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A Randomized Controlled Trial Comparing Rehabilitation Efficacy in Chronic Ankle Instability

Context: There is minimal patient-oriented evidence regarding the effectiveness of interventions targeted to reduce symptoms associated with chronic ankle instability (CAI). Additionally, clinicians aiming to prioritize care by implementing only the most effective components of a rehabilitative program have very little evidence on comparative efficacy. **Objective**: To assess the comparative efficacy of two common ankle rehabilitation techniques [wobble board (WB) balance training and ankle strengthening using resistance tubing (RT)] using patient-oriented outcomes. **Design**: Randomized controlled trial. **Setting**: Laboratory. **Patients**: Forty patients with CAI were randomized into two treatment groups: RT and WB. CAI inclusion criteria included a history of an ankle sprain, recurrent giving way, and a Cumberland Ankle Instability Tool (CAIT) score ≤ 25. **Interventions**: Participants completed 5 clinician-oriented tests (Foot lift test, Time-in-balance, Star Excursion Balance Test, Figure of 8 hop, and Side hop) and 5 patient-oriented questionnaires [CAIT, Foot and Ankle Ability Measure (FAAM) Activities of Daily Living (ADL) and FAAM Sport scale, Short-Form 36 (SF-36), and Global Rating of Function (GRF)]. Following baseline testing, participants completed 12 sessions over 4 weeks of graduated WB or RT exercise, then repeated baseline tests. **Main outcome measures:** For each patient- and clinician-oriented test, separate 2x2 RMANOVAs analyzed differences between groups over time (alpha set at $P=0.05$). **Results**: There was a significant interaction between group and time for the FAAM-ADL ($P=0.043$). Specifically, the WB group improved post intervention ($P<0.001$) whereas the RT group remained the same ($P=0.294$). There were no other significant interactions or significant differences between groups (all $P>0.05$). There were significant improvements post-intervention for the CAIT, FAAM-Sport, GRF, SF-36 and all 5 clinician-oriented tests (all $P<0.001$). **Conclusions**: A single exercise 4-week intervention can improve patient-and clinician-oriented outcomes in individuals with CAI. Limited evidence indicates that WB training was more effective than RT. Level of Evidence: Therapy, level 1b.

Key Words: sprain, balance training, resistance tubing, exercise

Chronic ankle instability (CAI) is a common sequelae of ankle sprain, affecting an average of 32±9% of patients with symptoms including sensations of giving way, subsequent sprains, and instability.[1-4] These symptoms can limit physical activity and activities of daily living for years post-injury,[1,5] as well as decrease quality of life.[6] Due to the high frequency of CAI and the problems associated with it, prevention and treatment of this pathology is very important to clinicians, especially those involved in the care of physically active populations where 42-70% of individuals have a history of at least one ankle sprain.[7,8]

Several ankle instability rehabilitation programs have been developed and published.[9,10] For example, a 2011 review by O'Driscoll and Delahunt[10] identified 14 controlled trials testing neuromuscular training programs for the treatment of CAI. Of these 14 controlled trials, 9 investigated balance or proprioception training alone, 2 strength training alone, and 3 included some combination of strength and balance training. Six trials involved multi-exercises programs (e.g. dynamic and static balance exercises), whereas the remaining 8 investigated the effect of a single exercise (e.g. Theraband strengthening alone). Balance training especially appears to have strong evidence supporting its utility in improving treatment outcomes.[9]

Based on this review, it might appear that the literature has established a fairly broad evidence base for both single exercise interventions and multi-exercise programs for strength, balance or both. However, the majority of these controlled trials (9) provided no patient- or clinician-oriented outcomes measures (such as patient reported symptoms, re-injury rates, functional test results)—providing instead only instrumented laboratory measures.[11] While instrumented laboratory measures can provide insight into understanding underlying mechanisms of pathology,[11] they generally provide evidence only at the systems-level of the disablement model.[12] In contrast, the whole-person and societal levels are generally most important to the patient and clinician.[12] For example, rather than recording an improvement in a patient's ankle eversion strength, it is of greater importance to the patient whether his or her functional ability has improved, or pain has diminished. Similarly, rather than recording decreased center of pressure velocity during balance testing, it would mean more to both the patient and clinician if they knew the re-injury risk was decreased. When these trials reported clinical outcomes measures, they were generally positive.[13-16] For example, Eils and Rosenbaum[17] reported decreased re-injury rate in individuals who completed a multi-station proprioceptive program once a week for six weeks. More recent CAI trials (published after the O'Driscoll and Delahunt[10] review) have acknowledged the importance of patient-oriented measures by intentionally including them in addition to traditional laboratory or clinician-oriented measures; all reported improvement post-intervention.[18-21]

Two of the most common individual exercises for CAI are Theraband strengthening[22-24] and wobble board balance training.[14,17,25] These techniques have the advantages of being simple to teach the patient, require minimal equipment that is often readily available, and can be completed independently by the patient in less than 10 minutes. Theraband strengthening has been shown to increase strength[22] and joint position sense,[22] but not measures of static balance or muscle fatigue.[24] None of the Theraband strengthening interventions provided measures of clinician- or patient-oriented outcomes.[22-24] Evidence for wobble board training found a decrease in muscle latency onset,[14] decreased postural sway,[25] and improvements in the Ankle Joint Functional Assessment Tool (AJFAT).[14] Again, this gives positive but limited evidence relating to clinician- or patient-oriented outcomes measures for wobble board training.

In summary, there is evidence that both balance and strength training interventions improve treatment outcomes as measured by laboratory measures and also (less frequently) by clinician- and patient-oriented outcomes measures. However, comparisons between the efficacy of various types of treatments is largely missing. There is insufficient evidence to advocate the prioritization of one exercise over another, or to select the most effective components of a rehabilitation program.

