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Study Protocol: Our Cultures Count -- The Mayi Kuwayu Study, a national longitudinal study of Aboriginal and Torres Strait Islander wellbeing

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Keywords:	Culture, Aboriginal and Torres Strait Islander, Indigenous Population, Longitudinal Studies, Social Determinants of Health

Title:

Study Protocol: *Our Cultures Count* -- The Mayi Kuwayu Study, a national longitudinal study of Aboriginal and Torres Strait Islander wellbeing

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ABSTRACT

Introduction

Aboriginal and Torres Strait Islander peoples are Australia's First Peoples and have been connected to the land for ≥65,000 years. Their enduring cultures and values are considered critical to health and wellbeing, alongside physical, psychological and social factors. We currently lack large-scale data that adequately represent the experiences of Aboriginal and Torres Strait Islander people; the absence of evidence on cultural practice and expression is particularly striking, given its foundational importance to wellbeing.

Method and analysis

Mayi Kuwayu: The National Study of Aboriginal and Torres Strait Islander Wellbeing (Mayi Kuwayu Study) will be a large-scale, national longitudinal study of Aboriginal and Torres Strait Islander adults, with linkage to health-related administrative records. The baseline survey was developed through extensive community consultation, and includes items on: cultural practice and expression, sociodemographic factors, health and wellbeing, health behaviours, experiences and environments, and family support and connection. The baseline survey will be mailed to 200,000 Aboriginal and Torres Strait Islander adults (≥16 years), yielding an estimated 16,000-40,000 participants, supplemented through face-to-face recruitment. Follow-up surveys will be conducted every 3-5 years, or as funding allows. The Mayi Kuwayu Study will contribute to filling key evidence gaps, including quantifying the contribution of cultural factors to wellbeing, alongside standard elements of health and risk.

Ethics and dissemination

The Mayi Kuwayu Study was developed and is conducted in partnership with Aboriginal and Torres Strait Islander organisations across States and Territories. It will provide an enduring and shared infrastructure to underpin program and policy development, based on measures and values of significance to Aboriginal and Torres Strait Islander peoples. Research findings will be disseminated through forms including community meetings, reports and feedback sheets; policy briefs; and manuscripts for peer-reviewed publication. Approved researchers can access confidentialised data and disseminate findings in accordance with study data access and governance protocols.

KEYWORDS: Culture; Aboriginal and Torres Strait Islander; Indigenous Population; Longitudinal studies; Social Determinants of Health

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- Mayi Kuwayu: The National Study of Aboriginal and Torres Strait Islander Wellbeing (Mayi Kuwayu Study) will be a large-scale, national longitudinal study of Indigenous Australian adults, with linkage to health-related administrative records.
- The baseline survey was developed through consultations with communities across Australia, and includes items on: cultural practice and expression, sociodemographic factors, health and wellbeing, health behaviours, experiences and environments, and family support and connection.
- The Mayi Kuwayu Study will contribute to filling key evidence gaps, including examination of the contribution of cultural factors to wellbeing, alongside standard elements of health and risk; in addition, the study will be an order of magnitude larger than any previous prospective study of Aboriginal and Torres Strait Islander adults, enabling the generation of robust, needed evidence on health and wellbeing.
- The Mayi Kuwayu Study will be an exemplar of Aboriginal and Torres Strait Islander research governance, providing enduring and shared infrastructure to underpin program and policy development, based on measures and values of significance to Aboriginal and Torres Strait Islander peoples.
- The Mayi Kuwayu Study is not intended to be representative of the entire Aboriginal and Torres Strait Islander adult population; however, the Study aims to capture much of the diversity of the Aboriginal and Torres Strait Islander population nationally, with sufficient heterogeneity across exposures.

INTRODUCTION

Rationale

Aboriginal and Torres Strait Islander peoples are Australia's First Peoples and have been connected to the land for at least the last 65,000 years.[1] Aboriginal and Torres Strait Islander cultures and values remain strong in contemporary Australia and are celebrated as among the longest continuing cultures in the world.

Broadly, culture may comprise the ideas and self-concepts of a group (e.g. artefacts, attitudes, beliefs, customs, norms, symbols and values) and the lived practice and expression of these in differing contexts. Culture also includes historical events and standards of behaviour that evolve and change over time.[2] According to the literature, key Aboriginal and Torres Strait Islander cultural domains may include: knowledges and beliefs; cultural expressions; country and caring for country (referring to the essential relationship between a people and their traditional territories); language; self-determination; and, family, kinship and community.[3]

From a holistic perspective, culture can be considered a foundational component of, and contributor to, health and wellbeing, in addition to physical, psychological and social factors. Despite the potential importance of culture to health and wellbeing, there is a paucity of research exploring the association between culture and wellbeing among Aboriginal and Torres Strait Islander peoples.[4] Further, the potential mechanisms through which culture impacts on wellbeing (and vice versa) remain unknown. Aboriginal and Torres Strait Islander culture is increasingly being recognised as a critical, yet under-researched, determinant of health by communities, organisations and policymakers.[5 6] There is a clear need for research that identifies how Aboriginal and Torres Strait Islander peoples navigate and express the differing cultures in which their lives exist, and how this relates to their health and wellbeing.

Mayi Kuwayu: The National Study of Aboriginal and Torres Strait Islander Wellbeing (Mayi Kuwayu Study) is designed to address this lack of knowledge on a national scale, generating evidence regarding culture and its relationship to health and wellbeing. 'Mayi Kuwayu' means 'to follow Aboriginal people over a long time' in Ngiyampaa language (language of the Wongaibon peoples of New South Wales, Australia). This data resource will help us to understand the role of culture in health and wellbeing. In addition, the study will be an order of magnitude larger than any previous prospective study of Aboriginal and Torres Strait Islander adults, enabling the generation of robust, needed evidence on health and wellbeing.

This study arose from the need to quantify what has been written about and often described as instinctive to many Aboriginal and Torres Strait Islander people: cultures and their relationship to wellbeing.[7] As such, this study is designed to privilege Aboriginal and Torres Strait Islander views and experiences. This study employs measures of culture that have been co-developed with a diversity of Aboriginal and Torres Strait Islander peoples through an iterative qualitative process. The Mayi Kuwayu Study employs a salutogenic framework, enabling identification of cultural and other assets that promote wellbeing.[8]

The Mayi Kuwayu Study aims to examine health and wellbeing in relation to cultural practice and expression, taking into account the varied contexts in which Aboriginal and Torres Strait Islander peoples live. This Study was developed primarily within a social epidemiology framework, concerned with the social structures, institutions and relationships that influence health and wellbeing. Culture may impact wellbeing directly, indirectly through social determinants of health, and/or through other pathways.[9]

Objectives

The primary aim of this study is to enable quantification of associations and pathways between cultural practice and expression, social determinants of health, health behaviours, and health and wellbeing outcomes for Aboriginal and Torres Strait Islander peoples. Specifically, the project will generate: (1) indicators of Aboriginal and Torres Strait Islander cultural practice and expression that capture diversity and maintain meaning across contexts; (2) large-scale data on cultural practice and expression, socio-demographic factors, health and wellbeing, health behaviours, experiences and environments, and family support and connection, both cross-sectionally and over time; and, (3) a state-of-the-art data resource for investigating Aboriginal and Torres Strait Islander wellbeing, which can also serve as a framework for policy and program planning.

The primary study hypothesis is that cultural practice and expression (e.g. connection to country, language use, kinship ties) is associated with health and wellbeing. Understanding and quantifying these associations could inform policy, for example by supporting program development that appropriately accounts for and promotes cultural engagement, in order to promote wellbeing. This evidence could also inform individual behaviour; for example, it might encourage cultural engagement and revitalisation by individuals and communities, which could in turn lead to an improvement in wellbeing.

