Presentation by

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"Fundamental Steps of Research Paper Writing"

PROFESSOR

Post-Graduate Department of Pharmacology

Government Medical College, Jammu (J&K)

Editor In Chief

JK Science Journal of Medical Education and Research (EMBASE)

Journal Midlife Health (MEDLINE/PUBMED) 2020-2021

Writing the Research Paper

- Necessary IEC Certificates/CTRI Number/Regulatory approval if applicable
- Title
- Abstract (Structured/Non Structured as per Requirement)
- Key Words (MeSH)
- Running Title
- Introduction
- Aim & Objectives
- Materials and Methods
- Results
- Discussion
- Limitation of the study
- Conclusion
- References
- Figs & Table
- Appendices

Title of Research

Simple specific and concise, but informative Interesting and eye-catching but no over-claiming Accurate and specific about paper's content State the subject in full May Indicate study design, animal species **Grammatically correct** Avoid long title (see previous article in journal) Avoid abbreviations Avoid repetition of aims and objective Should not conclude the study Should not State results

What is wrong in the title

Incorrect

 To Evaluate Efficacy And Safety of Caralluma Fimbriata In Overweight And Obese Patients With Or Without Associated Co-Morbid Conditions in Jammu Region

Correct

 Efficacy and Safety of Caralluma Fimbriata In Overweight and Obese Patients: A Randomized Double Bind Placebo Control Study

What is wrong in the title



Incorrect

Metformin increases cancer specific survival in colorectal cancer patients-National cohort study.

Correct

 An Effect of Metformin on cancer specific survival in colorectal cancer patients- A National cohort study

In-Correct

Is fasting plasma glucose in early pregnancy a better predictor of adverse obstetric outcomes than glycated haemoglobin?

Correct

Fasting plasma glucose Vs glycated haemoglobin in early pregnancy for prediction of adverse obstetric outcomes: A Comparative Clinical Study

In- Correct

First Indian study evaluating role of biochemical investigations and diagnostic tools in detection of adverse drug reactions.

Correct

Role of biochemical investigations and diagnostic tools in detection of adverse drug reactions: A Retrospective Observational Study

Abstract

 A Precise, accurate, Structured or Unstructured summary of the paper

- Purposes
 - Included in several abstracting services (including Medline/ EMBASE/Scopus/DOAJ)

Helps readers browse and decide

Abstract

- A brief statement of chief points
- Short but intelligible
- Informative and interesting
- Avoid unnecessary detail
- Should convey Every thing of the original work precisely
- Accurate
- Should generate Interest to read full paper

