بسم الله الرحمن الرحيم

"الذي علم بالقلم، علم الانسان ما لم يعلم"

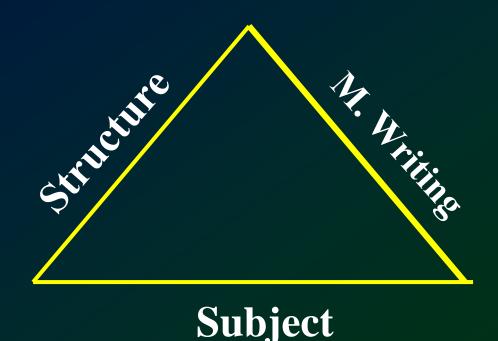
صدق الله العظيم

HOW TO WRITE A RESEARCH PROPOSAL

BY

Ahmed Shokeir, MD, PhD, FEBU Professor of Urology, Mansoura Urology & Nephrology Center, Mansoura, Egypt.

Research Proposal Three Essential Requirements "Basic Triad"



Research Proposal Three Essential Requirements "Basic Triad"

I- Subject worthwhile to report.

Subject

Research Proposal Three Essential Requirements I- Subject

- There should be an addition to the already existing literature.
- Read the relevant literature carefully.
- Make sure that you are not repeating what had been done successfully before.
- The hypothesis of your research project must be very clear and adds something new.

Research Proposal Three Essential Requirements I- Subject

It is better to spend 2 weeks reading in the library than 2 years working in the lab.

 Do not waste your time in writing a paper which will never see day-light.

Research Proposal Three Essential Requirements "Basic Triad"

II- Basic structure of manuscript.



Contents of The Research Proposal

- Title page.
- Introduction.
- Aim of the work
- Materials & Methods.
- Expected outcome.
- References.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Title Page

Title.

Candidate Affiliation .

Supervisors Affiliation.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Title Page The Title

- Informative, specific, comprehensive, and accurate stating exactly what you mean.
- Convey the maximum information with the minimum of words.
- Express (at least):
 - The main issue of the study.
 - The type of the study.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Title Page The Title

- Should be considered again, again and again when the project proposal is finished.
- The final title is the last sentence to be written in the proposal.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Title Page The Names

Be very careful to use only one name with the same spelling and the same initials for all your publications.

Example of different initials:

Ghoneim MA

Ghoneim M

Introduction.

Aim of the work

Materials &

Methods.

Expected

outcome.

References.

Title Page The Names

Example of different spelling:

Shokeir

Shokier

Shokair

shokeer

Introduction.

Aim of the

work

Materials &

Methods.

Expected

outcome.

References.

Title Page The Names

The compound names should be written as one word

Abd El Rahman

Abdulrahman



Introduction.

Aim of the

work

Materials &

Methods.

Expected

outcome.

References.

Introduction

Definition:

It introduces the subject but does not develop it.

Objectives:

- 1- To hold the reader's attention.
- 2- To give sufficient information to whet the appetite.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Introduction Importance

- It sets the tone and quality of the entire project.
- How a writer begins will determine whether his reader bothers to go on and how he ends will determine whether the reader is satisfied or unconvinced.

Introduction.

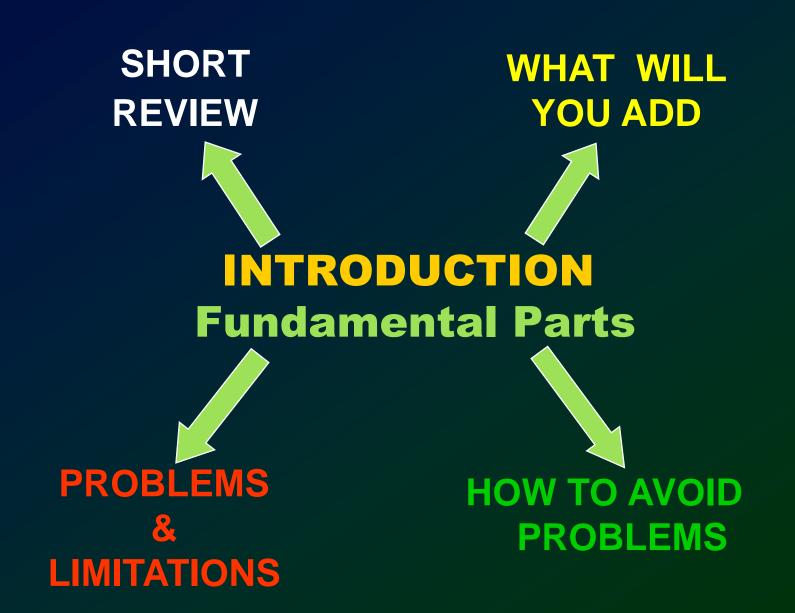
Aim of the work

Materials &

Methods.

Expected outcome.

References.



Introduction

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Fundamental Parts

1- Short Review

- Should touch the core of the subject.
- Should be concise and interesting, not boring.
- Should adequately cite the previous similar work.
- Should be provided by some updated references.