METHODS

Study recruitment

All Aboriginal and Torres Strait Islander people aged 16 years and older living in Australia are eligible to participate (Figure 1).

Primary sampling frame

The intended primary recruitment method for this study is through a mail-out to people registered as Aboriginal and/or Torres Strait Islander in the Medicare Australia database. Medicare Australia is the national healthcare administration database, including all Australian citizens and permanent residents. Aboriginal and Torres Strait Islander people who choose to self-identify as Indigenous in the Medicare Australia database are recorded through the Medicare Australia Voluntary Indigenous Indicator (VII); this “Medicare VII Database” constitutes the primary sampling frame for this study.

We estimate that the Medicare VII Database represents 68% of all Aboriginal and Torres Strait Islander people in Australia (total population=786,689, based on undercount-adjusted Census data[10]). As at October 2017, the Medicare VII database included 533,832 self-identified Aboriginal and Torres Strait Islander peoples, 313,732 of whom are in the eligible age range. The age and sex distribution of Aboriginal and Torres Strait Islander peoples self-identified in the Medicare VII database closely mirrors that of the total Aboriginal and Torres Strait Islander population (Table 1).

Table 1. Age and sex distribution of Aboriginal and Torres Strait Islander peoples in the Medicare VII Database (VII) and in the overall population

	Males				Females				Persons			
	VII		Census		VII		Census		VII		Census	
Age group	# (1000's)	%	# (1000's)	%	# (1000's)	%	# (1000's)	%	# (1000's)	%	# (1000's)	%
16-24	38.1	11.2	56.0	13.5	41.8	12.3	53.5	12.9	79.9	23.5	109.5	26.4
25-34	39.6	11.2	44.0	10.6	43.1	12.3	44.8	10.8	82.7	23.5	88.9	21.4
35-49	35.3	11.2	51.6	12.4	38.8	12.3	56.8	13.7	74.1	23.5	108.4	26.2
≥50	36.5	11.6	50.2	12.1	41.6	13.2	57.6	13.9	78.1	24.8	107.8	26.0
Total (≥16 years)	*149.4*	*47.5*	*201.8*	*48.7*	*165.4*	*52.5*	*212.7*	*51.3*	*314.7*	*100.0*	*414.5*	*100.0*

Medicare VII Database ("VII") data presented in this table includes persons registered on the Medicare VII Database and aged 16 and over; persons missing age are excluded from total (N=314,732).

Census data presented in this table reflect raw 2016 Census population counts for Aboriginal and Torres Strait Islander people aged 16 years and over (N=414,532).[11] *Data are not adjusted for undercount, as data are unavailable on the extent of undercount by age group and sex within the Aboriginal and Torres Strait Islander population.*

The Department of Human Services (DHS) extract a mailing list from the Medicare VII Database, and use this mailing list to distribute survey materials (information sheet, consent form, and baseline survey) to potential participants. Previous Australian studies have sampled from the total Australian population (using the full Medicare Australia database, not restricted to those self-identified as Indigenous through the VII)[12 13] and have recruited substantial numbers of Aboriginal and Torres Strait Islander people through this process (n=1,985).[12] However, no studies to date have purposely sampled the Aboriginal and Torres Strait Islander population using the Medicare VII Database.

We intend for Mayi Kuwayu Study materials to be distributed to a mailing list of 200,000 people from the Medicare VII Database. Previous mail-out surveys using the Medicare Australia database in the total Australian population have achieved response rates of 18-44%.[12 13] Given potential additional barriers to recruiting Aboriginal and Torres Strait Islander participants (such as increased mobility, respondent burden, mistrust in research), we conservatively estimate a response rate of 8-20%, which would result in a total of 16,000-40,000 participants through the primary recruitment method.

The aim will be to achieve a baseline sample that aligns with the population distribution across age group (16-24; 25-34; 35-49; ≥50 years), sex (male; female), and remoteness (major cities; inner and outer regional areas; remote and very remote). To achieve this, we will use stratified sampling, with strata based on the sex, age group and remoteness categories specified above. We will conduct a pilot mail-out of 20,000 surveys to estimate response rate for each strata (age group *by* sex *by* remoteness). This will inform the extent to which strata need to be oversampled in the main mail-out, allowing for differential response rates by age, sex, and remoteness, to achieve the desired sample distribution, and a minimum of 500 participants in each strata.

The study materials distributed in the pilot mail-out will match the materials distributed in the full mail-out. Surveys completed in the pilot study phase will be included in the baseline data collection.

All participants who receive a survey through the pilot and main mail-out will have the option to complete the paper-based survey or to complete the survey online or over the phone.

Supplementary recruitment methods

While the Medicare VII Database will serve as the primary sampling frame for the baseline survey, participation in the Mayi Kuwayu Study is not restricted to those who are registered with the Medicare VII Database. All Aboriginal and/or Torres Strait Islander persons aged 16 years or over are eligible to participate, regardless of whether or not they receive a survey through the mail-out process.

Field-testing during the development phase indicated that face-to-face (vs. self-complete) delivery supported participation by those with low literacy levels. Therefore, supplementary recruitment will occur through face-to-face surveying in selected areas expressing an interest, and/or areas demonstrating low response rates or high levels of missing data on completed surveys in the pilot mail-out. All participants recruited through the supplementary recruitment method will also have the option to complete the survey online or over the phone.

Supplementary recruitment may also occur through study promotion (such as advertising via social media and through local community-controlled organisations, and word-of-mouth). Any eligible person can complete the survey online or over the phone, or contact the Mayi Kuwayu Study to request a paper survey.

Given that this recruitment method potentially enables participants to complete the survey multiple times, baseline data will be checked for duplicates based on name, address, and other identifying information.

Study components

The Mayi Kuwayu Study encompasses four main components: (1) cultural indicator and survey development; (2) baseline survey (including pilot mail-out); (3) repeat follow-up surveys; and (4) data linkage (Figure 2), which are briefly outlined below.

Cultural indicator and survey *development*

Survey items, including indicators of Aboriginal and Torres Strait Islander culture, have been developed through reviewing the literature and through consultation with a total of 165 Aboriginal and Torres Strait Islander peoples attending 24 focus groups across Australia from 2014-2017. Participants in this process were aged 16 to >70 years and represent a diversity of contexts and lived experiences. Early versions of the Mayi Kuwayu baseline survey were pilot tested with 160 and 209 Aboriginal and Torres Strait Islander participants in two “proof-of-concept” studies, respectively.

The iterative processes of developing and refining the cultural indicators and other survey items will be detailed elsewhere. This process was critical to developing appropriate and meaningful questions about culture, to enable quantification of cultural expressions and contexts, and their associations with health and wellbeing outcomes, across diverse settings.

Baseline survey

The baseline survey will contain survey items on cultural practice and expressions, socio-demographic factors, health and wellbeing, health behaviours, experiences and environments, and family support and connection. Key survey themes within each domain are summarised in Table 2. All survey items included in the survey are based on established instruments, modified instruments, or instruments developed through the community consultation process.

Table 2: Key domains and measures included in the baseline survey

Domain	Theme
Cultural practice and expression	Country and connection to country; Indigenous beliefs and knowledge; cultural expression; self-determination and leadership; language; family, kinship and community; identity
Sociodemographic factors	Age; sex; housing; education; employment; financial situation; household composition
Health and wellbeing	Life satisfaction; health status; health conditions; medication use; social and emotional wellbeing; functional limitation
Health behaviours	Physical activity; alcohol and tobacco use; health service use
Experiences and environments	Services in the community; experiences of racism; community safety; environmental conditions; life events
Family support and connection	Family cohesion and connectedness; caring for others; Stolen generation

To enable data linkage and re-contact for follow-up surveys, the baseline survey will collect data on participants' first and last name, postal address, and email address. In addition, the baseline survey will collect contact details for an additional family member or friend (close contact) who can be approached to provide information to assist in re-contacting the participant if required.

