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Methods and Biostatistics: Common Shortcomings and Ways to Overcome Them

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Abstract—*All research papers include a method section. This section is of utmost importance to the scientific community as they facilitate reproducibility and replicability of the results (1). However, the rejection rate of scientific papers due to the method section is 30% (2) .*

Also unlike other science fields the method section of biostatistics is quite an upheaval task for a researcher due to its multitude of concepts and statistics(3). This paper aims to facilitate the process by pointing out common shortcomings and giving a brief and comprehensive view into each component via diagrams and flowcharts.
Furthermore the tailor made questionnaires provide a quick checklist and are a great resource for any researcher as it helps to make sure that no component of the methods section is left out or overlooked. Thus maximizing productivity and enhancing quality and accuracy. Also, various components of biostatistics literature and a multitude of papers talk about these components individually, but very few of them mention them collectively and rarely endeavor bringing these components of methods together and easing the complexity and facilitating approach by means of tools in a wholesome manner.

Keywords*: Biostatistics, methods, shortcomings, tailor made questionnaires, flowchart.*

1. INTRODUCTION

The Method Section of Biostatistics is a complex one. Due to the complexity the scope of errors is vast and there is a wide consensus stating the prevalence of these errors and shortcomings in medical research (3)(4)(5). This is a serious issue because if the methodology is flawed the results and conclusions are bound to be flawed. This paper discusses **10 components** with flowcharts, checklists and illustrative diagrams with the purpose to make the task of tackling the method section of biostatistics easier and help the researcher to focus on what's important and apply it with more discretion. Also, the common **Shortcomings/Pitfalls** are discussed in Biostatistics literature and papers, but all ten components are never collectively addressed. While the researcher while conducting his/her research has to face it collectively. This paper aims to do so by means of **flowcharts, simple illustrative diagrams and quick yet detailed list** of shortcomings that a researcher should look for. Also, efforts with the same motive have been done in the past but to no avail(3)(6).

Also, the paper is written keeping a beginner in mind who doesn't has any pre requisite knowledge of the field and hence can be used by a wide number of researchers (Biomedical researchers, Clinicians etc.). Although a wide number of Statistical software are available however **problem** can still arise in terms of data interpretation due to underlying insufficient statistical knowledge of basic statistical concepts(3). Furthermore, a basic understanding /Functional knowledge that this paper aims to provide is necessary because consulting **a biostatistician** takes place at a really far along stage and it makes it difficult to straighten out the shortcomings that occur in the earlier phase of investigation(7)(3).

2. COMPONENTS OF METHOD SECTION

The method section of a biostatistics paper is different than that of other sciences. It is comprised of the following components (**1) Hypothesis (2)Study Design (3)Protocol design (4)Participants/ Subjects (Sampling and Sample size justification) (5)Intervention (6) Ethical Clearance (7) Procedure (Data collection and Observation, Data analysis plan (8) Data collection (9) Statistical tests and Data Interpretation (10) Outcome/ Conclusion or findings reported**. The inter relationship of these components is explained in Fig 1.

