

Effectiveness of a Pasifika Women's Diabetes Wellness Program (PWDWP): Protocol for a Pilot Intervention and Feasibility RCT Study

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Submitted to: JMIR Research Protocols
on: December 12, 2023

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Effectiveness of a Pasifika Women's Diabetes Wellness Program (PWDWP): Protocol for a Pilot Intervention and Feasibility RCT Study

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Abstract

Background: Type 2 diabetes remains a major public health challenge for M?ori and Pasifika peoples living in Queensland. The women of these communities face a greater burden of type 2 diabetes-related mortality and comorbidities. Modification of personal behaviors through women's wellness programs aimed at early intervention has been shown to reduce the risk of developing complications in established type 2 diabetes and may reduce hospitalization rates due to preventable complications. The Pasifika Women's Diabetes Wellness Program (PWDWP) is a first culturally wh?nau (family)-centered intervention, co-designed with M?ori and Pasifika women living with type 2 diabetes to promote improve diabetes management.

Objective: This study aims to evaluate the feasibility, delivery, acceptability and effectiveness of PWDWP in partnership with M?ori and Pasifika community organizations and key stakeholders in Southeast Queensland.

Methods: This pilot study is a quasi-experimental design with two arms: an intervention and a control, to trial a 12-week intervention followed by 12-week follow up period. The study will utilise participatory talanoa (Pacific Indigenous) methodologies employing in-depth interviews, surveys, education workshops, online consultations and virtual talanoa support groups with motivational SMS text messages for the intervention. Control groups will receive usual care with their health professionals, a hard copy of the program materials, and motivational text messages. Quantitative data will quantify participants' objective diabetes control using a haemoglobin A1c as primary measure, and qualitative data will be collected to ascertain the program's feasibility and cultural appropriateness using talanoa focus groups.

Results: The PWDWP was successful in securing funding through Diabetes Australia Research Program Grant and Australian Health Research Alliance (AHRA) Women's Health Research Translation Network (WHRTN) Early and Mid-Career Researcher Funded Award in 2022. The study has recruited 50 participants with the intervention starting in February 2023. Data analysis and results reporting are expected to be completed in 2024.

Conclusions: The PWDWP is the first culturally framed intervention co-designed and co-developed with M?ori and Pasifika women living with type 2 diabetes in Queensland. This pilot study will assess the efficacy of the interventions based on quantitative values including HbA1c and body composition measurements, as well as qualitative data through focus groups talanoa with participants will determine measurement burden, acceptability, potential translation, and ease of intervention access. Clinical Trial: Australian New Zealand Clinical Trials Registry (ANZCTR) Number: 12622001100785p.

(JMIR Preprints 12/12/2023:55435)

DOI: <https://doi.org/10.2196/preprints.55435>

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Original Manuscript

Title: Effectiveness of a Pasifika Women's Diabetes Wellness Program (PWDWP): Protocol for a Pilot Intervention and Feasibility RCT Study

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Abstract

Background:

Type 2 diabetes poses public health challenges for Māori and Pasifika communities in Australia. The women of these communities face a greater burden from type 2 diabetes-related mortality and comorbidities. Lifestyle modification behaviours through previous women's wellness programs have been shown to reduce risk of developing complications in established type 2 diabetes. The Pasifika Women's Diabetes Wellness Program (PWDWP) pilot study, co-designed with Māori and Pasifika communities, was aimed at addressing late hospital presentations from diabetes-related complications.

Objective:

This study (1) examines the efficacy of women with type 2 diabetes in the where intervention group having improved HbA1c clinical levels and diabetes self-management compared to control group from baseline (T_0), week 12 (T_1) to week 24 (T_2) (post intervention) and (2) assesses the cultural adaptability, acceptability and feasibility of the pilot intervention for future studies.

Methods:

This study is a quasi-experimental design which involves a 24-week intervention. Fifty Māori and Pasifika women with type 2 diabetes (25 Intervention from the Southside of Brisbane and 25 Control from Northside of Brisbane) were recruited utilizing participatory talanoa methodologies. The intervention group participated in face-to-face and virtual whānau education workshops (5 weeks), had access to individual coaching and virtual support delivered by trained Māori and Pasifika health professionals and community health workers. The control group received usual care with their identified health provider. Both groups received copies of the PWDWP journal, factsheets and health check passbook with tailored motivational text messages. An Advisory Committee (AC) was set up to oversee the program implementation, including protocols of engagement, health checks and data collection in community settings. The quantitative data were collected at T_0 , T_1 , T_2 with Haemoglobin A1c as primary outcome measure. Secondary outcomes measured changes in diabetes self-care and body composition (e.g body mass index (BMI), waist circumference). Qualitative data will ascertain the program's feasibility and cultural adaptability using talanoa focus groups.

Results:

This pilot study was approved by the Queensland University of Technology Human Ethic Research Committee (5609) and began in January 2023 after participant recruitment between July – December 2022. The final data collection including health check, focus group and survey data was completed in November 2023 and with data analysis and reporting expected to conclude in 2024.

Conclusions:

This study provides a blueprint for PWDWP. Collaborative partnerships with community organizations and stakeholders are crucial for program success and suggest a potential model for targeting diabetes management for Māori and Pasifika communities, emphasizing the need for culturally relevant interventions. The findings will have significant implications for policy makers, practitioners when developing and implementing public health initiatives, particularly for communities with unique cultural nuances.

Trial registration:

Australian New Zealand Clinical Trials Registry (ANZCTR) Number: 12622001100785p.

Keywords: type 2 diabetes; Māori and Pasifika women; diabetes self-management; culturally co-

design intervention; Pasifika diaspora; talanoa

Introduction

The global prevalence of diabetes and its threat to public health continues to rise each year. Almost 90% of the estimated 537 million people currently living with diabetes worldwide is attributable to type 2 diabetes, despite it being largely preventable [1]. The Western Pacific region accounts for over a third of the worldwide burden of diabetes, with six Pacific Island Countries and Territories (PICTs) being among the top ten in the world with the highest prevalence of type 2 diabetes [1, 2]. Additionally, PICTs face a higher prevalence of debilitating diabetes complications as well as a higher prevalence of undiagnosed diabetes compared to other regions [2-5]. There are disparities in diabetes and diabetes-related conditions between people from the PICT and high-income countries with similar disparities in Australia among the Indigenous and non-Indigenous Australian [6]. As diabetes prevalence is positively associated with social and economic costs to individuals, families, and society, the severity and burden of type 2 diabetes is clearly highlighted [7-10].

