

The demise of a planned randomised controlled trial in an urban Aboriginal medical service

Beverly M Sibthorpe, Ross S Bailie, Maggie A Brady, Sandra A Ball
Polly Sumner-Dodd and Wayne D Hall

RANDOMISED CONTROLLED TRIALS (RCTs) are seen as the evidence “gold standard” for the effectiveness of clinical interventions. However, as a method of evaluating complex interventions in community-based settings they have significant limitations. Because of the poor uptake in Australia of secondary prevention for alcohol misuse among Indigenous people,¹ we set out to trial a brief intervention (involving motivational interviewing of individuals not presenting primarily with an alcohol problem²) in this population. This intervention has been subjected to a rigorous multinational trial under the auspices of the World Health Organization (WHO)³ and found to help patients reduce their risk of alcohol-related harm.^{4,5} However, there were too few Indigenous people in the Australian arm of the WHO trial to provide evidence of the effectiveness of the intervention in this population. Here we report on an attempt to address this gap through implementation of a trial in an urban Aboriginal Medical Service.

METHODS

The research partnership

This study was a joint community–university partnership which involved Aboriginal Medical Service (AMS) Board approval; joint application to the National Health and Medical Research Council (NHMRC) to develop, pilot and implement the trial; AMS management of grant funds and employment of the project officer; joint development of the study protocol; and AMS control over all aspects of implementation. The three key factors underpinning the partnership’s success were that

- the AMS was committed to trying a new approach to alcohol misuse and was willing to consider formal research processes;

ABSTRACT

To fill a gap in knowledge about the effectiveness of brief intervention for hazardous alcohol use among Indigenous Australians, we attempted to implement a randomised controlled trial in an urban Aboriginal Medical Service (AMS) as a joint AMS–university partnership. Because of low numbers of potential participants being screened, the RCT was abandoned in favour of a two-part “demonstration project”. Only 16 clients were recruited for follow-up in six-months, and the trial was terminated. Clinic, patient, Aboriginal health worker, and GP factors, interacting with study design factors, all contributed to our inability to implement the trial as designed. The key points to emerge from the study are that

- alcohol misuse is a difficult issue to manage in an Indigenous primary health care setting;
- RCTs involving inevitably complex study protocols may not be acceptable or sufficiently adaptable to make them viable in busy, Indigenous primary health care settings; and
- “gold-standard” RCT-derived evidence for the effectiveness of many public health interventions in Indigenous primary health care settings may never be available, and decisions about appropriate interventions will often have to be based on qualitative assessment of appropriateness and evidence from other populations and other settings.

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National Centre for Epidemiology and Population Health, Australian National University, Canberra, ACT.

Beverly M Sibthorpe, BA(Hons), PhD, Fellow.

Menzies School of Health Research and Flinders University Northern Territory Clinical School, Casuarina, NT.

Ross S Bailie, MD, FAFPHM, Associate Professor.

Centre for Aboriginal Economic Policy Research, Australian National University, Canberra, ACT.

Maggie A Brady, MA, PhD, Visiting Fellow.

Territory Health Services, Alice Springs, NT.

Sandra A Ball, BCom, GradDip Public Administration, Aboriginal Communities Health Information Project Officer.

Nunkuwarrin Yunti of South Australia Inc, Adelaide, SA.

Polly Sumner-Dodd, DipManagement, Chief Executive Officer.

National Drug and Alcohol Research Centre, University of New South Wales, Sydney, NSW.

Wayne D Hall, BSc, PhD, Professor, and Executive Director.

Reprints will not be available from the authors. Correspondence: Dr Beverly M Sibthorpe, National Centre for Epidemiology and Population Health, Australian National University, Canberra, ACT 0200. beverly.sibthorpe@anu.edu.au

- the AMS employed the project officer, who immersed herself in the daily life of the clinic, allowing for ongoing debate and negotiation with staff at all levels; and
- the development of a Memorandum of Understanding in which the partners agreed details relating to receipt, management and allocation of grant funds, study design, data collection, storage and access, and community feedback and publication.

Ethical approval

Ethical approval for this study was obtained from the Australian National University Human Research Ethics Committee.

