Epidemiology

Silvio Tafuri, MD, PhD

Agenda

- Eminence Based-Medicine
- Evidence Based-Medicine
- Systematic Reviews and Meta-Analysis
- The ethical aspects of medical research
- Publication Bias
- Even the big ones mistake

Eminence-Based Medicine

“do what I say because who I am”

Eminence-Based Medicine

- Clinical **decision** that is made by relying purely on the **opinion** of a **medical specialist** or any prominent **health professionals** rather than relying on critical appraisal of **scientific evidence available**
- Risk of **introducing logical fallacies** into medical practice
  - Vehemence
  - Eloquence
  - Providence
  - Nervousness

Celebrity-Based Medicine

E Ernst et al. Med J Aust 185 (11-12), 680-681. 2006 Dec 04. more

OBJECTIVE: To collect contemporary accounts of celebrity use of complementary and alternative medicine (CAM), to aid clinicians in determining which CAM treatments patients are likely to use.

DESIGN: Articles published during 2005 and 2006 reporting celebrity use of CAM.

RESULTS: 38 celebrities were found to use a wide range of CAM interventions. Homeopathy, acupuncture and Ayurveda were the most popular modalities.

CONCLUSIONS: There may be many reasons why consumers use CAM, and wanting to imitate their idols is one of them.

PubMed: 17181531

Vegan diet in children

Feeding Vegan Kids

by Reed Mangels, PhD, RD
From **Simply Vegan** 5th Edition

Many members of The Vegetarian Resource Group are glowing testimony to the fact that vegan children can be healthy, grow normally, be extremely active, and (we think) smarter than average. Of course it takes time and thought to feed vegan children. (Shouldn't feeding of any child require time and thought?) After all, the years from birth to adolescence are the years when eating habits are set, when growth rate is high, and to a large extent, when the sizes of stores of essential nutrients such as calcium and iron are determined.

World Health Organization

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Global Strategy on Diet, Physical Activity and Health

Children's diet

General Information

Currently there is no dietary recommendation of global utility available for children and adolescents.

However, individuals and populations are advised to:

- increase the consumption of fruit and vegetables, as well as legumes, whole grains and nuts;
- limit the energy intake from total fats and shift fat consumption away from saturated fats to unsaturated fats;
- limit the intake of sugars.

Morning Mix

An Italian baby raised on a vegan diet is hospitalized for severe malnutrition and removed from parents

By Mary Hui July 11, 2016

Malnourished baby dies after parents fed him insanely strict vegan diet

ALEX LASKER, AOL.COM

May 19th 2017 11:29AM

Food intolerance test

brown's PHARMACY

HOME PHARMACIES ABOUT US NEWS

Food Intolerance Test

Food Intolerance Test

So What Exactly Is Food Intolerance?

The complex way food affects our everyday lives is an emerging area and diagnosing the cause of symptoms which seem to be 'unexplained' is often difficult. People who experience some of the symptoms of food intolerance are often led by the medical profession and the media to believe that their condition is 'all in the mind' and are treated for the physical manifestation of the condition rather than the cause. However there are now answers to your questions and ways to identify the cause of your symptoms leading to long term relief.

Although not life threatening like food allergy, food intolerance should never be underestimated as its impact on sufferers can be significant, severely impacting on their ability to live normal healthy lives.

Guidelines for the Diagnosis and Management of Food Allergy in the United States

Report of the NIAID-Sponsored Expert Panel

Joshua A. Boyce, MD, Amal Assa'ad, MD, A. Wesley Burks, MD, Stacie M. Jones, MD, Hugh A. Sampson, MD, Robert A. Wood, MD, Marshall Plaut, MD, Susan F. Cooper, MSc, Matthew J. Fenton, PhD, S. Hasan Arshad, MBBS, MRCP, DM, FRCP, Sami L. Bahna, MD, DrPH, Lisa A. Beck, MD, Carol Byrd-Bredbenner, PhD, RD, FADA, Carlos A. Camargo, Jr, MD, DrPH, Lawrence Eichenfield, MD, Glenn T. Furuta, MD, Jon M. Hanifin, MD, Carol Jones, RN, AE-C, Monica Kraft, MD, Bruce D. Levy, MD, Phil Lieberman, MD, Stefano Luccioli, MD, Kathleen M. McCall, BSN, RN, Lynda C. Schneider, MD, Ronald A. Simon, MD, F. Estelle R. Simons, MD, Stephen J. Teach, MD, MPH, Barbara P. Yawn, MD, MPH, MSc, and Julie M. Schwaninger, MSc

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Fake tests for food intolerance and food allergy diagnosis: Italian Medical Federation publishes a complete list

Redazione Il Fatto Alimentare 12 settembre 2016 Sicurezza Alimentare Commenti
18,188 Visto

Gluten-free diet in healthy kids

SUPER HEALTHY KIDS®

HOME RECIPES BLOG MEAL PLANS FREE

BLOG POSTS

MEAL PLAN- GLUTEN FREE

It's so good to be home! We had a fun week at Lake Tahoe with my family, but it's always so nice to be home. Lake Tahoe is gorgeous! We swam, we hiked, we played games, and of course we ate! And now, I have laundry, a car to clean, groceries to buy, mail to read, and phone calls to return. ARGHHH!!

By Amy Roskelley

Gastroenterology

Volume 145, Issue 2, August 2013, Pages 320-328.e3

Original Research

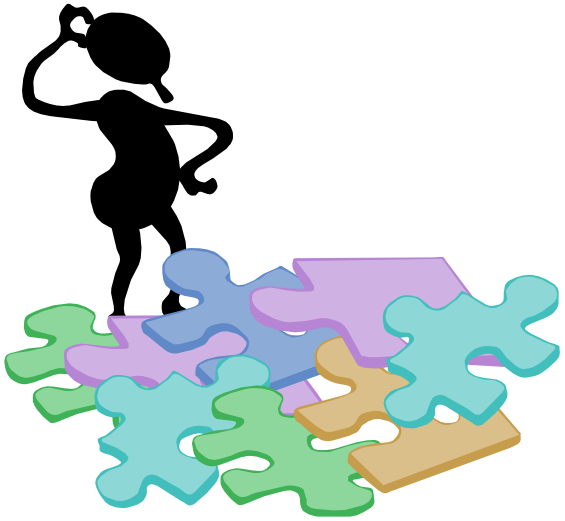
No Effects of Gluten in Patients With Self-Reported Non-Celiac Gluten Sensitivity After Dietary Reduction of Fermentable, Poorly Absorbed, Short-Chain Carbohydrates

Jessica R. Biesiekierski[1, 2], Simone L. Peters[2], Evan D. Newnham[1], Ourania Rosella[2], Jane G. Muir[2], Peter R. Gibson[2]

How do I decide what to do?

How do I make decisions?

- Dogma: “Natural is best”
- Tradition: “We’ve always done it that way”
- Convention: “Everyone does it this way”
- **Evidence-Based: “Evidence supports this way”**



Evidence Based Medicine

What is Evidence Based Medicine?

"… The conscientious , explicit and judicious use of current best evidence in making decisions about the care of individual patients."

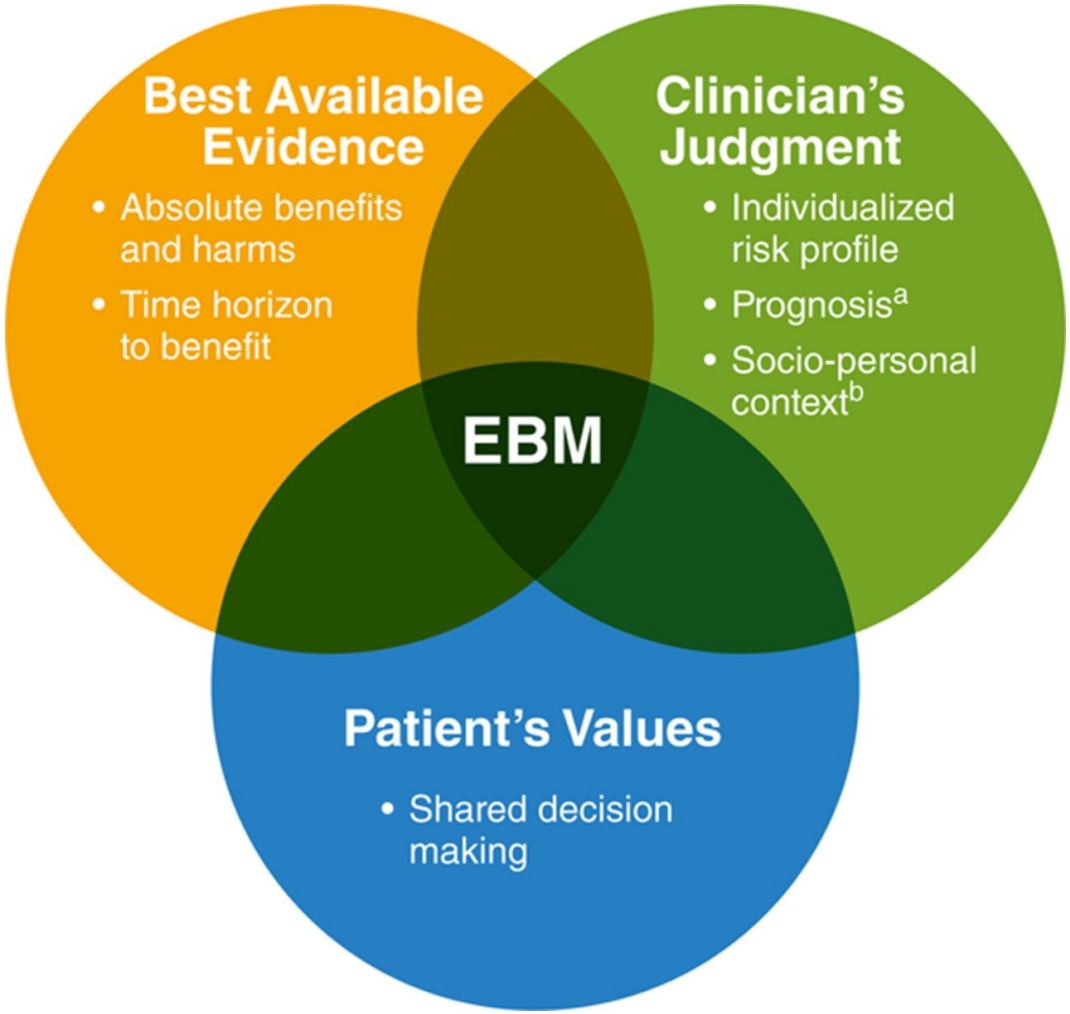
Dr. Sackett

Sackett DL (1996)

Evidence Based Medicine

- **Clinical practice**: based on the best current evidence
- **Patient Care**: compassionate, patient-oriented
- **Learning & Teaching**: problem-based, problem solving
- **Research**: more stringent approach, better proof criteria

Evidence Based Medicine



Makam AN (2017)

The five basic steps

- **Clinical question**
  - Patient focused, problem oriented
- **Find best evidence**
  - Literaly search
- **Critical appraisal**
  - Evaluate evidence for quality and uselfulness
- **Apply the evidence**
  - Implement useful findings in clinical practice
- **Evaluate**
  - The information, intervention and EBM process

Clinical question (PICO)

Elements	Promts the question
Patient	How would I descrive a group of patients similar to mine?
Intervention	What main action am I considering?
Comparison	What is/are the other options?
Outcome	What do I want to happen?

Eddy DM (1984)

An example

Elements	Promts the question
Patient	In kids under age 12 with poorly controlled asthma on metered dose inhaled steroids…
Intervention	would the addition of salmetrol to the current therapy
Comparison	compared to increasing the dose of current steroid
Outcome	lead to better control of symptoms without increasing side effects?

Eddy DM (1984)

Find best evidence

PsycINFO®

Cochrane

MEDLINE

PubMed

ScienceDirect

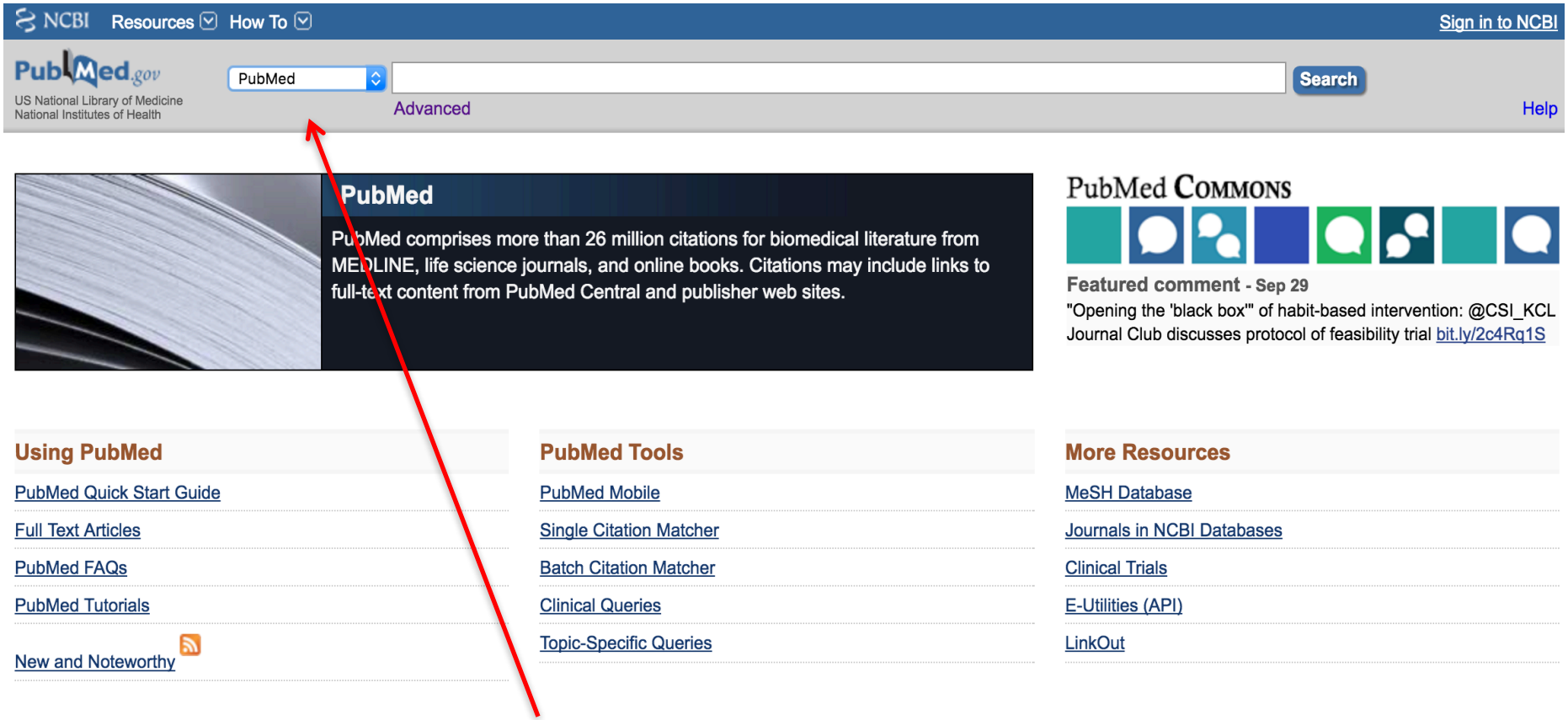
The best evidence is

- **External**: from outside resources (researchers, experts)
- **Current**: not out of date, most recent
- **High Quality**: accurate, precise, effective, safe
- **Patient focused**: applicable and appropriate for your individual patient

What is PUBMED?

- **Database** containing **about 16 million citations of scientific articles**, biomedical sciences or related sciences, from the 1950s to the present.
- Quotes come from MEDLINE (the first NLM database) and from other databases dedicated to life sciences.
- The **abstracts**, available since 1975, are present for 76% of the articles.
- PubMed allows access to full text articles available free of charge online.

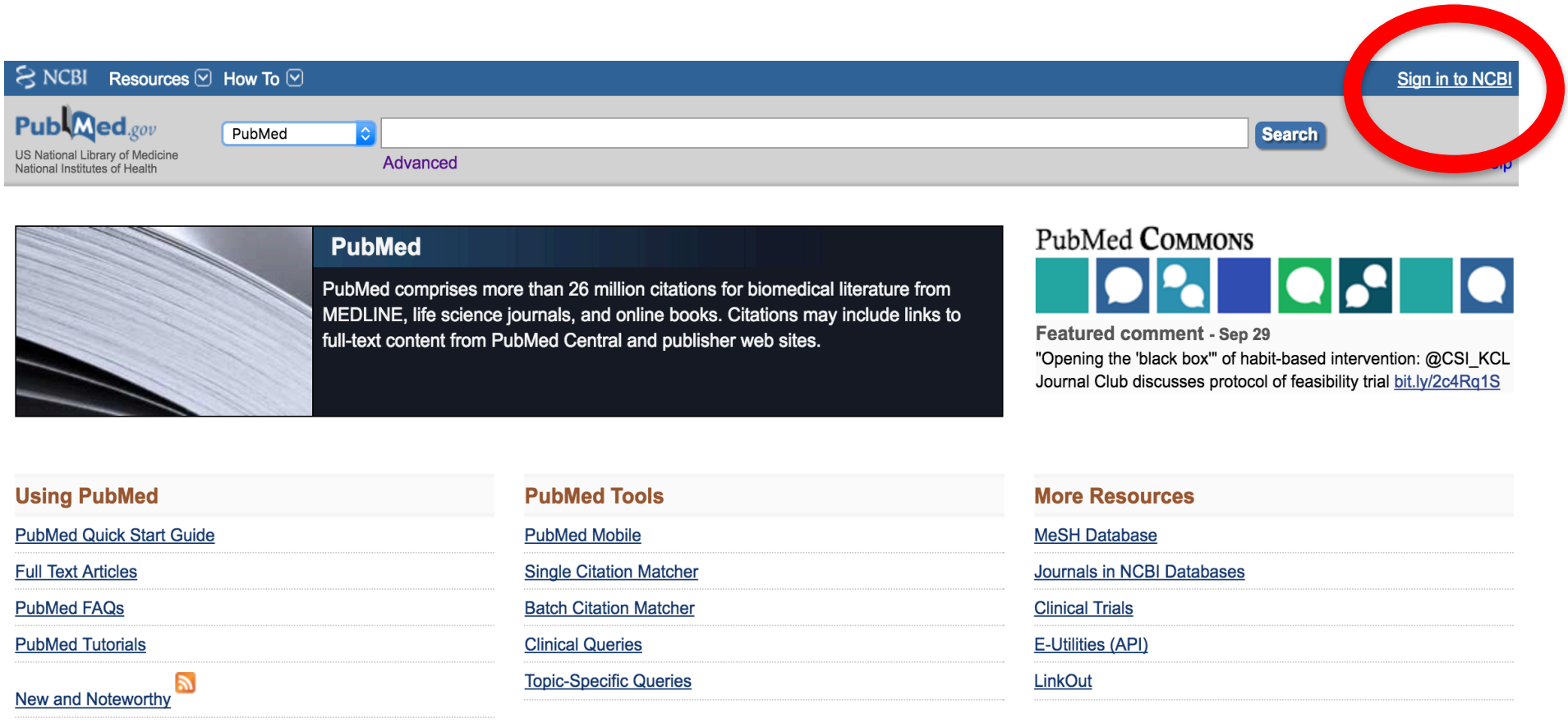
How to use PUBMED



Choosing the database where to search

Recommended: PubMED or ALL Databases

Create a personal profile: MY NCBI



Create a personal profile: MY NCBI

Create a personal profile: MY NCBI

My NCBI retains user information and database preferences to provide customized services for many NCBI databases.

