



**nutrition 2014**

Las Palmas de Gran Canaria. SPAIN

**9-12 November**

Congress

Banjul. GAMBIA

**5-7 November**

Pre-Congress Workshops

**III WORLD CONGRESS OF PUBLIC HEALTH NUTRITION**  
II LATIN AMERICAN CONGRESS OF COMMUNITY NUTRITION  
X CONGRESO DE LA SOCIEDAD ESPAÑOLA  
DE NUTRICIÓN COMUNITARIA (SENC)

PUBLIC HEALTH NUTRITION: THE CORE OF INTERNATIONAL COOPERATION FOR DEVELOPMENT

**CÁMARA**

**DEBATE**

## **Experiments or observations?**

MODERATOR:

*Miguel Ángel Martínez, University of Navarra, Spain*

SPEAKERS:

*Joan Sabaté, Loma Linda University, CA, USA*

*Walter Willett, Harvard School of Public Health, Boston, MA, USA*

**Experiments or observations?**

MODERATOR:

*Miguel Ángel Martínez, University of Navarra, Spain*

SPEAKERS:

*Joan Sabaté, Loma Linda University, CA, USA**Walter Willett, Harvard School of Public Health, Boston, MA, USA*

-**Contrast** between the results of observational studies and experimental trials, e.g.

- vitamin E
- beta-carotene

-How large is the room for **residual confounding** in observational studies, specially when overall dietary patterns are assessed?

-Do we always **need RCTs** with hard clinical endpoints to show **causality** in nutrition science?



## Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

**Data sources:** Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists.

**Study selection:** Studies showing the effects of using a parachute during free fall.

**Main outcome measure** Death or major trauma, defined as an injury severity score  $> 15$ .

**Results** We were unable to identify any randomised controlled trials of parachute intervention.

**Conclusions** As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials.

We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.



**Experiments or observations?**

MODERATOR:

*Miguel Ángel Martínez, University of Navarra, Spain*

SPEAKERS:

*Joan Sabaté, Loma Linda University, CA, USA**Walter Willett, Harvard School of Public Health, Boston, MA, USA*

- Are always **affordable** or ethically justified these large randomized trials?
- What are the main **methodological limitations** of these large randomized trials, even if they eventually support the initial hypothesis?
- What are the consequences of **negative** trials?



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Cardiovascular Effects of Intensive Lifestyle Intervention in Type 2 Diabetes

The Look AHEAD Research Group\*

**Futility**  
**no difference in  
the number of  
cardiovascular events  
was noted  
between the two groups  
after 9.6 y (median F-U).**

## Low-Fat Dietary Pattern and Risk of Cardiovascular Disease

The Women's Health Initiative Randomized Controlled  
Dietary Modification Trial

The diet had no significant effects on incidence of CHD (hazard ratio [HR], 0.97; 95% confidence interval [CI], 0.90-1.06), stroke (HR, 1.02; 95% CI, 0.90-1.15), or CVD (HR, 0.98; 95% CI, 0.92-1.05).

