Accepted Manuscript

BJGP OPEN

Embedding brief interventions for alcohol in general practice: a study protocol for the REACH Project feasibility trial

Sturgiss, Elizabeth; Gunatillaka, Nilakshi; Ball, Lauren; Lam, Tina; Nielsen, Suzanne; O'Donnell, Renee; Barton, Chris; Skouteris, Helen; Tam, Chun Wah Michael; Jacka, David; Mazza, Danielle; Russell, Grant

DOI: https://doi.org/10.3399/BJGPO.2021.0037

To access the most recent version of this article, please click the DOI URL in the line above.

Received 03 March 2021
Revised 29 March 2021
Accepted 31 March 2021

Title

Embedding brief interventions for alcohol in general practice: a study protocol for the REACH Project feasibility trial.

Authors

Elizabeth Sturgiss (PhD)[a]
Nilakshi Gunatillaka (BSc MIPH)[a]
Lauren Ball (PhD)[b]
Tina Lam (PhD)[c]
Suzanne Nielsen (PhD)[c]
Renee O'Donnell (PhD)[d]
Chris Barton (PhD)[a]
Helen Skouteris (PhD)[d, e]
Chun Wah Michael Tam[f, g]
David Jacka[c,h]
Danielle Mazza (MD)[a]
Grant Russell (PhD)[a]

[a]Department of General Practice, School of Primary and Allied Health Care, Monash University, Melbourne, Australia
[b]Menzies Health Institute Queensland and School of Allied Health Sciences, Griffith University, Brisbane, Australia
[c]Monash Addiction Research Centre, Eastern Health Clinical School, Monash University, Frankston, Victoria, Australia
[d]Health and Social Care Unit, NHMRC CRE in Health in Preconception and Pregnancy (CRE HiPP), School of Public Health and Preventative Medicine, Faculty of Medicine, Nursing and Health Sciences, Monash University, Melbourne, Victoria, Australia
[e]Warwick Business School, The University of Warwick, Coventry, United Kingdom
[f]Primary and Integrated Care Unit, South Western Sydney Local Health District, Liverpool, NSW, Australia
[g]School of Population Health, Faculty of Medicine, University of New South Wales (UNSW) Sydney, NSW, Australia
[h]Monash Health, Melbourne, Australia.

Corresponding author: Dr E Sturgiss, Department of General Practice, School of Primary and Allied Health Care, Monash University, Melbourne Australia, liz.sturgiss@monash.edu

Abstract

Background: Alcohol is a major source of harm in Australia that disproportionately affects low-income communities. Alcohol brief interventions (ABIs) combine an assessment of a person's alcohol use with advice to reduce health risks. Despite their effectiveness, clinicians do not routinely perform ABIs. This paper presents a protocol for a feasibility trial of pragmatic implementation strategies and a new set of resources to support clinicians to complete ABIs in Australian general practices.

Aim: To explore the facilitators and barriers to increasing the uptake of ABIs in primary care including acceptability, reach, adoption, fidelity and sustainability.

Design and setting: A mixed methods evaluation of the uptake of ABIs in general practice clinics serving lower income communities in Melbourne, Australia. Our approach is informed by the Consolidated Framework for Implementation Research and Normalisation Process Theory.

Methods: We will trial the implementation strategies and resources in five general practices over 12 months. Our primary outcome will be change in proportion of adult patients with a complete alcohol history in their electronic medical record. Baseline data collection includes a practice survey to describe practice routines for ABIs and de-identified patient medical record data on completed alcohol histories (repeated at three, six, nine and 12 months post intervention). We will also collect survey and interview data from clinicians, patients and Primary Health Network staff to assess acceptability and feasibility of the intervention.

Discussion: We will explore how our implementation strategies and resources can improve alcohol screening and management among low income patients in general practice.

Keywords

Primary health care, general practice, alcohol use disorder, low income population, feasibility studies

How this fits in:

1. Brief interventions for alcohol delivered in primary care are effective for reducing alcohol-related harm.
2. Currently, BIs are often not routinely delivered in primary care.
3. We have developed a new implementation strategy with supporting resources to increase the uptake of BIs in primary care.
4. This implementation trial will explore barriers and facilitators to increase routine delivery of BIs in primary care to inform future policy and practice.

