



BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Developing an ecological framework of factors associated with substance use and related harms among Aboriginal and Torres Strait Islander People: Protocol for a systematic review

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-024418
Article Type:	Protocol
Date Submitted by the Author:	25-May-2018
Complete List of Authors:	Snijder, Mieke; University of New South Wales - Randwick Campus, National Drug and Alcohol Research Centre Lees, Briana; University of New South Wales - Randwick Campus, National Drug and Alcohol Centre Ward, James; South Australia Health and Medical Research Centre; Flinders University Faculty of Medicine Nursing and Health Sciences Stearne, Annalee; Telethon Kids Institute Newton, Nicola; University of New South Wales, NHMRC Centre for Research Excellence in Mental Health and Substance Use, National Drug and Alcohol Research Centre Stapinski, Lexine; UNSW Sydney, NHMRC Centre of Research Excellence in Mental Health and Substance Use, National Drug and Alcohol Research Centre
Keywords:	Indigenous, PREVENTIVE MEDICINE, Substance misuse < PSYCHIATRY, EPIDEMIOLOGY

SCHOLARONE™
Manuscripts

Title: Developing an ecological framework of factors associated with substance use and related harms among Aboriginal and Torres Strait Islander People: Protocol for a systematic review

Authors: Snijder, M.^{1,2}, Lees, B.^{1,2}, Ward, J.^{3,4}, Stearne, A.⁵, Newton, N.^{1,2}, & Stapinski, L.^{1,2}

¹ *NHMRC Centre of Research Excellence in Mental Health and Substance Use*

² *National Drug and Alcohol Research Centre, University of New South Wales, Sydney, Australia*

³ *South Australian Health and Medical Research Institute, Adelaide, South Australia*

⁴ *Flinders University, Adelaide, South Australia.*

⁵ *Telethon Kids Institute, Perth, Western Australia*

Correspondence: m.snijder@unsw.edu.au, National Drug and Alcohol Research Centre, University of New South Wales, 22-32 King St, Randwick, Australia, 2031

For peer review only

Abstract

Objective: The purpose of this literature review is to synthesise the risk and protective factors associated with substance use and related harms among Aboriginal and Torres Strait Islander people, and critically appraise the methodological quality of the included studies.

Design: A systematic literature review. A total of seven peer-reviewed and two grey literature databases will be searched using search terms in line with the aims of this review and based on previous relevant reviews of factors associated with substance use in non-Indigenous populations. Studies published between 1 January 1990 and 31 April 2018 will be included if they identify risk and/or protective factors for substance use or related harms in a study sample that consists of at least 50% Aboriginal and Torres Strait Islander people.

Primary and Secondary outcomes: The factors will be organised using an ecological approach which will identify factors on individual, relationship, community, societal and cultural levels that can lead to a reduction or increase in substance-related outcomes. A critical appraisal of study quality will be conducted using the Joanna Briggs Institute Critical Appraisal Checklist for Studies Reporting Prevalence Data and the qualitative assessment tool by Godfrey and Long.

Results: Data extraction from identified studies is currently under way. This study will identify specific risk and protective factors associated with substance use among Aboriginal and Torres Strait Islander people and will appraise the methodological quality of the studies included in the review.

Conclusions: By synthesising evidence regarding the risk and protective factors associated with substance use and related harms, this review will provide researchers, policy makers and program developers with up-to-date information to guide the development of prevention initiatives that specifically target factors relevant for Aboriginal and Torres Strait Islander people.

Registration: PROSPERO registry of the University of York (registration number: CRD42017073734).

Keywords:

Aboriginal and Torres Strait Islander people, Indigenous, substance, alcohol and other drug, tobacco, risk factors, protective factors

Strengths and limitations of this study**Strengths:**

- Using an ecological model allows this paper to explore substance use and related harms from a more holistic perspective, rather than focusing on the individual factors
- This review will produce a model that can be used by program developers, researchers and policy makers when deciding on prevention strategies

Weakness:

- This review will not contain a meta-analysis. While a meta-analysis would provide stronger evidence for the factors associated with substance use among Aboriginal and Torres Strait Islanders, the expected heterogeneous outcomes likely does not warrant a meta-analysis.

1

2

3 Background

4

5

6 Aboriginal and Torres Strait Islander People have the oldest continuing culture in the world [1]. Like

7

8 other Indigenous Peoples around the world, many Aboriginal and Torres Strait Islander people’s

9

10 livelihoods were severely disrupted upon colonisation, with people often forcibly removed from

11

12 their traditional lands and prevented from utilising their traditional laws and culture. This has

13

14 resulted in negative impacts on wellbeing and sense of place in contemporary society, including a

15

16 reduced sense of self-determination [2]. The cycle of dispossession and disempowerment resulting

17

18 from colonisation, combined with ongoing policy failures in social services and health, continues to

19

20 negatively impact many Aboriginal and Torres Strait Islander people, as evidenced by the poorer

21

22 health and social outcomes when compared to non-Indigenous Australians [3-9].

23

24

25

26 Despite evidence of resilience in dealing with poorer outcomes on social determinants of health,

27

28 Aboriginal and Torres Strait Islander people experience high rates of substance use and related

29

30 harms [3, 10]. For example, among Aboriginal and Torres Strait Islander people aged 44 years and

31

32 younger, mental health and substance use disorders are the leading cause of disease and they

33

34 account for 14% of the health gap between Aboriginal and Torres Strait Islander people and non-

35

36 Indigenous Australians [11]. As substance use is a modifiable risk factor for disease, it is therefore an

37

38 important target area to close the gap in health outcomes between Aboriginal and Torres Strait

39

40 Islander people and non-Indigenous Australians [12, 13].

41

42

43

44

45 While past prevention programs and policies have made some improvements in substance use-

46

47 related outcomes over the past decades, these achievements have been slow and insufficient to

48

49 reduce substance use and related harms among Aboriginal and Torres Strait Islander people [14-17].

50

51 For example, a recent literature review found that only three out of six substance use prevention

52

53 programs for Aboriginal and Torres Strait Islander adolescents were effective in improving

54

55 substance-related outcomes [18]. One explanation for the reduced impact of policies and programs

56

57

58

59

60

could be that they do not adequately target the unique risk and protective factors that are associated with substance use for Aboriginal and Torres Strait Islander people. Identifying these specific factors has the potential to improve policies and programs that aim to reduce substance use and related harms experienced by Aboriginal and Torres Strait Islander people.

In assessing factors associated with substance use and related harms, it is beneficial to take an ecological approach to ensure that a comprehensive overview is created of the various factors influencing the outcomes of interest [19, 20]. In addition to influences of colonisation, intergenerational trauma and disempowerment, substance use and related harms are influenced by a variety of individual, community, relationship, societal and cultural factors [20-22]. While previous reviews have investigated the association of these factors with substance use for mainstream populations [19, 23-26], to date, no study has synthesised the evidence of risk and protective factors on all ecological levels associated with substance use and related harms for Aboriginal and Torres Strait Islander people in Australia. It is therefore the purpose of this literature review is to provide an overview of the risk and protective factors associated with substance-related outcomes, organised by ecological levels. By focusing on Aboriginal and Torres Strait Islander populations in Australia, this will provide the most robust evidence base to inform the development of culturally appropriate substance use prevention programs for Indigenous Australian youth, to ultimately reduce the health gap between Indigenous and non-Indigenous Australians.

Methods

This protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement [27, 28], found in the Additional File. This protocol has been registered in the PROSPERO registry of the University of York (registration number: CRD42017073734).

Objectives

The overall objective of this review is to identify and synthesise the risk and protective factors associated with substance use and related harms among Aboriginal and Torres Strait Islander people. Specifically, this review will aim to answer the following two questions: 1) what are the risk and protective factors for substance use and related harms among Aboriginal and Torres Strait Islander people, across individual, relationship, community, cultural and societal levels; and 2) what is the methodological quality of studies assessing the factors related to substance use and related harms for Aboriginal and Torres Strait Islander people?

Search strategy

The relevant literature published between 1 January 1990 and 30 April 2018 will be systematically searched in seven electronic peer-reviewed databases and two grey literature databases for quantitative and qualitative studies. Peer-reviewed databases will include: Cochrane, Embase, PsychInfo, Medline, ProQuest, Informit and CINAHL. Following previous literature reviews relating to Aboriginal and Torres Strait Islander health [29, 30], the grey literature databases will be: *HeathInfoNet* and Closing the Gap Clearinghouse. Table 1 provides an example of the search strategy that will be used in MEDLINE, which will be replicated for the other electronic databases. The reference lists of selected studies will be assessed for further relevant publications and papers will be solicited from researchers in the field.

[Include Table 1 here]

Search terms will be used to identify studies assessing the risk and protective factors of substance use and related harms for Aboriginal and Torres Strait Islander people. The search terms will be based on previous reviews into factors associated with substance use in adolescents in mainstream populations [19] and factors associated with wellness for Indigenous Peoples [20]. Search terms will be combinations of keywords related to the participants ('Aborigin*' OR "Torres Strait*" OR 'Indigenous' AND Australia), the outcomes (wellbeing OR "mental health" OR substance OR alcohol OR drug OR tobacco) and the factors ('risk' OR protec* OR resilienc* OR underlying OR ecological OR vulnerab* OR 'psychosocial' AND 'factor OR mechanism OR character*'). Two reviewers will independently screen articles, extract data and assess the methodological quality.

Eligibility Criteria

Eligibility criteria for this review are defined using PICOS (population, intervention/exposure, comparator, outcome, study characteristics) [28]. Inclusion criteria will be as follows: 1) 50% or more of the study sample are Aboriginal and Torres Strait Islander people, or a sub-analysis has been conducted for Aboriginal and Torres Strait Islander people when sample is less than 50%; 2) the study identifies or measures risk and/or protective factors for substance use or related harms; 3) the outcome of interest is substance use or related harms; 4) the study was published between 1 January 1990 and 30 April 2018; 5) full-text version is available; and 6) the publication includes a new data analysis. A more detailed description and definition of all PICOS criteria follows.

Population

Studies will be considered if they contain a sample where at least 50% of participants identified as Aboriginal and Torres Strait Islander people. Studies will also be considered if the participant sample

included less than 50% of Aboriginal and Torres Strait Islander people but a separate analysis for Aboriginal and Torres Strait Islander people was provided. Participants of all ages will be included.

Exposure

Studies must identify and measure risk and protective factors for substance use and related harms. The factors will be organised using an ecological approach, which includes factors on individual, relationship, community, societal, and culturally distinct levels [20]. Each ecological level is defined as follows:

- **Individual-level factors** include biological and personal history factors such as age, socio-economic status, health and psychosocial factors;
- **Relationship-level factors** include close relationships with peers, partners and family members who influence an individual’s behaviour;
- **Community-level factors** include the individual’s lifestyle settings such as the workplace or geographical location in which social relationships occur;
- **Societal-level factors** include social norms, social policy and availability of substances;
- **Culturally distinct-level factors** include historical contexts, languages, cultural practices, spirituality, values and social structures that are specific to cultural groups.

Comparator

No comparator or control group is necessary for studies to be included in this review. Studies that do include a comparator must compare Aboriginal and Torres Strait Islander people who use substances (or are heavy users) with Aboriginal and Torres Strait Islander people who do not use substances (or are not heavy users). Papers comparing Aboriginal and Torres Strait Islander people and non-Indigenous Australians will not be included in this review.

Outcomes

The primary outcomes of interest are substance use and associated harms. Outcome types will be classified based on previous research [19] which categorised substance use and related outcomes into three levels: 1) use or frequency; 2) regular, problem, heavy use or binge; 3) use disorder or abuse or dependence. Following Stone et. al (2012), the wording of each category will be consistent across risk and protective factors for inclusion in tables, but categories are defined separately. For risk factors the following definitions will be used:

- **Use or frequency** refers to increased likelihood of substance use initiation, irregular substance use or frequency of use not further specified;
- **Regular, problem, heavy use or binge.** Regular use is an increase in use to at least weekly substance use. Heavy and binge use is an increase in large consumption during one occasion of use. Problem use is an increase in use that causes problems, including substance related injuries or hospitalisations;
- **Use disorder or abuse or dependence** categorises increases in use and symptoms consistent with probable substance use disorder.

For protective factors the following definitions will be used:

- **Use or frequency** refers to a delay in initiation, an increase in abstinence or a reduction in frequency of use not further specified;
- **Regular, problem, heavy use or binge** refers to cessation or reduction of use following a period of regular, heavy or problem substance use and a reduction in substance-related harms;
- **Use disorder or abuse or dependence** refers to substance reduction or recovery from substance use disorder.

