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Protocol for a non-randomised stepped-wedge pilot trial for 'Nra:gi Ya:yun' (very good foods): a co-designed type 2 diabetes and metabolic syndrome initiative with Aboriginal people living on Ngarrindjeri Ruwe

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ABSTRACT

Introduction Type 2 diabetes mellitus (T2D) and metabolic syndrome (MetS) have reached epidemic proportions for Indigenous populations globally. In Australia, disproportionate rates of T2D and MetS are inextricably tied to the experience of colonisation. As part of a growing shift towards strengths-based, Aboriginal-led initiatives, this project sought to co-design and assess the feasibility of a metabolic remission initiative, whereby Aboriginal people living on Ngarrindjeri Ruwe (Country) are supported to adopt a low-carbohydrate diet.

Methods and analysis This 28-week pilot takes the form of a non-randomised stepped-wedge design. Aboriginal adults (≥18 years) living on Ngarrindjeri Ruwe with T2D or MetS will be recruited to two sites in rural South Australia. Participants will transition through three phases (control phase, remission phase and maintenance phase) with repeated measures taken across five key time points (T1–T5). While centring on the adoption of a low-carbohydrate diet, participants will be equipped with continuous glucose and ketone monitors and meal boxes and offered ongoing support through weekly to fortnightly check-ins. The primary outcome is to assess the feasibility of Nra:gi Ya:yun in preparation for a large-scale clinical trial of similar design. Feasibility will be assessed through recruitment, retention and adherence rates. Self-reported dietary recall, out-of-pocket food costs and national pharmaceutical and medical benefits scheme data will also be examined. Qualitative data obtained using the Aboriginal research method of yarning will aid analysis and interpretation of results. Clinical measures (such as blood pressure, weight, waist circumference, capillary ketones and capillary glucose) and venous blood draws will assist in the evaluation of our secondary outcome, namely the initiatives' preliminary effect on participant metabolic health.

Ethics and dissemination Findings will be disseminated to Community, participants and policymakers in the form of digital posters, manuals, infographics and peer-reviewed publications. Lessons from this study have the potential to provide insights and benefits to Australian public health policy and research, as well as Indigenous populations globally who face similar metabolic challenges. Findings will be used to advise on an implementation strategy for a large-scale clinical trial. Pilot trial approved by the Aboriginal Health Research Ethics Committee (HREC), Flinders University HREC and Southern Adelaide Local Health Network HREC.

Trial registration number Pilot prospectively registered with the Australian and New Zealand Clinical Trials Registry ACTRN12624001019594.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Adoption of a pragmatic, non-randomised stepped-wedge design to emulate the anticipated design of a large-scale trial, assess feasibility and ensure study complies with ethical research practices at national and community level.
⇒ This multicomponent intervention focuses on low-carbohydrate eating and will be assessed using clinical measures and yarning methods.
⇒ Intervention components and data collection methods draw on the strengths of Aboriginal ways of knowing, being and doing and Western epistemology, ontology and axiology.
⇒ As a pilot study, findings will produce limited external validity, but feasibility outcomes and preliminary metabolic outcomes will inform a large-scale trial with Aboriginal communities for potential wide-reaching impacts.

INTRODUCTION

Despite estimates that global health expenditure on diabetes will surpass US$490 billion by 2030,[1] diabetes remains a significantly underestimated global burden.[2 3] For Indigenous peoples globally, type 2 diabetes mellitus (T2D) and metabolic syndrome (MetS) disproportionally impact upon individual and collective health and well-being.[4] In Australia, T2D represents close to 90% of diabetes diagnoses,[5] with an estimated 10.7% of Aboriginal and Torres Strait Islander of adults living with T2D (terminology adopted throughout this protocol will reflect the focus of the study, specifically Aboriginal people living on Ngarrindjeri Country).[6] Beyond the pathophysiological consequences, T2D and MetS can incur psychological, social and financial challenges for individuals, families and communities, many of whom view the condition as inevitable and chronic.[7 8]

