

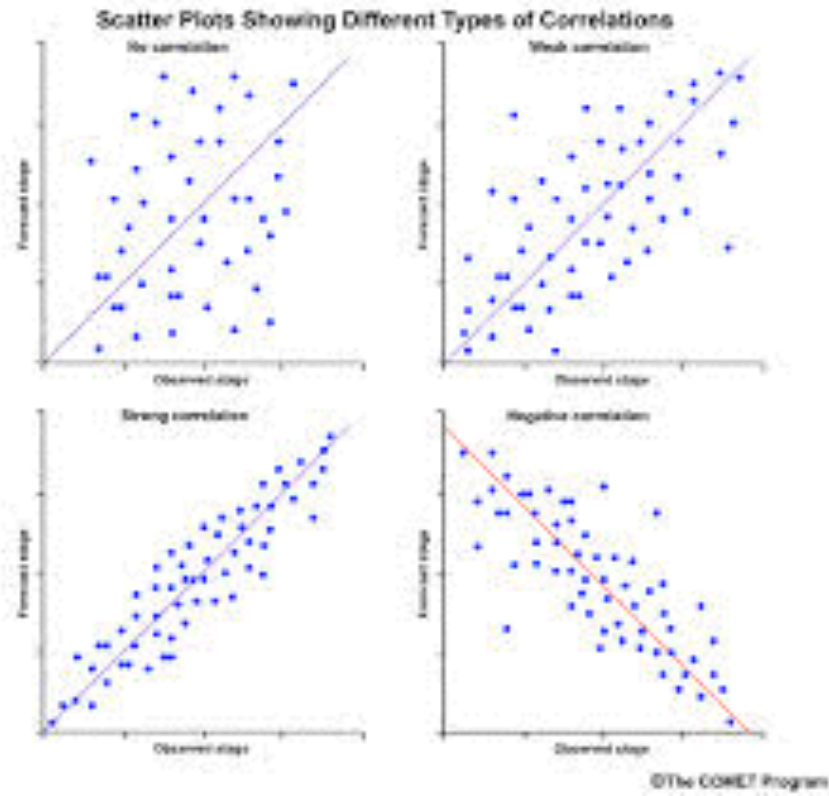
correlation and causation

The idea of a study is to determine if
an *exposure* gives rise to an *outcome*.
Thus a *causal link* is sought.

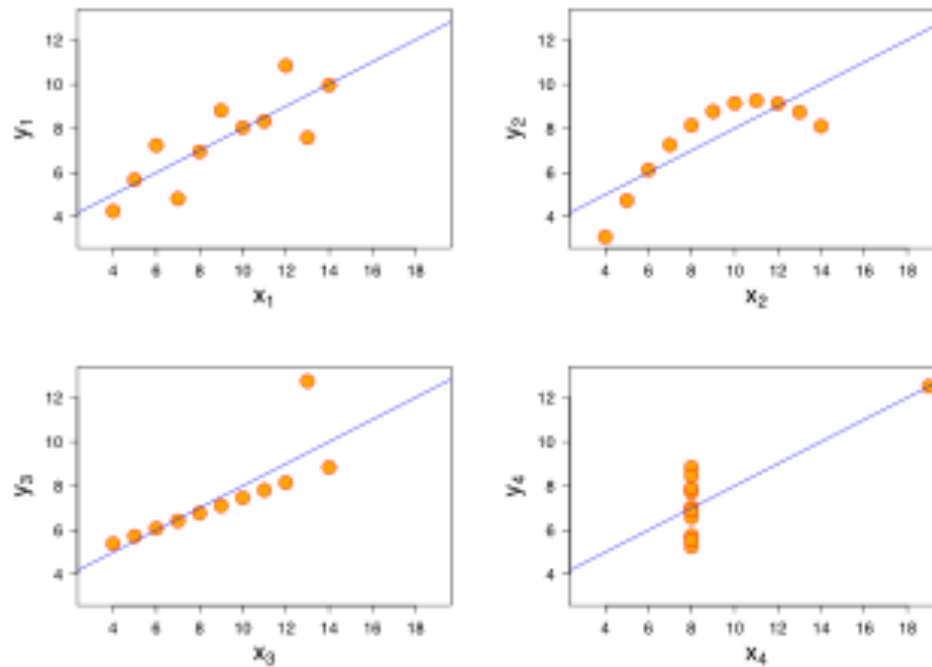
Ex. does smoking cause lung cancer?
Ex. does eating salt cause heart disease?

end of lecture 19

WARNING: correlation does not imply causation.



