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COMPARATIVE EFFICACY OF VIRTUAL REALITY THERAPY, TELEREHABILITATION, AND CONVENTIONAL PHYSIOTHERAPY FOR PAIN MANAGEMENT IN CHRONIC LOW BACK PAIN: A RANDOMIZED PARALLEL-GROUP TRIAL

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ABSTRACT
Background/Context: Chronic low back pain is a leading cause of disability worldwide, and structured exercise remains first-line care. However, evidence comparing virtual reality therapy, telerehabilitation, and conventional physiotherapy is scarce, particularly in Indian settings, warranting this three-arm randomized trial.
Methods: This prospective three-arm parallel-group randomized controlled trial enrolled 66 adults aged 25–45 years with chronic low back pain (>12 weeks). Participants were randomized equally to virtual reality therapy, telerehabilitation, or conventional physiotherapy, all receiving an identical six-week exercise protocol delivered via each modality. Pain intensity (Numeric Pain Rating Scale, 0–10) was assessed at baseline and Week 6 by a blinded assessor.
Results/Findings: cross arms (Kruskal–Wallis H = 11.22, p = 0.0037; ε^2R = 0.146). Virtual reality therapy produced the largest median reduction (4.0 NPRS points; 56.5%), exceeding conventional physiotherapy by 1.00 point (95% CI 1.00–2.00; p = 0.0019) — the only pairwise comparison surviving Bonferroni correction. Telerehabilitation (3.0 points; 54.4%) and conventional physiotherapy (3.0 points; 44.7%) did not differ significantly from either comparator arm, though all three arms improved from baseline ($p < 0.001$).
Conclusion/Implications: Virtual reality therapy significantly outperformed conventional physiotherapy for chronic low back pain, with telerehabilitation offering comparable benefit. Digital-first delivery is clinically effective and scalable, informing guideline development and resource allocation for pain management where access to in-person rehabilitation is limited.

KEYWORDS: Chronic low back pain (CLBP), Virtual reality therapy (VRT), Telerehabilitation (TRT), Conventional physiotherapy (CPT), Randomized controlled trial(RCT), Pain intensity, Digital rehabilitation.

1. INTRODUCTION

Chronic low back pain (CLBP) is among the most prevalent and disabling musculoskeletal conditions worldwide. In 2020, an estimated 619 million people (95% uncertainty interval 554–694 million) were living with low back pain globally, with occupational ergonomic factors, smoking, and high body mass index jointly explaining 38.8% of the associated years lived with disability (YLD) burden (1). Lifetime population estimates indicate that 70–85% of adults will experience low back pain at some point, that roughly 60% will still report symptoms one year after onset, and that 10–15% will develop the chronic form of the condition (2). The economic and social consequences are substantial: low back pain accounted for 57.6 million YLDs in 2016 alone, and the absolute number of affected cases increased by approximately 20% between 2007 and 2017 (2,3).

The burden is especially pronounced in India. A systematic review and meta-analysis of Indian epidemiological data reported that point, annual, and lifetime prevalence rates of low back pain are higher than global estimates, with the greatest impact observed among women, rural populations, and elementary workers (4). In a study conducted in a tertiary-care setting in Chandigarh, the lifetime prevalence of CLBP among 2,847 adults was 16% (95% CI 15–17), with 62% of affected individuals consulting a physician more than 10 times and 23% seeking a second opinion — health-seeking patterns indicative of refractory symptoms and high healthcare utilization (5). In rural settings the figures are starker: a population-based survey in Gadchiroli, Maharashtra found that 76% of adults reported pain in the back (including lower back, thoracic, and neck regions) in the preceding 12 months (6). Across 43 low- and middle-income countries, chronic back pain affects an estimated 6.9% of the population, underscoring the scale of the problem in resource-constrained settings (7).

Supervised exercise therapy remains the recommended first-line treatment for CLBP, and current guidelines consistently favor initial nonpharmacological management over pharmacotherapy (8,9). However, exercise-based interventions produce only modest effects, with Cochrane evidence showing small treatment benefits that are nonetheless superior to advice or education alone and to electrotherapy (10). Moreover, conventional clinic-based physiotherapy requires repeated travel, direct therapist supervision, and sustained attendance — logistics that are frequently prohibitive in India, where access to rehabilitation services is constrained by distance, cost, and caregiver dependence (11,12).

Digital delivery platforms offer a potential solution. Telerehabilitation studies report outcomes comparable to in-person therapy for nonspecific low back pain, including comparable improvements in Oswestry Disability Index scores and pain ratings at 8 weeks (13), with app-based programs performing as well as clinic-supervised exercise (14). A meta-analysis of randomized trials confirmed that telerehabilitation therapy is superior to passive usual care for pain relief and is comparable to active face-to-face therapy, though the authors cautioned that substantial heterogeneity and small subgroup samples limit certainty (15). In low- and middle-income countries, low-cost TRT has been shown to reduce travel-related costs by 40–60% while maintaining adherence comparable to in-person sessions (16).

Virtual reality therapy (VRT) represents a second emerging modality. Immersive VR-based training significantly reduces pain intensity immediately after intervention in individuals with CLBP (17), and placebo-controlled trials of behavioral skills-based VR programs demonstrate large treatment effects on pain and pain-related interference with activity, stress, mood, and sleep, with 46% of participants achieving at least a 50% reduction in pain (18,19).

1.1. Research Question

Among adults aged 25–45 years with chronic low back pain (pain duration > 12 weeks), are there differences among a 6-week course of virtual reality therapy (VRT), telerehabilitation therapy (TRT), and an exercise-content-identical, dosage-matched conventional physiotherapy protocol delivered in-clinic in the reduction of pain intensity from baseline to Week 6 — and, if so, do the two digital modalities each differ from conventional physiotherapy and from each other?

1.2. Research Gap

Despite the independent evidence supporting each modality, to our knowledge, no published three-arm randomized trial has yet established whether VRT and TRT are superior, equivalent, or inferior to conventional supervised physiotherapy for clinically meaningful outcomes with pain intensity as the primary outcome, and the existing telerehabilitation literature for low back pain is explicitly described as scarce and controversial (14). Three specific gaps justify this trial. First, the evidence base for VR and telerehabilitation in CLBP is dominated by trials conducted in high-income settings, with limited generalizability to Indian patients, and comparative effectiveness research in India remains scarce despite the burden of CLBP being highest in low- and middle-income populations (4,20). Second, although meta-analyses report significant immediate reductions in pain after VR-based training, the findings are marked by high heterogeneity and inconsistent short-term results, and the authors call for high-quality trials to establish longer-term benefits (17,21). Third, although Indian physiotherapists report positive perceptions of telerehabilitation and a willingness to adopt it in practice, barriers including equipment costs, digital literacy, and infrastructure persist, and rigorous local efficacy data are needed to inform scalable implementation (11,16).

1.3. Aim

The aim of this study is to compare the efficacy of virtual reality therapy, telerehabilitation, and conventional clinic-based physiotherapy in reducing pain among adults with chronic low back pain in India.

1.4. Objectives

Primary Objective: To compare the effect of VRT, TRT, and CPT (Clinic-based) on pain, measured as the change in pain intensity (Numeric Pain Rating Scale score) from baseline to Week 6, in adults with chronic low back pain.

Secondary Objectives:

1. To compare the change in NPRS scores between each digital intervention and conventional physiotherapy — specifically, VRT versus CPT and TRT versus CPT — at Week 6.
2. To compare the change in NPRS scores between VRT and TRT at Week 6.
3. To assess the within-arm change in NPRS scores from baseline to Week 6 in each of the three treatment arms.
4. To describe the incidence and nature of adverse events, including cybersickness symptoms (Simulator Sickness Questionnaire; Fast Motion Sickness Scale) and technology-related events, across the three arms.

1.5. Hypotheses

Null Hypothesis (H_0): There is no statistically significant difference in pain reduction (NPRS score) among the VRT, TRT, and CPT groups in patients with CLBP after 6 weeks.

Alternative Hypothesis (H_1): There is a statistically significant difference in pain reduction (NPRS score) among the VRT, TRT, and CPT groups in patients with CLBP after 6 weeks.

Directional Hypothesis (H_2): VRT produces a greater reduction in NPRS pain than CPT at Week 6.

Directional Hypothesis (H_3): TRT produces a greater reduction in NPRS scores than CPT at Week 6.

Directional Hypothesis (H_4): There is a statistically significant difference in pain reduction between the VRT and TRT groups at Week 6.

2. LITERATURE REVIEW

Low back pain is the leading cause of years lived with disability worldwide, and global YLDs attributable to LBP increased by 54% between 1990 and 2015, with the steepest rises in low- and middle-income countries (22); updated Global Burden of Disease analyses confirm that LBP remains the leading global cause of YLDs (23,24). In India, point, annual, and lifetime prevalence rates of LBP are higher than global estimates, disproportionately affecting women, rural populations, and elementary workers (4). Community-based data from rural Gadchiroli illustrate the scale of the problem: of 2,259 adults interviewed, 83% reported an episode of back or extremity pain in the preceding year, with a 12-month period prevalence of 76% for back pain (6), while a tertiary-care cohort in Chandigarh recorded a 16% (95% CI 15–17) lifetime prevalence of chronic low back pain, with 62% of affected patients consulting a physician more than 10 times (5). Because more than two-thirds of India's population lives in rural areas, often engaged in heavy manual labour (25), and because rehabilitation services remain concentrated in urban centres (16), evaluating scalable digital delivery models — virtual reality therapy and telerehabilitation — against established conventional physiotherapy is a pressing public health priority. Consistent with the present trial's primary outcome, this review foregrounds evidence on pain intensity and evaluates each modality, examines regional implementation considerations, and identifies the evidence gaps that motivate the present three-arm trial.

2.1. Virtual Reality Therapy for Chronic Low Back Pain

Virtual reality delivers an immersive, computer-generated environment through a head-mounted display, and its application to pain management rests primarily on distraction-based mechanisms augmented by relaxation, biofeedback, and graded movement exposure (26), together with distraction analgesia and body perception training (27). In a randomized controlled trial in patients with CLBP, VR-based distraction during low-load exercise induced hypoalgesia relative to control, indicating a capacity to reduce the pain experienced during active therapy (28). Meta-analytic evidence supports immediate and short-term analgesic benefits: Brea-Gómez et al. found significant reductions in pain intensity in favor of VR post-intervention (11 trials; n = 569; SMD = −1.92; 95% CI = −2.73 to −1.11; P < .00001) and at follow-up (4 trials; n = 240; SMD = −6.34; 95% CI = −9.12 to −3.56), although no significant differences were found for disability (21). Li et al. pooled 20 RCTs (1,059 patients) and reported significant immediate-term improvements in pain (MD −1.43; 95% CI −1.86 to −1.00; P < .001), with no statistically significant difference remaining at short-term (3–6-month) follow-up (P = .16); disability similarly improved immediately (MD −11.50; 95% CI −20.00 to −3.01; P = .008) but not in the short term (P = .43) (17). A further systematic review and meta-analysis supported VR therapy for chronic spinal pain (29), and a multilevel meta-analysis of 41 studies (194 effect sizes from 25 studies) estimated an overall effect size of 1.22 (95% CI 0.55–1.89; z = 3.56; P < .001) in favor of VR across chronic pain outcomes (30). Umbrella reviews conclude that VR is beneficial across pain populations, including chronic pain (31), though for these populations the evidence indicates only short-term improvement in pain intensity, with long-term outcomes deemed inconclusive (32), and one umbrella review stressed that included studies suffered critical weaknesses that precluded firm conclusions, calling for rigorously designed studies with long-term follow-up (33).

