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Results From a Randomized Controlled Trial to Address Balance Deficits After Traumatic Brain Injury

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Abstract

Objective: To evaluate the efficacy of an in-home 12-week physical therapy (PT) intervention that utilized a virtual reality (VR) gaming system to improve balance in individuals with traumatic brain injury (TBI).

Setting: Home-based exercise program (HEP).

Participants: Individuals (N=63; traditional HEP n=32; VR n=31) at least 1 year post-TBI, ambulating independently within the home, not currently receiving PT services.

Main Outcome Measures: Primary: Community Balance and Mobility Scale (CB&M); Secondary: Balance Evaluation Systems Test (BESTest), Activities-Specific Balance Confidence Scale (ABC), Participation Assessment with Recombined Tools-Objective (PART-O).

Results: No significant between-group differences were observed in the CB&M over the study duration (P=.9983) for individuals who received VR compared to those who received a HEP to address balance deficits after chronic TBI nor in any of the secondary outcomes: BESTest (P=.8822); ABC (P=.4343) and PART-O (P=.8822). However, both groups demonstrated significant improvements in CB&M and BESTest from baseline to 6, 12, and at 12 weeks follow-up (all P's <.001). Regardless of treatment group, 52% of participants met or exceeded the minimal detectable change of 8 points on the CB&M at 24 weeks and 38% met or exceeded the minimal detectable change of 7.81 points on the BESTest.

Conclusion: This study did not find that VR training was more beneficial than a traditional HEP for improving balance. However, individuals with chronic TBI in both treatment groups demonstrated improvements in balance in response to these interventions which were completed independently in the home environment.

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Suppliers

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Keywords

Balance; Evidence based medicine; Rehabilitation; Traumatic brain injuries; Virtual reality

Balance impairment is a common long-term deficit seen in individuals with traumatic brain injury (TBI),[1,2] which can negatively impact physical function, independence, and quality of life; increase fall risk and subsequent injury[3,4]; and limit community participation.[5] Despite rehabilitative efforts, balance deficits can persist in the chronic stages of TBI.[6] Currently, there is limited evidence for treatment of impaired balance in chronic TBI.[7]

Typically, individuals with TBI receive written home exercise programs (HEPs) for continued balance training following formal physical therapy (PT). Reported adherence of using HEPs to prevent falls in adults is poor[8] and there is limited research evaluating the efficacy and compliance associated with HEPs to manage balance impairments in adults with chronic TBI.

Virtual reality (VR) systems are computer-based applications that allow an individual to view a simulated environment and dynamically interact within this environment in real time.[9,10] VR has been evaluated as an intervention to address balance deficits associated with multiple neurologic conditions,[1,11-28] including TBI.[29-31] Studies have shown that individuals with neurologic conditions who utilize VR have improved aspects of balance[1,12-20,23-28,32,33] and some have also reported greater balance confidence using VR than traditional rehabilitation approaches.[29,31]

Although the evidence for the efficacy of VR in TBI rehabilitation remains limited,[34] this area of research may offer an affordable approach for ongoing treatment outside of a structured insurance-reimbursed rehabilitation program. The purpose of this study was to assess the efficacy of an individually structured 12-week home VR-based intervention compared to a traditional HEP to improve balance in individuals with chronic balance deficits after TBI. We hypothesized that individuals who received VR-based intervention would demonstrate statistically significant improvements in balance, as measured by the Community Balance and Mobility Scale (CB&M), over those who received a traditional HEP.

Methods

Setting and participants

This study was approved by the institutional review board and was registered on clinicaltrials.gov (NCT01794585). Participants were recruited using mailings, posters in the hospital, and contact with local outpatient facilities who met the following criteria: 18-65 years old; at least 1-year post moderate to severe TBI; and currently living in the geographical area. Potential participants were then screened for additional criteria: able to ambulate independently in the home, no participation in skilled PT for the 3 previous months, and self-report of balance deficits. After passing screening criteria, individuals were consented into the study by the study coordinator prior to completing baseline testing. All testing (baseline, 6, 12, 24wk) was completed in a rehabilitation hospital by blinded PT

assessors who underwent training and reliability testing on all measures. See figure 1 for subject recruitment and inclusion information.