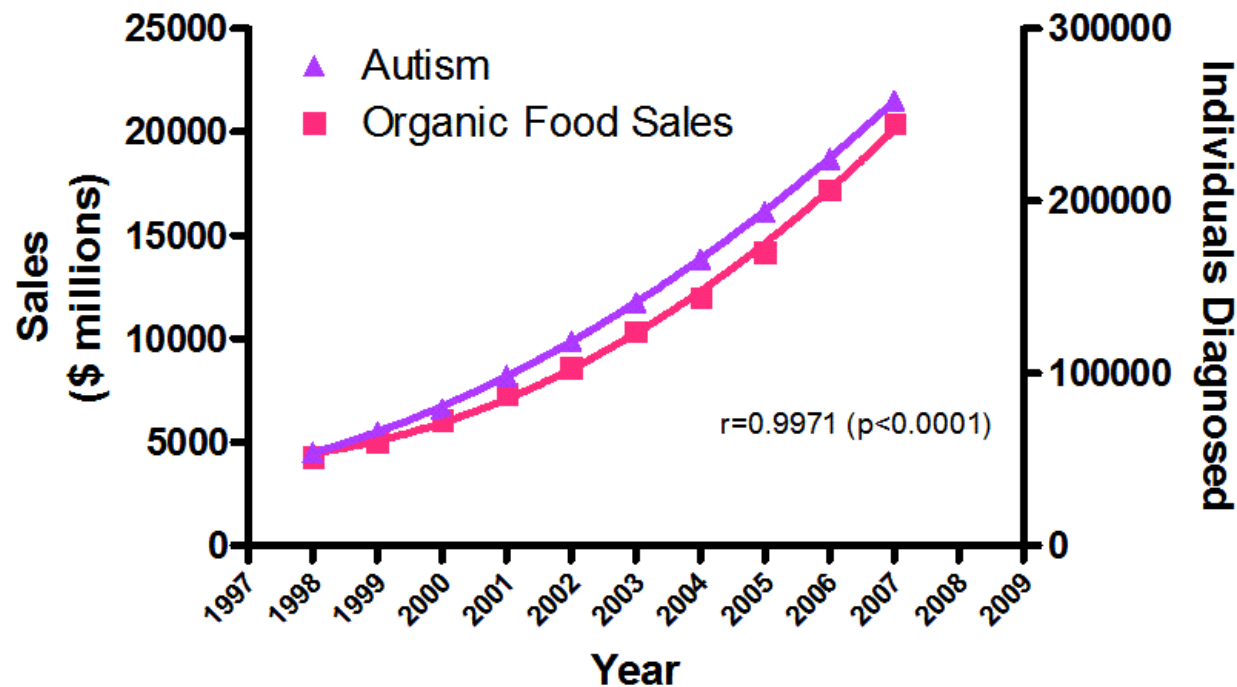
WARNING: correlation does not imply causation.