Introduction

Fundamental Parts

2- Limitations of existing literature

Aim of the work Con

Materials & Methods.

Title page.

Introduction.

Expected outcome.

References.

Convince the reader of the importance of your study.

Give reasons for investigating this particular subject.

Introduction

Title page.

Introduction.

3- How to avoid problems of previous studies

Aim of the work

Materials & Methods.

Expected outcome.

References.

You should explain how your study will help solving some of the problems of the existing literature.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Introduction

4- How will you add

- You have to explain how your study will add some of the new information to those already existing in the literature.
- The rationale of the study (Study hypothesis) must be strong and very clear.

Evaluation of the Introduction

Title page.

The reviewer asks the following questions:

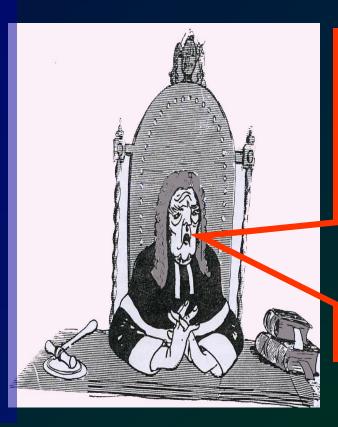
Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.



- 1- Are the objectives clear?
- 2- Is the importance of the study adequately emphasized?
- 3- Is the subject matter of the study new?
- 4-Is previous work on the subject adequately cited?



Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Aim of the work

The study should answer a timely and important question.

The aim should be achievable by the methods.



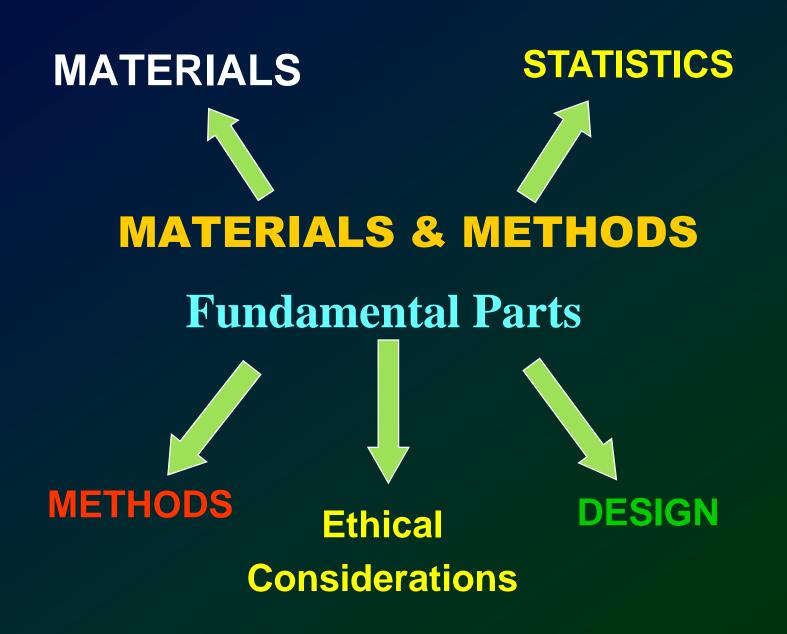
Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.



Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

1- Materials e.g. Patients

- Patients:
 - Number.
 - Demographics.
 - Locality of the study.
 - Duration of the study.
- Inclusion criteria.
- Exclusion criteria.

Introduction.

Aim of the work

Materials & Methods.

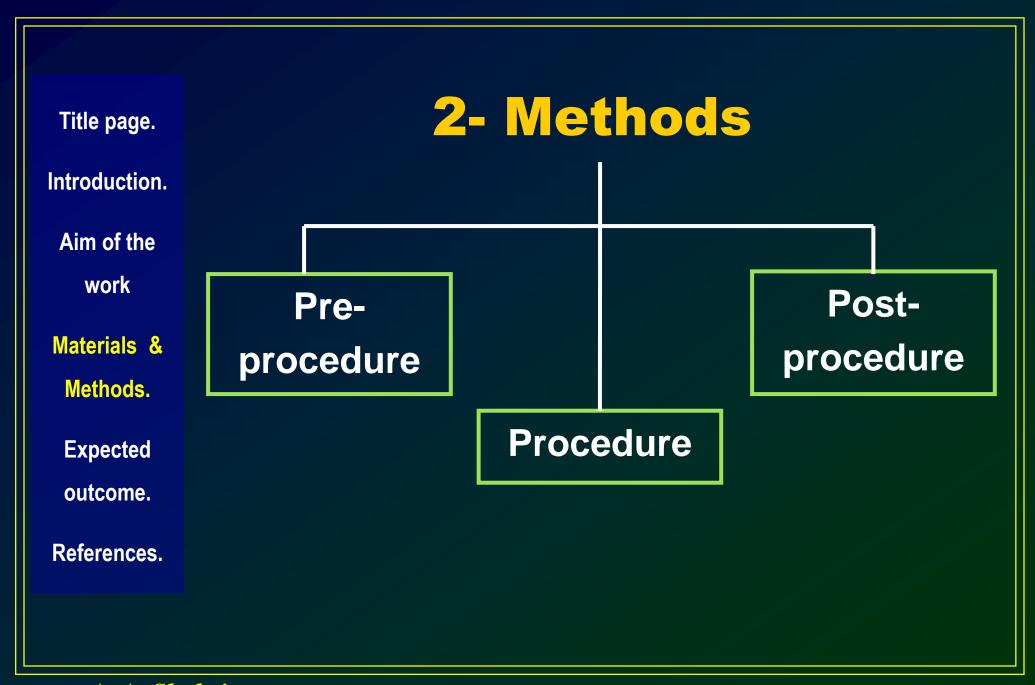
Expected outcome.

