How to Write a Protocol

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Failing to plan is planning to fail.—Alan Lakiel

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Key Points

- Thesis protocol acts as a blue print and should list the important details of your research
- In the first section of the thesis protocol general information about the researcher and study should be mentioned
- In the second section of the thesis protocol technical details of the study should be written
- A descriptive title is commonly used for a thesis protocol
- Aims and objectives of the study are not synonymous
- Inclusion and exclusion criteria should be supplementary and not complementary
- A pilot study should be performed when the investigator is not sure about the feasibility of the proposed research

What Is a Thesis Protocol?

Thesis Protocol is a document formulated to provide the reader a concise plan of the proposed research. In addition to giving a panoramic view to the research project, a written protocol enables clarity of thoughts and allows introspection into all possible aspects of the study. A thesis protocol acts as a road map and should list the various details that constitute a vital component of the thesis. It is reviewed and approved by members of the Institute scientific committee and Ethical board. Once approved, the student must adhere to the protocol of his/her thesis. Various Institute bodies usually have a prefixed format for the same.

Need for a Protocol

All research bodies require clearance from their scientific and ethic committees for a project to commence, which in turn would necessitate the drafting of a protocol. If the project is a clinical trial, the same protocol would also have to be registered with the clinical trial registry. Various funding groups also need the submission of a protocol to evaluate the same for grant assistance. Furthermore, the protocol acts as a blueprint, a standard operating procedure, that the investigator can fall back on while performing the research.

Components of a Thesis Protocol

The thesis protocol broadly has two major sections [1–3]. **The first section** has general information, which includes the following:

- Name and address of the candidate, Guide and Co guide with their contact information
- Name of the course (MD/MS/DM/MCh/Ph.D.) and branch. Month and year of admission to the course and appearing for the final examination.

- Study duration—It should include the follow-up period if it is a part of the study
- Details about setting in which the study will be done e.g. institutional/inter-institutional/international
- Details of funding

The **second section** consists of technical details of the study, under the following headings, all of which should be written in the future tense. It consists of the following parts:

- Title
- Background of the study
- Research question
- Aims and objectives
- Brief review
- Methodology
- Any previous work
- Case record form

Title

It should be concise (preferably not more than 15 words), specific and informative. It should mention the study design (case-control/randomized trial), population that is going to be studied, the intervention intended, the employment of controls if any and the expected outcome. A descriptive title is commonly used for a thesis protocol. Interrogative title (introducing the subject in the form of question) should be preferably avoided for a thesis protocol. Use of acronyms, linguistic jargons, sensationalism, irony and puns in the title should be avoided.

Examples of titles to avoided and how to improve it:

Poor title (Interrogative title): Is esomeprazole a better drug than pantoprazole in treating bleeding duodenal ulcer?

Recommended title (Descriptive title): A comparative study of esomeprazole and pantoprazole in bleeding duodenal ulcer—a prospective randomized study.

Poor title (idioms and phrases): Synbiotics in pancreatic surgery: A Hobson's choice.

Recommended title: Evaluation of the role of synbiotics in patients undergoing surgery for pancreatic diseases.

Background of the Study

It should begin by providing an insight into what is known about the problem and is followed by brief description of previous studies done in the same field to highlight the lacunae in the existing knowledge. This, in turn, will justify the rationale behind the present study. The novelty of the study to be undertaken should also be discussed. A detailed review of literature is not required.

Research Question or a Hypothesis

A research question is a question for which the researcher wants to find an answer, by conducting the study. The question should be framed such that both the planned intervention and the population to which it is being applied, are mentioned. A research hypothesis should be in the form of a sentence that states the expected outcome of the study.

Example:

Research question: Is drain fluid amylase measurement on post-operative day one a predictor of pancreatic fistula after pancreatic surgery?

Research hypothesis: Postoperative day one drain fluid amylase predict pancreatic fistula after pancreatic surgery.

Aims and Objectives

Often the students are confused with the terms aims and objectives and use them interchangeably. The aim is regarded as a general statement of what a researcher hopes to achieve and is usually written using an infinite verb. Objectives usually more than one is often expressed through an active sentence to state the specific steps taken to achieve the aim. Objectives should be specific, measurable and achievable.

Example

Thesis title: Evaluation of micronutrient deficiency in patients undergoing bariatric surgery—a prospective observational study.

Aim:

To evaluate micronutrient level and the prevalence of micronutrient deficiency among the morbidly obese patients undergoing bariatric surgery in a tertiary care hospital.

Objectives:

To determine the baseline micronutrient level among the morbidly obese patients undergoing bariatric surgery.

To assess the changes in the level of micronutrients and bone health during the post-operative period of 1 year.

To identify the factors associated with the level of micronutrients among morbidly obese patients undergoing bariatric surgery.