Outcomes

Community Balance and Mobility Scale—The CB&M is a standardized assessment for functional balance during community activities for individuals with TBI. It includes 13 activities scored from 0-96 points.[35] It has excellent interrater and intrarater and test-retest reliability for the TBI population.[35] Studies reported means and SDs for individuals with TBI in inpatient and outpatient settings ranging from 51.1-57.8 and 18.3-23.3, respectively.[35,36] Based on this information, exercise categories were created using a mean of 54 and a SD of 21 points to establish difficulty levels for protocol prescription. Participants who scored more than 1 SD below the mean (CB&M<33) were prescribed the basic protocol; those who scored within 1 SD below the mean (33-54) were prescribed the intermediate protocol and participants who scored within 1 SD above the mean (55-75) were prescribed the advanced protocol. Individuals with scores more than 1 SD above the mean (>75) were excluded from the study.

Activities-Specific Balance Confidence Scale—The Activities-Specific Balance Confidence Scale (ABC) is a self-report measure of fear of falling during community activities. This 16-item measure is scored from 0 (no confidence) to 100 (complete confidence).[37] It has excellent test-retest reliability and internal consistency, and adequate content validity.[38] The ABC has been used in previous TBI research, and has been shown to be sensitive to treatment effects.[29,36,39]

Balance Evaluation Systems Test—The Balance Evaluation Systems Test (BESTest) is a standardized 36-item test with scores ranging from 0 (maximum impairment) to 108 (within normal limits). The test has 6 subscales, corresponding with Horak's 6 balance systems[40]: Biomechanical Constraints, Stability Limits/Verticality, Anticipatory Postural Adjustments, Reactive Postural Responses, Sensory Orientation, and Stability in Gait. It is used in the Parkinson's Disease and vestibular disorder populations showing high reliability and validity,[41-43] but has not been commonly used in TBI.[44]

Participation Assessment with Recombined Tools-Objective—The Participation Assessment with Recombined Tools-Objective (PART-O) has 17 items designed to objectively measure community participation in individuals with TBI. Item scores range from 0 (never participate in these activities) to 5 (high participation in these activities). Higher scores indicate greater community participation. It has strong concurrent validity and adequate to excellent correlations with other participation and functional measures.[45,46]

Interventions

Participants were randomized to 1 of 2 treatment arms, traditional balance HEP or VR HEP. The focus of the balance programs in both the VR and traditional HEP groups was determined by the most impaired subscale of the BESTest. For example, when stability of gait was scored as the lowest BESTest subscale, Xbox Kinect games focusing primarily on dynamic standing activities such as single limb stance were included in the VR group

exercise program. In parallel, dynamic activities including single limb stance were also included in the HEP for the traditional group who scored lowest on the stability of gait subscale of the BESTest. Exercise difficulty (basic, intermediate, and advanced) was determined by the total CB&M score. See supplemental fig S1 (available online only at http://www.archives-pmr.org/) for examples of the various exercises prescribed. Both groups were instructed to complete their program 3-4 times per week for 12 weeks, with each session lasting 30 minutes.

All participants were trained in their home by a PT who evaluated the safety of their home environment and made specific recommendations. The PT set up the gaming system for those in the VR arm. A second visit occurred within 1 week to confirm participant understanding of treatment program and offer additional safety recommendations. Following week 6 testing, exercise difficulty was updated based on CB&M stratification. All participants were required to complete an activity log documenting completion of daily sessions and a separate log documenting any adverse events.

Power and sample size calculations

An a priori sample size estimation using PASS 11[a] was based on detecting a moderate treatment group by time effect size of 0.5 with 80% power in a 2-arm design with 4 unequally spaced repeated measurements of the CB&M at a 5% significance level. An effect size of 0.5 corresponds to an approximate difference in change between groups of 10.25 points (SD=20.5), being larger than an 8-point difference suggested as clinical meaningful change by the CB&M authors.[35] A minimum of 26 participants per treatment group were needed for this study, and a total of 66 participants were recruited to allow for attrition.

