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Supporting alcohol brief interventions and pharmacotherapy provision in Australian First Nations primary care: exploratory analysis of a cluster randomised trial

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Abstract

Introduction Primary care provides an important opportunity to detect unhealthy alcohol use and offer assistance but many barriers to this exist. In an Australian context, Aboriginal Community Controlled Health Services (ACCHS) are community-led and run health services, which provide holistic primary care to Aboriginal and Torres Strait Islander peoples. A recent cluster randomised trial conducted with ACCHS provided a service support model which showed a small but significant difference in provision of 'any treatment' for unhealthy alcohol use. However, it was not clear which treatment modalities were increased.

Aims To test the effect of an ACCHS support model for alcohol on: (i) delivery of verbal alcohol intervention (alcohol advice or counselling); (ii) prescription of relapse prevention pharmacotherapies.

Methods *Intervention*: 24-month, multi-faceted service support model. *Design*: cluster randomised trial; equal allocation to early-support ('treatment') and waitlist control arms. *Participants*: 22 ACCHS. *Analysis*: Multilevel logistic regression to compare odds of a client receiving treatment in any two-month period as routinely recorded on practice software.

Results Support was associated with a significant increase in the odds of verbal alcohol intervention being recorded (OR = 7.60, [95% CI = 5.54, 10.42], $p < 0.001$) from a low baseline. The odds of pharmacotherapies being prescribed (OR = 1.61, [95% CI = 0.92, 2.80], $p = 0.1$) did not increase significantly. There was high heterogeneity in service outcomes.

Conclusions While a statistically significant increase in verbal alcohol intervention rates was achieved, this was not clinically significant because of the low baseline. Our data likely underestimates rates of treatment provision due to barriers documenting verbal interventions in practice software, and because different software may be used by drug and alcohol teams. The support made little impact on pharmacotherapy prescription. Changes at multiple

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organisational levels, including within clinical guidelines for primary care, may be needed to meaningfully improve provision of alcohol treatment in ACCHS.

Trial registration ACTRN12618001892202 (retrospectively registered on 21/11/2018).

Keywords Alcohol, Aboriginal community controlled health organisation, Pharmacotherapy, Brief intervention, Counselling, Relapse prevention, Treatment, Primary care

Introduction

The International Classification of Diseases (ICD-11) describes a broad spectrum of 'unhealthy alcohol use'. This spans drinking patterns that increase risk of harm to self or others (hazardous alcohol use) through to alcohol use disorders, where patterns of consumption have already resulted in harm or dependence [1]. At the mildest end of the spectrum, hazardous alcohol use may be defined by consumption that is above national guidelines (e.g. Australian guidelines at the time of this study, recommended no more than two standard drinks per day to reduce lifetime risk of alcohol-related harm and no more than four per occasion to reduce risk of injury from single occasion drinking) [2]. There are short screening tools to help detect unhealthy drinking, for example, the three-item AUDIT-C (Alcohol Use Disorders Identification Test- consumption) [3].

A number of evidence-based options are available to respond to unhealthy alcohol use in primary care [4], ranging from brief intervention for hazardous or harmful drinking to counselling and psychological therapies (including shorter forms adapted to the busy setting), and medications for withdrawal management and for relapse prevention for dependent drinking. Mild to moderate alcohol dependence can often be managed in primary care [5], with more severe or complex cases referred to specialist services. Having alcohol care available in primary care can increase treatment access and reduce stigma for the patient [6]. Implementation of pharmacotherapies for relapse prevention in alcohol dependence in primary care has been studied internationally [7].

As well as being the most common point of health service contact for the population [8], primary care may often be the only opportunity for clinicians to detect unhealthy alcohol use and offer alcohol care [8]. Most (90%) Australians attend a primary care service each year. In contrast, when individuals with an alcohol use disorder are referred to specialist services, this often does not lead to treatment access [9]. This may be due to barriers such as distance to the nearest specialist service, financial constraints, and the stigma surrounding attendance [5, 9].

In Australia, the RACGP (Royal Australian College of General Practitioners) SNAP guidelines (Smoking, nutrition, alcohol physical activity; guidelines for managing behavioural risk factors in general practice) [10] include the use of pharmacotherapies in primary care among alcohol care options, while the recent alcohol treatment guidelines [11] advocate delivery of alcohol interventions at the point of detection of hazardous or harmful drinking for Aboriginal and Torres Strait Islander peoples (also herein respectfully referred to as First Nations Australians or First Nations peoples).

Australia's First Nations peoples may face additional barriers to specialist service access [12, 13]. For example, in 2014-15 the average distance travelled by First Nations Australians for alcohol or other drug treatment was 123 km compared with 53 km for non-Indigenous Australians [14]. Also, in 2017-18, care for alcohol, tobacco and other drugs was reported as a service gap by more than half (54%) of Aboriginal and Torres Strait Islander primary care organisations nationally [15]. Accordingly, primary care is an important way to provide assistance for unhealthy alcohol use.

In Australia, Aboriginal Community Controlled Health Services (ACCHS) are the main provider of primary care services to Aboriginal and Torres Strait Islander people and are the most common point of detection of health problems and health risks in this population [16]. With Australia's First Nations peoples accessing primary care 1.1 times more than their non-Indigenous Australians counterparts [15, 17], ACCHS are instrumental in addressing health inequalities experienced by Australia's First Nations peoples [18]. They are well placed to detect unhealthy alcohol use and offer a broad spectrum of alcohol care [13, 19] alongside health and social issues, in which alcohol can often be a factor [20].

Very few projects globally have studied implementation of the full range of alcohol interventions in First Nations primary care settings [21]. In Australia, and in other countries where First Nations peoples have been colonised, harms arising from colonisation have caused ongoing trauma and distress, and these can increase susceptibility to harms from alcohol [22]. Aboriginal and Torres Strait Islander Australians were systematically removed from their land, subjected to discrimination and racism in all aspects of life, and robbed of their autonomy [23]. At that same time as this erosion of self-determination was occurring, alcohol became far more readily available [24]. While overall, First Nations Australians today are more likely to abstain from alcohol than their non-Indigenous peers [2], in individuals, families

or communities that develop problems with alcohol, this can contribute to or exacerbate psychosocial or physical health problems [20]. So, accessible care for alcohol problems is particularly important for First Nations peoples [13].

