

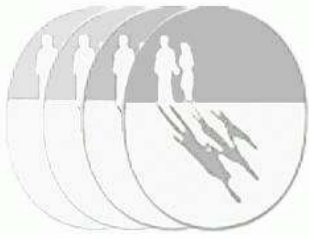
UNIDADE DE PESQUISA CLÍNICA
Centro de Medicina Reprodutiva Dr Carlos Isaia Filho Ltda.

Publicações em Estudos Clínicos

Apresentação: Me Natália Moreira Vieira

www.isaia.com.br

Porto Alegre/RS



CLINICAL TRIALS: PUBLICATION BIAS

BY: SHIVENDRA PAL

PUBLISHER

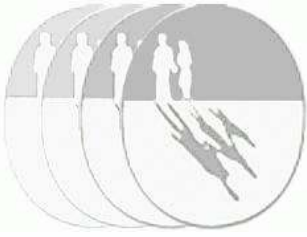
YOU CAN KEEP YOUR YOUR RESEARCH PAPERS THERE.....
..BASED ON THE CATEGORY... !!

CLINICAL TRIALS WITH

- +VE/ STATISTICALLY SIGNIFICANT RESULTS** → **FOR PUBLICATION**
- VE/ STATISTICALLY NON-SIGNIFICANT RESULTS** → **USE ME** (trash can)

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Mas e quando os estudos são publicados?

- Em um levantamento de Glasziou *et al.* (2008) foram analisadas **80 publicações** de ensaios clínicos e revisões sistemáticas, com maioria direcionado para a clínica geral (65) → **41** tinham informações faltando sobre a intervenção
- Descrição ruim → baixa reprodutibilidade

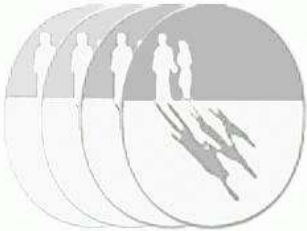
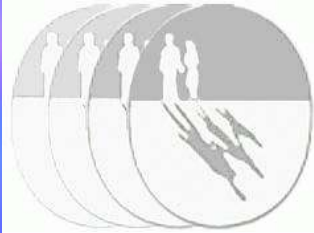


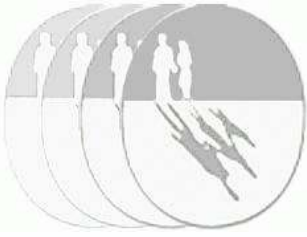
Table 1 | Some reasons for non-reproducibility for studies

Type of problem and examples	Additional information obtained
Description of method	
Craniocervical training programme for tension-type headache: home schedule not provided in publication	Authors provided details of the recommended regimen of exercises at home
Comprehensive lifestyle modification on diet, weight, physical fitness, and blood pressure control	Author provided website with protocol which included details and handbooks used
ACE inhibitor in coronary artery disease: review with several combinations of drug and dose	Author recommended two similar, acceptable regimens
Systematic review of probiotics for preventing antibiotic associated diarrhoea and treating <i>Clostridium difficile</i> disease	Author provided suggestions on appropriate types and doses of probiotic, plus websites
Lifestyle measures effective in patients with gastro-oesophageal reflux disease	Review author suggested appropriate variants
Access to educational materials	
Patient instructions for watchful waiting with hernia	Patient handout provided by author
Inadequate instructions for patient self-Epley procedure	Website and instructions found in a paper referenced in main paper
Name of IBS self help guidebook not given in paper or in references	Author did not reply (three attempts), but a colleague provided details of access to the guidebook via the publisher's website
Description of equipment	
BugBuster kit for eliminating head lice: needed details of combs and combing methods	Website found (via search engine) with treatment details and confirmed by author



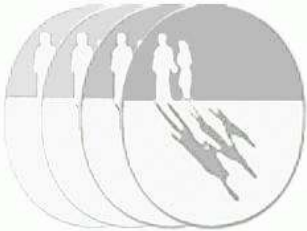
As intervenções de saúde precisam ser descritas com detalhes adequados em relatos de ensaios clínicos randomizados para permitir que os profissionais implementem intervenções efetivas de forma confiável

Glasziou, *et al.* (2010)



Mas e quando os estudos são publicados? (II)

- Na revisão de Ferrante di Ruffano *et al.* (2017) foram avaliados 103 publicações de ensaios clínicos indexados na CENTRAL (Cochrane), publicados entre 2004 e 2007
 - cardiovascular medicine (34%),
 - obstetrics and gynecology (17%),
 - gastroenterology (14%)
 - orthopedics (10%).
- Revistas mais frequentes: *Radiology* ($n = 5$), *Health Technology Assessment* ($n = 4$), *New England Journal of Medicine* ($n = 4$), *Human Reproduction* ($n = 4$), *American Journal of Obstetrics and Gynecology* ($n = 3$), *Journal of the American College of Cardiology* ($n = 3$), and *Ultrasound in Obstetrics and Gynecology* ($n = 3$).



Ferrante di Ruffano *et al.* (2017)

- Deveriam conter descrição adequada de:

- **Teste diagnóstico**

Técnica utilizada para realizar o teste.

Informar apenas o nome do teste foi considerado insuficiente.

