

IHS

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Brief interventions in primary care

We know they work, but are they fit for the 'real world' in routine practice?

A Cochrane Collaboration systematic review

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<http://www.thecochranelibrary.com>

<http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004148/frame.html>

Background

- Earliest brief intervention trials in the 1980's
- 56+ trials over the last quarter of a century
- Numerous reviews
 - Expert review (Bien, Anderson)
 - Commentaries (Drummond, Heather)
 - Systematic review (Whitlock)
 - Meta-analyses (Moyer, Bertholet, Ballesteros etc)
- Why another one?

What we know

- Enormous and growing body of work
- High methodological quality (Mesa Grande)
- Consistently positive effects of SBI
 - Particularly in non-treatment seekers (Moyer)
 - Cost-effective at 4 years (Fleming)
 - Effects not found at 10 years (Wutzke)
- General practice-based PHC a key setting
- Increasing amount of research in A&E

Yet not sufficient to encourage uptake and use of SBI in PHC



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- Clinicians do not widely use SBI in practice
- Some researchers seem over exercised on showing SBI doesn't work
- Implementation research has had positive but not sustained impact
- Policy-makers remain to be convinced and so do not prioritise or incentivise SBI

There are evidence gaps



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- SBI outside health settings e.g. CJS
- Impact on sub-groups e.g. young people, BME
- Impact in different countries /cultures
- Is screening (assessment) part of the 'active ingredient'
- How to identify cases efficiently i.e. targeted case finding
- Simple structured advice or counselling
- Effectiveness versus efficacy issue

Efficacy-Effectiveness

- Efficacy studies
 - Tightly controlled protocols
 - Ideal world – atypical practice
 - High internal validity – limited applicability
- Effectiveness studies
 - Pragmatic trial – reflect the ‘noise’ in practice
 - Closer to the real world – routine practice
 - High external validity – broader applicability

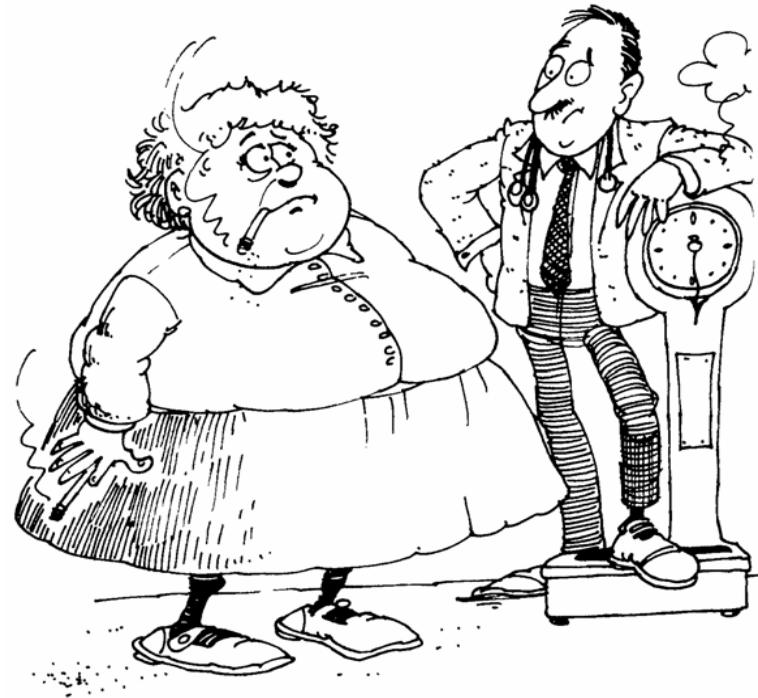
Has SBI been evaluated in ideal-world scenarios?

- Over recent years, there has been a growing view that most of the BI trials have been tightly controlled efficacy studies and not particularly representative of routine clinical practice

