

# Is the study treatment replicable by clinicians?



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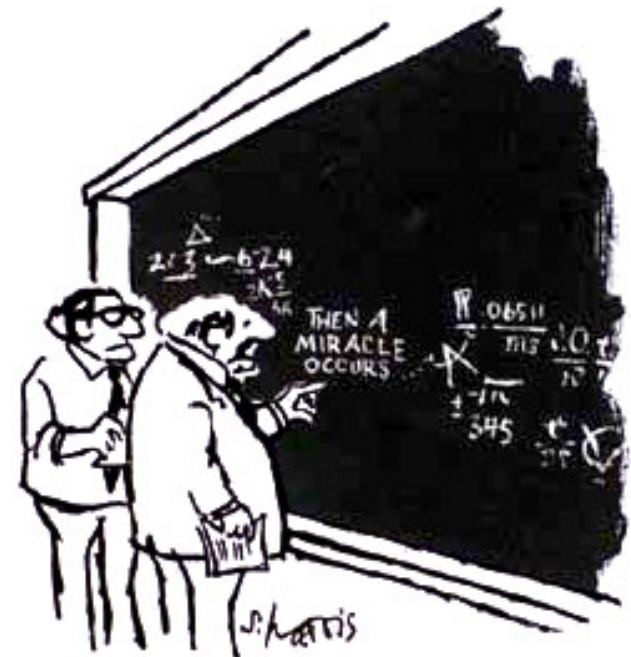
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# Background and Aims

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- CONSORT Item 22 requests:
  - "Precise details of the treatments intended for each group and how and when they were actually administered".
  - No studies of compliance
  
- Our aim: can we duplicate treatments studied?



"I THINK YOU SHOULD BE MORE EXPLICIT  
HERE IN STEP TWO."

# Do you use Salt (sodium) reduction for reducing high Blood Pressure?

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- The paper's description of sodium reduction
  - "Individual and weekly group counseling sessions were offered initially, with less intensive counseling and support thereafter, specific to sodium reduction."
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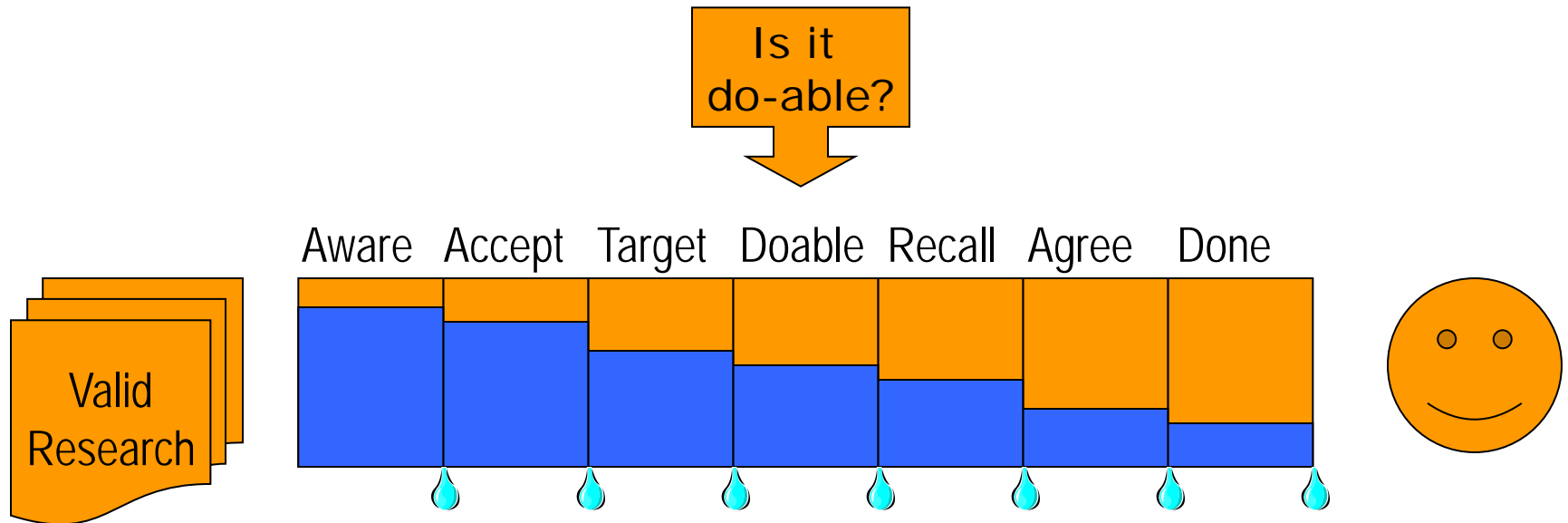