Introduction

Background and rationale

Alcohol is a major source of harm. Each year, harmful alcohol use contributes to 3 million deaths and the loss of 132.6 million Disability Adjusted Life Years (DALYs)(1). Low-income communities are at increased risk of alcohol-related harm (2). In Victoria, Australia, the burden of the 1200 deaths per year attributable to alcohol (3) falls disproportionately on the 13% of Victorians living in poverty (4).

Alcohol brief interventions (ABIs) involve assessing the amount of alcohol a person is consuming and offering individualised advice to reduce the associated health risks (5). ABIs provided by general practitioners (GPs) and nurses in community based primary care can reduce the number of episodes of risky drinking and weekly average alcohol consumption among people with problematic alcohol use (5). Alcohol-related harms affect more people with harmful alcohol use than those with alcohol dependency, and large reductions in alcohol-related harms can be achieved by reducing alcohol use in the former population (6, 7).

Strong primary care systems are the foundation of equitable healthcare service delivery {van Weel, 2018, Why strengthening primary health care is essential to achieving universal health coverage}. In the setting of alcohol harm, equity is especially important as people from lower socioeconomic groups experience a disproportionate amount of harm from alcohol use{Collins, 2016, Associations Between Socioeconomic Factors and Alcohol Outcomes}. Few trials on the effectiveness of ABIs have considered the specific needs of low-income groups, potentially contributing to greater health disparities (8). The overall aim of the project is to (a) increase screening for problematic alcohol use and (b) increase the application of ABIs in general practice. Our preferential focus on low- income

groups will aim to reduce health inequity by ensuring the approach is most acceptable, feasible and effective for low-income groups (9).

Objectives

We will use mixed methods to assess the acceptability and feasibility of an implementation strategy to increase the uptake of ABIs for alcohol in Australian general practices serving low-income communities.

Method

This is a single-arm implementation trial using mixed methods to evaluate the uptake of ABIs in primary care. Our approach is informed by: (1) the Consolidated Framework for Implementation Research (CFIR) to assess factors affecting implementation and effectiveness, and, (2) Normalisation Process Theory (NPT) to understand how change is embedded in a practice.

Study setting

The trial will be conducted in five general practice clinics located in northern metropolitan Melbourne, Australia in a region corresponding to a Primary Health Network (PHN) catchment (PHNs are federally funded to oversee primary care delivery in local regions) (10).

Participating general practice clinics will be located in a low-income area as identified by the PHN i.e. a Socio-Economic Index for Areas (SEIFA) score < 1000 (where a score of 1000 is the mean for all areas, and scores lower than this indicate relative disadvantage). Practices will use electronic patient medical record and billing software compatible with the PHN's practice data extraction tool (Pen CS CAT4^{TM}(11)). Consent will be gained from practice management and at least one GP. No specific eligibility criteria apply to participating GPs. No clinician in the practice will be mandated to use the resources. Patient participants will be aged over 18 years and able to understand eighth grade English. We will use interpreters for patient interviews when necessary.

Intervention

In preparation for this trial, we sought to understand participants' experiences of talking about alcohol in general practice settings and suggestions on how to promote and improve these conversations (12). We then co-designed a implementation strategies and an associated resource

pack to increase the uptake of ABIs in primary care (https://www.monash.edu/medicine/spahc/general-practice/research-projects/reach).

We used Normalisation Process Theory (13) as well as "priming" to construct the approach to implementation. We incorporated "sense making" for clinicians with training and resources on best practices for ABIs, "relational work" by identifying and supporting practice champions, "operational work" using in-consultation resources, "appraisal work" with regular updates to the clinics on alcohol screening rates, and "priming" the patients with posters and pamphlets to be more receptive to discussions about alcohol. Prior to trial commencement a state of emergency was declared in Australia due to the SARS-CoV2 pandemic. We then adapted our intervention for use during telehealth consultations (Supplementary Table 1).

Ethical issues

Ethics approval has been granted (see statement below). We have routine systems in place to offer assistance and follow-up any patient who is distressed by health-related research. This includes signposting opportunities for support plus personal follow-up at participant request. Survey and interview participants that express concerns about their alcohol use will be directed to seek help from their primary care provider or local drug and alcohol counselling services.