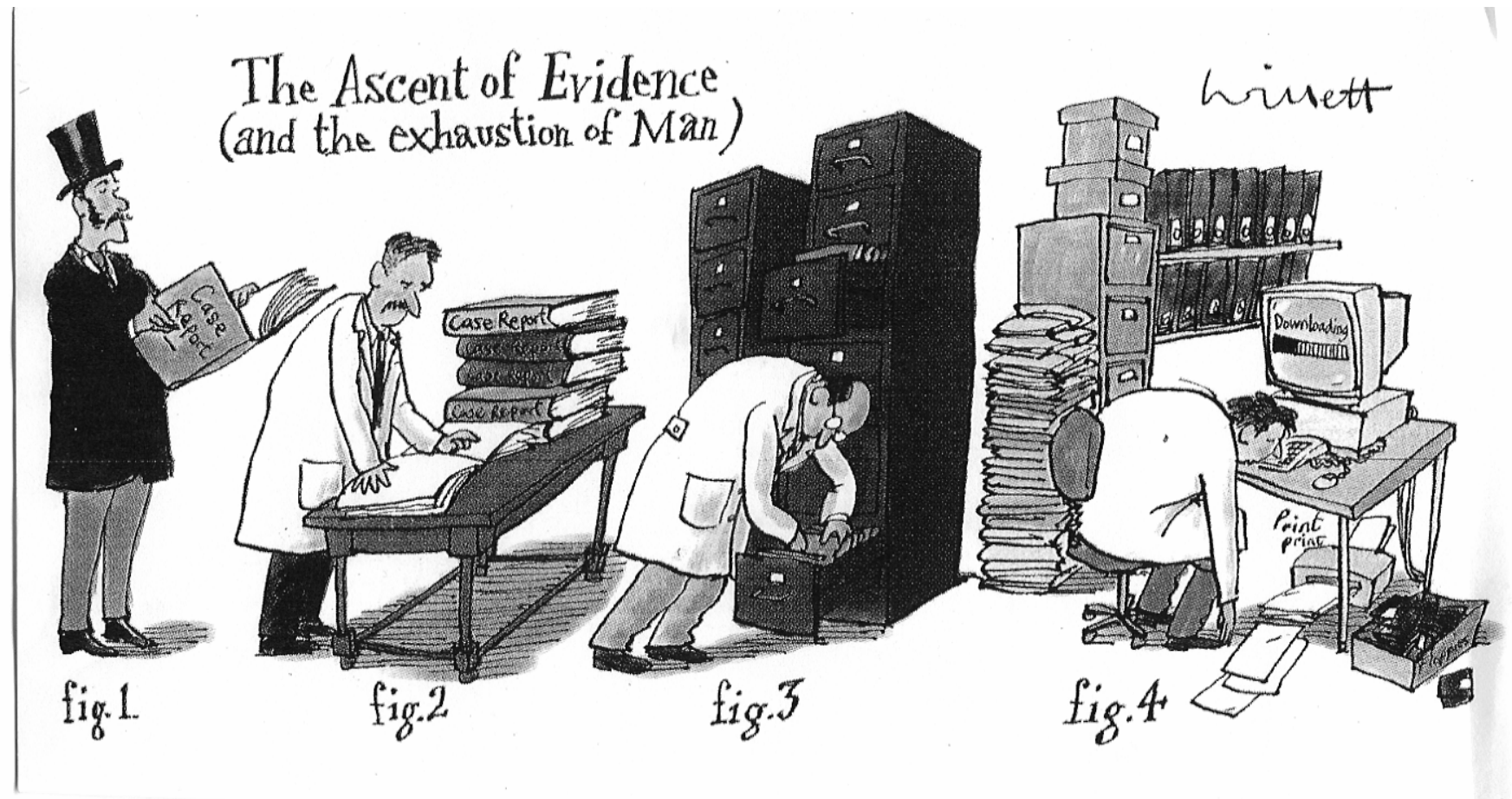


Is the evidence relevant to real world practice?

- Babor et al. 2006:
‘There has been little systematic research to evaluate the effectiveness and cost of SBI under conditions approaching typical clinical conditions’



Thus we decided to conduct a Cochrane Collaboration review



Aim

- To assess the effectiveness of brief intervention, delivered in primary care (general practice or accident & emergency settings), at reducing excessive alcohol consumption

Objectives

- To determine the effects of brief interventions at reducing excessive drinking & alcohol problems
 - Brief intervention versus control conditions
 - Brief intervention versus extended intervention
- To determine if overall treatment exposure (duration) influences SBI outcomes
- To characterise the types of drinkers to whom BI effects relate
- To assess whether BI outcomes differ between efficacy trials & pragmatic trials (in routine clinical contexts)

Method

- Pre-specified protocol & search strategy
- Cochrane Drug & Alcohol Group register (to 2006), MEDLINE (to 2006), EMBASE (to 2006), CINAHL (to 2006), PsycINFO (to 2006), Science Citation Index (to 2006), Social Science Citation Index (to 2006), Alcohol and Alcohol Problems Science Database (to 2003)
- Reference lists of key articles – previous reviews
- Hand search of Key Journals

Selection criteria

- Randomised controlled trials (& cRCTs)
- Patients presenting to primary care not specifically for alcohol treatment
 - General practice based PHC
 - Accident & Emergency Departments
- Brief intervention of up to 4-5 sessions

Data extraction

- By 2 researchers – working independently
- Adjudication by a 3rd researcher
- Data extraction form (previously piloted)
- Methodological quality assessed
 - Selection bias - Randomization, allocation concealment,
 - Performance bias – masking of clinicians, clustering
 - Attrition bias – loss to follow-up
 - Detection bias – blinding at outcome assessment

Analysis

- Main outcome ETOH per week in grams
 - Drinks/units to g using conversion appropriate to country
 - Focus on outcomes at 1 year (modal follow-up interval)
- Outcomes were mean difference (& SD) of final values or change scores
 - Weighted mean difference used to estimate pooled effect sizes & 95% CI
 - Dicotomous outcomes relative risk (95% CI) via Mantel-Haenzel weighting
- Magnitude of heterogeneity I^2 (χ^2 test for signif)
- Funnel plots – asses for bias
- Random effects meta-analysis
 - sensitivity analyses on methodological quality issues

Clinically representative if (a): (4 items- score 2, 1 or 0)



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- **Patients & problems**
 - Routinely presenting patients, wide range of problems
- **Practice Context**
 - Community-based setting, usual range of PHC services
- **Practitioners/therapists**
 - Qualified & Practising doctors/nurses, earn main living delivering PHC services
- **Intervention content**
 - Fits within normal consultation timing/style, 5-15 minutes for GP, 20-30 minutes for nurse, brief initial session plus follow-up visit for longer work

Clinically representative if (b): (score 1, ½ or 0)