My NCBI Overview

My NCBI features include:

- Save searches & automatic e-mail alerts
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- LinkOut, document delivery service & outside tool selections

NIH funded investigator?

Extramural NIH-funded investigators looking for NIH Public Access Compliance tools can sign in with either "eRA Commons" or "NIH Login". Use your eRA Commons credentials on the subsequent sign in page. Once signed in, navigate to the My Bibliography section.

Documentation for using these features is located in the Managing Compliance to the NIH Public Access Policy section of the NCBI Help Manual.

Information about the NIH Public Access Policy is located at https://publicaccess.nih.gov.

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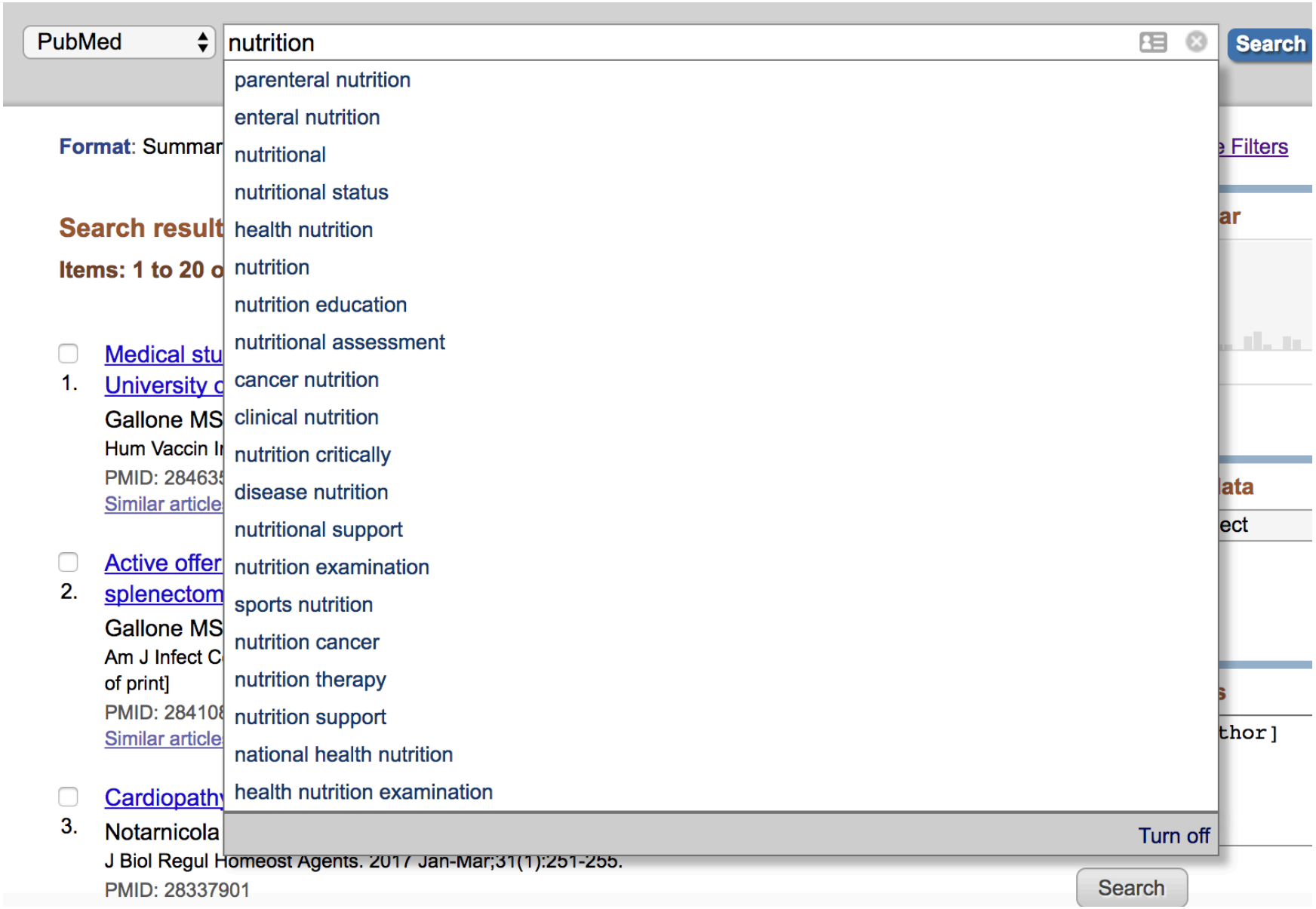
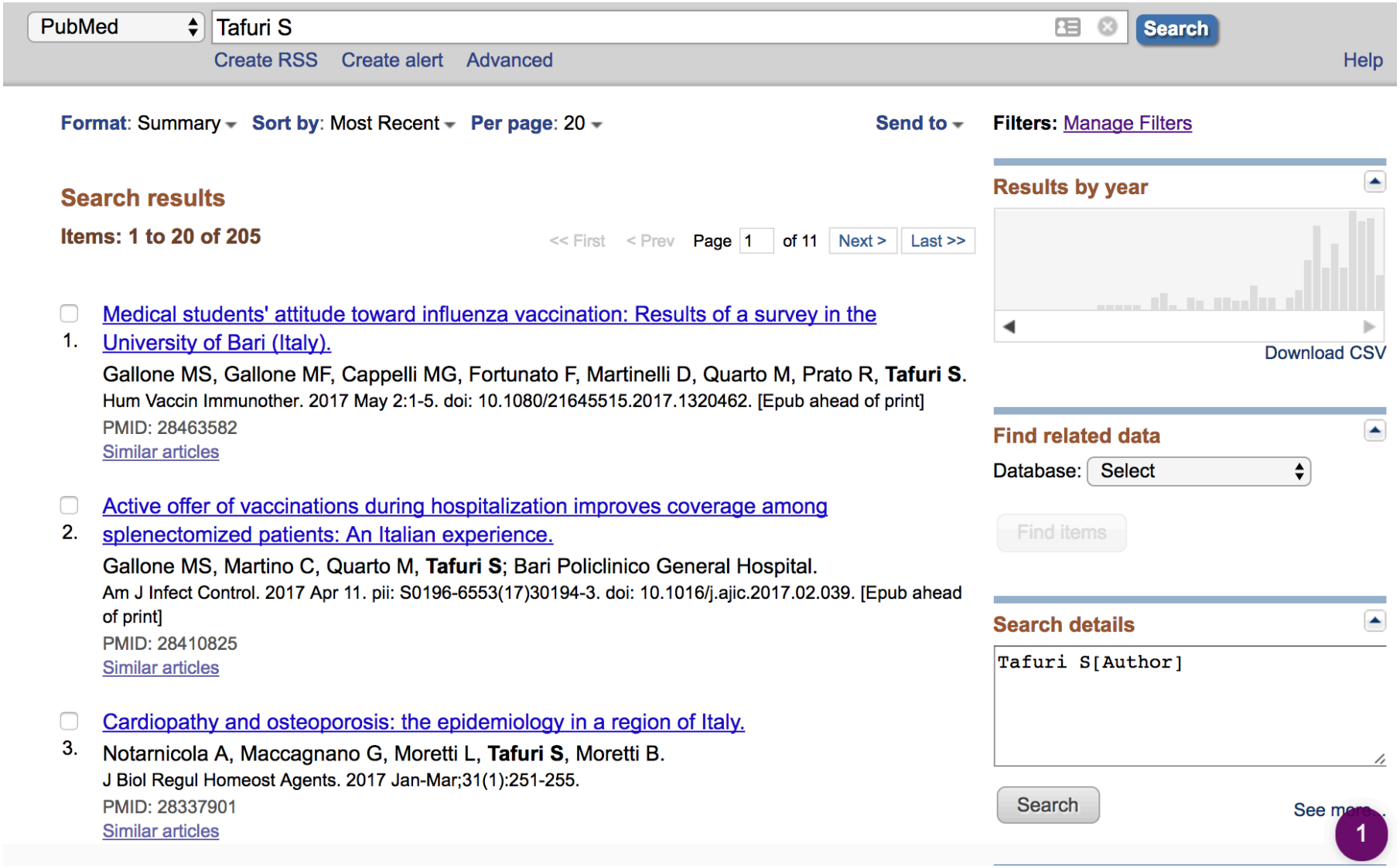
Research by topic



Research by author



PubMed nutrition Search

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1. The improvement of multi-contaminated sandy loam soil chemical and biological properties by the biochar, wood ash, and humic substances amendments.
   Pukalchik M, Mercl F, Panova M, Břendová K, Terekhova VA, Tlustoš P.
   Environ Pollut. 2017 Jun 16;229:516-524. doi: 10.1016/j.envpol.2017.06.021. [Epub ahead of print]
   PMID: 28628867
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2. Young leaves of reed (Phragmites communis) suppress melanogenesis and oxidative stress in B16F10 melanoma cells.
   Sim MO, Ham JR, Lee MK.
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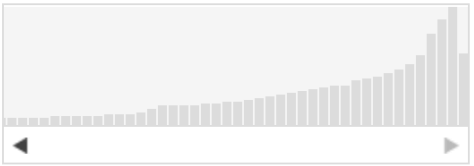