Since time immemorial, Aboriginal people on Ngarrindjeri Ruwe (Country) have been caring for and maintaining the health of Community and Country.[9] The Nra:gi Ya:yun protocol emerged out of a larger study to co-design a diabetes remission programme with Aboriginal people living on Ngarrindjeri Ruwe.[10] The project is Community-led, initiated by elders and senior Ngarrindjeri Community representatives who witness first-hand the impacts of diabetes prevalence on Ngarrindjeri Ruwe. Nra:gi Ya:yun is guided by Knowledge Interface Methodology[11] and Strengths-Based approaches, details of which have previously been published.[8 10 12] Findings from the formative and co-design phases of the Nra:gi Ya:yun project (phase 1 and phase 2)[8 13] have directly informed the nature of this protocol and further reinforce the need for holistic, community-centred and Aboriginal-led projects. Through the process of co-design, the title of the diabetes remission programme was gifted as Nra:gi Ya:yun translating to *very good food/very good eating* in Ngarrindjeri language. The spelling for 'Nra:gi Ya:yun' adopted throughout the remainder of the protocol is reflective of discussions with Ngarrindjeri Community elders. The authors recognise there may be multiple variations of spellings across Community. The method of co-design will be detailed in an upcoming publication,[13] but centred on 10 workshops conducted over a series of 6 months on Ngarrindjeri Ruwe.

For Aboriginal people, the impacts and prevalence of T2D and MetS are driven by a complex interplay of social and cultural determinants of health, inextricably tied to the legacy of ongoing colonisation.[14 15] Aboriginal ways of knowing, being and doing with regard to food consumption, production and distribution continue to be impacted, leaving long-lasting physical and psychological consequences.[16 17] Moreover, public health interventions that target metabolic outcomes have not prioritised the diversity of strengths and opportunities offered by Aboriginal knowledge systems. As advocated for by peak national research bodies, strengths-based approaches that privilege the lived experience of Aboriginal communities through a process of genuine co-design should be adopted to shift the narrative.[18–20] This study seeks to remedy the dearth of Western evidence by detailing the protocol for a co-designed, low-carbohydrate initiative informed by Aboriginal ways of knowing, being and doing.

Evidence suggests that a very low-carbohydrate or ketogenic diet can be effective at improving T2D and MetS outcomes and may put T2D into remission.[21–23] Endorsed by the Australian Diabetes Society Clinical Advisory Committee,[24] this approach is also hypothesised to be more feasible and sustainable for Aboriginal communities, especially given the limitations of alternative evidence-based treatments, such as low-calorie diets and limited access to bariatric surgery.[12]

Aims

The aims of this pilot study are twofold: first, to assess the feasibility of the Nra:gi Ya:yun initiative with Aboriginal people living on Ngarrindjeri Ruwe, to inform the implementation of a large-scale trial; second, to determine the preliminary effects of the initiative on participant metabolic health.

METHODS AND ANALYSIS

Study team

The trial will be implemented by an investigative team of Aboriginal and non-Aboriginal researchers, clinicians and health workers from the Riverland Mallee Coorong Local Health Network (RMCLHN), Flinders University (trial sponsor), Moorundi Aboriginal Community Controlled Health Service (MACCHS), Integrated Cardiovascular Clinical Network SA (iCCnet SA) and Coorong Medical Centre. Supported by the Australian Teletrial Program South Australia (ATP-SA), the study will emulate the form of a teletrial, whereby telehealth technology will be used to communicate between the primary site (Flinders University) and satellite sites located in the RMCLHN catchment area. Instrumental to the co-design and implementation of this trial is the Aboriginal Health Team at the RMCLHN. This group of Ngarrindjeri and Aboriginal investigators will be referred to as the Diabetes Remission Program (DRP) team.

