6. Designing a study protocol

6.1 Selecting an appropriate study design

Study designs are classified in various ways (Figures 1 and 2). As depicted in Figure 1, they may be broadly divided into descriptive and analytic study designs, which, in turn, may be quantitative or qualitative. Because you are expected to use a quantitative study design for the purposes of the DCFM undergraduate research project, this guide focuses on designing a quantitative study.¹

**Descriptive studies** involve assessing a sample at any given time to learn about the characteristics of the population, phenomenon, or observation of interest. There is no comparison group; making causal inferences is not an objective of research. By contrast, analytic studies test hypotheses about exposure-outcome relationships, and involve making comparisons between two or more groups.

![Figure 1. Types of study designs](image)

Epidemiological study designs are mostly quantitative and are divided into **observational** and **experimental** designs (Figure 2). In an observational study, the researcher studies/observes phenomenon but does not alter what occurs. By contrast, the researcher intervenes to assign exposures and observe outcomes in an experimental study (The Open University 2018; University of Ottawa n.d.). Observational studies include cohort studies, case control studies, cross-sectional studies, case reports/case series and ecological studies. Experimental studies include randomized control studies and quasi-randomized control studies (Grand Canyon University n.d.).

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¹ You may combine both quantitative and qualitative methods in a mixed methods design, if you wish to develop your qualitative skills.
Carrying out a **cross-sectional study** involves drawing a sample from the selected study population and recording information from participants in a systematic way during a given time. Thus, cross-sectional studies are well-suited for describing variables and their pattern of distribution. They may be used to determine **prevalence** (the proportion that has a disease/condition at a given time) at either one point in time (point prevalence) or over a defined period of time (period prevalence). Period prevalence is determined when it takes time to obtain sufficient information on a disease in a population, e.g. what proportion of 35 year old women residing in Nallur MOH Area undergo Pap smear over a year.

Cross-sectional studies may be used to examine associations; the prevalence of the outcome is compared to those with and without the exposure. These are called analytic cross-sectional studies. In other words, analytic studies may compare the proportion of exposed persons who are diseased with the proportion of non-exposed persons who are diseased to assess the relationship between exposure and outcome. The labeling of variables as exposures and outcome depend on the cause-effect hypotheses of the researcher. **It is not possible to make causal inferences using a cross-sectional design** (Hulley et al. 2007; Sivagnanasundaram 1999; University of Ottawa n.d.).

The research design you select will depend on your research objectives and the availability of time and funds. Most students select a descriptive cross-sectional study design for the purposes of the DCFM research project. If you decide to undertake a descriptive cross-sectional study, it is desirable to include an analytical component to ensure that you gain some experience with the application of inferential statistics. You may select a different study design (Figure 3), if you wish, but be mindful of the time constraints associated with the research project.
6.2 Defining your study population

The theoretical population is the entire group of people (or objects) you wish to generalize the study findings to. For example, your theoretical population may be adolescents aged 18 years in the Northern Province. The study population is the entire collection of possible observations that you will have access
to (Figure 4). Returning to the same example, the study population could be defined as all Grade 11 students registered at schools in the Northern Province. The study population is made up of study units. Note that the latter do not always refer to people, and may include other units such as families, households, operating theatres, clinics, and so forth (Sivagnanasundaram 1999).

![Diagram of population, study population, and sample]

Figure 4. Theoretical population versus study population versus sample (adapted from Web Centre for Social Research Methods 2006)

### 6.3.1 Inclusion and exclusion criteria

The study population is defined by inclusion and exclusion criteria. Inclusion criteria are attributes of participants that are essential for them to be eligible to participate in the study. For example, the inclusion criteria for a study of knowledge on sexually transmitted infections among 18 year old students in the Northern Province may include: 1) 18th birthday is in 2018; and 2) registration at a school in the Northern Province for at least 2 years. On the other hand, the exclusion criteria are attributes of eligible participants that disallow their participation. Returning to the same example, if the study instrument is a self-administered questionnaire, those who are unable to read and complete a questionnaire on their own may serve as an exclusion criterion. While this would exclude students with severe visual impairment, the ethical implications of exclusion must be considered. Students being absent on the day of data collection and/or unwillingness to participate are not exclusion criteria, and are accounted for by the non-response rate in the sample size calculation.