Statistical methods

Statistical analyses were conducted using SAS version 9.4[b] assuming a significance level of α=0.05, unless otherwise specified. Baseline demographic and injury characteristics were summarized by group and compared to assess for potential differences.

Data were analyzed as intent-to-treat, using all available data from all participants. Each outcome was analyzed using a repeated-measures linear mixed-effects model. All models included fixed effects for treatment group, assessment time, and the interaction between treatment group and time, as well as effects for age, time since injury, sex, and current living situation. For each model, the omnibus test of the treatment × time interaction effect was first tested to determine if the 2 treatment groups exhibited significantly different changes in the outcome variable over the 4 time points. If this interaction effect was significant (α=0.05), then post-hoc analyses were conducted to determine how the groups differed in their patterns of change from baseline. In particular, changes from baseline to week 6, 12, and 24 were compared between groups using a Bonferroni adjustment of α=0.05/3=0.0167 to control for multiple comparisons. Effect sizes were estimated to be the mean estimate (either the within-group change or the between-group difference in changes) divided by

[a] PASS, version 11; NCSS.
[b] SAS, version 9.4; SAS Institute Inc.

square root of the model based variance for each outcome at baseline. The average number of sessions completed per week from baseline to 6 weeks, 6 weeks to 12 weeks, and 12 weeks to 24 weeks was computed and compared between groups using *t* tests.

Results

Sample description

Table 1 shows the demographic and injury characteristics of the sample by treatment group, and the baseline cognitive measures are summarized in supplemental table S1 (available online only at http://www.archives-pmr.org/). The groups did not differ significantly on any demographic, injury, or baseline cognitive measures. Sample size assumptions were not met for statistical comparisons of education level between groups. No adverse events directly related to either intervention were reported.

The unadjusted means and SD for each outcome are in supplemental table S2 (available online only at http://www.archives-pmr.org/). The estimated means from the repeated measures models, adjusted for covariates, are plotted in figure 2. The model based estimated changes from baseline to each endpoint (6, 12, 24wk) within each group, and the differences in changes between groups are summarized for each outcome in table 2.

Community Balance and Mobility Scale

There were no significant differences between groups in mean CB&M change over the study duration (treatment × time interaction P=.9983) after adjusting for covariates. Similarly, there were no significant differences in the changes over time between groups from baseline to each endpoint (P's>.87). Between group effects sizes were near 0. However, both groups exhibited significant increases in mean CB&M from baseline to each endpoint. Regardless of group, CB&M increased on average about 5 units from baseline to 6 weeks, about 7 units from baseline to 12 weeks, and about 8 units from baseline to 24 weeks. Within-group effect sizes were 0.29-0.31 at 6 weeks, 0.43-0.44 at 12 weeks, and 0.48-0.49 at 24 weeks, all considered to be small (0.2) to moderate (0.5). Covariate effects in the adjusted model were not significant.

A minimal detectable change score of at least 8 units was used as suggested by the CB&M authors. Overall, 37% of subjects had a positive response to treatment at 6 weeks (40% VR, 33% HEP), 48% at 12 weeks (47% VR, 50% HEP), and 52% at 24 weeks (50% VR, 53% HEP). There were no between-group differences in response to treatment rates (P's>.59).

Balance Evaluation System Test

Similar to CB&M, there were not significant differences between groups in mean BESTest changes over the study duration (interaction P=.8822), after adjusting for covariates, nor were there significant differences in the changes over time between groups from baseline to 6, 12, or 24 weeks (P's>.65). Between-group effect sizes were near zero. Also similar to CB&M, both groups significantly increased in BESTest scores from baseline to 6, 12, and 24 weeks (approximately 4-7 units). Within-group effect sizes were small to moderate (0.23-0.40). Covariate effects in the adjusted model were not significant, except for a

significant positive relationship between baseline age and BESTest scores (slope=0.38, *P*=.0394), such that younger age was associated with lower (worse) BESTest scores.

