RESEARCH PROTOCOL

Full Title: ***Initiation of a novel In-Hospital Treatment for Patients with Type 2 Diabetes***

Short Title: ***REMIT-2-DS2 Project (stage 2)***

STUDY INVESTIGATOR(S)

Principal Investigator:

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[Role: Study design, leadership, recruitment]

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1. INTRODUCTION

"*Initiation of a novel In-Hospital Treatment for Patients with Type 2 Diabetes* (REMIT-2-D)"

This study will implement and rapidly optimize an in-hospital treatment package for people admitted to the Lyell McEwin Hospital (LMH), The Queen Elizabeth (TQEH) and Royal Adelaide (RAH) Hospitals with Type 2 Diabetes Mellitus (T2DM) . In-hospital educational resources to develop diabetes-related health literacy have been shown to be of benefit and there are advantages to a healthy eating and exercise pattern.[1-9] Our aim is to test a simple, effective treatment package that can be delivered by non-doctor or non-nurse personnel but who are suitably trained in the delivery of the educational resources. The focus is on health literacy to improve self-care and connect to community support. We know that a comprehensive package is of benefit, but we don't know which components of the package drive the benefit.

The study is the second stage of the MRFF funded "Reducing Morbidity Mortality and Costs by Initiation of a novel In-Hospital Intervention for Patients with T2DM (REMIT-2-D)" project. Stage one of the REMT-2-D project comprised: (i) an analysis of the patterns of admission, length of stay and re-admission of people with T2DM to the Lyell McEwin, The Queen Elizabeth and Royal Adelaide Hospitals; (ii) a systematic review of in-hospital interventions to improve outcomes for people with T2DM; (iii) focus groups with Aboriginal and Torres Strait Islander people who have T2DM and those who provide health care services to them and (iv) a more general group of health care professionals who provide services to people with T2DM.

In stage two of the REMIT-2-D project we have developed a set of initial best guess informed by stage one and using a process of adaptive randomized design propose to undertake a pilot trial to establish (i) which of these interventions if any, is most effective to improve Glycated Haemoglobin (HBA1c) a measure of overall control of blood sugar, (ii) reduce diabetes related distress and (iii) the psychosocial, environmental factors and other health related factors that affect an optimal outcome being achieved. In addition, we plan to conduct a data linkage analysis to measure late (12 months) readmission to hospital and if readmitted, length of stay. This is included in the protocol and is part of the patient information and consent, however our grant timeline means that we may not complete this by the due date (June 2021) and thus request from this committee to extend the timelines of approval for an extra two years to allow time for the data linkage analysis.

2. BACKGROUND

The Initiation of a novel In-Hospital Treatment for Patients with Type 2 Diabetes (REMIT-2-DS2) Project is one of several projects to receive funding in 2018 for one year through approved disbursements from the Medical Research Future Fund (MRFF) under its Rapid Applied Research Translation Program. The REMIT-2-DS2 project is the second stage of the *"Reducing Morbidity Mortality and Costs by Initiation of a novel In-Hospital Treatment for Patients with T2DM (REMIT-2-D)"* project, which received funding from the MRFF in 2017.

Type 2 Diabetes (T2DM) is a chronic condition that effects a large and growing proportion of the world's population. In Australia, it is the fastest growing chronic condition, increasing at a faster rate than other leading chronic diseases such as heart disease and cancer.[10] The Australian Institute for Health and Welfare found that prevalence of T2DM tripled between 1989/90 and 2014/15 with around 1.2 million known and registered Australians currently living with diagnosed T2DM, and an estimated additional 500,000 people with silent, undiagnosed T2DM whilst indigenous Australian

adults are almost 4 times as likely to have T2D as their non-Indigenous counterparts.[11] If T2DM continues to rise at the current rates, it is estimated that up to three million Australians over the age of 25 years will have T2DM by the year 2025.[12]

There is a 50% risk the children of a parent with T2DM will have a genetic susceptibility to the condition. However, the risk of developing the disease is strongly related to excess stores of body fat (85 – 90% of all people with the disorder are overweight or obese), and strongly influenced by a range of psychosocial and lifestyle related factors[10-13].

The complications of T2DM are serious and can include cardiovascular disease, stroke, kidney disease, limb amputation, depression, anxiety and blindness. Not only are the complications of T2DM preventable with good primary health care and in-hospital medical care, but the condition is preventable with appropriate lifestyle changes such as diet, exercise, smoking cessation, minimisation of alcohol consumption and stress management[10].

Finding sustainable solutions to curb the ill health, disability, mortality and costs associated with T2DM is an increasingly urgent priority for South Australian health practitioners and policymakers. Appropriate management of T2DM early in hospital admission may shorten length of stay, decrease readmissions rates and reduce the risk of morbidity due to long term complications[14].

Many people with T2DM have complex care needs because they have more than one health condition and require services across hospitals, general practice primary care, community services and social care. However, that care is often fragmented across the different services, resulting in poor outcomes and inefficient use of scarce resources.[15] Hospitalization presents an opportunity to coordinate multidisciplinary care, identify and initiate support that patients require in managing T2DM, and to build the capacity of patients in managing T2DM.

South Australia (SA) has the highest percentage of population with T2DM in Australia affecting' over 106,000 people (6% of the SA population). T2DM is most prevalent in Adelaide's north, is strongly associated with social disadvantage, lower health literacy, and among people with a lower sense of mastery over their lives. The northern suburbs also have the highest rates of potentially avoidable hospitalisations in SA[15] and 25% of people with T2DM in SA are re-admitted to hospital within 30 days, especially if they have co-morbid Cardiovascular Disease (CVD)[7]

Studies have found that 'recent' hospitalization is a risk factor for patient re-hospitalization unless discharge planning is adequately targeted to specific conditions, which may reduce unplanned hospital readmission. For example, failure to diagnose T2DM at the time of admission to hospital or acknowledging T2DM during discharge proved to be associated with increased level of hospital length-of-stay and 30-day readmission.[16-18] Nonetheless, most research studies pertaining to hospitalization do not target T2DM as a primary condition of concern.

Inpatient stay provides an important and frequently missed opportunity to assess and optimise care for patients with T2DM prior to discharge to the ambulatory setting. Numerous studies have reported on a range of effective interventions for patients with T2DM such as glycaemic control[19,20], diabetes education[21,22], role of medical specialists[23,24], medication adherence[25,26], healthy lifestyle activities[27,28] diet and exercise interventions [22] as well as substantial empirical evidence of the contribution of social and behavioural factors to functional status and the onset and progression of disease[28-30].

Results from a Systematic Review (unpublished) undertaken as part of stage one of the REMIT-2-D Project, suggests there is a gap in patient centred in-hospital interventions that deliver a comprehensive and integrated approach to in-hospital care for patients with T2DM through a

combination of the key interventions as referred to above. The REMIT-2-DS2 project for a patient centred in-hospital intervention aims to create a responsive, person-centered system of care which involves clinicians, primary healthcare providers and community services working with each other and with people with T2DM to ensure coordinated, effective and efficient patient care that reflects the whole of a person's health needs.

We will address this gap, focussing on assessing the validity and effectiveness of a comprehensive treatment package that includes:

- Health literacy (diabetes education for patients, families, patient self-care education and support)
- Psychosocial and social determinants (individual's lifestyle, food related behaviours, socio-economic status and disadvantage)

The implementation of in-hospital treatments for T2DM will, through better coordination and continuity of care, enhance the quality of care for patients by improving health outcomes, promoting patient safety, increasing patient satisfaction, and optimising the use of resources. From a patient's perspective, the treatments will aim to meet both their health and social needs, taking these as the starting point for redesigning their care, and making it an easier journey for the patient throughout their treatment.