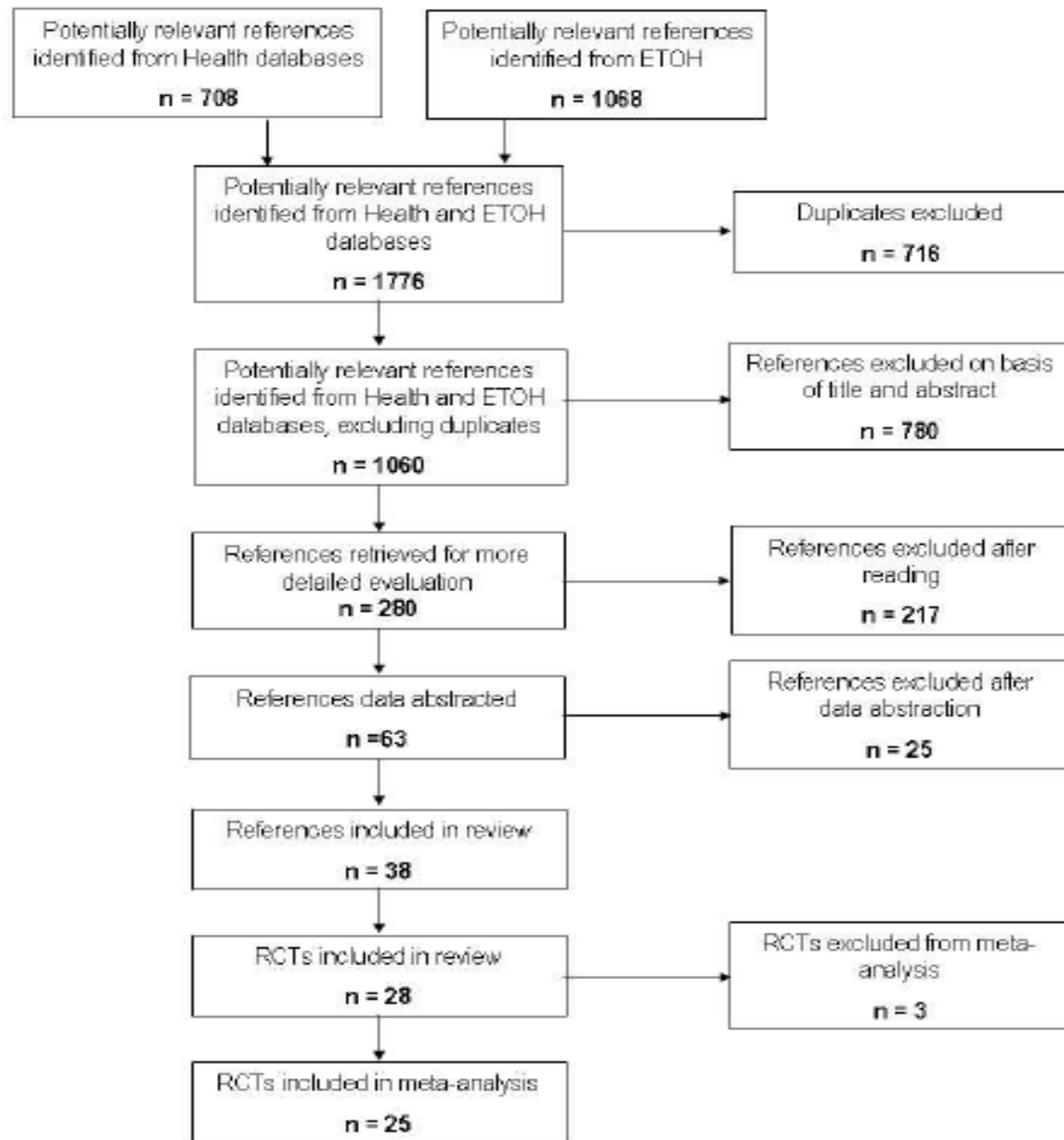


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- **Therapeutic flexibility**
 - Professional judgement allowed, free to focus on issues according to patient need
- **Pre-therapy training**
 - Fits with normal CPD/CME arrangements ie outreach visit for training, one-off training session etc.
- **Intervention support**
 - Could typically occur in practice, practice staff assist with screening, IT flagging of cases
- **Intervention monitoring**
 - Does not interfere overly intrude or interfere with clinician or patient behaviour or relationship

- If a trial scored 12 then it was likely to be highly clinically relevant
- Conversely a trial scoring 0 has more limited relevance for practice
 - If it was not possible to score an item due to poor reporting or if an item was judged to be partially clinically representative then the midpoint value was given
 - A binary variable was created using the median outcome score as the cut-off

Search Results



Results

- 28 RCTs met inclusion criteria (38 publications)
 - 23 in general practice
 - 5 in A&E (Crawford, Gentilelo, Kunz, Longabaugh, Rodriguez)
 - 10 in USA, 5 in UK, 5 in Spain, 2 Canada, 2 Finland, 2 Sweden, 1 France, 1 in Australia
- 21 in primary meta-analysis
 - Lost trials mainly due to inadequate reporting e.g. n's, SDs
- 7286 participants
 - Mean age 42
 - 76% male
 - 7 trials reported ethnicity, 71% subjects white

