



جامعة
الملك سعود
King Saud University



BASES OF RESEARCH Booklet

المجلس الطلابي

همم تسمو بالعطاء وأعمال ترتقي بالنجاح

2017
First
Edition

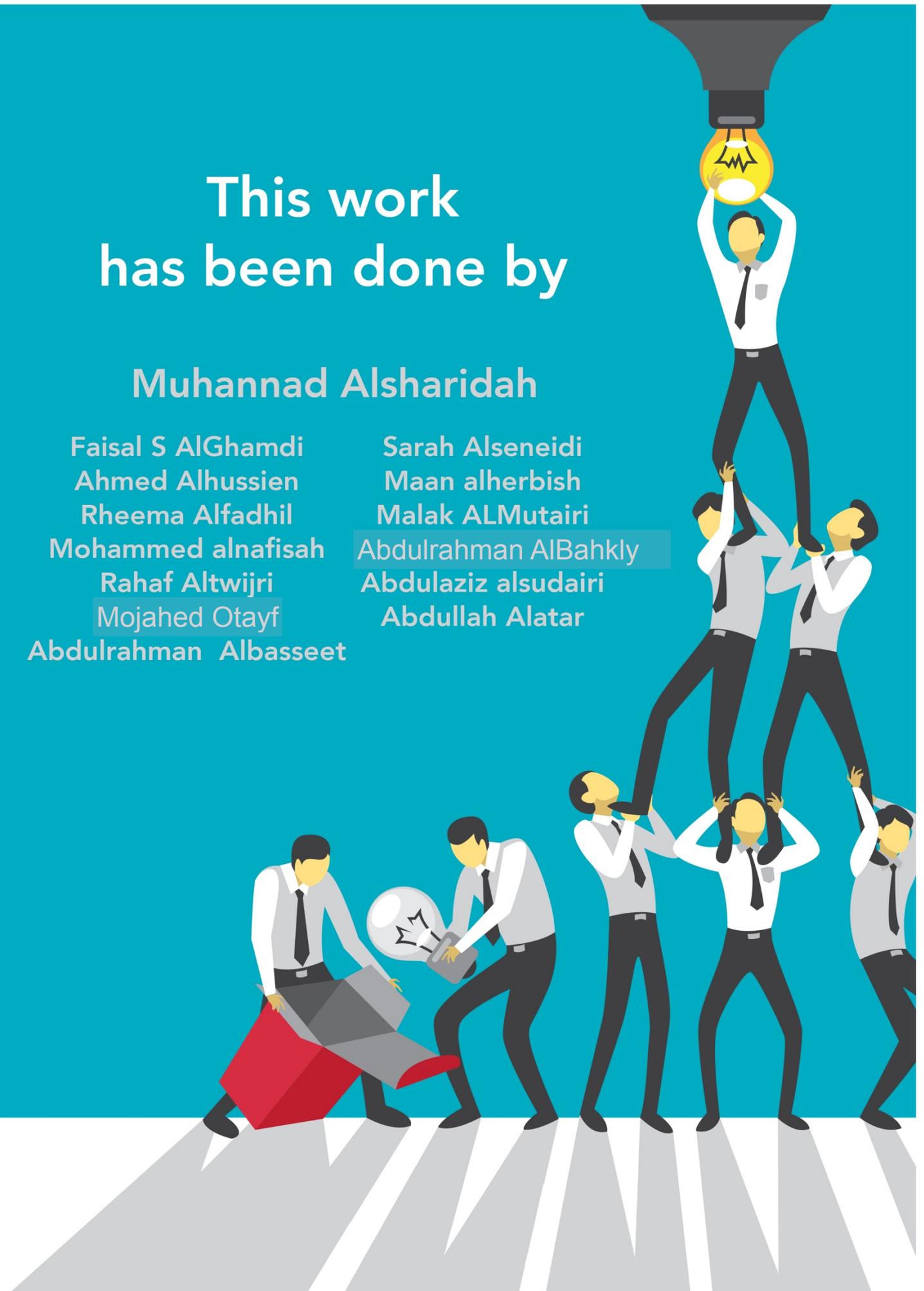
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بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

نقدّم لكم هذه المذكرة في نسختها الأولى والتي نأمل بها أن ترافقكم في رحلة البحث العلمي خلال سنوات دراستكم. تقرر إقامة هذا العمل نظرًا لأهمية البحث العلمي خلال مشوارنا في المجال الطبي، بالإضافة إلى تقديم المساعدة لتخطي العقبات والتحديات التي قد تواجهنا فيه. تم إنجاز هذه المذكرة بعمل وإشراف طلاب وطالبات كلية الطب بجامعة الملك سعود دفعة ٤٣٣

سائلين المولى ان تعم الفائدة للجميع

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Overview of the research process

1. What is research?

Research is often viewed as the corner stone of scientific progress. It is a systematic process based on scientific method that consists of testing hypotheses, careful observation and measurement, systematic evaluation of data, and drawing valid conclusions.

There are different research methods which are used in research, all with specific advantages and disadvantages. The main two types of research designs used in medicine are the quantitative research design, which generates numerical data or information that can be converted into numbers, and the qualitative research design generates non-numerical data that provides a complete description of the research topic.

2- Steps in conducting research

a- Identification of research problem:

It is the first statement made in any research. An example of a research problem, which may be of a local concern for the community is, violence among children. This is the problem to be investigated. At this stage, the identified problem is still too broad in scope. Therefore, the scope of the study needs to be narrowed down, which can only be done after a thorough literature review.

b- Carrying out a literature review:

Literature review is the process of searching for information related to the research topic, across multiple databases and information resources; reading, evaluating and analyzing them to help you understand a research topic, to establish the importance of a topic, and to help develop your own ideas. A good literature review will help in finding **gap(s)**, asking a good question, and accurately defining a problem, as well as identifying a proper methodology. After doing a thorough literature review, the focus can be narrowed down into violence among children who watch TV Programs which needs parental guidance.

c-Formulating the research question / research objective:

The next step in the research process after refining the objective through a literature review involves translating that research idea into an answerable question. The most important part of the question is to be researchable and answerable using established scientific methods and procedures.

d- Proposal writing:

The main purpose of writing a research proposal is to obtain ethical approval, as well as funding. It is a summary of the suggested process to be used to answer the research question. It is done through gathering information, reading, integrating, organizing ideas, and planning. **There is no common or specific format of the proposal.** Each research center has their specific format.

e- Institutional Review Board (IRB) approval and ethical consideration:

IRB is specific human-subjects committees that review and determine the ethicality of research. The main purpose of the IRB is to assure that appropriate steps are taken to protect the rights and welfare of participating as subjects in a research study. Finally, once the IRB approved, you can start conducting the research.

f- Data collection:

Data collection is the process of collecting the information that will be used to answer the research question. The development of the data collection form is a time consuming process, and it should be given enough attention to ensure it is clear, valid and reliable. It has to be piloted on a small sample of subjects to guarantee applicability, as well as identify any potential problems in the tool. Finally, once the necessary fine-tuning has been carried-out, data collection can be done through surveys, questionnaires, interviews, observations, data abstraction, etc.

g- Data entry, cleaning, and management

It is the process of entering the information (data) into the computer. There are many computer programs used for this purpose. The most widely used is the Statistical Package for Social Sciences (SPSS). Most of the time **data entry** is done manually. After finalizing data entry, a **data cleaning** process is carried out to check for any data errors or outliers. Once data is clean, **data management** starts which includes creating new variables from the existing ones based on pre-defined criteria.

h- Data analyses:

Data analysis is the process of analyzing data using statistical techniques in order to draw conclusions that support or reject the hypothesis, or answer the research question.

i- Research dissemination:

Data analyses results should be organized into tables and figures which serves multiple purposes such as: understanding the results, identifying missing analyses, comparing easily with other published articles, and preparing results for presentation. Publishing the research project is the final step of the research process, which entails summarizing the whole research findings in different forms, such as an abstract, presentation, report, or a manuscript published in a journal.

Research is to see what everybody else has seen, and to think what nobody else has thought...

Formulating a research question

1. What is a research question?

A research question is the fundamental core of research project. Well-defined and specific research question is the key for making decisions about study design and population and subsequently what type of data will be collected and analyzed.

2. Criteria of a good research question:

There are different criteria that define a good research question. A good research question should be feasible (can be done), interesting (to the investigator), novel (Confirms, refutes or extends previous findings), ethical, and relevant (has and implication). These criteria have been collectively Called **F.I.N.E.R**

3. Sources of research questions :

The researcher formulates a research question through different means. Personal interest /experience, research literature identifies the areas that need further study. Also clinical observation and insights. Other methods include previous research, journal clubs, social issues and conferences.

4. Elements of a research question:

Research question should include four elements; referred to as **PICO** that identifies the key elements of a research question that need to be addressed. The PICO concept is providing search terms, and saving time in literature search.

PICO letters stand for:

a. **P: Patient or population.** It describes patients" characteristics, such as age, gender, disease status, or any other patient-related characteristic.

b. **I: Intervention to be tested.** It is important to identify the exposure intended to be studied in the research project. This may include the use of a specific diagnostic test, treatment, adjunctive therapy, medication, etc. (what you plan to do for you patients?)

c. **C: Comparison.** The comparison component is the only optional one in the PICO question, since the researcher might study the intervention alone because either due to no interest in comparison or the lack of a comparable group. (What is the main alternative to compare with intervention like stander care or placebo?)

d. **O:** *Outcome* is considered as result of intervention. This may include cure or level of control of a disease, efficacy of a medication or a diagnostic test, etc. (what you hope to accomplish , measure ,and improve effects)

5. Criteria for a bad research question:

There are different criteria that define a bad research question summarized below. Too vague or ambiguous of the research question, too broad to reach conclusive results, and other criteria such as the time needed to carry out the study, high cost with limited funding, limited resources such as availability of expertise .Research question might be limited by ethical considerations or requirement of authorities" approval.

6. Example of a research question:

Topic of interest: men health

Narrowed topic: men and cancer

Focused topic: men smokers and colorectal cancer

PICO: P = men (age more than 35)

I = Cigarette smoking

C = No smoking

O = Colorectal cancer

Research question: Does smoking among men older than 35 years affect colorectal cancer risk compared to non-smokers?

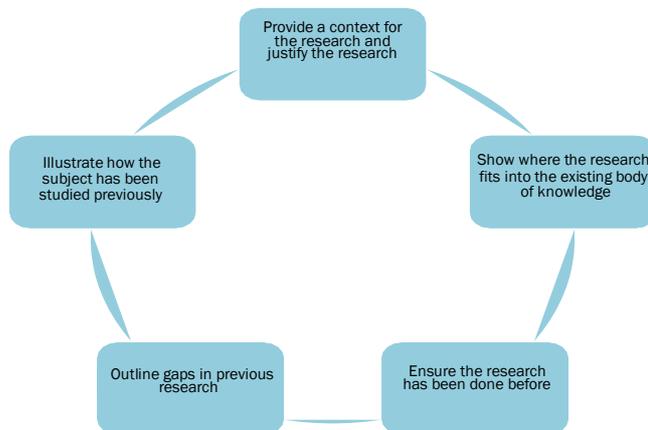
Conducting an effective literature review

1. Definition of a literature review

A literature review is a descriptive, analytic summary of the existing material relating to a particular topic or area of study. The literature review process involves a systematic examination of prior scholarly works.