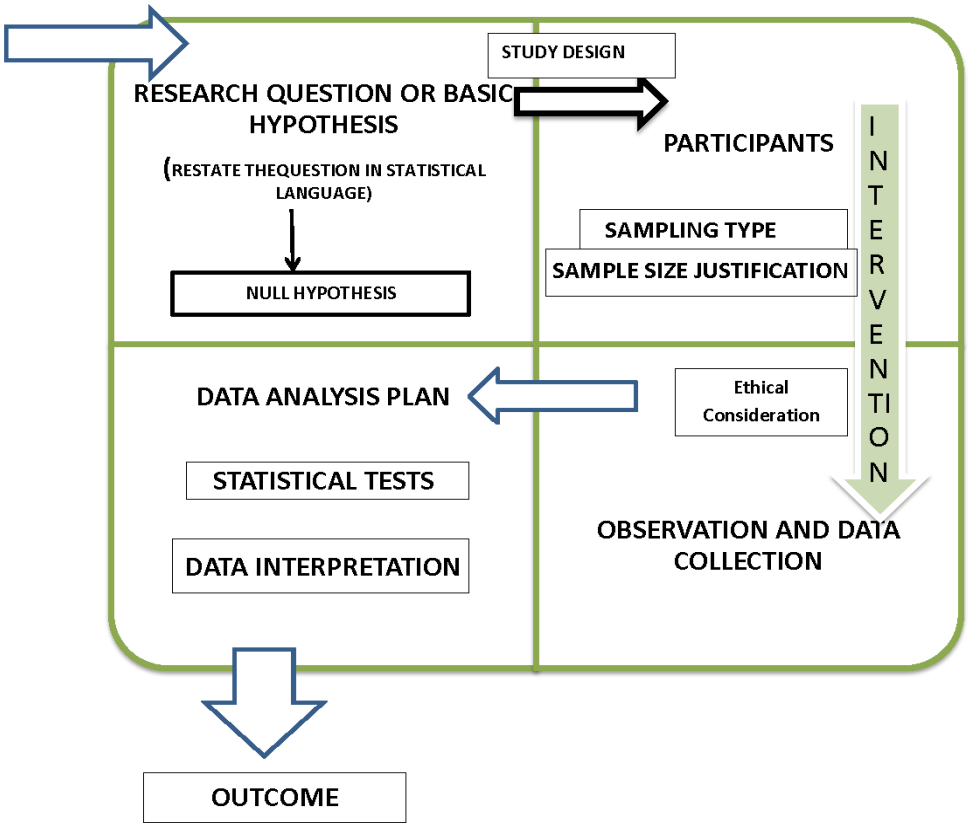

Figure 1: Interrelationship Matrix

The Explanation of these components is as follows:-

1. Hypothesis

The soundness of a hypothesis is based on the aptness of the research question. It should be simple, specific and stated in advance(8)(9) .The **Null Hypothesis** states that there is no association between the predictor and outcome variables in the population(9).While the **alternative hypothesis** states that there is an association.The alternative hypothesis cannot be tested directly,it is only accepted if the null hypothesis is rejected(9).

2. Study design

Study design is the procedure under which the study is carried out. Bless, Higson-Smith and Kagee (2006:71) define research design as "… operations to be performed, in order to test a specific hypothesis under a given condition"(10).It is further classified as Observational And Experimental . The observational research design is further classified into Cross Sectional, Survey based, Cohort study and Case control study. The experimental research study design is further classified as RCT(Randomized Controlled trial) and Quasi experimental study design (11).

3. Protocol design (1)(12)

A research protocol is basically a meticulous plan of study(1).

Why is it important

1. It aids clarity and encourages meticulous thinking.

2. Its an integral part of the research proposal and a conduit for funding.

3. It is a necessary aid to obtain the ethical approval as it showcases the technical know-how and aim of the study. The description should give a meticulous and a detailed account of the baseline measurements followed by a meticulous descriptions of independent and dependent variables.

4. Participants/Subjects

A sample can be defined as a unit of observation (13). The selection of a sample is important so as to reduce, limit and specify the number of subjects without biasing the findings. The sampling is of two types Random and Non random(13)(14)(15)(16).

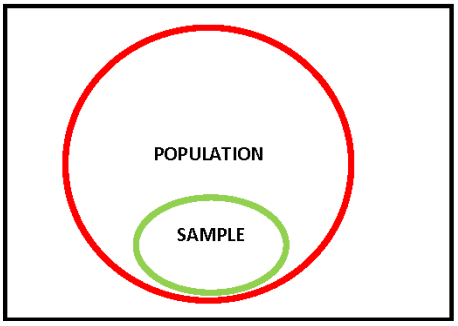

Figure 2 : Population and sample diagram

To understand the different types of sampling, refer to the figure below.

