

Institute for Health Research

Biostatistics Lunch Lecture Series

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UNDERSTANDING & CRITIQUING RESEARCH

PART 2: CRITICAL REVIEW

Workshop Presented by

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For the health and wellbeing of people and communities in need.

Critical appraisal

Carefully and systematically examining research to ascertain the *Trustworthiness, Value* and *Relevance*.

- Does the study have a clearly **focused research question**?
- Did the study use **valid methods** to collect data to address the question?
- Are the *valid* results of this study **relevant**?
- Are these *valid* and *relevant* results **applicable** in my setting?
- Are there any **conflicts of interest** declared by the authors?

Jumping to the Wrong Conclusions

- Overstating the results.
 - Cause & effect relationships
- Generalising to a larger group or target group.
 - Representative samples

Our beliefs can also cloud our judgements!

Experimental Validity

Two main types:

1. **Internal Validity**

To what extent did the test measure what was intended?

2. **External Validity**

How generalizable are the results?

Threats to Internal Validity

1. **Unplanned events**
things that occur during the experiment/treatment that are not part of the experiment or treatment.
2. **Maturation**
process within the participants that occur with time e.g. puberty, aging, fatigue.
3. **Testing**
the effect of participation on future tests e.g. Learning effect.
4. **Instrumentation**
calibration changes, measurement error, intra- & inter-tester error.
5. **Sample Bias**
selection processes.
6. **Attrition**
loss of participants due to non-random reasons.
7. **Selection-Maturation interactions**

Threats to External Validity

1. Effects of testing
reactive or interactive, like a placebo effect.
2. Selection bias
characteristic selection might not apply to greater population.
e.g. Youth results may not apply to children.
3. Testing Situations
results in testing environment might not transfer into real-life.
e.g. Mice testing for new drug may not apply to humans.
4. Multiple treatment Interference
previous treatments may affect subsequent treatments.

Measurement Validity

The degree or extent that a test or instrument measures what it intended.

Test or instrument validity is **DEPENDENT** upon reliability.

Image from http://en.wikipedia.org/wiki/File:Reliability_and_validity.svg



Unreliable & Invalid



Unreliable, But Valid



Reliable, Not Valid



Both Reliable & Valid

Measurement Error

Four main sources of measurement error:

1. **Participant:** Mood, fatigue, previous practice/skill
2. **Tests:** Processes and procedures, consistency
3. **Scoring:** Inter- / intra-rater accuracy
4. **Instrumentation:** Equipment calibration, test discrimination

- How was the sample selected?
- What variables did they measure?
- What type of research is it?
Observational or
Experimental?
- Did they have a control group?

Journal of Human Nutrition and Dietetics

RESEARCH PAPER

Dietary shortcomings in children on a gluten-free diet

K. Öhlund,* C. Olsson,† O. Hemell* & I. Öhlund*†

Abstract

Background: Coeliac disease (CD), or permanent gluten intolerance, is one of the most common chronic food-related diseases among children in Europe and the USA. The treatment is lifelong gluten-free diet (GFD) (i.e. the exclusion of wheat, rye and barley from the diet, which are important sources particularly of iron, dietary fibre and vitamin B). The present study aimed to evaluate dietary intakes of energy and nutrients in children and adolescents on GFD and compare these with intake of comparable age groups on a normal diet as well as current recommendations.

Methods: Thirty children, 4–17 years of age with confirmed CD and on GFD were agreed to participate in this study at the Department of Pediatrics, Umeå University Hospital. Weight and height were used to calculate individual energy requirement according to Nordic Nutrition Recommendations 2004 (NNR-04). Dietary intake was assessed using 5-day food records and household measures were used for quantities. Twenty-five children completed their dietary record.

Results: Thirteen of the 25 children did not meet the recommended energy intake and the dietary intakes were inadequate regarding quality of macronutrients and quantity of minerals and vitamins. The mean intakes of sucrose and saturated fatty acids were above and the intakes of dietary fibre, vitamin D, magnesium and selenium below the NNR-04. High intakes of sucrose and saturated fat and a low intake of dietary fibre were also noted in a previous national survey on healthy children on a normal diet. The nutrient density of vitamin D, riboflavin, niacin, thiamine, magnesium and selenium were lower among CD children than healthy children but, for iron and calcium, it was higher in CD children.

Conclusions: Children on GFD appear to follow the same trends as healthy children on a normal diet, with high intakes of saturated fat and sucrose and low intakes of dietary fibre, vitamin D and magnesium compared to recommendations.

- How was the sample selected?
- What type of research is it? Observational or Experimental?
- What variables did they measure?
- Did they have a control group?

Abstract

Background: The purpose of this paper was to investigate whether perceived sports competence mediates the relationship between childhood motor skill proficiency and subsequent adolescent physical activity and fitness.