2. The aim of a literature review

Literature review is a very important step in planning a research project. The reasons for doing a literature review are listed and summarized below:



3. Characteristics of a good literature review

A good literature review is characterized by the author's efforts to search, evaluate, and critically analyze the relevant work in the field. A good researcher has to develop good searching expertise, which will allow him/her to efficiently **search available resources** through the different **electronic engines**. Once the relevant articles are identified, the researcher has to have enough expertise to **assess the content of the article**, in terms of relevance, validity, etc. Finally, the researcher has to be able to **integrate the important and relevant work into his/her own research project**, specifically from the **methodology and results point of view**.

A good review should have the following characteristics which make it of value:

- a. **Comprehensive:** Evidence should be gathered from all relevant sources
- b. **Referenced:** Providing full references for reviewed papers.
- c. **Selective:** Using appropriate search strategies to find the most important evidence.
- d. **Relevant:** Focusing on related studies.
- e. **Balanced:** Providing objective evidence from papers with different findings.
- f. **Critical:** Following valid scientific critical appraisal of the literature.
- g. **Analytical:** Developing new ideas and understandings from the evidence.

4. Steps of a literature review:

The following steps provide a sense of how researchers should proceed in searching and reviewing the literature:

A. Develop a research question

The first step is to define a specific research question, which identifies the research or clinical problem the research is aiming to solve. Evidence based practice proponents advice using four elements in building the research question, specifically, the PICO (Patient, Intervention, Comparison, and Outcome).

B. Types of the sources used in a literature review

The term „sources“ refers to material needed to conduct the literature review, which could be summarized in three types:

- i. **Primary source:** Is a direct description of a research study written by a researcher who conducted the study.
- ii. **Secondary source:** Is a review of studies summarizing and providing new interpretations built from and often extending beyond the original study.
- iii. **Tertiary source:** Include perceptions, conclusions, opinions, and interpretations that are informally shared.

C. Search engines used in a literature review

There are different search engines that might be used to locate relevant material to be used in the literature review, which are summarized in the table below:

Database	URL	Characteristics
PubMed	www.pubmedcentral.nih.gov	<p>The National Library of Medicine's free search service.</p> <ul style="list-style-type: none"> ▪ Available through the World Wide Web. ▪ Rapid updates of published material. ▪ Some free full text material.
MEDLINE	www.nlm.nih.gov	<p>Contains abstracts and references from 1966 to the present.</p> <ul style="list-style-type: none"> ▪ Combines more than 3,900 medical and nursing journals into a single database. ▪ Includes Canadian Journal of Medical Radiation Technology, Radiography and Radiologic Technology.
CINAHL	www.cochrane.org	<ul style="list-style-type: none"> ▪ The Cumulative Index to Nursing and Allied Health contains abstracts and references. ▪ As well as more than 1,700 journals, CINAHL provides access to health care books, selected conference proceedings, and educational software.
Evidence-based Databases		
BMJ Clinical Evidence	www.clinicalevidence.bmj.com	<ul style="list-style-type: none"> ▪ The British Medical Journal's online decision-support resource describing the best available evidence from systematic reviews randomized controlled trials, and observational studies.
Cochrane Database	www.cochrane.org	<ul style="list-style-type: none"> ▪ Includes full text of the regularly updated systematic reviews of the effects of healthcare prepared by The Cochrane Collaboration. ▪ Free summaries are available; the full version is subscription only.

D. Establish the keywords and search strategy

To effectively conduct a search, keywords to be used in the search need to be identified, which are mainly the PICO elements. Moreover, a specific search Strategy using (AND, OR, and NOT) should be developed.

Example of PICO elements:

P (Problem or Patient or Population)	hospital acquired infection
I (intervention/indicator)	hand washing
C (comparison)	no hand washing; other solution; masks
O (outcome of interest)	reduced infection

E. Conducting the search:

The search could be carried out by the different search engines. PubMed is the primary database for researchers in the fields of biochemistry, molecular biology, and related life sciences. It was developed by the National Center for Biotechnology Information (NCBI) at the National Library of Medicine (NLM).

PubMed can be accessed at: <http://pubmed.gov> OR <http://www.nlm.nih.gov>.

The main screens of PubMed

the most important features in PubMed which a researcher needs to be familiarized with are:

1. The main page includes a database selection menu, a search box, and an advanced search link.

- On the PubMed's home page the **database selection menu** is displayed, where

the researcher can choose between PubMed and other NCBI databases

- A **search box** appears where keywords are entered.

Following are some top tips for focusing a search:

- Combine search terms with "**AND**" or "**OR**"
- Use "**Limits**" (Age group, Publication type, language, etc.)
- Search for your term as a word in the **title [ti]** or **title or abstract [tiab]**
- Try PubMed's **Clinical Queries** or **Topic-Specific Queries**
<https://www.ncbi.nlm.nih.gov/pubmed/clinical>
- Use the **Related Articles** link, once you find a set of relevant citations

Example:

If you want to search about Prevalence of heart diseases among young age group. In addition I want the search limited to **title and abstract** only. My keywords will be

- Hearts diseases AND young age [tiab]

2. The results of the search are displayed in the **Search Results Page** (see below). Use the **Display Settings menu** to change the display format, the number of citations per page and the sort order of your results. To view selected citations: Click on the box found to the left of each item number of interest.

3. My NCBI is a feature of the NCBI databases that allows the user to save records and searches, and customize the results display with filters and other options. Moreover, updates on saved searches might be requested to be sent to a personal e-mail.

F. Choosing the material to be included in the literature review

The choice of the articles found in the literature search to be included in the literature review may seem confusing as the number might be overwhelmingly high.

Thus, filtering the found articles is important to make sure that the most relevant ones to support the research will be chosen.

In narrowing the literature selection, more focused screening criteria are taken into consideration, such as:

- **Date of publication:** ex: only studies conducted between 2005 and 2012
- **Participants or subjects:** ex: children 6 to 12 years of age
- **Publication language:** ex: documents written in English
- **Research design:** ex: clinical trials
- **Authors:** ex: well-known author in a specific field
- **Journal:** ex: high impact journal, such as New England Journal of Medicine
- **Relevance:** ex: similar objectives addressed and methodologies adopted

Constructing a summary table of selected material will serve as a tool to organize a researcher's work.

G. Critically analyze and evaluate the information

Critical analyses of the chosen documents refer to the process of reading the introduction, methodology, results and discussion.

As for the critical evaluation of the document, it refers to assessing the validity of the methodology adopted, and relevance of the results reported.

Biases affecting each of the documents should be taken into consideration, and evaluated accordingly. Finally, integrate the reported results into the scope of the proposed research.

H. Cite literature properly

A researcher is supposed to protect the intellectual property of other researchers by acknowledging any work that has influenced the proposed research.

This is done by citing other people's work by denoting the following:

1. **Names of the authors.**
2. **The title of the paper.**
3. **The journal where it is published.**
4. **The year of publication.**

There are four main reasons why it is important to cite literature properly:

- To acknowledge the author(s) of the work that the researcher used.
- To provide context to the research and demonstrate that the research is Well-supported.
- To allow readers to find the original source and learn more about some aspects mentioned in the document.
- Avoid plagiarism, which occurs when a writer deliberately uses someone else's language, ideas, or other original material without acknowledging its source.

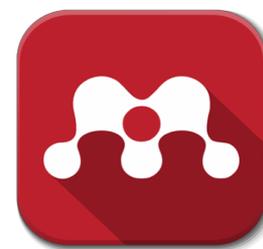
There are bibliographic management software programs that allow the researcher to search, collect and organize citations, and insert the citations into a word processing program in formatted bibliographic styles. Such available programs are: EndNote, Reference Manager, and ProCite.

5. Conclusion

At all stages of the process it is vital that the search process is evaluated. An effective review will increase likelihood of funding, generate new ideas and directions for investigation, and improve the quality (and likelihood) of peer-reviewed publication of primary research.

Managing references

EndNote



Comparison Table showing the different features between the three

Storage space	unlimited	300MB	2GB
Cost	Not free	Free- more price for storage	Free- more price
Web\Desktop App	Both	Both	Both
Web-browser Importer	No	Yes (chrome/ Firefox/	Yes (chrome/ Firefox/ safari)
Compatibility with Mac/Win/Linux	No (Mac/win only)	Yes	Yes
Literature search	Yes	No	No
Private Groups	Yes	Yes	Yes
Public Groups	No	Yes	Yes
Community network	No	Yes	Yes
Does it work with word processing software?	Yes	-Yes ++Google doc.	Yes
Highlight and annotate	Yes	Yes	Yes
Create Tags	Yes (with color	Yes	Yes (keywords)
Easy import of existing library	Yes	No	yes
IOS app	Yes (created by the	Yes by ZotPad	Yes (created by
Android app	No	Yes by Zandy	Yes (created by
Strengths	Good search and storage capacity.	Good in pulling metadata from web recourses.	-Large social Components. -automatic renaming of PDF files.

EndNote

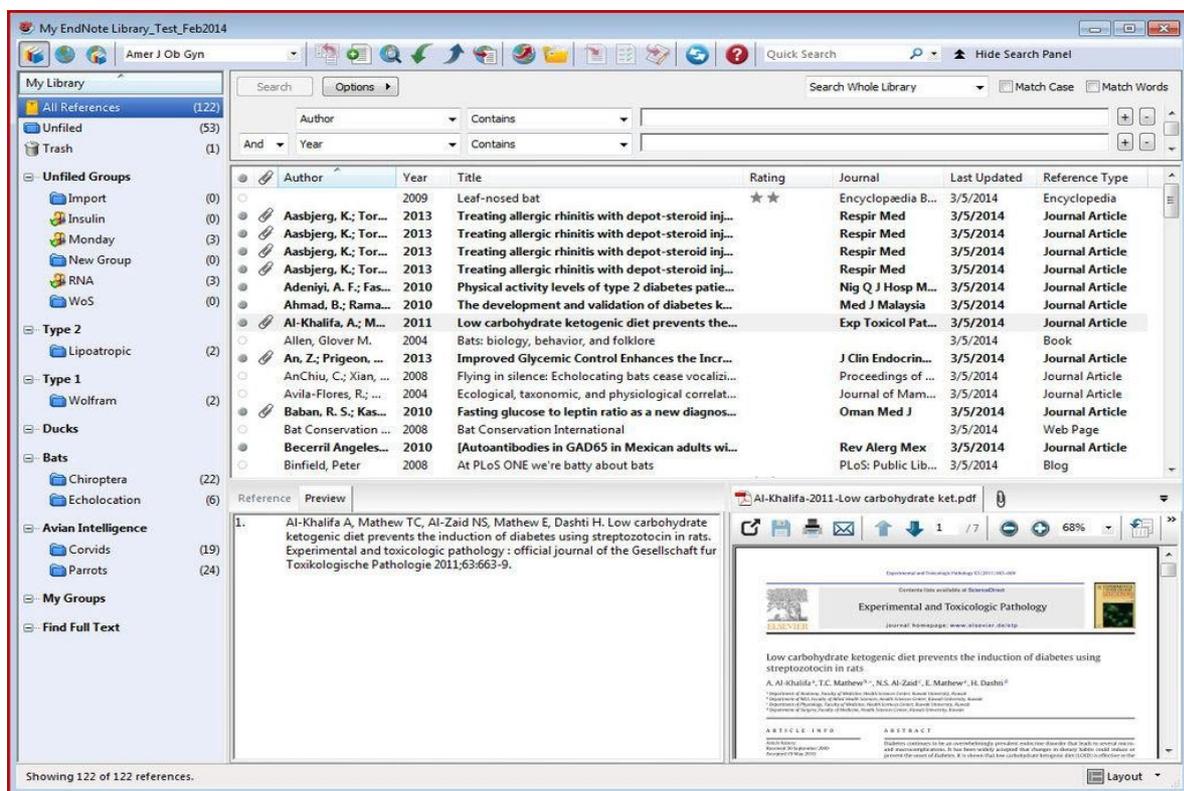
What is EndNote?