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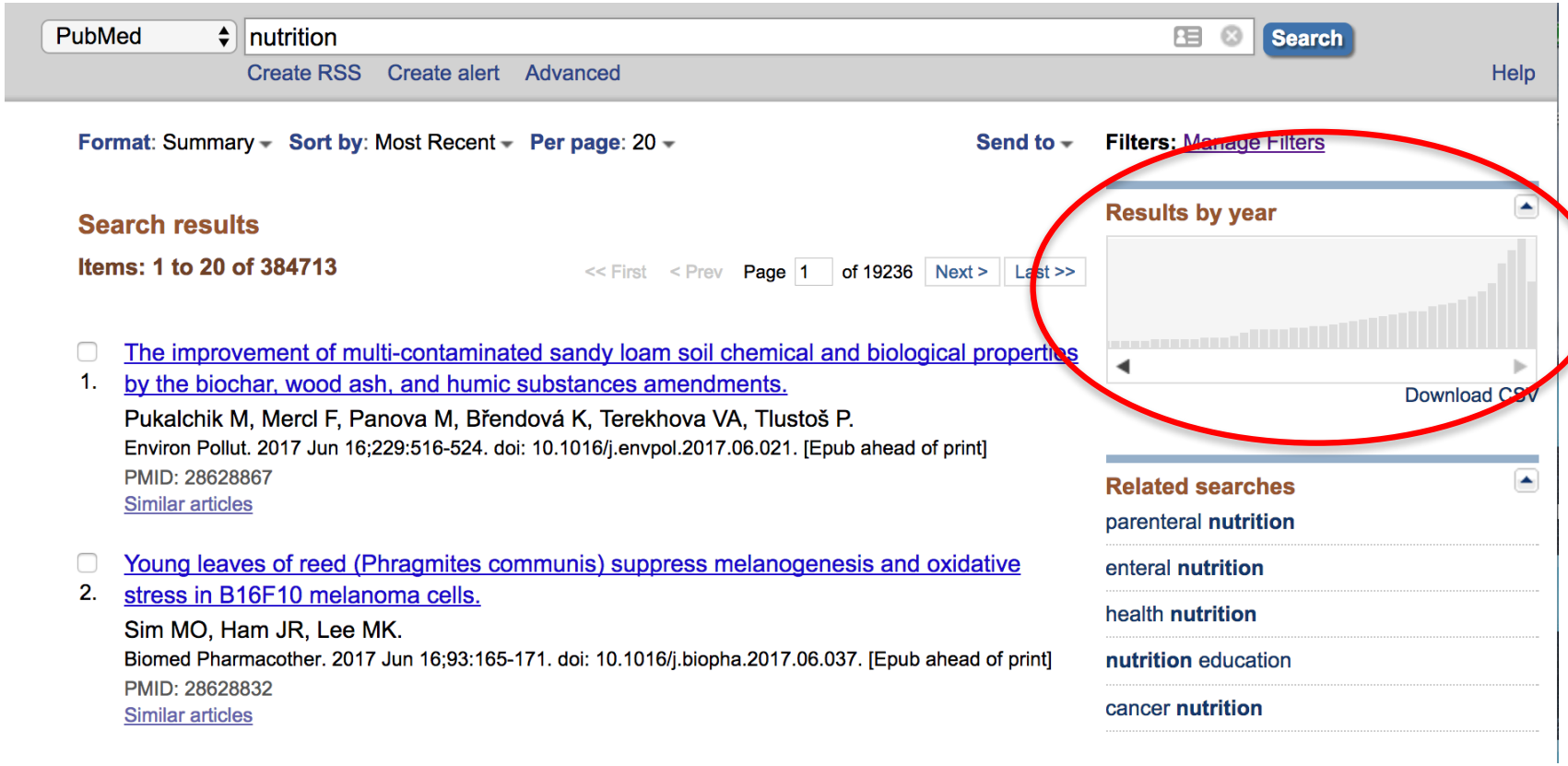
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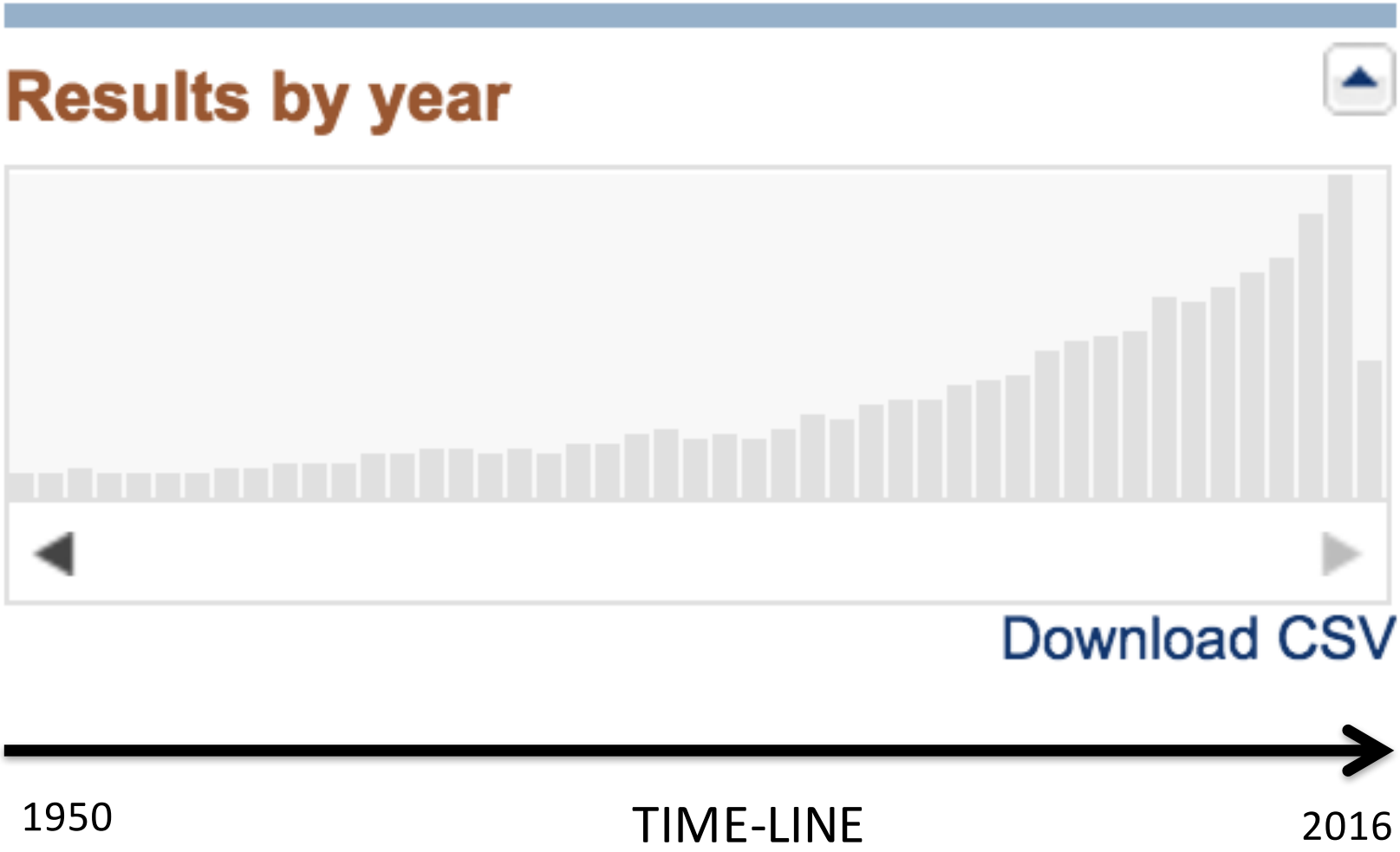
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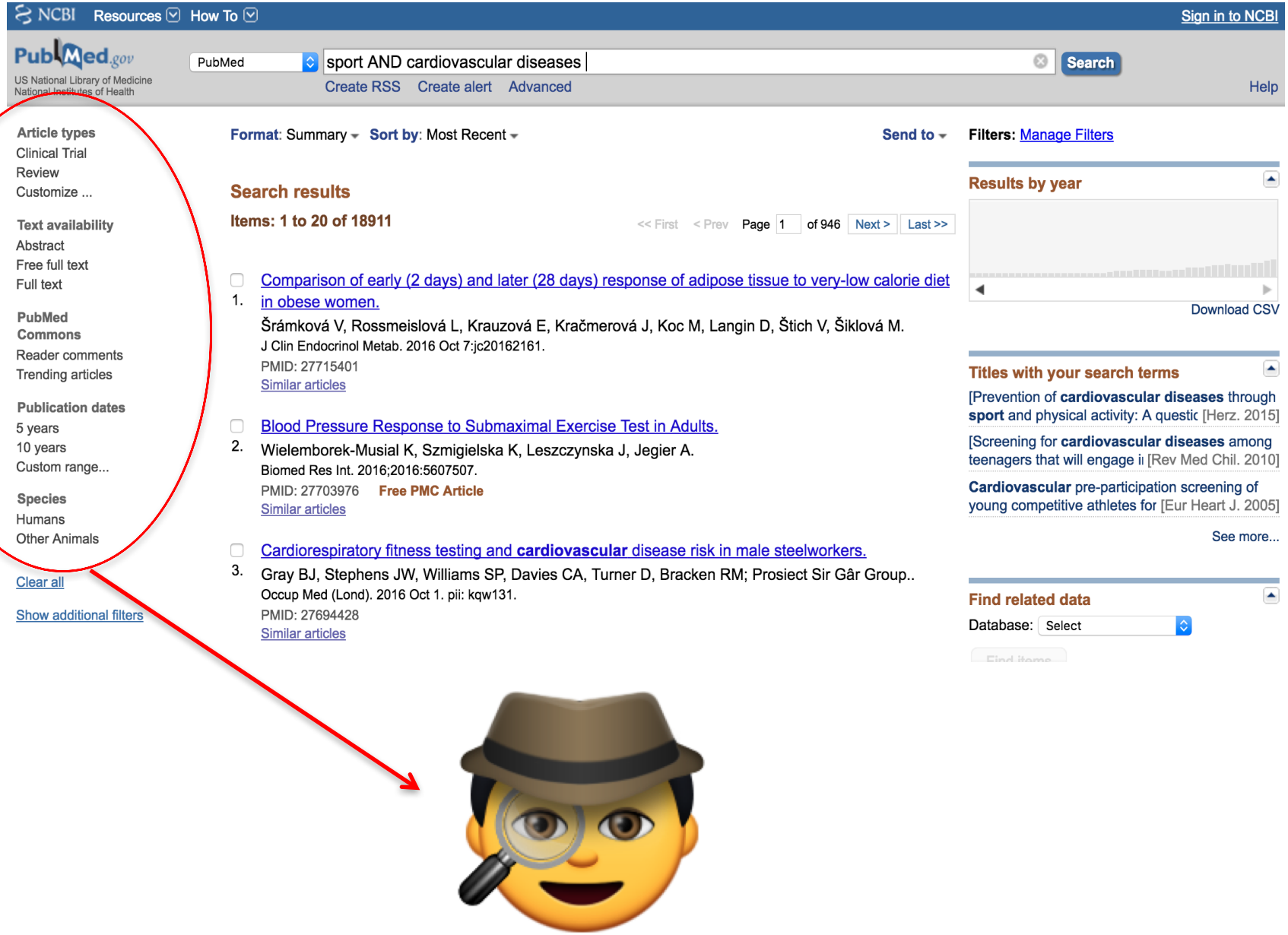
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1. Comparison of early (2 days) and later (28 days) response of adipose tissue to very-low calorie diet in obese women.
Šrámková V, Rossmeislová L, Krauzová E, Kračmerová J, Koc M, Langin D, Štich V, Šiklová M.
J Clin Endocrinol Metab. 2016 Oct 7:jc20162161.
PMID: 27715401
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2. Blood Pressure Response to Submaximal Exercise Test in Adults.
Wielemborek-Musial K, Szmigielska K, Leszczynska J, Jegier A.
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Gray BJ, Stephens JW, Williams SP, Davies CA, Turner D, Bracken RM; Prosiect Sir Gâr Group..
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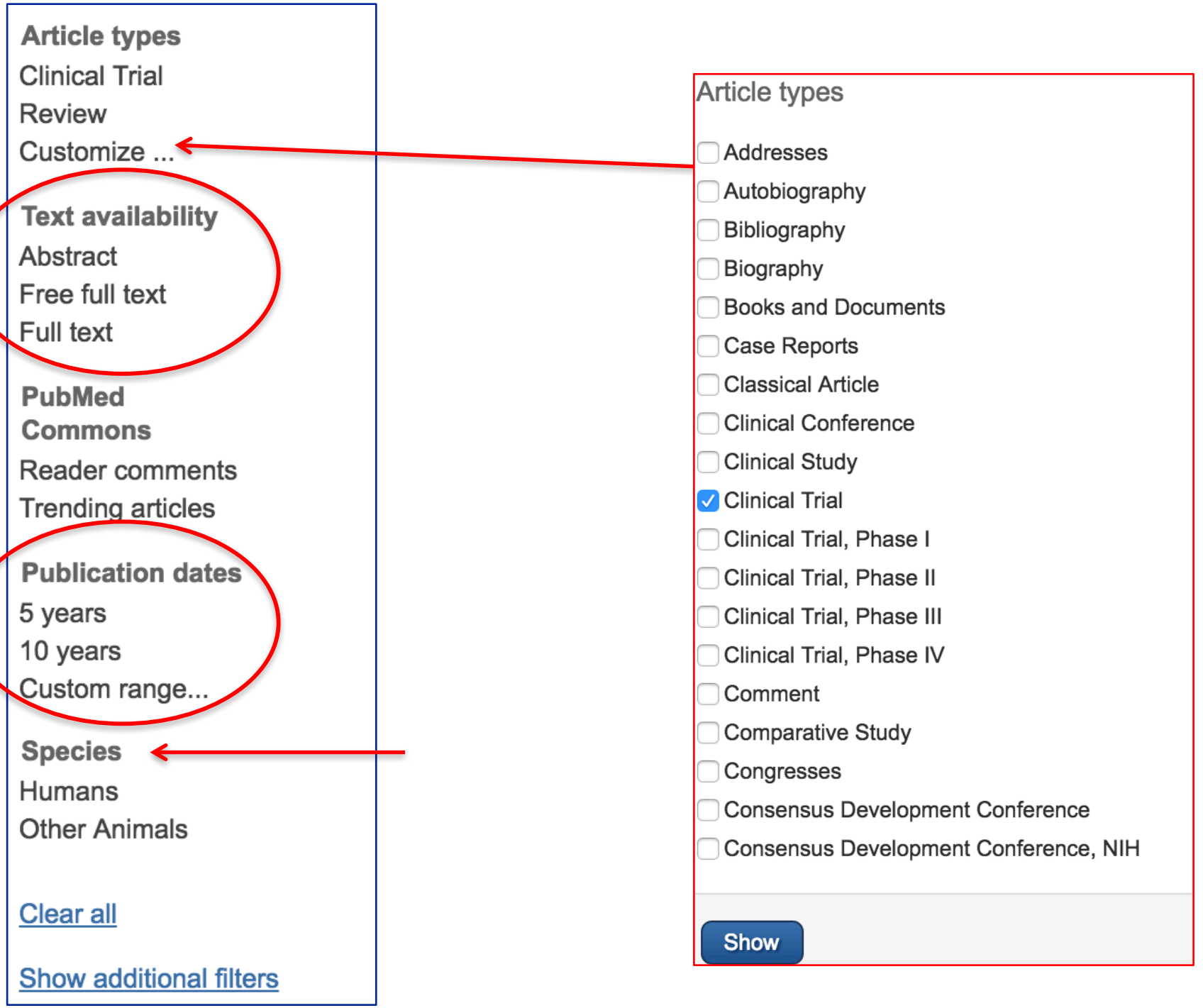
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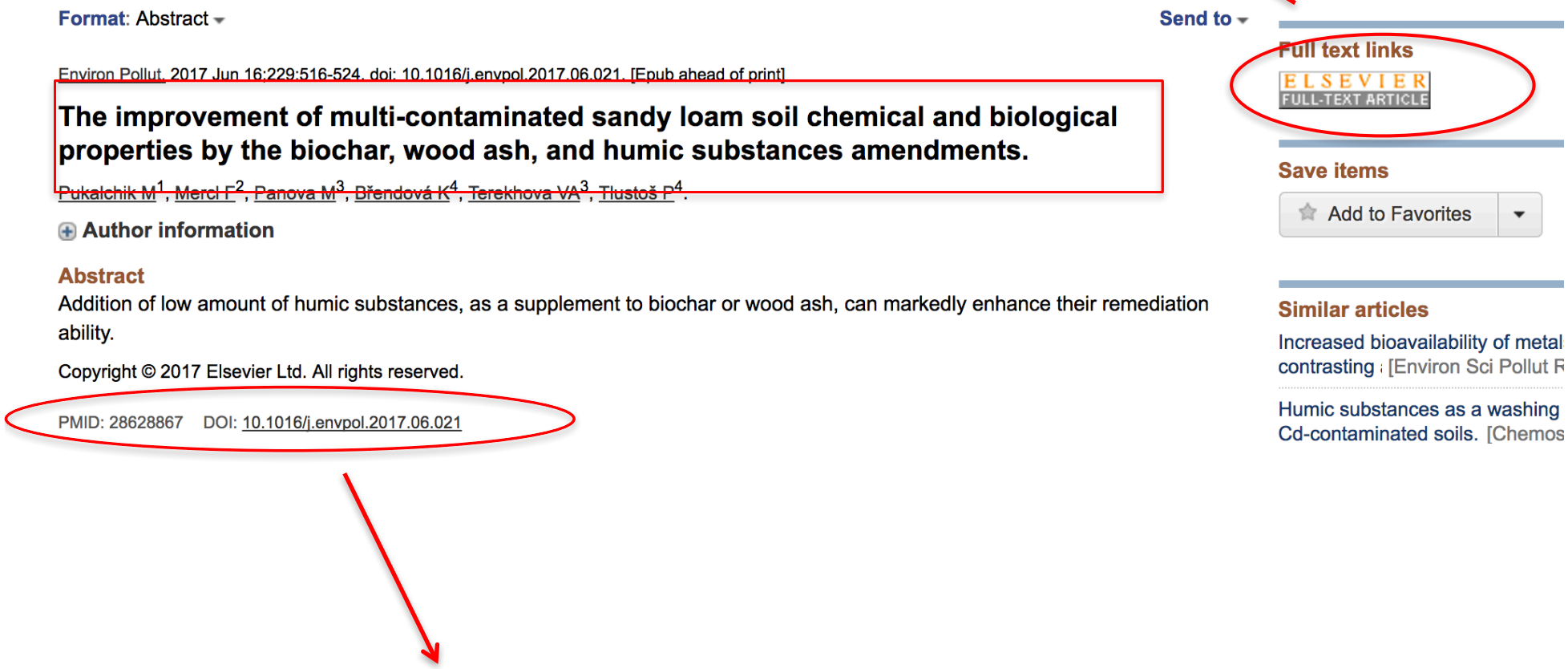

- PMID: Indexed for MedLine
- DOI: Virtual object identifier

Critical appraisal

- **You do NOT have to become** a researcher, epidemiologist, or **statistician** to practice EBM
- Focus on how to **USE research reports** – not on **how to generate them**!
- You must have a solid understanding of basic research principles and **study designs** in order to understand and interpret the evidence!

Type of studies and reports

- Randomized Controlled Trial - “The Gold Standard”
- Systematic review
- Meta-analysis
- Retroactive vs Prospective
- Incidence
- Prevalence
- Case Control
- Cohort (Follow-up)
- Cross-sectional
- Ecologic
- Longitudinal
- Experimental
- Blinded vs Open
- Qualitative Screening

Limitations

- **Lack of evidence** (shortage of studies)
- Difficulty applying evidence to care of a particular patient
- Barriers to the practice of high quality medicine
- Lack of skills (search, appraise, etc.)
- **Lack of time to learn and practice EBM** (promotes lifelong learning thru better focus)
- **Lack of physician resources for instant access to evidence** (EBM has worldwide applicability)

Timmermans S (2005)

Lack of evidence

PubMed | Isolated primary oesophageal lymphoma

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1. Paget's disease of the oesophagus associated with mucous gland carcinoma of the lower oesophagus.

   Haleem A, Kfoury H, Al Juboury M, Al Husseini H.

   Histopathology. 2003 Jan;42(1):61-5.

   PMID: 12493026

   Similar articles

2. **Isolated primary oesophageal** involvement by **lymphoma**: a rare cause of dysphagia: two case histories and a review of other published data.

   Taal BG, Van Heerde P, Somers R.

   Gut. 1993 Jul;34(7):994-8. Review.

   PMID: 8344590 **Free PMC Article**

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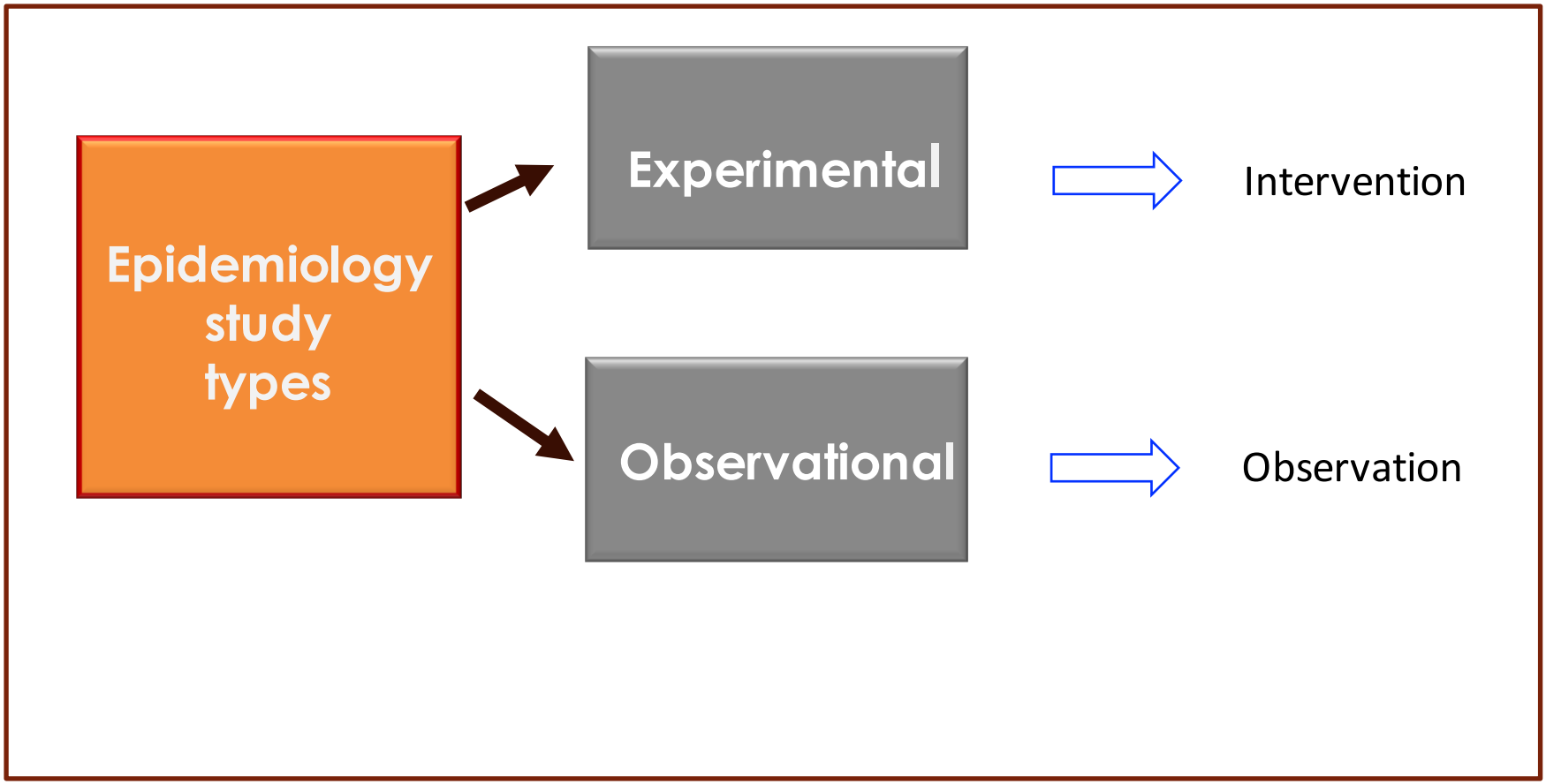
Primary sources

