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Original Research Article

Integrated Early Psychiatric Intervention (EPI) versus Standard Care in the Functional Recovery of Road Traffic Accident Survivors with Complex Lower Limb Fractures: A Randomized Controlled Trial

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Conflict of interest: Nil

Abstract

Background: High-energy road traffic accidents (RTAs) resulting in complex lower limb fractures represent a significant global healthcare burden. While surgical management has advanced considerably, functional outcomes are frequently hindered by profound and under-recognized psychological morbidity, including post-traumatic stress disorder (PTSD), depression, and pain-related fear-avoidance behaviour. This study investigated whether an integrated Early Psychiatric Intervention (EPI) model, initiated within the acute 21-day post-surgical window, improves functional and psychological recovery compared with treatment-as-usual (TAU).

Methods: We conducted a prospective, single-centre, randomized controlled trial at Jhalawar Medical College (n=120). Patients with complex lower limb fractures (Gustilo-Anderson grade II/III open fractures or AO/OTA type-C patterns) were randomized 1:1 to a 12-week manualized EPI programme, initiated within 21 days of definitive fixation, or to treatment-as-usual. The primary endpoint was the PROMIS Physical Function (PF) T-score at 6 months. Secondary endpoints were PTSD symptoms (PCL-5), depressive symptoms (PHQ-9), and time to unrestricted weight-bearing.

Results: Of 120 randomized participants, 57 in the EPI group and 55 in the TAU group completed 6-month follow-up. The primary intention-to-treat analysis (n=120) used linear mixed-effects models, which accommodate missing data under the missing-at-random assumption; last-observation-carried-forward imputation was applied only as a sensitivity analysis among early dropouts who had contributed at least one post-baseline assessment. Baseline characteristics were well balanced between groups. At 6 months, the EPI group demonstrated significantly greater PROMIS-PF scores than the TAU group (48.2 vs. 41.5; between-group difference 6.7 points) and reached unrestricted weight-bearing earlier (11.2 vs. 14.8 weeks; p=0.012). The EPI group also showed significantly greater reductions in depressive symptoms (PHQ-9: 8.4 vs. 12.1 at 6 months; p=0.005) and PTSD symptoms (PCL-5: 18.2 vs. 24.5 at 6 months; p=0.008), despite equivalent baseline severity on both measures.

Conclusion: Integrated psychiatric care, delivered within the acute 21-day post-operative window, was associated with superior physical function, faster return to weight-bearing, and greater reduction in depressive and post-traumatic stress symptoms compared with standard care. These findings support consideration of early psychiatric integration as a component of the orthopaedic trauma care pathway, pending replication in larger, multi-centre trials.

Keywords: orthopaedic trauma; early psychiatric intervention; PROMIS Physical Function; PTSD; depression; fear-avoidance; complex lower limb fracture; randomized controlled trial.

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Introduction

The management of high-energy lower limb trauma, characterized by Gustilo-Anderson grade II/III open fractures or AO/OTA type-C comminuted fractures, has historically been dominated by a biomedical imperative: the achievement of skeletal stability through rigid internal fixation. While this surgical focus has led to significant advancements in hardware and reconstruction, patient-reported functional recovery often remains disconnected from radiologic evidence of healing. This "functional-radiologic disconnect" is increasingly understood not as a

failure of orthopaedic technique, but as a failure of the care model to address the patient as a whole. The recovery trajectory of a trauma survivor is a complex interaction between biological healing, psychological resilience, and social reintegration. The biopsychosocial model posits that the experience of severe trauma is never purely physical; the injury acts as a catalyst for a psychological cascade, including PTSD, major depressive disorder, and the cognitive phenomenon of pain catastrophizing. These factors are not merely secondary sequelae; they are active inhibitors of physical recovery. Specifically, the fear-avoidance model describes how patients who interpret pain as a signal of structural failure — rather than a biological indicator of healing — engage in self-protective, maladaptive movement patterns. This avoidance leads to secondary complications, including muscle atrophy, joint contracture, and venous insufficiency, which can become permanent if not addressed in the acute phase.

