12-1-2023

At the cultural interface: A systematic review of study characteristics and cultural integrity from twenty years of randomised controlled trials with Indigenous participants

Tuguy Esgin
Edith Cowan University

Rona Macniven

Alan Crouch

Alexandra Martiniuk

10.1016/j.dialog.2023.100097
Esgin, T., Macniven, R., Crouch, A., & Martiniuk, A. (2023). At the cultural interface: A systematic review of study characteristics and cultural integrity from twenty years of randomised controlled trials with Indigenous participants. Dialogues in Health, 2, article 100097. https://doi.org/10.1016/j.dialog.2023.100097

Dialogues in Health 2 (2023) 100097

Contents lists available at ScienceDirect

Dialogues in Health

journal homepage: www.elsevier.com/locate/dialog

At the cultural interface: A systematic review of study characteristics and cultural integrity from twenty years of randomised controlled trials with Indigenous participants

Tuguy Esgin [a,b,c,*], Rona Macniven [d,e], Alan Crouch [f], Alexandra Martiniuk [g,h]

[a] Discipline of Exercise and Sport Science, Faculty of Medicine and Health Sciences, Discipline of Strategy, Innovation and Entrepreneurship, Business School, The University of Sydney, Sydney, New South Wales 2006, Australia
[b] Exercise Medicine Research Institute, Edith Cowan University, 270 Joondalup Drive, Joondalup, Western Australia 6027, Australia
[c] School of Management and Governance UNSW Business School, University of New South Wales Sydney, Kensington, New South Wales 2052, Australia
[d] School of Population Health, Faculty of Medicine and Health, University of New South Wales Sydney, Kensington, New South Wales 2052, Australia
[e] Faculty of Medicine, Health and Human Sciences, Macquarie University, Sydney, New South Wales 2019, Australia
[f] Department of Rural Health, The University of Melbourne, Ballarat Campus, Ballarat, Victoria 3350, Australia
[g] School of Health Sciences, Faculty of Medicine and Health, The University of Sydney, Sydney, New South Wales 2006, Australia
[h] Centre for Global Health Epidemiology Division, University of Toronto, Toronto, Ontario M5S 1A1, Canada

ARTICLE INFO

Keywords:
Australia
Randomised control trial
Aboriginal and Torres Strait Islander
Indigenous
Cultural appropriateness
Cultural integrity
Quality assessment

ABSTRACT

Purpose and aim: To identify and describe characteristics of Randomised Control Trial (RCT) design, implementation, and interpretation with a view tostrengtheningen the cultural integrity and scientific quality of this genre of research when used with, for and by Indigenous peoples.
Issue: RCTs are widely regarded as the 'gold standard' method for evaluating the efficacy of an intervention. However, issues of cultural acceptability and higher attrition rates among RCT participants from diverse populations, including Indigenous participants, have been reported. A better understanding of cultural acceptability and attrition rates of RCTs has the potential to impact the translation of findings into effective policies, programs and practice.
Method: A search of four electronic databases identified papers describing RCTs enrolling exclusively Australian Indigenous peoples over a 20-year period. The RCTs were assessed using: The Effective Public Health Practice Project's Quality Assessment Tool (EPHPP) and the Aboriginal & Torres Strait Islander Quality Appraisal Tool (QAT). The scores for each paper and the average scores of all papers were visualised using a Microsoft Excel™ Filled Radar Plot.
Results: Seventeen trials met the inclusion criteria. There was wide variation in the quality of the included trials as assessed by the EPHPP and almost universally poor results when assessed for cultural appropriateness and integrity by the QAT.
Conclusion: The value of the RCT research method, when applied to ultimately improve Australian Indigenous peoples' health, is diminished if issues of cultural integrity are not intrinsic to study design and execution. Our review found that it is feasible to have an RCT with both strong cultural integrity and high scientific quality. Attention to cultural integrity and community engagement, along with methodological rigour, may strengthen community ownership and contribute to more successful study adherence and potentially more effective translation of study findings into policy and practice.

Contents

* Corresponding author at: School of Management and Governance UNSW Business School, Sydney, New South Wales 2006, Australia.
E-mail address: tuguy1@gmail.com (T. Esgin).

http://dx.doi.org/10.1016/j.dialog.2023.100097
Received 27 July 2022; Received in revised form 7 December 2022; Accepted 5 January 2023
Available online 10 January 2023

1. Acknowledgement of country

The authors acknowledge the unceded lands on which this research project occurs, and we pay our respects to their ancestors and Elders both past and present. We also acknowledge our lead author's traditional unceded lands and we pay respects to his Noongar/Yamatji ancestors and Elders, past and present. We further acknowledge all Indigenous readers and their traditional lands. In addition, we recognise and reflect upon the strength and resilience of Indigenous peoples in Australia with the longest surviving cultures on earth, including that their lands were the place of age-old ceremonies, of celebration, initiation and renewal, and that the Indigenous peoples have had and continue to have a unique role in the life of these lands.

2. Research in context

Significant differences persist in the burden of disease between Australian Indigenous people and other Australians [1]. RCTs as intervention studies remain under-represented in Indigenous settings [2]. High quality, culturally safe and community controlled RCTs have the potential to inform and empower Indigenous communities to develop strategies to address preventable burden of disease.

3. Evidence before this study

Our review builds on a previous systematic review published over 20 years ago of 13 RCTs addressing Australian Indigenous peoples' health needs. The earlier review concluded that extending clinical trial research, allowing Indigenous communities to benefit from more high quality intervention studies required a sustained commitment to increasing local Aboriginal participation and community control [3].

4. Added value of this study

Our review has identified the need for greater efforts to address the differences between Western and Indigenous worldviews and the values that derive from these. It suggests embedding exploratory and interpretive qualitative approaches to inform the development of research questions and the framing of study objectives, enabling community-led intervention co-design and co-production of research.

5. Implication of all the available evidence

The findings suggest a disconnect between study rigour and community engagement – a trade-off that does not need to exist. Embedding interpretive qualitative approaches to inform the development of community-led interventions, and co-designing research may improve the cultural integrity of RCTs to improve Indigenous health.

6. Introduction

6.1. Traditional knowledge

For millennia, Australian Indigenous peoples have communicated their worldviews and histories through Lore and rituals of the Dreamtime. This Lore also provided the wisdom, through Elders, to maintain community order and promote physical, social and emotional wellbeing [4,5]. Lore has persisted to the present time, despite the dispossession, deculturation and disruption that has occurred since the earliest days of colonisation.

'Cultural Integrity' has been described as the "right of Aboriginal Peoples to maintain and develop the central and significant elements of their ancestral culture" [6] including understandings of health and wellbeing. Traditional understandings of physical, social and emotional wellbeing, framed by holistic and interconnected concepts, contrast starkly with western reductionist and individualistic beliefs [7]. The detailed attention to protocols of engaging with Indigenous peoples in all research processes enables the cultural validity of the results. Cultural integrity means that diverse Indigenous cultural knowledge is intrinsic to research design, governance, and evidence-based recommendations [8].

6.2. Randomised control trials (RCTs)

In Western epistemology, RCTs are viewed as the most objective, scientific, reliable and rigorous study design for experimental or intervention studies [9]. However, no single RCT study design has emerged as suitable for assessing all aspects of intervention effectiveness [10]. In an Indigenous context, the RCT lies well outside traditional understandings through Lore of physical, social and emotional wellbeing [5]. Since the year 2000, relatively few RCTs have been conducted in Indigenous communities in Australia [9].

The aim of this systematic review of RCTs enrolling exclusively Australian Indigenous people was to assess both methodological quality and cultural integrity of the trials. This review is positioned at the interface between distinctive Indigenous and Western worldviews.

