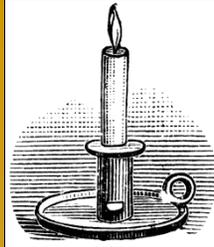




THE UNIVERSITY OF
ALABAMA AT BIRMINGHAM

Office
of
Energetics



David B. Allison, Ph.D.



*Myths, truths, skepticism,
and curiosity on null
findings: striking a balance*

Disclosure

I have received financial and other benefits from the following entities: the Frontiers Foundation; The Federal Trade Commission; The FDA; The Nutrition Science Initiative (NUSI), and numerous additional government, non-profit and for-profit (including publishing, food, restaurant, beverage, and pharmaceutical companies) organizations with interests in obesity, nutrition, and health.

Email: Dallison@UAB.edu

Slides Available on Request

Acknowledgments:

Emily Dhurandhar	Andrew Brown
Tapan Mehta	Kathryn Kaiser
Dwight Lewis	Cynthia Kroeger
Greg Pavela	Patrice Capers
Rositsa Dimova	Keisuke Ejima
J. Michael Oakes	TaShauna Goldsby
Brandon George	Peng Li
Diana Thomas	Kevin Hall
Steve Heymsfield	Nikhil Dhurandhar
Dale Schoeller	Asheley Skinner
John Dawson	Scott Keith

The above named individuals have contributed to some of the research, slides, or ideas to be presented in this talk. Their inclusion here does not necessarily imply that they endorse the views presented. I apologize to anyone neglected.

For key references to examples and explanations, see: Allison et al. Goals in Nutrition Science 2015-2020. *Frontiers in Nutrition*. (2015). <http://journal.frontiersin.org/article/10.3389/fnut.2015.00026/full>

Questions are being raised about the evidential basis for many proposals in our field.

“...research is important to determine which of these well-intentioned policies and programs are working and for whom. ...What seems reasonable to try is not always effective and may even have unanticipated effects.”



Myths: Beliefs held true despite substantial refuting evidence.

Large, rapid weight loss is associated with poorer long-term weight outcomes than is slow, gradual weight loss.

Small sustained changes in energy intake or expenditure will produce large long-term weight changes, e.g., increasing daily intake by 2 potato chips will cause 10 kg of weight gain in 10 years.

Setting realistic goals in weight loss therapy is important because otherwise patients will become frustrated and lose less weight.

Assessing “stage of change” or diet “readiness” is important in helping patients seeking weight loss treatment to lose weight.

Physical education classes as currently provided play an important role in preventing or reducing childhood obesity.

Breastfeeding is protective against obesity.

A bout of sexual activity burns 100 to 300 kcal for each person involved.

A Very Broad Taxonomy of How Science Can Go Wrong

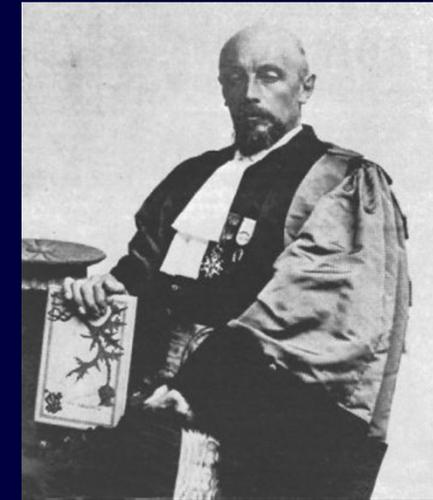
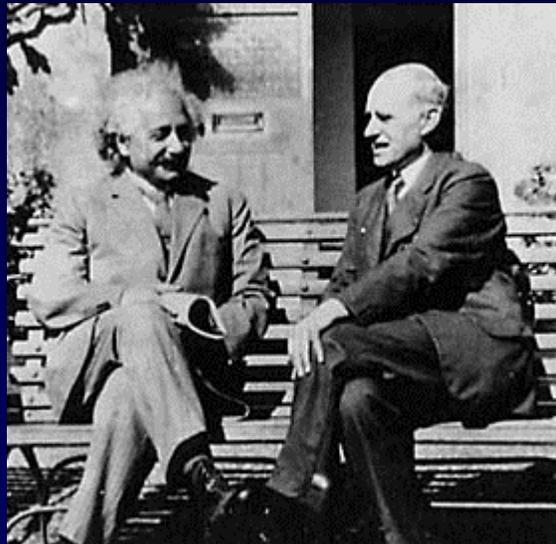
Fraud(?)

Distortion(?)

Gross Error



Gregor Mendel
1822-1884



René Prosper Blondlot
(1849-1930)

AMERICAN
Scientist

Current Issue Past Issues Scientists' Nightstand Multimedia

HOME > SCIENTISTS' NIGHTSTAND > September-October 2008 > Bookshelf Detail

RAISE FONT SIZE A A A VIEW PRINTER-FRIENDLY

BOOK REVIEW

CSI: Mendel
Stephen M. Stigler

ENDING THE MENDEL-FISHER CONTROVERSY. Allan Franklin, A. W. F. Edwards, Daniel J. Fairbanks, Daniel L. Hart and Teddy Soldenfeld. xii + 330 pp. University of Pittsburgh Press, 2008. Cloth, \$70; paper, \$27.95.

“Eddington had needed to make significant corrections to some of the measurements, for various technical reasons, and in the end decided to leave some of the Sobral data out of the calculation entirely.” -

<http://ircamera.as.arizona.edu/NatSci102/NatSci102/text/lightbend.htm>

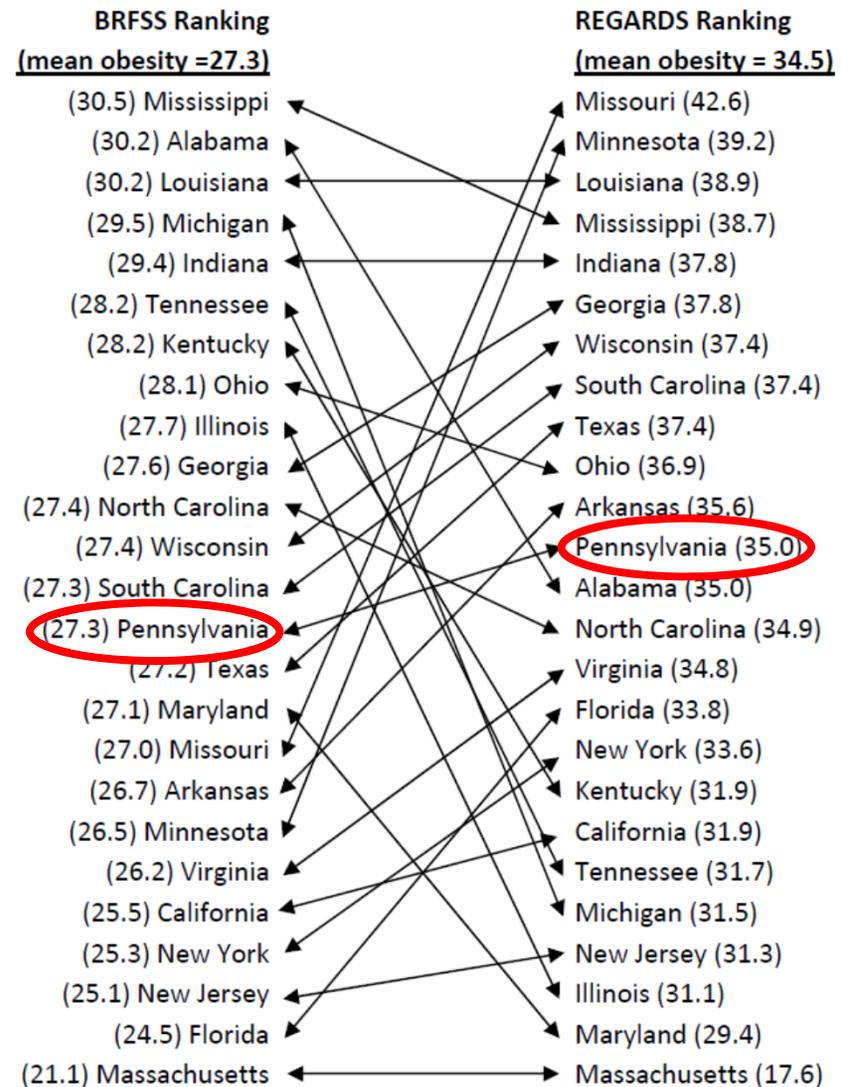
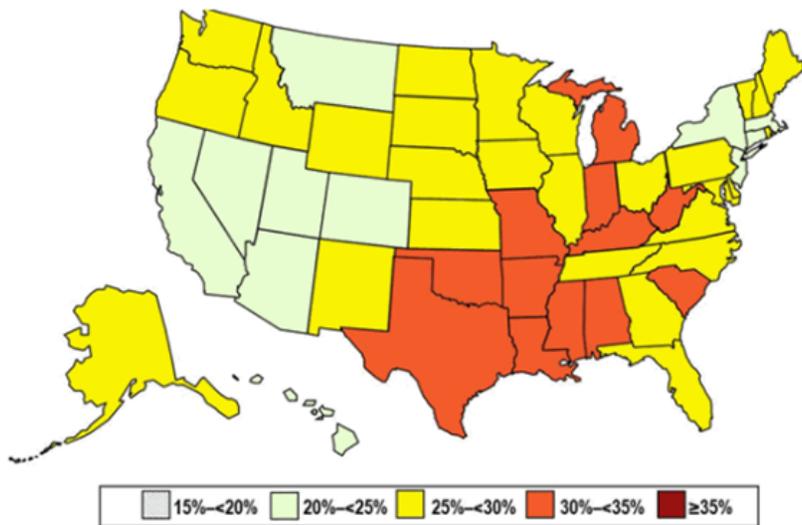
“The rays were detected by a calcium sulfide thread that glowed slightly in the dark when the rays were refracted through a 60-degree angle prism of aluminum.”

