HREA

Title: Diabetes Remission in Aboriginal Women (The DRAW project): Yarning to Reverse T2DM in Aboriginal Women. V1

By Waminda Aboriginal Health Services and the Australasian Society of Lifestyle Medicine

Contact John Stevens: tele 0428288526, email John.stevens@scu.edu.au

THE ROLES OF EACH ORGANISATION

ASLM is seen as the lead organization for managing and providing overall governance of the grant. ASLM will therefore manage the budget and oversee the implementation process as well consult and collaborate with Waminda. Waminda will engage participants in culturally appropriate ways and provide the diabetes management services to all participants. Waminda, the local Aboriginal community and ASLM will co-design the culturally responsive program and materials.

ASLM will produce the program and materials, support the providers in the MYU and the T2DM reversal and prevention program as well as manage the ethics, data and reporting to the Commonwealth.

A DESCRIPTION OF THE APPLYING ORGANISATIONS

The Australasian Society of Lifestyle Medicine (ASLM) is a multidisciplinary society, registered as a charity, leading the establishment of Lifestyle Medicine as central to health and wellbeing, healthcare in Australia and New Zealand. ASLM has pioneered the use Medical Yarn Ups with Aboriginal Communities. Waminda recognizes ASLM as a culturally responsive organization with a mission for restorative justice and autonomy for Aboriginal communities. Waminda has agreed to partner ASLM in this project knowing that ASLM will be culturally appropriate and that Waminda clients will be safe and treated with respect. The Waminda and ALSM collaboration has a growing record for improving health outcomes for Aboriginal women.

Waminda has consistently provided accessible and culturally safe health services to Aboriginal women in the South East of NSW. Waminda has delivered many projects, which seek to reduce the impact of chronic diseases in local communities by strategies that embrace early intervention, lifestyle medicine-oriented practice and holistic health care. Their Model of Care is based on integrated and coordinated care, centering a social model of health and they are known as a leader in combining culture, primary health care, chronic disease management, education and community development approaches to addressing the health needs of Koori communities on the south coast of NSW. They have extensive outreach services across the region and work closely with Aboriginal Elders, groups and community leaders to both consult with and inform the directions of projects like this one.

ASLM brings the expertise in MYUs and capacity to monitor and measure the outcomes of the program and Waminda draws on a strong and multi skilled workforce that can respond in culturally safe and professional ways to community's needs.

Waminda has strong relationships and partnerships with services at a local, regional and state-wide level, including the Illawarra Shoalhaven Local Health District and other Aboriginal Controlled Community Organisations in the Illawarra, Shoalhaven and far South Coast. ASLM has worked closely with this community through projects run with Waminda and others supported by COORDINARE the South East NSW PHN.

The partnership between Waminda and ASLM is pivotal for this project. Recently Waminda has worked with ASLM to pioneer Medical Yarn Ups (AKA Programmed Shared Medical Appointments) *(1)*. Waminda now have staff trained in this model and a specific Diabetes Educator, who is well positioned to lead this pilot. A recently completed (2 year) trial of PSMA (Medical Yarn Ups) in weight management showed high rates of program retention (77%), overall program satisfaction of patients and staff. There was good patient activation resulting in high rates of significant weight loss. The Medical Yarn Up was found to be 4 times more cost effective and up to 8 times more time efficient than standard weight reduction programs within in medical centres. *(2)*

In partnership we have capacity to undertake the project co-designing with community, providing the service and developing materials and processes, with ALSM consulting on Medical Yarn Ups and program design, implementation, continuous improvement and reporting on and publishing data.

1. Egger G, Stevens J, Egger S Volker N. 2019 'Programmed' Shared Medical Appointments (pSMAs) for weight management in primary care: A proof of concept intervention study. Aust Journal of General Practice Vol 48, No 10, 681-688.