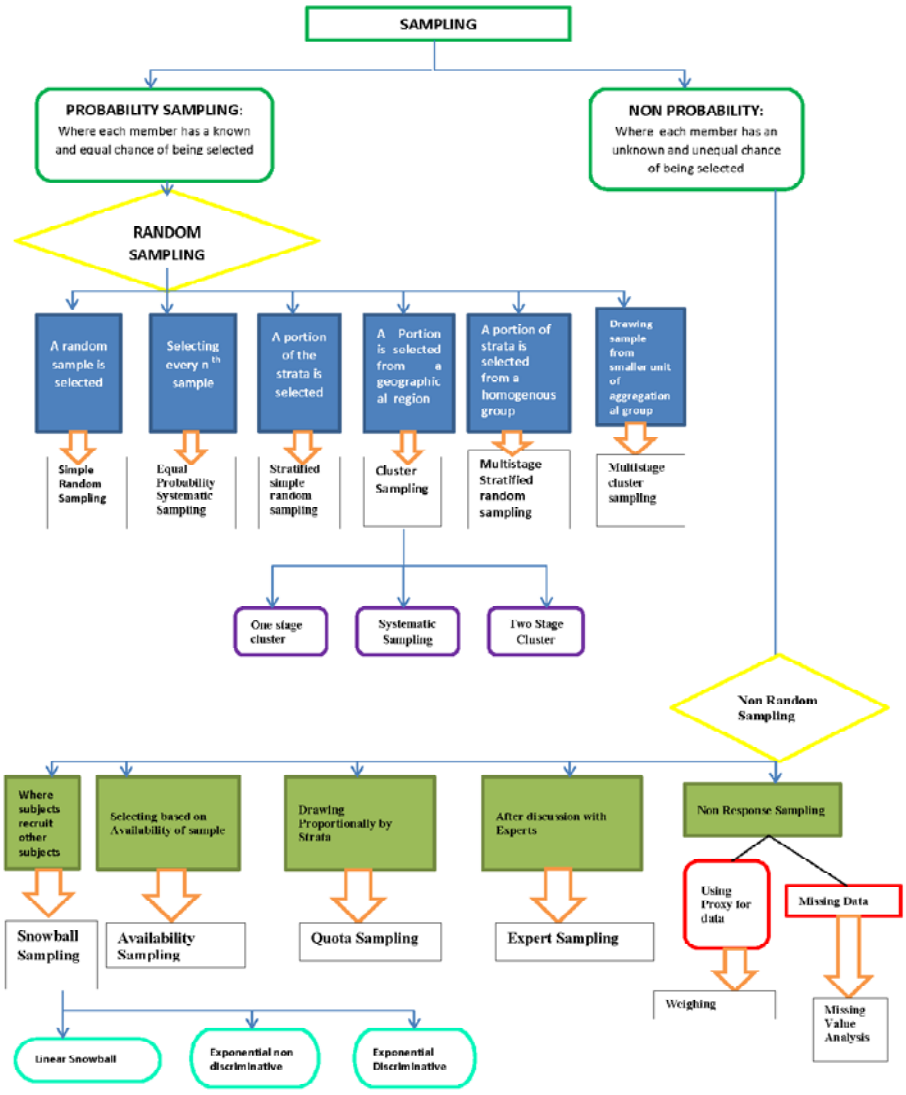

Figure 3: Sampling flowchart

SAMPLE SIZE CALCULATION

To ensure the sample is neither too small nor too large. Also, it should be calculated when changes are possible.it is important to make sure that the sample at hand is sufficiently large to test the hypothesis. It is ideal to calculate a varying range of sample sizes for varying range of assumptions and select the most suitable one from the range (16)(17)(8)(18)(19).

One should keep three components in mind:-

1. Planning value

2. Desired Margin Of Error

3. Confidence Interval

Formula For Calculating A Sample For Proportions

$$n_0 = \frac{Z^2 pq}{e^2}$$

Which is valid where n0 is the sample size, Z2 is the abscissa of the normal curve that cuts off an area α at the tails (1 - α equals the desired confidence level, e.g., 95%)1, e is the desired level of precision, p is the estimated proportion of an attribute that is present in the population, and q is 1-p. The value for Z is found in statistical tables which contain the area under the normal curve (16).

Other than this different formulas are used according to proportion, mean etc. examples of a few of them are E.g. **Simplified Formula For Proportions, Finite Population Correction For Proportion, Sample Size For The Mean** (16)**.**

5. INTERVENTION

Webster dictionary defines in intervention as "the act of interfering with the outcome or course especially of a condition or process so as to prevent harm or improve functioning".

In a biostatistics study research why a particular intervention was used should always be defined.

Generally the choice of intervention should explain its advantages over other factors or over established interventions(cost, side effects, ease of administration, or compliance (19)(20). The nature of the intervention should always be specified e.g. visual ,surgical, audio etc. The mode of intervention e.g. In case of a drug then mode of intervention could be oral, intravenous, nasal etc. and who shall be delivering the intervention e.g. health professional, social health worker, trained professional, community worker etc. should be mentioned(13). Also, two important things should always be kept in mind by the researcher i.e. informed consent and ethical clearance (21).

6. ETHICAL CLEARANCE

Other than the ethical clearance from the ethics committee A Participant Release form should be attached .It should comprise of details like (1) Right To Refusal (2)An explanation of the risks and Potential Discomfort (3) Opportunity to Withdraw without Penalty (4) Feedback(13). Even for noninvasive studies ethical clearance should be obtained as even the noninvasive studies can be detrimental to the psyche (20)(22).