Follow-up surveys

Participants in the baseline survey will be followed up by survey every 3-5 years, or as funding allows. Follow-up surveys will maintain the core components of the baseline survey, with potential for addition or removal of survey items depending on priority and resourcing. Follow-up surveys will be distributed directly to participants (mail, email, or phone). Participants will be able to nominate their preferred method of contact on the baseline survey.

Data Linkage

Retrospective and continuing prospective linkage of baseline survey data to health-related records will provide ongoing outcome data independent of resurvey. The types of linkage datasets pursued will include hospitalisation, cancer registrations, deaths and disease notifications.

Patient and Public Involvement statement

The Mayi Kuwayu Study arose from community-identified priorities, and has been developed through extensive consultation; these processes have enabled the generation of a survey that can meaningfully and appropriately collect data about Aboriginal and Torres Strait Islander cultures and wellbeing across diverse settings.

Study governance mechanisms will ensure that engagement is ongoing throughout the implementation of the baseline and follow-up surveys, and during research question prioritization, data analysis, and interpretation. In addition to supporting the generation of meaningful results, this will support ongoing cohort retention. For example, participants can nominate to receive Study newsletters, and appropriate social and Aboriginal and Torres Strait Islander media and forums will be used to inform participants of study progress and key outcomes.

The Mayi Kuwayu Study will create a collaborative resource governed by Aboriginal and Torres Strait Islander organisations, researchers, and communities. The Study is Indigenous-led, with direct involvement from Aboriginal and Torres Strait Islander researchers (including the Study's lead) who are leaders in their field and who are well respected in their communities, bringing a depth of experience and accountability to ensure adherence to appropriate community protocols. The governance structure will ensure that Aboriginal and Torres Strait Islander peoples and partner organisations from across Australia are involved at every level and every stage of the project.

STATISTICAL METHODS

Statistical analyses will involve both cross-sectional and longitudinal methods. This will include estimates of prevalence, incidence, and changes over time of cultural and health risk factors and health and wellbeing outcomes, and examination of their interrelationships at baseline and over time. We will examine whether cultural or other factors moderate or mediate associations between risk factors and health outcomes. Analyses will be informed by a conceptual framework developed for each research question and include a range of methods appropriate for cross-sectional, longitudinal, and linked data and causal modelling, adjusting for correlation of measures within individual over time and missing data, where appropriate.

We conservatively estimate that at least 16,000-40,000 Indigenous adults will participate in the baseline survey, based on the expected 8-20% response rate to baseline survey mail-out and supplementary recruitment. All participants in the baseline survey will be included for data linkage. If there is 20% loss to follow up, there will be 12,800-32,000 participants with longitudinal survey data.

For analyses of the prevalence, incidence and changes over time for cultural, health, or other factors, the study will allow highly precise estimation within sex and five-year age groups, with 95%CI for the smallest group within ±1.0-3.5% and 0.1 SDs for proportions and means respectively. For cross-sectional and longitudinal analyses, the study will have at least 80% power, with a 5% significance level, to detect sex-specific odds ratios of 1.2-1.3 for binary outcomes and hazard ratios of 1.2-1.4 for time-to-event analyses, for exposures of ≥10% prevalence and binary outcomes of 2-5% prevalence.

ETHICS AND DISSEMINATION

Development, recruitment, retention, and dissemination strategies utilised in the Mayi Kuwayu Study are based on principles of Indigenous data sovereignty and best practice for cohort studies of Aboriginal and Torres Strait Islander peoples.[14-17] It is intended that the study be perceived as an Indigenous community activity that promotes Indigeneity, building on Indigenous relationality, and the importance of family and kin networks.

Consent

Participation in the Mayi Kuwayu Study is voluntary. Potential participants will receive a plain-language information sheet about the study, along with the consent form and survey. The study uses a structured, staged consent form, where participants opt-in to specific study components (baseline survey, data linkage, and/or recontact), rather than a blanket consent form covering all study components. This empowers individuals to participate only in aspects of the study with which they are comfortable. This staged approach has been previously used in an Aboriginal and Torres Strait Islander cohort study, and has been demonstrated to be an appropriate method for recruiting and retaining Aboriginal study participants.[18] Participants can withdraw consent at any time.

Data sharing statement

Access to the Mayi Kuwayu data resource will be determined by a data access policy, developed and enforced by the Mayi Kuwayu governing body. This data access policy will ensure that Aboriginal and Torres Strait Islander peoples and organisations control the research that is conducted using data from the Study. Evaluation of data access requests for data access will include assessment of stakeholder needs, utility of findings to community and policy, and likely contribution to knowledge.

Approved researchers will have access to a confidentialised unit-record level dataset via a secure server. Each participant will be given a unique ID code, and any potentially identifying information (e.g. names, Medicare number, date of birth, address, or references to specific places or persons) will be removed from the dataset before it is released for researchers' use.

Dissemination

Dissemination of findings from the Mayi Kuwayu Study will be subject to approval from the governing body. With approval, findings will be disseminated through forms including community dissemination meetings, community reports and feedback sheets, policy briefs, manuscripts for peer-reviewed publication, conference presentations, and public seminars.

DISCUSSION AND IMPLICATIONS

Representativeness

The Mayi Kuwayu Study is not intended to be representative of the entire Aboriginal and Torres Strait Islander adult population. However, the Study aims to capture much of the diversity of the Aboriginal and Torres Strait Islander population nationally, with sufficient heterogeneity across exposures. The aim of the study is to generate evidence based on internal comparisons, and to examine within-population variation in these associations.

While this has not been explored specifically within the Aboriginal and Torres Strait Islander population, in general, representativeness is not necessary for reliable quantification of exposure-outcome relationships.[19 20] Algebraic work and simulation studies provide evidence on the validity of internal comparisons in the face of varying response rates.[21] Moreover, experience over time from a wide range of epidemiological research has also shown this to be the case. For example, the British Doctors' Study, where doctors are clearly not representative of the general population, yet findings based on internal comparisons remain valid (e.g. the association between smoking and mortality);[22] pooled analyses incorporating cohort studies, case-control and other study designs tend to find materially similar findings among studies with varying response rates.[23] Further, a representative sample may not contain sufficient numbers of specific exposures or outcomes of importance. Thus, while high response rates and representativeness are essential to censuses and population health surveys (where the main aim is to accurately estimate point prevalence), these features are not essential or recommended for cohort studies.[24]

Implications

The Mayi Kuwayu Study will establish an ethical, community-focused and Aboriginal-controlled resource that will contribute to a holistic and robust understanding of Aboriginal and Torres Strait Islander culture, health and wellbeing. It will be an Aboriginal-controlled collaborative resource for research, conducted in strict accordance with current ethical, community and Aboriginal and Torres Strait Islander research standards.[25-30] The participatory methods will support the relevance of findings for individuals, communities, health services, and policy makers across portfolios.

This novel study will be the first of its kind, providing a large-scale national cohort study about the wellbeing of Aboriginal and Torres Strait Islander adults. It will provide the first community-derived measures of culture, and the first quantitative evidence regarding Indigenous cultural expressions and contexts at the national level. It will enable the first large-scale investigation of the relationship between culture and wellbeing for Aboriginal and Torres Strait Islander adults. This will identify opportunities to incorporate culture in programs and policy to improve Aboriginal and Torres Strait Islander wellbeing.