# What is sodium reduction?

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- The paper's description
  - "Individual and weekly group counseling sessions were offered initially, with less intensive counseling and support thereafter, specific to sodium reduction."
- Previous reference
  - (i) an individual session followed by 10 weekly group 90 minute sessions with a nutritionist, followed by a transitional stage of some additional sessions
  - (ii) Topics in the weekly sessions included Getting Started, sodium basics, the morning meal, midday sources of sodium, the main meal, planning ahead, creative cooking, eating out, food cues, and social support,
  - (iii) the sessions included sampling of foods, discussion of articles on sodium reduction, and problem-solving,
  - (iv) patients kept diaries at least 6 days per week, and urine sodiums were measured.

# Many “Leaks” from research & practice



If 80% achieved at each stage then  
 $0.8 \times 0.8 \times 0.8 \times 0.8 \times 0.8 \times 0.8 \times 0.8 = 0.21$

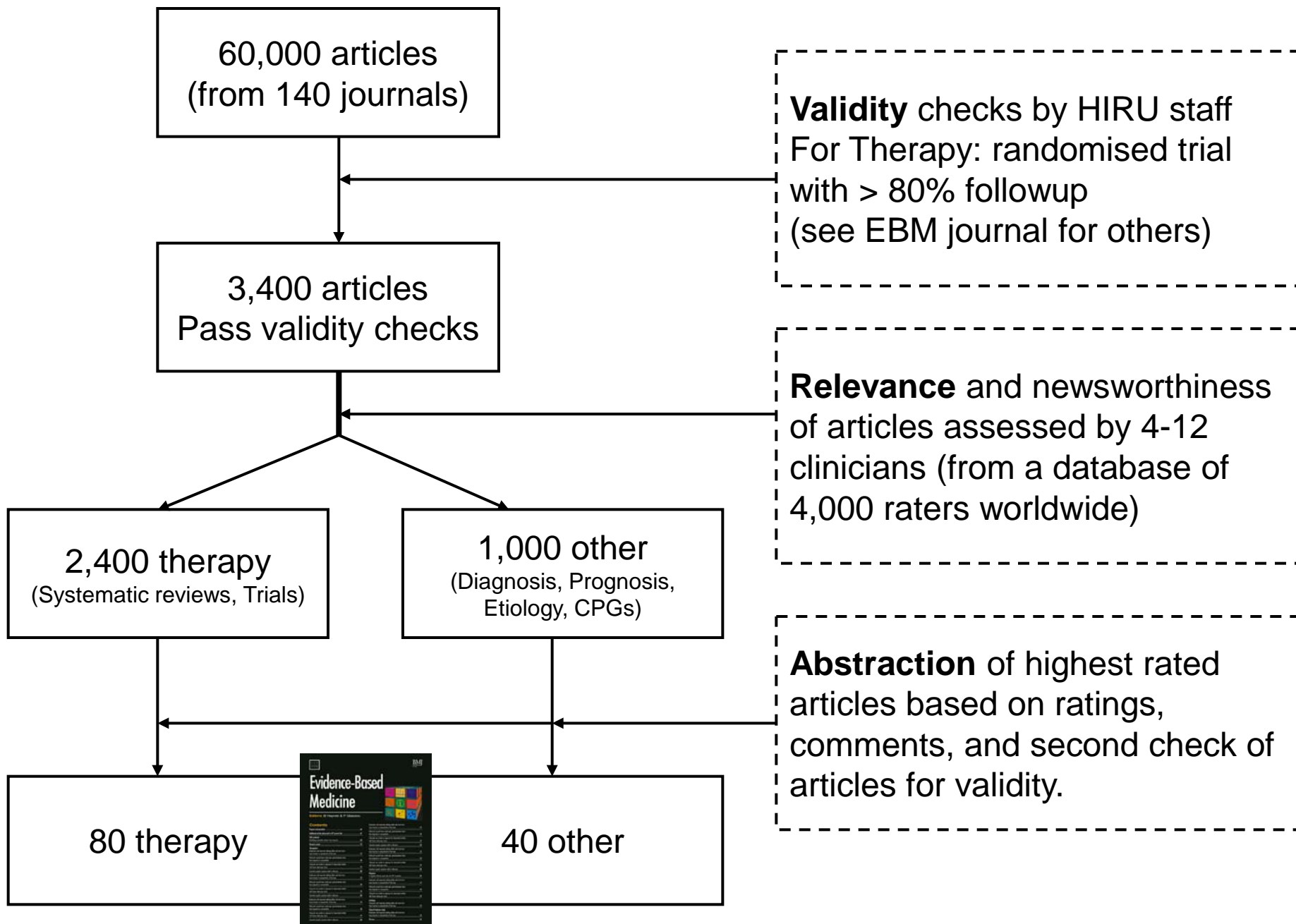
# What we did

## (1) Is the treatment replicable?

- 80 consecutive treatment reports selected for the EBM journal (10/'05-10/'06)
- For each study 2 active clinicians were asked:
  - “Could you use this treatment with a patient if you saw them tomorrow?”
  - If “No” is the problem with:
    - The treatment’s description
    - Resources
    - Own skills or training