Four sets of data with the same correlation of 0.816

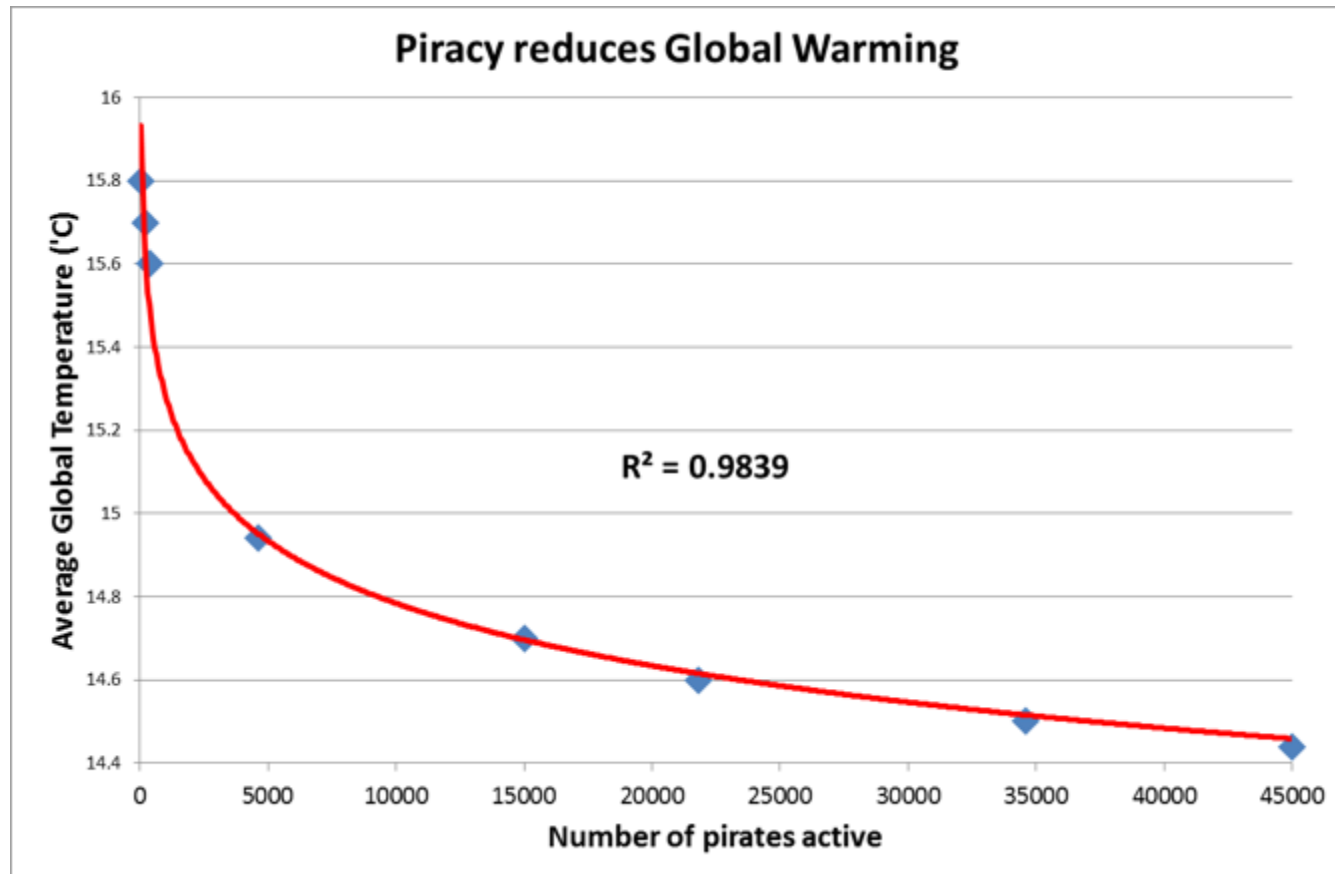
WARNING: correlation does not imply causation.

The real cause of increasing autism prevalence?



Sources: Organic Trade Association, 2011 Organic Industry Survey; U.S. Department of Education, Office of Special Education Programs, Data Analysis System (DANS), OMB# 1820-0043: "Children with Disabilities Receiving Special Education Under Part B of the Individuals with Disabilities Education Act"

WARNING: correlation does not imply causation.



WARNING: correlation does not imply causation.

- Young children who sleep with the light on are much more likely to develop myopia in later life.

Therefore, sleeping with the light on causes myopia.

This is a scientific example that resulted from a study at the University of Pennsylvania Medical Center. Published in the May 13, 1999 issue of *Nature*, the study received much coverage at the time in the popular press. However, a later study at Ohio State University did not find that infants sleeping with the light on caused the development of myopia. It did find a strong link between parental myopia and the development of child myopia, also noting that myopic parents were more likely to leave a light on in their children's bedroom

- As ice cream sales increase, the rate of drowning deaths increases sharply.
Therefore, ice cream consumption causes drowning.
- A study found a higher rate of skin cancer among power line workers and concluded that exposure to magnetic fields from power lines causes cancer.
- A study found that the rate of mental retardation was larger among people living downwind of a nuclear reactor [then it was realized that there was a home for mentally disabled people in that neighbourhood.]

Types of Studies

Types of Studies

Observational Study

An observational study is a study in which subjects are not randomized to the exposed or unexposed groups, rather the subjects are *observed* in order to determine both their exposure and their outcome status and the exposure status is thus not determined by the researcher

Cohort Study

A cohort study follows two or more groups of people and examines outcomes. At least one group will be exposed to something (the independent variable), but the groups will attempt to be matched otherwise.

