How To Write Methods Section in a Scientific Paper

Dr. Shatha Alduraywish, *MBBS; MEpi; PhD*

Assistant Professor

Department of Family and Community Medicine

College of Medicine, KKUH

King Saud University

October 2018

Learning Objectives

At the end of this session, you will be able to:

✓Understand the main function of the methods section.

✓Recognize the subsections of method section

✓Write a high quality method section

Structure of a Research Article

- Title
- Abstract
- Introduction
- Methods
- Results
- Discussion
- Conclusion
- References

Hindawi Publishing Corporation
Evidence-Based Complementary and Alternative Medicine
Volume 2014, Article ID 714389, 8 pages
http://dx.doi.org/10.1155/2014/714389

Hindawi

Research Article

Demographic Characteristics and Medical Service Use of Failed Back Surgery Syndrome Patients at an Integrated Treatment Hospital Focusing on Complementary and Alternative Medicine: A Retrospective Review of Electronic Medical Records

Hee Seung Choi, Eun Hya Chi, Me-riong Kim, Jaehoon Jung, Jinho Lee, Joon-Shik Shin, and In-Hyuk Ha

Jaseng Spine and Joint Research Institute, Jaseng Medical Foundation, 858 Eonju-ro, Gangnam-gu, Seoul 135-896, Republic of Korea

Correspondence should be addressed to In-Hyuk Ha; hanihata@gmail.com

Received 5 May 2014; Revised 7 August 2014; Accepted 7 August 2014; Published 4 November 2014

Academic Editor: Hyunsu Bae

Objective. To report the patient demographics and nonsurgical complementary and alternative medicine treatment used at a Korean medicine hospital for low back pain (LBP) and/or sciatica after surgery. *Methods.* Medical records of patients who visited a spine-specialized Korean medicine hospital at 2 separate sites for continuous or recurrent LBP or sciatica following back surgery were reviewed. The demographics, MRI and/or CT scans, and treatments were assessed. *Results.* Of the total 707 patients, 62% were male and the average age was 50.20 years. Ninety percent of patients presented with LBP and 67% with sciatica. Eighty-four percent were diagnosed with herniated nucleus pulposus at time of surgery. Of these patients, 70% had pain recurrence 6 months or later, but 19% experienced no relief or immediate aggravation of pain after surgery. Many patients selected traditional Korean medicine treatment as primary means of postsurgery care (47%). When time to pain recurrence was short or pain persisted after surgery, return of symptoms at the same disc level and side was frequent. *Conclusion.* An integrative treatment model focusing on Korean medicine and used in conjunction with radiological diagnostics and conventional medicine is currently used as a treatment option for patients with pain after lumbar spine surgery.

1. Introduction

Although low back pain (LBP) is considered to have a favorable natural prognosis, lumbar spine surgery is still frequently performed. In the US, the prevalence of lumbar fusion surgery has increased 220% from 1990 to 2001 [1], and 250,000 laminectomies are estimated to be conducted each year as of 2002 [2].

However, with the increase of surgery cases, the interest in failure rates is also on the rise. A 10- to 22-year follow-up study by Yorimitsu et al. on the outcomes of discectomy for lumbar herniated nucleus pulposus (HNP) reported 74.6% of patients had residual LBP and 12% required reoperation(s) [3]. In Korea, a retrospective cohort study using national health insurance data of 35,558 patients who received a first surgery for lumbar herniated intervertebral disc disease in 2003 reported that the cumulative reoperation rate at 5 years was 13.4% with half the reoperations performed in the first postoperative year [4]. Park and Kim reported the results of 186 patients seeking medical care due to persistent or aggravated pain after surgery, of whom 75% visited within 2 years of surgery and 35% required reoperations [5].

Other studies on the results of back surgery reported that adequate pain relief was not achieved in up to 30% of patients receiving a single lumbar segment operation [6] and that only 34% of reoperation patients had successful outcomes (at least 50% sustained relief of pain and satisfaction with the results), showing high postsurgery pain occurrence rates [7]. There are also studies reporting the difficulties of reoperation with success rates falling to 15% following a third back operation and around 5% after the fourth [8].

