Reducing waste in research

Paul Glasziou, Bond University

www.crebp.net.au

equator network

Enhancing the QUAlity and Transparency Of health Research

Lancet Adding Value, Reducing Waste 2014
www.researchwaste.net

Five stages of waste in research

Annual avoidable waste in research is estimated to be 85% - from avoidable design flaws (50%),
non-publication (50%) and
unusable reports (50%)
– for a global total of over $140 Billion/year.

http://blogs.bmj.com/bmj/2016/01/14/paul-glasziou-and-iain-chalmers-is-85-of-health-research-really-wasted/

THE LANCET

November 2016

Increasing value of biomedical research: the Lancet-REWARD campaign

Italian REWARD Conference, hosted by GIMBE Foundation

Bologna, November 9th, 2016

Recently, several initiatives have witnessed a renewed interest for biomedical research in Italy: a new call for the independent drugs research program by Italian Medicines Agency, funds for Human Technopole (a predictive medicine national centre), a call for a National Agency for Research. This has led to the need for indicators to measure the return of funds invested in biomedical research: scientific productivity, quality of published evidence, impact of research on the National Health Service and on health outcomes, beside patents and profits.

As first Italian organization endorsing the Lancet-REWARD campaign, GIMBE Foundation is encouraging all stakeholders to increase value and reduce waste in biomedical research. After the publication of the Italian version of REWARD recommendations, on the 9th of November GIMBE Foundation organized a national conference in Bologna attended by over 150 participants, representing all stakeholders: researchers, public and private funders, regulatory bodies, research institutions, ethics committees, publishers, patient organizations and government. The opening session focused on health research's funding in Italy: in 2015 drug companies invested € 1,5 billion, while public funds account for less than € 500 million. Sir Iain Chalmers illustrated the human consequences of waste identified in the Lancet series, namely failure to systematically review what is already known before embarking on additional research, and biased under-reporting of research. Up for discussion with various stakeholders, three interactive sessions led by Silvio Garattini (Director of Mario Negri Institute for Pharmacological Research) and Nino Cartabellotta (President of GIMBE Foundation) addressed problems leading to research waste. Delegates actively contributed using a tele voting system to score the relevance of 17 recommendations made in the Lancet series. Results of the survey and Conference report are available on GIMBE website (www.gimbe.org/ricerca).

GIMBE Foundation is now approaching the major Italian public funders in order to integrate the most relevant REWARD recommendations into national calls for biomedical research. Further steps and results will be presented in the REWARD session during the 8th EBHC International Conference, that will be held in Taormina from 25th to 28th October 2017 (www.ebhc.org).

GIMBE

Breathing exercises for COPD?

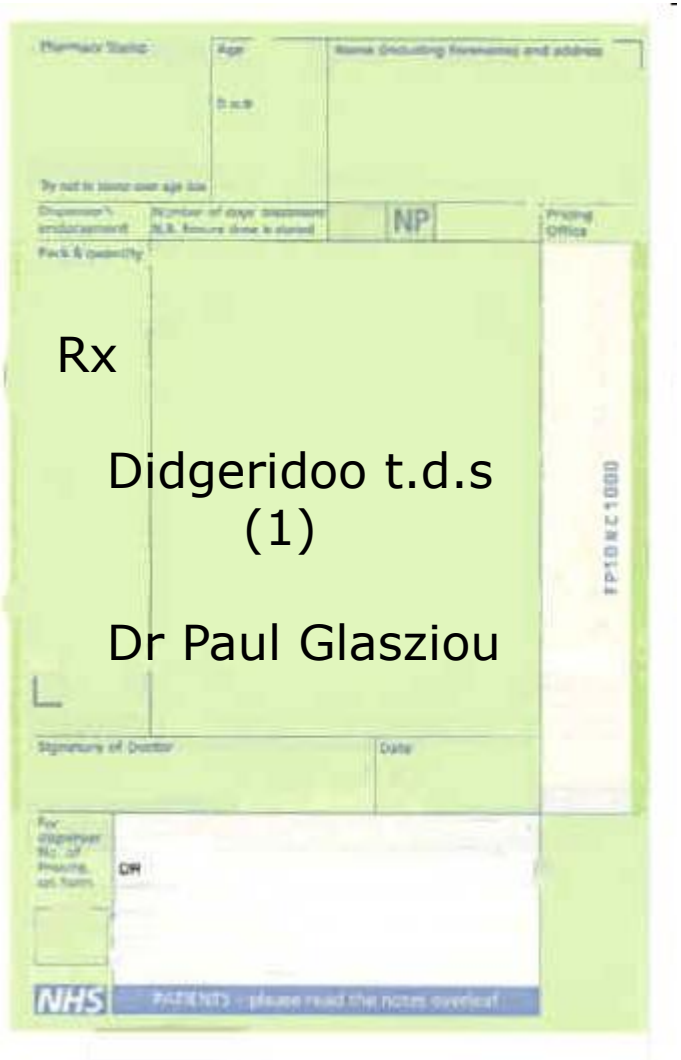
Long term smoker with chronic obstructive airways disease has recently quit smoking.

Has tried medications but does not like any.

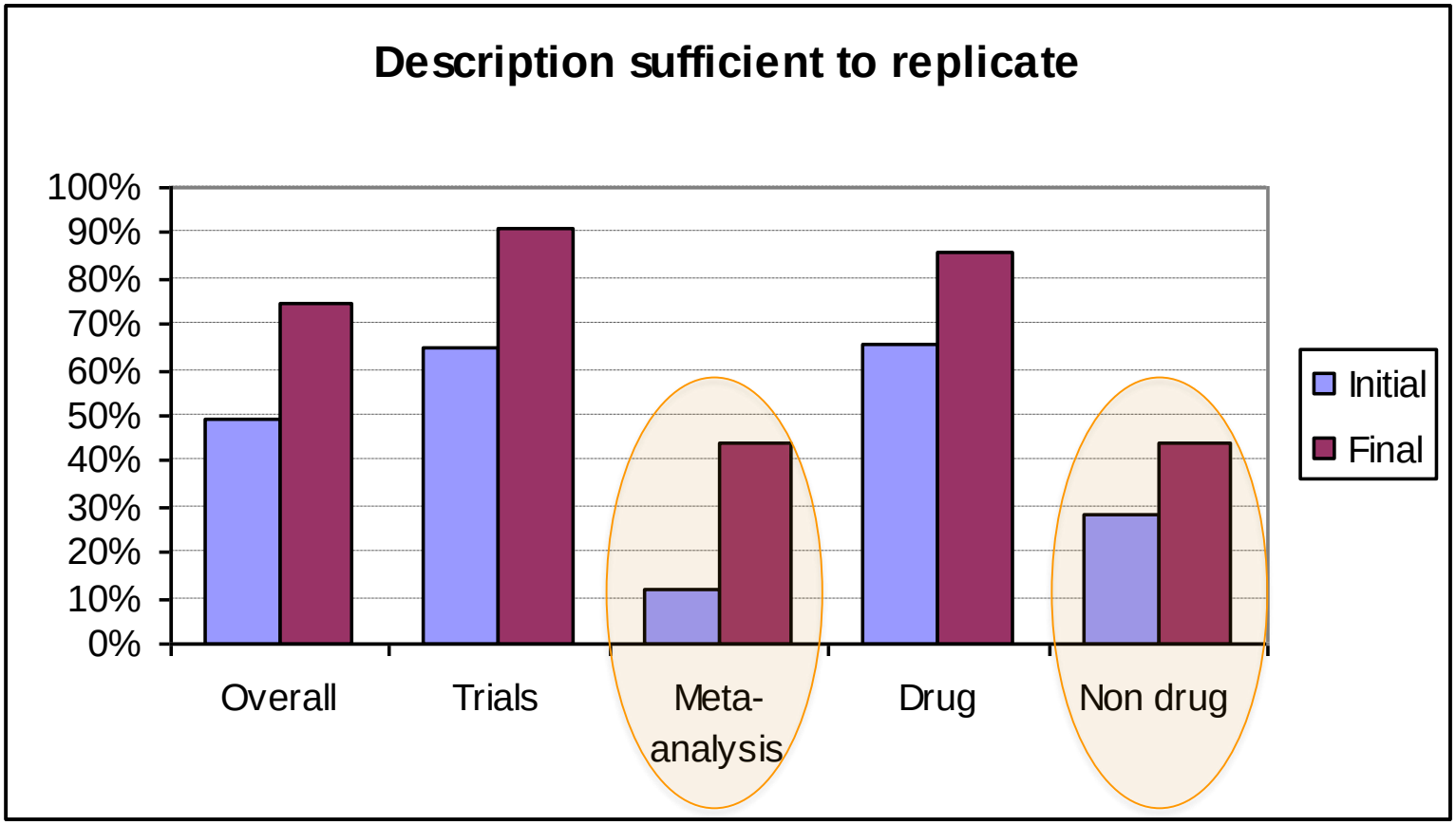
Asks: *are any "breathing exercises" I can recommend?*

What about didgeridoo playing?