Study characteristics

Quantitative observational studies (cross-sectional, longitudinal, cohort and case-control studies) and qualitative studies that provide original data will be included. Reviews, information in books or letters will not be included.

Selection procedure

Reviewer one (BL) will screen all titles and abstracts from the peer-reviewed databases to determine eligibility for inclusion in the review. Reviewer two (MS) will independently screen a random selection of 25% of abstracts to ensure accuracy in the study selection. Reviewer one will screen and assess the eligibility of publications from the grey literature and reference lists of other identified papers. Full-text versions of the potentially eligible studies will be assessed by both reviewers to further determine eligibility for inclusion. Cohen’s kappa will be calculated to assess the inter-rater agreement between the two reviewers at the full-text screening stage. Consultation between reviewers will be held at the time of abstract screening and full-text assessment to reconcile any differences of opinion. If there is no consensus, the senior author (LS) will assess the eligibility of the study.

An excel spreadsheet will be utilised to record the study title, authors, year, database and whether the study meets the eligibility criteria and should be included in the review. During abstract screening and full-text assessment, reasons for inclusion (PICOS) and exclusion will be recorded in the spreadsheet. Records from this spreadsheet will be used to generate the PRISMA Flowchart (see Figure 1) [31].

[Figure 1 here]

Data management

Bibliographic software (Endnote) will be used for the data management. All the search results from peer-reviewed databases, and screened publications from the grey literature, will be imported into the program. Duplicates will be removed by reviewer one.

Data extraction

Data extraction will be completed by reviewer one, into an excel spreadsheet developed by the authors. The following elements will be extracted from each study: sample size and age, study population, percentage of Aboriginal and/or Torres Strait Islander descent, sex, study characteristics, substance type measured and outcome type (use frequency, problem or heavy use, disorder or abuse), factors significantly associated with increased substance use and related harms (risk), factors significantly associated with reduced substance use and related harms (protective), and the effect size. To facilitate the comparison of risk and protective factors, odd ratios and/or rate ratios will be extracted from the studies. Where odds and/or rate ratios are not provided in the studies, we will calculate the odds ratios by extracting the total number of participants reported in each group of users or non-users who had the risk/protective factor or did not have the risk/protective factor. Where authors do not provide this information, we will contact the authors to ask them for these data.

Following previous reviews [19, 20], a narrative synthesis of the main results extracted from the studies will be completed. A meta-analysis is likely not warranted given the heterogeneous outcome measures to be included in this review and the known variable quality of studies with Indigenous populations [32]. A summary of each risk and protective factor statistically significantly associated with substance use and related harms will be reported in text, including effect sizes of specific

studies. A table of risk and protective factor results will be produced, summarising the authors, study population, sample size and age, substance, outcome type and findings. The ecological framework will be utilised to organise the risk and protective factors within the table, grouping by individual, relationship, community, societal and culturally-distinct levels. Findings will be discussed separately for each ecological level.

Data analysis and quality assessment

Following data extraction, the methodological quality of the studies will be assessed. The quality of quantitative studies will be appraised using the Joanna Briggs Institute Critical Appraisal Checklist for Studies Reporting Prevalence Data [33]. This nine-question tool assesses quality across six domains: selection bias and sample size, study design, potentially confounding factors, data collection methods, statistical analysis and response rate. A scoring system of one-point per question will be used to determine the overall summary rating and allow comparability across publications. The quality of qualitative studies will be appraised using the qualitative assessment tool by Godfrey and Long (2002) [34]. This will allow the reviewers to assess quality in four domains: sample, data collection, analysis and potential researcher bias, and policy and practical implications. A critical appraisal of all included studies will be completed by reviewer one and reviewer two will assess the quality of a random selection of 25% of included studies to ensure scoring accuracy. Consultation between reviewers will be held to reconcile any differences of opinion.

Discussion

Aboriginal and Torres Strait Islander people experience a higher burden of disease from substance use and related harms compared to their non-Indigenous counterparts [11]. Therefore, identifying which factors are associated with increased rates of substance use and related harms for Aboriginal and Torres Strait Islander people is critical to inform prevention programs and policies. Identifying risk and protective factors associated with substance use will provide a framework that can improve understanding of substance use among Aboriginal and Torres Strait Islander people. This review will provide such a framework based on an ecological model which identifies factors on individual, relationship, community, societal and cultural levels that can lead to a reduction (protective) or increase (risk) in substance use and related harms.

By synthesising evidence regarding the risk and protective factors, this review will provide researchers, policy makers and program developers with robust evidence base to guide the development of prevention programs and policies to specifically target the factors that are relevant for Aboriginal and Torres Strait Islander people. The review will also provide information about community and societal factors, and thus has the potential to guide government policies at a national and state level. This review seeks to improve health and social outcomes for Aboriginal and Torres Strait Islander people, by guiding the focus and tailoring of programs and policies to lead to more effective and impactful substance use prevention initiatives.

Figures, tables and additional files

Additional file: PRISMA-P checklist

Data availability

Not applicable.

Funding

This study is supported by funding from the Australian Government Department of Health. LS is supported by a National Health and Medical Research Council (NHMRC) Translating Research into Practice fellowship (GNT1132853). The authors declare that the funders of the study have no influence in developing the protocol and for the conduct of the review.

Competing interests

The authors declare they have no competing interests.

Authors’ contributions

MS and LS conceptualised the study. All authors developed the study design and protocol. MS and BL wrote the first draft of the manuscript. All authors read, revised and approved the final manuscript. MS is guarantor of the review.

Acknowledgements

We acknowledge the input of Professor Maree Teesson, Dr. Cath Chapman, Dr. Katrina Champion, Dr. Louise Birrell and Kate Ross in the design of this protocol as well as the members of the expert advisory group of the Positive Choices project, of which this review is a part.

Authors’ information

b.lees@unsw.edu.au, n.newton@unsw.edu.au, l.stapinski@unsw.edu.au , james.ward@sahmri.com,
Annalee.Stearne@telethonkids.org.au

References

1. Malaspinas, A.-S., et al., *A genomic history of Aboriginal Australia*. Nature, 2016. 538(7624): p. 207-214.
2. United Nations, *State of the world's Indigenous Peoples 2009*, New York: UN Permanent Forum on Indigenous Issues (UNPFII).
3. Atkinson, J., *Trauma trails, recreating song lines: the transgenerational effects of trauma in Indigenous Australia*. 2002, North Melbourne: North Melbourne : Spinifex Press.
4. Osborne, K., F. Baum, and L. Brown, *What works? A review of actions addressing the social and economic determinants of Indigenous health*. 2013, Canberra / Melbourne: Australian Institute for Health and Welfare / Australian Institute for Family Studies.
5. Anderson, I., et al., *Indigenous and tribal peoples' health (The Lancet-Lowitja Institute Global Collaboration): A population study*. The Lancet, 2016. 388(10040): p. 131-157.
6. Australian Institute for Health and Welfare, *The health and welfare of Australia's Aboriginal and Torres Strait Islander peoples: 2015*. 2015, Canberra: AIHW.
7. Australian Health Ministers' Advisory Council, *Aboriginal and Torres Strait Islander health performance framework: 2014 report*. 2015, Canberra: AHMAC.
8. Australian Institute for Health and Welfare, *National Drug Strategy Household Survey detailed report*. 2013, Canberra: Australian Government.
9. Gracey, M. and M. King, *Indigenous health part 1: Determinants and disease patterns*. The Lancet, 2009. 374(9683): p. 65-75.
10. Dudgeon, P., et al., *The Gayaa Dhuwi (Proud Spirit) Declaration: A call to action for Aboriginal and Torres Strait Islander leadership in the Australian mental health system*. Advances in Mental Health, 2016. 14(2): p. 126-139.
11. Australian Institute for Health and Welfare, *Australian burden of disease study: Impact and causes of illness and death in Aboriginal and Torres Strait Islander people 2011*. Australian Burden of Disease Study series. Vol. 6. 2016, Canberra: AIHW.
12. Commonwealth of Australia, *National Aboriginal and Torres Strait Islander Health Plan 2013-2023*. 2013, Canberra: Commonwealth of Australia.
13. Intergovernmental Committee on Drugs, *National Aboriginal and Torres Strait Islander Peoples' Drug Strategy 2014-2019*. 2014, Canberra: Commonwealth of Australia.
14. Altman, J.C., N. Biddle, and B.H. Hunter, *A historical perspective on indigenous socioeconomic outcomes in Australia, 1971-2001*. Australian Economic History Review, 2005. 45(3): p. 273-295.
15. Ring, I.T., et al., *Are Indigenous mortality gaps closing: How to tell, and when?* Medical Journal of Australia, 2016. 205(1): p. 11-12.

16. d'Abbs, P., *Widening the gap: The gulf between policy rhetoric and implementation reality in addressing alcohol problems among Indigenous Australians*. Drug and Alcohol Review, 2015. 34(5): p. 461-466.

17. Lovett, R., K. Thurber, and R. Maddox, *The Aboriginal and Torres Strait Islander smoking epidemic: what stage are we at, and what does it mean?* Public Health Research & Practice, 2017. 27(4): p.2741733.

18. Snijder, M., et al., *Preventing substance use among Indigenous adolescents in the United States of America, Canada, Australia and New Zealand: A systematic review of the literature*. Journal of the American Academy of Child and Adolescent Psychiatry, submitted.

19. Stone, A.L., et al., *Review of risk and protective factors of substance use and problem use in emerging adulthood*. Addictive Behaviors, 2012. 37(7): p. 747-775.

20. Burnette, C.E. and C.R. Figley, *Historical Oppression, Resilience, and Transcendence: Can a Holistic Framework Help Explain Violence Experienced by Indigenous People?* Social Work, 2017. 62(1): p. 37-44.

21. Midford, R., T. Stockwell, and D. Gray, *Prevention of alcohol-related harm: Community-based interventions*, in *National alcohol research agenda*, Commonwealth Department of Health and Ageing, Editor. 2002, Commonwealth Department of Health and Ageing: Canberra. p. 91-112.

22. Bronfenbrenner, U. and P.A. Morris, *The ecology of developmental processes*, in *Handbook of child psychology*, W. Damon and R. Lerner, Editors. 1998, John Wiley & Sons Hoboken, NJ, US. p. 993-1028.

23. Hawkins, J.D., R.F. Catalano, and J.Y. Miller, *Risk and protective factors for alcohol and other drug problems in adolescence and early adulthood: Implications for substance abuse prevention*. Psychological bulletin, 1992. 112(1): p. 64-105.

24. Bryden, A., et al., *A systematic review of the influence of community level social factors on alcohol use*. Health & Place, 2013. 21: p. 70-85.

25. Donovan, J.E., *Adolescent alcohol initiation: A review of psychosocial risk factors*. Journal of adolescent health, 2004. 35(6): p. 529. e7-18.

26. Ryan, S.M., A.F. Jorm, and D.I. Lubman, *Parenting factors associated with reduced adolescent alcohol use: a systematic review of longitudinal studies*. Australian and New Zealand Journal of Psychiatry, 2010. 44(9): p. 774-783.

27. Moher, D., et al., *Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement*. Annals of Internal Medicine, 2009. 151(4): p. 264-269.

28. Shamseer, L., et al., *Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: Elaboration & explanation*. BMJ, 2015. 349.