### 6.4 Selecting your study sample

#### 6.4.1 Estimating sample size

As the entire study population cannot be enumerated in a reasonable period of time, a subset of the population, or a sample, needs to be selected. Before sampling, the researcher must estimate the sample size. At the undergraduate level, you are not expected to be familiar with the complexities of
sample size calculation. But you should be familiar with related concepts that are used in estimating sample size, including effect size, the level of statistical significance, and power.

**Effect size** refers to the size of the association the researcher expects to find in the sample. An expected effect size is included in sample size equations. Researchers can draw on previous studies to make an informed estimation of the effect size, or, when data are not available, undertake a pilot study.

The **level of statistical significance** or \( \alpha (\text{alpha}) \) is the probability of making a Type I error (rejecting the null hypothesis when true – please refer your lecture notes). It is usually set at 0.05, which means the researcher has set 5 per cent as the maximum probability of incorrectly rejecting the null hypothesis.

\( \beta (\text{beta}) \) is the probability of making a Type II error (failing to reject null hypothesis when it is not true). The quantity \((1 - \beta)\) is referred to as the **power** of the study or the probability of correctly rejecting the null hypothesis in the sample if the actual effect in the population is equal to (or greater than) the effect size (Hulley et al. 2007). In other words, the study’s power is the probability that a statistically significant difference is found between the groups when it exists; a greater power requires a larger sample size. \( \beta \) is generally set at 0.2, which means that the researcher is willing to accept a 20 per cent chance of missing an association of a given effect size if it exists. This translates to a power of 80%.

**A key point is that sample size should be estimated in the design phase of the study.** Sample size planning entails selecting an adequate number of subjects to keep \( \alpha \) and \( \beta \) acceptably low within the limits of feasibility. The formula below is used to calculate sample size in a prevalence study:

\[
\begin{align*}
    n & = \frac{Z^2 \times p(1-p)}{d^2} \\
    \text{Where,} & \\
    n & = \text{Sample size} \\
    Z & = \text{Critical value of the normal distribution at } \alpha/2 \text{ (for a confidence level of 95%, } \alpha \text{ is 0.05, and the critical value is 1.96)} \\
    p & = \text{Expected proportion (based on results of a previous survey)} \\
    d & = \text{Acceptable margin of error at 5% (0.05)}
\end{align*}
\]

Remember account for non-responders (a 10% non-response rate should be fine).

Students usually extract the expected proportion from a previous study. The study should preferably be carried out in Sri Lanka. If a similar study has not been undertaken in Sri Lanka, you could use a proportion from a study that has been undertaken in a similar socio-cultural context. If such a study is not available, you may assume the proportion is 50 per cent, which will give you the largest possible sample size.

If a prevalence study seeks to estimate the prevalence of more than one variable (e.g. the prevalence of >1 risk factors for a particular disease), then the sample size for the study should be decided based on the expected proportion of the variable that gives you the largest sample size estimation (Hulley et al. 2007).
Sample size impacts the *margin of error* or the level of precision of a study. A narrower margin of error requires a larger sample size.

**6.4.2 Selecting a sampling technique**

Sampling is the process of selecting study units (e.g. people, households, schools, etc.) from a population of interest. In quantitative research, this is usually undertaken in a manner that allows the researcher to generalize the results to the theoretical population represented by the study population.

**6.4.2.1 Probability sampling**

Sampling methods fall into two broad categories: probability sampling and non-probability sampling. Probability sampling allows researchers to generalize the findings from the study sample to the theoretical population. Probability sampling methods use a random process where each study unit has a specified chance of being included in the sample. It allows for estimating the likelihood of the study findings representing the characteristics of the study population by significance testing and estimation of confidence intervals (Hulley et al. 2007). Widely used methods of probability sampling include: simple random sampling, systematic sampling, stratified random sampling, and cluster sampling.

A **simple random sample** is drawn by listing all study units in the study population and selecting a subset with the help of a random number table or a random number generator. Each member in the study population has an equal chance of being selected to participate in the study (Figure 5). The feasibility of this method is low, particularly in large scale population-based studies where complete lists of study populations (or sampling frames) are not available. Where available, the geographic spread of the population poses practical difficulties for the researcher. However, this method could be used where the sampling frame is readily available and geographic spread is not a concern. For instance, to select a random sample of pregnant women registered with Public Health Midwives in the Nallur MOH Area, you could obtain a list of all pregnant women residing in the Nallur MOH Area during a given time from the Nallur MOH Office and then use a random numbers table to select a random sample.