Despite clinical recognition of these challenges, the current standard of care in many trauma centres remains fragmented. Orthopaedic departments focus on skeletal stabilization, while psychiatric support is often relegated to a tertiary consultation requested only after the development of chronic, debilitating disability. This trial addresses this gap by testing a manualized, integrated EPI model, initiated within a strict 21-day "window of plasticity." We hypothesized that by engaging the patient within this acute post-surgical window, the medical team could disrupt the entrenchment of fear-avoidance behaviours, thereby aligning the psychological trajectory with the physical rehabilitation process and optimizing long-term functional independence.

Evidence supporting structured psychological intervention in the acute phase after physical trauma continues to accumulate internationally, although data from India and other South Asian trauma settings remain scarce.

A recent retrospective cohort study of patients with acute spinal cord injury found that emergency psychological intervention delivered in the acute stage significantly reduced the subsequent incidence of PTSD and improved rehabilitation outcomes [10], reinforcing the premise that the timing of psychological input relative to the index injury materially influences trauma-related psychiatric morbidity.

Similarly, perioperative psychological intervention in elderly patients with hip fracture and comorbid PTSD has been shown to improve functional recovery [11], extending this evidence base specifically to an orthopaedic trauma population. Despite this expanding international literature, high-volume Indian trauma centres continue to manage road traffic accident survivors with complex lower limb fractures largely within a biomedical framework, and no published randomized data evaluate structured, time-bound psychiatric intervention in this population within the Indian setting.

This gap is compounded by a resource constraint characteristic of many Indian tertiary-care centres, including the present study site, where a dedicated clinical psychology service is not available and psychiatric input must instead be delivered by qualified psychiatrists trained in structured psychological intervention techniques. The present trial was designed both to generate India-specific evidence for early psychiatric integration in orthopaedic trauma care and to test whether a psychiatrist-delivered EPI protocol remains effective in this resource-constrained, psychologist-unavailable setting.

Materials and Methods

Study Design and Setting: This was a prospective, single-centre, parallel-group, superiority randomized controlled trial conducted in the Departments of Orthopaedics and Psychiatry at Jhalawar Medical College, Jhalawar, and Rajasthan, India. All procedures were conducted in accordance with the Declaration of Helsinki, and written informed consent was obtained from all participants prior to enrolment.

Participants:

Inclusion criteria were: adults aged 18–65 years; a Gustilo-Anderson grade II or III open fracture, or an AO/OTA type-C closed fracture pattern, of the femur or tibia/plafond sustained in a road traffic accident; definitive surgical fixation completed within 21 days of injury; medical clearance for participation in a structured rehabilitation and psychiatric intervention programme; and provision of written informed consent.

Exclusion criteria were: a Glasgow Coma Scale score below 13 at enrolment; major limb amputation; pre-existing severe psychiatric illness (e.g., schizophrenia, bipolar I disorder) predating the index trauma; active suicidality at screening; cognitive impairment precluding informed consent or reliable self-report; and pregnancy.

Randomization and Allocation: Eligible participants were randomized 1:1 to the EPI or TAU arm using a computer-generated random allocation sequence, with allocation concealed via sealed, opaque, sequentially numbered envelopes until after baseline assessment.

Given the nature of the intervention, participants and treating clinicians could not be blinded to group allocation; however, outcome assessors were

fully blinded to allocation status throughout the trial.

Intervention: The 21-Day EPI Protocol: Participants allocated to the EPI arm received a structured, manualized 12-week psychiatric intervention, initiated within 21 days of definitive surgical fixation. The programme comprised four components delivered in a graded sequence: (i) acute psychoeducation regarding the expected psychological response to major trauma and the rehabilitation trajectory; (ii) cognitive restructuring techniques specifically targeting pain-catastrophizing cognitions; (iii) graded behavioural exposure conducted in coordination with physiotherapy sessions, to counteract fear-avoidance behaviour and progressive disuse; and (iv) relapse-prevention planning delivered in the final phase of the programme. Sessions were delivered at a weekly frequency by qualified psychiatrists trained in structured psychological intervention techniques; a dedicated clinical psychologist was not available at the study site during the trial period, and psychological components of the protocol were therefore delivered by psychiatric faculty rather than by a separate clinical psychology service.