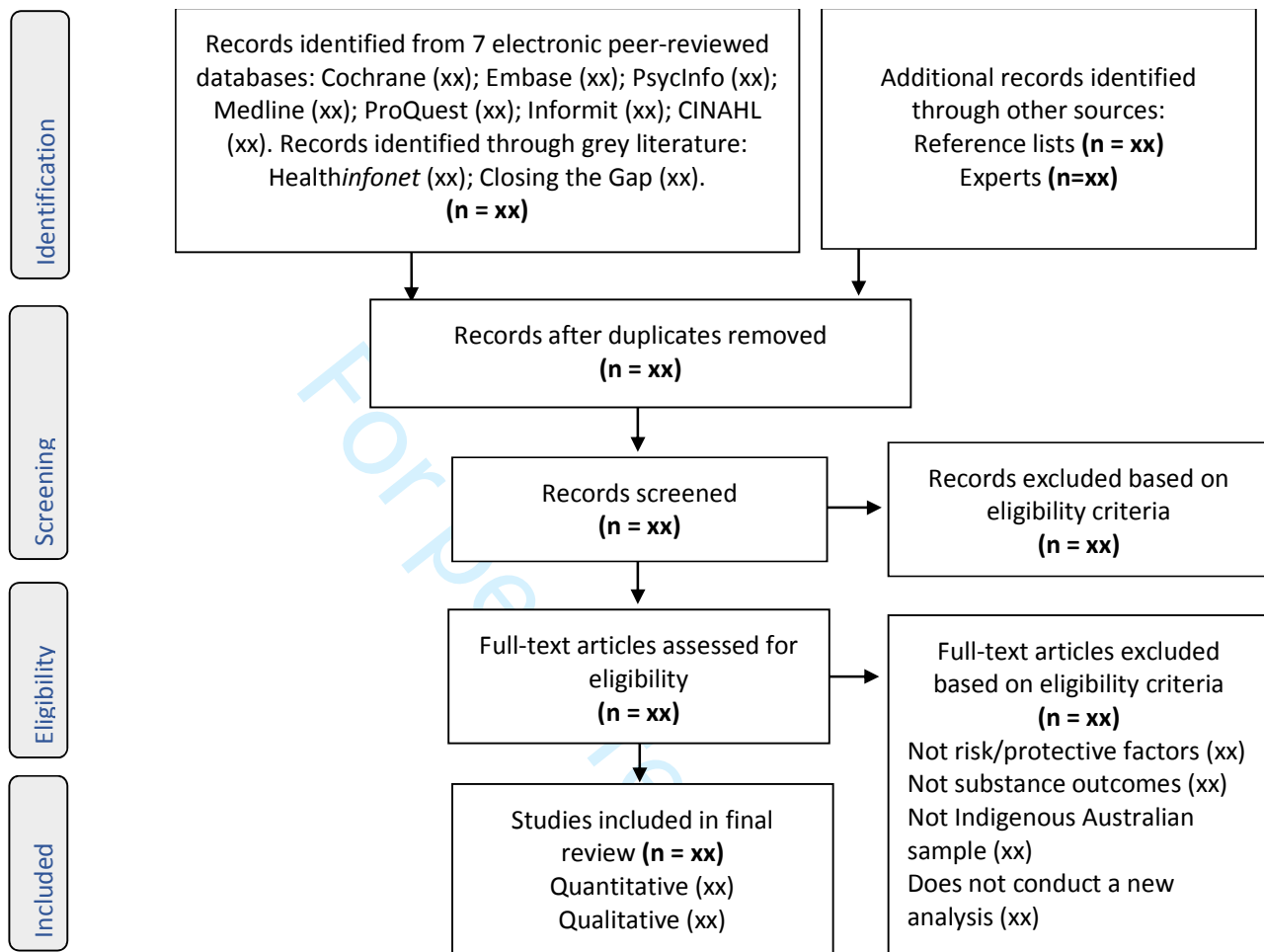
29. Snijder, M., et al., *A systematic review of studies evaluating Australian indigenous community development projects: The extent of community participation, their methodological quality and their outcomes*. BMC Public Health, 2015. 15(1): p. 1-16.

- 1
2
3 30. Snijder, M., et al., *Substance use prevention programs for Indigenous adolescents in the*
4 *United States of America, Canada, Australia and New Zealand: Protocol for a systematic*
5 *review*. JMIR Research Protocols, 2018. 7(2): p. e38.
6
7 31. Fairley, C.K., et al., *Randomized trial of an adherence programme for clients with HIV*.
8 *International Journal of STDs & AIDS*, 2003. 14(12): p. 805-809.
9
10 32. Clifford, A. and A. Shakeshaft, *A bibliometric review of drug and alcohol research focused on*
11 *Indigenous peoples of Australia, New Zealand, Canada and the United States*. Drug and
12 *Alcohol Review*, 2017. 36(4): p. 509-522.
13
14 33. Munn, Z., et al., *Methodological guidance for systematic reviews of observational*
15 *epidemiological studies reporting prevalence and incidence data*. International Journal of
16 *Evidence Based Healthcare*, 2015. 13(3): p. 147-153.
17
18 34. Long, A.F., et al., *Developing evidence based social care policy and practice. Part 3: Feasibility*
19 *of undertaking systematic reviews in social care*. 2002, Leeds: Nuffield Institute for Health.
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Table 1 Search strategy for systematic review of risk and protective factors of substance use and related harms among Aboriginal and Torres Strait Islander People (example: Medline search)

1	((Aborigin* OR "Torres Strait Islander" OR Indigenous) and Australia).mp.
2	((risk OR protec* OR resilienc* OR underlying OR ecological OR vulnerab* OR psychosocial) AND (factor OR mechanism OR character*).mp.
3	(wellbeing OR mental health OR substance OR alcohol OR drug OR tobacco).mp.
4	limit 1 to yr="1990 - 2017"
[mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	

Figure 1 PRISMA flow diagram of systematic review of studies assessing factors associated with substance use among Indigenous Australians.



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

For peer review only

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Additional file to: Snijder et al. *Developing an ecological framework of factors associated with substance use and related harms among Aboriginal and Torres Strait Islander People: Protocol for a systematic review.*

Section and topic	Item No	Checklist item	Information reported
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	<input checked="" type="checkbox"/>
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	<input type="checkbox"/>
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	<input checked="" type="checkbox"/>
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	<input checked="" type="checkbox"/>
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	<input checked="" type="checkbox"/>
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	<input type="checkbox"/>
Support:			
Sources	5a	Indicate sources of financial or other support for the review	<input checked="" type="checkbox"/>

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

Sponsor	5b	Provide name for the review funder and/or sponsor	<input checked="" type="checkbox"/>
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	<input checked="" type="checkbox"/>
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	<input checked="" type="checkbox"/>
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, outcomes and study characteristics (PICOS)	<input checked="" type="checkbox"/>
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICOS, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	<input checked="" type="checkbox"/>
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	<input checked="" type="checkbox"/>
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	<input checked="" type="checkbox"/>
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	<input checked="" type="checkbox"/>
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	<input checked="" type="checkbox"/>
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	<input checked="" type="checkbox"/>

Data items	12	List and define all variables for which data will be sought (such as PICOS items, funding sources), any pre-planned data assumptions and simplifications	<input checked="" type="checkbox"/>
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	<input checked="" type="checkbox"/>
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	<input checked="" type="checkbox"/>
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	<input type="checkbox"/>
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	<input type="checkbox"/>
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	<input type="checkbox"/>
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	<input checked="" type="checkbox"/>
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	<input type="checkbox"/>
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	<input checked="" type="checkbox"/>

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

For peer review only

BMJ Open

Developing an ecological framework of factors associated with substance use and related harms among Aboriginal and Torres Strait Islander People: Protocol for a systematic review

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-024418.R1
Article Type:	Protocol
Date Submitted by the Author:	18-Nov-2018
Complete List of Authors:	Snijder, Mieke; University of New South Wales - Randwick Campus, National Drug and Alcohol Research Centre Lees, Briana; University of New South Wales - Randwick Campus, National Drug and Alcohol Centre Ward, James; South Australia Health and Medical Research Centre; Flinders University Faculty of Medicine Nursing and Health Sciences Stearne, Annalee; Telethon Kids Institute Newton, Nicola; University of New South Wales, NHMRC Centre for Research Excellence in Mental Health and Substance Use, National Drug and Alcohol Research Centre Stapinski, Lexine; UNSW Sydney, NHMRC Centre of Research Excellence in Mental Health and Substance Use, National Drug and Alcohol Research Centre
Primary Subject Heading:	Public health
Secondary Subject Heading:	Addiction, Epidemiology, Global health, Mental health, Public health
Keywords:	Indigenous, PREVENTIVE MEDICINE, Substance misuse < PSYCHIATRY, EPIDEMIOLOGY

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Title: Developing an ecological framework of factors associated with substance use and related harms among Aboriginal and Torres Strait Islander People: Protocol for a systematic review

Authors: Snijder, M.^{1,2}, Lees, B.^{1,2}, Ward, J.^{3,4}, Stearne, A.⁵, Newton, N.^{1,2}, & Stapinski, L.^{1,2}

¹ *NHMRC Centre of Research Excellence in Mental Health and Substance Use*

² *National Drug and Alcohol Research Centre, University of New South Wales, Sydney, Australia*

³ *South Australian Health and Medical Research Institute, Adelaide, South Australia*

⁴ *Flinders University, Adelaide, South Australia.*

⁵ *Telethon Kids Institute, Perth, Western Australia*

Correspondence: m.snijder@unsw.edu.au, National Drug and Alcohol Research Centre, University of New South Wales, 22-32 King St, Randwick, Australia, 2031

For peer review only

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Abstract

Objective: The purpose of this literature review is to synthesise the risk and protective factors associated with substance use and related harms among Aboriginal and Torres Strait Islander people, and critically appraise the methodological quality of the included studies.

Design: A systematic literature review. A total of seven peer-reviewed and two grey literature databases will be searched using search terms in line with the aims of this review and based on previous relevant reviews of factors associated with substance use in non-Indigenous populations. Studies published between 1 January 1990 and 31 April 2018 will be included if they identify risk and/or protective factors for substance use or related harms in a study sample that consists of at least 50% Aboriginal and Torres Strait Islander people.

Primary and Secondary outcomes: The factors will be organised using an ecological approach which will identify factors on individual, relationship, community, societal and cultural levels that can lead to a reduction or increase in substance-related outcomes. A critical appraisal of study quality will be conducted using the Joanna Briggs Institute Critical Appraisal Checklist for Studies Reporting Prevalence Data and the qualitative assessment tool by Godfrey and Long.

Results: Data extraction from identified studies is currently under way. This study will identify specific risk and protective factors associated with substance use among Aboriginal and Torres Strait Islander people and will appraise the methodological quality of the studies included in the review.

Conclusions: By synthesising evidence regarding the risk and protective factors associated with substance use and related harms, this review will provide researchers, policy makers and program developers with up-to-date information to guide the development of prevention initiatives that specifically target factors relevant for Aboriginal and Torres Strait Islander people.

Registration: PROSPERO registry of the University of York (registration number: CRD42017073734).

Keywords:

Aboriginal and Torres Strait Islander people, Indigenous, substance, alcohol and other drug, tobacco, risk factors, protective factors

Strengths and limitations of this study**Strengths:**

- Using an ecological model allows this paper to explore substance use and related harms from a more holistic perspective, rather than focusing on the individual factors
- This review will produce a model that can be used by program developers, researchers and policy makers when deciding on prevention strategies

Weakness:

- This review will not contain a meta-analysis. While a meta-analysis would provide stronger evidence for the factors associated with substance use among Aboriginal and Torres Strait Islanders, the expected heterogeneous outcomes likely does not warrant a meta-analysis.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Background

Aboriginal and Torres Strait Islander People have the oldest continuing culture in the world [1]. Like other Indigenous Peoples around the world, many Aboriginal and Torres Strait Islander people’s livelihoods were severely disrupted upon colonisation, with people often forcibly removed from their traditional lands and prevented from utilising their traditional laws and culture. This has resulted in negative impacts on wellbeing and sense of place in contemporary society, including a reduced sense of self-determination [2]. The cycle of dispossession and disempowerment resulting from colonisation, combined with ongoing policy failures in social services and health, continues to negatively impact many Aboriginal and Torres Strait Islander people, as evidenced by the poorer health and social outcomes when compared to non-Indigenous Australians [3-9].

Despite evidence of resilience in dealing with poorer outcomes on social determinants of health, Aboriginal and Torres Strait Islander people experience high rates of substance use and related harms [3, 10]. For example, among Aboriginal and Torres Strait Islander people aged 44 years and younger, mental health and substance use disorders are the leading cause of disease and they account for 14% of the health gap between Aboriginal and Torres Strait Islander people and non-Indigenous Australians [11]. As substance use is a modifiable risk factor for disease, it is therefore an important target area to close the gap in health outcomes between Aboriginal and Torres Strait Islander people and non-Indigenous Australians [12, 13].

While past prevention programs and policies have made some improvements in substance use-related outcomes over the past decades, these achievements have been slow and insufficient to reduce substance use and related harms among Aboriginal and Torres Strait Islander people [14-17]. For example, a recent literature review found that only three out of six substance use prevention programs for Aboriginal and Torres Strait Islander adolescents were effective in improving

substance-related outcomes [18]. One explanation for the reduced impact of policies and programs could be that they do not adequately target the unique risk and protective factors that are associated with substance use for Aboriginal and Torres Strait Islander people. Identifying these specific factors has the potential to improve policies and programs that aim to reduce substance use and related harms experienced by Aboriginal and Torres Strait Islander people.