7. PROCEDURE

This section is composed of two elements **DATA COLLECTION AND OBSERVATION,AND DATA ANALYSIS PLAN.** This section provides a comprehensive account of a systematic sequence of the exact steps taken to **contact the participants, Obtain Cooperation and administer the intervention**. It should give a meticulous account of when, where and how the data was collected .However, for the sake ofbetter understanding Data collection will be talked about in a separate section.The procedure should also include steps that are **pre requisite to conduct data collection**(23)(15)(24)**.**

DATA ANALYSIS PLAN(15)(13)(25)

It should ideally have two phases:-

(1)Organizing the data analyses

(2)Describing the data type(Qualitative/ Quantitative).

(3) Tools e.g. Spreadsheets, Statistical packages, Qualitative Data analysis tools (eg. N_6)

8. DATA COLLECTION(26)(27)(28)

The main **data collection techniques** used should be mentioned with justification (29). It can be in the form of **semi structured interview, participant observation, group discussion ,Telephonic or mail survey**.it can also be in the form of accessing existing database (30).After data collection the next step is data analysis. The last steps include how the data was obtained, what statistical tests were applied and the p value hence obtained and its inference.

9. DATA ANALYSIS

The last steps include how the data was obtained, what statistical tests were applied and the p value hence obtained and its inference. You should also indicate the statistical procedures used to analyze your results, including the probability level at which you determined significance (usually at 0.05 probability) (16)(26)(27).

STATISTICAL TESTS

One of the biggest challenge a researcher faces when encountered with data analysis, whether in biostatistics or in various arenas of biomedical research is understanding the application of various statistical tests.

For a better understanding refer to Fig. 4.