Type 2 diabetes remains a major public health challenge for Māori and Pasifika peoples living in Queensland, which has the largest Pasifika diaspora after New Zealand [11]. Pasifika is a collective term used for Pacific peoples in Australia. Significant disparities in diabetes prevalence exist in these populations who are two to four times more likely to be hospitalized and die from diabetes-related complications compared to non- Māori and Pasifika populations [12]. Evidence indicates that culturally and linguistically diverse women, in particular face a greater burden of type 2 diabetes-related mortality and comorbidities including cardiovascular disease, kidney disease, vision impairment, and depression [12-15]. Access to diabetes care and support programs are less likely to be utilized by Māori and Pasifika women with diabetes due to low levels of health literacy, language barriers, and a strong cultural reluctance to seek help. Lack of culturally appropriate health and social services have resulted in an avoidance of engagement by Māori and Pasifika women [13]. Māori and Pasifika women carry significant cultural responsibility including expectations of acting as carers, leaders, and nurturers within their communities, often at the expense of their own chronic disease management [13,16]. This has significant implications for providing accessible, low cost and culturally appropriate diabetes care for Māori and Pasifika women with T2DM [9].

Encouraging healthier behaviors in Māori and Pasifika women with type 2 diabetes could potentially improve the health and well-being of women [16, 17]. Modification of personal behaviors through women's wellness programs aimed at early intervention have been shown to reduce the risk of developing complications in established type 2 diabetes and may reduce hospitalization rates due to preventable complications [18]. In a qualitative study of a multimodal behavioral intervention, the Women's Wellness with Type 2 Diabetes, found to be effective in supporting women in developing strategies to improve their wellbeing and avoid complications associated with diabetes [19]. Another study with Māori and Pasifika women with type 2 diabetes in Queensland reported effective strategies to improve self-management through culturally appropriate interventions and educational resources [16]. Thus, the first culturally framed intervention, the Pasifika Women's Diabetes Wellness Program (PWDWP) emerged from these studies that informed the study's principles and processes, including recruitment strategies and co-design of the delivery format into a whānau (family-centered) approach that harnesses digital technology [20]. The intervention was co-designed with Māori and Pasifika women living with type 2 diabetes in Queensland, underpinned by Social Cognitive Theory and the Fonofale Pasifika Health Model that focusses on family, culture, community and spirituality using talanoa, a Pacific form of dialogue, to promote sustainable self-management of type 2 diabetes [20, 21, 22]. This 24-week program is whānau (family)-centred with

five diabetes self-care behaviour and wellness component (Figure 1) and delivered by trained Māori and Pasifika health professionals. The program takes into consideration the cultural shame associated with acknowledging the disease and tailors the interventions using talanoa as the key strategy to reach a shared meaning for behavioral changes [22, 23].

The program team has previously ensured successful translation of interventions into practice through meaningful engagement with consumers, policymakers, health-service managers and clinicians [17-19]. This program will further consolidate collaborative partnerships between clinicians, health-service providers, Māori and Pasifika communities and organisations, and consumer advocates. The study will evaluate the clinical benefits of the intervention and will target improvements in HbA1c (measured using a 'point of care' (POC) device [24]) and diabetes self-care including diet, physical activity, stress and medication management, and routine health checks of Māori and Pasifika women with type 2 diabetes. The study builds on a robust and systematic program of work, beginning with scoping studies, needs assessments and early wellness trials in women [17].

Research Aim

The pilot study will evaluate the feasibility, acceptability, delivery and effectiveness of PWDWP using mixed- methods, in partnership with Māori and Pasifika community organisations and key stakeholders in Southeast Queensland.

Objectives

1. *Primary objective*: to examine efficacy where women with type 2 diabetes in the intervention group will have improved HbA1c clinical levels from baseline (T_0), week 12 (T_1) to week 24 (T_2) post intervention compared to the control group.
2. *Secondary objective*: to determine whether, compared to control participants, the intervention group achieves:
 - changes to bring body-composition measurements closer to recommended healthy range for specific cultural groups (e.g. BMI ≤ 30 kg/m²; waist circumference < 80 cm based on WHO Criteria) and improved diabetes self-care scores on diet, physical activity, routine health checks, and medication adherence assessed using the validated summary of diabetes self-care activities (SDSCA) scale [25 - 32].
3. Assess the potential for success of the proposed intervention by examining:
 - accessibility, acceptability, uptake and cultural adaptability of the intervention;
 - sustainability of, and adherence to, the intervention over time;
 - participants' perceptions of measurement burden;
 - the effectiveness of the planned recruitment strategy & retention of participants and;
 - documentation of women's experience with PWDWP through digital stories.

Hypothesis

- H1: Compared to control participants, intervention participants who receive intensive Whānau face-to-face and virtual support for type 2 diabetes management report improved HbA1c levels at 12 weeks and 24 weeks (post-intervention sustainability);
- H2: Compared to control participants, intervention participants who receive intensive Whānau face-to-face and virtual support for type 2 diabetes management will have reduced waist circumference and BMI at 12 weeks and 24 weeks;
- H3: Compared to control participants, intervention participants who receive intensive Whānau face-to-face and virtual support for type 2 diabetes management have improved diabetes self-care at 12 weeks and 24 weeks.

Data collection was at three timepoints: T_0 (before the commencement of the pilot program, week 1), at T_1 and T_2 (post-intervention). Data on the feasibility, accessibility and affordability of the PWDWP includes the satisfaction surveys for both the intervention group at the end of the workshop (week 5 only for intervention group), at week 12 and then at week 24. For the control group satisfaction surveys were completed in week 12 and week 24.

Qualitative data through focus groups talanoa with participants will determine measurement burden, acceptability, potential translation and ease of intervention access. Feasibility will be documented regarding how the participants were referred to the program, time taken to complete questionnaires, any strengths or weaknesses of the intervention, its cultural relevance, experience with accessing the intervention, perceptions of the digitally delivered coaching sessions and online virtual support sessions as well as face-to-face intervention and any suggested improvements to the study design or intervention.