In assessing factors associated with substance use and related harms, it is beneficial to take an ecological approach to ensure that a comprehensive overview is created of the various factors influencing the outcomes of interest [19, 20]. In addition to influences of colonisation, intergenerational trauma and disempowerment, substance use and related harms are influenced by a variety of individual, community, relationship, societal and cultural factors [20-22]. While previous reviews have investigated the association of these factors with substance use for mainstream populations [19, 23-26], to date, no study has synthesised the evidence of risk and protective factors on all ecological levels associated with substance use and related harms for Aboriginal and Torres Strait Islander people in Australia. It is therefore the purpose of this literature review is to provide an overview of the risk and protective factors associated with substance-related outcomes, organised by ecological levels. By focusing on Aboriginal and Torres Strait Islander populations in Australia, this will provide the most robust evidence base to inform the development of culturally appropriate substance use prevention programs for Indigenous Australian youth, to ultimately reduce the health gap between Indigenous and non-Indigenous Australians.

Methods

This protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement [27, 28], found in the Additional File. This protocol has been

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

registered in the PROSPERO registry of the University of York (registration number: CRD42017073734).

Objectives

The overall objective of this review is to identify and synthesise the risk and protective factors associated with substance use and related harms among Aboriginal and Torres Strait Islander people. Specifically, this review will aim to answer the following two questions: 1) what are the risk and protective factors for substance use and related harms among Aboriginal and Torres Strait Islander people, across individual, relationship, community, cultural and societal levels; and 2) what is the methodological quality of studies assessing the factors related to substance use and related harms for Aboriginal and Torres Strait Islander people?

Search strategy

The relevant literature published between 1 January 1990 and 30 April 2018 will be systematically searched in seven electronic peer-reviewed databases and two grey literature databases for quantitative and qualitative studies. Peer-reviewed databases will include: Cochrane, Embase, PsychInfo, Medline, ProQuest, Informit and CINAHL. Following previous literature reviews relating to Aboriginal and Torres Strait Islander health [29, 30], the grey literature databases will be: HeathInfoNet and Closing the Gap Clearinghouse. Table 1 provides an example of the search strategy that will be used in MEDLINE, which will be replicated for the other electronic databases. The

reference lists of selected studies will be assessed for further relevant publications and papers will be solicited from researchers in the field.

[Include Table 1 here]

Search terms will be used to identify studies assessing the risk and protective factors of substance use and related harms for Aboriginal and Torres Strait Islander people. The search terms will be based on previous reviews into factors associated with substance use in adolescents in mainstream populations [19] and factors associated with wellness for Indigenous Peoples [20]. Search terms will be combinations of keywords related to the participants ('Aborigin*' OR "Torres Strait*" OR 'Indigenous' AND Australia), the outcomes (wellbeing OR "mental health" OR substance OR alcohol OR drug OR tobacco) and the factors ('risk' OR protec* OR resilienc* OR underlying OR ecological OR vulnerab* OR 'psychosocial' AND 'factor OR mechanism OR character*'). Two reviewers will independently screen articles, extract data and assess the methodological quality.

Eligibility Criteria

Eligibility criteria for this review are defined using PICOS (population, intervention/exposure, comparator, outcome, study characteristics) [28]. Inclusion criteria will be as follows: 1) 50% or more of the study sample are Aboriginal and Torres Strait Islander people, or a sub-analysis has been conducted for Aboriginal and Torres Strait Islander people when sample is less than 50%; 2) the study identifies or measures risk and/or protective factors for substance use or related harms; 3) the outcome of interest is substance use or related harms; 4) the study was published between 1 January 1990 and 30 April 2018; 5) full-text version is available; and 6) the publication includes a new data analysis. A more detailed description and definition of all PICOS criteria follows.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Population

Studies will be considered if they contain a sample where at least 50% of participants identified as Aboriginal and Torres Strait Islander people. Studies will also be considered if the participant sample included less than 50% of Aboriginal and Torres Strait Islander people but a separate analysis for Aboriginal and Torres Strait Islander people was provided. Participants of all ages will be included.

Exposure

Studies must identify and measure risk and protective factors for substance use and related harms. The factors will be organised using an ecological approach, which includes factors on individual, relationship, community, societal, and culturally distinct levels [20]. Each ecological level is defined as follows:

- **Individual-level factors** include biological and personal history factors such as age, socio-economic status, health and psychosocial factors;
- **Relationship-level factors** include close relationships with peers, partners and family members who influence an individual’s behaviour;
- **Community-level factors** include the individual’s lifestyle settings such as the workplace or geographical location in which social relationships occur;
- **Societal-level factors** include social norms, social policy and availability of substances;
- **Culturally distinct-level factors** include historical contexts, languages, cultural practices, spirituality, values and social structures that are specific to cultural groups.

Comparator

No comparator or control group is necessary for studies to be included in this review. Studies that do include a comparator must compare Aboriginal and Torres Strait Islander people who use substances

(or are heavy users) with Aboriginal and Torres Strait Islander people who do not use substances (or are not heavy users). Papers comparing Aboriginal and Torres Strait Islander people and non-Indigenous Australians will not be included in this review.

Outcomes

The primary outcomes of interest are substance use and associated harms. Outcome types will be classified based on previous research [19] which categorised substance use and related outcomes into three levels: 1) use or frequency; 2) regular, problem, heavy use or binge; 3) use disorder or abuse or dependence. Following Stone et. al (2012), the wording of each category will be consistent across risk and protective factors for inclusion in tables, but categories are defined separately. For risk factors the following definitions will be used:

- **Use or frequency** refers to increased likelihood of substance use initiation, irregular substance use or frequency of use not further specified;
- **Regular, problem, heavy use or binge.** Regular use is an increase in use to at least weekly substance use. Heavy and binge use is an increase in large consumption during one occasion of use. Problem use is an increase in use that causes problems, including substance related injuries or hospitalisations;
- **Use disorder or abuse or dependence** categorises increases in use and symptoms consistent with probable substance use disorder.

For protective factors the following definitions will be used:

- **Use or frequency** refers to a delay in initiation, an increase in abstinence or a reduction in frequency of use not further specified;
- **Regular, problem, heavy use or binge** refers to cessation or reduction of use following a period of regular, heavy or problem substance use and a reduction in substance-related harms;

- **Use disorder or abuse or dependence** refers to substance reduction or recovery from substance use disorder.

Study characteristics

Quantitative observational studies (cross-sectional, longitudinal, cohort and case-control studies) and qualitative studies that provide original data will be included. Reviews, information in books or letters will not be included.

Selection procedure

Reviewer one (BL) will screen all titles and abstracts from the peer-reviewed databases to determine eligibility for inclusion in the review. Reviewer two (MS) will independently screen a random selection of 25% of abstracts to ensure accuracy in the study selection. Reviewer one will screen and assess the eligibility of publications from the grey literature and reference lists of other identified papers. Full-text versions of the potentially eligible studies will be assessed by both reviewers to further determine eligibility for inclusion. Cohen’s kappa will be calculated to assess the inter-rater agreement between the two reviewers at the full-text screening stage. Consultation between reviewers will be held at the time of abstract screening and full-text assessment to reconcile any differences of opinion. If there is no consensus, the senior author (LS) will assess the eligibility of the study.

An excel spreadsheet will be utilised to record the study title, authors, year, database and whether the study meets the eligibility criteria and should be included in the review. During abstract screening and full-text assessment, reasons for inclusion (PICOS) and exclusion will be recorded in

the spreadsheet. Records from this spreadsheet will be used to generate the PRISMA Flowchart (see Figure 1) [31].

[Figure 1 here]

Data management

Bibliographic software (Endnote) will be used for the data management. All the search results from peer-reviewed databases, and screened publications from the grey literature, will be imported into the program. Duplicates will be removed by reviewer one.

Data extraction

Data extraction will be completed by reviewer one, into an excel spreadsheet developed by the authors. The following elements will be extracted from each study: sample size and age, study population, percentage of Aboriginal and/or Torres Strait Islander descent, sex, study characteristics, substance type measured and outcome type (use frequency, problem or heavy use, disorder or abuse), factors significantly associated with increased substance use and related harms (risk), factors significantly associated with reduced substance use and related harms (protective), and the effect size. To facilitate the comparison of risk and protective factors, odd ratios and/or rate ratios will be extracted from the studies. Where odds and/or rate ratios are not provided in the studies, we will calculate the odds ratios by extracting the total number of participants reported in each group of users or non-users who had the risk/protective factor or did not have the risk/protective factor.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Where authors do not provide this information, we will contact the authors to ask them for these data.

Following previous reviews [19, 20], a narrative synthesis of the main results extracted from the studies will be completed. A meta-analysis is likely not warranted given the heterogeneous outcome measures to be included in this review and the known variable quality of studies with Indigenous populations [32]. A summary of each risk and protective factor statistically significantly associated with substance use and related harms will be reported in text, including effect sizes of specific studies. A table of risk and protective factor results will be produced, summarising the authors, study population, sample size and age, substance, outcome type and findings. The ecological framework will be utilised to organise the risk and protective factors within the table, grouping by individual, relationship, community, societal and culturally-distinct levels. Findings will be discussed separately for each ecological level.

Data analysis and quality assessment

Following data extraction, the methodological quality of the studies will be assessed. The quality of quantitative studies will be appraised using the Joanna Briggs Institute Critical Appraisal Checklist for Studies Reporting Prevalence Data [33]. This nine-question tool assesses quality across six domains: selection bias and sample size, study design, potentially confounding factors, data collection methods, statistical analysis and response rate. A scoring system of one-point per question will be used to determine the overall summary rating and allow comparability across publications. The quality of qualitative studies will be appraised using the qualitative assessment tool by Godfrey and Long (2002) [34]. This will allow the reviewers to assess quality in four domains: sample, data collection, analysis and potential researcher bias, and policy and practical implications. A critical

appraisal of all included studies will be completed by reviewer one and reviewer two will assess the quality of a random selection of 25% of included studies to ensure scoring accuracy. Consultation between reviewers will be held to reconcile any differences of opinion.

Discussion

Aboriginal and Torres Strait Islander people experience a higher burden of disease from substance use and related harms compared to their non-Indigenous counterparts [11]. Therefore, identifying which factors are associated with increased rates of substance use and related harms for Aboriginal and Torres Strait Islander people is critical to inform prevention programs and policies. Identifying risk and protective factors associated with substance use will provide a framework that can improve understanding of substance use among Aboriginal and Torres Strait Islander people. This review will provide such a framework based on an ecological model which identifies factors on individual, relationship, community, societal and cultural levels that can lead to a reduction (protective) or increase (risk) in substance use and related harms.

By synthesising evidence regarding the risk and protective factors, this review will provide researchers, policy makers and program developers with robust evidence base to guide the development of prevention programs and policies to specifically target the factors that are relevant for Aboriginal and Torres Strait Islander people. The review will also provide information about community and societal factors, and thus has the potential to guide government policies at a national and state level. This review seeks to improve health and social outcomes for Aboriginal and Torres Strait Islander people, by guiding the focus and tailoring of programs and policies to lead to more effective and impactful substance use prevention initiatives.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figures, tables and additional files

Additional file: PRISMA-P checklist

Data availability

Not applicable.

Funding

This study is supported by funding from the Australian Government Department of Health. LS is supported by a National Health and Medical Research Council (NHMRC) Translating Research into Practice fellowship (GNT1132853). The authors declare that the funders of the study have no influence in developing the protocol and for the conduct of the review.

Competing interests

The authors declare they have no competing interests.

Authors' contributions

MS and LS conceptualised the study. NN, JW and AS contributed to the conceptualisation of the study, including providing input in search terms. JW and AS contributed to definitions of levels of ecological model and cultural advice. All authors developed the study design and protocol. MS and BL wrote the first draft of the manuscript. LS, NN, JW and AS read, revised and approved the final manuscript. MS is guarantor of the review.

Acknowledgements

We acknowledge the input of Professor Maree Teesson, Dr. Cath Chapman, Dr. Katrina Champion, Dr. Louise Birrell and Kate Ross in the design of this protocol as well as the members of the expert advisory group of the Positive Choices project, of which this review is a part.

Authors' information

b.lees@unsw.edu.au, n.newton@unsw.edu.au, l.stapinski@unsw.edu.au , james.ward@sahmri.com,
Annalee.Stearne@telethonkids.org.au

References

1. Malaspinas, A.-S., et al., *A genomic history of Aboriginal Australia*. Nature, 2016. 538(7624): p. 207-214.

2. United Nations, *State of the world's Indigenous Peoples 2009*, New York: UN Permanent Forum on Indigenous Issues (UNPFII).