3. AIM OF STUDY/RESEARCH QUESTIONS

The aim of this study is to:

- Implement and rapidly optimise an effective, culturally appropriate, in-hospital treatment for patients admitted to the LMH, TQEH and RAH with T2DM.
- Determine whether a treatment package targeted at people admitted to LMH, TQEH and RAH and who have T2DM will improve glycaemic control at 6 weeks and reduce hospital admission or if re-admitted, reduce length of stay.

HYPOTHESIS

Primary Hypothesis

An In-hospital intervention in an Australian public hospital context for people identified as having T2DM, will lead to improvements blood sugars and reductions in diabetes related distress, and ultimately a lower probability of re-admission or if admitted and an admission of shorter duration.

4. STUDY DESIGN

In stage 1 of REMIT-2-D, a Participatory Action Research, informed by the systematic review and stakeholder input was utilised to develop a set of potential in-hospital treatments with specific consideration for the needs of Aboriginal and Torres Strait Islander (ATSI) patients [17]. These will be implemented in parallel and compared against a standard-of-care control by a "drop-the-loser design" to determine the optimal intervention. Drop-the-loser designs are a novel methodology for trial design that rapidly identify promising treatments, for example when several promising new treatments exist and there are relatively few patients to test them.

5. STUDY LOCATION

- Lyell McEwin Hospital, SA
- SA Department for Health and Ageing (e.g. centrally held data)

- The Queen Elizabeth Hospital
- The Royal Adelaide Hospital

6. STUDY POPULATION AND SETTING

The participants will be drawn from patients admitted to the Lyell McEwin The Queen Elizabeth (TQEH) and Royal Adelaide (RAH) hospitals in Adelaide, South Australia with Type 2 Diabetes Mellitus (T2DM).

We anticipate randomising 5 patients per week aiming to complete the study in the first quarter or 2020.

7. ELIGIBILITY CRITERIA

a. Inclusion criteria

1. Non-Indigenous and Indigenous peoples of age 18 years and over.
2. Patients with Type 2 DM admitted to LMH, TQEH and RAH

b. Exclusion criteria

1. Non-Indigenous and Indigenous peoples under the age of 18 years.
2. Women who are pregnant.
3. Patients unable to give informed consent.
4. Patients scheduled for coronary angiography

8. STUDY OUTCOMES

a. Quantitative

i. Primary Outcome

- Improved blood sugar control measured by HbA1C at 6 weeks

ii. Secondary Outcome(s)

a. Change in triglyceride and diabetes distress at 6 weeks

b. Reduction in readmission to hospital or if re-admitted, a reduction in length of stay

c. Relationship of psychosocial, environmental and health related factors to the effect of the intervention.

9. STUDY PROCEDURES

a. Recruitment of participants

Patients admitted to the Lyell McEwin hospital, The Queen Elizabeth Hospital and Royal Adelaide Hospital with Type 2 Diabetes Mellitus (T2DM) will be enrolled.

Advertising material may be distributed in the Hospital wards to inform potential participants of the trial (Appendix 1).

b. Study procedures

Care Coordinator role:

- Ask resident, registrar or nursing staff on the general medical and endocrine wards each weekday morning to identify any patients with Type 2 Diabetes and approach them to ask if the care coordinator can talk to them about the study.
- Approach identified patients to deliver information about study and gain consent
- Randomise patients to 1 of 4 groups (study group control 1 or study group intervention 2, 3 or 4). (Figure 1)
- Help patients to complete questionnaires (includes clinical, psychological, knowledge, literacy, access to appropriate health services and medical history) which should mostly take 1.5 hours. However, this may take 2-4 hours as the Care Coordinator will need to balance the need for timely completion of study processes with the need to provide support and understanding, respond to questions and engage in discussion that aims to improve health literacy and reduce diabetes related distress in accordance with the study procedures. If this is tiring for patients the Care Coordinator will ask patients if they would like to stage the process, further patients may request that they do not complete all the questionnaires.
  The study care coordinator will also collect some extra medical data from the medical records
  Ask patients if they would like a friend or relative with them and/ or, for Aboriginal patients, an Aboriginal health worker.
- Make a time for the Care Coordinator to return to deliver the randomisation intervention allocation. (Figure 1) Ask patients if they would like a friend or relative with them and/or, for Aboriginal patients, an Aboriginal health worker.

The questionnaires include the following (Figure 1) and will be site specific:
The Lyell McEwin Hospital

- Active Australia[26]
- Diabetes Distress Scale[27]
- Free Sugar Intake Behavior
- Fruits and Vegetables[28]
- General Practitioner information
- Medical Patient data
- Patient Health Questionnaire (Depression) 9[29]
- Coping Index [30]
- Coping self-efficacy index[31]
- Health literacy: Newest Vital sign UK[32]
- Perceived Diabetes self-management [33]Pittsburgh Sleep Quality Index[34]

The Queen Elizabeth and Royal Adelaide Hospitals

- Active Australia[26]
- Diabetes Distress Scale[27]
- Fruits and Vegetables[28]
- General Practitioner information

- Medical Patient data
- Patient Health Questionnaire (Depression) 9[29]
- Coping self-efficacy index[31]
- Health literacy: Newest Vital sign UK[32]
- Perceived Diabetes self-management [33]

IN-HOSPITAL TREATMENT PACKAGE FOR T2DM PATIENTS

There are 5 educational resources to develop diabetes-related health literacy. These were developed from a systematic review of the evidence and a series of focus groups with health professionals and consumers.

Study educational resources for diabetes -related health literacy (Appendix 3)

1. Diabetes self-care
2. Eat Whole Foods
3. Good sleep = Good health
4. Muscle resistance activity
5. Coping with diabetes to reduce diabetes distress

In addition, Diabetes Australia has produced several health literacy fact sheets freely available on the National Diabetes Service Scheme (NDSS) website: https://www.ndss.com.au/

1. NDSS_Understanding Type 2 Diabetes[35]
2. NDSS_Healthy Food Choices[36]
3. NDSS_Physical Activity[37]

The randomisation study groups are as follows (Figure 1):

Study group 1:
Standard factsheets from the Diabetes Australia Foundation (NDSS) on **Understanding T2 diabetes, Healthy Food Choices and Physical Activity**

Study group 2:
Study_Self-care, Coping, Sleep, and **NDSS_Healthy Food Choices**

Study group 3:
Study_Self-care, Coping, Sleep, and **Study_Eat whole foods and NDSS Physical activity**

Study group 4:
Study_Self-care, Coping, Sleep AND **Study_Eat whole foods and Study_ Muscle resistance activity.**

It is estimated that it will take 30 mins for the Care Coordinator to deliver these education resources to the participant.

Six-week follow-up visit
Two-three weeks post discharge from hospital the he Care Coordinator will post a pathology request form for the 6-week blood test. At 6 weeks the patient will receive a phone call from the Care Coordinator to conduct the 6-week Diabetes Distress scale questionnaire over the phone and ask whether they have had a blood test done. If not, they will receive another phone call from a blood collection nurse (study

coordinator, Denise Healy) requesting an appointment to visit the patient's home to collect the blood sample. At the home visit the study coordinator will also present some information about other clinical trials that maybe of interest to the patient. However, the patient is under no obligation to participate. y. In the event that the patient cannot be contacted by phone we will write to them and include an accompanying Diabetes Distress Scale questionnaire and a reply-paid envelope.

