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

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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

Study contexts

- 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

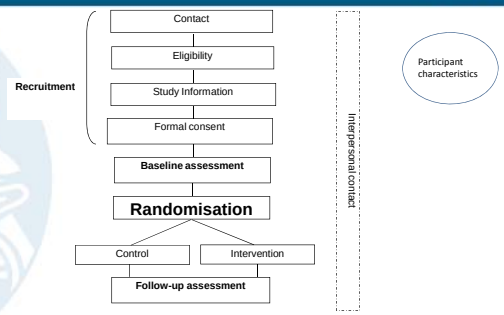
- Small effects of BIs vulnerable to various biases
- SR evidence that being assessed alone has effects
- Shared mechanisms of effect (on self-regulation)
- Interact with BI effects to introduce bias
- Are there other research participation effects?

...additivity, ceiling or synergistic effects?

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

*Cochrane DSR 2007; Issue 2, CD004148

Typical behaviour change trial process



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

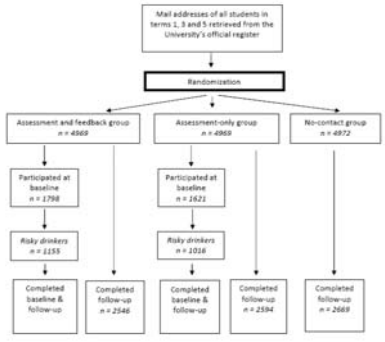
AMADEUS-1 outcome evaluation

- 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



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

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Thank you

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