2. Stevens J, Egger G, Morgan B. Programmed Medical Yarn Ups for weight management in Aboriginal and Torres Strait Islanders. Medical Journal of Australia 2018; 209 (1): 68. || doi: 10.5694/mja17.01240 Published online: 2 July 2018

Resources

This Project is being funded by Commonwealth Department of Health through

Indigenous Australians' Health Programme, Emerging Priorities Round 2

Grant Opportunity ID GO4300 to the value of $379,500 (includes GST)

BRIEF DESCRIPTION

This project will reverse T2DM in Aboriginal women with sustained HBA1c above 6.5% and prevent T2DM in Aboriginal women who are considered pre-diabetic with HBA1c between 5.6 and 6.4%. This will be achieved by co-designing culturally and scientifically responsive materials and information by and for Aboriginal women to be delivered by a GP, Aboriginal

Health Worker and Diabetes Educator through a procedure called Medical Yarn Ups. The project will address trauma, eating and nutrition, physical activity and other lifestyle determinants of T2DM. Performance indicators will include: sustained reductions in HBA1c to below 5.5%.; development, testing, satisfaction with and adoption of culturally and scientifically responsive materials and procedures that can be used sustainably in practice.

BACKGROUND

Literature review

Aboriginal population in NSW estimated to have a higher prevalence of most major long-term chronic conditions such as diabetes and asthma among several others. The 2020 Overcoming Indigenous Disadvantage report shows that indicators for obesity and nutrition amongst Aboriginal people are in regression. High body mass and physical inactivity are key risk factors for diabetes. Type 2 Diabetes is the fastest growing chronic disease in Australia and is mainly attributed to poor diet, inactivity and obesity (AIHW,2019). Indigenous Australians are four times more likely to be diagnosed with T2D and six times more likely to die from it. Hospitalisations and diabetes related deaths for Aboriginal women living in the Illawarra Shoalhaven and Southern NSW are significantly higher than for non-Indigenous women. The significant health gaps between Indigenous and non-Indigenous Australians stem from a long cycle of socio-political and economic discrimination and dispossession through colonization. Pre-colonisation, Indigenous Australians were free from metabolic diseases as a result of a highly active lifestyle, with moderate high protein nutrient dense diet with intermittent fasting (Bussey 2013; Pascoe 2014).

Indigenous Australians have much higher rates of T2DM compared to non-Indigenous Australians and there is little current research available on how lifestyle modifications can alter the course of their disease. Previous studies have shown that eating a more “traditional” diet consisting of higher fat, moderate protein, and low carbohydrate may produce good outcomes (O’Dea 2016). Furthermore, it has been shown that community owned and led programs consistently result in better uptake of nutritional interventions (Overcoming Indigenous Disadvantage Report 2020, Power et al. 2021).

Rationale

The population of the Illawarra Shoalhaven area in 2015 was 400,000 and is estimated to reach 455,000 by 2031 (Illawarra care service plan 2019), the fastest growing age group is 65-84yrs. It noted that, 64% of people are overweight or obese; 32% have high blood pressure, 11.8% have diabetes or high blood glucose levels and 12.6% are current smokers. This project will target Aboriginal communities in the Illawarra Shoalhaven, Jervis bay and far south coast. 4.7% of the Shoalhaven population, identify as Aboriginal and Torres Strait Islander compared to 2.9% in NSW. Aboriginal people make up 2.9% of the Illawarra population, 54.2% of the Jervis Bay area, 5.5% of the Eurobodalla population, and 0.5% of the Bega/Eden area.

Aboriginal women with a principal diagnosis of diabetes or who are pre diabetic make up about 15% of Waminda's existing clients. Waminda will target Aboriginal women, already engaged through their primary health clinics and wellbeing program (Dead or Deadly) located across at least 2 of their geographic areas of service. Waminda is the only ACCHO specifically working with Aboriginal women to support their health needs and have over 1500 clients accessing their service (Waminda Annual Report 2019). They have a strong focus on integrated and holistic health provision based on self-determination and challenging conventional and mainstream approaches.

AIM and Expected Outcomes

The aim of this project is to:
1) reverse Type 2 Diabetes Mellitus (T2DM) in Aboriginal women with a HBA1c > 6.5%; and
2) prevent Aboriginal women with pre- T2DM (HBA1c between 5.6 and 6.4%) from progressing to a full diagnosis of T2DM, thus significantly improving health outcomes for Aboriginal individuals.