A Brief Review of the Literature

In this section, the student should cite earlier studies and critically analyze them in terms of variations in methodology and research outcomes. Limitations of earlier studies and how the present research will add to the existing knowledge should be briefly explained. Seminal studies, RCTs and systematic reviews should not be missed out.

Methods

The methodology to be followed for the study should be elucidated in terms of the procurement of the study subjects, data collection, details of intervention, their frequency and duration, drug dosages, formulations, schedule and duration. Details of instruments used are also required. The duration of the study period should also be mentioned. Standardized and/or documented procedures/techniques should be described and bibliographic references, if not provided earlier should be provided. A graphic outline of the study design and procedures using a flow diagram must be provided. This should include the timing of assessments. The research protocol must give a clear indication of what follow up will be provided to the research participants and the duration of the same. This may include a follow-up, especially for adverse events, even after data collection for the research study is completed. The methodology should be self-explanatory and replicable by another researcher.

Study Design

Observational or Interventional (Experimental) (Fig. 1). In the observational study, the researcher just observes and analyses the events and has no control over the occurrence of the events [4]. Observational studies could be either descriptive or analytical. In descriptive studies, the researcher describes the prevalence/distribution of a health problem in relation to person, place and time. A descriptive study can be carried out as a cross-sectional or a longitudinal study. In the cross-sectional study, the study population is contacted or examined at one point in time to obtain the required information. Cross-sectional study is generally used to determine the

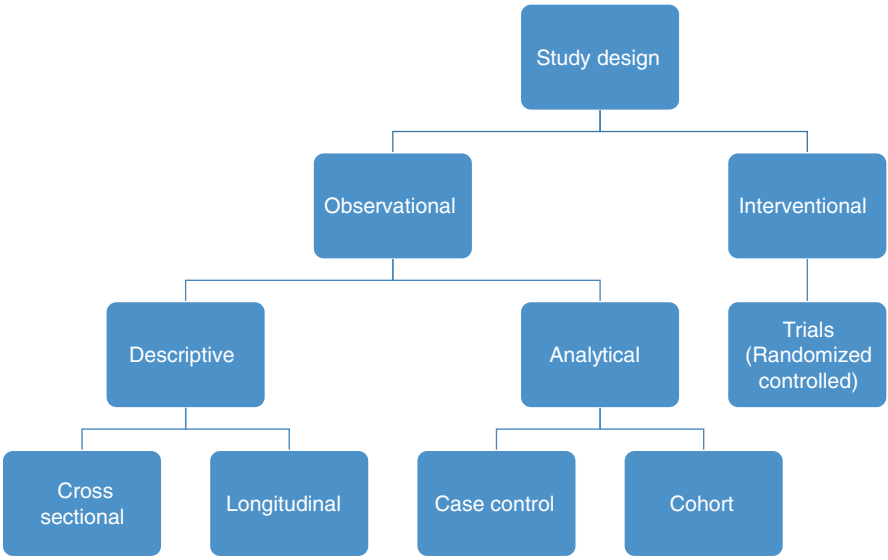

Fig. 1 Study design

prevalence of a health problem like anemia at one point in time. In a longitudinal study, a group of individuals (cohort) is followed over a period with frequent contact or examination to obtain the required information. An example of a longitudinal study is the determination of weight gain in pregnant women.

In the analytical study, the researcher attempts to determine the possible etiological or associated factors in addition to describing the health issue. Analytical studies are carried out as a case-control or cohort study. Case-control study is a retrospective study where the researcher goes back from the disease to the cause. The classical example of a case- control study is to determine whether smoking causes lung cancer the researcher selects patients with lung cancer and study the smoking pattern in them and compare it with those without lung cancer to arrive at a conclusion. In a cohort study, the researcher proceeds from cause to effect in a prospective manner. An example of a cohort study is to determine whether smoking causes lung cancer, a cohort of healthy people with the habit of smoking and another cohort of healthy people without smoking habit are followed for the occurrence of lung cancer and the incidence is compared to arrive at a conclusion.

In contrast to the descriptive study, in an interventional (experimental) study the researcher intervenes and has control over the events. Randomization and selection of study population play an important role in experimental studies. Interventional studies are generally performed to determine the efficacy of a new drug or procedure.

Study Setting

Hospital or community-based setting should be mentioned.

Study Participants

Whether the study involves humans or animals should be mentioned.

Inclusion and Exclusion Criteria

The criteria for eligibility to participate in the trial should be clearly listed as inclusion criteria. It should include disease condition, age group to be studied and in the case of animal studies the exact species and subspecies of experimental animals. Exclusion criteria often include characteristics or co-morbidities, which may confound the results and hence need to be excluded. Inclusion and exclusion criteria should be supplementary and not complementary. For example, a study on patients over 60 years of age should not mention all those below 60 years as exclusion criteria as it is obvious.

Sample Size, the Number in each Group

Details of the statistical method (power of the study, the level of significance) used for sample size calculation, along with the prior study details used to arrive at the calculated sample, should be mentioned. The number of participants in each group should be specified. Allowance for incomplete data and loss to follow up should also be accounted for in the calculation.