EndNote is a software program that works with Microsoft Word to automatically format in-text citations and end-of-paper reference lists with your chosen style (APA, MLA, Chicago, etc.)

What can EndNote do?

- a-Automatically insert well-formatted citations into your paper.
- b-Automatically reformat citation style in one click.
- c-Search live within your EndNote library.
- d-Access and manage your research from your desktop, online, and your iPad. Find full text for your references in one click.

EndNote main screen:



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Go Visit : <http://endnote.com/downloads>



Please watch this video before proceeding to the steps

[Click Here](#)

Or Go Visit:

<https://www.youtube.com/watch?v=S3xo6ZjBV6U>



1-To create library:

Open EndNote -> Go to File ->Select New ->Name your Library ->Add Citations to an EndNote Library

2-Entering references into a library:

a. Type data by hand

b-Download Data from a database and import into your library. Most databases, for example PubMed, allow you to export records directly into EndNote.

c-Connect directly to and search a database from EndNote.

3-Inserting references and generating bibliographies in Microsoft Word:

- a. From the EndNote library, highlight the reference you want to insert into the document
- b. Go to Word
- c. Put the cursor in the text where it needs to be inserted
- d. From the tools bar choose EndNote
- e. Choose Insert Citation
- f. Insert Selected Citation
- g. Change citation style of paper (MLA to APA, etc.)
- h. In your paper, choose Tools EndNote
- i. Format Bibliography
- j. Choose desired Output Style
- k. All EndNote tools are gathered in the –EndNote X3| tab at the top.



Mendeley

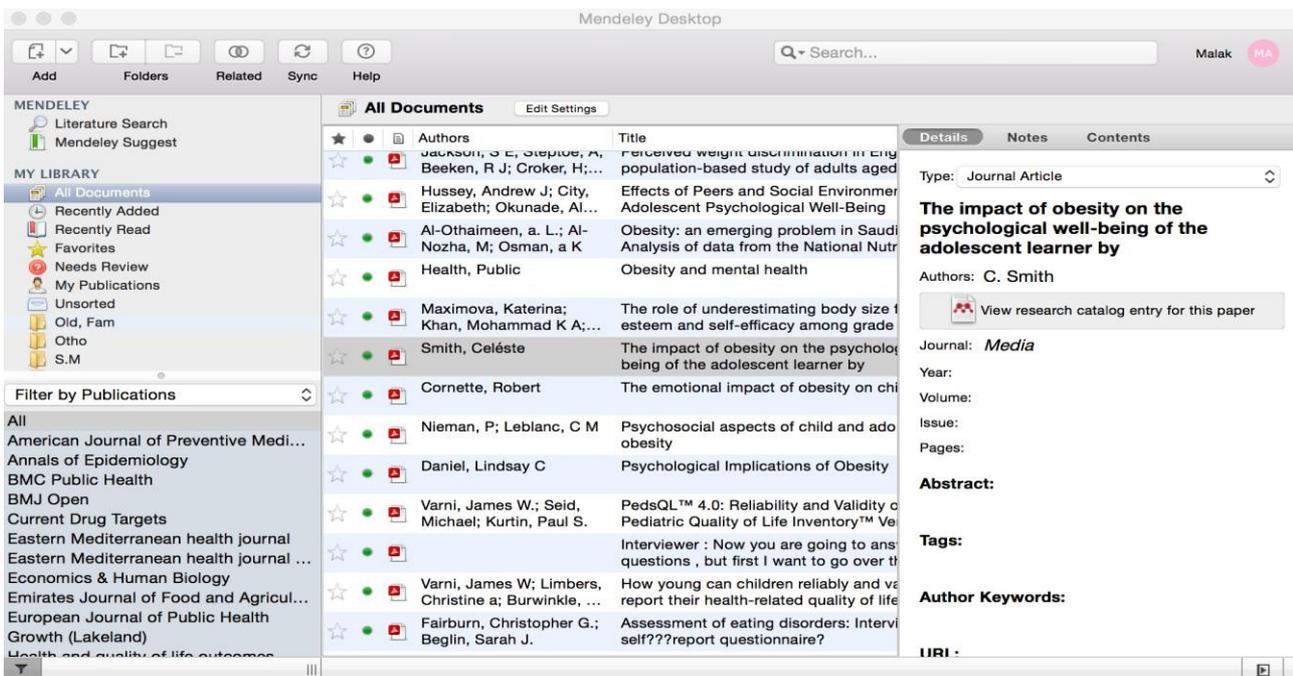
What is it?

It is free reference manager software that you can download to your desktop or use in-browser; it has an academic social network it helps researchers to organize their materials, to collaborate with others online by creating and joining groups and discovers the latest research in their field.

What can Mendeley do?

- Automatically generate bibliographies.
- Collaborate easily with other researchers online, creating or joining a group (private or public).
- Easily import papers from other research software, or from Pub-med database.
- Find relevant papers based on what you're reading.
- Access your papers from anywhere online, and having an online backup of your library.
- Read papers on the go, with IOS and Android apps.

Mendeley main screen:



The screenshot shows the Mendeley Desktop interface. On the left is a sidebar with navigation options like 'Literature Search', 'Mendeley Suggest', and 'MY LIBRARY'. The main area displays a list of documents under 'All Documents'. A detailed view of a selected document is shown on the right, including its title, authors, type, and abstract.

Authors	Title
Jackson, S E; Stepien, A; Beeken, R J; Croker, H;...	Perceived weight discrimination in Eng population-based study of adults aged
Hussey, Andrew J; City, Elizabeth; Okunade, Al...	Effects of Peers and Social Environmer Adolescent Psychological Well-Being
Al-Othaimen, a. L.; Al-Nozha, M; Osman, a K	Obesity: an emerging problem in Saudi Analysis of data from the National Nutr
Health, Public	Obesity and mental health
Maximova, Katerina; Khan, Mohammad K A;...	The role of underestimating body size f esteem and self-efficacy among grade
Smith, Celéste	The impact of obesity on the psycholog being of the adolescent learner by
Cornette, Robert	The emotional impact of obesity on chi
Nieman, P; Leblanc, C M	Psychosocial aspects of child and ado obesity
Daniel, Lindsay C	Psychological Implications of Obesity
Varni, James W.; Seid, Michael; Kurtin, Paul S.	PedsQL™ 4.0: Reliability and Validity o Pediatric Quality of Life Inventory™ Ve
Varni, James W; Limbers, Christine a; Burwinkle, ...	How young can children reliably and ve report their health-related quality of life
Fairburn, Christopher G.; Beglin, Sarah J.	Assessment of eating disorders: Interv self??report questionnaire?

Details Notes Contents

Type: Journal Article

The impact of obesity on the psychological well-being of the adolescent learner by

Authors: C. Smith

View research catalog entry for this paper

Journal: *Media*

Year:

Volume:

Issue:

Pages:

Abstract:

Tags:

Author Keywords:

URI:

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Or

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Please watch this video before proceeding to the steps

[Click Here](#)

Or Go Visit:

<https://www.youtube.com/watch?v=YqXxQ3cPNRY>



Importing files to **Mendeley**:

- You can add a file by clicking –File|| then add Files
- Or if you have full articles in a folder chose "add folder"
- Or if you have a library in other citation manger programs >> click on "import –and chose the program formats that you have.

Other ways:

- 1) By –literature search| >> by searching for the articles that you need >> chose the article >> click on –save reference||
- 2) Via PubMed: click on –send to|| >> chose citation manager >> "create file|| >> drag the file from the downloads folder up to **Mendeley**.

Documents (PDF Files):

It has an excellent PDF metadata retrieval. Also, you can highlight any part of the article with lots of colors and add a note to the PDF file. (*Only if the full article is available*).

Citation plugin:

First, activate it by clicking –Install MS Word plugin| from the –Tools| bar in **Mendeley** program then from the MS word via the _View‘ menu select the _**Mendeley**‘ option from the _Toolbars‘ list.

***Note:** in MS Word for Mac, the tool will appear as a separate panel which can be positioned wherever you like. **While**, in MS Word for Windows, the tool can be accessed via the References tab on the Ribbon. You should see a new set of tools for the "**Mendeley Cite-o-Matic**".

Insert a Citation in MS Word:

1. Put the cursor where you want to insert your first citation
2. Press the "Insert Citation" button on the toolbar.
3. The **Mendeley** Citation Editor Popup will appear.
4. Search your **Mendeley** library for the appropriate reference.
5. Enter a search term and choose the desired reference from the list of results.
6. Press Ok to insert a citation to the selected reference.

Another way:

1. Press the **_Go To Mendeley'** button to open **Mendeley** Desktop
2. Search for the specific reference you require using that interface.
3. Once you find your desired paper, press the "Cite" button, which temporarily appears in **Mendeley** Desktop.
4. To add your citation or press the "Cancel" button to return to your paper at any time.

Creating a bibliography:

1. Put the cursor where you want the bibliography to appear
2. Press the "Insert Bibliography" button on the plugin toolbar.
3. It'll style the list according to the Citation Style you have preferred.

***Note:** Your index will reorder and restructure itself every time you add or change an additional citation - there's no need to completely rebuild it.

Groups

You can create a group (private or public), or search via the website **–groups||** button for a Public group to join or follow up.