Study design and intervention

Due to the novel nature of this co-designed initiative and the pragmatic requirements of conducting research with Aboriginal communities,[18] a pilot trial will enable the investigative team to determine feasibility of the trial process, data collection methods, intervention components, resource requirements, cultural appropriateness and refine good clinical practices before the intended implementation of a large-scale trial with Aboriginal communities.[25] The decision to adopt a stepped-wedge design was informed by the co-design workshops, whereby the Community revealed their concerns for shared and equitable benefits across any and all research initiatives, suggesting all eligible participants be able to receive

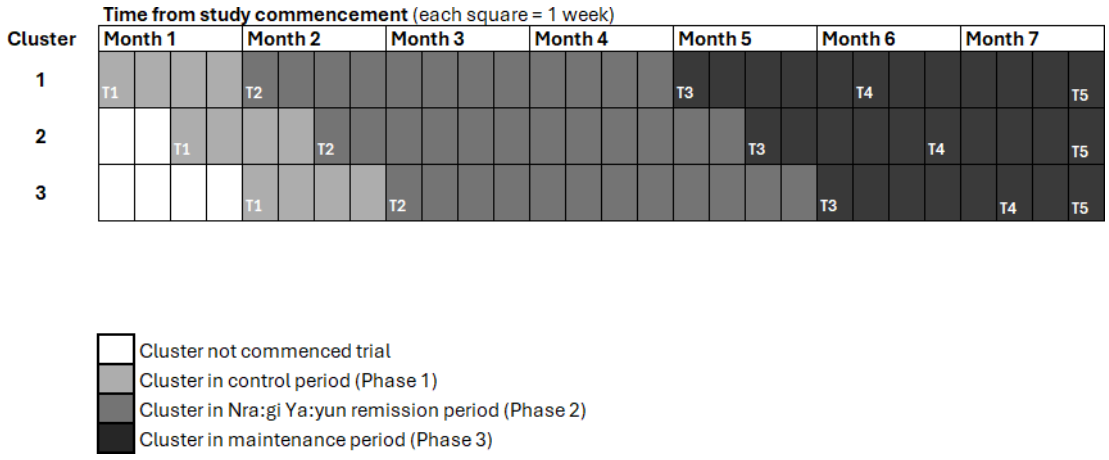

Figure 1 Schematic outline of the 28-week stepped-wedge Nra:gi Ya:yun pilot. T1—baseline, recorded at beginning of control period. T2—pre-remission exposure, collected post-control period. T3—post-remission exposure, collected post Nra:gi Ya:yun remission period. T4—follow-up, collected 6 weeks into maintenance phase. T5—final follow-up, collected at end of 28-week pilot.

the same intervention.[13] Moreover, a stepped-wedge design would support the team with pragmatic and logistical requirements while fulfilling the need for robust analysis.[26]

The study has been developed in line with Good Clinical Practise guidelines, Standard Protocol Items: Recommendations for Interventional Trials guidelines,[27] the National Health and Medical Research Council (NHMRC) guidelines,[19] and the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) guidelines for ethical research with Aboriginal and Torres Strait Islander communities.[18]

The 28-week non-randomised stepped-wedge pilot trial consists of two sites and three clusters. Each cluster will experience three phases: a control phase, a remission phase and a maintenance phase (ongoing). The remission phase is considered the active phase of the study, whereby participants will be supported to adopt a low-carbohydrate diet. During the maintenance phase, support systems are gradually withdrawn as participants are equipped with the knowledge, resources and support, as well as ongoing RMCLHN and MACCHS support, to sustainably maintain remission independently.

Each cluster will serve as its own control, initially experiencing a 4-week period of monitoring but no exposure. Exposure to the fixed 12-week remission phase will be staggered by cluster on a fortnightly basis, see figure 1. The assignment of 12 weeks for the active phase of the trial builds on existing research on habit formation.[28 29] Each participant will experience the project's three phases. Repeated measures will be taken across five time points (T1–T5).

Clusters will be allocated based on geographical convenience and participant preference (self-allocation). As a pilot study, randomisation and blinding will not be possible. This is primarily due to impractical and ethical constraints but fits in with best practice in Aboriginal health research which demands Aboriginal governance, community benefit and the prioritisation of research transparency and accountability.[18 19]

Co-design workshops identified the need for safe and appropriate communication, engagement and data collection methods. The Aboriginal research method of yarning was selected to facilitate rich qualitative data collection and ongoing participant engagement. To be led by the DRP team, yarning demands the development of relationships of reciprocity and accountability during the mutual sharing of stories.[30] This method has been shown to be an appropriate and legitimate data collection tool, producing thick data by offering a relaxed and safe space for participants to share their lived experiences.[30 31]

Intervention components

Details of intervention components and corresponding phases are outlined in table 1.