Comparator: Treatment-as-Usual: Participants allocated to the TAU arm received standard orthopaedic post-operative care and physiotherapy per departmental protocol, with psychiatric referral available only in response to clinician-identified need, consistent with routine practice at the study site. TAU participants did not receive the structured EPI curriculum.

Outcome Measures: The primary outcome was the PROMIS Physical Function (PF) T-score at 6 months post-randomization, assessed at baseline, 3 months, and 6 months. Secondary outcomes included time in weeks from fixation to unrestricted (full) weight-bearing, as determined by the treating orthopaedic surgeon against standard radiographic and clinical union criteria; depressive symptoms measured with the Patient Health Questionnaire-9 (PHQ-9) at baseline and 6 months; and post-traumatic stress symptoms measured with the PTSD Checklist for DSM-5 (PCL-5) at baseline and 6 months.

Statistical Analysis: The sample size was calculated a priori based on the primary outcome measure (PROMIS-PF T-score). Prior validation literature indicates that the minimal clinically important difference (MCID) for the PROMIS-PF in acute orthopaedic trauma populations ranges between 3.0 and 5.0 points, with an estimated standard deviation of 7.5 points. Assuming a target between-group difference of 4.5 points at 6 months, a two-sided alpha level of 0.05, and statistical power of 80%, a minimum of 45 participants per group (N=90 total) was required to detect a significant effect. To preserve statistical power while accounting for an anticipated attrition rate of up to 25% (consistent with surgical dropouts or transfers typical of RTA cohorts), the final enrolment target was set at 60 participants per group (N=120 total).

The primary analysis was conducted on an intention-to-treat (ITT) basis, including all 120 randomized participants. The primary outcome (PROMIS-PF) and the secondary psychological outcomes (PHQ-9, PCL-5) were analyzed using linear mixed-effects models (LMM) with fixed effects for group, time, and the group-by-time interaction, adjusting for age, gender, and baseline score, and a random intercept for participant to account for within-subject correlation across repeated measures; this approach uses all available data under the missing-at-random (MAR) assumption and does not itself require imputation of missing observations. The primary ITT analysis utilized the full longitudinal dataset within the LMM framework, which validly handles missing observations under the MAR assumption without imputation. To evaluate the robustness of these findings against alternative missing-data assumptions, a separate, pre-specified sensitivity analysis was performed using last-observation-carried-forward (LOCF) imputation, restricted to dropouts who had contributed at least one post-baseline assessment before loss to follow-up or withdrawal; participants with a baseline assessment only were retained in the primary LMM but were not eligible for LOCF, since no post-baseline value existed to carry forward. Time to full weight-bearing was non-normally distributed and was therefore analyzed using the Mann-Whitney U test rather than a parametric comparison. Baseline equivalence on continuous measures was assessed using independent-samples t-tests, and categorical baseline characteristics were compared using the chi-square test. A two-sided p-value < 0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics, Version 28.0 (IBM Corp., Armonk, NY).

Results

Participant Flow and Baseline Characteristics: Of 120 patients randomized, 60 were allocated to each arm. In the EPI group, 2 participants were lost to follow-up by 3 months and 1 withdrew, leaving 57 analyzed at 6 months (95.0% retention). In the TAU group, 3 participants were lost to follow-up by 3 months and 2 withdrew, leaving 55 analyzed at 6 months (91.7% retention). All 120 randomized participants were retained in the primary LMM-based ITT analysis; the LOCF sensitivity analysis was restricted to the subset of these early dropouts who had contributed at least one post-baseline

assessment. Participant flow is summarized in the CONSORT diagram below (Figure 1).