Puhan M, et al. BMJ, 2006



Descriptions in 80 **successful** treatment studies selected for EBM journal were often inadequate



Glasziou, Heneghan, Meats BMJ, 2008

From research to patient benefits?

Questions relevant to clinicians & patients?

Low priority questions addressed

Important outcomes not assessed

Clinicians and patients not involved in setting research agendas

Unbiased and usable report?

Over 30% of trial interventions not sufficiently described

Over 50% of planned study outcomes not reported

Most new research not interpreted in the context of systematic assessment of other relevant evidence

From research to patient benefits?

Questions relevant to clinicians & patients?

Low priority questions

Unbiased and usable report?

Over 30% of trial

Avoidable waste in the production and reporting of research evidence

Iain Chalmers, Paul Glasziou

www.thelancet.com **Published online June 15, 2009**

agendas

Questions relevant to clinicians and patients? → Appropriate design and methods? → Accessible full publication? → Unbiased and usable report?

not interpreted in the

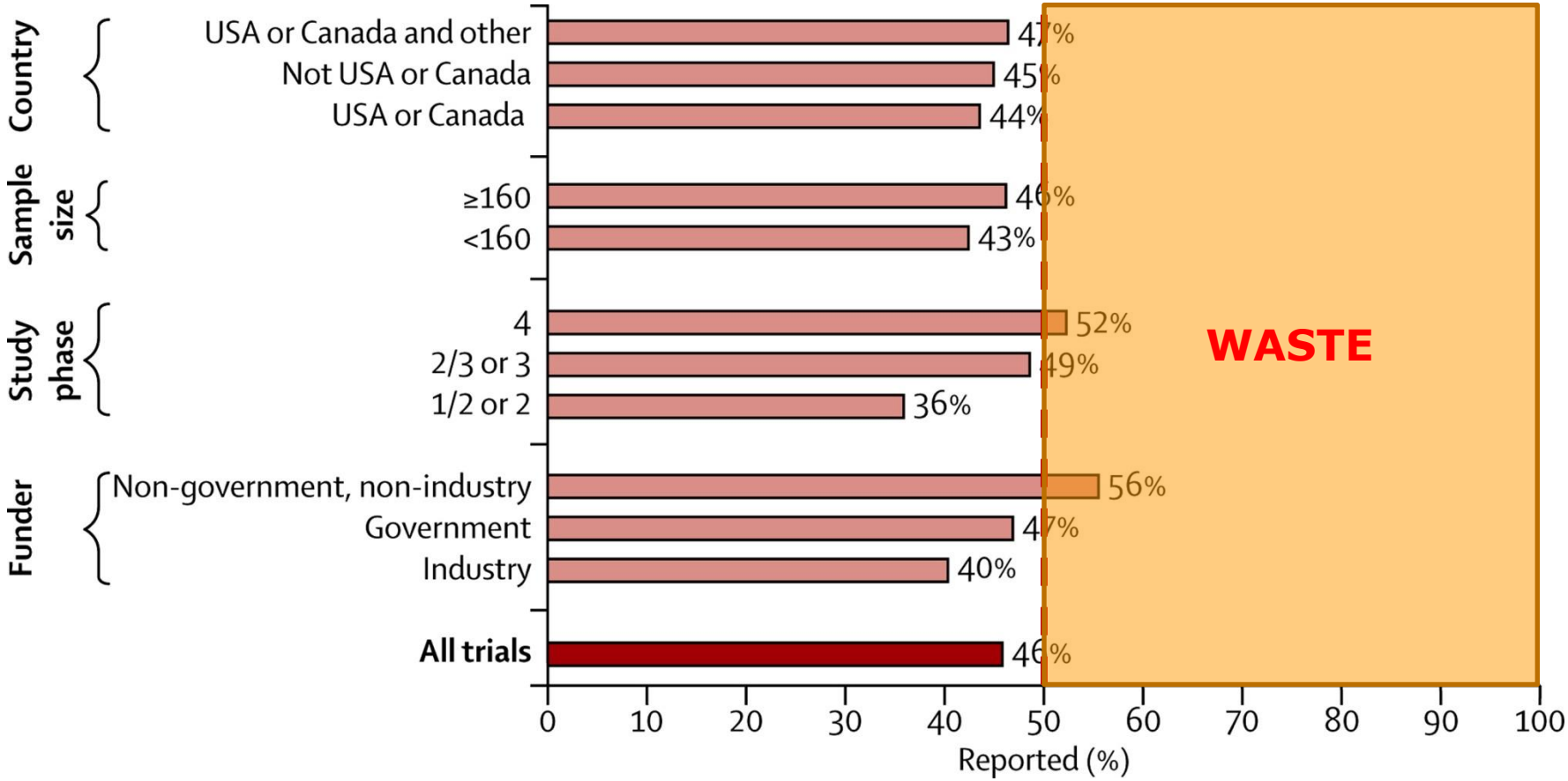
85% Research waste = over $100 Billion / year