3. Atkinson, J., *Trauma trails, recreating song lines: the transgenerational effects of trauma in Indigenous Australia*. 2002, North Melbourne: North Melbourne : Spinifex Press.

4. Osborne, K., F. Baum, and L. Brown, *What works? A review of actions addressing the social and economic determinants of Indigenous health*. 2013, Canberra / Melbourne: Australian Institute for Health and Welfare / Australian Institute for Family Studies.

5. Anderson, I., et al., *Indigenous and tribal peoples' health (The Lancet-Lowitja Institute Global Collaboration): A population study*. The Lancet, 2016. 388(10040): p. 131-157.

6. Australian Institute for Health and Welfare, *The health and welfare of Australia's Aboriginal and Torres Strait Islander peoples: 2015*. 2015, Canberra: AIHW.

7. Australian Health Ministers' Advisory Council, *Aboriginal and Torres Strait Islander health performance framework: 2014 report*. 2015, Canberra: AHMAC.

8. Australian Institute for Health and Welfare, *National Drug Strategy Household Survey detailed report*. 2013, Canberra: Australian Government.

9. Gracey, M. and M. King, *Indigenous health part 1: Determinants and disease patterns*. The Lancet, 2009. 374(9683): p. 65-75.

10. Dudgeon, P., et al., *The Gayaa Dhuwi (Proud Spirit) Declaration: A call to action for Aboriginal and Torres Strait Islander leadership in the Australian mental health system*. Advances in Mental Health, 2016. 14(2): p. 126-139.

11. Australian Institute for Health and Welfare, *Australian burden of disease study: Impact and causes of illness and death in Aboriginal and Torres Strait Islander people 2011*. Australian Burden of Disease Study series. Vol. 6. 2016, Canberra: AIHW.

12. Commonwealth of Australia, *National Aboriginal and Torres Strait Islander Health Plan 2013-2023*. 2013, Canberra: Commonwealth of Australia.

13. Intergovernmental Committee on Drugs, *National Aboriginal and Torres Strait Islander Peoples' Drug Strategy 2014-2019*. 2014, Canberra: Commonwealth of Australia.

14. Altman, J.C., N. Biddle, and B.H. Hunter, *A historical perspective on indigenous socioeconomic outcomes in Australia, 1971-2001*. Australian Economic History Review, 2005. 45(3): p. 273-295.

15. Ring, I.T., et al., *Are Indigenous mortality gaps closing: How to tell, and when?* Medical Journal of Australia, 2016. 205(1): p. 11-12.

16. d'Abbs, P., *Widening the gap: The gulf between policy rhetoric and implementation reality in addressing alcohol problems among Indigenous Australians*. Drug and Alcohol Review, 2015. 34(5): p. 461-466.
17. Lovett, R., K. Thurber, and R. Maddox, *The Aboriginal and Torres Strait Islander smoking epidemic: what stage are we at, and what does it mean?* Public Health Research & Practice, 2017. 27(4): p.2741733.
18. Snijder, M., et al., *Preventing substance use among Indigenous adolescents in the United States of America, Canada, Australia and New Zealand: A systematic review of the literature*. Journal of the American Academy of Child and Adolescent Psychiatry, submitted.
19. Stone, A.L., et al., *Review of risk and protective factors of substance use and problem use in emerging adulthood*. Addictive Behaviors, 2012. 37(7): p. 747-775.
20. Burnette, C.E. and C.R. Figley, *Historical Oppression, Resilience, and Transcendence: Can a Holistic Framework Help Explain Violence Experienced by Indigenous People?* Social Work, 2017. 62(1): p. 37-44.
21. Midford, R., T. Stockwell, and D. Gray, *Prevention of alcohol-related harm: Community-based interventions*, in *National alcohol research agenda*, Commonwealth Department of Health and Ageing, Editor. 2002, Commonwealth Department of Health and Ageing: Canberra. p. 91-112.
22. Bronfenbrenner, U. and P.A. Morris, *The ecology of developmental processes*, in *Handbook of child psychology*, W. Damon and R. Lerner, Editors. 1998, John Wiley & Sons Hoboken, NJ, US. p. 993-1028.
23. Hawkins, J.D., R.F. Catalano, and J.Y. Miller, *Risk and protective factors for alcohol and other drug problems in adolescence and early adulthood: Implications for substance abuse prevention*. Psychological bulletin, 1992. 112(1): p. 64-105.
24. Bryden, A., et al., *A systematic review of the influence of community level social factors on alcohol use*. Health & Place, 2013. 21: p. 70-85.
25. Donovan, J.E., *Adolescent alcohol initiation: A review of psychosocial risk factors*. Journal of adolescent health, 2004. 35(6): p. 529. e7-18.
26. Ryan, S.M., A.F. Jorm, and D.I. Lubman, *Parenting factors associated with reduced adolescent alcohol use: a systematic review of longitudinal studies*. Australian and New Zealand Journal of Psychiatry, 2010. 44(9): p. 774-783.
27. Moher, D., et al., *Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement*. Annals of Internal Medicine, 2009. 151(4): p. 264-269.
28. Shamseer, L., et al., *Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: Elaboration & explanation*. BMJ, 2015. 349.
29. Snijder, M., et al., *A systematic review of studies evaluating Australian indigenous community development projects: The extent of community participation, their methodological quality and their outcomes*. BMC Public Health, 2015. 15(1): p. 1-16.

30. Snijder, M., et al., *Substance use prevention programs for Indigenous adolescents in the United States of America, Canada, Australia and New Zealand: Protocol for a systematic review*. JMIR Research Protocols, 2018. 7(2): p. e38.

31. Fairley, C.K., et al., *Randomized trial of an adherence programme for clients with HIV*. International Journal of STDs & AIDS, 2003. 14(12): p. 805-809.

32. Clifford, A. and A. Shakeshaft, *A bibliometric review of drug and alcohol research focused on Indigenous peoples of Australia, New Zealand, Canada and the United States*. Drug and Alcohol Review, 2017. 36(4): p. 509-522.

33. Munn, Z., et al., *Methodological guidance for systematic reviews of observational epidemiological studies reporting prevalence and incidence data*. International Journal of Evidence Based Healthcare, 2015. 13(3): p. 147-153.

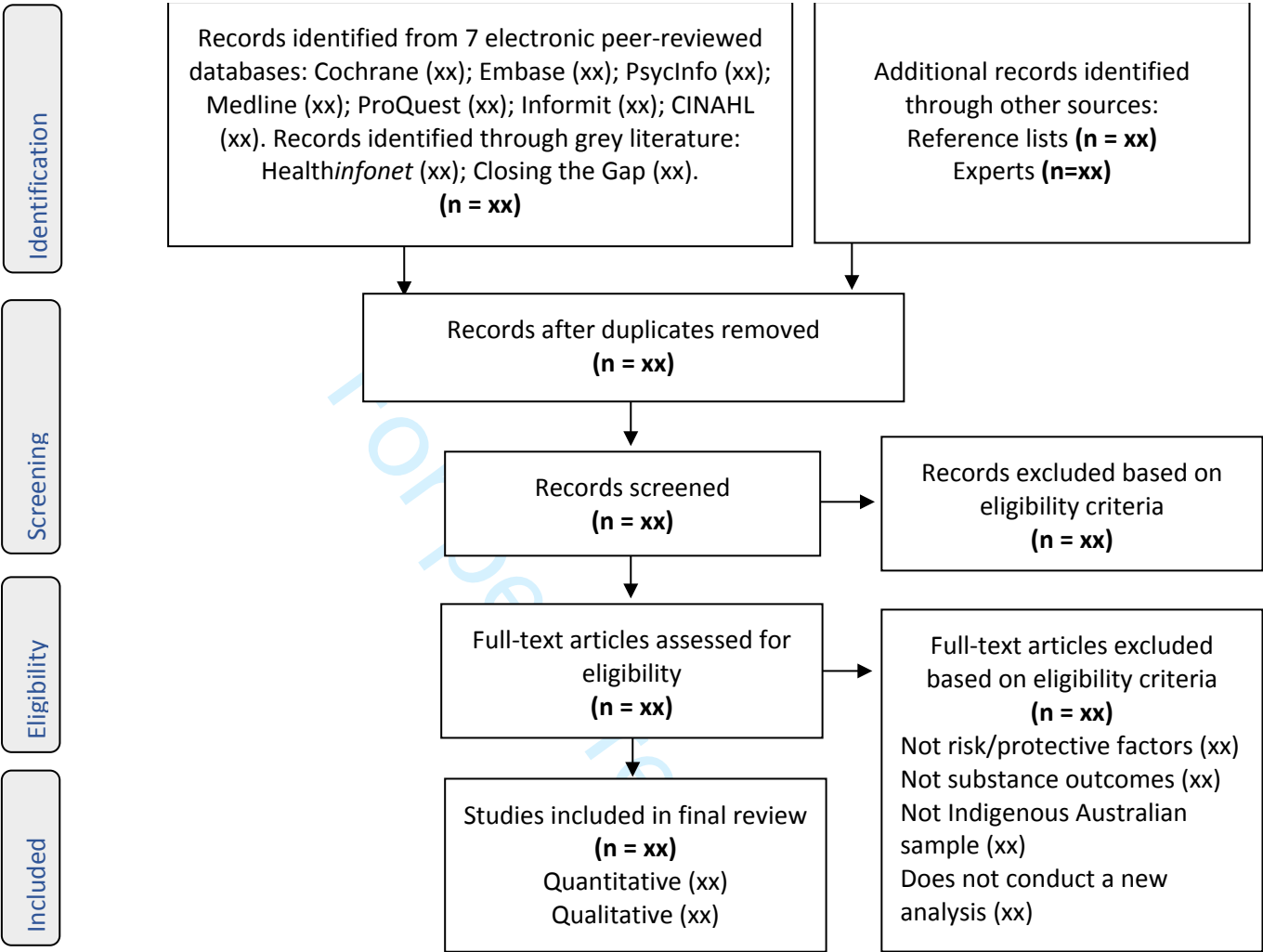
34. Long, A.F., et al., *Developing evidence based social care policy and practice. Part 3: Feasibility of undertaking systematic reviews in social care*. 2002, Leeds: Nuffield Institute for Health.

Table 1 Search strategy for systematic review of risk and protective factors of substance use and related harms among Aboriginal and Torres Strait Islander People (example: Medline search)

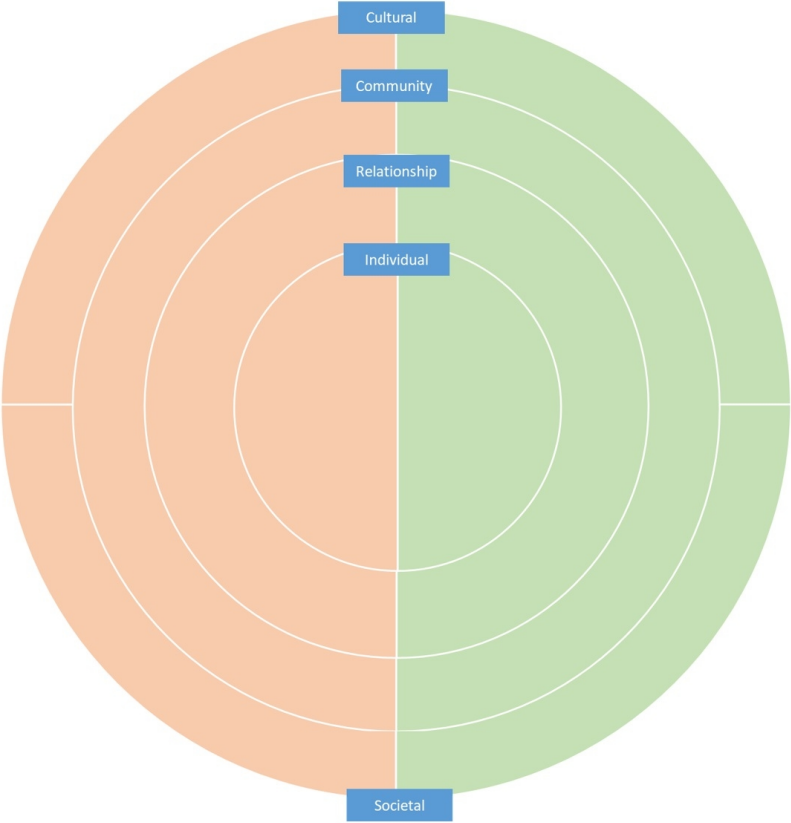
1	((Aborigin* OR "Torres Strait Islander" OR Indigenous) and Australia).mp.
2	((risk OR protec* OR resilienc* OR underlying OR ecological OR vulnerab* OR psychosocial) AND (factor OR mechanism OR character*).mp.
3	(wellbeing OR mental health OR substance OR alcohol OR drug OR tobacco).mp.
4	limit 1 to yr="1990 - 2017"
[mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Figure 1 PRIMSA flow diagram of systematic review of studies assessing factors associated with substance use among Indigenous Australians.