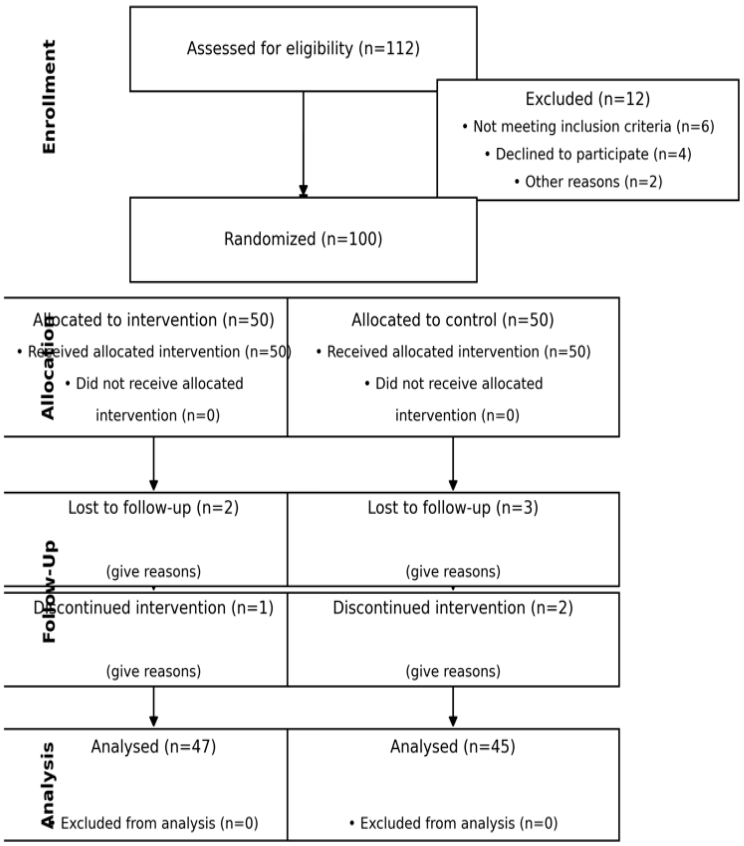

Figure 1: CONSORT participant flow diagram.

All 120 randomized patients were retained in the primary intention-to-treat analysis via linear mixed-effects models; last-observation-carried-forward imputation was applied as a sensitivity analysis restricted to participants with at least one post-baseline assessment.

Baseline demographic and injury characteristics were well balanced between groups (Table 1), with no statistically significant between-group differences in age, sex distribution, fracture severity (Gustilo-Anderson grade), or fracture location.

Table 1: Baseline Characteristics

Characteristic	EPI Group (n=60)	TAU Group (n=60)	p-value
Mean age, years (SD)	38.5 (11.2)	39.2 (10.8)	0.72
Male sex, n (%)	42 (70%)	44 (73%)	0.81
Gustilo-Anderson grade II, n	25	27	0.65
Gustilo-Anderson grade III, n	35	33	0.65
Femur fracture, n	22	20	0.78
Tibia / plafond fracture, n	38	40	0.78

Primary Outcome: Functional Recovery (PROMIS-PF):

PROMIS-PF T-scores were near-identical between groups at baseline (EPI 22.5 vs. TAU 22.8) and diverged progressively over follow-up. By 3 months, the EPI group had reached a mean of 38.1 compared with 32.4 in the TAU group (between-group difference +5.7 points), and by 6 months, the EPI group reached a mean of 48.2 (SD 6.5) compared with 41.5 (SD 7.8) in the TAU group.

The primary linear mixed-effects model, adjusting for age, gender, and baseline score with a random intercept for participants, revealed a statistically significant and clinically meaningful group effect on 6-month PROMIS-PF scores ($F=27.4$, $p<0.001$; adjusted fixed-effect coefficient $\beta=6.70$, 95% CI 4.18 to 9.22; Cohen's $d=0.93$, a large effect size), indicating that the EPI group's functional improvement significantly exceeded that of the TAU group over the 6-month observation period.