This will be achieved by an initiative using an accessible, culturally safe, scalable, intensive and focussed strategy to reduce HBA1c that includes:

1) the codesign and continual improvement of culturally responsive education and behavioural change information and resources;
2) persistent and strategic messaging using these culturally responsive resources and monitoring, within standard 1 to 1 consultations by Waminda General Practitioners and clinicians;
3) the opportunity to participate in Medical Yarn Ups (Programmed Shared Medical Appointments) in T2DM Reversal/Remission and Prevention.
4) innovative strategies that centre self-determination- and therefore women's control over their health (biometrics, nutrition, genetics, sleep & glucose monitoring)

Community Alignment
This project will build an evidence-base through a community engaged and co-designed approach to address the persistent issue of diabetes amongst Aboriginal women in his area. According to the ATSI Performance Framework (2017:5): there has been no improvement in the mortality rate for diabetes between 1998 and 2015. In 2012–13, 11% of Indigenous adults had diabetes (3 times the non-Indigenous rate). Of those with diagnosed diabetes, 61% had high blood sugar levels

Sustainability
General Practitioners can access MBS item numbers in their usual way for each patient that they individually consult with while in the MYU group. Once materials, resources and procedures have been improved and tested to be culturally safe and responsive this health program with Medical Yarn Ups can potentially be financially self-sustaining beyond the life of the Commonwealth grant that is supporting this trial.

RESEARCH METHODS

Time Frame

The aim is to commence the formal trial from January 2022 till August 2022 and data collection will be finalised by June 2023.

The Research Design

This project is a longitudinal, change from baseline, mixed methods, codesigned intervention trial. The materials and resource development will engage an iterative process and be continually improved based on feedback from participants, providers, the Waminda Cultural Safety committee and the research team.

Participants

The participants will be Aboriginal Women who are registered for Waminda services, in up to 4 community locations withing the Waminda service footprint in Southern NSW, aged between 18 and 75 years with HBA1c of > 6.5 for less than 5 years.

The project aims to recruit up to 40 women, in 4 groups of 10-12, to work with us to help develop and test the intervention.

The intention is to have 2 iterations of the research activity. The project aims to have 2 groups x 10 (total = 20) participants engage in the program at each iteration (grand total = 40). As part of adhering to the codesign principles, following iteration 1 the program will be quality improved based on experiences, observation and feedback from stakeholders and then reviewed by the Waminda Cultural committee then retested with a further group of 2 x 10 (20) participants.

A power analysis revealed that there was little value in including a control group comparing the intervention with usual care. Therefore, there will be no control group undertaking usual care recruited to this trial.

Recruitment

The Aboriginal Health Practitioners and Diabetes Educator responsible for recruitment have been working with the women in the Dead and Deadly program that has been running for approximately 7 years through Waminda.

It was the participants of the Dead or Deadly program who approached Waminda asking if more could be done to specifically address their T2DM. A co-design process was undertaken with the Waminda team, in consultation with ALSM and the Dead or Deadly participants as part of conceiving the DRAW project. Therefore, the potential participants for the DRAW project are already aware of the DRAW project and its requirements.

The participants will be recruited through Waminda networks directly by invitation from the existing Dead or Deadly program which is aimed more generally at improving Aboriginal Womens health.

The Aboriginal Health Practitioners and the General Practitioner working with the women in the Dead and Deadly program will provide information about the DRAW project verbally in culturally appropriate language and in writing with an information sheet approved by the Waminda Cultural Committee.

The formal consent process will occur if and when the invited participants choose to intend to arrive at Waminda for the commencement of the DRAW activities approximately 2 weeks later. The process will be further explained prior to the formal consent being obtained by the research project officer on the day of commencement.

The recruitment and consent process will be undertaken by Waminda staff who are experienced and skilled in research project work who will be known to the participants and are skilled and experienced in ensuring cultural safety for their clients.

Method

Up to 40 Aboriginal women from the existing Waminda client lists and networks will be recruited and asked to help develop and evaluate the DRAW program as well as refining the learning materials and procedures to make them as culturally responsive and efficacious as possible.