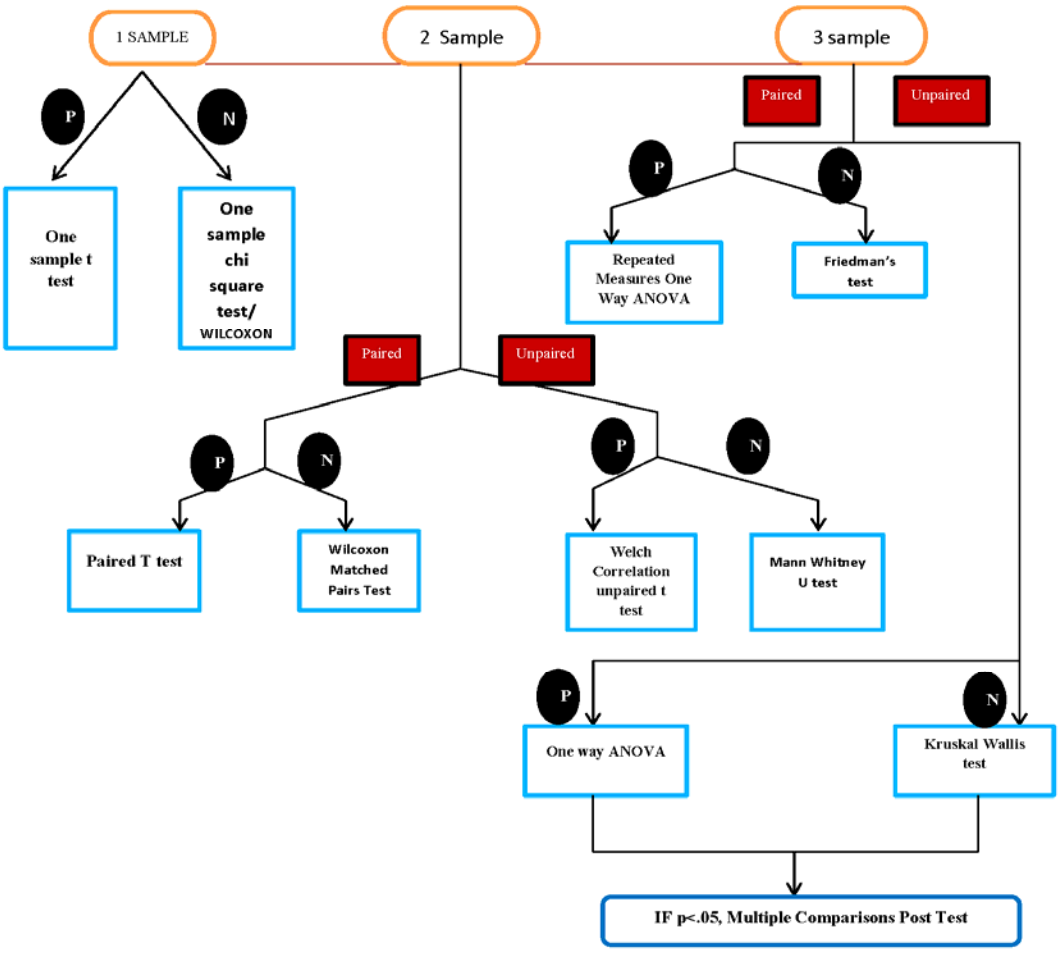

Figure 4: Flowchart of commonly used Statistical tests

DATA INTERPRETATION

It includes assessing the findings against the adopted evaluation criterion and making sense and deriving conclusion from the numerical values hence obtained.

10. OUTCOME /CONCLUSION

The results conclusions should be answered in three parameters **Null hypothesis** is rejected or accepted on basis of p value,**Level of significance** and **Confidence interval.**

Other than these some complexities encountered in biostatistics are :-

1. Incomplete /improper literature search

Not taking into account can result in incomplete data or knowledge and hence making the basic foundation of research study flawed.

2. Failure To list the Inclusion And Exclusion Criterion

It is a common omission error generally found in the papers

Listing the criterion is reflective of research specificity and congent rationale. The inclusion and exclusion criterion gives a precise and definite understanding of the participants or of the unit under observation. Also these criterion give a better insight of the contributing significance of the study and at the same time it helps the scientist/interested reader to decipher that how it might be different from the previously published studies (31)(20).

HOW TO AVOID

1. Use a checklist of common errors to avoid

2 Incase it's difficult to specify, one should look at the criteria used in previously published studies.

3. Failure to mention the error of your measurements

It is one of the most easily overlooked component .Only a handful of researcher reports these errors and most research just states that the examiners were calibrated.

3. Failure to mention the error of your measurements

It is one of the most easily overlooked component .Only a handful of researcher reports these errors and most research just states that the examiners were calibrated. It is essential as it is imperative in reproducing the results of the study. Also, great care should be taken to not overlook parameters like Method of training, standard of Performance And Reassessment of examiners (31)(32).

HOW TO AVOID

1. Incase of multiple examiners the examiners need to be Calibrated to a known standard before beginning of the study or prior to recruitment.

2. To find such an error the researcher needs to conduct a small test/ retest experiment.

4. DATA ANALYSIS ERROR(31)(15)

A wrong test or a failure to specify the exact statistical assumption is another commonly encountered error.For a basic overview of commonly used tests refer to Fig 4 .

Also before application of a particular test 3 reasons should be kept in mind :-

1. The type of data at hand (nominal/ non parametric or quantitative/parametric)

2. The type of sample (one sample /2 sample / 3 sample)

3. The Purpose of Analysis i. e whether the purpose is testing the hypothesis mathematically, Finding a Relationship O R Finding a Difference.

For most commonly encountered errors in data analysis refer to questionnaire 1 and 2.

5. Failure to implement adequate Bias control Measures

Bias control measures are highly deterministic of the quality of research . Few steps in Bias control include (1) Randomization of subjects to the areas, intervention and control conditions (2) Having supervised and credible control conditions.(3) Having Blinding Status check(31)(13)(33).

HOW TO OVERCOME

1. Monitor control conditions Regularly

2. Ensuring and Performing Periodic Blinding checks.

6. Failure to Report missing Data, Dropped subjects and Use of Intention to Treat

Excluding the dropouts can alter the conclusions of the study. A detailed account of dropped data, Subject dropout and Missing Data and How it was dealt with should be mentioned in the method section (31).

HOW TO OVERCOME

1. Having a pre enrollment Phase to Assess Eligibility and Ensure Longevity of recruitment before beginning of the study.

2. Incase of a choice Between exclusion and drop-out ,always choose Exclusion.

7. Failure to state the Limitations of your Study

Many research manuscripts fail to state the limitations of their Study and is therefore another reason for manuscript rejection. Trying to hide ,dodge or overshadow the limitation is never an ideal approach. Stating limitation or lacunae of the study is not only decisive of the rationale of the study and discretion of the researcher but it also lays a bedrock for further scientific studies based on those limitations (31)(15)(34) .

HOW TO OVERCOME

State and backup the limitation with justification.

8. Failure to vigorously recruit and retain subjects

Subjects must be recruited as per the inclusion and exclusion criterion. A Baseline subject recruitment plan prior to the beginning of the study is crucial.