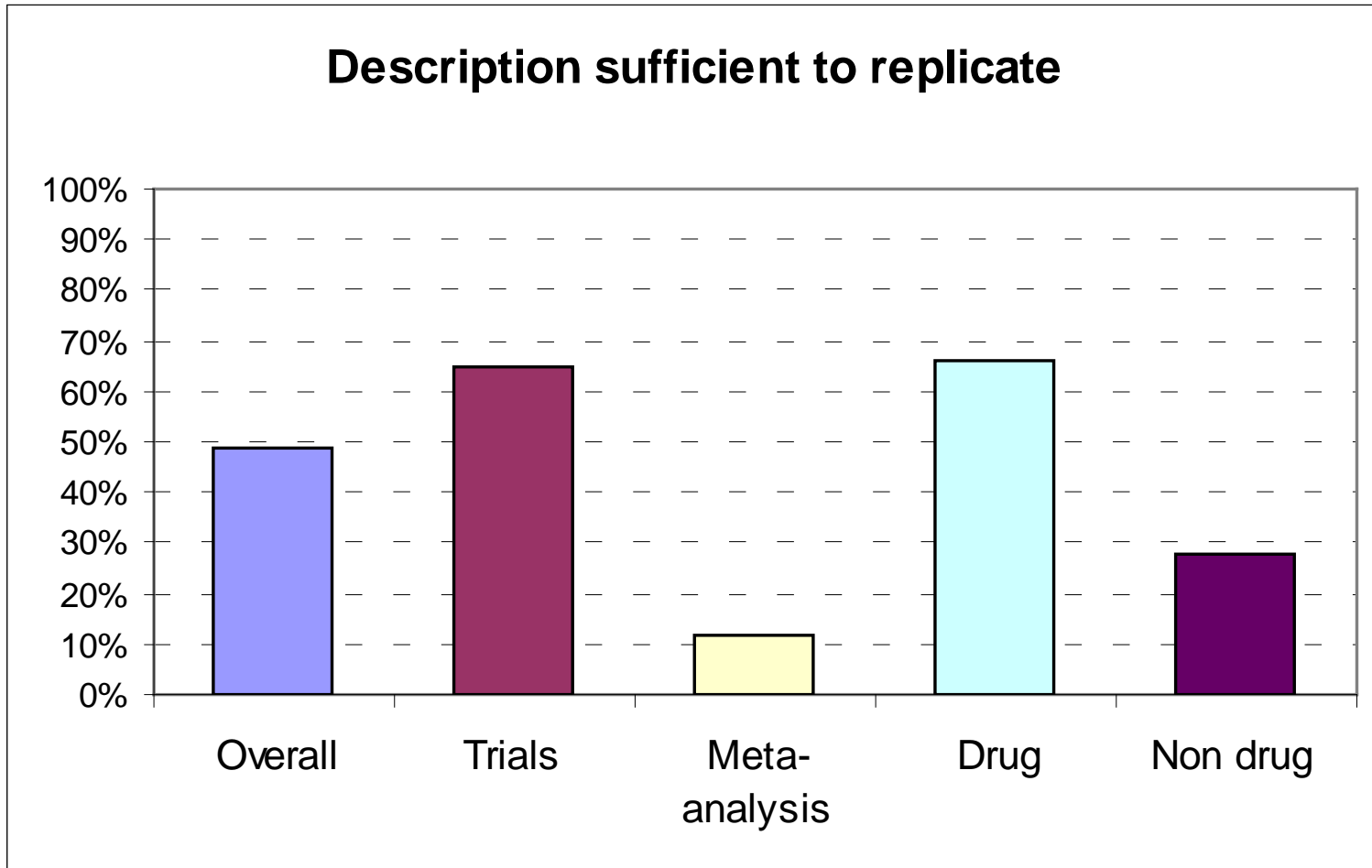


# Article Selection process (for EBM journal and project)



# Half the descriptions were sufficient

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# What we did

