Apps and Peer support for a Healthy future and Living Well with Diabetes – Mental Health (APHLID-M)



Sponsor

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# SUMMARY

|  |  |
| --- | --- |
| Study Title | The APHLID-M project: Apps and Peer support for a Healthy future and Living Well with Diabetes Project |
| Aims/Objectives | APHLID (Apps and Peer support for a Healthy future and Living with Diabetes study) aims to test whether a phone application - an “App” - for young people with diabetes and mental health (MH; particularly distress) conditions, improves distress, well-being and physical health (eg blood glucose), and reduces health care costs and burden.Parallel studies will examine the effect of the same approach on the response to short-term distress in young people with diabetes residing in regional Aboriginal Communities.Subgroup analyses will be undertaken in those with and without MH conditions, by gender, ethnicity, type of diabetes. |
| Study design | Randomised Controlled Trial (RCT) (study i-RCT) with nested secondary RCT (study ii-nested RCT) and parallel observational study (study iii-observational) |
| Planned sample size | Total 294 participants (i-RCT:n=142; ii-nested RCT: n=~142; iii-observational: n=~10) |
| Inclusion criteria | Aged 16-30 years, with T1DM, T2DM or rare forms of diabetes from eight hospital services with mental health conditions (i-RCT) or without mental health conditions (ii-nested RCT) and, from two AMS (iii-observational). |
| Study procedures | Phase-1 Collaborative model refinement with a multi-disciplinary team of experts and people with lived diabetes experience.Phase-2 Undertake a 6-month type 1 effectiveness-implementation hybrid randomised controlled trial of the model among young adults with T1DM or T2DM with (i-RCT) and without (ii-RCT-nested) mental health conditions to show effectiveness through improvements. A parallel study in the AMS’s (iii-observational) to evaluate implementation will be undertaken.Phase-3 Evaluate model cost-effectiveness and cost-utilityPhase-4 Development of pathway to scaling up across Australia |
| Study duration | 24 months |

T1DM - Type 1 diabetes mellitus, T2DM - Type 2 diabetes mellitus, AMS - Aboriginal Medical Services

# GLOSSARY

AARNet Australia's Academic and Research Network

ADDN Australian Diabetes Data Network

ADEA Australian Diabetes Educators Association

AMS Aboriginal medical services

APDC NSW Admitted Patient Data Collection

APHLID-M Apps and Peer support for a Healthy future and Living Well with Diabetes – Mental Health

BMI body mass index

bp blood pressure

CHeRe Centre for Health Record Linkage

CI confidence interval

DEPSR The Diabetes Eating Problem Survey-Revised

DES-SF Diabetes Empowerment Scale

EDDC Ambulance Data Collections; Emergency Department Data Collection

GP general practitioner

HbA1c glycated haemoglobin (A1c)

JDRF Juvenile Diabetes Research Foundation

LGA Local Government Area

MH mental health

MLK Master Linkage Key

NAP NSW Non-admitted Patient Data Collection

PGA Pharmacy Guild of Australia

PIS patient information sheet

PSA Pharmaceutical Society of Australia

PWD person with diabetes

QALYs quality adjusted life years

RCT randomised controlled trial

RN research nurse

SESLHD South Eastern Sydney Local Health District

SDSCA Summary of Diabetes Self-Care Activities

SWSLHD South Western Sydney Local Health District

T1DM Type 1 diabetes mellitus

T2DM Type 2 diabetes mellitus

# BACKGROUND AND RATIONALE

Diabetes is a growing health issue in young adults. Over 30, 000 young Australians aged 10–30 years with diabetes mellitus (DM) including 78% with T1DM are registered with the National Diabetes Services Scheme (1). The standardised mortality rates for females aged 20-29 years with T1DM and T2DM in 2004-2010 were 6.91 (95% CI 5.56-8.59) and 4.59 (95% CI 3.00-7.04), respectively (3). In similarly aged males it was 2.95 (95% CI 2.41-3.61) and 4.00 (95%CI 2.66-6.02) respectively. The overall hospitalisation rate for severe hypoglycaemia and diabetic ketoacidosis (DKA) among young adults is 5-fold that of older adults (4). Among young adults at Campbelltown Hospital (5,6) with T1DM, 38% suffered multiple episodes of DKA, and 13% had at least one episode of severe (life-threatening) hypoglycaemia. Mental health (MH) conditions are a further major diabetes co-morbidity. Within Campbelltown Hospital, the prevalence of a MH condition was 58% in those with T1DM and 55% with T2DM (5,6). This is consistent with international T1DM data where up to 63% of patients have depressive symptoms and up to 32% experience anxiety (9). Besides acute glycaemic events, the excess mortality risk is also ascribed to accidents and suicide (10,11).

