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A case study of the use of deception in brief intervention research: an ethical evaluation

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Deception in research

"Deception occurs when investigators intentionally communicate in a way that produces false beliefs...investigators may deceive subjects by intentionally giving them false information...by intentionally with-holding information in order to produce false beliefs"

Wendler and Miller (2004)

- Long used in health research eg Rosenhan, 1973
- Routinely used in experimental social psychology

Long history of deception in BI

- Oldest, largest and most influential studies typically did not disclose study focus on alcohol
- Chick et al. 1985
- Wallace et al. 1988
- WHO BI Study Group 1996
- Fleming et al. 1997
- Only one previous ethical evaluation (Fleming 1989)

Informed consent principle

"each potential subject must be adequately informed of the aims, methods…anticipated benefits and potential risks of the study"

Clause 24, Helsinki Declaration (WMA, 2008)

Criticised as being excessively individualistic

Ethical committee responsibility to assess and approve departures from principle

Ethical conflict

- Blinding recommended for clear methodological reasons to minimise bias & may involve deception
- Utilitarian need for progress towards the greatest good, interests of society important

vs

- Kantian respect for the autonomy of the individual, avoiding using participants as means to an end
- "central ethical dilemma" in public health (Krebs, 2008)

Limited guidance available

"There must be a clear and convincing argument for the use of deception online, which is only condoned if the research question can be seen to justify it... Strong justification is needed if the research involves deliberate misrepresentation by a researcher"

BPS, 2007

No public health research ethics guidance…

"taking a public health perspective on research ethics is associated with broadening the conceptualisation of risk and benefits deemed ethically relevant in deliberations on health research. To ascertain its social value, a comprehensive analysis must take into account not only the risks and benefits to the research participants themselves but also the benefits and risks to the population as a whole"

Buchanan & Miller, 2006

Study A (E-SBINZ)

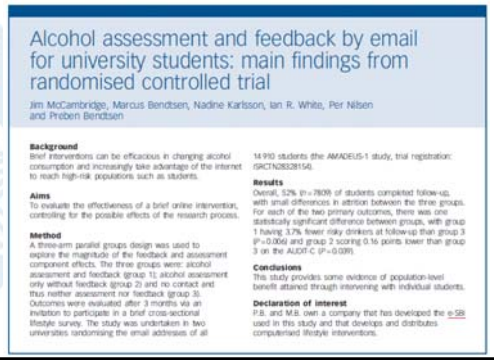
RESEARCH REPORT

Web-based alcohol intervention for Māori university students: double-blind, multi-site randomized controlled trial

Kypros Kypri[1,2], Jim McCambridge[3], Tina Vater[3], Steven J. Bowe[3], John B. Saunders[4], John A. Cunningham[5] & Nicholas J. Horton[3]

ABSTRACT

Study B (AMADEUS-1)



Alcohol assessment and feedback by email for university students: main findings from randomised controlled trial

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

Background
Brief interventions can be efficacious in changing alcohol consumption and increasingly take advantage of the internet to reach high-risk populations such as students.

Aims
To evaluate the effectiveness of a brief online intervention, controlling for the possible effects of the research process.

Method
A three-arm parallel groups design was used to explore the magnitude of the feedback and assessment component effects. The three groups were: alcohol assessment and feedback (group 1); alcohol assessment only without feedback (group 2) and no contact and thus neither assessment nor feedback (group 3). Outcomes were evaluated after 3 months via an invitation to participate in a brief cross-sectional lifestyle survey. The study was undertaken in two universities randomising the email addresses of all 14 910 students the AMADEUS-1 study, trial registration: ISRCTN28328154).

Results
Overall, 52% (n = 7809) of students completed follow-up, with small differences in attrition between the three groups. For each of the two primary outcomes, there was one statistically significant difference between groups, with group 1 having 3.7% fewer risky drinkers at follow-up than group 3 (P = 0.006) and group 2 scoring 0.16 points lower than group 3 on the AUDIT-C (P = 0.039).

