

## Core outcome set development reflecting patient values for orthodontic treatment

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### **Aim:**

The overall aim of the research is to develop a core outcome set for use in clinical trials involving orthodontic treatment of children and young people. The results will ultimately benefit decision-making by all stakeholders.

### **Objectives:**

1. Determine what primary and secondary outcome measures have been used in previous orthodontic clinical trials by means of a scoping literature review.
2. Determine what outcomes are important to patients with a range of malocclusions and their parents via qualitative research methodology.
3. Determine what outcomes are important to clinicians and patients by means of a Delphi survey.
4. Develop a core outcome set that echoes the views of both patients and clinicians.

### **Setting:**

This is a multicentre study involving four centres. The study will take place in a teaching hospital and a primary care practice in London and Sheffield, respectively.

### **Plan of investigation:**

For the purposes of this research, I will follow a similar methodology that was used by the team who developed a COS for the treatment of otitis media with effusion for children with cleft palate<sup>16</sup> and I will use the following methods:

#### Stage 1

Update my recently published review<sup>7</sup>, by analysing clinical trials published from 1st January 2013 - 31st December 2016. The present scoping review also involves delineation of outcome measures as well as domains, providing a greater depth of understanding to outcomes assessed within contemporary orthodontic trials.

#### Stage 2

Conduct focus groups and qualitative interviews with young people who are due to have, are undergoing or have recently had orthodontic treatment and their parents, to identify matters of importance arising from treatment and compile a long list of outcomes.

#### Stage 3

Conduct three-round electronic Delphi surveys with patients, parents and clinicians to identify and rank outcome measures of most importance. This will use information from the long list of outcomes developed in stages 1 and 2.

#### Stage 4

Arrange consensus conferences with clinicians and patients to prioritise the outcome measures for inclusion in the final COS in relation to orthodontic treatment.