Research Methodology Section

It is a part of a research paper that provides a clear description of :

- How the research was done.
- What was done to answer the research question
- How the results were analyzed.

Research Methodology Section

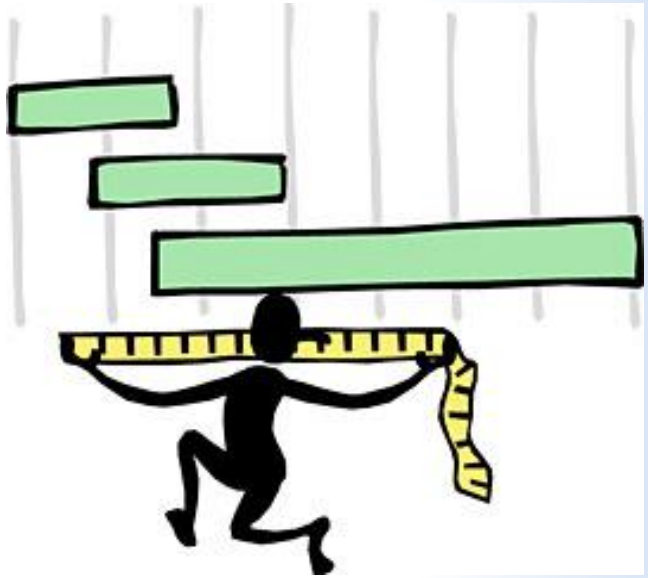
It must be written with enough information so that:

1.The research could be repeated by others to evaluate whether the results are **reproducible**, and

2.The audience can judge whether the results and conclusions are **valid**.

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Pilot study
- Data analysis plan
- Ethical considerations



What the Methods Section is Not!

- Results
- Discussion
- Summary
- Conclusions
- Future Work
- Introduction

- **It is a DESCRIPTION of HOW you did your work**
- **Include NO results and NO discussion!**

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Data analysis plan
- Ethical considerations
- Pilot study

Study Design

Present key elements of study design early in the paper.

To understand
the basics of the study

- Cross-sectional
- Case-Control
- Cohort
- Experimental
- Or mixture

+ exactly how and when

Study Design: Example

Design

"We will use a case-control study design, with a sample that will include women with breast cancer, with a 1:1 age matched with controls without breast cancer. We age-matched women newly diagnosed with breast cancer (cases) and women with benign breast changes (controls) at two referral services for diagnosis and treatment of cancer in Goiânia, (Goiás State capital)".

Exactly how

Study Design: Example

Exactly how

Design

LISAplus is a German population-based birth cohort study that recruited 3094 neonates between 1997 and 1999 from the cities of Munich, Leipzig, Wesel, and Bad Honnef. Questionnaires were completed by parents at birth, 6 months, 1, 1.5, 2, 4, 6, and 10 years of age. Details of the study design have been described elsewhere (23). The study was approval by the local Ethics Committees (Bavarian Board of Physicians, University of Leipzig, and Board of Physicians of North-Rhine-Westphalia) and written parental consent was obtained.

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Data analysis plan
- Ethical considerations
- Pilot study

Study Setting

Includes description of:

- Setting (recruitment sites or sources)
- Location (countries, towns, hospitals)
- Relevant dates
  - *Periods of recruitment*
  - *Exposure*
  - *Follow-up*
  - *Data collection*

Generalizability of a study's results

Study Setting: **Example**

Setting **Location**

- "The Pasitos Cohort Study will recruit pregnant women from Women, Infant, and Child clinics in Socorro and San Elizario, El Paso County, Texas and maternal-child clinics of the Mexican Social Security Institute in Ciudad Juarez, Mexico from April 1998 to October 2000. At baseline, prior to the birth of the enrolled cohort children, staff will interview mothers regarding the household environment. In this ongoing cohort study, we will target follow-up exams at 6-month intervals beginning at age 6 months"

Period of Enrolment

Period of recruitment

Follow-up

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Data analysis plan
- Ethical considerations
- Pilot study

Study Population

Detailed descriptions of the study participants

Inclusion, Exclusion

- **Eligibility criteria** – age, gender, diagnosis, co-morbid conditions, etc
- **Sources** and **methods** of selection of participants
- **Rationale** for the choice of cases and controls
- Sources and methods of case ascertainment and control selection
- **Matching criteria** and number of exposed and unexposed

Study Population

How do we pick a study population?