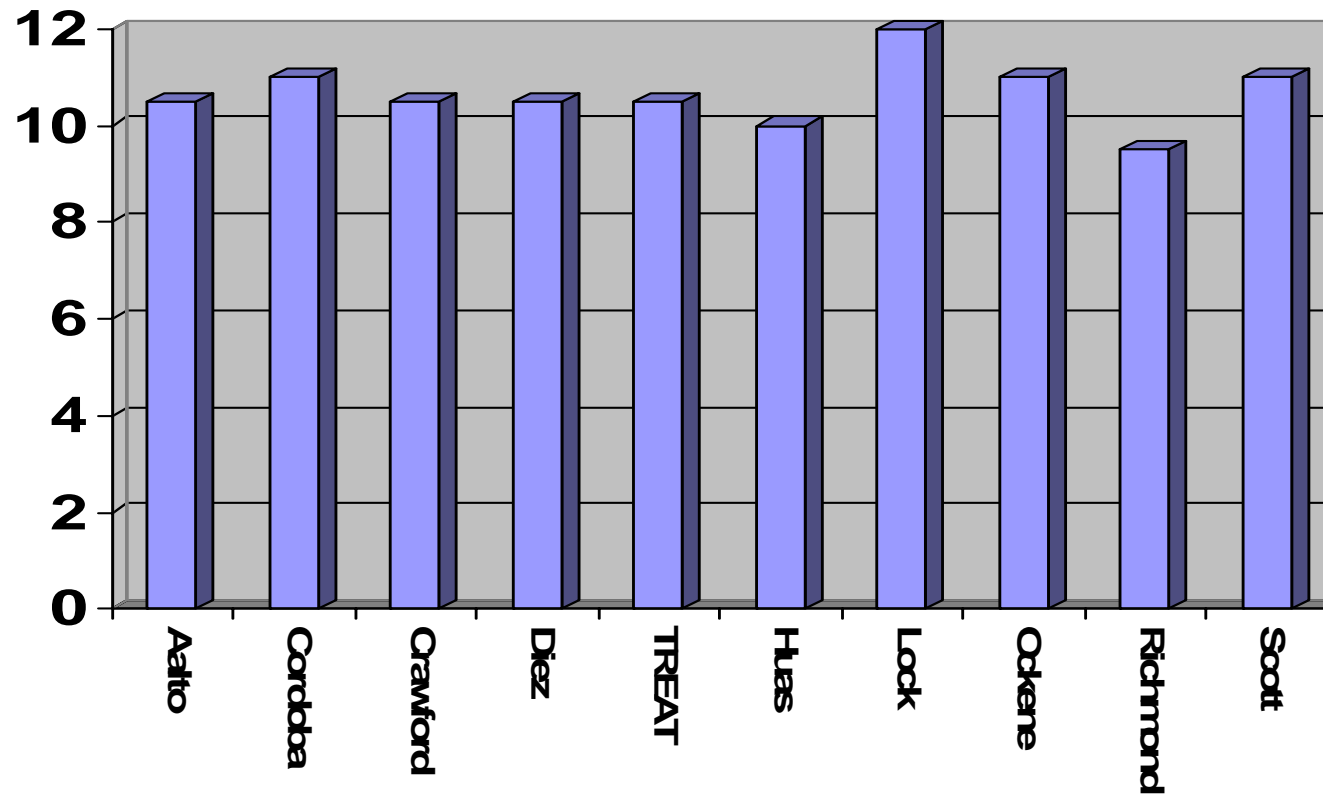
Description of Conditions

- Controls
 - Nothing, assessment only, usual care, leaflet
 - Could take up to 10 mins (Diez, Rodriguez)
- Brief intervention
 - Advice, CBT, MI, action plans, diaries
 - BI 1-5 sessions, total exposure 5 to 60 mins
 - EI 2-7 sessions, total exposure 65 to 175 mins

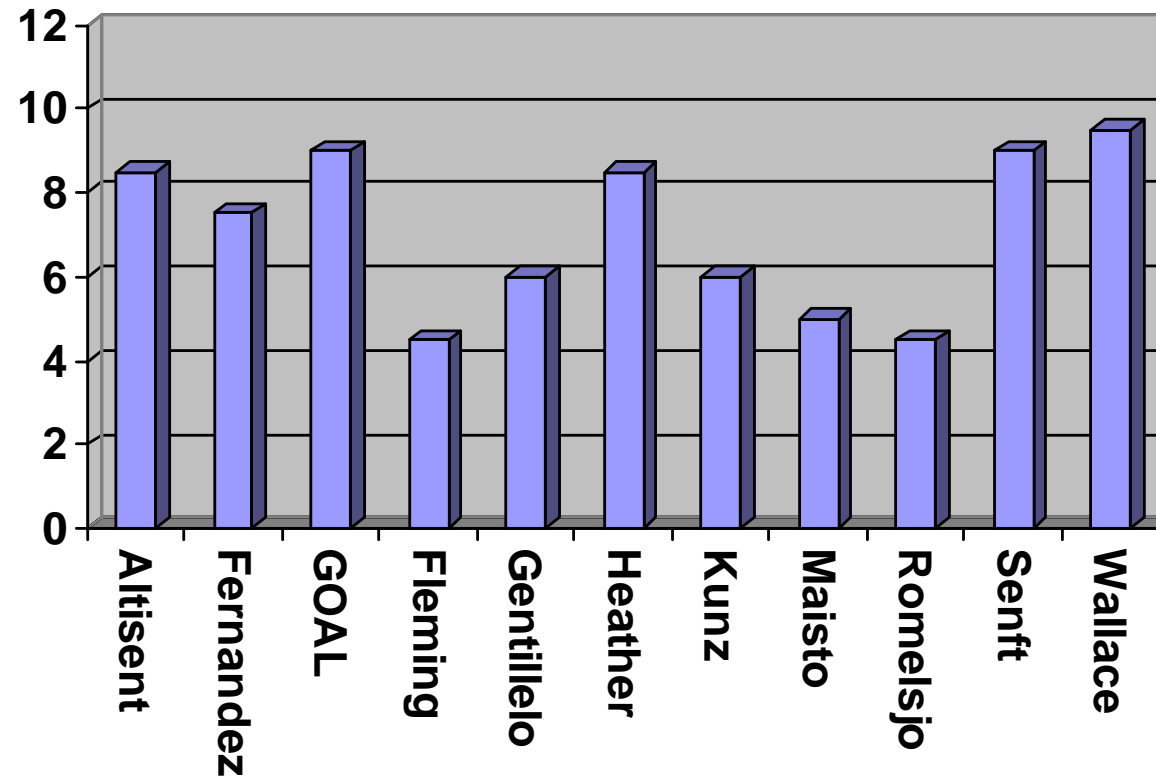
Efficacy/Effectiveness scores

- Lowest score 4.5 (Fleming, Romelsjo)
- Highest score 12 (Lock)
- Median 9 (IQR 8-10.5)
- Highly skewed toward the effectiveness domain
- 10 Effectiveness, 11 Efficacy at median cut-off
 - At midpoint 6, this would be 19 Effectiveness & 5 Efficacy

