Open-label placebo treatment in chronic low back pain: a randomized controlled trial.

Pain. 2016 Dec;157(12):2766-2772.
Carvalho C1, Caetano JM, Cunha L, Rebouta P, Kaptchuk TJ, Kirsch I.

June 20, 2017
Presented by: Tim Gutteridge (PGY-3, Palliative Care)

ABSTRACT:
This randomized controlled trial was performed to investigate whether placebo effects in chronic low back pain could be harnessed ethically by adding open-label placebo (OLP) treatment to treatment as usual (TAU) for 3 weeks. Pain severity was assessed on three 0- to 10-point Numeric Rating Scales, scoring maximum pain, minimum pain, and usual pain, and a composite, primary outcome, total pain score. Our other primary outcome was back-related dysfunction, assessed on the Roland-Morris Disability Questionnaire. In an exploratory follow-up, participants on TAU received placebo pills for 3 additional weeks. We randomized 97 adults reporting persistent low back pain for more than 3 months' duration and diagnosed by a board-certified pain specialist. Eighty-three adults completed the trial. Compared to TAU, OLP elicited greater pain reduction on each of the three 0- to 10-point Numeric Rating Scales and on the 0- to 10-point composite pain scale ($P < 0.001$), with moderate to large effect sizes. Pain reduction on the composite Numeric Rating Scales was 1.5 (95% confidence interval: 1.0-2.0) in the OLP group and 0.2 (-0.3 to 0.8) in the TAU group. Open-label placebo treatment also reduced disability compared to TAU ($P < 0.001$), with a large effect size. Improvement in disability scores was 2.9 (1.7-4.0) in the OLP group and 0.0 (-1.1 to 1.2) in the TAU group. After being switched to OLP, the TAU group showed significant reductions in both pain (1.5, 0.8-2.3) and disability (3.4, 2.2-4.5). Our findings suggest that OLP pills presented in a positive context may be helpful in chronic low back pain.

STRENGTHS:
- Creative research question (based on an unconventional but rational hypothesis)
- RCT design
- Validated tools
    - (numeric rating scales; Portuguese adaptation of Roland-Morris Disability Questionnaire)
- No industry funding or financial incentives

WEAKNESSES:
- Single center, small sample size, short treatment duration
- Non-blinded
- Patients may not fully represent a general population
    - Selected through advertisement of "a novel mind-body clinical study of chronic low back pain"
    - Many exclusions (including cancer pain and opioid use in the last 6 months)

RELEVANCE TO PALLIATIVE CARE:
- Affirms our multidimensional approach to Sx mgmt
    - Tx benefits attributed only to active ingredient of prescription may actually be biopsychosocial-spiritual
- Suggests that therapeutic encounter is not just where you determine what pills the patient will take later, but is an active tx itself
    - Hope, expectancy, cognitive/emotional engagement in tx plan, therapeutic relationship
    - Not just for the ID team
- As specialists in symptom management, we could consider further exploring and quantifying the multidimensional nature of responses to our medication regimens