# The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

APRIL 4, 2013

VOL. 368 NO. 14

## Primary Prevention of Cardiovascular Disease with a Mediterranean Diet

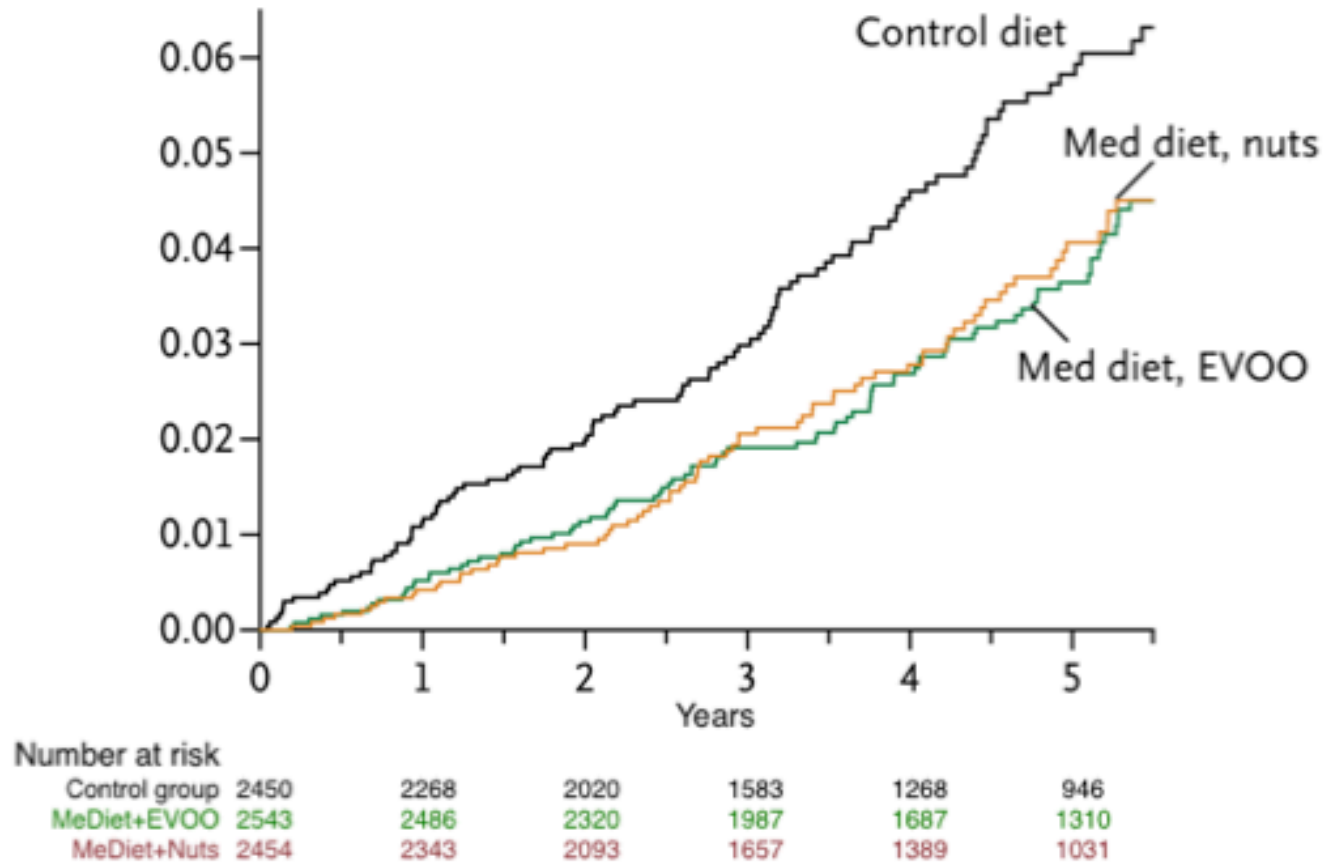
Ramón Estruch, M.D., Ph.D., Emilio Ros, M.D., Ph.D., Jordi Salas-Salvadó, M.D., Ph.D., María-Isabel Covas, D.Pharm., Ph.D., Dolores Corella, D.Pharm., Ph.D., Fernando Arós, M.D., Ph.D., Enrique Gómez-Gracia, M.D., Ph.D., Valentina Ruiz-Gutiérrez, Ph.D., Miquel Fiol, M.D., Ph.D., José Lapetra, M.D., Ph.D., Rosa María Lamuela-Raventós, D.Pharm., Ph.D., Lluís Serra-Majem, M.D., Ph.D., Xavier Pintó, M.D., Ph.D., Josep Basora, M.D., Ph.D., Miguel Ángel Muñoz, M.D., Ph.D., José V. Sorli, M.D., Ph.D., José Alfredo Martínez, D.Pharm., M.D., Ph.D., and Miguel Ángel Martínez-González, M.D., Ph.D., for the PREDIMED Study Investigators\*