- **Decisão diagnóstica**

Descrição dos critérios operacionais utilizados para chegar a um diagnóstico específico usando os resultados do teste

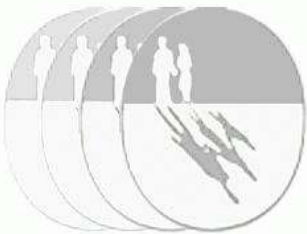
- **Manejo da decisão**

Como os tratamentos foram selecionados a partir do resultado do diagnóstico

- **Tratamento**

Como os tratamentos selecionados foram administrados.

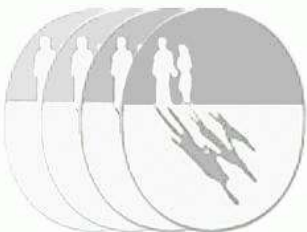
Apenas o nome do tratamento foi considerado insuficiente



Ferrante di Ruffano *et al.* (2017)

- Resultados:

- Todos os 4 componentes estavam faltando de pelo menos um braço de 43 ensaios (42%), incluindo 13% para as quais nenhuma informação foi apresentada para qualquer braço.
- As chances de omitir toda a descrição para as intervenções de controle (36%) eram o dobro do que para as intervenções experimentais (18%).
- 13% descreveram os quatro componentes das intervenções experimentais e 11% o fizeram para intervenções de controle.
- **Apenas 5 dos 103 ensaios clínicos descreveram os quatro componentes de teste-tratamento para ambos os braços de controle e estudo experimental.**

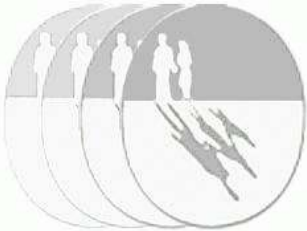


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Como melhorar?

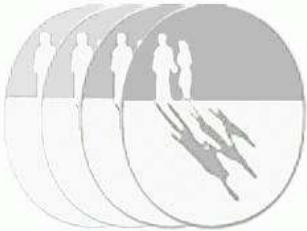
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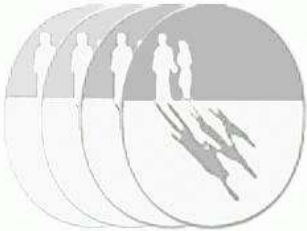
Metodologia!

- **CONSORT** (Consolidated Standards of Reporting of Trials)
- **SPIRIT** (Standard Protocol Items: Recommendations for Interventional Trials)
- **TIDieR** (Template for Intervention Description and Replication)



CONSORT

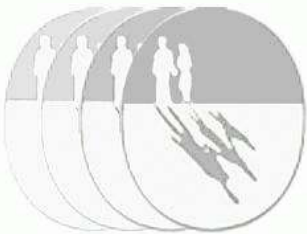
- <http://www.consort-statement.org/>
- Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. JAMA. 1996 Aug 28;276(8):637-9.
- Revisado em 2001 e depois em 2010 (versão atual)



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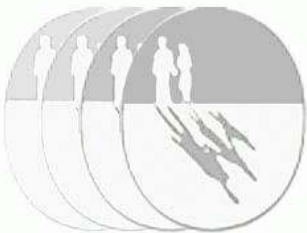
SPIRIT

- <http://www.spirit-statement.org/>
- Iniciativa em 2007, publicado em 2013
- Checklist para protocolos clínicos



TIDIER

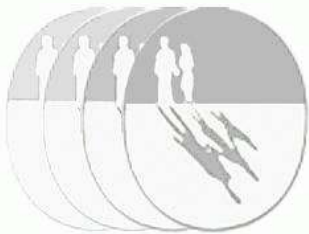
- Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 2014;348:g1687 <https://doi.org/10.1136/bmj.g1687>
- Extensão do item 5 do CONSORT e 11 do SPIRIT (intervenção)



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Resolve o problema?





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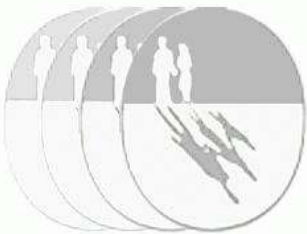
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I KEEP six honest serving-men
(They taught me all I knew);
Their names are **What** and **Why** and
When
And **How** and **Where** and **Who**.
I send them over land and sea,
I send them east and west;
But after they have worked for me,
I give them all a rest.

(...)

Rudyard Kipling
Poeta e autor britânico

Obrigada!



Referências

- Ferrante di Ruffano L, Dinnes J, Taylor-Phillips S, Davenport C, Hyde C, Deeks JJ. Research waste in diagnostic trials: a methods review evaluating the reporting of test-treatment interventions. *BMC Medical Research Methodology*. 2017;17:32. doi:10.1186/s12874-016-0286-0.

Glasziou P, Meats E, Heneghan C, Shepperd S. What is missing from descriptions of treatments in trials and reviews?. *BMJ* 2008;**336**:1472–4.

Glasziou P, Chalmers I, Altman DG, Bastian H, Boutron I, Brice A, et al. Taking healthcare interventions from trial to practice. *BMJ*. 2010;341:c3852. doi: 10.1136/bmj.c3852.