These estimates must, however, be weighed against a substantial body of counter-evidence. A meta-analysis by Grassini concluded that VR produced statistically non-significant improvements in chronic low back pain (CLBP) relative to control conditions, with effects no different from those of other active interventions such as exercise and laser therapy (34). Most critically, the large sham-controlled randomized trial of Spiegel et al. (N = 385; NCT04409353) found no significant differences between active VR (skills-based or distraction) and 2D sham VR on the primary outcome of PROMIS Pain Interference or on most secondary outcomes, the notable exception being a greater reduction in daily opioid use with distraction VR (p = 0.009); adverse events were predominantly mild and self-limited, with cybersickness most common, and adherence was high across groups (35). Counterbalancing this, the EaseVRx program — evaluated in a double-blind, randomized, placebo-controlled trial of an 8-week self-administered at-home skills-based VR program against sham VR (18) — produced significantly greater reductions in pain intensity and pain-related interference than sham, with 46% of EaseVRx participants achieving at least a 50% reduction in pain (19); a 6-month follow-up of the same cohort reported that lower pain intensity relative to sham was maintained (p = 0.001), with mean percentage change of −31.3% versus −15.9% and 38.0% versus 13.2% of participants achieving ≥50% reduction (19). Secondary analyses of the larger 1,067-participant national trial have further examined differential treatment response (36), and a sham-controlled effectiveness trial reported reductions in pain intensity and pain interference maintained to 12 months post-treatment (37). Taken together, the literature indicates that VR may confer meaningful short-term analgesic benefits in CLBP, but that its superiority over credible active or sham comparators — and its durability — is not yet established (32,33), justifying the present comparative evaluation. This mixed landscape is directly reflected in the present trial's provisional interpretation of its Week-6 VR advantage: immediate-term benefit without a sham control cannot be attributed to VR-specific mechanisms with certainty.

2.2. Telerehabilitation for Chronic Low Back Pain

Telerehabilitation delivers physiotherapy services remotely via information and communication technologies, encompassing mHealth self-management applications, synchronous video consultations, asynchronous tele-monitoring, and app-based exercise programs (15). A meta-analysis by Yin et al. found telerehabilitation significantly superior to passive usual care for pain relief (SMD = −1.65; 95% CI: −2.17 to −1.13; p < 0.001) and functional improvement, with outcomes comparable to active face-to-face therapy (pain SMD −0.27; 95% CI −0.81 to 0.27; disability SMD −0.26; 95% CI −0.81 to 0.29); the authors cautioned that substantial heterogeneity,

small subgroup samples, and potential publication bias warrant careful interpretation (15). Trial-level evidence converges on non-inferiority for pain outcomes: in a prospective randomized trial of 54 patients with nonspecific low back pain, an 8-week telerehabilitation-based exercise program using a smartphone application with integrated sensors produced Oswestry Disability Index improvements comparable to outpatient-based exercise — both groups exceeding a 10-point improvement — with no statistically significant between-group difference in NPRS at 8 weeks (mean difference −0.39; 95% CI −2.10 to 1.31; p = 0.642) and higher exercise completion in the telerehabilitation group (88.89% vs. 81.48%) (13). An app-based telerehabilitation program was as effective as the identical clinic-supervised exercise program in 68 patients with chronic nonspecific low back pain, including on pain intensity (14); telerehabilitation-delivered motor control exercises proved as effective as clinic-based delivery for CLBP (38); and telerehabilitation-based core-stability exercise improved pain and pain-related disability (39). Digital care programs combining exercise, education, and behavioral support have likewise demonstrated parity with conventional physiotherapy in randomized designs, with no significant between-group differences in disability or pain (40), and a 12-week digital care program substantially reduced pain, disability, and surgery interest (41). An app-based multidisciplinary program reduced pain intensity to a degree superior to combined physiotherapy plus online education (42), and a 10,264-participant longitudinal evaluation reported a 68.45% average improvement in VAS pain with 73.04% program completion (43). Recent developments extend this evidence: an AI-assisted multimodal exercise telerehabilitation program showed better therapeutic effects than conventional exercise telerehabilitation for chronic nonspecific low back pain (44), a randomized pilot found multidisciplinary digital therapeutics and conventional treatment equally effective for pain intensity, with significantly higher early compliance in the digital group (74.7% ± 27.4 vs. 53.1% ± 28.6; $p < 0.001$) (45), and a systematic review of sensor-based remote rehabilitation and VR reported positive effects on pain with completion rates of 73–90% (46). Telehealth-delivered VR has additionally reduced pain intensity and pain interference (18). Economic evidence further supports digital delivery: telerehabilitation was found to be cost-saving for non-specific CLBP, albeit in a small sample (47); telerehabilitation-based McKenzie therapy was identified as potentially the most economically efficient approach for chronic spinal pain, with larger multi-country evaluations called for (48); and a randomized economic evaluation found VR-based exercise cost-saving compared with clinic-based McKenzie extension therapy (49). Conversely, a systematic review of health economic evaluations concluded that the cost-effectiveness of extended reality interventions remains relatively unknown, with value for money linked more closely to clinical benefit than intervention cost (50), and an economic analysis of inpatient VR estimated average hospitalization cost savings of only $5.39 per patient (95% CI −$11.00 to $156.17) (51). A Cochrane review protocol is likewise in preparation to evaluate the benefits and harms of telerehabilitation versus usual care, education and advice, or comparable face-to-face interventions on pain intensity and disability (52). Overall, the evidence positions telerehabilitation as a clinically viable and potentially cost-saving alternative to in-person physiotherapy, particularly where access is limited — a profile consistent with the intermediate position of the TRT arm in the present trial, which did not differ significantly from either VRT or CPT after correction for multiple comparisons.

2.3. Conventional Physiotherapy for Chronic Low Back Pain

Conventional physiotherapy — supervised exercise, manual therapy, patient education, and activity modification — remains a principal first-line treatment for CLBP (53). The most recent Cochrane review found moderate-certainty evidence that exercise is probably effective for CLBP compared with no treatment, usual care, or placebo for pain, though treatment effects for functional limitations were small and did not meet the threshold for a minimal clinically important difference; exercise was probably more effective than advice or education alone and than electrotherapy, with no differences relative to manual therapy (10). Earlier meta-analytic work similarly characterized exercise as slightly effective at decreasing pain and improving function in adults with chronic low back pain (54), and an individual participant data meta-analysis of 3,514 participants from 27 randomized trials estimated a pain reduction of −10.7/100 (95% CI −14.1 to −7.4) compatible with a clinically important 20% smallest worthwhile effect (55). A systematic review of systematic reviews found no major differences in effectiveness among exercise types, with low-to-moderate quality evidence of mainly small, short-term effects on pain and disability (56); current clinical updates nevertheless recommend graded, individualized resistance or aerobic exercise at low-to-moderate intensity, two days per week for six weeks (57).

In the Indian context, the effectiveness of active physiotherapy is constrained by adherence problems rooted in patient education quality, cultural acceptability of prescribed interventions, and dissatisfaction with explanations and exercise content (58). Access barriers are equally consequential: long travel times, transportation costs, and the urban concentration of rehabilitation services limit regular clinic-based care for rural populations (16), and inaccessibility, caregiver dependence, and healthcare costs are recognized challenges to facility-based rehabilitation in low- and middle-income settings (12). Given these constraints, CPT serves as the pragmatic, guideline-endorsed comparator against which digital interventions — VRT and TRT — must be judged, while also being the delivery model that digital approaches seek to supplement or replace. Consistent with this modest-but-real effect profile, the CPT arm in the present trial showed a substantial within-arm reduction in pain from baseline to Week 6 (44.7%); as with the two digital arms, this pre–post change is descriptive and cannot be attributed to the intervention in the absence of a no-treatment control, and the comparative standing of the three modes is established by the between-arm analysis.

2.4. Digital Health Infrastructure and Literacy Challenges in the Indian Context

The translation of digital interventions into routine Indian physiotherapy practice depends on infrastructure and human factors that differ materially from the high-income settings where much evidence of efficacy was generated. Systematic evidence identifies unavailability of smartphones, network connectivity problems, an urban–rural digital divide, and technological illiteracy as major barriers to telehealth integration in India (59). Quantitatively, a study of 150 older adults in rural Mysore and Suttur reported digital literacy of only 11% and health literacy ranging from 3% to 27% across domains; mobile phone ownership was 50%, yet fewer than 10% used the internet to contact health professionals (60). Connectivity gaps persist: as of September 2022, rural India had 34.38 crore internet subscribers, and BharatNet aims to extend high-speed connectivity to over 2.5 lakh gram panchayats (61). Digital health literacy deficits among rural populations compound these problems, as the benefits of digital health programs risk bypassing communities with limited awareness and technological exposure (62).

At the policy level, India has constructed an ambitious digital health architecture — including Digital India (2015), the National Health Policy (2017), the National Digital Health Blueprint (2020), the 2020 telemedicine practice guidelines, and the e-Sanjeevani teleconsultation service (63). e-Sanjeevani, piloted in November 2019 and scaled during COVID-19, has been implemented in over 25,000 hubs and approximately 100,000 spokes, while the eSanjeevaniOPD app has exceeded three million downloads and 30 million teleconsultations (64), making it one of the world's largest digital healthcare delivery systems (65). Yet national telemedicine scale-up has been uneven: the National Digital Health Mission was launched in August 2020, but earlier ISRO-led telemedicine pilots connected only 45 remote and rural hospitals and 15 super-speciality hospitals over 20 years, attributed to limited infrastructure and lack of regulation (66).

Provider-side readiness is also incomplete. Surveys of Indian physiotherapists indicate that while a majority recognized that telerehabilitation should become a routine mode of service delivery (83% in Gujarat), only 30.6% currently use it as a preferred mode, with difficulty ensuring compliance and lack of technological infrastructure identified as the largest barriers (67). Physiotherapy professionals in Maharashtra cited inaccuracy in obtaining information (74%), lack of face-to-face monitoring (65%), and physical limitations among older adults (57%) as principal barriers (68). National survey data likewise show that most Indian physiotherapists used telerehabilitation for the first time during the pandemic, with lack of training and poor clinician–ICT linkage as key obstacles alongside the absence of India-specific practice guidelines (11). Similar barriers across comparable low-resource settings — limited smartphone penetration, intermittent connectivity, low digital literacy, and insufficient healthcare-worker training — were documented in a systematic review of telerehabilitation for CLBP in Sub-Saharan Africa, which noted that none of the included interventions incorporated sociocultural adaptation, while clinical outcomes remained comparable to traditional care (69). Surya and Someshwar likewise characterize limited access to reliable internet and devices, particularly in rural areas, as a digital divide within low- and middle-income countries, even while low-cost telerehabilitation reduced travel-related costs by 40–60% with adherence comparable to in-person sessions, and asynchronous, offline-enabled video therapy partly overcame connectivity constraints (16).