Intervention process

Before the trial, practices will identify a champion to promote the intervention to their colleagues. Practice engagement staff from the PHN will support implementation at the practice with quarterly visits to provide ongoing feedback on practice performance and to promote use of the clinical resources. This roll-out via the PHN was chosen as a pathway to support sustainability for future scale-up.

Outcomes

Our primary outcome is the change in the proportion of adult patients (>15 years) with completed alcohol histories in their electronic medical record. Implementation outcomes, informed by RE-AIM (14), include:

- Reach: the change in proportion of patient records with information on alcohol status (drinker, non-drinker) as a proxy marker for where a BI is likely to have occurred.
- Acceptability: to patients, clinicians, practice staff and PHN staff;
- Adoption within each practice and within the PHN processes;

- Fidelity of intervention implementation via project timelines completed by the PHN, research team and member checked during provider interviews;
- Sustainability as perceived by practice staff, clinicians and PHN staff.

Sample size

We will recruit five practices to evaluate the process of implementation. We will formally recruit at least one GP or practice nurse at each practice; other clinicians will have access to the resources and can participate in team feedback meetings. For the nested SMS survey study, we will recruit 140 patients who self-identify as drinking at risky levels across the five practices per the AUDIT-C questionnaire (15). We are interested in the response rate over time – both the number of responses at each time point, and the number of questions answered at each time point. We will also be able to detect changes in drinking patterns (10% change total standard drinks per week compared to baseline, power 0.8, significance 0.05).

Recruitment

Practices: The PHN will recruit practices via newsletters and the PHN website. A member of the research team will then contact practice management to explain the project and seek written informed consent.

Practice staff: Researchers will ask practice management to circulate information to their clinicians. Interested clinicians will contact the researchers for more information and to provide written consent.

Patients: The practice will send an SMS to all patients who visited the practice in the previous three months inviting patients to fill in a short survey on their experiences of discussing alcohol with their clinician. Patients will also indicate if they are happy to be contact for a follow-up surveys/or interview. Follow up surveys will be sent to participants who self-identify as drinking at risky levels.

Data collection methods

Table 1 shows data collection at the patient, provider, practice and PHN level.

Quantitative instruments

1. *De-identified patient data from Pen CS CAT4™* (11)*:* The PHN receives data from all practices in the catchment relating to completion of patient alcohol histories. We will enter into a data sharing agreement with the PHN and participating practices to access this data. The PHN will provide data on the patients with complete alcohol histories as determined by recording of “drinker”, “non-drinker”, “nothing recorded” and “patient under 15 years of

age with nothing recorded" in the patient's electronic medical record. The baseline measure will include all active patients, that is, those with at least three visits in the last 2 years. At three and six months, we will measure the change in proportion of patients with an alcohol history by comparing the proportion of patients with at least one visit to the practice in the preceding three months who had a complete alcohol history. These measures will be available for all other clinics (approximately 850) in the same catchment area for comparison.

2. *Practice survey:* will be administered at baseline to collect information about the practice's structure, staffing, record management systems, patient load and demographics, and processes for patient intake and assessment relevant to ABIs.
3. *"NoMAD (*Normalisation Measure Development)*" tool (16):* The "NoMAD" tool is a quantitative survey to be completed by participating GPs, practice nurses and practice administrative staff to assess how well ABIs were embedded into everyday practice.
4. *Patient survey:* via SMS to capture data on whether they were asked about alcohol use, how they found the experience, their alcohol use (AUDIT-C) (15) and demographics including low income status.
5. *Patient survey for patients with risky alcohol use:* Patients who self-report risky alcohol use (AUDIT-C) in the patient survey will be invited to participate in quarterly follow up SMS surveys. We will collect information on:
   - The average weekly consumption of alcohol in standard drinks
   - The frequency of episodes of high risk drinking
   - The number of attendances at the general practice.

   A subgroup analysis based on self-reported low-income status will be completed.

Qualitative instruments

The CFIR interview guides will inform our interviews tailored for each participant group (17)

1. *Patient interview:* We will interview 20 patients to provide further feedback about the acceptability of the intervention. We will purposively sample patients with self-reported low-income; and, we will consider maximum variation in gender, age, self-reported consultation experience when inviting patients for an interview. Interviews will focus on the acceptability of the intervention for patients, suggested improvements and any unintended consequences.
2. *Clinician interview:* We will interview at least two clinicians from each practice to assess how the intervention works within the consultation and any unexpected effects. Interviews will

focus on the feasibility of the intervention in daily practice, suggested improvements and sustainability of the intervention.