<http://skepdic.com/blondlot.html>

Errors of Measurement

Failure to take measurement as seriously as we do in other domains.

Prevalence of Self-Reported Obesity Among U.S. Adults
BRFSS, 2011



Le, A., Judd, S. E., Allison, D. B., Oza-Frank, R., Affuso, O., Safford, M. M., Howard, V. G., & Howard, G. (2014). The Geographic Distribution of Obesity in the US and the Potential Regional Differences in Misreporting of Obesity. *Obesity*, 22,(1), 300–306.

The Measurement Problem

International Journal of Obesity (13 November 2014) | doi:10.1038/ijo.2014.199

Energy balance measurement: when something is not better than nothing

N V Dhurandhar, D Schoeller, A W Brown, S B Heymsfield, D Thomas, T I A Sørensen, J R Speakman, M Jeansonne, D B Allison and the Energy Balance Measurement Working Group

ARTICLE TOOLS

SEARCH PUBMEI

- N V Dhurandhar
- D Schoeller
- A W Brown

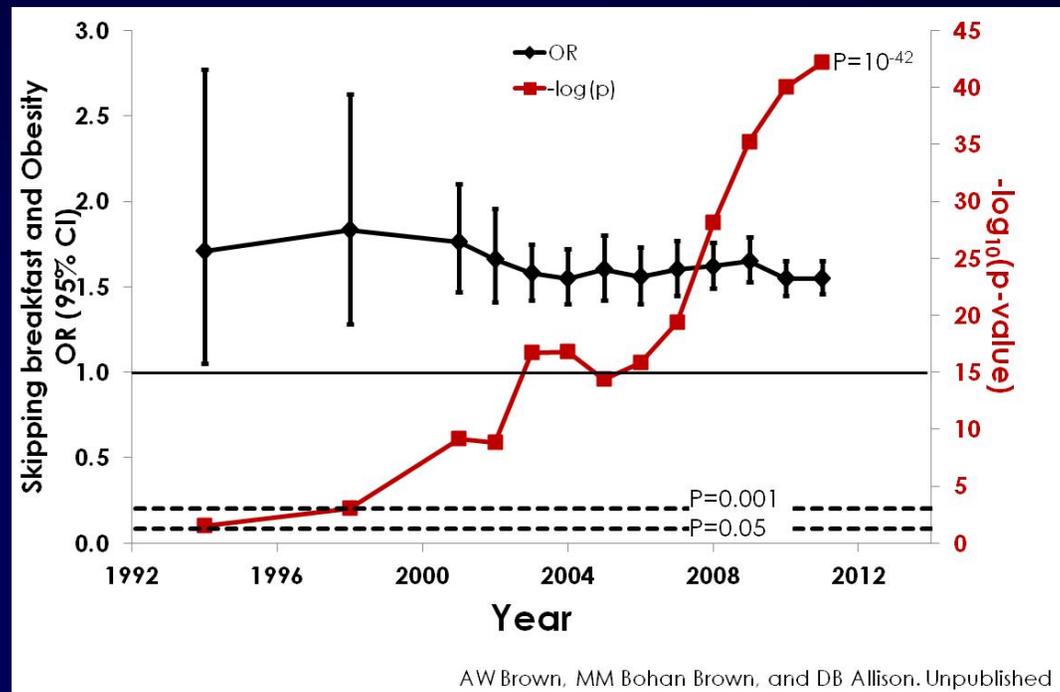
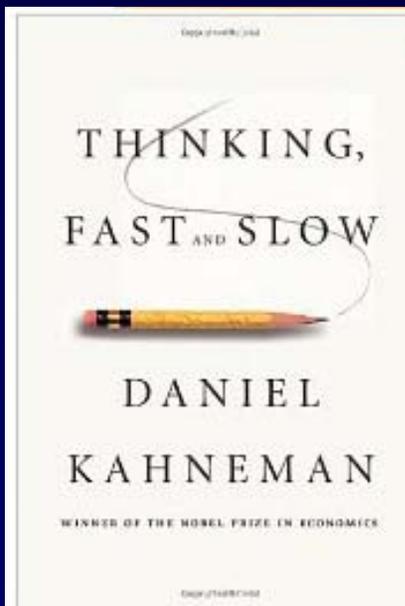
Just because the measurement method one has is the best available, does not make it adequate.

Errors of Design & Resource Allocation

Not Knowing When to Stop: The Mere Exposure Effect



'A reliable way to make people believe in falsehoods is frequent repetition, because familiarity is not easily distinguished from truth. Authoritarian institutions and marketers have always known this fact. ...you do not have to repeat the entire statement of a fact or idea to make it appear true. People who were repeatedly exposed to the phrase "the body temperature of a chicken" were more likely to accept as true the statement that "the body temperature of a chicken is 144" (or any other arbitrary number).'



So, we often devote our journal pages, time, and resources to research that increases belief, instead of to research that increases knowledge.

Brown, A. W., Bohan Brown, M. M., & Allison, D. B. (2013). AJCN.

Does Eating Breakfast Promote Weight Loss?

6 out of 6 RCTs say No.

Study	Sample	Results
Schlundt et al. AJCN 1992	52 Adult Women	No significant main effect for breakfast skipping (marginally significant interaction between treatment assignment and habitual pre-study breakfast habits).
Dhurandhar et al. AJCN 2014	309 Adults	No significant effect of breakfast skipping vs eating treatment assignment (numerically more weight loss in skipping group)
Betts et al. AJCN 2014	33 Adults	No significant effect of breakfast skipping vs eating treatment assignment (numerically more weight loss in skipping group)
Geliebter et al., J Nutritional Science, 2014	36 Adults	Assignment to breakfast skipping led to significantly more weight loss.
St-Onge et al. International J Nutrition, 2015	20 Children	No significant effect of breakfast skipping vs eating treatment assignment (numerically more weight loss in breakfast eating group)
Leidy et al. Obesity, 2015	57 Adolescents	No significant effect on weight gain. A high-protein breakfast over 12 weeks appeared to reduce fat gain, whereas a normal protein breakfast did not.

Errors of Analysis

Confusion Resulting From Testing Against Baseline Differences

Bland and Altman *Trials* 2011, **12**:264
<http://www.trialsjournal.com/content/12/1/264>



METHODOLOGY

Open Access

Comparisons against baseline within randomised groups are often used and can be highly misleading

J Martin Bland^{1*} and Douglas G Altman²

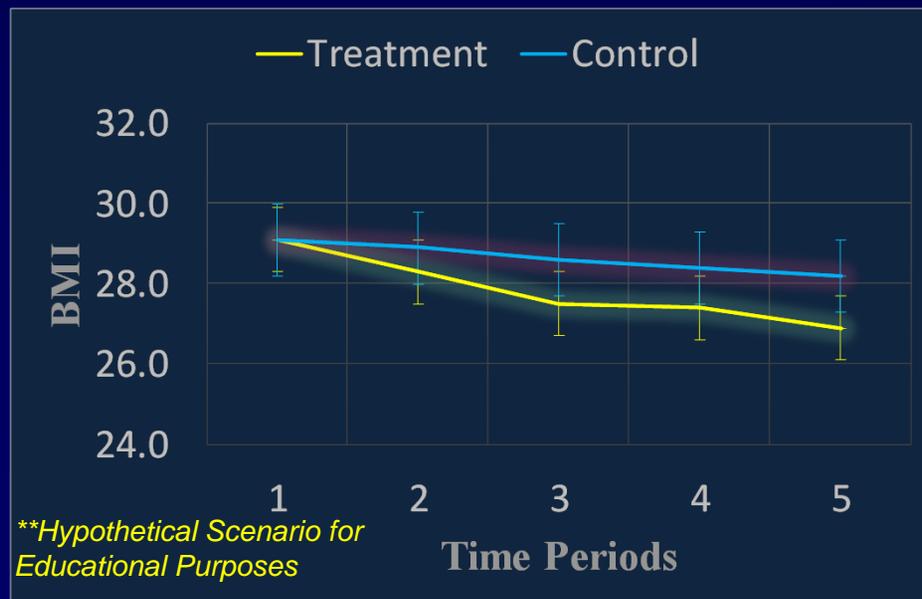
The American Journal of
CLINICAL NUTRITION

