

## Self-Directed Remote Rehabilitation Yields Similar Outcomes as Formal Physical Therapy for Patients with Lower-Extremity Fracture

*Rachel Seymour, PhD; Meghan Wally, PhD; Christine Churchill, BA; Susan Marie Odum, PhD; Madhav A. Karunakar, MD; Joseph R. Hsu, MD; Kevin Daniel Phelps, MD; Stephen H. Sims, MD; Laurence Kempton, MD; Michael J. Bosse, MD; EMIT*  
*Atrium Health, Charlotte, North Carolina, UNITED STATES*

**Purpose:** Rehabilitation is a critical component of recovery among patients with lower-extremity fractures. Formal post-injury, clinic-based rehabilitation (physical therapy [PT]) is typically standard of care for uncomplicated extremity fractures. However, no data exist to guide clinical decision-making regarding its necessity or to identify subgroups of patients who may achieve similar outcomes using less resource-intensive interventions, eg, self-directed remote rehabilitation (RR). Participating in formal PT can be a barrier to return to work, challenging to access, and increases out-of-pocket health-care costs. We conducted a pilot study to inform a large-scale comparative effectiveness trial with the hypothesis that patients with selected lower-extremity fractures receiving RR will have non-inferior patient-reported outcomes compared to patients receiving PT.

**Methods:** Formal PT was a clinic-based program per usual referral patterns. RR received a manual with detailed instructions on exercises, including repetitions, frequency, and required equipment. Adults aged 18+ years with select operative lower-extremity fractures were approached for enrollment in a randomized trial. The vast majority of patients were unwilling to be randomized due to preferences for one of the arms or concerns precluding participation in formal PT (~50% of our patients are uninsured/underinsured; enrollment during COVID-19 pandemic). Therefore, we enrolled patients and allowed the choice between formal PT and RR. The primary outcome, PROMIS (Patient-Reported Outcomes Measurement Information System)-29 Satisfaction with Social Participation, was selected based on patient-stakeholder feedback. All PROMIS-29 subscales, return to work/duty, and health-care utilization were measured at 3, 6, and 12 months. We tested the null hypothesis that RR will be non-inferior to formal PT.

**Results:** 85 patients were enrolled (RR n = 68, PT n = 17). 55% were male with mean age of 42 years (range, 20-65; P = 0.89). 73% had tibia fractures and 27% had femur fractures (P = 0.99); 16% sustained additional injuries (P = 0.29). While more RR patients were injured by high-energy mechanisms compared to PT patients (62% vs 24%; P = 0.006), all other demographics and injury characteristics were similar. All PROMIS subscale scores at each time interval and absolute change scores from baseline were similar between groups. Finally, hypothesis testing supports that RR is non-inferior to PT.

**Conclusion:** This study addresses a major gap in the literature on post-injury rehabilitation by comparing the effectiveness of formal PT to a self-directed, RR program following selected lower-extremity injuries, and provides parameter estimates to power a randomized controlled trial. Demonstrating that patients are likely to benefit equally from a self-directed remote rehabilitation program allows for flexibility and shared decision-making regarding rehabilitation strategy.

Δ OTA Grant

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device they wish to use in clinical practice.