When is a replication a replication?

An interview study of how intervention researchers manage adherence and adaptations in the research process

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Knut Sundell[2], Ulrika Förberg[2,3] and Henna Hasson[4,5]

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ESKILSTUNA VÄSTERÅS

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- Funders
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  - Forte [2014-0303].Sustainability amid ongoing change: Illuminating the adaptation and adherence dilemma in the evidence-to-practice pathway.
  - Swedish National Research Council [2016-01261] Adaptation and adherence on the research-to-practice pathway: perspectives of patients, employees, the health care system and evaluation.
- I have ‘no conflicts to report

Shared intellectual capital

- Henna Hasson
- The Procome research group, co-authors, doctoral students

VETENSKAPSRÅDET

FORTE: Swedish Research Council for Health, Working Life and Welfare

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Poll Question #1

- What is your primary role in VA?
  - student, trainee, or fellow
  - clinician
  - researcher
  - Administrator, manager or policy-maker
  - Other

Poll Question #2

- Which best describes your intervention (clinical, effect evaluations) and implementation research experience?

  I have:

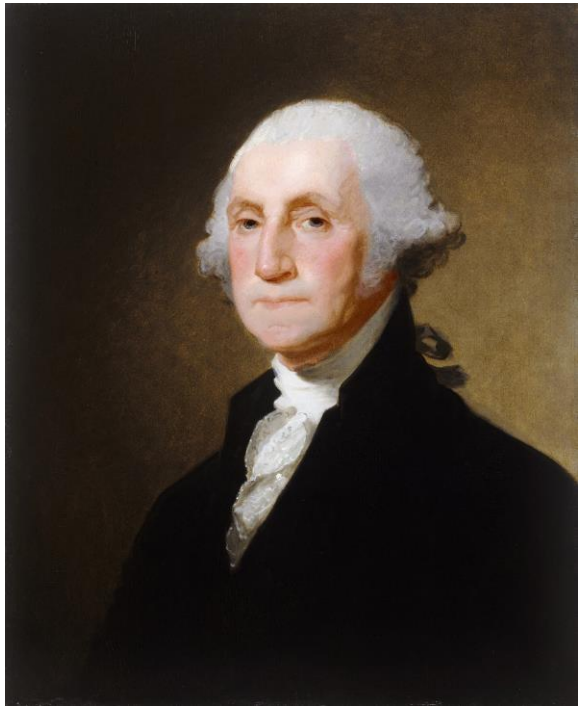
  – not done research
  – done basic research
  – done applied research, but not intervention/intervention
  – done intervention research
  – done implementation research

Poll Question #3

- Have you been involved in conducting systematic reviews, e.g. meta-analysis?
  - Yes
  - No

Overview of the talk

- A reminder of human shortcomings and why they matter for research designs
- The role of replications in the evidence-to-practice pathway
- Adaptations



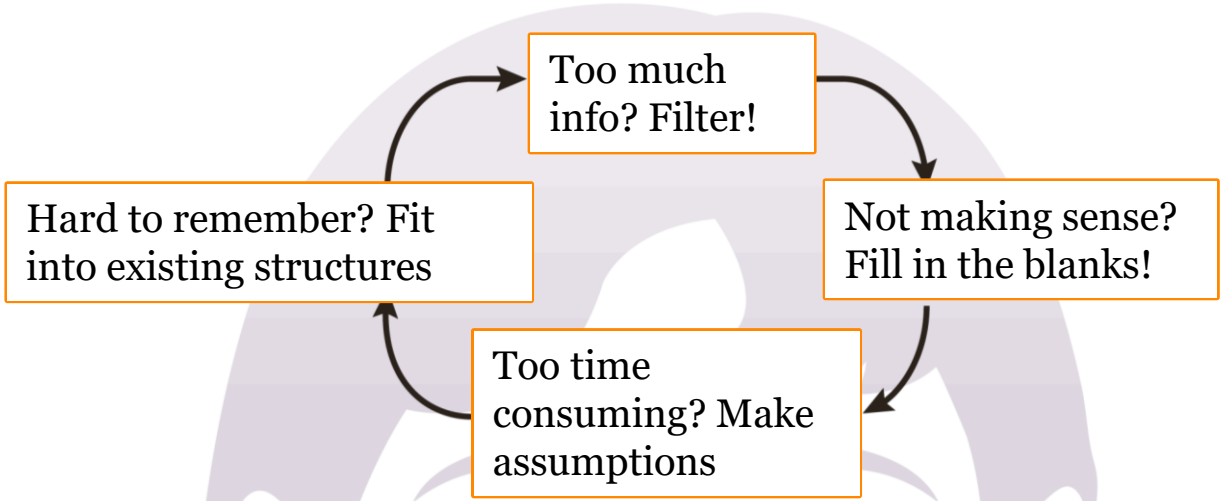
Drawing erroneous conclusions is human

We see relationships that does not exist

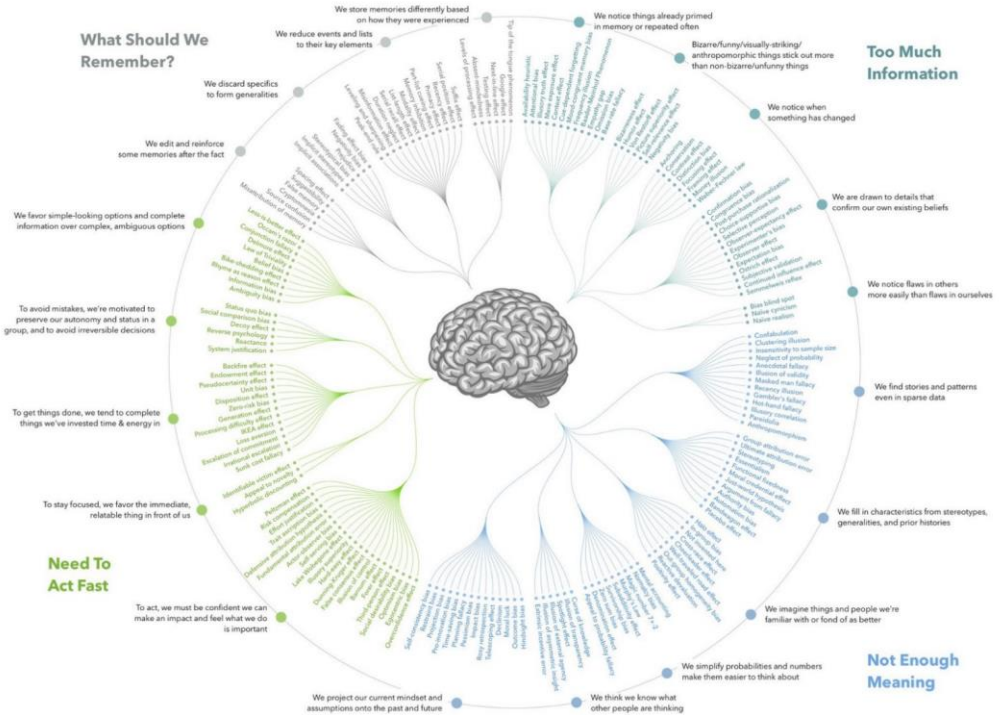
- We draw causal inferences from correlations
- Post Hoc, Ergo propter Hoc: We mistake time order as causal relationships
  - Placebo is mistaken for effect of intervention
  - Spontenous improvements are mistaken for effect of interventions
- We draw conclusions based on small and skewed samples
- We trust authorities, not facts

e.g. Kahneman, D. (2011). Thinking, fast and slow. Macmillan.