HOME | CURRENT ISSUE | EMAIL ALERTS | ARCHIVES | SUBSCRIPTIONS
CUSTOM PUBLICATION FAQ | ASN

© 2015 American Society for Nutrition

**Best (but oft forgotten) practices:
testing for treatment effects in
randomized trials by separate
analyses of changes from baseline in
each group is a misleading approach¹**

J Martin Bland^{2,*} and Douglas G Altman³



- “Randomised groups should be compared directly by two-sample methods and separate tests against baseline are highly misleading.”
- Pre-Post
 - Treatment $p < .05$
 - Control $p > .05$
- Between Groups
 - $p > .05$
- Misleading? Yes!
- With two groups, the false positive rate for declaring a difference between groups can be as high as 50%
 - Far higher than 5%!
- Equivalent to flipping two coins and declaring them different if they land on different sides

Inappropriate Testing Against Baseline Levels in Parallel RCT

Disability and Rehabilitation

Home All Issues Current Issue Early Online Aims & Scope Editorial Board Instructions for Authors

Issue TOC | Previous Article | Next Article [SHARE](#)

With your contact details, **David Miller** of expertise!

 Sign up for eAlerts

 Request a call back

 Publish with us

Letter to the Editor

Conclusion of “Nordic walking for geriatric rehabilitation: a randomized pilot trial” is based on faulty statistical analysis and is inaccurate

Posted online on January 19, 2015. (doi:10.3109/09638288.2014.1002580)

[David B. Allison](#), [Michelle S. Williams](#), [Gregory A. Hand](#), [John M. Jakicic](#), and [Kevin R. Fontaine](#)

[HTML](#)
[PDF \(100 KB\)](#)
[PDF Plus \(106 KB\)](#)
[Reprints](#)
[Permissions](#)

¹Department of Biostatistics, University of Alabama at Birmingham, Birmingham, AL, USA,
²Nutrition Obesity Research Center, University of Alabama at Birmingham, Birmingham, AL, USA,
³Office of Energetics, University of Alabama at Birmingham, Birmingham, AL, USA,
⁴Division of Preventive Medicine, University of Alabama at Birmingham, Birmingham, AL, USA,
⁵School of Public Health, West Virginia University, Morgantown, WV, USA,

<http://informahealthcare.com/doi/abs/10.3109/09638288.2014.1002580>

Errors in statistical analysis and questionable randomization lead to unreliable conclusions



Brandon J George¹, Andrew W Brown^{1,2}, David B Allison^{1,2,3}

We read with interest the paper, “The effect of food service system modifications on staff body mass index in an industrial organization”[1]. We noticed several substantial issues with data and calculations, calling into question the randomized nature of the study and validity of analyses.

The distribution of baseline weight was significantly different between groups (p-value = “0.00”). We replicated the test using reported means and standard deviations (SDs) and obtained a p-value of approximately 1.9×10^{-17} . It is

If every one of the roughly 7 billion persons on the planet each did their own RCT and in each of these RCTs tested 1,000 separate variables for baseline differences, and we used a Bonferroni correction to adjust for the (1000*7 billion) tests done, a p-value of 10^{-17} would still be significant.

Considering that the reported findings are essentially impossible given the stated study design, we encourage the authors to explain the treatment allocation and make the raw data available, or the journal to act according to the Committee on Publication Ethics[5] in situations where findings are unreliable.

Due to lack of author cooperation to provide the data used in the article “The effect of food service system modifications on staff body mass index in an industrial organization”, it is decided to remove the article from journal.

Meta-Analysts Often Err in Effect Size Calculation

“Distributions of standardized effect sizes arising in meta-analyses show that in domains of substantive research interest, it is unusual for this magnitude measure to be as big as 1.0, quite rare for it to be as big as 1.4, and extraordinary for it to be as big as 2.0.”

[J Consult Clin Psychol](#). 1996 Jun;64(3):513-6.

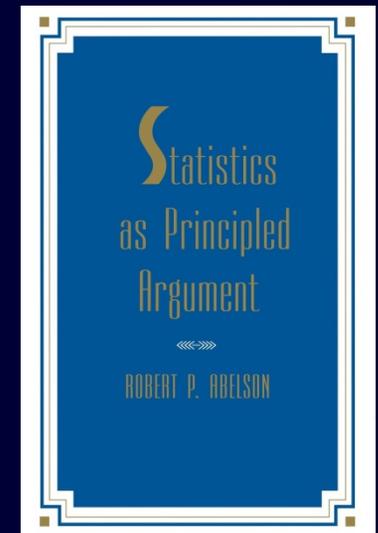
Hypnosis as an adjunct to cognitive-behavioral psychotherapy for obesity: a meta-analytic reappraisal.

Allison DB¹, Faith MS.

⊕ Author information

Abstract

I. Kirsch, G. Montgomery, and G. Sapirstein (1995) meta-analyzed 6 weight-loss studies comparing the efficacy of cognitive-behavior therapy (CBT) alone to CBT plus hypnotherapy and concluded that "the addition of hypnosis substantially enhanced treatment outcome" (p.214). Kirsch reported a mean effect size (expressed as d) of 1.96. After correcting several transcription and computational inaccuracies in the original meta-analysis, these 6 studies yield a smaller mean effect size (.26). Moreover, if 1 questionable study is removed from the analysis, the effect sizes become more homogeneous and the mean (.21) is no longer statistically significant. It is concluded that the addition of hypnosis to CBT for weight loss results in, at most, a small enhancement of treatment outcome.



Effect Size Calculations



Meta Confusion about Glucomannan

Maybe you've heard of glucomannan — a so-called "super fiber" that Dr. Oz hypes as "nature's skinny sponge." Maybe you read a systematic review and meta-analysis in *Nutrition* of the effect of glucomannan on body weight that concluded it "may help reduce body weight." As it turns out, that analysis was wrong.

<http://conscienhealth.org/2015/03/meta-confusion-about-glucomannan/>

Analysis of Cluster Randomized Trials – A Major Source of Confusion

Retraction Watch

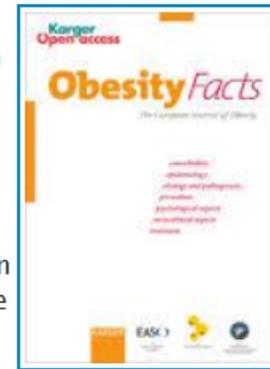
Tracking retractions as a

When should a paper be retracted? A tale from the obesity literature

with one comment

In our line of work, we see it all — [mega-corrections](#) that don't quite rise to the level of retraction, letters to the editor that point out seemingly fatal flaws in papers that remain untouched, and studies retracted for what seem like minor reasons. It can make you wonder what makes a paper worthy of a retraction. A recent case in an obesity journal may not provide a definitive answer, but it gives us a lot to chew on.

Here's the story: In September 2013, [Rosely Sichieri](#) and a colleague from the State University of Rio de Janeiro submitted an article to [Obesity Facts](#), "Unbalanced Baseline in School-Based Interventions to Prevent Obesity: Adjustment Can Lead to Bias?" The article examined statistical issues in randomized controlled trials of school-based weight loss programs. Peer reviewers said the paper needed major revisions before it could be accepted; the authors revised the paper enough in a second draft, submitted in November 2013, that the original reviewers accepted it. The paper was [published in June 2014](#).



Then, in September 2014, a group of authors including [David Allison](#) of the University of Alabama, Birmingham, and colleagues from Clemson, Thomas Jefferson, and the University of Minnesota, wrote a critical [letter that was published in the journal in April](#). The letter, according to a [just-published editorial](#):

“ expressed fundamental and severe criticism with regard to the above mentioned article that culminated in the conclusion that the article should be retracted.

More specifically, the letter argued that by criticizing some of the statistical tools used in these types of studies, the authors dissuade scientists from employing “legitimate power-enhancing analytic methods.” Here's [more from the letter itself](#):

Errors of Reporting

Misleading Visual Representation?



From D. Huff (1954). *How to Lie with Statistics*.