Using a minimal detectable change score of at least 7.81 units on the BESTest, 20% of subjects had a positive response to treatment at 6 weeks (23% VR, 17% HEP), 40% at 12 weeks (47% VR, 33% HEP) and 38% at 24 weeks (43% VR, 33% HEP). There were no between-group differences in response to treatment rates (*P*'s>.29).

ABC and PART-O

ABC and PART-O Summary showed no significant differences between treatment groups over the study duration (ABC *P*=.4343, PART-O Summary *P*=.4655). There were not significant within-group changes or between-group differences in changes from baseline to any endpoint (see table 2) for either outcome.

Dose and Compliance

Table 3 summarizes the mean number of sessions completed per week. Participants in the traditional HEP group reported a slightly higher average during the first 12 weeks and during 12 weeks of follow-up; however, no significant differences occurred between groups.

Discussion

This study found no between-group differences in balance in individuals with chronic TBI who received VR in comparison to a traditional HEP. However, both treatment groups demonstrated statistically significant and similar improvements in balance over a 24-week period. This is remarkable given the chronicity of injury of this sample. The improvements in both groups may be related to the design of the interventions which targeted individual-specific balance impairments. This study was powered to show a difference and not equivalence between the 2 treatment arms. The power for the latter type of study design would require a much larger sample size and so this study is not powered to show that the 2 interventions are equivalent.

There were no statistical differences between groups in balance confidence during the intervention phase or the follow-up period. These findings are contrary to Thornton et al[29] who reported that individuals 6 months post-TBI receiving VR training demonstrated greater balance confidence compared to a similar group receiving activity-based exercises. That study differed from this study as it did not analyze between-group statistical differences. Additionally, their participants were in the subacute phase of recovery, while these participants were at least 1 year post injury. Straudi et al[30] evaluated VR training compared to balance platform training in individuals with chronic TBI and reported similar results to this study as both groups demonstrated within-group improvement on the CB&M without significant between-group difference.

No previously published studies evaluating the effects of VR training on community participation after TBI were found, and no significant improvements were found in this domain in response to either treatment in this study either. This intervention did not directly target community participation, and the follow-up period may have been too short to see

changes in this domain. In regards to balance confidence, no significant improvements were noted in either group. Balance confidence did show an improvement at 6 weeks favoring the VR group (fig 2), but was not statistically significant and possibly due to the initial novelty of VR training.

Study limitations

There were limitations to this study. Although balance improvements are not expected in individuals with chronic TBI, no passive control group was available for comparison. This may have resulted in a halo effect as the blinded assessors were aware that both groups were receiving intervention, which may have introduced bias into their scoring. Dose was reported based on a self-report activity log. Previous studies suggest that dose and compliance may be an important factor for success in rehabilitation outcomes achieved in the home environment.[5,47,48] Enjoyment associated with training type was not measured; it may be important to measure this in future studies as this may influence whether individuals continue training outside of a structured follow-up period. Sample sizes were too small to examine the relationship between covariates and response to treatment. Future investigations with larger sample size should focus on identifying characteristics of responders vs nonresponders to either intervention.

Conclusion

VR training was not more beneficial than a traditional HEP for improving balance in a cohort of individuals with chronic TBI. However, individuals in both treatment groups demonstrated improvements in balance in response to these interventions, suggesting that individuals with chronic TBI can show improvements in balance years after injury. Current health care limitations may place an artificial ceiling on balance recovery due to limited outpatient benefits. This study demonstrates that both interventions addressing balance impairments can be carried out safely and effectively in the home environment.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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List of abbreviations:

ABC	Activities-Specific Balance Confidence Scale
BESTest	Balance Evaluation Systems Test
CB&M	Community Balance and Mobility Scale
HEP	home exercise program

PART-O	Participation Assessment with Recombined Tools-Objective
PT	physical therapy
TBI	traumatic brain injury
VR	virtual reality