![Figure 5. Simple random sampling](image)

A **systematic sample** is advantageous when the study population cannot be readily enumerated. Instead of using random numbers, this method uses a pre-defined periodic process (e.g. every third individual – Figure 6) to select the study sample. This process is open to manipulation by the investigator and may
also be influenced by natural periodicities in the population (Hulley et al. 2007). An example of systematic sampling would be to select every third patient who visits the OPD at DH Kondavil. This number is defined based on the estimated sample size and the availability of participants.

A **stratified random sample** allows for stratification of the study population by various characteristics in order to ensure inclusion of subsets of the population that are of interest to the researcher (Hulley et al. 2007). Returning to the example of pregnant women in the Nallur MOH Area, you may wish to study how a variable varies with age. Stratified random sampling would allow you to obtain adequate numbers of pregnant teenagers and pregnant mothers over forty, who may be few in the study population, by dividing the population into subgroups based on age (<20 years, 20-39, ≥ 40 years) and taking a random sample from within each subset of the population (Figure 7). A *proportionate stratified random sample* would include participants in the proportions they represent in the study population, while a *disproportionate sample* would draw the number of participants as required for statistical analysis.

**Cluster sampling** is widely used in population-based research to manage the geographic spread of the population under study. For instance, if you wish to study the nutritional status of O/L students in the Jaffna District, cluster sampling would involve selecting naturally occurring clusters (e.g. schools, classes) rather than randomly selecting participants from a list of all O/L students in the Jaffna district (Figure 8). Cluster sampling may be carried out at multiple stages. Two-stage cluster sampling would involve
selecting a set of clusters from within the selected clusters. For instance, returning to the example of O/L students, the investigators would select schools and then select classes within the selected schools.

Cluster sampling does increase feasibility and substantially lowers costs, but naturally occurring clusters tend to be homogenous, reducing the effective sample size. As the number of stages increases, the cluster effect increases, as does the required sample size (Hulley et al. 2007). In other words, the cluster effect needs to be accounted for in calculating sample size. While there are statistical methods used to calculate the cluster effect, you are not expected to be able to do this at the undergraduate level. Thus, if you use cluster sampling, simply double your estimated sample size to account for the cluster effect.

6.4.2.2 Non-probability sampling methods

Commonly used non-probability sampling methods include: convenience sampling, purposive sampling, and snow-ball sampling. A convenient sample is made up of people who meet the inclusion criteria and are easily accessible to the investigator. An example of convenient sampling is consecutive sampling where participants are selected on a consecutive basis. For instance, the selection of each patient who arrives at the out-patient department of DH Kondavil during a specified period.

Purposive sampling is widely used in qualitative research, and permits the researcher to select participants to serve a specific purpose. For example, in a study of satisfaction among healthcare users at the Teaching Hospital Jaffna, the researcher may want to approach the research question from a spectrum of social positions. This form of purposive sampling is called maximum variation sampling. Purposive sampling may be undertaken to serve other purposes.

Snowball sampling is generally used to access participants who are difficult to reach. For example, we may want to explore the healthcare experiences of a stigmatized population (e.g. LGBTQ persons). It is likely that members of this social group may have contacts with others of a similar orientation. Snowball sampling involves drawing on the networks of participants we recruit to our study to access more participants. It is called snowball sampling because a snowball gathers more snow and becomes larger when it rolls downhill. Whether non-probability sampling is appropriate or not depends on the methodological approach and the purpose of research.
6.5 Defining variables, indicators, and measures

The problem analysis would have led you to identifying several groups of factors that influence/are influenced by the research problem (see Section 4 of the research guide Part II). At this stage, you would have selected the factors that you wish to focus on in your study. This selection should have been guided by a survey of the literature, discussions with experts, and may be even your own experiences. Your literature survey should have covered both international and local literature to ensure you did not miss important factors that are known to influence/be influenced by your research problem.

![Diagram]

Figure 4. From factors to variables, indicators, and measures
In quantitative research, these factors are converted into variables, and the variables are subsequently operationalized into indicators and measures (Figure 4). Variables take on varying values; they may be a characteristic, object or phenomenon that is measurable. For example, sociodemographic factors, such as age, sex/gender, education level, and income level, are variables.