## (2) Is the poor description fixable?

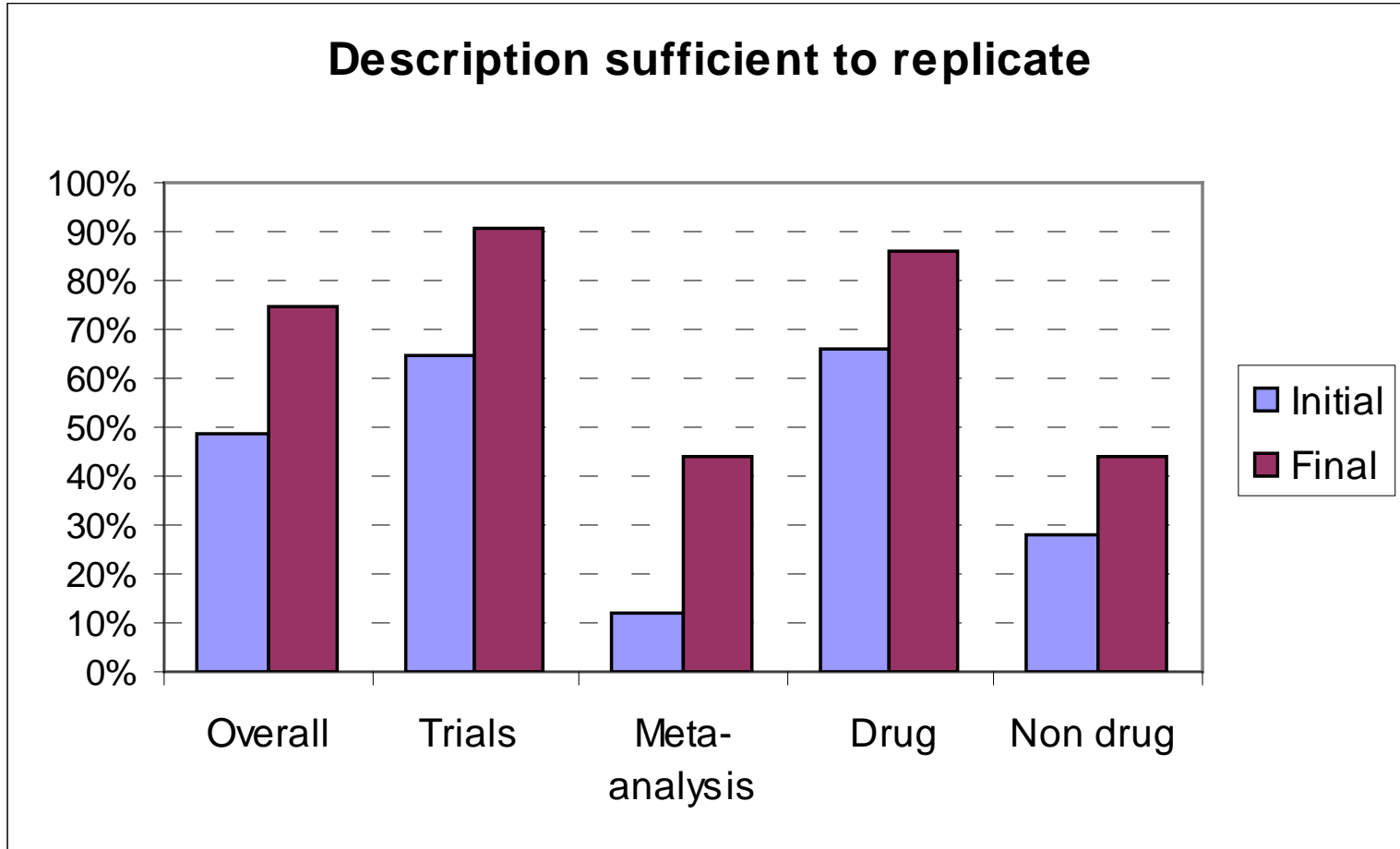
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To get complete treatment descriptions we:

- Checked references