In general populations internationally, rates of provision of brief verbal interventions (i.e., brief advice, education, or counselling) for unhealthy alcohol use are low in primary care settings [25–27]. In Australian primary care, such a verbal alcohol intervention was recorded in only 0.4% of primary care encounters in 2015-2016 [28]. In contrast, nearly one in five (17.3%) of Australians aged 18+exceeded the recommended Australian daily drinking limits (in 2014–2015) [2]. Alcohol pharmacotherapies are also under-used in Australia. Fewer than 3% of Australians with alcohol dependence are prescribed a pharmacotherapy (in any treatment setting) [29, 30]. To our knowledge there are no national data on the provision of alcohol brief interventions or pharmacotherapies to First Nations Australians.

The current paper reports on an exploratory analysis of data from a cluster randomised trial of a multifaceted service-wide support for ACCHS. The support, provided to services over 24-months, aimed to increase uptake of evidence-based screening and interventions for unhealthy alcohol use, delivered at point of care in a 'real world' clinical setting. The support model used continuous quality improvement techniques to support implementation [31, 32]. Data routinely collected in practice software were used to measure outcomes. Over 24 months of implementation, the support resulted in a significant increase in the odds of screening (OR=7.95, [95% CI=4.04, 16.63], $P<0.001$) and recording of 'any alcohol intervention' in practice software (i.e. alcohol advice, counselling or relapse prevention pharmacotherapies), (OR=1.89, [95% CI=1.19, 2.98], $p=0.01$) relative to waitlist control services. There was however no significant increase in 'alcohol advice' specifically (OR=1.95, [95% CI=0.53, 7.17], $p=0.32$) [33].

To further understand the support model's effect on provision of alcohol interventions, this paper aims to separately analyse the effects of the support model on provision of: (i) any alcohol verbal interventions (e.g. advice, brief intervention or counselling); and (ii) pharmacotherapies for alcohol relapse prevention.

Methods

The trial protocol was retrospectively registered (ACTRN12618001892202) and published [31–33]. This paper was prepared in accordance with the Consolidated Standards of Reporting Trial (CONSORT) extension for cluster randomised trials [34]. Eight ethics committees in Australian states or territories where the participating services were located approved this study [31]. Three were Aboriginal Australian-specific committees.

Study design and recruitment

The study was designed in consultation with two statewide umbrella Aboriginal Community Controlled Health Organisations and participating ACCHS were involved in refining the study design. ACCHS Boards and authorised representatives gave consent to participate in the study [31–33]. Services agreed to provide specific routinely collected data items to the research team. To preserve services' and clients' anonymity, outcomes data were aggregated in a way that prevented identification, and data fields containing free text, or attachments were not provided. Services could withdraw from the study at any time, including withdrawing data. Data provision was formalised through a memorandum of understanding. In line with data sovereignty principles, the ACCHS remained in control of the routinely collected practice data. Data extraction and provision were carried out either by the ACCHS or by a data manager from the Aboriginal Health Council of South Australia (AHCSA). The ACCHS retained joint IP rights to the research dataset that resulted from aggregating and curating their individual data contributions. ACCHS have been consulted on all report drafts prior to dissemination of findings via peer-reviewed publications. Contribution of the ACCHS was acknowledged on all publications without identifying individual services.

The study is a cluster randomized effectiveness trial with an equal allocation of services to early-support (treatment) arm and waitlist control arm (which received delayed support). Of the 140–143 ACCHS in Australia [35, 36], 132 were assessed for eligibility. ACCHS were eligible to participate if they met the following inclusion criteria: (i) used Communicare practice software; and (ii) provided care for 1,000 or more clients per year.

Sample size and randomisation

The study was powered to detect an increase in both screening (the primary outcome) and increase in offer of an intervention for unhealthy alcohol use (the secondary outcome). Power calculation was performed using Power Analysis and Sample Size (PASS) [37]. The focus of sample size calculation was intervention increase (brief intervention, counselling, or pharmacotherapies for alcohol relapse prevention) as this required a larger sample size than screening. A 15% increase in provision of care was judged to be clinically meaningful by the project's clinical investigators. In a service of 1000 clients per year, about 60% are likely to be aged 16 years or more [38], and 57% of these are likely to be screened at least once in a year [39]. Of those screened, at least 25% clients aged 16+ are likely to drink above Australian recommended levels

[40, 41], and 60% of these clients may have an intervention recorded [39]. Assuming intracluster correlation coefficient of 0.04 [42, 43], we calculated that 10 services in each arm were sufficient to detect a 13% increase in provision of alcohol interventions for unhealthy alcohol use (80% power and 2-sided significance of 0.05). We recruited an extra service per arm anticipating that over the study period there may be some service attrition. Accordingly we sought to recruit 22 services (11 per arm). Randomisation of ACCHS was stratified by remoteness (based on the road distance to the nearest urban centre) [44]. Randomisation was performed by the study statistician in SAS statistical software, using coded identifiers to ensure blinded allocation.

Implementation strategy

The 24-month support model consisted of eight core components (Fig. 1) and was designed to aid routine implementation of alcohol screening and appropriate alcohol intervention. The eight components were based on continuous quality improvement methods and included:

C1. Agreements with the participating services outlining the responsibilities and rights of the ACCHS and the researchers.
C2. Two-day workshops for service champions who would be responsible for leading implementation of strategies to increase screening and alcohol care provision.
C3. On-site training of ACCHS staff – all staff were eligible including administration and clinical staff and ACCHS chose which staff members participated; training included evidence-based alcohol screening and interventions as well as strategies to improve uptake and using data to monitor improvements.
C4. Provision of bi-monthly feedback reports to help ACCHS monitor improvements.
C5. Bi-monthly teleconferences for service champions to promote exchange of experiences and ideas.
C6. Technical support for practice software modification to include AUDIT-C screening.
C7. Online resource platform.
C8. Financial support for purchase of resources to help with alcohol care ($9000).

(See also Table S1).

Delivery of components to the early-support arm services occurred in two, 12-month phases: active (components c1-c8, 31 August 2017–30 August 2018) and maintenance (c4-c8, 31 August 2018 -15 August 2019). During this time services had the freedom of determining and implementing strategies to improve alcohol screening and care provision, while the research team's role was to provide support.

Waitlist control services did not receive any support during the 24 months. They had contact with the research team only when providing data. The waitlist control arm received their support after early-support services completed their 24 months.

