

انواع مطالعات

مسعود میرزابی

کارگاه روش تحقیق معاونت تحقیقات و فناوری

آبان ۱۴۰۲

بجای مقدمه:

- تفکر اپیدمیولوژیک
- روش های اپیدمیولوژیک
- انواع مطالعات



Avicenna approach to plague epidemic- 1036-AD- Isfahan

Asking questions

1. Iranian government needs to provide figures to WHO on the incidence of HIV in Australia

2. Zahra's mother is worried about Zahra using her mobile phone so much – she's heard they're not safe

3. Mrs Dehghan's GP is wondering whether Hejamat might help Mrs Dehghan's shoulder pain

4. Medical Services Advisory Board is considering whether to offer a Medicare rebate for Magnetic Resonance Imaging for investigation of joint problems

Study design: Definition

A study design is a specific plan or protocol for conducting the study, which allows the investigator to translate the conceptual hypothesis into an **operational** one.

Common Methodologies

- Methodologies are high-level approaches to conducting research.
 - The individual steps within the methodology might vary based on the research being performed.
- Two commonly used research methodologies:
 - Quantitative.
 - Qualitative.

Objectives

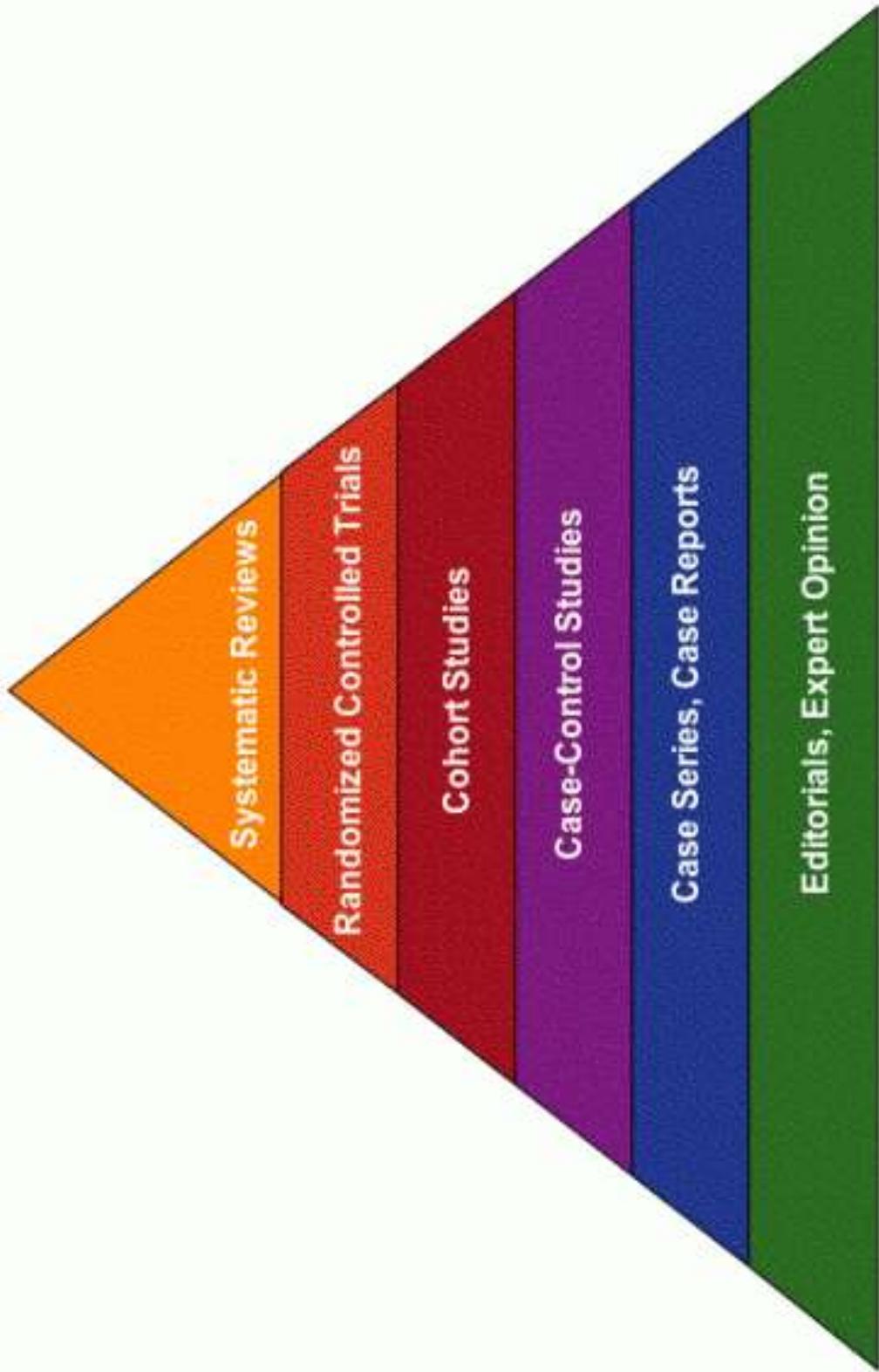
Different methodologies/Different Tools?

Pyramid of evidence

Analytic studies:

- Case control
- Cohort
- Historical cohort
- RCT
- Systematic review
- Meta analysis

هر م شو ا هد



Qualitative Designs

مکالمہ میری بھائی
۰۹۱۷۸۴۵۶۹۹ / / / ۰۹۱۷۸۴۵۶۹۹

جروسی ب + ۸۷۴۸۳۹۰

٠٩٦٢٥٣٥٩٧٨

نیز اسکندریہ
کے دو حصے میں
لے کر فروختی
کے لئے بھی
کامیاب تھا۔

۱۶: ۹۷۰۸۴۴

مکالمہ کلیہ فتوحہ مکاری

بـ ۱۴۰۷
جـ ۱۴۰۷
هـ ۱۴۰۷

بَلْ تَرْكِيَّةُ الْمُهَاجِرَاتِ

اللهم نرددْ
A - D +

حَمْدُ لِلّٰهِ رَبِّ الْعٰالَمِينَ

9808941847

کفتکو با ۱۰ متقاضی فروش کلیه

رئیس انجمن خبریه «حصایت از بیماران کلیوی ایران» چندی پیش اعلام کرد: «به طور میانگین به ازای هر بیمار کلیوی که در انتظار بودن است، صرف نظر از گروه خونی، حداقل چهار متقاضی فروش وجود دارد.» تکاهی به در و دیوار برخی خیابان‌های اطراف بیمارستان‌های تهران و همچنین خیابان فرهنگ حسینی که این انجمن خبریه در آن واقع شده است تا حدود زیادی این جمله را تایید می‌کند.

تاریخ: ۲۴ دی ۱۳۹۶ - ۵:۵۷

رئیس انجمن خبریه «حصایت از بیماران کلیوی ایران» چندی پیش اعلام کرد: «به طور میانگین به ازای هر بیمار کلیوی که در انتظار بودن است، صرف نظر از گروه خونی، حداقل چهار متقاضی فروش وجود دارد.» تکاهی به در و دیوار برخی خیابان‌های اطراف بیمارستان‌های تهران و همچنین خیابان فرهنگ حسینی که این انجمن خبریه در آن واقع شده است تا حدود زیادی این جمله را تایید می‌کند.

اگهیها و بیوارنویسی‌های فروش کلیه در تهران و برخی دیگر شهرهای ایران سال‌های است که رواج دارد. تاکنون نیز خبرگزاری‌ها و روزنامه‌های ایران چندین مرتبه در این رابطه گزارش‌هایی منتشر کرده و نسبت به افزایش تفایل در جامعه به‌خصوص در میان قشر جوان برای فروش کلیه هشدارهایی داده‌اند.