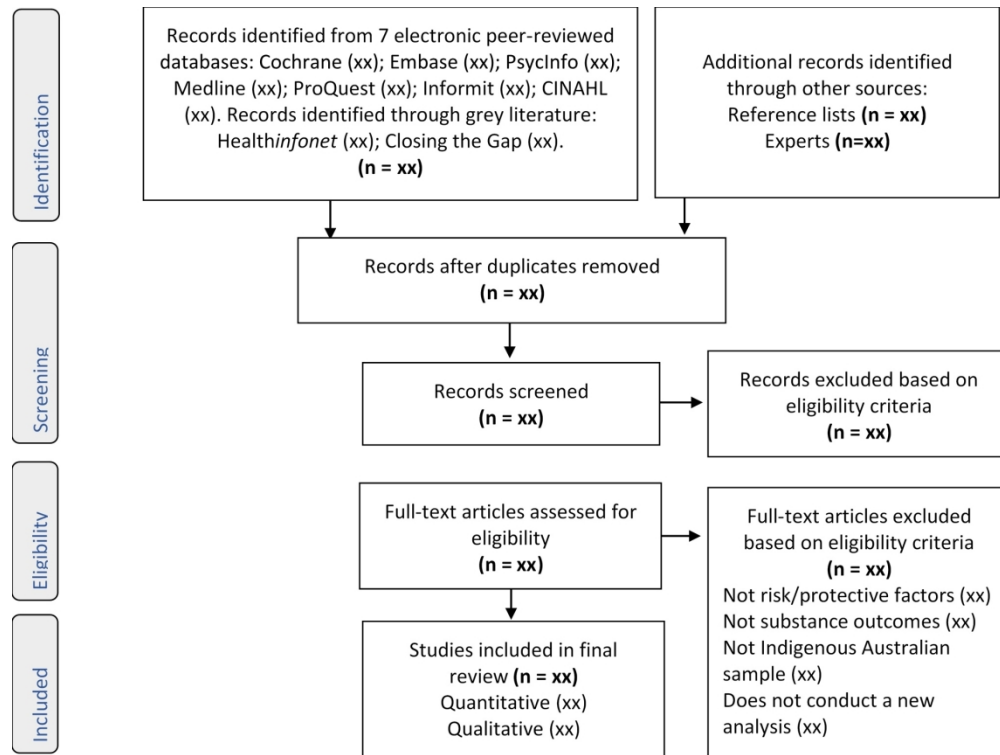


For peer review only



Proposed ecological model of risk and protective factors associated with substance use and related harms among Aboriginal and Torres Strait Islander people

118x98mm (288 x 288 DPI)



PRISMA-P Flow Diagram

179x135mm (288 x 288 DPI)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Additional file to: Snijder et al. *Developing an ecological framework of factors associated with substance use and related harms among Aboriginal and Torres Strait Islander People: Protocol for a systematic review.*

Section and topic	Item No	Checklist item	Information reported
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	<input checked="" type="checkbox"/>
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	<input type="checkbox"/>
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	<input checked="" type="checkbox"/>
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	<input checked="" type="checkbox"/>
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	<input checked="" type="checkbox"/>
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify such and list changes; otherwise, state plan for documenting important protocol amendments	<input type="checkbox"/>
Support:			
Sources	5a	Indicate sources of financial or other support for the review	<input checked="" type="checkbox"/>

Sponsor	5b	Provide name for the review funder and/or sponsor	<input checked="" type="checkbox"/>
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	<input checked="" type="checkbox"/>
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	<input checked="" type="checkbox"/>
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, outcomes and study characteristics (PICOS)	<input checked="" type="checkbox"/>
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICOS, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	<input checked="" type="checkbox"/>
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	<input checked="" type="checkbox"/>
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	<input checked="" type="checkbox"/>
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	<input checked="" type="checkbox"/>
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	<input checked="" type="checkbox"/>
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	<input checked="" type="checkbox"/>

Data items	12	List and define all variables for which data will be sought (such as PICOS items, funding sources), any pre-planned data assumptions and simplifications	<input checked="" type="checkbox"/>
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	<input checked="" type="checkbox"/>
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	<input checked="" type="checkbox"/>
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	<input type="checkbox"/>
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	<input type="checkbox"/>
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	<input type="checkbox"/>
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	<input checked="" type="checkbox"/>
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	<input type="checkbox"/>
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	<input checked="" type="checkbox"/>

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

For peer review only

BMJ Open

Developing an ecological framework of factors associated with substance use and related harms among Aboriginal and Torres Strait Islander People: Protocol for a systematic review

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-024418.R2
Article Type:	Protocol
Date Submitted by the Author:	26-Feb-2019
Complete List of Authors:	Snijder, Mieke; University of Sydney, The Matilda Centre for Research in Mental Health and Substance Use Lees, Briana; University of Sydney, The Matilda Centre for Research in Mental Health and Substance Use Ward, James; South Australia Health and Medical Research Centre; Flinders University Faculty of Medicine Nursing and Health Sciences Stearne, Annalee; Curtin University National Drug Research Institute Newton, Nicola; University of Sydney, The Matilda Centre for Research in Mental Health and Substance Use Stapinski, Lexine; University of Sydney, The Matilda Centre for Research in Mental Health and Substance Use
Primary Subject Heading:	Public health
Secondary Subject Heading:	Addiction, Epidemiology, Global health, Mental health, Public health
Keywords:	Indigenous, PREVENTIVE MEDICINE, Substance misuse < PSYCHIATRY, EPIDEMIOLOGY

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Title: Developing an ecological framework of factors associated with substance use and related harms among Aboriginal and Torres Strait Islander People: Protocol for a systematic review

Authors: Snijder, M.¹, Lees, B.¹, Ward, J.^{2,3}, Stearne, A.⁴, Newton, N.¹, & Stapinski, L.¹

¹ *The Matilda Centre for Research in Mental Health and Substance Use, The University of Sydney, Australia*

² *South Australian Health and Medical Research Institute, Adelaide, South Australia*

³ *Flinders University, Adelaide, South Australia.*

⁴ *Telethon Kids Institute, Perth, Western Australia*

Keywords: Aboriginal and Torres Strait Islander people, Indigenous, substance use, alcohol and other drug, tobacco, risk factors, protective factors

Word count: 2,615

Corresponding Author: Mieke Snijder, mieke.snijder@sydney.edu.au, +61 2 8627 9038 The Matilda Centre, The University of Sydney, Darlingtown NSW 2006 Australia

Abstract

Introduction: Aboriginal and Torres Strait Islander people experience high rates of substance use and related harms. Previous prevention programs and policies have met with limited success, particularly among youth, and this may be a result of inadequately targeting the unique risk and protective factors associated with substance use for Aboriginal and Torres Strait Islander people. The purpose of this systematic review is to therefore synthesise the risk and protective factors associated with substance use and related harms among Aboriginal and Torres Strait Islander people, and critically appraise the methodological quality of the included studies.

Methods and analysis: A total of seven peer-reviewed (Cochrane, Embase, PsychInfo, Medline, ProQuest, Informit, CINAHL) and two grey literature (HeathInfoNet, Closing the Gap Clearinghouse) databases will be systematically searched using search terms in line with the aims of this review and based on previous relevant reviews. Studies published between 1 January 1990 and 31 April 2018 will be included if they identify risk and/or protective factors for substance use or related harms in a study sample that consists of at least 50% Aboriginal and Torres Strait Islander people. A narrative synthesis will be undertaken where the identified factors will be organised using an ecological approach into individual, relationship, community, societal and cultural levels. A critical appraisal of study quality will be conducted using the Joanna Briggs Institute Critical Appraisal Checklist for Studies Reporting Prevalence Data and the qualitative assessment tool by Godfrey and Long.

Ethics and dissemination: Formal ethics approval is not required as primary data will not be collected. The results will be disseminated through a peer-reviewed publication, conference presentations and social media.

Trial registration number: International Prospective Register for Systematic Reviews (PROSPERO) number: CRD42017073734.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Strengths and limitations of this study

- This systematic review will be the first to synthesise the risk and protective factors associated with substance use and related harms among Aboriginal and Torres Strait Islander people, identified from peer-reviewed and grey literature publications.
- This review will move away from an individual-level focus on substance use prevention towards an ecological approach, which can be used by program developers, researchers and policy makers when deciding on intervention strategies.
- The expected heterogeneous outcomes of the included papers means we will not conduct a meta-analysis and will likely reduce the quality of the final model.

Introduction

Aboriginal and Torres Strait Islander People have the oldest continuing culture in the world [1]. Like other Indigenous Peoples around the world, many Aboriginal and Torres Strait Islander people's livelihoods were severely disrupted upon colonisation, with people often forcibly removed from their traditional lands and prevented from utilising their traditional laws and culture. This has resulted in negative impacts on wellbeing and sense of place in contemporary society, including a reduced sense of self-determination [2]. The cycle of dispossession and disempowerment resulting from colonisation, combined with ongoing policy failures in social services and health, continues to negatively impact many Aboriginal and Torres Strait Islander people, as evidenced by the poorer health and social outcomes when compared to non-Indigenous Australians [3-9].

Despite evidence of resilience in dealing with poorer outcomes on social determinants of health, Aboriginal and Torres Strait Islander people experience high rates of substance use and related harms [3, 10]. For example, among Aboriginal and Torres Strait Islander people aged 44 years and younger, mental health and substance use disorders are the leading cause of disease and they account for 14% of the health gap between Aboriginal and Torres Strait Islander people and non-Indigenous Australians [11]. As substance use is a modifiable risk factor for disease, it is therefore an important target area to close the gap in health outcomes between Aboriginal and Torres Strait Islander people and non-Indigenous Australians [12, 13].

While past prevention programs and policies have made some improvements in substance use-related outcomes over the past decades, these achievements have been slow and insufficient to reduce substance use and related harms among Aboriginal and Torres Strait Islander people [14-17]. For example, a recent literature review found that only three out of six substance use prevention programs for Aboriginal and Torres Strait Islander adolescents were effective in improving

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

substance-related outcomes [18]. One explanation for the reduced impact of policies and programs could be that they do not adequately target the unique risk and protective factors that are associated with substance use for Aboriginal and Torres Strait Islander people. Identifying these specific factors has the potential to improve policies and programs that aim to reduce substance use and related harms experienced by Aboriginal and Torres Strait Islander people.

In assessing factors associated with substance use and related harms, it is beneficial to take an ecological approach to ensure that a comprehensive overview is created of the various factors influencing the outcomes of interest [19, 20]. In addition to influences of colonisation, intergenerational trauma and disempowerment, substance use and related harms are influenced by a variety of individual, community, relationship, societal and cultural factors [20-22]. While previous reviews have investigated the association of these factors with substance use for mainstream populations [19, 23-26], to date, no study has synthesised the evidence of risk and protective factors on all ecological levels associated with substance use and related harms for Aboriginal and Torres Strait Islander people in Australia. It is therefore the purpose of this literature review is to provide an overview of the risk and protective factors associated with substance-related outcomes, organised by ecological levels. By focusing on Aboriginal and Torres Strait Islander populations in Australia, this will provide the most robust evidence base to inform the development of culturally appropriate substance use prevention programs for Indigenous Australian youth, to ultimately reduce the health gap between Indigenous and non-Indigenous Australians.

Methods and analysis

This protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement [27, 28], found in the Additional File. This protocol has been

registered in the PROSPERO registry of the University of York (registration number: CRD42017073734).

Objectives

The overall objective of this review is to identify and synthesise the risk and protective factors associated with substance use and related harms among Aboriginal and Torres Strait Islander people. Specifically, this review will aim to answer the following two questions: 1) what are the risk and protective factors for substance use and related harms among Aboriginal and Torres Strait Islander people, across individual, relationship, community, cultural and societal levels; and 2) what is the methodological quality of studies assessing the factors related to substance use and related harms for Aboriginal and Torres Strait Islander people?