- Randomized clinical trials
- Observational studies
  - Case-control studies
  - Cohort studies
- Case series and case report

Epidemiology Study Types



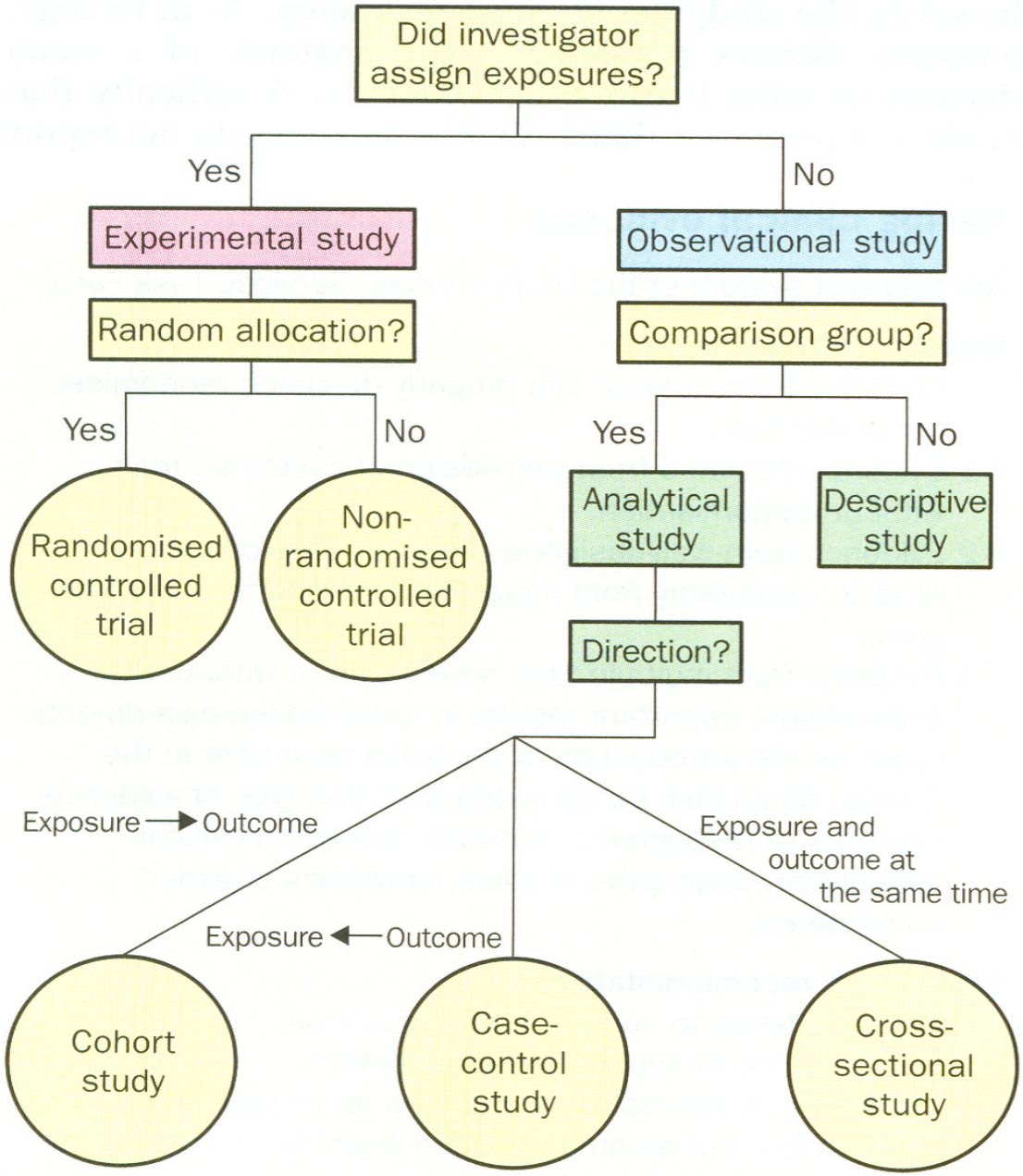
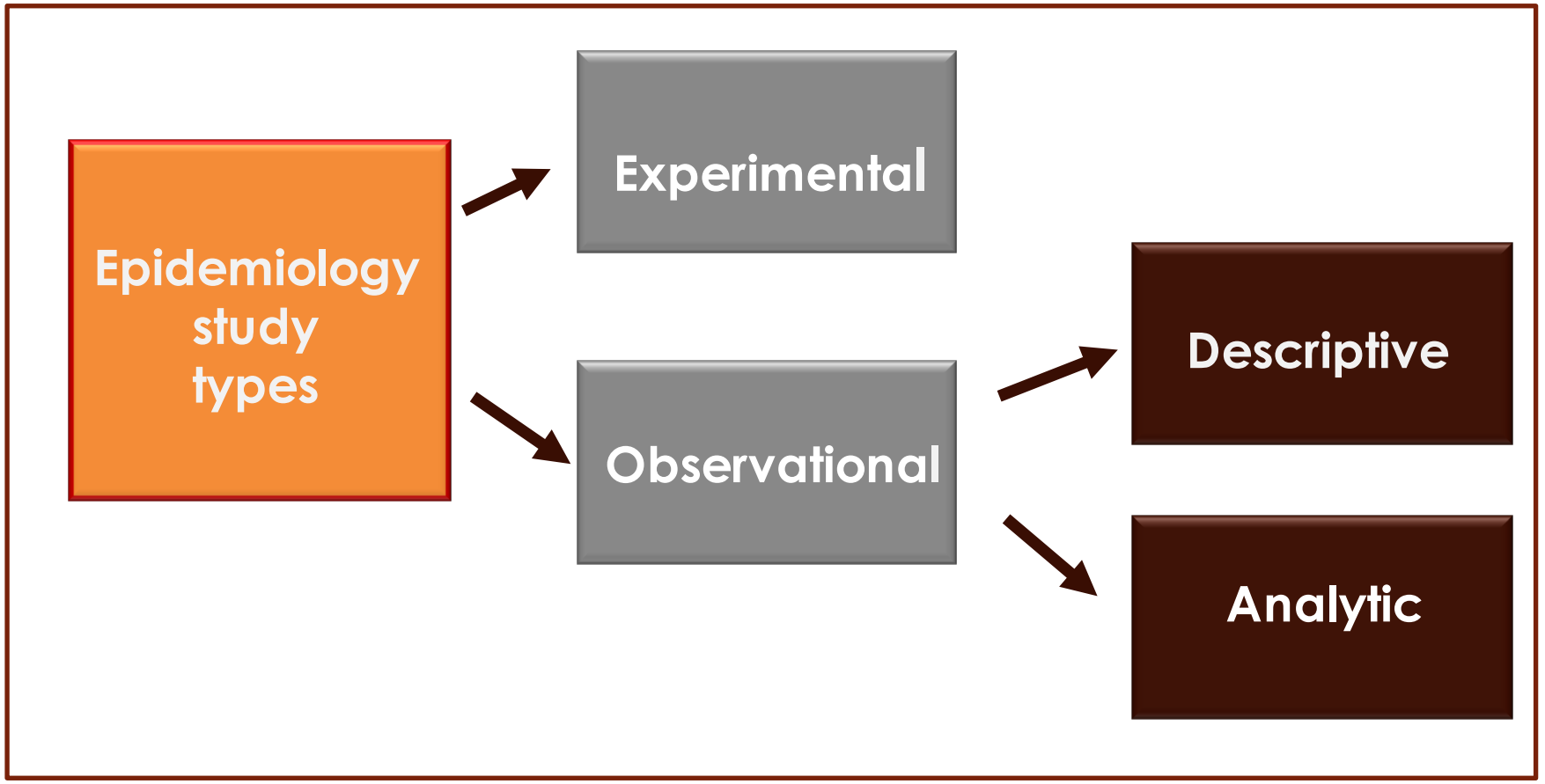


Figure 1: **Algorithm for classification of types of clinical research**

Grimes DA and Schulz KF 2002. An overview of clinical research. Lancet 359:57-61.

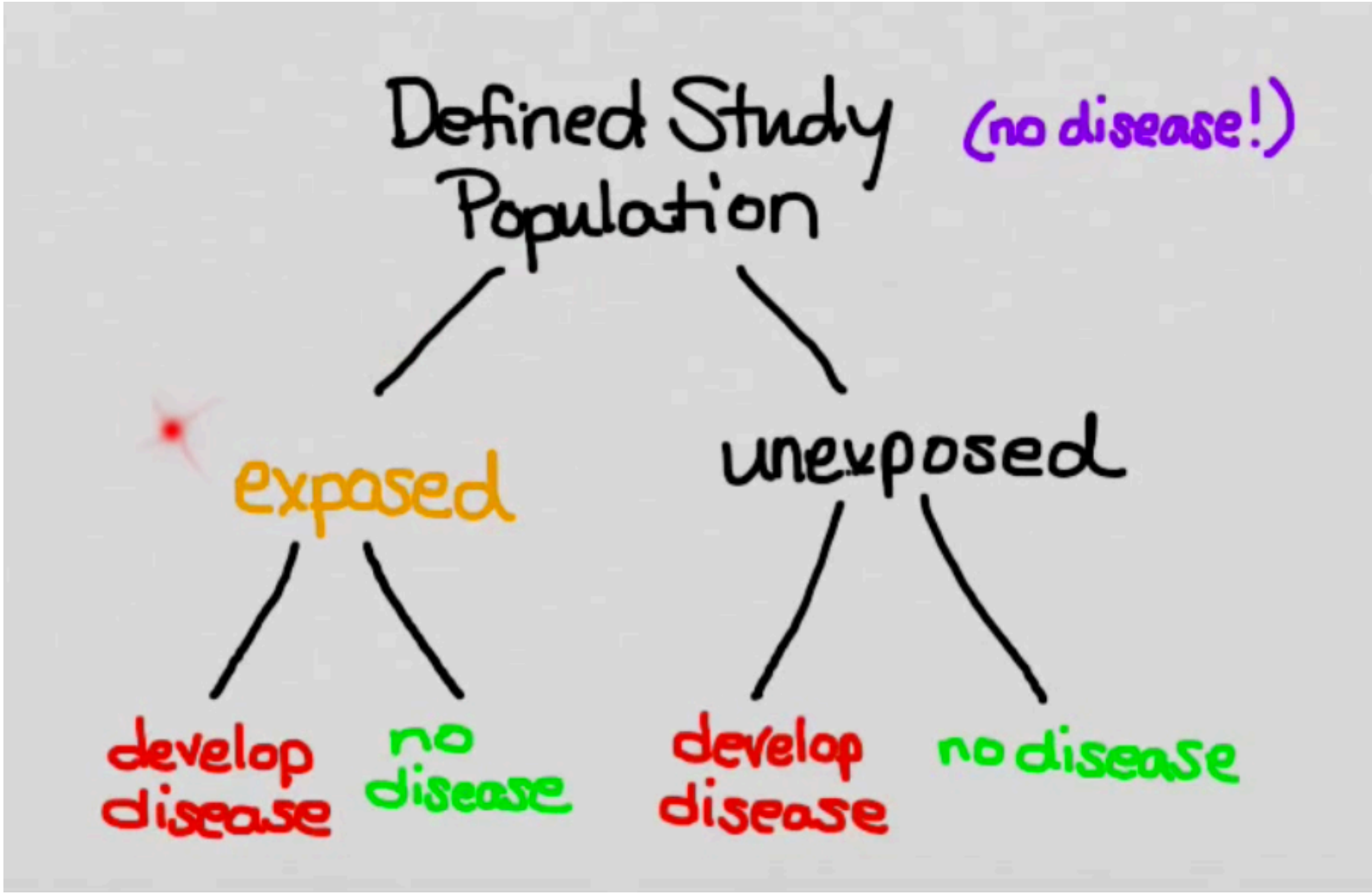
Epidemiology Study Types



Observational Studies

- **Descriptive**: describe occurrence of outcome
  - ✓ Case reports & case series (Clinical)
  - ✓ Ecological
  - ✓ Cross-sectional (Epidemiological)
- **Analytical**: describe association between exposure and outcome
  - ✓ Cohort
  - ✓ Case-control

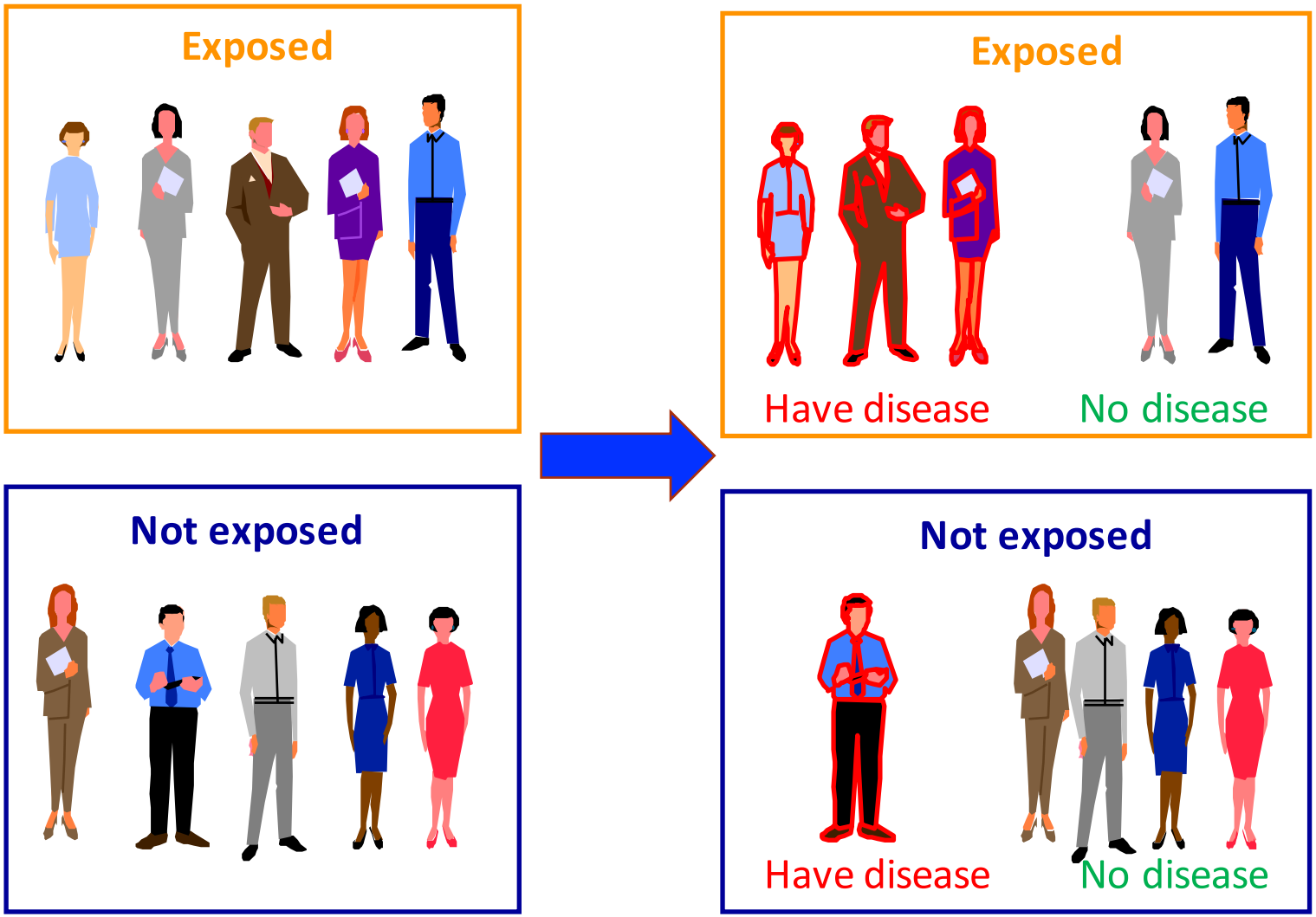
Cohort study design



What is a cohort?

- Group of individuals
  - sharing same experience
  - followed up for specified period of time
- Examples:
  - birth cohort
  - cohort of guests at barbecue
  - occupational cohort of chemical plant workers
  - the cohort of this course

Cohort study design



Relative Risk (RR)

How much more likely?