For more Videos and Tutorials visit

[–Mendeley Guide Videos|](#)

Or

Go Visit: <https://www.mendeley.com/guides/videos>



Zotero

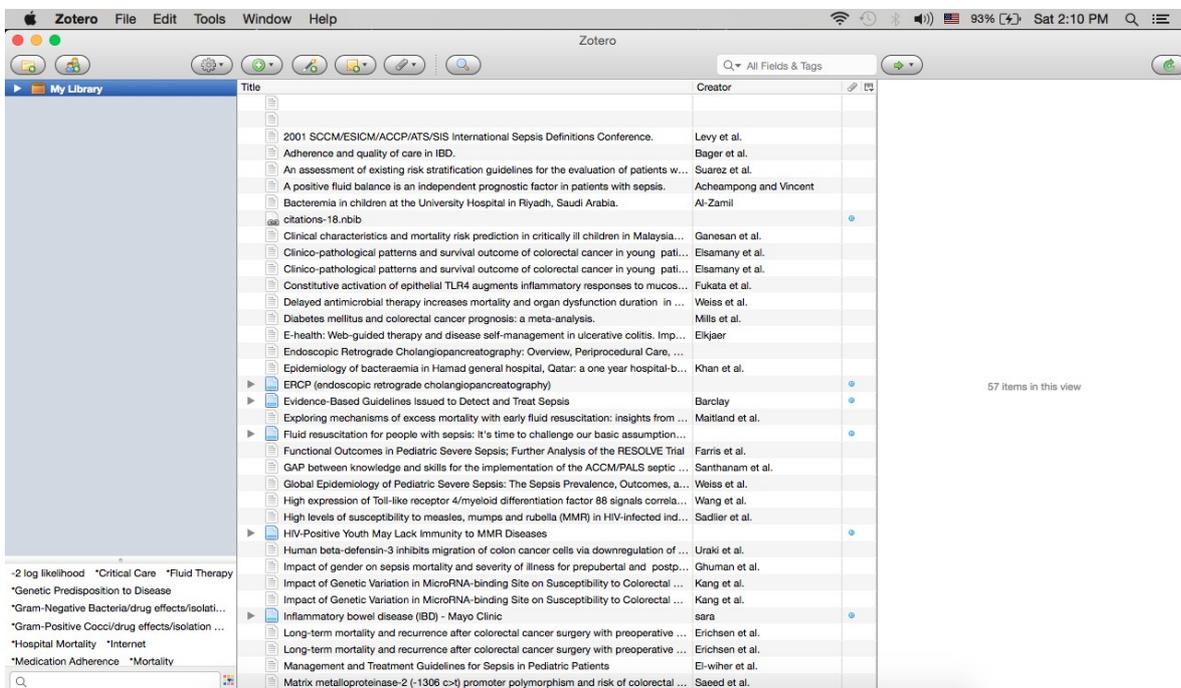
What is Zotero?

It is the most basic level, a reference manager. It is designed to store, manage, and cite bibliographic references, such as books and articles. In Zotero, each of these references constitutes an item.

What can Zotero do?

- 1- Organize: collections, tags, Searches, saved searches.
- 2- Collect: attachment, notes, files, links, snapshot, capturing items, web pages.
- 3- Cite: many different bibliographic styles, word processor integration, automatic bibliographies and manual bibliographies.
- 4- Collaborate: syncing, Zotero servers and groups.

Zotero main screen:



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https://www.youtube.com/watch?v=7zcCdyWR_1E&t



1- To create collection:

Open Zotero -> File -> new collection.

2- Entering references into library:

You can download data from journals or database then use one of the 3 ways:

a- Drag the PDF\file and drop it into Zotero.

a- File -> Import

C- File copies and file links can be created by clicking the –New ) button at the top of the center column and selecting –Store Copy of File...|| or –Link to File... || , respectively. This creates standalone items.

3- Inserting references and generating bibliographic in Microsoft word:

a- You can begin citing with Zotero by clicking the –Add/Edit Citation|  button. Pressing the button brings up the citation dialog.

a- Start typing part of a title, the last names of one or more authors, and/or a year in the dialog box.

b- Select an item by clicking on it. The item will appear in the dialog box in a shaded field.

c- Clicking the –Add/Edit Bibliography|  button inserts a bibliography at the cursor location.

4- Adding Files via the Browser:

With Zotero for Firefox, you can right-click a link to a file in the browser (e.g. to a PDF) and select –Zotero|| > –Save Link as Zotero Item|| . This will save a copy of the file to your library as a standalone item. You can also right-click an image in Firefox and select –Zotero|| > –Save Image as Zotero Item|| .

Writing a proposal

What is research proposal?

It is a summary of the suggested process to be used to answer the research question. It is done through gathering information, reading, integrating, organizing ideas, and planning.

There are 3 main aims for research proposal:



Sections of research proposal:

The format of a research proposal depends on the institution at which the study will be carried out. In this guide, we are going to explain the specific format of King Saud University – Institutional Review Board (**IRB**) form.

Page number	Page content	Details
1	Arabic Cover page	The Arabic page should be written as exact translation of the English cover-page. Usually it is the last page to fill before submitting the IRB.
2	Abstract	An abstract should concisely describe the background of the proposal, critically evaluate the rationale to carry out the study or the gap in knowledge, and it should highlight the objectives of the project. It also should briefly describe the methodology, data analysis, as well as the significance and relevance of the project. Not more than 1 page, and usually 250 words and less.
3	Investigators information	Usually the supervisor (faculty) is considered the principal investigator, unless agreed otherwise within the research group.
4	Research Problem and Significance	This section referred to as –rationale sometimes. It aims to convince the audience that the research is worth doing it. It should answer the question why the audience should want to read/fund/support the project. One way to do this is by describing how the results may be used.
5	Research Objectives	The purpose of the study should answer the research question by the proposed research. A research project should have one primary objective, and one or more secondary objectives which should all be detailed in this section. Your objectives should be SMART: Specific, Measurable, Achievable, Relevant and Time-bound
6-8	Literature review	Explained in detail in chapter 3
7	Research methodology	It should be written in detail, because it is the main section that will be assessed by the reviewers.
8	References	Using standard methods of citing references, e.g. Vancouver style (New England Journal of Medicine)
9	Role of the investigators	E.g. Review of literature, study design, data collection, Data management and analysis, progress report, data analysis, final report and manuscript writing (as applies to each investigator).
10	Detailed Budget	If there is a budget, or leave it blank.
11	Research time schedule	Expected time of processing till the finishing of the project.

Sample size calculation

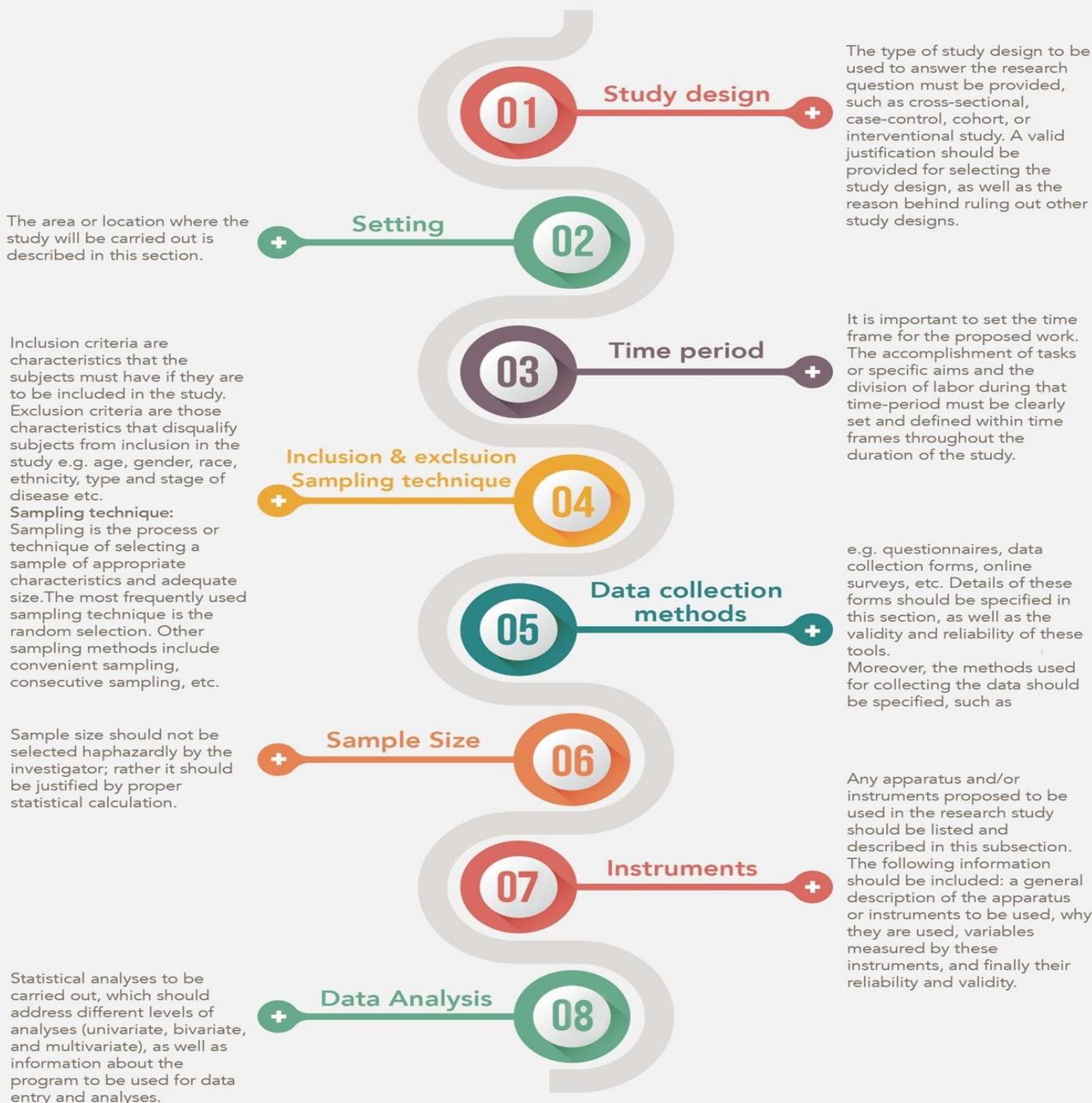
IS AN IMPORTANT STEP CARRIED OUT TO CALCULATE THE NUMBER OF SUBJECTS NEEDED TO BE INCLUDED IN THE RESEARCH PROJECT. DIFFERENT RESEARCH QUESTIONS REQUIRE THE USE OF DIFFERENT EQUATIONS FOR THE CALCULATION OF THE SAMPLE SIZE.

TYPICALLY, THE FOLLOWING ARE THE BASIC INFORMATION NEEDED FOR SAMPLE SIZE CALCULATION:

- A. LEVEL OF STATISTICAL SIGNIFICANCE (α), AND IS USUALLY CONSIDERED AT 0.05 (5%).
- B. THE VALUE OF THE POWER DESIRED ($1-\beta$), AND IT IS USUALLY CONSIDERED AT 0.8 (80%).
- C. AN ESTIMATE OF THE EXPECTED PREVALENCE OR INCIDENCE RATE IN THE CONTROL GROUP (OR UNEXPOSED), AS WELL AS THE EXPECTED DIFFERENCE IN RESPONSE RATES TO BE DETECTED BETWEEN THE TWO GROUPS. THIS COULD BE ACHIEVED BY CONSIDERING THE DIFFERENCE THAT WOULD BE CLINICALLY IMPORTANT IN MANAGEMENT OF THE SPECIFIC PATIENTS, OR FROM PREVIOUS WORK CARRIED OUT ON THE SAME TOPIC.