- Convenience and feasibility
- Likely response rate
- Population characteristics
  - Socioeconomic
  - Racial and ethnic

Generalizability of findings

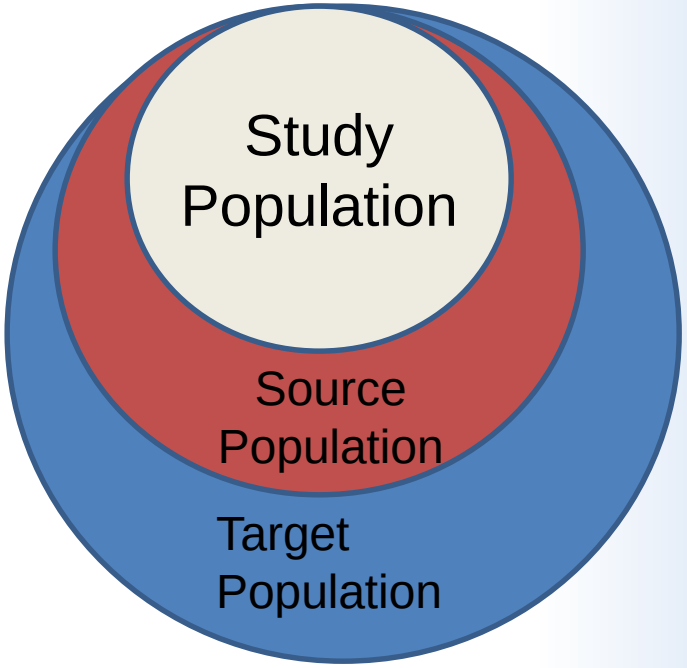
Study Population

Study population, source population, Target population

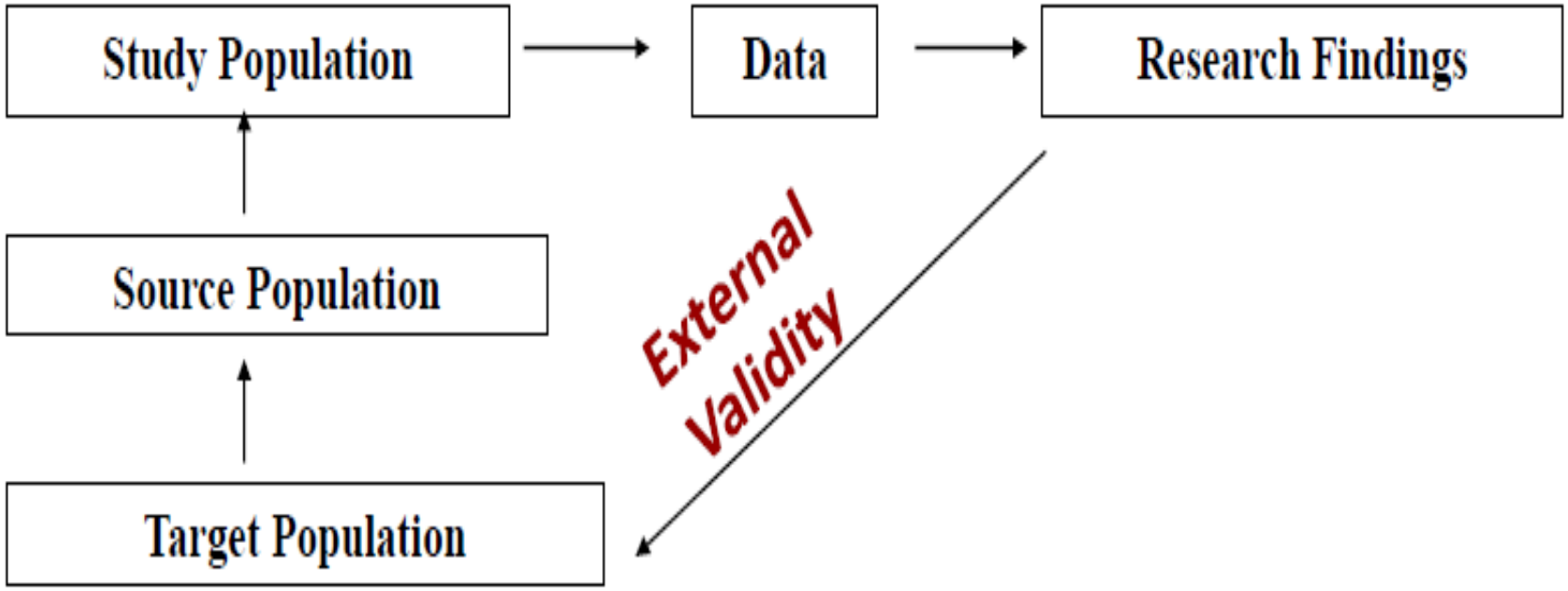
The group studied

The group from whom the study population is drawn

The group to whom inferences will be made



Study Population



Study Population: Example

- "Participants in the Iowa Women's Health Study will be selected by a random sample of all women ages 55 to 69 years derived from the state of Iowa automobile driver's license list in 1985, which represents approximately 94% of Iowa women in that age group....

- "We will aim to select 5 controls for every case from among individuals in the study population who had no diagnosis of autism or other pervasive developmental disorders (PDD) recorded in their general practice record and who are alive and registered with a participating practice on the date of the PDD diagnosis in the case.

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Data analysis plan