7. Methods

7.1. Search strategy

The systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Keywords

corresponded to the PICO design, as follows: Population: Australian Indigenous people, Intervention: RCT studies; Comparing: 100% Indigenous enrolment RCT papers; Outcomes: As reflected in individual RCT studies.

Following guidance from a research librarian, four databases were searched: (Ovid MEDLINE, CINAHL, Scopus and Web of Science – Jan 1, 2000 to April 15, 2020). April 2020 was set as an endpoint date because of the COVID-19 pandemic and its impact on trial operations at a time when researchers, considered as non-essential personnel, could not enter many Indigenous communities, or collect data and thus, many trials were halted or altered. The search strategy for all databases combined: Indigenous Peoples/ or indigen* or Torres strait island* or Aborigin* and health services, Indigenous and Australia* or Australia/ or Western Australia or Queensland, New South Wales, Northern Territory, Victoria and Randomised Controlled Trials or randomised control trial* randomised clinical trial* or randomised clinical trial. The search results were exported to the reference manager software Endnote version X9 (Thomson Reuters, New York, USA).

7.2. Study selection

Titles and abstracts of the articles, or when indicated, the full text was reviewed to determine which studies met the inclusion criteria. The full article was reviewed if the paper satisfied the following criteria: enrolled Australian Indigenous people exclusively; contained a formal description of methods and results; presented a well-formulated research question from which a precise hypothesis was stated and aimed to answer the research question using an individually randomised design comparing the effects of an intervention with a concurrent control group prospectively. Exclusion criteria included: less than 100% Indigenous enrolment; conducted prior to 2000, and cluster RCTs due to their distinct design features particularly relating to cultural integrity.

7.3. Data extraction

One researcher (TE - Indigenous) carried out data extraction using predefined data fields from elements of the Effective Public Health Practice Project (EPHPP). Extraction was independently verified by co-author (AC non-Indigenous). For each article meeting the inclusion criteria the following data were collected: year and journal of publication; state(s) or territory where the trial was conducted, whether the trial enrolled individuals from single-centre/community or multicentre/community, type of funding; study size as (total number of participants across the study); randomisation method; use and degree of blinding; outcome reporting; description of primary and/or secondary outcome measures; power calculation and its basis; description of adverse events; description of follow-up and loss to follow-up, and intention-to-treat analysis.

7.4. EPHPP and QAT quality appraisal tools

The appropriateness of the EPHPP instrument, described by Beserra et al. [11] as consisting of six assessment criteria with each rated as “strong”, “moderate”, or “weak”, for assessing studies included in systematic reviews, has been well established [12]. Both independent reviewers assessed the quality of each paper using the EPHPP. Each study received an overall assessment of strong, moderate, or weak quality. Differences, where they occurred, in initial scores assigned by each author were discussed until consensus was reached.

The Aboriginal and Torres Strait Islander Quality Appraisal Tool (QAT) [13] was used to assess the cultural integrity of the research conception, design, implementation and interpretation from the perspective of Indigenous peoples. The QAT provides a measure of the degree to which cultural contexts and perspectives have informed the conduct of research. Its use addresses potential harm associated with the conduct of research and aims to improve the quality and transparency of research when engaging in the community [13]. This tool is intended to be used in parallel with other assessment instruments (such as EPHPP). Two authors (TE and RM; Noongar/Yamatji Aboriginal (Indigenous) and non-Indigenous respectively) completed the appraisal, and where there were differences, further discussion resulting in consensus was undertaken. While there is another related tool – called the CONSIDER Statement (CONSolIDated critERtia for strengthening the reporting of health research involving Indigenous Peoples), we chose to use the QAT as it was designed to assist with assessing the quality of a study from an Indigenous perspective, after its completion, whereas the CONSIDER statement guides the authors themselves when reporting their study findings.

7.5. Risk of bias

The AMSTAR 2 Risk of Bias for Systematic Review tool [14] was applied by the authors to the review process. In this context, two questions in the tool were deemed to be not applicable due to their focus on evidence synthesis or meta-analysis, as the systematic review focus was on quality of design and implementation.

7.6. Data visualisation

Data visualisation techniques, including the Microsoft Excel™ Filled Radar Plot, illustrate comparisons of multiple items against multiple criteria

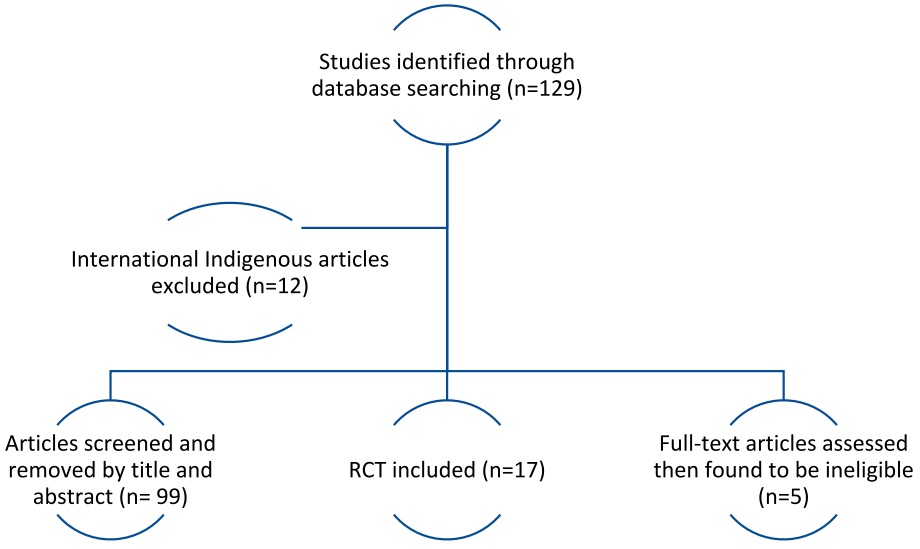

Fig. 1. Selection of studies. Abbreviations: RCT Randomised Control Trial.

Table 1
List of included studies.