Based on the 6-week HbA1C results, the 2 study groups from 2, 3 and 4 with the least change in HbA1C from baseline will no longer be followed (called 'drop the loser') with the remaining study group left to compare with study group 1.

The HbA1C and triglyceride blood test at 6 weeks is part of normal routine practice and therefore billed to Medicare.

c. Access to Existing Data

Patient medical records including enrolled patient's HbA1C and triglyceride blood tests.

d. Data Linkage Management

Data linkage methods will be required to link enrolled patient blood test results and admission data to readmission and length of study data from the SA Health Integrated South Australian Activity Collection (ISAAC. This is of interest in the 12-month period following the patients index admission and subject to further funding.

i) Privacy and Confidentiality

- A random unique patient identifier will be created and appended to the linked data file
- The following potentially identifying data items will be dropped:
    - Medicare Number/IRN
    - Date of birth (replaced with the calculated field age)
    - Hospital URN
    - Separation date/time and admission date/time (replaced by length of stay hours)

ii) During the Project

The research and questionnaire data of participants will be recorded in an Adelaide University REDCap (Research Electronic Data Capture) database, identified by a unique study number only. Participant identifying information will be recorded on a separate spreadsheet and stored on a password protected computer, accessible only to study staff for the 6-week follow-up visit.

The data analysts will discuss options with the data custodians to ensure that separation of data is managed appropriately such that individuals will only have access to the information needed to perform their role i.e. those involved in linking the datasets only see the identifying information to create the links between different datasets; while those involved in analyzing the integrated data only have access to de-identified data specific to the project requirements.

The de-identified data files will be stored on and accessible from an encrypted USB drive and will be kept in a locked drawer when not in use.

iii) After the Project

The original data files will be archived on an encrypted USB drive at Adelaide University and stored in a safe until for five years and subsequently destroyed.

e. Safety considerations

Privacy and protection of identifiable data will be managed as above. In the delivery of the interventions, any issues raised by enrolled patients with the Care Coordinator will be supported with a process of medical assessment.

f. Data monitoring

The Principal Investigator and the REMIT-2-D Project Expert Advisory Group (**Appendix 2)** will be responsible for the monitoring and review of data collection and storage, including the review of data protocols and associated agreements.

The researchers will provide regular reports to the Expert Advisory Group regarding the use of the data and will immediately report any potential breaches.

In addition, the University of Adelaide owns any data that is generated from the study, owns the protocol and administers the grant funding. Professor Wittert the CPI is employed by University Adelaide.

10. DATA ANALYSIS

a. Quantitative

i. Sample size and statistical power

Due to low accrual rates the sample size has been revised down.

Sample Size: It is anticipated that 5 patients will be recruited per week and expect a 20% drop-out for assessment of the primary endpoint, HbA1c at 6 weeks post randomization. Patients will be randomized equally between the four intervention groups (three experimental and standard of care control), two of which will be dropped at the interim analysis. As such with N=198 randomized equally (ie 33 in each arm at each stage) there is 90% power to detect a difference in means equivalent to effect size of 0.6 SD between the best performing experimental arm and control using a t-test in the final analysis (1-sided alpha=0.10).

It is not possible at this stage to determine the number of Aboriginal and Torres Strait Islanders (ATSI) patients included.

ii. Statistical methods

We will implement a two-stage drop-the-loser design initially comparing three experimental interventions against control. The first stage requires 132 patients at which the two worse performing experimental interventions will be dropped. The difference in means with control arm as common reference are assumed multivariate normally distributed allowing for control of the type I error rate.[38] Being an early phase trial focusing on proof-of-concept evidence of intervention efficacy, we set the type I error rate to be 10% (one-sided), while maintaining a small type II error rate.

iii. Secondary Analysis: Bayesian

As a secondary analysis of the primary outcomes will consist of a Bayesian analysis .both at the interim and final assessments. An empirical prior distribution for the difference in means is constructed from diabetes studies registered on ClinicalTrials.org reporting HbA1c as the primary outcome. In particular the search criteria were: (i) completed (ii) phase 3 (iii) supremacy (iv) interventional (v) randomized (vi) controlled trials (vii) in adults (viii) with diabetes (ix) reporting data allowing the calculation of group mean differences for HbA1c (% units as opposed to mg/dL) (x) assessed within 7 months post randomization. For HbA1c, only studies reporting percentage units (as opposed to mg/dL) were included. When multiple assessments were reported per study only the earliest (post randomization) are included the analyses. For assessment of the between study variance, when multiple experimental (or comparator) groups are reported at an assessment these are merged with the total experimental (or comparator) group means and variances estimates calculated accordingly. For the multivariate joint prior at the interim analysis a between arm correlation of 0.5 is assumed due to equal randomized allocations and assumed equal within group variances at each assessment. Random-effects meta-analyses were performed to estimate the between study variance and thereby the total variance in the treatment effects using restricted maximum likelihood estimation (metafor R package).

We identified 257 studies reporting group mean differences for HbA1c (% units) as the primary outcome assessed a median 24 weeks (interquartile range=[24, 26]) post randomization. The random effects meta-analyses estimated weighted mean of differences between experimental and comparator groups in HbA1c was -0.50%, with a between study variance (SD) of 0.13 (0.36) representing I^2=94% of the total variance.

We set the joint prior distribution for the Bayesian analyses to be bivariate Gaussian normal with mean zero, marginal variances (as estimated above) and the between group correlations to be ρ=0.5 at the interim analysis (see Figure 1). At each assessment we calculate both the joint and marginal posterior probabilities of the group mean difference between experimental and control arms lying being lower than 0 (ie positive treatment effect) and/or lower than 0.3% (a commonly used minimal clinically interesting difference for HbA1c).

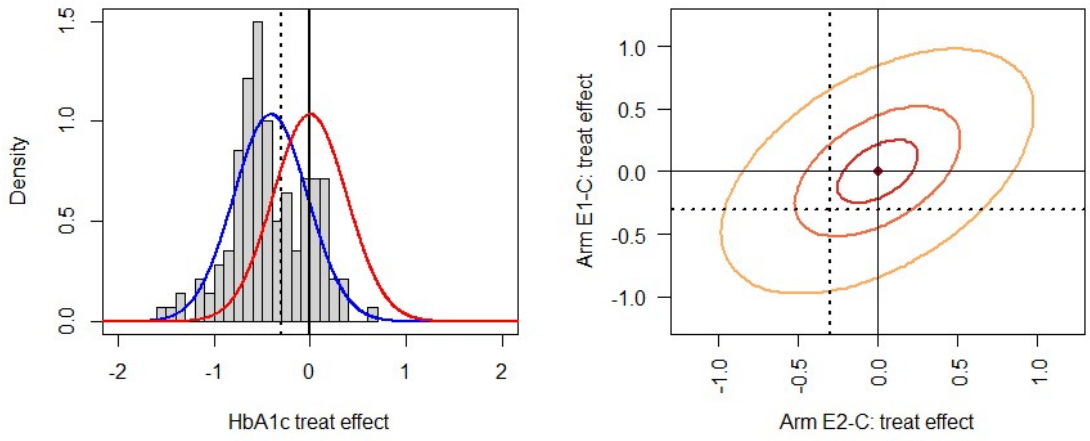


Figure 1: *(A) Density distribution of observed study results (grey), and Gaussian distributions with estimated between-study mean differences (blue) and the same distribution centered at zero difference (skeptical prior); and (B) the contour plot of the Bayesian joint prior distribution of treatment effects for the interim analysis. The dashed lines indicate differences of ±0.3.*

b. Qualitative

N/A

11. DATA HANDLING AND RECORD KEEPING

a. Data Collection and Management Responsibilities

- Screening, recruitment, consenting, delivery of interventions and data collection will be conducted by a trained Care Coordinator and is resource at 1 FTE for 8 months.
- Intervention formatting, ethical, financial, human resource, data management and assistance with 6 week phone follow-ups if required will be conducted by a Project Manager and is resourced at 0.8 then 0.4 FTE for 12 months.
- The expert advisory group will oversee all study processes, study reports and supervise study design and outcomes.

b. Study Records Retention

The Principal Investigator will maintain all records pertaining to this study for a period of 15 years from the date of publication.