در ایران فروش اعضاً بین افراد زنده ممنوعیت قانونی ندارد، تاکنون تنها یکبار مجلس شورای اسلامی در سال ۱۳۷۳ تلاش کرد با ورود به این موضوع به اقدامات در این حوزه جنبه قانونی بدهد. البته آنچه نمایندگان به‌جهنم نوره مجلس شورای اسلامی در نظر داشتند به تصویب بررسانند «لایحه اجازه بیوئند اعضاً بین غوت‌شدگان در موارد خاص» بود که در نهایت طرح بررسی این موضوع در صحن علنی مجلس رای نیاورد و از آن تاریخ تاکنون این موضوع مسکوت مانده است.

Qualitative Research Techniques

- Participant observation (field notes)
- Interviews / Focus group discussions with key informants
- Video / Text and Image analysis (documents, media data)
- Surveys
- User testing

Methodology Comparison

Quantitative

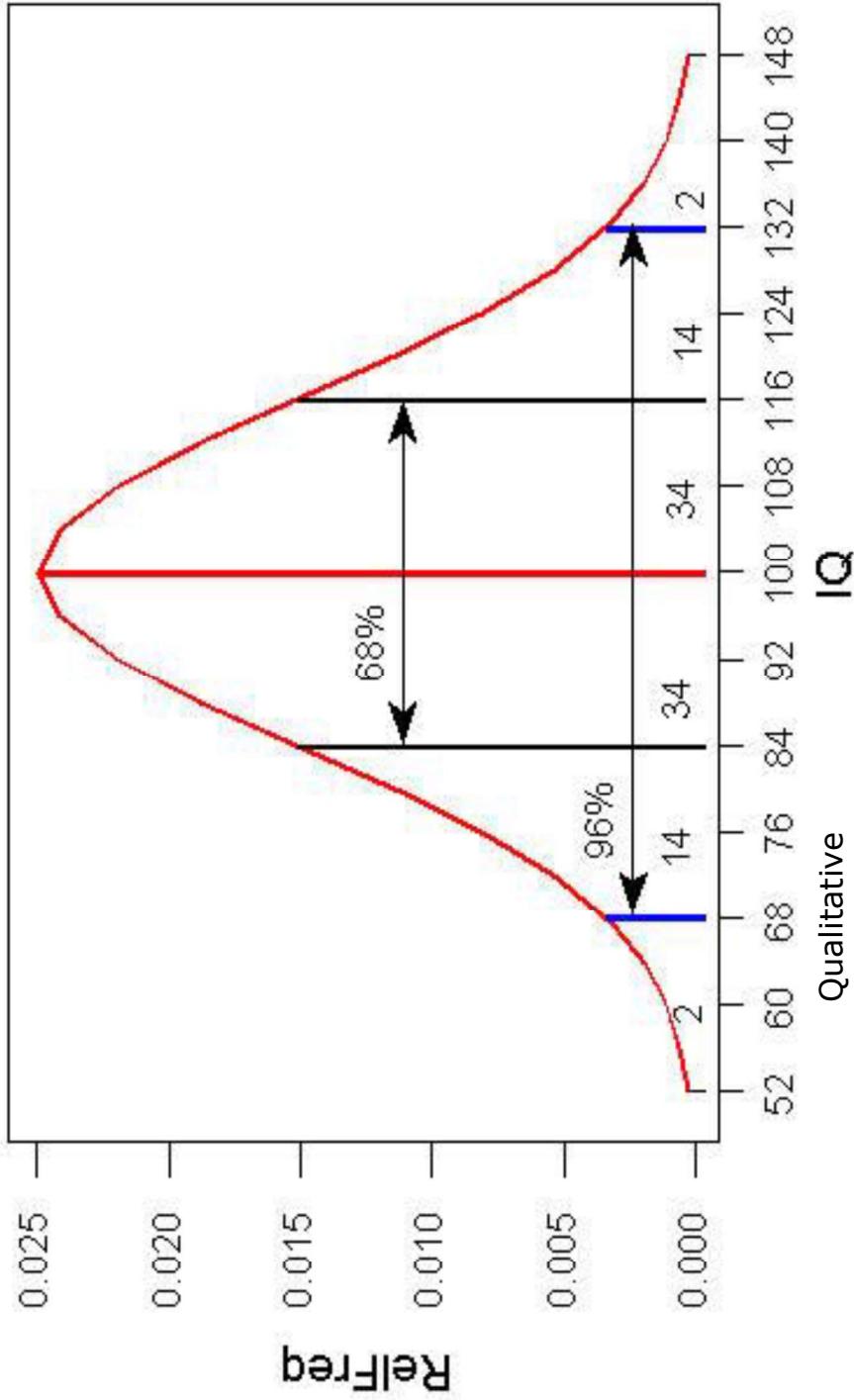
- Explanation, prediction
- Test theories
- Known variables
- Large sample
- Standardized instruments
- Deductive

Qualitative

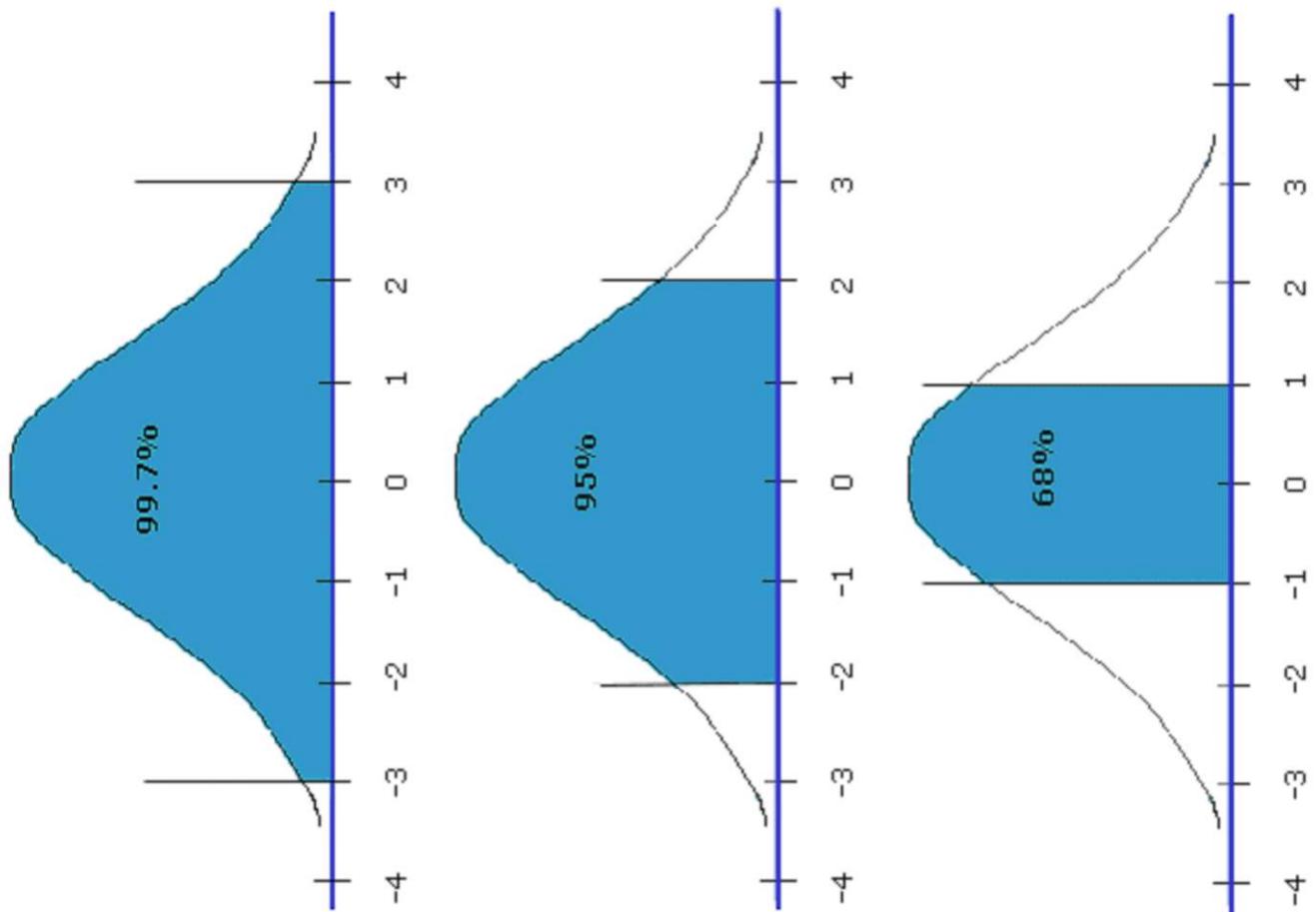
- Explanation, description
- Build theories
- Unknown variables
- Small sample
- Observations, interviews
- Inductive