There is currently limited incorporation of Aboriginal and Torres Strait Islander culture in programs and policies – a dimension that is likely to be critical to effectiveness and acceptability. Evidence from the Mayi Kuwayu study may increase the prioritisation of culture in the design of program and policy.

Author contributions: RL conceived the study. KT, RJ, and RL drafted the manuscript. All authors provided comments and critical revisions on the manuscript and approved the final version.

Ethics approvals: Ethics approval for the study has been received from the following Human Research Ethics Committees (HRECs): the Australian Institute of Aboriginal and Torres Strait Islander Studies HREC (approval number: E030/22052015); the Australian Government Department of Health HREC (10-2017); the Aboriginal Health and Medical Research Council of New South Wales Ethics Committee (1268/17); Central Australian Human Research Ethics Committee (CA-17-2810); the Northern Territory Department of Health and Menzies HREC (2017-2804); the Australian National University HREC (2016/767); the University of Tasmania HREC (H0016473); Aboriginal Health Research Ethics Committee (14-07-723); St. Vincent's Hospital Melbourne HREC (HREC 132/17); the Western Australian Aboriginal Health Ethics Committee (787).

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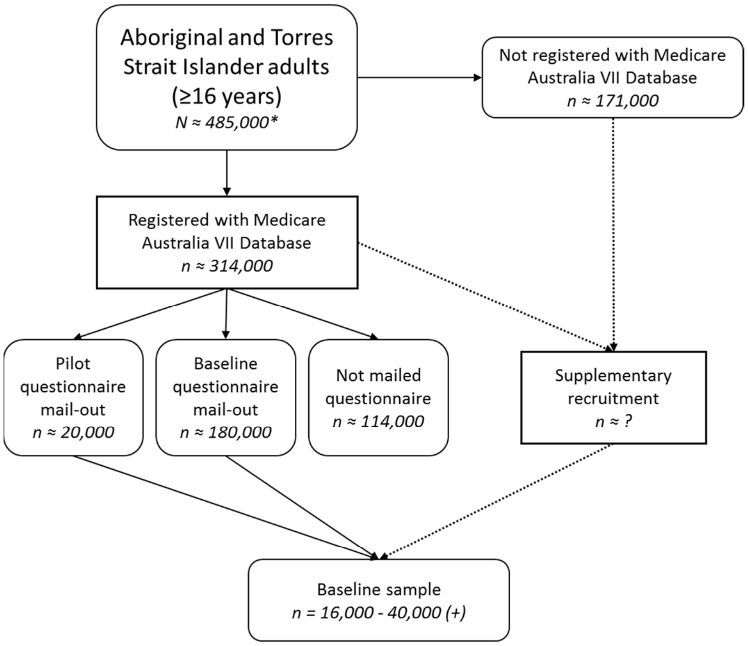
FIGURE LEGENDS

Figure 1. Flow diagram for Mayi Kuwayu Study recruitment

**Estimated undercount-adjusted population of Aboriginal and Torres Strait Islander peoples aged ≥16 years. Calculated by adjusting the raw Census count (n=414,532) for the overall 2016 Census undercount for the Aboriginal and Torres Strait Islander population (17.5%).[10] Data are unavailable on the extent of undercount by age group within the Aboriginal and Torres Strait Islander population.*

Figure 2. Mayi Kuwayi Study timeline



Flow diagram for Mayi Kuwayu Study recruitment

*Estimated undercount-adjusted population of Aboriginal and Torres Strait Islander peoples aged ≥16 years. Calculated by adjusting the raw Census count (n=414,532) for the overall 2016 Census undercount for the Aboriginal and Torres Strait Islander population (17.5%).10 Data are unavailable on the extent of undercount by age group within the Aboriginal and Torres Strait Islander population.

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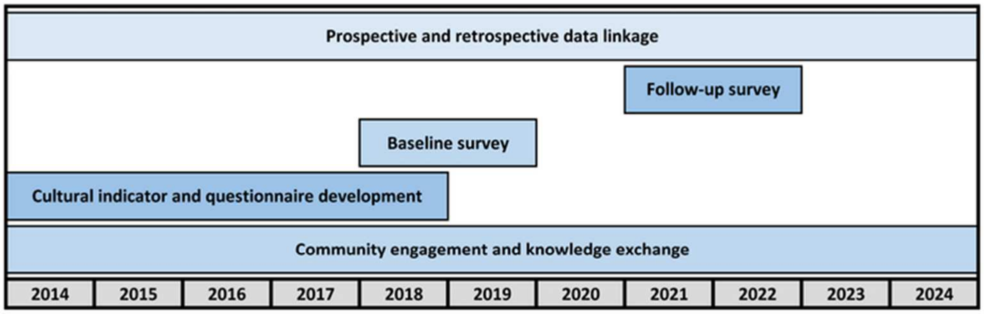

Mayi Kuwayi Study timeline

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1, 2	'longitudinal study'
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2	'Method and analysis' section
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4	'Rationale' section
Objectives	3	State specific objectives, including any prespecified hypotheses	5	'Objectives' section, and hypothesis
Methods				
Study design	4	Present key elements of study design early in the paper	5-8	Sections on study recruitment (primary sampling frame, supplementary recruitment methods) and study components (survey development, baseline survey, follow up surveys, data linkage).
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-8	As above
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5-8	As above
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed	5-8	As above

		Case-control study—For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9	'Statistical methods' section
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7	Key survey domains and measures outlined in Table 2
Bias	9	Describe any efforts to address potential sources of bias	8-11	'Statistical methods' and 'representativeness' sections
Study size	10	Explain how the study size was arrived at	5-8	Sections on study recruitment (primary sampling frame, supplementary recruitment methods) and study components (survey development, baseline survey, follow up surveys, data linkage).
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9	'Statistical methods' section; Key survey domains and measures outlined in Table 2
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9	'Statistical methods' section provides an overview of methods to be applied to this Study (note: this paper is a study protocol and does not report specific analysis)
		(*b*) Describe any methods used to examine subgroups and interactions	8-9	As above
		(*c*) Explain how missing data were addressed	8-9	As above
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	8-9	As above

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy		
		(*e*) Describe any sensitivity analyses	8-9	As above
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA	NA – Study Protocol
		(b) Give reasons for non-participation at each stage	NA	NA – Study Protocol
		(c) Consider use of a flow diagram	NA	NA – Study Protocol
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA	NA – Study Protocol
		(b) Indicate number of participants with missing data for each variable of interest	NA	NA – Study Protocol
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA	NA – Study Protocol
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA	NA – Study Protocol
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA	NA – Study Protocol
		Cross-sectional study—Report numbers of outcome events or summary measures	NA	NA – Study Protocol
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA	NA – Study Protocol
		(*b*) Report category boundaries when continuous variables were categorized	NA	NA – Study Protocol
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	NA – Study Protocol
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA	NA – Study Protocol
Discussion				
Key results	18	Summarise key results with reference to study objectives	NA	NA – Study Protocol
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8-11	‘Statistical methods’ and ‘representativeness’ sections
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	NA	NA – Study Protocol
Generalisability	21	Discuss the generalisability (external validity) of the study results	10	‘Representativeness’ sections

Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12	‘Funding statement’

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Study Protocol: Our Cultures Count -- The Mayi Kuwayu Study, a national longitudinal study of Aboriginal and Torres Strait Islander wellbeing

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Keywords:	Culture, Aboriginal and Torres Strait Islander, Indigenous Population, Longitudinal Studies, Social Determinants of Health

Title:

Study Protocol: *Our Cultures Count* -- The Mayi Kuwayu Study, a national longitudinal study of Aboriginal and Torres Strait Islander wellbeing

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ABSTRACT

Introduction

Aboriginal and Torres Strait Islander peoples are Australia's First Peoples and have been connected to the land for ≥65,000 years. Their enduring cultures and values are considered critical to health and wellbeing, alongside physical, psychological and social factors. We currently lack large-scale data that adequately represent the experiences of Aboriginal and Torres Strait Islander people; the absence of evidence on cultural practice and expression is particularly striking, given its foundational importance to wellbeing.