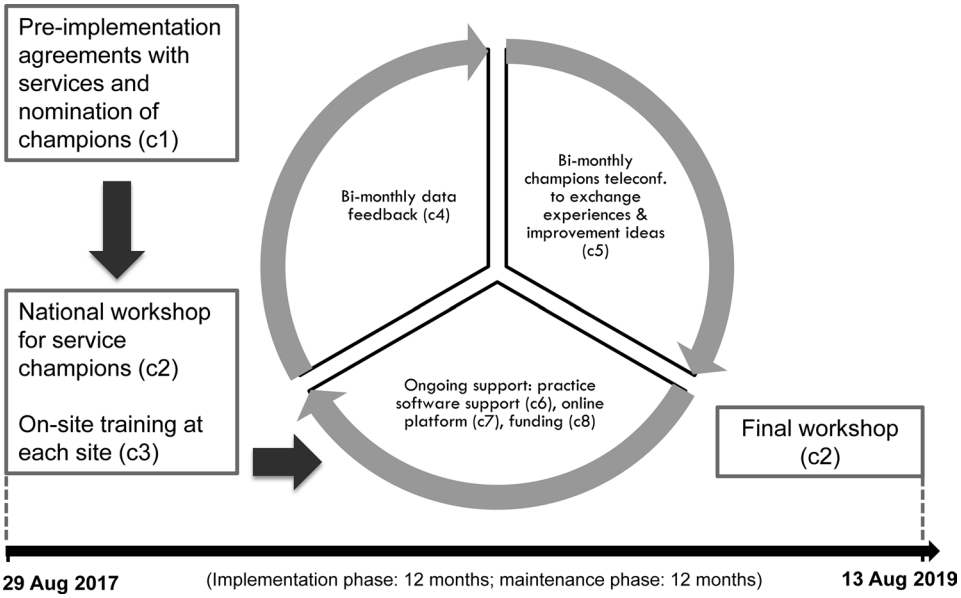

Fig. 1 Graphic summary of the support model trialled during this study c1 – c8: Eight components of the support model. Implementation is considered as commencing on 31 August 2017, when early-support arm service champions returned to their services following the workshop. Implementation ended on the last day of the final workshop on 15 August 2019. Figure first published in Dzidowska et al. 2021, https://doi.org/10.1111/add.15712 (CC BY-NC 4.0)

Outcome measures

Outcomes were measured via routinely collected clinical data recorded in the practice software, Communicare. Services provided data every 2 months. Twelve months of data retrospectively from the date of implementation was used as baseline. Clients' records were matched through client IDs. If a client attended in a two-month period, this resulted in an observation, which included age, gender, and outcome variables. Outcomes were defined as documentation of the following events in Communicare practice software within any 2-month period:

- Pharmacotherapies for relapse prevention: practice software record of prescription of naltrexone, acamprosate or disulfiram.
- Verbal alcohol intervention: practice software record of either alcohol advice, or alcohol counselling.

Communicare did not have dedicated clinical items which clearly differentiated between specific types of verbal alcohol interventions (e.g. brief intervention, counselling, psychosocial therapies). Verbal alcohol interventions could be recorded using the checkboxes for 'alcohol advice' or 'alcohol counselling'. Given the time pressures on clinicians in ACCHS, where there are competing health problems to address, it is likely that any verbal alcohol intervention recorded under either 'advice' or 'counselling' would be in line with the aims and duration of a brief intervention, which is typically 5–30 min [45]. Therefore, intervention recorded in these fields were grouped together in this report using a single outcome, 'verbal alcohol intervention'. This approach has precedent in several previous studies using practice software data, where a combination of education-style or counselling fields was used as a record for brief intervention [25, 46, 47]. Of note, it is routine in ACCHS for verbal alcohol interventions to be recorded by any clinician, including Aboriginal health workers, Aboriginal health practitioners, nurses, general practitioners, drug and alcohol workers or psychologists. This is in line with the holistic 'wrap-around' care provided by ACCHS, in which a range of health professionals are employed as part of multi-disciplinary teams.

Analysis

We tested whether the support model improved the odds of prescription of alcohol relapse prevention pharmacotherapies and of verbal alcohol intervention. We conducted the analysis using R statistical software version 4.0.2 [48]. We focused on testing the following fixed effects:

- 'trial arm' – whether a service was assigned to the early-support (trial arm = 1), or waitlist control arm (trial arm = 0).
- 'post-implementation' – whether the observation occurred after the start of the implementation of the support model on 31 August 2017 (post-implementation = 1) or before (post-implementation = 0).
- 'intervention' – effect of support model, given by the interaction between the variables trial arm and post-implementation. This interaction represents relative change in the odds for the early-support arm when compared to the waitlist control arm, post-implementation.

Since the support model was aimed at the services, and clients and their visits 'belong' to those services, the repeated observations for each client were likely to be correlated. To account for the effect of clustering in the analysis, multilevel logistic regressions were fitted using the 'lme4' package [49]. For all models, the fixed effects were: trial arm, implementation, and intervention. A range of random effects were tested including a random intercept for services, a random intercept for clients, and a random slope of post-implementation by service. Of the models that converged, the model with the lowest Bayesian information criteria (BIC) was considered best fitting [50]. This model was compared with simpler, nested models using likelihood ratio testing. If the fit of a more parsimonious model was not significantly worse than the best fitting model, then the simpler model was preferred. Confidence intervals were calculated for the fixed effects using the Wald estimation. Changes in outcome variables were estimated over time for the early-support arm (simple slope analysis) using the delta method ('car' package) [51, 52]. Adjusted intracluster correlation coefficients (ICC) were calculated using the 'performance' package [53, 54] to describe the proportion of variability explained by differences between clusters. The predicted probabilities were calculated and plotted to illustrate the fixed effects using 'ggeffects' and 'ggplot2' packages [55, 56].

Missing data

All data used in our study were extracted from practice management software. We used the date of clinical records to place records as being before or after implementation. For clinical outcomes, it is not possible to know if the lack of a clinical record is due to missing data, or due to a clinical measurement not being performed. For example, when no AUDIT-C screen result is in a clinical record, we cannot definitively determine whether this was due to AUDIT-C not being performed, or whether it was performed and not recorded. Accordingly, we must

assume that the clinical data are complete and correct. However, for demographic characteristics, we used complete-case analysis to compare trial arms at baseline.

Results

Twenty-two ACCHS recruited to the study from six Australian states and territories served 83,032 individual clients between 29 August 2016 and 15 August 2019 (Fig. 2). Each client provided an average of 5 observations over the study period. From January 2019 onwards, one service in the waitlist control arm was unable to provide data due to a change in practice software.