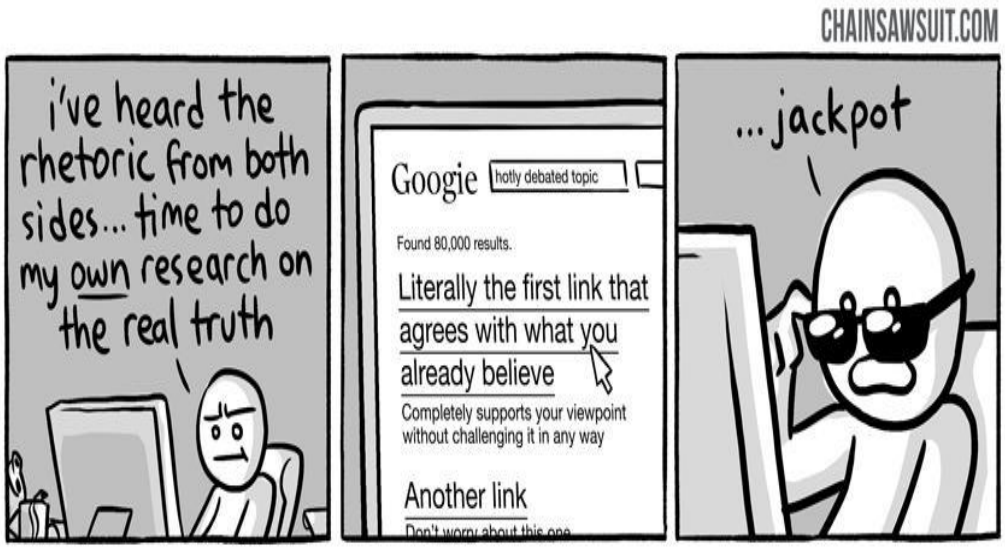
We have ways to protect what we already believe is true



COGNITIVE BIAS CODEX, 2016



ALGORITHMIC LAYOUT + DESIGN BY JM3 - JOHN MANOOGIAN III // CONCEPT + METICULOUS CATEGORIZATION BY BUSTER BENSON // DEEP RESEARCH BY WIKIPEDIANS FAR + WIDE



http://chainsawsuit.com/comic/archive/2014/09/16/on-research/
Kahneman, D. (2011). Thinking, fast and slow. Macmillan.

Confirmation bias at work?

The way I operate, I need to make it my own. Even if you have come to a certain conclusion in research, I will dismiss that if it is not in line with my own experience. You can talk about evidence as much as you want: I won't buy it. But if it supports my experience, I will accept it full-fledged.

(Manager in Social Services, Sweden)

Mosson, R.,Hasson, H., Wallin, L., & von Thiele Schwarz, U. (2016). Exploring the role of line managers in implementing evidence-based practice in social services and older people care. British Journal of Social Work,

CONFIRMATION BIAS AT WORK?

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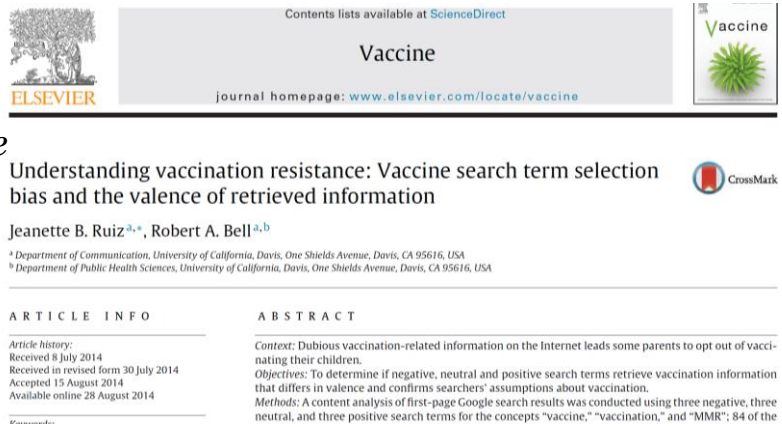
Confirmation bias at work?

"The concerned parent who seeks information about the risks of childhood immunizations will find more websites that perpetuate vaccine myths and recommend against vaccination than the parent who seeks information about the benefits of vaccination. "



Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Understanding vaccination resistance: Vaccine search term selection bias and the valence of retrieved information

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ABSTRACT

Context: Dubious vaccination-related information on the Internet leads some parents to opt out of vaccinating their children.
Objectives: To determine if negative, neutral and positive search terms retrieve vaccination information that differs in valence and confirms searchers' assumptions about vaccination.
Methods: A content analysis of first-page Google search results was conducted using three negative, three neutral, and three positive search terms for the concepts "vaccine," "vaccination," and "MMR"; 84 of the

Early trials: Daniel 1:12-14

- 12 “Please test your servants for ten days:
  Give us nothing but vegetables to eat and
  water to drink. 13 Then compare our
  appearance with that of the young men who
  eat the royal food, and treat your servants in
  accordance with what you see.” 14 So he
  agreed to this and tested them for ten days.
- 15 At the end of the ten days they looked
  healthier and better nourished than any of
  the young men who ate the royal food. 16 So
  the guard took away their choice food and
  the wine they were to drink and gave them
  vegetables instead

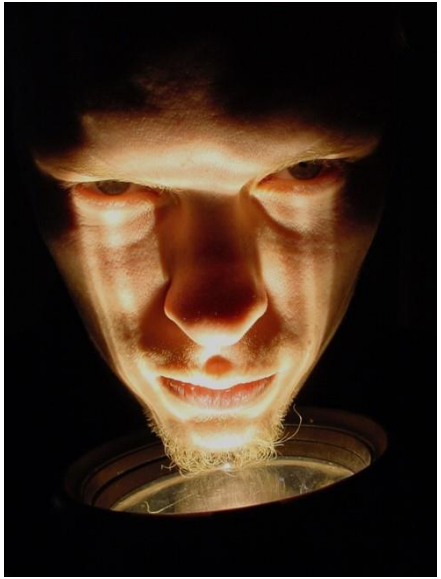
Daniel 1:12-14

"On the 20th of May 1747, I selected twelve patients in the scurvy, on board the Salisbury at sea. Their cases were as similar as I could have them. They all in general had putrid gums, the spots and lassitude, with weakness of the knees. They lay together in one place, being a proper apartment for the sick in the fore-hold; and had one diet common to all, viz. water gruel sweetened with sugar in the morning; fresh mutton-broth often times for dinner; at other times light puddings, boiled biscuit with sugar, etc., and for supper, barley and raisins, rice and currants, sago and wine or the like. Two were ordered each a quart of cyder a day. Two others took twenty-five drops of elixir vitriol three times a day . . . Two others took two spoonfuls of vinegar three times a day . . . Two of the worst patients were put on a course of sea-water . . . Two others had each two oranges and one lemon given them every day . . . The two remaining patients, took . . . an electary recommended by a hospital surgeon . . . The consequence was, that the most sudden and visible good effects were perceived from the use of oranges and lemons;

Dunn, P. M. (1997). James Lind (1716-94) of Edinburgh and the treatment of scurvy. *Archives of Disease in Childhood-Fetal and Neonatal Edition*, *76*(1), F64-F65.

To avoid to err through design: Good evidence is evidence that can be trusted

- Compare ”equal to equal”
- Compare groups of individuals that represent different conditions
- Have a sufficient number of individuals in all groups
- Randomize
- Control conditions for the control group (e.g. placebo or best-available treatment)
- Blind & Double-blind