Thus, it was the purpose of this study to answer a clinical question concerning the comparative effectiveness of two common rehabilitation exercises aimed at reducing CAI in physically active individuals. This investigation measured comparative efficacy both from a patient-oriented perspective (symptoms reduction) and clinician-oriented outcomes perspective (enhanced ability to perform clinical tests). The aim of the study was to provide practical evidence to the clinician about the comparative effectiveness of these two common techniques for improving ankle function and reducing patient reported symptoms of instability.

Methods

Design

A randomized controlled trial was conducted to test the comparative efficacy of two types of rehabilitation exercises (wobble board vs. resistance tubing) on patient- and clinician-oriented outcomes measures.

Participants

Fifty-five potential participants were recruited from two university populations between September 2012 and April 2014. After screening, fifteen were ineligible (Figure 1), resulting in a final sample of 40 participants. The current study was approved by the Institutional Review Board of both universities. Inclusion criteria consisted of a history of ≥1 inversion ankle sprain which required protected weight bearing, immobilization, and/or limited activity for ≥ 24 hours.[26] The initial sprain must have occurred greater than 1 year prior to study enrollment.[27] Additionally, subjects had to self-report recurrent episodes of giving-way, and have a

Cumberland Ankle Instability Tool (CAIT) on the involved side of ≤ 25.[28] In the case of bilateral instability, the subjectively reported worse ankle was considered the involved ankle.

Participants were excluded if they had a history of fracture or surgery to the involved knee, lower leg or ankle, or if they participated in <1.5 hours of moderate-vigorous physical activity per week. Participants were also excluded if they had any acute symptoms of lower extremity musculoskeletal injury on the day of testing.

Estimated sample size for this study was calculated using data from Hale et al.,[15] specifically change scores on the Foot and Ankle Disability Index [FADI, the predecessor of the Foot Ankle Ability Measure (FAAM)] following a four week rehabilitation intervention. Using this data a sample size of n= 16 per group would have 80% power to detect differences in the means at the 0.05 level. To accommodate potential loss to follow up, we targeted an enrolled sample size of n=20 per group.

Patient-Oriented Instruments

Cumberland Ankle Instability Tool. The CAIT has excellent test-retest reliability (intraclass correlation coefficient $[ICC]_{2,1} = 0.96$), and is scored on a 30-point scale, with lower scores indicating decreased stability.[28,29]

Foot and Ankle Ability Measure. The FAAM consists of the Activities of Daily Living (ADL) and Sport subscales, both scored from 0-100% with higher scores indicating greater functional ability.[30] It has been shown to be a reliable, responsive and valid measure of physical function.[30,31]

Global Rating of Function (GRF). The GRF is a single-item question: "On a scale from 0-100, what would you rate your ankle use as if 0 = no use of your ankle (cannot put weight on it at all) and 100 = full use of your ankle (not limited at all)?" The GRF has been shown to have moderate to strong correlations with FAAM subscales,[31] and has the benefit of being quick to administer, easy to score, and the potential to compare against other diverse pathologies which also use a version of the GRF.

Short Form-36v2 Health Survey (SF-36). The SF-36 measures health-related quality of life (HR-QOL) and is not region or disease specific. The SF-36 physical component summary (PCS) is reported on a norm-based scale with a population mean of 50 and a standard deviation of 10. This measure has good reliability (ICC = 0.87), good construct validity, and individuals with CAI have shown PCS deficits.[32,33] A customized computer program (Access, Microsoft Corporation, Redmond, WA) recorded and scored all questionnaires except the SF-36. The SF-36 was scored using QualityMetric Health Outcomes™ Scoring Software 2.0 (Lincoln, RI, USA).

Clinician-Oriented Instruments

Foot Lift Test. For the foot lift test,[34] participant was asked to stand on the involved leg on a firm surface, with their hands on iliac crests, the uninvolved limb slightly flexed at hip and knee, and eyes closed. They were given the instructions: "Remain as motionless as possible for 30 seconds, if you move out of position, please return to it as soon as possible and continue the trial." The examiner counted the number of foot lifts, which included any part of the involved foot lifting off the floor, or the uninvolved limb touching floor (with an extra error for every second out of position). Participants were given one practice trial, then completed three trials with at least 30 seconds rest between each trial. The average of three trials was used for analysis.

Time-in-balance. Methods of Chrintz et al.[35] and Linens et al.[36] were used for this test. The participant assumed the same position as the foot lift test, but was given the following instructions: "Remain as motionless as possible for as long as you can. I will time you, and tell you when to stop. If you move out of the testing position, the trial will end." The examiner timed the participant using a handheld stop-watch, recording times to the nearest hundredth of a second. Maximum trial time was 60 seconds. Again, the participant was given one practice trial followed by three recorded trials with at least 30 seconds rest between each trial. The best trial (longest) was used for analysis.

Star Excursion Balance Test. Star Excursion Balance Test was performed according to methods described by Hertel et al.[37] in the PM direction only.[36] Participants stood on their involved limb at the center of a grid laid on the floor with three cloth tape measures extending at 45-degree angle from center. Hands were placed on their iliac crests. They were instructed to reach in the PM direction as far as possible with the uninvolved limb. They touched the measuring tape with their great toe without placing weight on the uninvolved limb, then returned to the starting position. The examiner recorded the distance to the nearest millimeter. The participant was given four practice trials followed by a brief rest, then three recorded trials with at least 10 seconds rest between each trial. The average of three trials was normalized to participant's leg length and used for analysis.