References.

2- Materials

e.g. Animals

- Animals:
 - Species, strain.
 - Weight.
 - Gender.
 - Number.
 - Locality of the study.
 - Duration of the study.
- Animal Model
 - Full description.



2- Methods

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

A- Pre- procedure

- How to prepare your patient to be included in the study e.g.:
 - History.
 - Clinical exam.
 - Lab.
 - Inves.
 - Imaging.
 - etc.....

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

2- Methods

B- Procedure

- Full description of the procedures e.g.
 - Surgical technique.
 - Radiological technique.
 - Lab. Technique.
 - Drug intake.

Introduction.

Aim of the work

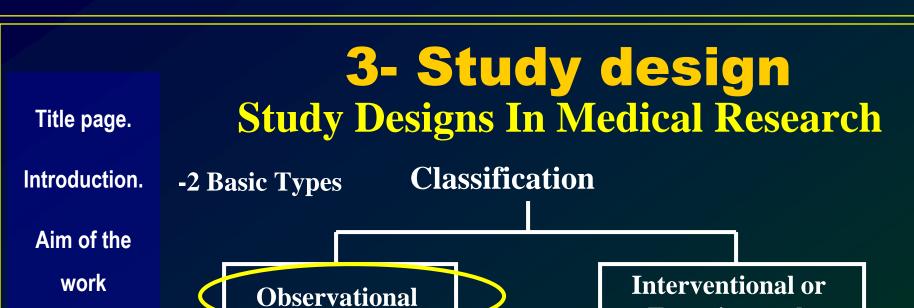
Materials & Methods.

Expected outcome.

References.

2- Methods C- Post- Procedure

- Follow-up.
 - Tools of follow-up.
 - Time interval.
 - Duration.
- Analysis.
 - How will you interpret your data.



Materials & Methods.

Expected outcome.

References.

Subjects are observed

No intervention

-Unclassified Type

Meta-analysis

Experimental

- Intervention is done
- •Effect of interv. observed

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

3- Study DesignClassification

Observational Studies

4 Types

- 1) Case series
- 2) Case control
- 3) Cross sectional
- 4) Cohort

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

3- Study Design Classification

Observational Studies

Initial Step

Generate Hypothesis

Case – series Studies

- The simplest design
- Author describes some interesting observations
- A small number of patients
- Leading to generation of hypothesis

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

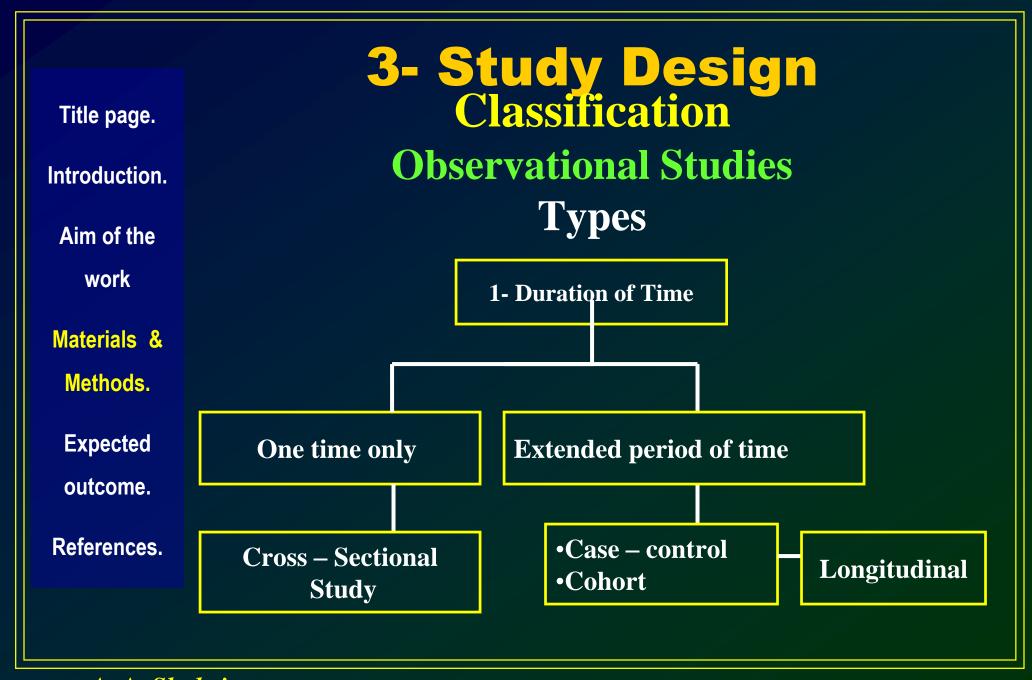
References.