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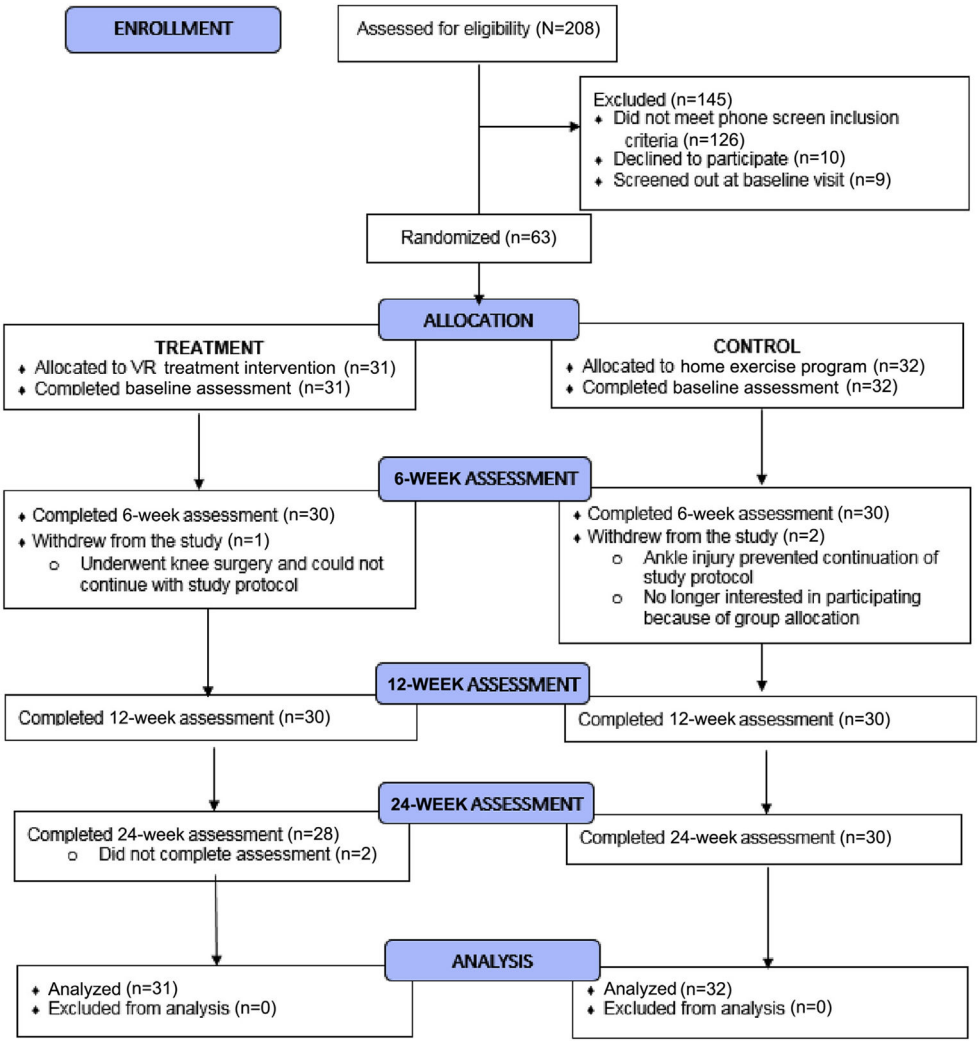

Fig 1.
CONSORT diagram.