Table 1 shows selected descriptive characteristics of the baseline sample (52,678 clients, 142,519 observations). There were no missing demographic data. The odds of a record of pharmacotherapy prescription or a verbal alcohol intervention were negligible in both trial arms prior to implementation of support (Tables 2 and 3). Over the study period, 28,270 clients were screened with AUDIT-C. Of these, more than 42% clients in both trial arms (8411 early-support, 3884 waitlist controls) had AUDIT-C scores that suggested drinking above recommended levels (cut-off scores are AUDIT-C 4+in males and 3+in females [57]).

Verbal alcohol intervention

Over the study period, there were 945 clients with a record of provision of verbal alcohol intervention. Unadjusted rates of verbal alcohol intervention by service are shown in Fig. 3.

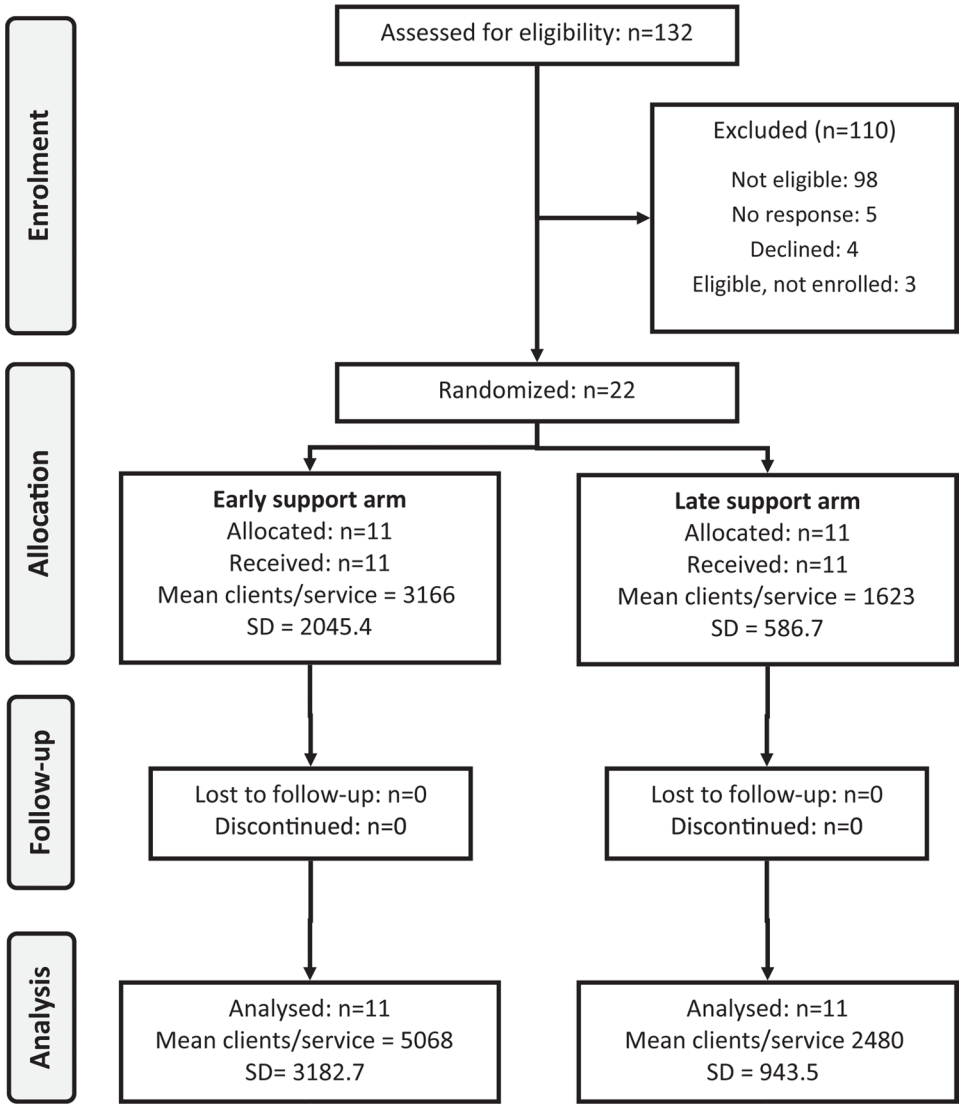

Fig. 2 Flow diagram of participating services (n = number of services) One service was unable to provide data from January 2019 to 15 August 2019 (end of early-support phase) as they stopped using Communicare to log AUDIT-C results. Duration of follow-up was 24 months. Figure first published in Dzidowska et al. 2021, https://doi.org/10.1111/add.15712 (CC BY-NC 4.0)

Table 1 Service characteristics by trial arm over the 12-month baseline period

Characteristic	Early support	Waitlist controls
Services		
$N_{services}$	11	11
Mean clients per service (SD)	3166 (2045.4)	1623 (586.7)
Remoteness		
Urban and inner regional	5	5
Outer regional and remote	2	3
Very remote	4	3
Clients		
$N_{clients}$	34,829	17,849
Mean age of clients (years) (SD)	37.4 (16.0)	37.8 (16.4)
Number of female clients (%)	19,578 (56.2)	10,009 (56.1)
Mean observations[a] per client (SD)	2.7 (1.8)	2.7 (1.7)
Clients screened with AUDIT-C (%)	5435 (15.6)	3626 (20.3)
Clients with AUDIT-C indicating UAU (%)[b]	2320 (42.7)	1522 (42.2)
Clients recorded as receiving verbal alcohol intervention (%)[c]	132 (0.6)	138 (0.9)
Clients recorded as receiving pharmacotherapies (%)[c]	84 (0.4)	35 (0.2)

The Baseline period: from 29.08.2016 to 30.08.2017 inclusive. [a]An observation appeared in the dataset for a client if they attended their service for a consultation in the preceding two-month reference period at least once. [b]UAU – unhealthy alcohol use as indicated by AUDIT-C. For Aboriginal and Torres Strait Islander populations in Australia the cut-off scores are AUDIT-C 4+in males and 3+in females; expressed as a percentage of clients with a recorded AUDIT-C screen; [c]alcohol intervention as recorded in Communicare (i.e. advice or counselling recorded using selected clinical items or pharmacotherapies prescribed), expressed as percentage of clients with UAU

Table 2 Fixed effects of the support model on the odds of receiving verbal alcohol intervention