The NEW ENGLAND JOURNAL OF MEDICINE

HOME ARTICLES & MULTIMEDIA ▾ ISSUES ▾ SPECIALTIES & TOPICS ▾ FOR AUTHORS ▾

ORIGINAL ARTICLE

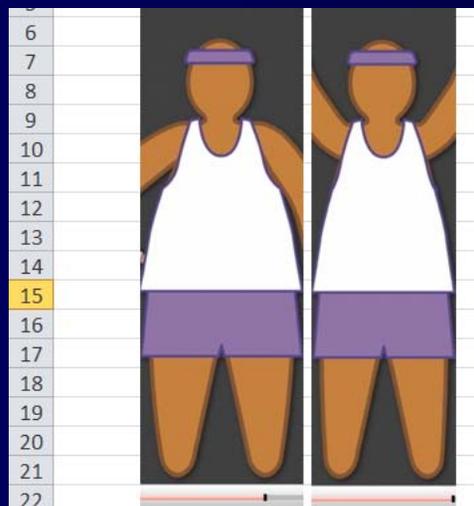
A Randomized, Controlled Trial of 3.0 mg of Liraglutide in Weight Management

Xavier Pi-Sunyer, M.D., Arne Astrup, M.D., D.M.Sc., Ken Fujioka, M.D., Frank Greenway, M.D., Alfredo Halpern, M.D., Michel Krempf, M.D., Ph.D., David C.W. Lau, M.D., Ph.D., Carel W. le Roux, F.R.C.P., Ph.D., Rafael Violante Ortiz, M.D., Christine Bjorn Jensen, M.D., Ph.D., and John P.H. Wilding, D.M. for the SCALE Obesity and Prediabetes NN8022-1839 Study Group

N Engl J Med 2015; 373:11-22 | July 2, 2015 | DOI: 10.1056/NEJMoa1411892

Result: The investigators report only a **7.3% reduction in WC** in the liraglutide treated group.

From NEJM Video Describing the Results.



Percent Reduction in Horizontal Width = **11.4%**.

See PubMed Commons comment at <http://www.ncbi.nlm.nih.gov/pubmed/26132939>

Conclusion Spinning: Effect of the Healthy Schools Program on Prevalence of Overweight and Obesity in California Schools, 2006–2012

Headline



“Now, as the Alliance celebrates its 10-year anniversary, a new peer-reviewed study confirms we are delivering on our mission of reducing the prevalence of childhood obesity.”
“an important means of supporting schools in reducing obesity.”

Study

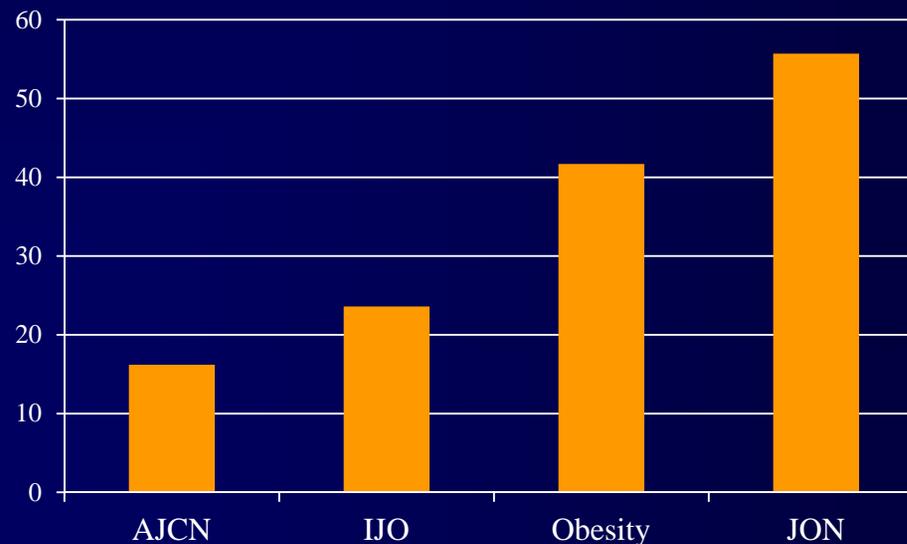
- Analyses showed no difference between Healthy School Program schools and control schools in overweight and obesity prevalence
- Healthy School Program appears to be an important means of supporting schools in reducing obesity...

<http://www.wassermanfoundation.org/news/new-study-shows-that-combating-childhood-obesity-in-schools-works/>
http://www.cdc.gov/pcd/issues/2015/15_0020.htm

Use of Causal Language in Observational Studies of Obesity and Nutrition

Stacey S. Cofield^a Rachel V. Corona^b David B. Allison^{a,c}

Percent of articles
using unjustified
causal language.



Curious Errors & the Power of Simple Mathematics

• 66 •

World Journal of Acupuncture-Moxibustion (WJAM)
Vol. 25, No.1, 30th Mar. 2015



Letters

Letter to the Editor: Exceptional Data in Paper on “The effect of meridian massage on BM, BMI, WC and HC in simple obesity patients: a randomized controlled trial”

14, November, 2014

Dear Editor:

Given the tremendous need for effective weight loss treatments, we read with interest the paper by Yan et al.^[1] and were intrigued by the reported finding that a form of massage produced weight loss in a randomized controlled trial.

Upon closer inspection, we were struck by the magnitude of the results. Specifically, in an 8-week period, the treatment (massage) group lost over 7 kg, more than 9% of their baseline body weight, and 3.7 kg more than the control group lost. Such results rival those of all available obesity treatment procedures except surgery and very

Using approximations involving geometric means, we were able to show that this would have required a growth in height of ~6 cm.

No, Adults do not grow 6 cm in height in 8 weeks.

Errors of Interpretation

Math Problems

Modeling Potential Effects of Reduced Calories in Kids' Meals with Toy Giveaways

Maysoun Y. Freij, PhD, MPH,¹ Randall L. Sell, ScD,² Anne K. Bozack, MPH,¹
Linda J. Weiss, PhD,¹ and Ana C. Garcia, MPA³

calculation is based on the fact that a pound of body fat equals approximately 3500 calories. Therefore, a child who eats a kids' meal with a toy twice per week would avoid approximately 132 calories per week if he or she consumed an NPLAN-like regulated kids' meal in place of an unregulated kids' meal. This equals approximately 6864 calories per year (132 calories \times 52 weeks) or approximately two pounds per year averted. A lower calorie limit

nance). Calculations in the model include children who are estimated to eat fast food four or more times per day. Though rare, such children could theoretically expect to avert weight gain of 27 pounds per year if an NPLAN-like toy ordinance were fully implemented.

<http://www.ncbi.nlm.nih.gov/pubmed/25496036> (original article retracted).

From Kevin Hall:
"I used the 'rule of thumb' equations relating excess body weight to excess energy intake ... [from PMID: 24349967]. I came up with about 0.5 kg of excess weight ... by increasing daily intake by 19 kcal/d from 7 to 12 years."

So, the original investigators were off by a factor of about 9.

Fruit and Vegetable Consumption and Changes in Anthropometric Variables in Adult Populations: A Systematic Review and Meta-Analysis of Prospective Cohort Studies. PLoS One. 2015 Oct 16;10(10):e0140846.

“No significant changes could be observed for combined fruit and vegetable consumption or vegetable consumption.”

“Higher intake of fruits was inversely associated with weight change (decrease) (beta-coefficient per 100-g increment, -13.68 g/year; 95% CI, -22.97 to -4.40).”

$$\frac{\frac{100 \text{ g Fruit}}{d} \times \frac{365 d}{yr}}{\frac{-13.68 \text{ g BW}}{d} \times \frac{1 \text{ kg}}{1000 \text{ g}}} = \mathbf{2.67 \text{ tonnes of fruit per 1 kg weight loss per year}}$$