The participants will also continue to receive care from the usual Waminda GP visits but also be invited to participate in the research which would include, additionally, attending up to 7 Medical Yarning sessions with a trained Facilitator, Aboriginal Health Practitioner and the Waminda GP.

Participants, completers and non-completers, will also be asked to participate in semi-structured focuss group interviews to obtain qualitative data about their experiences during and after the trial.

Outcome measures

The health program will aim for remission in those with T2DM (HBA1c > 6.5%) and prevention of T2DM for those who are considered pre-diabetic (HBA1c 5.6-6.4%).

Primary outcome measures: 1) Sustained lowered HbA1c levels to below 5.5%; compared with before data and data from non-completers 12 months; 2) Development and testing of culturally responsive and translated materials. An iterative process of continual improvement using the collected data to evaluate material and processes by the research team and the Waminda Cultural Safety committee will be engaged to support ongoing program delivery, safety and accessibility. 3) Financial sustainability. The cost of running the program will be modelled against potential income from Medicare and other sources.

Secondary Outcomes: Improvements between, pre and post PAID tool, body weight/body fat %/waist circumference. Patient and Provider satisfaction with processes as measured by survey and focus group interviews; Patient activation as measured by PAM, Evaluation of MYU group retention rates.

The Research Activity in Detail

The research activity includes up to four groups of Aboriginal women (located in up to 4 community settings across the south coast of NSW).

- Each participant will be orientated to and fitted with a wearable Continuous Glucose Monitor (CGM) that has a lifespan of 3 months and which provides blood sugar level data to their existing device (phone or computer) and that of their GP and researcher.
- Each participant will join a group of up to 10-12 other participants
- Each group will attend a Nyully cooking class weekly for 7 weeks and engage in learning about how to 'de-colonise' their diet and preparing and sharing a different meal each week.
- Following the Nyully cooking session each group will engage a Medical Yarn Up (MYU). The MYU consists of a 20 minute (approx.) education session about their T2DM. This is led by either an Aboriginal Health Practitioner and or Diabetic Educator and is followed by a facilitated consultation with their General Practitioner.

Co-Designed Resources and Materials

The latest scientific findings and Health Department advice will be translated into culturally meaningful resource materials, positioning Aboriginal women as the knowledge translators and using traditional (visual) graphics and Aboriginal English as the vehicles for communication. The program of information and behavioural change needed to reverse and prevent T2DM in Aboriginal women will uniquely engage participants in culture and science to manage trauma, eating, physical activity and other determinants in order to effect HBA1c levels. Program improvements will be made based on the Aboriginal women's feedback.

The Medical Yarn Up Procedure

Australian studies (ASLM) align with those from overseas showing that shared medical appointments (Medical Yarn Ups) increase medical centre efficiencies, patient outcomes and satisfaction, especially with chronic illness like T2DM including with Aboriginal patients, who have named the process Medical Yarn Ups.

Data and Collection Methods include:

- Weight (Pre and Post intervention and then every three months),
- Blood Panel (including HBA1c, Blood lipids, Fasting insulin, HOMA-IR). These blood measures and their frequency are standard for managing T2DM and people on insulin. The data for this trial will be obtained from medical records by permission and not require additional collection specific for this trial)
- PAM *and PAID (pre and Post intervention and 6 and 12 months),*

- *Patient Satisfaction Survey (Post intervention and 12 months)*
- *Direct observation,*
- *Qualitative interviews (Yarning) This will be from semi structured interviews (the interview schedule is attached in the submission documents).*
- *Continuous Glucose Monitoring data (fitted 1 week prior to intervention for three months – three months is the life of the monitor). The specifications for the CGM are provided in the submission documents*
- *Changes in medication dosage and usage (obtained from medical records by permission)*

Analysis of Data

Quantitative data will be recorded, coded and analysed using the latest SPSS package available at the time. The project has engaged a statistician in the planning of this protocol to ensure the best data collection methods and tools are being used.
Qualitative data from semi structured focuss group interviews will be transcribed and thematic analysis applied.