Lancet Adding Value, Reducing Waste 2014
www.researchwaste.net

Five stages of waste in research

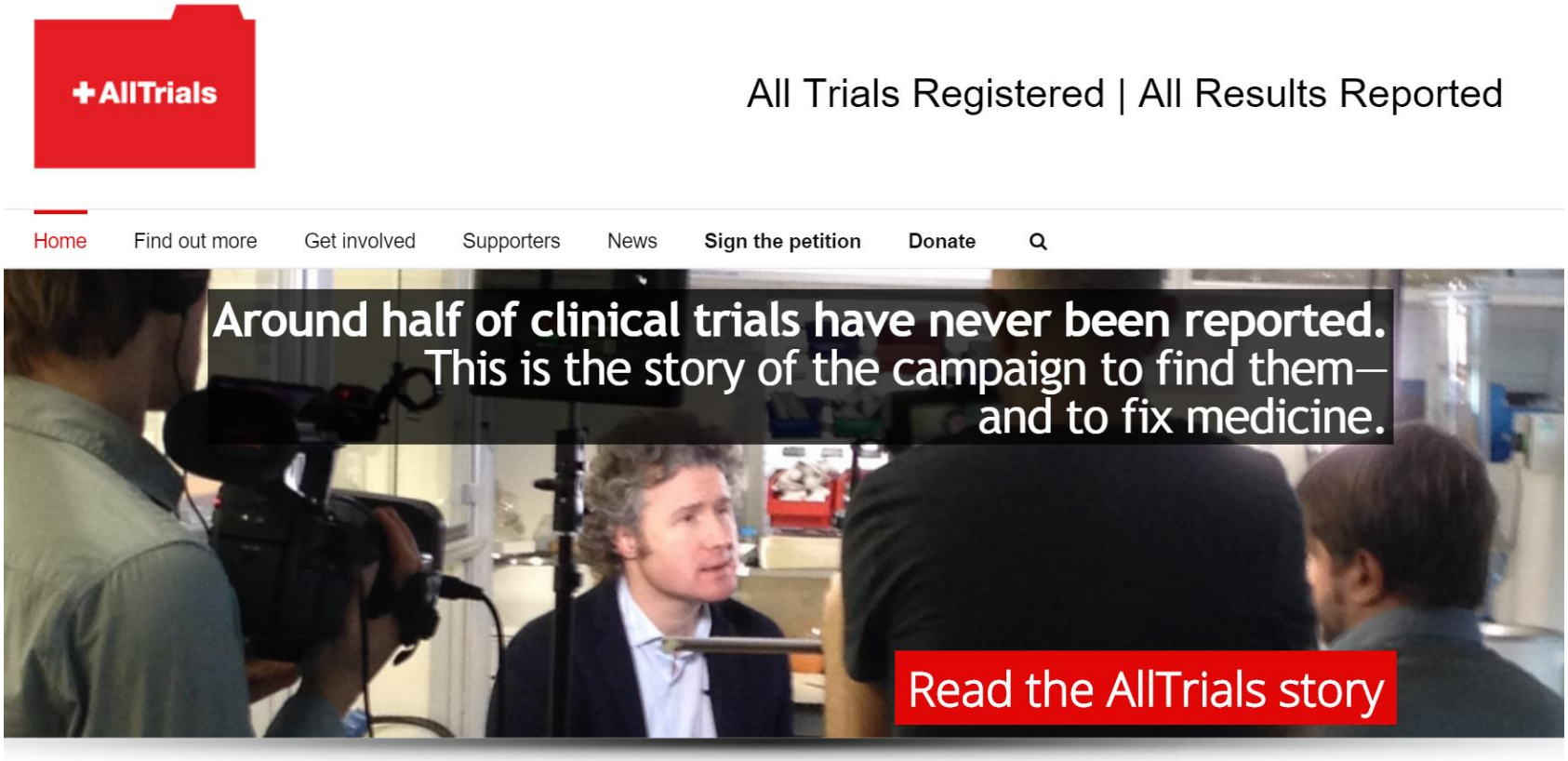
50% of research is not published

But similar across countries, size, phase, …



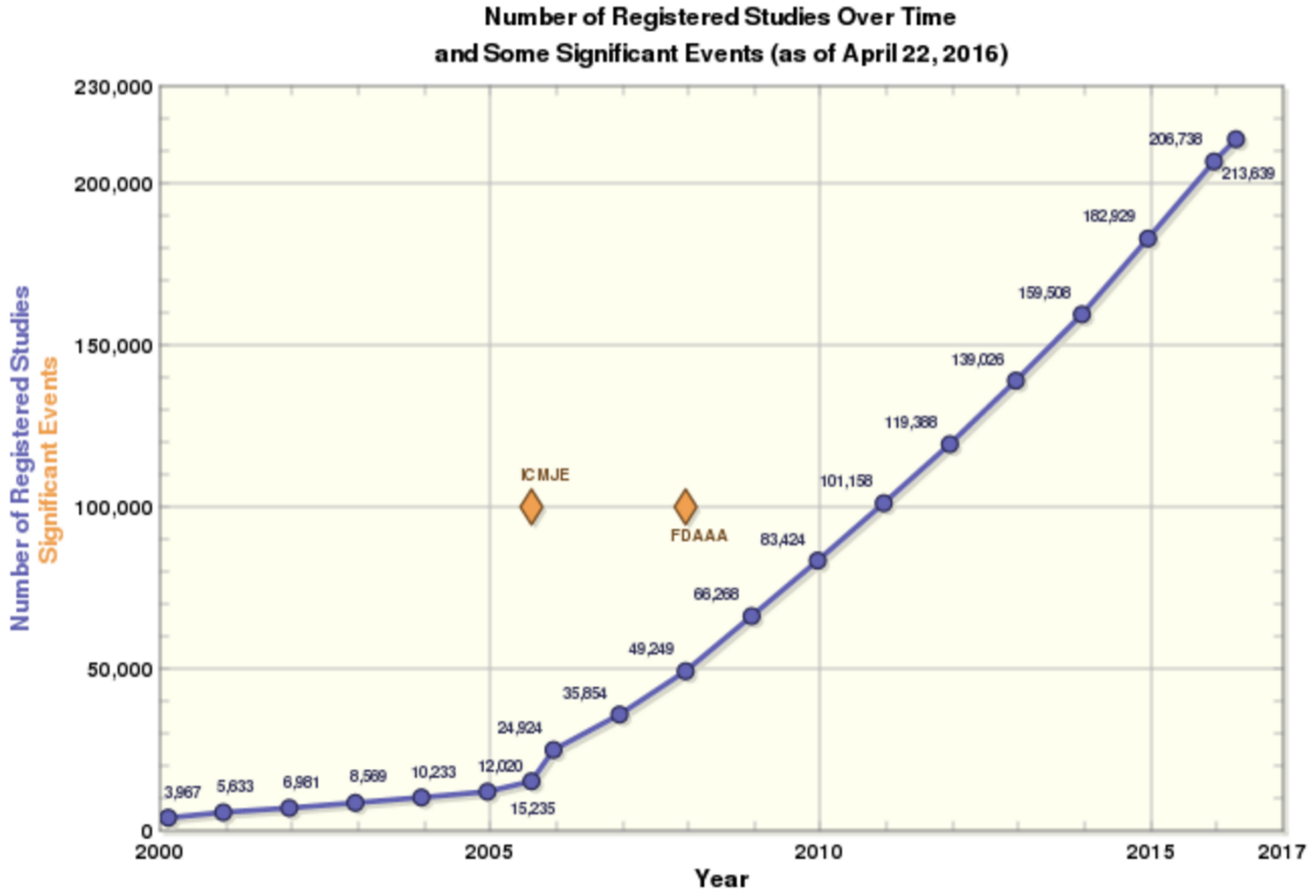
Lancet 2014;383:257–66

Non-Publication: a solution*



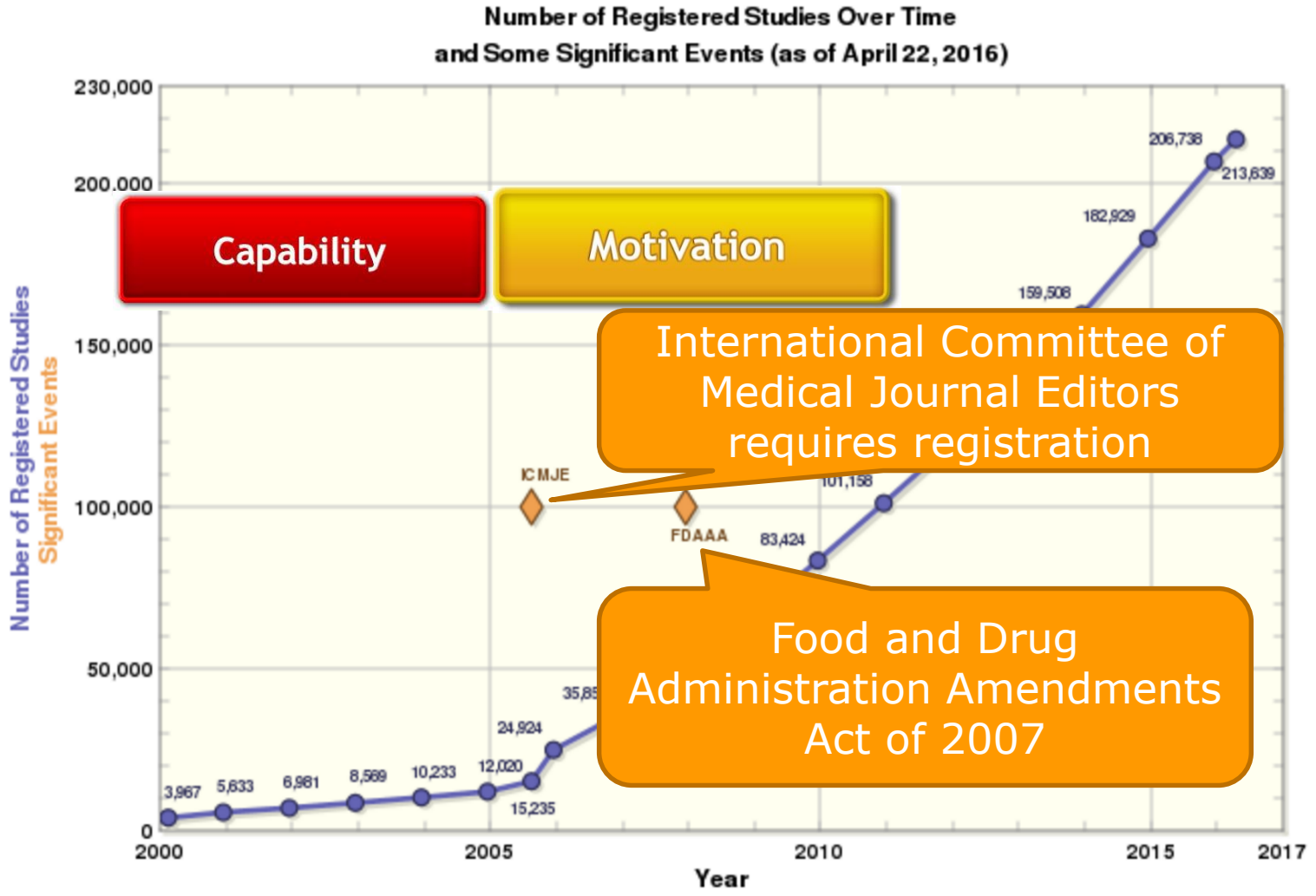
www.alltrials.net/

Trials registration rates: 2000-2016



Source: https://ClinicalTrials.gov

Trials registration rates: 2000-2016



Source: https://ClinicalTrials.gov

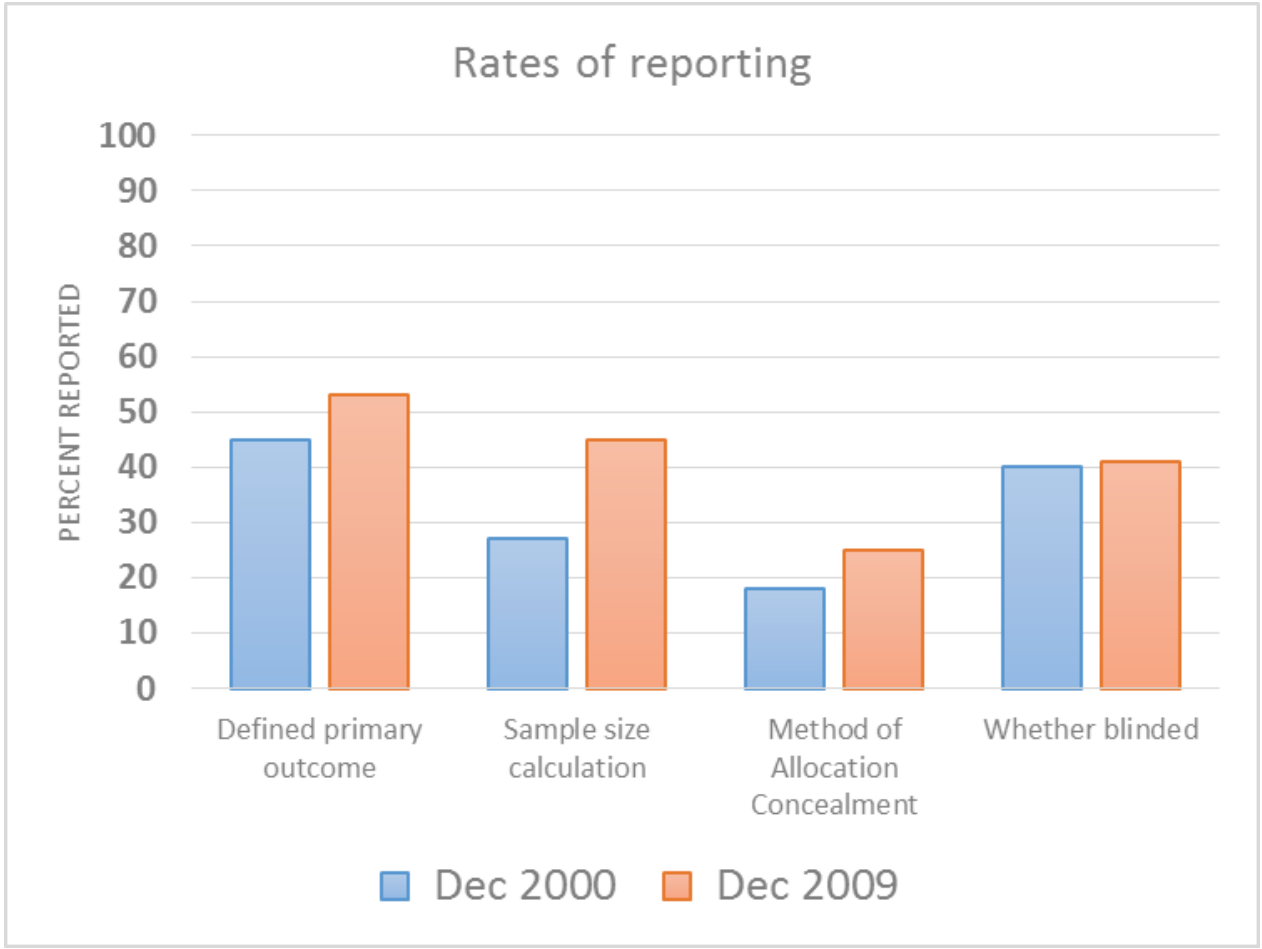
Posting of Summary Trial Results means 10% "extra" trials available

Source: https://ClinicalTrials.gov

Lancet Adding Value, Reducing Waste 2014
www.researchwaste.net

Five stages of waste in research

What is report for RCTs
Often missing essential methods



Chen & Altman, Lancet 2005; Hopewell BMJ 2010

What should be report for RCTs CONSORT checklist 2010 (25 items)

- *TITLE & ABSTRACT*

INTRODUCTION

- Background
- Objectives

METHODS

- Trial design
- Participants
- Interventions
- Outcomes
- Sample size
- Randomization
  - **Sequence generation**
  - **Allocation concealment**
  - **Implementation**
- Blinding (Masking)
- Statistical methods

- *RESULTS*

- Participant flow
- Recruitment
- Baseline data
- Numbers analyzed
- Outcomes and Estimation
- Ancillary analyses
- Harms

DISCUSSION

- Limitations
- Generalisability
- Interpretation

OTHER INFORMATION

- Registration
- Protocol

Funding

Poor descriptions of treatments

BMJ

BMJ 2013;347:f3755 doi: 10.1136/bmj.f3755 (Published 10 September 2013) Page 1 of 10

RESEARCH

Poor description of non-pharmacological interventions: analysis of consecutive sample of randomised trials

OPEN ACCESS

Tammy C Hoffmann *associate professor of clinical epidemiology*, Chrissy Erueti *assistant professor*, Paul P Glasziou *professor of evidence-based medicine*

Centre for Research in Evidence-Based Practice, Faculty of Health Sciences and Medicine, Bond University, Qld, Australia, 4229

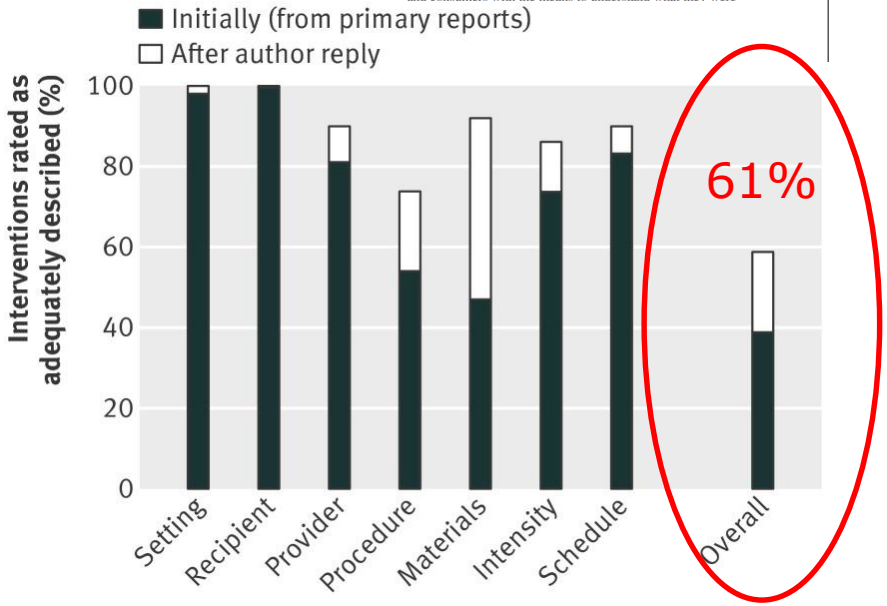
Abstract

Objectives To evaluate the completeness of descriptions of non-pharmacological interventions in randomised trials, identify which elements are most frequently missing, and assess whether authors can provide missing details.

Design Analysis of consecutive sample of randomised trials of non-pharmacological interventions.

Introduction

Secret remedies—branded drugs whose ingredients were kept secret—were once common, until successful campaigns in the United States and United Kingdom in the early 20th century required labels to include all ingredients.[1] This policy allowed independent evaluation of treatments and provided clinicians and consumers with the means to understand what they were



BMJ

BMJ 2014;348:g1687 doi: 10.1136/bmj.g1687 (Published 6 March 2014) Page 1 of 13

RESEARCH METHODS & REPORTING

Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide

Tammy C Hoffmann *associate professor of clinical epidemiology*[1], Paul P Glasziou *director and professor of evidence based medicine*[1], Isabelle Boutron *professor of epidemiology*[2], Ruairidh Milne *professorial fellow in public health and director*[3], Rafael Perera *university lecturer in medical statistics*[4], David Moher *senior scientist*[5], Douglas G Altman *professor of statistics in medicine*[6], Virginia Barbour *medicine editorial director, PLOS*[7], Helen Macdonald *assistant editor*[8], Marie Johnston *emeritus professor of health psychology*[9], Sarah E Lamb *Kadoorie professor of trauma rehabilitation and co-director of Oxford clinical trials research unit*[10], Mary Dixon-Woods *professor of medical sociology*[11], Peter McCulloch *clinical reader in surgery*[12], Jeremy C Wyatt *leadership chair of ehealth research*[13], An-Wen Chan *Phelan scientist*[14], Susan Michie *professor*[15]

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located ** Primary paper (page or appendix number)	Other [1] (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.		
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.		
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).		
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.		
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.		
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.		
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.		

Salvaging NonDrug trial research: **H**andbook of **N**on-**D**rug **I**nterventions

60 entries; 15 new / year
Free access at
www.racgp.org.au/handi/
Indexed in PubMedHealth

and Raquel Newman (medical writer); Joanna Ong & Gisele Rocha (RACGP senior project officers)

HANDI Committee
GPs, Occupational Therapist, Physiotherapist, Physician

Lancet Adding Value, Reducing Waste 2014
www.researchwaste.net

Five stages of waste in research

New research should build on previous research

Horn J et al. Very Early Nimodipine Use in Stroke (VENUS): a randomized, double-blind, placebo-controlled **TRIAL**. Stroke. 2001
RESULTS: At trial termination, after inclusion of 454 patients (225 nimodipine, 229 placebo), **no effect** of nimodipine was found.

Horn J, et al. Calcium antagonists for acute ischemic stroke. The Cochrane Database of **SYSTEMATIC REVIEWS**. 2001.
RESULTS "46 trials were identified of which 28 were included (7521 patients). **No effect** of calcium antagonists on poor outcome at the end of follow-up (OR 1.07), or on death at end of follow-up (OR 1.10) was found."

Horn J et al. Nimodipine in **ANIMAL** model experiments of focal cerebral ischemia: a **SYSTEMATIC REVIEW** Stroke. 2001 Oct.
"20 studies … **review did not show convincing evidence** to substantiate the decision to perform trials with nimodipine in large numbers of patients."

New research should build on previous research

Horn J et al. Very Early Nimodipine Use in Stroke (VENUS): a
L. Stroke. 2001
4 patients
lipine was found.