- Ethical considerations
- Pilot study

Sample size

How to calculate the sample size?

Use the following formula if you know **the prevalence** or you can get the prevalence of the condition from the literature:

$$N= (Z\ 1-\alpha)\ (P(1-P)/D^2)$$

N= The sample size

Z= Confidence intervals=1- α (1.96)

P= Prevalence of the condition

D= Precision (0.05)

Sample size: **Example**

“A survey of postnatal depression in the Middle East had documented a prevalence of 19.8%.

The sample size for the prevalence of post natal depression in a population in Saudi Arabia with 0.5% precision and 80% power was calculated

$$N = (Z\ 1-\alpha)\ (P(1-P)/D^2)$$

N= The sample size

Z= Confidence intervals=1- α (1.96)

P= Prevalence of the condition

D= Precision (0.05)

Thus for a condition of prevalence of 20% the sample size will be

$N = 1.96x\ (0.20\ (1-0.2)/0.5^2) = 246$

Sample size

What if you there are no previous studies?

- Conduct a pilot study to have an idea in about the prevalence in your population

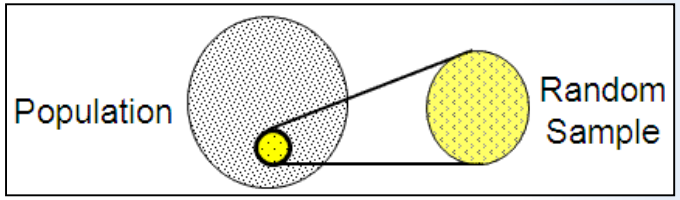
- Assume that the prevalence is 50% which will give the largest possible sample size