Effect	OR [95% CI]	*p*
Intercept	0.00 [0, 0]	< 0.001
Post-implementation (post)	0.27 [0.21, 0.36]	< 0.001
Trial arm (early-support)	0.41 [0.15, 1.15]	0.89
Intervention	7.60 [5.54, 10.42]	< 0.001
Intracluster correlation coefficient (ICC)	54%	

This table presents the fixed-effects results from a multi-level logistic regression. No additional control variables were used beyond those listed in this table. Post-implementation (Post)=the effect of client visit occurring in any two-month period after implementation of the support model; Trial arm (early-support)=the effect of allocation to the early-support (treatment) arm; Intervention=the effect of client in the early-support arm having a visit in any 2-months after implementation; OR=odds ratio; CI – confidence interval

To investigate the effect of the support model on the odds of having a record of verbal alcohol intervention for unhealthy alcohol use, the model incorporating random intercepts of service and client was chosen as it had the best fit (Additional material, Table S2). The differences between services accounted for 54% of the variance in the odds of clients being recorded as receiving verbal alcohol intervention within two-month reference periods (Table 2). This indicates that just over half of variance was not generalisable across services, but attributable to unique contexts at services.

Table 3 Fixed effects of support on the odds of receiving pharmacotherapies for relapse prevention

Effect	OR [95% CI]	*p*
Intercept	0.00 [0, 0]	< 0.001
Post-implementation (Post)	0.47 [0.30, 0.75]	0.01
Trial arm (early-support)	1.04 [0.43, 2.52]	0.94
Intervention	1.61 [0.92, 2.80]	0.10
Intracluster correlation coefficient (ICC)	98%	

This table presents the fixed-effects results from a multi-level logistic regression. No additional control variables were used beyond those listed in this table. Post-implementation (Post)=the effect of client visit occurring in any two-month period after implementation of the support model; Trial arm (early-support)=the effect of allocation to the early-support (treatment) arm; Intervention=the effect of client in the early-support arm having a visit in any 2-months after implementation; OR=odds ratio; CI – confidence interval

From baseline to post-implementation, the odds of a client having a record of verbal alcohol intervention within a two-month reference period doubled for the early-support arm (simple slope OR=2.08, 95% CI=1.74, 2.49). In contrast, the odds decreased for waitlist controls (OR=0.27, [95% CI=0.21, 0.36], $p<0.001$). The relative improvement in the odds of having recorded verbal alcohol intervention following implementation was 7.6 times greater in the early-support arm than waitlist controls (OR=7.60, [95% CI=5.54, 10.42], $p<0.001$) (Table 2). Probabilities of having a recorded verbal alcohol intervention, adjusted for the effects of the support model are shown in Fig. 4.

Pharmacotherapies

Over 24 months post-implementation, 253 clients (in 479 consultations) had a record of prescription of at least one of the three pharmacotherapies for alcohol relapse prevention. Of the 22 participating services, 21 had records of prescription. Unadjusted rates of pharmacotherapy prescription by service are shown in Fig. 5.

Of the three multilevel logistic regression models that converged (Additional material, Table S3), the model incorporating the random intercepts of service and client had the best fit and was used in the analysis. Differences between services accounted for 98% of the variance in the odds of prescribing alcohol pharmacotherapies, indicating that the intervention had very little effect on prescription of pharmacotherapies. This means that prescribing of pharmacotherapy was mostly not generalisable across services, and almost entirely explained by the unique contexts at services (Table 3).

After implementation, there was no clear evidence of change in the odds of prescribing pharmacotherapies in the early-support arm (simple slope OR=0.76, 95%CI=0.56, 1.03), but there was a significant reduction in the waitlist control arm (OR=0.47, [95%CI=0.30, 0.75], $p=0.01$). There was no clear evidence of a

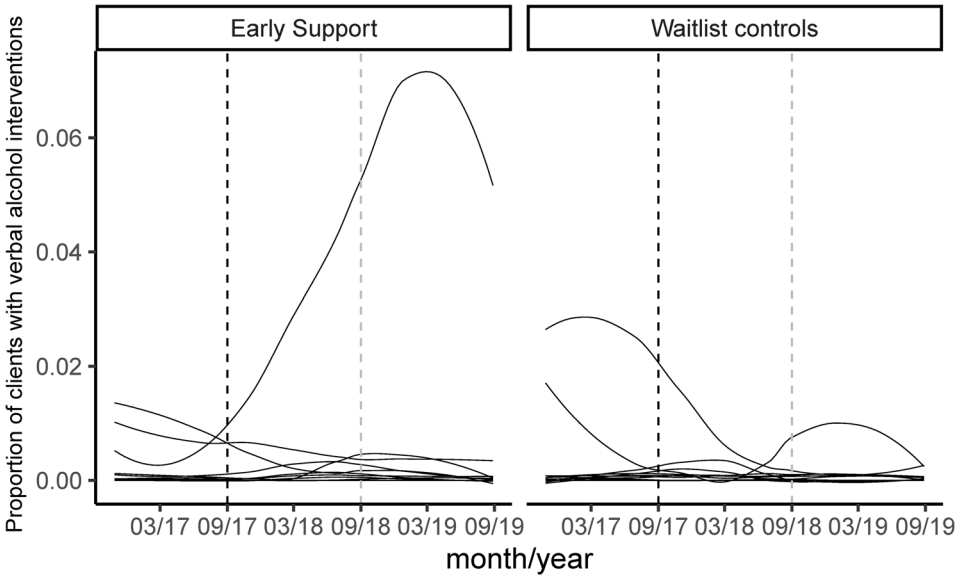

Fig. 3 Unadjusted smoothed rates of verbal alcohol intervention by service and trial arm. Rates are records of any verbal alcohol intervention for a patient per two-month reference period. Each smoothed curve represents a service in the trial arm. Black dashed vertical line denotes start of active implementation phase. Grey dashed vertical line denotes start of maintenance phase

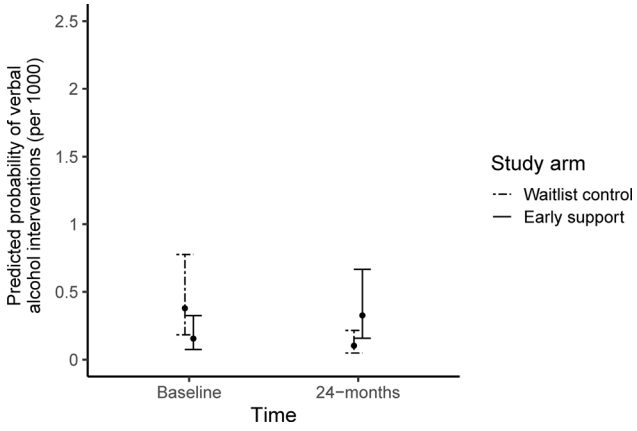

Fig. 4 Predicted probabilities of receiving verbal alcohol intervention in the early-support and waitlist control arms at baseline and during 24 months of implementation

difference in the odds of prescribing pharmacotherapy between early-support arm and controls (OR=1.61, [95%CI=0.92, 2.80], p=0.1), (Table 3). Probabilities of a client having a record of pharmacotherapy prescription in any 2-month period adjusted for the effects of the support model are shown in Fig. 6.

