The impact of open-label placebo administration in chronic back pain patients on patient-reported pain intensity, functional disability and spine movement

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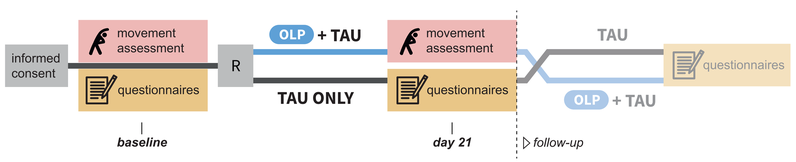
Background and aim

The open application of placebos (OLP) has been heralded as a new way to harness the beneficial effects of placebos for pain relief and reduction of pain-related disability without the need for deception. OLP in addition to treatment as usual (TAU) has been reported to reduce pain and disability scores in chronic low back pain patients (Carvalho et al., 2016), but effects on objective outcome measures have not been investigated yet. In this study, we assessed both subjective, patient-reported measures (pain ratings and disability) and objective outcomes (range of motion (RoM) and velocity of spine motion (VoM)) in a large cohort of chronic back pain (CBP) patients.

Methods

Fig. 1 - Study design



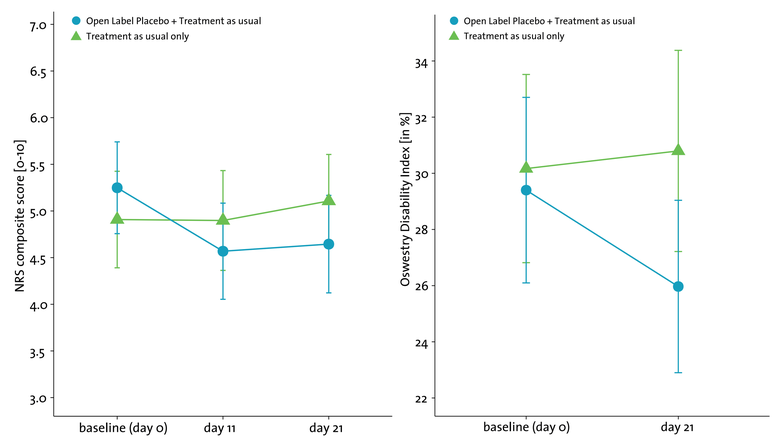
Single-blinded randomized controlled trial. Subjective outcomes were assessed at baseline, day 11 and day 21. Objective motion assessment was performed at baseline and day 21. Additionally, patients were offered to switch groups after day 21 and to enter a follow-up phase with additional assessment of subjective outcomes 3 months after crossover.

N=127 CBP patients (pain duration >12 weeks) were included in this single-blinded RCT over 21 days. At baseline, subjects were shown a video providing standardized information about the placebo analgesic effect and recent research findings suggesting possible beneficial effects of OLP. Patients were randomized into two groups, which both received stable treatment as usual (TAU). Group 1: OLP twice daily for three weeks (OLP+TAU); Group 2: no OLP (TAU). Patients in group 2 were offered OLP administration upon completion of the study to increase compliance and to compensate for potential disadvantage. Subjective outcome measures were assessed at baseline and after 3 weeks comprised composite pain intensity ratings (average of last 7 days), Oswestry Disability Index (ODI), Patient-Specific Functional Scale (PSFS) and Depression Anxiety Stress Scales (DASS). Objective outcome measures taken at baseline and after 3 weeks included range and velocity of spine movement (Epionics Medical GmbH, Epionics SPINE, Berlin, Germany) as assessed by a blinded experimenter. Fig. 1 provides an overview of the study design.