Also a plan for retaining the subjects with an intention to treat or provide useful incentives(incase the study includes incentives for participants that is approved by the ethics committee) should be pre planned and integrated in the study. Also reason for subject drop out should be thought of, analyzed and worked on (31)(35)(36).

HOW TO OVERCOME

1. Have a specified “Subject recruitment plan”.

2. It is integral to have more than one or another backup plan .

3. Reason for Subject dropout should be analyzed and worked on.

To facilitate the process furthermore regarding the various components table 1 has been provides:-

Table 1 : Various components Table

QUESTION	SPECIFIED	NOT SPECIFIED	REASON: IF ANY
1. Restate the question in statistical language			
2. hypothesis type (null hypothesis, alternative hypothesis, one tailored hypothesis, two tailored alternate hypothesis)			
3. Research design/Study design			
4.Specify Participants			

AGE **ETNICITY** **OTHER DEMOGRAPHICAL CHARACTERISTICS**			
5.Time and Place of study			
6.Sampling type (see fig.2)			
7. Sample size justification			
8.Sample size Justification			
9.Ethical permission			
10.Intervention **Who received it?** **Who delivered it** **Mode**			
11. Data Collection tools			
13. Data analysis soft wares **Statistical tests applied(see fig 3)** **P value**			
14.Inference Drawn/Conclusion			

3. DISCUSSION

The aim of this paper is to provide tools[(visual tools like illustrative diagrams, flowcharts, various quick yet details checklist AND QUESTIONNAIRES (SEE APPENDICES)of shortcomings] to a non-statistician and provide an overview of basic fundamentals and functional knowledge in order to produce a statistically sound output . Using these tools can improve the functioning knowledge of the researcher without reading the vast literature of biostatistics and still gaining the basic required functioning knowledge required for his/her research . Also, according to some research evidence the review process in statistics by medical journal editors is flawed (37)(6), so these tools can be used by them to ease and enhance the review process (3).

As per the Ethical Guidelines for Statistical Practice, American Statistical Association, 1999 The use of statistics in medical diagnoses and biomedical research may affect whether individuals live or die, whether their health is protected or jeopardized, and whether medical science advances or gets sidetracked. [...] Because society depends on sound statistical practice, all practitioners of statistics, whatever their training and occupation, have social obligations to perform their work in a professional, competent, and ethical manner."(38).We hope the paper is a contribution for the same.

4. LIMITATION

It is still Always advisable to consult a statistician in the early phase of your research, and supplement your work with the means of these tools to maximize productivity. These tools are no replacement for an expert opinion ,just a means to facilitate and smoothen the research process.

REFERENCES

1. Kallet RH, Faarc RRT. How to Write the Methods Section of a Research Paper. 2004;(2):1229–32.
2. Erdemir F. How to write a materials and methods section of a scientific article ? 2013;39(Supplement 1):10–5.
3. Strasak AM, Zaman Q, Pfeiffer KP, Göbel G, Ulmer H. Statistical errors in medical research - A review of common pitfalls. Swiss Med Wkly. 2007;137(3–4):44–9.
4. Goodman SN, Altman DG, George SL. Statistical reviewing policies of medical journals caveat lector? J Gen Intern Med. 1998;13(11):753–6.
5. Altman DG. How Statistical Expertise Is Used in Medical Research. Jama [Internet]. 2002;287(21):2817. Available from: http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.287.21.2817
6. Strasak AM, Zaman Q, Marinell G, Pfeiffer KP, Ulmer H. The Use of Statistics in Medical Research. Am Stat. 2007;61(1):47–55.
7. Ray JG. Judging the judges: The role of journal editors. QJM - Mon J Assoc Physicians. 2002;95(12):769–74.
8. Hulley S, Cummings S, Browner W, Grady D, Newman T. Designing Clinical Research [Internet]. 2013. 367 p. Available from: https://www.bjcancer.org/Sites/Uploaded/File/2016/11/30636160943115667893758296l.pdf