The Nra:gi Ya:yun Remission Journey resource will be developed iteratively throughout the pilot, informed by participant needs as disclosed during the weekly to fortnightly yarning check-ins. Early indications from the co-design workshops suggest that low-carbohydrate recipes, meal plans or culturally tailored T2D and MetS guides may be beneficial. The fortnightly gatherings are envisioned to create a shared and welcome environment for discussion of these resources and overall remission progress. To support participants along their remission journey, members of the DRP team will also receive health coach training and mentorship from the Low Carb Keto Health team.

A staggered transition into the maintenance phase will empower participants to continue their T2D and MetS remission journey, with sustainability of health outcomes in mind. In this final phase, Nra:gi Ya:yun Fresh boxes will not be supplied, but participants will be supported by the DRP staff to source ingredients independently. To support Community ownership of the process, fortnightly gatherings, check-in yarns and online supports

Table 1 Intervention components for participants and corresponding study phases

	Component	Details and purpose	Phase 1 (control)	Phase 2 (remission)	Phase 3 (maintenance)
Equipment and resources	Continuous glucose monitor (CGM) and continuous ketone monitor (CKM)	▶ Encourage participant motivation and compliance ▶ Ensure up-to-date glucose and ketone readings for programme staff ▶ Readings uploaded automatically every 5 min	✓ For last 2 weeks	✓	✓ For first 2 weeks
	Home monitoring using point of care testing (PoCT) equipment and tablets	▶ Record basic physiological measures, CGM/CKM discomfort scores, e-yarns* on participant well-being ▶ Home monitoring to be completed daily ▶ Takes approximately 10 min to complete monitoring questions ▶ Results uploaded automatically to tablet via Bluetooth	✓ For last 2 weeks	✓	✓ For first 2 weeks
	Physiological check-ins using in-person PoCT	▶ Weekly to fortnightly, face-to-face ▶ Inclusive of basic physiological measures such as capillary ketones and glucose	X	✓	X
	Nra:gi Ya:yun fresh meal boxes	▶ Meal boxes containing ingredients per participant ▶ Supplied weekly with donations from local providers	X	✓	X
	Nra:gi Ya:yun Remission Journey	▶ Incremental provision of tailored programme infographics (eg, pantry lists, meal plans, recipe cards) adapted with consent from Duke University Keto Protocol[22 54] ▶ Planned development of a Nra:gi Ya:yun recipe book and programme guide (electronic versions available)	X	✓	✓ Retain access from Phase 2
Participant support	Check-in yarns	▶ Weekly to fortnightly yarning check-ins and support sessions with Diabetes Remission Program (DRP) team on trial progress and challenges ▶ Length and medium of session (face-to-face or over the phone) directed by participant and DRP team ▶ To build on previous week's check-in, facilitating relationship building with participant	X	✓	✓ Transition to Community-led
	Fortnightly gatherings	▶ Fortnightly 1-hour gatherings (education sessions on low carbohydrate diet, type 2 diabetes mellitus (T2D) and metabolic syndrome (MetS), and physical activity) facilitated by the DRP team ▶ Session focus informed by participant feedback on Community concerns raised during the formative co-design phase of the study (eg, walking on Country, diabetes education)	X	✓	✓ Transition to Community-led
	Online support	▶ Online support for participants who cannot attend in person (ie, due to work, family/caring commitments) through telephone messages or phone calls ▶ Electronic resources and short videos on key content of fortnightly gatherings	X	✓	✓ Transition to Community-led

*E-yarns will take the form of a modified Visual Analogue Scale (VAS) on physical and psychological health, followed by the option to share a video response with staff. Participants will be encouraged to contact DRP team, local and national service providers if they require a more comprehensive or 'proper' yarn to discuss well-being.