Figure of 8 Hop Test. Methods described by Docherty et al.[38] were used for this task. Participants hopped on the involved leg in a figure-8 pattern (Figure 2). Participants were told the goal was to complete the five meter figure-8 pattern twice as fast as they could. Participants were familiarized with the task by walking through the course, then hopping one time through the course at half-speed. Following a rest period, they completed their first timed trial, rested for at least 60 seconds, then completed their second timed trial. Due to the fatiguing nature of this and the side-hop test, only two trials of each were recorded. The examiner gave verbal encouragement during the task, and recorded time with a handheld stopwatch to the nearest hundredth of a second. The best trial (shortest) was used for analysis. Following completion, the participant was asked to report their perceived ankle stability during the task on a scale of 0-10 with 0 being very unstable and 10 being very stable.[39]

Side-Hop Test. Methods described by Docherty et al.[38] were used for this task. Participants hopped laterally on the involved leg across a 30cm line for 10 repetitions (side to side counted as one repetition; Figure 2). Participants were told the goal was to complete the 10 repetitions as fast as they could. Participants were familiarized with the task by completing 3-4 repetitions at partial speed. Following a rest, they completed their first timed trial, rested for at least 60 seconds, then completed their second timed trial. The examiner gave verbal encouragement during the task, and recorded time with a handheld stopwatch to the nearest hundredth of a second. The best trial (shortest) was used for analysis. Following completion, the participant was asked to report their perceived ankle stability during the task on the same 0-10 scale as the Figure-8 test.

Testing Procedures

Participants reported to the testing facility for enrollment procedures and baseline evaluation. Following informed consent, participants completed an injury history questionnaire and several patient oriented questionnaires including the CAIT, FAAM, GRF and SF-36. The injury history questionnaire collected information about the initial ankle sprain, symptoms of giving way and re-sprains, and rehabilitation history (see Table 1). If the initial ankle sprain was evaluated and graded by a medical professional, we asked the participant to report the diagnosed severity of injury. One limitation of the study is that due to its retrospective design, we did not have control over the grading criteria; however, we believe that limited data were better than no data. All sprains that were not evaluated by a medical professional were labeled as unknown severity.

Next, the investigator measured and recorded participant height and mass, uninvolved leg-length, and ankle laxity. The investigators evaluated ankle-joint laxity using the anterior drawer and talar tilt tests, performed according to Ryan.[40] Grading for both tests was on a scale of 1 to 5, with 1 = very hypomobile, 2 = slightly to moderately hypomobile, 3 = normal, 4 = slightly to moderately hypermobile, and 5 = very hypermobile.[40] Good reliability for these tests has been reported using these methods ($ICC_{2,1}$ >0.80).[41] Grading was then condensed into clinically-relevant categories of positive (scores of 4 or 5) or negative (scores of 1-3).

The participant then completed baseline clinical tests as a measure of the clinician-oriented outcomes of our rehabilitation interventions. Clinical tests included three balance tests (foot lift test,[34] time-in-balance,[35] SEBT posterior medial (PM) direction),[36,37] and two hopping tests (figure of 8 hop test[38] and side-hop test).[38] The order of the three balance tests was counterbalanced, followed by the two hopping tests (also counterbalanced). Due to potential for fatigue, the two hopping tests were always administered after the balance tests. The selected clinical tests have been shown to differ between individuals with and without ankle instability,[36,38] and may be affected by either rehabilitative exercise.[42] Protocol for the five clinical tests have been previously described and are summarized below.[42] All testing was performed barefoot.

Following all baseline testing, the participant was randomly assigned to either the resistive tubing (RT) or wobble board (WB) training group. Block randomization with a block size of four participants was used to ensure equal enrollment in both groups. To ensure concealed allocation, an individual not involved in the current study prepared numbered envelopes which contained the random group allocation. Participants were assigned an enrollment number in sequential order. After randomization, neither the study investigators nor participants were blind to treatment group. The participant received instruction for his or her training group and completed the first exercise session on the enrollment day. Upon completion of the four week protocol, all baseline measures were post-tested within 1-3 days including reassessing all patient- and clinician-oriented measures.

Rehabilitation Protocol

Each participant completed three sessions each week for four weeks, all sessions were supervised.[13-15] The exact amount of time to complete each protocol was not recorded for each session, however, observationally both protocols took the same amount of time to complete (approximately 5 minutes).

Wobble Board protocol. Methods of Linens et al.[42] were used for the wobble board protocol. For each session, participants stood on a wobble board placed near a wall on their involved limb (Figure 3). Participants completed five 40 second sets of clockwise and counter-clockwise rotations (alternating direction every 10 seconds), with 60 seconds of rest between sets. Participants could place their fingers on the wall for stability. Training started on the lowest level (level 1 out of 5) of the wobble board, and progression was made based on the participant's ability to complete smooth circular rotations in both directions and make smooth transitions between direction changes. Generally, progressions were made every 2-4 sessions.

Resistance Tubing protocol. RT methods were modified from those of Kaminski et al.[23] to follow the same four week time frame of the WB protocol. For each session, participants completed resistance training using Theraband tubing in four directions (plantarflexion, dorsiflexion, inversion and eversion; Figure 3). Subjects were seated on the floor with their knee extended, and instructed to perform the movement at the ankle joint without allowing extraneous movement from other joints. The Theraband was doubled and attached to a table leg or hook on a wall. The training resistance was determined using the methods of Kaminski et al.,[23] in brief, by calculating 70% of the resting length of the Theraband, then adding this distance to the resting length of the Theraband. Using this calculated distance, a mark was placed on the floor and participants had to stretch the Theraband to this standardized distance when performing three sets of 10 repetitions in each of four directions. Every three sessions, the subject progressed to the next Theraband color level (red →green→blue→black).

Statistical Analyses

To ensure that groups were similar at baseline and establish internal validity, independent t-tests were used to compare baseline demographic data and ankle sprain history (Table 1). Chi-squared (or Fisher's exact tests if observed cell count was <5) were used to test for baseline differences in all categorical variables. Alpha was set *a priori* at p=0.05.

Separate 2 (group) x 2 (time) repeated measures ANOVAs were conducted for each of the patient-oriented outcomes (CAIT, 2 FAAM scales, SF-36 and GRF), clinician oriented outcomes (side-hop, figure-8 hop, foot lift, time-in-balance, and SEBT-PM direction) and self-reported stability during the side hop and figure-8 tests. Significant interactions were investigated using paired t-tests (to test group changes over time). Alpha level for post hoc tests was Bonferroni corrected to P=0.0125. The magnitude of significant main effects was described by calculating the percent change from baseline, as well as Hedge's g effect size with 95% confidence intervals (CI). Effect sizes were interpreted: 0.2 = small, 0.5=moderate, 0.8=large.