The transition period between youth and adulthood often correlates with increased risk-taking behaviour including drugs, alcohol in addition to moving out of the parental home, changes in social and employment situations, all of which may be associated with emotional and financial hardship (12). Moving from assisted, to self-managed diabetes is fraught with conflicts, clinic non-attendance and insulin omission, particularly if isolated from peers due to the additional (and at times embarrassing) demands of diabetes management. Disordered eating can be present in up to 50% (vs 2-4% background) (13,14). Not surprisingly, 80% of young adults with diabetes aged 19–24 years do not achieve the glycaemic target (HbA1c of 7.0%) (15), At Campbelltown, the mean entry HbA1c in those aged 17-18 years was 10.2% and 9.6% with and without MH problems respectively (5,6).

While several interventions have been implemented to address these risk factors for morbidity and premature mortality, improved outcomes have been better achieved using a combination of diabetes and psychological interventions (16,17). However, evidence is limited among young adults. Most young adults are likely to have a “smart phone” and be confident with using “Apps” (19), making Apps a potentially useful approach to deliver suitable interventions and provide a conduit to maintain MH at a level below a threshold for clinical intervention. Perx is an Australian company that has developed and clinically validated health Apps for chronic conditions in real-world settings (20–22) and in clinical trials (22). For example, the technology and App have been adopted by cohorts of young adults through programs such as the Perx program for Cystic Fibrosis Australia, and the Perx program for HCF Insurance. The aim of this study is to test the efficacy of App delivered mental health and diabetes support using the Perx digital platform.

# STUDY AIMS/OBJECTIVES

APHLID-M aims to test whether young adults with either T1DM or T2DM diabetes have reduced psychological distress (primary outcome) through the use of a digital platform application (App), which has been shown to facilitate improvements in diabetes self-management via and digital psychological interventions.

**Primary Objective:** To demonstrate improved psychological distress with the App.

**Secondary Objectives:** To demonstrate improvements in other mental health, metabolic and clinical outcomes

# PARTICIPATING SITES

The details of the recruitment sites are described **Table 1**.

Table 1. Details of Project sites in for the APHLID-M study on young adults aged 16-30 years with T1DM, T2DM or rare forms of diabetes attending specialist diabetes.

|  |  |  |
| --- | --- | --- |
| **Number** | **Site** | **Profile/Catchment/Challenges** |
| 1 | SWSLHD -3 sites | Paediatric clinic, Campbelltown HospitalTransition clinics: Campbelltown Hospital, Liverpool Hospital, Bankstown-Lidcombe Hospital, 7 LGAs |
| 2 | SESLHD - 2 sites | Transition clinics: St George’s Hospital; Prince of Wales Hospital, 7 LGAs |
| 3 | The Children’s Hospital Westmead - 1 site | One hospital - Cumberland LGA |
| 4 | St Vincent’s Hospital Network - 1 site | One hospital City of Sydney LGA |
| 5 | Goulburn Valley Health - 1 site | One hospital - 5 LGAs located within Victoria |
| 6 | Aboriginal Medical Services | Not in the RCTBiripi Aboriginal Corporation Medical Centre (Taree) located within Greater Taree, NSWWerin Aboriginal Corporation Medical Clinic, NSW |

SWSLHD – South Western Sydney Local Health District, SESLHD – South Eastern Sydney Local Health District, RCT-Randomised controlled trial, LGA-Local Government Area, NSW - New South Wales

# STUDY DESIGN

The APHLID-M Project will develop a technology enabled model of care, using a clinically-validated digital platform- an “App”. The study will include a 6-month RCT across eight hospitals that will rigorously test the effectiveness of this model in ‘real world’ settings in improving young people’s mental health (particularly distress), well-being and physical health (e.g., blood glucose) and reducing health care costs and burden (**Figure 1**). Parallel studies will examine the effect of the approach on response to short-term distress (in a nested RCT) and its use in regional Aboriginal communities (in an observational study).

