

## FEATURES SECTION

# How to write a protocol

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This short article outlines the main steps in producing a protocol for a research project. It is not our intention to be prescriptive in the outline, we are simply providing guidelines for the potential researcher who hopes to carry out a research project. None of these ideas are our own, they are a condensation of those derived from several readily available sources. Throughout this paper we will provide examples from a hypothetical project, which aims to investigate the influence of functional appliances upon facial growth.

A protocol is a document that explicitly states the reasoning behind and structure of a research project. The preparation of a protocol is a most important stage in the research process and is carried out for the following reasons:

- 1 It states the question you want to answer.
- 2 It encourages you to plan the project in detail, before you start.
- 3 It allows you to see the total process of your project.
- 4 It acts as a guide for all personnel involved in the project.
- 5 It acts as a 'reminder' to you and your supervisor (or co-workers) of the initial structure and aims of the project.
- 6 It enables you to monitor the progress of the project.
- 7 It is necessary if you need to apply for funding or ethical approval

All protocols are divided into two main sections: (i) the problem to be investigated and (ii) a method of investigation. These sections may be further subdivided as follows.

### *The problem to be investigated*

- Project title;
- the research problem;
- background (including the literature review);
- the aims;
- the hypothesis.

### *Method of investigation*

- Plan of the investigation (including sample size calculation and statistical methods);
- project milestones;
- dissemination of the results;
- resources required.

## The problem to be investigated

### *The project title*

The project title is one of the most important features of the protocol because it attracts the attention of the potential reader. It is, therefore, necessary to make it as short and to the point as possible. If we consider two possible examples:

- 1 "An investigation to evaluate the effect of the Herbst and Twin Block functional appliances on skeletal growth during the treatment of Class II skeletal growth anomalies. A randomized controlled trial."

This title is overlong and states the obvious in a rather 'wordy' way. It goes without saying that because it is the title of a research protocol it is an investigation that will evaluate something. A preferable approach may be:

- 2 A randomized trial of Herbst and Twin Block appliances.

The second title comes straight to the point without stating the obvious. It not only attracts the attention of a reader, but it immediately tunes them into the subject matter.

### *The research problem*

Before you can create a problem of your own you must first know what a research problem is. This is a difficult step especially if you are an inexperienced researcher. Research problems are explanatory devices; they are carefully designed sentences about what you intend to find out.

It is difficult to design a problem statement and you should give it a great deal of careful thought. When you write the problem statement, your words must show an understanding of the research phenomena and should explicitly reveal your purpose.

You should go directly to the problem in the first sentence of page 1. Resist the temptation to give background or set the stage for the problem. When the protocol is read, the reader will want to know the purpose of the study immediately. They will not want to search through several pages of text to discover what the protocol is about. To be effective your opening words should be clear and demand attention, for example:

- 1 In this study I intend to find whether the use of a fixed functional appliance (the Herbst appliance) will result in greater skeletal change than a removable functional appliance (the Twin Block). If I can show that this occurs this will be an important finding for orthodontic care.
- 2 This will be an investigation to evaluate the effect of functional appliances upon facial growth.

If we examine the two statements above, statement 1 is easier to read because it is in the first person. This should be your preferred writing style as opposed to the use of passive voice (statement 2). You should, however, be careful that the first person is not over-used and that your protocol does not read like a 'letter to mum'.

Avoid the 'look around' approach to a research problem. It is very important to avoid the 'lets start a project and see what happens' approach. This will inevitably lead to a poorly co-ordinated and cumbersome project, which drifts and may not have a well-defined ending. As a result, the statement of the problem should be explicit.

#### *Background (including the literature review)*

The most important feature of the background to the project is that it should be brief and to the point. For a research protocol the background should be no longer than two pages of A4 paper. In this section, you should concisely review the literature that is relevant to the problem that you are trying to solve. In this respect, it is probably good practice to limit the number of papers quoted to less than 20.

When you write the review, you should draw attention to the good points and the deficiencies of the studies quoted. You should also remember that it does not always mean that if a study has been published in a

journal, it is flawless in its methodology and conclusion. Nevertheless, you should not be too critical of previous investigators because research technology and understanding of data analysis is a fast-moving field. Remember, if your study is published and it is considered state of the art today, it could be torn to shreds by neophyte researchers in 10 years time!

In terms of writing style it is good practice to make your writing flow. There is a tendency to introduce concepts and previous studies by simply going through a shopping list of papers, for example:

'McNamara has shown that the Frankel appliance produces an increase in mandibular length of 3 mm, Pancherz (1979) used Herbst appliances and showed an effect of 3 mm increase in mandibular length. This is in agreement with a study by Hansen (1984). However, Tulloch *et al.* (1990) have suggested that it is not possible to come to any conclusions concerning the effect of functional appliances'.

It is better to take the following approach:

'There have been many retrospective investigations that have concluded that either fixed or removable functional appliance have a growth modifying influence on the mandible (McNamara, 1984; Pancherz; 1986, Hansen, 1991). However, Tulloch *et al.* (1990) in a review of this literature have been critical of past research and concluded that most studies are characterized by weak designs. As a result, it is not possible to come to any conclusions concerning the effect of functional appliances'.

The literature review should logically lead to the statement of the aims of the proposed project.

#### *The aims*

The aims of the project should be explicitly stated. These should be confined to the intention of the project and they should arise from the literature review.