Quantitative Designs

Distribution of IQ in the UK



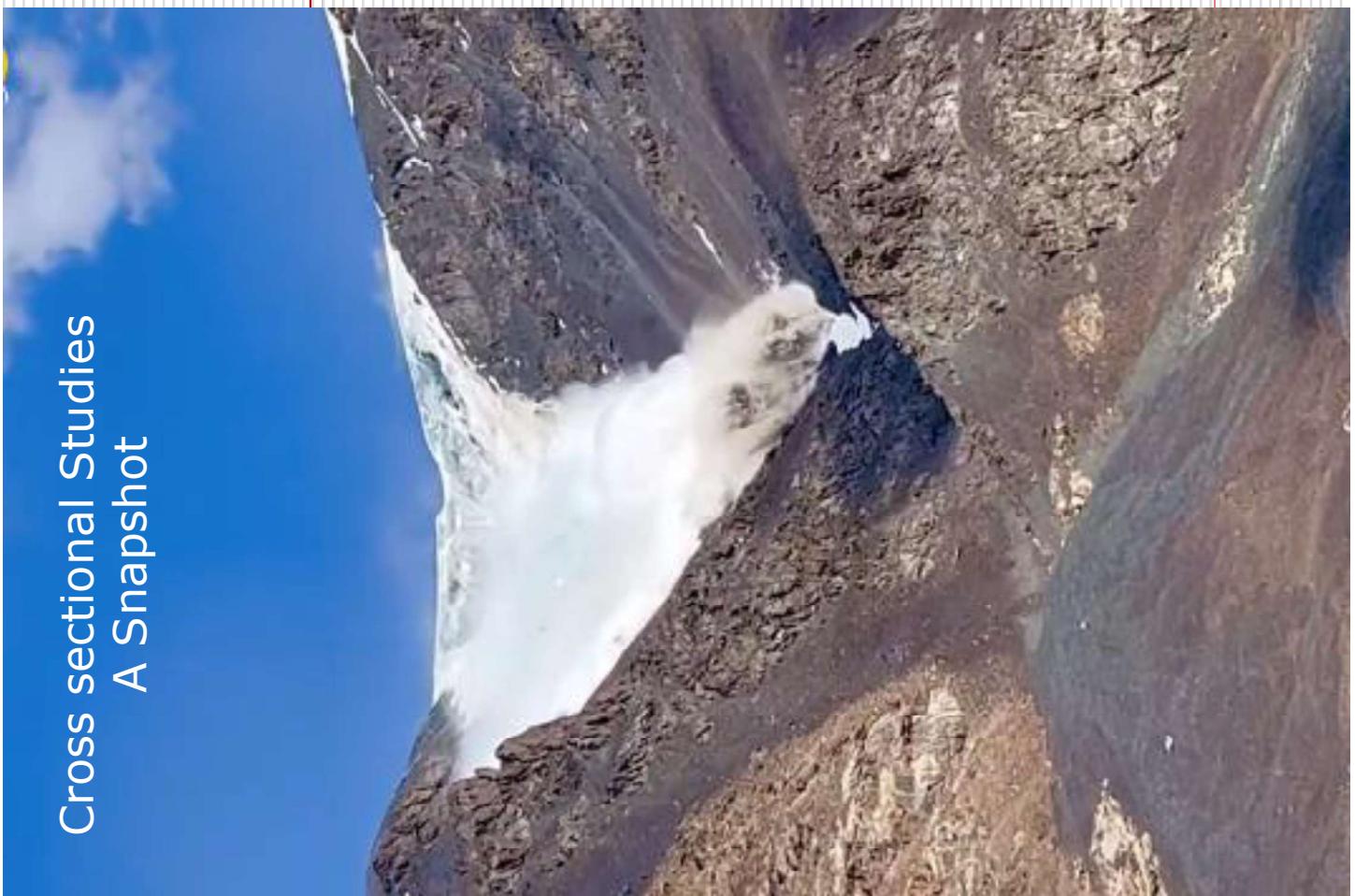
Normal Distribution Curves



Quantitative designs

- Descriptive
- Analytic

Cross sectional Studies
A Snapshot



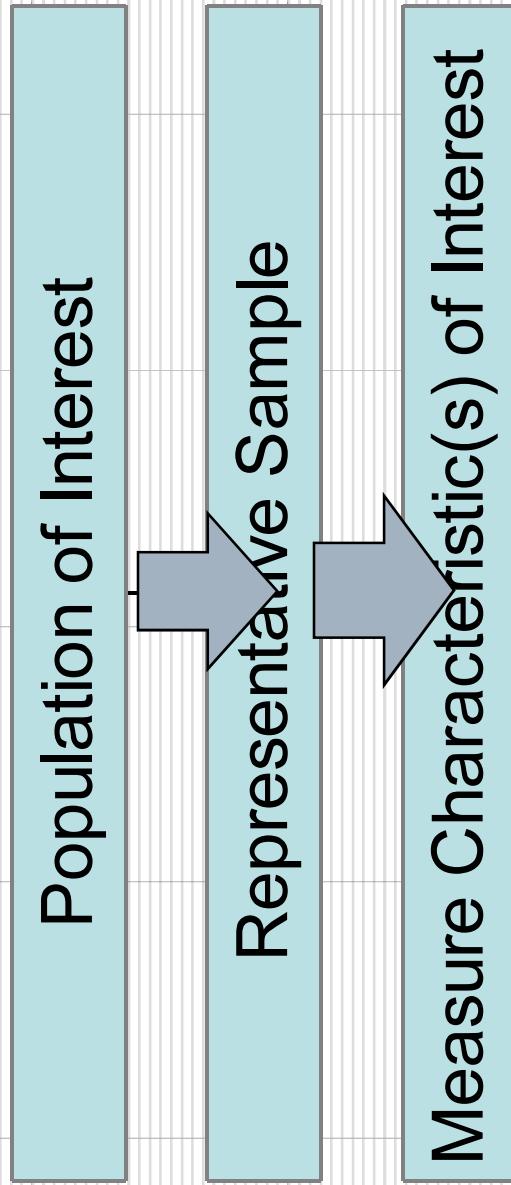
Prospective study



Retrospective Study

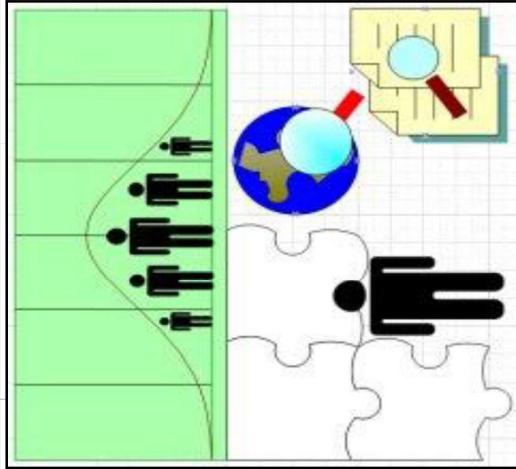


Descriptive Studies



Descriptive Studies

Used for answering questions about frequency



Usually cross-sectional studies

May be cohort studies

Examples

- Prevalence survey of TB
- Prevalence of domestic violence
- Incidence of playground injury in a school population over one year

Analytic studies

Used for answering questions of aetiology or the effect of intervention (causality):

- Randomised controlled trial
- Cohort study
- Case control study
- Cross sectional analytic study (longitudinal)
- Before and after study
- Ecological study

Analytic Studies: cross sectional analytic

Subjects selected because they were present at the time of the study.