Results

A CONSORT diagram shows participant flow through enrollment, allocation, follow-up and analysis (Figure 1). Participant demographics and injury characteristics are shown in Table 1. There were no differences for demographic or injury characteristic variables (all P>0.05), except for the frequency with which participants reported performing some sort of rehabilitation following ankle injury. Specifically, participants in the WB group reported rehabilitation at a higher rate than those in the RT group.

All participants completed all 12 rehabilitation sessions and all returned for follow-up testing. Due to 100% follow-up with participants it was not necessary to perform intention to treat analysis.

Patient-Oriented Questionnaires

There was a significant interaction between group and time for the FAAM-ADL ($F_{1,38}$=4.381, P=0.043; descriptive data in Table 2). Specifically, the WB group improved post intervention (t=-4.199, df=19, P<0.001; Hedge's g=0.928, 95% CI=0.28-1.58) whereas the RT group remained the same (t=-1.080, df=19, P=0.294; Hedge's g=0.247, 95% CI=-0.38-0.87). There were no other significant interactions, nor any significant main effects for groups for patient-oriented questionnaires (all P>0.05, Table 2). There was a significant effect for time on the remaining 4 patient-oriented outcomes (CAIT: $F_{1,37}$=31.42, P<0.001; FAAM-Sport: $F_{1,38}$=17.997, P<0.001; GRF: $F_{1,30}$=4.944, P=0.034; SF-36: $F_{1,38}$=s22.696, P<0.001). Regardless of group, there were significant post-intervention improvements for these 4 outcome measures (Table 2; CAIT= 26.9% improvement, Hedge's g=0.858, 95% CI=0.39-1.32; FAAM-Sport= 15.2% improvement, Hedge's g=0.764, 95% CI=0.31-1.22; GRF= 14.6% improvement, Hedge's g=0.940, 95% CI=0.42-1.47; SF-36= 5.6% improvement, Hedge's g=0.198, 95% CI= -0.24-0.64). Change scores by group with 95% confidence intervals are reported in Table 2.

Clinician Oriented Outcomes

There were no significant interactions or group differences for performance on the five clinical tests (all P>0.05; Table 3). There was a significant effect for time on all five clinical tests (foot lift test: $F_{1,38}$=24.402, P<0.001; time-in-balance test: $F_{1,38}$=12.458, P=0.001; SEBT-PM: $F_{1,38}$=35.411, P<0.001; side hop test: $F_{1,38}$=21.298, P<0.001; Figure-8 test: $F_{1,38}$=36.085, P<0.001). All tests improved post-intervention regardless of treatment group (Table 3; SEBT-PM=6.5% improvement, Hedge's g=0.69, 95% CI=0.24-1.14; foot lift test= 29.3% improvement, Hedge's g=0.56, 95% CI =0.11-1.00; time-in-balance= 24% improvement, Hedge's g=0.40, 95% CI=0.05-0.84; Figure-8 test= 16.6% improvement, Hedge's g=0.63, 95% CI =0.18-1.07; side hop test= 30.2% improvement, Hedge's g=0.73, 95% CI=0.28-1.18). Change scores by group with 95% confidence intervals are reported in Table 3. There were no significant interactions or group differences for self-reported stability during the side hop and figure-8 tests (all $P>0.05$). However, both groups showed significant improvements in self-reported stability post-intervention (figure-8 test: $F_{1,38}=47.852$, $P<0.001$, 25.1% improvement, Hedge's g=1.02, 95% CI=0.56-1.49; side hop test: $F_{1,38}=86.000$, $P<0.001$, 35.2% improvement, Hedge's g=1.22, 95% CI=0.74-1.69).

Discussion

The purpose of this study was to assess the comparative efficacy of a 4-week intervention of either WB or RT exercises. This investigation measured comparative efficacy both from a patient-oriented perspective (symptoms reduction) and clinician-oriented perspective (enhanced ability to perform clinical tests). Overall, our results supported the use of either intervention to reduce symptoms and improve performance. With one exception (FAAM-ADL)**,** no group differences were found that would support the use of one intervention over the other.

Our results show that a single exercise 4-week intervention can reduce symptoms and improve clinical test performance in individuals with CAI. Our interventions were designed to require minimal equipment and require minimal supervision. Despite the fact these exercises require minimal supervision, we chose to supervise every session to minimize any question that the results of this study could be attributed to variable adherence and/or incorrect performance. One rationale for this design was so clinicians in high volume, low resource settings (such as high school athletics) could feasibly utilize these protocols proactively with all patients exhibiting symptoms of CAI or recurrent sprain. The current results show that such a program would be effective at reducing symptoms and improving clinical test performance immediately following the 4-week intervention.

While overall both interventions were effective, there is limited evidence to support use of the WB protocol as the preferred method. Specifically, FAAM-ADL scores improved in the WB group but not the RT group. In addition, the WB protocol was anecdotally preferred by participants who found it more engaging than the RT protocol. Specifically, it appeared that the challenge of controlling the WB movement was game-like, whereas the repetitions of the RT protocol were less fun or mentally stimulating (although still physically challenging). While our reporting of participant preference is anecdotal, it may be important. We believe patients will be more likely to adhere to a rehabilitation protocol that they enjoy and feel presents a healthy amount of challenge.