Search strategy

The relevant literature published between 1 January 1990 and 30 April 2018 will be systematically searched in seven electronic peer-reviewed databases and two grey literature databases for quantitative and qualitative studies. Peer-reviewed databases will include: Cochrane, Embase, PsychInfo, Medline, ProQuest, Informit and CINAHL. Following previous literature reviews relating to Aboriginal and Torres Strait Islander health [29, 30], the grey literature databases will be: *HeathInfoNet* and Closing the Gap Clearinghouse. Table 1 provides an example of the search strategy that will be used in MEDLINE, which will be replicated for the other electronic databases. The

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

reference lists of selected studies will be assessed for further relevant publications and papers will be solicited from researchers in the field.

[Include Table 1 here]

Search terms will be used to identify studies assessing the risk and protective factors of substance use and related harms for Aboriginal and Torres Strait Islander people. The search terms will be based on previous reviews into factors associated with substance use in adolescents in mainstream populations [19] and factors associated with wellness for Indigenous Peoples [20]. Search terms will be combinations of keywords related to the participants ('Aborigin*' OR "Torres Strait*" OR Indigenous' AND Australia), the outcomes (wellbeing OR "mental health" OR substance OR alcohol OR drug OR tobacco) and the factors ('risk' OR protec* OR resilienc* OR underlying OR ecological OR vulnerab* OR 'psychosocial' AND 'factor OR mechanism OR character*'). Two reviewers will independently screen articles, extract data and assess the methodological quality.

Eligibility Criteria

Eligibility criteria for this review are defined using PICOS (population, intervention/exposure, comparator, outcome, study characteristics) [28]. Inclusion criteria will be as follows: 1) 50% or more of the study sample are Aboriginal and Torres Strait Islander people, or a sub-analysis has been conducted for Aboriginal and Torres Strait Islander people when sample is less than 50%; 2) the study identifies or measures risk and/or protective factors for substance use or related harms; 3) the outcome of interest is substance use or related harms; 4) the study was published between 1 January 1990 and 30 April 2018; 5) full-text version is available; and 6) the publication includes a new data analysis. A more detailed description and definition of all PICOS criteria follows.

Population

Studies will be considered if they contain a sample where at least 50% of participants identified as Aboriginal and Torres Strait Islander people. Studies will also be considered if the participant sample included less than 50% of Aboriginal and Torres Strait Islander people but a separate analysis for Aboriginal and Torres Strait Islander people was provided. Participants of all ages will be included.

Exposure

Studies must identify and measure risk and protective factors for substance use and related harms. The factors will be organised using an ecological approach, which includes factors on individual, relationship, community, societal, and culturally distinct levels [20] (See Figure 1 for proposed model). Each ecological level is defined as follows:

- **Individual-level factors** include biological and personal history factors such as age, socio-economic status, health and psychosocial factors;
- **Relationship-level factors** include close relationships with peers, partners and family members who influence an individual's behaviour;
- **Community-level factors** include the individual's lifestyle settings such as the workplace or geographical location in which social relationships occur;
- **Societal-level factors** include social norms, social policy and availability of substances;
- **Culturally distinct-level factors** include historical contexts, languages, cultural practices, spirituality, values and social structures that are specific to cultural groups.

[Figure 1 here]

Comparator

No comparator or control group is necessary for studies to be included in this review. Studies that do include a comparator must compare Aboriginal and Torres Strait Islander people who use substances (or are heavy users) with Aboriginal and Torres Strait Islander people who do not use substances (or are not heavy users). Papers comparing Aboriginal and Torres Strait Islander people and non-Indigenous Australians will not be included in this review.

Outcomes

The primary outcomes of interest are substance use and associated harms. Outcome types will be classified based on previous research [19] which categorised substance use and related outcomes into three levels: 1) use or frequency; 2) regular, problem, heavy use or binge; 3) use disorder or abuse or dependence. Following Stone et. al (2012), the wording of each category will be consistent across risk and protective factors for inclusion in tables, but categories are defined separately. For risk factors the following definitions will be used:

- **Use or frequency** refers to increased likelihood of substance use initiation, irregular substance use or frequency of use not further specified;
- **Regular, problem, heavy use or binge.** Regular use is an increase in use to at least weekly substance use. Heavy and binge use is an increase in large consumption during one occasion of use. Problem use is an increase in use that causes problems, including substance related injuries or hospitalisations;
- **Use disorder or abuse or dependence** categorises increases in use and symptoms consistent with probable substance use disorder.

For protective factors the following definitions will be used:

- **Use or frequency** refers to a delay in initiation, an increase in abstinence or a reduction in frequency of use not further specified;

- **Regular, problem, heavy use or binge** refers to cessation or reduction of use following a period of regular, heavy or problem substance use and a reduction in substance-related harms;
- **Use disorder or abuse or dependence** refers to substance reduction or recovery from substance use disorder.

Study characteristics

Quantitative observational studies (cross-sectional, longitudinal, cohort and case-control studies) and qualitative studies that provide original data will be included. Reviews, information in books or letters will not be included.

Selection procedure

Reviewer one (BL) will screen all titles and abstracts from the peer-reviewed databases to determine eligibility for inclusion in the review. Reviewer two (MS) will independently screen a random selection of 25% of abstracts to ensure accuracy in the study selection. Reviewer one will screen and assess the eligibility of publications from the grey literature and reference lists of other identified papers. Full-text versions of the potentially eligible studies will be assessed by both reviewers to further determine eligibility for inclusion. Cohen's kappa will be calculated to assess the inter-rater agreement between the two reviewers at the full-text screening stage. Consultation between reviewers will be held at the time of abstract screening and full-text assessment to reconcile any differences of opinion. If there is no consensus, the senior author (LS) will assess the eligibility of the study.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

An excel spreadsheet will be utilised to record the study title, authors, year, database and whether the study meets the eligibility criteria and should be included in the review. During abstract screening and full-text assessment, reasons for inclusion (PICOS) and exclusion will be recorded in the spreadsheet. Records from this spreadsheet will be used to generate the PRISMA Flowchart (see Figure 2) [31].

[Figure 2 here]

Data management

Bibliographic software (Endnote) will be used for the data management. All the search results from peer-reviewed databases, and screened publications from the grey literature, will be imported into the program. Duplicates will be removed by reviewer one.

Data extraction

Data extraction will be completed by reviewer one, into an excel spreadsheet developed by the authors. The following elements will be extracted from each study: sample size and age, study population, percentage of Aboriginal and/or Torres Strait Islander descent, sex, study characteristics, substance type measured and outcome type (use frequency, problem or heavy use, disorder or abuse), factors significantly associated with increased substance use and related harms (risk), factors significantly associated with reduced substance use and related harms (protective), and the effect size. To facilitate the comparison of risk and protective factors, odd ratios and/or rate ratios will be

1
2
3 extracted from the studies. Where odds and/or rate ratios are not provided in the studies, we will
4
5 calculate the odds ratios by extracting the total number of participants reported in each group of
6
7 users or non-users who had the risk/protective factor or did not have the risk/protective factor.
8
9

10 Where authors do not provide this information, we will contact the authors to ask them for these
11
12 data.
13
14
15

16 Following previous reviews [19, 20], a narrative synthesis of the main results extracted from the
17
18 studies will be completed. A meta-analysis is likely not warranted given the heterogeneous outcome
19
20 measures to be included in this review and the known variable quality of studies with Indigenous
21
22 populations [32]. A summary of each risk and protective factor statistically significantly associated
23
24 with substance use and related harms will be reported in text, including effect sizes of specific
25
26 studies. A table of risk and protective factor results will be produced, summarising the authors, study
27
28 population, sample size and age, substance, outcome type and findings. The ecological framework
29
30 will be utilised to organise the risk and protective factors within the table, grouping by individual,
31
32 relationship, community, societal and culturally-distinct levels. Findings will be discussed separately
33
34 for each ecological level.
35
36
37
38
39
40
41
42
43

44 Data analysis and quality assessment

45
46
47

48 Following data extraction, the methodological quality of the studies will be assessed. The quality of
49
50 quantitative studies will be appraised using the Joanna Briggs Institute Critical Appraisal Checklist for
51
52 Studies Reporting Prevalence Data [33]. This nine-question tool assesses quality across six domains:
53
54 selection bias and sample size, study design, potentially confounding factors, data collection
55
56 methods, statistical analysis and response rate. A scoring system of one-point per question will be
57
58 used to determine the overall summary rating and allow comparability across publications. The
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

quality of qualitative studies will be appraised using the qualitative assessment tool by Godfrey and Long (2002) [34]. This will allow the reviewers to assess quality in four domains: sample, data collection, analysis and potential researcher bias, and policy and practical implications. A critical appraisal of all included studies will be completed by reviewer one and reviewer two will assess the quality of a random selection of 25% of included studies to ensure scoring accuracy. Consultation between reviewers will be held to reconcile any differences of opinion.

Patient and public involvement

Patients and the public were not involved in this systematic review protocol.

Ethics and dissemination

Ethical approval is not required for this study. The systematic review will be published in a peer-reviewed journal, presented at conferences and will be shared on social media platforms.

Conclusion

Aboriginal and Torres Strait Islander people experience a higher burden of disease from substance use and related harms compared to their non-Indigenous counterparts [11]. Therefore, identifying which factors are associated with increased rates of substance use and related harms for Aboriginal and Torres Strait Islander people is critical to inform prevention programs and policies. Identifying risk and protective factors associated with substance use will provide a framework that can improve understanding of substance use among Aboriginal and Torres Strait Islander people. This review will provide such a framework based on an ecological model which identifies factors on individual,

relationship, community, societal and cultural levels that can lead to a reduction (protective) or increase (risk) in substance use and related harms.

By synthesising evidence regarding the risk and protective factors, this review will provide researchers, policy makers and program developers with robust evidence base to guide the development of prevention programs and policies to specifically target the factors that are relevant for Aboriginal and Torres Strait Islander people. The review will also provide information about community and societal factors, and thus has the potential to guide government policies at a national and state level. This review seeks to improve health and social outcomes for Aboriginal and Torres Strait Islander people, by guiding the focus and tailoring of programs and policies to lead to more effective and impactful substance use prevention initiatives.

References

1. Malaspinas, A.-S., et al., *A genomic history of Aboriginal Australia*. Nature, 2016. 538(7624): p. 207-214.

2. United Nations, *State of the world's Indigenous Peoples* 2009, New York: UN Permanent Forum on Indigenous Issues (UNPFII).

3. Atkinson, J., *Trauma trails, recreating song lines: the transgenerational effects of trauma in Indigenous Australia*. 2002, North Melbourne: North Melbourne : Spinifex Press.

4. Osborne, K., F. Baum, and L. Brown, *What works? A review of actions addressing the social and economic determinants of Indigenous health*. 2013, Canberra / Melbourne: Australian Institute for Health and Welfare / Australian Institute for Family Studies.

5. Anderson, I., et al., *Indigenous and tribal peoples' health (The Lancet-Lowitja Institute Global Collaboration): A population study*. The Lancet, 2016. 388(10040): p. 131-157.

6. Australian Institute for Health and Welfare, *The health and welfare of Australia's Aboriginal and Torres Strait Islander peoples: 2015*. 2015, Canberra: AIHW.

7. Australian Health Ministers' Advisory Council, *Aboriginal and Torres Strait Islander health performance framework: 2014 report*. 2015, Canberra: AHMAC.

8. Australian Institute for Health and Welfare, *National Drug Strategy Household Survey detailed report*. 2013, Canberra: Australian Government.

9. Gracey, M. and M. King, *Indigenous health part 1: Determinants and disease patterns*. The Lancet, 2009. 374(9683): p. 65-75.

10. Dudgeon, P., et al., *The Gayaa Dhuwi (Proud Spirit) Declaration: A call to action for Aboriginal and Torres Strait Islander leadership in the Australian mental health system*. Advances in Mental Health, 2016. 14(2): p. 126-139.

11. Australian Institute for Health and Welfare, *Australian burden of disease study: Impact and causes of illness and death in Aboriginal and Torres Strait Islander people 2011*. Australian Burden of Disease Study series. Vol. 6. 2016, Canberra: AIHW.

12. Commonwealth of Australia, *National Aboriginal and Torres Strait Islander Health Plan 2013-2023*. 2013, Canberra: Commonwealth of Australia.

13. Intergovernmental Committee on Drugs, *National Aboriginal and Torres Strait Islander Peoples' Drug Strategy 2014-2019*. 2014, Canberra: Commonwealth of Australia.

14. Altman, J.C., N. Biddle, and B.H. Hunter, *A historical perspective on indigenous socioeconomic outcomes in Australia, 1971-2001*. Australian Economic History Review, 2005. 45(3): p. 273-295.