Methodology

Advisory Committee

An Advisory Committee (AC) was established to oversee the pilot study, including its setup, ongoing management, promotion, implementation, and evaluation with outcome deliverables including appropriate dissemination. The AC includes members of the Māori and Pasifika communities including the Pasifika Women's Alliance (PWA) and Pacific Island Council of Queensland (PICQ), and key organisations such as the Good Start Program for Māori and Pacific Islander Peoples (Children's Health Queensland), and Academia (including Queensland University of Technology and University of Technology Sydney through the Women's Wellness Research Program). A series of group talanoa undertaken with AC community members ensures that the pilot study is implemented and evaluated within the talanoa cultural framework. The AC meets regularly every –four months to review the study protocols including recruitment strategies, health checks and data collection methods and approaches and how these are disseminated. The AC provides input on the trial progress, adherence to protocol, participant safety and consideration of new information as well as advise on the location and place of delivery (intervention and data collection) considered to be culturally acceptable to the participants.

Participatory Talanoa Methodologies

The research uses participatory action research (PAR) utilizing co-design and talanoa methods as the theoretical and cultural framework in the collection and analysis of data.

Description of talanoa

Talanoa is a way of communicating in a Pacific context. It has been described as the co-construction of knowledge through respectful, reciprocal conversation. It is a process enabling critical discussions and knowledge construction allowing for rich contextual and inter-related information to surface as co-constructed stories [21]. Vaiioleti uses the metaphor of kakala:

Toli – deciding on, selecting and picking the flowers – equating to recognizing a problem, participants are chosen and data collected and analysed [21].

Tui - process of making and weaving the kakala - where the stories, and emotions of deep talanoa encounters are integrated and synthesized – this involves deciding on the type and amount of data to use, how the data are arranged in relation to each other and how they are presented.

Luva – is the giving away of the kakala – when the research is given for the benefit of the community and solutions can be found.

In this context, the community engagement including recruitment, data collection and analysis processes are forms of talanoa. All data are analysed through talanoa with the AC and community researchers (CR). In this context, talanoa is a method embedded within a participatory methodology [21] which informs the protocol of this study.

Study Design

This pilot study is a quasi-experimental design with two arms: an intervention (delivered in -person and online for those who preferred virtual delivery) and an attention control arm receive written information and text messages) to trail a 12-week intervention followed by 12-week follow up period (over 24 weeks) delivered by trained Māori and Pasifika health professionals (diabetes educator, clinicians, community health workers (CHW) and community researchers. The study was conducted in Southeast Queensland, Australia with Māori and Pasifika women living with type 2 diabetes who are recruited through participatory community engagement with the Māori and Pasifika community leaders and organizations.

The study utilizes participatory talanoa methodologies employing in-depth interviews, surveys and involves in-person talanoa education workshop (5 weeks) as well as virtual workshops (5 weeks for those participants not in Brisbane and unable to attend in-person), three online via zoom individual talanoa consultations (coaching) and online virtual talanoa support group with motivational SMS text messages. The control participants receive the usual care with their identified health professionals, a hard copy of the program materials (which includes program journal, recipe book, fact sheets and passbook) as well as SMS general motivational text messages. The process evaluation includes satisfaction surveys after the workshop session at week 5, week 12 and week 24 as well as talanoa focus group with the participants after the intervention. Figure 2 is an overview of the PWDWP pilot study in Southeast Queensland, Australia (2022-2024). The detailed intervention is described below.

Intervention

The PWDWP intervention includes:

1. **Whānau Talanoa Workshop** 5 x 2-hour sessions covering the wellness components. Whānau talanoa workshops provide interactive knowledge-based education on targeted health knowledge and behaviors with culturally specific tools to manage type 2 diabetes within a family, community and spiritual context (See Table 1).
2. **Individual Talanoa Consultations** A 3 x 1-hour one-on-one sessions where the first session consists of a routine check-up, appropriate screenings, and discussion to facilitate tailored education, goal setting and specialist advice to support individualized plans and goals for a healthy weight, diet, physical activity, stress management, sleep, and medications. The second session revisits goals set during session 1 and, if necessary, discusses prevention strategies and identification of barriers. The third session reviews participant progress including barriers to self-management, reinforcement of positive behaviour and setting future goals for maintenance.
3. **Talanoa Support Group and Text Messages** A virtual peer support group facilitated by CHWs to encourage and support women on targeted topics including stress management, barriers, understanding family situations, mindfulness, nutrition/diet, importance of health checks, regular visits to GPs and specialists, monitoring blood sugars, medication adherence and maintenance. SMS text motivational messages are sent regularly to reinforce key messages.

Table 1: Whānau talanoa education workshops on diabetes wellness components delivered by trained Pasifika diabetes educator and community health workers.

Education Component	Content Delivery	Weeks Delivered
Becoming Healthy	Will provide practical information on type 2 diabetes, its symptoms, risk factors, diagnosis, treatment and management, medication and self-care. This session will also cover practical and cultural ways to deal with issues related to the shame and stigma of developing type 2 diabetes and the impact of denial.	1
Healthy Thinking & Feeling	Will provide information and tools to deal and cope with stress, barriers and ways to improve wellness that incorporate elements of Pasifika values, spirituality and faith.	2
Healthy Eating	Will provide information and tools for healthy eating with a self-care healthy eating plan and strategies for managing cultural hospitality requirements without losing face.	3
Staying Active	Will cover ways to get moving, types of exercises to do with your family, practical tips to remain motivated to stay active while managing family and community obligations.	4
Healthy Living	Will encourage, motivate and maintain healthy living including looking after your bones, eyes, kidney and heart, sleep and menopause with spirituality, family and community wellbeing.	5

Cross-Intervention and Control Conditions

The *intervention group* receives the complete intervention over the 24 weeks and has access to an interactive program journal (hardcopy and electronic), a recipe book, a passbook for health check and fact sheets as well as text messages with reinforcing positive motivational behaviors (Table 2). The participants also have access to a website that includes culturally developed resources (such as podcasts, digital stories and information materials).

Table 2: The intervention component for the Māori and Pasifika women with type 2 diabetes from the South side of Brisbane, Queensland, Australia

Intervention components	Weeks (1 - 24)
Whānau talanoa workshops (in person and virtual)	1 – 5*
Individual talanoa consultation (coaching via zoom)	6-7, 13-14, 20-21
Motivational SMS text message	8, 10-11, 15, 17-18, 22-23
Talanoa support group (via zoom)	9, 16, 19
Data collection (DC) (T0, T1 and T2) In-person	0 (Baseline), 12 and 24**
Talanoa focus group (TFG) (in-person)	24

*Offered either (1) in-person (face-to-face) with women and (2) online virtual who cannot attend in-person)

**DC: Data collection at Week 0 (T₀), Week 12 (T₁) and Week 24 (T₂); TFG: Talanoa focus group in-person

The program provides all necessary health promotion content and supports participants to log relevant health information in the journal (either on hardcopy or electronic version). Weekly diet, physical activity and diabetes self-care checklist will encourage participants to plan ahead. The interactive website aims to reinforce educational content, enabling home monitoring of measurable health indicators and will allow participants to fill out questionnaires and other data. The website will also be adapted for all computing platforms, including mobile phones for future studies. Figure 3 illustrates the intervention participant journey of Māori and Pasifika women with type 2 diabetes from the South side of Brisbane over 24-weeks (January - November 2023).