Variables are classified as categorical (qualitative) and numerical (quantitative) variables (Figure 10). In turn, categorical variables may be divided into nominal and ordinal variables. Nominal variables have two or more categories that cannot be ordered (e.g. sex/gender, ethnicity, stream of study, etc.). Ordinal variables have two or more ordered categories that may be arranged from highest to lowest or vice versa (e.g. education level, stress levels, etc.).

Numerical variables are divided into discrete and continuous variables. Discrete variables are those that can take a finite number of values; they do not have values between values (e.g. number of children in a family → may be 1 or 2 but not 1.5). By contrast, continuous variables may take on an infinite number of values between values (e.g. weight, height → may be 1 or 2 and 1.1, 1.11, and so on).

Variables may also be classified as: independent, dependent, and controlling variables. Understanding the difference between independent and dependent variables is important. The researcher designs the study to observe changes in the dependent variable by using varying values of the independent variable (Singh et al. 2006). For example, the researcher may select participants of various age groups (independent) to find out how diet (dependent) may change with age.

Controlling variables are extraneous variables that the researcher does not wish to investigate. However, these variables need to be kept constant to investigate the true nature of the relationship between independent and dependent variables. For instance, in the study on diet and age, family income may influence the availability of food and, in turn, diet, and may need to be controlled for. You are not expected to control for variables for the purposes of the undergraduate research project.
Indicators are formed by defining and stating variables in operational terms (Sivagnanasundaram 1999). In developing indicators, you need to clearly define the variables and their attributes. An attribute is a specific value of a variable. The attributes of a variable must include all possible responses (‘exhaustive’) and respondents should not be able to respond to two attributes simultaneously (‘mutually exhaustive’) (Web Centre for Social Research Methods 2006a).

For example, tobacco use (variable) may be operationalized as ‘smoking status’ (indicator) and could have two attributes: ‘smoker’ and ‘non-smoker.’ You would need to clearly define a smoker and a non-smoker in a way that ensures that research participants cannot belong to both categories. For example, the attributes of ‘smoking status’ may need to be updated to ‘current smoker’ and ‘current non-smoker’ to make sure that non-smokers with a history of smoking can only belong to one category. The purpose is to operationalize the variables in such a way that makes absolutely clear how you intend to measure each variable (McLeod 2008; Sivagnanasundaram 1999).

Table 1. Variables and their measurement

<table>
<thead>
<tr>
<th>Variable</th>
<th>Definition of variable</th>
<th>Scale of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Child’s age at admission to hospital, calculated from date of birth and date of admission.</td>
<td>Months and years</td>
</tr>
<tr>
<td>Patient has dengue fever</td>
<td>Dengue fever confirmed by serology (IgM positive or four-fold rise in IgG titre) or virology.</td>
<td>Yes/No/Not available</td>
</tr>
<tr>
<td>Social class</td>
<td>Head of household’s main occupation as stated by respondent in answer to a question in a structured questionnaire.</td>
<td>Detailed occupation, classified into social class I - V</td>
</tr>
<tr>
<td>Haemoglobin</td>
<td>Haemoglobin concentration in capillary blood, measured by haemoglobinometer.</td>
<td>g/dl</td>
</tr>
</tbody>
</table>

Source: Extracted from Singh et al. (2008)

Measurement scales have their basis in the type of variable that is to be measured (Singh et al. 2008). Four scales of measurement are widely used in quantitative research: nominal, ordinal, interval and ratio. Nominal scales measure categorical data by simply assigning numbers to names or other identifiers, which have no rank/order (e.g. male-1/female-2 or yes-1/no-2). Ordinal scales order a series of relationships, such as ranked categories (e.g., socio-economic status (I-2 to V-5). The interval between two ranks is not equal in ordinal scales.

Interval scales measure quantities and consist of equal units, but zero represents simply an additional point of measurement (e.g. Fahrenheit scale). The ratio scale is similar to the interval scale in that it also represents quantity and comprises equal units, but it always has an absolute zero. Physical measures generally represent ratio data (e.g. height and weight). A few examples of variables, their operationalization and scales of measurement are presented in Table 1.
Researchers may group ratio data into categories for the purposes of measurement. For example, age could be measured in months and years and converted into age groups. By grouping, ratio data may be transformed into ordinal data where the difference in age between age groups cannot be quantified in a meaningful way. However, it is always desirable to collect higher level data (age in months and years) and convert them to categories, instead of measuring age as a category in the study instrument. This way you would be able to use both grouped and ungrouped data as required (Cornell University n.d.).