**i-RCT**

**ii-RCT-nested**

\*RCT iii (observational) will include 10 participants recruited from two Aboriginal Medical Services

Figure 1. APHLID- M Study Design

## Expected study duration

The study will run for 24 months. Recruitment into the i-RCT and ii-nested RCT-nested will occur over 7 months. The RCT intervention period will run for 6 months.

## Population and data source

### Population 1

For studies i-RCT and ii-nested RCT, young adults aged 16-30 years with T1DM, T2DM or rare forms of diabetes attending specialist diabetes services across 8 hospitals will be recruited, including:

* Liverpool Hospital – Elizabeth Street, Liverpool, NSW, 2170.
* Bankstown-Lidcombe Hospital - 68 Eldridge Road, Bankstown, NSW 2200.
* Campbelltown Hospital - Therry Road, Campbelltown, NSW, 2560.
* St George Hospital - Gray St, Kogarah NSW, 2217.
* Prince of Wales Hospital - 320-346 Barker St, Randwick, NSW, 2031.
* The Children’s Hospital Westmead - Corner Hawkesbury Road and, Hainsworth St, Westmead, NSW, 2145.
* St Vincent’s Hospital Network Sydney - 390 Victoria St, Darlinghurst, NSW, 2010.
* Goulburn Valley Health - Goulburn Valley Health, Graham Street, Shepparton, VIC, 3630.

### Population 2

For study iii (observational), young adults aged 16-30 years with T1DM, T2DM or rare forms of diabetes attending Aboriginal Medical Services (AMS) across two sites will be recruited:

* Werin Aboriginal Corporation Medical Clinic - 14 Lake Rd, Port Macquarie, NSW, 2444.
* Biripi Aboriginal Corporation Medical Centre - 2A Edward Dr, Purfleet, NSW, 2430.

### Data source 1 - Quantitative

All participants recruited will be asked to complete a questionnaire to obtain baseline and follow up data.

### Data source 2 - Qualitative

Participants from population 1 and population 2 will be invited into qualitative sub-studies (likely to be 25 to 30 participants -until saturation).

### Data source 3 - Linkage

## Participants in the program, both population 1 and population 2 (participants of study i:RCT and study ii: nested RCT), will be asked to provide consent for future linkage of their study data to the health system administrative data. Due to time constraints imposed by study milestones, and the impact of the Christmas break, a separate ethics application will be submitted for this proposed linkage at a later date. The data requested will be those in New South Wales sites that are held in the Master Linkage Key (MLK) at the Centre for Health Record Linkage (CHeReL) which comprises: Ambulance Data Collections; Emergency Department Data Collection (EDDC); NSW Admitted Patient Data Collection (APDC); NSW Mental Health Ambulatory Data Collection; NSW Non-admitted Patient Data Collection (NAP); and cause of death and register of death. The same data will be requested for the Victorian site (Goulburn Valley Health), from the Centre for Victorian Data Linkage. The data will be requested for the period 2019 to 2025 for the program participants for 3 years pre-program and 3 years post- programme comparisons. Recruitment and screening

### Population 1: i-RCT and ii-nested RCT

Due to APHLID-M being a RCT a multi-pronged approach will be used to recruit participants consisting of the following methods:

* For studies i-RCT and ii-RCT-nested: Recruitment will occur via the RN through the transition/young adult/paediatric/other clinics either during clinic visits, or outside of clinic visits using the clinic register.
* The waiting area of the clinics will have posters informing participants of the study. The clinic staff will receive training about the study, to enable them to answer questions about the study if they are approached by patients.
* A RN will be assigned to perform the recruitment. Potential participants will be approached by the RN in the waiting area who will briefly explain the study, and provide a patient information sheet (PIS). People expressing interest in study participation will then meet with the RN after their clinic appointments to discuss the study in more detail. All eligible young adults will be approached, except those who are unwell during their clinic visit.
* Additionally, an RN placed within the paediatric clinics in Campbelltown, Sydney Children's Hospital Network will approach eligible study participants, explain the purpose of the study and provide an opportunity for patients to participate. All eligible patients who indicate that they would like to participate in the study will be given a PIS and instructions on how to enrol in the study by the RN.
* The clinical team at each of the recruitment sites will also identify patients on their register who meet the inclusion criteria and attend the relevant transition clinics. Research nurses will contact eligible patients via phone or email to invite them to participate in the study. An email with a PIS and instructions on how to enrol in the study will be sent by the RN to all eligible patients who indicate that they would like to participate in the study.