An example of an epidemiological question that can be answered using a cohort study is: does exposure to X (say, smoking) associate with outcome Y (say, lung cancer)? Such a study would recruit a group of smokers and a group of non-smokers (the unexposed group) and follow them for a set period of time and note differences in the incidence of lung cancer between the groups at the end of this time.

Types of Studies

Case Control Studies

A case control study considers two groups of people, one with the attribute being studied (say, lung cancer) and one without, called the *control* group. One then checks if more of the cases share a possible cause (say, smoking) than the control group.

The most important drawback in case-control studies relates to the difficulty of obtaining reliable information about an individual's exposure status over time.

Randomized Controlled Study

Subjects are randomly selected to receive treatment or a *placebo*, the latter group is the control group. Sometimes the other group receives a previously tested treatment. This is called a *positive-control study*.

Types of Studies

Ex. To test whether power lines cause cancer, researchers questioned cancer patients to see if they lived near power lines.

Ex. To test whether power lines cause cancer, researchers followed the health history of 100 people living near power lines.

Types of Studies

Ex. To test whether power lines cause cancer, researchers questioned cancer patients to see if they lived near power lines.

case control

Ex. To test whether power lines cause cancer, researchers followed the health history of 100 people living near power lines.

cohort study

Designing Studies

Removing possible sources of bias is crucial to good study design.

(1) design bias

Judith Wallerstein's longitudinal study of divorced children is based on a very small sample of white, upper middle class, California families and no control group BUT it has confirmed the basic belief that divorce is bad for kids, so it is difficult to argue that divorce can be either harmless or useful.

study dropouts (attrition effect)

(2) measurement bias

measurement bias exists when researcher fails to control for the effects of data collection and measurement

ex. problems with self reporting (socially acceptable answers, answers the researcher wants to hear)

non binary (or judgmental) outcomes

Designing Studies

(3) sampling bias

sampling bias exists when the sampling procedure introduces bias

having too small a sample leads to problems in the reliability of the conclusions

ex. most medical studies have been done on white or black males

targeting the most desirable or most accessible sample

ex. in research on the effectiveness of batterers treatment programs, some researchers use conflictual couples seeking marriage counseling, and exclude court referred batterers, batterers with co-existing mental disorders, batterers who are severely violent, and batterers who are substance abusers . . . and then conduct the research in suburban university settings

(4) procedural bias

procedural bias exists most often when we administer the research interview or questionnaire under adverse conditions

- using students
- paying subjects
- e.g. administering questionnaires in a brief interval