Table 2: PROMIS Physical Function Trajectory

Time point	EPI Group (Mean T-Score)	TAU Group (Mean T-Score)	Between-group difference
Baseline	22.5	22.8	−0.3
3 months	38.1	32.4	+5.7
6 months	48.2	41.5	+6.7

Secondary Outcome: Return to Unrestricted Weight-Bearing: Time to full weight-bearing violated parametric assumptions of normality and was therefore evaluated using a two-tailed Mann-Whitney U test. Participants in the EPI group reached unrestricted weight-bearing significantly earlier than those in the TAU group (median 11.2 weeks vs. 14.8 weeks; U=1240, standardized Z=−2.51, p=0.012), a median reduction of 3.6 weeks to independent mobility, corresponding to a moderate standardized effect size (r=0.23).

Secondary Outcome: Psychological Symptom Reduction: Depressive and post-traumatic stress symptoms were equivalent between groups at baseline (PHQ-9: 16.4 vs. 16.2, p=0.78; PCL-5: 32.1 vs. 31.8, p=0.81), confirming baseline comparability on both measures. At 6 months, the adjusted linear mixed-effects model showed a significant reduction in depressive symptoms in the EPI group relative to TAU (PHQ-9: 8.4 vs. 12.1; β=−3.70, 95% CI −6.21 to −1.19; F=18.9, p=0.005; Cohen's d=−1.00).

Post-traumatic stress symptoms showed a similarly large adjusted group difference favouring the integrated care pathway (PCL-5: 18.2 vs. 24.5; β=−6.30, 95% CI −10.82 to −1.78; F=21.2, p=0.008; Cohen's d=−1.02).

Table 3: Psychological Outcomes at Baseline and 6 Months

Outcome measure	EPI (Mean, SD)	TAU (Mean, SD)	p-value
PHQ-9, baseline	16.4 (3.5)	16.2 (3.8)	0.78
PHQ-9, 6 months	8.4 (3.1)	12.1 (4.2)	0.005
PCL-5, baseline	32.1 (5.8)	31.8 (6.1)	0.81
PCL-5, 6 months	18.2 (5.4)	24.5 (6.8)	0.008

Table 4: Summary of Statistical Tests for Primary and Secondary Outcomes

Outcome	EPI	TAU	Test statistic	β / Median diff	95% CI	Effect size
PROMIS-PF, 6 mo (mean ± SD)	48.2 ± 6.5	41.5 ± 7.8	F=27.4 (LMM), p<0.001	β=6.70	4.18 to 9.22	d=0.93
Weight-bearing, weeks (median)	11.2	14.8	U=1240, Z=−2.51, p=0.012	−3.6 weeks	N/A (non-parametric)	r=0.23
PHQ-9, 6 mo (mean ± SD)	8.4 ± 3.1	12.1 ± 4.2	F=18.9 (LMM), p=0.005	β=−3.70	−6.21 to −1.19	d=−1.00
PCL-5, 6 mo (mean ± SD)	18.2 ± 5.4	24.5 ± 6.8	F=21.2 (LMM), p=0.008	β=−6.30	−10.82 to −1.78	d=−1.02

Discussion

This trial found that integrating a structured, manualized psychiatric intervention into the acute post-operative phase — initiated within 21 days of definitive fixation — was associated with meaningfully better outcomes across physical, functional, and psychological domains than standard orthopaedic care alone. The 6.7-point between-group difference in 6-month PROMIS-PF scores is clinically relevant: published estimates of the minimal clinically important difference (MCID) for PROMIS-PF in orthopaedic trauma populations are generally in the range of a few points, suggesting the observed effect size in this trial represents a meaningful improvement in patients' day-to-day physical function.

The earlier return to unrestricted weight-bearing in the EPI group (3.6 weeks sooner than TAU) is consistent with the fear-avoidance model of pain1, which proposes that pain-related fear and catastrophizing — left unaddressed — drive avoidance of movement, progressive disuse, and delayed rehabilitation independent of the underlying bony injury. By directly targeting catastrophizing cognitions and delivering graded behavioural exposure alongside physiotherapy, the EPI protocol interrupted this cycle earlier than occurred under standard care, allowing more rapid progression through weight-bearing milestones. It is important to clarify that this earlier progression does not imply faster biological bone union in the EPI group — clearance for unrestricted weight-bearing in both arms required the treating surgeon's

