

INEBRIA-10, Roma 20/09/13

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

Alcohol assessment & feedback by e-mail for university students: AMADEUS-1 RCT

Jim McCambridge, Marcus Bendtsen, Nadine Karlsson, Ian R. White, Per Nilsen, Preben Bendtsen

Improving health worldwide www.lshtm.ac.uk

A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

Summary

Background: Quantification of the disease burden caused by different risks informs prevention by providing an estimate of health loss different to that provided by a disease-by-disease analysis. The complete causes of global disease burden caused by risk factors has been done since a comparative risk assessment in 2000, and no previous study has had several changes to burden attributable to risk factors over time.

Methods: We estimated deaths and disability-adjusted life years (DALYs) rates of years lived with disability (YLL) and years of life lost (YLL) attributable to the independent effect of 67 risk factors and clusters of risk factors for 21 regions in 1990 and 2010. We estimated exposure distributions for each year, region, sex, and age group, and related a risk profile of exposure to estimates of mortality and disability-adjusted life years (DALYs) from the Global Burden of Disease Study 2010. We calculated the burden attributable to each risk factor exposure compared with the theoretical minimum-risk exposure. We compared estimates of disease burden, relative risks, and exposure rates over estimates of attributable burden.

Findings: In 2010, the three leading risk factors for global disease burden were high blood pressure (17.0% DALYs attributable), tobacco smoking (including second-hand smoke) (14.5%), and alcohol use (13.7%). In 1990, the leading risk was childhood underweight (7.0%), followed by tobacco smoking (6.4%), alcohol use (5.4%), and tobacco smoking including second-hand smoke (5.3%). In 2010, disease risk factors and global mortality collectively accounted for 60.0% (95% CI 58.3-61.7) of global DALYs in 2010, with the most prominent dietary risks being diets low in fruits and those high in sodium. Several risks that previously affect children and young adults, including congenital or acute malnutrition and childhood malnutrition deficiencies, fell in rank between 1990 and 2010, with congenital or acute malnutrition accounting for 0.9% (95% CI 0.7-1.1) of global DALYs in 2010. However, in most of sub-Saharan Africa, childhood underweight (16.5%) and non-communicable and communicable malnutrition were the leading risks in 2010, while HIV was the leading risk in south Asia. The leading risk factor in Eastern Europe, most of Latin America, and southern sub-Saharan Africa in 2010 was an alcohol use. In most of Asia, North Africa and Middle East, and central Europe, it was high blood pressure. Despite declines in tobacco smoking including second-hand smoke, the leading risk in high-income north America and western Europe. High body mass index has increased globally and is the leading risk in northeastern and southern Latin America, and also ranks high in other high-income regions, North Africa and Middle East, and Oceania.

Interpretation: Worldwide, the contribution of different risk factors to disease burden has changed substantially, with a shift away from risks for communicable diseases in children towards those for non-communicable diseases in adults. These changes are related to the ageing population, increased mortality among children younger than 5 years, changes in cause of death composition, and changes in risk factor exposures. New risks have led to changes in the magnitude of key risks including congenital or acute malnutrition, vitamin A and zinc deficiencies, and malnutrition deficiencies among children. The most notable epidemiological shift has occurred and when the leading risks currently are rates growth across regions. In much of sub-Saharan Africa, the leading risks are still those associated with poverty and those that affect children.

Study contexts

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

- Comprehensive alcohol policies needed
- Student drinking age old concern: Swedish universities – see alcohol as part of their responsibilities
- Internet offers new possibilities for reach of individualised interventions in whole populations
- Accumulating evidence & unresolved methodological issues in “brief interventions” (BI) literature

Methodological challenges in BI

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

- Small effects of BIs vulnerable to various biases
- SR evidence that being assessed alone has effects
- Shared mechanisms of effect (on self-regulation)
- Interact with BI effects to introduce bias
- Are there other research participation effects?

...additivity, ceiling or synergistic effects?