will continue, but with a transition towards Community-led, informal initiatives facilitated by the DRP team. This approach was directly informed by the priorities identified during the co-design workshops, embedded in holistic, sustainable and relational ways of doing.[13] Ensuring Community ownership over the initiative not only supports wider efforts to implement culturally safe chronic disease promotion,[32] but has been shown to improve metabolic health outcomes.[33 34]

The utilisation of point of care testing (PoCT) components is informed by existing research demonstrating the clinical and cultural effectiveness of PoCT for diabetes management in Aboriginal communities.[35 36] PoCT devices used in home monitoring and weekly to fortnightly physiological check-ins, while serving a secondary purpose of secondary outcome data collection and clinical oversight, are primarily intended to encourage participant motivation and T2D or MetS self-management. The provision of PoCT components and continuous glucose monitors (CGMs) throughout the trial is supported by a substantial evidence base, with earlier studies demonstrating positive impacts on motivation, behaviour change and self-management of diabetes control.[36–39]

Study timeline

Planned recruitment dates are from December 2024, with trial completion expected in August 2025.

Study setting

This study will take place on Ngarrindjeri Ruwe, an area rich in knowledges, oral traditions and biodiversity situated throughout the lower Murray, Lakes and Coorong

Table 2 Nra:gi Ya:yun inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Aboriginal person living on Ngarrindjeri Ruwe*	Pregnancy
Aged ≥18 years	Type 1 diabetes
Records measurements consistent with previously diagnosed type 2 diabetes mellitus (T2D) OR meeting the MetS criteria,[55] as defined by three of five of the following outcome measures: ► Waist circumference: >90 cm men or >80 cm women (WHO method).[42] ► Blood pressure: systolic >130 or diastolic >85 mm Hg OR taking antihypertensive medication. ► High-density lipoprotein (HDL): non-fasting <1.03 men and <1.29 women OR drug treatment for reduced HDL. ► Elevated glucose: HbA1c levels >6.0% triglycerides: non-fasting >1.98 or fasting >1.7 mmol/L OR drug treatment for elevated triglycerides.[56]	End-stage liver failure or undergoing dialysis
	Type 3c diabetes (primary pancreatic disease)
	Breastfeeding women
	Self-reported eating disorders (anorexia, nervosa, bulimia)
	On SGLT2 inhibitors for reasons other than diabetes (ie, renal disease or heart failure)

*Due to colonisation, a range of Aboriginal language groups are represented on Ngarrindjeri Ruwe. Inclusion criteria are therefore not limited to Ngarrindjeri people.

region of South Australia. Site 1 is classified as a large rural town (MM 3) and site 2 a small rural town (MM 5) on the Modified Monash (MM) model.[40] The two study sites align with RMCHLN service area.

Participant eligibility

Inclusion and exclusion criteria are outlined in table 2. Time since diagnosis of T2D or MetS will not impact eligibility. Exclusion criteria will be assessed against participants' self-reported conditions and compared to participants' medication profile at baseline.

Sample size justification

As a pilot trial, the sample size is informed by recruitment considerations and pragmatics of the study.[25] Drawing on high Community interest with Nra:gi Ya:yun established during the co-design workshops, we initially anticipated being able to recruit approximately 120 participants. However, due to unforeseen delays in the project and informal conversations with the DRP at the Community level, a target of 60 participants was agreed upon. This still adheres to the current rule of thumb for pilot studies, whereby 12 to 35 per group is recommended for continuous outcomes.[41]

Our justification is further informed by national data reporting the T2D rate for Aboriginal people as 10.7%.[6] With an estimated 700 Aboriginal people living across townships throughout Ngarrindjeri Ruwe, we expect over 70 individuals to have an existing T2D diagnosis in Community. Combined with individuals meeting MeTs inclusion criteria, and the tendency for underreported T2D rates among Aboriginal communities, we anticipate the number of eligible participants to be much higher.