Method and analysis

Mayi Kuwayu: The National Study of Aboriginal and Torres Strait Islander Wellbeing (Mayi Kuwayu Study) will be a large-scale, national longitudinal study of Aboriginal and Torres Strait Islander adults, with linkage to health-related administrative records. The baseline survey was developed through extensive community consultation, and includes items on: cultural practice and expression, sociodemographic factors, health and wellbeing, health behaviours, experiences and environments, and family support and connection. The baseline survey will be mailed to 200,000 Aboriginal and Torres Strait Islander adults (≥16 years), yielding an estimated 16,000-40,000 participants, supplemented through face-to-face recruitment. Follow-up surveys will be conducted every 3-5 years, or as funding allows. The Mayi Kuwayu Study will contribute to filling key evidence gaps, including quantifying the contribution of cultural factors to wellbeing, alongside standard elements of health and risk.

Ethics and dissemination

This study has received approval from national Human Research Ethics Committees, and from States and Territories committees, including relevant Aboriginal and Torres Strait Islander organisations. The study was developed and is conducted in partnership with Aboriginal and Torres Strait Islander organisations across States and Territories. It will provide an enduring and shared infrastructure to underpin program and policy development, based on measures and values important to Aboriginal and Torres Strait Islander peoples. Approved researchers can access confidentialised data and disseminate findings according to study data access and governance protocols.

KEYWORDS: Culture; Aboriginal and Torres Strait Islander; Indigenous Population; Longitudinal studies; Social Determinants of Health

STRENGTHS AND LIMITATIONS OF THIS STUDY:

- Mayi Kuwayu: The National Study of Aboriginal and Torres Strait Islander Wellbeing (the Mayi Kuwayu Study) will be a large-scale, national longitudinal study of Indigenous Australian adults, with linkage to health-related administrative records.
- With an estimated minimum 16,000 participants, the study will be an order of magnitude larger than any previous prospective study of Aboriginal and Torres Strait Islander adults.
- The baseline survey was developed through consultations with individuals and communities across Australia, and includes items on: cultural practice and expression, sociodemographic factors, health and wellbeing, health behaviours, experiences and environments, and family support and connection.
- The Mayi Kuwayu Study will be an exemplar of Aboriginal and Torres Strait Islander research governance.
- The Mayi Kuwayu Study is not intended to be population representative; the aim of the study is to generate evidence based on internal comparisons, and to examine within-population variation.

INTRODUCTION

Rationale

Aboriginal and Torres Strait Islander peoples are Australia's First Peoples and have been connected to the land for at least the last 65,000 years.[1] Aboriginal and Torres Strait Islander cultures and values remain strong in contemporary Australia and are celebrated as among the longest continuing cultures in the world.

Broadly, culture may comprise the ideas and self-concepts of a group (e.g. artefacts, attitudes, beliefs, customs, norms, symbols and values) and the lived practice and expression of these in differing contexts. Culture also includes historical events and standards of behaviour that evolve and change over time.[2] According to the literature, key Aboriginal and Torres Strait Islander cultural domains may include: knowledges and beliefs; cultural expressions; country and caring for country (referring to the essential relationship between a people and their traditional territories); language; self-determination; and, family, kinship and community.[3]

From a holistic perspective, culture can be considered a foundational component of, and contributor to, health and wellbeing, in addition to physical, psychological and social factors. Despite the potential importance of culture to health and wellbeing, there is a paucity of research exploring the association between culture and wellbeing among Aboriginal and Torres Strait Islander peoples.[4] Further, the potential mechanisms through which culture impacts on wellbeing (and vice versa) remain unknown. Aboriginal and Torres Strait Islander culture is increasingly being recognised as a critical, yet under-researched, determinant of health by communities, organisations and policymakers.[5 6] There is a clear need for research that identifies how Aboriginal and Torres Strait Islander peoples navigate and express the differing cultures in which their lives exist, and how this relates to their health and wellbeing.

Mayi Kuwayu: The National Study of Aboriginal and Torres Strait Islander Wellbeing (Mayi Kuwayu Study) is designed to address this lack of knowledge on a national scale, generating evidence regarding culture and its relationship to health and wellbeing. 'Mayi Kuwayu' means 'to follow Aboriginal people over a long time' in Ngiyampaa language (language of the Wongaibon peoples of New South Wales, Australia). This data resource will help us to understand the role of culture in health and wellbeing. In addition, the study will be an order of magnitude larger than any previous prospective study of Aboriginal and Torres Strait Islander adults, enabling the generation of robust, needed evidence on health and wellbeing.

This study arose from the need to quantify what has been written about and often described as instinctive to many Aboriginal and Torres Strait Islander people: cultures and their relationship to wellbeing.[7] As such, this study is designed to privilege Aboriginal and Torres Strait Islander views and experiences. This study employs measures of culture that have been co-developed with a diversity of Aboriginal and Torres Strait Islander peoples through an iterative qualitative process. The Mayi Kuwayu Study employs a salutogenic framework, enabling identification of cultural and other assets that promote wellbeing.[8]

The Mayi Kuwayu Study aims to examine health and wellbeing in relation to cultural practice and expression, taking into account the varied contexts in which Aboriginal and Torres Strait Islander peoples live. This Study was developed primarily within a social epidemiology framework, concerned with the social structures, institutions and relationships that influence health and wellbeing. Culture may impact wellbeing directly, indirectly through social determinants of health, and/or through other pathways.[9]

Objectives

The primary aim of this study is to enable quantification of associations and pathways between cultural practice and expression, social determinants of health, health behaviours, and health and wellbeing outcomes for Aboriginal and Torres Strait Islander peoples. Specifically, the project will generate: (1) indicators of Aboriginal and Torres Strait Islander cultural practice and expression that capture diversity and maintain meaning across contexts; (2) large-scale data on cultural practice and expression, socio-demographic factors, health and wellbeing, health behaviours, experiences and environments, and family support and connection, both cross-sectionally and over time; and, (3) a state-of-the-art data resource for investigating Aboriginal and Torres Strait Islander wellbeing, which can also serve as a framework for policy and program planning.

The primary study hypothesis is that cultural practice and expression (e.g. connection to country, language use, kinship ties) is associated with health and wellbeing. Understanding and quantifying these associations could inform policy, for example by supporting program development that appropriately accounts for and promotes cultural engagement, in order to promote wellbeing. This evidence could also inform individual behaviour; for example, it might encourage cultural engagement and revitalisation by individuals and communities, which could in turn lead to an improvement in wellbeing.

METHODS

Study recruitment

All Aboriginal and Torres Strait Islander people aged 16 years and older living in Australia are eligible to participate (Figure 1).

Primary sampling frame

The intended primary recruitment method for this study is through a mail-out to people registered as Aboriginal and/or Torres Strait Islander in the Medicare Australia database. Medicare Australia is the national healthcare administration database, including all Australian citizens and permanent residents. Aboriginal and Torres Strait Islander people who choose to self-identify as Indigenous in the Medicare Australia database are recorded through the Medicare Australia Voluntary Indigenous Indicator (VII); this “Medicare VII Database” constitutes the primary sampling frame for this study.