Encouragingly, Indian feasibility evidence is accumulating: digital physiotherapy interventions have been developed for low-resource Indian settings (70), digital tools have been deployed to improve rehabilitation access in rural India (71), and the first Indian study of telerehabilitation via a video-conferencing platform reported that back pain was the most common presentation (45.16% of cases) (72). A 2026 cross-sectional study of 257 patients (72.8% rural) receiving telehealth physical therapy for musculoskeletal complaints reported symptom relief in 75.1% and preference for telehealth for future care in 68.9%, with over 90% successfully accessing and understanding exercises; residual barriers included lack of time (48.6%), difficulty comprehending techniques (12.1%), and unavailability of local-language content (10.9%) (73). Rural patients receiving telerehabilitation have also reported high satisfaction, time savings (91.2%), and willingness to recommend the service (91.2%), despite technical difficulties in 38.2% of sessions (74). These data collectively indicate that efficacy evidence generated abroad cannot be assumed to generalize to Indian populations without accounting for connectivity, literacy, language, cultural, and provider-training conditions — considerations that motivate regional evaluation of VRT and TRT.

2.5 Evidence Gaps: Long-Term Persistence and Three-Way Comparisons

A critical unresolved question concerns the durability of treatment effects on pain. Li et al. found no significant short-term (3–6-month) differences for VR-based training relative to control in pain ($P = .16$), despite robust immediate-term benefits, and noted that no data were available on mid- or long-term effects beyond 6 months (17); the umbrella review of Rooney et al. likewise concluded that evidence for VR in chronic pain indicates only short-term improvement, with long-term outcomes inconclusive (32). Counter-evidence comes from García et al., who reported 6-month durability of clinically meaningful reductions in pain intensity and pain-related interference after an 8-week home-based VR program (19), and from Maddox et al., whose sham-controlled effectiveness trial found reductions in pain intensity and pain interference maintained to 12 months post-treatment (37). Even trial designers acknowledge the limits of current follow-up: a landmark digital care program RCT explicitly noted it did not investigate outcomes beyond the first 12 weeks (41), and reviews of sensor-based digital rehabilitation continue to call for long-term randomized trials (46). The apparent divergence between these findings underscores genuine uncertainty about whether gains from digital interventions persist after the intervention period — a gap the present trial, with its 6-week endpoint, is not designed to resolve, and which its discussion explicitly acknowledges as a limitation.

A second gap is structural. Existing trials have almost exclusively compared a single digital modality against usual care, sham, or in-person physiotherapy in isolation (15,34), and few adequately powered studies have directly randomized patients with CLBP to VRT, TRT, and CPT within a single parallel-group design; none have done so in the Indian context despite the region-specific infrastructure and literacy considerations outlined above. Economic evidence in low-resource settings likewise remains preliminary, based on small samples and calling for long-term evaluation from patient and societal perspectives (47,48). Head-to-head evaluation of the three modalities using standardized, CONSORT-compliant methodology — with pain intensity as the primary outcome — is therefore needed to inform treatment selection, resource allocation, and implementation strategy design suited to Indian healthcare conditions, constituting the rationale for the present trial.

3. **MATERIALS AND METHODS**

3.1. Trial Design

This study was a prospective, three-arm, parallel-group, randomized controlled trial conducted to assess the comparative effectiveness of Virtual Reality Therapy (VRT), Tele-Rehabilitation Therapy (TRT), and Conventional Physiotherapy (CPT) on pain intensity in adults with chronic low back pain (CLBP).

3.2. Participants

Eligible participants were adults aged 25–45 years, of either gender, with a clinical diagnosis of CLBP (pain duration > 12 weeks), who provided written informed consent and agreed to be randomized to any of the three treatment arms. Because two arms involve digitally delivered modalities, particular care was taken not to conflate willingness to participate with digital proficiency: agreement to undergo VR- or video-delivered therapy was recorded as part of the consent process but was not used as an eligibility filter, and no minimum level of technological skill, smartphone ownership, or home internet access was required for enrollment. Instead, the factors most likely to influence engagement and outcomes were measured at baseline and treated as covariates: digital literacy, assessed using the eHealth Literacy Scale (eHEALS), an instrument previously applied in Indian rural populations (60)]; prior exposure to VR and telehealth, recorded by self-report (never / at least once / regular use); and private access to a smartphone and the internet. This approach explicitly separates acceptance of digital care from the actual capability to use it, avoiding the selective recruitment of technologically adept volunteers that can inflate feasibility and adherence estimates (75,76). All digital interventions were delivered at the study sites using study-provided hardware and broadband connectivity, with telerehabilitation sessions conducted with the participant and therapist in separate rooms within the same facility; neither personal devices nor domestic internet connections were therefore required. Participants who reported difficulty operating the technology received a standardized orientation and supervised practice session before their first treatment session, with technical support available throughout the intervention. Per digital protocol, four participants who remained unable to use the technology were given training on how to use before the session start and permitted to continue the common exercise protocol with therapist assistance for the first time and analyzed by intention to treat; the number of such participants is reported in the participant flow.

Participants were excluded if they were receiving alternative treatment for back pain or sciatica (e.g., surgery, nerve blocks, analgesic medication); had non-spine-related or soft-tissue conditions potentially associated with back pain (e.g., pregnancy, spinal tumour, rheumatoid arthritis); had a history of spinal operation, vertebral fracture, or dislocation; or presented with severe neurological deficit or symptoms (e.g., cauda equina syndrome).

3.3. **Settings and Location**

The trial was conducted in outpatient physiotherapy departments or rehabilitation centres located in the Faridabad and Gurugram districts of the National Capital Region (NCR), Haryana, India.

3.4. Sample Size

Primary estimand. The primary estimand is the between-group difference in the change in NPRS pain intensity from baseline to Week 6 (change score = baseline − Week 6), summarised by the per-group means and distributions of the change scores; the null hypothesis is equality of the change-score distributions across the three arms. Because outcome data exist at exactly two time points, the group × time interaction of a repeated-measures ANOVA is algebraically equivalent to a one-way ANOVA on the change scores, and the pre-specified primary test — the Kruskal–Wallis test on change scores — is the rank-based analogue of this same test. The sample size was therefore calculated for this estimand, and the analytic hierarchy (Section 3.6) is fully aligned with the power calculation.

Effect-size source. The assumed effect was anchored to the minimal clinically important difference for pain intensity in CLBP, reported as 1 point on the 0–10 Pain Intensity NRS regardless of pre-treatment pain level (77), and to the 1–2-point between-group range defining a moderate effect on the NRS (78). A between-group difference of 1.0 NRS point with an assumed within-arm SD of change of approximately 1.0 corresponds to an effect of $f \approx 0.40$ (large by Cohen's convention) — an assumption that is conservative relative to published meta-analytic estimates of the effect of VR-based interventions on pain in CLBP (post-intervention SMD −1.92; 95% CI −2.73 to −1.11 (21); mean difference −1.43; 95% CI −1.86 to −1.00 (17); overall SMD 1.22; 95% CI 0.55–1.89 for VR across chronic pain outcomes (30)) and to the 2-point/30% within-patient thresholds commonly cited for clinically meaningful change in low back pain outcomes (79,80).

Calculation. Using G*Power (version 3.1.9.7) (81) for an F-test (ANOVA: repeated measures, within–between interaction) with three groups, two measurement points, nonsphericity correction $\varepsilon = 1$, $\alpha = 0.05$, and power $(1 - \beta) = 0.80$, an effect of $f = 0.40$ yields a noncentrality parameter $\lambda = 10.56$, critical $F = 3.14$ ($df = 2, 63$), and a required total sample of 66 (22 per arm), with achieved power of 81.8%. Because the asymptotic relative efficiency of the Kruskal–Wallis test relative to the one-way F-test is approximately 0.96 for normally distributed data, this sample size is also adequate for the planned rank-based primary analysis of the same estimand. The a priori assumption of $\sigma\_change \approx 1.0$ was consistent with the pooled within-arm SD of change scores (0.83) subsequently observed.

Attrition allowance. The calculation did not include an inflation factor for anticipated attrition. In the event, all 66 randomized participants completed the Week 6 assessment and were included in the primary analysis (100% retention; Section 4.1), so the planned analytic sample was fully realized and the trial retained its planned power. However, because attrition in digital health trials is typically substantial (82,83), the absence of an a priori attrition allowance — together with the unusually high retention, likely reflecting clinic-based recruitment of a motivated, urban sample — is acknowledged as a limitation (Section 6.4).

3.5. Outcome

The pre-specified primary outcome was pain intensity, measured using the Numeric Pain Rating Scale (NPRS, 0–10) (84), with assessment undertaken at baseline (Week 0) and at the end of the 6-week intervention period (Week 6) by a blinded assessor.

3.6. Ethics Approval and Study Design Registration

GDGU Research Ethics Committee approval for the study at GDGU OPD was granted under reference number GDGU/SoMAS/2023/168A, dated 29-08-2023. No-objection certificates were obtained from the study sites in Faridabad and Gurugram, NCR region, as of 31-08-2023. Ethical approval was obtained from the Waves Women Empowerment Trust Independent Ethics Committee as of 05-10-2023 under reference number WWET/2023/IEC-AP/04. The clinical trial was prospectively registered with CTRI as of 14-11-2023 under registration number CTRI/2023/11/059788.

3.7. Participants and Interventions

All three groups received an identical exercise protocol; only the mode of delivery differed by group, thereby permitting isolation of the delivery-mode effect from that of exercise content. The common protocol comprised a 10-minute warm-up of low-intensity bodily movements; core-strengthening exercises comprising flexion exercises (sit-ups, knee-to-chest, toe touch, squat training) and extension exercises (prone press-ups/push-back arch, back extension, back arch); and a five-minute stretching cool-down. The protocol was administered five days per week for six weeks (30 sessions total per participant), with each daily session comprising 30-minute treatment bouts.

Table 1. Intervention groups and modes of delivery

Group	**Mode of Delivery**
CPT (Comparator)	Delivered face-to-face under the direct physical supervision of a physiotherapist within the clinical setting.
TRT (Intervention)	Delivered with the patient and therapist in separate rooms and connected synchronously via an online video-conferencing platform using Microsoft Teams (a subscription product of Microsoft 365 app for Enterprise); the therapist provided live instruction and corrective feedback remotely, without physical contact.
VRT (Intervention)	Delivered within a virtual reality environment in a separate room; session completion and exercise performance were objectively monitored and verified through the VR system's integrated tracking functionality rather than by patient self-report, to minimize adherence/reporting bias. [Utopia 360 headset Android-compatible]

Candidates were screened before randomization for conditions that contraindicate immersive VR, including a history of epilepsy or seizures, vestibular dysfunction, pronounced susceptibility to motion sickness, and uncorrected visual impairment [specify the screening checklist used]; participants meeting any of these criteria were not allocated to the VRT arm [specify: excluded from the trial or restricted to TRT/CPT allocation]. During each VRT session, participants were monitored for symptoms of cybersickness — eyestrain, nausea, fatigue, headache, blurred vision, and postural instability (85) — the most commonly reported adverse event in VR trials for chronic pain (35); structured monitoring using a validated instrument [Simulator Sickness Questionnaire] with a predefined stopping rule [specify threshold] was applied (86). Fall risk was mitigated by conducting sessions in an obstruction-free defined space, with participants seated or, for standing exercises, within arm's reach of a trained spotter [specify per protocol]. Headsets were cleaned between participants according to the manufacturer's instructions using [specify disinfectant and procedure], given that hygiene of shared equipment is recognized as essential to safe delivery (87). All intervention providers completed standardized XR-specific training covering device operation, exercise supervision within the virtual environment, recognition of cybersickness, and emergency procedures before the trial commenced; provider credentials and training details are summarized in [Table 6] (87). These elements — hardware and software specification, participant safety screening, adverse-event monitoring, hygiene procedures, and provider training — are reported in line with the TIDieR-X checklist, which identifies them as critical for reproducibility and safe clinical translation (87); corresponding process details for the telerehabilitation arm are reported following TIDieR-telehealth (88). *The three interventions are described in*

accordance with the TIDieR checklist and the TIDieR-Telehealth extension, with references to pages/lines provided in Supplementary Table 6.