Methods: In 2000, children's motor skill proficiency was assessed as part of a school-based physical activity intervention. In 2004/07, participants were followed up as part of the Physical Activity and Skills Study and completed assessments for perceived sports competence (Physical Self-Perception Profile), physical activity (Adolescent Physical Activity Recall Questionnaire) and cardiorespiratory fitness (Multistage Fitness Test). Structural equation modelling techniques were used to determine whether perceived sports competence mediated between childhood object control skill proficiency (composite score of kick, catch and overhand throw), and subsequent adolescent self-reported time in moderate-to-vigorous physical activity and cardiorespiratory fitness.

Results: Of 928 original intervention participants, 481 were located in 28 schools and 276 (57%) were assessed with at least one follow-up measure. Slightly more than half were female (52.4%) with a mean age of 16.4 years (range 14.2 to 18.3 yrs). Relevant assessments were completed by 250 (90.6%) students for the Physical Activity Model and 227 (82.3%) for the Fitness Model. Both hypothesised mediation models had a good fit to the observed data, with the Physical Activity Model accounting for 18% ($R^2 = 0.18$) of physical activity variance and the Fitness Model accounting for 30% ($R^2 = 0.30$) of fitness variance. Sex did not act as a moderator in either model.

Conclusion: Developing a high perceived sports competence through object control skill development in childhood is important for both boys and girls in determining adolescent physical activity participation and fitness. Our findings highlight the need for interventions to target and improve the perceived sports competence of youth.

International Journal of Behavioral Nutrition and Physical Activity 2008, 5:40 doi:10.1186/1479-5868-5-40

Methods

Subjects

In 2000, 1045 children from 18 randomly selected and stratified primary (elementary) schools in a study area comprising 24,555 square kilometres in New South Wales (NSW), Australia, had their proficiency in a battery of

Research

[Open Access](#)

Perceived sports competence mediates the relationship between childhood motor skill proficiency and adolescent physical activity and fitness: a longitudinal assessment

Lisa M Barnett^{*1}, Philip J Morgan², Eric van Beurden^{3,4} and John R Beard^{1,4,5}

ABSTRACT

Objective To determine the extent to which intensive dietary intervention can influence glycaemic control and risk factors for cardiovascular disease in patients with type 2 diabetes who are hyperglycaemic despite optimised drug treatment.

Design Randomised controlled trial.

Setting Dunedin, New Zealand.

Participants 93 participants aged less than 70 years with type 2 diabetes and a glycated haemoglobin (HbA_{1c}) of more than 7% despite optimised drug treatments plus at least two of overweight or obesity, hypertension, and dyslipidaemia.

Intervention Intensive individualised dietary advice (according to the nutritional recommendations of the European Association for the Study of Diabetes) for six months; both the intervention and control participants continued with their usual medical surveillance.

Main outcome measures HbA_{1c} was the primary outcome. Secondary outcomes included measures of adiposity, blood pressure, and lipid profile.

Results After adjustment for age, sex, and baseline measurements, the difference in HbA_{1c} between the intervention and control groups at six months (-0.4%, 95% confidence interval -0.7% to -0.1%) was highly statistically significant (P=0.007), as were the decreases in weight (-1.3 kg, -2.4 to -0.1 kg; P=0.032), body mass index (-0.5, -0.9 to -0.1; P=0.026), and waist circumference (-1.6 cm, -2.7 to -0.5 cm; P=0.005). A decrease in saturated fat (-1.9% total energy, -3.3% to -0.6%; P=0.006) and an increase in protein (1.6% total energy, 0.04% to 3.1%; P=0.045) in the intervention group were the most striking differences in nutritional intake between the two groups.

Conclusions Intensive dietary advice has the potential to appreciably improve glycaemic control and anthropometric measures in patients with type 2 diabetes and unsatisfactory HbA_{1c} despite optimised hypoglycaemic drug treatment.

Trial registration Clinical trials NCT00124553.

How was the sample selected?

What type of research is it? Observational or Experimental?

What variables did they measure?

Did they have a control group?

Nutritional intervention in patients with type 2 diabetes who are hyperglycaemic despite optimised drug treatment—Lifestyle Over and Above Drugs in Diabetes (LOADD) study: randomised controlled trial

Cite this as: BMJ 2010;341:c3337
doi:10.1136/bmj.c3337

Conflict of Interest in Research

“... refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising a researcher's professional judgment in conducting or reporting research.”

from <http://coi.ucsf.edu/>

Researchers must declare any **conflicts of interest** when reporting research.

Types of Conflict of Interest

- Employment
- Ownership interests
- Board membership
- Consultancy fees/honorarium
- Grants
- Support for travel or accommodation
- Meals/beverages
- Entertainment
- Gifts or gratuities (freebies)

Most journals require authors to declare any conflicts of interest when submitting or on acceptance of a paper for publication.