Abstract

Structured/unstructured

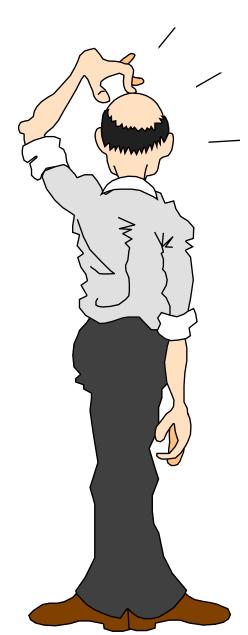
Length: 150-250 words

No references or abbreviations

Include main statistical conclusions

Structured abstract

- Background
- Objective
- Study Design
- Methods
- Results
- Conclusion

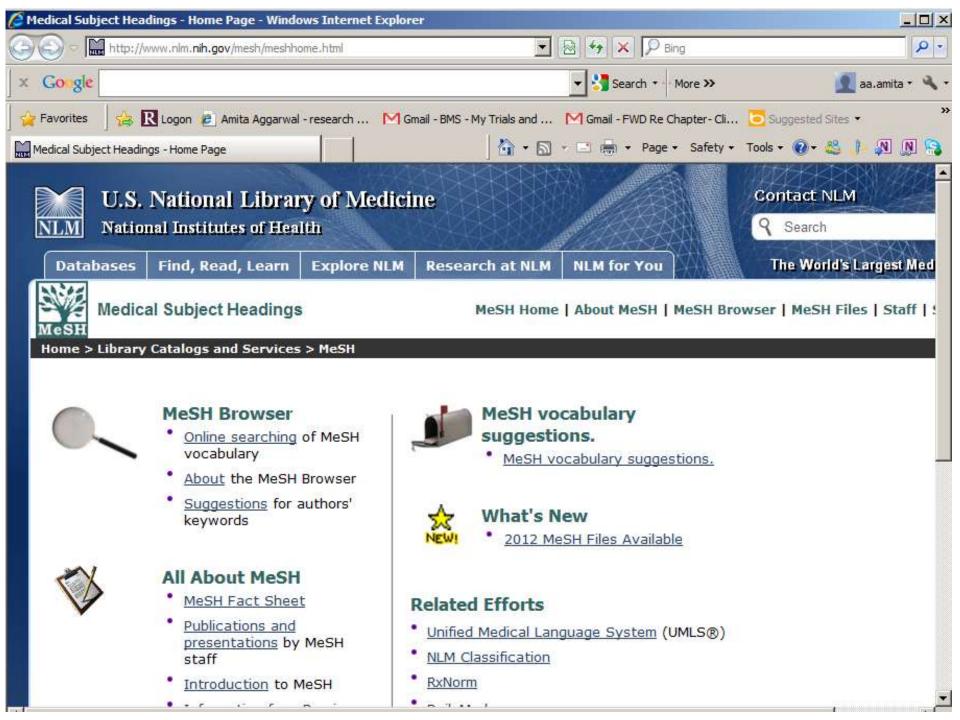


Keywords

- Words or short phrases used for crossindexing, and retrieval
- 3-10 identifiers representing main concepts included in the article
- Exclude words already in title
- Arrange alphabetically
- References of an Article gives insight for Key words

Key words

 Use terms from the latest Medical Subject Headings (MeSH) list of Index Medicus.



Sir Bradford Hill's Questions

Introduction Why did you start?

M Methods What did you do?

R Results What did you find?

A and

D Discussion What does it all mean?

Summery How to write Introduction

- Essentially this section must introduce the subject
- Should reflect Volume of the problem
- Give a concise background of the study
- Do not review literature extensively but provide the most recent work that has a direct bearing on the subject. Reflect the gap in the knowledge briefly
- Rationale and Justification for research aims and objectives must be clearly mentioned without any ambiguity.
- What new It is adding
- Significance and relevance of study
- The purpose of the study should be stated at the end.

Example

We wish to suggest a structure for the salt of deoxyribose nucleic acid (D.N.A.). This structure has novel features which are of considerable biological importance.

Watson JD, Crick FHC. A structure for deoxyribose nucleic acid. Nature 1953; 171: 737-8.

Problems

- Historical details
- Frequently too long
- Too general and vague
- Contains 'discussion' material
- Mechanism
- Imitative (Copying Some one)
- Chemical Structures
- Details of the research design
- information that is not directly relevant to your study
- Problems other than the one being examined



How many Objectives

- One or two maximum three
- Too Many Objective become difficult to meet and study start becoming directionless and purposeless and it decreases the chance of its successful completion

Stating the objectives

- Reason for doing the study
- Use action verbs: To determine, to compare, to verify, to describe, to establish, To evaluate, To find correlation, analyze
- Avoid verbs: To appreciate, to comprehend, to realize