The story is not in one single study

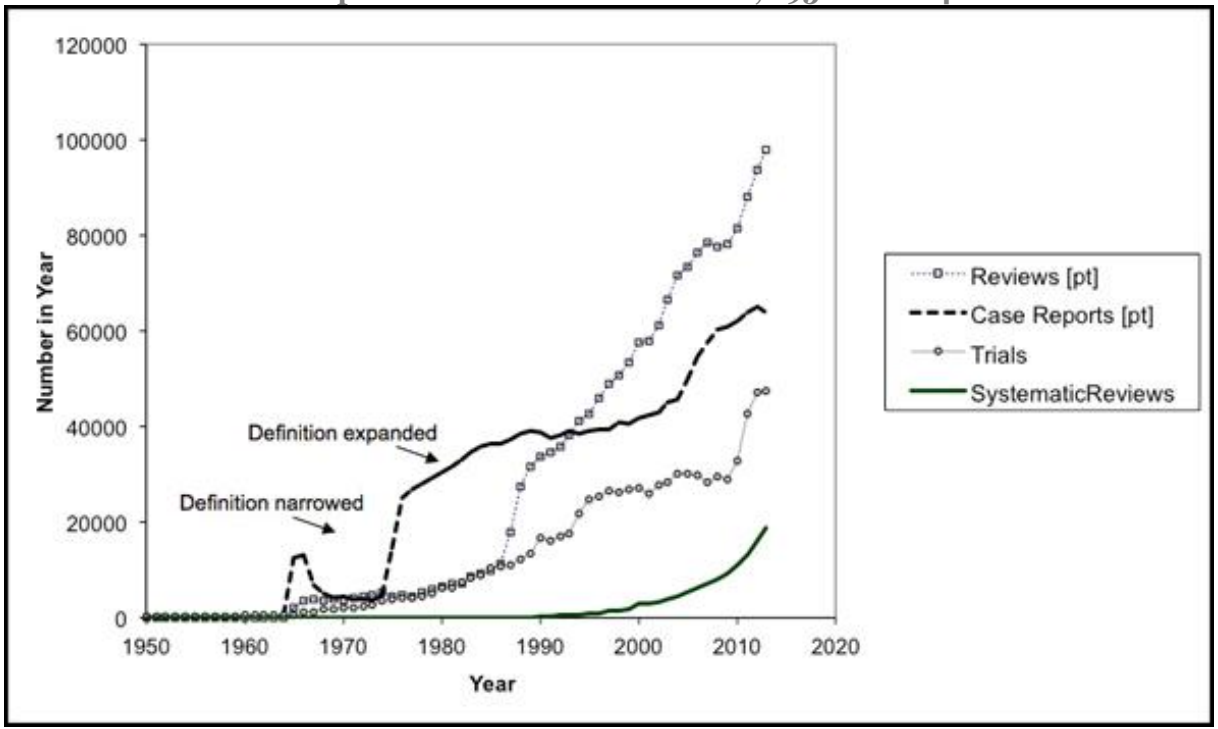

Early report

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

RETRACTED

Single studies provides insufficient support for a method efficacy

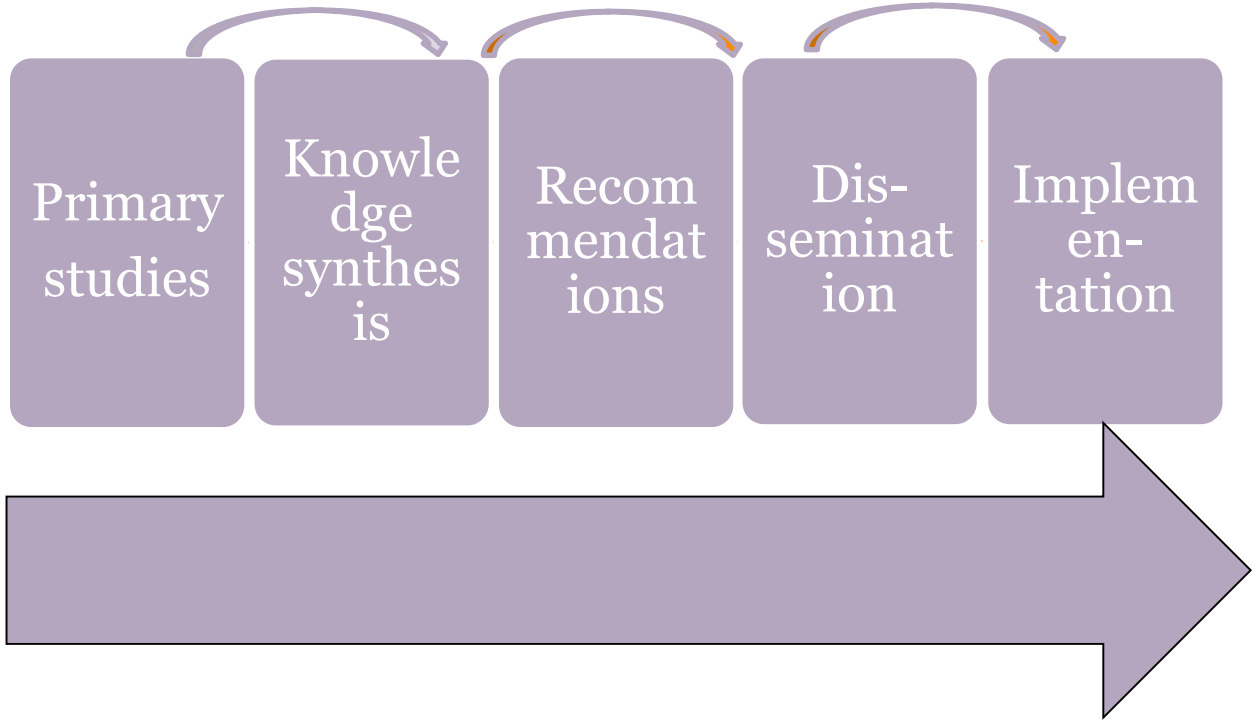
Number of published trials and Reviews, 1950 to 2014.



Bastian H, Glasziou P, Chalmers I (2010) Seventy-Five Trials and Eleven Systematic Reviews a Day: How Will We Ever Keep Up?. PLOS Medicine 7(9):
https://statistically-funny.blogspot.se/p/the-rise-in-trials-and-sys.html

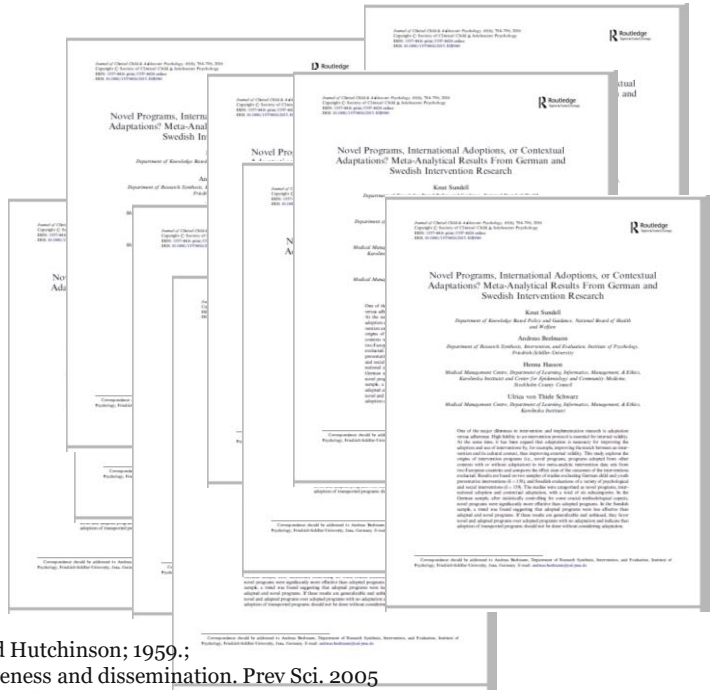
PLOS | MEDICINE

From Research to Practice



In effect evaluations, focus is on fidelity

- To establish an evidence base, you need replications[1,2]
- Two types[3,4]:
  - Direct replication (exact copy of the study)
  - Conceptual replications (testing under different circumstances)
- Both requires the intervention to be "frozen"



1Popper KR. The logic of scientific discovery. London: England Hutchinson; 1959.;
2Flay et al., Standards of evidence: criteria for efficacy, effectiveness and dissemination. Prev Sci. 2005
3Schmidt Shall we really do it again? The powerful concept of replication is neglected in the social sciences. Rev Gen Psychol. 2009;13:90.
4Park CL. What is the value of replicating other studies? Res Eval. 2004;

But in practice, adaptations happens

"…Of course you have to make adaptations!

We can never take something that has been developed in big cities like Stockholm and run with it as it is; we have to adapt it."