- RR > 1
- RR = 1
- RR < 1

Benefits and limitations

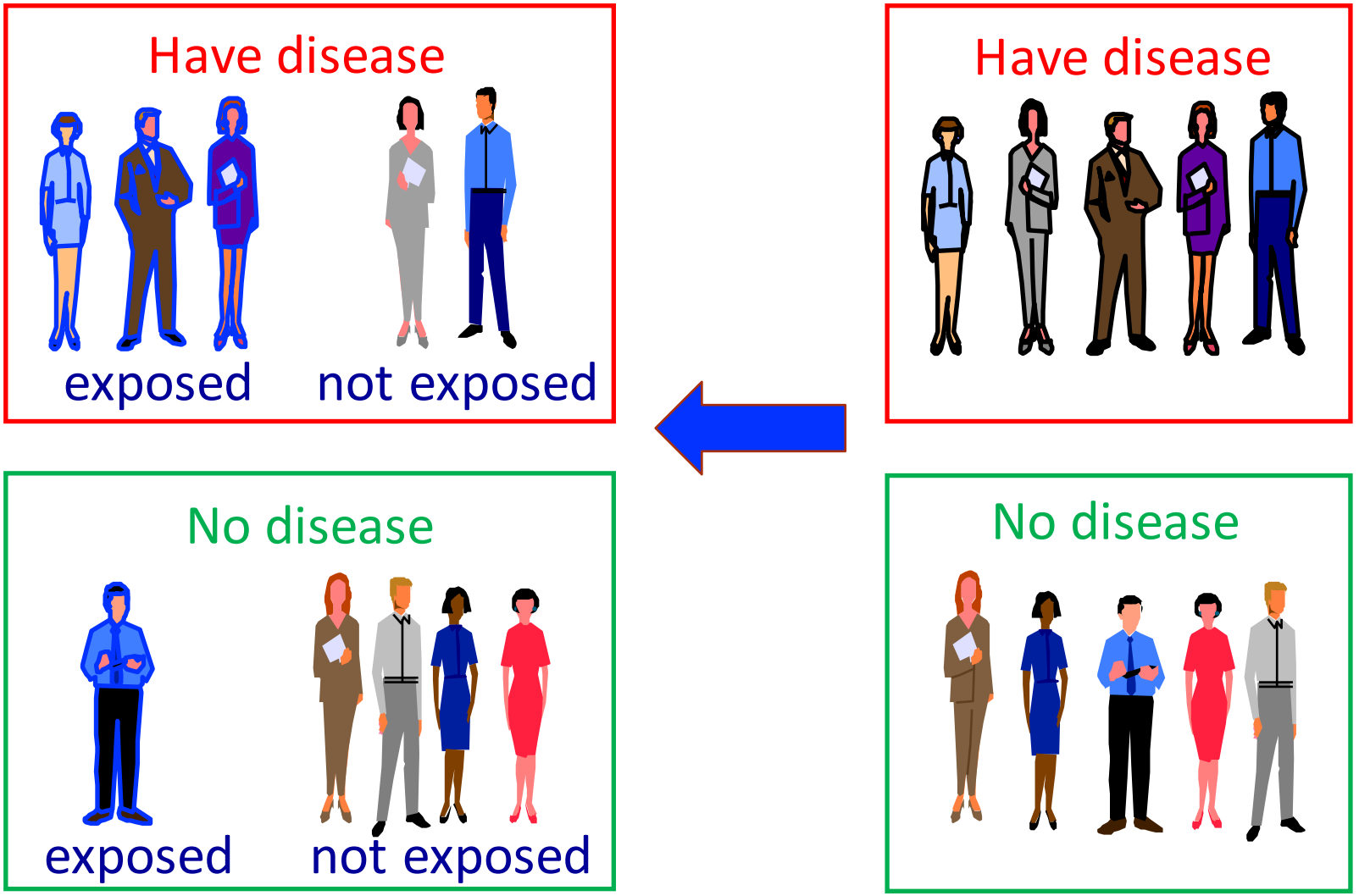
- Incidence data
- Can measures multiple outcomes and exposure
- Can study rare exposures

- Very expensive
- Long follow up
- No rare disease

Case-control study

1) Start with the CASES of disease
2) Create a CONTROL group of individuals without the disease
3) Compare EXPOSURE in cases and controls

Case-control study: design



Controls

- **Matched**: to limit the effect of confounding variables
- Matching criteria: set of factors chosen to define how cases are related to controls (e.g. sex, age)
- **Unmatched**

Odds ratio

- Used to determine whether an exposure is related to disease outcome
- Used to compare magnitude of different risk factors
- OR = 1 *exposure does not affect odds of disease*
- OR > 1 *higher odds of disease (the exposure is a risk factor)*
- OR < 1 *lower odds of disease (the exposure is a protective factor)*

Benefits and limitations

- Cheap
- Can measures multiple exposures for one outcome
- **Investigating outbreak where there is a urgent need to understand potential causes of the disease**
- Can study rare outcome

- No incidende, no prevalence
- Not suitable for rare exposures

Experimental epidemiology

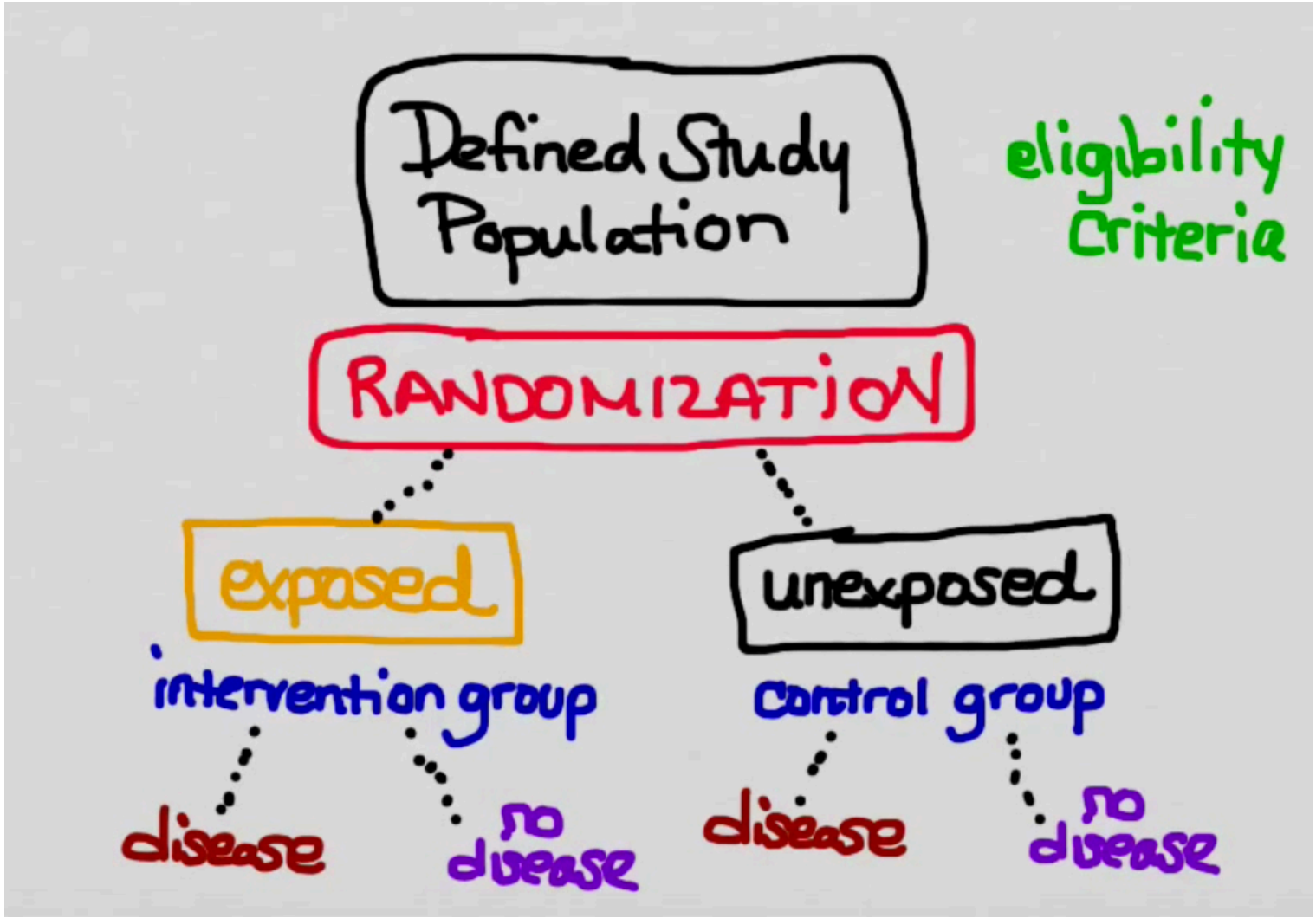
through experimental studies it is possible to evaluate the effectiveness of health interventions:

- Preventive: screening, health education campaigns, vaccination strategies, campaigns
- Therapeutic: drug testing, surgical techniques, instrumental therapies

Clinical Trials

- Randomized controlled trials
- Randomized trials
- Clinical trial
- Intervention study
- Experimental trial
- Trial

RCT


Defined Study Population
eligibility Criteria
RANDOMIZATION
exposed
unexposed
intervention group
control group
disease
no disease
disease
no disease

Controlled

- The first piece of RCT
- Control group:
  - Placebo
  - Standard of care

Randomized

- The second piece of RCT
- Randomization:
  - To prevent selection bias
  - To make the groups comparable

Randomization process

1. Double blind RCT
   - Both researchers and patients “blinded”
   - Never break the code unless you’re closing the study

2. Blind RCT

Analytical Perspectives

- **Intention to treat** analysis
- **Per Protocol** analysis

Per protocol analysis

- **Excludes** patients who deviated from the protocol
- It can introduce a form of bias called **attrition bias**, in which the groups of patients being compared no longer have similar characteristics
- Provides a **lower level of evidence** but better reflect the effects of treatment when taken in an optimal manner
- **Useful** for interpreting non-inferiority trials and for analysing the adverse effects of treatments

Per Protocol

- Can only be restricted to the **participants** who **fulfill the protocol** in the terms of the **eligibility**, **interventions**, and **outcome assessment**.
- **Comparison of treatment g**roups that includes only those patients who completed the treatment originally allocated
- It **excludes** noncompliant subjects and dropouts

Intention-to-treat

Once randomized, always analyzed

- A comparison of the treatment groups that includes all patients as originally allocated after randomization
- Recommended method in superiority trials to avoid any bias
- ITT analysis includes every subject who is randomized according to randomized treatment assignment
- Ignores noncompliance, protocol deviations, withdrawal, and anything that happens after randomization

Boutis K et al, CMAJ 2010

Intention to treat analysis

- Reflects the **practical clinical scenario** because it admits noncompliance and protocol deviations
- Gives an **unbiased estimate** of treatment effect
- **Preserves** the sample size

Secondary sources

- **Sintetize** one or more primary sources
- Provide an **overview of current medical knowledge of a topic**
- Research on database is simpler because of **key words** (es. systematic review, meta-analysis)
- Pre-filtered and evaluated in quality (methodological quality, conflict of interest, etc.)

- **Examples**: Systematic reviews, meta-analysis, guide lines EB, specialized text, position statements and reviews of health organizations and scientific societies.

Systematic Review and Meta-analysis

- Literature review focused on a single question which tries to identify, appraise, select and synthesize all high quality research evidence relevant to that question

- **Meta-analysis:** *a particular type of systematic review* that uses **quantitative methods** to combine the results from a number of studies

What is a Systematic Review?

"A review that is conducted according to clearly stated, scientific research methods, and is designed to minimize biases and errors inherent to traditional, narrative reviews."

Margaliot, PRS Journal, 2007

What is the significance of Systematic Reviews?

- The **large amount of medical literature** requires clinicians and researchers alike to rely on **systematic reviews** in order to make an informed decision

- Systematic Reviews **minimize bias**: is a more scientific method of summarizing literature because specific protocols are used to determine which studies will be included

Key Characteristics of Systematic Reviews

- **Clear analysis** of the results of the eligible studies
  - statistical synthesis of data (**meta-analysis)** if appropriate and possible;
  - or qualitative synthesis

- **Structured report** of the review clearly stating the aims, describing the methods and materials and reporting the results

What is meta-analysis???

In 1976, Glass coined the term **META-ANALYSIS:**

"The statistical analysis of a large collection of analysis results from individual studies for the purpose of integrating the findings"

Glass GV. Educational Researcher, 1976

Meta-analysis: definition

Is a quantitative, formal, epidemiological study design used to s**ystematically assess previous research studies** to derive conclusions about that body of research.

Outcomes may include a **more precise estimate** of the effect of treatment or risk factor for disease, or other outcomes, than any individual study contributing to the pooled analysis.

Haidich AB, HippoKratia, 2010

Use of Meta-analysis

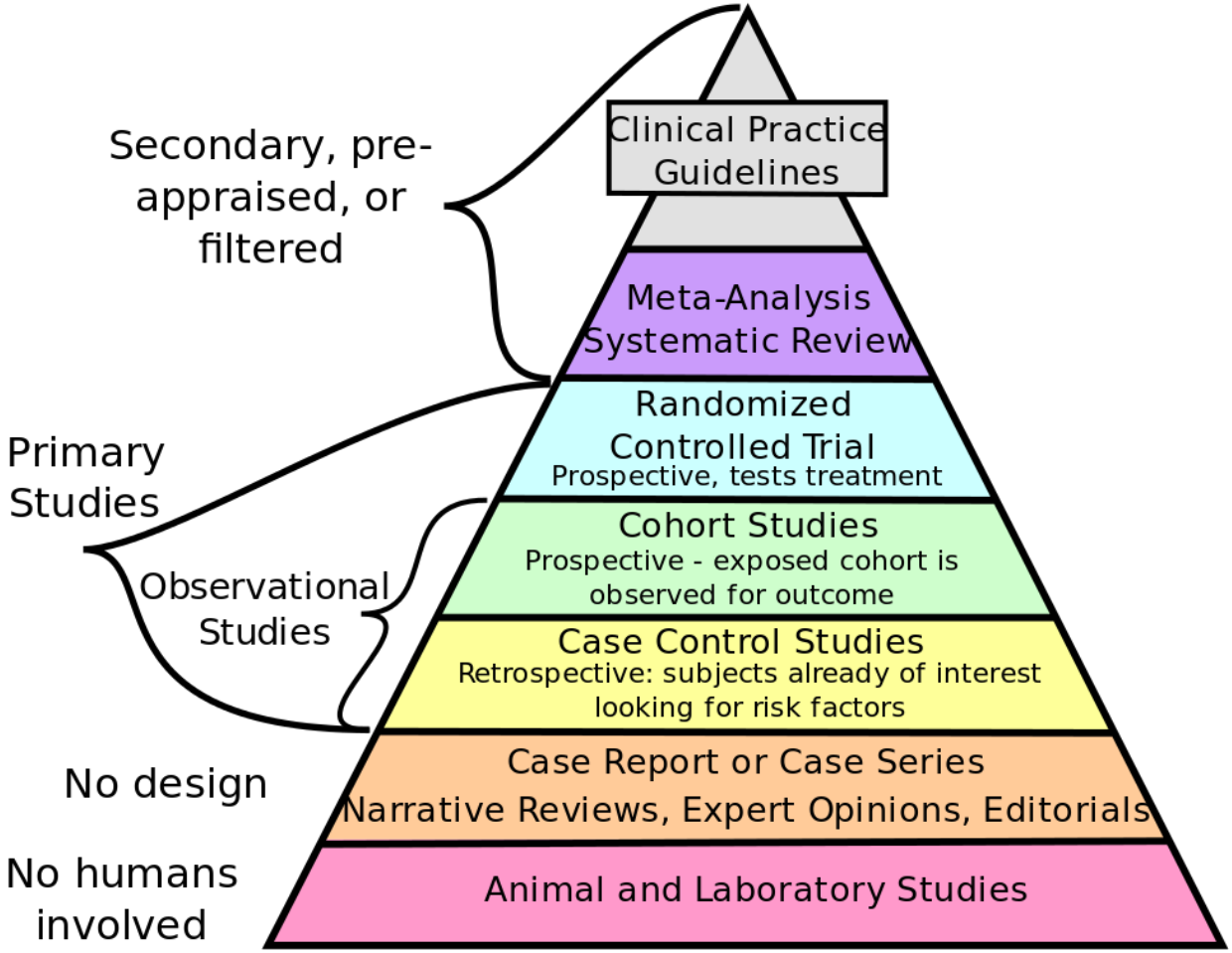
Meta-analyses are conducted to assess the strength of evidence present on a disease and treatment:

- to determine **whether an effect exists;**
- to determine **whether the effect is positive or negative**;
- to obtain a single summary estimate of the effect.

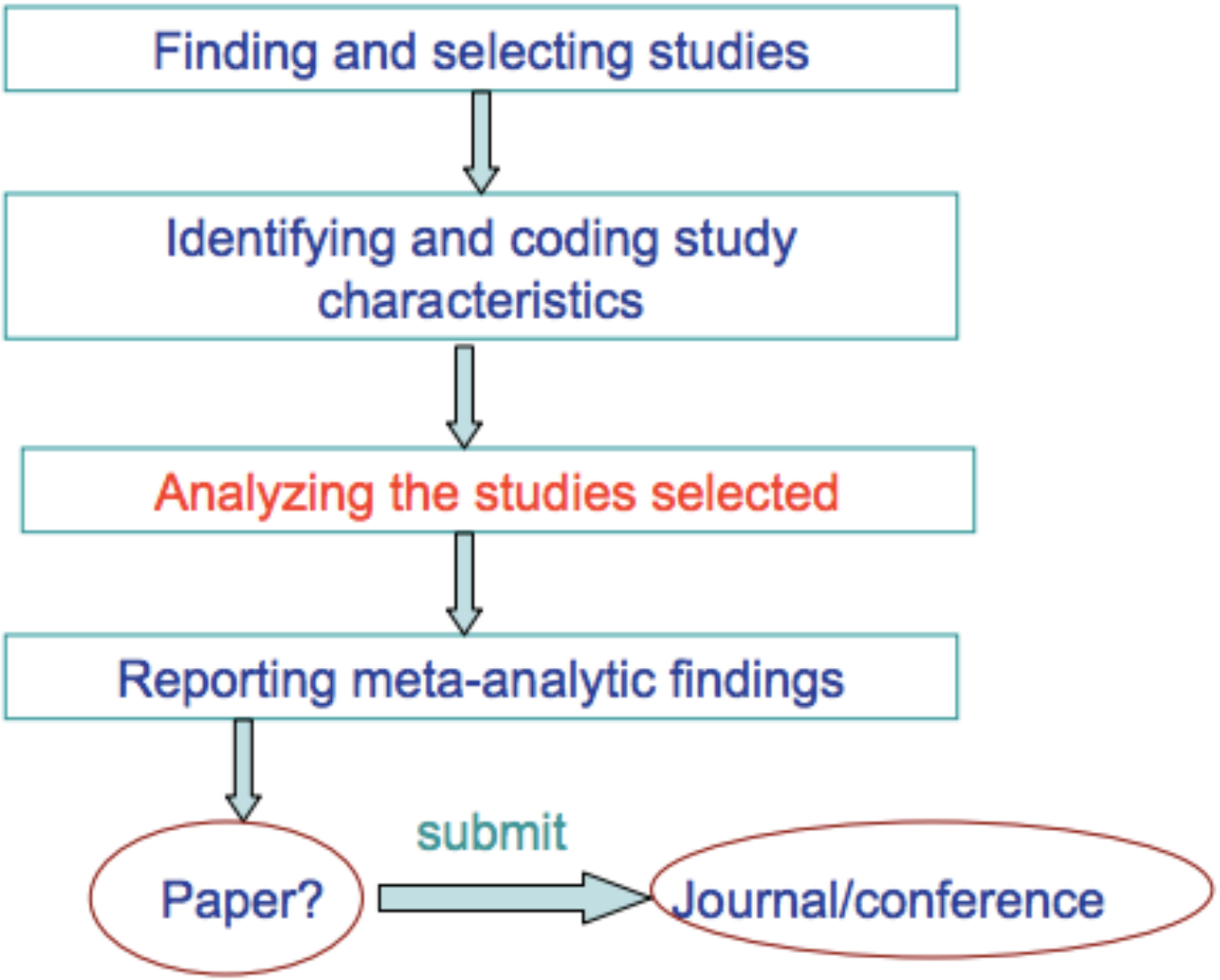
Function of Meta-analysis

- Identify heterogeneity in effects among multiple studies and provide summary measure
- **Increase statistical power and precision to detect an effect**
- **Develop, refine and test hypothesis**
- Reduce the subjectivity of study comparisons by using systematic and explicit comparison procedure
- Identify ***data gap*** in the knowledge base and suggest direction for future research
- Calculate *sample size* for future studies