3. *PHN interview:* We will interview up to five PHN staff who have been involved in the implementation of the REACH resources. We will focus on the CFIR "Outer Setting" to better understand how the broader policy environment has influenced the implementation process.

Data analysis

We will use both qualitative and quantitative data to assess the acceptability, feasibility, and relative effectiveness of the intervention. The data will be collected concurrently and integrated to gain a better understanding of the implementation process for REACH.

Quantitative analysis

Quantitative data will be analysed descriptively, with means and standard deviations or medians and ranges reported for continuous variables, and proportions for categorical variables. Correlations will be calculated using Spearman rho due to the anticipated non-normal distribution of scores. Repeated measures data will be analysed using a non-parametric statistics such as the McNemar and Wilcoxon signed-rank test. Multiple regressions will be conducted to assess associations between the intervention measures.

Interrupted time series

We will perform an interrupted time series analysis using data from the enrolled clinics, as well as the 850 clinics within the same catchment to determine how much alcohol screening has changed in the intervention clinics and across whole PHN over the study period.

Analyses will be computed in IBM SPSS version 24 (IBM Corp, Armonk, New York, United States).

Qualitative analysis

Audio files of interviews will be de-identified and professionally transcribed. Analyses will be conducted using NVivo 10 or higher (QSR international).

Although the interview guides will be based on CFIR, we will use inductive thematic coding to ensure our findings are grounded in the data and not a pre-existing framework.

Summarised findings and early interpretations will be discussed with the research team in regular small team meetings. We will also meet on a minimum of two occasions with the entire investigator team to finalise the themes from the data.

Table 2 outlines our approach to the mixed methods analysis of the data.

Discussion

Our implementation trial will generate evidence on the effectiveness of our implementation strategy at increasing the uptake of ABIs in primary care, as well as the acceptability and feasibility of this strategy, with a particular focus on low-income patients. We have used implementation and behaviour change theory to guide both the design of ABI strategy and resources, and, the approach to the evaluation. Our co-design approach and existing collaborations are strengths of this work. The work will be influenced and shaped by the global pandemic – we will use the unique opportunity to learn more about primary care delivery in high risk situations that may be useful in other disaster settings (e.g. bushfire, flood). There is a potential that the pandemic may alter our implementation findings and some will be inapplicable to non-disaster settings. We will generate new knowledge on how similar interventions can be adapted for telehealth consultations and how preventive healthcare is affected by a global pandemic.

Additional Information

Funding

This work is supported by the Victorian Health Promotion Foundation via an Impact Research Grant. The competitive grant was for a specific topic to inform their future policy work. The funder did not have involvement in the design, execution, analysis of the study or decision to submit the publication.

Research ethics approval

This project has been approved by the Monash University Human Research Ethics Committee. Approval number 22865.

Declaration of interests

A/Prof. Nielsen has received funding from Seqirus and Indivior for work relating to pharmaceutical opioid related harms and treatment of opioid dependence (not in relation to this grant or project).

The other researchers have no potential conflicts of interest to declare.

Dissemination policy

Findings will be presented to the funding agency, partners, general practice clinicians via professional colleges, Primary Health Networks, and Australian federal and state level policy advisors via meetings and workshops, reports, press releases, the project website and social media. We disseminate a plain language summary of our progress via a newsletter every 3-4 months.