3.8. Safety Protocol for the Digital-Care Arms (For TRT & VRT participants)

3.8.1. Pre-Randomization Screening for Digital-Care Eligibility

Table 2. Pre-randomization digital-care eligibility screening and onboarding pathway

Stage	Action
Pre-enrolment screening	Brief Digital Literacy Checklist (5 items: owns/has access to a smartphone(Android 8+/iOS 13+) or laptop, with ≥3 GB RAM, a front-facing camera, and stable internet ; able to answer a video call unassisted; able to download & install an app with guidance; has stable home Wi-Fi/data (≥10 Mbps download); has a family member/caregiver available to assist if needed) eHealth Literacy Scale (eHEALS; 8 items, 5-point Likert) (60); a score ≥24/40 was the minimum threshold, mirroring the median levels reported in Indian samples where mean eHEALS often sits below this range (89).
Stratification	Participants scoring low on the checklist are not excluded, but are flagged for enhanced onboarding support
Enhanced onboarding session	A dedicated 20–30 minute in-person or supported session prior to the first digital-care session: app/platform download performed with a research team member present; hands-on practice joining a test Teams call or donning the VR headset with a dummy video; illustrated one-page quick-reference guide provided (large font, numbered steps, minimal text).
Environmental and caregiver support/**family involvement**	With participant consent, identification of a household member or local health worker able to assist with technical setup/stand-by during the first two sessions (consistent with Baroni et al. (90) and Yau et al. (91) who note reliance on family or friends as a common mediator).
Buddy/helpline system	A dedicated technical support phone line (staffed during clinic hours) is provided to all TRT/VRT participants for real-time troubleshooting before or during a session.
Re-assessment	Digital confidence is briefly re-checked at Session 1 and Session 2. Participants still unable to manage the technology independently or with caregiver support after two supported attempts are transitioned to Re-training (in-person) without penalty or prejudice.

3.8.2. Handling Participants Unable to Use the Technology

A predefined, three-tier conversion pathway was applied, rather than enrolling and dropping such participants:

- Tier A — Accommodation. Candidates failing only the digital-skill or connectivity domain received a 30-minute facilitated onboarding (tablet/SIM provided by the study, mobile data recharge, printed pictorial exercise cards, WhatsApp-based check-ins). They remained in their originally allocated arm. This reflects the recommendation that low digital-health literacy need not be exclusionary if appropriate supports are in place (90).
- Tier B — Caregiver-mediated delivery. Candidates with sensory or cognitive limitations that prevented direct device use but who had a competent household member/caregiver received the intervention through that proxy, with proxy training equal in duration to provider training (see §3.x.7). This is consistent with current telerehabilitation practice, where proxy users are an established workaround.
- Tier C — Cross-arm conversion. Candidates who, after the faculty-supervised onboarding session, could not operate the device safely or meaningfully (e.g., unable to launch the call, persistent failure to position the HMD, severe cybersickness on brief headset exposure) were discontinued from the digital arm and converted to conventional physiotherapy under an a priori–defined rescue pathway. The original allocation was preserved in the intention-to-treat analysis; the conversion was logged as a protocol deviation with the pre-specified reason.

Reasons for conversion were recorded verbatim on a structured Case Report Form field ("Unable to operate device", "Connectivity failure >2 consecutive sessions", "Cybersickness preventing exposure", "Other") to enable transparent reporting per the TIDieR-Telehealth extension.

3.8.3. Adverse-Event Definitions and Reporting

Adverse events were defined per ICH-GCP as any unfavourable medical occurrence in a participant, whether or not related to the intervention. Serious adverse events were death, life-threatening events, hospitalisation, persistent or significant disability, or any event the principal investigator judged as medically significant. Specific AEs of anticipated interest in TRT included: fall during home exercise, musculoskeletal flare attributable to prescribed exercises, and technology-related events (video-call dropout, electrical/audiovisual disturbance, privacy breach). Reporting windows: AEs collected continuously; SAEs reported to the DSMB within 24 hours and to the IEC within 7 days. Causality was adjudicated by an independent clinician blinded to allocation, using a 5-point scale (unrelated/unlikely/possible/probable/definite).

3.8.4. VRT-Specific Contraindication Screening

The VRT arm applied additional exclusions at screening, supported by international working-group guidance for VR clinical trials (85) and recent implementation reviews (92) (93). In addition to general chronic low-back-pain trial entry criteria, candidates were excluded from VRT if any of the following applied:

- Vestibular and oculomotor: active vestibular disorder, recurrent vertigo, peripheral neuropathy sufficient to impair postural control, abnormal videonystagmography suggestive of central/mixed/peripheral vestibular disease (94); history of severe cybersickness or VR intolerance.

● Neurological/seizure risk: documented photosensitive epilepsy or a first-degree history thereof, traumatic brain injury in the past 12 months, or current uncontrolled migraine. Although contemporary risk in appropriately programmed content is low and historical rather than absolute (95), and the OEM-reported baseline prevalence is ~1 in 4000 (96), we excluded participants with these conditions because our HMD software does not allow per-user flash-rate verification.
● Visual/hearing: corrected visual acuity worse than 20/200; severe hearing impairment precluding verbal cueing; active ocular infection.
● Cardiorespiratory: uncontrolled hypertension, recent (<3 months) myocardial infarction, or any condition in which a transient sympathetic surge (startle, postural challenge) would be unsafe.
● Cognitive/psychiatric: Mini-Mental State Examination <24, active psychosis, severe anxiety disorder where immersive exposure could precipitate crisis, or substance use disorder meeting DSM-5 criteria within the past year (97) (98).
● Skin/contact: open facial wounds, active dermatitis, or known silicone allergy (relevant to HMD facial interface).

3.8.5. Cybersickness Monitoring

Cybersickness is the most reproducible, pretrial-reported AE for HMD-based interventions; its symptom cluster (eyestrain, nausea, fatigue, headache, blurred vision, postural instability) arises from sensory mismatch between the visual and vestibular/proprioceptive systems (85) (99) (100). The trial applied the following monitoring ladder:

Pre-exposure assessment.

● In the first session, we performed a 5-minute controlled headset familiarisation and observed and documented early behavioural indicators of incipient cybersickness (atypical saccades, sweating, repeated HMD adjustment, pallor) (100).
● Baseline susceptibility was probed using the Fast Motion Sickness Scale (FMS, 0–20) at 0, 5, and 10 minutes. During each session.
● The FMS was administered at 10-minute intervals; participants were encouraged to self-report symptoms at any time.
● Sessions were capped at 20 minutes of continuous immersion (with mandatory ≥5-minute seated rest), in line with current recommendations that prolonged exposure is dose-dependently associated with symptom onset (97) (100).

Post-session assessment.

● The Simulator Sickness Questionnaire (101) was administered after every session (immediately and at 10 minutes). Total SSQ scores were computed using the original Kennedy weighting; the more recent Cybersickness in VR Questionnaire was added because of its superior internal consistency and a cognitive-performance component not captured by the SSQ (102).

Pre-specified stop criteria (any one triggers session termination and review).

● Total weighted SSQ score ≥40: this threshold has been empirically tied to dropout risk in contemporary HMDs, replacing the older "≥20 = bad" criterion (103) (100).
● FMS ≥7 ("moderate" or above on the FMS-10 behavioural-rating bands associated with non-trivial dropout probability) (104).
● Participant request to stop, marked pallor, repeated vomiting-like motions, or frank disequilibrium.
● Two consecutive symptom-triggered stoppages require mandatory HMD resizing/refitting review and consideration of downgrade to non-immersive VR or TRT, mirroring escalation pathways in V-TIME-style trials (105) (106).

For cybersecurity and reproducibility, SSQ raw values were not floored to zero, acknowledging the "erroneous zero-baseline assumption" criticised by Brown et al. (103).

3.8.6. Falls-Risk Screening and Mitigation

Despite gains in motor learning, HMD-VR transiently impairs dynamic postural control, elevating near-term fall risk (93). The protocol therefore added a two-stage falls assessment:

Stage 1 — Screening at baseline.

● The Centers for Disease Control and Prevention STEADI algorithm (Timed Up & Go, 30-Second Chair Stand, Four-Stage Balance) was administered in-person at enrolment to classify each participant as low, moderate, or high fall risk. Telehealth-adapted STEADI administration has been shown to be reliable and valid in older adults when camera framing is standardised (107) (108); equivalent reliability for TUG and FTSTS delivered remotely in older adults has been documented up to excellent agreement (109).
● The Mini-BESTest was used as the reference standard to validate risk categorisation (108).

Stage 2 — In-session environmental controls.

● All VRT sessions were conducted seated for the first two weeks, with progression to standing or postural-shifting tasks only after two tolerance-checked immersion sessions and a re-administered TUG of ≤12 seconds (93).
● A spotter was present (research assistant/caregiver) within arm's reach during all standing-phase VR tasks.
● The HMD headstrap was fitted and weight-balanced by the provider; the Guardian/Boundary system was enabled at ≥2 m radius; controllers were tethered.

● Any reported near-fall, slip, or trip was logged as an AE of special interest and triggered a clinical review within 48 h; two such events precipitated withdrawal from standing-VR tasks.

3.8.7. Headset and Controller Cleaning / Infection Control

A Standard Operating Procedure for head-mounted display decontamination was mandated and applied before and after every participant use, drawing on published healthcare-VR infection-control guidance (110) (111) (112) (113):

● Pre-use. Provider donned non-sterile gloves; visual inspection of the HMD (face cushion, strap, lenses, controllers) for cracks, soiling or damage that would hinder decontamination; damaged devices were quarantined (111). A disposable replaceable face cover (silicone/PU) was fitted for each new participant.

● During use. Participants with upper-respiratory symptoms, facial rash, or ocular infection were rescheduled; the face cover was changed between participants.

● Post-use. All user-contact surfaces (face cushion, inner and outer facepieces, strap, controller buttons and grips, lens area) were wiped with quaternary ammonium / alcohol-free disinfectant wipes recommended by the HMD manufacturer; isopropyl alcohol was avoided where the manufacturer contraindicates it because of potential polymer degradation (112) (96). Contact time matched the wipe product label; a second wipe was used if the first became soiled before label contact time elapsed. The headset was then stored in a clean, dry, dedicated cabinet separate from used equipment (111).

● Documentation. Each decontamination event was logged (date, time, provider initials, wipe batch, condition of device) on a Cleaning Log CRF.

● Audit. A monthly infection-control audit (random sampling of 10% of decontamination events) was performed by an independent safety officer; deviations triggered provider re-training.

3.8.8. TRT-Specific Safety Overlays

Most TRT safety procedures mirror those above (training, AE reporting, cleaning of loaned peripherals). Two additional elements applied:

● Synchronous sessions required a video-on check at session start; the provider confirmed environment, lighting, and that the participant was alone or accompanied as agreed.

● Asynchronous sessions used a study diary plus photo/video upload as evidence of completion; participants were called within 24 h if a session remained unlogged. Falls-risk screening was repeated at 6 weeks and at trial exit, consistent with telerehabilitation adverse-event review findings (91) (114).