Recruitment will cease once 142 participants have been recruited for study RCT (i).

### Population 2: iii-observational

Recruitment will occur at community events held at the two participating AMS sites. A promotional flyer will be provided to each AMS which will promote the opportunity to register for the study and contain details of the designated contact at each AMS. All participants who register their interest will be invited to a project kick-off day that will include the registration of eligible participants. Participant registration will be managed by the project’s Indigenous Health lead, Aunty Kerrie Doyle, and through site Aboriginal Health Workers.

## Inclusion criteria

Both populations for studies i-RCT and ii-nested RCT: Adolescents and young adults with T1DM, T2DM or rare forms of diabetes, aged 16–30 years, willing to give written/online informed consent. The participants must be familiar with smartphones and possess a smart phone (either Apple or android operating systems) that is compatible with the App.

For study iii-observational, in addition to the above, individuals must be of Aboriginal background.

## Exclusion criteria

For study population 1 (i-RCT, ii-RCT nested) and population 2 (iii- observational): Individuals indicating a current pregnancy, without a smartphone and those who are unable to provide written/online informed consent will be ineligible to participate in the study. As the App is in English those who cannot converse effectively in English will also be excluded from study participation.

## Consent process

Eligible participants recruited during clinic visits, who agree to participate in the study will be provided with a PIS and consent form.. Participants contacted via the RN over the phone will be emailed a consent form and a PIS and suitable arrangements will be made for the patient to attend the clinic for recruitment to take place. Online consent will be sought through electronic consent on the first webpage screen of online the baseline questionnaires prior to any study-related assessments or procedures, whereby participants cannot progress to complete the questionnaire unless they have completed the consent page.Hard copies of the PIS consent form will be available to obtain written consent In the event that participants are unable to consent electronically due to technical issues.

By providing consent participants will consent to participate in the study and to

1. the future linkage of their study data to health system administrative data held in the Master Linkage Key (MLK) at the Centre for Health Record Linkage
2. a blood sample being collected at baseline and 6 months, to test for metabolic markers associated diabetes related complications and cardiovascular related risk (including HbA1c; lipids and adiponectin)
3. the storage of samples by the study group for use in future studies of diabetes and its risk factors and complications.
4. to be contacted for one on one or group discussions to evaluate the study

Participants will be given the option to participate, and ‘opt out’ of one or all of the above (1-3).

Once consent is obtained, participants will complete baseline online questionnaires listed in **Table 2,** after which their weight, height, blood pressure and a single baseline blood test will be taken. All participants will complete baseline questionnaires listed in **Table 2.**

The RN will assist the participants in completing the study documents.

## Study Phases

### Phase 1: Collaborative model refinement with a multi-disciplinary team of experts and consumers

* Adaptation of the existing Perx App to include T1DM and T2DM components in addition to a mental health component, the establishment of which will be supported by a Project Reference Group with representation from mental health clinicians, academics, and consumers. The Project Reference Group will review the adapted Perx App and approve the modified App.

### Phase 2: Randomised controlled Trials

#### Allocation of participants to RCT study groups

* Results from completed questionnaires including Completed Problem Areas in Diabetes (PAID; score≥40), Kessler Psychological Distress Scale (K10; score ≥20), or past diagnosed MH history will be used to allocate participants into the two groups: with (i-RCT) and without (study ii-RCT nested) MH conditions. It is anticipated that at least 50% of participants will have an MH condition. In addition to usual care, these participants will be provided with a mobile App containing resources on MH and diabetes self-management, to download onto their smartphone. Those identified as having a severe MH condition will be referred to the site psychologist if available or to their general practitioner for management, but will not be excluded from the study. Some sites have an “in-house” psychologist, and some participants will already have their own psychologist/psychiatrist: these services will continue unchanged.
* The details of participants who are randomised for the App intervention within both RCTs will be added to the Perx portal. Perx will then send them emails and SMS notifications with details on how to download the modified Perx App and sign-in to their device. A diabetes service member (local diabetes educator/dietitian/other service team member), is already nominated to help with the project (with sign off of associated costs by health services as part of the grant application), to assist them with the download of the Perx App to their device if needed, and add the referral code for access. If no download occurs within 14 days, Perx will advise the study team, who will inform the diabetes service member for follow-up . Once the participant downloads the Perx App, they will be prompted and provided with tutorials to set up their health schedule including medications. (estimated to take approximately 15 minutes). An in-App live chat is provided by Perx If assistance is required. Participants’ engagement with the App will be monitored during both RCTs.
* All consenting study participants (with and without the App) will be provided with an activity tracker. The RN will explain the importance of, and encourage participants to wear the activity tracker for the duration of the trial. Questionnaires, measurements and blood tests will be repeated after 6 months. Quantitative data including HbA1c measurement (which is routinely performed in patients with T1DM and T2DM to assess and monitor long-term glycemic control (REF)) and blood pressure will be extracted from clinic medical records by the RN to assess metabolic management (Table 2). Study staff will collect data blinded to group allocation for objective outcome measurement.