University of Adelaide records, once created and captured, must not be damaged, altered or destroyed other than in accordance with General Disposal Schedules No 24 - South Australian Universities or an alternative Disposal Schedule, and with authorisation from the University Archivist or delegate in consultation with relevant business owners.

Responsibility: All employees, titleholders, consultants, contractors and volunteers of the University of Adelaide must:

a. Create records that adequately document the activities and decisions of the University in which they take part, whether related to learning and teaching, research, commercialisation or administration;
b. Capture important business records into the University recordkeeping system or an alternative business system with functionality to retain records in a secure manner for as long as they are legally required;
c. Take appropriate steps to ensure the reliability of University records and ensure records can be located;
d. Manage security of University records or restrict access if appropriate;
e. Ensure records are described adequately to allow the University to store, dispose and/or archive them in accordance with academic, business and legal requirements; and
f. Comply with legal requirements and standards including the State Records Act 1997, State Records Adequate Records Management Standards and the Australian Standard AS ISO 15489, as well as the University's procedures and processes in relation to records management.

c. Protocol Deviations

A protocol deviation is any noncompliance with the study protocol, Good Clinical Research Practice, or HREC requirements.

The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be implemented promptly.

The principal investigator will use continuous vigilance to identify and report deviations within 72 hours of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the approving HREC.

12. PUBLICATION & INTELLECTUAL PROPERTY

All existing Intellectual Property rights created by the University in the course of the REMIT-2-DS2 study vest in the University and on their creation, all future intellectual property rights created in the course of providing the study will also vest in the University.

The REMIT-2-DS2 Expert Advisory Group **(Appendix 2)** will be responsible for developing publication procedures and resolving authorship issues.

At the end of the study, the Principal Investigator will make results of the research available to participants, the research community and public at large.

It is anticipated that journal articles associated with the project may be submitted for publishing.
It is anticipated that study results will be made available on the SA Academic Health Science Translation Centre website and other relevant websites i.e. SA ACDC.

Dissemination of results to participants

The study results will be synthesised and presented in a form that is meaningful and applicable for clinicians, managers and policy makers to guide sustainable changes to systems and services within the SA hospital system to facilitate and drive the translation of that evidence into practice. Dissemination mechanisms and systems will be utilised that will make it easy for users (practitioners, managers, policy makers and consumers) to access the information/evidence generated by the study to facilitate the uptake of knowledge and drive system and behaviour change.

The dissemination of project outcomes will be designed to get the right message to the target audience. This will be achieved through a wide variety of dissemination methods including newsletters, flyers, and press releases to create awareness about the study, reports, journal articles, and web sites to transmit information about the study, and conference presentations and web sites to promote the study and its outcomes.

13. ETHICAL CONSIDERATIONS

a. Indemnity & Compensation for Injury

This study will be protected by an appropriate insurance and indemnity documentation arrangement to cover compensation for injury. The PI will provide supporting documentation to the Research Governance Organisation (RGO) including relevant insurance certificates and an email from Adelaide

University as the partnering organization with LMH- NALHN and TQEH and RAH- CALHN confirming that this study is covered by insurance. As an employee of Adelaide University, the Care Coordinator working with participants residing in a SA Health facility (LMH, TQEH, RAH), will be covered by appropriate insurance.

a. Vulnerable populations

The design of in-hospital treatment package suitable for implementation in Australian public hospital context will include consideration of the needs of Aboriginal and Torres Strait Islander patients. As such ethics approval for this project is being sought from the Aboriginal Health Research Ethics Committee.

Extensive consultation with stakeholders has taken place during the design phase of the in-hospital intervention including (but not limited to) organisations such as the Aboriginal Health Council SA, Aboriginal Health Services, the Aboriginal community controlled health sector, the Wardliparingga Aboriginal Research Unit, SAHMRI, the South Australian Aboriginal Chronic Disease Consortium (SA ACDC) Community Reference Group, Nunkuwarrin Yunti Primary Care services and the Northern Health Network to ensure that the cultural distinctiveness of Aboriginal and Torres Strait Islander communities are fully considered.

The Expert Advisory Group (**Appendix 2**) in consultation with the SA ACDC will utilise existing community evidence identified in the South Australian Aboriginal Diabetes Strategy which was developed following extensive consultation with Aboriginal Leaders and organisational stakeholders by the Wardliparingga Aboriginal Research Unit, SAHMRI and is being implemented by the SA ACDC through the SA Aboriginal Chronic Disease Consortium Road Map for Action 2017-2021.

During the consultation phase the Expert Advisory Group will seek to identify and address any potential negative consequences of the design of the in-hospital intervention for Aboriginal and Torres Strait Islander Peoples.

b. Waiver of Consent

There is no request for consent waiver.

c. Confidentiality

Participant data will be presented in a de-identified format, participants will not be identified or in publications arising from the research. Data will only be published at an aggregate level. There are no restrictions on the ability to ensure confidentiality of participants in this study, nor will there be data sharing at an individual, identifiable level.

d. Ethical Review

The study will be conducted in full conformance with principles of the "Declaration of Helsinki", Good Clinical Practice (GCP), the National Statement on Ethical Conduct in Human Research (NHMRC, 2007), Australian Code for the Responsible Conduct of Research (2007) and within the laws and regulations Australia.

Ethical approval will be sought from the following HRECs:

- The Central Adelaide Local Health Network (CALHN)- SA Department for Health and Ageing Human Research Ethics Committee
- Aboriginal Health Research Ethics Committee (AHREC).

e. Site/Governance Review

In accordance with the *SA Health Research Governance Policy Directive,* Site Specific Assessment (SSA) Approval will be sought from Lyell McEwin hospital, NALHN and The Queen Elizabeth and Royal Adelaide Hospitals, CALHN where the project is being conducted, including.

14. OUTCOMES AND SIGNIFICANCE

The outcomes of the study will provide new information as to (i) the feasibility of an approach to identify an optimal in hospital treatment; (ii) treatments that can be initiated during a hospital stay, not directly related to the diabetes that will improve blood sugar control and reduce diabetes related distress by improving health literacy and self-efficacy and providing support, (iii) determine the barriers and enablers of an effective outcome. Ultimately, we aim to reduce the risk of subsequent admission and if admitted, length of stay.

The ultimate long-term objective is to deliver an effective in-hospital treatment package for T2DM that is suitable for implementation in an Australian public hospital context with consideration of the needs of Aboriginal and Torres Strait Islander patients, leading to a reduction in the length of hospital stays, the likelihood of readmission and greater efficiency and value within health care delivery systems, benefiting patients, healthcare providers, and care systems alike.