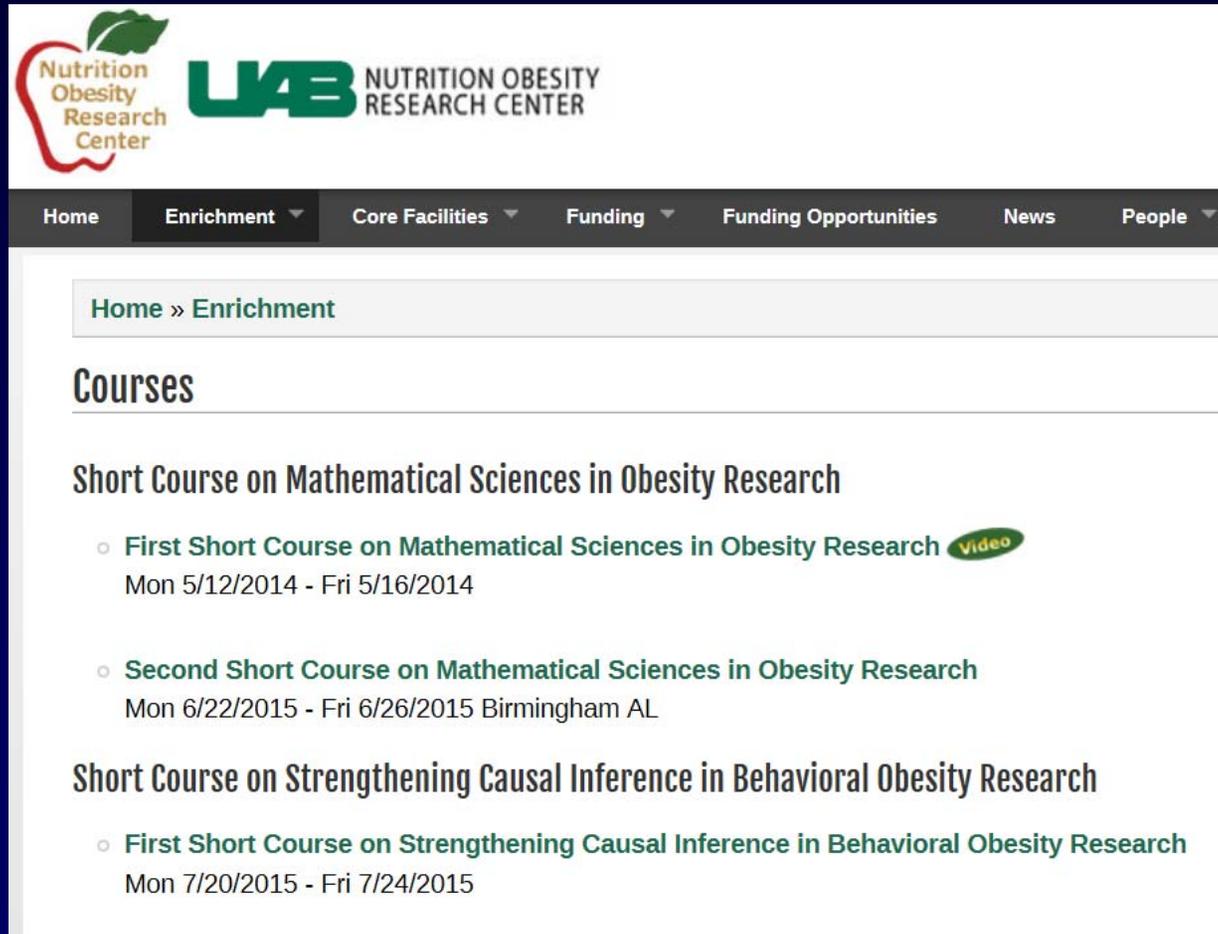
A serving of apple is 100 grams and 47 kcal. Based on this estimate, a person would need to eat about 3431 kcal of apples per day to lose 1 KG per year. Given that the average person consumes less total energy than that per day, how can this work?!

“...these findings have public health relevance and support all initiatives to increase fruit and vegetable intake.”

Thanks to Andrew Brown and Kathryn Kaiser for calculations.

Going Forward

UAB NORC Courses



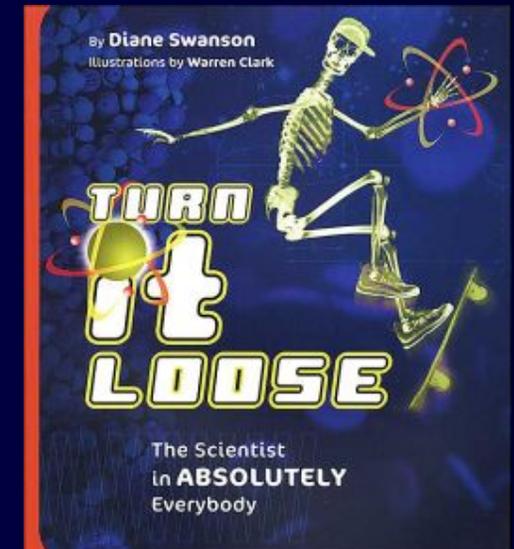
The screenshot shows the website for the UAB Nutrition Obesity Research Center (NORC). The header includes the NORC logo and navigation links: Home, Enrichment, Core Facilities, Funding, Funding Opportunities, News, and People. The main content area is titled "Courses" and lists three short courses:

- Short Course on Mathematical Sciences in Obesity Research**
 - **First Short Course on Mathematical Sciences in Obesity Research** 
Mon 5/12/2014 - Fri 5/16/2014
 - **Second Short Course on Mathematical Sciences in Obesity Research**
Mon 6/22/2015 - Fri 6/26/2015 Birmingham AL
- Short Course on Strengthening Causal Inference in Behavioral Obesity Research**
 - **First Short Course on Strengthening Causal Inference in Behavioral Obesity Research**
Mon 7/20/2015 - Fri 7/24/2015

<http://www.norc.uab.edu/courses/shortcourse>

Going Forward

- Treat obesity as a science as meriting the same rigor as any other science.
- Don't believe everything you read. Go back to the original source and read yourself.
- Recognize that short-term studies, studies of intermediary endpoints, and observational studies all have their place, but should not be our stopping points or bases for overreaching conclusions.
- Develop and fund a set of 'meta-methods' (e.g. clinical trials registries, CONSORT statements, public data sharing, etc.) which will collectively buttress/ensure the implementation of the fundamental scientific methods that already exist.
- Teach our students and ourselves that unfailingly pursuing truth through science is not a job, but a discipline, a vocation, and a privilege.



Come visit us in Alabama and we can talk some more
on the trail.



謝謝您

Cheaha Mountain
Photo courtesy Rohan Dhurandhar.

Some References and Extra Slides

Distortions In The Mass Media

Headline: Skipping breakfast to lose weight makes you fatter - and far more likely to raid the vending machine.

Study: Presentation at proceedings; MRI results and observations of how much subjects ate at lunch after skipping breakfast. No body weight, no vending machines.

Headline: How Calico cats could help cure obesity.

Study: Conference abstract involving X-inactivation in mouse cells – no cats or obesity involved

Headline: Diet Soda Leaves Your Gut Unsatisfied, Contributes To Obesity.

Study: Assessment of metabolic responses to different carbohydrates loads of bacteria in vitro. Humans, diet soda, and obesity were not studied.

Headline: US Farm Subsidy Policies Contribute To Worsening Obesity Trends, Study Finds.

Paper: There is no study – paper is an author's commentary/review on farm subsidies.

Headline: Drinking 5 cups of coffee everyday may lead to obesity: study.

Headline: Wrong amount of coffee could kill you.

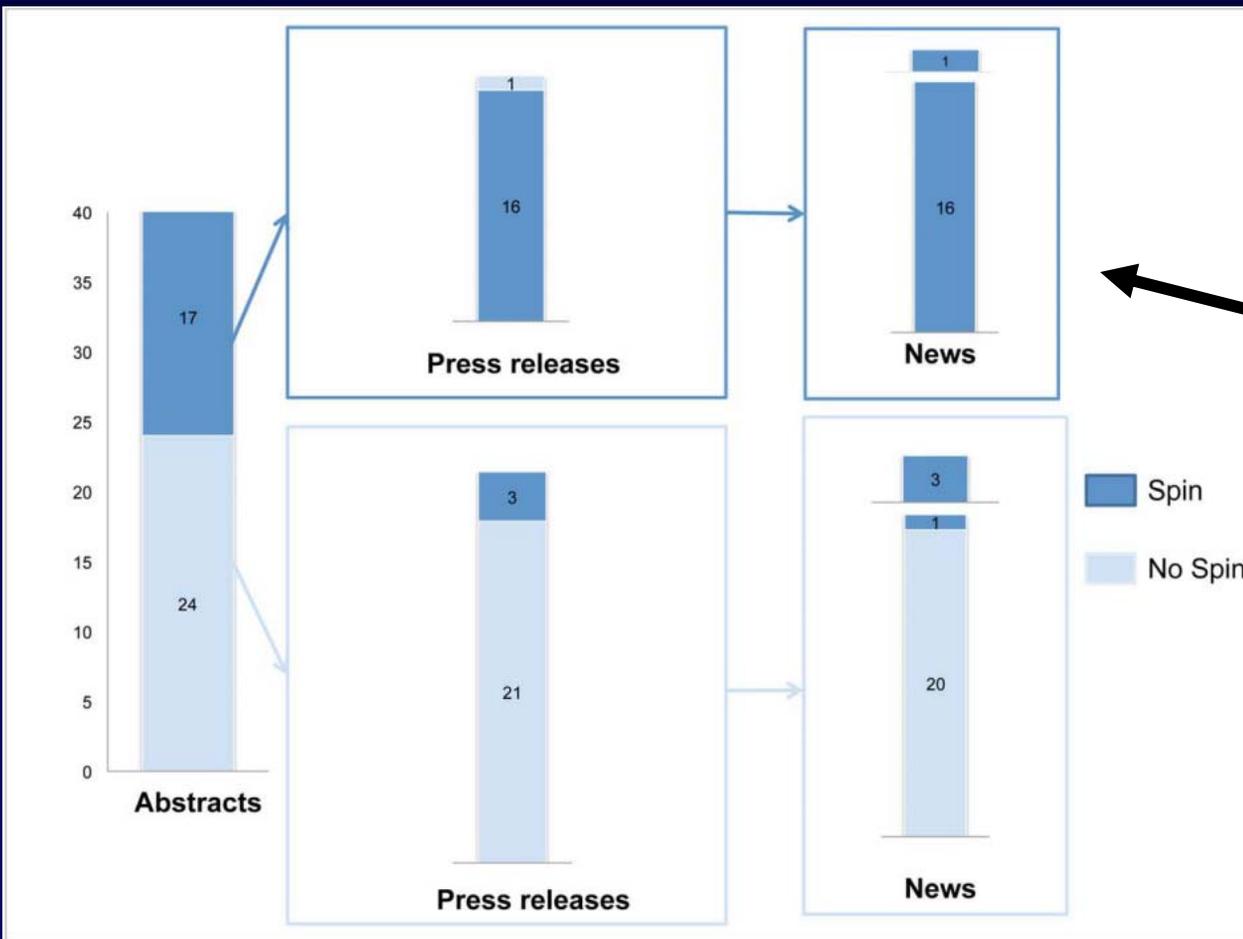
Study: A study of mice, involving a substance found in coffee, but no coffee, showed no significant weight gain, and reported no deaths.