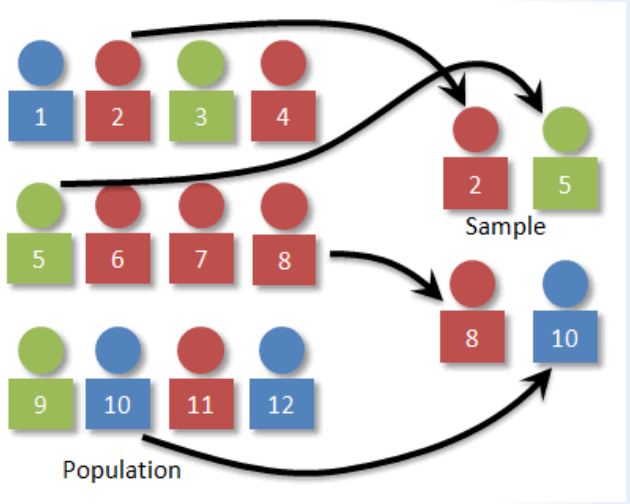
Sample size: Example

The sample size for the INTERSTROKE study was based on an intention to include at least 1000 case-control pairs from all major regions in the world, to permit a globally representative sample in the overall study and to provide an estimate of association for common risk factors within each region. The sample size was also determined to be adequate to detect an odds ratio (OR) of 1·2 or greater for minor allele frequencies of 0·1 for all stroke and ischaemic stroke, and OR of 1·3 or greater for minor allele frequencies of 0·3 for each of the ischaemic and haemorrhagic stroke subtypes, assuming an additive genetic model at genome-wide significance. The sample size was calculated on the basis of level of significance, two-sided test at $\alpha=0\cdot01$ for traditional risk factors and $\alpha<5\times10^{-8}$ for genetic markers (ie, genome-wide significance); power $(1-\beta)$ of 80%; and effect size (the minimum OR considered to be clinically important,

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Pilot study
- Data analysis plan
- Ethical considerations





Sampling methods

Probability Sampling:

Each member has the same chance (equal and independent)

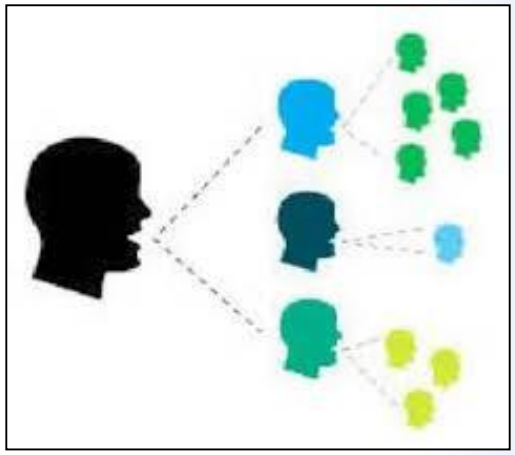
- Simple random sampling
- Systematic sampling
- Stratified random sampling
- Cluster sampling
- Multi-stage sampling

Sampling methods

Non-probability Sampling

Each member does not have the same chance

- Convenience sampling
- Snowball Sampling
- Purposive Sampling
- Quota Sampling



Sampling methods

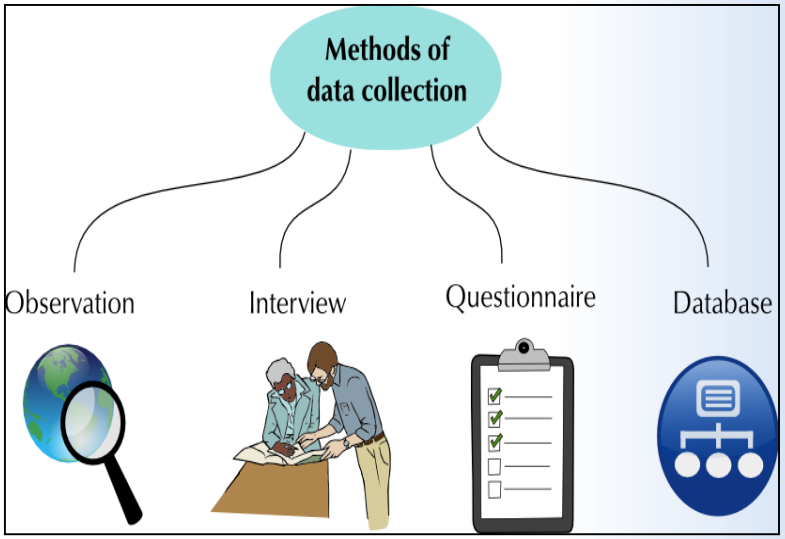
Example

"A simple random sampling design will be used.