Effectiveness trials

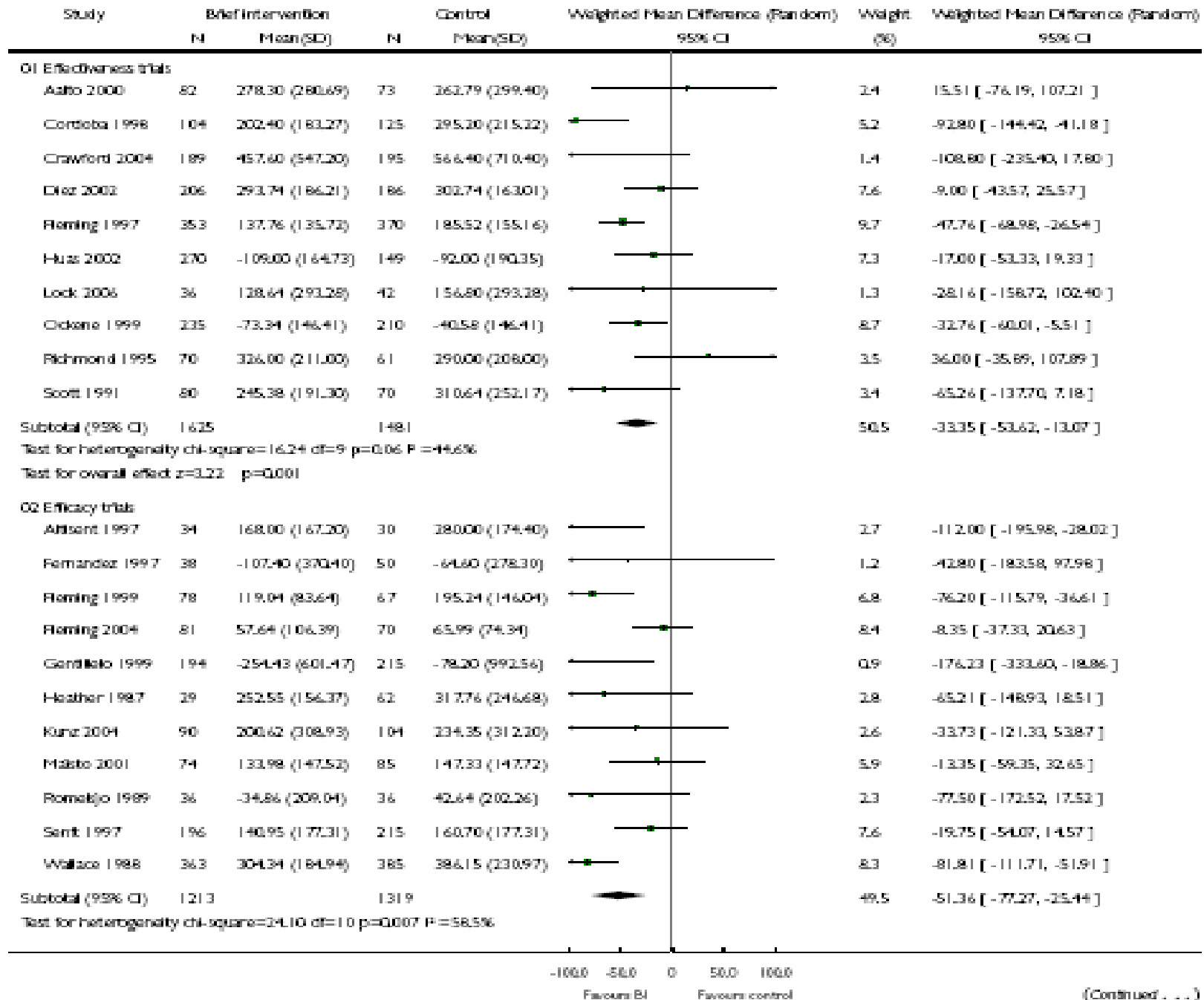


Efficacy trials



Quantity of ETOH per week (g)