Selection is NOT on the basis of either exposure or outcome.

Example:

- Does being overweight cause arthritis?

This could be examined in a study in which both weight and arthritis symptoms are measured at the same time

مقایسه عوارض حاملگی در دو گروه سالم و نی (مطالعه کوهورت)

ମୁଦ୍ରଣ କରିଲା # ନଗଜ୍ଞ ପ୍ରକାଶନ ଅଧ୍ୟକ୍ଷ

* دانشکده علوم پزشکی و خدمات بهداشتی - درمانی شهید رجایی، حلبان شهداد، رویوی درب دوم بادگان

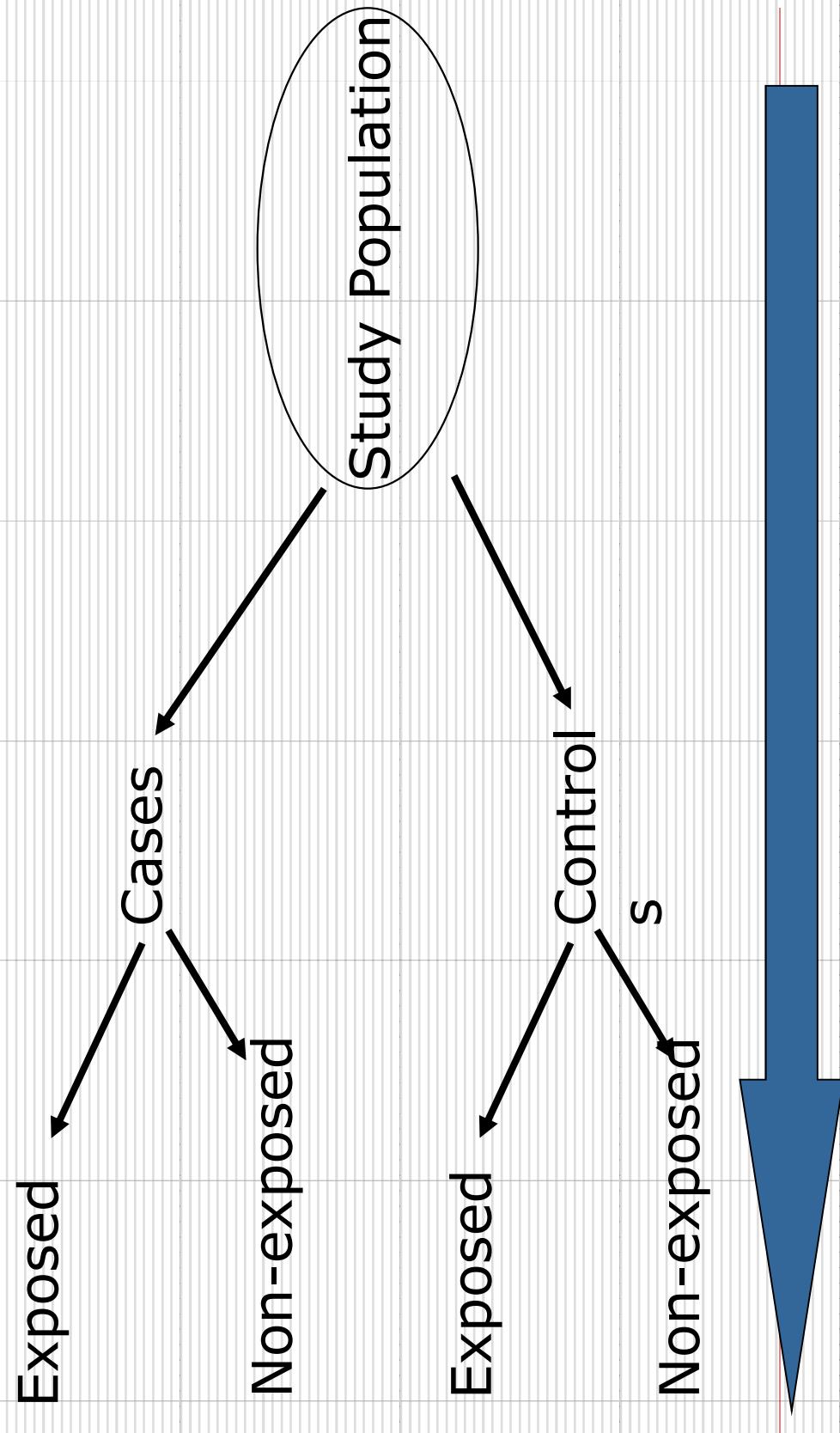
Analytic studies – case control

Subjects selected on presence [cases] or absence [controls] of the outcome factor

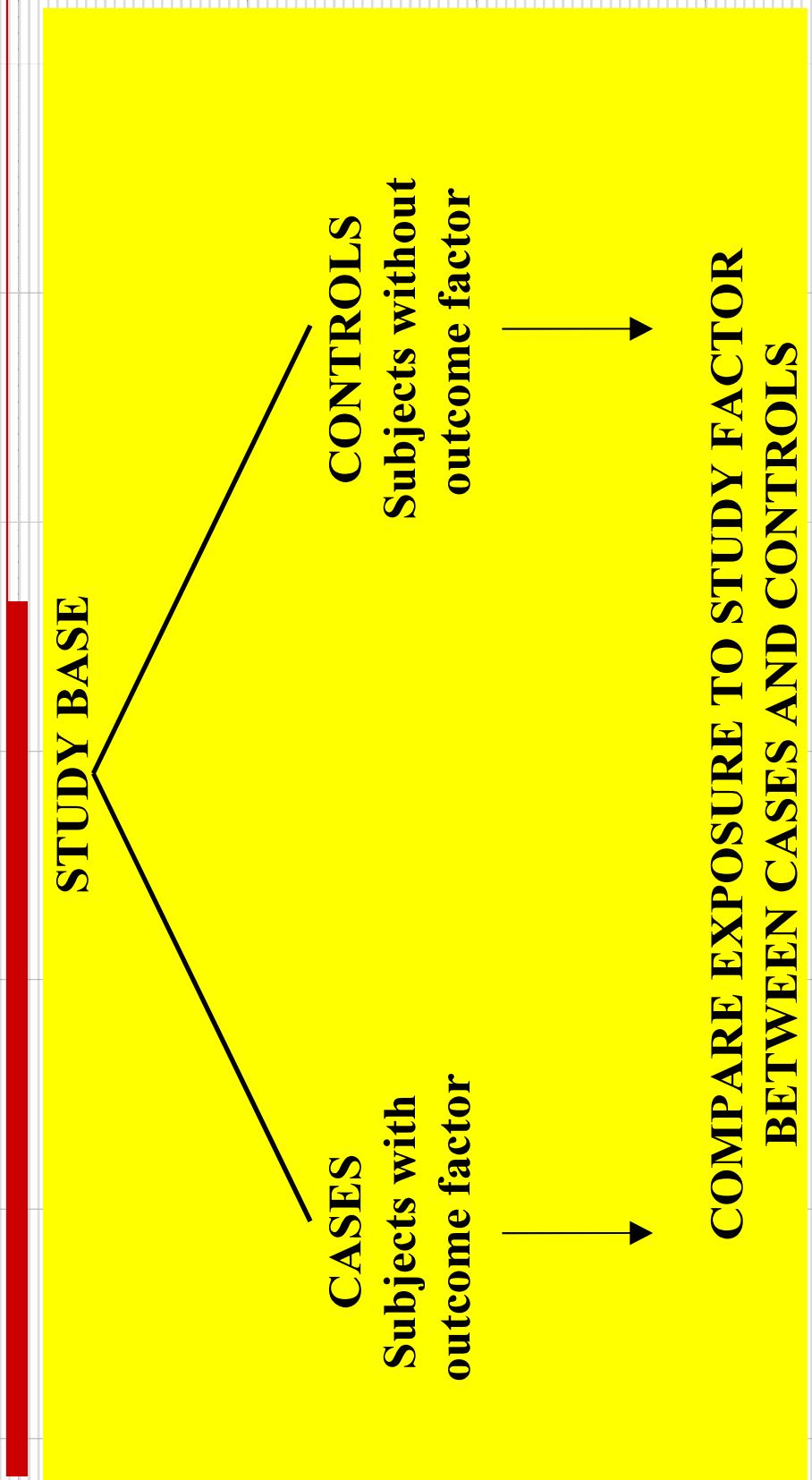
Then exposure factor[s] is measured in cases and controls [i.e., after outcome is known].