Sampling Method

Of the various sampling techniques (Random/Systematic/Stratified/Convenience/Judgmental/Snowball/Quota Sampling), the method used in the current study should be mentioned.

Randomization Techniques

Technique of randomization (Simple, Block, Minimization or Response-adaptive randomization, etc.) should be specified for a randomized controlled trial.

Ethical Considerations

Level of risk to the participant (less than minimal risk/minimal risk/more than minimal risk) to the study subjects should be mentioned (based on ICMR Code on Ethical Guidelines), for the ethical committee's assessment [5]. Patient information sheet and consent forms, both in the local language and English, should be enclosed. If the participant is a minor, then Parent consent/Assent forms should be enclosed.

List of Variables and Measurement Methods

The primary and secondary outcome measures should be defined, and the statistical tools for their estimation should be precisely mentioned**.**

Data Collection Methods and Periodicity

A timeline of participant's visits should be framed. The various parameters assessed at the baseline and at follow up visits should be given here.

List of Variable Wise Statistical Tests

Names of the statistical tests (parametric/nonparametric) being used for dependent and independent variables are given in this section.

References

A list of 10–15 relevant references should be written in Vancouver (ICJME) style of referencing.

Any Previous Work Done

A research thesis should not be started without getting an appropriate clearance is obtained from the ethics committee. However, the candidate can mention here about the preliminary collection of information from literature, seeing feasibility based on past records available.

Case Record Form (CRF)

Once ethical approval is obtained, participants can be recruited into the study. The data should be collected in CRF, which should have all the parameters mentioned in the methodology section of the protocol. Participant's details, history, examination, lab reports and follow up assessments should be written in an unambiguous manner in the CRF. The data collected will be used for statistical analysis. CRF is also called as patient proforma and is enclosed with the protocol.

Pilot Study

A pilot study is a small version of the proposed study to determine the feasibility and logistics of a proposed large-scale study [6]. In general, it is done before phase III randomized trials to avoid the potentially disastrous consequences of conducting a non-feasible large study. Occasionally postgraduates might need to do a pilot study to know whether the topic selected for the thesis is feasible. Pilot study helps to determine the feasibility of the processes (like recruitment/compliance rate) that are key to the success of the main study. Also, time and resource (budget) problems, information regarding treatment safety and safe dose level can be obtained from the pilot study. Although the pilot study is small-scale study, it is a complete study by itself in contrast to an exploratory study which is an incomplete study. The researcher should ensure that the study subjects of pilot study are not included in the main study.

To formulate a protocol that is both succinct and delivers the idea across it is essential to avoid flowery language and to stick to short and simple sentences. Also, maintaining the font size and ensuring accurate grammar goes a long way. Prior to submitting the protocol, it helps to have it reviewed by peers as well as experienced individuals and altering the needed revisions before tendering the document in (Fig. 2).

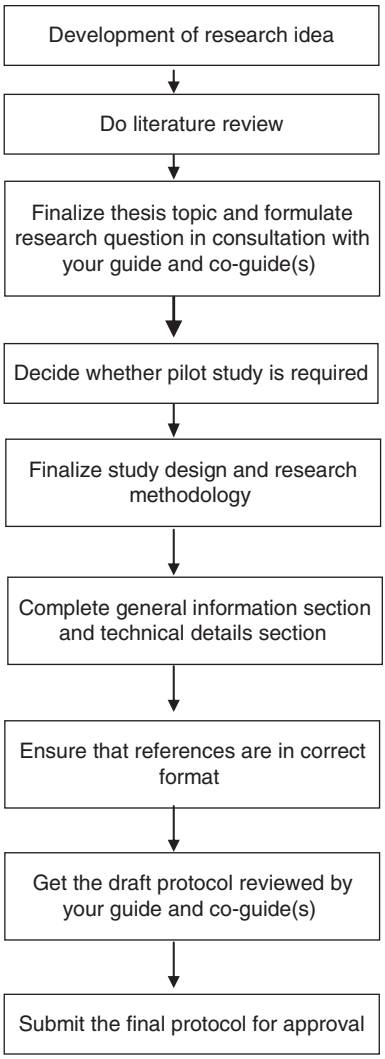

Fig. 2 Algorithm for writing a thesis protocol

Case Scenarios

1. You are planning to do a prospective study on the predictive value of different fistula risk scores to accurately predict clinically relevant postoperative pancreatic fistula. You have titled the study as "Fistula risk score and clinically relevant POPF—close, but not cigar." Comment on the title.
   Key: Avoid using acronyms and linguistic jargons in the title. The study design is not mentioned.
2. You are planning to do a thesis on a novel laboratory test. You are not sure about the feasibility of the study process like resource requirements. Before choosing the study as your thesis topic, what should be your approach?
   Key: to do a pilot study.

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