References

1. World Health Organisation. Global status report on alcohol and health. Switzerland: WHO; 2018.
2. Roche A, Kostadinov V, Fischer J, Nicholas R. Evidence review: The social determinants of inequities in alcohol consumption and alcohol-related health outcomes . Melbourne: Victorian Health Promotion Foundation; 2015.
3. Gao C, Ogeil R, Lloyd B. Alcohol's burden of disease in Australia. Canberra: FARE and VicHealth in collaboration with Turning Point; 2014.
4. Australian Council of Social Service in partnership with the University of New South Wales. Poverty in Australia 2018. Sydney; 2018.
5. Kaner EF, Beyer FR, Muirhead C, Campbell F, Pienaar ED, Bertholet N, et al. Effectiveness of brief alcohol interventions in primary care populations. Cochrane Database Syst Rev. 2018;2:CD004148.
6. Beyer F, Lynch E, Kaner E. Brief Interventions in Primary Care: an Evidence Overview of Practitioner and Digital Intervention Programmes. Curr Addict Rep. 2018;5(2):265-73.
7. The Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edn. ed. East Melbourne, Victora: Royal Australian College of General Practitioners; 2018.
8. O'Donnell A, Anderson P, Newbury-Birch D, Schulte B, Schmidt C, Reimer J, et al. The impact of brief alcohol interventions in primary healthcare: a systematic review of reviews. Alcohol Alcohol. 2014;49(1):66-78.
9. Newman L, Javanparast S, Baum F, Hutchinson C. Evidence review: Settings for addressing the social determinants of health inequities. Melbourne: Victorian Health Promotion Foundation; 2015.
10. Australian Government Department of Health. Primary Health Networks 2020 [Available from: https://www1.health.gov.au/internet/main/publishing.nsf/Content/PHN-Home.
11. Pen Clinical Systems. Clinical Audit Tool (CAT) 4 [Available from: https://www.pencs.com.au/products/cat4/.
12. Sturgiss E, Lam T, Russell G, Ball L, Gunatillaka N, Barton C, et al. Patient and clinician perspectives of factors that influence the delivery of alcohol brief interventions in Australian primary care: A qualitative study (paper under review).
13. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Med. 2010;8:63.

14. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999;89(9):1322-7.
15. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Arch Intern Med. 1998;158(16):1789-95.
16. Rapley T, Girling M, Mair FS, Murray E, Treweek S, McColl E, et al. Improving the normalization of complex interventions: part 1 - development of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). BMC Med Res Methodol. 2018;18(1):133.
17. CFIR Research Team. Consolidated Framework for Implementation Research [Available from: https://cfirguide.org/.
18. Guetterman TC, Fetters MD, Creswell JW. Integrating Quantitative and Qualitative Results in Health Science Mixed Methods Research Through Joint Displays. Ann Fam Med. 2015;13(6):554-61.

Tables and figures

Table 1: Data sources and data collection timepoints

Data source		Practice		Provider		Patient			Primary Health Network	
Tool/survey		*Electronic patient database (PENCS CAT4™*(11))	Practice survey	NoMAD tool*	Interview	Patient survey (All)	Interview	Follow up SMS survey	Interview	Project timelines
Contact point timeline	Baseline	X	X							
	Post consultation					SMS link	Telephone			
	3-months	X						X	X	X
	6-months	X		X				X	X	X
	12-months	X		X	X			X		X

*Normalisation Measure Development Questionnaire (16)

Table 2: Mixed methods data collection, analysis and outcomes: implementation matrix adapted from Guetterman et al (18)

Data Type	Study Aim	Data Collection Procedure	Data Analysis Procedure	Theoretical framework	Products or Outcomes	Points of integration
Qualitative	To identify the barriers and facilitators to implementing alcohol BIs in general practice	Interviews: patients; clinicians; practice staff; PHN staff	Inductive thematic coding	CFIR RE-AIM	Perception of implementation processes from multiple viewpoints (acceptability; adoption; fidelity)	Triangulate with NoMAD data to inform implementation process Compare with practice level data on % alcohol intake recording to look for patterns on increased uptake, or not
Quantitative	Increase uptake of alcohol BIs	Routine data extraction from practice to PHN (drinker, non-drinker, not recorded; gender; age); PHN to share the amalgamated data with research team	Descriptive statistics every 3 months Interrupted time series analysis compared to all practices in PHN catchment. Data will be collected monthly.	CFIR RE-AIM	% change in patient records with alcohol intake recorded (reach; adoption)	Compare with qualitative interview data to understand barriers and facilitators to % change
Quantitative	To identify the barriers and facilitators to implementing alcohol BIs in general practice	NoMAD survey from practice managers and clinicians	Likert scale	Normalisation Process Theory	Measure of provider assessment of potential "normalization" of new procedure (acceptability; adoption; sustainability)	Triangulate with interview data from providers to identify implementation processes
Quantitative	Nested SMS study to determine response rates to SMS surveys over 9-12 months	SMS survey to patients at 3 monthly intervals using 2-way SMS (Qualtrics)	% response rate % of questions completed at each time point	NA	Response rate to SMS surveys over time	NA