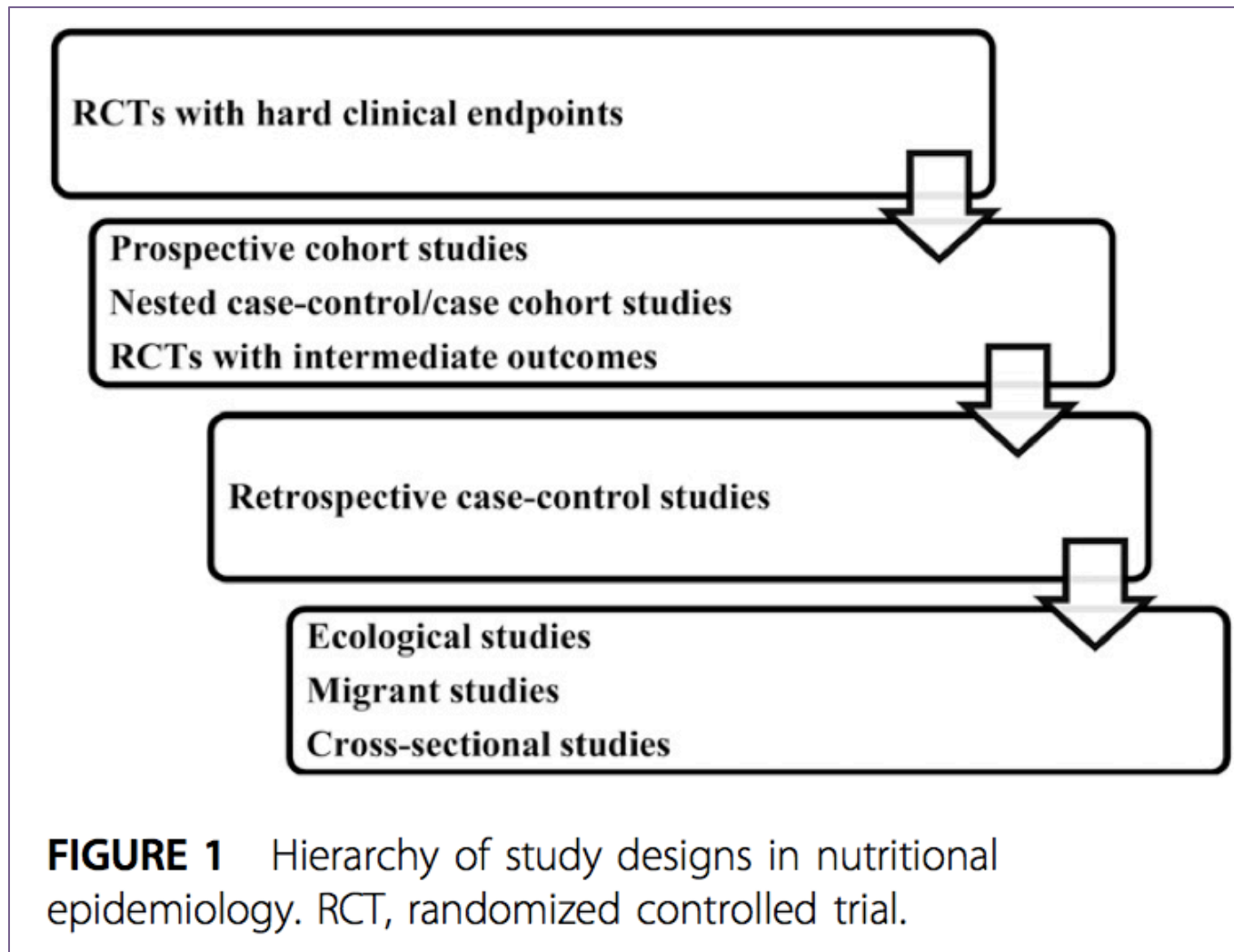
*Predimed*  
Prevenção con Dieta Mediterránea

### Hazard Ratios (95% CI)\*

**EVOO: 0.70 (0.53-0.91), P=0.009**

**Nuts: 0.70 (0.53-0.94), P=0.016**





[Science, 2009.](#)

## Research designs

Source: Martínez JA, Martínez-González MA. *Nutrition Research Methodology: the scientific method and nutritional research*.

In: Gibney MJ, et al. *Introduction to Human Nutrition. The Nutrition Society Textbook series*. London: Blackwell Science, 2009.