- THIS WEBSITE WILL HELP TO CALCULATE SAMPLE SIZE (<https://www.surveysystem.com/sscalc.htm>)

Methodology section



Data collection, entry, cleaning and management

The purpose of this section is to explain how to collect data as appropriate for the nature of your project, and what to do with them once they're collected to be ready for the statistical analysis.

Introduction

- Before going through this section, you need to be familiar with some **terminologies** that are important in the process of data collection:

- **Variable:** A changeable piece of information (Can be changed), e.g. Heart rate is a variable that can be 90 BPM in one patient and 80 in another.
- **Types of variables (There are two main types):**

1-Categorical: fixed (non-continuous) variables that can be grouped into categories. They're further subdivided into:

A. Dichotomous: When the piece of information is one of two responses (either or), e.g. hypertensive vs non-hypertensive, Pass or fail and so on.

B. Nominal: When the piece of information can be one of three or more responses, and the responses cannot be sequenced (ordered), e.g. blood groups (A, B, O, and AB).

C. Ordinal: When the piece of information can be one of three or more responses, and the responses can be sequenced, e.g. the severity of any disease can be (mild, moderate or severe).

2-Continuous: Variables that have the potential to be any value within a continuous range.

Simply, Time for instance is a range of continuous values. E.g. when you are collecting data about time of admission, it can be 2:30 pm, 2:31 pm, 2:32 pm ...etc.

Other examples are: Age, Blood pressure, Height, Weight.

- **Coding:** During entering your data into the sheet, it's the process of giving numbers (Codes) for non-numerical data. E.g. 1 for males, 2 for females. **Why don't we keep letters in our sheet?** Because Statistical analyzing programs (e.g. SSPS) won't accept letters to do their job.

Data Collection

- **What is Data?** Data is the facts (Pieces of information) collected and not yet interpreted, organized or processed by any means.

So "Data collection" is a symmetric gathering of data for a particular purpose.

- **How data can be collected?** Many methods used to collect data depending of the nature and the need of the study, including questionnaire, interviews, observation, records and files. **Basically, any paper or electronic form used to collect data is accepted as long as contains the data of interest.**

E.g. the figure below is an example of a data collection form gathering their information from patients' records.

Patient's file number	Added information	Parameter	Result(s) of Parameter
		Gender	Male () Female ()
		Age	
		Year of admission	
		Section of Admission	
Patient's telephone number (Optional)		Diagnosis	1. 2. 3. 4. 5. 6. 7. 8.
		Isolated microorganism	
DVT		Gram stain	P () N ()
Present () Information :		Type of catheter	
		Side of insertion	R () L ()
		Vein of insertion	
		Number of lumen	
		Date of insertion	
		Date of infection development	
		Date of removal	
		Location of insertion	
		Temperature (C)	
		Outcome of catheter insertion	
		Type of infection	CLABSI ()
			LCBSI ()

Database Structure

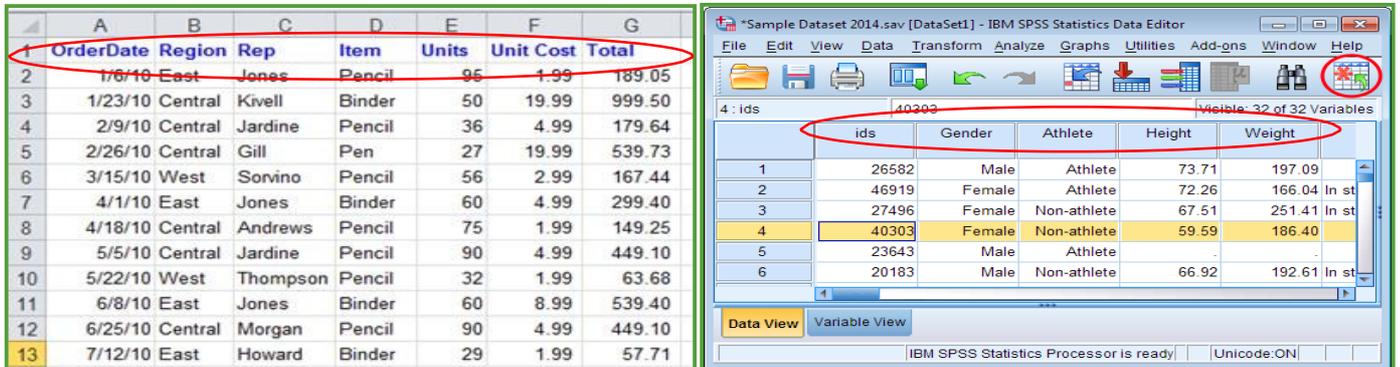
- **What is database?** It is all the data collected and organized but not yet interpreted. It can be easily reached and updated. Databases can be structured in many computer programs such as Microsoft Excel, Microsoft access, SPSS.

- **Each of these can be used for data entry, archiving, and for analysis too.**

However, what is done usually by researchers is entering and archiving their database in Microsoft excel till it's complete and ready, at this step it's transferred to SPSS for the statistical analysis.

Generally, SPSS is more superior than Microsoft excel and preferred by researchers and statisticians for the following reasons:

1 - First horizontal line is usually used in excel for the names of the variables (Age, Sex ...etc.), while in SPSS, variables are defined already and the first line is saved for data as shown in the next two figure.



2 - SPSS provides an easy way to define the codes given for each variable, while excel requires much time and effort to give codes.

3 - Finally, excel is much harder and needs an expert to perform data analysis.

- In SPSS and other programs, for each variable in the database,

6 things need to be defined:

Name It is the short name of the variable that should not include any spaces.

Type It specifies the format of the variable, such as numeric (anything that **Type** includes only numbers), dates (anything where date is involved), or string (where a combination of letters, numbers or symbols are included).

Width Number of digits allowed for numeric variables (e.g. for 999, width is 3)

Decimals Number of decimals needed for numeric variables (e.g. 1.25, decimals are 2)

Label It is a place where the full definition of the variable could be provided

Values It is where the coding of the variable is specified

(This figure shows an example from SPSS)

	Name	Type	Width	Decimals	Label	Values	Missing	Columns	Align	Measure
1	SN	Numeric	3	0	SN	None	None	7	Center	Scale
2	MRN	String	6	0	Medical Record Number	None	None	8	Center	Nominal
3	Age	Numeric	2	0	Age	None	None	7	Center	Scale

To fully understand the point, let's have an example: Abdullah is conducting a research in order to identify the risk factors of STEMI vs Non-STEMI in King Khaled University Hospital; he collected data about age, family history, cholesterol level, smoking status ...etc.

Before entering the data in SPSS, he has to specify 6 things for each variable he has. Let's apply this on Family history.

NAME	TYPE	WIDTH	DECIMALS	LABEL	VALUES
FH	Numeric (1,2)	1	0	Family history	1 = "Yes" 2 = "No"

By the way, family history is a categorical dichotomous variable.

Data Entry

- It is the process of typing the data you got into a computer program. It can be single (entered into one computer) or double (entered into two computers, then the two databases are compared and any discrepancy will be resolved by computer). Double data entry is used to avoid or reduce errors in data entry.

Data Cleaning

- **Data cleaning** is a process where the data is checked for entry errors or extreme values in the database. **It's a very important point as errors may occur no matter how the person is cautious.**

- There are **2** steps of data cleaning:

1-Identifying the errors: There are many methods to do that.

2-Correcting the errors: Once errors are identified, they are corrected through going back to the data collection form and finding the correct information.

Data Management

- It is a crucial step just before data analysis. The goal is to create new variables based on the available ones. There are **3** types of data management:



1-Recoding: creating new variables from the already coded variables, e.g. when you gathered information about smoking status and you got (0=non-smoker) (1=ex-smoker) (2=smoker), if you're further interested in having a new variable of (smoker vs non-smoker) only, you can merge non-smokers and ex-smokers as (non-smokers=0, in the new variable), while smokers remains the same with a new code=1.

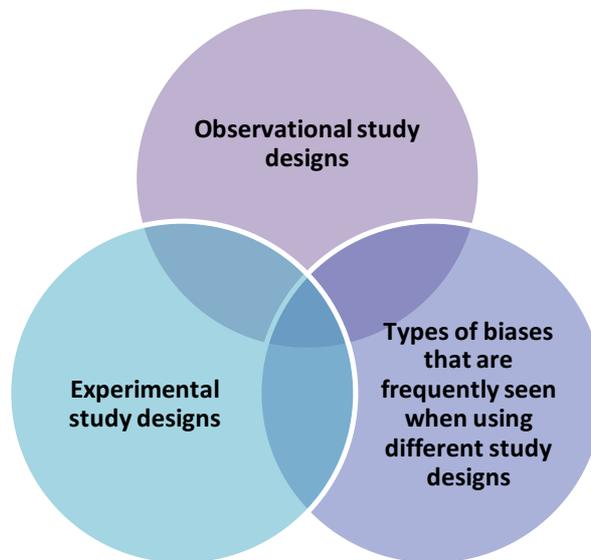
2-Categorization: When one "continuous" variable is divided into more, e.g. SBP is divided into hypotensive, normotensive and hypertensive.

3-Computation: is having a new variable from doing mathematical equations of more than 1 variable, e.g. calculating BMI from weight and height.

Overview of Study Designs

This chapter is going to provide you with a brief overview on the different types of study designs, and how to choose the right study design for your research project.

It will cover:



Generally, all study designs have similar components from the **PICO** formulation. All study designs have a defined population (**P**), outcome (**O**). The intervention (**I**) and comparison (**C**) may or may not be present in all study designs (**we have them in experimental and analytic observational study designs**).

–The first distinction is whether the study is analytic or non-analytic.

A non-analytic It does not try to quantify the relationship but tries to give us a picture of what is happening in a population, E.g., the prevalence, incidence, or experience of a group.

Descriptive studies Include case reports, case-series, qualitative studies And surveys (cross-sectional) studies, which measure the Frequency of several factors, and hence the size of The problem. Some may include analytic work.

An analytic study It attempts to quantify the relationship between two factors, that is, the effect of an intervention (I) or exposure (E) on an outcome (O). To quantify the effect, we will need to know the rate of outcomes in a comparison (C) group as well as the intervention or exposed group.

Experimental studies, or randomized controlled trials That is, subjects are allocated to two or more groups to receive an intervention or exposure and then followed up under carefully controlled conditions. Such studies controlled trials, particularly if randomized and blinded, have the potential to control for most of

(RCTs). The biases that can occur in scientific studies.

analytic observational studies The researcher simply measures the exposure or treatments of The groups. Analytical observational studies include case control studies, cohort studies and some population (cross-sectional) studies. These studies all include matched groups of subjects an assess of associations between exposures and outcomes.

Observational studies It investigates and record exposures (such as interventions or risk Factors) and observe outcomes (such as disease) as they occur. Such studies may be purely descriptive or more analytical.