9. Banerjee A, Chitnis U, Jadhav S, Bhawalkar J, Chaudhury S. Hypothesis testing, type I and type II errors. Ind Psychiatry J [Internet]. 2009;18(2):127. Available from: http://www.industrialpsychiatry.org/text.asp?2009/18/2/127/62274
10. Ngai EWT, Wat FKT. A literature review and classification of electronic commerce research. Inf Manag. 2002;39(5):415–29.
11. Straub DW. Validating Instrument in MIS Research. Vol. 13, MIS Quarterly. 1989. p. 147–69.
12. The Ways of Knowing Introduction to Ways of Knowing. 2005;26–39.
13. Kyrgidis A, Triaridis S. Methods and Biostatistics: a concise guide for peer reviewers. Hippokratia [Internet]. 2010;14(Suppl 1):13–22. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21487486%5Cnhttp://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC3049416
14. Myers M. Chapter 3 research methodology. MIS Q. 1991;21(2):241–2.
15. Fong W-K, Matsumoto H, Ho C-S, Ng BYS, Perron P, Johansen SS, et al. Methodology. J Econom [Internet]. 2013;2461(2):1–4. Available from: http://dx.doi.org/10.1016/j.enpol.2013.05.099%5Cnhttp://linkinghub.elsevier.com/retrieve/pii/S0165188910000680%5Cnhttp://scholar.google.com/scholar?hl=en&btnG=Search&q=intitle:Chapter+29#0%5Cnhttp://faculty.wcas.northwestern.edu/~lchrist/course/assignment
16. Israel GD. Determining Sample Size. 2003;5. Available from: http://www.tarleton.edu/academicassessment/documents/Samplesize.pdf
17. Melorose J, Perroy R, Careas S. Research Methodology2. Statew Agric L Use Baseline 2015 [Internet]. 2015;1:131–56. Available from: http://repository.um.edu.my/283/2/4 PhD Chapter3.pdf
18. Theresa A Scott. Sample Size Planning, Calculation, and Justification. Vanderbilt Univ Dep Biostat [Internet]. 2006;(92/07/2011):1–12. Available from: http://biostat.mc.vanderbilt.edu/wiki/pub/Main/TheresaScott/SampleSize.TAScott.handout.pdf
19. Tamayo-Sarver JH, Albert JM, Tamayo-Sarver M, Cydulka RK. Advanced statistics: How to determine whether your intervention is different, at least as effective as, or equivalent: A basic introduction. Acad Emerg Med. 2005;12(6):536–42.
20. Kotz D, Cals JWL. Effective writing and publishing scientific papers, part IV: Methods. J Clin Epidemiol [Internet]. 2013;66(8):817. Available from: http://dx.doi.org/10.1016/j.jclinepi.2013.01.003
21. Document G. Draft Guidelines Audio-Visual Recording of Informed Consent Process in Clinical Trial. 2014;(January):1–10.
22. Indian Council of Medical Research. Ethical Guidelines for on Human Participants Indian Council of Medical Research. Biomed Res. 2006;1–120.
23. Hahn Fox B, Jennings WG. How to Write a Methodology and Results Section for Empirical Research. J Crim Justice Educ. 2014;25(2):137–56.
24. Fogelin RJ, Duggan TJ. Fallacies. Argumentation. 1987;
25. Richardson L, Adams St. Pierre E. Handbook of qualitative research. In: Writing: A Method of Inquiry. 2000.
26. Bem DJ. Writing the Empirical Journal Article. Am Psychol Assoc. 2003;171–201.
27. Guthrie D. Writing a chapter. Kans Nurse [Internet]. 1986;61(4):5, 20. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19788348
28. Sharp D. Kipling's guide to writing a scientific paper. Croat Med J [Internet]. 2002;43(3):262–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12035130%5Cnhttp://hrcak.srce.hr/file/36791
29. Wee B Van, Banister D. How to Write a Literature Review Paper? Transp Rev. 2016;36(2):278–88.
30. Macnamara J. PR metrics: How to measure public relations and corporate communication. PR Metrics - Res Plan Eval PR Corp Commun [Internet]. 2005;1–54. Available from: http://amecorg.com
31. Clark GT, Mulligan R. Fifteen common mistakes encountered in clinical research. J Prosthodont Res [Internet]. 2011;55(1):1–6. Available from: http://dx.doi.org/10.1016/j.jpor.2010.09.002
32. Weisburd D, Britt C. Measurement: The basic building block of research. Stat Crim Justice. 2014;13–33.
33. Caroll R. Fallacies of Insufficient Evidence. In: The Critical Thinker's Dictionary: Biases, Fallacies, and Illusions and What You Can Do About Them. 2013.
34. North Bristol NHS Trust. How Do I Write A Research Paper? 2015; Available from: http://homepages.vub.ac.be/~lmahens/guide.html
35. Anderson G. How to write a paper in scientific journal style and format. Copyr Bates Coll [Internet]. 2004;1–17. Available from: http://scholar.google.com/scholar?hl=en&btnG=Search&q=intitle:How+to+Write+a+Paper+in+Scientific+Journal+Style+and+Format#3
36. Foundation MF. Clinical trials recruitment best practices manual. 2011;1–11.
37. Lang TA, Altman DG. Basic Statistical Reporting for Articles Published in Biomedical Journals: The SAMPL Guidelines. Sci Ed Handb [Internet]. 2013;29–32. Available from: http://www.equator-network.org/wp-content/uploads/2013/07/SAMPL-Guidelines-6-27-13.pdf
38. ASA. Ethical Guidelines for Statistical Practice: American Statistical Association. Am Stat Assoc [Internet]. 2016;(April):1–12. Available from: http://www.amstat.org/about/ethicalguidelines.cfm

Appendices

Questionnaire 1

ERROR CHECKLIST TABLE

ERROR	CHECKED FOR	MISTAKES DONE	CORRECTION
1. Hypothesis			
1.Type of research question			
2. Restating the question in statistical language			
3. Null hypothesis			

2.Study Design			
1.Failure to use and report Randomization Stated			
2.Reporting Blinding			
3.Equality of baseline characteristics			
4.Inappropriate Testing for Equality			
5.Comparability Of study groups			
6.Control groups (Make Sure Control Groups are Appropriate)			
INTERVENTION			
1.Not Specifying the reason for choosing the intervention			
2.Not specifying why it was the best intervention of choice			
3.Not having a specified plan to deal with the potential risk factors caused by the intervention			
Ethical Clearance			
1. Overlooking approval of ethics committee for non invasive studies			
2. Not keeping a steady track of consent forms			
3.Not following the guidelines for the Informed consent			
DATA ANALYSIS			
Wrong test			
1.Use of Wrong Test			
2.Unpaired Test For Paired Data			
3.Inappropriate use of Parametric methods			
5.Use of Wrong Test For Hypothesis Under Investigation			
Inflation of Type 1 error			

Failure to include a multiple-comparison correction			
Inappropriate post-hoc Subgroup analysis			
Typical errors with Student's t-test			
Failure to prove test assumptions			
Unequal sample sizes for paired t-test			
Improper multiple pair-wise comparisons of more than two groups			
Use of an unpaired t-test for paired data or vice versa			
No explicit statement of the tested Null-Hypotheses			
Failure to use multivariate techniques to adjust for confounding factors			
DOCUMENTATION			
1.Failure to specify the tests used clearly and correctly			
2.Failure to state the number of tails			
3.Failure to mention the type of tests (Paired/Unpaired)			
4. Incorrect names of tests			
5. Usage of unusual methods without reference			
6.Not being able to justify the Reason for the test			
PRESENTATION			
1. Inadequate Description of tools			
2. Inadequate Discussion of data			
3. Improper Discussion of data			
4. Use of SD to describe non- normal data			

5. Use of Unlabeled Error Bars			
RESULT			
1. Inappropriate or poor reporting of results			
2. Inappropriate Or poor Reporting of result			
3.Not stating confidence intervals			
4.Confidence Interval given for each group rather than for contrast			
5. Not stating the values correctly (eg. p= N.S, p<.05)			
WRONG INTERPRETATION OF RESULTS			
1. Drawing Conclusions not supported by Supported by study data			
2.Significance claimed without Data analysis or statistical tests			
Poor Interpretation of Results			
1.Overlooking Type 2 Error When reporting non significant result			
2. Overlooking the Discussion Of Confounding Bias And Confounding Factors			

Questionnaire 1

HYPOTHESIS

1. What is the null hypothesis??

2. What is the basic research question? Is it being expressed clearly?

STUDY DESIGN

1. What is the study design like ?

PARTICIPANTS?

1. Who are the participants/study subjects?

2. How were the subjects recruited? Were they paid any incentives?

3. What is the inclusion and exclusion criterion?

4. What type of sampling is it ?

5. Has the sample size justification been provided?

6. What is the time and place of study?

7. What is the study duration?

INTERVENTION

1. What is the intervention/exposure?
2. What is the mode of intervention?
3. Who is delivering the intervention?
4. Were any instruments used,if yes please specify?
5. Has the subject been informed duly?
6. Has the consent been obtained?
7. Has the ethical clearance been obtained beforehand?

DATA ANALYSIS

A. What is the data analysis plan?

B. What statistical tests were used?

C. What data analysis are used and why?