Relative frequency of the exposure in cases and controls is compared.

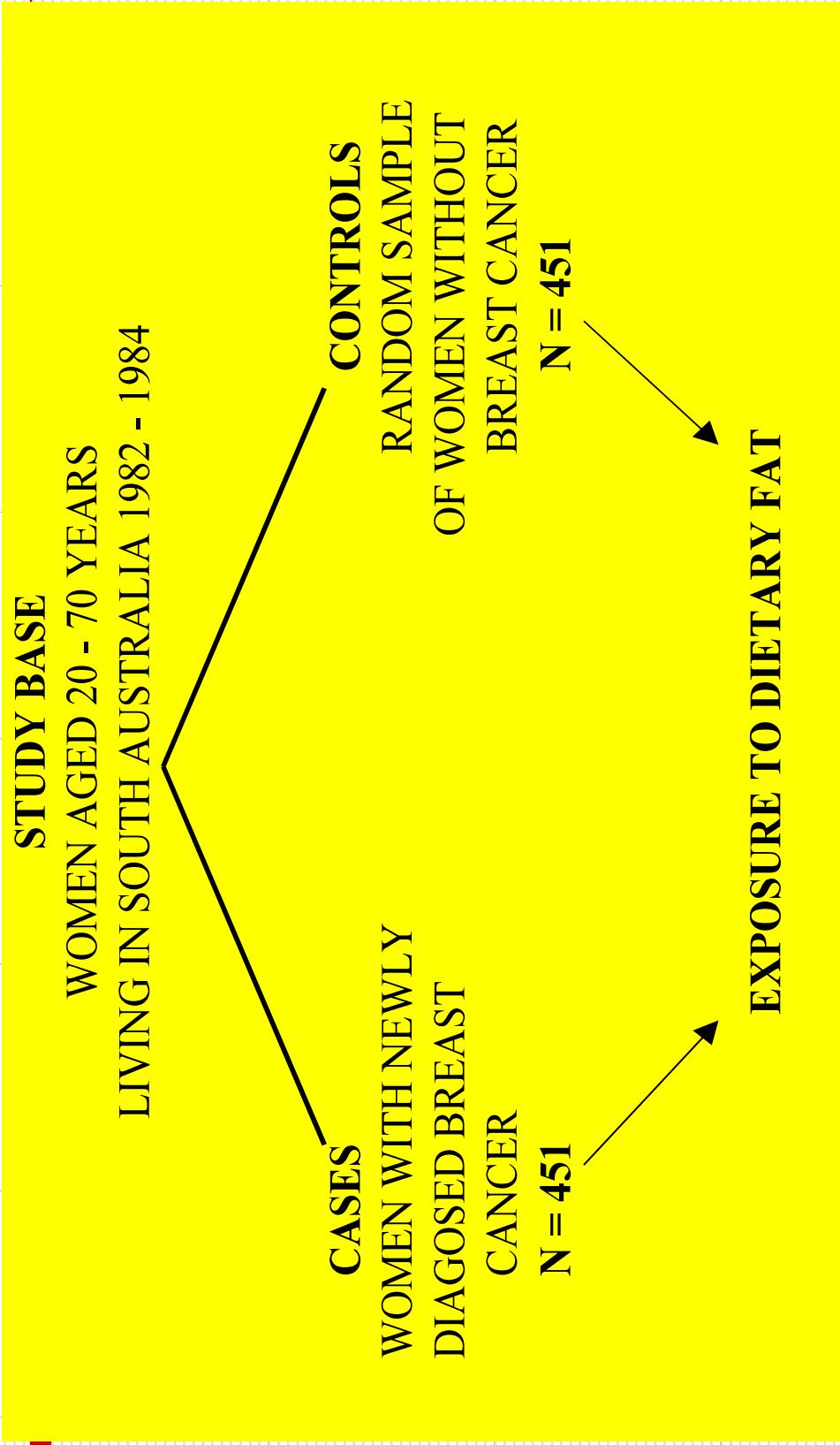
Case-control study



Analytic studies – case control



Analytic studies - Case Control



بزسی از تابع عوامل تعذیب ای و انفارکتوسما خاد میوکارد

* 172 : 1820 : 2020 : 2220 : 2420 : 2620 : 2820

* مرکز مطالعات و توسعه آموزش پژوهشی، دانشگاه علوم پزشکی و خدمات بهداشتی درمانی ایران، تهران

کلید واژه: انفارکتوسیس، حد میوکارد، عوامل خطر تقدیمی، بیماری های فلزی عرقوفی، مواد غذایی