3.8.9. Stopping Rules and Arm-Specific Withdrawal Criteria

● Individual stop: SAE judged possibly/probably/definitely related; ≥3 cybersickness stoppage events; documented fall during standing VRT; participant withdrawal of consent.

● Arm stop: if AE-related withdrawal rate exceeded 25% in a rolling 10-participant cohort or if any SAE was adjudicated as definitely VR-related, recruitment into VRT was paused for DSMB review. This mirrors the conservative safety stance adopted in earlier VR-augmented rehabilitation RCTs (106) (98).

● Arm stop: any privacy breach affecting >1 participant or any device-related SAE triggered a similar pause.

3.9. Randomization Procedures

Following eligibility confirmation and consent, participants were randomly allocated in a 1:1:1 ratio to the VRT, TRT, or CPT group using a computer-generated sequence.

3.9.1. Permuted Block Randomization

Participants were randomly allocated in a 1:1:1 ratio to the VRT, TRT, or CPT group using permuted block randomization, with a fixed block size of 6 (yielding two allocations per arm per block across 11 blocks). The allocation sequence was generated by Dr. Shashikant Gupta, a statistician independent of participant recruitment and outcome assessment, using the Research Randomizer online tool. Allocation concealment was maintained through sequentially numbered, opaque, sealed envelopes (SNOSE) prepared prior to enrollment and held by an independent researcher not involved in recruitment or assessment; envelopes were opened in sequence only after a participant was confirmed eligible and had provided written informed consent.

3.9.2. Allocation Concealment

Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes (SNOSE), prepared and held by a researcher independent of recruitment and outcome assessment, until assignment of the interventions.

3.9.3. Implementation

Dr. Shashikant Gupta generated the random allocation sequence using computer-generated permuted block randomization (block size 6) prior to the start of enrollment. Participants were enrolled by **Bharat Bhushan**, principal investigator and treating physiotherapist, at the outpatient physiotherapy departments in Faridabad and Gurugram, following confirmation of eligibility and receipt of written informed consent. Dr. Kamran and **Dr. Monika** assigned the enrolled participants to their allocated groups (VRT, TRT, or CPT) by opening the next sequentially numbered, opaque, sealed envelope from the pre-prepared set only after enrollment was confirmed, thereby maintaining allocation concealment until the point of assignment.

3.9.4. Blinding

Given the visibly and experientially distinct nature of the three delivery modes (in-person, video-mediated, and VR-based), blinding of participants and treating therapists to group allocation may not have been feasible (115).

The outcome assessor who recorded NPRS scores at baseline and Week 6 was blinded to group allocation (assessor-blind design).

3.9.5. Similarity of Interventions

Exercise content was held constant across all three arms (Section 3.3) such that only delivery mode varied between groups.

3.10. Statistical Analysis

The pre-specified primary estimand was the between-group difference in the change in NPRS pain intensity from baseline to Week 6 (change = baseline − Week 6), with the null hypothesis that the change-score distributions are equal across the three arms. Because outcome data exist at exactly two time points, the group × time interaction of the originally planned repeated-measures ANOVA
is algebraically equivalent to a one-way ANOVA on the change scores; the pre-specified primary test, the Kruskal–Wallis test on change scores, is the rank-based analogue of this same analysis, addresses the same estimand, and is the method for which the trial was sized (Section 3.4).

3.10.1. Descriptive statistics

Descriptive statistics (mean ± standard deviation [SD]) were computed for demographic and baseline variables across the three groups, and baseline comparability was assessed using one-way analysis of variance (ANOVA) on baseline NPRS scores. Normality of the NPRS change-score distributions was assessed using the Shapiro-Wilk test, and homogeneity of variance was assessed using Levene's test. As the change scores in all three arms appeared to deviate significantly from normality, the Kruskal-Wallis test was used as the primary between-group test, consistent with the pre-specified Statistical Analysis Plan's contingency for assumption violation; a one-way ANOVA was additionally reported as a parametric sensitivity analysis, since, with outcome data at exactly two time points, the group × time interaction of the originally planned repeated-measures ANOVA is mathematically equivalent to a one-way test on the change score. Within-group change from baseline to Week 6 was assessed using the paired t-test. Within-arm pre–post effect sizes were expressed as the standardized mean change for paired data (Cohen's d_z), calculated as $d_z = \bar{d}/s_d = t/\sqrt{n}$, where $\bar{d}$ is the mean within-arm change score (baseline − Week 6), s_d is the sample standard deviation of the change scores, t is the paired t-statistic, and n = 22. This coefficient quantifies the magnitude of within-arm change relative to the dispersion of individual changes within the same arm; it is a within-arm, pre–post descriptive index and is **not** a comparative treatment effect. It is therefore not directly comparable with the between-arm effect sizes reported for the primary estimand (Kruskal-Wallis $\varepsilon^2R = 0.146$; one-way ANOVA $\eta^2 = 0.204$) or with the between-group standardized differences for the pairwise comparisons (e.g., VRT vs. CPT d = 1.12). Approximate 95% confidence intervals for d_z were computed as $d_z \pm 1.96 \times SE(d_z)$, with $SE(d_z) = \sqrt{1/n + d_z^2/[2(n-1)]}$, derived from the delta method applied to the ratio of the mean change to its standard deviation.

3.10.2. Additional analyses

Post-hoc pairwise comparisons following the significant omnibus test result were conducted using the Mann–Whitney U test with Bonferroni correction (adjusted $\alpha = 0.05/3 = 0.0167$), a rank-based, distribution-free post-hoc procedure consistent with the Kruskal–Wallis primary analysis. Because the NPRS change scores deviated significantly from normality, the parametric Tukey's HSD test — whose normality assumption is violated by these data (116) — was not used for post-hoc inference. For the primary between-arm rank-based analysis, epsilon-squared ($\varepsilon^2R = (H - k + 1)/(N - k)$) was reported as the omnibus effect size, and Hodges–Lehmann estimates of pairwise median differences with 95% CIs accompanied the Bonferroni-corrected Mann–Whitney comparisons (117). Because NPRS change scores are discrete, confidence limits derived from test inversion can be unstable on ordinal scales (118). Intention-to-treat analysis was the primary analytic approach. Statistical significance was set at $p < 0.05$ throughout. All analyses were conducted in Python using the SciPy statistical library.

4. **RESULTS**

4.1. Participant Flow

A total of 66 participants were recruited and randomized (22 per arm) between 20 November 2023 and 5 December 2024, matching the original protocol target. All 66 participants completed the 6-week intervention and were included in the primary intention-to-treat analysis; no losses to follow-up or analysis exclusions occurred in any group. The analyzed sample therefore equaled the planned sample (N = 66; 22 per arm); retention was 100%, and the trial retained its planned statistical power. Consistent with the *a priori* effect assumption, the observed omnibus between-group effect on pain reduction (one-way ANOVA $F(2,63) = 8.06$, $p < 0.001$, $\eta^2 = 0.204$, equivalent to $f \approx 0.51$) exceeded the assumed f = 0.40.

Of the 66 participants randomized, all completed the 6-week intervention and were included in the analysis. No apparent losses to follow-up or analysis exclusions occurred in any group. Consequently, the final sample size was 22 participants in each of the three intervention arms (N = 66), which may indicate retention of the planned analytical sample in accordance with the original protocol.

4.2. Baseline Characteristics

Enrollment dates ranged from 20 November 2023 to 5 December 2024, consistent with the CTRI-registered start of enrollment (on or after 19 November 2023); recruitment occurred on a rolling basis over this period. Baseline Numeric Pain Rating Scale (NPRS) scores were broadly comparable across the three arms (one-way analysis of

variance (ANOVA): F = 2.79, p = 0.069), which may suggest no statistically significant baseline imbalance, although the p-value remained relatively close to the conventional threshold (Table 3).

Table 3. Baseline and post-intervention NPRS scores by treatment arm (mean ± SD).

Treatment arm	Sample size (N)	Baseline Numeric Pain Rating Scale (NPRS)	Week 6 NPRS	Mean reduction ± SD	95% confidence interval (CI)	% Reduction
VRT	22	6.86 ± 0.77	2.95 ± 0.49	3.91 ± 0.87	3.52–4.29	56.5%
TRT	22	6.36 ± 0.79	2.91 ± 0.68	3.45 ± 0.67	3.16–3.75	54.4%
CPT	22	6.50 ± 0.60	3.59 ± 0.91	2.91 ± 0.92	2.50–3.32	44.7%

The arm-level means at baseline and Week 6 are displayed in Figure 2.

4.3. Assumption Checks

All checks below were applied to the pre-specified primary estimand — the change in NPRS pain intensity from baseline to Week 6 (change = baseline − Week 6) — using the full intention-to-treat dataset (N = 66; 22 per arm).

Distributional assessment. Normality of the NPRS change-score distributions was assessed per arm using the Shapiro–Wilk test. All three distributions exhibited statistically significant departures from normality (VRT W = 0.777, TRT W = 0.684, CPT W = 0.740; all $p < 0.001$), a pattern consistent with the discrete, restricted-range character of the 0–10 NPRS, whose post-intervention scores are frequently non-normal (116). Because this assumption violation was anticipated in the registered analysis plan, analysis followed the pre-specified contingency: the Kruskal–Wallis test on change scores was designated the primary between-group test, with a one-way ANOVA reported as a parametric sensitivity analysis. Since outcome data exist at exactly two time points, the group × time interaction of the originally planned repeated-measures ANOVA is algebraically equivalent to the one-way ANOVA performed on the change scores, and the Kruskal–Wallis test is the rank-based analogue of this same analysis addressing the identical estimand (Sections 3.4 and 3.6).

Homogeneity and independence. Levene's test suggested no statistically significant difference in change-score variance across the three arms (statistic = 2.90, p = 0.062), supporting the variance assumption underlying the parametric sensitivity analysis. Independence of observations was secured by design: each participant was randomized once (1:1:1 ratio; permuted blocks of six) and contributed a single change score to exactly one arm, and the three delivery modes were physically separated (TRT and VRT sessions conducted in dedicated rooms with therapist–patient interaction online), minimizing the risk of cross-arm contamination. Baseline comparability was additionally examined with a one-way ANOVA on baseline NPRS scores, which suggested no statistically significant imbalance across arms (F = 2.79, p = 0.069).

Missing data and attrition handling. Retention was complete: all 66 randomized participants completed the 6-week intervention and the Week-6 assessment, with no losses to follow-up and no analysis exclusions in any group. No missing outcome data were therefore present at the primary endpoint, no imputation was required, and the intention-to-treat sample was identical to the complete-case sample. Because dropout is typically substantial in digital-health trials (82,83), the sample-size calculation deliberately included no attrition-inflation factor (Section 3.4); although the observed 100% retention meant the planned analytic sample was fully realized, the possibility that it reflects selection of a highly motivated, urban sample rather than the attrition profile of routine digital delivery is acknowledged as a limitation.