Bibliography
Carvalho, C., Caetano, J. M., Cunha, L., Rebouta, P., Kaptchuk, T. J., & Kirsch, I. (2016). Open-label placebo treatment in chronic low back pain: a randomized controlled trial. Pain, 157(12), 2766-2772. doi:10.1097/j.pain.0000000000000700

Results

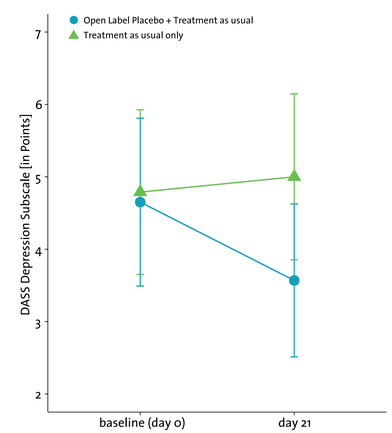
Fig. 2A and 2B - Subjective pain intensity (A) and disability (B)



A) Errorbars indicate 95% CIs. Mean changes of subjective pain intensity ratings at baseline, day 11 and day 21. Composite score includes average, minimum and maximum pain intensity ratings during the last 7 days on a 11-point numeric rating scale („no pain" – „worst pain").

B) Errorbars indicate 95% CIs. Mean changes of functional disability assessed by the Oswestry Disability Index from baseline to day 21.

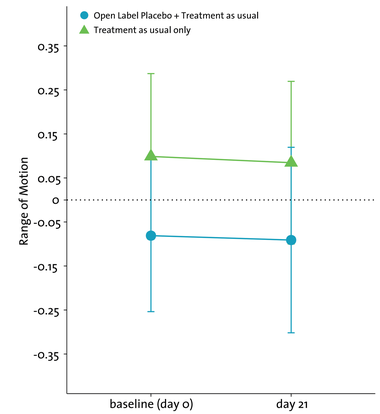
Fig. 3 - Depressivity (DASS-D)



Errorbars indicate 95% CIs. Mean changes of depressivity assessed by the Depression Anxiety Stress Scales (DASS) depressivity subscale from baseline to day 21.

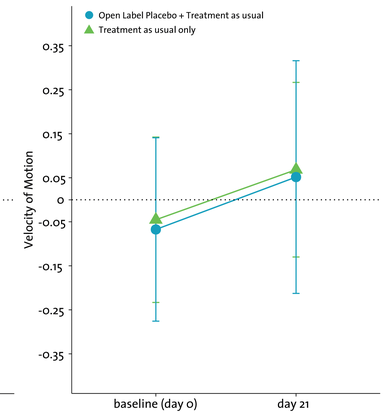
N=122 subjects (age 59.36 ± 14.56 years, M± SD)) completed the trial (N=63 OLP+TAU-group, N=59 TAU-group). Groups did not differ in age, gender and pain intensity at baseline. Linear mixed model analyses on the pain intensity revealed a significant interaction of treatment (group) and time, indicating a significantly stronger decrease of composite pain ratings over the 21 days for the OLP compared to the TAU group ($t(212)=-3.2$, $p=0.001$, $\Delta\beta=-0.73$) (see Fig. 2A). Furthermore, there was a treatment x time interaction for reported functional disability with a significantly stronger improvement in ODI scores for OLP+TAU-treatment compared to TAU only ($t(115)=-2.4$, $p=0.017$, $\Delta\beta=-3.86$) (see Fig. 2B). There were no significant effects for changes in PSFS scores. Further analyses showed a significant treatment x time interaction for depression scores (DASS Depression subscale) indicating a stronger decrease in depression scores after OLP+TAU treatment compared to the TAU-only-group ($t(112)=-2.6$, $p=0.01$, $\Delta\beta=-1.44$)(see Fig. 3). The analysis of the motion assessment parameters of both groups showed no significant changes in RoM and VoM (see Fig. 4 and 5) over time or between groups indicating no effect of OLP on spine motion capabilities.

Fig. 4 - Range of spinal motion



Errorbars indicate 95% CIs. Mean changes of range of spinal motion assessed with an objective movement measurement tool from baseline to day 21.

Fig. 5 - Velocity of spinal motion



Errorbars indicate 95% CIs. Mean changes of range of spinal motion assessed with an objective movement measurement tool from baseline to day 21.

Conclusions

Our results provide further evidence that open-label placebo treatment can be effective in reducing pain and increasing patient-reported functional disability. However, our findings suggest that OLP effects on objective outcome measures may differ from changes in patient-reported outcome. Additional research is needed to explore this potential discrepancy in more detail.

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