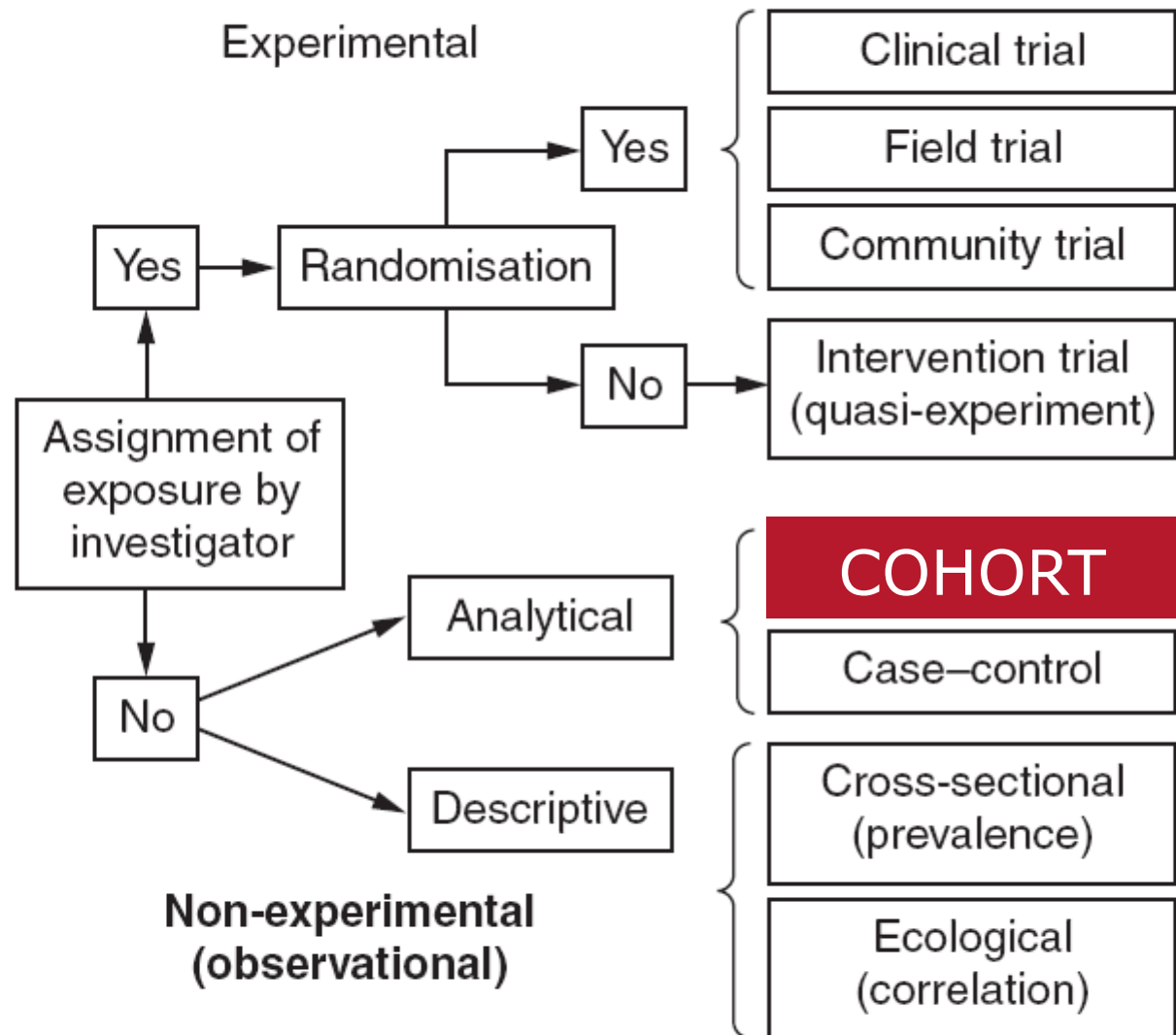
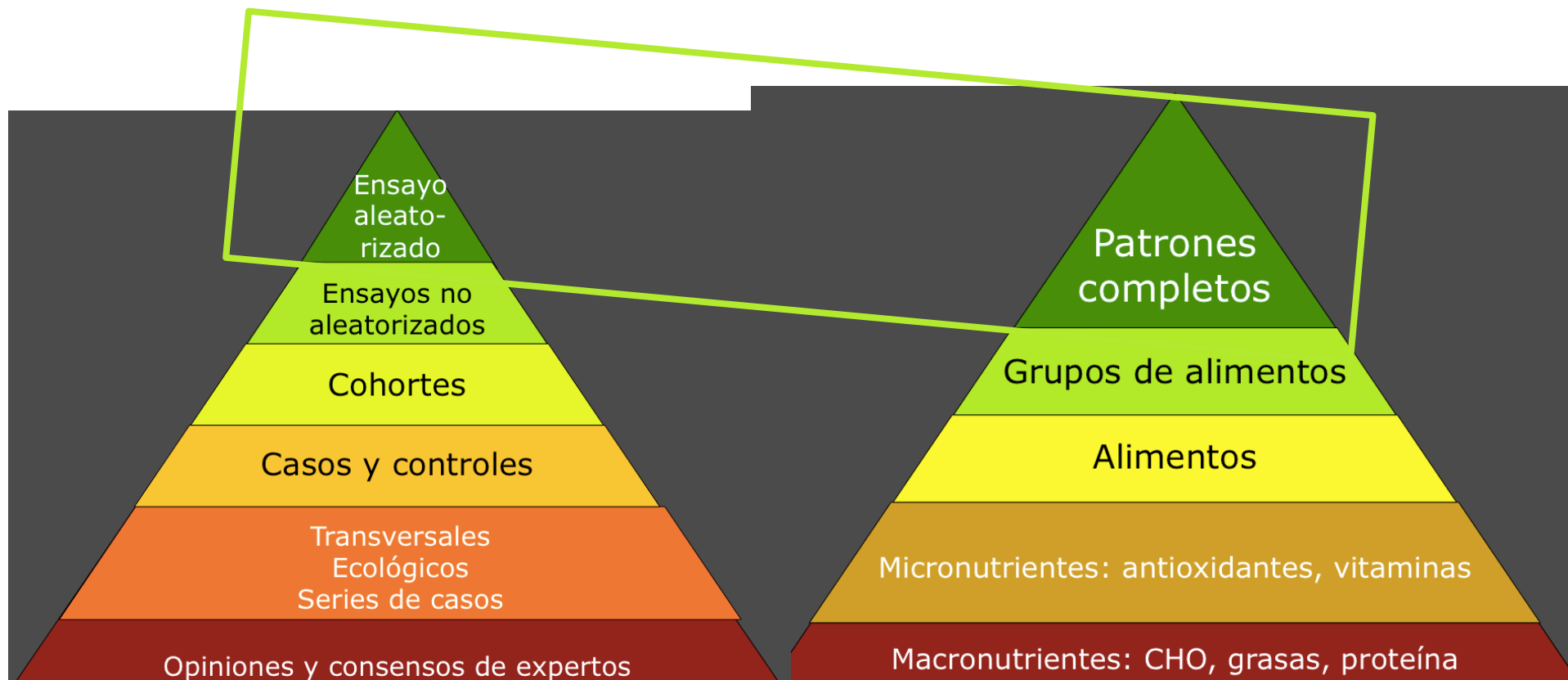