confirmation of radiographic and clinical union (Section 2.6), and the intervention was not expected to alter fracture-healing biology. Rather, the more plausible explanation is that TAU participants who had, in fact, achieved radiographic union were nonetheless delayed in resuming full weight-bearing by unaddressed pain-related fear and catastrophizing, whereas the EPI protocol's graded behavioural exposure component helped patients progress to full weight-bearing at the point their bony union already permitted it, rather than delaying further out of avoidance. This distinction — faster resumption of an already biologically permissible milestone, rather than accelerated healing — is consistent with the fear-avoidance framework and should be stated explicitly to avoid the (unintended) implication that the intervention influenced bone-healing rates.

The concurrent reductions in PHQ-9 and PCL-5 scores in the EPI group are consistent with prior evidence that early, structured psychological intervention after major trauma can reduce depressive and post-traumatic stress symptom burden [2,3], and that psychological factors measured early after skeletal trauma are prognostically significant for later disability and pain4. Taken together, the physical and psychological findings support the broader argument that recovery from complex lower limb trauma is not a purely biomechanical process, and that biopsychosocial models of care [5,6] offer measurable advantages over conventional orthopaedic pathways alone.

These findings should be interpreted alongside the broader literature on cognitive-behaviourally informed rehabilitation after musculoskeletal injury, which has similarly shown benefit for pain and functional outcomes [7–9]. The present trial extends this literature specifically to the acute, in-hospital phase following complex, high-energy lower limb trauma, and to a randomized, psychiatrist-delivered protocol, delivered by psychiatrists trained in structured psychological intervention techniques in the absence of a dedicated clinical psychology service, rather than a physiotherapy-embedded psychological component alone.

Limitations

This trial has several limitations that should be considered when interpreting its findings. First, it was conducted at a single centre, which may limit generalizability to other healthcare settings, particularly those with different resource availability for psychiatric staffing. Second, participants and treating clinicians could not be blinded to group allocation given the nature of the intervention, which may introduce performance- or expectation-related bias, particularly for patient-reported outcomes such as PROMIS-PF, PHQ-9, and PCL-5. Third, loss to follow-up, while modest (5.0% in the EPI group and 8.3% in the TAU group), was somewhat higher in the TAU arm. The primary ITT analysis addressed this using linear mixed-effects models, which handle missing data under the missing-at-random assumption without requiring imputation; a supplementary LOCF sensitivity analysis was restricted to participants who had contributed at least one post-baseline assessment, since participants lost to follow-up before their first post-baseline visit had no observed value to carry forward. Nonetheless, alternative imputation approaches (e.g., multiple imputation) would further strengthen confidence in the results, and the possibility that dropout was informative rather than at random cannot be fully excluded. Fourth, the 6-month follow-up window, while sufficient to demonstrate early divergence in outcomes, does not establish whether the observed benefits of EPI are sustained over longer-term follow-up (e.g., 12–24 months). Finally, the specific mechanisms driving improvement (e.g., reduced catastrophizing versus improved treatment adherence versus generic supportive contact) were not isolated in this design, and further mediation analysis would help clarify which components of the EPI protocol are most responsible for the observed effects.

Conclusion

In this single-centre randomized controlled trial, an integrated Early Psychiatric Intervention initiated within the acute 21-day post-surgical window produced significantly better 6-month physical function, faster return to unrestricted weight-bearing, and greater reduction in depressive and post-traumatic stress symptoms than treatment-as-usual, in survivors of road traffic accidents with complex lower limb fractures. These findings support further evaluation of early, structured psychiatric integration as a component of the modern ortho-plastic trauma care pathway, ideally through larger, multi-centre trials with longer-term follow-up and blinded outcome assessment.

Declarations

Availability of data and materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Author contributions: Dr. Manish Thangaraj: conceptualization, study design, methodology, data acquisition, formal analysis, manuscript drafting, and corresponding author. Dr. Rashid Gouri: design of the psychiatric intervention, psychiatric methodology, critical review and interpretation of psychological outcomes. Dr. Hitesh Sewawat:

study supervision, methodology, critical revision, and final approval.

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