Patient-oriented outcomes

Improvements in the FAAM (or its predecessor the Foot and Ankle Disability Index) have consistently been reported post-intervention for a variety of rehabilitation protocols.[15,16,20,21] We found moderate effect sizes for improvements in the FAAM-Sport in both groups, but only the WB group improved in the FAAM-ADL. The ADL scale does have a noted ceiling affect in physically active populations,[43] and this may have played into the failure to find significant differences in the RT group, as both groups had a fairly high pre-intervention FAAM-ADL score. The magnitude of improvement in our WB group averaged 6.1% on the FAAM-ADL scale (large effect size) and 12.1% on the FAAM Sport (moderate effect size), compared to previously reported changes of 5.2-11.2% and 6.6-15.1% on the ADL and Sport subscales, respectively.[15,16,20,21] Interestingly, previous studies used multi-exercise rehabilitation programs (largely targeted at balance and proprioception), which took 20-30 minutes to complete.[15,16,20]

Our single-exercise WB protocol more efficiently (5-10 minutes) achieved a similar magnitude improvements on the FAAM-ADL and Sport subscales. For clinicians and patients, this could save time and money. It is possible that the multi-exercise programs have other desirable effects which are not captured in the FAAM measure; however, until evidence is presented to confirm additional benefits we recommend the more efficient WB protocol.

Similarly, increases in CAIT have been reported after both balance training[18] and strength and proprioception training[19] interventions. Kim et al.[19] found that a combined intervention of strength and proprioceptive training resulted in an average 5.3 point increase in CAIT score, significantly more than the 3.2 point increase seen with strength training alone. Cruz-Diaz[18] reported a 3.8 point increase following a 6 week balance training intervention. The CAIT increases found in the current single-exercise intervention (3.2 with RT, 5.7 with WB) are of a similar magnitude as previous work, providing evidence that either of our interventions were as effective as other protocols in decreasing instability as measured by the CAIT.

Similar to our WB group, Clark and Burden[14] also investigated the isolated effect of WB training. However, direct comparison of their patient-oriented outcomes is difficult as they used the Ankle Joint Functional Assessment Tool (AJFAT).[14] This questionnaire compares the involved ankle to the contralateral ankle, making it best suited for individuals with unilateral instability. As we did not want to limit our subjects to only those with unilateral instability we did not utilize this measure in the current research. Although direct comparison is limited, the percent increase seen in their study (28.4%) is comparable to percent increases we found using our region-specific questionnaires (CAIT = 26.9%, FAAM-ADL = 4.3%, FAAM-Sport = 15.2%).

To our knowledge, previous CAI literature has not documented the effect of rehabilitation on GRF, nor on HR-QOL as documented by the SF-36. We included the GRF because it is a single-item function assessment. For clinicians practicing in settings where collecting and calculating multi-item questionnaires like the CAIT or FAAM might not be realistic, we hoped the GRF would present a viable alternative. However, the GRF had high variability, and the investigators anecdotally noted participant confusion and/or discomfort with subjectively assigning a number to their ankle function. While large effect sizes and significant improvements in GRF were found, we would not recommend sole reliance on this measure.

The SF-36 PCS improved 2.8 and 3.2 points in the WB and RT groups respectively**,** representing a significant but small effect size. Previous research has shown that deficits as small three points were associated with 25% higher risks of job loss and 40% higher risk of inability to work.[32] Thus, although apparently small, the small improvements found in the current study could have important implications for HR-QOL. While the current study was not designed to explain variance in the SF-36 or other questionnaires, previous research has investigated potential factors. Specifically, Houston et al.[44] sought to explain variance in the SF-12 PCS (an abbreviated version of the SF-36), FAAM-ADL and FAAM Sport using a linear regression model and 17 clinician and laboratory measures. Their modeling explained between 18-28% of variance in these measures, with significant variables including plantar cutaneous sensation, dorsiflexion range of motion, time-to-boundary measures, eversion rotation and SEBT reach in the posterolateral direction. Future research should attempt to identify variables that (a) explain a larger percent of variance, and (b) can be modified with therapeutic interventions.

Clinician-oriented outcomes

Clinical tests were used as a measure of the clinician-oriented outcomes of our rehabilitation interventions. Although it is possible to show improvements in patient reported outcomes without significant changes in laboratory measures,[20] we felt the inclusion of clinical measures was essential for establishing the efficacy of our treatment interventions. Regardless of treatment group, all five clinical tests showed significant improvement post-intervention. Only 1 clinical test had a small effect size for time (time-in-balance=0.40), all the rest had moderate effect sizes (0.56-0.73). Based on the significant effect for time but no treatment group effect, it was concluded that both treatments were effective, but neither treatment was shown to be significantly better than the other at improving clinician-oriented outcomes.

We used the time-in-balance test and foot lift test to measure static balance, as these tests have previously be identified to discriminate between individuals with and without CAI.[36] The magnitude of change for the foot lift test in our participants (30.6% & 28.2% for the WB and RT groups respectively) is similar to that reported in previous work using just the WB protocol (31.9-43.6%).[42,45] In contrast, our improvements in time-in-balance (22.0% & 26.0% in WB and RT groups, respectively), are slightly smaller than those reported in Cain et al. (49.8%).[45] However, Cain et al.[45] tested the effectiveness of WB intervention of high school students, and speculated that their large effect sizes might be due in part to the greater neuroplasticity of this age group.

The SEBT is one of the most commonly used dynamic balance outcome measures in ankle rehabilitation literature.[16,18,21,42,45] The current study reported increases in PM reach distance of 5.1% and 8.7% for the WB and RT groups, respectively. Interestingly, these improvements are similar in magnitude to those reported in several multi-exercise rehabilitation interventions (5.3-11.0%).[16,18,21] This again provides evidence that a single exercise intervention can be equally effective at increasing clinical test performance as a more time intensive multi-exercise program.

The figure of eight hop test and side hop test have both been used to identify individuals with and without CAI.[36,38] Especially in physically active populations, these tests may be seen as the most functional of the clinical tests completed in this study. Again, our results for the side hop test (22.6% decrease in completion time) are similar in magnitude to previous research using the same WB protocol (20.1-24.9% decrease)[42,45] and are similar to the average task time previously reported for healthy control subjects (9 seconds).[46] Participants in the RT group averaged the same post-intervention time to completion (9.14 seconds) as our WB group (9.18 seconds), however since they started with slightly poorer performance the percent improvement (36.6%) appears greater although statistically insignificant.