General Terms in Research

- **Prevalence:** is an indication of how frequent a specific outcome or disease is present in a specified population. It is calculated by dividing the number of subjects with a particular outcome or disease in a given population by the total number of people in that population at a specific point in time. It is represented as a fraction, proportion, or a percentage. For example, the prevalence of diabetes in the Kingdom of Saudi Arabia was estimated to be 30%, calculated by dividing the number of diabetic patients (1,792 patients) over the total number of subjects included in the study (6,024 subjects).
- **Incidence:** Is an indication of how fast the outcome or disease is growing in a specific community. It is calculated by dividing the number of newly diagnosed subjects with a specific outcome or disease by the total number of people in that population over a specific period of time. For example, the incidence of intrauterine fetal deaths after 26 weeks of gestation was found to be 6.1 per 1,000 total births, which was calculated by dividing the number of deaths (103 cases) by total number of pregnancies (16,882).
- **Exposure and outcome:** two terms that researchers use when they carry out clinical research. An exposure might also be called a risk factor or an independent variable, and they all reflect the variable one is interested in seeing; the effect of on a certain outcome, also called disease or dependent variable. As an example, a researcher might be interested in studying the effect of physical activity (exposure) on obesity (outcome), but another researcher might be interested in studying the effect of obesity (exposure) on diabetes (outcome).
- **Contingency table** (two by two table or cross tabulation): Is a method used to display the frequency distribution of two variables across each other, for the purpose of assessing the association between these two variables. It is a method used in the different study designs, but what differs is the measure of association calculated, which is dependent on the type of study carried out.

Observational study designs

In *observational* studies, the researcher observes and systematically collects information, but does not try to change the people (or animals, or reagents) being observed. In an observational study there is no intervention.

- Examples of observational studies:

- A survey of drinking habits among students;
- A researcher who joins a biker gang to study their lifestyle.
- Taking blood samples to measure blood alcohol levels during Monday morning lectures.

- Types of observational study designs: Many, but the main ones are:

1- Cross-sectional surveys.

- Example: what is the prevalence of diabetes in this community?
- Here, you draw a random sample of people and record information about their health in a systematic manner.
- You can also compare people with, and without, diabetes in terms of characteristics (such as being overweight). The problem is that you cannot be sure which came first. We say that there is an inability to discern temporality or that there is a lack of a temporal relationship (i.e. which came first, the hen or the chicken?)

2-Systematic Review

• A summary of the clinical literature. A systematic review is a critical assessment and evaluation of all research studies that address a particular clinical issue. The researchers use an organized method of locating, assembling, and evaluating a body of literature on a particular topic using a set of specific criteria. A systematic review typically includes a description of the findings of the collection of research studies.

3-Cohort, or "longitudinal", or "prospective" studies

- These are like surveys, but extend over time. This allows you to study changes and to establish the time-sequence in which things occur. Therefore, you can use this to study causes.
- For example, you want to see whether using a cell phone leads to brain cancer. So, collect information on how many minutes each student uses his or her phone each week, and collect this information over a *long* time, and then eventually collect information on who gets brain cancer. In technical terms, you record the incidence of cancer among those who use their phones more than a pre-determined amount and compare this to the incidence in the non-users. You could calculate the relative risk.
- The advantages, it can establish that the phone usage predates the cancer, and it allows for accurate collection of exposure information.
- The disadvantages, Brain cancer is rare, so you will need a very large cohort of students; you will also need to keep in contact with them for a very long time and you will probably get very bored waiting for the results.

4-The "case-control" study

- It is a "retrospective" study. This you begin at the end, with the disease, and then work backwards.
- In our example, you could identify a group of patients with brain cancer (these would be the cases in "case-control"). Then identify a control group who do not have brain cancer. Then, collect information on their previous use of cell phones, dating back as far as you can manage. The hypothesis would be that phone usage would be significantly higher in the cancer group than the control group.
 - The advantages are that a case-control study is faster and more cheaply than a cohort study.
 - The disadvantages, may be difficult to collect the information you require on past exposures, and there may be *other* ways in which the cases and controls differ, not just the cell phone use, which could also be causing the cancer. Sometimes you also have difficulty in being sure which came first: the disease or the exposure.

5-Meta-Analysis

- A way of combining data from many different research studies. A meta-analysis is a statistical process that combines the findings from individual studies. It is the most broad and most accurate type of research

6-Case Reports and Series

- A report on a series of patients with an outcome of interest. No control group is involved.

Experimental study designs

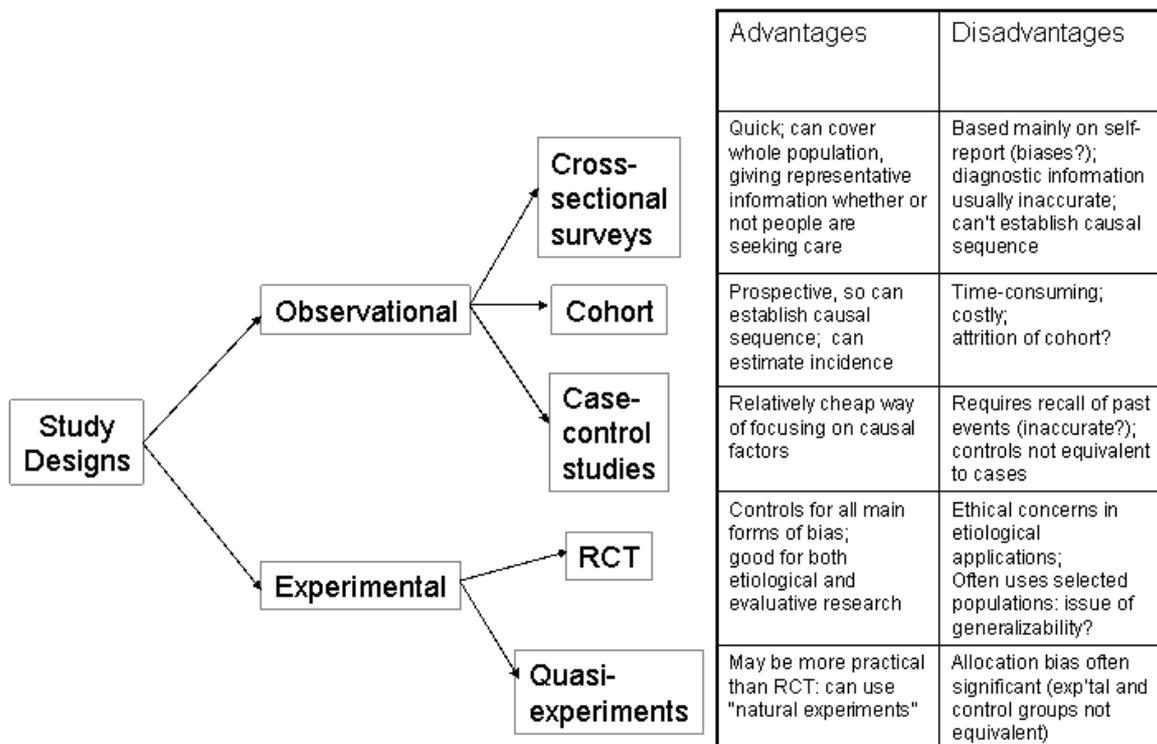
In an *experiment*, when compared to observational studies, the researcher intervenes to change something (e.g., gives some patients a drug) and then observes what happens.

- Example: Warning one group of students that you are going to take blood alcohol levels next Monday to test for alcohol, and comparing their levels to another group that you did not warn.

How to conduct:

- A sample of patients with the condition, and who meet other selection criteria, is randomly allocated to receive either the experimental treatment, or the control treatment.
- Occasionally, a placebo or sham treatment will be used in the control group, but where there is already an accepted treatment, it is unlikely to be ethical to use a placebo.
- The experimental and control groups are then followed for a set time, and relevant measurements are taken to indicate the results (or 'outcomes') in each group.

Summary of advantages and disadvantages of the most common study designs:



❖ Biases in Research:

It is any deviation of results or inferences from the truth, or processes leading to such deviation. Bias can result from several sources: one-sided or systematic variations in measurement from the true value (systematic error); flaws in study design; deviation of inferences, interpretations, or analyses based on flawed data or data collection; etc. There is no sense of prejudice or subjectivity implied in the assessment of bias under these conditions.

- Major Types:

Selection bias: -Occurs when the selection of subjects into a sample or their allocation to a treatment group produces a sample that is not representative of the population, or treatment groups that are systematically different.
-prevented by random selection and random allocation.

Detection bias: -Occurs when observations in one group are not sought as diligently as in the other.
-prevented by observer blinding.

Observer bias: -Occurs when the observer is able to be subjective about the outcome.
-prevented by observer blinding and outcome measure design.

Recall bias: -Occurs when patients know which group they have been allocated to, which influences the way they report past history and symptoms.
-i.e. If patient knows they are in the placebo group they may exaggerate their 'untreated' symptoms.
-prevented by patient blinding.

Response bias:

-Occurs when patients who enroll in a trial may not represent those of the population as a whole.
-i.e. The obese patients who enroll in a weight loss. Medication trial may be more motivated than those in the general population.
-Prevention -> random sampling from population.

Publication bias:

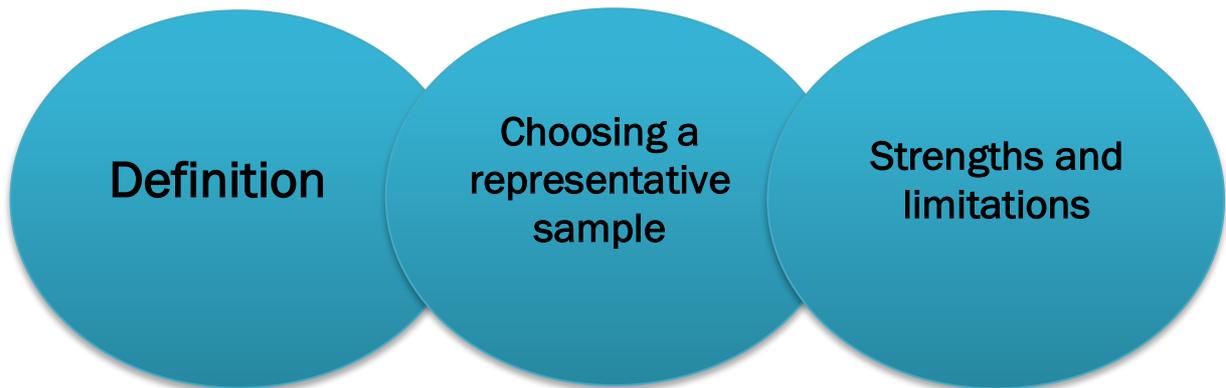
-Occurs because negative studies less likely to be submitted and/or published than positive ones
-Prevented by clinical trials registries and ensuring all well conducted studies are submitted and published (should be mandatory)
-In meta-analysis, the possibility of absent negative studies should be sought for by funnel plot analysis.

YOU are almost done keep going!!

The Cross-Sectional Study Design

This chapter will provide you with the most important elements when it comes to the **cross sectional study design**.