Study number, author and year, location	Paper title	Aim/Objective	Population and inclusion criteria	Results	Participant withdrawal from the RCT
1 Borg et al., [2] Vic	Communication-based interventions for increasing influenza vaccination rates among Aboriginal children: A randomised controlled trial	Evaluate whether sending a letter or sending a pamphlet directly to parents/guardians would improve influenza vaccine uptake among Aboriginal identified children.	Parents or guardians of Aboriginal children in Vic (aged 6 months to <5 years). Households (n = 5534) were randomised to receive either a personalised letter (n = 1845), a pamphlet (n = 1845), or no direct communication (control) (n = 1844).	The control group's vaccination rate was 4.4%, higher than in previous years. The pamphlet group achieved a similar vaccination rate (4.5%). The letter group's vaccination rate of 5.9% was significantly higher than the control group [v2 (1, n = 3689) = 4.33, p = 0.037].	Not applicable. Parents/guardians of all eligible children were enlisted through mail out methods in this trial. While the denominator is known for each arm, actual response to the interventions / no intervention is reflected in the reported respective vaccine coverage levels achieved post intervention. This outcome measure required an 'opt in' response from the intervention recipients.
2 Canuto et al., [3] SA	A pragmatic randomised trial of a 12-week exercise and nutrition program for Aboriginal and Torres Strait Islander women: clinical results immediate post and 3 months follow-up	Evaluate the effectiveness of a 12-week structured exercise and nutrition program	Sedentary Aboriginal and Torres Strait Islander Women in Adelaide SA with a waist circumference greater that 80 cm (n = 100).	A statistically significant change in blood pressure, weight and BMI from baseline (T1), 3 months (T2) and six months (T3).A t T2, −1.65 kg and −0.66 kg/m2 and at T3, −2.50 kg and −1.03 kg/m2, respectively. Systolic and diastolic blood pressure also had a statistically significant difference from baseline in the active group compared to the waitlisted group at T2, −1.24 mmHg, p = 0.674 and −2.46 mmHg and at T3, −4.09 mmHg and −2.17 mmHg, respectively.	Reported as 'significant loss to follow-up' without quantitative detail.
3 Couzos et al., [4] WA	Effectiveness of ototopical antibiotics for chronic suppurative otitis media in Aboriginal children: a community-based, multicentre, double-blind, randomised controlled trial	To compare the effectiveness of topical antibiotics ciprofloxacin (0.3%; CIP) with framycetin (0.5%), gramicidin, dexamethasone (FGD) eardrops (5 drops twice daily for 9 days) together with povidone-iodine (0.5%) ear cleaning as treatments for chronic suppurative otitis media (CSOM) in Aboriginal children	147 Aboriginal children with chronic suppurative otitis media in WA and Qld	111 children (CIP, 55; FGD, 56) completed treatment. CSOM cures occurred in 64% (CIP, 76.4%; FGD, 51.8%), with a significantly higher rate in the ciprofloxacin group (P = 0.009, absolute difference of 24.6% [95% CI, 15.8%–33.4%]). TM perforation size and the level of hearing impairment did not change.	18 were lost to follow-up (CIP, 10; FGD, 8), 8 had incomplete follow-up (CIP, 3; FGD, 5), nine withdrew for reasons unrelated to the study, mainly because of families leaving (CIP, 6; FGD, 3), and one (CIP) withdrew as otorrhoea cleared up before the scheduled assessment.
4 Eades et al., [5] QLD WA	An intensive smoking intervention for pregnant Aboriginal and Torres Strait Islander women: a randomised controlled trial	To determine the effectiveness of an intensive quit-smoking intervention on smoking rates at 36 weeks' gestation among pregnant Aboriginal and Torres Strait Islander women.	Participants in the intervention group (n = 148) and usual care group (n = 115) were similar in baseline characteristics, except that more women had recently quit smoking in the intervention group than the control group.	At 36 weeks, there was no significant difference between smoking rates in the intervention group (89%) and the usual care group (95%) (risk ratio for smoking in the intervention group relative to the usual care group, 0.93 [95% CI, 0.86–1.08]; P = 0.212). Smoking rates in the two groups remained similar when baseline recent quitters were excluded from the analysis.	High turnover of staff resulted in high loss of follow up in participants. Usual care group (n = 115) and lost to follow-up (n = 37). Intervention group (n = 148) and lost to follow-up (n = 50)
5 Hoy et al., [6] NT	A randomised controlled trial of potential for pharmacologic prevention of new-onset albuminuria, hypertension and diabetes in a remote Aboriginal Australian community, 2008–2013	Conducted a double-blind randomised controlled trial in a remote-living Australian Aboriginal group at high risk for chronic disease to assess whether pharmacological treatment with angiotensin converting enzyme inhibitor (ACEi) could delay the onset of albuminuria, hypertension or diabetes in people currently free of those conditions.	Aboriginal adults on Tiwi Island NT (n = 125)	Angiotensin Converting Enzyme (ACEi) probably delays the development of albuminuria, diabetes and hypertension in females and of non-albumin creatinine ratio events overall. There was no benefit of ACEi in males, but a probable benefit on diabetes/ hypertension events. There was a probable reduction of diabetes (zero *vs* 4 events, p = 0.068 and of diabetes or hypertension (zero *vs* 5 events, p = 0.037).	High withdrawal rate of 47%, which was higher than the estimate of 25% used in power calculations.

6 Jamieson et al., [7] SA	Dental Disease Outcomes Following a 2-Year Oral Health Promotion Program for Australian Aboriginal Children and Their Families: A 2-Arm Parallel, Single-blind, Randomised Controlled Trial	To worked with Aboriginal Australian communities to develop a multifaceted oral health promotion initiative to reduce children's experience of dental disease at age 2 years	Women in SA Aboriginal communities (n = 448) to develop a multifaceted oral health promotion initiative to reduce dental disease	Mean decayed teeth at age two years was 0.62 (95% CI 0.59 to 0.65) for the intervention group and 0.89 (95% CI 0.85 to 0.92) for the control group (mean difference −0.27 (95% CI −0.31, −0.22)).	Loss to follow up – 2 years Intervention 59 (26.5%) Control 53 (23.6%)
7 Ju et al., [8] WA	Efficacy of an oral health literacy intervention among Indigenous Australian adults	To determine the effect of an oral health literacy intervention on oral health literacy-related outcomes among rural-dwelling Indigenous Australian adults	Rural-dwelling Indigenous Australian adults (n = 400) in SA.	The intervention successfully improved dental-related knowledge, specifically regarding sugar-sweetened beverages (cordial) and the importance of fluoride in drinking water. It partially succeeded in improving oral health literacy and oral health literacy-related outcomes (mean change = 1.3, 95% CI: 1.1, 1.6)	Loss to follow-up Intervention 51 (25%) Control 55 (28%)
8 Kapellas et al., [9] NT	Effects of full-mouth scaling on the periodontal health of Indigenous Australians: a randomised controlled trial	The objective of this randomised controlled trial was to evaluate oral health effects of single visit, non-surgical periodontal therapy compared to no treatment	Indigenous adult participants (n = 273) from the NT.	Periodontal therapy produced improvements in shallow periodontal pockets and measures of gingival bleeding. PD ≥4 mm (mean difference −2.86, [95% CI -5.01 to 0.71], p = 0.009) and gingival bleeding (mean difference 0.25, [95% CI -0.43 to –0.08], p = 0.005) but not deeper pockets Pocket Depth ≥ 5 mm (mean difference −0.48, [95% CI -1.78 to 0.82], p = 0.468) or plaque scores.	After one year of recruitment, almost 40% of the initial sample was lost to follow-up. Comparisons between those who completed and those that were lost to follow-up revealed significantly more males completed both appointments (p = 0.020)
9 Kapellas et al., [10] NT	Effect of Periodontal Therapy on Arterial Structure and Function Among Aboriginal Australians A Randomised, Controlled Trial	To determine the effect of a periodontal intervention on the progression of carotid intima-media thickness (IMT)	Adult Aboriginal Australians (n = 273) in the NT.	Periodontal therapy reduced subclinical arterial thickness, but not function, suggesting periodontal disease and atherosclerosis are significantly associated. Intima-media thickness decreased significantly. The difference in intima-media thickness change between treatment groups was statistically significant (−0.026 [95% CI, −0.048 to −0.003] mm; P = 0.03).	Fifty-one people in the treatment and 53 in the control group were not assessed at the 3-month time point, and 49 and 56 in the treatment and control groups, respectively, were lost to follow-up at the 12-month time point. Reasons for lost to follow up were not stated.
10 Leach et al., [11] NT	Topical Ciprofloxin *Versus* Topical Framycetin-Gramicidin-Dexamethasone in Australian Aboriginal Children with Recently Treated Chronic Suppurative Otitis Media	The aim of the study was to assess the effectiveness and safety of topical CIP drops compared with topical framycetin-gramicidin-dexamethasone (FGD) in children who have recently failed to respond to recommended treatment with topical FGD	Children aged from 1 to 16 years of age from three remote Aboriginal communities with chronic suppurative otitis media in the NT (n = 97, n = 50 topical ciprofloxacin; control n = 47 topical framycetin-gramicidin-dexamethasome).	The study showed a similarly low rate of improvement or cure for both topical therapies. Ear discharge failed to resolve at the end of therapy in 70% of children regardless of allocation risk difference −2%; (95% CI: −20 to 16).	A relatively large proportion of the randomised children were lost to follow-up (24%) or had missing clinical data (56%)
11 Marley et al., [12,13] WA	The Be Our Ally Beat Smoking (BOABS) study, a randomised controlled trial of an intensive smoking cessation intervention in a remote aboriginal Australian health care setting	This paper describes the outcome of a study that aimed to test the efficacy of a locally-tailored, intensive, multidimensional smoking cessation program.	Patients at two ACCHS in remote WA towns of Derby and Kununurra (n = 163, intervention n = 55)	Overall participants reported that clinic staff provided advice on risks of smoking (75%), recommended quitting smoking (71%), recommended medication to assist with quitting (54%), discussed passive smoking (61%), provided practical advice on quitting (50%), provided written advice on quitting (46%), arranged for a follow-up appointment (46%), and set a quit date (32%). There was no difference between groups. Participants were predominantly offered NRT Patches (39%) or varenicline (14%).	Loss to follow-up Allocated to usual care = 20 Allocated to intervention = 11