Prespecified deviations. No departures from the registered protocol affected the analysis dataset. The analytic hierarchy was applied exactly as registered: the use of the Kruskal–Wallis test as the primary test (with the algebraically equivalent one-way ANOVA as sensitivity analysis) in response to non-normal change scores was a prespecified contingency for assumption violation, not a post hoc change. The Tier C cross-arm conversion pathway (Section 3.7.2) was defined a priori for participants unable to operate the technology, with any activation to be logged as a protocol deviation and the verbatim reason recorded; the participant-flow records confirm that all 66 participants completed the intervention, none was lost, discontinued, or excluded, and all were analyzed under their original allocation by intention to treat, so no exclusion or imputation decisions were required. Blinding proceeded as prespecified: participants and treating therapists could not be blinded to the visibly distinct delivery modes, and the outcome assessor recorded NPRS scores at baseline and Week 6 while blinded to allocation (115).

4.4. Pain Outcomes

Primary Outcome: Between-Group Comparison

The three arms appeared to differ significantly with respect to pain reduction (Kruskal–Wallis H(2) = 11.22, p = 0.0037), with a rank-based effect size of epsilon-squared ($\varepsilon^2R = 0.146$, 95% CI [0.013–0.381]) (119), a moderate effect (120), indicating that approximately 15% of the variance in the ranks of pain reduction was accounted for by treatment arm. Median reductions in NPRS pain intensity from baseline to Week 6 were 4.0 (IQR 3–5) points in the VRT arm, 3.0 (IQR 3–4) points in the TRT arm, and 3.0 (IQR 2–4) points in the CPT arm. Hodges–Lehmann estimates of the pairwise median difference with 95% CIs (117), corresponding to the Bonferroni-corrected Mann–Whitney comparisons (adjusted $\alpha = 0.0167$), located the between-arm effect: VRT exceeded CPT by an estimated 1.00 point (95% CI [1.00–2.00]; p = 0.0019, the only comparison to survive the adjusted threshold), whereas TRT versus CPT (1.00 point; 95% CI [0.00–1.00]; p = 0.054) and VRT versus TRT (0.00 points; 95% CI [0.00–1.00]; p = 0.073) did not, consistent with the intermediate position of the TRT arm. Individual patient reductions (baseline − Week 6) and arm-level means are displayed in Figure 1. These findings suggest that the

null hypothesis of no difference among groups may be rejected; the parametric sensitivity analysis was consistent (one-way ANOVA $F(2,63) = 8.06$, $p < 0.001$, $\eta^2 = 0.204$, indicating a large effect).

4.4.1. Post Hoc Pairwise Comparisons

Table 4. Post hoc pairwise between-group comparisons of NPRS pain reduction at Week 6

Comparison	Mean Diff.	Mann–Whitney p (Bonferroni α = 0.0167)	Cohen's d
VRT vs. CPT	1.00	0.0019 — significant[a]	1.12 (large)
TRT vs. CPT	0.55	0.054 — n.s.	0.68 (medium)
VRT vs. TRT	0.45	0.073 — n.s.	0.59 (medium)

[a] $p < 0.0167$, the Bonferroni-adjusted threshold for three pairwise comparisons.

All post hoc comparisons were rank-based (Mann–Whitney U with Bonferroni correction); no parametric post hoc p-values (e.g., Tukey HSD) are reported, consistent with the non-normal distribution of the change scores (116).

Clinical significance of the comparison. Although the VRT–CPT difference was statistically significant after Bonferroni correction ($p = 0.0019$), the 1.0-point magnitude must be read against established thresholds for clinical meaningfulness, which differ in magnitude and in frame of reference. The most frequently cited values — approximately 2 points or 30% on the NRS (79,121), a 1-point MCID obtained regardless of pre-treatment pain level (77), and 1.5–3.2 points for patients with baseline scores below 7 (122) — refer to within-patient change and are not directly applicable to between-group differences in a randomized trial. For between-group comparisons, the U.S. CDC guideline characterizes a mean difference of 0.5–1.0 points on a 0–10 NRS as a "small" effect and cautions that small effects may not meet proposed thresholds for clinically meaningful effects (78). The observed between-group difference of 1.0 point thus coincides with the upper bound of that small-effect band and falls below the 2-point/30% within-patient threshold, positioning the VRT advantage as borderline for clinical importance: statistically robust, but not definitively clinically meaningful.

Reconciliation with larger recent trials. The present findings derive from a smaller cohort (N = 66) than the large 2026 three-arm trial of Spiegel et al. (N = 385; NCT04409353), which found no significant differences between active VR (skills-based or distraction) and 2D sham VR on its primary outcome of change in PROMIS Pain Interference or on most secondary outcomes (35). Design differences help reconcile the divergent results. First, the comparators differed fundamentally: Spiegel et al. contrasted VR against an inert sham, whereas the present trial compared immersive exercise-delivered VR against an active, dosage-matched therapist-supervised protocol — comparisons plausibly sensitive to different effect magnitudes (35). Second, endpoints and intervention content differed: PROMIS Pain Interference and skills-based behavioral VR programming (biofeedback, interoceptive training, relaxation) in the larger trial, versus NRS change and a distraction- and engagement-oriented exercise VR in ours (35). Third, the meta-analytic literature itself is divided — pooled analyses report significant immediate-term VR benefits in CLBP (SMD −1.92; 95% CI −2.73 to −1.11 (21); MD −1.43; 95% CI −1.86 to −1.00 (17)), whereas other syntheses report non-significant effects relative to control (34). Given this heterogeneity and the absence of a sham control in our design, the VRT–CPT effect is best regarded as hypothesis-generating, requiring confirmation in larger, adequately powered, sham-controlled trials before superiority claims are warranted.

VRT produced significantly greater pain reduction than CPT (large effect size), the only comparison to survive Bonferroni correction. TRT appeared intermediate and did not differ significantly from either arm.

4.4.2. Within-Group Change (Baseline vs. Week 6)

Table 5. Within-group change in NPRS pain from baseline to Week 6

Arm	Baseline Mean	Week 6 Mean	Paired t (df = 21)	p-value	Cohen's d_z (within-arm)	95% CI for d_z
VRT	6.86	2.95	21.13	< 0.001	4.50	3.08–5.92
TRT	6.36	2.91	24.15	< 0.001	5.15	3.54–6.76
CPT	6.50	3.59	14.81	< 0.001	3.16	2.12–4.20

All three arms showed statistically significant reductions in NPRS pain from baseline to Week 6 on paired testing ($p < 0.001$ in every arm). These results are reported as within-arm changes. Because the trial included no-treatment or usual-care control, statistically significant pre–post change cannot be interpreted as evidence that the intervention itself produced the improvement: regression to the mean, the natural history of CLBP, expectancy, and the effects of repeated measurement can all contribute to within-arm change over a six-week period. Consistent with this, the Cohen's d_z values (3.16–5.15) are standardized within-arm pre–post effects — the mean within-arm change divided by the SD of within-arm change scores — and serve as descriptive indices only; they do not estimate a comparative treatment effect and were not compared with the between-arm effect size (e.g., VRT vs. CPT Cohen's d = 1.12). The 95% CIs are wide, reflecting the small per-arm sample (n = 22): the VRT estimate, for instance, is compatible with d_z values from 3.08 to 5.92. The conventional "very large" benchmark, applied to these within-arm standardized changes, therefore overstates the certainty with which the improvements can be attributed to the interventions, and no efficacy claim in this report is based on these magnitudes. The mean pain trajectories from baseline to Week 6 for the three arms are illustrated in Figure 1.

Efficacy claims rest on the pre-specified randomized between-arm contrast: the Kruskal–Wallis test on change scores detected an overall difference across arms ($H(2) = 11.22$, $p = 0.0037$; $\varepsilon^2R = 0.146$, 95% CI 0.013–0.381) (119,120), and the Bonferroni-adjusted pairwise comparisons with Hodges–Lehmann effect estimates and 95% CIs (117) located the difference: VRT exceeded CPT by a median of 1.00 point (95% CI 1.00–2.00; $p = 0.0019$), whereas TRT versus CPT (1.00 point; 95% CI 0.00–1.00; $p = 0.054$) and VRT versus TRT (0.00 points; 95% CI 0.00–1.00; $p = 0.073$) did not survive the adjusted threshold; the parametric sensitivity analysis was consistent (one-way ANOVA $F(2,63) = 8.06$, $p < 0.001$, $\eta^2 = 0.204$).

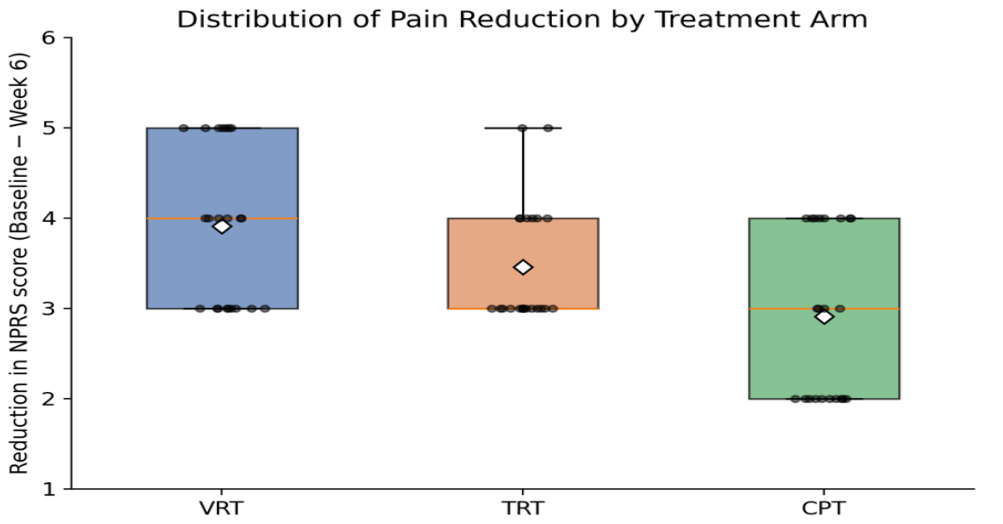

Figure 1. Distribution of NPRS reduction (baseline − Week 6) by arm. Diamond = group mean; dots = individual patients.

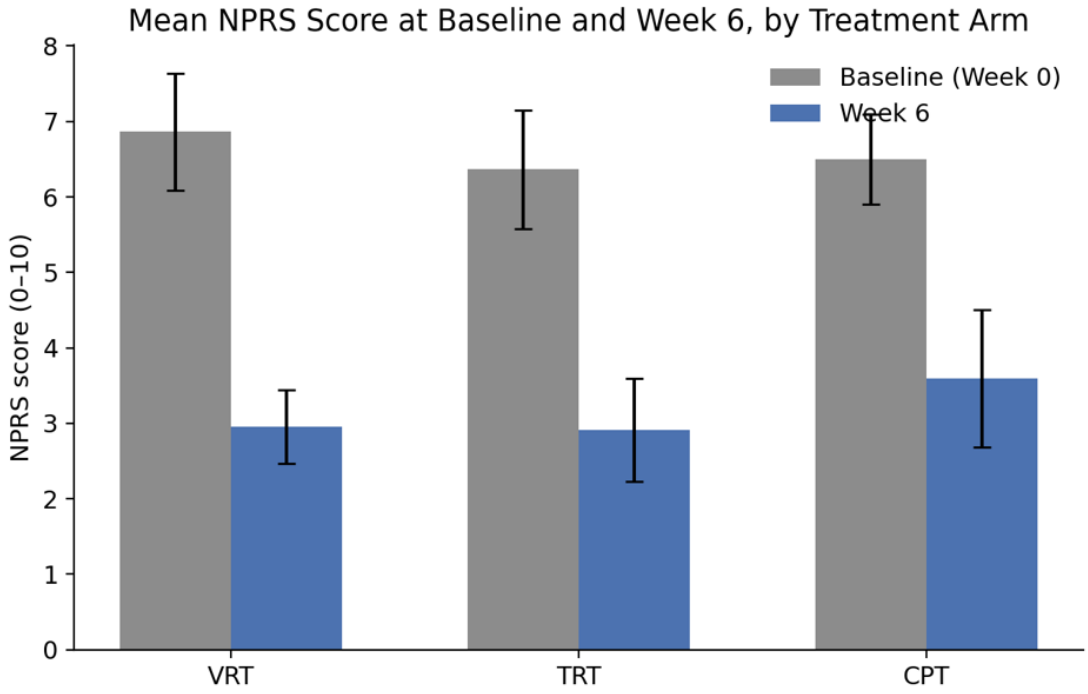

Figure 2. Mean NPRS score at baseline and Week 6 by arm (error bars = ± 1 SD).