Discussion

In recent years there has been a call for greater implementation of interventions for unhealthy alcohol use in primary care, including prescription of relapse prevention medicines [5, 7]. This is particularly important to Australia's First Nations peoples who face many barriers in access to specialist treatment. In this cluster randomised trial, we showed that the model of support provided to 22 ACCHS was associated with a significant relative increase in the odds of a client having a record of a verbal alcohol intervention. We were unable to demonstrate a comparable effect for prescriptions of relapse prevention pharmacotherapies. However, the rates of recorded provision of verbal alcohol intervention and alcohol pharmacotherapies in this study remained low and observed increases were not clinically significant.

The study is important as it examines implementation of care for the full spectrum of unhealthy alcohol use and is the first randomised controlled alcohol care implementation trial in a First Nations Australian primary care setting. A key strength of the study is its co-design with ACCHS and state-based umbrella Aboriginal and Torres Strait Islander organisations to ensure appropriateness to suit local contexts.

Verbal alcohol interventions

Implementation of the support model increased the odds of clients in the early-support arm having a record of a verbal alcohol intervention compared to waitlist controls. This significant increase was due to: (i) an increase in the odds of verbal alcohol intervention in the early-support arm after implementation, together with (ii) a consistent reduction in the records of verbal alcohol interventions in the waitlist controls. The decrease of records in the waitlist controls was also seen for pharmacotherapies. This could indicate that the support model prevented a drop in verbal alcohol intervention in the early-support arm. It is not clear why the frequency of providing alcohol care dropped off in control services. Local policy decisions, staffing and other changes at the waitlist control services

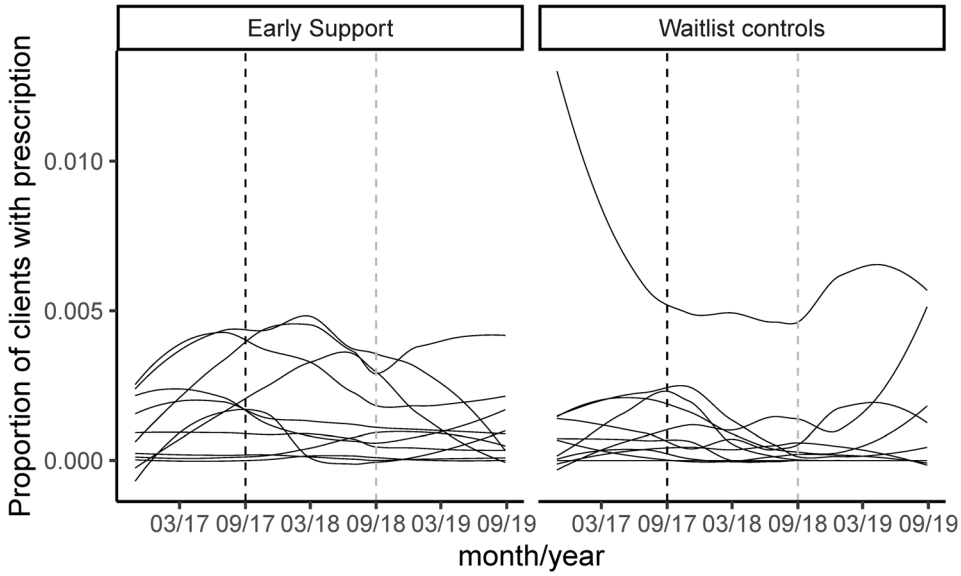

Fig. 5 Unadjusted smoothed rates of pharmacotherapies by service and trial arm. Rates are records of any pharmacotherapies for a patient per two-month reference period. Each smoothed curve represents a service in the trial arm. Black dashed vertical line denotes start of active implementation phase. Grey dashed vertical line denotes start of maintenance phase

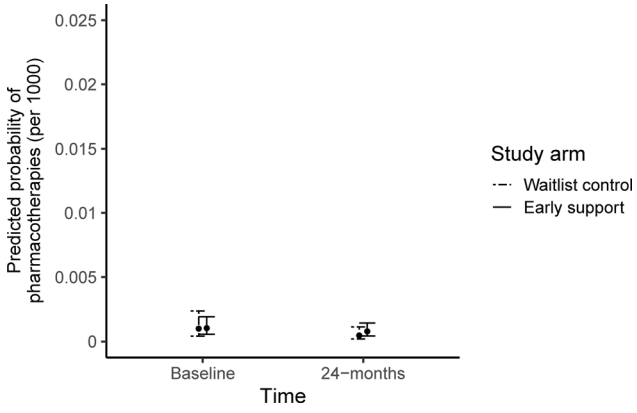

Fig. 6 Predicted probabilities of receiving pharmacotherapies in the early and waitlist control arms at baseline and during 24 months of implementation

may have contributed to this effect, though this cannot be verified as no contextual data were collected in this trial. The service recruitment process included discussions with staff and service board, which may have raised awareness of alcohol intervention options. This effect may have worn off in the face of competing priorities for individual patients and service [12] in services that were not yet receiving support.

This trial also demonstrated high variability between services with some health centres recording far more verbal alcohol interventions than others. Reasons for this could be due to a more stable workforce, or strong 'champions' within the centres with higher rates. It could also be attributable to greater recording rather than more interventions. Data to allow us to understand the differences between services were not collected but many barriers to alcohol care delivery have been documented in other studies [58, 59].

The rates of provision of verbal alcohol intervention in both early-support and waitlist control services (Figs. 3 and 4) mean that any relative increases are not clinically meaningful. Only 945 (3.3% of screened clients) had a record of receiving a verbal alcohol intervention at any time during the 24 months of follow-up (implementation and maintenance). In contrast AUDIT-C scores suggested unhealthy alcohol use in 60% of those clients who were screened. This figure demonstrates the potentially high demands on staff time, if all eligible patients were to receive a verbal alcohol intervention.