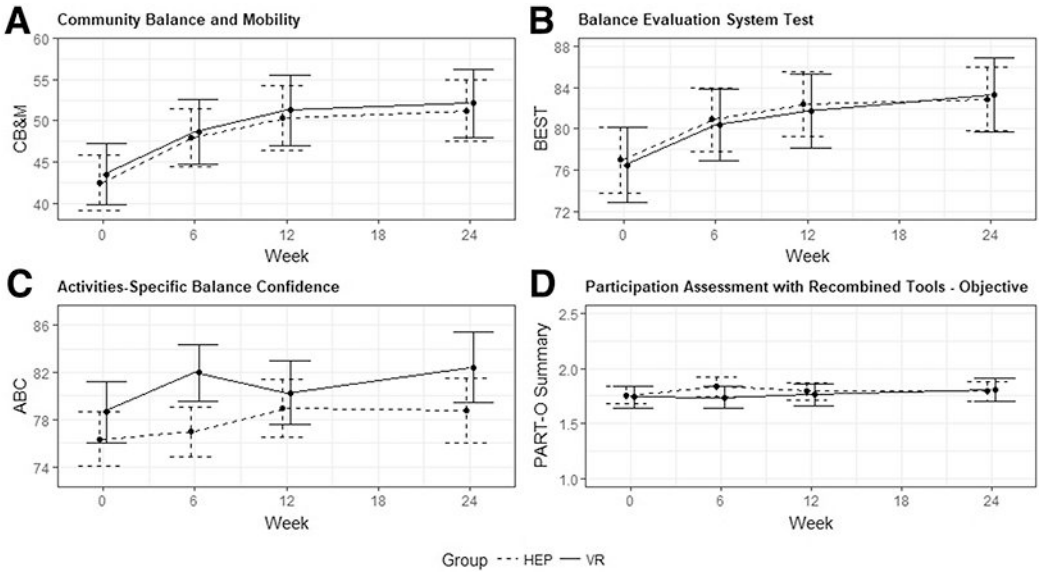

Fig 2.
Adjusted mean outcome measure change.

Table 1

Demographic and injury characteristics

Characteristics	VR (n=31)	HEP (n=32)	Comparison
Continuous Covariates	**Mean ± SD**	**Mean ± SD**	***P* Value**
Age	48.1±12.4	49.5±12.4	.6528
Time since Injury	8.3±9.2	8.5±7.3	.9405
Categorical Covariates	**n (%)**	**n (%)**	***P* Value**
Sex			.0697*
Male	23 (74.2)	16 (50.0)	
Female	8 (25.8)	16 (50.0)	
Race			.5131
White	29 (93.5)	30 (93.8)	
Black	0 (0.0)	1 (3.1)	
Hispanic	2 (6.5)	1 (3.1)	
Education			_†
HS diploma	3 (9.7)	6 (18.8)	
Some college	18 (58.1)	10 (31.3)	
Bachelor's degree	9 (29.0)	5 (15.6)	
Master's or doctoral degree	1 (3.2)	11 (34.4)	
Employment			.4593
Employed	11 (35.5)	6 (18.8)	
Unemployed	10 (32.3)	11 (34.4)	
Retired	9 (29.0)	14 (43.8)	
Other	1 (3.2)	1 (3.1)	
Marital status			.5208
Married	18 (58.1)	16 (50.0)	
Not married	13 (41.9)	16 (50.0)	
Living with currently			.2782
Alone	6 (19.4)	10 (31.3)	
Not alone	25 (80.6)	22 (68.8)	

Categorical Covariates	n (%)	n (%)	*P* Value
Military service			.6149
Yes	3 (9.7)	2 (6.3)	
No	28 (90.3)	30 (93.8)	
Mental health treatment			.3346
Yes	9 (29.0)	13 (40.6)	
No	22 (71.0)	19 (59.4)	
Cause of injury			.0951
Vehicular	23 (74.2)	19 (59.4)	
Violence	0 (0.0)	3 (9.4)	
Falls	7 (22.6)	5 (15.6)	
Sports	1 (3.2)	5 (15.6)	

Abbreviation: HS, high school.

*Fisher exact test.

†Chi-square test may not be valid due to low cell counts.