Line manager in social services, rural area, Sweden

Mosson, R.,Hasson, H., Wallin, L., & von Thiele Schwarz, U. (2016). Exploring the role of line managers in implementing evidence-based practice in social services and older people care. British Journal of Social Work, DOI 10.1093/bjsw/bcw/004

Adaptations are common in practice

- Violence prevention youth programs: 44% of users make adaptations (Moore et al., 2013).
- Only 17% of those familiar with Swedish National Guidelines for Prevention of Disease state that they do not make any adaptations at all (Kaketto et al., 2017).
- School based prevention programs: 81% of the schools made adaptations (Hallfors & Godette, 2002), with up to 80% of components being removed (Durlak & DuPre, 2008).
- 97% of the sessions in a substance abuse prevention program was adapted (97% based on observations: 68% according the teacher ratings (Miller-Day et al., 2013)

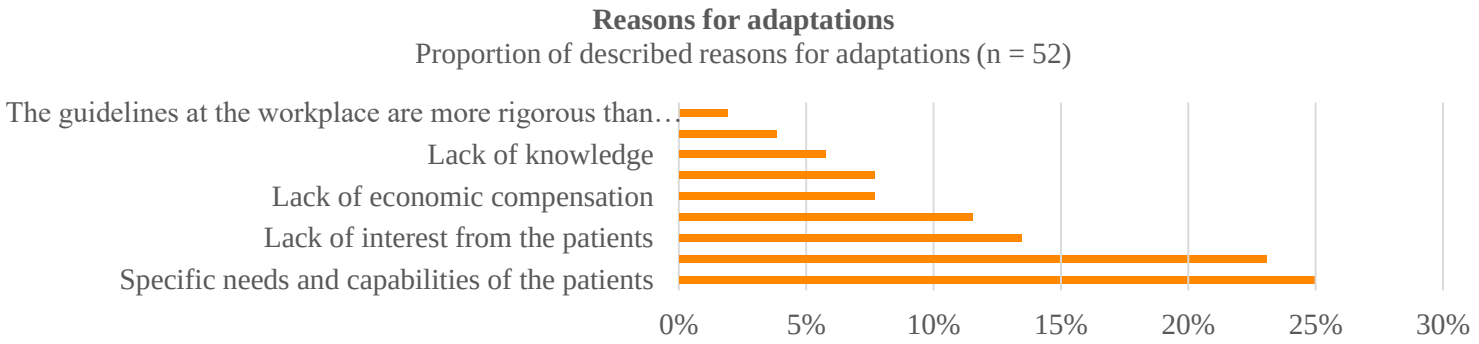
Moore et al., (2013). Examining adaptations of evidence-based programs in natural contexts. Journal of Primary Prevention, 34(3), 147–161

Hallfors, D. & Godette, D. (2002). Will the ”principles of effectiveness” improve prevention practice? Health Education Research, 17, 461–470.

Durlak, J.A. & DuPre, E.P. (2008). Implementation matters: A review of research on the influence of implementation on program outcomes and the factors affecting implementation. American Journal of Community Psychology

Miller-Day et al. (2013). How prevention curricula are taught under real-world conditions: Types of and reasons for teacher curriculum adaptations. Health Education,

Adaptations are made to meet patient needs, because of lack of time, lack of routines, knowledge etc



Kakeeto, M., Hasson, H., Lundmark, R., & von Thiele Schwarz, U. (2017). Meeting patient needs trumps adherence. A cross-sectional study of adherence and adaptation to National guidelines for preventive care. Journal of Evaluation in clinical practice, 23(4), 830-838.

"This is all very complex. … Our clients, they are people with multiple problems, where multiple methods and processes are involved. It is not only evidence-based methods from psychiatry, there is also substance abuse and many of the clients have cognitive disabilities. So it is not so damn easy! Not when you are suppose to follow an evidence-based method.

Mosson, R.,Hasson, H., Wallin, L., & von Thiele Schwarz, U. (2016). Exploring the role of line managers in implementing evidence-based practice in social services and older people care. British Journal of Social Work, DOI

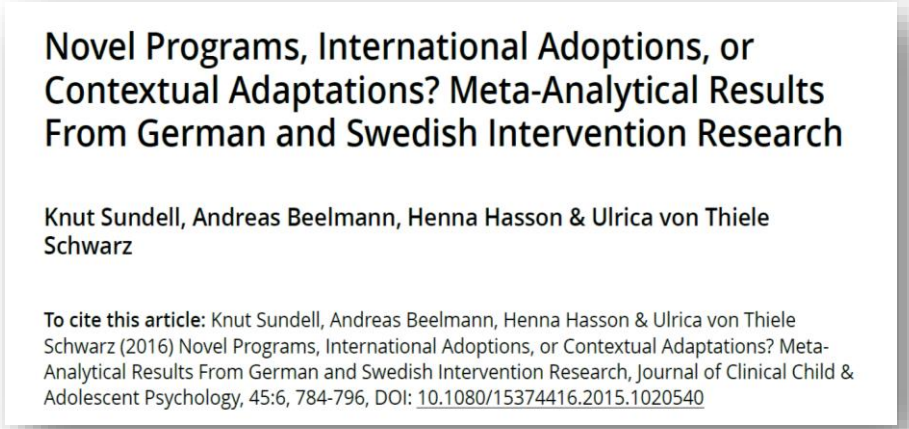
… and about fidelity …. Most manuals are developed for adults, and then used for children… Sometimes, there are studies, other times not-so-much. But even so, if you for example think of a social phobia treatment with 15 sessions: that alone makes it impossible, because we don't do 15 session treatments in primary care.. So you end up picking things the child needs from the treatment. I must say, that for first-line psychiatric care for children in primary care – high fidelity would be very questionable, because it is not fit for our purpose. So it would not be very helpful do follow the methods as they were developed.

Psychologist, CBT-therapist, Primary care

Ongoing study on adherence and adaptation in primary care

Adaptations make interventions more effective – results from a meta-analysis

- Swedish sample: Behavioral health interventions conducted in Sweden (n=139)
  - Both preventive and rehabilitative, all ages
- German speaking countries: child- and youth prevention och promotion only (158 studies)
- Published between 1995 – 2012 with a randomized or non-randomized control group
- Coded for type of adaptations
  - 3 categories, 5 sub-categories
- Calculation of effect size
  - Controlled for study design and sample size
  - Hedges and Olkin's - random effect model.



Novel Programs, International Adoptions, or Contextual Adaptations? Meta-Analytical Results From German and Swedish Intervention Research

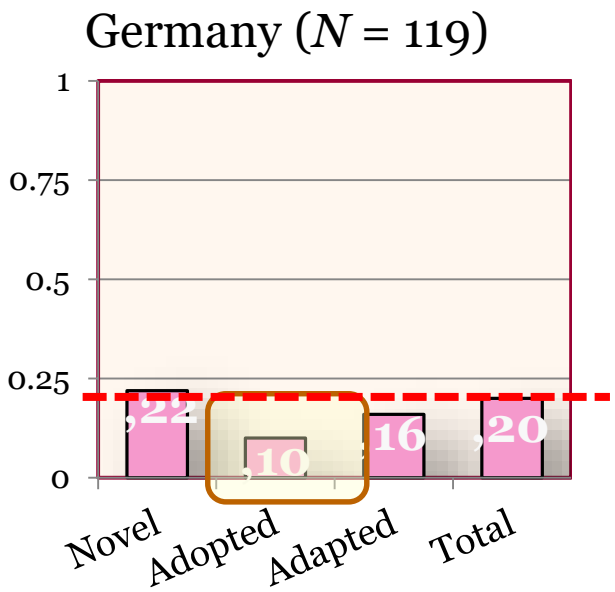
Knut Sundell, Andreas Beelmann, Henna Hasson & Ulrica von Thiele Schwarz