Developing and piloting the trial protocol

The primary objective of the study was to determine the acceptability (including cultural appropriateness) and effectiveness of brief intervention in at-risk attendees of an urban AMS. We were also interested in determining whether training in brief intervention helped providers broach and address the difficult topic of alcohol use with Aboriginal patients. The project was based in the AMS's two busiest clinics. The design included using the internationally validated 10-question screening tool known as the Alcohol Use Disorders Identification Test (AUDIT) to screen clinic attendees, random allocation of hazardous drinkers to either brief intervention or usual care, an on-the-spot fingerprick blood test for γ -glutamyltransferase (GGT), a blood sample drawn for laboratory testing for carbohydrate-deficient transferrin (CDT), and follow-up in six months for repeat AUDIT and blood tests. Those determined eligible by AUDIT screening were given a more detailed explanation of the project, including the meaning and implications of random allocation to control and intervention groups, and asked to sign the consent form, which had separate spaces for consent to the blood tests. Because of sensitivity about this issue among Indigenous people, it was agreed that patients should be able to participate without having either blood test.

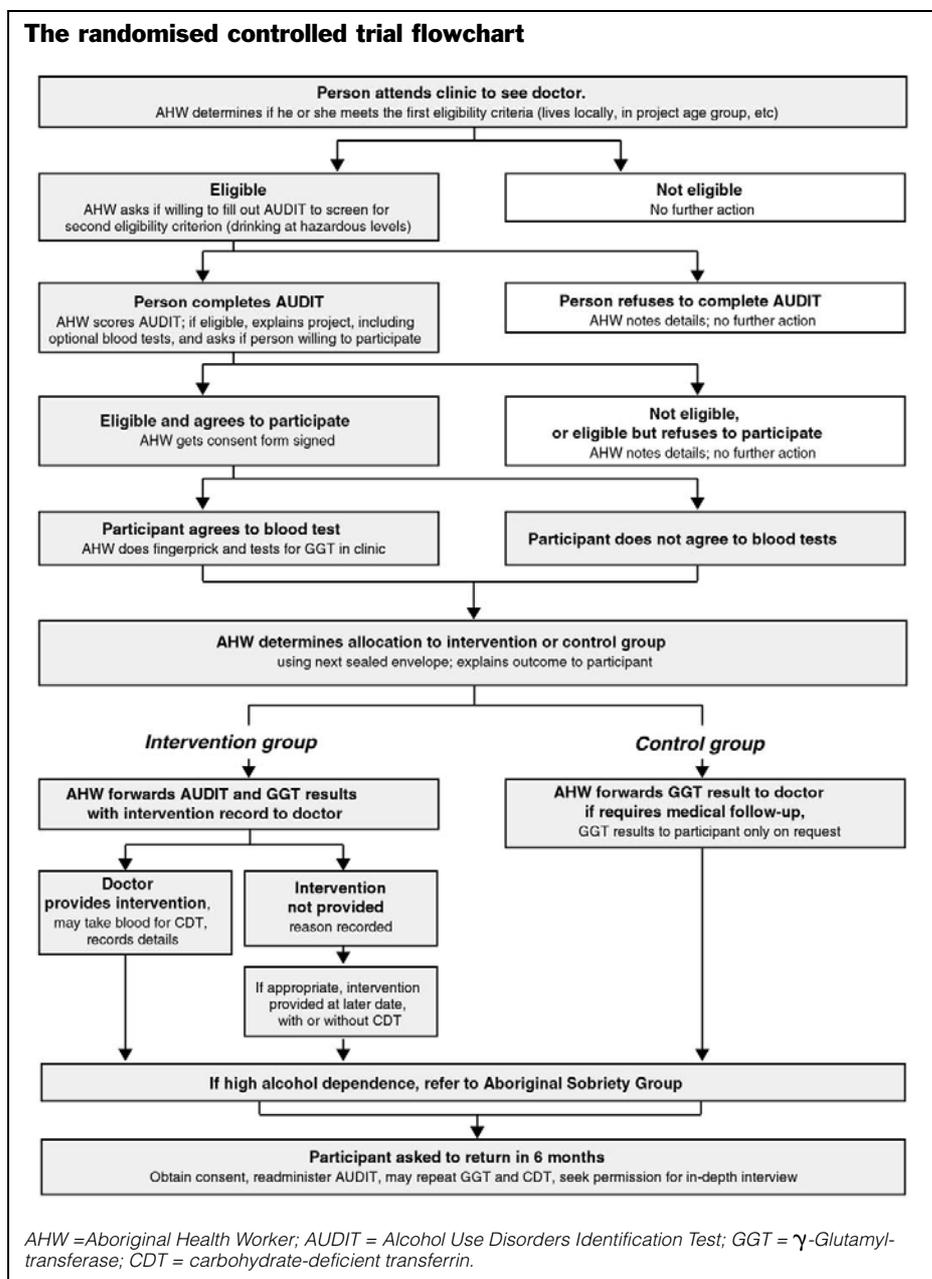
We estimated we needed around 400 participants (200 intervention, 200 con-