15. REFERENCES

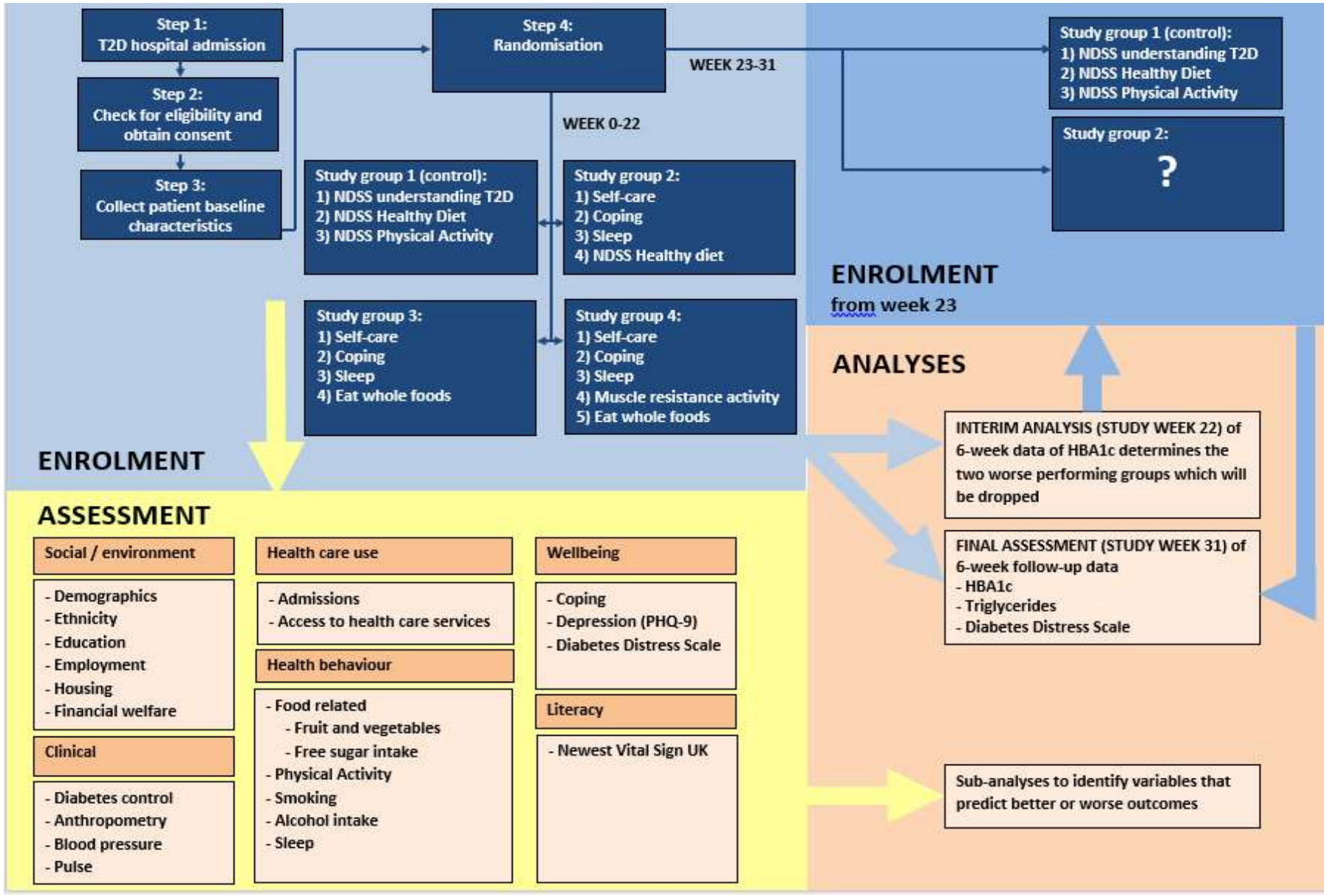
1. Wexler D, Beauharnais C, Regan S, Nathan D, Cagliero E, Larkin M. Impact of inpatient diabetes management, education, and improved discharge transition on glycemic control 12 months after discharge. Diabetes research and clinical practice [Internet]. 2012; 98(2):[249-56 pp.]. Available from: http://cochranelibrary-wiley.com/o/cochrane/clcentral/articles/754/CN-00867754/frame.html.
2. Gan JKL, Brammer JD, Creedy DK. Effectiveness of educational interventions to promote oral hypoglycaemic adherence in adults with Type 2 diabetes: a systematic review. 2011.
3. Funke A. Systematic review protocol: what is the impact of diabetes specialist nurses on inpatient care? 2017.
4. Mirjam N-N, Daena C, Jodian H, Denise N, Aileen F. The effectiveness of education by a certified diabetes educator for adult inpatients with type 2 diabetes initiated on insulin during their hospital stay on readmission rates and/or glycohemoglobin levels. 2018.
5. Burke RE, Ferrara SA, Fuller AM, Kelderhouse JM, Ferrara LR. The effectiveness of group medical visits on diabetes mellitus type 2 (dm2) specific outcomes in adults: a systematic review. 2011.
6. Shah M, Norwood C, Farias S, Ibrahim S, Chong P, Fogelfeld L. Diabetes transitional care from inpatient to outpatient setting: pharmacist discharge counseling. Journal of pharmacy practice [Internet]. 2013; 26(2):[120-4 pp.]. Available from: http://cochranelibrary-wiley.com/o/cochrane/clcentral/articles/580/CN-00968580/frame.html.

7. Andrew M, Zayd T, William H, Neil M, Martin W, Simon de L. A systematic review of adherence rates by medication class in type 2 diabetes. 2015.
8. Henny-Kristine H, Anne-Marie A. The effectiveness of low-carbohydrate diet in management of type 2 diabetes: a systematic review. 2013.
9. Leah A, Nicola OB, Darren F, Linda E, David F, Michael T. A systematic review assessing the effectiveness of behaviour change interventions that target a single behaviour versus multiple behaviours of adults with type 2 diabetes. 2015.
10. Diabetes Australia. About diabetes Canberra: Diabetes Australia; [cited 2018 2 May]. Available from: https://www.diabetesaustralia.com.au/about-diabetes.
11. Australian Health and Welfare. Australia's health 2016. Australia's health series no. 15. Cat. no. AUS 199. Canberra: AIHW; 2016.
12. Baker IDI. Diabetes: the silent pandemic and its impact on Australia. Diabetes Australia; 2012
13. American Diabetes Association. Diabetes basics USA: American Diabetes Association; [cited 2018 2 May]. Available from: http://www.diabetes.org/diabetes-basics/
14. Monash Centre for Health Research and Implementation. Australian National Diabetes Audit - Australian Quality Self-Management Audit 2016 Final Report. Canberra: Commonwealth of Australia; 2016.
15. Productivity Commission. Integrated Care, Shifting the Dial: 5 year Productivity Review. Canberra: Productivity Commission; 2017. Report No.: Supporting Paper No. 5.
16. SA Health; Preliminary Study of the Economic Cost of Diabetes in South Australia July 2007
17. Hotspots of potentially preventable hospitalisations in South Australia's public hospitals: Pinpointing potential health inequalities by analysis of public hospital activity data. Health Perfomance Council, December 2017
18. Robbins JM, Webb DA. Diagnosing diabetes and preventing rehospitalizations: the urban diabetes study. Medical care. 2006;44(3):292.
19. Sampson MJ, Dozio N, Ferguson B, Dhatariya K. Total and excess bed occupancy by age, specialty and insulin use for nearly one million diabetes patients discharged from all English Acute Hospitals. Diabetes research and clinical practice. 2007;77(1):92-8.
20. Graham KL, Auerbach AD, Schnipper JL, Flanders SA, Kim CS, Robinson EJ, et al. Preventability of Early Versus Late Hospital Readmissions in a National Cohort of General Medicine Patients. Annals of internal medicine. 2018.
21. Does a hospital diabetes inpatient service reduce blood glucose and HbA1c levels? A prospective cohort study Fergus William Gardinera,b, Ezekiel Uba Nwosea, Phillip Taderera Bwititic, Judith Crocketta, Lexin Wangc Annals of Medicine and Surgery Volume 26, February 2018, Pages 15-18.
22. Elinav H, Wolf Z, Szalat A, Bdolah-Abram T, Glaser B, Raz I, et al. In-hospital treatment of hyperglycemia: effects of intensified subcutaneous insulin treatment. Current medical research and opinion [Internet]. 2007; 23(4):[757-65 pp.]. Available from: http://cochranelibrary-wiley.com/o/cochrane/clcentral/articles/662/CN-00579662/frame.html.
23. Merrill A, Jones S. Effectiveness of tight glycemic control in the medical Intensive Care Unit: a systematic review. 2011.
24. Korytkowski M, Salata R, Koerbel G, Selzer F, Karslioglu E, Idriss A, et al. Insulin therapy and glycemic control in hospitalized patients with diabetes during enteral nutrition therapy: a randomized controlled clinical trial. Diabetes care [Internet]. 2009; 32(4): [594-6 pp.]. Available