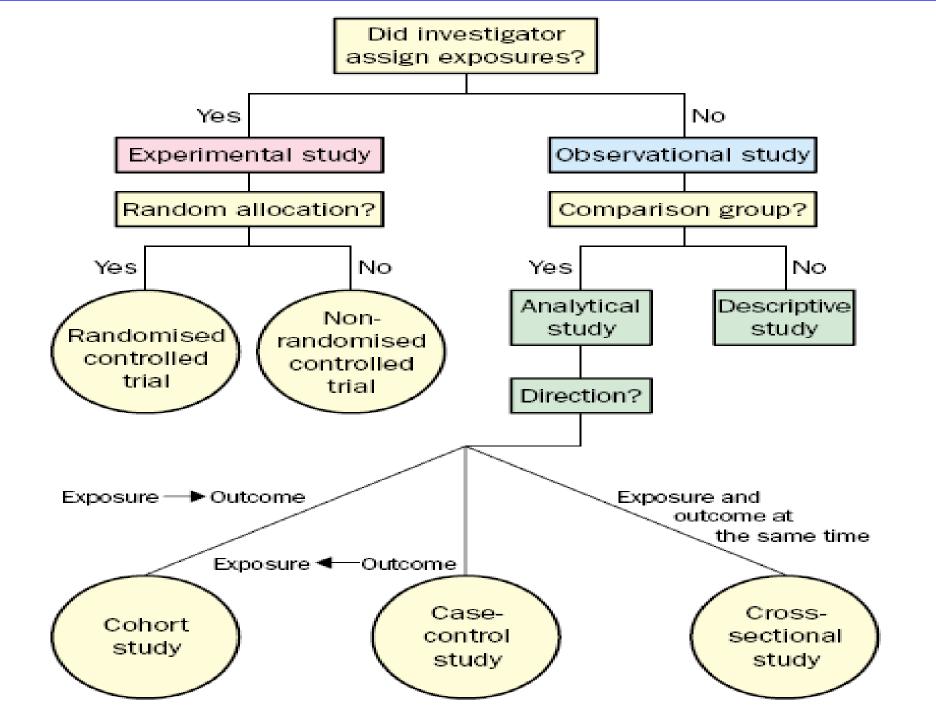
Always better to have

Primary Objective

Secondary Objectives

Information to include

- An expression describing an overall approach (To asses, to compare, to determine etc)
- Names of all medicine being evaluated
- Dose / dose range/ Regimen
- Disease being evaluated
- Type of patient being evaluated
- Purpose Efficacy safety, pharmacokinetic
- Specific purpose- Superiority to placebo / Equivalence / Non Inferiority





- Study Design
- Randomization
- Blinding
- Time and duration of study
- Place of study and collaborating Department
- IRB/IEC Clearance/Regulatory Clearance
- Clinical trial registration Number
- Informed consent
- Define study population and number
- Explain protocol clearly
- Detail of Baseline Clinical/ Biochemical Screening

- Inclusion criteria
- Exclusion criteria
- Define Study Groups allocation Clearly
- Detail of Methods with original references
- Clearly define if any modification made
- Basis of Dose selection Important
- Principles of precaution and risk minimization
- Assessment of Outcomes- primary and secondary
- Very Important to Define Parameters of Evaluation and their Time protocol and their interpretation
- CONSORT Flow diagram

CTRI India at NIMS (ICMR)

- CTRI is a primary registry of the International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/search/en/). Registered trials are freely searchable both from the WHO's search portal, the ICTRP as well as from the CTRI.
- All clinical trials conducted in India to be **prospectively** registered, i.e. before the enrolment of the first participant.
- It also accept registration of trials conducted in other countries in the region, which do not have a primary registry of its own.
- The Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics (NIMS), is a free and online public record system for registration of clinical trials being conducted in India from 2007. (www.ctri.nic.in)
- Initiated as a voluntary measure, since 2009, trial registration in the CTRI has been made mandatory by the Drugs Controller General of India (DCGI).
- Editors of Biomedical Journals of 11 major journals of India declared that only registered trials would be considered for publication.

Parallel study design With Placebo

PATIENTS OF COPD WITH OA

120 PATIENTS

Inhaled Salbutamol X 2WK+ Exercise +Local treatment of Joint 2 WK

RANDOMISATION

GROUP I n=60
Diacerine 50 mg daily+
Inhaled Salbutamol+
Exercise+ Local T/t

GROUP II n=60
Placebo+
Inhaled Salbutamol+
Exercise +Local Joint T/t

Post Drug *Objective Parameters* like lung functions (FEV₁ and FVC, FEV, FEF25-75) And *Subjective Parameters* like improvement in respiratory symptoms, QOL & safety (BP, HR, ADR) were assessed and Compared

Patients above 55 years Both sexes Patients giving consent COPD with OA Stable COPD FEV1 <60% FEV1/FVC Ratio <70% One Knee Joint Involved with mild to moderate OA

Chronic respiratory disease other than COPD. **Asthma** Unstable respiratory status Recent viral, bacterial Pulmonary infection Continuous daily oxygen requirement Congestive cardiac failure Inability to discontinue **COPD** medication Uncooperative H/O sensitivity to any of the drugs Patients not giving consent Patients taking drugs likely to interact with the drugs under study NSAID, Corticosteroids, Glucosamine or DA requirement must

STATISTICAL ANALYSIS

Results

- Start with demographic and baseline results
- Results of all experiments

 in natural order
 in subsections similar to methods and

 parameters evaluated
- Do not duplicate information text, tables, figures
- Statistical analysis

Results

- Should not include
 - Any methods
 - Data for which methods are not included
 - Interpretation of data
 - References

Results

- Results may be presented in the form of
- Frequency distribution tables or
- Using diagrams such as bar diagram, pie chart, pictogram, histogram, line diagram, scatter diagram etc.

