**Title of study**

**List of authors on publication**

**Introduction/Background**

Give clinical background and rationale for study. Provide results of literature review on the topic. This section (or parts of it) can later be used in the introduction of the results paper.

**Study objectives**

Explain the objectives of the study in one or two sentences. This should be similar to the last sentence in the introduction of results papers.

The specific study aims are:

1. xxx
2. yyy
3. zzz
4. etc

**Design and Methods**

Provide some general information relevant for this study: single/multi-centre, prospective/retrospective, etc.

Then give a detailed list of the specific study endpoints: What is the primary endpoint, and what are secondary endpoints? What measurement instruments (i.e. ODI, VAS) will be used? What patient groups will be compared?

*Study endpoints*

1. primary endpoint:
2. secondary endpoint 1:
3. secondary endpoint 2:
4. etc

*Determination of eligibility*

Define the inclusion and exclusion criteria for the study (possibly in a table). Explain the reasons for these criteria.

*Assessments*

List all variables collected for this study in a table. Explain how data is collected: By whom, when and where are data recorded? Is there blinding of investigators to other information?

*Statistical analysis*

1. Primary endpoint: detailed description of the statistical tests used
2. Secondary endpoint 1: detailed description of the statistical tests used
3. Secondary endpoint 2: detailed description of the statistical tests used
4. etc

*Sample size considerations*

Define minimum expected difference (effect size), estimated measurement variability, desired power and significance criterion. Calculate the number of patients required to provide the specified to detect effect.

*Ethical approval*

If applicable, say whether ethical approval has been obtained or applied for.

**Discussion/Significance**

Explain the special features of this study. Why is this study important? What can we learn from the study (regardless of the actual results)?