For references, see: ObesityandEnergetics.org.

Perpetuation of Spin

Misrepresentation of Randomized Controlled Trials in Press Releases and News Coverage: A Cohort Study

Amélie Yavchitz^{1,2,3}, Isabelle Boutron^{1,2,3*}, Aida Bafeta^{1,2,3}, Ibrahim Marroun⁴, Pierre Charles⁴, Jean Mantz⁵, Philippe Ravaud^{1,2,3}



Spin: reporting strategies emphasizing the beneficial effect of the experimental treatment

Spin perpetuates throughout the reporting

The Randomization That Wasn't

Short paper

Open Access

Improving perceptions of healthy food affordability: results from a pilot intervention

Lauren K Williams^{*}, Gavin Abbott, Lukar E Thornton, Anthony Worsley, Kylie Ball and David Crawford

* Corresponding author: Lauren K Williams Lauren.Williams@mcri.edu.au

International Journal of Behavioral Nutrition and Physical Activity 2014, **11**:33

doi:10.1186/1479-5868-11-33

This article also has 0 [comment](#) on PubMed Commons [?](#)

Erratum

Lauren Williams (2014-12-01 13:30) Murdoch Childrens Research Institute

In the methods section of the manuscript we state "Consenting participants were randomised to either intervention or control group".

We would like to ammend and elaborate this statement with the following:

"Consenting participants were allocated to either intervention or control group. Participants were initially (N=29) consecutively allocated to the intervention group to ensure adequate numbers in the intervention condition, after which time participants were allocated to intervention (N=13) and control groups (N=26). Group allocation was not based on any pre-conceived factors."

clinicalobesity

Perspective

Stagnation in the clinical, community and public health domain of obesity: the need for probative research

K. Casazza¹ and D. B. Allison²

Article first published online: 1 NOV 2012

DOI: 10.1111/j.1758-8111.2012.00052.x

© 2012 The Authors. Clinical Obesity © 2012
International Association for the Study of Obesity

Issue



Clinical Obesity

Volume 2, Issue 3-4, pages 83
–85, June-August 2012

NIH seems interested: “Pragmatic Research in Healthcare Settings to Improve Diabetes and Obesity Prevention and Care (R18).” <http://grants.nih.gov/grants/guide/pa-files/PAR-15-157.html#sthash.HtuU1cpk.dpuf>

Widespread Prevalence of Misleading Pre/Post Analysis

- Cooking oil replacement
 - <http://online.liebertpub.com/doi/abs/10.1089/dia.2013.0178>
- Exercise regimens in children
 - http://www.kjp.or.kr/upload/JustAccepted_KJP-13-254.pdf
 - <http://www.sciencedirect.com/science/article/pii/S0190740913003903>
- Mobile device intervention in minority girls
 - <http://www.sciencedirect.com/science/article/pii/S0749379713006946>
- Liquid vs solid intake
 - <http://www.ncbi.nlm.nih.gov/pubmed/10878689>
 - <http://www.ncbi.nlm.nih.gov/pubmed/21720441>
- Yoga as weight management
 - <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4278132/?report=printable>
- Enteral nutrition in Crohn's disease patients
 - <http://www.ncbi.nlm.nih.gov/pubmed/25632205>
- Nordic walking for physical therapy
 - <http://informahealthcare.com/doi/abs/10.3109/09638288.2012.717580>
- Meal size vs frequency
 - <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4265261/>
- Flaxseed diets
 - <http://www.nutritionj.com/content/14/1/5>
- Vegetable juice diets
 - <http://www.lipidworld.com/content/13/1/102>

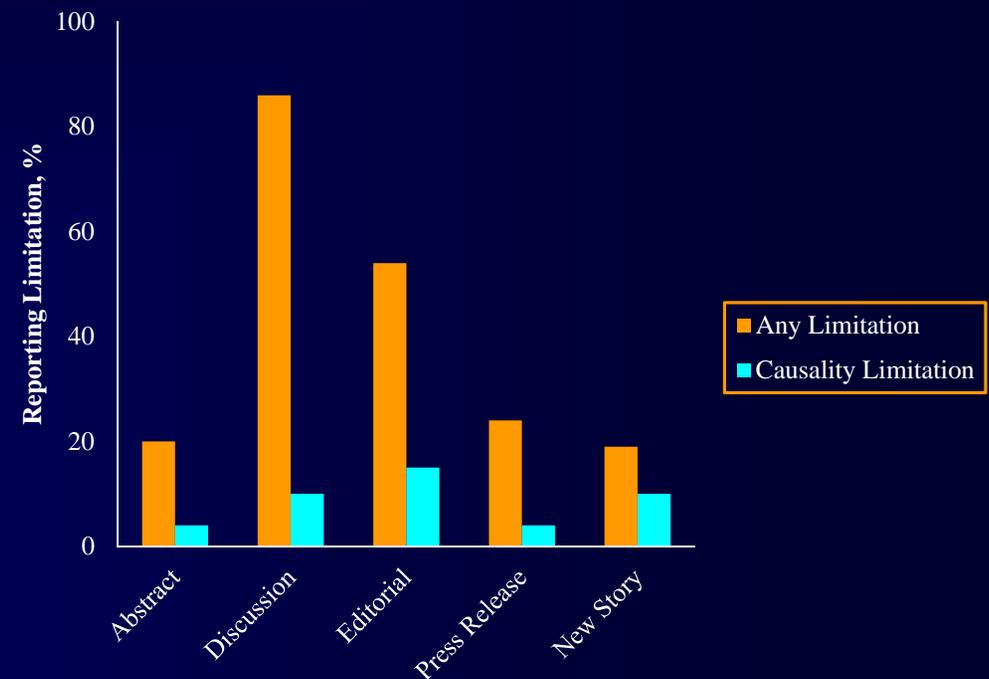
cRCT references

Title	Link	Type
Best (but often forgotten) practices: designing, analyzing, and reporting cluster randomized controlled trials	http://ajcn.nutrition.org/content/early/2015/05/27/ajcn.114.105072.abstract	Tutorial
The Assertion that Controlling for Baseline (Pre-Randomization) Covariates in Randomized Controlled Trials Leads to Bias Is False	http://www.karger.com/Article/FullText/381434	Correcting Letter
Comment on “School-Based Obesity Prevention Intervention in Chilean Children: Effective in Controlling, but not Reducing Obesity”	http://www.hindawi.com/journals/job/2015/183528/	Correcting Letter
Comment on “Intervention Effects of a School-Based Health Promotion Programme on Obesity Related Behavioural Outcomes”	http://www.hindawi.com/journals/job/2015/708181/	Correcting Letter

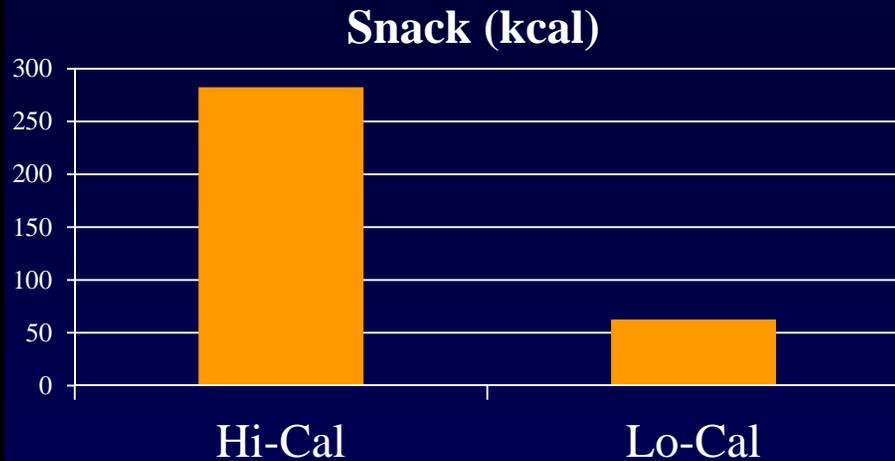
Reporting of Limitations of Observational Research