Meta-analysis: the best scientific study



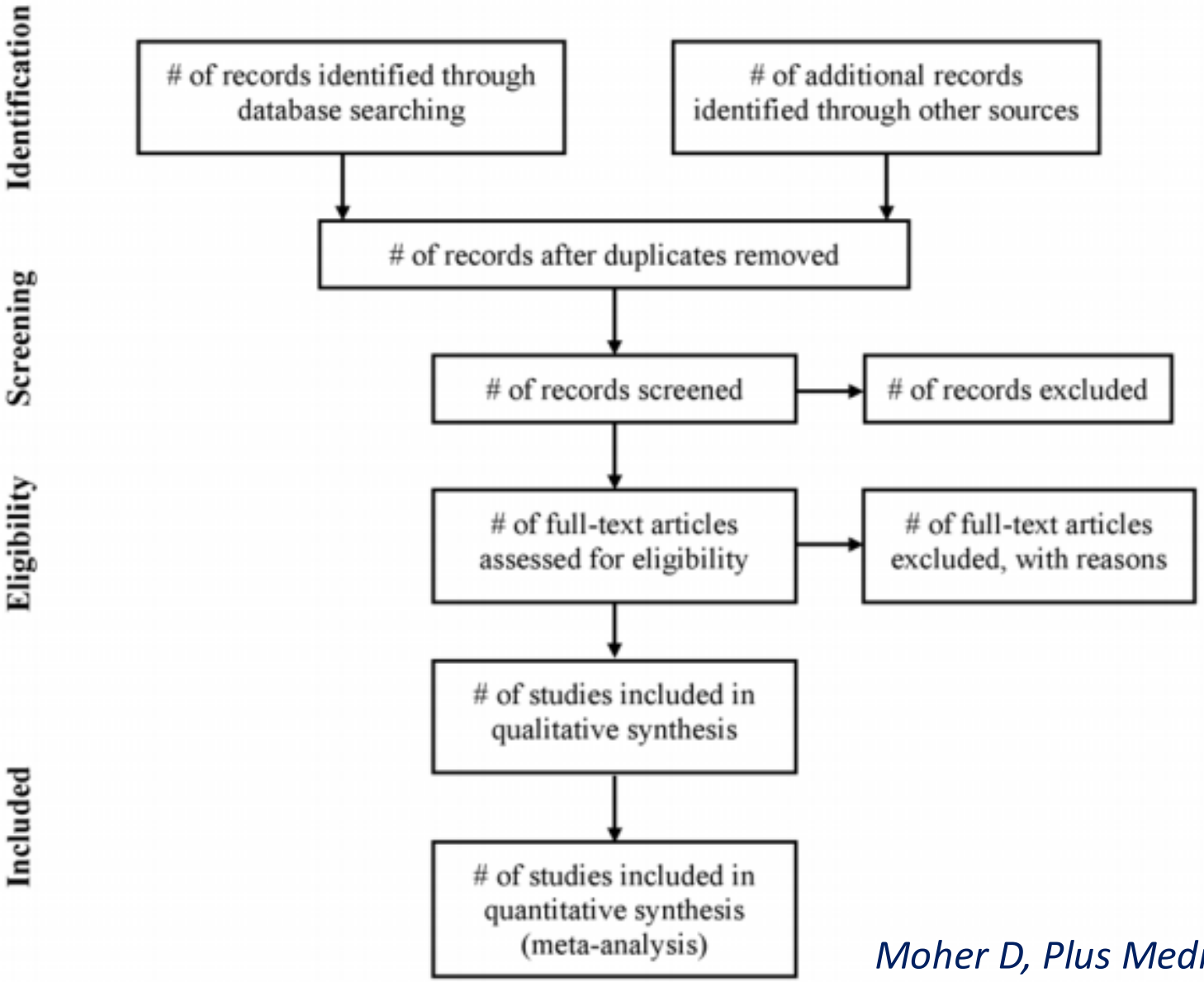
Guidelines for meta-analysis



Weaknesses of Meta analysis

- **Heterogeneity** between different studies:
  - Patients
  - Interventions
  - Outcome definitions
  - Design
- Biases/pubblication biases
- **Quality of each stu**dy

Four-phase flow diagram



Moher D, Plus Medicine, 2009

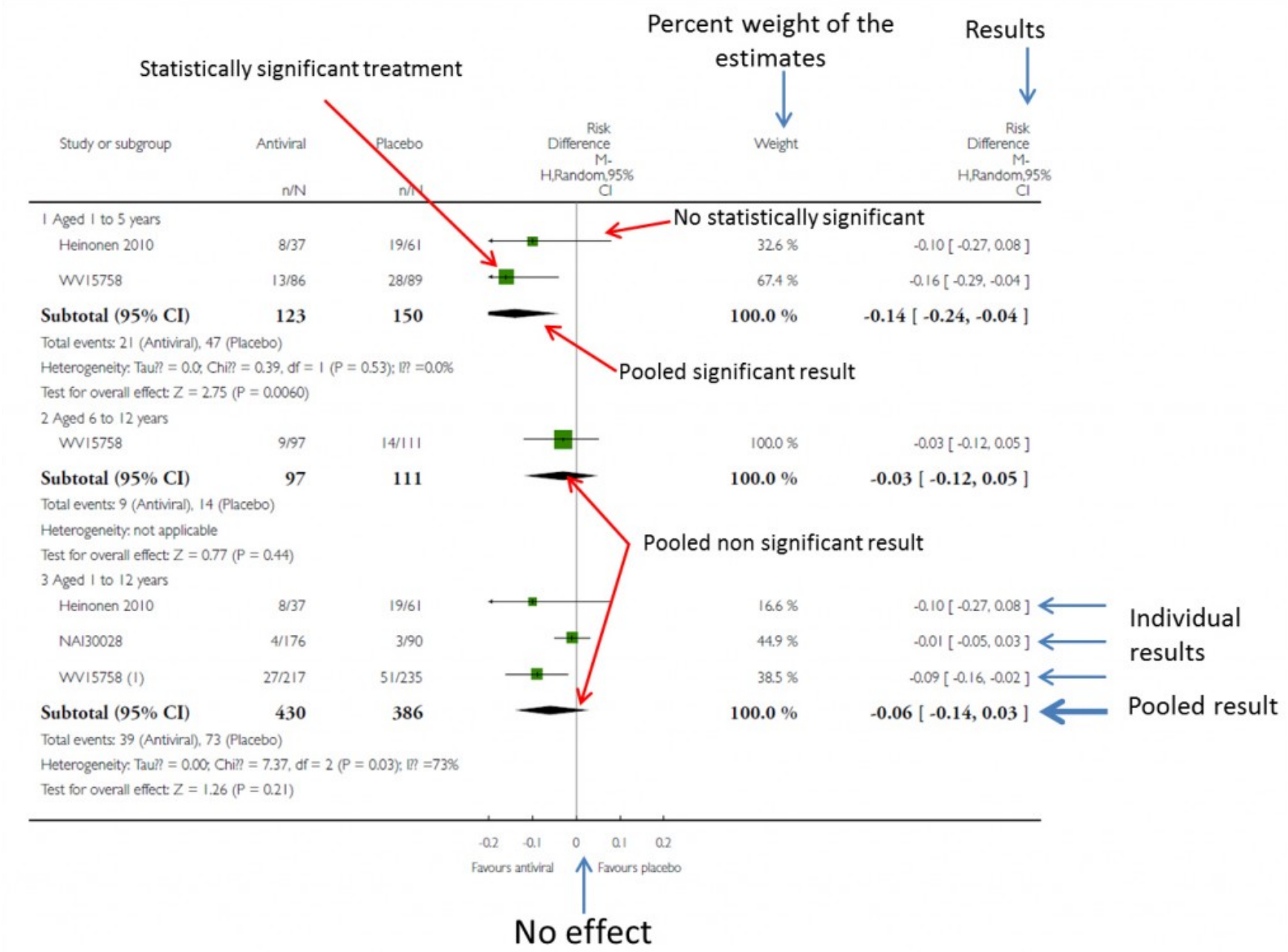
Forest plot

It is a **graphical representation** of a meta-analysis

It is called *forest plot* because the lines are thought to resemble trees in a forest

- Usually accompanied by a **table listing references** (author and date) of the studies included;
- **Mean scores and standard deviations** of these scores from **each of the included studies**;
- Number of participants in each study

Forest plot


Statistically significant treatment
Percent weight of the estimates
Results
Study or subgroup
Antiviral n/N
Placebo n/N
Risk Difference M-H,Random,95% CI
Weight
Risk Difference M-H,Random,95% CI
1 Aged 1 to 5 years
Heinonen 2010 8/37 19/61 32.6 % -0.10 [-0.27, 0.08]
WV15758 13/86 28/89 67.4 % -0.16 [-0.29, -0.04]
Subtotal (95% CI) 123 150 100.0 % -0.14 [-0.24, -0.04]
Total events: 21 (Antiviral), 47 (Placebo)
Heterogeneity: Tau? = 0.0; Chi? = 0.39, df = 1 (P = 0.53); I? =0.0%
Test for overall effect: Z = 2.75 (P = 0.0060)
2 Aged 6 to 12 years
WV15758 9/97 14/111 100.0 % -0.03 [-0.12, 0.05]
Subtotal (95% CI) 97 111 100.0 % -0.03 [-0.12, 0.05]
Total events: 9 (Antiviral), 14 (Placebo)
Heterogeneity: not applicable
Test for overall effect: Z = 0.77 (P = 0.44)
3 Aged 1 to 12 years
Heinonen 2010 8/37 19/61 16.6 % -0.10 [-0.27, 0.08]
NAI30028 4/176 3/90 44.9 % -0.01 [-0.05, 0.03]
WV15758 (1) 27/217 51/235 38.5 % -0.09 [-0.16, -0.02]
Subtotal (95% CI) 430 386 100.0 % -0.06 [-0.14, 0.03]
Total events: 39 (Antiviral), 73 (Placebo)
Heterogeneity: Tau? = 0.00; Chi? = 7.37, df = 2 (P = 0.03); I? =73%
Test for overall effect: Z = 1.26 (P = 0.21)
No statistically significant
Pooled significant result
Pooled non significant result
Individual results
Pooled result
-0.2 -0.1 0 0.1 0.2
Favours antiviral
Favours placebo
No effect

Pediatric nutrition: an example of meta-analysis

Yee et al. International Journal of Behavioral Nutrition and Physical Activity (2017) 14:47
DOI 10.1186/s12966-017-0501-3

International Journal of Behavioral Nutrition and Physical Activity

REVIEW Open Access

The influence of parental practices on child promotive and preventive food consumption behaviors: a systematic review and meta-analysis

Andrew Z. H. Yee*, May O. Lwin and Shirley S. Ho

Abstract

Background: The family is an important social context where children learn and adopt eating behaviors. Specifically, parents play the role of health promoters, role models, and educators in the lives of children, influencing their food cognitions and choices. This study attempts to systematically review empirical studies examining the influence of parents on child food consumption behavior in two contexts: one promotive in nature

Methods: From a total of 6,448 titles extracted from Web of Science, ERIC, PsycINFO and PubMED, seventy eight studies met the inclusion criteria for a systematic review, while thirty seven articles contained requisite statistical information for meta-analysis. The parental variables extracted include active guidance/education, restrictive guidance/rule-making, availability, accessibility, modeling, pressure to eat, rewarding food consumption, rewarding with verbal praise, and using food as reward. The food consumption behaviors examined include fruits and vegetables consumption, sugar-sweetened beverages, and snack consumption.

modeling effects (Healthy: $r = .32$, $p < .001$; Unhealthy: $r = .35$, $p < .001$) show the strongest associations with both healthy and unhealthy food consumption. In addition, the efficacy of some parenting practices might be dependent on the food consumption context and the age of the child. For healthy foods, active guidance/education might be more effective ($r = .15$, $p < .001$). For unhealthy foods, restrictive guidance/rule-making might be more effective ($r = -.11$, $p < .01$). For children 7 and older, restrictive guidance/rule-making could be more effective in preventing unhealthy eating ($r = -.20$, $p < .05$). For children 6 and younger, rewarding with verbal praise can be more effective in promoting healthy eating ($r = .26$, $p < .001$) and in preventing unhealthy eating ($r = -.08$, $p < .01$).

Conclusions: This study illustrates that a number of parental behaviors are strong correlates of child food consumption behavior. More importantly, this study highlights 3 main areas in parental influence of child food consumption that are understudied: (1) active guidance/education, (2) psychosocial mediators, and (3) moderating influence of general parenting styles.

Keywords: Parent, Child, Nutrition, Food, Eating, Fruits, Vegetables, Sugar, Healthy, Unhealthy, Consumption

Pediatric nutrition: an example of meta-analysis

- **11 keywords**
- **6448 titles** extracted from *WebofScience, ERIC, PsycINFO and PubMED*
- **78 studies** met inclusion criteria for the systematic review
- **37 articles** contained requisite statistical information for meta-analysis
- **Multiple variables** extracted: active guidance/education, restrictive guidance/rule making, availability, accessibility, modelling, pressure to eat, rewarding food consumption, rewarding with verbal praise, using food as reward

Tertiary sources

- Summarize/re-elaborate a series of secundary sources
- Any re-elaboration does not include predefined quality criteria
- Prevalent language is english

Example: Encyclopedias, textbooks, CAT (Critically Appraised Topic) sites, narrative reviews, non-EB guidelines, specialized prints and websites, web portals

European Food Safety Authority

EFSA Journal 2011;9(7):2303

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to creatine and increase in physical performance during short-term, high intensity, repeated exercise bouts (ID 739, 1520, 1521, 1522, 1523, 1525, 1526, 1531, 1532, 1533, 1534, 1922, 1923, 1924), increase in endurance capacity (ID 1527, 1535), and increase in endurance performance (ID 1521, 1963) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to creatine and increase in physical performance during short-term, high intensity, repeated exercise bouts, increase in endurance capacity, and increase in endurance performance. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claims is creatine. The Panel considers that creatine is sufficiently characterised.

Increase in physical performance during short-term, high intensity, repeated exercise bouts

The claimed effects are "energy metabolism", "muscular effort", "bodily constitution", "increasing strength", "increasing mass", "increasing power", "increasing performance", "muscular

FOOD FACTS

From the U.S. Food and Drug Administration

Dietary Supplements

Dietary Supplements can be beneficial to your health — but taking supplements can also involve health risks. The U.S. Food and Drug Administration (FDA) does not have the authority to review dietary supplement products for safety and effectiveness before they are marketed.

You've heard about them, may have used them, and may have even recommended them to friends or family. While some dietary supplements are well understood and established, others need further study. Read on for important information for you and your family about dietary supplements.

Before making decisions about whether to take a supplement, talk to your healthcare provider. They can help you achieve a balance between the foods and nutrients you personally need.

What are dietary supplements?

Dietary supplements include such ingredients as vitamins, minerals, herbs, amino acids, and enzymes. Dietary supplements are marketed in forms such as tablets, capsules, softgels, gelcaps, powders, and liquids.

What are the benefits of dietary supplements?

Some supplements can help assure that you get enough of the vital substances the body needs to function; others may help reduce the risk of disease. But supplements should not replace complete meals which are necessary for a healthful diet – so, be sure you eat a variety of foods as well.

Unlike drugs, ***supplements are not intended to treat, diagnose, prevent, or cure diseases***. That means supplements should not make claims, such as "reduces pain" or "treats heart disease." Claims like these can only legitimately be made for drugs, not dietary supplements.

Are there any risks in taking supplements?

Yes. Many supplements contain active ingredients that have strong biological effects in the body. This could make them unsafe in some situations and hurt or complicate your health. For example, the following actions could lead to harmful – even life-threatening – consequences.

- Combining supplements
- Using supplements with medicines (whether prescription or over-the-counter)
- Substituting supplements for prescription medicines
- Taking too much of some supplements, such as vitamin A, vitamin D, or iron

Some supplements can also have unwanted effects *before, during, and after* surgery. So, be sure to inform your healthcare provider, including your pharmacist about any supplements you are taking.

Some Common Dietary Supplements

- Calcium
- Echinacea
- Fish Oil
- Ginseng
- Glucosamine and/or
- Chondroitin Sulphate
- Garlic
- Vitamin D
- St. John's Wort
- Saw Palmetto
- Ginkgo
- Green Tea

Note: These examples do not represent either an endorsement or approval by FDA.

FOOD FACTS

Who is responsible for the safety of dietary supplements?

FDA is not authorized to review dietary supplement products for safety and effectiveness before they are marketed.