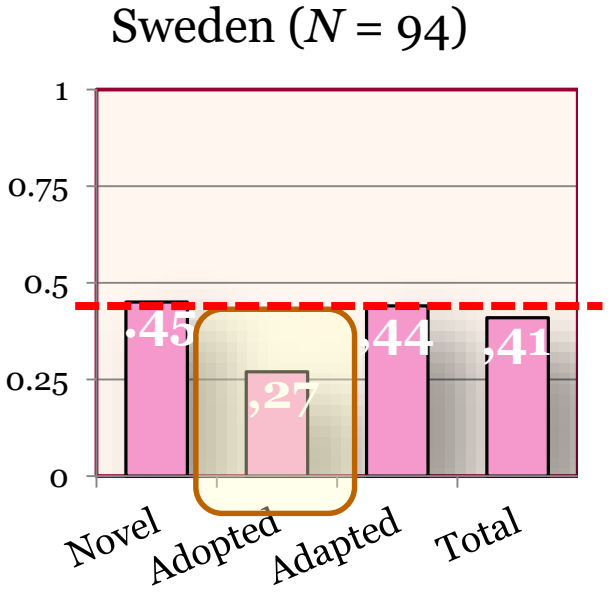
To cite this article: Knut Sundell, Andreas Beelmann, Henna Hasson & Ulrica von Thiele Schwarz (2016) Novel Programs, International Adoptions, or Contextual Adaptations? Meta-Analytical Results From German and Swedish Intervention Research, Journal of Clinical Child & Adolescent Psychology, 45:6, 784-796, DOI: 10.1080/15374416.2015.1020540

Categorization

- Novel: Testing of a new program
  - Innovations
  - Conceptually new
- Adopted: Full replication of an evidence-based program in a new context
- Adapted: Use of an evidence-based program, but with adaptations based on local conditions
  - Cultural adapations
  - Pragmatic adaptations
  - Eclectic

Replications without adaptations (adopted interventions) less effective than other types





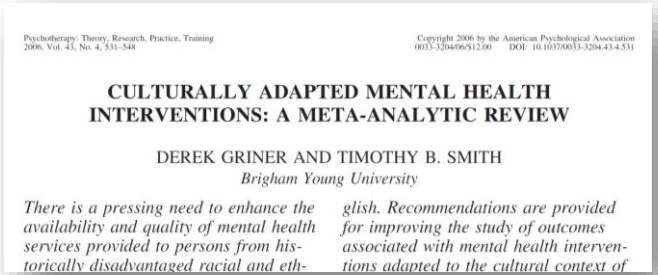
Sundell, Beelmann Hasson, & von Thiele Schwarz, (2016). Novel Programs, international adoptions or contextual adaptions? Meta-analytic results from German and Swedish intervention research. *Journal of Clinical Child and Adolescent Psychology.*

Methodological limitations

- The categorization was based on the information available in the published articles
- Limited descriptions of adaptations
- Wide variety of studies – comparison of apples and pears?
- A risk for publication bias (not all intervention studies are published)
- Small study samples, especially to sub-types of adapted programs
- Differences between the two samples

Additional reviews show similar results

Cultural adaptations



Psychotherapy: Theory, Research, Practice, Training
2006, Vol. 43, No. 4, 531–548

0033-3204/06/$12.00 DOI: 10.1037/0033-3204.43.4.531

CULTURALLY ADAPTED MENTAL HEALTH INTERVENTIONS: A META-ANALYTIC REVIEW

DEREK GRINER AND TIMOTHY B. SMITH
Brigham Young University

There is a pressing need to enhance the availability and quality of mental health services provided to persons from historically disadvantaged racial and ethglish. Recommendations are provided for improving the study of outcomes associated with mental health interventions adapted to the cultural context of

Journal of Counseling Psychology
2011, Vol. 58, No. 3, 279–289

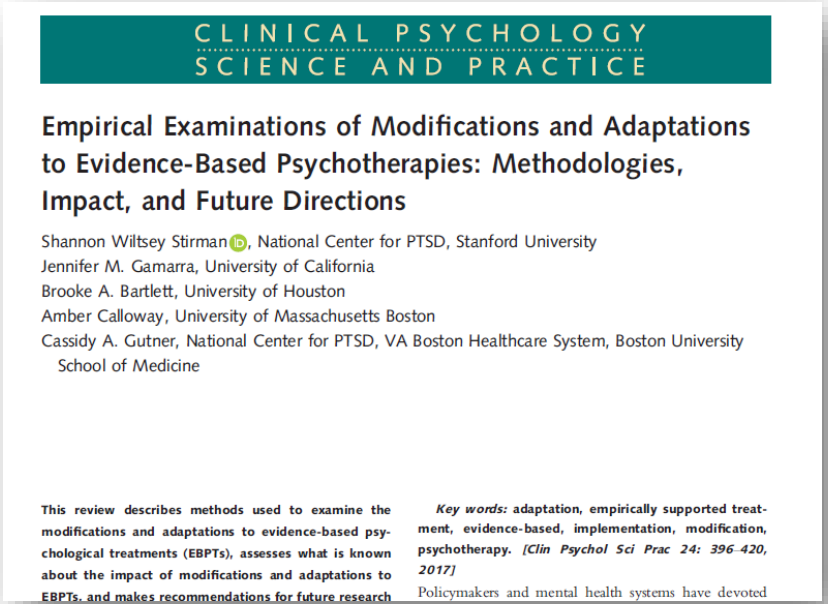
0022-0167/11/$12.00 DOI: 10.1037/a0023626

Culturally Adapted Psychotherapy and the Legitimacy of Myth: A Direct-Comparison Meta-Analysis

Steven G. Benish, Stephen Quintana, and Bruce E. Wampold
University of Wisconsin—Madison

Psychotherapy is a culturally encapsulated healing practice that is created from and dedicated to specific cultural contexts (Frank & Frank, 1993; Wampold, 2007; Wrenn, 1962). Consequently, conventional psychotherapy is a practice most suitable for dominant cultural groups within North America and Western Europe but may be culturally incongruent with the values and worldviews of ethnic and racial minority groups (e.g., D. W. Sue, Arredondo, & McDavis, 1992). Culturally adapted psychotherapy has been reported in a previous meta-analysis as more effective for ethnic and racial minorities than a set of heterogeneous control conditions (Griner & Smith, 2006), but the relative efficacy of culturally adapted psychotherapy versus unadapted, bona fide psychotherapy remains unestablished. Furthermore, one particular form of adaptation involving the explanation of illness—known in an anthropological context

Clinical Adaptations



CLINICAL PSYCHOLOGY
SCIENCE AND PRACTICE

Empirical Examinations of Modifications and Adaptations to Evidence-Based Psychotherapies: Methodologies, Impact, and Future Directions

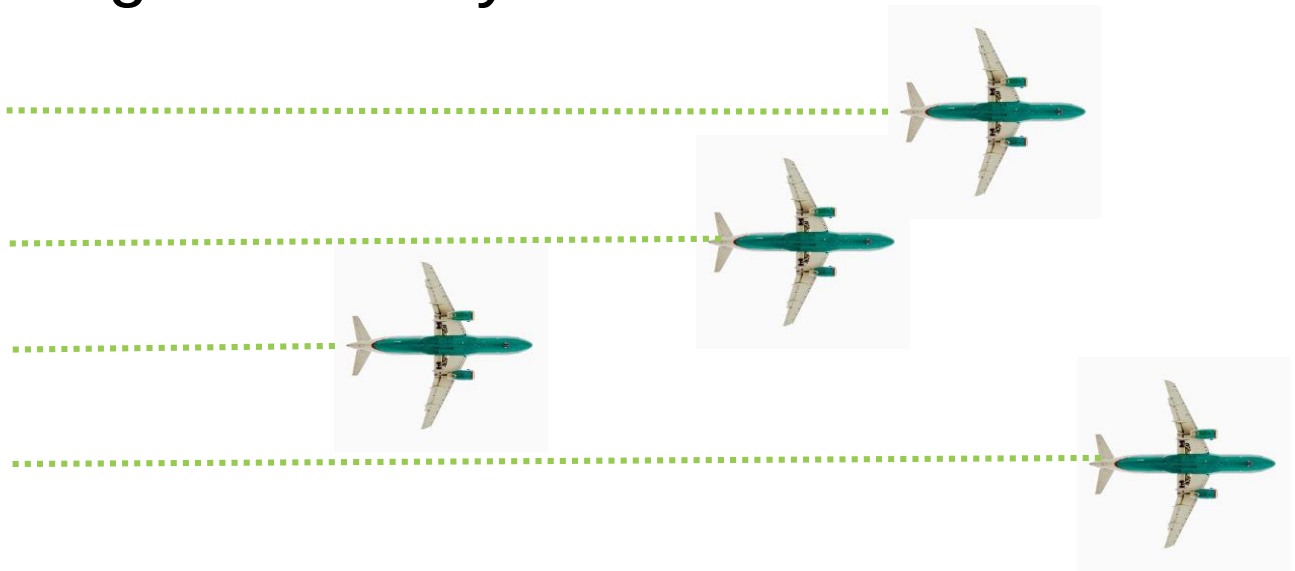
Shannon Wiltsey Stirman, National Center for PTSD, Stanford University
Jennifer M. Gamarra, University of California
Brooke A. Bartlett, University of Houston
Amber Calloway, University of Massachusetts Boston
Cassidy A. Gutner, National Center for PTSD, VA Boston Healthcare System, Boston University School of Medicine