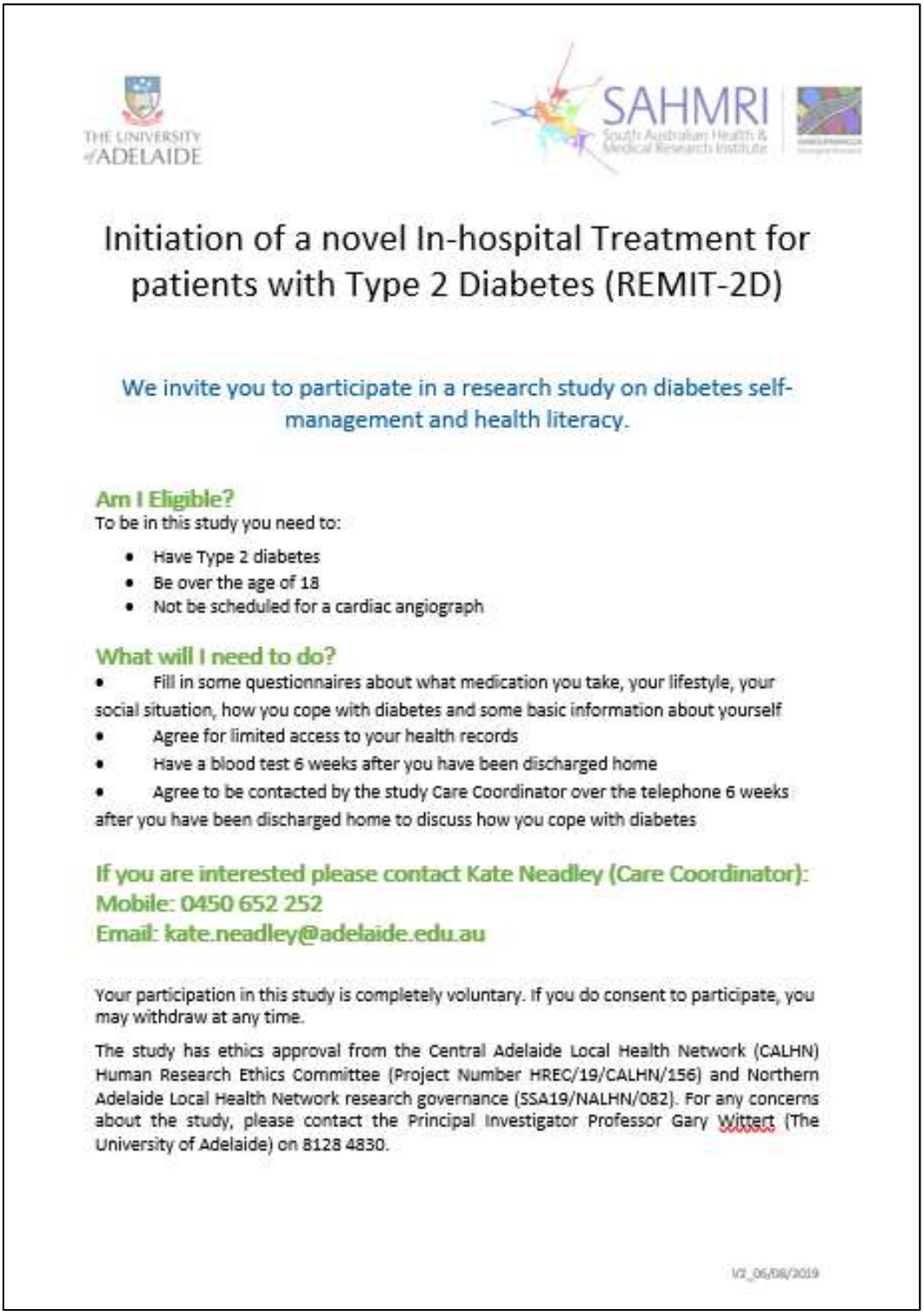
from: http://cochranelibrary-wiley.com/o/cochrane/clcentral/articles/279/CN-00703279/frame.html

25. Kawahara T, Takahashi K, Inazu T, Arao T, Kawahara C, Tabata T, et al. Reduced progression to type 2 diabetes from impaired glucose tolerance after a 2-day in-hospital diabetes educational program: the Joetsu Diabetes Prevention Trial. Diabetes care [Internet]. 2008; 31(10):[1949-54 pp.]. Available from: http://cochranelibrary-wiley.com/o/cochrane/clcentral/articles/432/CN-00649432/frame.html.
26. Australian Institute of Health and Welfare (AIHW) 2003. The Active Australia Survey: a guide and manual for implementation, analysis and reporting. Canberra: AIHW.
27. Polonsky WH1, Fisher L, Earles J, Dudl RJ, Lees J, Mullan J, Jackson RA. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. Diabetes Care. 2005 Mar;28(3):626-31.
28. For BRFSS Survey Questions Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System Survey Questionnaire. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2009. http://www.cdc.gov/brfss/suggestedcitation.htm
29. van Steenbergen-Weijenburg KM, de Vroege L, Ploeger RR, Brals JW, Vloedbeld MG, Veneman TF, Hakkaart-van Roijen L, Rutten FF, Beekman AT, van der Feltz-Cornelis CM. Validation of the PHQ-9 as a screening instrument for depression in diabetes patients in specialized outpatient clinics. BMC Health Serv Res. 2010 Aug 12;10:235.
30. Stallman, H.M. (2017). Coping Index. Adelaide: University of South Australia
31. Stallman, H. M. (2018). Coping Self-Efficacy Index. Adelaide: University of South Australia
32. Rowlands G, Khazaezadeh N, Oteng-Ntim E, Seed P, Barr S, Weiss BD. Development and validation of a measure of health literacy in the UK: the newest vital sign. BMC Public Health. 2013 Feb 7;13:116.
33. Wallston KA, Rothman RL, Cherrington A.Psychometric properties of the Perceived Diabetes Self-Management Scale (PDSMS). J Behav Med. 2007 Oct;30(5):395-401. Epub 2007 May 24.
34. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res. 1989 May;28(2):193-213
35. Diabetes Australia, National Diabetes Service Scheme (NDSS). Understanding Type 2 Diabetes. Accessed 17/4/2019. https://www.ndss.com.au/understanding-type-2-diabetes
36. Diabetes Australia, National Diabetes Service Scheme (NDSS). Making healthy food choices with diabetes. Accessed 17/4/2019. https://www.ndss.com.au/food-choices-for-people-with-diabetes
37. Diabetes Australia, National Diabetes Service Scheme (NDSS). Physical Activity. Accessed 17/4/2019. https://www.ndss.com.au/physical-activity
38. Wason J, Stallard N, Bowden J, Jennison C, A multistage drop-the-loser design for multi-arm clinical trials. 2017 26(1) February 2017. Statistical Methods in Medical Research.