15. Ring, I.T., et al., *Are Indigenous mortality gaps closing: How to tell, and when?* Medical Journal of Australia, 2016. 205(1): p. 11-12.

16. d'Abbs, P., *Widening the gap: The gulf between policy rhetoric and implementation reality in addressing alcohol problems among Indigenous Australians*. Drug and Alcohol Review, 2015. 34(5): p. 461-466.
17. Lovett, R., K. Thurber, and R. Maddox, *The Aboriginal and Torres Strait Islander smoking epidemic: what stage are we at, and what does it mean?* Public Health Research & Practice, 2017. 27(4): p.2741733.
18. Snijder, M., et al., *Preventing substance use among Indigenous adolescents in the United States of America, Canada, Australia and New Zealand: A systematic review of the literature*. Journal of the American Academy of Child and Adolescent Psychiatry, submitted.
19. Stone, A.L., et al., *Review of risk and protective factors of substance use and problem use in emerging adulthood*. Addictive Behaviors, 2012. 37(7): p. 747-775.
20. Burnette, C.E. and C.R. Figley, *Historical Oppression, Resilience, and Transcendence: Can a Holistic Framework Help Explain Violence Experienced by Indigenous People?* Social Work, 2017. 62(1): p. 37-44.
21. Midford, R., T. Stockwell, and D. Gray, *Prevention of alcohol-related harm: Community-based interventions*, in *National alcohol research agenda*, Commonwealth Department of Health and Ageing, Editor. 2002, Commonwealth Department of Health and Ageing: Canberra. p. 91-112.
22. Bronfenbrenner, U. and P.A. Morris, *The ecology of developmental processes*, in *Handbook of child psychology*, W. Damon and R. Lerner, Editors. 1998, John Wiley & Sons Hoboken, NJ, US. p. 993-1028.
23. Hawkins, J.D., R.F. Catalano, and J.Y. Miller, *Risk and protective factors for alcohol and other drug problems in adolescence and early adulthood: Implications for substance abuse prevention*. Psychological bulletin, 1992. 112(1): p. 64-105.
24. Bryden, A., et al., *A systematic review of the influence of community level social factors on alcohol use*. Health & Place, 2013. 21: p. 70-85.
25. Donovan, J.E., *Adolescent alcohol initiation: A review of psychosocial risk factors*. Journal of adolescent health, 2004. 35(6): p. 529. e7-18.
26. Ryan, S.M., A.F. Jorm, and D.I. Lubman, *Parenting factors associated with reduced adolescent alcohol use: a systematic review of longitudinal studies*. Australian and New Zealand Journal of Psychiatry, 2010. 44(9): p. 774-783.
27. Moher, D., et al., *Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement*. Annals of Internal Medicine, 2009. 151(4): p. 264-269.
28. Shamseer, L., et al., *Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: Elaboration & explanation*. BMJ, 2015. 349.
29. Snijder, M., et al., *A systematic review of studies evaluating Australian indigenous community development projects: The extent of community participation, their methodological quality and their outcomes*. BMC Public Health, 2015. 15(1): p. 1-16.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

30. Snijder, M., et al., *Substance use prevention programs for Indigenous adolescents in the United States of America, Canada, Australia and New Zealand: Protocol for a systematic review*. JMIR Research Protocols, 2018. 7(2): p. e38.

31. Fairley, C.K., et al., *Randomized trial of an adherence programme for clients with HIV*. International Journal of STDs & AIDS, 2003. 14(12): p. 805-809.

32. Clifford, A. and A. Shakeshaft, *A bibliometric review of drug and alcohol research focused on Indigenous peoples of Australia, New Zealand, Canada and the United States*. Drug and Alcohol Review, 2017. 36(4): p. 509-522.

33. Munn, Z., et al., *Methodological guidance for sestematic reviews of observational epidemiological studies reporting prevalence and incidence data*. International Journal of Evidence Based Healthcare, 2015. 13(3): p. 147-153.

34. Long, A.F., et al., *Developing evidence based social care policy and practice. Part 3: Feasibility of undertaking systematic reviews in social care*. 2002, Leeds: Nuffield Institute for Health.

Figure legends

Figure 1 Proposed ecological model resulting from the systematic literature review

Figure 2 PRIMSA flow diagram of systematic review of studies assessing factors associated with substance use among Indigenous Australians.

Tables

1	((Aborigin* OR "Torres Strait Islander" OR Indigenous) and Australia).mp.
2	((risk OR protec* OR resilienc* OR underlying OR ecological OR vulnerab* OR psychosocial) AND (factor OR mechanism OR character*).mp.
3	(wellbeing OR mental health OR substance OR alcohol OR drug OR tobacco).mp.
4	limit 1 to yr="1990 - 2017"
[mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]	

Table 1 Search strategy for systematic review of risk and protective factors of substance use and related harms among Aboriginal and Torres Strait Islander People (example: Medline search)

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Authors’ contributions:

MS and LS conceptualised the study. NN, JW and AS contributed to the conceptualisation of the study, including providing input in search terms. JW and AS contributed to definitions of levels of ecological model and cultural advice. All authors developed the study design and protocol. MS and BL wrote the first draft of the manuscript. LS, NN, JW and AS read, revised and approved the final manuscript. MS is guarantor of the review.

Acknowledgements

We acknowledge the input of Professor Maree Teesson, Associate Professor Cath Chapman, Dr. Katrina Champion, Dr. Louise Birrell and Kate Ross in the design of this protocol as well as the members of the expert advisory group of the Positive Choices project, of which this review is a part.

Funding statement:

This work is supported by the Australian Government Department of Health, grant number.BL is supported by a National Health and Medical Research Council Postgraduate Scholarship (GNT1169377), NN is supported by a National Health and Medical Research Council Career Development Fellowship (GNT1166377), and LS is supported by a National Health and Medical Research Council Translating Research into Practice fellowship (GNT1132853). The authors declare that the funders of the study have no influence in developing the protocol and for the conduct of the review.

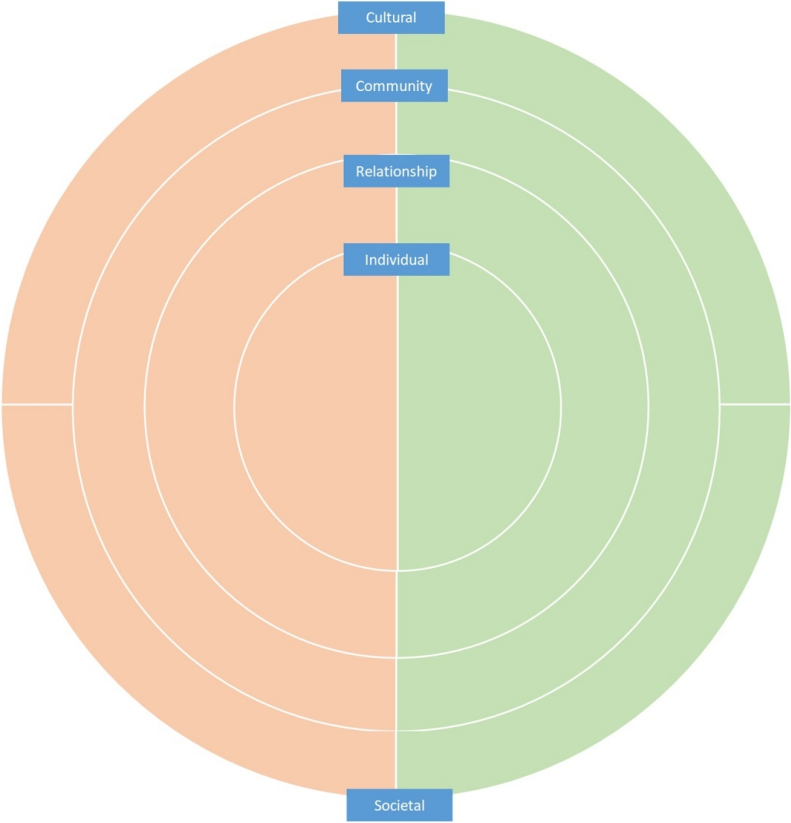
Competing interests:

The authors declare they have no competing interests.

Supplement Files:

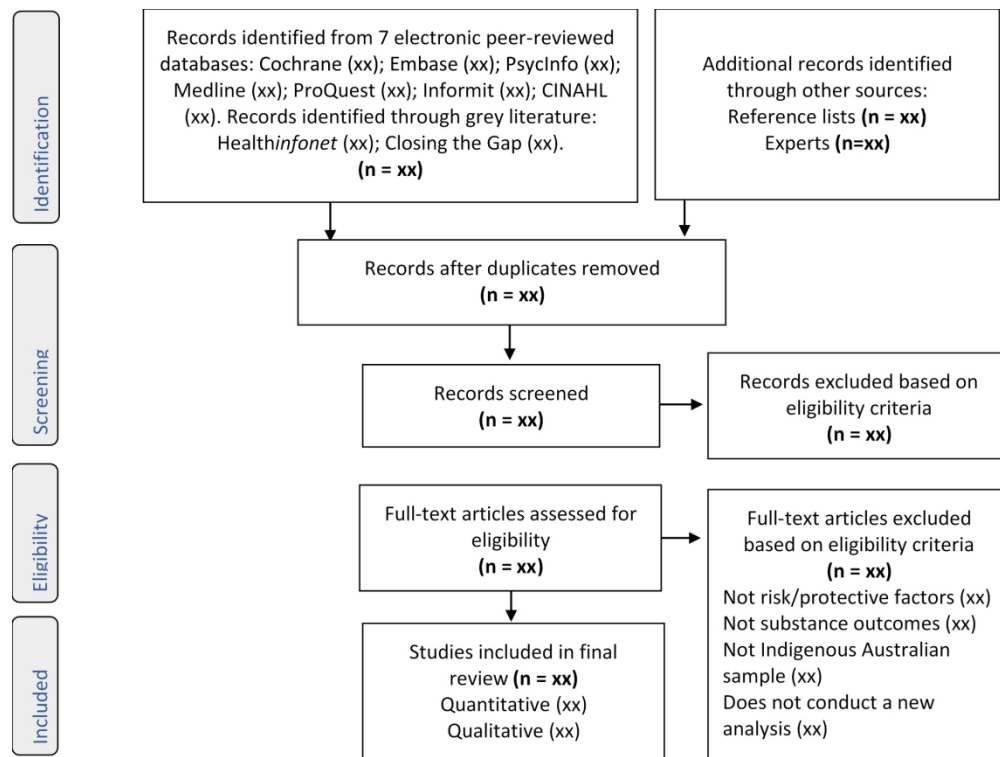
Supplementary Methods: PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol.

For peer review only



Proposed ecological model of risk and protective factors associated with substance use and related harms among Aboriginal and Torres Strait Islander people

118x98mm (288 x 288 DPI)



PRISMA-P Flow Diagram

179x135mm (288 x 288 DPI)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Additional file to: Snijder et al. *Developing an ecological framework of factors associated with substance use and related harms among Aboriginal and Torres Strait Islander People: Protocol for a systematic review.*

Section and topic	Item No	Checklist item	Information reported
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	<input checked="" type="checkbox"/>
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	<input type="checkbox"/>
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	<input checked="" type="checkbox"/>
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	<input checked="" type="checkbox"/>
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	<input checked="" type="checkbox"/>
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify such and list changes; otherwise, state plan for documenting important protocol amendments	<input type="checkbox"/>
Support:			
Sources	5a	Indicate sources of financial or other support for the review	<input checked="" type="checkbox"/>

Sponsor	5b	Provide name for the review funder and/or sponsor	<input checked="" type="checkbox"/>
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	<input checked="" type="checkbox"/>
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	<input checked="" type="checkbox"/>
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, outcomes and study characteristics (PICOS)	<input checked="" type="checkbox"/>
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICOS, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	<input checked="" type="checkbox"/>
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	<input checked="" type="checkbox"/>
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	<input checked="" type="checkbox"/>
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	<input checked="" type="checkbox"/>
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	<input checked="" type="checkbox"/>
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	<input checked="" type="checkbox"/>

Data items	12	List and define all variables for which data will be sought (such as PICOS items, funding sources), any pre-planned data assumptions and simplifications	<input checked="" type="checkbox"/>
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	<input checked="" type="checkbox"/>
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	<input checked="" type="checkbox"/>
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	<input type="checkbox"/>
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	<input type="checkbox"/>
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	<input type="checkbox"/>
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	<input checked="" type="checkbox"/>
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	<input type="checkbox"/>
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	<input checked="" type="checkbox"/>

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

For peer review only