The mobile phone network of the STC will be chosen as a sampling frame. Computer generated random number list will be generated. STC mobile phone numbers will be the sampling element"

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Data analysis plan
- Ethical considerations
- Pilot study



Data collection methods

- Forms [questionnaire/ case report form]
- Interviews
- Records
- Measurements [e.g. biometric / anthropometric]
- Laboratory investigations [types, referenced techniques / kits for each]

Data collection methods

- For each variable of interest, give **sources of data** and details of **methods of measurement**

- Describe **comparability of assessment methods** if there is more than one group.

- Report the **way of measurement**, esp. for different groups

Data collection methods

- Report the findings of any studies of the **validity** or **reliability** of assessments or measurements

The materials and methods should describe the study in sufficient detail so that a skilled investigator in the field could replicate the study

Wahabi *et al. BMC Public Health* 2013, **13**:341
http://www.biomedcentral.com/1471-2458/13/341

BMC Public Health

RESEARCH ARTICLE Open Access

Effects of secondhand smoke on the birth weight of term infants and the demographic profile of Saudi exposed women

Hayfaa A Wahabi[1*], Rasmieh A Alzeidan[1], Amel A Fayed[3,4], Ahmed Mandil[2], Ghadeer Al-Shaikh[5] and Samia A Esmaeil[1]

Data on SHS exposure will be collected by self-administered questionnaire, data on the maternal demographic characteristics and obstetric performance will be collected from maternal medical records and data for the neonatal anthropometric measurements which are measured by the attending midwife will be collected from the delivery records. The study will be carried out for 12 months

Gestational diabetes mellitus: maternal and perinatal outcomes in King Khalid University Hospital, Saudi Arabia

Hayfaa A. Wahabi[a], Samia A. Esmaeil[a], Amel Fayed[c] and Rasmieh A. Alzeidan[b]

[a]Sheikh Bahmdan Chair of Evidence-Based Healthcare and Knowledge Translation, College of Medicine, King Saud University, [b]Department of Basic Science, King Saud Ben Abdel Aziz University for Health Sciences, Riyadh, Kingdom of Saudi Arabia and [c]Department of Biostatistics, High Institute of Public Health, Alexandria University, Alexandria, Egypt

Correspondence to Amel Fayed, MD, PhD, Department of Biostatistics, High Institute of Public Health, Alexandria University, Alexandria, Egypt
Tel: +966 5943 95059;
e-mail: fayeda@ksau-hs.edu.as

Received 22 January 2013
Accepted 20 April 2013

Journal of the Egyptian Public Health Association 2013, 88:104–108

Background

The prevalence of gestational diabetes mellitus (GDM) has increased worldwide, with a subsequent increase in the associated adverse pregnancy outcomes.

Objectives

The objective of this study was to determine the prevalence of GDM and to compare the maternal and neonatal outcomes of women with GDM with nondiabetic women.

Materials and methods

This is a retrospective cohort study investigating the maternal and the neonatal outcomes of women with GDM who delivered in King Khalid University Hospital as compared with the outcomes of nondiabetic women who delivered during the same period. The data were collected from the 1st of January to the 31st of December 2010 from the labor ward registry. The pregnancy outcomes of the women with GDM were compared with the outcomes of nondiabetic women who delivered during the same

Data collection methods: **Example**

“The BMI will be calculated for each subject using the maternal weight and height which will be recorded during the booking visit, according to the following equation;

BMI=weight (kg) / height (m) ^{2}”

Data collection methods: **Example**

The diagnosis of gestational diabetes will be based on the results of 75g oral glucose tolerance test (OGTT) done between 24-32 weeks gestation and requires that two or more of the venous plasma glucose concentrations exceed the following: fasting, 5.3mmol/l (95 mg/dl), one hour, 10.0mmol/l (180 mg/dl), two hours, 8.6mmol/l (155 mg/dl) and three hours, 7.8mmol/l (140 mg/dl).