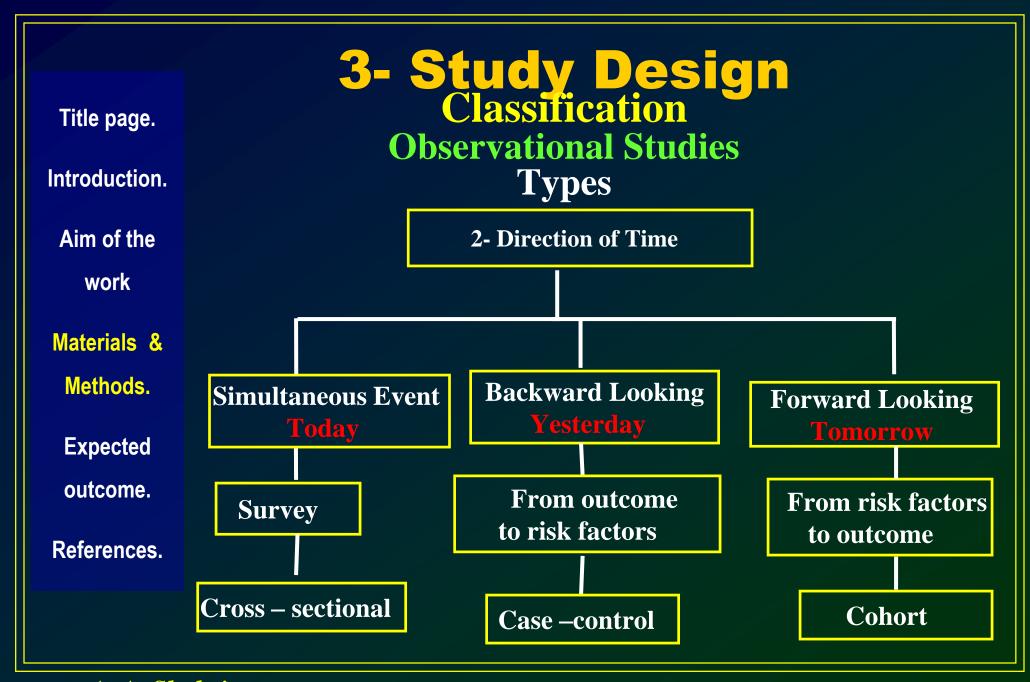
3- Study DesignClassification Observational Studies

Subsequent Step

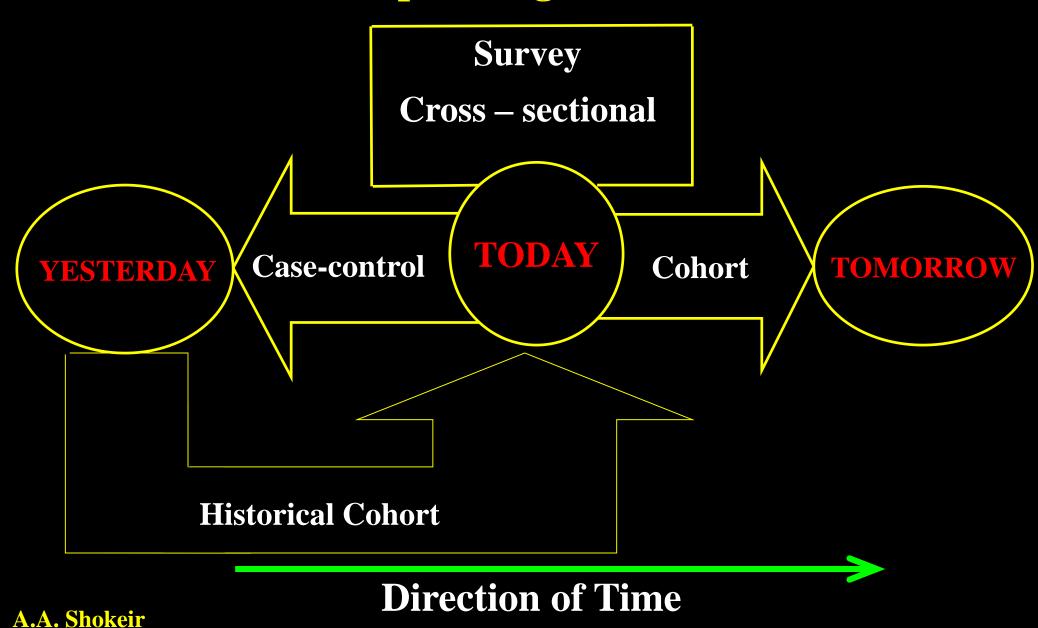
Test Hypothesis

- Hypothesis generated by case series studies are further investigated by the other 3 types of observational studies depending upon 2 factors :
 - **1- Duration of Time**
- 2- Direction of Time





Time relationship among observational studies



Time Relationship Among Observational

Studies

Title page.