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

		Assessment
Brief Intervention	Y	-52g???
	N	-14g
	Diff	-38g*

*Cochrane DSR 2007; Issue 2, CD004148

Typical behaviour change trial process

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

```

    graph TD
      subgraph Recruitment
        R1[Contact] --> R2[Eligibility]
        R2 --> R3[Study Information]
        R3 --> R4[Formal consent]
      end
      R4 --> R5[Baseline assessment]
      R5 --> R6[Randomisation]
      R6 --> R7[Control]
      R6 --> R8[Intervention]
      R7 --> R9[Follow-up assessment]
      R8 --> R9
      R9 --- R10[Participant characteristics]
      R10 --- R11[Interpersonal contact]
  
```

Routine practice in Sweden

- All university students receive an e-mail from the student healthcare service inviting consideration of own drinking
- They click on a link to access a brief questionnaire
- Receive normative feedback and tailored advice on screen & in printable pdf format
- Further help available as necessary

AMADEUS-1 design features

- Manipulation of lack of timing of routine practice
- Dismantling design to evaluate two components: assessment plus feedback (G1) & assessment-only (G2)
- Compared to no contact control group (G3) in 3 arm trial
- Randomisation of e-mail addresses & routine service provision permits removal of many possible sources of research participation effects

Blinding

- Participants are unaware:
 - they are involved in research at all when they access interventions
 - they are participating in a randomised controlled trial at any point in the study
 - that their individual behaviour is being tracked over time
 - of the true purpose of the research (until afterwards)
- justifications for deception in AJOB [in press]

AMADEUS-1 recruitment

- Power calculation required approx 15,000 students randomised to detect 0.08 SD
- Complete populations of 2 universities randomised
- Some differences in participation at baseline (36% and 33% in Groups 1 and 2), no differences in proportions of risky drinkers or in attrition among them
- Also at follow-up (51%, 52% and 54% in Groups 1, 2 and 3 respectively)
- No sociodemographic or other differences between groups

AMADEUS-1 outcome evaluation

- Pilot trial (JMIR, 2012) found approx 10% higher participation in group 3 when invited to alcohol survey
- Invitation to participate in a brief cross-sectional lifestyle survey used instead
- Concealed focus (3/15 alcohol questions) & efficient measure (AUDIT-C)
- Hypotheses tested 3 ITT analyses of contiguous groups (universal prevention), 1 per-protocol (risky drinkers only)

AMADEUS-1 flowchart

AMADEUS-1: Unobtrusive evaluation of Swedish national system in two universities
Trials 2012; 13(1):49

```

graph TD
    A[Mail addresses of all students in terms 2, 3 and 5 retrieved from the University's official register] --> B[Randomisation]
    B --> C[Assessment and feedback group n = 4869]
    B --> D[Assessment-only group n = 4869]
    B --> E[No-contact group n = 4872]
    C --> C1[Participated at baseline n = 1798]
    D --> D1[Participated at baseline n = 1621]
    E --> E1[ ]
    C1 --> C2[Risky drinkers n = 1135]
    D1 --> D2[Risky drinkers n = 1058]
    E1 --> E2[ ]
    C2 --> C3[Completed baseline & follow-up n = 2546]
    D2 --> D3[Completed baseline & follow-up n = 2594]
    E2 --> E3[Completed follow-up n = 2669]
    
```

ITT primary outcomes data



	Group 1 n=2546	Group 2 n=2594	Group 3 n=2669
Risky drinking n, %	1136 (44.6%)	1194 (46.0%)	1288 (48.3%)
AUDIT-C score geometric mean, SD	3.46 (3.09)	3.44 (3.17)	3.60 (3.14)
P-values from adjusted models	Groups 1 vs 2	Groups 2 vs 3	Groups 1 vs 3
Risky drinking n, %	0.334	0.079	0.006
AUDIT-C score geometric mean, SD	0.773	0.039	0.073

AMADEUS-1 additional analyses



- No effects on secondary outcomes in ITT or PP
- No effects of feedback in PP planned analyses
- Group 1 lower weekly consumption in unplanned analysis than Group 2 (65.9 vs 73.4 g/week, $p=0.04$)
- Missing data analyses, mixed evidence on whether participants MNAR

Interpretation



- Completely online, highly naturalistic evaluation study
- Dismantling study shows little additional benefit of feedback
- Nested methodological question answered – assessed control group produces bias
- Costs very low, small effects likely very cost-effective

Conclusions 1 [Br J Psychiatry, in press]



- Provides rare evidence of population-level benefit attained through intervening with individuals
- Questions alone effective in unselected pop, feedback may be additionally useful to hazardous & harmful
- BI may contribute to shifting the distribution a la Rose
- Multi-level studies which explore synergy with other interventions & in other pops needed

Conclusions 2 [Br J Psychiatry, in press]



- Bias in existing evidence of intervention effectiveness needs to be quantified to rectify slow progress, for alcohol & far beyond
- Much scope for innovations in trial design
- Ethical issues associated with the use of deception in these studies warrant careful consideration
- Possible to use methodological findings for novel intervention designs

Funding acknowledgements



Thank you

Wellcome Trust, FAS