#### *Hypothesis*

A hypothesis is the supposed relation between variables. The hypothesis that you are trying to prove should be stated in the simplest form possible. It is general practice that hypotheses are stated in the null form, because they have their basis in inferential statistics. You challenge the hypothesis of no difference. The result of statistical

testing gives the probability that the hypothesis of no difference is true. For our project the hypothesis will be:

‘The null hypothesis is: There is no difference in the proportion of overjet change due to antero-posterior growth of the mandible and maxilla between patients treated with the Herbst or Twin Block appliance.’

The alternative hypothesis is, then, either:

‘There is a difference in the proportion of overjet change due to antero-posterior growth of the mandible and maxilla between patients treated with the Herbst or Twin Block appliance’

or

‘There is a greater change in the proportion of overjet change due to antero-posterior growth of the mandible and maxilla in patients treated with the Herbst than in patients treated with Twin Block appliance.’

## Method of investigation

This is a description of the tactics of the research and is probably the easiest part of a research protocol to prepare. If you want to make the method easy to read, it is better to use the active voice, instead of the passive, for example: ‘We will randomly allocate the subjects to the Twin Block and Herbst group, stratifying on age and sex’. This is easier to read than: ‘The subjects will be randomly allocated to Twin Block and Herbst groups, stratified by operator and sex’.

In a study protocol, the method should be stated in the future tense. The method should be structured using the following subheadings: (i) subjects; (ii) design; (iii) experimental procedure; (iv) materials, measurements, and apparatus used; (v) sample size calculation; and finally (vi) the statistical methods that you are going to use.

### *The subjects*

Many studies analyse information derived from patients that have been or are going to be treated. It is very easy for us to lapse into clinical language and state that the population under investigation is ‘patients’. This is patently not so when we have an untreated control group. It is therefore better practice to refer to the study population as subjects. When you describe the subjects of a study, you should report the following information:

- 1 The population the subjects will be drawn from.
- 2 The total number and the number in any subgroups within the investigation.

- 3 All aspects of subject selection that will provide information on the removal or minimization of bias.
- 4 The inclusion and exclusion criteria for the subjects.

### *The design*

At this stage of the protocol your readers should be beginning to understand the general design of your project. In this part of the method they will learn exactly how you are going to do the study. The best way to approach this is to describe exactly how the total subject pool is to be divided into comparison groups.

‘Subjects will be eligible for inclusion in the study if they satisfy the following inclusion criteria: (i) they have an overjet of greater than 7 mm; (ii) they are still growing; (iii) they have all their permanent teeth erupted apart from the second and third molars . . . Subjects with congenital clefts, or who have suspected or identifiable syndromes will be excluded from enrolment. All subjects who are eligible for inclusion will be interviewed and the purpose of the trial will be outlined. If informed consent is obtained, the operator will contact the central trial coordinator and provide details of the subject. The subject will then be randomly allocated, stratifying for operator and sex, to the Herbst or Twin Block groups.’

### *The procedure*

This will describe exactly what you are going to do with the subjects. This includes details of (i) treatment to be provided to the experimental group and (ii) the method to be used to collect data. For example:

‘We will provide treatment to the subjects using the Twin Block appliance and Herbst appliance according to agreed protocols . . . When all the treatment is completed cephalometric measurements will be taken and changes evaluated’

### *Measurement used*

Describe the materials and the outcome measure to be used in the study. For example:

‘The outcome measure for this study will be the proportion of overjet change that is due to skeletal change. We will take lateral cephalograms at the start and conclusion of the treatment periods.

The cephalograms will be analysed with the Pancherz analysis by a trained examiner.’

You also need to include here any forms or questionnaires you intend to use, and also how you will store and handle the data.

#### *Sample size calculation*

We do not intend to describe the various methods for calculating the sample sizes to be used in an investigation. This is adequately covered in most statistical textbooks. Nevertheless, we should emphasize that this is an essential part of all protocols. If the sample size is too small there is a considerable risk that the study may not be sufficiently powerful to detect a difference between the groups, if a true difference exists. The study would, therefore, be worthless and a great deal of effort will be wasted.

#### *Statistical methods to be used*

It is also essential that the statistical methods to be used in the investigation are outlined in detail. It is not sufficient to merely state the names of the tests to be used; you should describe the rationale for your choice of statistical tests. For example:

‘The research question is concerned with the comparison of two groups (Herbst versus Twin Block). The dependent variable will be the proportion of overjet change that is due to skeletal change. The independent variables will be study group, sex, age, compliance, initial malocclusion severity. Before we analyse the data, we will check for normality and if necessary transform the data. Because the influence of several, possibly inter-related independent variables will be evaluated, we will use linear regression analysis’.

#### *Project milestones*

This section is not essential. Nevertheless, it does provide a guide (and reminder!) for you and your supervisor to inform if you are ahead or behind schedule with your project.

#### *Method of dissemination of findings*

Again, this is not always essential, but it does let the reader know what you intend to do with the results of the study. It is occasionally possible to list the potential titles and publication strategy of the investigators. However, this can sometimes be considered an over optimistic approach.

#### *Resources required*

Finally you should make a list of all the resources that you are likely to require to successfully complete your investigation. If these resources have cost implications, you should also note the potential cost of the investigation.

In this document we hope that we have provided some basic information without being too prescriptive. Preparing and presenting a protocol is one of the most difficult parts of carrying out a research project. It can also be the most interesting and satisfying. The result of this process should be a short (no more than 2500 words) document that clearly outlines your research project. If the protocol is poorly prepared and not adhered to, it is unlikely that the project will yield the information that you hope for. At worst, the project may become unwieldy as you aimlessly drift through the research process discovering little except disenchantment.