- Wrote to authors
- Did internet searches
- And other things:
  - ▣ Checked with local pharmacy, asked colleagues, ...

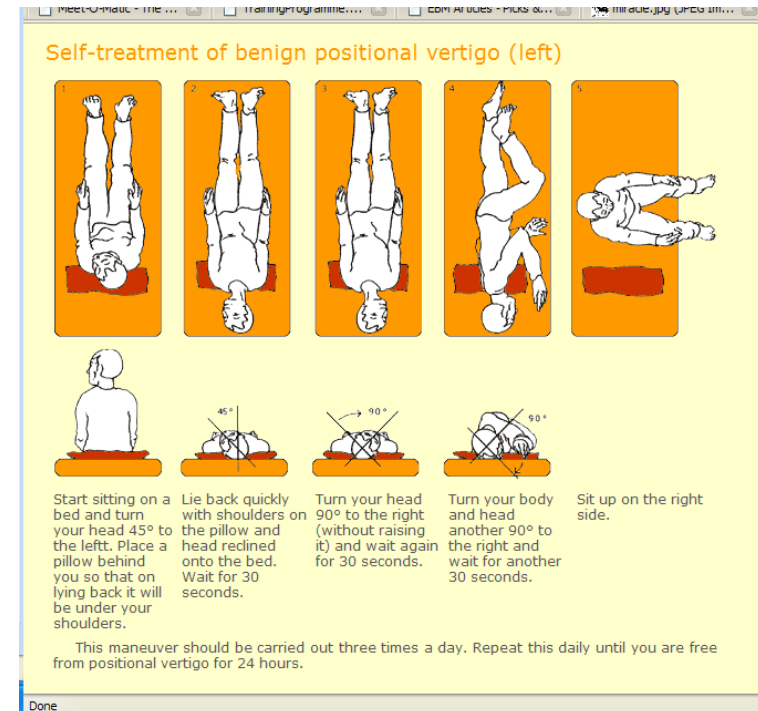
# Half the inadequate description were “readily” fixable

