Suggestions in Hypnosis to Aid Pain Education (SHAPE): A pilot feasibility randomised controlled trial

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Trial Protocol Registered at osf.io/frhvq

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KEY POINTS

1. Pain science education enhanced with hypnosis for low back pain showed positive treatment acceptability ratings and promising within group clinical improvements.
2. Protocol modifications to recruitment strategy and to reduce burden of assessments are warranted prior to progressing to a full scale trial.

Background

Recent recommendations have called for the investigation of new treatment strategies for back pain that might adjunctively enhance clinical effects (Buckbinder et al. 2018; Clark & Horton 2018).

Objectives

1. To evaluate the ***feasibility*** of undertaking a randomised controlled clinical trial of hypnotically delivered pain science education
2. To evaluate the participant-reported ***acceptability*** of the intervention.

Methods

Study Design: Randomised Controlled Trial

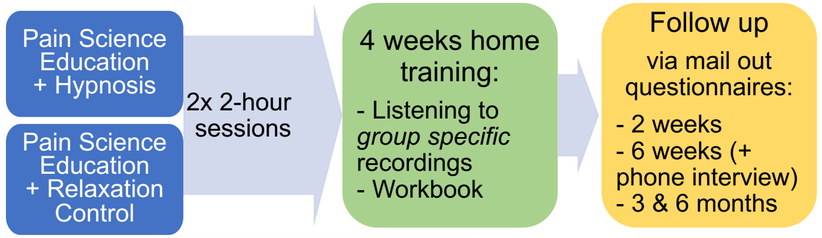
Participants: 20 people with persistent low back pain [7 female/13 male; mean age 44.5 (13.6)]

- 13 recruited from the Pain Management Unit waitlist of a public hospital
- 7 recruited from the community

A priori thresholds for feasibility and acceptability were set.

Secondary clinical outcomes were collected at baseline, post-treatment, and at 3- and 6-months.

Intervention: Participants were randomised to receive either a) hypnotically delivered pain science education (hypnotic suggestions to enhance uptake of pain science concepts) or b) pain science education with progressive muscle relaxation as an attention control. Participants in each group attended two in-person sessions and undertook 4 weeks of at-home activities (workbook activities and audio-recorded hypnosis or progressive muscle relaxation).



Pain Science Education Target Concepts

1. Differentiation of nociception and pain
2. Protective function of pain
3. Peripheral and central sensitization
4. Upregulation of brain mechanisms that serve protection
5. State of 'hyper-protection' offered by normal biological adaptations
6. Concept of an internal 'Protectometer' that is modulated by a multifactorial mix of danger and safety cues.

Hypnotic Suggestion:
"Knowing and understanding that your brain is highly adaptable"

Relaxation Prompt:
"Focus on relaxing your arm more and more"

Results

Twenty participants were recruited, ***however***, not solely from the hospital; community sampling was required (13 hospital, 7 community).

Timely completion of in-person treatments **was partially met** (60% hypnosis, 50% control). Completion of home treatments could not be reliably assessed (25% returned participant diaries).

Completion rate of follow-up assessments ***was poor*** (3-months: 40% hypnosis, 60% control; 6-months: 50% hypnosis, 60% control).

Most participants ***did not*** **start new treatments** during the trial (50% hypnosis, 80% control).

60% of participants reported **high questionnaire burden**.

Assessor **un-blinding occurred** for 35% of participants.

Participants rated the intervention format as **acceptable** (89% hypnosis, 100% control) and content as **helpful** (67% hypnosis, 78% control). Some participants advocated for **additional in-person sessions** (n=2 hypnosis, n=3 control).

Exploratory comparisons indicated a **significant improvement in pain intensity** (hypnosis), and pain knowledge and pain interference (both groups).

Notably, most criteria were met in the community sample, but not the hospital sample.

Table 1. Acceptability ratings of treatment delivery content and format

	Overall (n=18)	Hypnosis-enhanced pain science education (n=9)	Pain Science Education Control (n=9)
Treatment delivery content			
Perceived as helpful	72.2% (n=13) 65% of total sample	66.7% (n=6)	77.8% (n=7)
Treatment delivery format			
Perceived as acceptable (overall)	94.4% (n=17) 85% of total sample	88.9% (n=8)	100.0% (n=9)
• In-person sessions	100.0% (n=18) 90% of total sample	100.0% (n=9)	100.0% (n=9)
• At home sessions	72.2% (n=13) 65.0% of total sample	55.5% (n=5)	88.9% (n=8)

Table 2: Within group mean differences and 95% confidence intervals for hypnosis-enhanced pain science education and pain science education-control.

	Two-week follow up	6-week follow up	12-week follow up	26-week follow up
Hypnosis-enhanced Pain Science Education				
Average Back Pain Intensity	**-1.57 [-2.97, -0.17]**	**-1.75 [-3.27, -0.23]**	-1.75 [-3.75, 0.25]	-1.00 [-3.25, 1.25]
rNPQ	1.71 [-0.89, 4.31]	3.00 [-3.15, 9.15]	0.75 [-4.51, 6.01]	**2.25 [0.25, 4.25]**
PROMIS Pain Interference	-3.43 [-7.63, 0.77]	-5.60 [-11.59, 0.39]	**-4.75 [-8.73, -0.77]**	-4.50 [-10.66, 1.66]
Pain Science Education Control				
Average Back Pain Intensity	-0.75 [-1.62, 0.12]	-1.17 [-3.51, 1.17]	-1.17 [-3.31, 0.98]	-0.43 [-2.11, 1.25]
rNPQ	**2.63 [1.29, 3.96]**	3.00 [-1.50, 7.50]	**3.17 [0.92, 5.41]**	**2.43 [0.24, 4.62]**
PROMIS Pain Interference	-1.63 [-3.62, 0.37]	-2.00 [-4.97, 0.97]	-3.83 [-7.78, 0.12]	**-2.86 [-4.81, -0.90]**

rNPQ: revised Neurophysiology of Pain Questionnaire

Discussion

Protocol modifications are needed before progressing to a full scale trial. Community recruitment may be warranted given most feasibility criteria were met in this sample. Improvements to blinding procedures (including clear instructions to participants) and reducing assessment burden through removal of questionnaires and assessment time-points, which is likely to also enhance retention, are warranted. **While cautious interpretation of within group clinical changes is required, such clinical improvements paired with positive treatment acceptability ratings, are promising.**

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