Introduction.

Aim of the

work

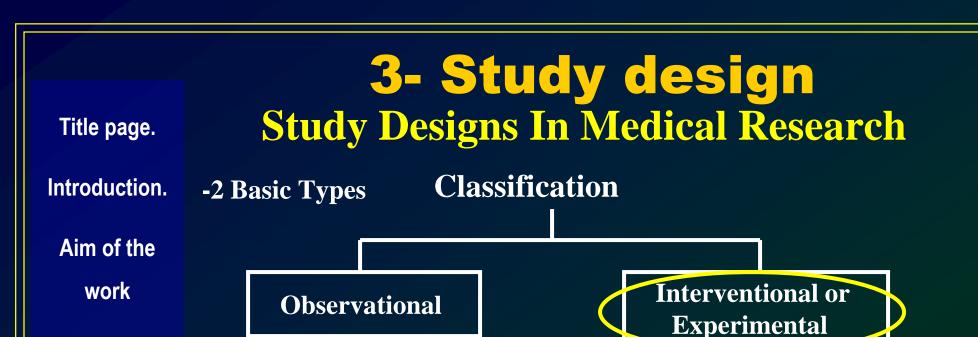
Materials & Methods.

Expected outcome.

References.

Study	Time	Terminology	Question
Cross sectional	Right now	Survey	What is happening?
Case-control	In the past	Retrospective	What happened?
Cohort	In the future	Prospective	What will happen?

A. A. Shokeir



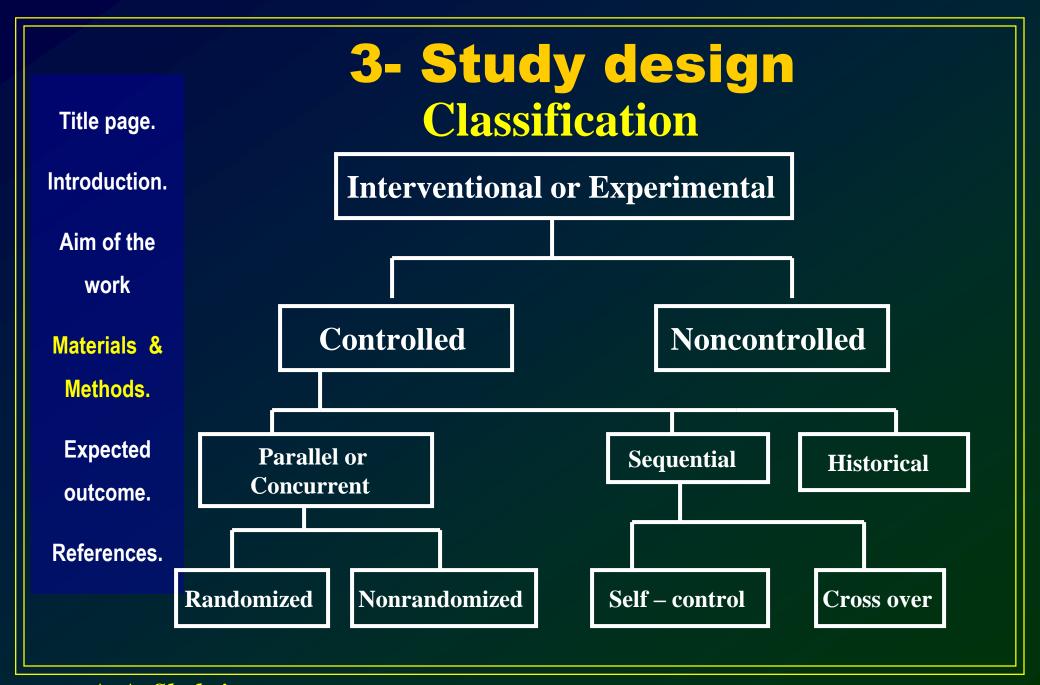
- Materials & Methods.
- Expected outcome.

References.

- Subjects are observed
- No intervention
- -Unclassified Type

Meta-analysis

- Intervention is done
- Effect of interv. observed



A. A. Shokeir

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Types of control in RCT

- Types of controls in RCT
 - Or standard of care.
 - 2) Placebo
 - 3) Sham

Introduction.

Aim of the work

Materials &

Methods.

Expected

outcome.

References.

3- Study design

How To Do Randomization

The most common:

□ Closed envelop

□ Computer generated random tables.

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Masking Randomized Clinical Trials (RCT)

Types	Patient	Doctor
1- Open-label	$\sqrt{}$	$\sqrt{}$
2- Blind	X	$\sqrt{}$
3- Double Blind	X	X

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

RCT_s As part of Drug Approval

- RCT_s are not suited to the initial investigation of a new treatment.
- When used as part of the drug approval process, RCT are frequently referred to as phase III trials.

Title page.

Introduction.

Aim of the

work

Materials & Methods.

Expected outcome.

References.

Phases of Pharmaceutical Trials Phase I Trial

- Initial efforts to administer the treatment to human being.
- It includes experimental animal studies to adjust the dosage regimen and to evaluate potential toxicities.
- It also includes human volunteers.
- It provides only a preliminary look at the potential efficacy of the therapy.

