Transcending barriers to pain care in rural America:

A pragmatic comparative effectiveness trial of evidence-based, on-demand, digital behavioral treatments for chronic pain

Poster # 1228

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BACKGROUND

Evidence-based behavioral treatments for chronic pain are largely inaccessible, as are mental health providers, especially in rural areas.

OBJECTIVES

To conduct a decentralized randomized controlled trial comparing two evidence-based chronic pain management programs, testing virtual reality (VR) vs. traditional methods**—in a rheumatic and musculoskeletal disease (RMD) and chronic pain population**

- 3D immersive Skills-Based Virtual Reality **(EaseVRx+)**
- 2D interactive online pain coping skills training **(painTRAINER)**

METHODS

- Patients recruited from 4 sources (**Figure 1**)
- **Inclusion criteria:**
  - ICD-10 code associated with chronic pain
  - Primary ZIP code defined as rural
  - Age ≥13
  - ≥4 pain on 0-10 scale
  - No history of seizure (contraindication to VR)
- **1:1 randomization** to 3D VR vs. 2D web app
- **16** REDCap surveys over **12** weeks
- **Measured improvement in pain intensity** (primary outcome) between baseline and week 8; assessed minimal clinically important difference (MCID) of 2 points
- **Secondary outcomes included**
  - PROMIS anxiety and pain interference (T-score metric (mean = 50, SD = 10)
  - Pain catastrophizing (scale: 0–52)
  - Pain self-efficacy(scale: 0–60)

Figure 1: Recruitment Sites

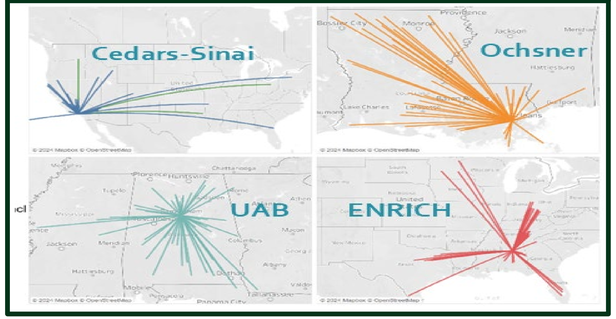
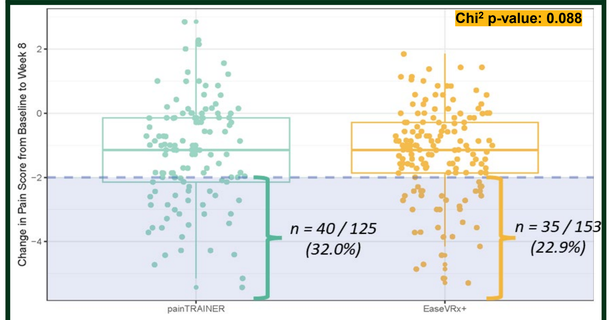