(continued on next page)

Table 1 (*continued*)

Study number, author and year, location	Paper title	Aim/Objective	Population and inclusion criteria	Results	Participant withdrawal from the RCT
12 McHugh et al., [14] NT	Birth outcomes in Aboriginal mother–infant pairs from the Northern Territory, Australia, who received 23-valent polysaccharide pneumococcal vaccination during pregnancy, 2006–2011: The PneuMum randomised controlled trial.	We report adverse birth events as secondary outcomes from the 'PneuMum' randomised controlled trial of 23-valent pneumococcal polysaccharide vaccination (23vPPV) in pregnancy (August 2006–January 2011)	NT Aboriginal mother-infants pairs were recruited from urban and remote communities (n = 227; intervention n = 75) aged 17–39 years.	225 participants (75 vaccinated, 150 unvaccinated with excellent participant compliance and retention rate for antenatal care in 1st trimester (97%) there was a numerically higher rate of preterm births among women who received 23vPPV in pregnancy compared to unvaccinated pregnant women. Risk differences in adverse birth outcomes between 23vPPV vaccinated and unvaccinated pregnant women were; preterm birth 9% *vs* 4% (HR 2.79; 95% CI 0.94–8.32) P = 0.07; LBW 9% *vs* 5% (HR 2.09; 95% CI 0.76–5.78) P = 0.15; and SGA 15% *vs* 17% (HR 1.02; 95% CI 0.50–2.06) P = 0.96.	There were 11 withdrawals from baseline of 75 participants in the original study. 22 occurred during the antenatal period and nine during the postnatal period from birth until infant age seven months. Therefore, for the purposes of the research, there were two withdrawals by the time the observation period ceased at the birth of the infant. Following the two antenatal withdrawals.
13 Nagel et al., [15] NT	Approach to treatment of mental illness and substance dependence in remote Indigenous communities: Results of a mixed-methods study	To develop and evaluate a culturally adapted brief intervention for Indigenous people with chronic mental illness.	The study was undertaken in three remote island communities in the Top End of the Northern Territory (NT) (n = 49; intervention n = 24) with chronic mental illness in NT.	Random effects regression analyses showed a significant advantage for the treatment condition in terms of wellbeing with changes in the health of the nation outcome scales (P < 0.001) and Kessler 10 (P = 0.001), which were sustained over time. There was also a significant advantage for treatment for alcohol dependence (P = 0.05), with response also evident in cannabis dependence (P = 0.064) and with changes in substance dependence sustained over time	Three patients formally withdrew consent, and two died from suicide during the 18 months. Between one and five patients were not able to be located at any given follow-up assessment point. Thirty-five (71%) participants were followed up at the final assessment point 18 months later
14 Phillips et al., [16] NT	Can mobile phone multimedia messages and text messages improve clinic attendance for Aboriginal children with chronic otitis media? A randomised controlled trial	Does phone multimedia messages (MMS) to families of Indigenous children with tympanic membrane perforation (TMP): (i) increase clinic attendance; (ii) improve ear health; and (iii) provide a culturally appropriate method of health promotion?	Aboriginal children 13 years or under in the NT (NT = 53; intervention N = 30)	There was no significant difference in clinic attendance, with 1.3 clinic visits per child in both groups (mean difference −0.1; 95% confidence interval (CI) −1.1, 0.9; P = 0.9). Secondary outcomes: (i) there was no significant change in healed perforation (risk difference 6%; 95% CI −10, 20; P = 0.6), middle ear discharge (risk difference −1%; 95% CI −30, 30; P = 1.0) or perforation size (mean difference 3%; 95% CI −11, 17; P = 0.7) between the groups; (ii) 84% (95% CI 60, 90) in the control and 70% (95% CI 50, 80) in the intervention group were happy to receive MMS health messages in the future.	Loss to follow-up Intervention 0 (0%) (intention-to-treat analysis) Intervention 2 (7%) (treatment received analysis) Control 4 (17%)
15 Ritchie et al., [18] NT	Efficacy of Lactobacillus GG in Aboriginal children with acute diarrhoeal disease: A Randomised Clinical Trial	To assess the efficacy of probiotics in Australian Aboriginal children in the Northern Territory admitted to hospital with diarrhoeal disease.	Aboriginal children (ages 4 months–2 years), admitted to hospital with acute diarrhoeal disease (n = 70, probiotic n = 38, control n = 32)	Both groups showed a mean improvement in the sucrose breath test after 4 days; however, there was no difference (mean, 95% confidence interval) between probiotic (2.9 [cumulative percentage of the dose recovered at 90 min]; 1.7–4.2) and placebo (3.7; 2.3–5.2) groups. Probiotics did not change the duration of diarrhoea, total diarrhoea stools, or diarrhoea score compared with placebo. There was a significant (P < 0.05) difference in diarrhoea frequency on day 2 between probiotics (3.3 [loose stools]; 2.5–4.3) and placebo (4.7; 3.8–5.7) groups	Allocation arm Parental withdrawal n = 1, Probiotic arm Discharged before intervention n = 4, Parental withdrawal n = 1,

16 Smithers et al., [19] SA	Diet and anthropometry at 2 years of age following an oral health promotion programme for Australian Aboriginal children and their carers: a randomised controlled trial	The study aimed to reduced Aboriginal children's intake of sugars from discretionary foods at 2 years of age.	Participants were women residing in SA who were pregnant or had given birth to an Aboriginal child in the previous 6 weeks.	Intention-to-treat analyses showed that the %EI of sugars in discretionary foods was 1·6% lower in the treatment group compared with the control (95% CI −3·4, 0·2).	Reported one withdrawal but didn't offer any explanation as to why	
17 Stephen et al., [20] NT	Impact of swimming on chronic suppurative otitis media in Aboriginal children: a randomised controlled trial	To measure the impact of 4 weeks of daily swimming on rates of ear discharge among Aboriginal children with a tympanic membrane perforation (TMP) and on the microbiology of the nasopharynx and middle ear	To measure the impact of 4 weeks of daily swimming on rates of ear discharge among Aboriginal children (n = 89; intervention N = 41) with a tympanic membrane perforation (TMP) and on the microbiology of the nasopharynx and middle ear conducted in two remote Northern Territory Aboriginal communities	Of 89 children randomly assigned to the swimming or non-swimming groups, 58 (26/41 swimmers and 32/48 non-swimmers) had ear discharge at baseline. After 4 weeks, 24 of 41 swimmers had ear discharge compared with 32 of 48 non-swimmers (risk difference, −8% (95% CI, −28% to 12%).	Intervention group: 5 lost to follow up. Control (non-swimming) group: 2 lost to follow up.	

