94	19.86±1.22	0.557
Height, m	1.63±0.18	1.70±0.08	0.328
Weight, kg	70.48±16.26	71.07±10.05	0.930
Time since initial sprain, y	6.00±3.82	7.00±3.46	0.589
Limited weight bearing, d	15.60±19.60	7.14±5.15	0.286
Lifetime number of re-sprains	1.71±1.64	2.00±1.63	0.710
Episodes of giving-way, month	7.29±15.53	2.67±2.73	0.484
Global rating of function, immediately post-intervention	91.67±6.33	90.71±5.12	0.740
Global rating of change, immediately post-intervention	10 (71%) improved 4 (29%) not improved	5 (71%) improved 2 (29%) not improved	1.000
Gender	2 (14%) male 12 (86%) female	2 (29%) male 5 (71%) female	0.574
Initial ankle sprain evaluated by a medical professional?	10 (71%) Yes 4 (29%) No	6 (86%) Yes 1 (14%) No	0.624
Severity of initial ankle sprain	2 (14%) Mild 5 (36%) Moderate 3 (21%) Severe 4 (29%) Unknown	1 (14%) Mild 5 (71%) Moderate 0 (0%) Severe 1 (14%) Unknown	0.369
Rehabilitation performed?	2 (14%) Yes 12 (86%) No	5 (71%) Yes 2 (29%) No	0.017 ^a
Rehabilitation supervised by therapist?	2 (100%) Yes 0 (0%) No	4 (57%) Yes 3 (43%) No	0.120
Anterior drawer laxity	8 (57%) positive 6 (43%) negative	2 (29%) positive 5 (71%) negative	0.361
Talar tilt laxity	6 (43%) positive 8 (57%) negative	6 (86%) positive 1 (14%) negative	0.159

Values are presented as either mean ± standard deviation or n (percent).

^a Significant difference between groups using Fisher's exact test