Conflict of Interest Statements

Funding: This work was supported by the Queensland Injury Prevention Council (QIPC) Grant #00.01/01. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing Interests: The authors have declared that no competing interests exist.

PLOS ONE | DOI:10.1371/journal.pone.0117948 February 25, 2015

Disclosure Statement

No conflicts of interest are declared.

Ann Nutr Metab 2014;64:262–270
DOI: 10.1159/000365031

Conflicts of interest None.

Osteoporos Int
DOI 10.1007/s00198-015-3071-8

Can Conflict of Interest affect Research?

Citation: Bes-Rastrollo M, Schulze MB, Ruiz-Canela M, Martinez-Gonzalez MA (2013) Financial Conflicts of Interest and Reporting Bias Regarding the Association between Sugar-Sweetened Beverages and Weight Gain: A Systematic Review of Systematic Reviews. PLoS Med 10(12): e1001578. doi:10.1371/journal.pmed.1001578

Abstract Conclusion

“Financial conflicts of interest may bias conclusions from SRs [systematic reviews] on SSB [sugar-sweetened beverages] consumption and weight gain or obesity.”

The main finding of our assessment was that those SRs with stated sponsorship or conflicts of interest with food or beverage companies were five times more likely to report a conclusion of no positive association between SSB consumption and weight gain or obesity than those reporting having no industry sponsorship or conflicts of interest. This difference could be explained by a potential bias in the design, analysis, or interpretation of the results obtained in the SRs, depending on whether the authors reported having any financial conflict of interest or not.

Funding: No funding was received for this work.

Competing Interests: The authors have declared that no competing interests exist.

Key Terms

Term	Definition
Citation	A quotation or a reference to a source. In research it is typically the reference to the source i.e. a journal.
Cochrane Review	A database of systematic and meta-analyses which summarise and interpret the results of health related research. www.Cochrane.org .
Systematic Review	A structured review of the literature focused on a research question that aims to identify, appraise, and synthesize all high quality research evidence relevant to that question.
Meta-analysis	A statistical method of combining research data from a number of high quality research studies to derive a single quantitative estimate or summary effect size.
Effect Size	Measures the strength of the relationship.

Activity

Critical Review

Critically review research based information.

Article

Interventions with potential to reduce sedentary time in adults: systematic review and meta-analysis.

Martin A, Fitzsimons C, Jepson R, et al. Br J Sports Med doi: <http://bjsm.bmj.com/content/49/16/1056>

Task Question

How many authors?

Did they use inclusion criteria?

How many databases did they search?

How many records did they evaluate?

What type of study design was this paper looking at?

Did this review show that interventions were sufficient to produce clinically meaningful changes in SB?

Were there any conflicts of interest?

Article

Interventions with potential to reduce sedentary time in adults: systematic review and meta-analysis.

Task Question	Answer
How many authors?	8 plus a consortium
Did they use inclusion criteria?	Yes
How many databases did they search?	13
How many records did they evaluate?	8087
What type of study design was this paper looking at?	RCTs
Did this review show that interventions were sufficient to produce clinically meaningful changes in SB?	No. Showed it was promising but need more high quality research.
Were there any conflicts of interest reported?	None reported.

Article

Interventions with potential to reduce sedentary time in adults: systematic review and meta-analysis.

Points of interest:

- Page 2 Study Selection.
 - Systematic / meta analysis: 2 reviewers, 3rd for disputes.
- Bias reported: page 3-4.
- Quality of evidence page 6.
- Strengths & limitations page 8.
 - What implication might the limitation have?

Article

Optimizing Implementation of Obesity Prevention Programs: A Qualitative Investigation Within a Large-scale Randomized Controlled Trial.

Samantha L. Kozica; Helena J. Teede, Cheryce L. Harrison, Ruth Klein, & Catherine B. Lombard. *The Journal of Rural Health* 32 (2016) 72–81
<https://www.ncbi.nlm.nih.gov/pubmed/26249333>

Task Question

How many authors?

What kind of sampling procedure was used?

How was the data collected?

What was the sample size?

What were the three main ways identified for building local rural capacity?

Who was the trial approved by?

Were there any conflicts of interest?

Article

Optimizing Implementation of Obesity Prevention Programs: A Qualitative Investigation Within a Large-scale Randomized Controlled Trial.

Task Question	Answer
How many authors?	5
What kind of sampling procedure was used?	Purposive sampling (criteria based convenience p73)
How was the data collected?	In-depth interviews
What was the sample size?	24
What were the three main ways identified for building local rural capacity?	Uni partnerships; ownership & feedback.
Who was the trial approved by?	Monash Health HREC
Were there any conflicts of interest?	None reported

Article

Optimizing Implementation of Obesity Prevention Programs: A Qualitative Investigation Within a Large-scale Randomized Controlled Trial.

