

Is a videotape to change beliefs and behavior superior to a standard videotape in acute low back pain? A randomized controlled trial
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Morbidity: Acute low back pain

Type of study: prospective RCT

Interventions: Videotape designed to change beliefs and behaviors, standard videotape

Outcomes: Oswestry Disability Index, Pain and Impairment Relationship Scale, Fear-Avoidance Beliefs Questionnaire, medical costs related to LBP and total medical costs incurred over 1-year of follow-up

Cohort: 138 subjects

Inclusion: 18-70 years with acute LBP defined as maximal pain between L1 and the gluteal folds lasting for < 3 months.

Exclusion: Current malignancy, osteoporosis, a spondyloarthropathy, previous lumbar surgery, a neurologic deficit on examination suggestive to nerve root compression or cauda equine syndrome, systematic disease causing LBP, pregnancy, multiple musculoskeletal problems, no access to videocassette recorder.

Overall Evaluation:

This may not meet the evidence for criteria. The participation rate was low with a 38 percent of subjects not completing the initial questionnaire and another 19 percent dropping out by the end of the 1- year study period. Assessors and analysts were not blinded. The study may not be sufficiently powered to detect clinically important differences in outcomes.

May not meet criteria for evidence.

Green: 8/27

Yellow: 7 /27

Red: 7/27

Not Applicable: 5 /27

EW: Non-participation is high for both groups; a null result for the comparison does not constitute evidence for or against the comparison.

Inadequate for evidence, but adequate for a general information statement that giving a video is no sufficient for patient education.

Criterion	Green	Yellow	Red	Comments
Randomization	X			
Concealment of allocation			X	Not addressed
Participant recruitment and eligibility	X			Patients presenting to institutional centers of origin
Blinding of patients and caregivers		X		Caregivers blinded, patients not aware of contents of other video
Blinding of assessors of outcome and of data analysts			X	Assessors not blinded
Blinding success			X	Not discussed
Participant follow-up	X			Figure 1
Length of follow-up	X			Followed for one year
Baseline comparison		X		Demographic data and other co-variable data not presented.
Primary outcome		X		Primary outcome not specified
Analysis of results			X	Not addressed
Adverse effects			X	Not addressed
Attrition		X		19% loss
Co-interventions (performance bias)	X			Through a questionnaire
Presentation of outcome data	X			
Sample size and precision of results		X		Not discussed, study may not be sufficiently powered to observe clinically significant differences. For example, study is powered to see a 8.9 difference for Oswestry Disability Index and 10.45 difference for Fear-avoidance beliefs.
Description of interventions	X			

Criterion	Comments		
	Red	Yellow	Green
Psychosocial variables	X		
Dose-response relationships			NA
Sponsorship and funding		X	Not fully disclosed.
Protocol availability	X		Not available
Baseline symptoms		X	
Crossover trials			NA
For nonrandomized cohort studies with accurate measurement of treatment and outcome, and adjustment for measured confounders, a large treatment effect is observed			NA
For nonrandomized cohort studies, there is a clear dose-response gradient, especially if there is a rapid response to treatment			NA
For nonrandomized studies, adjustment for plausible confounders are expected to increase confidence in the treatment effect			NA
Medical and biological plausibility and coherency		X	