Designing Studies

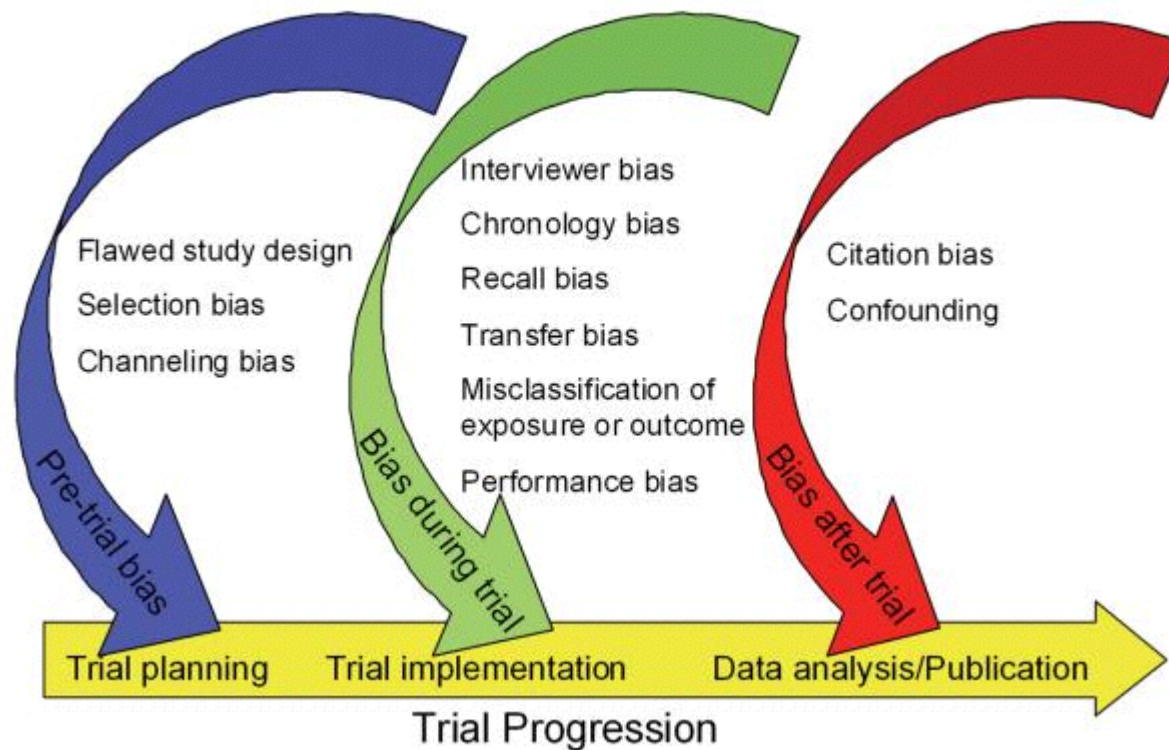
Recall bias

Recall bias refers to the phenomenon in which the outcomes of treatment (good or bad) may color subjects' recollections of events prior to or during the treatment process.

ex. One common example is the perceived association between autism and the MMR vaccine. This vaccine is given to children during a prominent period of language and social development. As a result, parents of children with autism are more likely to recall immunization administration during this developmental regression, and a causal relationship may be perceived

Designing Studies

Major Sources of Bias in Clinical Research



Designing Studies

Type of Bias	How to Avoid
Pre-trial bias	
Flawed study design	<ul style="list-style-type: none">• Clearly define risk and outcome, preferably with objective or validated methods. Standardize and blind data collection.• Select patients using rigorous criteria to avoid confounding results. Patients should originate from the same general• Assign patients to study cohorts using rigorous criteria.
Selection bias	
Channeling bias	
Bias during trial	
Interviewer bias	<ul style="list-style-type: none">• Standardize interviewer's interaction with patient. Blind interviewer to exposure status.• Prospective studies can eliminate chronology bias. Avoid using historic controls (confounding by secular trends).• Use objective data sources whenever possible. When using subjective data sources, corroborate with medical record.• Carefully design plan for lost-to-followup patients prior to the study.• Clearly define exposure prior to study. Avoid using proxies of exposure.• Use objective diagnostic studies or validated measures as primary outcome.• Consider cluster stratification to minimize variability in surgical technique.
Chronology bias	
Recall bias	
Transfer bias	
Exposure Misclassification	
Outcome Misclassification	
Performance bias	
Bias after trial	
Citation bias	<ul style="list-style-type: none">• Register trial with an accepted clinical trials registry. Check registries for similar unpublished or in-progress trials prior to• Known confounders can be controlled with study design (case control design or randomization) or during data analysis
Confounding	

Designing Studies

blinding

A major tool for controlling bias is *blinding*. This means (i) making the researcher unaware of certain trial conditions (ii) making the subjects unaware of certain trial conditions. Doing both is called *double blinding*.

Ex. A nurse evaluates subjects to see if a treatment for Parkinson's disease is working. She is blinded if she does not know if the patients are on treatment or placebo.

Ex. A subject is being tested for response to cellphone EM radiation and is not told if the cellphone is on or off.

Designing Studies

binary assessment

It is important to make assessments of trial outcomes as impartial as possible. Restricting choices to 'yes' or 'no' helps.

Ex. A nurse evaluates a patient to test the efficacy of a drug treatment:

- (i) asks the patient how he feels
- (ii) assesses the patient's alertness, fatigue level, and pallor
- (iii) runs a diagnostic blood test
- (iv) administers a pass/fail reflex test

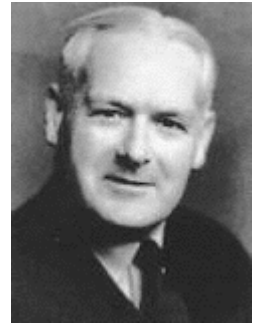
Designing Studies

the Jadad scale [0:5]

- is the study randomised? (1)
- is the study double blind? (1)
- were dropouts and withdrawals described? (1)
- was the method of randomisation described? (1)
- was the method of blinding described? (1)

Designing Studies

The minimal conditions establishing cause and effect in medical diagnosis.