Conclusions
This study provides some evidence of population-level benefit attained through intervening with individual students.

Declaration of interest
P.B. and M.B. own a company that has developed the e-SBI used in this study and that develops and distributes computerised lifestyle interventions.

Study C (ESDA)

STUDY PROTOCOL Open Access

Effects of Study Design and Allocation on participant behaviour-ESDA: study protocol for a randomized controlled trial

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Abstract

Background: What study participants think about the nature of a study has been hypothesised to affect subsequent behaviour and to potentially bias study findings. In this trial we examine the impact of awareness of study design and allocation on participant drinking behaviour.

Methods/Design: A three-arm parallel group randomised controlled trial design will be used. All recruitment, screening, randomisation, and follow-up will be conducted on-line among university students. Participants who indicate a hazardous level of alcohol consumption will be randomly assigned to one of three groups. Group A will be informed their drinking will be assessed at baseline and again in one month (as in a cohort study design). Group B will be told the study is an intervention trial and they are in the control group. Group C will be told the study is an intervention trial and they are in the intervention group. All will receive exactly the same brief educational material to read. After one month, alcohol intake for the past 4 weeks will be assessed.

Discussion: The experimental manipulations address subtle and previously unexplored ways in which participant behaviour may be unwittingly influenced by standard practice in trials. Given the necessity of relying on self-reported outcome, it will not be possible to distinguish true behaviour change from reporting artefact. This does not matter in the present study, as any effects of awareness of study design or allocation involve bias that is not well understood. There has been little research on awareness effects, and our outcomes will provide an indication of the possible value of further studies of this type and inform hypothesis generation.

Trial Registration: Australia and New Zealand Clinical Trials Register (ANZCTR): ACTRN12610000946022

Deceptions used 1

- Studies A, B & C the true purpose of the research is withheld from participants
- Study B participants unaware behaviour being tracked
- Study C participants aware of being individually followed-up, given false information about why
- Studies A & B & 1/3 in C, participants unaware they are participating in a randomised controlled trial

Deceptions used 2

- 1/2 Study A not made aware that they are in receipt of an intervention being evaluated for capacity to change their behaviour (i.e. feedback), believing instead they are participating in a survey
- Study B participants not aware they are involved in research at all when they access interventions
- 1/3 Study C are led to believe that they are receiving a potentially effective intervention when they are not

Childress et al, 2002

- effectiveness
- proportionality
- necessity
- least infringement
- public justification

"justificatory conditions" for resolving conflicts between public health goals and other ethical principles

Pragmatism in clinical research ethics

- Strives to balance the moral value of socially useful research with moral responsibilities to participants
- Dilemmas are practical problems, requiring judgements about which reasonable people may disagree
- Moral problem-solving case study method
- Ethical principles are potentially useful instruments rather than fixed rules

Pragmatism & research data

- Orientation to the likely consequences of decisions aided by empirical data
- Sparse data on attitudes to deception in research
- Focus group study explored in-depth reactions to being debriefed in person in AMADEUS-1
- Found heightened distrust of research invitations, interwoven with confidentiality and privacy concerns

We judge deception acceptable here

- AMADEUS-1 denies participants widely accepted right to informed consent
- Participants themselves not excessively concerned – "don't sweat"
- No (other) obvious harms caused to participants
- Debriefing possible source of harm - distrust

Conclusions of ethical evaluation

"If it is judged useful or necessary to produce more valid inferences, the moral costs involved in obtaining such data need to be considered in relation to the moral benefits that the data may produce, which are in turn contingent upon the scientific and social value of the research. Evaluation of the costs and benefits will be enhanced by empirical data. We recognise one possible consequence of our own openness to deception, and any favourable attention to the issues raised here, is that there may be more of it. We thus see it as an obligation, which we are happy to accept, that the use of deception in research should be accompanied by empirical studies to inform ethical decision-making and that there should be both scientific debate and public justification." [AJOB, in press]

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Thank you

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