Table 1: Baseline Demographics of Patients Who Completed the Primary Endpoints

	Overall 278	painTRAINER 125	EaseVRx+ 153	SMD
Age, median (IQR)	56 (47, 64)	55 (47, 63)	57 (47, 65)	0.077
Female sex, n(%)	202 (72.7)	89 (71.2)	113 (73.9)	0.060
Race, n(%)				0.458
White	221 (79.5)	100 (80.0)	121 (79.1)	
Black or African American	35 (12.6)	13 (10.4)	22 (14.4)	
American Indian or Alaska Native	4 (1.4)	1 (0.8)	3 (2.0)	
Asian	4 (1.4)	0 (0.0)	4 (2.6)	
Other	13 (4.7)	11 (8.8)	2 (1.3)	
Unknown	1 (0.4)	0 (0.0)	1 (0.7)	
Ethnicity, n(%)				0.117
Non-Hispanic or Latino	254 (91.4)	112 (89.6)	142 (92.8)	
Hispanic or Latino	18 (6.5)	10 (8.0)	8 (5.2)	
Unknown	6 (2.2)	3 (2.4)	3 (2.0)	
Education, n(%)				0.296
No Secondary School or High School	2 (0.7)	1 (0.8)	1 (0.7)	
Some Secondary School or High School	35 (12.6)	14 (11.2)	21 (13.7)	
High School or Secondary School Degree	96 (34.5)	37 (29.6)	59 (38.6)	
Associate's or Technical Degree	70 (25.2)	32 (25.6)	38 (24.8)	
College or Baccalaureate Degree	49 (17.6)	29 (23.2)	20 (13.1)	
Doctoral or Postgraduate Education	26 (9.4)	12 (9.6)	14 (9.2)	
Employment, n(%)				0.073
Full-time	82 (29.5)	35 (28.0)	47 (30.7)	
Part-time	28 (10.1)	12 (9.6)	16 (10.5)	
Not employed	168 (60.4)	78 (62.4)	90 (58.8)	
Relationship Status, n(%)				0.307
Married	173 (62.2)	81 (64.8)	92 (60.1)	
Divorced	52 (18.7)	19 (15.2)	33 (21.6)	
Never Married	22 (7.9)	14 (11.2)	8 (5.2)	
Widowed	19 (6.8)	6 (4.8)	13 (8.5)	
Separated	9 (3.2)	4 (3.2)	5 (3.3)	
Domestic Partner	3 (1.1)	1 (0.8)	2 (1.3)	
Income, n(%)				0.366
$0-$24,999	57 (14.1)	24 (19.2)	33 (21.6)	
$25,000-$49,999	71 (17.6)	28 (22.4)	43 (28.1)	
$50,000-$74,999	39 (9.7)	19 (15.2)	20 (13.1)	
$75,000-$99,999	34 (8.4)	15 (12.0)	19 (12.4)	
$100,000-$149,999	31 (7.7)	18 (14.4)	13 (8.5)	
$150,000-$199,999	13 (3.2)	7 (5.6)	6 (3.9)	
$200,000 or more	9 (2.2)	4 (3.2)	5 (3.3)	
Prefer not to answer	24 (6.0)	10 (8.0)	14 (9.2)	
Baseline 7-day pain average, mean (SD)	6.20 (1.73)	6.27 (1.74)	6.15 (1.72)	0.072
Baseline 7-day MME average, mean (SD)	448.24 (4762.66)	580.81 (5548.25)	339.93 (4024.67)	0.050
Baseline PROMIS anxiety, mean (SD)	53.56 (9.59)	53.77 (9.50)	53.39 (9.70)	0.039
Baseline Pain Catastrophizing Scale, mean (SD)	8.31 (3.81)	8.14 (3.88)	8.45 (3.77)	0.082
Baseline PROMIS pain interference, mean (SD)	64.25 (6.33)	64.50 (6.45)	64.04 (6.24)	0.072
Baseline Pain Self-Efficacy, mean (SD)	5.88 (3.07)	5.81 (3.19)	5.94 (2.98)	0.043
Primary Diagnosis				0.063
Rheumatology	136 (48.9)	59 (47.2)	77 (50.3)	
Chronic Pain	142 (51.1)	66 (52.8)	76 (49.7)	

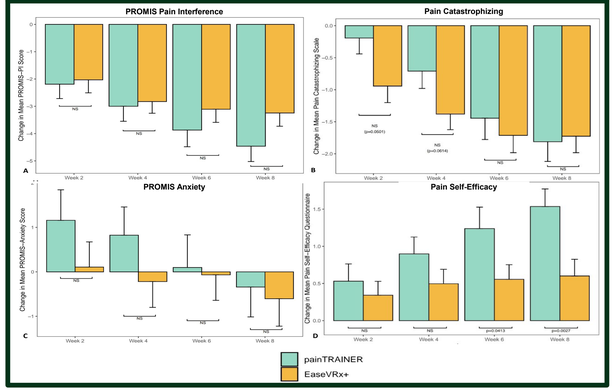
SMD: Standardized mean difference; IQR: Interquartile range; MME; Morphine milligram equivalents; PROMIS: Patient-Reported Outcomes Measurement Information System; SD: Standard deviation.

Figure 2: ITT Analysis of Pain Intensity Between Baseline and Week 8



ITT: Intent-to-treat. MCID: minimal clinically important difference.
Note: ITT analyses of the primary endpoint required responses to at least >=4 of the 7 daily assessments.

Figure 3: Mean Weekly Changes in Secondary Outcomes



RESULTS

- 330 participants (**169: EaseVRx+ and 161: painTRAINER**) – **46.7 were rheumatic disease patients**
- 84.2 participants completed trial, provided data for primary endpoint (**Table 1**)
- Average pain score improved in both arms (Mean[SD]: 1.22[1.48] units)
- No clinically significant difference:
  - EaseVRx+ (22.9 achieving MCID ≥2)
  - PainTRAINER (32.0) (p = 0.088) **(Figure 2)**
- Baseline and week 8, mean (SD) changes for Ease VRx+ and painTRAINER
  - PROMIS pain interference -3.2 (6.0) vs. -4.5 (6.3)
  - Pain catastrophizing -1.7 (3.2) vs. -1.8 (3.5)
  - PROMIS anxiety -0.6 (7.6) vs. -0.3 (7.6)
  - Pain self-efficacy for 0.6 (2.8) vs. 1.5 (2.7), respectively **(Figure 3)**
    - Statistically significant difference in pain self-efficacy in favor of painTRAINER

CONCLUSIONS

- Trial displays effectiveness of two autonomous (self-paced) digital behavioral treatments for chronic pain anchored in virtual reality and traditional cognitive behavioral therapy approaches
- EaseVRx+ and painTRAINER both shown as
  - Effective and accessible behavioral pain treatment for chronic pain
  - Could improve health equity in underserved populations for management of chronic pain

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