Too valuable to waste

Hoe verkwisten we zo weinig mogelijk waarde van dierproeven en klinische trials? Aanstaande vrijdag behandelen diverse sprekers deze vraag.

Registration

Meer waarde uit dierproeven halen

FederaPrijs voor dr. Janneke Horn, neuroloog-intensivist aan het AMC

Too valuable to waste: Experiments on humans and animals

Human clinical trials and animal experiments for medicine need a sound regulation. That is needed to get valid results and to avoid waste of efforts. However, meetings of clinical trial researchers with animal experiments researchers are taken place very rarely. The FederaDag 2017 will offer knowledge ánd connection to experts in both fields.

Friday June 16th, the FederaDag 2017 takes place at NWO in The Hague, and is organized by Federa in cooperation with ZonMw.

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VIEW Stroke. 2001 Oct.
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The Vienna Principles

By hnykvist | 21 March, 2016 | No Comments |

Principles of collaboration on development of automation in systematic reviews released.

The Vienna Principles

1. Systematic reviews involve multiple tasks, each with different issues, but all must be improved.
2. Automation may assist with all tasks, from scoping reviews to identifying research gaps as well protocol development to writing and dissemination of the review.
3. The processes for each task can and should be continuously improved, to be more efficient and more accurate.
4. Automation can and should facilitate the production of systematic reviews that adhere to high standards for the reporting, conduct and updating of rigorous reviews.
5. Developments should also provide for flexibility in combining and using, e.g. subdividing or merging steps and allowances for different users to use different interfaces.

EVENTS

Herrenhausen Conference: “Lost in the Maze? Navigating Evidence and Ethics in Translational Neuroscience”, February 14 – 16, 2018, Herrenhausen Palace, Hanover, Germany

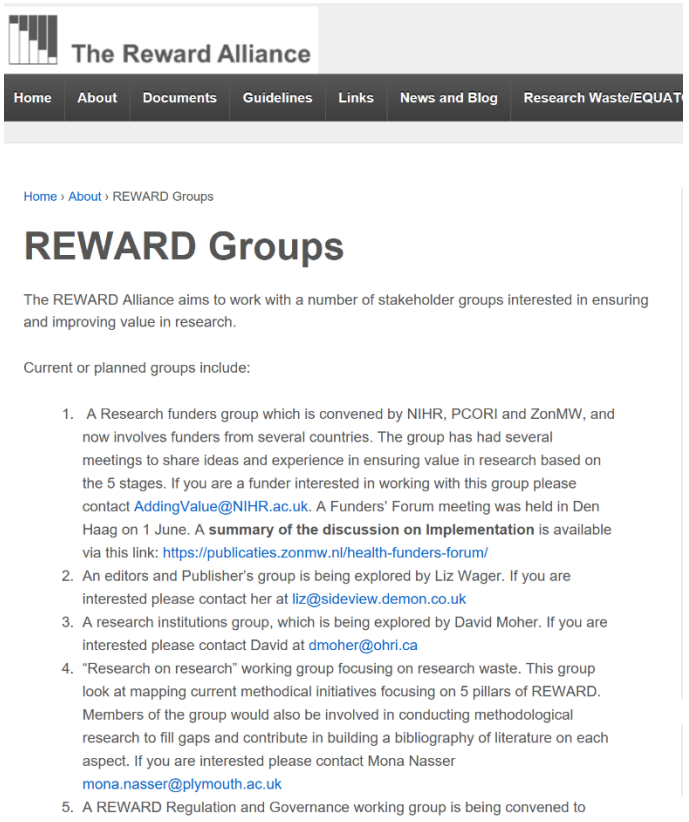
8th International Conference of EBHC Teachers & Developers hosted by GIMBE Foundation, 25th – 28th October, Taormina, Italy

Global Evidence Summit 2017, 12-16 September, Cape Town, South Africa

NEWS

Some Conclusions

- 85% of research wasted
- Much waste is fixable, but requires work from several groups
  - Funders
  - Publishers
  - Institutions
  - Ethics/regulation
  - Research on Research



The Reward Alliance

Home | About | Documents | Guidelines | Links | News and Blog | Research Waste/EQUAT

Home › About › REWARD Groups

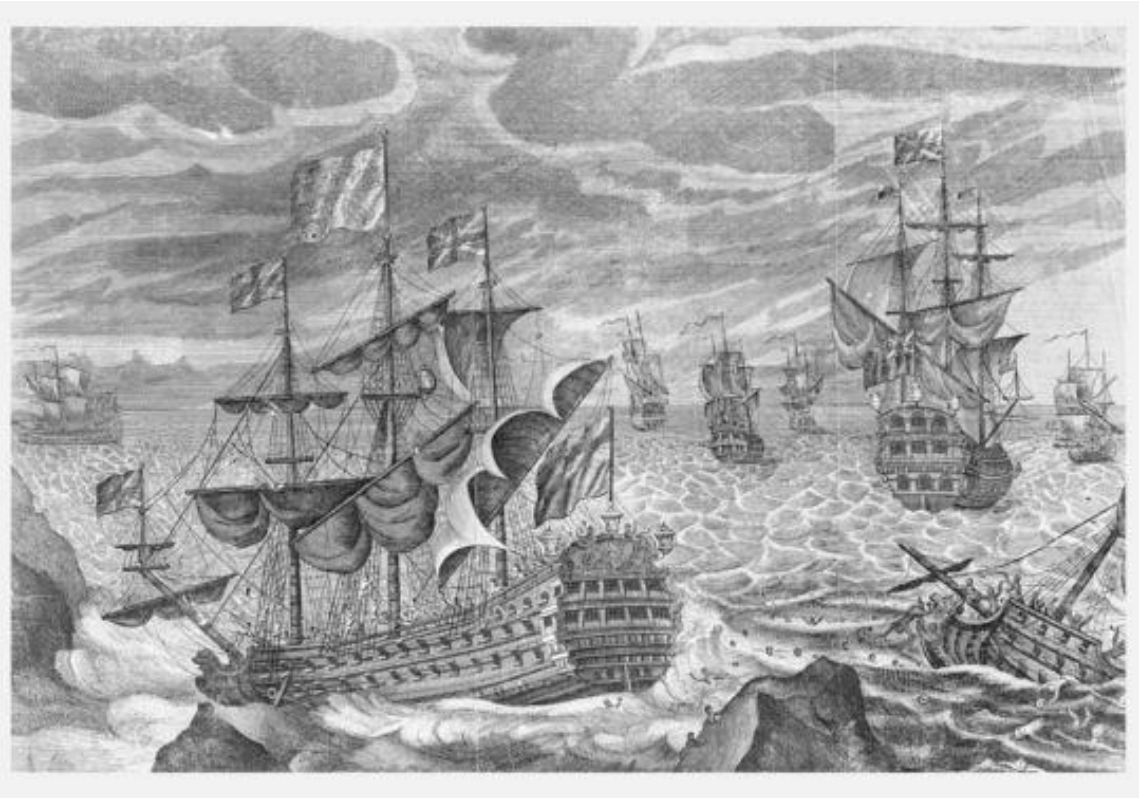
REWARD Groups

The REWARD Alliance aims to work with a number of stakeholder groups interested in ensuring and improving value in research.

Current or planned groups include:

1. A Research funders group which is convened by NIHR, PCORI and ZonMW, and now involves funders from several countries. The group has had several meetings to share ideas and experience in ensuring value in research based on the 5 stages. If you are a funder interested in working with this group please contact AddingValue@NIHR.ac.uk. A Funders' Forum meeting was held in Den Haag on 1 June. A **summary of the discussion on Implementation** is available via this link: https://publicaties.zonmw.nl/health-funders-forum/
2. An editors and Publisher's group is being explored by Liz Wager. If you are interested please contact her at liz@sideview.demon.co.uk
3. A research institutions group, which is being explored by David Moher. If you are interested please contact David at dmoher@ohri.ca
4. "Research on research" working group focusing on research waste. This group look at mapping current methodical initiatives focusing on 5 pillars of REWARD. Members of the group would also be involved in conducting methodological research to fill gaps and contribute in building a bibliography of literature on each aspect. If you are interested please contact Mona Nasser mona.nasser@plymouth.ac.uk
5. A REWARD Regulation and Governance working group is being convened to

A Prize to "solve" research waste?