trol) to complete follow-up. This estimate was based on the conservative assumptions that by the end of the trial between 50% and 95% of control-group clients would still be drinking at hazardous levels (AUDIT score of 6 or more for women, 7 or more for men), and that there would be a 20% difference between the intervention and control groups (at a significance level of 1% and power of 90%). Thus, allowing for 20% attrition, we needed to recruit around 500 people. About 2500 clients had attended the AMS in 1996, of whom around half were in the study age

range of 18–65 years. AMS staff estimated that around 40% of these might be hazardous drinkers, leaving an estimated 500 clients in a year eligible to take part. This meant we had a margin for refusal and loss to follow-up of only 20%, and so we anticipated possibly having to extend recruitment beyond the one year planned.

We recruited a project officer to work on site, and the whole team worked with AMS staff to develop a study protocol. Having two clinics, six general practitioners (GPs) to train in brief intervention, many Aboriginal health workers

The randomised controlled trial flowchart



and nurses involved in screening and blood testing and fairly complex testing and laboratory pick-up logistics required extensive planning and coordination. Significant effort was also made to generate interest in and commitment to the project among the staff.

The project protocol was revised several times before it was felt to be adequate. However, it remained extremely complicated (see Box 1), particularly in the context of a busy health clinic. It involved Aboriginal health workers approaching clients, administering the AUDIT, scoring the responses to determine whether clients were drinking at hazardous or harmful levels, tagging the client's file, seeking participation, obtaining informed consent, undertaking the fingerprick GGT test, and completing the randomisation procedures. GPs were responsible for conducting the brief intervention, collecting some additional information, and taking the blood sample for CDT testing. In addition, the project officer had to develop methods for determining potential eligibility for the project and keeping track of clients and their data as they moved through the project, the latter made more complicated by the number of staff involved.

We began a pilot of the study protocol in November 1997. During the first week, 40 people were asked by the Aboriginal health workers if they would complete the AUDIT. Of these, 35 declined. Of the five who agreed, all had scores indicating "hazardous" (or the more extreme "harmful") use, and all agreed to take part in the trial.

The low participation rate was attributed to a number of factors, but primarily the reluctance of patients to answer questions about their use of alcohol, particularly when asked by other Aboriginal people whom they knew. This reluctance also extended to non-Aboriginal staff with whom patients had ongoing contact. Aboriginal health workers also seemed reluctant to ask people to complete the AUDIT.

To overcome these barriers, a revised protocol was developed and a second pilot carried out. This time, the project officer, who was non-Aboriginal and not known to patients, was responsible for the screening, consent and random allocation processes. She sat in the AMS

reception area and asked people if they were willing to fill out the AUDIT. Of the 12 people asked in this way, five agreed to fill in the AUDIT, of whom four agreed to take part in the project. While this resulted in slightly improved recruitment, it lessened the integration of the intervention into clinical processes. Difficulty in assessing who met the pre-screening eligibility criterion (come to see a doctor) and lack of privacy in the reception area also made this method of screening inefficient and more disruptive.

After 15 working days, 53 attendees had been approached, but only 10 had agreed to complete the AUDIT. All 10 were scored as drinking above safe levels and nine had agreed to participate in the study. Based on our recruitment estimates we needed to have recruited at least 30 participants — two per day — by this time, but had recruited less than one per day.

Study design revisited

We suspended the project and early in the new year undertook a round of meetings and interviews with all the relevant staff to try to identify what the problems were. The key points to emerge were:

- project processes did not fit well with clinic processes and the project was a "hassle";
- alternative project processes preferred by staff did not fit the study protocol;
- patients were embarrassed or resentful about being approached by Aboriginal health workers about their drinking, and did not want to discuss it with people who often already knew about their drinking;
- the Aboriginal health workers felt uncomfortable approaching the patients about drinking (especially those who were older, known to them socially, or members of their extended families) and were uncomfortable administering the AUDIT, which was seen as too long and too intrusive;
- random allocation was felt by Aboriginal health workers to be unethical, on the one hand, and like "telling people what to do", on the other;
- Aboriginal health workers felt under pressure to recruit people;

- there was a perception that there was no incentive for patients to be in the project; and

- there was a strong preference among the Aboriginal health workers and nurses for the GPs to take over most of the responsibilities of approaching the issue of drinking with clients, administering the AUDIT, obtaining consent, and random allocation, as well as conducting the brief intervention.