6.5.1 Some tips on questionnaire development

Once variables are operationalized and scales of measurement selected, the next step is to develop your study instrument(s). Students tend to use questionnaires, data extraction forms, checklists, and/or portable measuring tools (e.g. weighing scales, Snellen chart, etc.) in the research project.

Before developing a questionnaire, you should consider whether a questionnaire is the most appropriate tool to collect the required information. For instance, if you intend to assess academic performance by term test marks, a self-administered questionnaire may not be the best method to obtain this information. Instead, you could extract the marks from school registers (after obtaining permission and consent as required, of course). Similarly, measuring height and weight of participants instead of asking participants for their height and weight will increase the validity of your study.

Once you confirm that you will use a questionnaire, the next step is to decide whether it will be self-administered or interviewer-administered. The advantages of each are listed below on Table 2.

### Table 2. Comparison of self-administered and interviewer-administered questionnaires

<table>
<thead>
<tr>
<th>Self-administered questionnaires</th>
<th>Interviewer-administered questionnaires</th>
</tr>
</thead>
<tbody>
<tr>
<td>No interviewer bias</td>
<td>Respondent literacy is not necessary</td>
</tr>
<tr>
<td>Less time spent on administration</td>
<td>Questions and responses can be clarified by interviewer</td>
</tr>
<tr>
<td>Easier to question larger numbers of people</td>
<td>Fewer blanks; allows probing for additional information</td>
</tr>
<tr>
<td>May permit more careful responding</td>
<td>Complex and open-ended questions are possible</td>
</tr>
<tr>
<td>More anonymity; may yield higher quality data on sensitive issues</td>
<td>Answering of questionnaire by intended person is assured</td>
</tr>
<tr>
<td>Printed visual aids may be incorporated</td>
<td>Participation may be increased by personal contact</td>
</tr>
</tbody>
</table>

Adapted from WHO (n.d.).

You may either use a validated measurement tool that already exists (these may need to be adapted to the context) or develop your own questionnaire. At the undergraduate level, you are not expected to validate your questionnaire in a comprehensive way, but you need ensure that your tool is assessed for content validity and be familiar with other concepts related to validity (see Section 6.5.2).

Seeking guidance when developing your questionnaire will facilitate smoother ERC approval. You can also follow the guidelines provided in Chapter 10 of *The Medical Research Handbook* (Singh et al. 2008). You need to ensure that questions are clear, easy to understand, and appropriate to the respondent’s level of education. The layout should be easy to read and the questions must be placed in logical sequence so that the respondent does not have to move back and forth unnecessarily between topics. The questionnaire should not be unnecessarily intrusive or lengthy, and should not include extraneous
sections that do not help you to achieve your specific objectives. If translation is required, please translate from English to Tamil and back-translate to improve accuracy of the translation.

6.5.2 Assessing validity and reliability

Validity refers to the tool’s ability to measure what needs to be measured accurately. Important dimensions of validity include: content validity (including face validity), criterion-related validity, and construct validity. You are expected to address content and face validity.

Content validity refers to the extent to which the measurement covers all aspects of the phenomenon of interest. Face validity, a component of content validity, refers to the extent to which a tool appears valid at face value. Addressing the aspects outlined in Section 6.5.1 and asking an expert to review your questionnaire/study tool will enable you to improve content and face validity. Please note that a comprehensive problem analysis at the initial stages of research will help you improve content validity.

Criterion-related validity refers to the extent to which the measurement obtained from the tool correlates with proven measures. This is usually measured against an external criterion. For instance, self-reported data on sanitary facilities obtained from a questionnaire can be validated by reviewing census data. You are not expected to assess criterion-related validity.

Construct validity addresses the extent to which the assumptions of the tool conform to theoretical constructs. For instance, if a questionnaire is developed to measure knowledge on dental caries and it is hypothesized that high knowledge scores are associated with fewer dental caries, the questionnaire would demonstrate construct validity if there is a marked difference in the number of dental caries in those who obtain high and low knowledge scores. You are not expected to assess construct validity.

Reliability refers to the tool’s precision or its ability to obtain nearly the same value each time the variable is measured. Precision of an instrument is affected by observer variability (due to researcher), subject variability (variability in study subjects), or variability of the environment (Hulley et al. 2007). You are not expected to assess the reliability of your study tool.