Recruitment

Recruitment will be staggered over 10 weeks to cover the three clusters incrementally. Recruitment will be achieved through four mechanisms: (1) partnering with general practitioners, (2) Community outreach by the DRP team, (3) programme champions and (4) Community screening days. Programme champions will be embedded Community members who are interested in participating in the Nra:gi Ya:yun initiative and willing to promote the programme. Screening days will use PoCT devices to measure HbA1c and lipid profiles, as well as additional MetS criteria,[42 43] to assess participant eligibility (see online supplemental table 1).

Participants must provide written informed consent after reviewing the information sheet with the DRP team, before joining any pilot activities, including Community screening days. Participants will not be renumerated but will have access to the subsidised Nra:gi Ya:yun Fresh boxes, CGM/continuous ketone monitors (CKMs) and resources detailed in table 1.

Outcome measures and data collection

Table 3 details the proposed data collection methods for our two aims respectively and the corresponding data collection time points. For our secondary aim, these methods were designed to emulate outcome measures for the larger trial and assess feasibility. These parameters will act as indicators for protocol adherence and retention rates. As demonstrated in table 1, repeated measurements will be taken across five time points (T1–T5).

Check-in yarns with the DRP team will be conducted face-to-face; however, phone or videoconferencing communication is encouraged where this is not possible. A short yarning guide (online supplemental 2) has been developed to aid with check-in yarns and support the capture of relevant outcomes from table 3. However, as the DRP team will lead the yarns in a process of mutual story sharing, the guide serves only as a reference, with the DRP team directing the flow and format. Rapid check-in yarning and the weekly to fortnightly physiological measurements may be obtained during the collection

Table 3 Outcome measures for feasibility and preliminary metabolic effects

Outcome	Measured parameters	Data collection method	Time points
Primary outcome measures (feasibility)			
Feasibility and adherence	Recruitment, retention, adherence, completion rates	Study records	Continuous
	Modified 24-hour dietary recall	Rapid weekly to fortnightly check-in yarning with Diabetes Remission Program (DRP) team	T1–T5, and weekly to fortnightly during phase 2
Individual financial feasibility	Self-reported weekly food expenses	Rapid weekly to fortnightly check-in yarning with DRP team	T1–T5, and weekly to fortnightly during phase 2
	Closing the Gap Program (CTGP), Medical Benefits Scheme (MBS) and Pharmaceutical Benefits Scheme (PBS)	Services Australia data request	T1, T5
Acceptability	Participant opinions on acceptability	Rapid weekly to fortnightly check-in yarning with DRP team	T1–T5, and weekly to fortnightly during Phase 2
	Participant group evaluation on acceptability	Group yarning facilitated by DRP team	End of study
Secondary outcome measures (preliminary metabolic effects)			
Type 2 diabetes mellitus (T2D) or metabolic syndrome (MetS) clinical effects	Clinical measures including blood pressure, weight, waist circumference, capillary ketones and glucose, blood oxygen, temperature	(1) Face-to-face data collection with DRP team and (2) home monitoring using point of care testing (PoCT) equipment	1. Weekly to fortnightly during Phase 2 2. Daily during phase 2 and 2 weeks on either side
	HbA1c, glucose, insulin, electrolytes, estimated glomerular filtration rate, gamma-glutamyl transferase, urate, total triglycerides, ketones, C-peptide, albumin/creatine ratio (urine sample), complete blood examination haemoglobin, C-reactive protein, serum iron, active B_{12}, red blood cell folate	Fasting venous blood and urine sample	T1–T5
	Blood glucose and ketone concentrations	Continuous glucose monitor (CGM) and continuous ketone monitor (CKM) and associated phone applications	Continuous wear during phase 2 and 2 weeks on either side of phase 2
Knowledge	Participant knowledge (eg, diabetes and ketosis knowledge, understanding, lessons learnt)	Rapid yarning with DRP team	T1–T5
Effect of T2D or MetS on life course	Modified social and emotional e-yarns and Visual Analogue Scale (VAS) (home monitoring)	Self-monitoring PoCT	Daily during phase 2, 2 weeks on either side of phase 2
	Participant reflections on impacts of T2D or MetS	Rapid yarning with DRP team	T1–T5
	Quality of life— EuroQol 5-Dimension 5-Level (EQ-5D-5L)	Questionnaire administered by DRP team	T1–T5
	Modified VAS sleep scale	Rapid weekly to fortnightly check-in yarning with DRP team	T1–T5, and weekly to fortnightly during phase 2

of Nra:gi Ya:yun Fresh boxes. Participants will be asked to consent to house visits by the DRP team if no contact can be made for a well-being check.