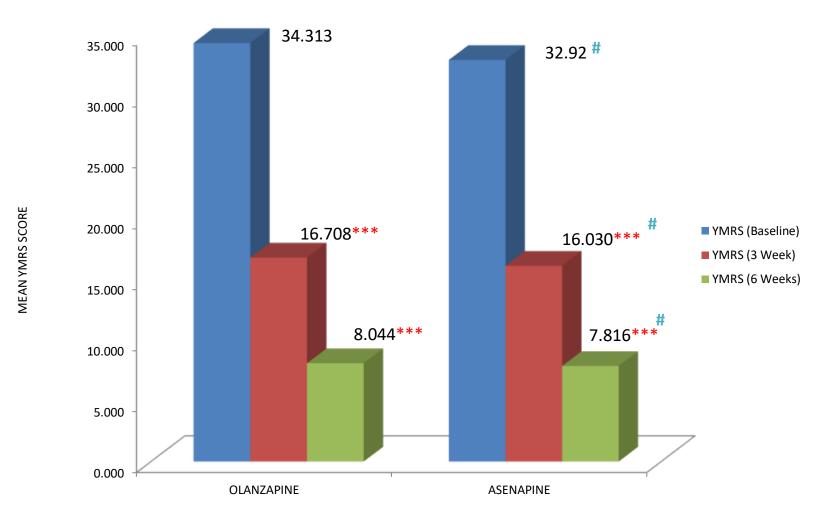
Base line Characteristics

TABLE 3: MEAN DIFFERENCE (% CHANGE) FROM RESPECTIVE BASELINES OBSERVED WITH OLANZAPINE AND ASENAPINE ON YMRS SCORE AT WEEK 3 AND 6

Variable	Drugs		Statistical Inference	
Mean Difference of YMRS	Olanzapine (Mean ± SEM) (% Change)	Asenapine (Mean ± SEM) (% Change)	t	p
At 3 Weeks	-17.60 ± 0.93 NS (51.30)	-16.89 ± 0.75 NS (51.31)	-0.60	0.55#
At 6 Weeks	-26.40 ± 0.65 *** (76.94)	-24.64 ± 0.69*** (74.86)	-1.86	0.07#

The data is shown in Mean \pm SEM; YMRS: Young Mania Rating Scale Paired't' test in comparison to respective baselines * p < 0.05; ** p < 0.01; *** p < 0.001 Comparison between the groups at Baseline, 3 weeks and 6 weeks with Unpaired Student't' test p < 0.05; p < 0.01; p < 0.01; p < 0.001; p < 0.001

Fig. 1 EFFECT OF OLANZAPINE Vs ASENAPINE ON YMRS SCORE IN PATIENTS OF ACUTE MANIA



The data is shown in Mean \pm SEM; YMRS: Young Mania Rating Scale Paired't' test in comparison to respective baselines * p<0.05; *** p<0.01; *** p<0.001; NS = Non Significant Comparison between the groups at Baseline, 3 weeks and 6 weeks with Unpaired Student't' test

