Altamash Institute of Dental Medicine Research Development and Evaluation Committee

Research design

You may need to split into phases of study

You may use these type of study designs:

- 1) Cross sectional study: Including questionnaire based study and study that use secondary data.
- 2) Cohort or prospective study.
- 3) Case control study.
- 4) *Interventional study:* Non-randomized controlled trial, randomized controlled trial, interventional study without control, any matching or blinding applied.

Study area

Where will you collect your data? Introduce the place if necessary.

Study population

Reference population: The overall or big population that your study findings is able to represent. Must be appropriate for the level of your study design.

e.g. Periodontitis patients.

Target population: The specific target group that you will recruit from the source population (Target population may be similar to reference population in small scale study)

e.g. Periodontitis patients who attended outpatient AIDM hospital.

Source population / sampling pool: The source where your subject will be recruited

e.g. Periodontitis patients attending Hospital/College OPD.

Sampling frame: The list / register from where you will sample your subject

e.g. AIDM attendance list for Periodontitis patients.

Subject criteria

Inclusion & exclusion criteria (for each group if more than one group)

Sample size estimation

Estimate sample size for each objective as much as possible. Add if necessary, sample size estimation when considering nonresponse or drop out percentage.

State the software/formula used and the measures used to calculate. State the 95% CI, power of study 80%.

Sampling method and subject recruitment

Sampling method – how you select a subject from the sampling frame.

Research tool

List all research tool(s) and its validity, reliability, or source whenever applicable.

Operational definition

Definition of certain category used in your study.

Data collection method

How you will collect the data, may be written in phases. What EACH subject will undergo, and the quality assurance of data collected.

How you handle sample – ensuring confidentiality, labelling, sample flow chain and storage, sample destruction post study (whenever applicable). This is applicable in both the interventional and non-interventional and allows researcher to explain how they store specimens collected from subjects. Mainly this is related to privacy protection.

Study flowchart

Diagrammatic illustration of the how the study will be conducted.

Data analysis

You may use these as a general template for descriptive statistics [note that software & its version may need to be revised accordingly]

Data will be entered and analyzed using SPSS version 25. Descriptive statistics will be used to summarize the socio-demographic characteristics of subjects. Numerical data will be presented as mean (SD), or median based on their normality distribution. Categorical data will be presented as frequency (percentage).

State statistical analysis to be used for each objective.

Expected result(s)

Dummy tables

Gantt chart & milestone

- *Provide table to illustrate the time plan of study process according to month and year in line with the study duration.*
- *Milestone of study progress may be presented as monthly or 3-monthly.*

Budget proposal [If applicable]:

State your grant type application and its status as well as the budget estimates. Please attached research grant approval if applicable.

Ethical consideration(s) [if applicable]:

1. Subject vulnerability

Identify and state how you are going to handle the issue. A participant is considered vulnerable if his/her ability to give true and informed consent has a potential for abuse and exploitation due to conditions such as:

- 1) They lack capacity to give consent such as people with mental problem.
- 2) There is an increase in susceptibility to coercion or exploitation.
- 3) There is increased risk of harm. [Taylor, 2004; Lange et al, 2013]

Vulnerable groups include those who are:

1. Economically and medically disadvantage

2. Unable to give or refuse consent for themselves. These may include the underage, women and elderly.

- *3. not getting any benefit personally from the research*
- 4. whom the research is combine with care. [Carl H. Coleman, 2009]

Please state how you will handle the vulnerability issues:

Example:

1. The subject is a patient under your care as a doctor. However, the patient will be given full freedom to participate or not without affecting his/her medical condition management and care.

2. The subject is your subordinate in your entity of management. The data will be independent and will not be disclose to the management authority to be used for any achievement assessment and decision related to work.

2. Declaration of absence of conflict of interest

Conflict of interest (COI) is any circumstances by other secondary bodies that may create influence on researcher's professional judgements or actions on the conduct of the study procedure or the interpretation and reporting the study findings. These may include:

- 1. Payment to researcher(s) in company driven study.
- 2. Benefits in any form of any researchers in the team from the study findings

Declare the relevant situation and your absence of COI.

State how you will ensure and preserved study integrity.

3. Privacy and confidentiality

You may use these as a general template [note that this is only for the confidentiality of the data that you have collected. You may need to add relevant information accordingly]

All forms are anonymous and will be entered into SPSS software. Only research team members can access the data. Data will be presented as grouped data and will not identify the responders individually.

State feedback to subject if applicable

Please add relevant information with regard to your study

4. Community sensitivities and benefits

If applicable in case of issues that can triggers social stigma, etc.

This study will benefit the community By (please state if you plan to give feedback to subject).

Example:

The questionnaire or interview questions may cause distress or anxiety or are socially sensitive. Explain how you will minimize the sensitivity.

5. Honorarium and incentives

Example:

- 1. Token of appreciation will be given to all responders.
- 2. Cost for transportation will be covered by the research funding.

6. Other ethical review board approval [if

applicable] Please state

- *i. The name of the relevant board*
- *ii.* Status of application pending or approve. If approved, please attach the approval letter.

References

List all references for this study proposal.