The manufacturers and distributors of dietary supplements are responsible for making sure their products are safe BEFORE they go to market.

If the dietary supplement contains a NEW ingredient, manufacturers must notify FDA about that ingredient prior to marketing. However, the notification will only be reviewed by FDA (not approved) and only for safety, not effectiveness.

Manufacturers are required to produce dietary supplements in a quality manner and ensure that they do not contain contaminants or impurities, and are accurately labeled according to current Good Manufacturing Practice (cGMP) and labeling regulations.

If a serious problem associated with a dietary supplement occurs, manufacturers must report it to FDA as an adverse event. FDA can take dietary supplements off the market if they are found to be unsafe or if the claims on the products are false and misleading.

How can I find out more about the dietary supplement I'm taking?

Dietary supplement labels must include name and location information for the manufacturer or distributor.
If you want to know more about the product that you are taking, check with the manufacturer or distributor about:

- Information to support the claims of the product
- Information on the safety and effectiveness of the ingredients in the product.

How can I be a smart supplement shopper?

Be a savvy supplement user. Here's how:

- When searching for supplements on the internet, use noncommercial sites (e.g. NIH, FDA, USDA) rather than doing blind searches.
- Watch out for false statements like "works better than [a prescription drug]," "totally safe," or has "no side effects."
- Be aware that the term *natural* doesn't always means *safe*.
- Ask your healthcare provider for help in distinguishing between reliable and questionable information.
- Always remember – safety first!

Report Problems to FDA

Notify FDA if the use of a dietary supplement caused you or a family member to have a serious reaction or illness (even if you are not certain that the product was the cause or you did not visit a doctor or clinic).

Follow these steps:

1. Stop using the product.
2. Contact your healthcare provider to find out how to take care of the problem.
3. Report problems to FDA in either of these ways:
   - Contact the **Consumer Complaint Coordinator** in your area. Locate a coordinator here: **http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators**
   - File a safety report online through the **Safety Reporting Portal** at: **http://www.safetyreporting.hhs.gov**

To learn more about dietary supplements, visit: **http://www.fda.gov/Food/DietarySupplements/default.htm**

For more information, contact the U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition's Food and Cosmetic Information Center at **1-888-SAFEFOOD** (toll free), Monday through Friday 10 AM to 4 PM ET (except Thursdays from 12 PM to 1 PM ET and Federal Holidays). Or, visit the FDA website at **http://www.fda.gov/educationresourcelibrary**

#WithRefugees: WHO-trained Syrian health workers provide services in Turkey

19 June 2017 – More than 3 million Syrian refugees are now living in Turkey. In 2016, the Turkish government enacted a law that allows Syrian health professionals to enter the workforce in the Turkish health system, with the aim of both integrating Syrian professionals into the health system and also ensuring that Syrian refugees can receive health care without encountering language or cultural barriers. WHO and the Public Health Institution of Turkey created an adaptation training for Syrian health workers living Turkey – including doctors, nurses and midwives.

EPA/S. Suna

– News release
– Refugee and migrant health

Author information

Abstract

BACKGROUND/OBJECTIVES: Although lifestyle modifications remain the cornerstone therapy for non-alcoholic fatty liver disease (NAFLD), the optimal lifestyle intervention is still controversial. The aim of this meta-analysis was to evaluate the effect of exercise and/or dietary interventions, type or intensity of exercise and type of diet, on liver function outcomes (liver enzymes, intrahepatic fat and liver histology), as well as on anthropometric and glucose metabolism parameters in NAFLD patients.

SUBJECTS/METHODS: Literature search was performed in Scopus and US National Library of Medicine databases to identify all randomized controlled clinical trials (RCTs) in adult patients with NAFLD, diagnosed through imaging techniques or liver biopsy, published in English between January 2005 and August 2016. Studies' quality was evaluated using the Cochrane Risk of Bias Tool. Heterogeneity was tested using the Cochran's Q test and measured inconsistency by I^2. Effect size was calculated as the standardized mean difference (SMD). T[redacted] was performed in accordance with PRISMA guidelines.

RESULTS: Twenty RCTs with 1073 NAFLD patients were included. Compared to standard care, exercise improved serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST) (all $P<0.05$). Intrahepatic fat also improved, irrespectively of weight change (SMD=-0.98, 95% CI: -1.30 to -0.66). Regarding the type of exercise, aerobic compared to resistance exercise did not yield any superior improvements on liver parameters, whereas moderate-to-high volume moderate-intensity continuous training was more beneficial compared to continuous low-to-moderate-volume moderate-intensity training or high intensity interval training. Interventions combining exercise and diet showed decreases in ALT ($P<0.01$) and improvement in NAFLD activity score (SMD=-0.61, 95% CI: -1.09 to -0.13). Moderate-carbohydrate diets yielded similar changes in liver enzymes compared to low/moderate-fat diets.

CONCLUSIONS: Exercise alone or combined with dietary intervention improves serum levels of liver enzymes and liver fat or histology. Exercise exerts beneficial effects on intrahepatic triglycerides even in the absence of weight loss.

KEYWORDS: Diet; Lifestyle; NAFLD; Physical activity; Weight loss

Metabolism. 2017 Mar;68:119-132. doi: 10.1016/j.metabol.2016.12.006. Epub 2016 Dec 16.

Effects of lifestyle interventions on clinical characteristics of patients with non-alcoholic fatty liver disease: A meta-analysis.

Katsagoni CN[1], Georgoulis M[1], Papatheodoridis GV[2], Panagiotakos DB[1], Kontogianni MD[3].

Author information

Abstract

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Abstract

OBJECTIVE: The potential influence of dietary factors on inflammation is important for cancer prevention. Utilizing data from control participants (312 men, 911 women) in 2 nested case-control studies of cancer within [redacted] we examined the associations of red and processed meat intake with serum levels of leptin, adiponectin, C-reactive protein (CRP), tumor necrosis factor (TNF)-α, and interleukin (IL)-6 and the mediator effect of body mass index (BMI) on the above associations (if present).

METHODS: Multivariable linear models were applied to assess the association between red and processed meat intake at cohort entry and serum biomarker levels measured 9.1 years later after adjusting for covariates and to determine the mediator effect of BMI.

RESULTS: Overall red and processed meat intake was positively associated with serum leptin levels in men ($\beta = 0.180$, $p = 0.0004$) and women ($\beta = 0.167$, $p < 0.0001$). In women, higher red and processed meat consumption was significantly associated with higher CRP ($\beta = 0.069$, $p = 0.03$) and lower adiponectin levels ($\beta = -0.082$, $p = 0.005$). In mediation analyses with red and processed meat intake and BMI as predictors, the associations of red and processed meat with biomarkers decreased substantially (as indicated by percentage change in effect: leptin in men, 13.4%; leptin in women, 13.7%; adiponectin in women, -4.7%; CRP in women, 7.4%) and were no longer significant ($p > 0.05$), whereas BMI remained significantly associated with serum leptin (men: $\beta = 3.209$, $p < 0.0001$; women: $\beta = 2.891$, $p < 0.0001$), adiponectin (women: $\beta = -1.085$, $p < 0.0001$), and CRP (women: $\beta = 1.581$, $p < 0.0001$).

CONCLUSION: The current data suggest that the amount of excess body weight or the degree of adiposity may mediate the relations between dietary red and processed meat intake and serum biomarkers associated with obesity and inflammation.

KEYWORDS: Red and processed meat; adiposity marker; body mass index; inflammation marker; mediator effect

J Am Coll Nutr. 2017 Jun 19:1-8. doi: 10.1080/07315724.2017.1318317. [Epub ahead of print]

Dietary Red and Processed Meat Intake and Markers of Adiposity and Inflammation: The Multiethnic Cohort Study.

Chai W[1], Morimoto Y[2], Cooney RV[3], Franke AA[2], Shvetsov YB[2], Le Marchand L[2], Haiman CA[4], Kolonel LN[2], Goodman MT[5], Maskarinec G[2].

Author information

Abstract

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Abstract

BACKGROUND: Online dietary assessment tools offer advantages over printed questionnaires, such as the automatic and direct data storage of answers, and have the potential to become valuable research methods. We developed an online survey system (web-FFQ) for the existing printed FFQ used in the JPHC-NEXT protocol, the platform of a large-scale genetic cohort study. Here, we examined the validity of ranking individuals according to dietary intake using this web-FFQ and its usability compared with the printed questionnaire (print-FFQ) for combined usage.

METHODS: We included 237 men and women aged 40-74 years from five areas specified in the JPHC-NEXT protocol. From 2012 to 2013, participants were asked to provide 12-day weighed food records (12d-WFR) as the reference intake and to respond to the print- and web-FFQs. Spearman's correlation coefficients (CCs) between estimates using the web-FFQ and 12d-WFR were calculated. Cross-classification of intakes was compared with those using the print-FFQ.

RESULTS: Most participants (83%) answered that completing the web-FFQ was comparable to or easier than completing the printed questionnaire. The median value of CCs across energy and 53 nutrients for men and women was 0.47 (range, 0.10-0.86) and 0.46 (range, 0.16-0.69), respectively. CCs for individual nutrient intakes were closely similar to those based on the print-FFQ, irrespective of response location. Cross-classification by quintile of intake based on two FFQs was reasonably accurate for many nutrients and food groups.

CONCLUSION: This online survey system is a reasonably valid measure for ranking individuals by intake for many nutrients, like the printed FFQ. Mixing of two FFQs for exposure assessments in epidemiological studies appears acceptable.

J Epidemiol. 2017 Jun 15. pii: S0917-5040(17)30135-1. doi: 10.1016/j.je.2016.08.021. [Epub ahead of print]

Online version of the self-administered food frequency questionnaire for the Japan Public Health Center-based Prospective Study for the Next Generation (JPHC-NEXT) protocol: Relative validity, usability, and comparison with a printed questionnaire.

Kato E[1], Takachi R[2], Ishihara J[3], Ishii Y[4], Sasazuki S[4], Sawada N[4], Iwasaki M[4], Shinozawa Y[4], Umezawa J[4], Tanaka J[5], Yokoyama Y[1], Kitamura K[1], Nakamura K[1], Tsugane S[4].

Author information

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Abstract

BACKGROUND: Despite the improvements of surgical techniques and postoperative management of patients with liver transplantation, biliary complications are one of the most common and important adverse events. We present a choledochoduodenostomy using magnetic compression following a massive resection of the small intestine due to strangulated ileus after living donor liver transplantation.

CASE PRESENTATION: The 54-year-old female patient had end-stage liver disease, secondary to liver cirrhosis, due to primary sclerosing cholangitis with ulcerative colitis. Five years earlier, she had received living donor liver transplantation using a left lobe graft, with resection of the extrahepatic bile duct and Roux-en-Y anastomosis. The patient experienced sudden onset of intense abdominal pain. An emergency surgery was performed, and the diagnosis was confirmed as strangulated ileus due to twisting of the mesentery. Resection of the massive small intestine, including choledochojejunostomy, was performed. Only 70 cm of the small intestine remained. She was transferred to our hospital with an external drainage tube from the biliary cavity and jejunostomy. We initiated total parenteral nutrition, and percutaneous transhepatic biliary drainage was established to treat the cholangitis. Computed tomography revealed that the biliary duct was close to the duodenum; hence, we planned magnetic compression anastomosis of the biliary duct and the duodenum. The daughter magnet was placed in the biliary drainage tube, and the parent magnet was positioned in the bulbus duodeni using a fiberscope. Anastomosis between the left hepatic duct and the duodenum was accomplished after 25 days, and the biliary drainage stent was placed over the anastomosis to prevent re-stenosis. Contributions to the successful withdrawal of parenteral nutrition were closure of the ileostomy in the adaptive period, preservation of the ileocecal valve, internal drainage of bile, and side-to-side anastomosis.

CONCLUSIONS: Choledochoduodenostomy with magnet compression could be a less invasive and safer method for treatment of biliary stricture that cannot be accessed by conventional surgery.

KEYWORDS: Choledochoduodenostomy; Living donor liver transplantation; Magnetic compression anastomosis; Primary sclerosing cholangitis; Short bowel syndrome

Surg Case Rep. 2017 Dec;3(1):73. doi: 10.1186/s40792-017-0349-4. Epub 2017 May 25.

Biliary-duodenal anastomosis using magnetic compression following massive resection of small intestine due to strangulated ileus after living donor liver transplantation: a case report.

Saito R[1], Tahara H[2], Shimizu S[1], Ohira M[1], Ide K[1], Ishiyama K[1], Kobayashi T[1], Ohdan H[1].

Author information

Abstract

BACKGROUND: Despite the improvements of surgical techniques and postoperative management of patients with liver transplantation, biliary complications are one of the most common and important adverse events. We present a first case of choledochoduodenostomy using magnetic compression following a massive resection of the small intestine due to strangulated ileus after living donor liver transplantation.

CASE PRESENTATION: The 54-year-old female patient had end-stage liver disease, secondary to liver cirrhosis, due to primary sclerosing cholangitis with ulcerative colitis. Five years earlier, she had received living donor liver transplantation using a left lobe graft, with resection of the extrahepatic bile duct and Roux-en-Y anastomosis. The patient experienced sudden onset of intense abdominal pain. An emergency surgery was performed, and the diagnosis was confirmed as strangulated ileus due to twisting of the mesentery. Resection of the massive small intestine, including choledochojejunostomy, was performed. Only 70 cm of the small intestine remained. She was transferred to our hospital with an external drainage tube from the biliary cavity and jejunostomy. We initiated total parenteral nutrition, and percutaneous transhepatic biliary drainage was established to treat the cholangitis. Computed tomography revealed that the biliary duct was close to the duodenum; hence, we planned magnetic compression anastomosis of the biliary duct and the duodenum. The daughter magnet was placed in the biliary drainage tube, and the parent magnet was positioned in the bulbus duodeni using a fiberscope. Anastomosis between the left hepatic duct and the duodenum was accomplished after 25 days, and the biliary drainage stent was placed over the anastomosis to prevent re-stenosis. Contributions to the successful withdrawal of parenteral nutrition were closure of the ileostomy in the adaptive period, preservation of the ileocecal valve, internal drainage of bile, and side-to-side anastomosis.

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Acta Diabetol. 2017 Jul;54(7):653-662. doi: 10.1007/s00592-017-0987-9. Epub 2017 Apr 12.

Exploring single nucleotide polymorphisms previously related to obesity and metabolic traits in pediatric-onset type 2 diabetes.

Miranda-Lora AL[1], Cruz M[2], Aguirre-Hernández J[3], Molina-Díaz M[4], Gutiérrez J[2], Flores-Huerta S[5], Klünder-Klünder M[6,7].

⊕ Author information

Abstract

AIMS: To evaluate the association of 64 obesity-related polymorphisms with pediatric-onset type 2 diabetes and other glucose- and insulin-related traits in Mexican children.

METHODS: Case-co[redacted]studied 99 patients with pediatric-onset type 2 diabetes, their siblings (n = 101) without diabetes, 83 unrelated pediatric controls and 137 adult controls. Genotypes were determined for 64 single nucleotide polymorphisms, and a possible association was examined between those genotypes and type 2 diabetes and other quantitative traits, after adjusting for age, sex and body mass index.

RESULTS: In the [redacted] polymorphisms were associated with increased likelihood of pediatric-onset type 2 diabetes; only one of these polymorphisms (CADM2/rs1307880) also showed a consistent effect in the case-sibling analysis. The associations in the combined analysis were as follows: ADORA1/rs903361 (OR 1.9, 95% CI 1.2; 3.0); CADM2/rs13078807 (OR 2.2, 95% CI 1.2; 4.0); GNPDA2/rs10938397 (OR 2.2, 95% CI 1.4; 3.7); VEGFA/rs6905288 (OR 1.4, 95% CI 1.1; 2.1) and FTO/rs9939609 (OR 1.8, 95% CI 1.0; 3.2). We also identified 16 polymorphisms nominally associated with quantitative traits in participants without diabetes.

CONCLUSIONS: ADORA/rs903361, CADM2/rs13078807, GNPDA2/rs10938397, VEGFA/rs6905288 and FTO/rs9939609 are associated with an increased risk of pediatric-onset type 2 diabetes in the Mexican population.

KEYWORDS: Adolescents; Children; Metabolic syndrome; Single nucleotide polymorphisms; Type 2 diabetes

PMID: 28401323 DOI: 10.1007/s00592-017-0987-9

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⊕ Author information

Abstract

AIMS: To evaluate the association of 64 obesity-related polymorphisms with pediatric-onset type 2 diabetes and other glucose- and insulin-related traits in Mexican children.

METHODS: Case-control and case-sibling designs were followed. We studied 99 patients with pediatric-onset type 2 diabetes, their siblings (n = 101) without diabetes, 83 unrelated pediatric controls and 137 adult controls. Genotypes were determined for 64 single nucleotide polymorphisms, and a possible association was examined between those genotypes and type 2 diabetes and other quantitative traits, after adjusting for age, sex and body mass index.

RESULTS: In the case-pediatric control and case-adult control analyses, five polymorphisms were associated with increased likelihood of pediatric-onset type 2 diabetes; only one of these polymorphisms (CADM2/rs1307880) also showed a consistent effect in the case-sibling analysis. The associations in the combined analysis were as follows: ADORA1/rs903361 (OR 1.9, 95% CI 1.2; 3.0); CADM2/rs13078807 (OR 2.2, 95% CI 1.2; 4.0); GNPDA2/rs10938397 (OR 2.2, 95% CI 1.4; 3.7); VEGFA/rs6905288 (OR 1.4, 95% CI 1.1; 2.1) and FTO/rs9939609 (OR 1.8, 95% CI 1.0; 3.2). We also identified 16 polymorphisms nominally associated with quantitative traits in participants without diabetes.

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J Pediatr Rehabil Med. 2017 May 19;10(2):107-136. doi: 10.3233/PRM-170436.