Our data relied on routine recording by clinicians. The true rate of verbal alcohol intervention provision may be higher. It is possible that clinicians recorded some verbal alcohol intervention in free-text notes, that were not able to be collected in this study. For example, alcohol use is routinely recorded as part of the annual preventive health assessment ('Health Check') which includes a free-text area for advice given. Also, alcohol advice may have been documented but not extractable in Mental Health Care Plans. This is consistent with other primary care research that shows that clinicians frequently do not code all clinical conditions in the electronic medical record [60]. Also, based on consultation with services, the data typically reflect only what is done in the primary care section of the ACCHS. Several services had separate drug and alcohol or mental health and wellbeing units or staff, which used different software to record interventions. Nonetheless, the data reflect the challenges of systematic and

accurate recording, and of implementation of verbal alcohol intervention in busy primary care settings serving populations with complex needs.

Pharmacotherapies for relapse prevention

The support offered in this study included training on the role and prescription of alcohol relapse prevention pharmacotherapies. Also, bi-monthly feedback to participating ACCHS included rates of prescription of these medicines. Despite this, there was not conclusive evidence for the effect of the support model on the rate of prescription of relapse prevention pharmacotherapies. This was due to very low baseline rates of pharmacotherapy prescription, and the very high heterogeneity among services (ICC=98%) and within services over time. From observations made over the course of this study it is possible that a single health professional may have a significant impact on the use of the pharmacotherapies at a service. For example, an individual doctor who was more confident to prescribe relapse prevention medication and more impressed by their effectiveness, could increase the prescription rate. By observation, once that doctor leaves, prescription rates may fall again.

There were very few records of prescriptions of these medicines in this sample – only 253 of the 83,000 clients (0.03% of clients) had a record of prescription at least once during the trial. Recent studies estimate the 12-month prevalence of alcohol dependence among Aboriginal and Torres Strait Islander peoples is estimated to be between 1.6% in primary care (from baseline data of the current sample) [61] and 2.2% in a representative community sample [62]. Therefore, the pharmacotherapy prescription rates observed during the support phase are likely to represent treatment for only a very small fraction of clients who could benefit from it.

The acceptability of pharmacotherapies for alcohol relapse prevention for Australia's First Nations peoples has not been formally studied, however they have been used in ACCHS [11 61], which are known for providing culturally secure care. A prior evaluation noted use of relapse prevention medications as part of the 'Healing at Home' ambulatory alcohol detox program pilot conducted in another ACCHS [13]. Our own baseline data showed pharmacotherapy prescriptions before any project support was provided [61]. Further, interviews with Aboriginal staff from 11 ACCHS at baseline of the current study, suggested that pharmacotherapies can be delivered as part of 'bicultural care' – drawing on the best of Western medicine and First Nations cultural practice [19].

Clinician barriers to prescribing pharmacotherapies in alcohol dependence have been studied and include lack of knowledge and experience in prescribing these medications, and belief that specialist addiction qualifications or experience are required to treat dependence [29, 63]. Other factors that influence GP engagement in alcohol treatment include time pressure, personal interest, access to continuing professional education, and availability of collaborative care between general practitioners and addiction specialist services [64]. The complex physical, mental health and social needs of their clients may reduce time available for focus on alcohol use disorders. Also, for some patients, severe health conditions (e.g. liver disease for naltrexone, renal disease for acamprosate) may preclude these medications.

There are no policy barriers to prescribing alcohol relapse prevention medicines in Australia. Acamprosate and naltrexone are subsidised via the Pharmaceutical Benefits Scheme, with the Close the Gap Scheme providing further discount or free access for Aboriginal and Torres Strait Islander people. Disulfiram is not subsidised by the government and may not have been affordable for many people.

The most recent Australian Alcohol Treatment Guidelines advocate treatment of alcohol dependence for Aboriginal and Torres Strait Islander peoples at the point of detection because of the barriers to accessing specialist services [11]. For First Nations Australians, the point of detection is often in an ACCHS. However, the use of pharmacotherapies does not appear to be consistently recommended in clinical guidelines specific to primary care at the time of writing. The RACGP SNAP guidelines mention the option of alcohol pharmacotherapy prescription [10]. However, two other guidelines on preventive health do not mention treatment of alcohol dependence in primary care [65, 66]). Inconsistent inclusion of alcohol pharmacotherapies in general practice clinical guidelines may reinforce a perception on the part of general practitioners that prescribing these medicines requires specialist skills.

Recommendations

ACCHS have shown great benefits to the health of First Nations Australians, enhancing preventive health and providing treatment to a population with a high chronic disease burden [8] and complex needs [20]. However, they also face challenges to service provision, including high staff turnover, inadequate electronic record systems and lack of funding continuity [59]. There is a clear need to support clinicians and services to deliver brief interventions and other verbal interventions for unhealthy alcohol use and to prescribe alcohol pharmacotherapies when clinically appropriate [11].

Clinical reminders and improved recording options

A range of health professionals working in ACCHS may deliver brief verbal interventions for alcohol, including general practitioners, Aboriginal health workers and

nursing staff. Our data did not allow us to differentiate who provided a verbal intervention. Modifications in practice software could be made to remind clinicians to consider offering and recording these options. For example, a simple prompt box could appear in response to entry of an elevated AUDIT-C score and be used to record if an alcohol brief intervention occurred. A link could be provided to clinical or patient resources. These approaches are similar to those adopted in large alcohol intervention implementation trials including PPRNet-TRIP [47, 67, 68].

At a national level, alcohol care could be 'incentivised' by including it as a funded item under the Australian Medicare Benefits Schedule (MBS). Such items have been included on the MBS for smoking cessation since July 2021, for both face-to-face and telehealth services [69].

Improving uptake of alcohol relapse prevention medicines

Only general practitioners (or, where available, suitably trained, nurse practitioners [70]) are able to prescribe alcohol relapse prevention pharmacotherapies. Anecdotally there have been efforts over many years to increase training of Australian medical students in use of these relapse prevention pharmacotherapies, and several publications provide guidance on their use for primary care practitioners [71, 72]. Clinician training resources for addiction treatment are also available in Australia. For example, RACGP has an online Alcohol and Other Drugs Education program [73]. HealthPathways are localised guidelines developed by and for primary care clinicians in collaboration with Local Health District clinicians, which provide guidance on delivery on screening, brief intervention, pharmacotherapies and referral to specialist services. Online information and referral services, as well as a 24/7 telephone drug and alcohol specialist advisory service operate in Australia, providing clinical advice to medical and allied health practitioners [74]. However, many general practitioners are not aware of existing telephone service or referral and treatment options [64].