This review describes methods used to examine the modifications and adaptations to evidence-based psychological treatments (EBPTs), assesses what is known about the impact of modifications and adaptations to EBPTs, and makes recommendations for future research

Key words: **adaptation, empirically supported treatment, evidence-based, implementation, modification, psychotherapy.** ***[Clin Psychol Sci Prac 24: 396–420, 2017]***

Policymakers and mental health systems have devoted

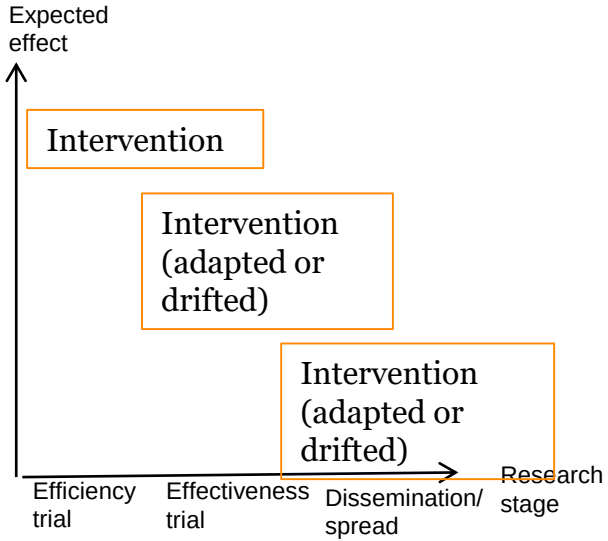
At the same time – there are ample of studies showing that fidelity is related to better effect

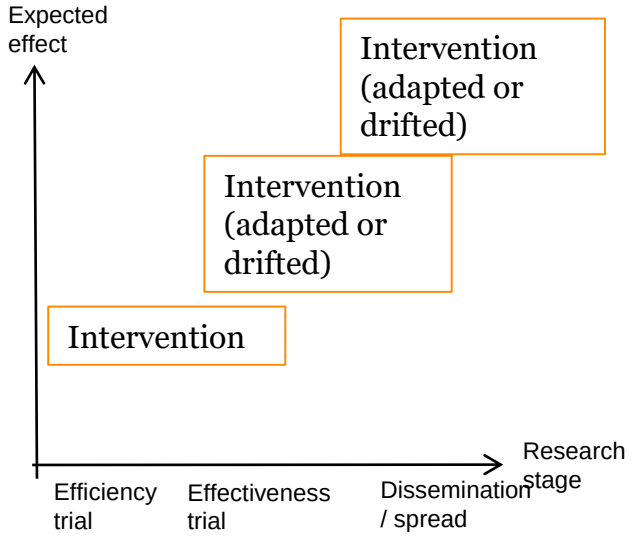


Wilson et al., 200; Keith et al., 2010, Abbot et al., 1998; Blakely et al., 1987, Blakely et al., 1987; Dane & Schneider, 1998; Hansen et al., 1991; Rohrbach et al., 1993; Becker et al., 2001.

How do we reconcile that adherence/fidelity and adaptations are both related to larger effects?

- Is adherence better when there is little variation but maybe not when there is a lot of variation?
- Is adherence better than modifications/drift, but not necessarily than adaptations?

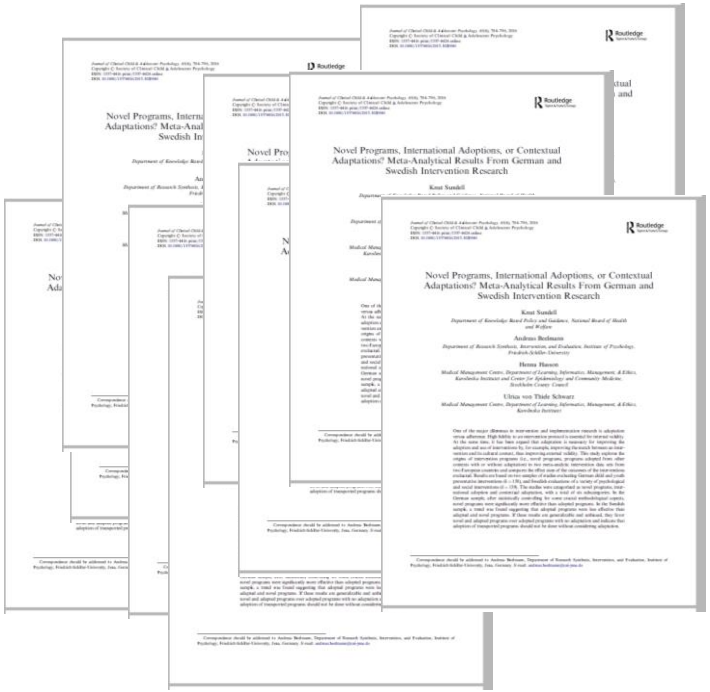




Chambers *et al. Implementation Science* 2013 **8**:117

Contradictions in conceptual replications

- Conceptual replications may **both** require adaptations to be effective **and** fidelity, in order to be a replication
- How do intervention researches reconcile this contradiction?



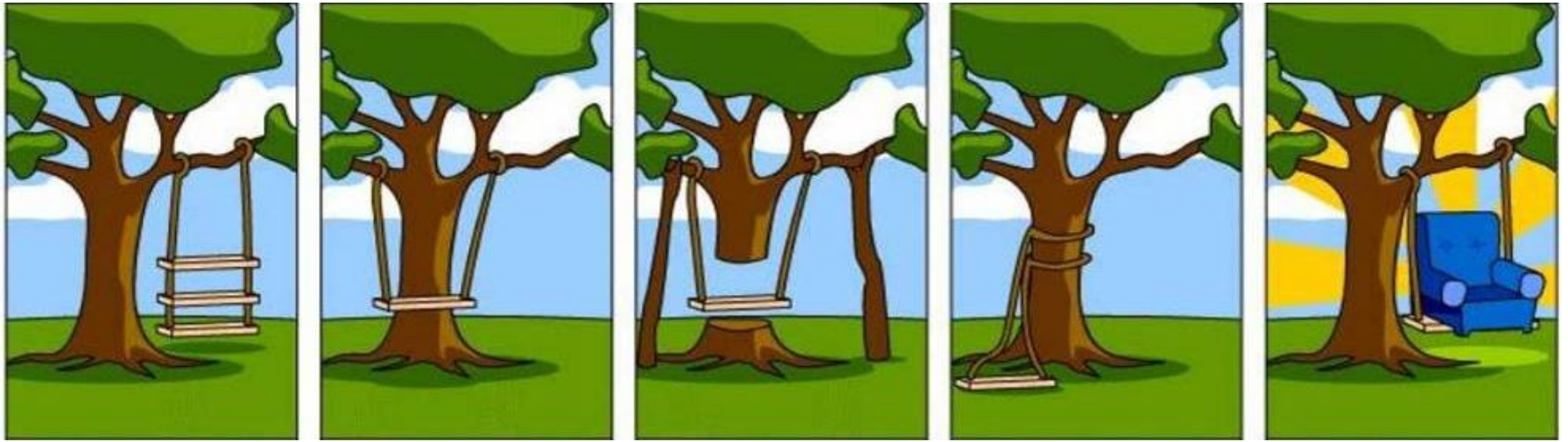
AIM

To explore how investigators of effect evaluation studies describe

- what adaptations they made
- their reasoning about adaptations and adherence
- how adaptations are reported in publications

von Thiele Schwarz, U., Förberg, U., Sundell, K., Hasson, H. (2018). Colliding ideals – An interview study of how intervention researchers address adherence and adaptations in replication studies". BMC Medical research methodology.