Evidence to support treatment options for children with swallowing and feeding disorders: A

Gosa MM[1,2], Carden HT[3], Jacks CC[3], Threadgill AY[3], Sidlovsky TC[1].

⊕ Author information

Abstract

PURPOSE: A rise in pediatric patients with swallowing and feeding problems has resulted in increased interest in multidisciplinary treatments to address these issues. examined the published evidence for the use of common strategies used by clinicians across disciplines to treat pediatric swallowing and feeding problems.

METHODS: A systematic search of 10 electronic databases was completed to identify relevant, peer reviewed literature published in English prior to December 2015 reporting original data that addressed at least one of the five identified clinical questions.

RESULTS: Sixty-one studies of varying methodological quality were included. The majority of the included studies (60/61) focused on the use of behavioral therapies to remediate swallowing and feeding disorders in children and reported mixed findings across all of the targeted outcomes.

CONCLUSION: There is insufficient quantity of evidence to determine the effects of oral motor, sensory, and pharmaceutical therapies on functional feeding outcomes in pediatric populations. A larger body of phase 1 evidence is available that establishes the efficacy of behavioral strategies to treat some swallowing and feeding difficulties in small cohort and single subject studies. This analysis identified limited high quality (phase 4) research articles that establish the efficacy and benefit of joint nutrition and behavior intervention programs and systematic desensitization and operant conditioning behavioral therapy approaches to improve functional feeding and swallowing outcomes in children.

KEYWORDS: Pediatrics; dysphagia; feeding disorders; treatment

J Pediatr Rehabil Med. 2017 May 19;10(2):107-136. doi: 10.3233/PRM-170436.

Evidence to support treatment options for children with swallowing and feeding disorders: A systematic review.

Gosa MM[1,2], Carden HT[3], Jacks CC[3], Threadgill AY[3], Sidlovsky TC[1].

⊕ Author information

Abstract

PURPOSE: A rise in pediatric patients with swallowing and feeding problems has resulted in increased interest in multidisciplinary treatments to address these issues. This evidence based systematic review (EBSR) examined the published evidence for the use of common strategies used by clinicians across disciplines to treat pediatric swallowing and feeding problems.

METHODS: A systematic search of 10 electronic databases was completed to identify relevant, peer reviewed literature published in English prior to December 2015 reporting original data that addressed at least one of the five identified clinical questions.

RESULTS: Sixty-one studies of varying methodological quality were included. The majority of the included studies (60/61) focused on the use of behavioral therapies to remediate swallowing and feeding disorders in children and reported mixed findings across all of the targeted outcomes.

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KEYWORDS: Pediatrics; dysphagia; evidence based systematic review; feeding disorders; treatment

Eur J Clin Nutr. 2017 May 24. doi: 10.1038/ejcn.2017.79. [Epub ahead of print]

Impact of the n-6:n-3 long-chain PUFA ratio during pregnancy and lactation on offspring neurodevelopment: 5-year follow-up of a

Brei C[1], Stecher L[1], Brunner S[1], Ensenauer R[2,3], Heinen F[4], Wagner PD[5], Hermsdörfer J[5], Hauner H[1,6].

⊕ Author information

Abstract

BACKGROUND/OBJECTIVES: Evidence regarding the effect of n-3 long-chain polyunsaturated fatty acid (LCPUFA) supplementation during pregnancy on offspring's neurodevelopment is not conclusive.

SUBJECTS/METHODS: In this analysis, the effect of a reduced n-6:n-3 LCPUFA ratio in the diet of pregnant/lactating women (1.2 g n-3 LCPUFA together with an arachidonic acid (AA)-balanced diet between 15th wk of gestation-4 months postpartum vs control diet) on child neurodevelopment at 4 and 5 years of age was assessed. A child development inventory (CDI) questionnaire and a hand movement test measuring mirror movements (MMs) were applied and the association with cord blood LCPUFA concentrations examined.

RESULTS: CDI questionnaire data, which categorizes children as 'normal', 'borderline' or 'delayed' in different areas of development, showed no significant evidence between study groups at 4 (n=119) and 5 years (n=130) except for the area 'letters' at 5 years of age (P=0.043). Similarly, the results did not strongly support the hypothesis that the intervention has a beneficial effect on MMs (for example, at 5 years: dominant hand, fast: adjusted mean difference, -0.08 (-0.43, 0.26); P=0.631). Children exposed to higher cord blood concentrations of docosahexaenoic acid, eicosapentaenoic acid and AA, as well as a lower ratio of n-6:n-3 fatty acids appeared to show beneficial effects on MMs, but these results were largely not statistically significant.

CONCLUSIONS: Our results do not show clear benefits or harms of a change in the n-6:n-3 LCPUFA ratio during pregnancy on offspring's neurodevelopment at preschool age. Findings on cord blood LCPUFAs point to a potential influence on offspring development.European Journal of Clinical Nutrition advance online publication, 24 May 2017; doi:10.1038/ejcn.2017.79.

Eur J Clin Nutr. 2017 May 24. doi: 10.1038/ejcn.2017.79. [Epub ahead of print]

Impact of the n-6:n-3 long-chain PUFA ratio during pregnancy and lactation on offspring neurodevelopment: 5-year follow-up of a randomized controlled trial.

Brei C[1], Stecher L[1], Brunner S[1], Ensenauer R[2,3], Heinen F[4], Wagner PD[5], Hermsdörfer J[5], Hauner H[1,6].

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The ethical aspects of medical research

Special Communication

November 27, 2013

World Medical Association Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects

World Medical Association

Article Information

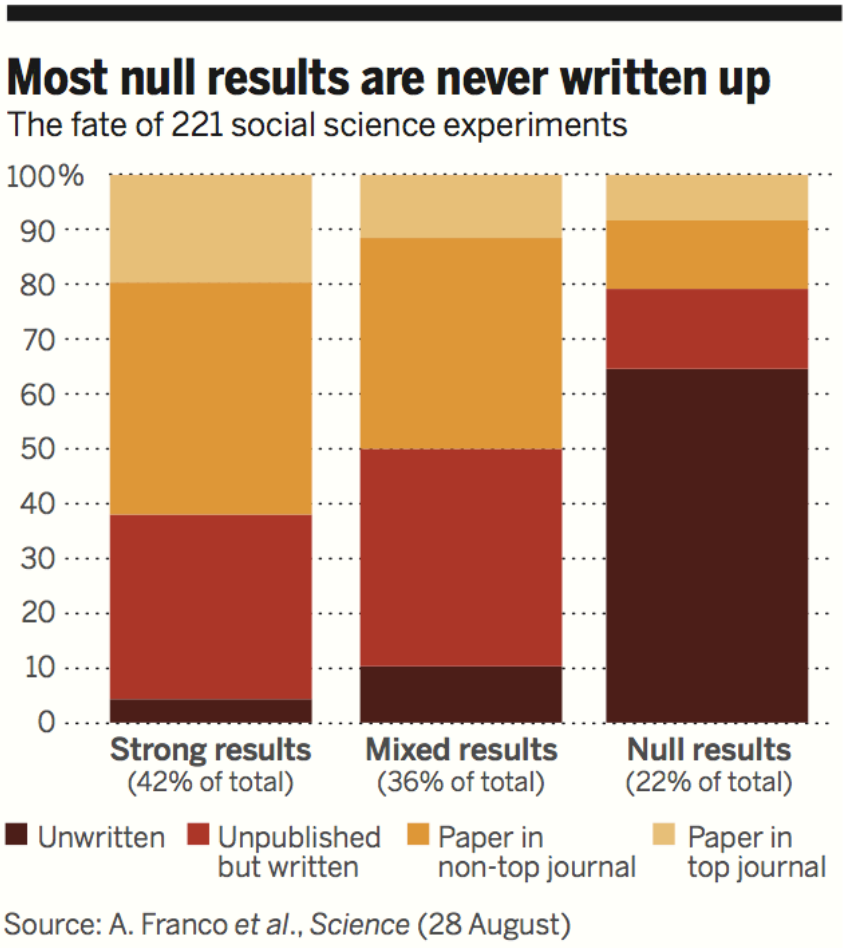
JAMA. 2013;310(20):2191-2194. doi:10.1001/jama.2013.281053

Declaration of Helsinki Website

- The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data
- **“The health of my patient will be my first consideration”**
- “A physician shall act in the patient's best interest when providing medical care”

Publication bias (1)

- Occours in **published research**, when the publication depends not just on the quality, but also on:
  - the hypothesis tested
  - the significance and direction of effects detected
- In **observational** and **experimental** studies
- Great potential for **promoting false conclusions** and for **patient harm**



Rothstein H (2005); Song F (2010)

Publication bias (2)

- Arises when studies are published or not depending on their results:
  - **Published work** is more likely to be **positive** than unpublished research (**Positive-results bias**)
  - Research **without statistically significant** results **takes longer to achieve publication** than research with significant results
  - When multiple outcomes are analyzed, but the **reporting** of these **outcomes** is dependet on the **strenght and direction** of its results (**Outcome reporting bias**)

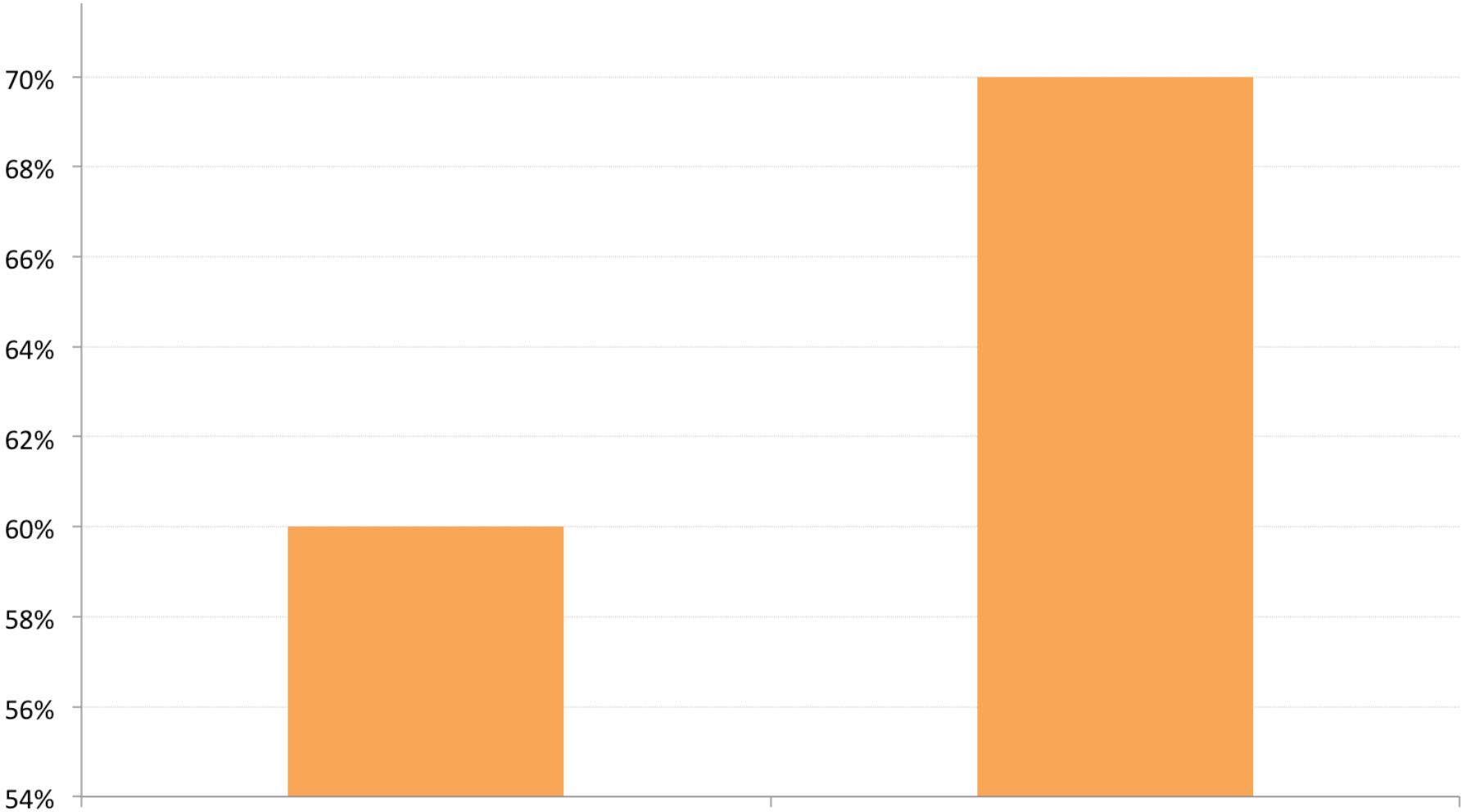
Rothstein H (2005); Sackett DL (1979); Kerr NL (2010); Chan AW (2005)

Solutions to Publication bias

- Special sections in journals for publishing negative findings
- *Journal of Negative Results in Biomedicine*
- **Research register**: provide basic information about trials that remain unpublished
- **WHO**: basic information about all clinical trials should be registered, at inception, and this information should be publicy accessible through the WHO International Clinical Trials Registry Platform

Rothstein H (2005); Dickersin K (2011)

A “graphical” abuse



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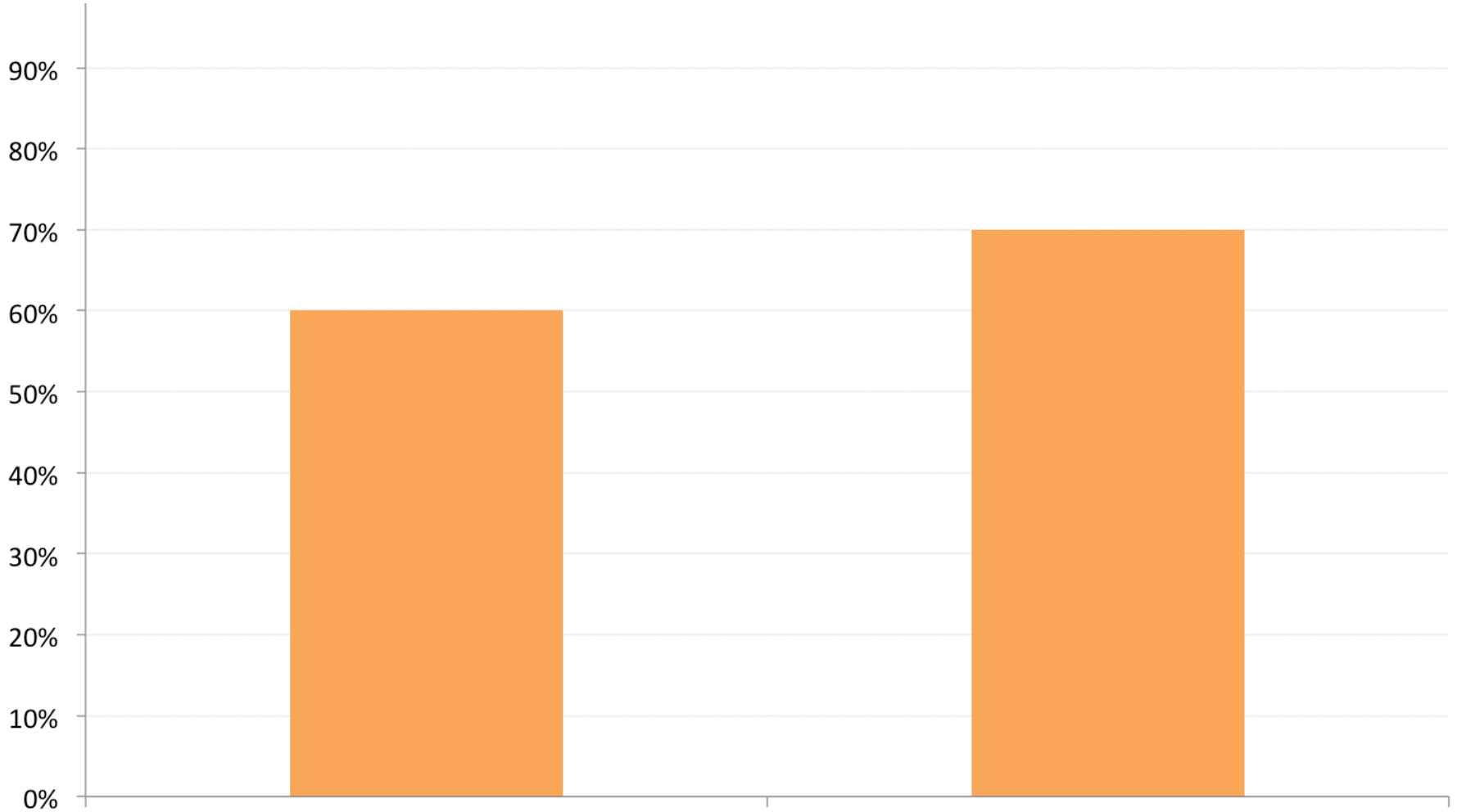

Even big ones make a mistake…

THE LANCET

The Lancet, Volume 351, Issue 9103, Pages 637 - 641, 28 February 1998
doi:10.1016/S0140-6736(97)11096-0

This article was retracted

RETRACTED: Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

Dr AJ Wakefield FRCS [a], SH Murch MB [b], A Anthony MB [a], J Linnell PhD [a], DM Casson MRCP [b], M Malik MRCP [b], M Berelowitz FRCPsych [c], AP Dhillon MRCPath [a], MA Thomson FRCP [b], P Harvey FRCP [d], A Valentine FRCR [e], SE Davies MRCPath [a], JA Walker-Smith FRCP [a]

Summary

Background

We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods

12 children (mean age 6 years [range 3–10], 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development

Summary

To practice EBM you have to know some elements of statistic

- Classification of sources of information
  - Primary source
  - Secondary source
  - Tertiary source
- Evaluation of quality of source of information (randomization, blind, ITT)
- Reading results