- Observational research is abundant, but frequently generates unreliable findings
- 583 articles were assessed for mentioning any limitation regarding causality versus was an explicit statement “causality could not be inferred”
- Explicit statements causality were rarely mentioned in the abstract and press releases

Reporting of Limitations of Observational Research



Short-Term Studies Are Insufficient: Example - *Learned Compensation in Humans*



Appetite, 1989, 12, 95-103

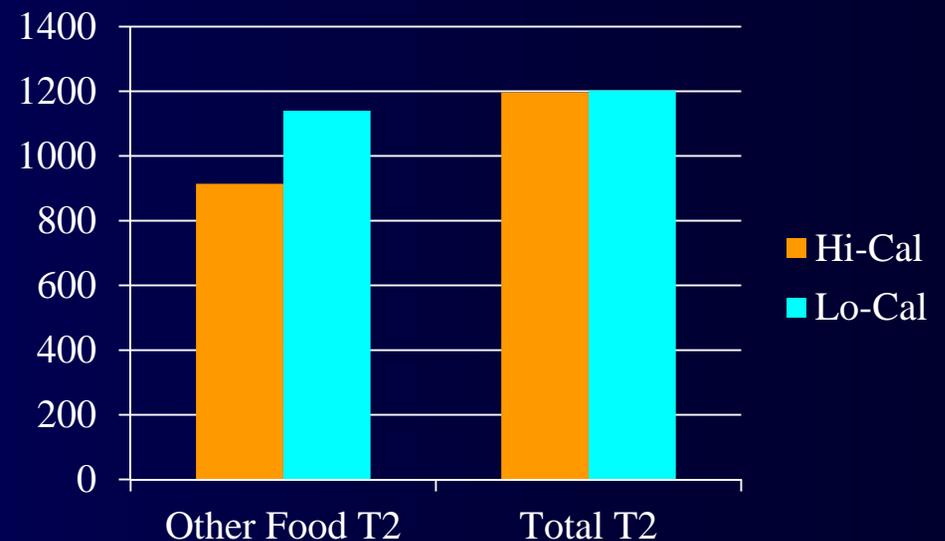
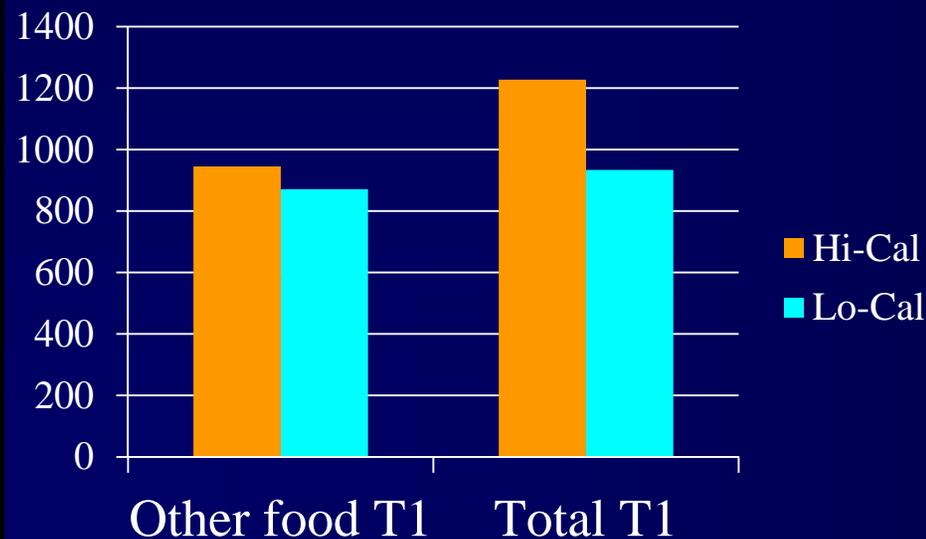
Learned Caloric Adjustment of Human Intake

JEANINE LOUIS-SYLVESTRE, ALAIN TOURNIER,
PHILIPPE VERGER, MICHÈLE CHABERT and
BRIGITTE DELORME

Laboratoire de Neurobiologie de la Nutrition E.P.H.E., Université Paris 6

JOSEPH HOSSENLOPP

Ecole Nationale des Sciences de l'Industrie Alimentaire



Conclusion Spinning

The impact of area-based initiatives on physical activity trends in deprived areas; a quasi-experimental evaluation of the Dutch District Approach

Daniëlle Kramer^{1*}, Mariël Droomers¹, Birthe Jongeneel-Grimen¹, Marleen Wingen², Karien Stronks¹ and Anton E Kunst¹

* Corresponding author: Daniëlle Kramer d.kramer@amc.uva.nl

For all author emails, please [log on](#).

► Author Affiliations

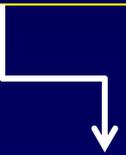
International Journal of Behavioral Nutrition and Physical Activity 2014, **11**:36
doi:10.1186/1479-5868-11-36

Published: 11 March 2014

Wow, that's a lot of null.



But, wait...



Results

Deprived target districts showed a significantly positive change in walking trend between the pre-intervention and intervention period. The trend change in the deprived target districts was significantly larger compared to the rest of the Netherlands, but not compared to other deprived districts. For cycling and sports, neither deprived districts nor control districts showed a significant trend change. For all leisure-time PA outcomes, trend changes were not related to the intensity of environmental interventions in the deprived target districts.

Conclusion

Some evidence was found to suggest that ABIs like the District Approach have a positive impact on leisure-time PA in deprived districts, regardless of the intensity of environmental interventions.



Int J Obes (Lond). Author manuscript; available in PMC 2010 Jul 1.

PMCID: PMC2815336

Published in final edited form as:

NIHMSID: NIHMS155044

[Int J Obes \(Lond\). 2010 Jan; 34\(1\): 84–83.](#)

Published online 2009 Dec 1. doi: [10.1038/ijo.2009.239](https://doi.org/10.1038/ijo.2009.239)

White Hat Bias: Examples of its Presence in Obesity Research and a Call for Renewed Commitment to Faithfulness in Research Reporting

[Mark B Cope](#), PhD

Department of Pharmacology and Toxicology, School of Medicine, University of Alabama at Birmingham, Birmingham, AL, USA. Email: mbcope@uab.edu

[David B Allison](#), PhD

Department of Biostatistics; School of Public Health; and Clinical Nutrition Research Center, University of Alabama at Birmingham, Birmingham, AL, USA. Email: Dallison@uab.edu

Unreasonable Extrapolation

The Study Abstract

Assessing non-digestible compounds in apple cultivars and their potential as modulators of obese faecal microbiota in vitro. Food Chem. 2014 Oct 15;161:208-15.

“The health benefits of apple bioactive compounds have been extensively reported. However, only few studies have focused on bioactive compounds that are not absorbed and metabolised during gastrointestinal digestion and can induce changes in microbial populations of faeces. We have characterised Braeburn, Fuji, Gala, Golden Delicious, Granny Smith, McIntosh and Red Delicious cultivars and found significant differences for extractable phenolics (1.08-9.2mg/g) non-extractable proanthocyanidins (3.28-5.7mg/g), and dietary fibre (20.6-32.2%) among cultivars with Granny Smith having the highest contents.

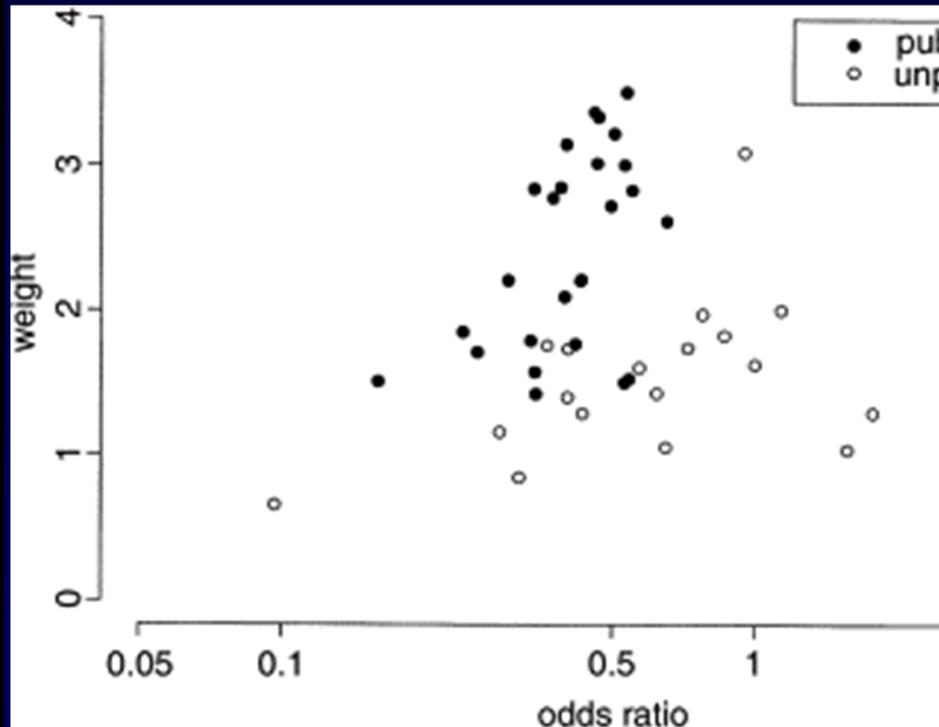
Granny Smith was used after in vitro digestion for fermentation of faeces from diet-induced obese mice. Results showed that relative abundances of Firmicutes, Bacteroidetes, Enterococcus, Enterobacteriaceae, Escherichia coli, and Bifidobacterium in apple cultured faeces tended to resemble the abundance in faeces from lean mice with increased trend in the production of butyric acid. These results suggest that apple non-digestible compounds might help to re-establish a disturbed microbiota balance in obesity.”