1707 - Scilly naval disaster 1707
1714 - The Board of Longitude founded
1787 - Harrison's clock awarded the £20,000 prize

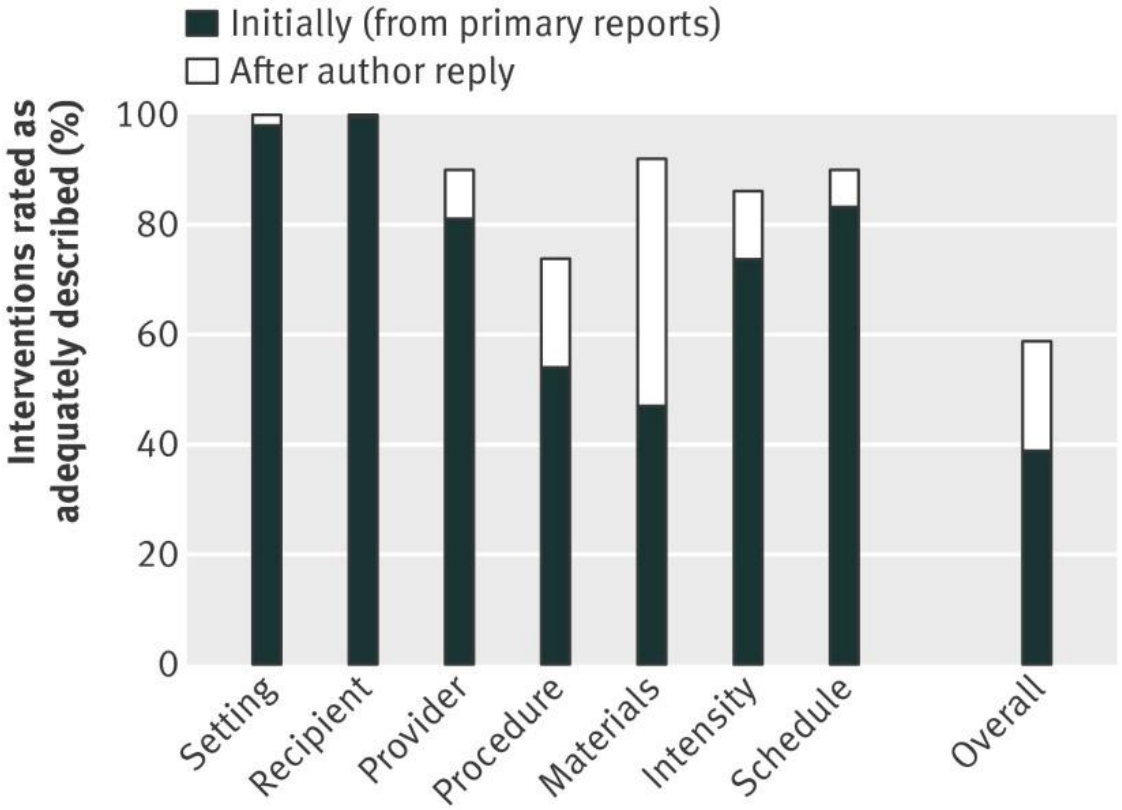
The Vienna Principles:

General principles of collaboration and development in the automation of systematic reviews

1. Systematic reviews involve multiple tasks, each with different issues, but all must be improved.
2. Automation may assist with all tasks, from scoping reviews to identifying research gaps as well protocol development to writing and dissemination of the review.
3. The processes for each task can and should be continuously improved, to be more efficient and more accurate.
4. Automation can and should facilitate the production of systematic reviews that adhere to high standards for the reporting, conduct and updating of rigorous reviews.
5. Developments should also provide for flexibility in combining and using, e.g. subdividing or merging steps and allowances for different users to use different interfaces.
6. Different groups with different expertise are working on different parts of the problem; to improve reviews as a whole will require collaboration between these groups.
7. Every automation technique should be shared, preferably by making code, evaluation data and corpora available for free.
8. All automation techniques and tools should be evaluated using a recommended and replicable method with results and data reported.

Drafted by members of International Collaboration for the Automation of System Reviews (ICASR) at their first meeting, 2 October 2015, Vienna, Austria.

Poor reporting of non-pharmacological interventions in 6 major medical journals



Of 133 trials in 2010

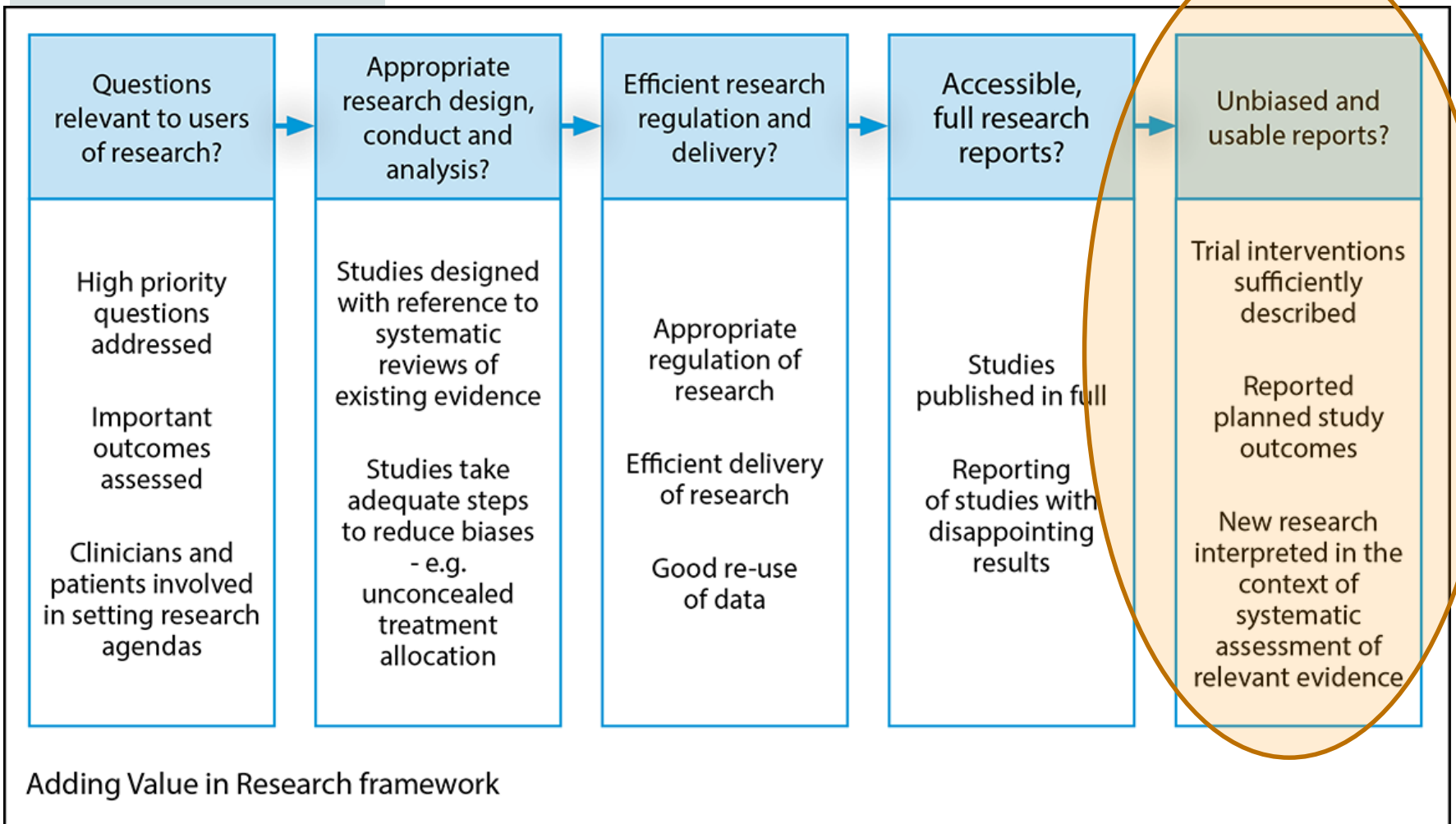
59% adequate after contacting author

39% adequate in primary sources

Hoffmann, Erueti, Glasziou. Poor description of non-pharmacological interventions: A remediable barrier to evidence use in practice? BMJ 2013

Lancet Adding Value, Reducing Waste 2014
www.researchwaste.net

5. REPORTING



Summary

- Effective NonDrug treatments: many developed, but poorly described and little used
  - www.racgp.org.au/handi
- Waste in Research: over 85%, due to poor design, non-publication, and poor reporting
  - http://rewardalliance.net/

Summary

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New research should build on previous research

Very Early Nimodipine Use in Stroke (VENUS)
A Randomized, Double-Blind, Placebo-Controlled Trial

J. Horn, MD; R.J. de Haan, PhD; M. Vermeulen, MD, PhD; M. Limburg, MD, PhD

Backgound and Purpose—The Very Early Nimodipine Use in Stroke (VENUS) trial was designed to test the hypothesis that early treatment with nimodipine has a positive effect on survival and functional outcome after stroke. This was suggested in a previous meta-analysis on the use of nimodipine in stroke. However, in a recent Cochrane review we were unable to reproduce these positive results. This led to the early termination of VENUS after an interim analysis.

Methods—In this randomized, double-blind, placebo-controlled trial, treatment was started by general practitioners or neurologists within 6 hours after stroke onset (oral nimodipine 30 mg QID or identical placebo, for 10 days). Main analyses included comparisons of the primary end point (poor outcome, defined as death or dependency after 3 months) and secondary end points (neurological status and blood pressure 24 hours after inclusion, mortality after 10 days, and adverse events) between treatment groups. Subgroup analyses (on final diagnosis and based on the per-protocol data set) were performed.