We estimate that the Medicare VII Database represents 68% of all Aboriginal and Torres Strait Islander people in Australia (total population=786,689, based on undercount-adjusted Census data[10]). As at October 2017, the Medicare VII database included 533,832 self-identified Aboriginal and Torres Strait Islander peoples, 313,732 of whom are in the eligible age range. The age and sex distribution of Aboriginal and Torres Strait Islander peoples self-identified in the Medicare VII database closely mirrors that of the total Aboriginal and Torres Strait Islander population (Table 1).

Table 1. Age and sex distribution of Aboriginal and Torres Strait Islander peoples in the Medicare VII Database (VII) and in the overall population

	Males				Females				Persons			
	VII		Census		VII		Census		VII		Census	
Age group	# (1000's)	%	# (1000's)	%	# (1000's)	%	# (1000's)	%	# (1000's)	%	# (1000's)	%
16-24	38.1	11.2	56.0	13.5	41.8	12.3	53.5	12.9	79.9	23.5	109.5	26.4
25-34	39.6	11.2	44.0	10.6	43.1	12.3	44.8	10.8	82.7	23.5	88.9	21.4
35-49	35.3	11.2	51.6	12.4	38.8	12.3	56.8	13.7	74.1	23.5	108.4	26.2
≥50	36.5	11.6	50.2	12.1	41.6	13.2	57.6	13.9	78.1	24.8	107.8	26.0
Total (≥16 years)	*149.4*	*47.5*	*201.8*	*48.7*	*165.4*	*52.5*	*212.7*	*51.3*	*314.7*	*100.0*	*414.5*	*100.0*

Medicare VII Database ("VII") data presented in this table includes persons registered on the Medicare VII Database and aged 16 and over; persons missing age are excluded from total (N=314,732).

Census data presented in this table reflect raw 2016 Census population counts for Aboriginal and Torres Strait Islander people aged 16 years and over (N=414,532).[11] Data are not adjusted for undercount, as data are unavailable on the extent of undercount by age group and sex within the Aboriginal and Torres Strait Islander population.

The Department of Human Services (DHS) extract a mailing list from the Medicare VII Database, and use this mailing list to distribute survey materials (information sheet, consent form, and baseline survey) to potential participants. Previous Australian studies have sampled from the total Australian population (using the full Medicare Australia database, not restricted to those self-identified as Indigenous through the VII)[12, 13] and have recruited substantial numbers of Aboriginal and Torres Strait Islander people through this process (n=1,985).[12] However, no studies to date have purposely sampled the Aboriginal and Torres Strait Islander population using the Medicare VII Database.

We intend for Mayi Kuwayu Study materials to be distributed to a mailing list of 200,000 people from the Medicare VII Database. Previous mail-out surveys using the Medicare Australia database in the total Australian population have achieved response rates of 18-44%.[12, 13] Given potential additional barriers to recruiting Aboriginal and Torres Strait Islander participants (such as increased mobility, respondent burden, mistrust in research), we conservatively estimate a response rate of 8-20%, which would result in a total of 16,000-40,000 participants through the primary recruitment method.

The aim will be to achieve a baseline sample that aligns with the population distribution across age group (16-24; 25-34; 35-49; ≥50 years), sex (male; female), and remoteness (major cities; inner and outer regional areas; remote and very remote). To achieve this, we will use stratified sampling, with strata based on the sex, age group and remoteness categories specified above. We will conduct a pilot mail-out of 20,000 surveys to estimate response rate for each strata (age group *by* sex *by* remoteness). This will inform the extent to which strata need to be oversampled in the main mail-out, allowing for differential response rates by age, sex, and remoteness, to achieve the desired sample distribution, and a minimum of 500 participants in each strata.

The study materials distributed in the pilot mail-out will match the materials distributed in the full mail-out. Surveys completed in the pilot study phase will be included in the baseline data collection.

All participants who receive a survey through the pilot and main mail-out will have the option to complete the paper-based survey or to complete the survey online or over the phone.

Supplementary recruitment methods

While the Medicare VII Database will serve as the primary sampling frame for the baseline survey, participation in the Mayi Kuwayu Study is not restricted to those who are registered with the Medicare VII Database. All Aboriginal and/or Torres Strait Islander persons aged 16 years or over are eligible to participate, regardless of whether or not they receive a survey through the mail-out process.

Field-testing during the development phase indicated that face-to-face (vs. self-complete) delivery supported participation by those with low literacy levels. Therefore, supplementary recruitment will occur through face-to-face surveying in selected areas expressing an interest, and/or areas demonstrating low response rates or high levels of missing data on completed surveys in the pilot mail-out. All participants recruited through the supplementary recruitment method will also have the option to complete the survey online or over the phone.

Supplementary recruitment may also occur through study promotion (such as advertising via social media and through local community-controlled organisations, and word-of-mouth). Any eligible person can complete the survey online or over the phone, or contact the Mayi Kuwayu Study to request a paper survey.

Given that this recruitment method potentially enables participants to complete the survey multiple times, baseline data will be checked for duplicates based on name, address, and other identifying information.

Study components

The Mayi Kuwayu Study encompasses four main components: (1) cultural indicator and survey development; (2) baseline survey (including pilot mail-out); (3) repeat follow-up surveys; and (4) data linkage (Figure 2), which are briefly outlined below.

Cultural indicator and survey *development*

Survey items, including indicators of Aboriginal and Torres Strait Islander culture, have been developed through reviewing the literature and through consultation with a total of 165 Aboriginal and Torres Strait Islander peoples attending 24 focus groups across Australia from 2014-2017. Participants in this process were aged 16 to >70 years and represent a diversity of contexts and lived experiences. Early versions of the Mayi Kuwayu baseline survey were pilot tested with 160 and 209 Aboriginal and Torres Strait Islander participants in two "proof-of-concept" studies, respectively.

The iterative processes of developing and refining the cultural indicators and other survey items will be detailed elsewhere. This process was critical to developing appropriate and meaningful questions about culture, to enable quantification of cultural expressions and contexts, and their associations with health and wellbeing outcomes, across diverse settings.

Baseline survey

The baseline survey will contain survey items on cultural practice and expressions, socio-demographic factors, health and wellbeing, health behaviours, experiences and environments, and family support and connection. Key survey themes within each domain are summarised in Table 2.

All survey items included in the survey are based on established instruments, modified instruments, or instruments developed through the community consultation process.

Table 2: Key domains and measures included in the baseline survey

Domain	Theme
Cultural practice and expression	Country and connection to country; Indigenous beliefs and knowledge; cultural expression; self-determination and leadership; language; family, kinship and community; identity
Sociodemographic factors	Age; sex; housing; education; employment; financial situation; household composition
Health and wellbeing	Life satisfaction; health status; health conditions; medication use; social and emotional wellbeing; functional limitation
Health behaviours	Physical activity; alcohol and tobacco use; health service use
Experiences and environments	Services in the community; experiences of racism; community safety; environmental conditions; life events
Family support and connection	Family cohesion and connectedness; caring for others; Stolen generation

To enable data linkage and re-contact for follow-up surveys, the baseline survey will collect data on participants' first and last name, postal address, and email address. In addition, the baseline survey will collect contact details for an additional family member or friend (close contact) who can be approached to provide information to assist in re-contacting the participant if required.

Follow-up surveys

Participants in the baseline survey will be followed up by survey every 3-5 years, or as funding allows. Follow-up surveys will maintain the core components of the baseline survey, with potential for addition or removal of survey items depending on priority and resourcing. Follow-up surveys will be distributed directly to participants (mail, email, or phone). Participants will be able to nominate their preferred method of contact on the baseline survey.

Data Linkage

Retrospective and continuing prospective linkage of baseline survey data to health-related records will provide ongoing outcome data independent of resurvey. The types of linkage datasets pursued will include hospitalisation, cancer registrations, deaths and disease notifications.