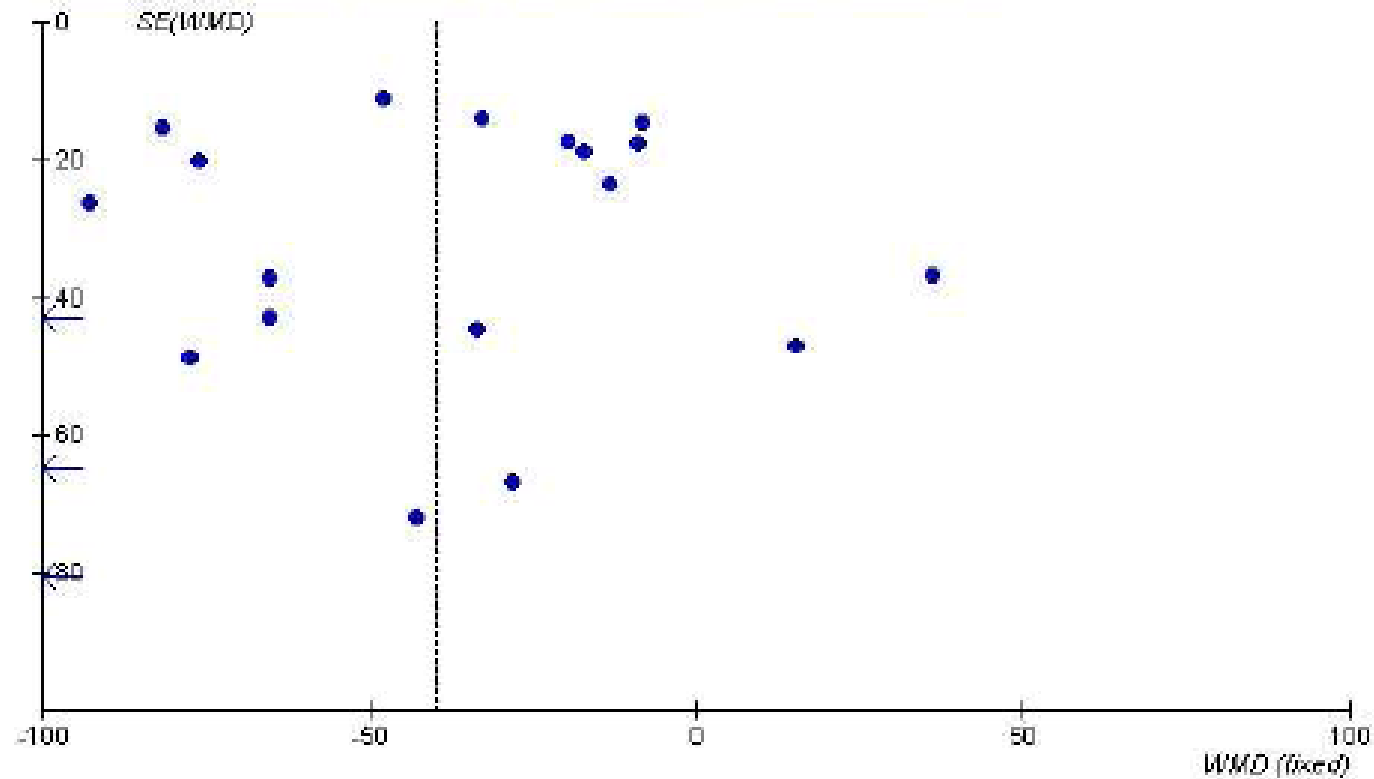
- Mean difference -41g (95% CI -57 to 25)
- No significant difference in outcome between efficacy & effectiveness trials
 - Effectiveness -33g (95% CI -54g to -13g)
 - Efficacy -51g (95% CI -77g to -25g)
- Substantial heterogeneity $I^2=52\%$
- Forest plot showed little asymmetry
 - no obvious difference between treatment effect and efficacy/effectiveness score (confirmed by meta-regression)



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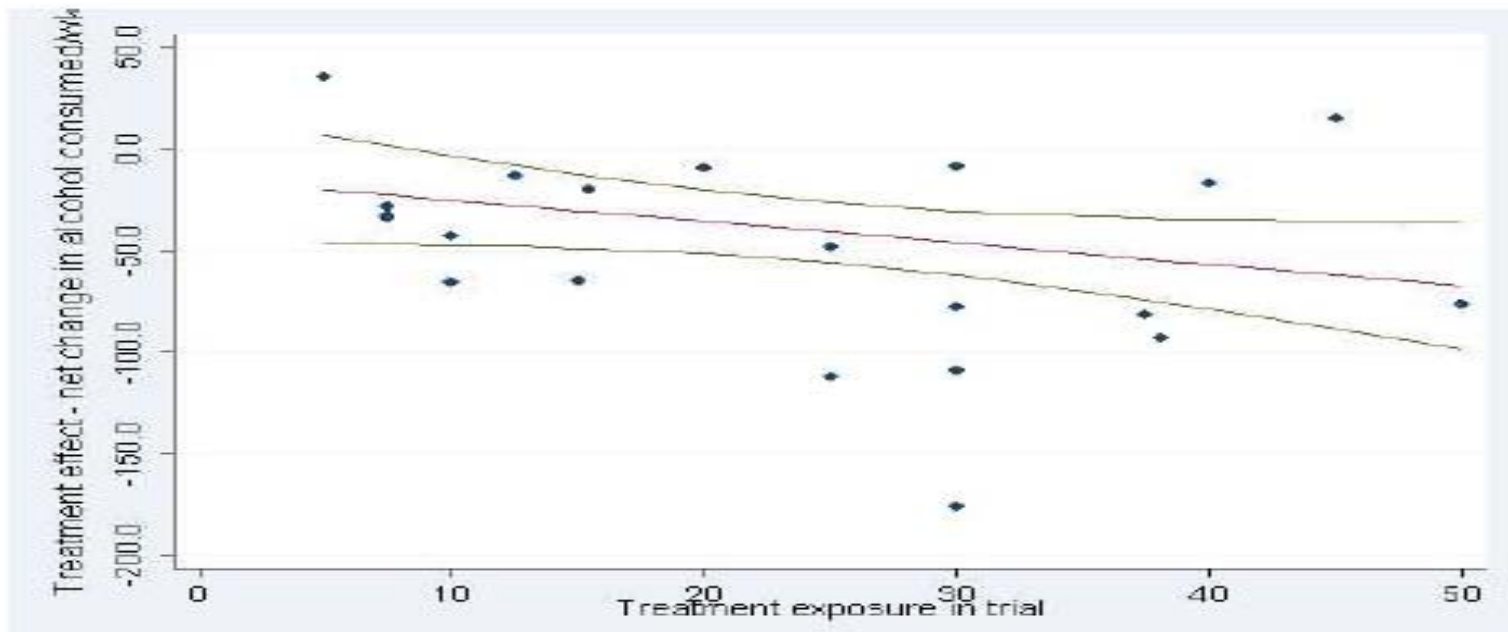
Funnel plot