Figure 1. Study Flow chart



Appendix 1. Lyell McEwin Hospital Advertising Material Master V2.0



THE UNIVERSITY of ADELAIDE

SAHMRI South Australian Health & Medical Research Institute

Initiation of a novel In-hospital Treatment for patients with Type 2 Diabetes (REMIT-2D)

We invite you to participate in a research study on diabetes self-management and health literacy.

Am I Eligible?

To be in this study you need to:

- Have Type 2 diabetes
- Be over the age of 18
- Not be scheduled for a cardiac angiograph

What will I need to do?

- Fill in some questionnaires about what medication you take, your lifestyle, your social situation, how you cope with diabetes and some basic information about yourself
- Agree for limited access to your health records
- Have a blood test 6 weeks after you have been discharged home
- Agree to be contacted by the study Care Coordinator over the telephone 6 weeks after you have been discharged home to discuss how you cope with diabetes

If you are interested please contact Kate Neadley (Care Coordinator):
Mobile: 0450 652 252
Email: kate.neadley@adelaide.edu.au

Your participation in this study is completely voluntary. If you do consent to participate, you may withdraw at any time.

The study has ethics approval from the Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee (Project Number HREC/19/CALHN/156) and Northern Adelaide Local Health Network research governance (SSA19/NALHN/082). For any concerns about the study, please contact the Principal Investigator Professor Gary Wittert (The University of Adelaide) on 8128 4830.

V2_06/08/2019

Appendix 2. REMIT-2D Expert Advisory Group

Member	Organisation
Professor Gary Wittert (Chair)	UoA
Professor Alex Brown	Wardliparringa, SAHMRI
Professor Mark Boyd	Public Health, LMH
Ms Wendy Keech	Health Translation SA
Dr Anthony Zimmermann	LMH
Dr Peak Mann Mah	Endocrinologist, LMH
Dr Isuru Ranasinghe	Cardiology, CAHLN
Dr Elaine Pretorius	Deputy Executive Director Medical Services, NALHN, SA Health
Dr Chris Moy	GP Representative
Ms Sally Nguyn	Adelaide PHN
Professor Robert Adams	UoA
Dr Odette Pearson	Wardliparringa, SAHMRI
Mr Amal Chakraborty (Research Assistant REMIT -2-D)	SAHMRI
Dr. Carolyn Astley (Project Mgr. REMIT-2-D)	SAHMRI
Ms Angelique Pasalidis	Diabetes SA
Dr. Tanja Effing (Epidemiologist and Data Manager REMIT-2D)	SA Health
Dr. Helen Stallman	Health and Wellbeing, Uni SA
Dr. Andrew Vincent	Statistician, UoA
Mr Kurt Towers	Aboriginal Health (LMH catchment area)
Dr David Jesudason	Endocrinologist, The Queen Elizabeth hospital

Appendix 3. Educational resources to develop diabetes-related health literacy

DIABETES SELF-CARE

THE WELLNESS WHEEL

BE HEALTHY

Healthy eating, regular activity, good sleep and a healthy mind

MEDICATIONS

Take your medications regularly. Learn about the drugs you are taking.
https://www.nps.org.au/medical-info/consumer-info/managing-your-medicines

PRIMARY CARE

Seeing a health professional regularly can identify problems early.

HEALTH CHECKS

Weight, blood pressure, HBA1C (average blood sugar over 3mths), blood fats and urinary protein

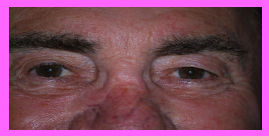
SELF-CARE

Understanding what's normal for you and knowing when to seek help

Foot care

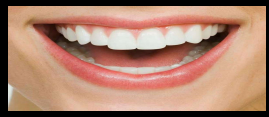
- **Check your feet every day**
- **Look for ulcers, swelling, blisters, bruising, cuts- seek medical help**
- **See a podiatrist**

EYE CARE



- **Have an eye test regularly**
- **Seek medical help if vision worsens**

DENTAL CARE



- **Have regular teeth and gum checks**
- **Quit smoking**
- **No sugary drinks**

MONITOR YOUR HEALTH

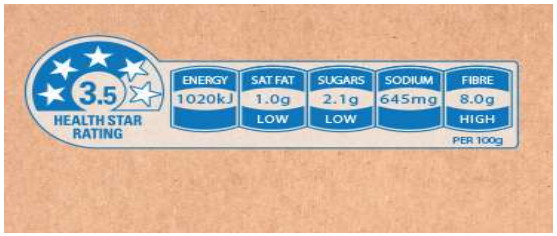
Weigh yourself regularly, keep a diet and activity diary, check your blood sugars.

RESOURCES

Heart Foundation Helpline ph 131211 and website: https://www.heartfoundation.org.au/healthy-eating

Diabetes Australia Helpline ph 1300 136 588 and website: https://www.ndss.com.au/

Healthy Star rating: designed to show the nutritional content of packaged food, but it does not mean low in sugar or healthy. Fresh whole foods, mostly plants are best. Website: http://healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/content/home



Get Healthy, ph 1300 806 258 M-F 8am-8pm website: www.gethealthy.sa.gov.au

Keep Sight Australia, website https://www.keepsight.org.au/

The Sleep Health Foundation, P: 02 8814 865,**E**:admin@sleephealthfoundation.org.au, Website: https://www.sleephealthfoundation.org.au/obstructive-sleep-apnea.html

Sleep Health Service Clinics, SA Health, Locations:

Clinic B, level 2, Flinders Medical Centre, **P:** (08) 8204 5193 or First Floor, Noarlunga GP Plus Super Clinic **P:** (08) 8164 9131

Adelaide Sleep Clinic, Wellington Centre, 3a/2 Portrush Rd, Payneham, **P:** 1300 075 337

E: **info@sleepclinic.com.au**

Centre for Physical Activity and Ageing, 207-255 Hampstead Rd, Northfield Ph 08 8222 1891, website: http://sacommunity.org/org/197186Centre_for_Physical_Activity_in_Ageing

Active Ageing Australia, 118 Richmond Rd Marleston SA 5033, Ph: 08 8423 0960, email: admin@activeageing.org.au, website: https://activeageing.org.au/