Table 2

Adjusted changes from baseline in balance and participation outcomes

Treatment Group	Endpoint	Estimate	SE	95% CI	*P* Value		ES
CB&M							
VR	Wk 6	5.19	1.31	(2.57-7.81)	.0002	*	0.29
HEP	Wk 6	5.49	1.31	(2.87-8.11)	<.0001	*	0.31
VR – HEP	Wk 6	−0.30	1.85	(−4.01 to 3.40)	.8716		0.02
VR	Wk 12	7.73	1.66	(4.41-11.05)	<.0001	*	0.43
HEP	Wk 12	7.87	1.66	(4.55-11.19)	<.0001	*	0.44
VR – HEP	Wk 12	−0.14	2.35	(−4.84 to 4.55)	.9522		0.01
VR	Wk 24	8.60	1.39	(5.81-11.38)	<.0001	*	0.48
HEP	Wk 24	8.73	1.37	(5.99-11.48)	<.0001	*	0.49
VR – HEP	Wk 24	−0.14	1.95	(−4.05 to 3.77)	.9438		0.01
ABC							
VR	Wk 6	3.30	1.76	(−0.23 to 6.82)	.0663		0.26
HEP	Wk 6	0.65	1.75	(−2.86 to 4.16)	.7138		0.05
VR – HEP	Wk 6	2.65	2.49	(−2.32 to 7.62)	.2910		0.21
VR	Wk 12	1.62	1.64	(−1.66 to 4.90)	.3271		0.13
HEP	Wk 12	2.60	1.64	(−0.67 to 5.88)	.1171		0.21
VR – HEP	Wk 12	−0.98	2.32	(−5.62 to 3.65)	.6723		0.08
VR	Wk 24	3.75	1.91	(−0.08 to 7.57)	.0550		0.30
HEP	Wk 24	2.45	1.86	(−1.28 to 6.18)	.1940		0.19
VR – HEP	Wk 24	1.30	2.67	(−4.05 to 6.64)	.6292		0.10
BESTest							
VR	Wk 6	3.90	1.31	(1.28-6.52)	.0042	*	0.23
HEP	Wk 6	3.89	1.31	(1.27-6.51)	.0043	*	0.23
VR – HEP	Wk 6	0.01	1.85	(−3.70 to 3.71)	.9973		0.00
VR	Wk 12	5.27	1.69	(1.89-8.65)	.0028	*	0.31
HEP	Wk 12	5.36	1.69	(1.99-8.74)	.0023	*	0.31
VR – HEP	Wk 12	−0.09	2.39	(−4.87 to 4.68)	.9693		0.01
VR	Wk 24	6.80	1.44	(3.92-9.68)	<.0001	*	0.40

Treatment Group	Endpoint	Estimate	SE	95% CI	*P* Value		ES
HEP	Wk 24	5.89	1.42	(3.05-8.74)	.0001	*	0.34
VR – HEP	Wk 24	0.91	2.02	(−3.14 to 4.96)	.6558		0.05
PART-O Summary							
VR	Wk 6	0.00	0.05	(−0.11 to 0.10)	.9523		0.00
HEP	Wk 6	0.08	0.05	(−0.03 to 0.19)	.1494		0.18
VR – HEP	Wk 6	−0.08	0.08	(−0.23 to 0.07)	.2867		0.18
VR	Wk 12	0.02	0.05	(−0.09 to 0.13)	.7023		0.04
HEP	Wk 12	0.04	0.05	(−0.07 to 0.14)	.4977		0.09
VR – HEP	Wk 12	−0.02	0.08	(−0.17 to 0.14)	.8341		0.04
VR	Wk 24	0.07	0.07	(−0.08 to 0.21)	.3676		0.15
HEP	Wk 24	0.04	0.07	(−0.11 to 0.18)	.6204		0.09
VR – HEP	Wk 24	0.03	0.10	(−0.17 to 0.23)	.7645		0.07

NOTE. Statistically significant (α=0.0167) for comparison of changes between groups. Abbreviations: CI, confidence interval;ES, effect size;SE, standard error.

*Statistically significant (α=0.05) for within-group changes.

Table 3

Average number of weekly sessions by group

	VR		HEP		Comparison
Time Frame	**n**	**Mean ± SD**	**n**	**Mean ± SD**	***P* Value**
Baseline-6 wk	27	3.60±1.83	28	4.09±2.04	.3525
6 wk-12 wk	27	2.98±2.11	28	3.55±2.29	.3446
12 wk-24 wk	27	1.88±2.10	28	1.98±2.46	.8650