Review: Effectiveness of brief alcohol interventions in primary care populations.
Comparison: 01 Brief intervention vs. control
Outcome: 01 Quantity of drinking (g/week) subgrouped by effectiveness/efficacy



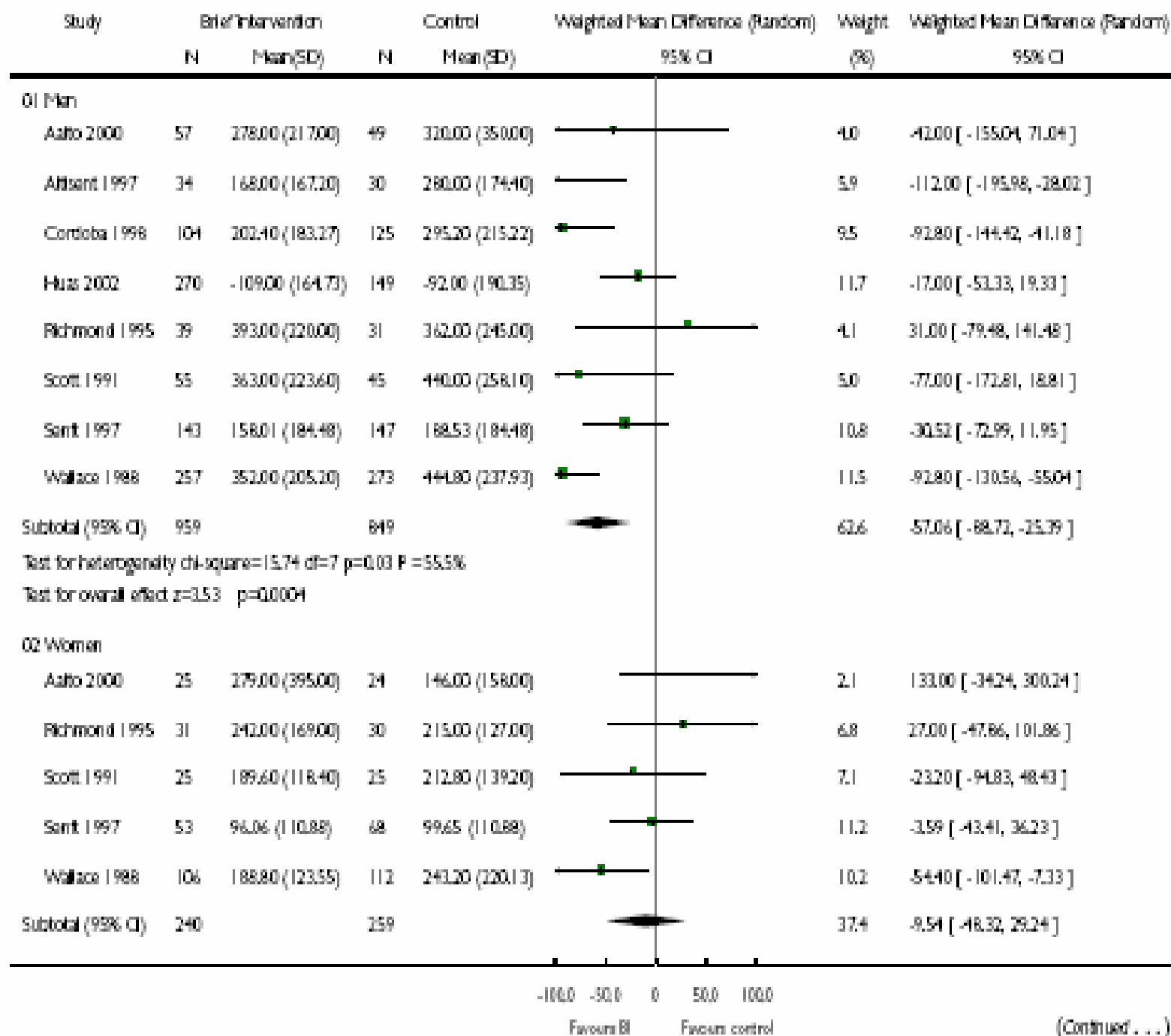
Treatment exposure

- Longer BI did not achieve significant extra benefits in terms of reduced drinking
 - 1.1g for each additional minute of BI



Sex

- Only 5 trials reported sufficient information (mean, SD & number assessed) to consider women separately from men
- Men experienced significant benefits of BI
 - -57g/week (95% CI -89g to -25g)
- Women did not show significant benefit of BI
 - -10g/week (95% CI -48g to 29g)



(Continued . . .)

Secondary outcomes (1)

- Percentage of binge drinkers - significant
 - 3 trials (Fleming 1997, 1999, Kunz 2004)
- Percentage of heavy drinkers – significant
 - 6 trials (Altisent 1997, Cordoba 1998, Fernandez 1997, Fleming 1997, 1999, 2004)
- Visits to A&E (ER) and % injuries - significant
 - 1 trial each (Crawford 2004, 0.5 per year, Gentilelo 1999, 47% drop new injuries)
- Frequency of binge drinking – null effect
 - 3 trials (Fleming 1997, 1999, 2004)
- Number of drink days/wk – null effect
 - 2 trials (Senft 1997, Aalto 2000)
- Amount of ETOH per drink day – null effect
 - 4 trials (Aalto 2000, Crawford 2004, Maisto 2001, Senft 1997)
- GGT & MCV – null effect
 - 4 trials (Aalto 2000, Romelsjo 1989, Wallace 1988, Seppa 1992)