Hopefully, by the end of this chapter, you will learn the following:



❖ Definition:

- A **cross-sectional** study is an observational descriptive study, where the main objective is describing a particular status among a specific community. Such a study is observational since the researcher is not intervening in any way with the subjects, whereas the researcher is only observing the subjects and recording information on them.
- A cross-sectional study represents a snap shot about a particular status in a specific community, at a specific point in time (i.e. one time). This is where the cross-sectional aspect of the study comes from. Although the study might take few months to be conducted, the cross-sectional aspect is specific to each subject, where he/she will be assessed only once, and no follow-up is done.
- In other words, in a cross-sectional study, data are collected on the whole study population at a single point in time to examine the relationship between disease (or other health related state) and other variables of interest.

- Cross-sectional studies therefore provide a snapshot of the frequency of a disease or other health related characteristics in a population at a given point.

Note: Cross-sectional studies are sometimes carried out to investigate associations between risk factors and the outcome of interest. They are limited, however, by the fact that they are carried out at one time point and give no indication of the sequence of events

- Whether exposure occurred before, after or during the onset of the disease outcome. This being so, it is impossible to infer causality.

❖ Types of Cross-sectional Studies:

Descriptive	Analytical
<ul style="list-style-type: none"> • A cross-sectional study may be purely descriptive and used to assess the frequency and distribution of a particular disease in a defined population. For example a random sample of schools across London may be used to assess the burden or prevalence of asthma among 12- 14 year olds. 	<ul style="list-style-type: none"> • Analytical cross-sectional studies may also be used to investigate the association between a putative risk factor and a health outcome. • However this type of study is limited in its ability to draw valid conclusions about any association or possible causality because the presence of risk factors and outcomes are measured simultaneously. • It may therefore be difficult to work out whether the disease or the exposure came first. The collection of information about risk factors is also retrospective, running the risk of recall bias.

❖ Choosing a Representative Sample:

One of the most important challenges of a cross-sectional study is the selection of a representative sample. For instance, in a study assessing the prevalence of hypertension among Saudi adult population, the sample should include a random sample of all Saudi adult population; otherwise the results will not be valid because of selection bias.

Sampling Methods:

1- Probability Sampling: This is also known as random sampling. This method helps to utilize some form of random selection. In order to have a random selection method, you must set up some process or procedure that assures that the different units in your population have equal probabilities of being chosen.

Humans have long practiced various forms of random selection, such as picking a name out of a hat, or choosing the short straw. These days, we tend to use computers as the mechanism for generating random numbers as the basis for random selection.

- **Simple random sampling:** size n is produced by a scheme which ensures that each subgroup of the population of size n has an equal probability of being chosen as the sample.
- **Stratified random sampling:** Divide the population into "strata". There can be any number of these. Then choose a simple random sample from each stratum.
- **Systemic random sampling**
- **Cluster random sampling:** divide the population into groups, obtain a simple random sample of so many clusters from all possible clusters, and obtain data on every sampling unit in each of the randomly selected clusters.

2- Non-Probability Sampling, or convenience sampling, Non-probability sampling is a sampling technique where the samples are gathered in a process that does not give all the individuals in the population equal chances of being selected.

- **Snowball Sampling:** s usually done when there is a very small population size. In this type of sampling, the researcher asks the initial subject to identify another potential subject who also meets the criteria of the research.
- **Judgmental Sampling:** In this type of sampling, subjects are chosen to be part of the sample with a specific purpose in mind. The researcher believes that some subjects are fit for the research compared to other individuals.
- **Convenience Sampling:** the samples are selected because they are accessible to the researcher. Subjects are chosen simply because they are easy to recruit. This technique is considered easiest, cheapest and least time consuming.

❖ Strengths and Weaknesses:

The few strengths and weaknesses of cross-sectional studies are:

Strengths

- Relatively easy to conduct, as the study methodology involves identifying a group of subjects, collecting information about them, and analyzing the data.
- It is a study that could be done over short periods of time, since there is no follow-up involved.
- Data on all variables (exposure, outcome, and confounders) are only collected once.
- Possibility of assessing prevalence for all factors being studied.
- Multiple exposures and outcomes can be studied.
- The prevalence of disease or other health related characteristics are important in public health for assessing the burden of disease in a specified population and in planning and allocating health resources.
- Good for providing descriptive results and for generating hypotheses.

Weaknesses

- Time sequence of exposure and outcome is not implicated in this design, i.e. it is difficult to determine which one came first, the exposure or the outcome.
- Not suitable for studying rare diseases, since very few subjects will be captured in the study, even if it includes a big number of participants.
- The incidence of a disease cannot be calculated through this study design.
- Susceptible to selection bias because of sampling and low response.
- Susceptible to information bias because of recall.
- Susceptible to confounding bias due to inability to collect information on all potential confounders.

❖ Cross-sectional study vs. cohort study:

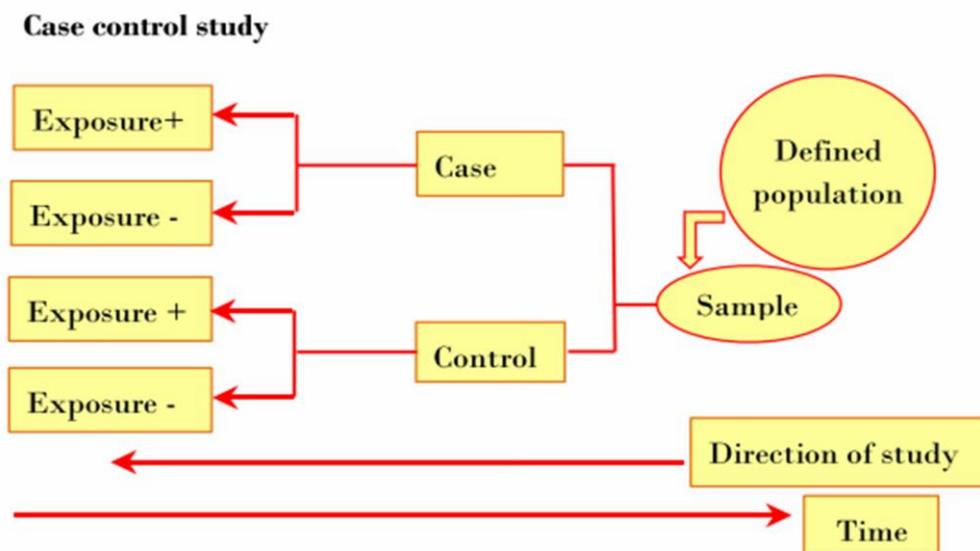
	Cohort Study	Cross sectional
Population at risk	Population at-risk	Entire population (or sample)
Common Measures	Risks and Rates	Prevalence

Case control study designs

A. Definition:

A case control study is an epidemiological study where participants are selected **based on their disease status**. Two groups of subjects are included, **cases** (having the disease under research) and **controls** (Free of the disease). We study the exposure history and compare it between the cases and the controls to assess whether an association exists between the exposure and the outcome.

– In case control study both exposure and outcome already happened in the patients.



▪ Graph Explanation:

In case control, we have defined population so we take a sample from them to study it. This sample will be divided into **cases** (with the disease) and **controls** (without the disease), we'll study the history of exposure in each of them and come up with +ve exposure or -ve exposure.

B. Identifying cases and controls:

If cases are a random sample of cases in the population, then controls should be a random sample of all non-cases in the population sampled at the same time. One general rule is that controls should be at risk of the

Disease. The controls should resemble the cases in all aspects like (age, gender,...etc.) except for the presence of disease.

C. Exposure assessment:

Information about exposure history can be collected by questionnaires.

D. Strengths and limitations:

1-Strengths of case-control studies are:

- a. No follow up is needed, least time-consuming and low financial cost.
- b. Useful for studying rare diseases, since patients are selected based on the outcome status.
- c. Appropriate for assessing the association between different risk factors and one outcome.

2- Limitations of case-control studies are:

- a. Liable to selection bias.
- b. Liable to Recall bias, since information collected has happened long in the past, and it might not be accurate (people with a condition will be more motivated to recall details about past exposures).
- c. Not appropriate for studying rare exposures, since not enough subjects will be found to be exposed.

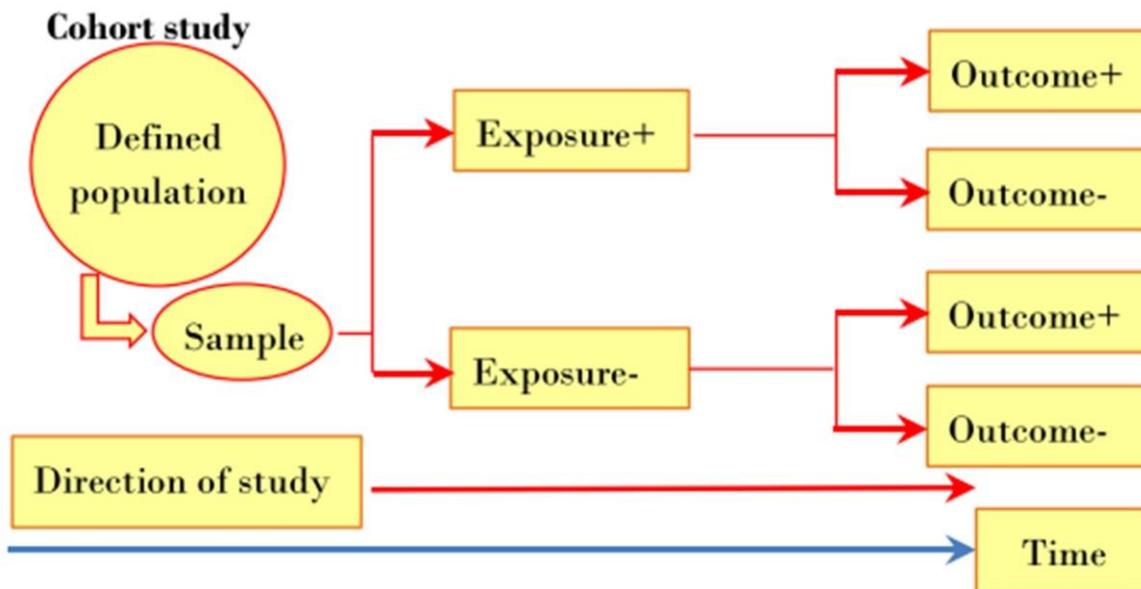
Cohort study designs

A. Definition:

A cohort study is a study where participants are selected **based on their exposure status**. Two groups of subjects are included in this type of study, **exposed** (having the exposure under research) and **unexposed** (not exposed to the factor under research).

Both exposed and unexposed subjects are **free of the disease** under research, but they are *at risk* of developing it. Subjects are then followed prospectively over time to identify those who develop the disease.

Cohort studies could be either **prospective** (None of the subjects have developed any of the outcomes) or **retrospective** (All the events - exposure, latent period, and subsequent outcome - have already occurred in the past).^(2,3) Important thing to know is that the investigator in retrospective cohort studies *does not follow* subjects as it is in the prospective cohort studies.