It is evident that more work needs to be done to improve and maintain uptake of appropriate prescription of pharmacotherapies for alcohol dependence in ACCHS and in other primary care settings in Australia. Improved uptake would require a multifaceted approach. This could include raising awareness of existing support for general practitioners through specialist services, including advice on treatment of dependence, as well as developing support resources specifically for the ACCHS health staff and their clients about this treatment option. Further studies focussing on barriers and facilitators to prescribing pharmacotherapies in this setting could aid the design of future implementation strategies. The consistent inclusion of pharmacotherapies in primary care guidelines as a treatment option, and ongoing advocacy and support for treatment of alcohol dependence in primary care would also help in promoting confidence around general practice treatment of dependence.

Limitations

There are two main areas of limitations in this trial; lack of contextual information on environmental elements that may have influenced uptake of the support model over the course of the study, and limitations arising from the use of routinely collected practice data.

It is not possible to corroborate whether a clinical action was recorded correctly in the software, whether it was recorded but did not occur, or if an action occurred but was not recorded (e.g. due to stigma associated with alcohol misuse), and which clinicians were recording it. As well as human error or time constraints, an intervention may not appear in the database for other reasons. Some practices advised us that they recorded counselling provided by specific drug and alcohol or mental health teams using different software. Systematic collection of contextual data, e.g. via staff interviews, would have facilitated a clearer understanding of the findings of this study.

In relation to relapse prevention medications, baseline data from this study revealed that most prescriptions were not for a person who had been screened on that occasion with AUDIT-C [61]. This may indicate that the prescriptions were not initiated at the ACCHS but were a continuation of treatment started elsewhere (e.g., at a specialist service). We do not have data on referrals to or from specialist services, which could have confirmed this theory. Referrals are not available as coded fields but either as attachments or text entered directly, and often include personal identifiers. So, for both technical reasons and privacy concerns these were not examined. The data also did not inform us of how many offers of relapse prevention medicines were refused by clients, or if a client who accepted the prescription filled the script. A more detailed analysis of the client record, including examination of free-text notes, was not possible due to privacy concerns and resource constraints.

Conclusion

While there was a significant increase in recording of verbal alcohol interventions with 24-months of service-wide support (relative to waitlist control services), these gains were not clinically significant. Observed low rates of provision of verbal alcohol interventions could in part be due to challenges with recording these in practice software. The evidence for the support model's effect on pharmacotherapy prescription rates was inconclusive. Ongoing efforts, at multiple organisational levels, are needed to support provision of alcohol care in ACCHS, including verbal interventions and pharmacotherapies. These

findings are also likely to be relevant for other primary care services, especially those caring for populations with complex health needs, socioeconomic disadvantage, or poorer access to specialist alcohol treatment services.

Abbreviations

ACCHS	Aboriginal Community Controlled Health Services
AUDIT-C	Alcohol Use Disorders Identification Test - consumption
CI	Confidence interval
ICC	Intracluster correlation coefficient
MBS	Medical Benefits Schedule
OR	Odds ratio
RACGP	Royal Australian College of General Practitioners
SNAP	Smoking, nutrition, alcohol and physical activity

Supplementary Information

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Supplementary Material 1

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Author contributions

MD conceived and developed the study protocol, undertook the data preparation and statistical analysis, drafted paper, synthesised co-authors' comments. KL was chief investigator on the grant supporting this work; contributed to development of the manuscript, reviewed drafts of paper. JC supervised statistical analysis, reviewed analysis results and draft of paper. SW was chief investigator on the grant supporting this work; informing team on health service and policy implications of the study in Aboriginal and Torres Strait Islander settings; reviewed draft of paper. NH was chief investigator on the grant supporting this work; informing team on practical aspects of primary care delivery in Aboriginal and Torres Strait Islander settings; reviewed draft of paper. RI was chief investigator on the grant supporting this work; informing team on health services and clinical implications for the study. ensured relevance for primary care and Aboriginal Community Controlled Health Services; reviewed draft of paper. JV was informing team on practical aspects of primary care delivery in Aboriginal and Torres Strait Islander settings; reviewed draft of paper. PH was chief investigator on the grant supporting this work; informing team on practical aspects of primary care delivery; reviewed draft of paper. KC was chief investigator on the grant supporting this work; contributed to protocol and manuscript development, oversaw the scientific integrity of the study, reviewed drafts of paper. All listed authors have reviewed the manuscript and approved the submission.

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Data availability

The datasets generated and/or analysed during the current study are not publicly available due to ethics restrictions. Data can only be made available upon additional approvals from the ethics committees and consent from the 22 participating services.

Declarations

Compliance with guidelines and regulations

This project was conducted in compliance with the National Statement on Ethical Conduct in Human Research 2007 (Updated 2008), The Australian Code for the Responsible Conduct of Research 2018, and Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders 2018.

Ethics approval and consent to participate

This study has received ethics approvals from eight Australian human research ethics committees listed in the table below, which cover all 22 study sites. Informed consent for service participation was sought from each Aboriginal Community Controlled Health Service at institutional level, from authorised representatives and the board. The names of the boards cannot be revealed to preserve anonymity of the participating services. As this study used routinely collected data a waiver of individual informed consent was granted by all ethics committees: New South Wales (NSW):The Aboriginal Health & Medical Research Council of NSW Ethics Committee (1217/16). Northern Territory (NT):Central Australian Human Research Ethics Committee (CA-17-2842), Human Research Ethics Committee of Northern Territory Department of Health and Menzies School of Health Research (2017-2737). Queensland (Qld):Central Queensland Hospital and Health Service Human Research Ethics Committee (17/QCQ/9), Far North Queensland Human Research Ethics Committee (17/QCH/45-1143). South Australia (SA):The Aboriginal Health Research Ethics Committee, South Australia (04-16-694). Victoria (Vic) :St Vincent's Hospital Melbourne Human Research Ethics Committee (LRR 036/17). Western Australia:Western Australian Aboriginal Health Ethics Committee (project 779)

Competing interests

The authors have none to declare.

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