NT- Northern Territory, SA -South Australia, TSI – Torres Strait Islands, QLD – Queensland, WA – Western Australia, VIC - Victoria.

and are used across a range of disciplines [15]. For this review, intrinsic limitations in the use of Radar Plot techniques [16] were addressed by assigning the same values for upper, intermediate and lower levels respectively for each of the EPHPP and QAT assessment framework variables. For the EPHPP variables, these were: 1 - Weak; 4 -Moderate, and 10 - Strong. For the QAT variables, these were: 1 -No; 2 - Unclear; 4 - Partial, and 10 - Yes. In each case, these values were assigned to notionally reflect levels of researcher effort and organisation, and therefore to highlight the distinction, between lowest to highest assessment levels. The scores for each reviewed paper and the average scores of all papers were visualised for comparison using the Radar Plot.

8. Results

A total of 126 titles and abstracts were identified through the database searches between the years of 2000 to 2020. Seventeen papers were finally included in this systematic review. The PRISMA flow chart is shown in Fig. 1 (see Table 1).

8.1. Study characteristics

The 17 RCTs reviewed in this paper were published between 2000 and 2020 (inclusive). The RCTs were conducted in most Australian states and territories; three studies recruited participants across various states/territories. The mean sample size for 17 of the studies was 283; although for one study, the sample size was 2431 participants. Most of the RCTs were multicentre studies (n = 12; 57.1%). Of these 12 RCT multicentre studies, the focus of the intervention included:

- Ear health (n = 4) [16,18,19];
- Smoking (n = 2) [18];
- Oral Health (n = 5) [19,20] and;
- Vaccination (n = 1) [21].

Most of the papers were rated by the study team using the EPHPP as providing evidence in the moderate to the strong range. Across the papers study design rated strongly; selection bias, confounders and data collection rated moderately, and blinding rated weaker. Research reports were typically weakened by inadequate information about randomisation, double-blinding and power calculations. Fig. 2, a visualisation of the degree of compliance of studies to the EPHPP assessment fields, indicates areas of relative strengths and weaknesses. In addition to the EPHPP criteria for scientific rigour (Fig. 2), this study also investigated reporting on cultural integrity of studies using the QAT instrument (Fig. 3). All studies rated poorly across all domains.

Most of the articles reported research funding (n = 14; 82%), predominately from Australian National Health and Medical Research Council grants. Three studies (18%) did not state the source of research funding. Shorter-term funding sources, undermining the investment of time and effort to strengthen community control and ownership of RCT conception, design, implementation and interpretation, is a further constraint to fulfilling both methodological quality and cultural integrity [18].

As shown in Table 2, according to the EPHPP quality assessment tool, eleven studies (65%) were assessed as strong, four as moderate (24%), and three (12%) as weak (Fig. 2). In addition to the EPHPP criteria, this systematic review also assessed whether RCTs reported a power calculation, with most of the papers (n = 16, 94%) reporting this parameter. Of these, all (100%) reported this calculation based on the primary outcome [22].

The QAT assessment of the included studies indicated that the studies were poor in culturally integrity design with most recording a 'no' or 'unclear' response as show in Table 3. Table 4 describes the ten studies (59%) that reported single blinding of assessor(s) and 5 reported double-blinding of both assessor(s) and participants. Two (12%) were unblinded.

Participant withdrawal was an issue for some studies (Table 5). Two studies stated that the reason for withdrawal was 'unrelated to the study'. One study with a higher withdrawal rate wrote that this was likely due to

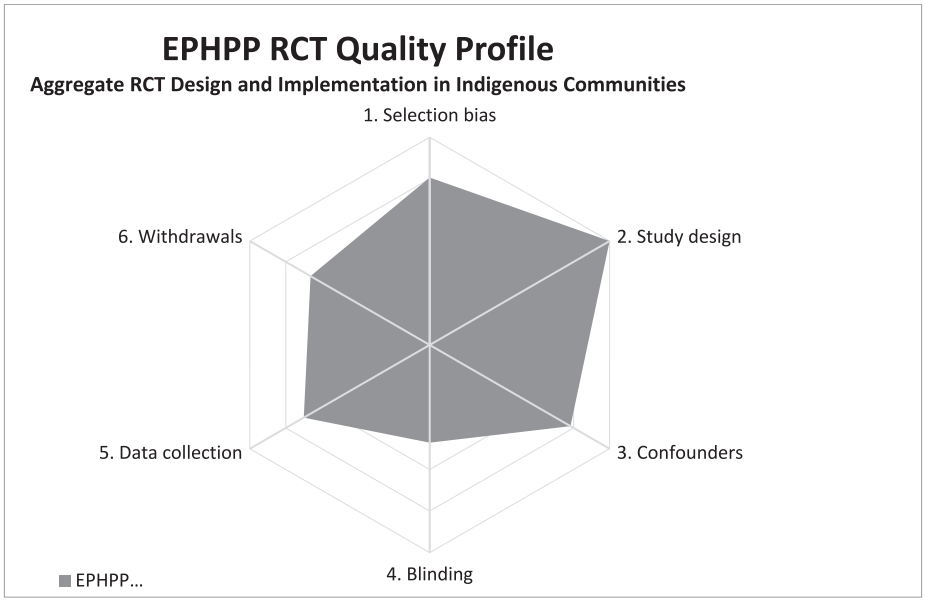

Fig. 2. EPHPP RCT Quality Profile.

high staff turnover, with usual care group (32%) and intervention group (33%) lost to follow up.

9. Discussion

This systematic review analysed the research quality and cultural integrity of RCTs enrolling Australian Indigenous people exclusively. The review noted almost universally poor performance of RCTs when assessed for cultural integrity through the QAT [23].

An earlier systematic review [3] summarising RCTs addressing Australian Indigenous People's health, identified 13 papers, published between 1976 and 1996. The low numbers of RCTs in the current review published subsequently that met inclusion criteria may be attributed to several factors. These include the application of highly resourced, tightly controlled research conditions and the transition into Indigenous communities; [24] the perception that seeking medical solutions for problems related to socio-economic disadvantage is a waste of resources [3]; the need for operational changes within health centres to deliver RCT interventions; and unrealistic timeframes for completing the research where true engagement is embedded [18]. Other cultural factors may also influence the lower frequency of RCTs enrolling Indigenous people or addressing unique Indigenous community needs. Specifically, in the context of acute, life-extending interventions, the significance of living on country during the end-of-life period over seeking medical attention off country may be critical [24].

Discrepancies between the protocol description of blinding status and the actual blinding achieved in the RCT as implemented were present in the majority of registered protocols and published manuscripts as reported in a 2020 systematic review of RCTs [25]. Two studies stated that they were designed as ‘a pragmatic trial’ and that this reflected real-world practice [20,26]. These findings suggest that determining culturally relevant

Fig. 3. QAT RCT Cultural Integrity Profile.

Table 2
EPHPP Quality assessment of studies included in review.

