“Look, It Works on Him”. The Effects of Open-Label Placebo Reinforced by Observational Learning

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Background and aims

There is growing evidence that open-label placebo (OLP) is an effective way to help patients suffering from pain. What is important, the ethical concerns that usually accompany the use of a deceptive placebo seems to be limited when using OLP. Therefore, understanding the induction methods and mechanisms of OLP seems to be important for clinical practice.

So far, the OLP effect has been most often induced by more or less specific verbal suggestions. Several studies have also tested the effectiveness of classical conditioning in evoking OLP. **The main aim** of this study is to verify whether observational learning – the method which was proved to be effective in producing the deceptive placebo effect – may reinforce the OLP effect induced by verbal suggestions. **The secondary aim** is to examine the pure effects of the OLP suggestion and the observation.

Study design

The study consists of four groups:
1) open-label placebo induced by suggestion and observational learning,
2) open-label placebo induced by verbal suggestion alone,
3) placebo effect induced by observational learning alone,
4) control group without any manipulations.

Four consecutive phases of the experiment will be implemented: calibration, baseline, manipulation, and testing.

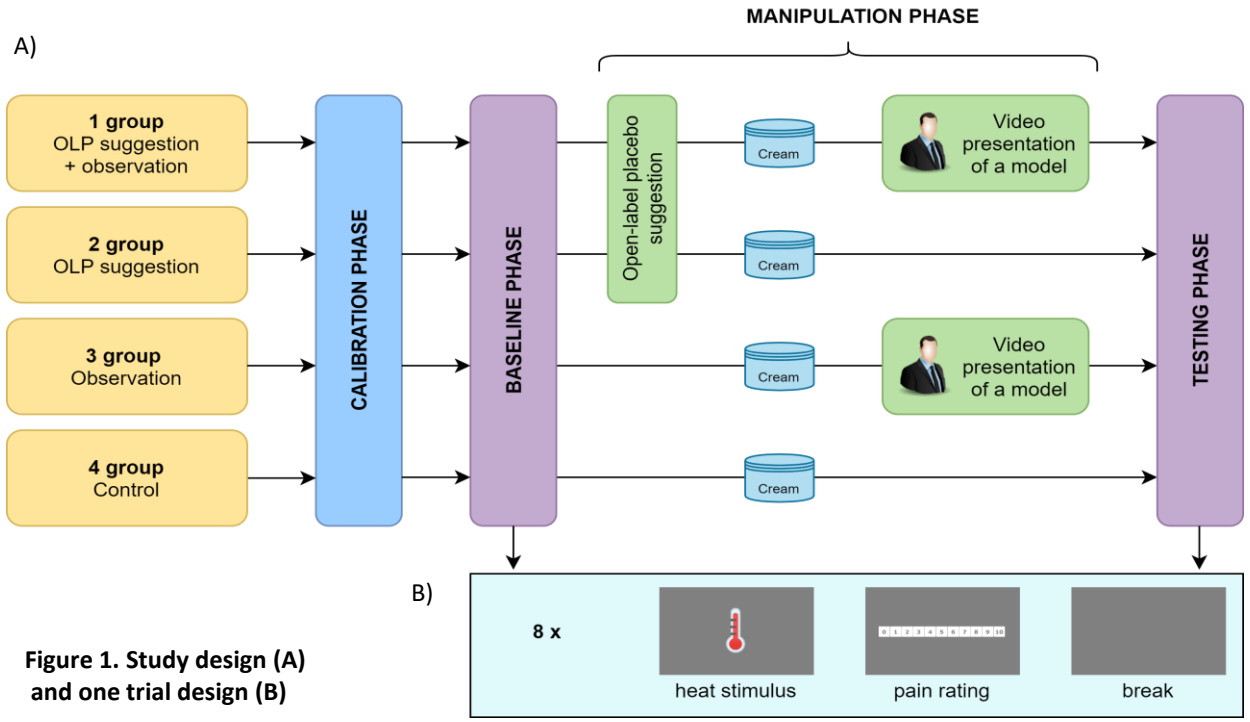

Figure 1. Study design (A) and one trial design (B)

Procedures

Participants. The sample size calculation indicated a required sample size of 100 participants (25 in each group). Participants are physically and mentally healthy, aged 18-45, free of pain, and not taking any pain medication.
Pain stimuli. Thermal heat pain is delivered by the Thermo Sensory Analyzer (TSA-II; Medoc, Israel).
Placebo cream. Consists of a mixture of standard moisturizing cream and couple drops of thyme oil.
Pain measurement. Pain intensity is measured on an 11-point numeric rating scale (NRS), ranging from 0 = ‘no pain’ to 10 = ‘the most pain that is tolerable’.

In the **baseline** and **testing phases**, participants receive a series of thermal stimuli at the temperature rated as 4,5 or 6 on the NRS in the **calibration phase.** They rate the intensity of each pain stimulus on the NRS.

During the **manipulation phase**, the groups 1 and 2 receive a placebo cream along with honest information that the obtained substance is inert. Moreover, participants from group 1 watch a model on the video recording who, similarly to participants, is rating pain on the NRS in two phases separated by the application of the placebo cream. The pain ratings given by the model after the application of the placebo cream are lower (1,2, and 3 on the NRS) than those given by him in the first phase (4,5 and 6 on the NRS). In group 3, participants receive a placebo cream with no information about its effect, then they watch the same video recording. In the control group, placebo cream with no additional information is applied between the baseline and testing phases.

The data is currently being collected. Preliminary results will be presented during the poster session.