Results—At trial termination, after inclusion of 454 patients (225 nimodipine, 229 placebo), no effect of nimodipine was found. After 3 months of follow-up, 32% (n=71) of patients in the nimodipine group had a poor outcome compared with 27% (n=62) in the placebo group (relative risk, 1.2; 95% CI, 0.9 to 1.6). A treatment effect was not found for secondary outcomes and in the subgroup analyses.

Conclusions—The results of VENUS do not support the hypothesis of a beneficial effect of early nimodipine in stroke patients. **(*Stroke.* 2001;32:461-465.)**

Key Words: calcium channel blockers ■ cerebrovascular disorders ■ nimodipine ■ randomized controlled trials

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New research should build on previous research

Nimodipine in Animal Model Experiments of Focal Cerebral Ischemia

A Systematic Review

J. Horn, MD; R.J. de Haan, PhD; M. Vermeulen, MD; P.G.M. Luiten, PhD; M. Limburg, MD

"20 studies were included. The methodological quality of the studies was poor."

"The results of this review did not show convincing evidence to substantiate the decision to perform trials with nimodipine in large numbers of patients."

Stroke 2001

Was enrolling 7,500 patients justified?

- VENUS trial -> 454 patients
- 28 human studies with 7,500 patients
- -> No clear effect

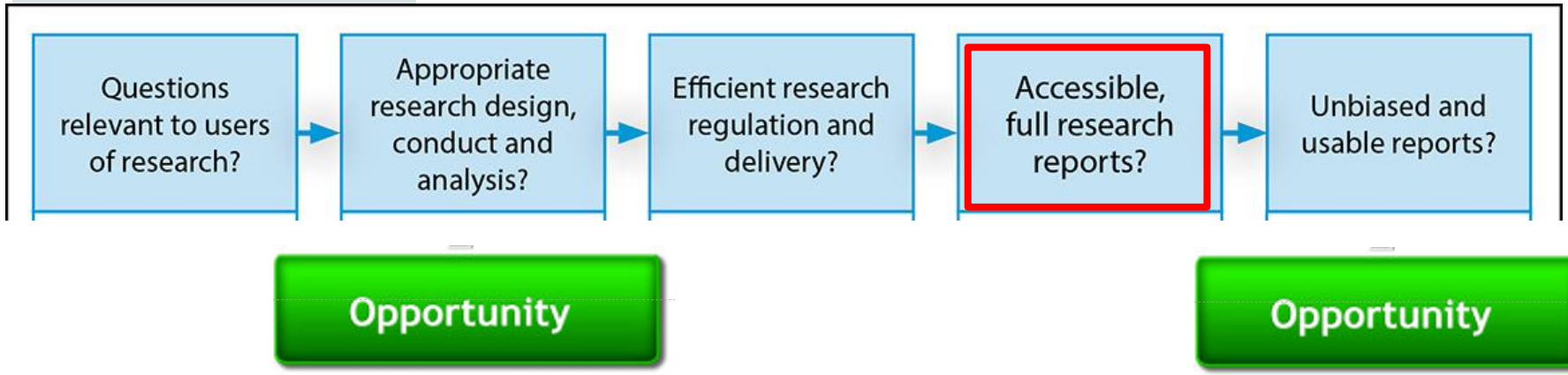
- 20 animal studies -> no clear effect

3 Research funders and regulators should demand that proposals for additional primary research are justified by systematic reviews showing what is already known, and increase funding for the required syntheses of existing evidence

- Monitoring—audit proposals for and reports of new primary research

Lancet Adding Value, Reducing Waste 2014
www.researchwaste.net

Five stages of waste in research



Monitoring "the solution" Automated tracking by institution

Who's not sharing their trial results?

Trials registered on ClinicalTrials.gov should share results on the site shortly after completing, or publish in a journal. But many organisations fail to report the results of clinical trials. We think this should change. Explore our data (last updated October 2016) to see the universities, government bodies and pharmaceutical companies that aren't sharing their clinical trial results.

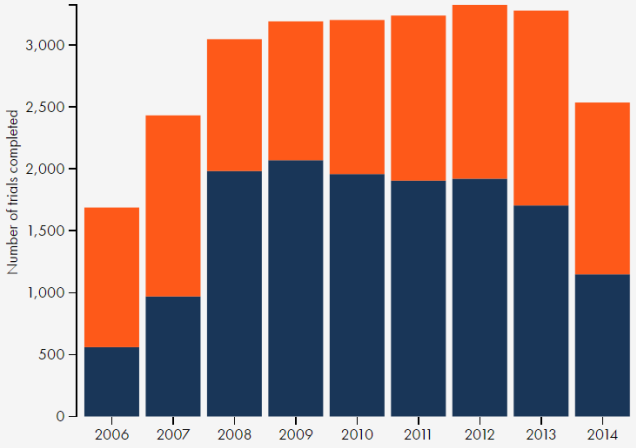
Trial sponsors

We've ranked the major trial sponsors with the most unreported trials registered on ClinicalTrials.gov. Click on a sponsor's name to find out whether it's getting better at reporting completed trials - or worse.

	Name of sponsor	Trials missing results	Total eligible trials	Percent missing
1	Sanofi	285	435	65.5%
2	Novartis Pharmaceuticals	201	534	37.6%
3	National Cancer Institute (NCI)	194	558	34.8%
4	Assistance Publique - Hôpitaux de Paris	186	292	63.7%
5	GlaxoSmithKline	183	809	22.6%
6	Mayo Clinic	157	312	50.3%
7	Yonsei University	139	194	71.6%
8	Seoul National University Hospital	131	207	63.3%
9	Alliance for Clinical Trials in Oncology	129	160	80.6%

Trials by year

Since Jan 2006, **all major trial sponsors** completed 25,927 eligible trials and **haven't published results for 11,714 trials**. That means 45.2% of their trials are missing results.



https://trialstracker.ebmdatalab.net/#/

Pulmonary Rehabilitation is effective

1.2.10 Pulmonary rehabilitation

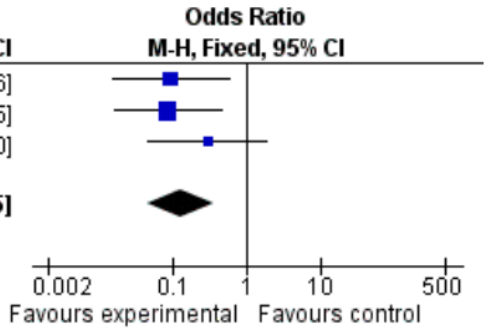
Pulmonary rehabilitation is defined as a multidisciplinary programme of care for patients with chronic respiratory impairment that is individually tailored and designed to optimise the individual's physical and social performance and autonomy.

1.2.10.1 Pulmonary rehabilitation should be made available to all appropriate patients with COPD. **A**

Figure 2. Forest plot of comparison: 1 Rehabilitation versus control, outcome: 1.1 Hospital admission (to end of follow-up).

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Behnke 2000	3	14	9	12	34.0%	0.09 [0.01, 0.56]
Man 2004	2	20	12	21	47.1%	0.08 [0.02, 0.45]
Murphy 2005	2	13	5	13	18.9%	0.29 [0.04, 1.90]
Total (95% CI)		**47**		**46**	**100.0%**	**0.13 [0.04, 0.35]**
Total events	7		26			

Heterogeneity: Chi² = 1.11, df = 2 (P = 0.57); I² = 0%
Test for overall effect: Z = 3.98 (P < 0.0001)



Great – but what is pulmonary rehabilitation??