Author/s	Year	Selection bias	Study design	Confounders	Blinding	Data collection	Withdrawals	Global score
Borg et al	2018	Strong	Strong	Strong	Strong	Strong	N/A	Strong
Canuto et al	2012	Moderate	Strong	Strong	Weak	Strong	Weak	Weak
Couzos et al	2003	Strong	Strong	Strong	Strong	Strong	Strong	Strong
Eades et al	2012	Strong	Strong	Strong	Weak	Strong	Strong	Moderate
Hoy et al	2019	Moderate	Strong	Moderate	Strong	Strong	Strong	Strong
Jamieson et al	2018	Strong	Strong	Strong	Weak	Moderate	Moderate	Moderate
Ju et al	2017	Strong	Strong	Strong	Weak	Moderate	Moderate	Moderate
Kapellas et al	2013	Strong	Strong	Moderate	Strong	Strong	Strong	Strong
Kapellas et al	2014	Moderate	Strong	Strong	Weak	Moderate	Weak	Weak
Kiran et al	2010	Strong	Strong	Moderate	Weak	Moderate	Weak	Moderate
Leach et al	2008	Strong	Strong	Strong	Moderate	Weak	Moderate	Moderate
Marley et al	2014	Moderate	Strong	Moderate	Weak	Moderate	Strong	Moderate
McHugh et al	2020	Strong	Strong	Strong	Moderate	Moderate	Strong	Strong
Nagel et al	2009	Strong	Strong	Strong	Strong	Moderate	Strong	Strong
Phillips et al	2014	Weak	Strong	Moderate	Weak	Strong	Weak	Weak
Ritchie et al	2010	Strong	Strong	Strong	Strong	Strong	Strong	Strong
Smithers et al	2017	Strong	Strong	Moderate	Moderate	Strong	Strong	Strong
Stephen et al	2013	Strong	Strong	Strong	Strong	Strong	Strong	Strong

N/A – Borg. Participant withdrawal was impossible; it was excluded as an assessment criterion.

strategies for blinding should be negotiated at the conceptualisation and development stage. Several studies included in our review have noted the need to improve cultural integrity, methodologic quality and reporting of RCTs in Indigenous communities [2,27]. There were no obvious links between any of the fields of the QAT and the attrition rates reported in the studies While several of the 17 reviewed papers identified the need for community engagement and the involvement of the community at every stage, few reported on how this was conducted and how the findings from this engagement and consultation impacted study design and implementation. Loss to follow up is a concern of any study; with differential loss by study arm an important concern. Greater than 20% loss poses serious validity threats to a study [28]. Loss to follow up may indicate higher mobility of participants [19], cultural community responsibilities taking priority [29], and/or high turnover of staff within organisations. Nine of the 17 reviewed papers reported this detail (Table 5). Of these, four of the studies reported >20% loss to follow up [19,29,30].

Two of the studies embedded formal qualitative research methodologies on community engagement within the RCT [31,32]. Other studies identified in this systematic review have suggested further means by which RCTs can meet the cultural needs of communities to improve health outcomes, including: community ownership; including Aboriginal ways of knowing, being and doing [33]; community-embedded skill-building interventions; alignment with and adaptation to cultural perspectives, and; robust community partnerships and engagement strategies for the framing of study recommendations [19,20,29,31]. Those papers that discussed community engagement reported on similar themes: sharing stories and traditional health practices [34]; collaborating with community and employing community members [29]; deep and sustained involvement of community [19]; ensuring a culturally safe and non-judgmental approach [20], and the social determinants of health [29]. Approximately 34% [35] of the overall burden of disease in Aboriginal communities has been attributed to the social determinants of health. These social factors (education, employment, housing, transport, financial and food security) represents an direct link with health [36], and community development and highlight structural injustices and inequity experiences in Aboriginal community settings. There have been reports in the generic RCT design literature of the utility of embedding exploratory and interpretive qualitative approaches and community-led intervention co-design strategies [38] into RCT study development, implementation and interpretation. These studies have suggested that the use of participative methodologies in the framing of RCT research objectives and in structuring community leadership in the decision-making processes including intervention design have the potential to strengthen the study quality and the applicability of findings.

It has been suggested that RCTs may not be acceptable to Indigenous communities, unless longstanding relationships have been developed between researchers and the community. RCTs with improved study design may be appropriate in some contexts, given that there may have been (and continue to be) significant missed opportunities to assess the effectiveness of innovations in prevention, diagnosis and treatment in Indigenous community settings [3].

An inverse relationship between RCT 'scientific rigour' and 'cultural integrity' was observed in our review (Tables 2 and 3). This may imply that power structures in the development and implementation of RCTs have historically mitigated against community control of the research process. This may reflect a lack of experience, expertise, connection, knowledge between both researchers with RCT skills, and Indigenous communities as well as perhaps few Indigenous researchers with RCT expertise themselves.

This current analysis found that the reporting in included RCT studies of conception, design and implementation elements reflecting cultural appropriateness and cultural integrity was poor (see Fig. 3). One study highlighted three limitations of intervention studies which are of particular relevance to ensuring cultural appropriateness and integrity for Indigenous people [31]. These limitations include: the validity of the instrument that obtained the baseline and/or outcome measures; the statistical power of the study and the likelihood of measurement biases such as observer bias.

The drivers for effective interventions ought to be the expressed needs of Indigenous community members and not only the expert opinions of health or other professionals [24]. Collectively, our review of recent RCTs enrolling Indigenous people in Australia highlights the need for greater effort in ensuring strong cultural integrity along with strong scientific quality in RCTs – and these need not be mutually exclusive. Researchers embarking on research with Indigenous people can be guided by the QAT [13] when designing and planning their study, along with the CONSIDER statement [40] when writing up their work.

Research enrolling, about, and ultimately for, Indigenous people should start and end with a community leadership, co-design and co-production approach that addresses issues of values, control, ownership and equity in the research enterprise. What is measured, and how, who benefits, and when – and capacity development and relationships matter along the way. Funding bodies and policies must enable the time required to cultivate and deliver research that is upheld to the highest standards of scientific quality and cultural integrity. Shorter-term funding sources (<5 years), undermining the investment of time and effort to strengthen community control and ownership of RCT conception, design, implementation and interpretation, is a further constraint to fulfilling both methodological quality and cultural integrity [18].

The low levels of reporting in the reviewed RCT papers of the mechanisms and degree of inclusion of Indigenous communities in the determination of effective health interventions suggests, for whatever reason, a lack of priority for community co-design and co-production of studies by research

Table 3
Cultural Integrity assessment of studies included in review.

Study	Need and Priority	Consultation and Engagement	Leadership	Governance	Protocols	IP & Cultural property protection	IP & cultural property ownership	Management	Indigenous research paradigm	Strength based approach	Findings into policy and practice	Benefit to communities	Capacity Strengthening	Collective learning
Borg et al. (2018)	Unclear	Partially	Yes	Yes	Unclear	No	No	Unclear	Unclear	Unclear	Unclear	Yes	Yes	Unclear
Canuto et al. (2013)	No	Unclear	No	Partially	Unclear	No	No	Partially	No	Partially	No	Unclear	Partially	Unclear
Couzos et al. (2015)	Yes	Unclear	Yes	Yes	Unclear	No	No	Unclear	No	Partially	Unclear	Unclear	Partially	Unclear
Eades et al. (2012)	Partially	No	No	No	Unclear	No	No	No	No	No	No	Partially	No	No
Hoy et al. (2019)	Yes	Yes	No	Yes	Unclear	No	No	Yes	No	Partially	No	Yes	No	Unclear
Jamieson et al. (2018)	Unclear	Partially	No	Yes	Unclear	No	No	No	No	No	Unclear	Partially	Yes	Yes
Ju et al. (2017)	No	Unclear	Partially	No	Unclear	No	No	No	No	No	Unclear	Yes	Yes	Unclear
Kapellas et al. (2013)	No	Partially	Partially	No	Unclear	No	No	No	No	No	No	Partially	No	No
Kapellas et al. (2014)	No	No	No	No	Unclear	No	No	No	No	No	No	Partially	No	No
Leach et al. (2008)	Partially	Unclear	No	No	Unclear	No	No	No	No	No	No	Partially	Yes	Unclear
Marley et al. (2014)	No	Unclear	No	Yes	Unclear	No	No	No	No	No	No	Unclear	No	No
McHugh et al. (2020)	No	Unclear	No	No	Unclear	No	No	No	No	No	No	Partially	Yes	Yes
Nagel et al. (2009)	No	No	No	No	Unclear	No	No	No	No	No	No	No	No	No
Phillips et al. (2014)	No	No	No	No	Unclear	No	No	No	No	No	No	No	Partially	Unclear
Ritchie et al. (2010)	Unclear	Yes	No	Yes	Unclear	No	No	No	No	No	Unclear	Partially	Yes	Yes
Smithers et al. (2017)	Unclear	Unclear	No	Unclear	No	No	No	No	No	No	Unclear	No	Unclear	Unclear
Stephens et al. (2012)	Unclear	Unclear	No	Unclear	No	No	No	No	No	No	Unclear	No	Unclear	Unclear