B. Strengths and limitations:

1-strengths of cohort studies are:

- a. Easier and cheaper than experimental studies.
- b. Establish a relation between exposure and outcome. So, you can build evidence for the causes, and the association between one exposure to different outcomes.
- c. Appropriate for studying rare exposures, since patients are selected based on the exposure status.
- d. A retrospective cohort study is fast to be carried out.

2-Limitations of cohort studies are:

- a. Expensive and takes a long time. (more if prospective). Thus, Loss to follow-up.
- b. Could lead to bias if there is too many subject characteristics.
- c. Not appropriate for studying rare outcomes or Diseases.

Systematic Reviews

A systematic review summarizes the results of available carefully designed healthcare studies (controlled trials) and provides a high level of evidence on the effectiveness of healthcare interventions. Judgments may be made about the evidence and inform recommendations for healthcare.

- **The review plan**

Review authors set about their task very methodically following, step by step, an advance plan called a protocol. The protocol describes the steps that will be followed when preparing a review. PRISMA and Cochrane are examples of widely used protocols.

- **The review question**

The purpose of the review is to assess the effects of [intervention or comparison] for [health problem] in [types of people, disease or problem], and healthcare setting if appropriate.

The parts of the review question are often referred to as 'PICO' (Participants, Interventions, Comparisons and Outcomes).

- **The review data**

The frame of searching and analyze the data depend on review protocol have been chosen. In general those steps are followed regardless type of protocol:

1. **A search for relevant data** from research that matches certain criteria. For example, only selecting research that is good quality and answers the defined question.
2. **'Extraction' of relevant data.** This can include how the research was done (often called the method or 'intervention'), who participated in the research (including how many people), how it was paid for (for example funding sources) and what happened (the outcomes).
3. **Assess the quality of the data** by judging it against criteria identified at the first stage
4. **Analyze and combine the data** (using complex statistical methods) which give an overall result from all of the data.

- **The review title**

Titles of Cochrane reviews also have a set layout: Intervention for problem in a disease or population, and sometimes an outcome. An example is: Surgical excision margins for primary cutaneous melanoma. This is a statement of the types of population (participants in controlled clinical studies), types of interventions (and what they are compared to, even if it is no treatment), and the types of outcomes that are of interest.

- **You can find a full course for systematic reviews in the following link:**

<https://www.youtube.com/playlist?list=PL897F6E0EE60F04EB>

Manuscript Writing

1. Overview

Writing and publishing the results of a study is the most important step a researcher has to accomplish. Unless the results are published, the value of the whole research project will remain minimal. This step is important for the researcher as it provides documentation of the work done and the findings found, and it will provide public knowledge about the research project which may enhance medical knowledge and act as a milestone in the field of research.

A scientific manuscript is an original text of an author's work which is submitted to a publisher. The structure of a manuscript follows strict criteria by the scientific method. It includes different sections that provide the reader with the information needed to understand what was done and what results found, and it depends on the journal to which the article is being submitted.

2. Manuscript preparation

The scientific manuscript is made up of the following sections: *(see Appendix)*

Title Page

1. Abstract and Key words
2. Introduction
3. Methods
4. Results
5. Discussion
6. Conclusion
7. Referances
8. Tables and Graphs

a. Title Page

The title page should have the following information:

- **Title of the manuscript:** It should be simple, concise and informative.
- **Authors' names and institutional affiliations.**
- **Contact information for corresponding author:** The name, mailing address, telephone and e-mail address of the author responsible for all correspondence about the manuscript.
- **Source(s) of funding:** It includes the sources from which funding was provided to carry out the study, if any.
- **Conflict-of-Interest:** To prevent potential conflicts of interest from being overlooked or misplaced, this information needs to be part of the manuscript.

b. Abstract and key words

An abstract **summarizes the major aspects of the entire research project.** The length of the abstract should be kept between **200-300 words maximum** (a typical standard length for journals.) Although there are various abstract forms, which depend on each journal; generally, an abstract should include the following parts:

- **Objectives** or study aims
- **Methods**, such as study design, sample size, inclusion/exclusion criteria, and data collected
- **Results** found which highlights the main findings of the study
- **Conclusion** which summarizes the main conclusion of the study

The abstract helps readers decide whether they want to read the rest of the paper, and it is may be the only part they can be obtained via electronic literature searches; therefore, Sufficient information need to be included to make it comprehensive by itself. It is usually the last part written to make sure that the information in it is in agreement with what is written in the paper.

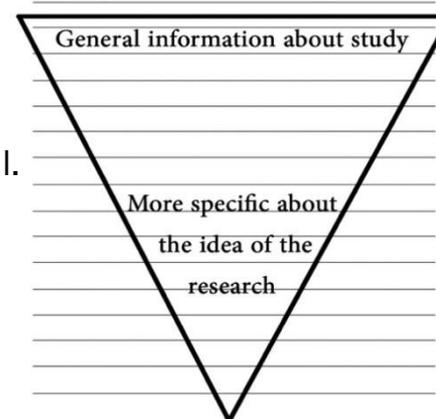
c. Introduction

The introduction provides a context or **background for the study** (**nature of the problem and its significance**) supported by data from the **available literature**, the study objectives and questions that were answered by the study. The structure of the Introduction can be thought of as an **inverted triangle**: (Picture)

The broadest part at the top (early in the introduction) which represent the most **general information** and focusing down to narrow the context to the specific problem you studied.

Finally arriving at your statement of purpose and rationale. It should be able to drive the readers to understand and agree that the idea of the study performed is necessary and reasonable.

• Manuscript introduction



d. Methods

In this section, the following should be explained:

- The study design
- Time and place of the study
- Inclusion and exclusion criteria
- Sampling technique (subject selection) and Sample Size
- Information collected throughout the study
- Informed-consent (if applicable)
- Statistical analyses used to reach the results

e. Results

The study results must be presented in a logical sequence in the text. Overview of the study sample should be provided , followed by results related to the objective of the study. **This section serves as a summary of the tables, but it should not replicate them, rather it should highlight the most important findings.**

f. Discussion

This section **emphasizes the new and important findings** in light of what is found in the literature. Results should not be repeated in this section, rather implications of the results should be addressed. **Specifically, this section should include possible mechanisms or explanations for the findings, comparison of the results with other relevant studies**, indication to the strengths and limitations of the study, as well as implications for future research and for clinical practice.

g. Conclusion

This section summarizes the **potential significance of the paper and final implications on similar research or clinical practice** concluded from the study.

h. References

It is a list of published scientific material (papers, books, etc.) that were used in the manuscript.

i. Tables and graphs

These are the summary of the results obtained from the study under consideration, and should be clearly presented with titles and footnotes.

Some tips after writing the manuscript:

- Read it few times to make sure it flows well, and is free from typos, incomplete sentences, and grammatical errors.
- Give it to some colleagues for review and final comments.

After the manuscript has been written according to the guideline provided by the journal, and once the researcher is comfortable with the manuscript as it stands, submission to a scientific journal is **next**.

3. Manuscript submission

Choosing the appropriate journal for publishing your research papers is a tiresome process. **Research paper should be submitted to a journal whose target audience and scope is relevant**, otherwise the chance of the publication will be low.

Factors to be considered during journal selection:

- a. If the journal is peer-reviewed or not
- b. Scope of the journal
- c. Does it publish original research or review papers
- d. Impact factor of the journal
- e. Average duration of review process
- f. Does it have online submission system?
- g. Cost of publication (page charges etc.)

A cover letter should be prepared and submitted along with the manuscript. It should include the following:

- a. A statement that the manuscript is original work of the author and has not been published before in another journal or other media
- b. Statements about any sponsor that potentially may cause any conflict of interest
- c. A statement that the manuscript has been read and approved by all the authors
- d. The name, address, and telephone number of the corresponding author, who is responsible for communicating with the journal

The next step is to submit the manuscript to the selected journal, following the step-by-step submission process, which varies from journal to journal. Most of the scientific journals nowadays accept electronic submission of manuscripts. Authors should consult the journal's –Instructions for Authors|| for detailed description of the submission process. Many journals provide a pre-submission checklist to help the author ensure that all the components of the submission have been included.

4. Submission response

The time between submission and receiving the response from the journal could be as short as a day and as long as few months.

There are three possible responses to the submission of the paper:

a. Acceptance as is

Indicates that the editorial office, **accepts the manuscript without any further modifications**, which is rarely the case. Accordingly, the next step is to finalize the process by signing the –copyright transfer agreement|| that is specific to each journal.

b. Conditional acceptance

Indication that the manuscript has good chances of being accepted for publication. Usually, lists of comments are sent to the author. Some of these comments could be minor (such as typos) or major (such as further analyses). **The next step for the authors is to address each and every comment received with as much details as possible**, by either abiding by the suggestions or by not taking them into consideration. In either case, the authors should justify their action. At this point, the modified draft of the manuscript, along with a point by point letter addressing the comments should be sent to the journal, through the online system. It might take few rounds of revisions before the manuscript is accepted.

So, you will send two files for the journal: the edited manuscript and a sheet with the answers for their comments

c. Rejection

Indicates that the manuscript is rejected for publication in that journal, for reasons that might be based on the topic, the quality, the conclusion, or just that it does not fall within the scope of the journal. At this point, the authors should look for another journal to which they should submit their manuscript.

Although the publication process might be time and effort consuming, it is very important and it gets easier with time, as the researcher publishes more papers. One last thing to keep in mind is that most research projects are publishable in scientific journals, but the type and impact of the journal in which it will be published might differ.

Appendix: Manuscript Template

Title Page

Authors

Affiliations

Corresponding author

Conflict of interest:

Abstract

Background:

Objectives:

Methods:

Results:

Conclusion:

Keywords:

Introduction

1- Background information about the topic

2- What is known

3- Gap in knowledge

Conclude the Introduction section with a statement about the objective(s) of the study

Methods

Study design:

Setting:

Study population:

- a. Inclusion criteria

- b. Exclusion criteria

Sampling: (Selection of patients)

Data collection:

1. Method of data collection
2. Data collected

I.Information

- a. what
- b. when

II.Questionnaire used

Endpoints:

Ethical considerations:

- 4- IRB approval
- 5- Consent forms
- 6- Confidentiality

Statistical analyses:

- I. Program used
- II. Data cleaning
- III. Data management
- IV. Data analyses
 - a. Univariate
 - b. Bivariate
 - c. Multivariate

Results

Overall description of participants (demographic characteristics and socioeconomic profile)

Summary of findings

Multivariate analyses

Discussion

Summary of study and findings

1. Overall methodology and objective

2. Overall finding

Comparison with literature (comparing results to similar studies)

Strengths and limitations

Future recommendation

Conclusion (final statement about the overall study)

Tables and Graphs

References

Resources:

- Introduction to clinical research for residents from SCFHS.
- https://www.ihrp.uic.edu/files/DuBois_litreviews_june2012.pdf
- https://sph.unc.edu/files/2015/07/nciph_ERIC8.pdf
- <https://www.nature.com/ebd/journal/v7/n1/full/6400375a.html>
- <http://www.uniteforsight.org/research-methodology/module2>

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تمنياتنا لكم بالتوفيق