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# Missing patient handout: in reference

- ❑ 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 ..."
- ❑ PROBLEM: Instructions not in article but available in reference 5:
  - Radtke, A. Neurology 1999;53:1358



# Missing guidebook: hard to track down!

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- ❑ STUDY: Self-help interventions in patients with a primary care diagnosis of irritable bowel syndrome. Gut 2006.
- ❑ TREATMENT: Patients received a **comprehensive self-help guidebook** produced following a series of focus group meetings with other IBS patients ...
- ❑ PROBLEM: Missing details of guidebook.
  - No response from author to 3 emails
  - Colleague said booklet was on sale
  - Google search found the book



Price: £8.99



# Missing instructions: author provided

- ❑ STUDY: Craniocervical training programme for tension-type headache; a randomized clinical trial. *Cephalalgia* 2006;26:983–91
- ❑ TREATMENT: Physiotherapy and home exercises
- ❑ PROBLEM: Missing home instructions
- ❑ Author response:
  - protocol craniocervical training (during the treatment period): max. 15 min. and at home twice a day, 10 min per session)
  - 10 X retroversion, pause, 5 repetitions
  - max. retroversion position, 10 sec. isometric contr. 5 repetitions
  - middle/optimal position, 10 sec. isometric contr. 5 repetitions (posture coaching)

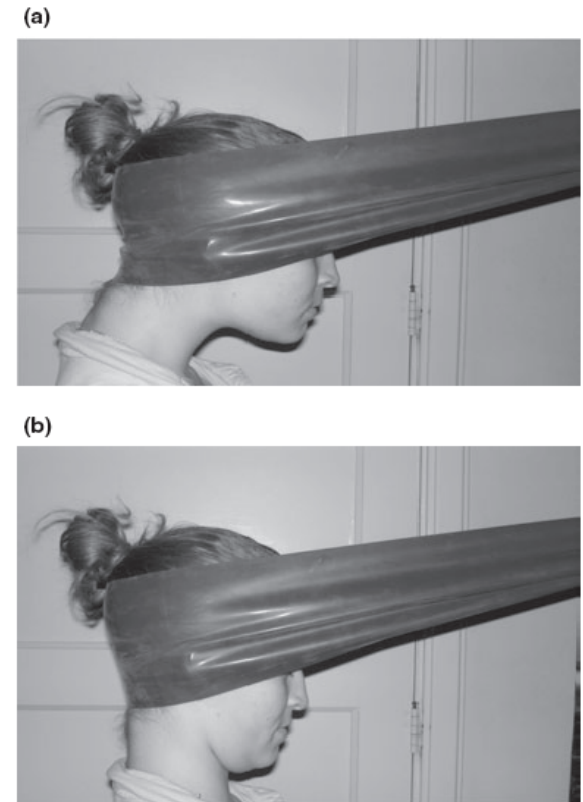


Figure 1 (a) Starting position in craniocervical extension (anteversion). (b) Final position with craniocervical flexion (retroversion).