Table 4
Summary study characteristics.

Characteristic	n	%
Primary outcome measures	17	100
Secondary outcome measures	13	77
Single blinding of assessor	10	59
Double blinding	5	29
Unblinded studies	2	12
Pragmatic trial design	2	12
Research funding	14	82
Embedded Qualitative Studies	2	11
Focus area		
Ear health	4	24
Smoking	2	12
Oral Health	5	29
Vaccination	1	6
Other	5	29

Table 5
Withdrawal characteristics of each study.

Withdrawal reason	Withdrawal %	Author
High Staff turnover	33%	Eades et al., [5]
Death	2%	Hoy et al., [6]
	3%	Jamieson et al., [7]
	2%	J. V. Marley et al., [13]
	4%	McHugh et al., [14]
	3%	Smithers et al., [19]
Elite Sporting commitments	Number not stated	Hoy et al., [6]
Moved away	Number not stated	Hoy et al., [6]
	6%	Smithers et al., [19]
	5%	Couzos et al., [4]
Loss to follow up	25%	Jamieson et al., [7]
	26%	Ju et al., [8]
	38%	Kapellas et al., [9]
	33%	Eades et al., [5]
	11%	Kapellas et al., [10]
	1%	J. V. Marley et al., [13]
	18%	McHugh et al., [14]
	11%	Phillips et al., Stephen et al., [20]
	8%	
Pregnancy & onset of unrelated medical condition	7%	Hoy et al., [6]
Withdrew consent	1%	J. V. Marley et al., [13]
	1%	McHugh et al., [14]
	6%	Nagel et al., [15]
	3%	Ritchie et al., [18]

team leaders, their managers, academic and publishing systems. This potentially limits the translation of knowledge gained into effective and sustained health programs in communities and also further marginalises Indigenous communities, by limiting access to a deeper understanding of the specific enablers and barriers of health-based interventions, which may be unique to each community. This situation specifically demands a first-principles reconsideration of the conceptualisation, design, and implementation of RCTs in these settings, to embody the elements of co-design of the trials and co-production of their implementation and findings.

There are potential limitations to our approach in this review. We used only the reported information extracted from each of the 17 studies. Prioritisation by publishers and authors (including restrictive word limits) may have precluded the addition of details relevant to cultural integrity, which may have been documented in other study outputs. Missing data from any of the studies may impact the EPHPP and QAT scores we allocated. Risks of bias may include the non-publication of negative results in the included papers. This review included those RCTs enrolling only

Indigenous peoples. Other Australian RCTs may have included Indigenous people but did not identify them as such in the enrolment or analyses/outcomes or where they may have made up a proportion of the sample.

This review has identified the need for greater efforts by research teams to address the differences between Western and Indigenous worldviews and the values that derive from these. Future research and insights into the appropriateness of embedded qualitative studies guiding design and implementation, as well as clustered, stepped-wedge and cross-over RCT methodologies in Indigenous community settings would be useful. Given the evidence of continuing disproportionate disease burden and the under-representation of RCTs by, with, and for Indigenous people, increasing the number, scientific quality and cultural integrity of RCTs for, and with, Indigenous is an urgent priority.

Contributions

TE and AC developed the study outline, accessed and verified the data sources. TE, AC, RM and AM designed the study. TE and AC collected and organised the data. TE, RM, AC and AM analysed the data. TE and AC wrote the first draft of the study. AC and AM provided supervision. AC designed the MS Excel™ visualisation figs. TE, AC, RM and AM reviewed and edited the manuscript. TE prepared the final draft and submitted the manuscript for consideration.

Funding

There was no grant funding source for this study.

Data sharing

All data generated or analysed during this study are included in this published article and the appendix.

Declaration of Competing Interest

The authors declare they have no conflicts of interest with his article.

Acknowledgements

We would like to acknowledge the Yorta Yorta (Shepparton Victoria) and Eora Nations (Sydney) the locations the first author was based and engaged in writing this manuscript. We want to thank the authors of the randomised control trials we included in this systematic literature review. We acknowledge and respect this work, particularly in dealing with trying conditions and the contributions made within Indigenous communities in which these studies have been conducted. A Finally, we express our thanks to Ms. Kanchana Ekanayake University of Sydney Faculty Liaison Librarian for her ongoing assistance in sourcing the papers included in this review.