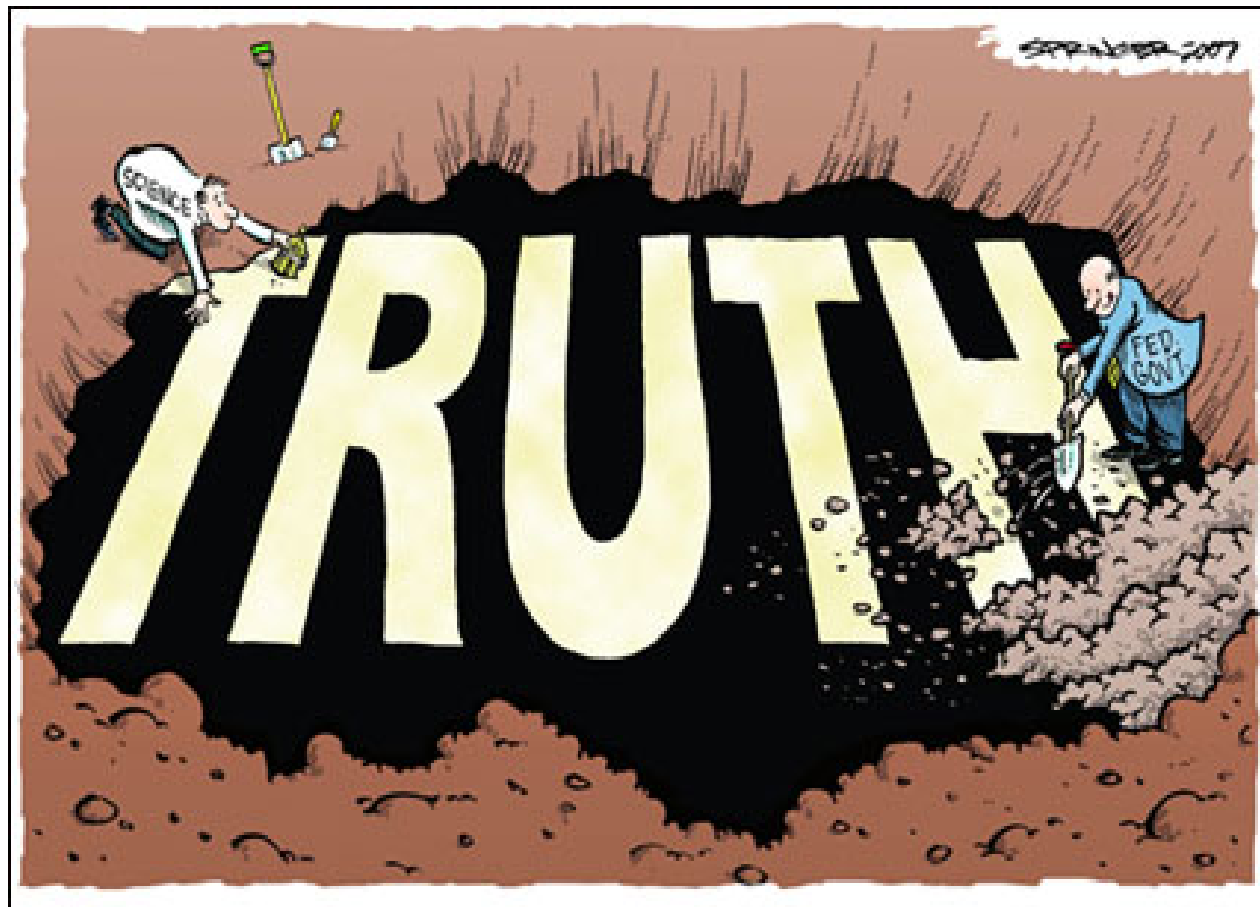
Extended Intervention

- 4 trials (Aalto 2000, Israel 1996, Maisto 2001, Richmond 1995)
 - Patients receiving EI drink less than those receiving BI but not significantly so
 - Mean difference -28g (95% CI -62g to 6g)

Conclusions

- In risky drinkers, BI reduces average weekly drinking by 41g (about 4-5 units per week) compared to controls
 - As little as 5 minutes of structured advice enough
 - No significant benefit of longer BI or EI
 - BI is highly effective in men, we need more evidence in women
- There is no significant difference in outcomes between efficacy and effectiveness trials
 - Most of the evidence is skewed to the effectiveness domain
- BI evidence is highly relevant to routine PHC

**Is this enough to persuade
politicians & policy-makers?**



Not in England!

- Trailblazer trials - £3M
 - across General practice & A&E
 - Extending BI to Criminal Justice Settings
- Questions
 - How best to screen
 - Advice versus counselling
 - Implementation issues
 - (BI in patients with existing chronic disease)
- Government also rolling out £15M
 - Natural experiment in the NHS

Also on the 'to do' list

- Most of the research is from Anglo-Saxon countries though a growing number of studies in Scandinavian & Mediterranean countries
 - There is no research in developing or transitional countries
- Subjects in BI trials are primarily white, male and middle aged
 - We need more research in BME groups
 - And in young people who drink differently to adults



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More unresolved issues...

- Screening effect – is this enough for some?
- Assessment length & impact
- Variation in control conditions – some > than BI
- Wide variety of outcome measures
- Definition of risky drinking seems to be dropping over time (harmful to hazardous)
 - Some recent studies include subjects who are drinking within ‘sensible limits’
- We still do not know what are the ‘active ingredients’ of BI

When BI works, what is it that has the effect?





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**In the field of SBI, there is
still a lot to do!**

Thank you for your time

Any questions?

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