# Missing booklet & software: unusable

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- STUDY: Randomised trial of telephone intervention in chronic heart failure: DIAL trial (BMJ 2005)
- TREATMENT: “ ... patients allocated to the intervention **received an education booklet**. Nurses ... did frequent telephone follow-up from the telephone intervention centre. “Nurses had **special software** with which they recorded data on every call.”
- PROBLEM: missing booklet and software. Response from authors
  - Is the education booklet available?
    - *“yes, but it is in Spanish”*
  - What is the software program that was used, and is it available?
    - *“It is available but not for public use”*
  - What was the nurse training?
    - *The training included classes, reading materials and role playing. We have the guide that they used to interview each patient, but in Spanish*



# Systematic review: what specific regimen?

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- ❑ STUDY: meta-analysis of behavioural interventions for insomnia adults
  - “.. confirms the efficacy of behavioral interventions for person with chronic insomnia.”
- ❑ PROBLEM: No regimens for ‘behavioural intervention’ described
  - Author asked: “what specific treatment regime (or regimes) would you recommend based on your review?”
  - Author response: “It was found that cognitive, behavioral and relaxation therapies all in general lead to similar improvements in sleep outcomes---although cognitive approaches might have been a bit better. The references for these studies are found in the article. ”

Rx

“Behavioural Intervention”

*Paul Glasgow*



# Conclusions: what is in the non-pill?

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1. Descriptions of treatment are often insufficient to permit a clinician to use in practice.
2. Readily available details could improve about half the descriptions
3. Inadequate treatment descriptions represent a vast waste of research resources and a lost opportunity to improve patient care.





# Some Recommendations

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## □ Journals

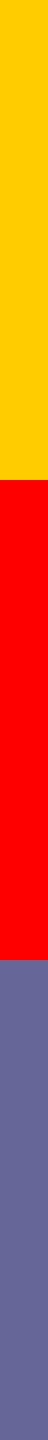
- should request sufficient detail to allow use of the treatment

## □ Authors

- Should provide such descriptions but avoid journal copyright.

## □ Non-pharmacopeia

- A web-based “open source” repository of treatment descriptions is needed



# What next? Schroter et al

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- Retrospective review of BMJ RCTs
- Prospective fixing of BMJ RCTs

**Conclusions** Acupressure was effective in reducing low back pain in terms of disability, pain scores, and functional status. The benefit was sustained for six months.

## **Interventions**

Each participant received six sessions within one month. One senior acupressure therapist gave each session of acupressure treatment to ensure a uniform technique and consistent experience. The participants in the physical therapy group received the