References

[1] Australian Institute of Health and Welfare. Australian burden of disease study: impact and causes of illness and death in Australia 2018; 2021.
[2] Borg K, Sutton K, Beasley M, Tull F, Faulkner N, Halliday J, et al. Communication-based interventions for increasing influenza vaccination rates among Aboriginal children: a randomised controlled trial. Vaccine. 2018;36(45):6790–5.
[3] Canuto K, Cargo M, Li M, D'Onise K, Esterman A, McDermott R. Pragmatic randomised trial of a 12-week exercise and nutrition program for Aboriginal and Torres Strait Islander women: clinical results immediate post and 3 months follow-up. BMC Public Health. 2012;12(1):933. https://doi.org/10.1186/1471-2458-12-933.
[4] Couzos S, Lea T, Culbong M, Mueller R, Murray R. Effectiveness of ototopical antibiotics for chronic suppurative otitis media in aboriginal children: a community-based, multicentre, double-blind randomised controlled trial. Med J Aust. 2003;179(4):185–90.
[5] Eades SJ, Sanson-Fisher RW, Wenitong M, Panaretto K, D'Este C, Gilligan C, et al. An intensive smoking intervention for pregnant Aboriginal and Torres Strait Islander women: a randomised controlled trial. Med J Aust. 2012;197(1):42–6.
[6] Hoy WE, Reid CM, Huq M, McLeod BJ, Mott SA. A randomised controlled trial of potential for pharmacologic prevention of new-onset albuminuria, hypertension and diabetes in a remote Aboriginal Australian community, 2008-2013. Contemp Clin Trials Commun. 2019;14:100323. https://doi.org/10.1016/j.conctc.2019.100323.
[7] Jamieson L, Smithers L, Hedges J, Parker E, Mills H, Kapellas K, et al. Dental disease outcomes following a 2-year oral health promotion program for Australian Aboriginal children and their families: a 2-Arm parallel, single-blind, randomised controlled trial. EClinicalMedicine. 2018;1:43–50.
[8] Ju X, Brennan D, Parker E, Mills H, Kapellas K, Jamieson L. Efficacy of an oral health literacy intervention among indigenous Australian adults. Commun Dentist Oral Epidemiol. 2017;45(5):413–26. https://doi.org/10.1111/cdoe.12305.
[9] Kapellas K, Do LG, Mark Bartold P, Skilton MR, Maple-Brown LJ, O'Dea K, et al. Effects of full-mouth scaling on the periodontal health of Indigenous Australians: a randomized controlled trial. J Clin Periodontol. 2013;40(11):1016–24. https://doi.org/10.1111/jcpe.12152.
[10] Kapellas K, Maple-Brown L, Bartold P, Brown A, Do L, O'Dea K, et al. Effect of a periodontal intervention on pulse wave velocity in Indigenous Australians with periodontal disease: the PerioCardio randomized controlled trial; 2014.
[11] Leach A, Wood Y, Gadil E, Stubbs E, Morris P. Topical ciprofloxin versus topical framycetin-gramicidin-dexamethasone in Australian aboriginal children with recently treated chronic suppurative otitis media: a randomized controlled trial. Pediatr Infect Dis J. 2008;27(8):692–8.
[12] Marley, Kitaura T, Atkinson D, Metcalf S, Maguire GP, Gray D. Clinical trials in a remote Aboriginal setting: lessons from the BOABS smoking cessation study. BMC Public Health. 2014;14(1):1–9.
[13] Marley JV, Kitaura T, Atkinson D, Metcalf S, Maguire GP, Gray D. Clinical trials in a remote Aboriginal setting: lessons from the BOABS smoking cessation study [article]. BMC Public Health. 2014;14(1). https://doi.org/10.1186/1471-2458-14-579. Article 579.
[14] McHugh L, Binks M, Ware RS, Snelling T, Nelson S, Nelson J, et al. Birth outcomes in Aboriginal mother–infant pairs from the Northern Territory, Australia, who received 23-valent polysaccharide pneumococcal vaccination during pregnancy, 2006–2011: the PneuMum randomised controlled trial. Aust New Zealand J Obs Gynaecol. 2020;60(1):82–7. https://doi.org/10.1111/ajo.13002.
[15] Nagel T, Robinson G, Condon J, Trauer T. Approach to treatment of mental illness and substance dependence in remote Indigenous communities: results of a mixed methods study. Aust J Rural Health. 2009;17(4):174–82.
[16] Phillips JH, Wigger C, Beissbarth J, McCallum GB, Leach A, Morris PS. Can mobile phone multimedia messages and text messages improve clinic attendance for Aboriginal children with chronic otitis media? A randomised controlled trial. J Paediatr Child Health. 2014;50(5):362–7.
[18] Ritchie BK, Brewster DR, Tran CD, Davidson GP, McNeil Y, Butler RN. Efficacy of Lactobacillus GG in aboriginal children with acute diarrhoeal disease: a randomised clinical trial [article]. J Pediatr Gastroenterol Nutr. 2010;50(6):619–24. https://doi.org/10.1097/MPG.0b013e3181bbf53d.
[19] Smithers LG, Lynch J, Hedges J, Jamieson LM. Diet and anthropometry at 2 years of age following an oral health promotion programme for Australian Aboriginal children and their carers: a randomised controlled trial. Br J Nutr. 2017;118(12):1061–9. https://doi.org/10.1017/S000711451700318X.
[20] Stephen A, Leach A, Morris P. Impact of swimming on chronic suppurative otitis media in Aboriginal children: a randomised controlled trial. Med J Aust. 2012;199(1):51–5. https://doi.org/10.5694/mja13.10533.
[21] Sibthorpe BM, Bailie RS, Brady MA, Ball SA, Sumner-Dodd P, Hall WD. The demise of a planned randomised controlled trial in an urban aboriginal medical service. Med J Aust. 2002;177(4):222–3.
[22] Morris P. Randomised controlled trials addressing Australian Aboriginal health needs: a systematic review of the literature. J Paediatr Child Health. 1999;35(2):130–5.
[23] Gibson C, Crockett J, Dudgeon P, Bernoth M, Lincoln M. Sharing and valuing older Aboriginal people's voices about social and emotional wellbeing services: a strength-based approach for service providers. Aging Ment Health. 2020;24(3):481–8.
[24] Gee G, Dudgeon P, Schultz C, Hart A, Kelly K. Aboriginal and Torres Strait Islander social and emotional wellbeing. Working together: Aboriginal and Torres Strait Islander mental health and wellbeing principles and practice, 2. 2014. p. 55–68.
[25] Slattery B. What are aboriginal rights. Osgoode digital commons. Osgood Hall Law School of York University; 2007.
[26] Chandler D, Reid J. 'Being in being': contesting the ontopolitics of indigeneity. Eur Leg. 2018;23(3):251–68.
[27] Lock MJ, Walker T, Browne J. Promoting cultural rigour through critical appraisal tools in first nations peoples' research. Aust N Z J Public Health. 2021;45(3):210–1.
[28] McCallum GB, Versteegh LA, Morris PS, McKay CC, Jacobsen NJ, White AV, et al. Mobile phones support adherence and retention of indigenous participants in a randomised controlled trial: strategies and lessons learnt. BMC Public Health. 2014;14:622.
[29] Olsen L, Saunders RS, JM McGinnis, editors. Applying evidence for patient-centered care: standards and expectations. Patients charting the course: citizen engagement and the learning health system: workshop summary. National Academies Press (US); 2011.
[30] Beserra BT, Fernandes R, do Rosario VA, Mocellin MC, Kuntz MG, EBJCN Trindade. A systematic review and meta-analysis of the prebiotics and synbiotics effects on glycaemia, insulin concentrations and lipid parameters in adult patients with overweight or obesity. 2015;34(5):845–58.
[31] Saucedo-Araujo RG, Chillón P, Pérez-López IJ, Barranco-Ruiz Y. School-based interventions for promoting physical activity using games and gamification: a systematic review protocol. Int J Environ Res Public Health. 2020;17(14):5186.
[32] Harfield S, Pearson O, Morey K, Kite E, Canuto K, Glover K, et al. Assessing the quality of health research from an Indigenous perspective: the Aboriginal and Torres Strait Islander quality appraisal tool. BMC Med Res Methodol. 2020;20:1–9.
[33] Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. Bmj. 2017:358.

[34] Saary MJ. Radar plots: a useful way for presenting multivariate health care data. J Clin Epidemiol. 2008;61(4):311–7.
[35] Stafoggia M, Lallo A, Fusco D, Barone AP, D'Ovidio M, Sorge C, et al. Spie charts, target plots, and radar plots for displaying comparative outcomes of health care. J Clin Epidemiol. 2011;64(7):770–8.
[36] Eades SJ, Sanson-Fisher RW, Wenitong M, Panaretto K, D'Este C, Gilligan C, et al. An intensive smoking intervention for pregnant Aboriginal and Torres Strait Islander women: a randomised controlled trial. Med J Aust. 2012;197(1):42–6.
[38] Jamieson L, Smithers L, Hedges J, Parker E, Mills H, Kapellas K, et al. Dental disease outcomes following a 2-year oral health promotion program for Australian aboriginal children and their families: a 2-arm parallel, single-blind, randomised controlled trial. EClinicalMedicine. 2018;1:43–50.
[40] McHugh L, Binks M, Ware RS, Snelling T, Nelson S, Nelson J, et al. Birth outcomes in Aboriginal mother–infant pairs from the Northern Territory, Australia, who received 23-valent polysaccharide pneumococcal vaccination during pregnancy, 2006–2011: the PneuMum randomised controlled trial. Aust New Zealand J Obs Gynaecol. 2020; 60(1):82–7.