Are interventions sufficiently described for replication?



Glasziou et al., 2008. What is missing from descriptions of treatment in trials and reviews? BMJ
Hoffmann et al., (2013). Poor description of nonpharmacological interventions: analysis of consecutive sample of randomised trials. BMJ

Poll question #4

- In your experience, are interventions sufficiently described in study protocols to allow replications?
  - → Absolutely not
  - → Somewhat
  - → Quite OK
  - → Absolutely sufficiently
  - → I don’t know

Methods – selection and recruitment

- The 139 behavioral health interventions from the Swedish sample (n=139)
- All studies reported adaptations selected (n =36)
- Interviewees': All 21 principal investigators of the 36 studies invited, 20 agreed to participate (no of studies = 33)
- Analyses:
  - Manifest content analysis to identify types of adaptations[1]
  - Content analysis to explore reasoning and reporting of adaptations and adherence

von Thiele Schwarz *et al. BMC Medical Research Methodology* (2018) 18:36
https://doi.org/10.1186/s12874-018-0496-8

BMC Medical Research Methodology

RESEARCH ARTICLE Open Access

Colliding ideals – an interview study of how intervention researchers address adherence and adaptations in replication studies

Ulrica von Thiele Schwarz[1,2*], Ulrika Förberg[1,3], Knut Sundell[1] and Henna Hasson[1,4]

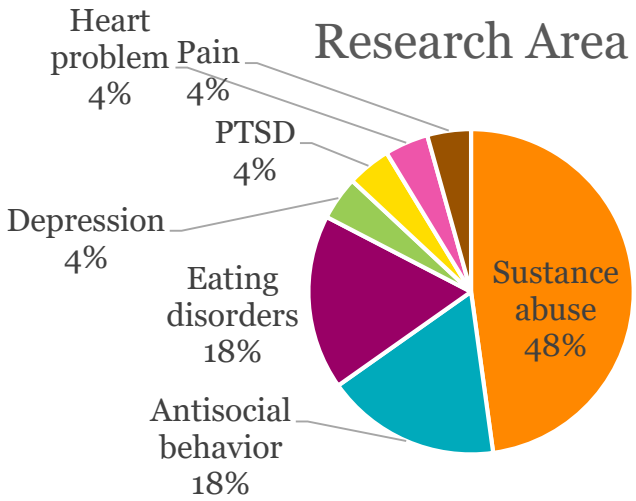
Abstract

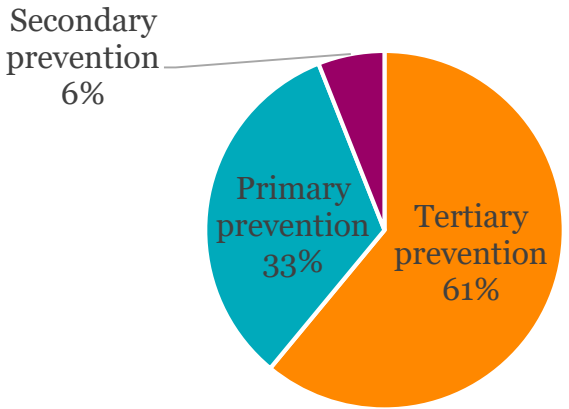
Background: For an intervention to be considered evidence-based, findings need to be replicated. When this is

1. Stirman et al., (2013). Development of a framework and coding system for modifications and adaptations of evidence-based interventions. Implementation Science, 8(1), 65.

The 33 included studies …

…. Were randomized	76%
… had an active control group	70%
… were effectiveness trials	53%
… or efficacy trials	47%
…. targeted adults	70%





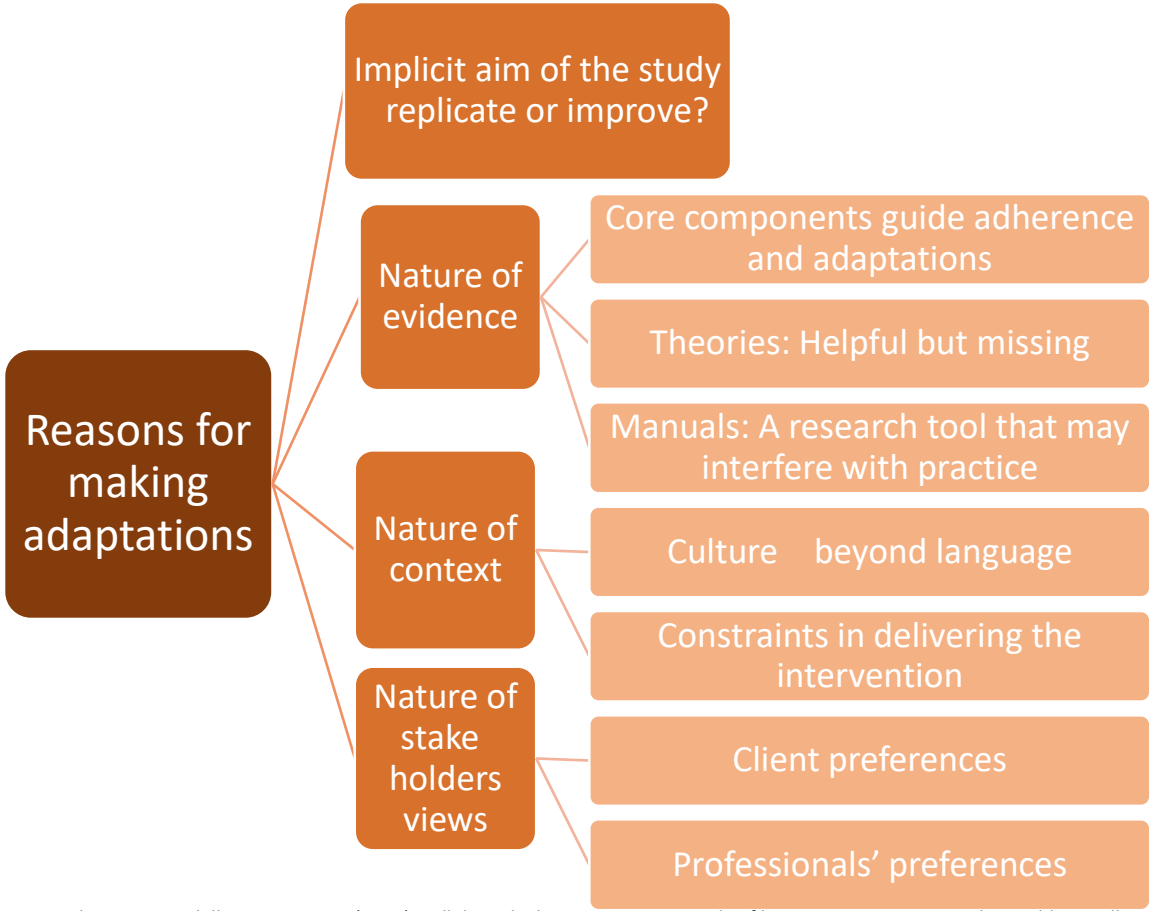
von Thiele Schwarz, U., Förberg, U., Sundell, K., Hasson, H. (2018). Colliding ideals – An interview study of how intervention researchers address adherence and adaptations in replication studies". BMC Medical research methodology.