The use of modified Visual Analogue Scales (VAS) for measuring sleep, CGM/CKM discomfort and social and emotional well-being (SEWB) will be paired with rapid yarning led by the DRP team. The use of VAS for sleep and SEWB has been previously validated in other settings;[44 45] however, modifications, led by the DRP team, will ensure the scale accounts for the sociocultural and Community health contexts of participants living on Ngarrindjeri Ruwe.

To assess participants' health-related quality of life, the EuroQol 5-Dimension 5-Level (EQ-5D-5L)[46] questionnaire will be administered by the DRP team. Whilst the EQ-5D-5L has been validated in Aboriginal populations,[47] it remains limited in its ability to capture Aboriginal dimensions of cultural, social or spiritual health,[48] and the various interacting domains such as family, Country or autonomy.[47 49] The administration of EQ-5D-5L in conjunction with weekly to fortnightly yarning is intended to provide researchers with additional context and data to accurately position participants' lived experience with Nra:gi Ya:yun.

Statistical methods

The study will follow Consolidated Standards of Reporting Trials reporting guidelines for stepped-wedge trials,[26 49] and Strengthening the Reporting of Observational Studies in Epidemiology guidelines for observational studies,[50] noting that these guidelines will be combined to ensure accurate reporting of this non-randomised study. Study analysis will primarily be informed by descriptive statistics. As a pilot study, inferential statistical tests and power calculations are not applicable.[25] Intervention feasibility and preliminary effects will be examined using mixed methods analysis. Patient demographics will be presented as general descriptive statistics—means, SD and/or counts (%) for the step-wedge cohort as a whole. Preliminary metabolic effects will be presented using the trajectory of change for key measures (such as HbA1c and weight circumference), with plotted time trends and means across T1–T5.

Participant cost data will be combined with outcome data to inform both cost-effectiveness and cost-utility analyses of the upscaled Nra:gi Ya:yun remission programme. These analyses will compare the 7-month costs and outcomes of the Nra:gi Ya:yun remission programme to those from the 7-month period prior to programme implementation. Cost-effectiveness will be expressed as the incremental cost of participant engagement, while cost-utility will be presented as the incremental cost per quality-adjusted life year (QALY) gained. QALYs will be estimated using EQ-5D-5L responses collected during the study to reflect programme-related quality of life, and supplemented by published literature to approximate baseline (pre-programme) quality of life.

Qualitative data from weekly to fortnightly rapid yarns and evaluation yarns (concerning quality of life, knowledge and programme acceptability) will be inductively coded in NVivo software using a constructivist approach to grounded theory,[51] and themes generated across time points compared for analysis. Data will be collaboratively interpreted with Aboriginal investigators to confirm validity. Group yarns held at the end of the pilot will further explore programme feasibility and acceptability, seeking recommendations on how to upscale this intervention for wider uptake.

Data collected on behalf of ATP-SA will be provided to the ATP-SA and combined with information from additional teletrial participants to assess the effectiveness of the teletrial model for individuals in regional, rural and remote areas. Analysis will be conducted by research teams from James Cook University and Queensland University of Technology and reported back to the Australian Government Department of Health.

ETHICS AND DISSEMINATION

This protocol has been approved by the Aboriginal Health Research Ethics Committee (04-24-1120), the Southern Adelaide Local Health Network (HRE00133) and Flinders University Human Research Ethics Committee (5847). NHMRC and AIATSIS guidelines for ethical research with Aboriginal and Torres Strait Islander communities were followed.