Suggested reading:


6.6 Planning for data collection

The selection of data collection methods depends on the study objectives, how others have answered similar questions in previous work, opinions of experts, and feasibility concerns. Students generally use self- or interviewer-administered questionnaires and/or basic clinical measures to collect data. However, you are encouraged to explore other methods if you wish. By the time you submit your draft proposal, you should have planned the data collection process thoroughly.

6.6.1 Pilot study

You are expected to carry out a pilot study - a small scale preliminary trial on a sample recruited from a different study population (not a pre-test, which is a trial of a data collection technique)—before data collection proper. The purpose is to implement your research protocol to identify problems with the study design, and make amendments accordingly. Please note that you must collect data and analyze them as part of your pilot study. The pilot study is extremely important because it enables you to make adjustments in both your study design and study instruments.

6.7 Planning data analysis

Data analysis should be planned at the proposal stage. Dummy tables are useful for planning your analysis. Dummy tables do not contain any numbers. They help the researcher plan the analysis based on the specific objectives of the study. In creating dummy tables, you should address the following: Which descriptive statistical methods will be used for analysis of which variables? How will the descriptive data be presented? Which inferential statistical methods will be used for analysis of which variables? How will they be presented? It will be helpful to go back to the literature for ideas on data presentation.

Please note that the dummy tables should address both descriptive and analytical components of the study, and should include tables/charts/graphs, cross tabulations for associations, including the tests to be used to assess statistical significance. Note that you are expected to formulate your data analysis plan at the proposal stage, and include it in your research proposal. The details below are provided for guidance.

6.7.1 Descriptive statistics

Descriptive statistics allow you to summarize large amounts of data and present them in ways that are easily accessible. They describe the sample under study and are specific to the sample – they do not aim to generalize the results to the theoretical population. Widely used descriptive statistics include measures of frequency (e.g. percentages, proportions), measures of central tendency (e.g. mean, median, and mode), measures of dispersion (e.g. range, variance, and standard deviation), and measures of position (interquartile range, percentiles) (Campus Labs 2018). You are expected to present...
your descriptive data in clear and accessible ways. Tables and diagrams (e.g., bar charts, pie charts, histograms, box plots, etc.) may be helpful (Duke University 2017; Sivagnanasundaram 1999).

6.7.2 Inferential statistics

Inferential statistics are used when you want to move beyond simple description and draw conclusions based on your data. They help you to make comparisons (by different groups and even across time) or make predictions based on data that has been collected. These predictions (inferences) are about the theoretical population. Inferential statistical tests may be broadly divided into parametric and non-parametric tests. Parametric tests assume a normally distributed or symmetric outcome variable, while non-parametric tests do not make this assumption (Marshall n.d.). Various algorithms have been developed to guide selection of statistical tests (Gonzalez-Chica et al. 2015; Vassarstats n.d).

Students generally use the Chi-Square test and/or Student’s t-test for inferential statistical analysis. However, you are encouraged to use other tests, if necessary. The Chi-Square test is a non-parametric test that is used to assess whether the relationship between two categorical variables is significant. It may be used regardless of the number of categories of the outcome or the exposure variables. Its assumptions include: 1) the two variables are measured at an ordinal or nominal level (i.e., categorical data); 2) the data in the cells are frequencies, or counts of cases; 3) the levels (or categories) of the variables are mutually exclusive – that is, a particular subject fits into only one level of each of the variables; 4) no expected value in the contingency table is equal to 0; and 5) the frequencies in the contingency table may not be lower than five in more than 20% of cases (none of the expected values for dichotomous exposure and outcome measurements may be <5). If frequencies are lower than this, the Chi-square test with Yates’ continuity correction (when the total sample size is greater than 20) or Fisher's exact test may be used (Gonzalez-Chica et al. 2015; Laerd Statistics 2013; Marshall n.d.).

The independent t-test is a parametric test that may be used to compare the means of two unrelated groups. It assumes, 1) the dependent variable is measured on a continuous scale (i.e., interval or ratio level); 2) the independent variable consists of two categorical, independent groups; 3) there is independence of observations, which means there is no relationship between the observations in each group or between the groups – this means there must be different participants in each group with no participant being in more than one group (if this is not the case, another statistical test such as the paired-samples t-test may be required); 4) there are no significant outliers; 5) the dependent variable is approximately normally distributed for each group of the independent variable (this may be tested using the Shapiro-Wilk test of normality on SPSS); and 6) there is homogeneity of variances (this may be tested using Levene’s test for homogeneity of variances on SPSS) (Laerd Statistics 2013).