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Phases of Pharmaceutical Trials Phase II Trial

Usually small-scale controlled or uncontrolled trials.

The aim is to establish whether full-scale

RCT should be conducted.

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Phases of Pharmaceutical Trials

Phase III Trial

- It is a classic RCT.
- The FDA requires 2 independently conducted RCT before reviewing a drug for approval.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

3- Study design Phases of Pharmaceutical Trials Phase IV Trial

Post marketing trials.

Studies after FDA approval and use of

the drug in the market.

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

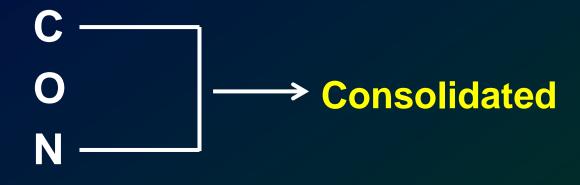
Sample Size

Calculation of sample size is an

integral part of RCTs.

CONSORT flow chart

- It is an integral part of any RCT



S → Standard

 $O \longrightarrow OF$

R ------> Reporting

T → Trials

CONSORT flow chart (5 stations)

Assessed for Eligibility

No.Pts.Included

Enrollment

No.Pts.Excluded

Allocation

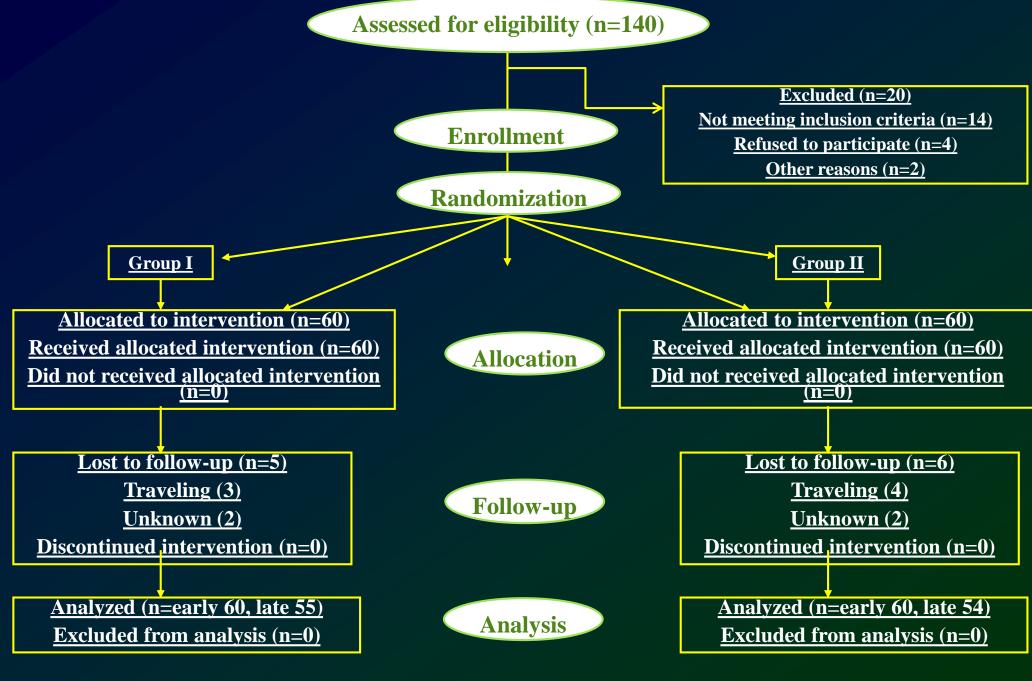
No.Pts. Available for randomization

Fllow-up

No.Pts. Lost for follow-up

Analysis

No.Pts. Available for Analysis



CONSORT flow chart

4- Statistical Analysis

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

In biological sciences, all measurements are inexact. The only way to describe this variability is to use statistics intelligently.

4- Statistical Analysis

Introduction.

Aim of the

work

Materials & Methods.

Expected outcome.

References.

Univariable.

Bivariable.

Multivariable.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

5- Ethical Considerations

- Consent.
- Approval by the ethical committee.
- Funding.
- Conflict of interest.
- Declaration of Helsinki.

Materials And Methods

General Advice

Title page.

Introduction.

Only new methods are described in details.

Aim of the work

Previously published methods:

Materials & Methods.

- Common: Enumeration + reference.

Expected outcome.

- Uncommon: Short summary + reference.

References.

Do not lose your objective. All methods used should be devoted to satisfying the objectives.

Evaluation of the Materials and Methods

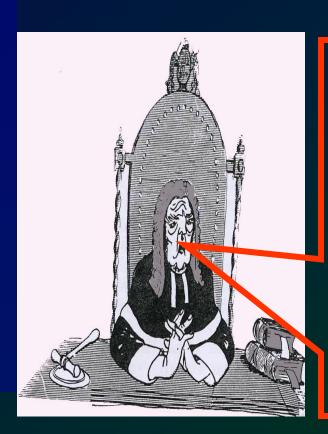
Introduction. The reviewer asks the following questions:

Aim of the work

Materials & Methods.