For the figure of eight hop test, we recorded average improvements of approximately 2.5 seconds (16%) post-intervention in both groups. In contrast, Linens et al. [42] reported much larger improvements of 7.15 seconds (36.6%) following a four week WB intervention in a similar subject population. However, since the WB group post-intervention scores for both studies are almost identical (12.94 vs. 12.40 seconds), the greater percent improvement reported in Linens et al.[42] was due to an increased deficit pre-intervention, rather than a decreased treatment effect in the current study. Importantly, the post-intervention values for the current study are similar to previously reported values for healthy control subjects (11 seconds),[46] demonstrating that both WB and RT protocols were effective in returning participants to normal values.

Since previous work has reported differences between individuals who do and do not report instability during hopping tasks,[39] we also felt it important to document subjective instability during task completion. Both our WB and RT groups improved their subjective stability post-intervention by 1.7-2.3 points (23-39%) during the two hopping tasks. This demonstrates that stability improvements are felt during specific tasks, as well as during the more general activities targeted by the other patient reported questionnaires.

Participant characteristics

There were no significant baseline differences in the WB and RT group, except the WB group had more participants who reported participating in rehabilitation following their initial ankle sprain. The implications (if any) of this group difference are unclear—especially considering there were no significant differences in other documented injury characteristics. It could be participants in this group had more access to therapy services or sought therapy because of a greater perceived need. However, it's interesting to note that these individuals had at least an equal response to treatment than the RT group despite their history of therapy following the initial injury.

Limitations and Considerations for Future Research

Due to a focus on clinical and patient-oriented measures (as opposed to laboratory measures), we have a limited ability to infer the exact mechanisms by which WB and RT training improved these measures. Laboratory measures have an important place;[11] however, we felt that previous research had established sufficient evidence in this area[10,14,22,23] and thus we chose to focus on only clinician- and patient-oriented measures.

There are a few limitations in the study design that affect internal validity. First, once the participant was assigned to their treatment group neither the participant nor the examiner documenting outcomes was blind to treatment group. Due to the nature of treatment, blinding of the participant to group would have been impossible, although they were blind to any study hypotheses. Blinding of the examiner was not possible due to limited personnel, and a desire to maintain consistency in the measurement of pre- and post-intervention measurements. Additionally, without a control group it can't be said with absolute certainty that any changes seen were not due to practice or natural improvement over time, or a placebo effect from patient's treatment expectations. Regarding, a practice effect or natural improvement over time it should be noted that the efficacy of this WB protocol was previously compared to a control (no intervention) condition.[42] This separate research did not find significant improvements in the control group, whose performance was relatively stable over the four week time period, providing evidence that without treatment meaningful change is unlikely in this population.[42] While the aforementioned limitations may affect internal validity, the external validity of the study remains high as the study design answers a clinically relevant question using clinically applicable methods. For example, in clinical practice, the same clinician (not blind to treatment) would administer patient- and clinician-oriented outcomes before and after an intervention to assesses effectiveness, and a control or placebo group would not be used for ethical reasons.

Participants were recruited from a general university population. While they may have responded to the study out of a desire to seek treatment, to our knowledge they were not actively seeking treatment prior to enrollment. Thus, their characteristics may be different than a population who is actively seeking treatment. Additionally, participants enrolled in the study had not engaged in recent rehabilitation, thus it's possible that any ankle rehabilitation protocol would have elicited a positive effect. While most of the current literature excludes individuals who have engaged in recent rehabilitation out of a desire to eliminate a potential confounding variable, in the real world patients may engage in multiple rehabilitation attempts in sequence if they are not satisfied with their outcomes. Future research should test the effect of WB and RT training in individuals who have had recent rehabilitation, but potentially not achieved the results they desire.

We utilized two established rehabilitation protocols in this study.[23,42] Both protocols elected to start all participants at the same level and then systematically progress them throughout the rehabilitation duration. Since starting difficulty level was not tailored to each individual's abilities, participants may have experienced unequal level of challenge especially at the start. Anecdotally, all participants reported fatigue and/or difficulty as they progressed through the levels of the protocol. Recent research has proposed a new paradigm of treating CAI, which tailors exercise type and difficulty to each individual's assessed impairments.[47] This approach has several advantages, and future research should investigate whether use of this paradigm results in improved outcomes. However, as the purpose of this study was to investigate the comparative efficacy of 2 simple rehabilitation exercises requiring minimal equipment or clinician time, an individually tailored protocol did not meet the research aims of the current study.

The current study does not measure long-term clinical outcomes. Future research should investigate whether long term injury rates and giving-way episodes decrease post-intervention. This information is especially important if the WB or RT protocols were to be used as preventative measures for all individuals who have screened positive for CAI (e.g. at a high school or university athletic training room).

Conclusions

We found that a simple 4-week intervention with 1 exercise (WB or RT) can significantly enhance patient- and clinician-oriented outcomes in individuals with CAI. These changes are similar in magnitude to those seen with multi-exercise rehabilitations programs, yet with less time and resource use. There is limited evidence indicating that WB training is more effective than RT. However, given the strong evidence supporting the efficacy of either treatment, a clinician could feel confident selecting whichever intervention best fits with their resources and patient needs.

Acknowledgements

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Legend to Figures

FIGURE 1. CONSORT flow diagram

FIGURE 2. Figure-8 Hop Test (A) and side hop test (B)

FIGURE 3. Wobble Board (A) and Resistance Tubing (B) intervention setup. Resistance tubing is shown only in the inversion direction, not pictured are eversion, plantarflexion and dorsiflexion.