Clinical monitoring will occur by clinical members of the investigative team, including an experienced general practitioner and an endocrinologist, as part of the weekly Safety Monitoring Committee (SMC). The SMC will assess the clinical and cultural safety of the intervention and make changes as required. Members of the DRP team will sit on the committee. Participants will be closely monitored, and referrals provided when required. A clinical distress protocol has been developed outlining clinical parameters and necessary follow-up procedures.

Weekly clinical monitoring will be informed by the daily CGM and CKM readings, daily home monitoring PoCT results, weekly to fortnightly physiological measures and pathology blood draws, see table 2. Patient-centred alerts will be established on the home-monitoring PoCT. Participants will be triaged to (A) the clinical team for remission, (B) General Practitioner (GP) or emergency department for other clinical standard of care or (C) project staff for supports. Deprescribing guidelines endorsed by the Australian Diabetes Society Clinical Advisory Committee will be followed.[4] SGLT2 inhibitors will be ceased at the commencement of the remission phase.

A multidisciplinary Medical Monitoring Board will also be established to provide oversight in the form of quarterly reviews, ensuring participant safety and making recommendations for continuing or stopping the study. The committee will be comprised of clinicians, researchers and external representatives from local health services.

Data management

Researchers involved in this project will act as data custodians for the duration of the study, upholding their ethical and legal obligations throughout the collection, management and release of data.[52] At pilot trial completion, the study team will work with Ngarrindjeri Elders to achieve data repatriation, ensuring that any and all data retention, interpretation and outputs reflect the needs, interests and experiences of Aboriginal people living on Ngarrindjeri Country.[1] With the exception of national pharmaceutical and medical health data, all data are owned by participants themselves.

All study data will be stored on a protected and secure Flinders University localised server. At pilot completion, all data will remain securely stored on the Flinders University server for fifteen years, after which it will be safely destroyed. Only members of the DRP team and clinical investigators cited on the ethics application will have access to re-identifiable data, strictly for safety monitoring purposes. Investigators conducting data analysis will retain access to the relevant de-identified sets only. As per ATP-SA requirements, at pilot completion, de-identified ATP-SA data (postcode, age, gender, study completion status) will be securely transferred to and stored at James Cook University and Queensland University of Technology.

Aboriginal leadership, governance and capacity building

This study will abide by NHMRC and AIATSIS guidelines for ethical research.[18 19] Aboriginal governance is central to oversight of the programme. The study will be overseen by an Aboriginal project manager and Aboriginal coordinating principal investigator (CPI) and draws on strong Aboriginal leadership evidenced through the seven Aboriginal investigators. Ongoing monthly Steering Committee meetings, established as part of the initial project, will continue throughout the pilot.

The study team recognises the substantial role and responsibility of the DRP team, who will likely become the face of the programme. The DRP team will be offered weekly check-ins via phone or videoconference with the CPI to debrief on any implementation challenges, in addition to scheduled weekly videoconference meetings with Flinders University investigators for additional support.

Initially informed by the wishes of Ngarrindjeri senior Community members and reinforced during the co-design workshops, a foundational intent of the larger Nra:gi Ya:yun study was to stimulate ongoing RMCLHN and MACCHS support and capacity building, encouraging the continuation of programme activities after the conclusion of this study. As part of this, the DRP team will receive ongoing training on research methods, PoCT device usage, and T2D and MetS coaching. With the benefit of multiple community partnerships offering financial and in-kind supports, including RMCLHN, iCCnet, ATP-SA and food donations from Thomas Foods, Goolwa PipiCo and Ancient Lakes Magnesium, this study is anticipated to provide long-lasting benefits to Aboriginal people living on Ngarrindjeri Ruwe.

Dissemination

A summary of the research findings from the study will be disseminated to all interested participants, Aboriginal organisations involved in this study, along with peak bodies, stakeholders and Aboriginal Services. Project findings and materials will take the form of digital posters, manuals, infographics and recipe book(s), created through engagement with Ngarrindjeri artists. Findings will be disseminated through publication in peer-reviewed journals and conference presentations or proceedings.[53]

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