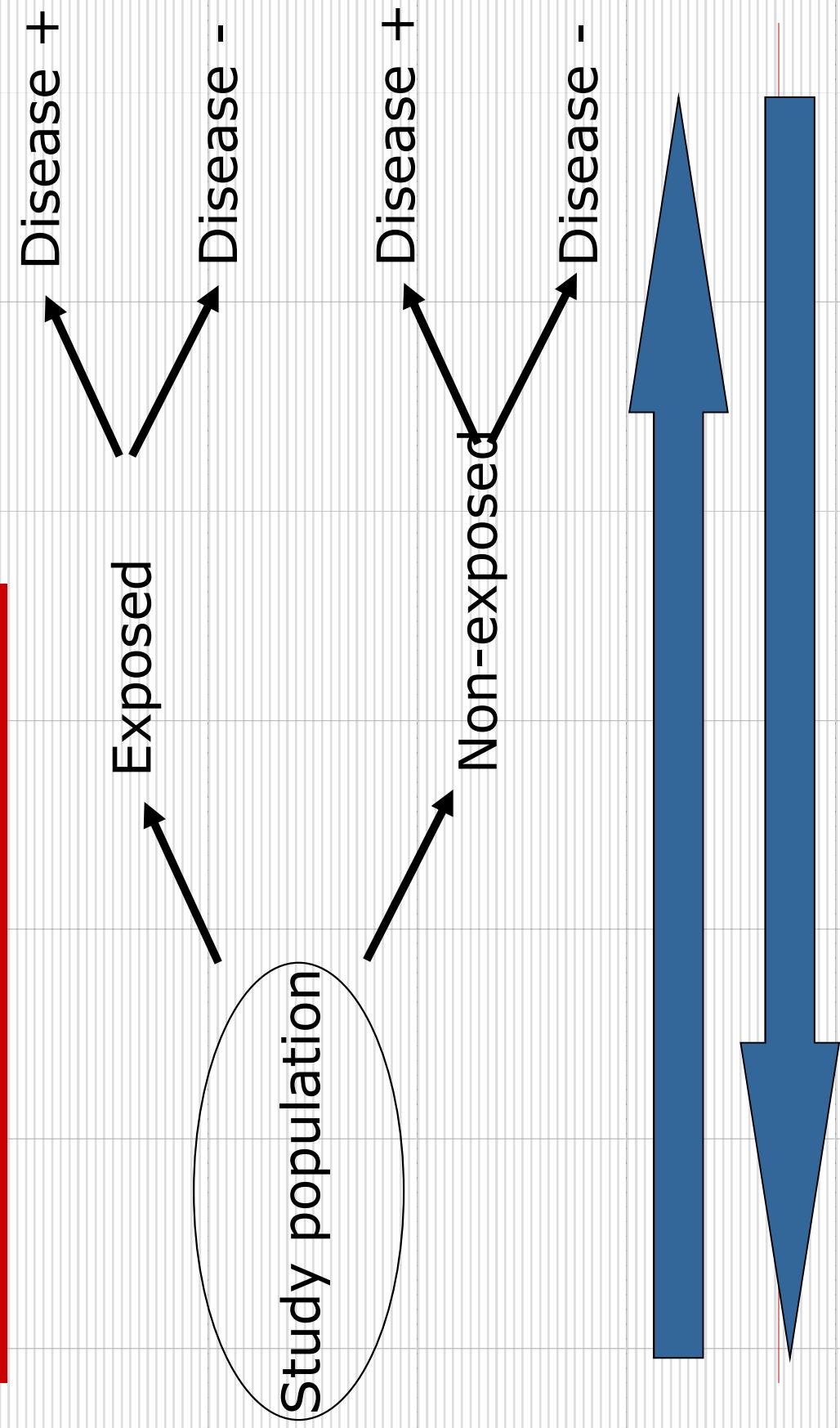
Analytic studies - cohort

Exposure to study factor determined by subjects

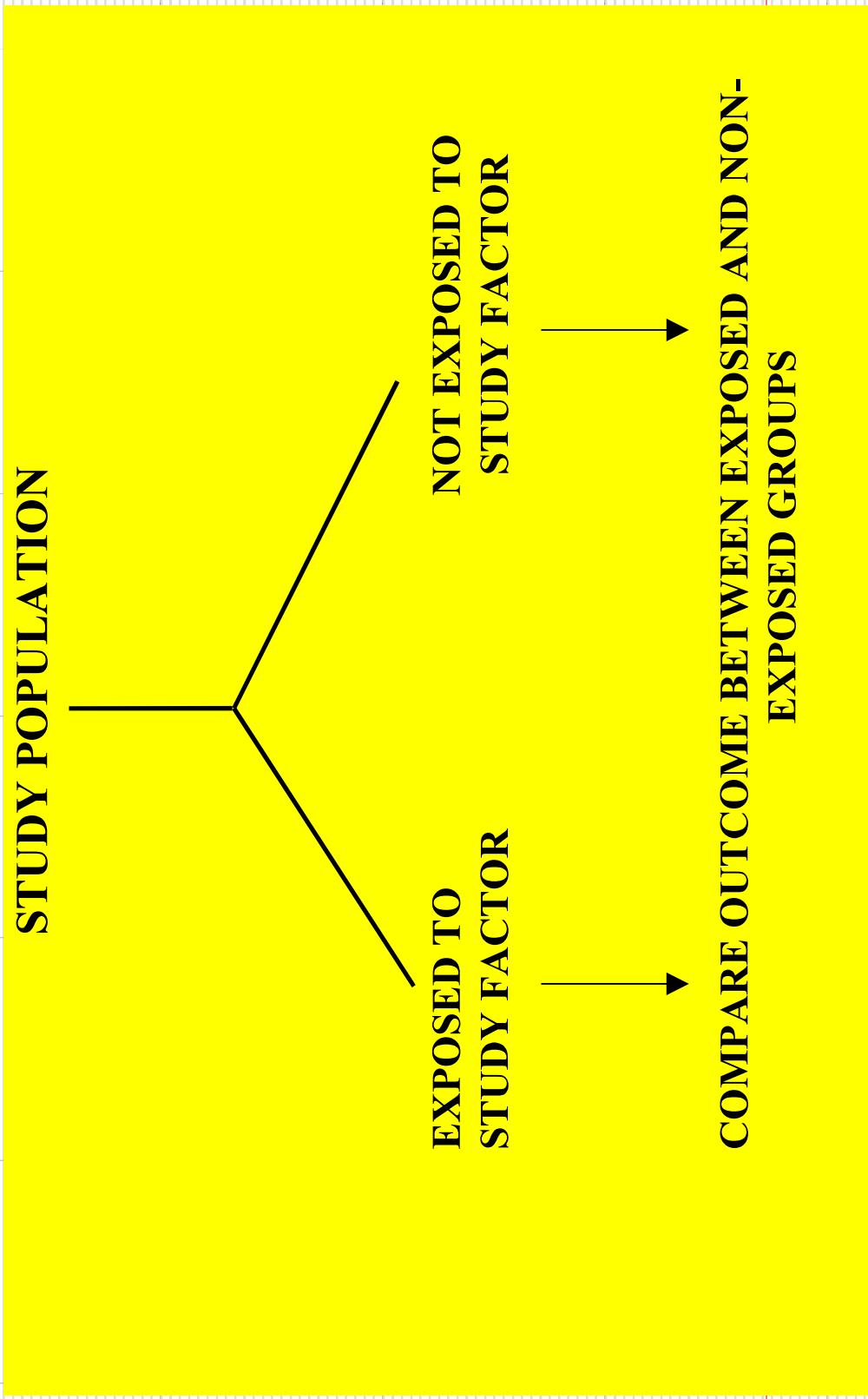
Investigators measure the extent of exposure