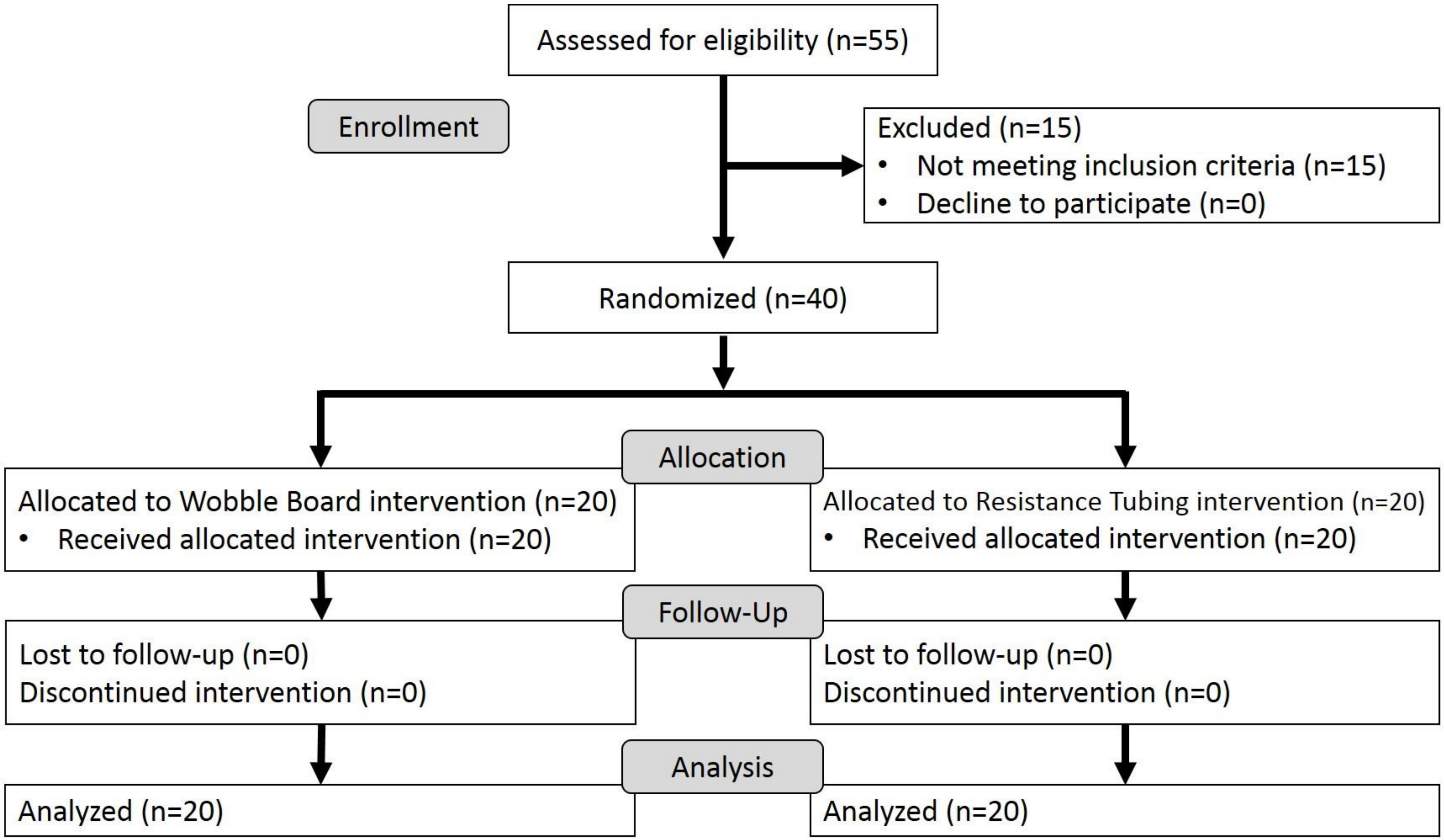


FIGURE 1. CONSORT flow diagram

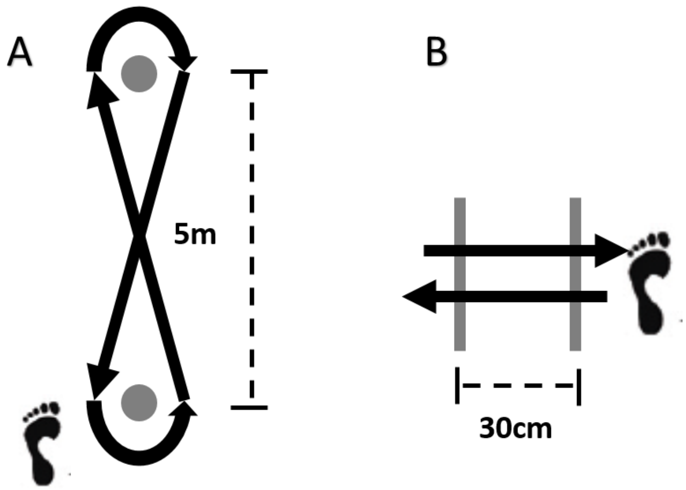
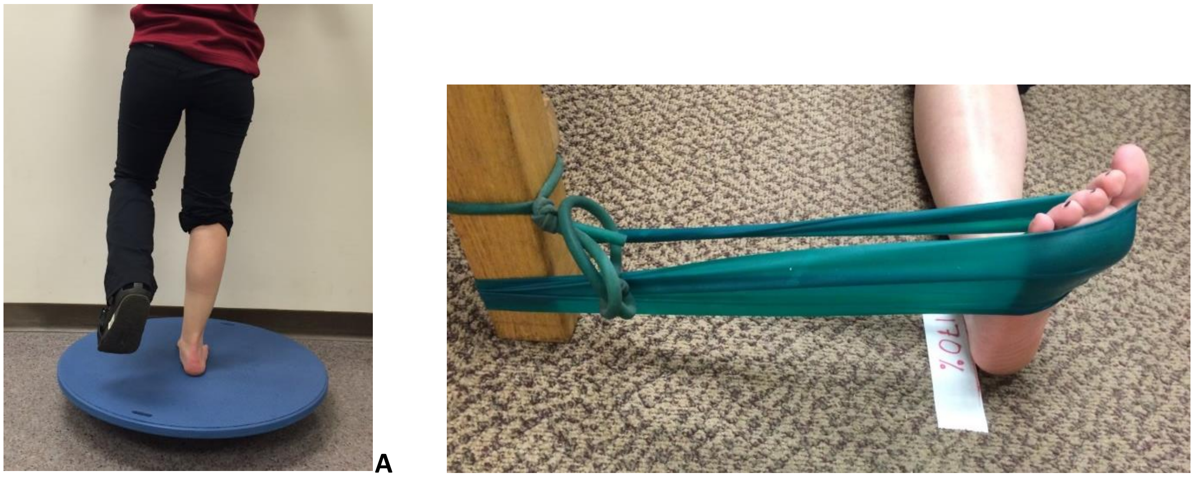