The transcriptions and analyses will be presented to the participants for verification of their intended meaning before being included in the final analysis and reporting.

Management of Data and Private Information

*Data required will include***:**
Information will be collected about an individual especially as it relates to lifestyle behaviours and issues that may be contributing to T2DM and their ability to participate in the trial. This data will be collected by the Waminda research team on a one to one basis only after the information and consent has been provided.

The participants will be asked to provide consent to the Waminda research team for access to a limited amount of their health care data from existing medical records held by Waminda. This data will be limited to measures specifically related to this project and as it relates to their T2DM management.

Qualitative data will be obtained through focuss group discussions. The participants will not be identified and only written transcripts will be provided to ALSM for analysis so that voices, circumstances and language will not accidently identify individuals.
Surveys will be administered and coded by Waminda and individuals de-identified before analyses and reporting is undertaken by ALSM.

There will be do disclosure of personal information beyond the participants and research team.
All data will be retuned to and retained by Wamnda and kept securely under their existing data protection strategies

Individuals will have access to their own results. Individual results will not be shared among the group by the research team.

Incidental findings and reporting

The most likely incidental findings from this project will be related to the sequalae of T2DM, such as other diagnoses of eye kidney and vascular disease for example. The participants will already be in

care with the Waminda health and research team. The management of these findings would be seen as an element of the standard care already being provided.

Data Security

All personal data and all de-identified coded data (following analysis and reporting as discusses previously) will be retuned to and retained by Waminda and kept securely under their existing data and privacy protection strategies and policies. The specific research data will be kept for, as per NHMRC Guidelines, at least 5 years and might be used in quality improvement projects if the protocol is embedded into Waminda or other Aboriginal health service, practices in the future.

The project data will be stored with Waminda. Waminda already meets legislative requirements to securely store sensitive patient data and will continue to review processes regularly to ensure legislative and organisation requirements are managed.

Disbursement of Findings

It is intended to publish this study in peer reviewed journals and present at appropriate conferences but not before the findings have been presented to the Waminda Cultural Committee for review. Waminda will also use the project outcomes in their decision process to include, or not, this protocol as part of their regular Waminda services. The participants and their communities will also have the outcomes of the project presented to them in a culturally appropriate manner as decided by the Waminda cultural committee.

The findings will also be used to apply for further funding to expand the project and/or join other studies undertaking similar work.

Mitigating participant results disappointment

The main consideration is to mitigate disappointment if the disseminated results report on non-positive outcomes. The potential for this occurring and the process for mitigation and management will be clearly explained during the recruitment process and regularly as the trial progresses. Individuals who are unable to complete the trial and or do not improve their health status, especially when compared to their group counterparts, will be counselled by the research team and the GP and offered alternate supports or the opportunity to engage the protocol again at some later time. The participants will all be made aware that the results, positive or negative are useful and will be used to improve the program for others in future.

Other uses of Data

The overall outcome of this trial will inform the development of services that will help manage the health of Waminda clients and the community in which it operates. It would be

anticipated that a successful trial will lead to funding applications to extend the trial through Waminda and at other locations and Aboriginal Health Services.

No personal data will be used beyond this specific trial or shared with any other organisation or researchers. Only data that has been de-identified and coded for analysis will be shared if required with other future partner organisations. Such requests for use of this data will be reviewed by the Waminda Cultural and Research committees.

On reviewing requests the Waminda Cultural and Research committees will decide if patient consent to re-use data from the original trial is required.

Potential Clinical Risks and Their Mitigation and Management

Risk

1, Hypoglycaemia. Many of the participants will have T2DM that is managed with insulin. As the eating plan and behavioural change elements of the program take effect blood sugar levels should decrease. If the participants insulin is not being adjusted appropriately then hypoglycaemia is a risk.

2.That trauma can be triggered or retriggered through participation . That reflecting on one's narrative in understanding how participants have developed T2DM may require exploring personal or their communities' past and current experiences.