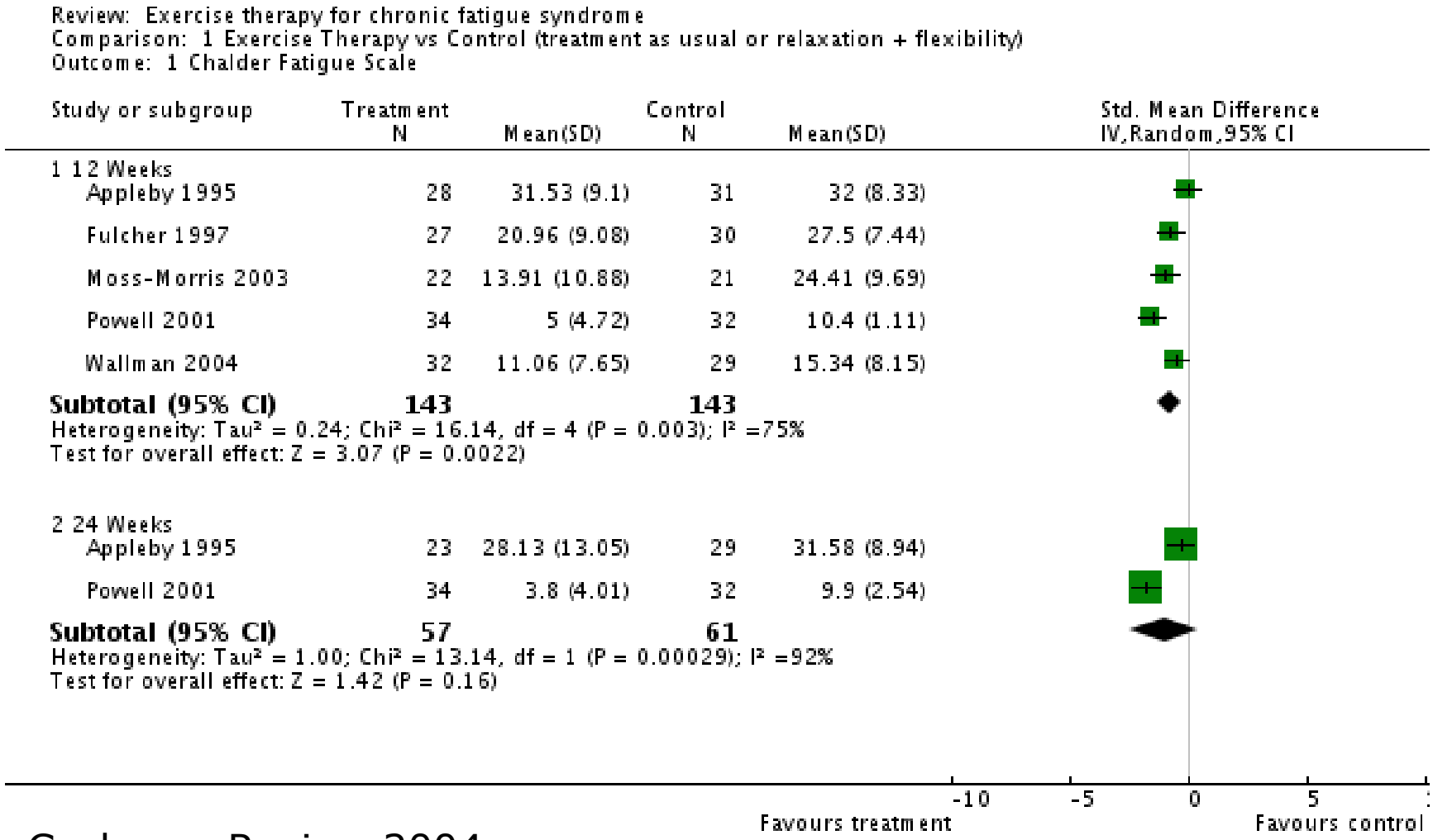
Found: a good description of pulmonary rehabilitation

My consultant at King's offered me "*pulmonary rehabilitation*". I didn't know what that was, so I asked and he said it was *an exercise program*.
I thought the man was mad because I couldn't get out of a chair.

(Later interview – she is much improved)

http://www.youtube.com/watch?v=cthKnGK6Gzs

Chronic Fatigue Syndrome
Graded Exercise improves fatigue



Cochrane Review 2004

Exercise prescription for individuals with chronic fatigue syndrome

Karen E Wallman, Alan R Morton, Carmel Goodman and Robert Grove

Prescription for graded exercise

- Exercise every 2nd day
- Target RPE of 11-14 ->
- Every 2 weeks increase duration by 2-5 minutes

1 Borg's Ratings of Perceived Exertion Scale*

Perceived exertion	Rating
	6
Very, very light	7
	8
Very light	9
	10
Fairly light	11
	12
Somewhat hard	13
	14
Hard	15
	16
Very hard	17
	18
Very, very hard	19
	20

Wallman. Med J Aust. 2005 Aug 1;183(3):142-3.

OPEN ACCESS Freely available online

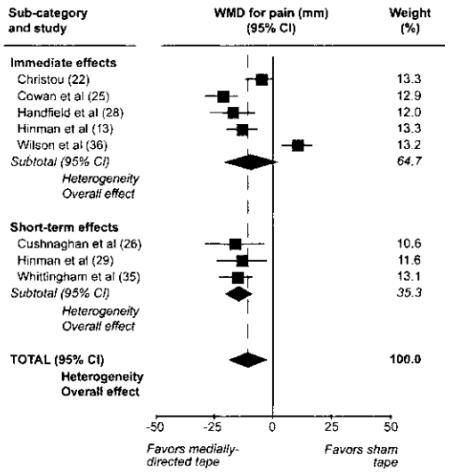
PLOS | MEDICINE

Guidelines and Guidance

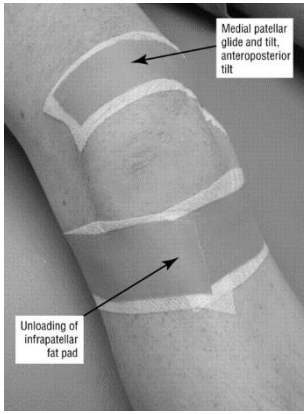
Intervention Synthesis: A Missing Link between a Systematic Review and Practical Treatment(s)

Paul P. Glasziou[1]*, Iain Chalmers[2], Sally Green[3], Susan Michie[4]

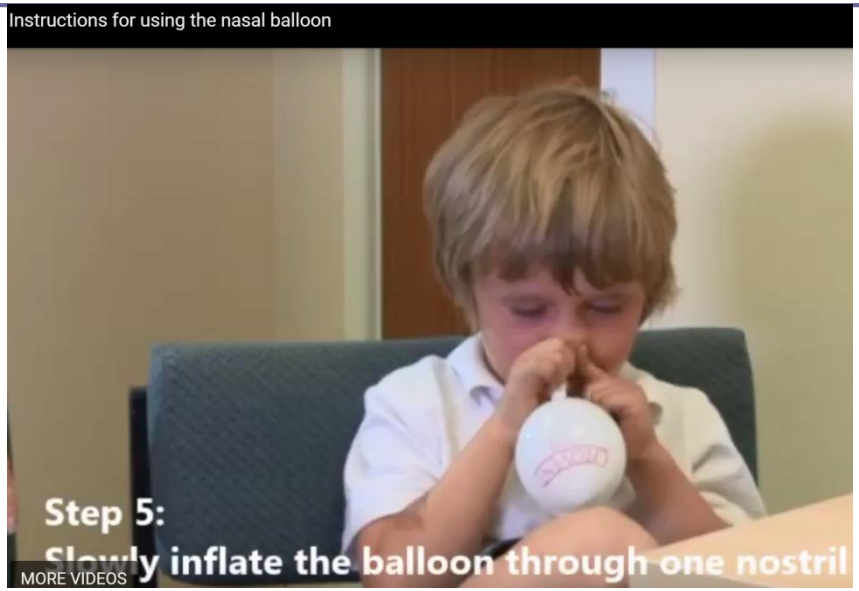
- "Whether to"
  - Evidence quality
  - Individual applicability



- "How to"
  - What & where?
  - How long & how often?

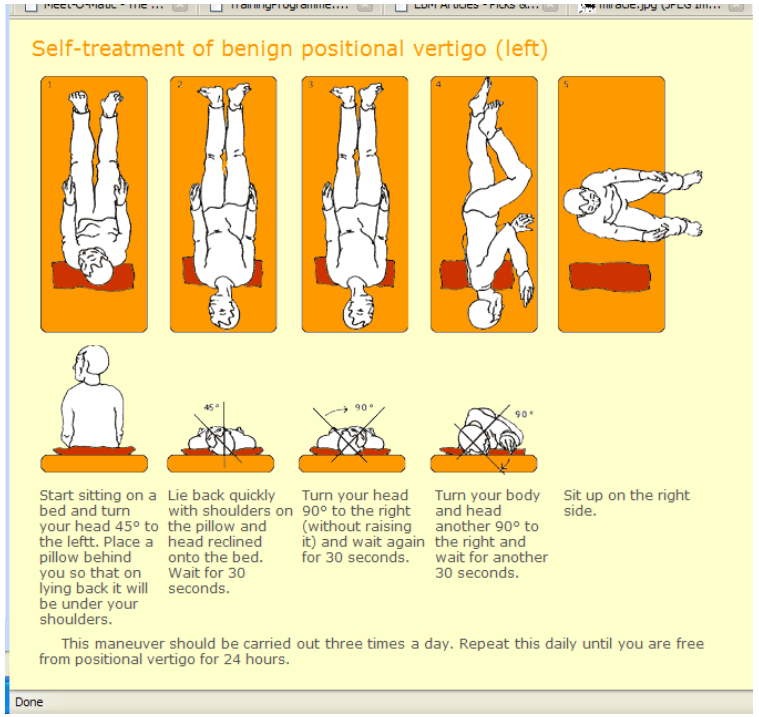


BMJ 2003; 327 : 135


Instructions for using the nasal balloon
Step 5:
MORE VIDEOS

3. Procedures: Epley for BPPV (Vertigo)

- STUDY: Self-treatment for benign paroxysmal positional vertigo of the posterior semicircular canal. Neurology 2005.
- TREATMENT: "Each head position has to be maintained for more than 30 seconds. ***Patients received illustrated instructions*** for the specific maneuver …"



- All agreed "useful"
- 3 months later
  - only 2 doctors did it
  - Put video in intranet
- Another 3 months later
  - Still only 2 doctors
  - Trained each person to do