Outcome is measured LATER

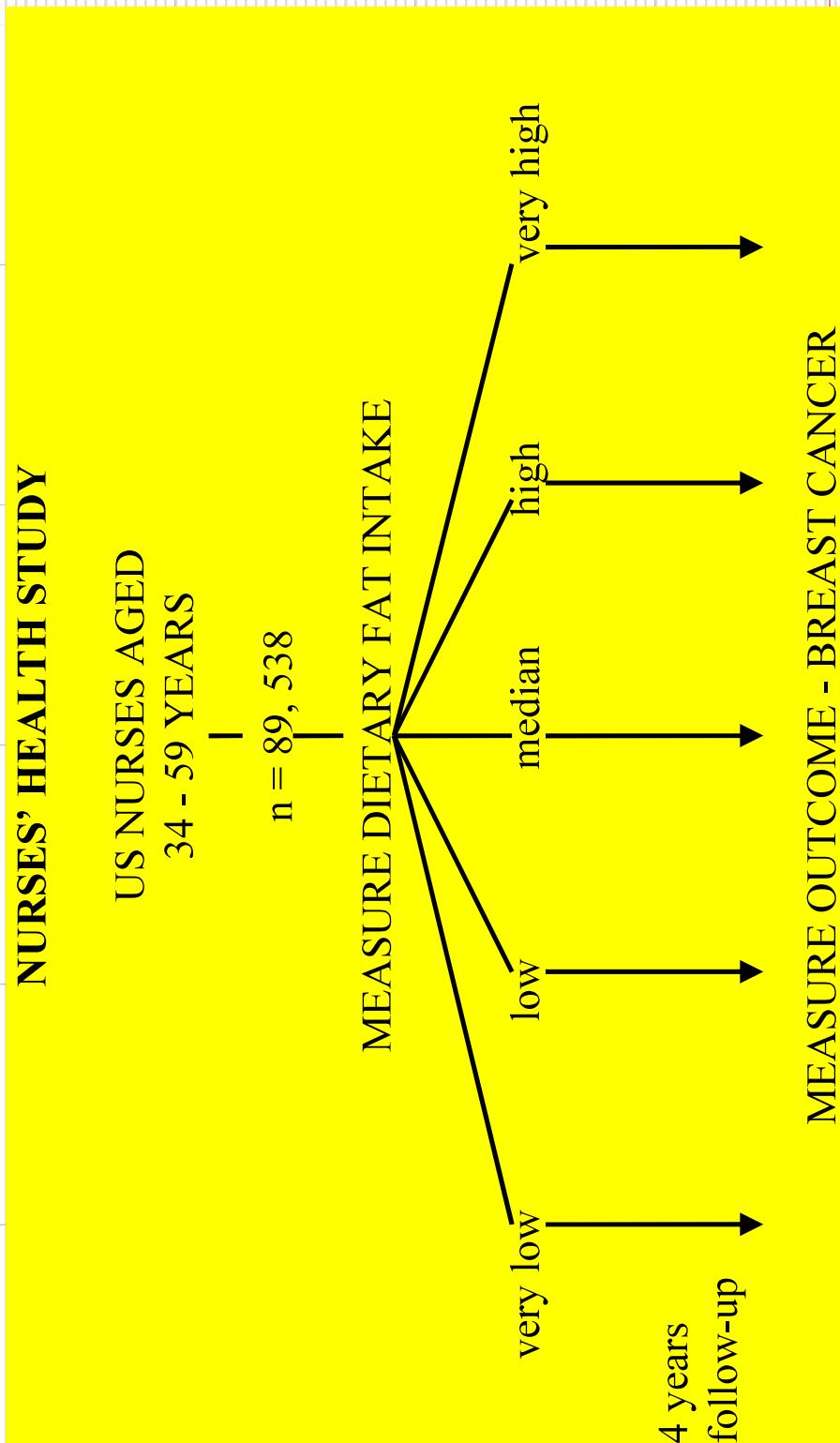
Historical cohort study



Analytic studies - cohort



Analytic studies - cohort



Case-control versus cohort studies

In a COHORT STUDY of smoking (exposure) and lung cancer (outcome):

- begin with a group of smokers (exposed to study factor) and a group of non-smokers (not exposed to study factor; “controls”)
- follow them forward in time to see who develops lung cancer (outcome factor)

Case-control versus cohort studies

In a CASE-CONTROL STUDY of smoking and lung cancer

- begin with a group in whom outcome is known: eg lung cancer patients (**cases**) and a group of people without lung cancer (**controls**)
- assess their past history of smoking (**exposure factor**)

Population-based incidence of Type 2 diabetes and its associated risk factors: results from a six-year cohort study in Iran

Hadi Harati ✉, Farzad Hadaegh ✉, Navid Saadat ✉ and Fereidoun Azizi ✉

Prevention of Metabolic Disorders Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University (M.C), Tehran, Iran

The screenshot shows a Microsoft Word document with the following content:

Background

The Middle East is estimated to have the largest increase in prevalence of diabetes by 2030; yet there is lack of published data on the incidence of Type 2 diabetes in this region. This study aimed to estimate Type 2 diabetes incidence and its associated risk factors in an Iranian urban population.

Methods

Among 3307 non-diabetics ≥ 20 years (mean age 42 ± 13 years, 42% males), glucose tolerance test was performed at baseline in 1999–2001 and at two consecutive phases in 2001–2005 and 2005–2008. Diabetes and glucose tolerance status were defined according to the ADA 1997 criteria. Logistic regression was used to determine the independent variables associated with incident diabetes and their odds ratios (OR).

Results

After median follow-up of 6 years, 237 new cases of diabetes were ascertained corresponding to an age and sex standardized cumulative incidence of 6.4% (95%CI: 5.6–7.2) and incidence rate of 10.6 (9.2–12.1) per 1000 person years. Besides classical diabetes risk factors, female sex and low education level significantly increased risk of diabetes in age adjusted models. In full model, the independent predictors were: age [OR, 95%CI: 1.2 (1.1–1.3)], family history of diabetes [1.8 (1.3–2.5)], body mass index ≥ 30 kg/m 2 [2.3 (1.5–3.6)], abdominal obesity [1.9 (1.4–2.6)], high triglyceride [1.4 (1.1–1.9)], Isolated impaired fasting glucose (IFG) [7.4 (3.6–15.0)], Isolated impaired glucose tolerance (IGT) [5.9 (4.2–8.4)] and combined IFG and IGT [42.2 (23.8–74.9)].

Conclusion

More than 1% of the Iranian urban population older than 20 years develops Type 2 diabetes each year. Combination of IFG and IGT was the strongest predictor of incident diabetes among the modifiable risk factors.

Background

The document also includes a navigation bar with links to "Top", "Abstract", "Background", "Methods", "Results", "Conclusion", "Competing interests", "Authors' contributions", "Acknowledgements", "References", and "Pre-publication history". A right-click context menu is visible, showing options like "Download XML", "Email to a friend", "Order reprints", "Post a comment", "Post to:" (with links to Citeulike, Connotea, Del.icio.us, Facebook, Mendeley, and Twitter), and "Page", "Safety", "Tools". The status bar at the bottom shows "Internet | Protected Mode: Off", "EN", "Inbox - Microsoft ...", "Cohort Golestan...", "PDF", "WORK MIR (G:)", "Biomed Central | ...", "Inbox - Microsoft ...", "Untitled - Paint", and system icons for battery, signal, and date/time.

Sardasht-Iran Cohort Study of Chemical Warfare Victims: Design and Methods

The screenshot shows a Microsoft Word document with the following citation:

Tooba Ghazanfari PhD^{1,2}, Soghraat Faghizadeh PhD³, Hassan Aragizadeh MD⁴, Mohammad-Reza Soroush MD⁵, Roya Yaraee PhD^{1,2}, Zuhair Mohammad H Moin MD²², Abbas Rezaei PhD²³, Amina Kariminia MD²⁴, Soheila Ajdary PhD²⁴, Mahmoud Mahmoudi PhD²⁵, Rasoul Roshan MD²⁶, Sulayman Ghaderi MSc²⁷, Mahmoud Babai MD⁴, Mohammad-Mehdi Naghizadeh MSc², Mostafa Ghanem MD¹², and the Sardashti-Iran Cohort Study Research Group*

A small red rectangular icon containing the letters "PDF" in white, positioned next to a larger, faint PDF file icon.

Corresponding author and reprints: Tooba Ghazanfari, PhD, Department of Immunology, Medical Faculty, Shahed University, Tehran, Iran. P.O. Box 14155-7435, Tel: +98-218-896-4792, Fax: +98-218-896-6310, E-mail: ghazanfari@shahed.ac.ir, tghazanfari@yahoo.com □ 

Accepted for publication: 16 August 2008

Background: Insights into long-term clinical consequences of sulfur mustard have emerged from some investigations but less is known about the basic and molecular mechanisms of these complications. Sardasht-Iran Cohort Study is a comprehensive historical cohort study on Sardasht chemical victims' population which was designed to find out the long-term complications of sulfur mustard exposure and the basic mechanisms underlying clinical manifestations. This paper describes the design and methodology of Sardasht-

Methods: In Sardasht-Iran Cohort Study, 500 individuals including 372 subjects from Sardasht, as the exposed group, and 128 subjects from Rabat, as the unexposed age-matched control group were evaluated. The exposed group was divided into two groups based on the severity of clinical complications at the time of exposure. Different samples including blood, sputum, saliva, tear, urine, and semen were collected for immunologic, hematologic, biochemical, and other laboratory analysis. Data were gathered from medical Iran Cohort Study.