The *control group* receives their usual care with the hard copy of the program materials (i.e. program journal, recipe book, fact sheets and passbook) and SMS text messages (Table 3). At the completion of the intervention, control participants receive a modified one-day workshop covering talanoa education workshops. Figure 4 illustrates the control participant journey of the Māori and Pasifika women with type 2 diabetes from the North side of Brisbane over 24-weeks (January - November 2023).

Table 3: The control component for the Māori and Pasifika women with type 2 diabetes from the North side of Brisbane, Queensland, Australia

Control components	Weeks (1 - 24)
Usual care with hard copy program booklet (The participants will be asked to document on the study journal (encouraged daily and/or weekly) but will be at their own discretion).	1 - 24
Motivational SMS text message	4, 8, 10-11, 15, 17-18, 22-23
Data collection – in person (T0, T1, T2)	0, 12 and 24
Talanoa focus group (TFG)	24

* DC: Data collection at T₀ (Week 0), T₁ (Week 12) and T₂ (Week 24); TFG: Talanoa focus group in-person

Inclusion and exclusion criteria

Inclusion criteria include Māori and Pasifika women with type 2 diabetes, aged 18 years and over, diagnosed with type 2 diabetes and with access to the internet. Participants are excluded if they are pregnant women and diagnosed with gestational diabetes, high-risk pregnancy, and those not diagnosed with type 2 diabetes.

Locations and online forums

Whānau talanoa Intervention (Onsite)

The onsite face-to-face whānau talanoa sessions will occur in the community setting as recommended by the AC to ensure it is culturally acceptable to the participants in a whānau setting that is inclusive of community.

Online virtual talanoa intervention

The online sessions will occur via zoom platform over the five weeks covering the same content delivered face-to-face. The zoom setup is organised and managed through the QUT secured system which will enable the project coordinator to host and manage each session and recordings. All the recording and transcripts are stored with password protection and secured to the QUT shared drive project folder for access by project team only (Chief investigator and coordinator).

Individual talanoa consultation

The individual talanoa consultations (either via zoom or telephone) are delivered by a trained CHWs educator and managed through case notes which are uploaded (including zoom recordings) to a secured project folder within the QUT shared drive.

Methods

Study Population and Setting

This is a participatory community-based study. Māori and Pasifika women living with type 2

diabetes are recruited from the Pasifika communities in Southeast Queensland through a range of organisations, representing various sectors of the Māori and Pasifika communities in Queensland. The intervention and control groups are geographically distinct to minimize cross contamination, as members within the same community socialize, and this is the design the advisory committee recommended as culturally appropriate.

Intervention Group: The intervention participants are recruited from the South side of Brisbane and including Logan, Ipswich and Gold Coast, geographically separated from the control group to minimize potential for cross-contamination. Inclusion criteria for intervention participants are female aged 18 years and over from the Southside of Brisbane, diagnosed with type 2 diabetes, and have access to the internet. Exclusion criteria are pregnant women and diagnosed with gestational diabetes and those not diagnosed with type 2 diabetes. They are excluded because they may have potential higher risks (especially those with high-risk pregnancies). These exclude women with type 2 diabetes from Northside of Brisbane (based on location).

Control Group: The control participants are recruited from the North side Brisbane including Sunshine Coast. Inclusion criteria for control participants are female aged 18 years and over from the Northside of Brisbane, diagnosed with type 2 diabetes. Exclusion criteria are pregnant women diagnosed with gestational diabetes (and/ or at high-risk pregnancy). These also exclude women with type 2 diabetes from the Southside of Brisbane (based on location).

Sample Size

The sample size is calculated based on previous studies for detecting a difference of 1% reduction in HbA1c (primary outcome) with standard deviation of 1.4% in the intervention group. A significance level (α) of 0.05 is considered with study power of 80% [28]. Based on this, a sample of 64 participants is needed (32 for control group and 32 for intervention), with a target sample of 90 participants to compensate for 40 % of attrition rate. While the program received approximately 90 expression of interest responses, challenges with community engagement, complexities arising from COVID-19 and participant drop-out resulted in a total of 50 participants, with 25 in the control group and 25 in the intervention group who enrolled and completed the pilot program.

Community settings

The program for *the intervention group* is provided in community settings, Pasifika Te Haus in Runcorn and Adam Gould community Centre in Logan on the Southside of Brisbane that has a large Māori and Pasifika population in Southeast Queensland. For *the control group*, the first health checks and data collection occurred at a Pasifika Community Church but with follow ups, home visits were undertaken as requested by participants. The community locations were recommended by the AC.

Recruitment Strategies

Recruitment for both intervention and control groups were multimodal and through distribution of study flyers, email invitations and advertisements via social media (Facebook, websites), local ethnic radio, newsletters as well as community networks including church groups, organisations and Māori and Pasifika health workers. Recruitment also occurred through presentations and dialogue with community partners and organisations including the Pasifika Women's Alliance Inc (PWA), Oceania Pacific Health Association (OPHA) and Multicultural Communities Council Gold Coast (MCCGC), who have representatives on the Advisory Committee, and they promoted the study through their networks and social media.

Ethics, Consent and Data Management

Ethical consideration

The PWDWP was approved by the Queensland University of Technology Human Ethic Research Committee (5609). All data will be aggregated with no individuals able to be identified. Collected data will be coded for analysis. The anonymity and privacy of all participants will be maintained through the use of fictional names, unique participant identification numbers, and secure data storage. All data will be stored securely on a password protected research drive as per QUT's Management of research data policy and NHMRC guidelines for trials with access restricted to only the principal and co-investigator.