Patient and Public Involvement statement

The Mayi Kuwayu Study arose from community-identified priorities, and has been developed through extensive consultation; these processes have enabled the generation of a survey that can meaningfully and appropriately collect data about Aboriginal and Torres Strait Islander cultures and wellbeing across diverse settings.

Study governance mechanisms will ensure that engagement is ongoing throughout the implementation of the baseline and follow-up surveys, and during research question prioritization, data analysis, and interpretation. In addition to supporting the generation of meaningful results, this will support ongoing cohort retention. For example, participants can nominate to receive Study newsletters, and appropriate social and Aboriginal and Torres Strait Islander media and forums will be used to inform participants of study progress and key outcomes.

The Mayi Kuwayu Study will create a collaborative resource governed by Aboriginal and Torres Strait Islander organisations, researchers, and communities. The Study is Indigenous-led, with direct involvement from Aboriginal and Torres Strait Islander researchers (including the Study's lead) who are leaders in their field and who are well respected in their communities, bringing a depth of experience and accountability to ensure adherence to appropriate community protocols. The governance structure will ensure that Aboriginal and Torres Strait Islander peoples and partner organisations from across Australia are involved at every level and every stage of the project.

STATISTICAL METHODS

Statistical analyses will involve both cross-sectional and longitudinal methods. This will include estimates of prevalence, incidence, and changes over time of cultural and health risk factors and health and wellbeing outcomes, and examination of their interrelationships at baseline and over time. We will examine whether cultural or other factors moderate or mediate associations between risk factors and health outcomes. Analyses will be informed by a conceptual framework developed for each research question and include a range of methods appropriate for cross-sectional, longitudinal, and linked data and causal modelling, adjusting for correlation of measures within individual over time and missing data, where appropriate.

We conservatively estimate that at least 16,000-40,000 Indigenous adults will participate in the baseline survey, based on the expected 8-20% response rate to baseline survey mail-out and supplementary recruitment. All participants in the baseline survey will be included for data linkage. If there is 20% loss to follow up, there will be 12,800-32,000 participants with longitudinal survey data.

For analyses of the prevalence, incidence and changes over time for cultural, health, or other factors, the study will allow highly precise estimation within sex and five-year age groups, with 95%CI for the smallest group within ±1.0-3.5% and 0.1 SDs for proportions and means respectively. For cross-sectional and longitudinal analyses, the study will have at least 80% power, with a 5% significance level, to detect sex-specific odds ratios of 1.2-1.3 for binary outcomes and hazard ratios of 1.2-1.4 for time-to-event analyses, for exposures of ≥10% prevalence and binary outcomes of 2-5% prevalence.

ETHICS AND DISSEMINATION

Ethics approval for the study has been received from national Human Research Ethics Committees, and from committees in States and Territories, including relevant Aboriginal and Torres Strait Islander organisations. Development, recruitment, retention, and dissemination strategies utilised in the Mayi Kuwayu Study are based on principles of Indigenous data sovereignty and best practice for cohort studies of Aboriginal and Torres Strait Islander peoples.[14-17] It is intended that the study be perceived as an Indigenous community activity that promotes Indigeneity, building on Indigenous relationality, and the importance of family and kin networks.

Consent

Participation in the Mayi Kuwayu Study is voluntary. Potential participants will receive a plain-language information sheet about the study, along with the consent form and survey. The study uses a structured, staged consent form, where participants opt-in to specific study components (baseline survey, data linkage, and/or recontact), rather than a blanket consent form covering all study components. This empowers individuals to participate only in aspects of the study with which they are comfortable. This staged approach has been previously used in an Aboriginal and Torres Strait

Islander cohort study, and has been demonstrated to be an appropriate method for recruiting and retaining Aboriginal study participants.[18] Participants can withdraw consent at any time.

Data sharing statement

Access to the Mayi Kuwayu data resource will be determined by a data access policy, developed and enforced by the Mayi Kuwayu governing body. This data access policy will ensure that Aboriginal and Torres Strait Islander peoples and organisations control the research that is conducted using data from the Study. Evaluation of data access requests for data access will include assessment of stakeholder needs, utility of findings to community and policy, and likely contribution to knowledge.

Approved researchers will have access to a confidentialised unit-record level dataset via a secure server. Each participant will be given a unique ID code, and any potentially identifying information (e.g. names, date of birth, address, or references to specific places or persons) will be removed from the dataset prior to use.

Dissemination

Dissemination of findings from the Mayi Kuwayu Study will be subject to approval from the governing body. With approval, findings will be disseminated through forms including community dissemination meetings, community reports and feedback sheets, policy briefs, manuscripts for peer-reviewed publication, conference presentations, and public seminars.

DISCUSSION AND IMPLICATIONS

Representativeness

The Mayi Kuwayu Study is not intended to be representative of the entire Aboriginal and Torres Strait Islander adult population. However, the Study aims to capture much of the diversity of the Aboriginal and Torres Strait Islander population nationally, with sufficient heterogeneity across exposures. The aim of the study is to generate evidence based on internal comparisons, and to examine within-population variation in these associations.

While this has not been explored specifically within the Aboriginal and Torres Strait Islander population, in general, representativeness is not necessary for reliable quantification of exposure-outcome relationships.[19 20] Algebraic work and simulation studies provide evidence on the validity of internal comparisons in the face of varying response rates.[21] Moreover, experience over time from a wide range of epidemiological research has also shown this to be the case. For example, the British Doctors' Study, where doctors are clearly not representative of the general population, yet findings based on internal comparisons remain valid (e.g. the association between smoking and mortality);[22] pooled analyses incorporating cohort studies, case-control and other study designs tend to find materially similar findings among studies with varying response rates.[23] Further, a representative sample may not contain sufficient numbers of specific exposures or outcomes of importance. Thus, while high response rates and representativeness are essential to censuses and population health surveys (where the main aim is to accurately estimate point prevalence), these features are not essential or recommended for cohort studies.[24]

Implications

The Mayi Kuwayu Study will establish an ethical, community-focused and Aboriginal-controlled resource that will contribute to a holistic and robust understanding of Aboriginal and Torres Strait Islander culture, health and wellbeing. It will be an Aboriginal-controlled collaborative resource for research, conducted in strict accordance with current ethical, community and Aboriginal and Torres Strait Islander research standards.[25-30] The participatory methods will support the relevance of findings for individuals, communities, health services, and policy makers across portfolios.

This novel study will be the first of its kind, providing a large-scale national cohort study about the wellbeing of Aboriginal and Torres Strait Islander adults. It will provide the first community-derived measures of culture, and the first quantitative evidence regarding Indigenous cultural expressions and contexts at the national level. It will enable the first large-scale investigation of the relationship between culture and wellbeing for Aboriginal and Torres Strait Islander adults. This will identify opportunities to incorporate culture in programs and policy to improve Aboriginal and Torres Strait Islander wellbeing.

There is currently limited incorporation of Aboriginal and Torres Strait Islander culture in programs and policies – a dimension that is likely to be critical to effectiveness and acceptability. Evidence from the Mayi Kuwayu study may increase the prioritisation of culture in the design of program and policy.

Author contributions: RL conceived the study. KT, RJ, and RL drafted the manuscript. RL, EB, CD, TD, MW, SE, LS, MD, WD, AO, JS, JC, RJ and KT contributed to developing the study design and content. All authors provided comments and critical revisions on the manuscript and approved the final version.