 † p<0.05; †† p<0.01; †††† p<0.001; $^{\sharp}$ = Non Significant

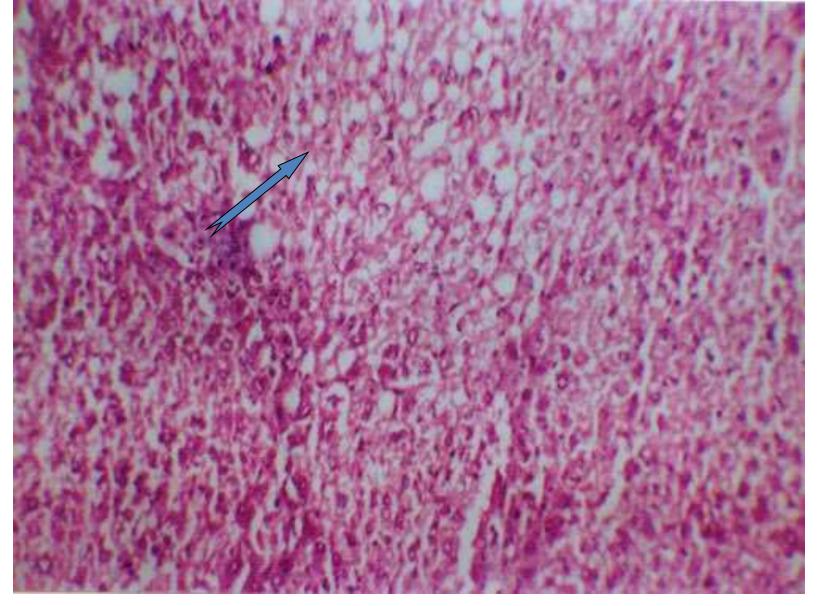


Figure 3 . Section of the liver tissue of rats treated with VNE (100 mg/kg. wt) and antitubercular drug challenge showing macrovesicular fatty change (H& E, $100~\rm X$)

Discussion

- First answer question posed in introduction
- Compare studies in agreement
- Discuss weaknesses and discrepancies
- Lay down Possible reason in discrepancies
- Lay down Possible Hypothesis / Explanation of the findings
- Discuss Unexpected Findings also
- Explain what is new without exaggerating
- Discuss perspectives, implications, Impact on available research and clinical practice
- Limitations of study

Discussion

Avoid:

Repletion of results

Too verbose, theoretical texts that are irrelevant to the research problem*

Inadequate discussions on the significant results

Failure to justify negative results

Conclusion

- Be specific
- No hypothesis
- Finally conclude major results findings of study as per research question

Efficacy and Safety of Asenapine Versus Olanzapine in Combination With Divalproex for Acute Mania: A Randomized Controlled Trial

OBJECTIVE: To compare the efficacy and safety of asenapine and olanzapine when used in combination with divalproex in patients with acute mania.

CONCLUSION: This study found that asenapine was an effective and well-tolerated atypical antipsychotic alternative to olanzapine in combination with divalproex for the short-term management of acute mania.

Referencing Styles

Some important referencing style in the medical sciences are:

- American Psychological Association (APA) (Author year Title Journal and vol and page)
- Chicago-style ("author-date" style)
- Harvard Style (alphabetical Referencing)
- Vancouver Style (numbered referencing style)



References Vs Bibliography



Reference Elements

- Authors (use et al. after 6 authors, if there are more than six authors, complete names should not be written. "et al" must be in italics)
- Article title (should be exact as existing)
- Journal name (should be in standard PubMed abbreviations, full journal name should not be written)
- Year
- Volume
- Page numbers (445-447 to be written as 445-47)

Singh JK, Bawa M, Kanojia RP, Ghai B, Menon P, Rao KL.

Idiopathic simultaneous intussusceptions in a neonate.

Pediatr Surg Int 2009;25:445-7.

Punctuation Marks

Coma followed by space after each author do not write and before the last author

Full stop after the last author followed by space and then _ the article title

Singh JK, Bawa M, Kanojia RP, Ghai

B, Menon P, Rao KL. ~

Idiopathic simultaneous

intussusceptions in a neonate.

Pediatr Surg Int 2009;25:445,7.

Full stop followed by space

Full stop at the end of the ref.

Hyphen to separate the page no.

Semicolon; after the year without any space

Colon: after volume no. without any space

Single space between the journal abbreviation and the year, place no other punctuation marks

Reference checking facility on the www.journalonweb.com website

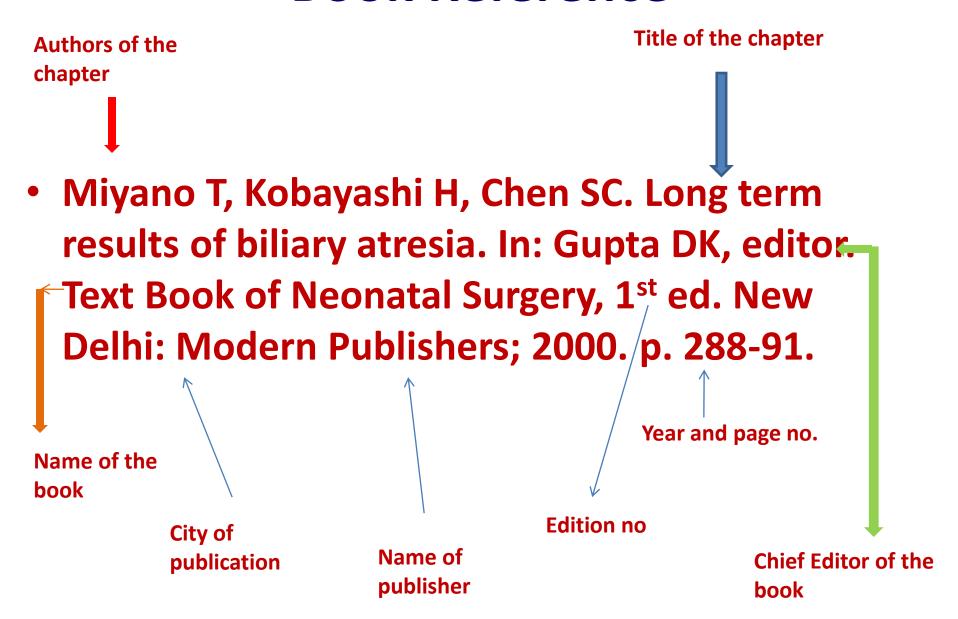
- The manuscript submission web site offers the authors a method where they can check the correctness of the references they have used
- The following slides will demonstrate how to use it