The randomised design was subsequently abandoned in favour of a two-part "demonstration project" with a specific focus on the acceptability and cultural appropriateness of the intervention, and on the impact of training on the providers' ability to address alcohol-related issues with clients. Under Part A, brief intervention was offered by the GPs to any patient who might benefit as part of standard clinical practice. This was predicated on the demonstrated effectiveness of the intervention in other settings. Part B comprised a study of a subset of patients who received the intervention (ie, consent was sought for participation in an effectiveness study). Initial screening by the Aboriginal health workers was reduced to two questions already on the clinic's client induction form, while responsibility for other study processes was transferred to the GPs, including screening (where this had not already been done), and administering the AUDIT. The AUDIT was now to be used as the baseline assessment rather than the screening tool.

The project recommenced on April 15, 1998. Over the next six months, about 900 individuals in the study age range had a consultation with a GP and the great majority of these were screened using the two questions (it was not possible to determine the exact numbers). Of the 900 attendees, only 64 were identified as drinking at hazardous levels. Of these 64, 25 received the intervention and 16 of these agreed to take part in the effectiveness study. Instead of the original target of two people per week we had recruited only one per fortnight. After much debate the project was brought to an end and we wrote to the NHMRC to terminate our funding.

CONCLUSIONS

Clinic, patient, Aboriginal health worker and GP factors, interacting with study design factors, all contributed to our inability to implement the trial as designed. Two different sets of clinic processes; the inevitable complexity of the study protocol; problems with the screening technique; patient reluctance to talk about alcohol consumption; sensitivity of the staff about broaching the subject; staff attitudes to random allocation (also reported by others⁶); GP reluctance or inability to follow through with eligible attendees because of discomfort, patient ill-health or time constraints; and patient reluctance to be involved in research — all contributed to the study's non-viability. In addition, we may have overestimated the numbers likely to be eligible. Many of those screened appeared to be non-drinkers, perhaps partially explained by the fact that the health service provided nearly twice as many consultations for women as it did for men. Males were particu-

larly under-represented in the 16–44-years age range. In addition, 27% of all consultations were for people aged 0–17 years. Only 8% of consultations were for those aged 16–25 years. Thus, people in the age groups most likely to drink at hazardous levels were under-represented among AMS attendees. Similarly low recruitment to a GP brief intervention study has been described elsewhere.⁷

COMPETING INTERESTS

None declared.

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book review

Overview of drug use

Understanding, influencing and evaluating drug use. Jonathan G A Dartnell. Melbourne: Therapeutic Guidelines, 2001 (x + 98 pp, \$31.90). ISBN 0 9586 198 2 4.

THE TITLE OF THIS BOOK is ambitious for such a slim volume, but the result is a very readable discussion which will be of interest to those involved in, or wishing to become better versed in, issues relating to prescription drug use. Jonathan Dartnell is a pharmacist with a long involvement in hospital drug use evaluation studies. He is well qualified to address these issues and the discussion is timely, as evidence grows of the human and financial consequences of suboptimal use of prescription drugs.

The text is extensively referenced, although readers should not assume that it provides a comprehensive

review of all the pertinent research on a particular topic. The evidence presented is international, but, where possible, focuses on Australian research. The book's strength lies in its breadth rather than its depth, particularly in Chapter 2, which is a whistle-stop tour of the "actors and factors in the drug use environment". The result is occasionally unsatisfying, as the topics are constantly changing and many are not canvassed in sufficient detail for the interested reader. However, the references are a useful starting point for further research. This minor criticism is outweighed by the value of drawing together in one place research on so many issues.

Chapter 3, "Influencing drug use", and Chapter 4, "Evaluating drug use", are more narrowly focused, and provide more detailed explorations of these topics. The diverse literature on

strategies to influence drug use practice is well described and provides a good review of this important topic. The chapter on drug use evaluation (DUE) has a predominantly hospital focus, although its guiding principles and methods are equally relevant to the community setting. Useful appendices list the websites and summarise the focus of international networks and Australian groups interested in the quality use of medicines.

What began as a literature review for a PhD thesis has found another life as a valuable resource for those interested in drug use and its evaluation.

Jane Robertson

Lecturer in Pharmacoepidemiology
University of Newcastle, NSW

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