FIGURE 2. Figure-8 Hop Test (A) and side hop test (B)



A B

FIGURE 3. Wobble Board (A) and Resistance Tubing (B) intervention setup. Resistance tubing is shown only in the inversion direction, not pictured are eversion, plantarflexion and dorsiflexion.

TABLE 1. Participant demographics

Descriptor	Wobble Board	Resistance Tubing	Statistical Analysis
Age, y	22.60±5.89	21.45±3.24	t=0.765, df=38, P=0.449
Height, m	1.66±0.15	1.66±0.87	t=0.017, df=38, P=0.987
Weight, kg	70.25±15.08	76.38±19.34	t= -1.12, df=38, P=0.270
Time since initial sprain, y	8.26±5.86	5.95±3.49	t=1.481, df=36, P=0.147
Limited weight bearing, d	8.89±13.53	9.94±11.45	t= -0.248, df=33, P=0.806
Number of re-sprains	2.95±3.44	3.16±3.70	t= -0.182, df=37, P=0.857
Episodes of giving-way, month	4.71±7.06	9.07±18.69	t= -0.949, df=35, P=0.349
Gender	6 male 14 female	5 male 15 female	X^2=0.125, df=1, P=0.723
Initial ankle sprain evaluated by a medical professional?	17 (85%) Yes 3 (15%) No	12 (60%) Yes 8 (40%) No	Fisher's P=0.155
Severity of initial ankle sprain	3 (15%) Mild 9 (45%) Moderate 4 (20%) Severe 4 (20%) Unknown	1 (5%) Mild 5 (25%) Moderate 4 (20%) Severe 10 (50%) Unknown	X^2=4.714, df=3, P=0.194
Rehabilitation performed?	11 (55%) Yes 9 (45%) No	4 (20%) Yes 16 (80%) No	Fisher's P=0.048*
Rehabilitation supervised by therapist?	11 (100%) Yes 0 (0%) No	2 (50%) Yes 2 (50%) No	--†
Anterior drawer laxity	8 (40%) positive 12 (60%) negative	11 (55%) positive 9 (45%) negative	X^2=0.902, df=1, P=0.342
Talar tilt laxity	11 (55%) positive 9 (45%) negative	9 (45%) positive 11 (55%) negative	X^2=0.400, df=1, P=0.527

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

* Significant difference between groups. † Unable to calculate Fisher's exact test due to cell count of 0.

TABLE 2. Results of patient-oriented outcome measures

	Wobble Board Group						Resistance Tubing Group					
	PRE		POST		Change Score		PRE		POST		Change Score	
Outcome Measure	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**
CAIT, score	16.63	5.55	22.20†	3.82	5.74	5.18	16.15	5.65	19.30†	4.85	3.15	4.72
FAAM-ADL, %	91.1*	8.22	97.19*	3.89	6.10	6.49	91.34*	7.52	93.00*	5.50	1.66	6.89
FAAM-Sport, %	59.61	14.94	71.75†	9.80	12.14	15.99	60.21	11.80	66.25†	9.75	6.04	10.58
Short Form-36, PCS score	54.77	5.40	57.57†	3.94	2.80	2.62	52.36	5.94	55.56†	4.11	3.19	4.98
Global Rating of Function, %	82.19	16.19	93.88†	5.07	11.69	13.31	77.81	14.60	83.06†	23.45	11.60	10.66

Abbreviations: CAIT = Cumberland Ankle Instability Tool, FAAM-ADL = Foot and Ankle Ability Measure Activities of Daily Living Scale, FAAM-Sport = Foot and Ankle Ability Measure Sport Scale, PCS = Physical Component Summary, M = Mean, SD = Standard Deviation

* Significant group by time interaction ($p<0.05$)

† Significant difference between pre- and post-intervention scores ($p<0.05$)

TABLE 3. Results of clinical tests for function and balance

	Wobble Board Group						Resistance Tubing Group					
	PRE		POST		Change Score		PRE		POST		Change Score	
Clinical Test	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**	**M**	**SD**
SEBT-PM, cm	0.98	0.09	1.03*	0.08	0.05	0.04	0.92	0.10	1.00*	0.08	0.08	0.08
Foot Lift Test, errors	6.27	3.73	4.35*	2.59	1.92	2.35	6.98	4.41	5.02*	2.96	1.97	2.61
Time in Balance test, sec	34.07	22.17	41.57*	22.35	7.51	15.92	33.06	17.15	41.65*	19.22	8.59	12.75
Figure of 8 Hop test, sec	15.60	5.70	12.94*	3.78	2.65	3.54	15.55	3.93	13.02*	2.61	2.53	1.54
Figure of 8 Hop test, stability rating	7.10	1.58	8.75*	1.08	1.65	1.38	6.45	2.39	8.20*	1.15	1.75	1.71
Side Hop test, sec	11.86	5.99	9.18*	3.54	2.68	2.78	14.37	7.94	9.14*	1.97	5.23	7.15
Side Hop test, stability rating	6.45	1.35	8.50*	1.36	2.05	1.56	5.75	2.41	8.50*	1.65	2.25	1.36

Abbreviations: M = Mean, SD = Standard Deviation.

* Significant difference between pre- and post-intervention scores ($p<0.01$)