Efficacy of Biofeedback Interventions for Fibromyalgia: A Systematic Review of Randomised Controlled Trials

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Introduction

- **Fibromyalgia (FM)** affects ~2–4% of the population and is characterized by chronic widespread pain, fatigue, sleep disturbances, and impaired quality of life (Häuser et al., 2017).
- Standard treatments (e.g., pharmacological therapy, exercise, CBT) often show only modest and short-term effects.
- **Biofeedback (BF)** interventions target self-regulation of physiological processes (e.g., EMG, HRV, EEG) and may provide a low-risk, non-pharmacological treatment option (Steen et al., 2024).
- Evidence to date is promising but inconsistent; the most recent systematic reviews are outdated or methodologically limited (Glombiewski et al., 2013).

Aim: To systematically evaluate the efficacy and safety of biofeedback interventions for adults with fibromyalgia, with pain intensity at immediate post-intervention (T1, ≤2 weeks) as the primary outcome.

Methods

P **Adults (≥18 years) with formal fibromyalgia diagnosis**

I **Biofeedback as primary therapeutic component**

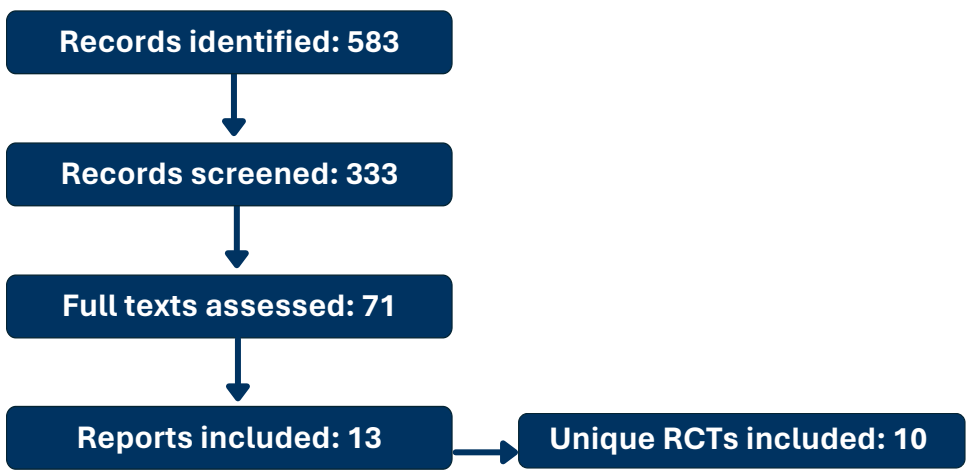
C **Sham, TAU, attention control, or other eligible controls**

O **Pain at T1 + HRQoL, fatigue, sleep, depression, anxiety**

- Systematic review conducted according to PRISMA 2020 and SWiM
- Databases: PubMed, Web of Science, PsycINFO, and Scopus
- Primary search: 21 July 2025; updated search: 2 October 2025
- Eligible studies: peer-reviewed RCTs in adults with fibromyalgia
- Eligible modalities: EMG biofeedback, EEG neurofeedback, HRV biofeedback
- Primary outcome: validated patient-reported pain intensity at T1
- Risk of bias: Cochrane RoB 2, effect of assignment to intervention (ITT)

PRISMA Flow Diagram

Figure 1. PRISMA flow diagram of study selection



Conflict of Interest:
The authors declare no conflicts of interest.

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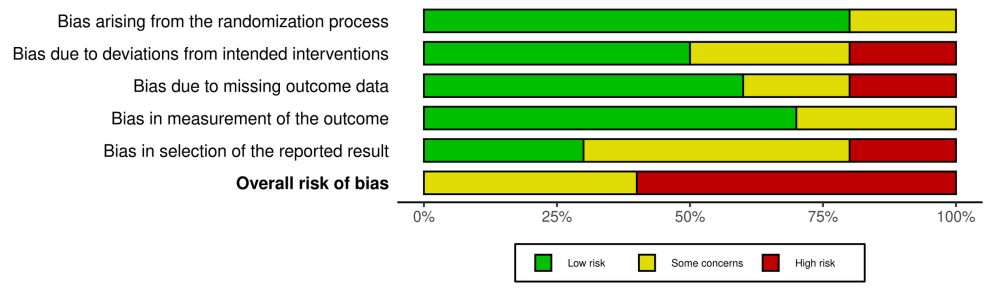
Results

Figure 2. Overall RoB 2 judgements for the primary pain outcome



- Overall RoB: Low 0/10, Some concerns 4/10, High 6/10
- Main concerns: missing outcome data and selective reporting

Table 1. Outcome summary by modality at T1

Modality	Included evidence	Comparator	Pain at T1
EEG	6 RCTs	5 sham/yoked 1 telephone-support	No reproducible superiority over sham
EMG	4 RCTs	1 sham 2 usual care 1 education / attention	Mixed / heterogeneous; no consistent T1 benefit
HRV	0 RCTs	Not synthesised in final review	No eligible validated T1 pain outcome

Note. T1 = immediate post-intervention (≤2 weeks). Summaries reflect between-group evidence at post-treatment

Table 2. Secondary outcomes at T1

Outcome Domain	Summary at T1	Key caveat
HRQoL	No consistent between-group advantage at T1	Wu et al. (2021) improved vs telephone support only (non-sham comparator)
Fatigue	No consistent between-group advantage at T1	EMG findings heterogeneous / imprecisely reported
Sleep	No consistent subjective sleep benefit at T1	Goldway et al. (2019) showed objective sleep improvement without treatment-specific self-reported sleep effect
Depression / Anxiety	No consistent between-group advantage at T1	Non-sham trials heterogeneous and often incompletely reported

Note. T1 = immediate post-intervention (≤2 weeks). Summaries reflect between-group evidence at post-treatment

Additional findings

- Adverse events were infrequently reported and, when described, were mild and non-serious.
- Follow-up was reported in 6 studies; findings were heterogeneous and between-group reporting was inconsistent.
- Adherence among completers was moderate to high where reported; T1 dropout ranged from 0–23.2% in biofeedback arms and 0–26.7% in control arms.

Clinical Implications & Conclusion

- Current RCT evidence does not support a reproducible short-term pain benefit of biofeedback over sham in fibromyalgia.
- Findings versus non-sham comparators were mixed and often incompletely reported; secondary outcomes showed no reproducible T1 advantages.
- Biofeedback may still be considered as an adjunct within multimodal care, but adequately powered sham-controlled trials with complete T1 reporting are needed.