Sir Austin Bradford Hill
(1897 – 1991)

The Bradford Hill Criteria

Temporality

There is a time relationship between cause and effect in that the effect occurs after the cause. Also, if it is to be expected that there is some delay between cause and effect then that delay should also be observed.

Strength and association

Cause-and-effect may be observed by statistical correlation between these in repeated events or experiments. Full strength correlation has a coefficient of 1. A weaker association between cause and effect will see greater variation.

Biological gradient (dose-response)

In treatment, there might be expected to be a relationship between the dose given and the reaction of the patient. This may not be a simple linear relationship and may have minimum and maximum thresholds.

Consistency

One apparent success does not prove a general cause and effect in wider contexts. To prove a treatment is useful, it must give consistent results in a wide range of circumstances.

Plausibility

The apparent cause and effect must make sense in the light of current theories and results. If a causal relationship appears to be outside of current science then significant additional hypothesizing and testing will be required before a true cause and effect can be found.

Specificity

A specific relationship is found if there is no other plausible explanation. This is not always the case in medicine where any given symptoms may have a range of possible causing conditions.

Evidence

A very strong proof of cause and effect comes from the results of experiments, where many significant variables are held stable to prevent them interfering with the results. Other evidence is also useful but can be more difficult to isolate cause and effect.

Analogy

When something is suspected of causing an effect, then other factors similar or analogous to the supposed cause should also be considered and identified as a possible cause or otherwise eliminated from the investigation.

Coherence

If laboratory experiments in which variables are controlled and external everyday evidence are in alignment, then it is said that there is coherence.

Studies in Practice

Studies in Practice

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November 2010

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Lies, Damned Lies, and Medical Science

MUCH OF WHAT MEDICAL RESEARCHERS CONCLUDE IN THEIR STUDIES IS MISLEADING, EXAGGERATED, OR FLAT-OUT WRONG. SO WHY ARE DOCTORS—TO A STRIKING EXTENT—STILL DRAWING UPON MISINFORMATION IN THEIR EVERYDAY PRACTICE? DR. JOHN IOANNIDIS HAS SPENT HIS CAREER CHALLENGING HIS PEERS BY EXPOSING THEIR BAD SCIENCE.

convincingly refuted: 80 percent of non-randomized studies (by far the most common type) turn out to be wrong, as do 25 percent of supposedly gold-standard randomized trials, and as much as 10 percent of the platinum-standard large randomized trials. The article spelled out his belief that

Studies in Practice

NATURE NEUROSCIENCE | PERSPECTIVE

Erroneous analyses of interactions in neuroscience: a problem of significance

Sander Nieuwenhuis, Birte U Forstmann & Eric-Jan Wagenmakers

[Affiliations](#) | [Contributions](#) | [Corresponding author](#)








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Abstract

[Abstract](#) • [References](#) • [Author information](#)

In theory, a comparison of two experimental effects requires a statistical test on their difference. In practice, this comparison is often based on an incorrect procedure involving two separate tests in which researchers conclude that effects differ when one effect is significant ($P < 0.05$) but the other is not ($P > 0.05$). We reviewed 513 behavioral, systems and cognitive neuroscience articles in five top-ranking journals (*Science*, *Nature*, *Nature Neuroscience*, *Neuron* and *The Journal of Neuroscience*) and found that 78 used the correct procedure and 79 used the incorrect procedure. An additional analysis suggests that incorrect analyses of interactions are even more common in cellular and molecular neuroscience. We discuss scenarios in which the erroneous procedure is particularly beguiling.

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<http://www.badsience.net/2011/10/what-if-academics-were-as-dumb-as-quacks-with-statistics/#more-2405>

Studies in Practice

Do Certain Countries Produce Only Positive Results? A Systematic Review of Controlled Trials

Andrew Vickers, Niraj Goyal, Robert Harland, and Rebecca Rees

Research Council for Complementary Medicine, London, UK (A.V., R.R.); and Queen Mary & Westfield College, London, UK (N.G., R.H.)

Table 1 Results of Controlled Clinical Trials of Acupuncture by Country of Research

Country	Total Trials Analyzed	Favoring Test Treatment	
		Number	Percentage
USA	47	25	53
China	36	36	100