Expected outcome.

References.



- 1- Is the study population detailed adequately?
- 2- Are the methods described well enough to reproduce the experiment?
- 3- Is the study design clear?
- 4- Are statistical methods included?



Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Expected Outcome

What is your expectations?

How your study will add to the

scientific community?

Are there any economic benifits?



Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

REFERENCES

Styles

1- Alphabetical: For thesis.

2- Vancouver: For Journals.

Introduction.

Aim of the

work

Materials &

Methods.

Expected

outcome.

References.

REFERENCES Alphabetical Style

In the text :

Shokeir, 2016

Shokeir and Ghoneim, 2016

Shokeir et al., 2016

Introduction.

Aim of the work

Materials &

Methods.

Expected

outcome.

References.

REFERENCES Alphabetical Style

In the reference section:

Journal Reference

- Authors (Family, Initials)
- Year
- Title
- Journal
- Volume
- Pages (First-last)

Introduction.

Aim of the

work

Materials &

Methods.

Expected

outcome.

References.

REFERENCES Alphabetical Style In the reference section

Book Reference

Author of the chapter

Chapter title, In

Names of editors

Book title

Year

Publisher (Company, town, country).

Pages of the chapter (first - last).

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

REFERENCES Arrangement

References are arranged in the

reference section alphabetically

without numbers.

General Advice

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

 Each journal has its own style of references (house-style).

 All references should be written in the same style with the same arrangement.

A. A. Shokeir

General Advice

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

Recent references are better than old ones.

A book reference is of the least significance.

General Advice

Title page.

Introduction.

Aim of the work

Materials & Methods.

Expected

outcome.

References.

The integrity of the references is the

responsibility of the authors only

(neither the referee nor the journal).

Title page.

Evaluation of References

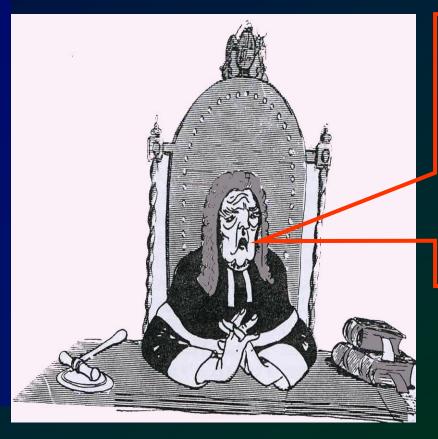
Introduction.

Aim of the work

Materials & Methods.

Expected outcome.

References.

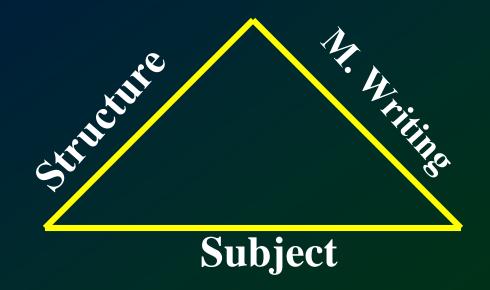


If you are lax with the references you may have been lax with the entire protocol.