Points of interest:

- Strengths & limitations page 80.
 - What implication might the stakeholders varied experience have?
 - “unable to meet data saturation” what does this mean and what implications might it have on the conclusions drawn?

Article

A cost-benefit analysis of three older adult fall prevention interventions.

Vilma Carande-Kulis, Judy A. Stevens, Curtis S. Florence, Bonita L. Beattie, Ileana Arias. Journal of Safety Research (2015), <http://dx.doi.org/10.1016/j.jsr.2014.12.007>

Task Question

Who is the lead author?

What was the purpose of this study?

What was the methodology used?

Did they use primary or secondary data?

Who do you think the third party payer is?

Was the participation in fall prevention interventions cost-saving from a third party payer perspective?

Were there any conflicts of interest?

Article

A cost-benefit analysis of three older adult fall prevention interventions.

Task Question	Answer
Who is the lead author?	Vilma Carande-Kulis
What was the purpose of this study?	To identify if the interventions were feasible, effective and provide good return on investment.
What was the methodology used?	Third party perspective
Did they use primary or secondary data?	Secondary data
Who do you think the third party payer is?	Health care funders, e.g. health insurance?
Was the participation in fall prevention interventions cost-saving from a third party payer perspective?	Yes
Were there any conflicts of interest?	Statement is not reported.

Article

A cost-benefit analysis of three older adult fall prevention interventions.

Points of interest:

- Special report from the CDC.
 - Brings credibility to the paper.
- Third – party payer details are scarce.
- Methodology refers to an article, preference to have more detail.
- If you wanted to replicate the study is there enough information?

Article

Adoption of obesity prevention policies and practices by Australian primary schools: 2006 to 2013.

N. Nathan, L. Wolfenden, C. M. Williams, S. L. Yoong, C. Lecathelinais, A. C. Bell, R. Wyse, R. Sutherland, J. Wiggers.
Health Education Research, Volume 30, Issue 2, 1 April 2015, Pages 262–271 <https://doi.org/10.1093/her/cyu068>.

Task Question

What year was the article published?

Data was collected from 2006 – 2013: what type of study is this?

What was the selection process? What was the sample size? What was the overall response rate?

How was the data collected and on whom?

What is the study evaluating?

What were the key conclusions?

Were there any conflicts of interest?

Article

Adoption of obesity prevention policies and practices by Australian primary schools: 2006 to 2013.

Task Question	Answer
What year was the article published?	2015, advance access Dec 2014
Data was collected from 2006 – 2013: what type of study is this?	Longitudinal
What was the selection process? What was the sample size? What was the overall response rate?	Representative random selection (stratified random) 476 primary schools 193 (40.6%) all four interviews, 333 (70%) three.
How was the data collected and on whom?	Four telephone interviews with School Principals.
What is the study evaluating?	School policies and procedures for obesity prevention.
What were the key conclusions?	Improvement, different dissemination, ongoing monitoring.

Article

Global trends and projections for tobacco use, 1990-2025: an analysis of smoking indicators from the WHO Comprehensive Information Systems for Tobacco Control.

Ver Bilano, et al. The Lancet Volume 385, No. 9972, p966–976

DOI: [https://doi.org/10.1016/S0140-6736\(15\)60264-1](https://doi.org/10.1016/S0140-6736(15)60264-1)

Task Question

What evidence would support the notion that this is a high quality report?

Where has the data been drawn from?

Over what years has data been evaluated?

What is the purpose of the study?

What was the systematic review used for in this study?

Was there a conflict of interest?

Article

Global trends and projections for tobacco use, 1990-2025: an analysis of smoking indicators from the WHO Comprehensive Information Systems for Tobacco Control.

Task Question	Answer
What evidence would support the notion that this is a high quality report?	Published in Lancet World Health Organisation author and data
Where has the data been drawn from?	WHO Comprehensive Information Systems for Tobacco Control
Over what years has data been evaluated?	1990-2010 (Abstract), 2014 in methods?
What is the purpose of the study?	Model projections of smoking into 2025.
What was the systematic review used for in this study?	Determine if anyone had reported systematic assessment of recent trends/projections. p.974
Was there a conflict of interest?	None reported p975; Funding source statement p969

Critically Appraise Research

1. Are the results of the study **valid**?

- Sound methodology
- Sound analysis

2. What are the **results**?

- Is there a treatment effect?
- Is there a clinically relevant treatment effect?

3. Can I **apply** the results?

- Do the results apply to my setting/clients?
- Do benefits outweigh possible harm or costs?

Question Time