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Data analysis plan
- Ethical considerations
- Pilot study

Data Analysis

Plan for statistical techniques and methods to be used

- Descriptive
- Analytical

  as related to study objectives / expected outcomes

The statistical methods should be explained with enough details to enable a knowledgeable reader with access to the original data to verify the reported results

Wahabi *et al. BMC Public Health* 2013, **13**:341
http://www.biomedcentral.com/1471-2458/13/341

BMC Public Health

RESEARCH ARTICLE Open Access

Effects of secondhand smoke on the birth weight of term infants and the demographic profile of Saudi exposed women

Hayfaa A Wahabi[1*], Rasmieh A Alzeidan[1], Amel A Fayed[3,4], Ahmed Mandil[2], Ghadeer Al-Shaikh[5] and Samia A Esmaeil[1]

Statistical analysis

Statistical analyses will be performed using SPSS, version 18.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics will be computed for non-smoking pregnant women exposed and unexposed to SHS. Univariate analyses will be performed to compare the birth weight, infant's length and head circumference between the two groups as well as to evaluate the baseline characteristics between the groups which we considered as confounding factors. Chi-squared will be used to compare dichotomous outcomes and Student's t- test will be used to compare continuous outcomes. Stepwise logistic regression models will be used to adjust for potential confounders including maternal age, parity, BMI, GDM and gestational age (37–42 weeks). *P* value of < 0.05 will be considered statistically significant.

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Data analysis plan
- Ethical considerations
- Pilot study

Expectations of Ethical Considerations

- Design of a **consent form** (for written approval of participants)
- Assurance of **respect of human rights** in research involving human subjects, including:
  1. Benefits outweigh risks
  2. Confidentiality
  3. Anonymity
  4. Voluntary participation

Expectations of Ethical Considerations

Example

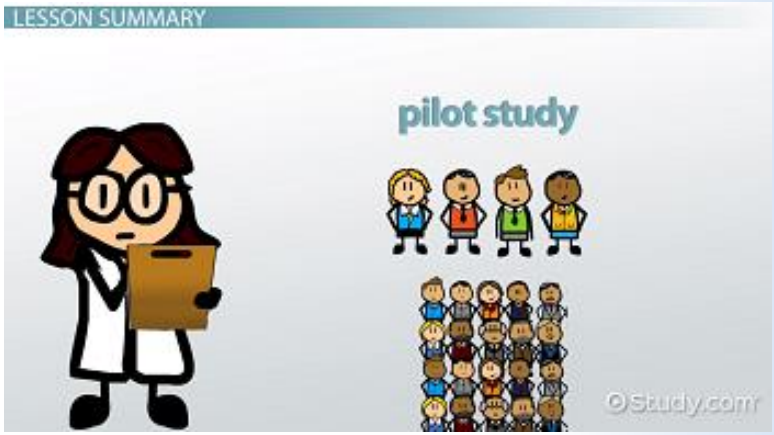
- All participants will receive a **written consent form**. The interviewer will inform all participants about the purpose of the research, why they were chosen, all potential risks and benefits and that they could refuse to participate, or could withdraw from the study at any point in time.

- Participants **anonymity** will be assured by assigning each student with a code number for the purpose of analysis only.

- **No incentives or rewards** will be given to the participants, the purpose of the snack and refreshments is to establish a bond with the students and is offered to all students with no obligation to participate.

Structure of Methods Section:

- Study design
- Study setting
- Population under study
- Sample Size
- Sampling Technique
- Data collection method
- Data analysis plan
- Ethical considerations
- Pilot study



The Pilot Study

Purpose of the pilot study

1. Estimate the sample size…..????
2. Examine the logistics
3. Test the questionnaire administration
4. Test reliability and validity of the survey…????

The Pilot Study

- Pilot studies should have a well-defined set of aims and objectives to ensure methodological rigor and scientific validity.

- Participants pilot study should not later be included in the main study

- The analysis of a pilot study should be mainly descriptive or should focus on confidence interval estimation.

The Pilot Study

- Results from hypothesis testing should be treated as preliminary and interpreted with caution, as no formal power calculations have been carried out.

- The temptation not to proceed with the main study when significant differences are found should be avoided.

- The methods section should be in **past tense.**
- **Chronological** presentation (but related methods described together)
- Questions about **"how"** and **"how much"** are answered for the reader and not left for them to puzzle over
- When a large number of components are used prepare **tables** for the benefit of the reader


THANK YOU