Figure 13.2 Classification of epidemiological designs.





# Causalidad: base para políticas alimentarias

- *prospective cohort studies provide statistical associations but not causations. (??)*
- **Only** (?) randomized controlled trials (RCT) can answer causal questions.
- RCT are considered superior in inferring **causality** (...) randomly assigning participants to treatment groups nullifies all sources of measured and **unmeasured** confounding.
- the critical assumption of “**no unmeasured or residual confounding**” that is needed to infer **causality** cannot be empirically verified in observational epidemiology.

Se llegaría al **absurdo** de:

En ausencia de ensayos...

- No intervención
- No políticas
- No guías / recomendaciones

No es **oro** todo lo  
que reluce en **ensayos**

...incluso a veces  
es mejor la **cohorte**

## Limitaciones de grandes ensayos nutricionales

1. No pueden ser a dobles ciegos
2. Mayores pérdidas y además selectivas
3. *Cumplimiento* subóptimo de las dietas
4. Poco contraste intervención vs. control
5. Larga duración y *obsolescencia* al final
6. Comparador (*control*) siempre problemático

# Limitaciones de grandes ensayos nutricionales

- 1.No pueden ser a doble ciego
- 2.Mayores pérdidas y además selectivas
- 3.Cumplimiento subóptimo de las dietas
- 4.Poco contraste intervención vs. control
- 5.Larga duración y obsolescencia al final
- 6.Comparador (control) siempre problemático

7.Problemas *éticos*

8.*Complejidad* de componentes de la dieta

**9.**Menor validez externa: alto riesgo, exclusiones

10.Espectro limitado de preguntas

11.Costes altísimos

# Ventajas de cohortes

1. Mayor factibilidad y eficiencia
2. Capturan bien complejidad de la dieta
3. Periodos, dosis-exposiciones variables
  - Mayor contraste entre extremos
4. Previenen ciertos sesgos
  - causalidad inversa
  - selección controles
  - sesgo de recuerdo

# Ventajas de cohortes

1. Mayor factibilidad y eficiencia
2. Capturan bien complejidad de la dieta
3. Periodos, dosis-exposiciones variables
  - Mayor contraste entre extremos
4. Previene ciertos sesgos
  - causalidad inversa
  - selección controles
  - sesgo de recuerdo
5. Pueden ajustar por multitud de confusores
6. Medidas repetidas dieta y confusores
7. Mayor validez externa
8. Bien hechas y ajustadas: equivalen a Ensayos



- Strength of association
- Temporal sequence
- Graduality
  
- Consistency
- Coherence
- Biological plausibility
- Specificity
- Analogy
- Experimental evidence