Table 2. Overview of variables and data that will be collected for the APHLID-M study studies i-RCT and ii-nested RCT and iii- observational, young adults aged 16-30 years with T1DM, T2DM or rare forms of diabetes attending specialist diabetes services across 8 hospitals.

|  |
| --- |
| Clinical Outcomes (measured at baseline and after 6 months) |
| Psychological distress | K10; Diabetes distress |
| Quantitative data to assess metabolic management | HbA1c; If testing/using Continuous Glucose Monitoring Sensor /Flash Glucose Monitoring System: Time in/above/below range, Glucose variability; mean glucose; blood pressure; lipids; BMI; weight, height (baseline only); CVD risk-adiponectin |
| Hospitalisation | Number of ED or hospital admissions or ambulance treatment and released in the last 3 years (i) total admissions ii) DKA/ hyperglycaemia (iii) Hypoglycaemia |
| Patient engagement | Missed appointments in last 6 months; provision of self-monitoring data;Medication adherence; sick day planning; hypo treatment; Contraception use; needle/set changes; App use. |
| Psychosocial and behavioural outcomes | The Diabetes Eating Problem Survey-Revised [DEPS-R) Self-efficacy |
| Self-management | Summary of Diabetes Self-Care Activities (SDSCA) PA tracker time spent in low, moderate and vigorous PA and sedentary behaviour, time spent sleeping and quality of sleep. |
| Patient reported outcomes | Diabetes Empowerment Scale – Short Form (DES-SF)  |
| Sample collection and storage | Samples will be taken for the measurement of total/high-molecular-weight adiponectin using a quantitative monoclonal sandwich ELISA, and stored for use in future studies of diabetes and its risk factors and complications.  |
| Cost-Utility | EQ5D-5L; Hospital service utilisation including telephone and online occasions of service; Acute glycaemic hospitalisation/ED visits; Economic evaluation (includes ICER)-see below |
| Other: includes qualitative research | Consumer and healthcare professional perspectives on the intervention and its impacts on patient, provider, and health-system implementation |

HbA1c- glycated haemoglobin (A1c), BMI – body mass index, CVD-cardiovascular disease, ED-emergency department, DKA - diabetic ketoacidosis, ELISA – enzyme linked immunosorbent assay, PA- physical activity

#### Study evaluation and establishment of focus groups – qualitative data

Upon completion of the intervention:

* All participants/carers/healthcare staff involved in the studies three study groups will be invited via email to complete an online evaluation survey of each component of the model.
* A sub-group of participants/carers from the three studies will be invited to participate in a Focus groups or one to one interview (online or face to face) as per the participants preference/availability.
* Email and phone invitation from the research team to healthcare staff from each of the clinics will also invite them to participate in interviews and focus groups, to provide their feedback on the feasibility of rolling out of the intervention more widely and sustaining it at their clinic. Focus groups with participants and health care staff will be separate
* The Evaluation will be guided using the RE-AIM Framework. Which includes
	+ Reach - % clinics participating, how many sign up.
	+ Effectiveness – RCT and perceived how many sign up.
	+ Adoption – was the app used and if so how
	+ Implementation – how the service used the intervention, feasibility or rolling out issues from a patient and health care practitioner point of view
	+ Maintenance – how patients and health care practitioners are engaged.