Findings
- types of adaptations[1]

- The decision was typically made by the researcher (67%)
- Involved changes in the target population (42%)

  … or setting (36%)
- The nature of adaptations included
  - adding components (45%)
  - removing components (33%)
  - tailoring components (24%)

[1] Stirman, S. W., Miller, C. J., Toder, K., & Calloway, A. (2013). Development of a framework and coding system for modifications and adaptations of evidence-based interventions. *Implementation Science*, *8*(1)



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Is the Implicit aim to replicate or improve?

“Well, from a methodological perspective, I believe that one should adhere if one has decided to do a replication. Now, for our study, I guess the main aim was not to replicate but rather to search for methods that had worked and also had certain shortcomings, and then we attempted to address those shortcomings”

Interview 2

What are the nature of the evidence underlining the intervention?

manuals, theories and core components;

"It is both good and not so good to stay very faithful to a manual. What is good about it is that you do not miss or forget anything. What is bad about being too faithful to a manual is that you stand the risk of implementing something that you really should have avoided."

Interview 20

What are the nature of the evidence underlining the intervention?

manuals, theories and core components;

You have to adhere to the theory, the philosophy. It is like a stew. If you make a beef stew, then it is the beef and the tomato sauce that are the main ingredients. If these ingredients are kept in the stew, then you can call it a beef stew. You can then adjust the seasoning and add one vegetable or the other…but if you all of a sudden add fish instead, even with the tomato sauce, sorry, then it is not a beef stew anymore, it is a fish stew

Interview 12

What are the nature of the evidence underlining the intervention?

manuals, theories and core components;

“We know so little about what actually works in different methods. Most often, we have tested the whole packages to see if they work or not. Dismantling studies, they are scarce.”

Interview 15

What is special with the context where the intervention is set?

Cultural adaptations – beyond language –
and constraints in delivering the intervention

“Many of these exercises were very American in the original version. It was a bit more toned-down in the Swedish version.”

Interview 18

What is special with the context where the intervention is set?

Cultural adaptations – beyond language –
and constraints in delivering the intervention

Well, we made many adaptations to relate to the Swedish law and context, one could say. We were in a small town and included all patients that we met, including both easier and more difficult cases, whereas the method originally addresses more difficult cases

Interview 8

What is special with the context where the intervention is set?

“Sometimes these programmes aren’t worth adapting, because they don’t work in another context. [xxx]. I have looked at people who have been involved in many programmes, developed in the US. They’ve tried them here, and the programmes haven’t worked, and it’s not because they’re being adapted in the wrong way, but it’s because the society is different.”

Interview 22

What are the needs of the stakeholders?

Client *and* Professionals' preferences

Well, you try to apply the methods equally the best you can. However, it is impossible to do the exact same thing for different individuals. You have to adapt to the different clients as well

Interview 13

What are the needs of the stakeholders?

Client *and* Professionals' preferences

"Someone says: we should deliver this service, this intervention. The fact that it may deviate from the original plan, well, I guess that's the way it is, to be a human being."

Interview 18

Poll question #5

- What factors influencing decisions about adaptation to you recognize from your experience?
  - → The implicit aim - to replicate or improve
  - → The nature of the evidence underlying the intervention
  - → The context where the intervention is set
  - → The needs of the stakeholders

Select all that apply

Reporting of adaptations in scientific journals involved a conflict between transparency and practical concerns

I think it's important to describe adaptations that might influence the outcome. I think it's extremely important to do that. You have to—I mean, in theory, there shouldn't be anything that stops you from doing that, no

Interview 22

Conclusions - Struggle with dual demands

Adhere and replicate, or adapt, improve and make it fit but mess up the replication?

- Two divergent goals:

1) Test in a new context to confirm/disconfirm previous findings:

   Only context varies

1) Expend or limit the application of an intervention:

   Both intervention & context varies

- Two divergent approaches to knowledge accumulation:

1) Replication, synthesis, dissemination & scale-up
2) Incremental improvements

- Focus on fit – practical, philosofical, cultural (Moore et al., 2013; Cooper et al., 2016)
- One-sided focus on fidelity despite that adaptations were expected

Implications of an incremental approach to knowledge accumulation

- Requires understanding of intervention components and interaction with context: what works for whom when? (e.g. Adaptome; Chambers & Norton., 2016).
- For intervention research:
  - Other types of analyses – e.g. dismantling studies, component analysis, mediation and moderation analysis, realist evaluation, and Bayesian statistics
  - Other types of designs: adapted (flexible) designs, factorial designs, randomized micro-trials and hybrid designs; tailored interventions and implementations
- For research synthesis
  - Build synthesis around program logic to explicate core components, change mechanisms and contextual influences (e.g. realist synthesis and qualitative comparative analysis)
  - Test moderation or compare active components/treatments (meta-regression, network meta-analysis, mixed treatment comparisons

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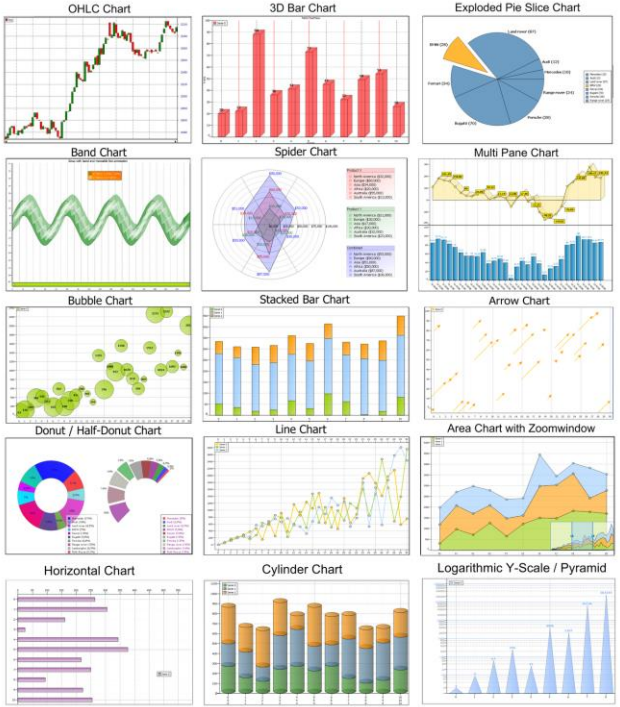
Focus on fit

- Adaptations as a way to create fit
- Aligns well with previous empirical findings from adaptations in practice (Moore et al., 2013; Cooper, 2016; Kakeeto, 2017)
- Aligns with Person-Environment fit models from organisational psychology

Kristof-Brown et al., (2005). Consequences of Indiviudals' fit at work: a meta-analysis of person-job, person-organization, persongroup and person-supervisor fit. Pers Psychol.
Nielsen & Randall (2015). Assessing and addressing the fit of planned interventions to the organizational context. In: Karanika-Murray M, Biron C, editors. Derailed organizational interventions for stress and well-being. Dordrecht: Springer;

Do not neglect adaptations

- Monitor adaptations
- Support professionals in managing adaptations that does not threat the integrity of the intervention [1-6]
- Create data system that allows learning and development as interventions are implemented and used - for example based on patient progress [7-10]



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Dual demands in reporting

- These were the studies that DID describe adaptations in the articles – what about the rest?
- Support for better reporting practices needed
  - Expect adaptations?
  - Include adaptations in reporting guidelines (e.g. Hoffmann et al., 2014)

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., ... & Lamb, S. E. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *Bmj*, *348*, g1687.

Limitations

- Only PIs for studies reporting adaptations included
- Focus on interventions transported from one country to another (mostly US → Sweden)
- Memory test
- ”Old” studies –have the awareness of adaptations increased?

What does these results mean for how we establish an evidence base?

- What does it mean there are several studies showing that an intervention is effective?
  - Is the intervention truly the same?
  - If it is, is the results applicable across contexts?
- How do we establish an evidence-base given the challenges of doing conceptual replications?
  - By core functions rather than form ?

Thank you!

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