Reinforcement of the open-label placebo effect. Determining and comparing the effectiveness of different learning processes in producing the non-deceptive placebo effect

It is not uncommon for medical doctors to include placebos in the treatment of their patients. The placebo effect occurs when a pharmacologically inactive substance or procedure (e.g. sugar pill, sham surgery) has a beneficial impact on our health. Although this kind of treatment may be effective in relieving many symptoms and diseases, it is being criticized as unethical - mainly for requiring patients to be misled. However, there is growing evidence that shows that it is possible to obtain the placebo effect even when participants know that they receive inactive substances. Placebo administered openly, successfully diminished a variety of bothersome symptoms, and its effectiveness was often comparable with deceptive placebo use. Therefore this effect seems very promising for clinical practice, nevertheless, it has not been fully understood yet.

The standard placebo effect (based on misleading the patients) in the field of pain is proved to be successfully induced by four methods. One of them is a verbal suggestion that a certain substance or procedure will alleviate the pain sensation. The second is called observational learning and it is based on acquiring behaviors through the observation of another person. Observation of the person who has experienced decreased pain after the use of placebo may also reduce the observer's pain sensation in the similar situation. What is more, the placebo effect can be induced by previous direct experience. If the previous experience was based on evoking association between the placebo substance and the active treatment, we call it classical conditioning. If the reaction to the pain stimulation was previously followed by a desired or unpleasant event and is therefore more or less likely to occur in the future, we call it operant conditioning. All these methods of inducing deceptive placebo effects in the field of pain are well established and are still being developed. In contrast, not much is known about methods of inducing the open-label placebo effect. So far, it was evoked only by verbal suggestions or by verbal suggestions combined with classical conditioning.

Apart from the methods of inducing placebo effects, there is another crucial component of this phenomenon – psychological mechanisms that underlie the observed effectiveness of placebo effects. Previous research and experts' agendas showed that psychological processes connected with deceptive placebo responses are not likely to adequately explain the benefits obtained in the open-label placebo trials. One of the suggested possible mechanisms of non-deceptive placebo use is the quality of the treatment provider interaction. However, there are a few previous studies that examined the quality of the provider interaction, and there is none that investigated this interaction in the open-label studies on pain.

Along with studies results, some research gaps are revealed and the following questions arise. How can we enhance the open-label placebo effect? Which method will be the most effective? What is the psychological mechanism of this effect? Three experiments have been planned to answer these questions. The first study will test whether observation of another person can reinforce the magnitude of the open-label placebo effect, as well as compare its effect to the standard placebo effect induced that way. The second study will verify whether operant conditioning can reinforce the magnitude of the open-label placebo effect, as well as compare its effect to the standard placebo effect induced that way. In the third experiment, observation, operant and classical conditioning will be compared with regard to their effectiveness in reinforcing the open-label placebo effect and durability of this effect in time. Moreover, one of the possible psychological mechanisms of open-label placebo – the quality of the provider interaction – will be tested. In all experiments, participants will be healthy volunteers, who will receive thermal heat pain stimulation. An inactive ointment will serve as a placebo substance. In all experiments, both subjective pain ratings and physiological responses, as well as expectation of pain intensity will be measured.

The knowledge gained in the course of the project will contribute to a deeper understanding of the open-label placebo effect. Moreover, it could be meaningful for clinical practice, as it might help clinicians to develop the most effective and durable way of open-label placebo implementation. What is more, the results will establish the meaning of the treatment provider interaction with the patients, which may result in developing new effective patient approach strategies.