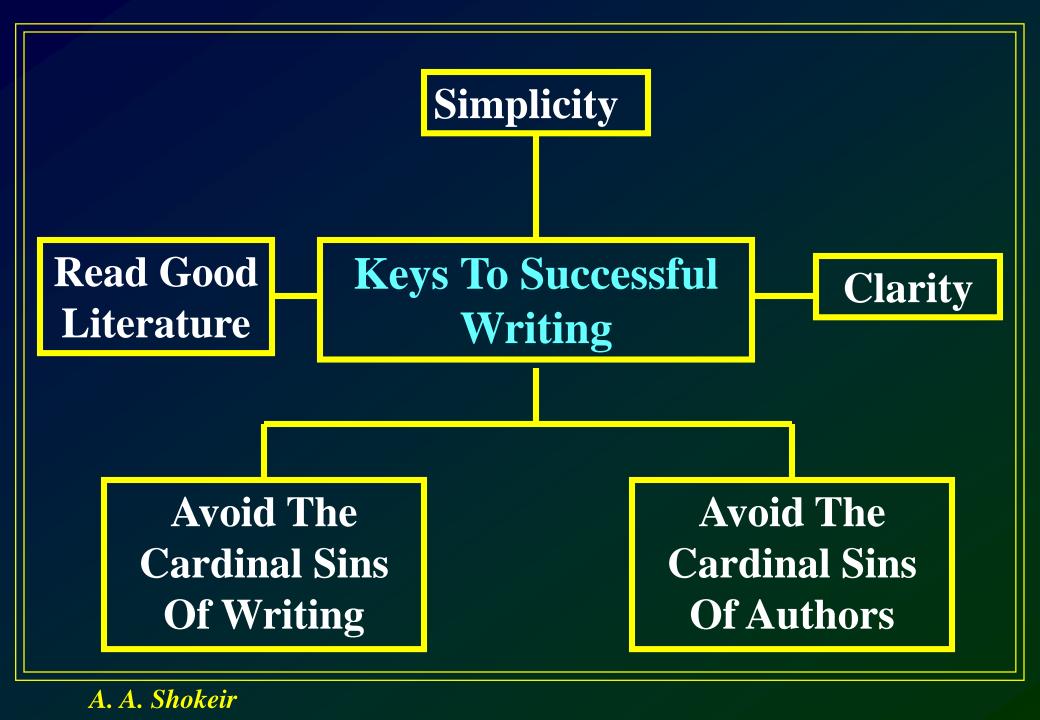


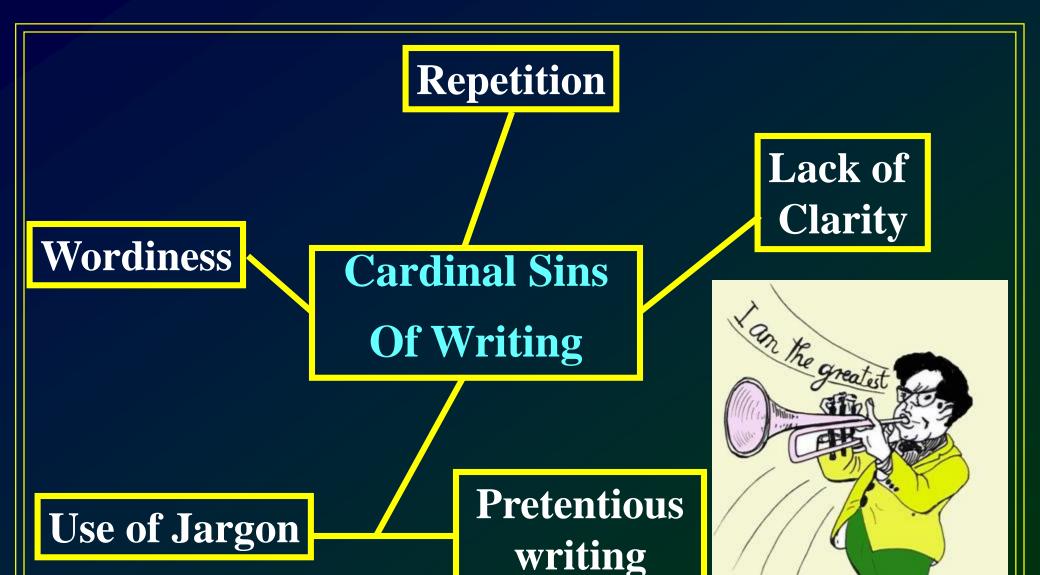
Research Proposal Three Essential Requirements "Basic Triad"

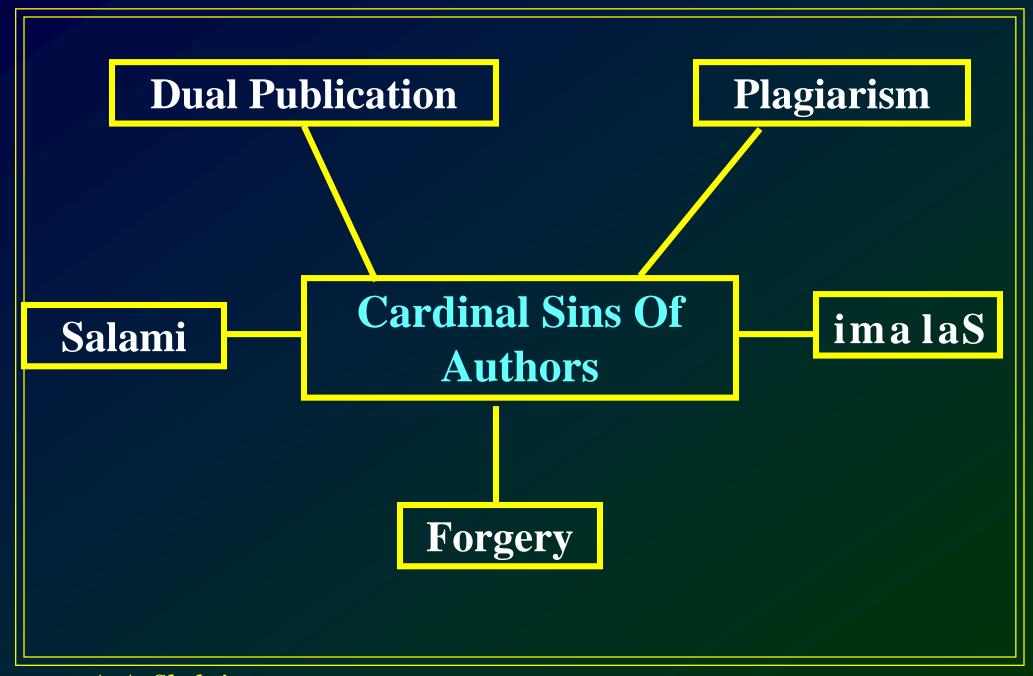
III- Mechanics of Writing.



Verb Tenses Introduction **Present** Methods **Future Expected Future** outcome







THANK YOU