The Pearson’s correlation is a measure of the strength and direction of association that exists between two continuous variables. It assumes, 1) the two variables are continuous; 2) there is a linear relationship between the two variables (may be checked with a scatter plot on SPSS); 3) there are no outliers; and 4) that the variables are normally distributed (Laerd Statistics 2013). The test is used when both variables are measured by the researcher. If the researcher manipulates one of the variables, simple linear regression is the preferred statistical method.
Stating you will use SPSS for analysis is inadequate as a data analysis plan. You need to specify which descriptive and inferential statistical methods you will use in your analysis.

Suggested reading:


6.8 Ethical considerations

You are expected to think through the ethical implications of your research. Please pay attention to the following areas: informed consent, voluntary participation (and withdrawal without penalty), privacy and confidentiality, assessment of risk and benefits of participation, medical/psychological support for participants (if necessary), complaint procedures, fate of data, and plans for data dissemination.

7. Writing up the research proposal for first submission

The research proposal should consist of 8-10 pages (excluding annexure), be printed on both sides with 1.5 spacing and 3 cm margins, and Times Roman font size 12. It should contain the following sections:

1. Cover page

This should include the title of project, your names and registration numbers, names and signatures of your supervisors, and the place and date of submission. Please insert the following statement at the bottom of the page:

“This Research Proposal is submitted as a requirement in Community Medicine at the Second Examination for Medical Degrees [YEAR]”

2. Summary

This section should provide a brief overview of your project. It should introduce the research problem, state the general and specific objectives, and briefly describe how you intend to achieve your objectives (methods). It should end with a short description of the possible uses of the study findings.
A Step-by-Step Research Guide for Medical Students – Sections 6 and 7
Department of Community and Family Medicine, Faculty of Medicine, University of Jaffna

3. Introduction

The introduction should consist of the background, justification, and objectives. The background is essentially where you introduce the research problem and other related concepts the reviewer needs to be familiarized with to understand the contents of your proposal. The justification should explain the importance of carrying out your research, particularly in relation to the research setting. The introduction should end with a clear statement of the general and specific objectives, presented in numbers. A good background and justification flow naturally to the objectives.

4. Literature review

At the proposal writing stage, you would have performed a comprehensive survey of the literature. The literature review presents the current state of knowledge on your topic obtained through the literature survey. A common mistake is to confine the literature review to journal publications accessible via Google or Google Scholar. You are expected to widen the literature search to other online databases (e.g. PubMed) and local literature that may not show up on these data bases. Sri Lanka Journals Online provides open access to journals published in Sri Lanka. Visiting the library or contacting local authorities or reviewing past undergraduate research reports will give you a better understanding of the local context in relation to your research problem, and will make your literature review much stronger.

The purpose of a literature review is to critically engage with the literature and present it in a way that sets up the study that is to be undertaken. Do not cut and paste a set of abstracts that use similar research methods. Please note it is not acceptable to ‘cut and paste’ from online sources (see Section 7.1).

By the time you write up your research proposal, you would have analyzed the research problem and developed your research objectives. You should organize the literature review into themes according to the research objectives. For example, a research group in the 36th Batch carried out a study on the prevalence and severity of dysmenorrhoea and associated menstrual characteristics among A/L students in the Jaffna Educational Division. The literature review for this study could be organized under the following subsections:

- Prevalence and severity of dysmenorrhoea (presented in a manner that justifies selected age group and highlights gaps in the literature on dysmenorrhoea in Jaffna/Northern Province);
- Factors influencing the prevalence and severity of dysmenorrhoea (presented in a manner that justifies focus on menstrual characteristics over other associated factors in the study);
- Approaches to assess measure the presence and severity of dysmenorrhoea (presented in a manner that suggests that you are familiar with standard approaches/tools used to measure the presence and severity of dysmenorrhoea)

Organizing the literature review in this way allows the reader to gain an understanding of the status of knowledge on the topic as relevant to the research objectives. Writing up a strong literature review at this stage will not only make a stronger research proposal but will also save you time on the long run as you would not need to work on expanding and improving this section in the final research report.
5. Methods

Your methods section should be finalized by the time you submit your proposal. This section should clearly lay out how you intend to achieve your objectives, and should address:

5.1 Study design

State the study design you will adopt (see Figures 1 and 2). For the purposes of the undergraduate research project, most students use a cross-sectional study design.