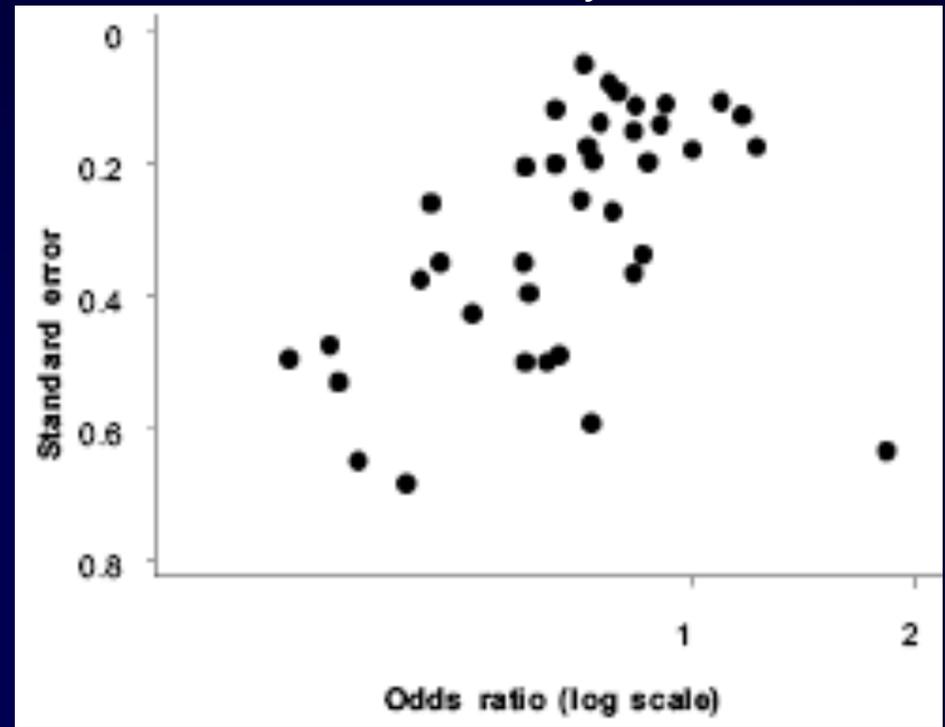
The screenshot shows the Medical Daily website interface. At the top, the site name 'Medical Daily' is displayed in a large blue font. Below it is a navigation bar with links for 'HOME', 'US / WORLD', 'CONSUMER NEWS', 'POLICY / BIZ', and 'SCIENCE / TE'. A prominent advertisement for 'ampyra' is featured, with the text 'Walk on' and 'Ask your doctor about the AMPYRA FREE* TRIAL'. Below the ad, the article title 'An Apple A Day Keeps The Fat Away; Granny Smith's Fiber And Polyphenol Count Promote Overall Health' is shown, along with the author 'Samantha Olson' and the date 'Sep 30, 2014 11:58 AM EDT'. Social media sharing icons for Facebook, Twitter, LinkedIn, Google+, and a plus sign are visible, along with a '34' comment count. The article text begins with 'The saying "an apple a day keeps the doctor away" may not be that far from the truth when it comes to treating the obesity epidemic. Researchers from Washington State University cut open an assortment of apples, took a closer look at its

Distortions Via Publication Bias

Simulated Data



WHO Report on Breast-Feeding and Obesity



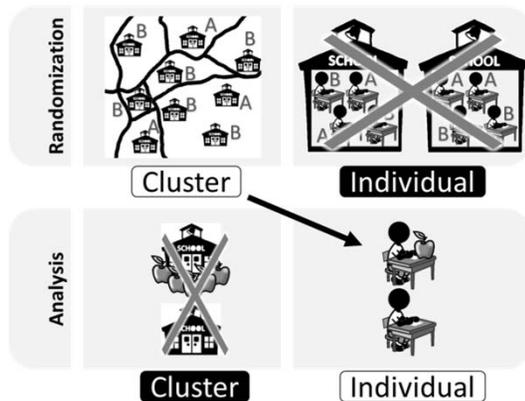
Norma Terrin, Christopher H. Schmid, Joseph Lau
Journal of Clinical Epidemiology, Volume 58,
Issue 9, September 2005, Pages 894–901
<http://dx.doi.org/10.1016/j.jclinepi.2005.01.006>

WHO report: “Evidence of the Long-Term Effects of Breastfeeding: Systematic Reviews and Meta-Analysis”
(http://www.who.int/child-adolescent-health/New_Publications/NUTRITION/ISBN_92_4_159523_0.pdf)

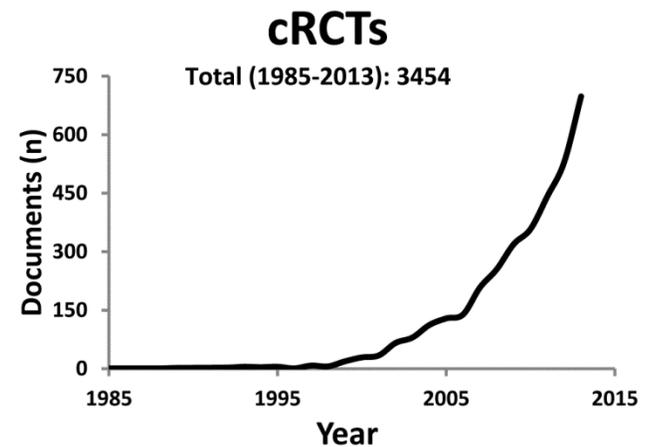
Cluster Randomized Controlled Trials: An Opportunity for Improvement

What They Are

- Randomize at group level
- Measure and analyze at individual level



Increasingly Used



Special Design and Analysis Issues

- Intraclass correlation (ICC)
- Power calculations
- Cluster size versus number of clusters
- Defining clusters
- Statistical analysis
- Reporting guidelines

Often Badly Botched

- Zero degrees of freedom
- Advising against baseline covariates
- Ignoring clustering in analysis
- Misunderstanding cluster levels
- Mistaking observational unit for experimental unit

See: Brown et al. AJCN 2015 doi: 10.394/ajcn.114.105072

cRCT references at end of slide set

Choice of Studies: Over-reliance on Observational Studies

<i>ID no.</i>	<i>Pos.</i>	<i>Neg.</i>	<i>No. of claims</i>	<i>Treatment(s)</i>	<i>Reference</i>
1	0	1	3	Vit E, beta-carotene	<i>NEJM</i> 1994; 330 : 1029–1035
2	0	3	4	Hormone Replacement Ther.	<i>JAMA</i> 2003; 289 : 2651–2662, 2663–2672, 2673–2684
3	0	1	2	Vit E, beta-carotene	<i>JNCI</i> 2005; 97 : 481–488
4	0	0	3	Vit E	<i>JAMA</i> 2005; 293 : 1338–1347
5	0	0	3	Low Fat	<i>JAMA</i> . 2006; 295 : 655–666
6	0	0	3	Vit D, Calcium	<i>NEJM</i> 2006; 354 : 669–683
7	0	0	2	Folic acid, Vit B6, B12	<i>NEJM</i> 2006; 354 : 2764–2772
8	0	0	2	Low Fat	<i>JAMA</i> 2007; 298 : 289–298
9	0	0	12	Vit C, Vit E, beta-carotene	<i>Arch Intern Med</i> 2007; 167 : 1610–1618
10	0	0	12	Vit C, Vit E	<i>JAMA</i> 2008; 300 : 2123–2133
11	0	0	3	Vit E, Selenium	<i>JAMA</i> 2009; 301 : 39–51
12	0	0	3	HRT + Vitamins	<i>JAMA</i> 2002; 288 : 2431–2440
Totals	0	5	52		

“The 12 clinical trials tested 52 observational claims. They all confirmed no claims in the direction of the observational claims...To put it another way, 100% of the observational claims failed to replicate. In fact, five claims (9.6%) are statistically significant in the clinical trials in *the opposite direction* to the observational claim.” – Young & Karr. 2011, *Significance*; 8: 116-120.