# Ford's Fundamental Feedback Formula

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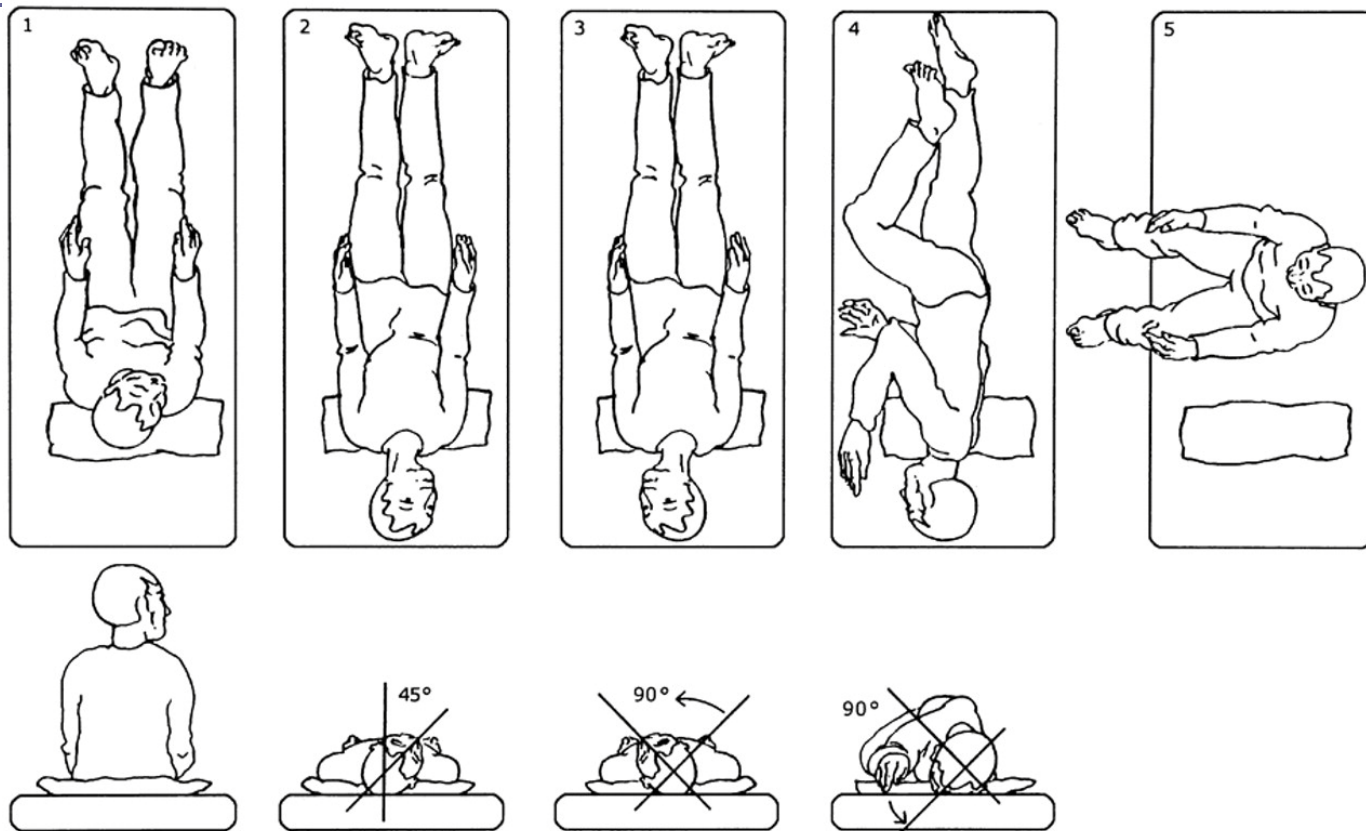
- ❑ Back in the 1920's, Congress was investigating river pollution and invited Henry Ford, as a top industrialist, to testify. When Ford took the stand, he chided the Congress for wasting good tax money on complicated ant-pollution laws. "All you need," he said, "was one simple law to clear up all polluted rivers."
- ❑ *Anyone can take any amount of water from any river for any purpose whatsoever, as long as they return the water upstream from where they took it out*
- ❑ Ford's Fundamental Feedback Formula says, if you want people to change what they're doing, make sure they are fed back the consequences of what they're doing.

# zero users give zero insights

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- Why You Only Need to Test With 5 Users
  - Jakob Nielsen
- Listening to what people say is misleading: you have to watch what they actually do.

**Figure 1. Instruction for the modified Epley's procedure (for benign paroxysmal positional vertigo of the posterior semicircular canal of the right ear)**



Radtko, A. et al. Neurology 1999;53:1358

# What is the treatment?

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- The paper's description of sodium reduction
  - "Individual and weekly group counseling sessions were offered initially, with less intensive counseling and support thereafter, specific to sodium reduction."
- Previous reference's description (reference 23)
  - (i) an individual session followed by 10 weekly group 90 minute sessions with a nutritionist, followed by a transitional stage of some additional sessions
  - (ii) Topics in the weekly sessions included Getting Started, sodium basics, the morning meal, midday sources of sodium, the main meal, planning ahead, creative cooking, eating out, food cues, and social support,
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# Other non-replicable treatments (author responses to requests)

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- Low fat diet (JAMA)
  - “The manual is not online. We do have a book chapter that describes the first 18 sessions (copyrighted materials attached for your reference only, not to be shared). ”
  
- Handwashing training (Lancet)
  - “The pamphlets and field training materials used for the behavior change are in Urdu”
  - “.. if you believe they would be of value, we can explore ways of providing an electronic copy to you.”



# Description of treatment insufficient to duplicate

