# Identifying placebo responders and predictors of response in osteoarthritis: a protocol for individual patient data meta-analysis

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PMID: 27793184 PMCID: PMC5084436 DOI: 10.1186/s13643-016-0362-x

## **Background**

Currently, there is no cure for osteoarthritis (OA). The treatments that are available, aim to reduce pain levels, but are often unsuccessful and also have undesirable side effects.

In clinical trials that test pain relief medication we use a dummy treatment called a placebo, which often looks like the real tablet or gel but doesn't contain any drug. Half the people in the study will get the drug treatment and half will get the placebo but everything else, including how often they are seen by the researchers, what information they are given or what measurements are taken, is exactly the same.

In trials of OA treatments, around 75% of the pain relief benefit can be put down to a placebo response rather than the specific effect of the medication. This response varies greatly from patient to patient.

#### Aim of the study

To identify which patients best respond to placebo in treating OA related pain and to identify potential factors that can affect the placebo response.

#### How the study will be carried out

In collaboration with the OA Trial Bank, we are going to analyse individual patient data collected from trials that have compared a treatment for osteoarthritis pain alongside a placebo.

The OA trial bank have previously identified all drug studies that have been carried out. These include using non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen applied to the skin as a patch, cream or gel; or capsaicin (the spicy substance in chillies) also applied to the skin; steroid injections or glucosamine tablets and gels.

The data from all these studies will be combined and analysed. We will compare the characteristics of those people who responded to the placebo treatment compared to those who did not. We hope to be able to identify a subgroup of people with osteoarthritis who are most likely to respond to placebo and to be able to identify factors that will predict a response.

### Significance of the study to Pain Centre's research

Identifying factors that will predict a response to placebo treatments will be useful for future studies as it will allow us to separate participants into groups based on their likely response. It will also be useful for pharmaceutical companies who can improve the design of their studies in order to separate the 'specific' effect of their drug or treatment from the 'non-specific' placebo effect.