### Phase 3: Evaluation of the cost effectiveness, cost utility and workload impacts of the intervention.

* The primary outcome for economic evaluation is the Quality Adjusted Life Years (QALYs), as measured by EQ5D-5L that will be completed at baseline and at the follow-up assessment for both groups (i-RCT and ii-RCT nested). Data on medical services, workplace absenteeism and presenteeism (paid and unpaid) would be collected from study participants using a resource-use questionnaire (RUQ) at baseline and follow-up.
* The Australian health sector and societal perspectives will be used for the analyses to reflect the different decision makers and contexts and per the current guidelines for reference cases in economic evaluations. The health sector costs include those paid by the government of primary and acute care, medication costs, and ambulatory costs as well as the out-of-pocket costs of health care resources paid by the participants during the trial period. Societal costs comprise the health sector costs in addition to the costs of patient transportation (costs per km travelled for visits to health care providers), food and effects on productivity (labour market earning loss of paid work and unpaid lost productivity due to illness). In addition, costs to carers and/or support person(s) will be determined including direct and indirect costs.
* The intervention costs of using the adapted Perx App will include developmental costs, training costs, and maintenance costs specific for the RCTs.

### Phase 4: Scale up plan for intervention

* Development of a distribution plan through health services (e.g., through ADDN), diabetes consumer organisations (e.g., Diabetes Australia including National Diabetes Services Scheme, JDRF), mental health consumer organisations (e.g., headspace), and health professional organisations (e.g. ADEA which would then reach those in the private as well as the public sector, PSA and PGA i.e. through pharmacists).
* Our testing of the ability to distribute the Perx-App (overview of the Perx App available in Appendix) through 10 diabetes services, will demonstrate that scalability through other health organisations is also possible, and a plan for national scaling is part of the project.

### Indigenist APHLID adaption

Project meetings will be undertaken at both AMS sites to coordinate the research timelines. Workshops will be held at both AMS sites to provide education to the clinical staff regarding the study eligibility and procedures. Separate ethics approval will be gained through the Aboriginal Health and Medical Research Council (AH&MRC) and this arm of the study will be run in accordance with the AH&MRC guidelines. The project team will work with an Aboriginal Health Worker to coordinate the recruitment of participants. Within the Indigenist adaption, no randomisation will occur and all participants will be provided with the intervention (App). The Indigenists adaption roll-out may be seen in Appendix 15.2.

## Research design and methods

### Sample size and power

Recruitment, implementation and evaluation of the research program. Based on data published previously (behavioural intervention K10 change 21.2 ± 9.4 vs baseline 25.7 ± 9.7 Cohen d =0.5), a sample size of 64 per group in the primary RCT will be required to identify a moderate effect size of 0.5 between intervention and control groups, in a t-test model with power=0.8, alpha 0.05. An additional 14 participants will be included to allow for an attrition rate of 10% (total n=142). A similar sample size is expected in the secondary RCT among the young adults without a mental health disorder identified at the time of study entry.

### Randomisation

1:1 block randomisation, stratified by site and MH condition or not, will be undertaken using an electronic randomiser independent of the study team. The study coordinating team will review participants’ details, verify their eligibility, and enter their details in the bespoke study randomiser. The study number and randomization arms will be recorded in a study register. The coordinating team will send a notification to the study sites once the randomisation is complete.

## Consumer and community involvement

The study will be guided by a Consumer Advisory Group to ensure the appropriateness of the research. The project team includes a young adult consumer who links into people with diabetes across Australia through active participation in the public and private spaces of the diabetes online community. In June 2021, young adults within the Campbelltown Hospital Transition clinic were surveyed with 89% reporting that diabetes significantly impacts their MH (Net Promoter Score -22.22), with average to below-average ratings of confidence in self-management of diabetes and MH. Approximately 50% of respondents indicated it would be extremely unlikely for them to engage with MH support in-person or by phone. However, 66% indicated that they would engage with MH support if delivered via an App, and would continually engage with an App if it offered integration with additional health components such as blood glucose logs and exercise trackers. One of the key groups of young adults whose diabetes management is particularly challenged are those from culturally and linguistically diverse communities. We have consulted with leaders from Pasifika communities and multicultural organisations (including Harmony Alliance and Community Migrant Resource Centre representing diverse migrant and refugee communities). Diabetes consumer organisations have indicated their support for the work and the need to address this important gap in services including the Juvenile Diabetes Research Foundation (JDRF), the leading non-profit organisation driving progress for T1DM.