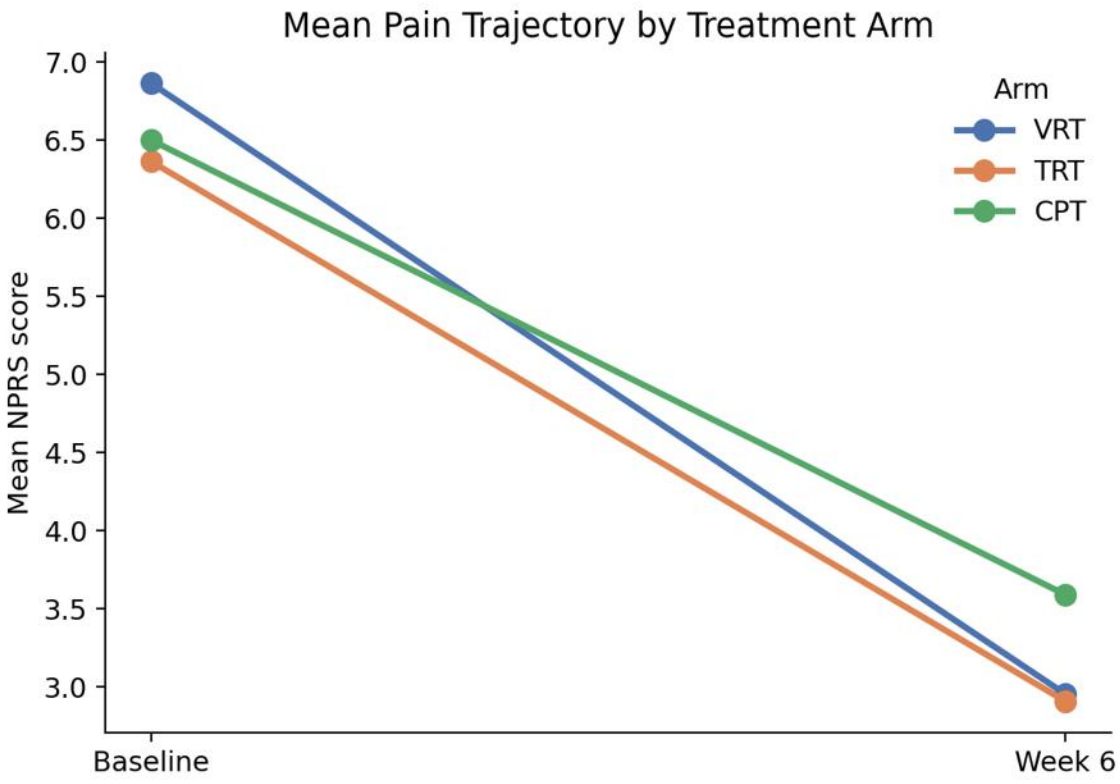

Figure 3. Mean pain trajectory (baseline to Week 6) by arm.

5. **DISCUSSION**

This three-arm randomized trial suggests that, when the underlying exercise protocol is held identical across delivery modes and only the mode of delivery varies, virtual reality therapy may be associated with significantly greater short-term pain reduction than CPT in patients with CLBP, while tele-rehabilitation therapy performed at an intermediate level and did not differ significantly from either arm after correction for multiple comparisons. All three arms showed large within-arm reductions in pain from baseline to Week 6; consistent with the absence of a no-treatment or usual-care control, these are reported strictly as within-arm changes and do not by themselves establish that any mode of delivery produced the improvement. Claims of differential efficacy rest on the randomized between-arm contrast, in which VRT exceeded CPT by a median of 1.00 point (95% CI 1.00–2.00; p = 0.0019) — the only pairwise difference to survive correction for multiple comparisons; the shared exercise protocol's comparable contribution across arms is inferred from this between-arm analysis, not from the within-arm magnitudes. However, this advantage should be regarded as provisional: the trial was unblinded, included no sham-VR control, and the broader evidence base for VR-specific effects on CLBP is mixed, with meta-analytic findings showing no significant advantage of VR over control conditions in chronic low back pain (34) and a randomized trial of 385 participants reporting no active-versus-sham differences on its primary outcome (35). These findings are therefore best interpreted as hypothesis-generating rather than as confirmation of VRT's superiority.

A plausible explanation for VRT's advantage is the VR system's built-in, objective monitoring of these metrics, which may have improved adherence and correct-form execution relative to delivery modes involving less systematic monitoring, consistent with the practice in recent VR trials of collecting objective device-use data rather than relying on self-report (18). Gamified feedback and immersive engagement may also have increased patient motivation and the effective exercise dosage completed. Although attendance and compliance were not analysed as pre-specified outcome endpoints, this explanation need not rest on speculation alone, as the trial captured platform-generated proxy measures. The VRT platform's integrated tracking functionality recorded session completion and exercise performance in real time without reliance on patient self-report; the fidelity documentation for each arm recorded the percentage of sessions completed as planned together with technology-specific deviations (e.g., connectivity loss, headset malfunction, cybersickness-related early termination), with TRT session completion further corroborated through session logs and follow-up calls for unlogged asynchronous sessions (Section 3.7.8); and no participant was lost, discontinued, or withdrawn in any arm, indicating that no cybersickness- or device-related early terminations undermined engagement. These system-generated usage metrics are compatible with sustained engagement in the VRT arm and mirror the engagement- and completion-level indices that digital-health reporting guidance identifies as essential (76,82), as well as the high completion rates (73–90%) reported for gamified, sensor-based remote rehabilitation (46). Tentativeness remains warranted, however: these proxies were not pre-specified as mediation or dose–response endpoints, equivalent objective

metrics were not captured uniformly across arms, and no minimum-engagement threshold was defined, so the adherence explanation cannot yet be formally distinguished from alternative mechanisms. TRT's intermediate, non-significant standing relative to both other arms is consistent with tele-rehabilitation's positioning in the broader literature as broadly comparable to in-person care (123), although this trial may not have been adequately powered for a formal non-inferiority assessment.

The magnitude of the VRT-CPT difference (≈ 1.0 NPRS point) should be interpreted alongside its clinical, not just statistical, significance. Thresholds commonly cited for clinically important change in CLBP pain — approximately 2 points or a 30% reduction on the NRS (79,121), a 1-point MCID estimated regardless of pre-treatment pain level (77), and 1.5–3.2 points for patients with baseline scores below 7 (122) — are all estimates of *within-patient* change: they describe the before-and-after improvement an individual patient must show to register as clinically important and do not directly benchmark differences between randomized groups. For *between-group* differences, the U.S. CDC guideline defines a mean difference of 0.5–1.0 points on a 0–10 NRS as a "small" effect and explicitly cautions that such effects may not meet proposed thresholds for clinically meaningful effects; it reserves the 1–2-point band for classification of a moderate between-group effect, not for a consensus MCID (78). The observed difference of 1.0 point therefore falls at the upper boundary of the CDC's small-effect band and below the 2-point/30% within-patient benchmark: statistically robust, but borderline rather than definitively clinically important, and it should be presented with this caveat rather than as an unqualified endorsement of VRT's superiority.

5.1. Interpretation

These findings suggest that while VRT provides an immersive interface capable of enhancing engagement, the durability of its benefits may depend on sustained patient interaction, reflecting broader evidence that VR-based mindfulness and biofeedback show promise in mitigating pain interference (124). Conversely, the performance of the tele-rehabilitation arm aligns with evidence indicating that while virtual modalities facilitate efficient home-based exercise, efficacy may remain contingent upon the integration of AI-assisted feedback to bridge the gap in clinical oversight (44). Mechanisms underlying these modality-specific effects likely involve a combination of an immersive delivery interface, cognitive distraction, and heightened motor awareness, whereas cognitive behavioral therapy content, biofeedback, interoceptive training, or relaxation modules are not incorporated. The trial was therefore not designed to evaluate skills-based VRT in the sense of programs in which behavioral pain-management skills are taught and practiced across sessions (35,125), and the findings should not be generalized to such programs. VR gamification or remote movement-sensor biofeedback may realign maladaptive movement patterns more effectively than standard verbal cues (126). Furthermore, while current outcomes demonstrate a promising trend toward enhanced symptom management, the variability in individual responsiveness suggests that future investigations must account for heterogeneous patient reactions to exercise-induced hyperalgesia (127). Crucially, these efficacy estimates must be interpreted alongside the socio-technological and infrastructural conditions under which digital rehabilitation is expected to scale. In low- and middle-income settings, implementation barriers — intermittent connectivity, limited access to affordable devices, and low digital literacy among patients and healthcare workers — rather than clinical efficacy now represent the primary constraint on the broad scalability of telerehabilitation, and these barriers are not unique to any single region but prevail across LMICs, including India (69). Surya and Someshwar similarly identified inadequate digital infrastructure, limited access to affordable devices, and variable internet connectivity as major barriers, particularly in rural areas, highlighting a pronounced digital divide within LMIC populations (16). This context bears directly on the present trial: participants were recruited in well-connected, urbanized NCR districts with study-provided broadband and hardware, and only patients willing to undergo digitally delivered therapy were enrolled, so the sample was unlikely to reflect the connectivity and literacy profiles of the broader Indian population. Evidence from rural India underscores the scale of this gap — digital literacy was only 11% among a sample of older rural adults, health literacy ranged from 3% to 27% across domains, mobile phone ownership was 50%, and fewer than 10% used the internet to contact health professionals (60). Indian telerehabilitation studies further report difficulty navigating digital systems due to limited computer literacy, unreliable internet connections, and language barriers (72), and emphasize that technology training is essential, particularly beyond educated, urban, computer-literate samples (12). Accordingly, the scalability claim of this trial should be conditional: realizing comparable outcomes at scale will require connectivity-resilient delivery, such as asynchronous or offline-enabled platforms (16); culturally and linguistically tailored intervention content that supports long-term engagement (69); and hybrid models that route patients without reliable connectivity or adequate digital skills toward in-person care. Until such practical implementation challenges are addressed, the present findings should be regarded as evidence of efficacy under favorable infrastructure conditions, with generalizability to infrastructure-constrained Indian settings to be established in future implementation research.