3. Covid 19 risks. That the participants and staff are more likely to be exposed to SARS 2 virus through participation.

Mitigation

1 Hypoglycaemia mitigation: The participants taking insulin are already aware of the assessment and management of hypoglycaemia. The CGM will provide participant, researcher and GP with data to their devices. The CGMs will alarm if BSL is outside of set parameters and appropriate action to manage the BSL can be applied. The GP will provide regular monitoring and management of medications including insulin to match the changing BSL profile during the course of the intervention.

2. Trauma risk mitigation: The staff delivering the protocol are experienced in the processes of care with the participants in this community and have developed many options for assisting people in trauma. The Lead investigator at Waminda has a post grad in Indigenous trauma and can monitor cultural safety and appropriate care throughout the project. The protocol will be co-developed with the community and experienced staff to minimise this occurring. However, the team will have strategies available if this does occur such as access to Aboriginal Health Practitioners, counsellors and General Practitioners.

3. Covis 19 risk mitigation: The most contemporary COVID 19 risk management procedures will be followed as the protocol is rolled out. The protocol can be adapted to use a virtual (ZOOM) approach to avoid personal contact if required.

Risk	Cause	Potential High-Medium -Low	Mitigation strategy
Increased risk of hypoglycaemia	Decreased blood sugar levels from protocol and the participants insulin not being adjusted appropriately	Medium	The participants taking insulin are already aware of the assessment and management of hypoglycaemia. The CGM will provide participant, researcher and GP with data to their devices. The CGMs will alarm if BSL is outside of set parameters and appropriate action to manage the BSL can be applied. The GP will provide regular monitoring and management of medications including insulin to match the changing BSL profile during the course of the intervention.
That trauma can be triggered or retriggered through participation	That reflecting on one's narrative in understanding how participants have developed T2DM may require exploring personal or their communities' past and current experiences.	Medium	The staff delivering the protocol are experienced in the processes of care with the participants in this community and have developed many options for assisting people in trauma. The Lead investigator at Waminda has a post grad in Indigenous trauma and can monitor cultural safety and appropriate care throughout the project. The protocol will be co-developed with the community and experienced staff to minimise this occurring. However, the team will have strategies available if this does occur such as access

			to Aboriginal Health Practitioners, counsellors and General Practitioners.
COVID risks	That the participants and staff are more likely to be exposed to SARS 2 virus	medium	That the most contemporary COVID 19 risk management procedures will be followed as the protocol is rolled out. The protocol can be adapted to use a virtual (ZOOM) approach to avoid personal contact if required.

SUMMARY OF 5 KEY PRINCIPLES as per: AH&MRC Ethical Guidelines: Key Principles (2020) V2.0

1) Net Benefits to Aboriginal people and communities: This research will design and examine a culturally responsive protocol to help manage growing Type 2 Diabetes and related issues specifically among Aboriginal people and communities.

2) Aboriginal community controlled research: This research methodology and the research protocol and the majority of resources are designed by Waminda in consultation with ASLM and overseen by the existing Waminda Cultural Committee and advisory group. The research is co-designed with the community to respond directly to the needs of the Aboriginal women participants. Quaterly advisory group meeting will be held to monitor progress, risk and cultural compliance and to have oversight of outcomes and any publications that might result.

3) Cultural sensitivity: This research is only being conducted through Waminda at this stage. Waminda workers and ASLM partners have undertaken cultural induction and are sensitive to the region's various cultural protocols. The research materials such as information brochures and consent forms and the program that we are trialling have been designed by Waminda in consultation with community and overseen by the Waminda Cultural committee and the Research Advisory group.

4) Reimbursement of costs: Waminda has undertaken many research projects within their community and fully support the principle of ensuring that directs costs for foods, materials and services are paid for by the organisation and that participants are reimbursed appropriately if required for their time and knowledge.

5) Enhancing Aboriginal skills and knowledge: Waminda will ensure that, with ASLM collaboration, Aboriginal people are actively engaged in undertaking the clinical and research activities, in disseminating the results and in acting on the results to improve the protocol and ultimately the care of Aboriginal people. The research team from Waminda have been provided professional development in the facilitation of Medical Yarn Ups. The team meets regularly to yarn about the research process and ways of improving the experience for the participants.