Conclusion: The important distinctions setting this study apart from the previous ones are discussed. The Sardasht-Iran Cohort Study provides important information on various aspects of long-term consequences of sulfur mustard exposure.

Keywords: Clinical complications? immune responses? inflammation? sulfur mustard? toxicology

Analytic studies - RCT

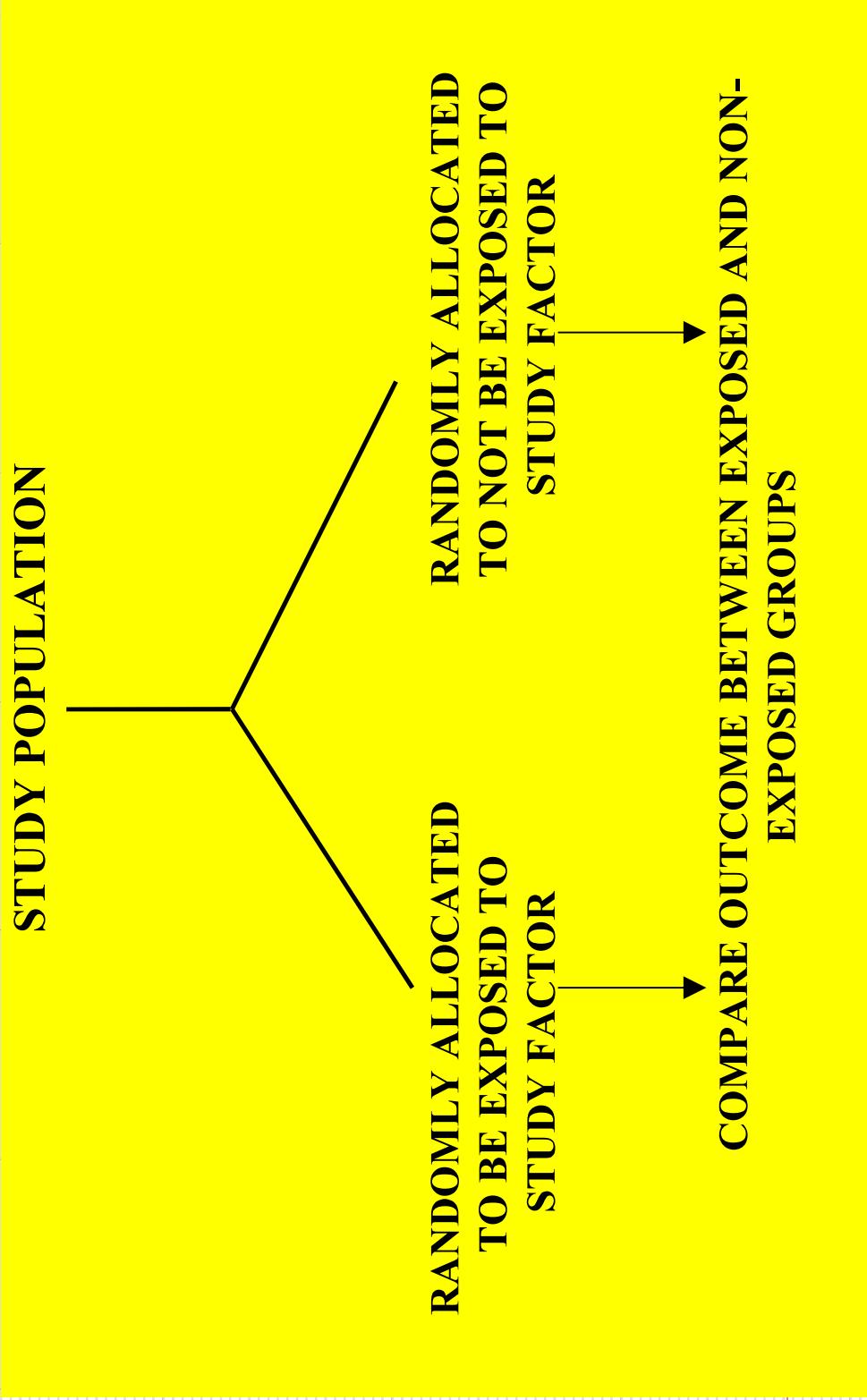
Chance alone determines exposure to study factor

Outcome is measured later

MAJOR STRENGTH:

There is no difference between the exposed and unexposed group EXCEPT for the study factor

Analytic studies - RCT



Analytic studies – RCT

Randomised control trial of efficacy of midwife-managed care

Lancet 1996;348:213-218

1299 pregnant women

randomised

648 midwife managed care

651 shared care

Measured obstetric outcomes and satisfaction with care



صفری ۴۰ هشتم فرانک، صالحان تهمه، گنجی فرمان، بگوی میزان

* دانشکده انسانی و مهندسی، دانشگاه علوم پزشکی شهید کرد، شهرکرد، ایران

رسمنه و هدف: بکی ار علل تا خبر بهبودی بعد از اعمال جراحی شکمی از حمله سرارین، تا خیر در برگشت حرکات روده ای بس از عمل سرارین انتشاری در زمان نخست را در بهمارستان هاجر شهرکرد صورت گرفت. روش بررسی: این مطالعه به صورت کارآمدی بالینی تصادفی شده بر روی ۱۲ بیمار خواستار سرارین در بهمارستان هاجر شهرکرد، انجام شد. بهماران گروه ادامس در دووان بس از عمل، ۴ بار در روز ادامس جویدند و این کار را به مخصوص هوشیاری شروع و تازمان دفع گاری مدفع ادله دادند و گروه کنترل نزد رژیم معمول بعد از عمل را دریافت کردند. میانگین رسان اولین سمع صدای روده، دفع گار، مدفع و احساس حرکات روده بین دو گروه مقایسه گردید. تعزیره و تحلیل نتایج به دست امده با ازموں های تی و کای دو صolut گرفت. $P < 0.05$ یافته ها: در گروه ادامس نسبت به گروه کنترل، اختلاف میانگین فاصله زمانی سمع صدای روده (2.5 ± 0.5) ساعت در برابر (1.5 ± 0.5) ساعت، در یاری (2.0 ± 0.5) ساعت، زمان احساس حرکات روده (2.3 ± 0.7) ساعت در برابر (1.7 ± 0.7) ساعت)، دفع مدفع (4.8 ± 2.3) ساعت در برابر (1.5 ± 0.5) ساعت ($P < 0.001$).

卷之三





CONSORT 2010 checklist of information to include when reporting a randomised

Section/Topic	Item No	Checklist item
Title and abstract		1a Identification as a randomised trial in the title 1b Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those

	assessing outcomes) and how
11b	If relevant, description of the similarity of interventions
12a	Statistical methods used to compare groups for primary and secondary outcomes
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results	
Participant flow (a diagram is strongly recommended)	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
Recruitment	13b For each group, losses and exclusions after randomisation, together with reasons 14a Dates defining the periods of recruitment and follow-up 14b Why the trial ended or was stopped
Baseline data	15 A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion	
Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21 Generalisability (external validity, applicability) of the trial findings
Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information	
Registration	23 Registration number and name of trial registry
Protocol	24 Where the full trial protocol can be accessed, if available
Funding	25 Sources of funding and other support (such as supply of drugs), role of funders

Systematic reviews and meta-analysis

Examines results from different studies

Meta-analysis is a statistical method of combining results from multiple studies

Conclusions