Graphical abstract

Cognitive functional therapy with or without movement sensor biofeedback versus usual care for chronic, disabling low back pain (RESTORE): a randomised, controlled, three-arm, parallel group, phase 3, clinical trial.

Kent P, Haines T, O'Sullivan P, Smith A, Campbell A, et al.

1 The study

Participants: 492 adults, 59% female, median age 47 years. Inclusion criteria: low back pain ≥ 3 months, average pain intensity ≥ 4/10, ≥ moderate pain-related physical activity limitation, and sought some care <6 weeks prior for this episode of pain.

Intervention: Cognitive functional therapy (CFT) only or CFT plus movement sensor biofeedback.

Comparator: Usual care.

Primary outcome: Activity limitation at 13 weeks, self-reported by participants using the 24-point Roland Morris Disability Questionnaire, and quality-adjusted life-years (QALYs).

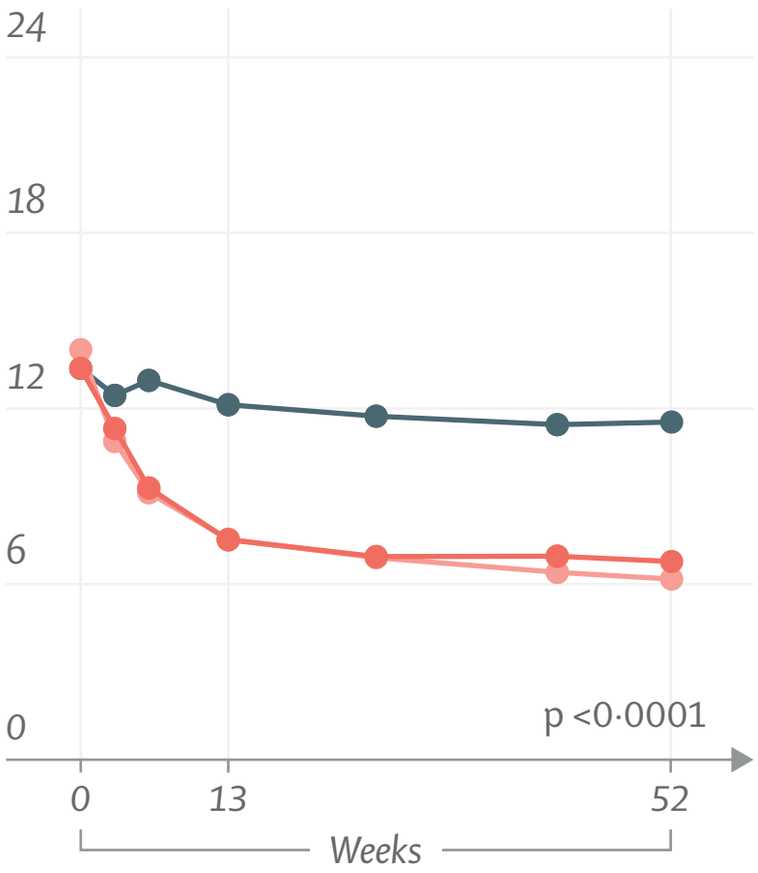
Key limitation: All clinical outcomes and some economic outcomes were self-reported and because participants were not blinded this may have affected expectations and produced some bias. Although, expectations were controlled for in the analysis.

2 Findings

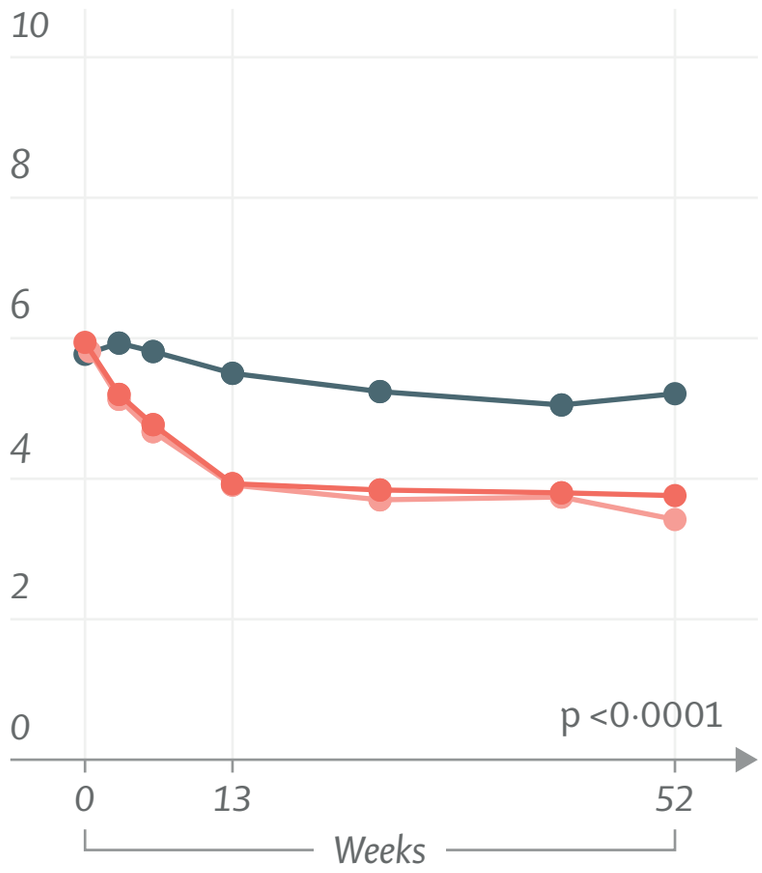
All outcomes were better than usual care by substantial clinically important amounts, improvements were sustained at 12 months follow-up, and both CFT groups were substantially more cost effective than usual care.

CFT only	164 participants	CFT + biofeedback	163	Usual care	165

Pain-related physical activity limitation
Mean RMDQ score (95% CI)



Pain intensity: average pain past 14 days
Mean NRS score (95% CI)



3 Research in context

Before this study
No trials had compared CFT with usual care, included an economic analysis, or the added effect of movement sensor biofeedback.

Added value
CFT was clinically effective, cost efficient and safe. Wearable movement sensor biofeedback did not add to effectiveness.

Implications
CFT might offer a high-value, low-risk, and low-cost clinical pathway for patients with persistent disabling low back pain.