Ethics approvals: Ethics approval for the study has been received from the following Human Research Ethics Committees (HRECs): the Australian Institute of Aboriginal and Torres Strait Islander Studies HREC (approval number: E030/22052015); the Australian Government Department of Health HREC (10-2017); the Aboriginal Health and Medical Research Council of New South Wales Ethics Committee (1268/17); Central Australian Human Research Ethics Committee (CA-17-2810); the Northern Territory Department of Health and Menzies HREC (2017-2804); the Australian National University HREC (2016/767); the University of Tasmania HREC (H0016473); Aboriginal Health Research Ethics Committee (14-07-723); St. Vincent's Hospital Melbourne HREC (HREC 132/17); the Western Australian Aboriginal Health Ethics Committee (787).

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Competing interests: The authors declare no conflict of interest.

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Mayi Kuwayu Study Team members not listed as authors on this manuscript include (ordered alphabetically): Ngaire Brown (South Australian Health and Medical Research), Patricia Bushby (Aboriginal Health Council of Western Australia), Dawn Casey (National Aboriginal Community Controlled Health Organisation), David Cooper (Aboriginal Medical Services Alliance Northern Territory), Raylene Foster (Tasmanian Aboriginal Centre), Jill Guthrie (The Australian National University), Nadine Hunt (The Australian National University), Rochelle Jones (The Australian National University), Louise Lyons (Victorian Aboriginal Community Controlled Health Organisation Inc.), Shane Mohor (Aboriginal Health Council of South Australia), John Paterson (Aboriginal Medical Services Alliance Northern Territory), Sharnie Read (Tasmanian Aboriginal Centre), Lachlan Russell (The Australian National University), Julie Tongs (Winnunga Nimmityjah Aboriginal Health and Community Services Ltd), Patricia Turner (National Aboriginal Community Controlled Health Organisation), and Alyson Wright (The Australian National University).

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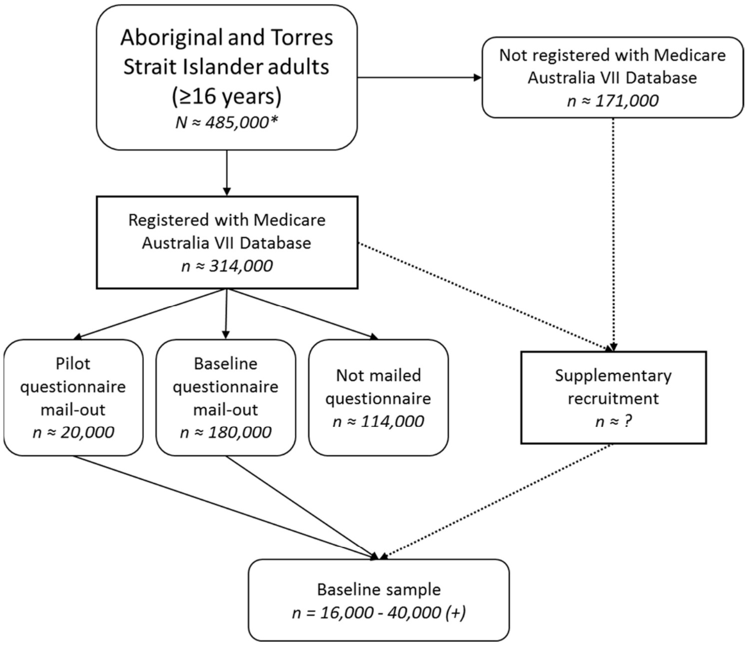
FIGURE LEGENDS

Figure 1. Flow diagram for Mayi Kuwayu Study recruitment

**Estimated undercount-adjusted population of Aboriginal and Torres Strait Islander peoples aged ≥16 years. Calculated by adjusting the raw Census count (n=414,532) for the overall 2016 Census undercount for the Aboriginal and Torres Strait Islander population (17.5%).*[10] *Data are unavailable on the extent of undercount by age group within the Aboriginal and Torres Strait Islander population.*

Figure 2. Mayi Kuwayi Study timeline



Flow diagram for Mayi Kuwayu Study recruitment

*Estimated undercount-adjusted population of Aboriginal and Torres Strait Islander peoples aged ≥16 years. Calculated by adjusting the raw Census count (n=414,532) for the overall 2016 Census undercount for the Aboriginal and Torres Strait Islander population (17.5%).10 Data are unavailable on the extent of undercount by age group within the Aboriginal and Torres Strait Islander population.

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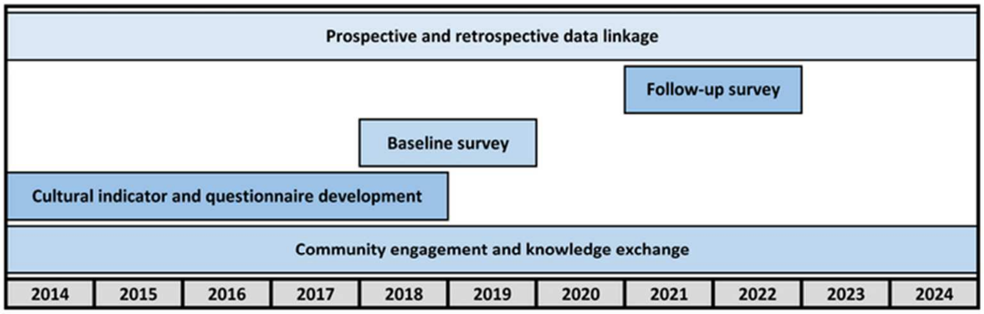

Mayi Kuwayi Study timeline

62x22mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1, 2	'longitudinal study'
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2	'Method and analysis' section
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4	'Rationale' section
Objectives	3	State specific objectives, including any prespecified hypotheses	5	'Objectives' section, and hypothesis
Methods				
Study design	4	Present key elements of study design early in the paper	5-8	Sections on study recruitment (primary sampling frame, supplementary recruitment methods) and study components (survey development, baseline survey, follow up surveys, data linkage).
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5-8	As above
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5-8	As above
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed	5-8	As above

		Case-control study—For matched studies, give matching criteria and the number of controls per case		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9	'Statistical methods' section
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7	Key survey domains and measures outlined in Table 2
Bias	9	Describe any efforts to address potential sources of bias	8-11	'Statistical methods' and 'representativeness' sections
Study size	10	Explain how the study size was arrived at	5-8	Sections on study recruitment (primary sampling frame, supplementary recruitment methods) and study components (survey development, baseline survey, follow up surveys, data linkage).
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8-9	'Statistical methods' section; Key survey domains and measures outlined in Table 2
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8-9	'Statistical methods' section provides an overview of methods to be applied to this Study (note: this paper is a study protocol and does not report specific analysis)
		(*b*) Describe any methods used to examine subgroups and interactions	8-9	As above
		(*c*) Explain how missing data were addressed	8-9	As above
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	8-9	As above

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy		
		(*e*) Describe any sensitivity analyses	8-9	As above
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA	NA – Study Protocol
		(b) Give reasons for non-participation at each stage	NA	NA – Study Protocol
		(c) Consider use of a flow diagram	NA	NA – Study Protocol
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA	NA – Study Protocol
		(b) Indicate number of participants with missing data for each variable of interest	NA	NA – Study Protocol
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	NA	NA – Study Protocol
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	NA	NA – Study Protocol
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA	NA – Study Protocol
		Cross-sectional study—Report numbers of outcome events or summary measures	NA	NA – Study Protocol
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA	NA – Study Protocol
		(*b*) Report category boundaries when continuous variables were categorized	NA	NA – Study Protocol
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA	NA – Study Protocol
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA	NA – Study Protocol
Discussion				
Key results	18	Summarise key results with reference to study objectives	NA	NA – Study Protocol
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	8-11	'Statistical methods' and 'representativeness' sections
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	NA	NA – Study Protocol
Generalisability	21	Discuss the generalisability (external validity) of the study results	10	'Representativeness' sections

Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12	'Funding statement'

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.