Consent Process

Potential participants were contacted to discuss the study and consent processes. Those who agreed were posted a 'participant information pack' with an introduction letter detailing the program information, timelines, demographics questionnaires and participant consent information. Two follow up phone call by the project officer to each participant before the intervention was to finalize details regarding the program, confirming on the mode of preference for receiving part 1 (in -person or online) of the intervention, discuss issues or concerns with participation, access to own GP, dropout and any other issues that the women may have and would like to discuss. Participants who consented to participate were asked to get a medical checkup prior to the start of the program and with any concerns raised to be discussed with the project officer. All participants (intervention and control) that consented were allocated a unique ID number and registered on a trial database. Any reasons for non-participation are recorded. The original informed consent at primary data collection allows the secondary analysis without additional consent.

Any cultural, spiritual and personal concerns about disclosure in relation to cultural and religious beliefs especially around stigma associated with diabetes diagnosis was discussed and clarified with participants before obtaining consent to disclose or use any sensitive information. Cultural sensitivity and respect form the underpinning guiding value in this research process especially when working with Māori and/or Pasifika families from various ethnic and religious backgrounds. This also included talanoa style of conversations to clearly explain the reason for choosing the two different locations (sites) for recruitment of control and intervention participants and the benefits and risks for each group allocation.

Whilst we acknowledge that the Pasifika communities are well connected and share familial relationships, there was a possibility of cross communication regarding the pilot study. Due to the interconnectedness of the communities, there is a possibility of lack of confidentiality. One way this is addressed is by discussing with participants the importance of anonymity whilst at the same time acknowledging this can be difficult in close-connected collective communities. This is a limitation to the study.

All participants, including control and intervention, are remunerated with a \$20 (for health checks) and \$30 (focus group) gift vouchers or 'Koha' to compensate for their out-of-pocket expenses, travel time and costs with participating at each data collection.

Data Collection

Training of Community Health Workers, Community researchers and research team

Before the study commenced (July – December 2022), the Pasifika CHWs, health professionals, facilitators and the project team (including community researchers) received training on cultural protocols of engagement, community values and working with families across different Māori and

Pasifika including the use of talanoa methods and approaches to coaching and delivering interventions within cultural Pasifika health model frameworks, and the protocols to be followed.

Training was undertaken by the principal investigator and the diabetes educator in the form of role play, storytelling, interactive activities using scenarios. Advisory committee members were invited to participate in the training as well as to contribute and share cultural experience/advice in relation to working with Māori and Pasifika communities in a culturally safe and sensitive manner. All training was recorded and minuted with registration attendance noted. The community researchers were also provided with step-be-step instruction manual on data collection.

Quantitative Outcomes

Quantitative data are collected through face-to-face or in-person using online questionnaires at three-time intervals: T₀, T₁, T₂, between January 2023– March 2024 in a community-based location, for both intervention and control participants. Data collected include anthropometric (height, weight, waist circumference, BMI), sociodemographic (age, marital status and employment status, income, postcode and ethnicity), diabetes (self-care, self-efficacy), physical activity and dietary changes, and clinical (HbA1c using point-of-care device, DVA Vantage® HbA1c kit (Siemens) [25 - 32]. The diabetes educator and CHWs collected anthropometric and clinical data and the CR undertake online Qualtrics™ survey [33] using a tablet. Each participant was given a unique identifier.

Quantitative Data Analysis

This will include following steps:

1. Raw data will be examined for missing entries, inconsistencies, and data entry errors.
2. Any identified problems will be corrected by checking the data against the hard copy questionnaire. To further ensure reliability and accuracy of the data entry, the researcher will randomly re-enter 10% of collected data and compare the two files [34].

Data are analysed using the IBM SPSS® 24 statistical software and any missing data, outliers, normality, and multicollinearity, will be examined using procedures outlined in Pallant [34, 35]. Methods of data analysis will include descriptive, bivariate, and logistic regression analysis. The levels of statistical significance will be set at *P* value ($P=0.05$), to reduce the risk of type 1 errors [34]. The analyses will inform change in primary and secondary outcomes from baseline to week 12 and week 24 for Māori and Pasifika women with type 2 diabetes who completed the intervention. Descriptive statistics will examine participants' baseline measures and characteristics and will also explore trends in the data over time. Mean $\pm$ standard deviations (SD) will report for continuous variables, percentages, and frequencies for categorical variables. Independent *t*-tests will be used for continuous variables and chi-squared for categorical variables will be used to compare mean groups. Normality of the included variables will be evaluated using the Shapiro-Wilks normality test, and a non-parametric test (Mann-Whitney test) will be used if data are not normally distributed to detect differences between groups. Two-sided $P = 0.05$ will be considered significant for all analyses [34, 35].

The study will also provide initial parameter estimates for the primary endpoint from which sample size calculations can be performed to determine sufficient power for the main trial. The primary endpoint between group differences at 12 and 24 weeks will be estimated using a linear mixed model with a treatment-time interaction. While aiming for an intention-to-treat analysis, we recognise there will be some withdrawal from the study. A pre-specified multiple imputation model will be used to obtain intention to treat estimates. Sensitivity analyses will explore the impact of non-ignorable missing data. Analysis of secondary endpoints will follow the same approach where changes will be

compared in intervention and control groups using linear mixed models.

Process Evaluation

The process evaluation includes satisfaction surveys and focus group talanoa of the intervention and the control participants to evaluate for the feasibility of the program. This includes evaluating the

- Training of Pasifika CHWs, CR and the project team
- Types of delivery (in-person and online/ virtual for education sessions)
- Core messages through text reinforces positive mindset and behaviors.
- Talanoa approach via online and in-person delivery of intervention, shared understanding and core messages across the project team including CHWs CRs and workshop facilitator.
- Satisfaction with the program assessed at T_1 and T_2 and capturing where the participants heard about the program, was accessibility to program easy, what were some of the challenges with the program, what would change.

Qualitative Outcomes

Qualitative data is collected using a focus group talanoa to gather information of the participants' experiences with the program and its acceptability, usefulness, barriers and enablers to participation, feasibility of time commitment, burden and cultural relevance. Data gathered will explore time taken to complete data surveys, strengths and weaknesses of the intervention, perceptions of the digitally delivered sessions, and any suggested improvements to the study design or intervention as well as whether control participants had heard about the program, spoken to the intervention participants, and whether this influenced their participation.

Qualitative Data Analysis

Talanoa focus groups are conducted in a community setting, facilitated by community researchers and the principal researcher using guide co-developed with the AC and CR used to facilitate the focus group discussion. The talanoa discussions lasting 90 minutes were audio-recorded using digital recorder and transcribed verbatim for analysis [36]. The trained CR took detailed notes using the guide. Immediately after the talanoa focus group session, the notetaker and the CR summarized and prepared debrief notes that highlight key points from the group. These were presented back to the focus group. The participants were also given the opportunity to read a copy of what they have said and make any changes [36].

NVivo software will be used for data management and manual coding or identifying recurring keywords and phrases to ascertain measurement burden, acceptability, potential translation, and ease of intervention access. Co-analysis using inductive and deductive approach will involve participatory talanoa processes with the Pasifika CR and participants iteratively [21, 23, 36]. The key themes from the co-analysis will be collated and presented to the AC for discussion. Patterns of meanings and interpretations during the analysis processes will be further deliberated by the AC to ensure community and cultural context are considered. Participants will be given progress feedback of results and study outcomes. Giving feedback will be an integral part of the participatory research cycle where the participants will have the opportunity to construct, reconstruct or retell, and reflect on the stories of their experience in the pilot program including both positive and negative feedback. A copy of the result findings and action outcomes will be disseminated to the participants, health providers, community organisations, and the research team.

Results

The pilot program began in February 2023 with 50 participants who were enrolled between January 2022 – January 2023). Methods of quantitative data analysis will include descriptive, bivariate and

logistic regression analysis. The focus group was conducted in November 2023 and the results are being analysed using an inductive-deductive approach.

The study participants from the intervention and control are from diverse Pacific cultural backgrounds and include Fijians, Fiji Indians, Samoans, Māori, Tongans, Cook Islanders and those who identify with more than one cultural group. The anticipated results from the quantitative and qualitative analysis would highlight the relevance that culturally co-designed programs have the potential to lead to improved diabetes self-care outcomes including the HbA1c clinical levels, positive changes in body-composition measurements such as BMI and waist circumference and enhanced diabetes self-care scores within the intervention group. The final data analysis and results are expected to be completed in 2024.

Discussion

Type 2 diabetes is a costly, rapidly growing, and largely preventable disease. Encouraging healthier lifestyles in Māori and Pasifika women with type 2 diabetes could potentially improve the health and well-being of women, prevent complications and reduce health expenditure.

This paper describes the protocol of a quasi-experimental pilot study based on a culturally co-designed whānau (family)-centered intervention for Māori and Pasifika women living with type 2 diabetes in Queensland, Australia [20]. The study consists of two arms: an intervention and a control, to trial a 12-week intervention followed by 12-week follow up period, delivered by trained Māori and Pasifika health professionals and community health workers.

This study will report the clinical benefits of the intervention and will target improvements in glycated haemoglobin HbA1c and diabetes self-care including diet, physical activity, medication management, and routine health checks for Māori and Pasifika women with type 2 diabetes. Community-based interventions among Australian Samoans in Sydney Australia have showed reduction in HbA1c [37], which would be promising for our study. Studies with Māori and Pasifika have shown that using community-based approaches and culturally tailored interventions are likely to improve health behaviours [38, 39]. The qualitative data from the focus groups will inform measurement burden, acceptability, potential translation and ease of intervention access, which has not been evaluated in other community-based studies with Māori and Pasifika communities in Australia. The potential for success of the proposed intervention will be examined for accessibility, acceptability, uptake, sustainability, adherence, participants' perceptions of measurement burden, effectiveness of recruitment strategy and retention, and the participants' overall experience, based on the women's wellness with type 2 diabetes programs [18, 19]. This will inform the program's cultural adaptability, acceptability and feasibility for future studies.

This study recruited 50 Māori and Pasifika women with type 2 diabetes through community-led participatory approaches and with the input from the AC to ensure that the protocols of engagement with the community and recruitment of participants including implementation and evaluation of the program are community-driven and culturally appropriate [21, 23]. Interventions that are specifically co-designed with communities ensure cultural relevance, effectiveness and sustainability for addressing chronic conditions such as type 2 diabetes of programs [40, 41]. Equally important is the community-led participatory approaches that embeds Māori and Pasifika cultural values within program design and implementation are pivotal to engaging and empowering communities to successfully improve health behaviours, particularly in tackling type 2 diabetes [39 - 41]. Developing health and lifestyle programs in communities, partnered with stakeholders including, health services, government and non-government and academic institutions has been shown to be essential in empowering underserved populations, particularly as it aims to understand and support behavioural changes leading to better health and wellbeing outcomes [37-41]. This program supports the

participants to develop knowledge and practical skills in preventing and managing type 2 diabetes as well as overcoming challenges that participants and their families may face in living a healthy life [16, 23]. As a result, this has enabled the production of five digital stories of women from diverse Pasifika background in the intervention, documenting their experiences and journey which will be used as a health promotion resource for the program in future studies.

Despite these strengths, this pilot study has limitations. One inherent limitation is the potential for cross-contamination. Due to the close nature of the subject communities, it is likely that they will speak to each other regarding the program. For this reason, the intervention and control groups were allocated based on geographic location to attempt to minimize this. The sample size is too small to assess the extent to which the metabolic improvements are due to self-management (e.g. lifestyle change) or clinical management and may also results in non-significant (p value <0.05) for some of the measurement outcomes. In addition, community-based studies are difficult to conduct in a rigorous randomized controlled trial (RCT) design without significant funding, for which pilot data is important to inform study design, including power calculations [37]. However, this study is undertaken as a pilot study to provide proof of concept prior to undertaking a stepped-wedge RCT or multi-centre RCT. Regardless of this, the outcomes of this pilot study will provide valuable information regarding the culturally appropriate implementation and evaluation. The lessons learned in this pilot trial will help us to plan the larger trial with regard to recruitment strategies, intervention implementation and data collection. The evidence-based synthesis of findings with community participants/researchers including dissemination of the pilot study outcomes will have future application aimed at leading to larger studies implementing a state or nation-wide program and undertaking a T1 translation research with potential for development of innovative digital or virtual delivery of the program with health data collection interphase, website platform for virtual delivery and/or use of mobile application.

In conclusion, this study provides a blueprint for PWDWP and proposes a model for evaluating intervention efficacy and effectiveness in partnership with Māori & Pasifika community organisations and key stakeholders in Southeast Queensland, Australia. The study findings will have significant implications for policy makers and practitioners when implementing diabetes management program for Māori and Pasifika communities, emphasizing the need for culturally relevant interventions. Collaboration with communities and stakeholders are crucial, when developing diabetes management and lifestyle, particularly for communities with unique cultural nuances. The findings of this study may suggest a potential model for addressing health disparities in other culturally and linguistically diverse populations.

Dissemination Plan

The study findings will be disseminated through presentations at state and national (e.g, Queensland Women's Health Forum, Australian Public Health) and international meetings and conferences (e.g the International Diabetes Congress) as well as published in peer-reviewed journals. In addition, we will work closely with our partners to identify strategies to disseminate study findings in the community through community talanoa forums and meetings. Other social media network platforms and local community radio will be used to disseminate the study findings.

Acknowledgement

We would like to thank the Māori and Pasifika women with type 2 diabetes, the Advisory Committee members, many of whom are elders and leaders within their communities and the Pasifika health workers for their dedication, time and commitment in the design of this study protocol.

Data Availability

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Author's Contributions

The authors fulfil the criteria for authorship by contributing to the planning, development and write up of the protocol for this study. HA is the principal investigator and drafted the preliminary protocol, ethics and trial registry with DG who is co-investigator. HA, WN, DG contributed to the design of study protocol HG and WN provided Pasifika cultural oversight. MC drafted the initial paper for publication with input and advice from HA. All authors contributed to the writing of the paper, and all have read and approved the final manuscript.

Funding statement

The research program was successful in securing funding through Diabetes Australia Research Program Grant [Grant number Y22G-AKBH] and Australian Health Research Alliance (AHRA) Women's Health Research Translation Network (WHRTN) Early and Mid-Career Researcher Funded Award 2021. A progress interim report and final report with study findings and outcomes will be provided to the funders.

Conflicts of Interest

The authors declared the following potential conflicts of interest with respect to the research, authorship, and publication of this paper: Danielle Gallegos is currently funded by the Queensland Children's Hospital Foundation via a philanthropic grant from Woolworths.

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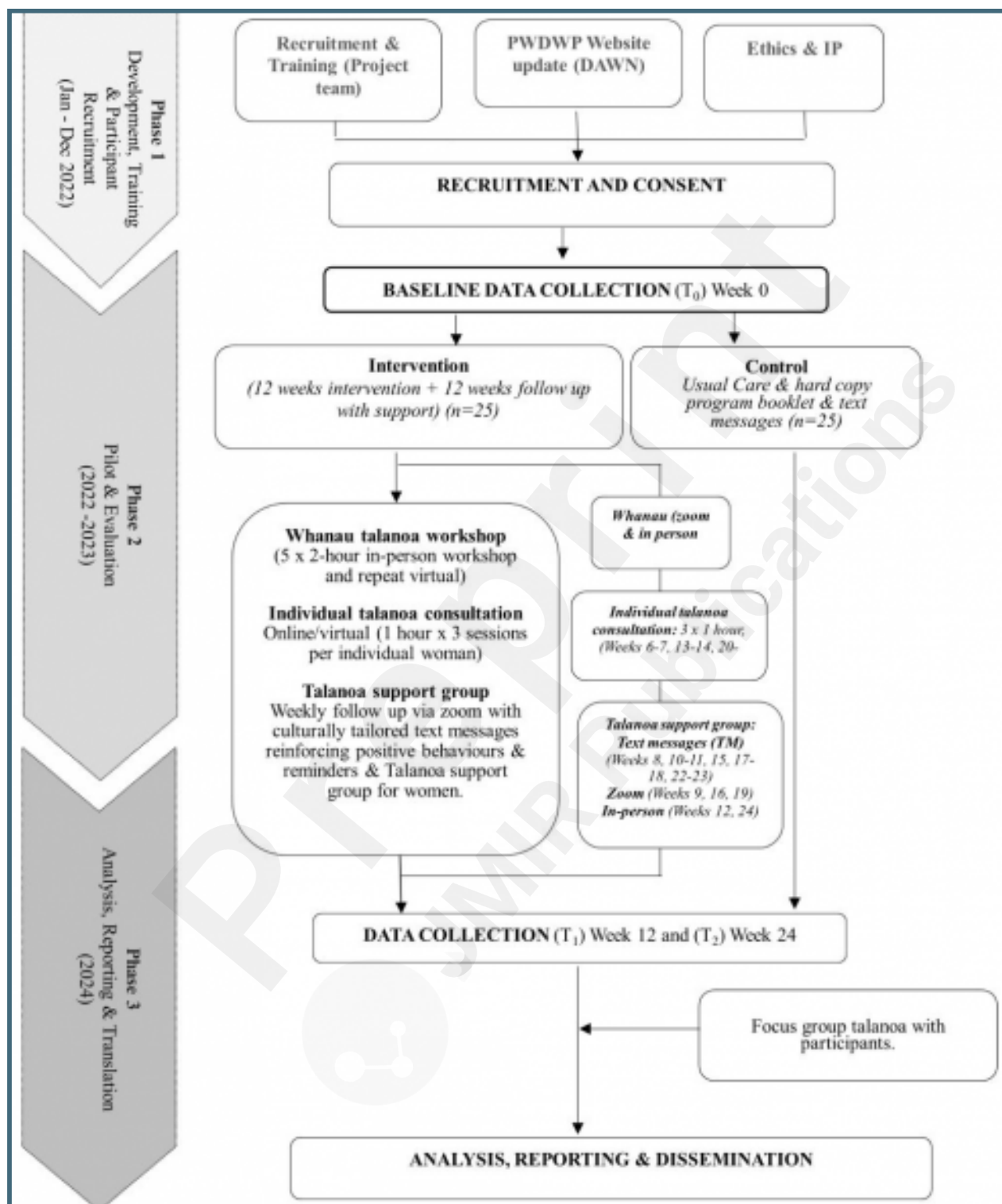
Supplementary Files

Figures

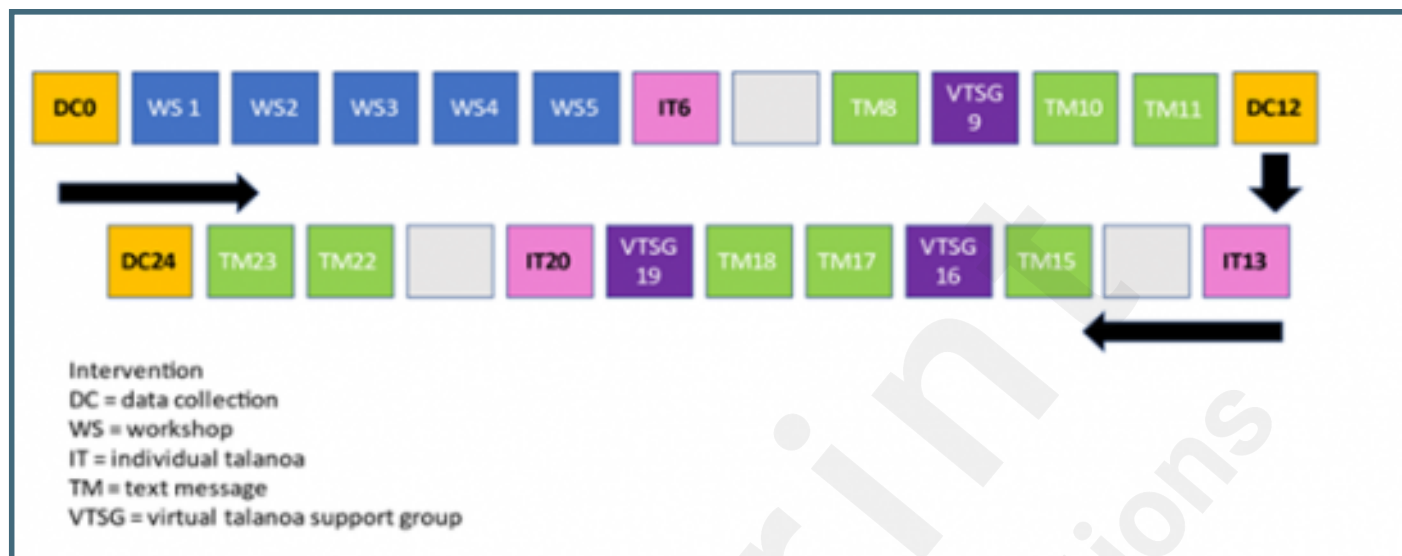
The Pasifika Women's Diabetes Wellness Program and the 'Wellness' Components. Untitled.



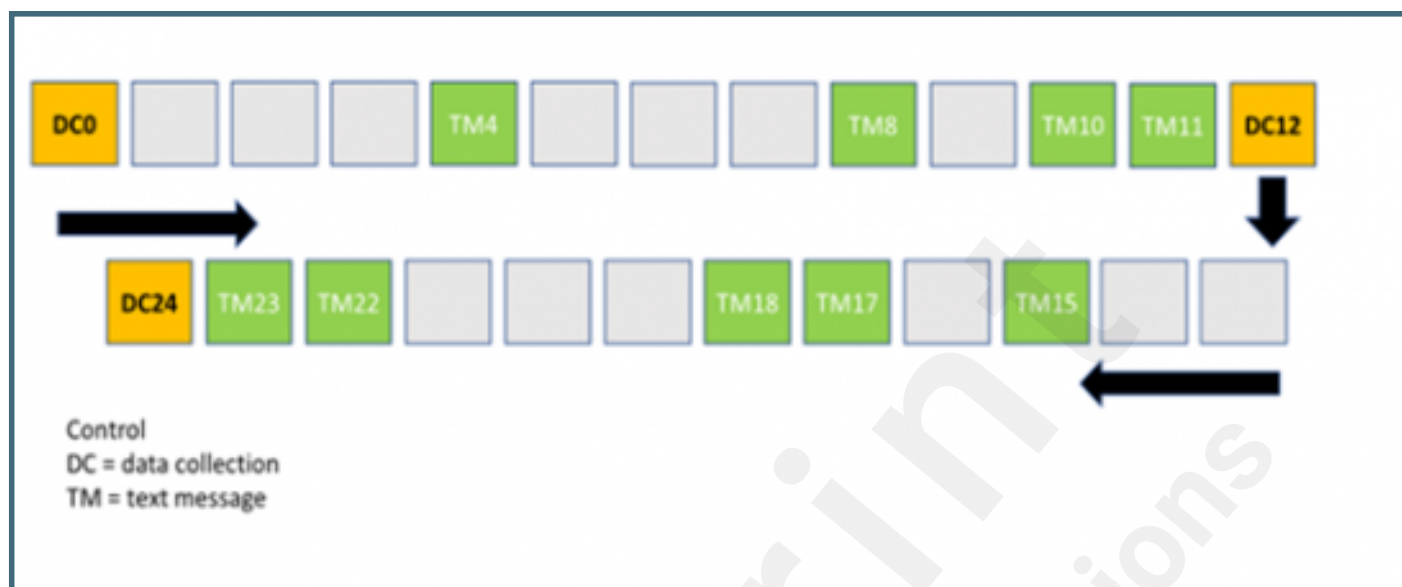
Overview of the Pasifika Women's Diabetes Wellness Program Pilot Study in Southeast Queensland, Australia (2022-2024).Untitled.



Intervention participant journey of M?ori and Pasifika women with type 2 diabetes from the South side of Brisbane, Queensland over 24-weeks (January - November 2023). The intervention participants received 5 x 2-hour education workshops (WS) (either face-to-face or virtual), 3 x individual talanoa (IT) and 3 x virtual talanoa support group (VTSG) with text messages (TM). .



Control participant journey of Māori and Pasifika women with type 2 diabetes from the North side of Brisbane over 24-weeks (January - November 2023). The control participants received their usual care with their preferred health provider and motivation text messages (TM).



Multimedia Appendixes

Peer Reviewed Successful Diabetes Australia Research Program Grant.

URL: <http://asset.jmir.pub/assets/ddb22bd7b1c2d7c607eaf171e6879633.pdf>

Grant review application.

URL: <http://asset.jmir.pub/assets/c4916722b482a886dab087d6857e6782.pdf>

Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12622001100785p.

URL: <http://asset.jmir.pub/assets/435d8471b19bf8903fec81c9efbb8ff7.txt>

RR1 Registered Report.

URL: <http://asset.jmir.pub/assets/a6f7d6a0a812b50a407c8b337549eb3e.pdf>



Related publication(s) - for reviewers eyes onlies

Towards collective community education: Pasifika diabetes health forums in Southeast Queensland, Australia.

URL: <http://asset.jmir.pub/assets/c4e0c3c5b361f1546c0768c9031fe057.pdf>

Using Talanoa in Community-Based Research with Australian Pacific Islander Women with Type 2 Diabetes.

URL: <http://asset.jmir.pub/assets/05ec8db7b994f19102a19d3d5a94430c.pdf>