# Sample collection and storage

Samples will be requested from all participants at baseline and 6 months to identify new molecular biomarkers to assess mental and physical health based linked to the questionnaire and other data collected. Samples will be used for adiponectin (an anti-diabetes and anti-atherogenic hormone secreted by adipocytes). Samples collected in this study will be stored for use in future studies of diabetes and its risk factors and complications. Blood will be collected and processed at each site by a delegated staff member. Samples will either be stored on site at -20° and transported on ice to the lead site (Campbelltown), or shipped to the lead site following collection. Samples will be stored at Macarthur Clinical School/WSU Campbelltown in a secure -80° freezer until processing.

# RESEARCH FLOW CHART

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Figure 2. Outline the process of the APHLID Randomised Control Trial and the Peer Support Program

# STUDY PROCEDURE BENEFITS

The current approach to the management of T1DM/T2DM in young adults is insufficient to reduce the short, and long term risks from hyperglycaemia and wider metabolic disorders. MH disorders are not only an adverse outcome themselves, but also impact seriously on diabetes management and self-management: often every day of the young person’s life. These can be exacerbated by social situations that the young adult is learning to navigate and overcome, often from a disempowered and isolated position.

Pain points experienced include:

* limited range of expertise of the care team
* limited time with specialist team to provide patient support
* adherence issues through eg denial and lack of engagement
* acceptance but low self efficacy not wishing to be different from peers
* limited timely support at the time of life crises
* limited knowledge, skills or tools to deal with individual situations and MH states
* disorganised living and diabetes as a low priority

Our trial tests an App to provide real time choices for the young PWD to facilitate benefiting or solving these pain points.

## Ethical considerations

### Standard ethical considerations

#### Recruitment and Selection of Participants

Direct recruitment will occur in the clinic waiting area, which is a standard approach. Participants will have ample time to consider, and participation will be voluntary. No dual relationships, conflicting concerns, coercion will exist. Although principal investigator and Co-investigator work in the Transition Clinic, no recruitment will occur during consultation. Participants will provided with an activity tracker to enable the participant to take part in the study.

#### Informed Consent

All participants will receive a PIS explaining the purpose, procedure, possible physical discomfort/risks, and benefits of the study. Participants will be given a reasonable amount of time to ask questions and discuss the study before and after their clinic appointments and to consider whether to participate in the study. Participants who wish to participate in the study will be required to sign a written consent document.

#### Confidentiality and privacy

All screening data will be stored securely by the research nurses. All hard copy material (consent forms, survey forms) will be stored in locked facilities and all soft copy materials such as the transcripts and data will be stored on the WSU secure password protected Australia's Academic and Research Network (AARNet). All individuals recruited in the transition clinic will be approached by the health practitioner in a clinical setting and guidelines around patient privacy adhered to. All questionnaire derived data will be collected using an online secure custom built study database (BTR), which will run on a WSU governed server. The BTR platform uses a top-down authorisation system that can restrict users to only viewing project data that they need to and only allowing data input if needed. Data blinding can also be enabled whereby a password is required to retrieve and view restricted content. Qualitative recordings will be securely stored and deleted following transcription. Qualitative transcripts will be linked to participant ID, and any identifying information will be removed from qualitative data transcripts, and names will be replaced with pseudonyms.

### ***Special ethical considerations***

In the case of minors (those < 18 years), the parent /guardian and the minor will be involved in the decision making process, and the minor will be enrolled in the study if both parties agree. However the consent form is required to be signed by the guardian.

## Data storage and retention

Handling of all electronic and paper records will follow standard information governance requirements. The researchers will keep all hard copy material (consent forms, survey forms) in locked facilities. Consent forms and any written data will be kept separate so that the participants cannot be identified. All soft copy materials such as the transcripts and data will be stored on the Western Sydney University secure password protected platform AARNet. Records will be retained for at least 5 years from the date of publication.

# CONFLICT OF INTEREST

Principal investigators working in a clinical setting will not recruit patients during clinical consultations.

# FUNDING

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# RESEARCH OUTCOMES

The study findings will be published in peer reviewed journals and presented at National and International conferences. Participants are invited to receive a summated and de-identified final report of the study by email. If the App and model of care are of benefit, the research team will work with state and national bodies for translation into service

# APPENDIX

## The Perx Technology Platform

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