A further consideration concerns the durability of the gains observed at Week 6. The VRT arm in this trial delivered a distraction- and engagement-oriented immersive experience rather than a skills-based program: no pain neuroscience education, biofeedback, interoceptive training, or relaxation modules were incorporated, in contrast to programs in which behavioral pain-management skills are taught and practiced across sessions (36,125). Recent evidence suggests that analgesic effects attributable primarily to distraction may be transient, reflecting novelty and engagement rather than sustained therapeutic learning (32,124), and meta-analytic data show significant immediate—but not short-term—differences for VR-based training in CLBP, with no available

data beyond 6 months (17). Because the present VRT–CPT contrast was assessed only at the 6-week endpoint, with no post-intervention follow-up, we cannot determine whether this advantage persists or diminishes as the novelty of the immersive interface wanes. Notably, where durable benefits have been demonstrated in the VR literature, they have been reported for skills-based programs: García et al. found reductions in pain intensity and pain-related interference maintained at 6 months post-treatment after an 8-week self-administered skills-based VR program (19), and Maddox et al. (2024) reported maintained reductions in pain intensity and pain interference at 12 months (37). The gains observed here should therefore be characterized as short-term effects with uncertain persistence; durable change may require incorporating skills-based components—such as cognitive-behavioral self-regulation and pain education—or periodic booster sessions (35,125). Extended follow-up was not feasible within this trial's design, but it is the necessary next step to establish whether the observed Week 6 advantage reflects sustained therapeutic change or an early engagement effect (19).

5.2. Strengths

The three-arm design employed an identical, dosage-matched exercise protocol across all delivery modes, thereby isolating the effect of delivery mode from exercise content. Although trials have compared telerehabilitation or digital care with in-person physiotherapy, sometimes with matched content (14), and VR has been evaluated as a skills program, an adjunct, or across VR-only arms (18,35,53), no trial we identified combines all three—VR, telerehabilitation, and in-person physiotherapy—under identical dose-matched exercise content, isolating delivery mode rather than content as the variable of interest.

The trial was prospectively registered with the Clinical Trials Registry of India (CTRI) before enrolment, and the registered, pre-specified statistical analysis plan was followed, including its contingency for non-normal data.

The 100% follow-up rate, while eliminating attrition-related bias, is atypical for digital health trials, where substantial dropout is the norm (82,83), and suggests that the eligibility criteria — including willingness to undergo VR- and video-delivered therapy — and clinic-based recruitment may have selected for a highly motivated, technologically adept population, limiting generalizability to populations with typical digital-health attrition patterns (76,128).

The VRT arm incorporated objective, system-verified adherence tracking, thereby reducing reliance on self-reported compliance.

5.3. **LIMITATIONS**

1. The absence of post-intervention follow-up beyond the 6-week endpoint precludes assessment of long-term persistence. Meta-analytic evidence indicates that VR-based training yields significant immediate improvements in pain, pain-related fear, and disability, but no significant differences at short-term follow-up, with no available data on mid- or long-term effects beyond 6 months(17) (19) and 12 months (37) as discussed in the interpretation.

2. Within-arm effect sizes are descriptive only. The Cohen's d_z values (3.16–5.15) are standardized pre–post changes computed as mean change divided by the SD of change (equivalently, t/√n); they do not estimate the comparative treatment effect and were not compared with the between-arm effect size. With 22 participants per arm and no no-treatment control arm, these within-arm estimates cannot separate intervention effects from time-related phenomena such as regression to the mean and spontaneous improvement, and their 95% CIs (VRT 3.08–5.92; TRT 3.54–6.76; CPT 2.12–4.20) indicate substantial sampling uncertainty. The "very large" label is therefore a statistical convention applied to within-arm standardized change, not evidence of clinical certainty; any claim of superiority rests on the between-arm comparison rather than on the within-arm magnitudes.

3. Technological and infrastructural barriers constrain implementation beyond the study setting. The trial was conducted in well-connected, urbanized NCR districts with study-provided broadband, hardware, and videoconferencing, enrolling only participants willing to undergo digital therapy. Such favorable infrastructure does not reflect typical scaling conditions: poor connectivity, limited device access, and low digital literacy—rather than clinical efficacy—remain the primary constraints on digital rehabilitation in low- and middle-income settings (16,69). Even within India, telerehabilitation awareness is low (40.7%), with willingness concentrated among younger, male, and better-educated respondents (129). Findings may therefore generalize poorly to populations facing these barriers, and infrastructure costs add an implementation burden not captured in this trial.

4. In many VR trials, reporting of trial conduct fell short of emerging extended reality standards. Cybersickness—the most common adverse event in home-based VR trials (35), with symptoms including eyestrain, nausea, fatigue, headache, blurred vision, and postural instability (85)—was not systematically screened using a validated instrument, despite recommendations that structured, validated cybersickness recording be standard practice (86); adverse-event data were unavailable, so their potential influence on adherence and retention could not be characterized. No explicit infection-control protocol for shared VR hardware was documented, although the cleaning and hygiene of equipment shared within clinical settings are recognized as essential to safe delivery (87). As Goldsworthy et al. (2025) argue, the absence of standardized reporting—spanning hardware, software, user interactions, and side effects—hampers replication and clinical translation, and the TIDieR-XR elaboration checklist offers a mechanism for improving intervention reporting quality and thereby strengthening the evidence base (87). Future trials should incorporate cybersickness screening and structured adverse-event recording, documented headset hygiene procedures, and reporting aligned with these emerging checklists.

5.4. Clinical Implications

These findings suggest that clinicians may support personalized rehabilitation planning by tailoring the delivery modality to patient preferences, technology access, and self-efficacy profiles, rather than defaulting to a "one-size-fits-all" model (130),(131). Future pragmatic trials with more heterogeneous cohorts are required to confirm whether these outcomes persist across varying levels of patient digital literacy and socioeconomic status (132),(133). Furthermore, the establishment of integrated, hybrid rehabilitation pathways that permit seamless transitions between digital and face-to-face modalities may better accommodate patients with varying needs and environmental constraints (134),(75). Such longitudinal confirmation is essential to determine whether the superior outcomes observed in the VRT group remain stable beyond the initial six-week interval or whether they merely reflect an early engagement effect (19).

6. **CONCLUSION**

In this randomized, parallel-group trial, virtual reality therapy appeared to produce significantly greater short-term pain reduction than conventional physiotherapy (median difference 1.00 point on the NPRS; 95% CI 1.00–2.00) in patients with chronic low back pain (CLBP), using a dosage-matched exercise protocol that isolated the effect of delivery mode. The VRT–CPT advantage, while consistent with our prespecified analyses, should be considered provisional: a recent 385-participant three-arm trial found no significant differences between active and sham VR on its primary pain outcome, and durable VR effects in the literature are predominantly reported for skills-based programs — suggesting the present effect may partly reflect expectation and novelty rather than durable therapeutic benefit(35). Telerehabilitation appeared to perform comparably to conventional care. These findings may support the viability of technology-delivered rehabilitation as a scalable alternative to in-clinic physiotherapy for CLBP, while underscoring the need for longer-term follow-up and multi-region replication before they could inform broader clinical or policy recommendations. Multi-region replication must account for localized socio-technological barriers — the digital divide in infrastructure and literacy — since implementation constraints, rather than efficacy, now limit the scalability of digital rehabilitation in LMIC settings (16,69).

7. TIDieR checklist and the TIDieR-Telehealth extension

Three intervention arms were reported in accordance with the appropriate checklist for each delivery mode. Conventional Physiotherapy (CPT), being delivered entirely in-person, was reported using the original TIDieR checklist (135). Tele-Rehabilitation Therapy (TRT) and Virtual Rehabilitation Therapy (VRT) both involve synchronous, technology-mediated interaction between a remotely located therapist and the patient, and were therefore reported using the TIDieR-Telehealth extension (88), which provides additional guidance beyond the original 12 items for describing remote-delivery infrastructure, connectivity, and technology-specific fidelity considerations.

Table 6. Description of the three intervention arms in accordance with the TIDieR checklist and the TIDieR-Telehealth extension

TIDieR Item	**CPT (In-Person)**	**TRT (Teams Videoconference)**	**VRT (Utopia 360 Headset)**
TIDieR reporting	Conventional Physiotherapy — in-person, clinic-based, therapist-supervised exercise delivery (standard TIDieR reporting applies)	Tele-Rehabilitation Therapy — synchronous videoconference-delivered exercise via Microsoft Teams, patient and therapist in separate locations (TIDieR-Telehealth reporting applies)	Virtual Rehabilitation Therapy — exercise delivered via Utopia 360 VR headset with real-time remote therapist supervision/guidance (TIDieR-Telehealth reporting applies)
1. Brief Name	Conventional Physiotherapy (CPT): in-person, therapist-supervised exercise	Tele-Rehabilitation Therapy (TRT): synchronous videoconference-delivered exercise via Microsoft Teams	Virtual Rehabilitation Therapy (VRT): therapist-guided exercise delivered through Utopia 360 VR headset with remote supervision
2. Why	Evidence-based standard of care; direct physical correction and hands-on cueing	Expand access, reduce travel burden, validate remote delivery of an effective in-person intervention	Combine remote-access benefits with immersive, first-person visual/motor learning to enhance exercise comprehension and engagement
3. Materials	Clinic treatment space, mats, standard exercise equipment, printed handouts	Patient's own smartphone/tablet/laptop, Microsoft Teams application, stable internet connection, joining-link instructions	Utopia 360 VR headset, compatible smartphone (inserted into headset), VR exercise application, remote-monitoring link/software allowing therapist to view and guide session
4. Procedures	Therapist demonstrates and physically corrects exercise technique in real time	Therapist observes patient via Teams video feed, cues verbally, corrects form based on webcam view	Therapist connects remotely to observe/guide session while patient views 360° exercise demonstration inside headset; correction delivered

			via audio cueing through headset or companion device
5. Who Provided	Registered physiotherapist; standard in-person clinical training	Registered physiotherapist; additional competency in videoconferencing platform and remote clinical assessment	Registered physiotherapist; additional competency in VR platform operation and remote-monitoring interface
6. How (Mode)	Face-to-face, individual, synchronous	Remote, individual, synchronous, bidirectional (audio + video)	Remote, individual, synchronous; audio (and where available video) cueing while patient is immersed in VR content
7. Where	Clinic treatment room (single location)	Two locations: patient's room + therapist's remote location, connected via Teams	Two locations: patient's room (space/safety-checked for movement while wearing headset) + therapist's remote monitoring location
8. When & How Much	Standardised dose: 5 sessions/week × 6 weeks duration, in person at clinical setting matched across arms for comparability	Same planned dose as CPT: 5 sessions/week × 6 weeks duration, delivered via Teams	Same planned dose as CPT: 5 sessions/week × 6 weeks duration, delivered via VR headset
9. Tailoring	Exercise progressed based on direct in-person assessment	Exercise tailored based on patient self-report and visual assessment via webcam (no physical palpation)	Exercise tailored based on patient self-report and remote visual monitoring; VR video content/difficulty level adjusted by therapist as needed
10. Modifications	Any in-session protocol changes documented (what/why/when/how)	Any changes to platform, session format, or connectivity workaround documented	Any changes to VR content, headset setup, or connectivity workaround documented
11. Fidelity (Planned)	In-person checklist/observation by senior physiotherapist	Session recording review and/or clinician self-report checklist to confirm protocol adherence via Teams	Clinician self-report checklist plus verification that the remote-monitoring connection allowed adequate observation of patient performance
12. Fidelity (Actual)	% sessions completed as planned; reasons for missed in-person sessions	% sessions completed as planned; technology-specific deviations logged (connectivity loss, platform failure, rescheduling)	% sessions completed as planned; technology-specific deviations logged (headset malfunction, connectivity loss, cybersickness-related early termination)

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