5.2 Study setting

State the location(s) in which you will carry out research with some descriptive details.

5.3 Study population

State the study population.

5.4 Sampling

5.4.1 Estimated sample size

Estimate the sample size assuming that you will use a probability method of sampling (see 6.4.1). You are not expected to be familiar with the various sample size equations that are used in quantitative research. DCFM expects you to estimate sample size using the sample size equation for a descriptive cross-sectional study (see Section 6.4.1). If you are using a different study design, and hope to have your findings published, please seek further guidance on sample size estimation.

5.4.2 Expected sample size

You should estimate what your sample size will be considering the limited time you have for data collection and the feasibility of accessing participants. For example, if you carry out a clinic-based study, estimate the achievable sample size by multiplying the number of clinics that will be conducted during the data collection period by the average number of patients attending each clinic (this information can be obtained from the clinic). If the numbers are less than your estimated sample size, state that you will include all patients who attend the relevant clinics during the data collection period. If the numbers exceed your estimated sample size, you may adopt a suitable probability sampling method to select your sample.

5.4.3 Sampling technique

State your sampling method and describe how you will carry out your sampling.

5.5 Study instrument(s)

Provide details about your study instrument(s). Your questionnaires/data extraction forms/check lists should be annexed to your proposal. Remember to reference the relevant annex in brackets.

5.6 Data collection (including pilot study)

Provide details about your intended pilot study and your plans for data collection.

5.7 Data analysis
Provide details about your data analysis plan, including the descriptive and inferential statistical methods you will use. **Please note that stating you will use SPSS to analyze your data is insufficient.**

5.8 Ethical considerations and permissions

Please follow the guidelines set by the Ethics Review Committee, Faculty of Medicine, University of Jaffna, and use the templates provided by the ERC when developing the informed consent forms, available here. Include consent forms for illiterate participants, if you expect that such persons may participate in your study. If persons of <18 years of age are expected to participate, include informed consent forms for parents and assent forms for participants. Please annex all forms to your proposal.

State your plans for obtaining permission from the relevant authorities, as applicable.

6. **Timeline**

Include a Gantt chart to indicate the intended time frame for data collection, analysis, and write up of the final research report. Please consider the timeline provided by the department.

7. **Budget**

Anticipated expenses and sources of funding (if applicable) should be included.

8. **Annexure**

Questionnaires, data extraction forms, checklists, other tools (if applicable), informed consent forms, and assent forms (if applicable) must be appended.

Please see the sample research proposals included at the end of The Medical Research Handbook: Planning a Research Project (Singhe et al. 2008) and the other references listed below for guidance.

**Suggested reading:**

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3282423/.

Biribo, S. (2016). Guidelines for the development of a health research proposal

University of Nevada, Reno (n.d.). Undergraduate research: Prepare your research proposal
https://www.unr.edu/undergradresearch/proposal.


7.1 A note on plagiarism

The work you submit must be your own. **Please do not ‘cut and paste’ from online resources.** Any proposal containing ‘cut and pasted’ material will be returned, and the proposal will need to be resubmitted. Cutting and pasting is a form of plagiarism. As a medical student you are expected to understand that any form of plagiarism is unacceptable and will not be tolerated.

**Suggested reading:**

https://www.ox.ac.uk/students/academic/guidance/skills/plagiarism?wssl=1.
7.2 Referencing style

You are expected to use Harvard referencing style consistently throughout your research proposal. Pay attention to both in-text citations and your reference list.

Suggested reading:
Vancouver Community College (2012). Harvard Citation Style http://library.vcc.ca/media/vcc-library/content-assets/documents/Research_VCCStyleGuideToHarvard.pdf

7.3 Mendeley Reference Management Software

Reference management software helps researchers at all levels store, track, and cite reference information about their research materials, including books, journal articles, archives, interviews, maps, works of art, and many other types of materials. There are many types of software available, some of them, such as Mendeley, available at no cost to the researcher (Imperial College 2017). DCFM expects you to gain experience using Mendeley in your research activities. The software may be downloaded free-of-charge here. Guidance for working with Mendeley is available here.

Suggested reading: