Column: Tips on Research and Publication

WRITING THE METHODS SECTION IN A MANUSCRIPT

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In the IMRAD format that is followed while writing scientific manuscripts, the methods section follows the introduction. In the introduction, the research gap is identified, and the objectives of the study are revealed. The methods section details how the study was carried out to achieve the stated objectives. It is the easiest section to finish, as it was already written while the research protocol was being prepared, provided enough attention was paid to the details in that stage. At the same time, the methods section should not be different from what was originally planned. As it is mandatory to register intervention studies in clinical trial registries prospectively, these details will already be available in the public domain, and it will be easy for the reviewers and editors to identify any deviations from the protocol. Hence, the researchers should update the trial registry with such changes and also justify them in the final research report.

How much to write under the methods?

Ideally, the methods should be written in sufficient detail so that someone else can reproduce the study after reading the section. This means all the details regarding the conduct of the study should be included. However, it may not always be practical to add all the details, especially because of the word limits imposed by the journals. So, a compromise is to write the details to such an extent that the research paper appears reliable. Sometimes, when the researcher has more than one manuscript from the same study, the methods section can be kept short, the first paper can be cited, and the readers can be suggested to look that up if they want more details.

The components that go into the methods are: a) study design, setting, duration (exact year); b) ethical considerations such as approval from the scientific and ethics committees (mention the name and unique numbers assigned), written informed consent from the participants, trial registration, and any other special permissions obtained (e.g., permission to translate or validate a rating scale); c) sampling, sample size calculation, eligibility criteria; d) methods of randomization, allocation concealment, blinding; e) assessment tools (e.g., rating scales, devices), scoring, properties (reliability, validity), interpretation; f) outcome measures (primary, secondary), confounders; g) description of interventions in all the groups (e.g., active and sham); h) statistical analysis (software, tests). However, to ensure blinded reviews, at the time of the initial submission, details such as the name and city of the institution, name of the ethics committee and the number assigned, etc., can be masked in the manuscript file. However, include such information on the title page or cover letter so that the editors are aware of the details.

Organization of the methods section

Use standard subheadings to organize this section (though some journals allow without subheadings). One widely used style is *participants, tools/measures, procedure, and statistical analysis*. However, other subheadings too can be used, depending on the research paper. A common error in submitted manuscripts is that

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this portion is not organized in a paragraph format and is rather presented using bullet points, with multiple subheadings and 'single-line paragraphs' (e.g., "study design: cross-sectional observational. Study setting: a tertiary care referral centre"). However, though such style may be suitable for a protocol, thesis, or PowerPoint slide, it is inappropriate for a journal article. Remember to organize the content into paragraphs using the standard subheadings.

Mention the study design early under the methods (if not already mentioned as part of the objectives), possibly in the first sentence itself. For example, "This was a cross-sectional, observational study carried out …" Avoid unclear expressions such as "retrospective/prospective study". The major study types are: qualitative or quantitative, experimental or observational, cohort, case-control, or cross-sectional (See https://doi.org/10.4103/IJPSYM.IJPSYM_66_19 for details on how to describe a study design). The operational definitions of key variables should be mentioned, with appropriate citations (For example, there are multiple definitions of "treatment-resistant depression.") Mention the confounders considered while planning the study and how they were managed (e.g., changes in sampling or eligibility criteria, planning additional assessments). However, avoid discussing confounders that were revealed as an afterthought from looking at the study results; they are better placed in the discussion section.

Under *participants*, describe the study sample, including the sampling frame, sampling procedure, sample size calculation, and eligibility criteria. Describe the sampling procedure, rather than just stating the sampling type (e.g., instead of "random sampling was used," write "simple random sampling was done using random number table"). Mention the method of recruitment (e.g., advertisements or social media posts). Similarly, sample size calculation too should be detailed (e.g., "Estimated sample based on 20% prevalence, 95% confidence interval, and 5% precision for the infinite sample was 246"). Post hoc sample size and power calculations are not helpful and are better avoided. Mention the eligibility criteria clearly. Avoid overlap of content between inclusion and exclusion criteria (e.g., if "age range 18-60 years" is mentioned as inclusion criteria, do not mention "less than 18 years and more than 60 years" under the exclusion criteria). Don't mention "those who refused to consent" as exclusion criteria. Give details of the control subjects too, and if matching was done, how it was done (e.g., it is not sufficient to say just "age, education, and sex-matched controls"). Mention the ethics committee that approved the study. Manuscripts without ethics approval will usually be desk rejected. A statement confirming that the study followed the guidelines from the Declaration of Helsinki may be added here, though not mandatory. State explicitly whether written informed consent (along with assent in minors) was obtained from the participants. Add trial registry information here. Check the journal's author guidelines for information on whether the trial registry registration number should be revealed in the manuscript file or not.

Tools section includes all rating scales and questionnaires, with details such as the version, items, scoring, modifications or adaptations, translations, information on reliability and validity, and interpretation of scores. It is not sufficient to describe the psychometric properties of the original scale; reliability and validity measures in the Indian population will be more helpful. Do not elaborate on common rating scales (e.g., Hamilton Depression Rating Scale or HAM-D). However, mention which version of the scale was used (e.g., "11-item version of HAM-D"). Specify, with references, if more than one version is available for the same scale (e.g., Structured Interview Guide for HAM-D or SIGH-D rather than HAM-D, if the structured interview version was used). Mention whether it is self- or clinician-administered, and the scoring criteria and interpretation, especially for less frequently used scales. If more than one rater administered the scales, mention interrater reliability if available. Mention, with appropriate citation, the cut-off scores for defining categories (e.g., caseness or severity level such as mild, moderate, or severe), as different investigators may have used different cut-offs. If any device is used, mention the make and specifications (e.g., Soterix 1×1 tDCS instrument, Soterix Medical Inc., New York).

The *procedure* section details how the sample was selected, how and when the assessments were done, who conducted the assessments, and if relevant, what intervention was done. Interventions should be described in detail (specifically if it is new), including active or placebo arms, drug, dose, and route. (e.g.,

"The dose of medications was flexible and was titrated based on tolerability up to X mg/d in two divided doses. The control group received similar-looking placebo tablets twice daily.") If relevant, the method of randomization and allocation concealment should be clearly mentioned (e.g., "Randomization was done using a random-number table. Allocation concealment was done using an opaque, sealed envelope"). Information on who was blinded and how the blinding was achieved is more beneficial to the readers than just mentioning single- or double-blind.

If the journal follows blinded peer review, don't include the abbreviations of author names (e.g., "SA did the randomization while SKP applied the rating scales"). Instead, say "first author", "second author", etc., or mask them during initial submission ("X did the randomization while Y applied the rating scales").

Be specific while describing *statistical analyses*. Mention the statistical software used and its version (beware of the pirated versions of the software). Mention whether data normality was examined, and if so, how (e.g., "Data normality was examined using Shapiro-Wilk test and histograms"). State if any data transformation was done prior to the analysis. Mention the tests used and for which variables (e.g., "Independent sample t-test was used to compare the means of X"). Mention which effect size measure was used and what cut-off was used to interpret (e.g., small, medium, and large). Add references for any unusual statistical procedures – here, cite standard journals or textbooks only. Exploratory analyses done, if any, should be clearly spelt out.

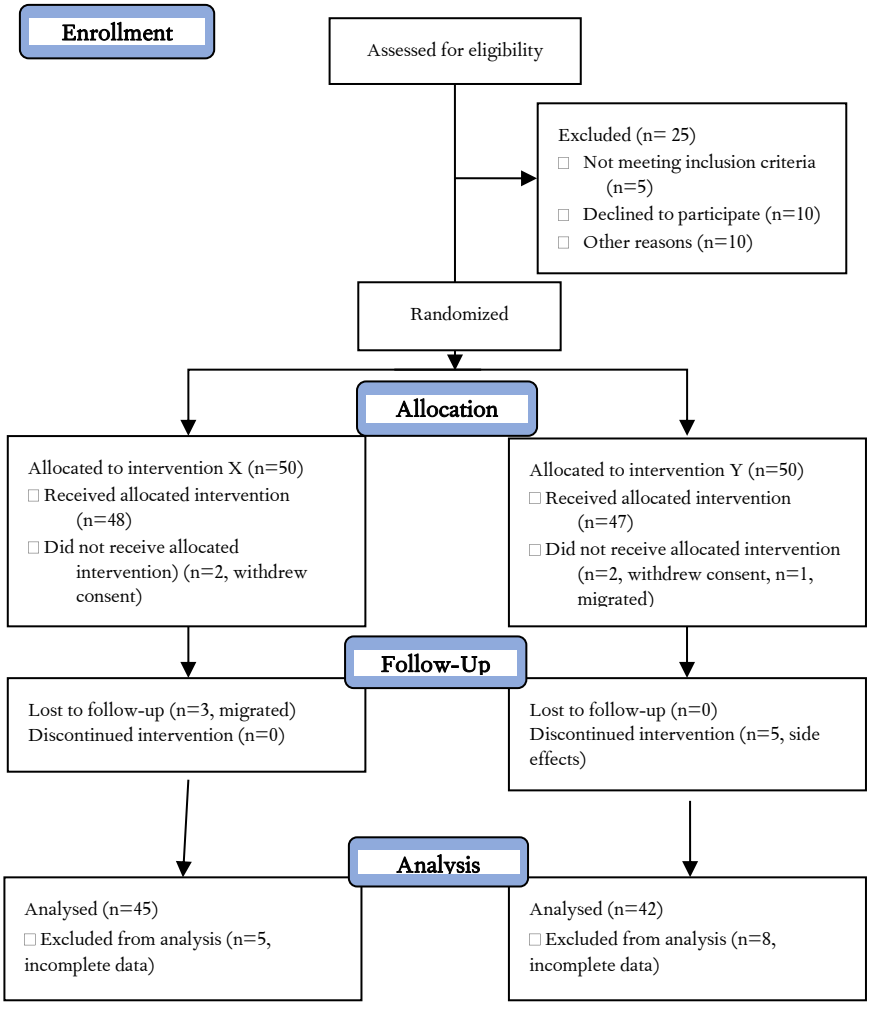

Fig 1: CONSORT diagram showing the flow of participants

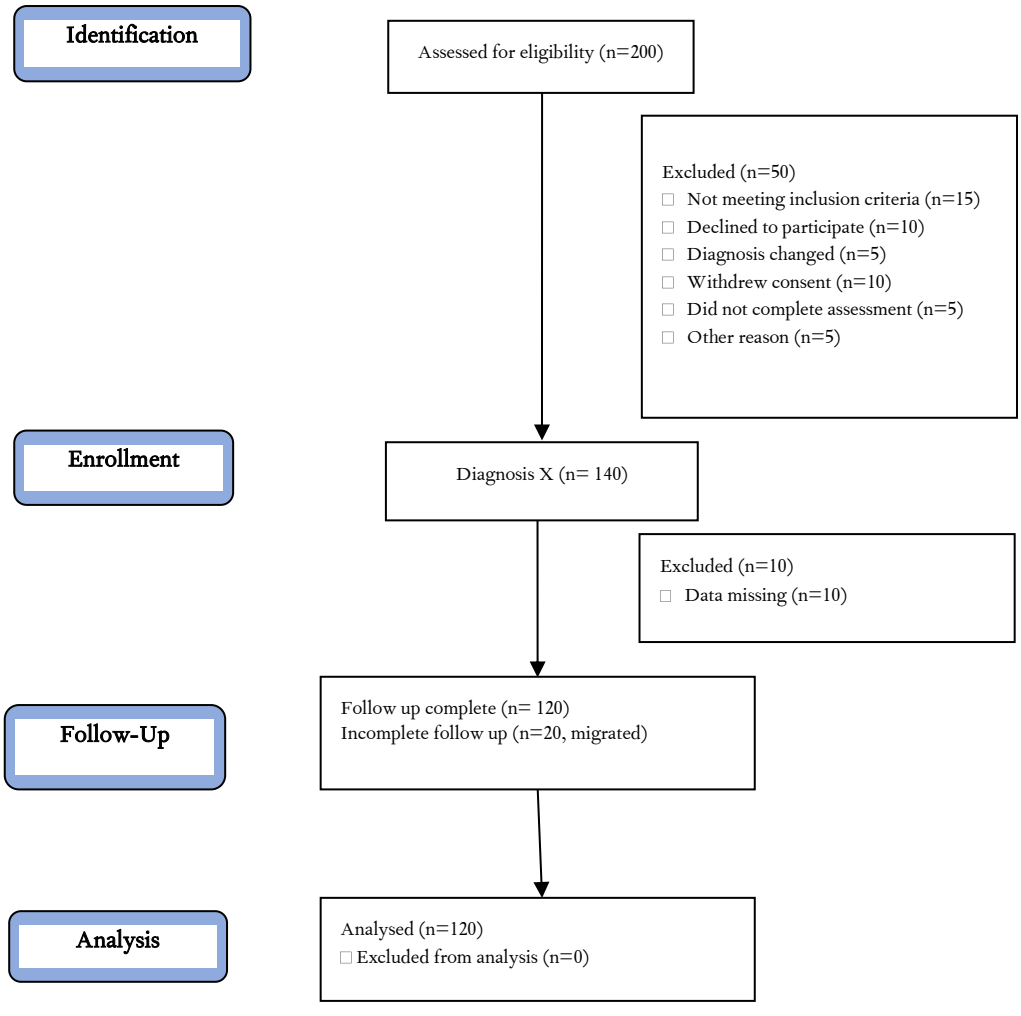

Fig 2: STROBE diagram showing the flow of participants

Describe how missing data were handled (e.g., "Last observation carried forward was used to impute the missing data") and which level of significance was considered in the study (e.g., "P<0.05 was considered significant"). If any corrections were used for multiple testing (e.g., Bonferroni correction or Hochberg procedure), it should be specified, including the resulting p-value that was eventually used.

Some suggestions for writing good methods section

Be exhaustive

This section is one of the longest in the manuscript. Describe in detail all the aspects of the study methodology as described above. Though the typical readers are less likely to go through the minutiae detailed in this section, the editors and peer reviewers will assess it for internal validity and judge your study based on the information provided here.

Use algorithms or figures

The flow of participants in the study can be described using a diagram. A CONSORT diagram is available for randomized clinical trials (e.g. Fig 1). A similar flowchart can be used for observational studies, too (e.g. Fig 2). Sometimes, figures can be helpful to summarize part of an experiment (e.g., sites of stimulation as in Fig 3) or a complete experimental setup.

Avoid writing results

Do not write how many participants were screened and how many were recruited, which is part of the results. (e.g., instead of "304 patients were screened, and of them, 240 were recruited," mention "consecutive patients were screened and those fulfilling eligibility criteria were recruited").

Mind your Language

Write in the past tense

The content in the methods section is written in the past tense. This is the only change required in the content

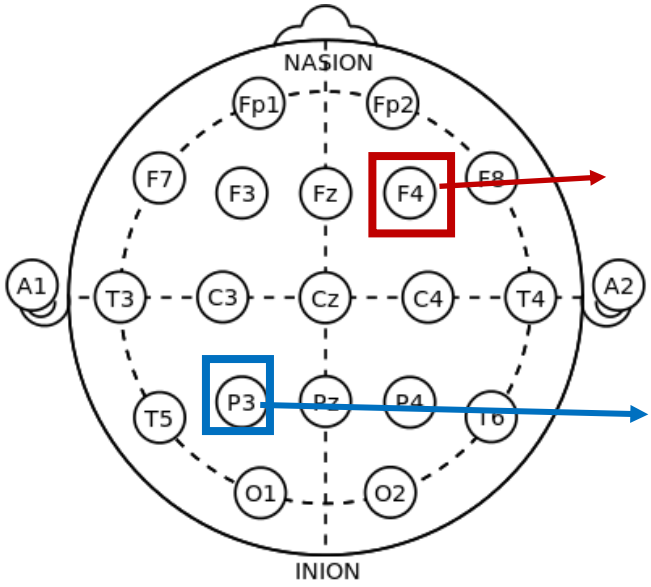

Fig 3: Transcranial direct current stimulation showing anode (F4) and cathode (P3)

written in the protocol, which would have used future tense. Use active rather than passive voice. For example, instead of writing "…50 patients with depression were recruited in the study," mention as "We recruited 50 patients with depression…"

Add variations

Do not write in a boring style. For example, "We recruited ….", "We administered…", We evaluated…". Occasionally, adding passive voice sentences is required to break the monotony. However, it is advisable not to mix both active and passive voices in the same paragraph.

Avoid common mistakes

Some language errors commonly encountered in this section are Writing "performa" instead of "proforma;" writing "population" instead of "sample" in a few places, probably to introduce variety; writing "student's t-test" instead of "Student's t-test" (the s needs to be capitalized); writing Fischer exact test or Fisher exact test instead of Fisher's exact test; writing X2 instead of $\chi 2$ (use the Greek letter chi and not X from English); confusing between random sample and randomization (the former is a sampling strategy, whereas, the later is an allocation method used in randomized trials).

Be careful while writing about descriptive and inferential statistics in the Statistical Analysis section. Rather than using the same verb to describe them both (e.g., "Mean, standard deviation, and correlation were carried out." or "Means, standard deviation, and non-parametric analyses were done"), describe them separately and specify which variables were examined (e.g., "Mean, and standard deviation were computed for X, and Y. Pearson's correlation analysis was carried out to examine the relationship between X and Y." "Means and standard deviation were calculated for continuous variables. Non-parametric analyses (Mann-Whitney U and Kruskal-Wallis test) were done to compare group differences for X and Y").

You cannot mess up the recipe!

The methods section is the most crucial part of the manuscript. A poorly written section will cast doubt in the readers' minds about the study's internal validity. Also, omitting essential methodological details risks rejection by the editors. Don't add new elements that are not mentioned in the protocol. The reviewers and editors are likely to cross-check the methods section from the protocol if publicly available in trial registries. If written well, it is one of the strongest parts of the manuscript.

Suggested readings

1. Cargill M, O'Connor P. Writing Scientific Research Articles - Strategy and Steps. John Wiley & Sons: Chichester, UK. 2009.
2. Katz MJ. From Research to Manuscript-A Guide to Scientific Writing, 2e. Springer Science: Cleveland. 2009.
3. Sahni P, Aggarwal R, editors. Reporting and Publishing Research in the Biomedical Sciences. Springer: Singapore. 2018.