Citing References in the text

 References should be numbered using Arabic numerals in box parentheses e.g. [1] in the order of appearance in the text as a superscript.

diameter of 6 to 7 mm and the renal artery measures 2.8 mm. [11] WT surgery is a safe and partially standardized procedure. However, major bleeding and vascular injuries can occur. The frequency of vascular injuries has been reported as 1.5% in the NWTS-3 and 4. [12, 13] Severe hemorrhage occurs at a higher rate. Further, there exists a hidden surgical mortality. [14]

Book Reference



The punctuation marks are to followed as seen in this example

Journal article on the Internet

Abood S. Quality improvement initiative in nursing homes: the ANA acts in an advisory role. Am J Nurs [Internet]. 2002 Jun [cited 2002 Aug 12];102(6):[about 1 p.]. Available from: http://www.nursingworld.org/AJN/2002/june/Wawat ch.htmArticle

 Digray NC, Mengi Y, Goswamy HL. Hydrocephalus in children. Analysis of 50 cases. JK Practitioner 1998 (in press).

Goswamy HL, Mengi Y, Digray NC.
 Organisation of Trauma Care. Presented at the
 meeting of North Chapter of ASI at Jammu,
 J&K-India, Oct 24–25, 1998.

How to Improve

- Good writing is rewriting
- Self review after a gap of few days
- Peer Review
- Your supervisor/professor is not here to teach you basic grammar and spelling
- Restrict to word count as per the type of article
- Use <u>grammar check</u> software <u>http://www.grammarcheckforsentence.com</u>
- Plagiarism Checker software- https://www.quetext.com/
- Reference checking facility on the www.journalonweb.com website



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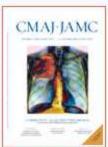
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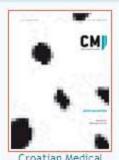
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- Journals: Extended Deadline for Applications (09/09)
- ✓ Update on FDAAA from ClinicalTrials.gov (06/08)
- ✓ All Announcements, Updates & Editorials

Frequently Asked Questions at a Glance

- ✓ Will the ICMJE consider clinical trial results posted at ClinicalTrials.gov in compliance with the Food and Drug Administration Act of 2007 to be prior publication? FULL ANSWER
- → How do I obtain a print copy of the

Prepare Manuscript as per

STROBE Guidelines

(Strengthening the reporting of observational studies in epidemiology)

Observational studies including cohort, case-control, and cross-sectional studies (25 Point Check list)

https://www.strobe-statement.org/index.php?id=available-checklists

CONSORT Guidelines (25 Point check list)

Consolidated Standards of Reporting Trials

Randomized controlled trials

http://www.consort-statement.org/

CARE Guidelines

Case Report

https://www.care-statement.org/checklist



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You can check and verify accuracy and style of references.

- The style as well as bibliographic elements should be 100% accurate to get the references verified from the system. A single spelling error or addition to verifying the reference.
- · Only the references from journals indexed in PubMed would be checked.
- · Enter each reference in new line, without a serial number.
- Maximum 15 reference at time

Example:

Sheahan P, O'leary G, Lee G, Fitzgibbon J. Cystic cervical metastases: Incidence and diagnosis using fine needle aspiration biopsy.

Download a PowerPoint presentation on common reference styles and using the reference chec [Courtesy Dr. Ravi Kanojia]

Write or paste the ref in this box then click the tab below

Personal details...

Массалас

Check References

Clear

Publish and Flourish