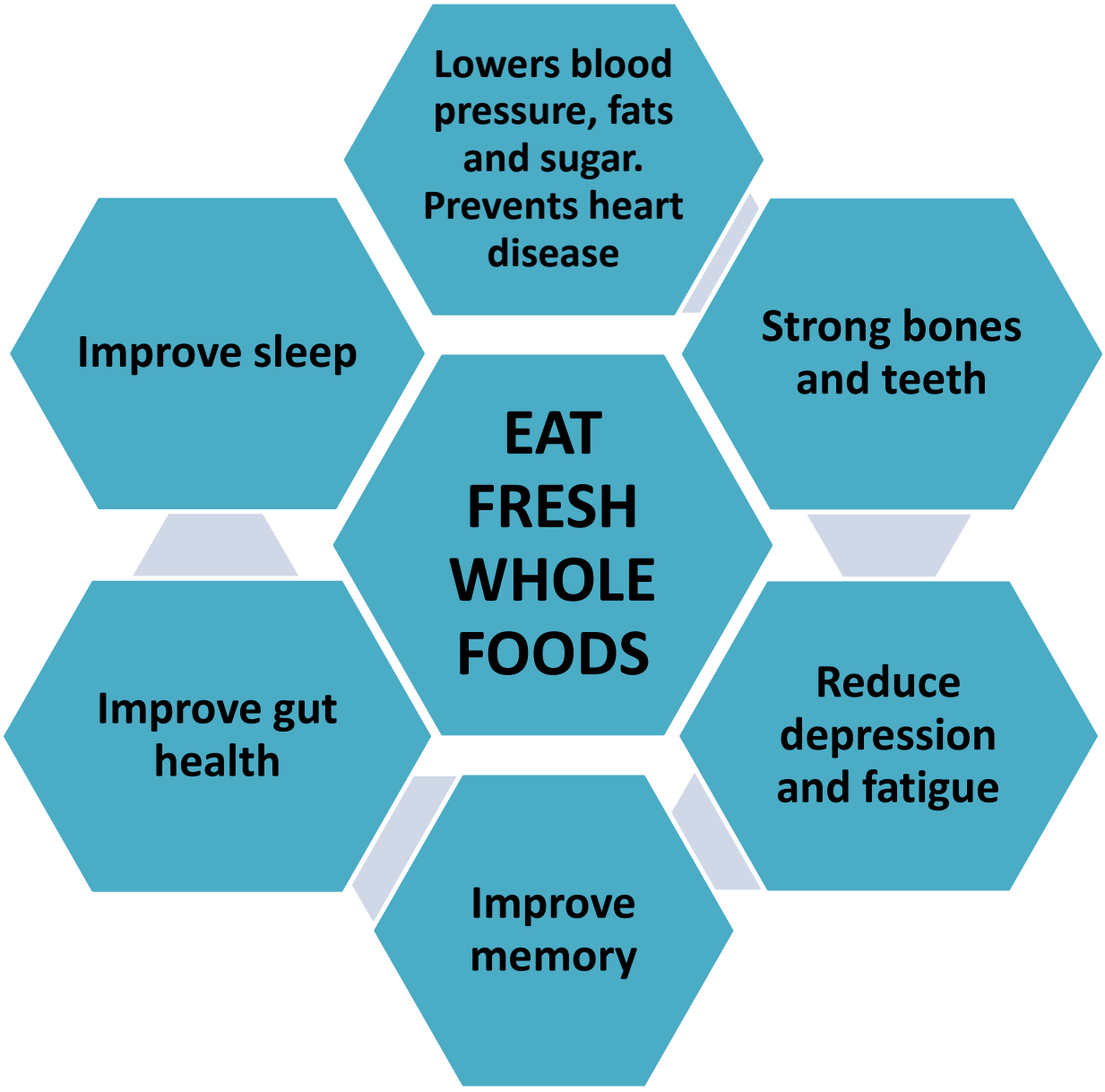
Depression and Anxiety

Beyond Blue, P: 1300 224 636, Website: https://www.beyondblue.org.au/

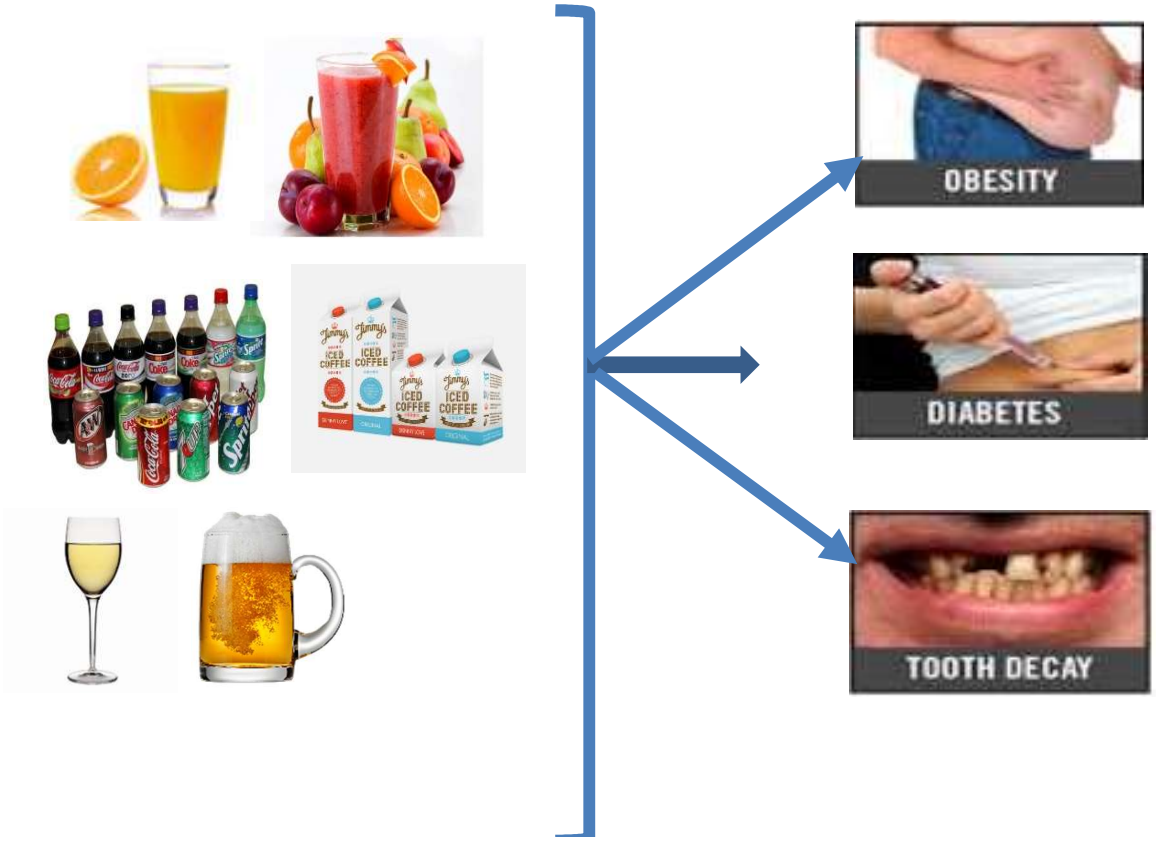
EAT FRESH, WHOLE FOODS

THE WELLNESS WHEEL

BENEFITS OF HEALTHY FOOD



THINK BEFORE YOU DRINK



Drink Water

ENERGIZE MUSCLES

ELIMINATE TOXINS

CONTROL CALORIES

HEALTHY KIDNEYS

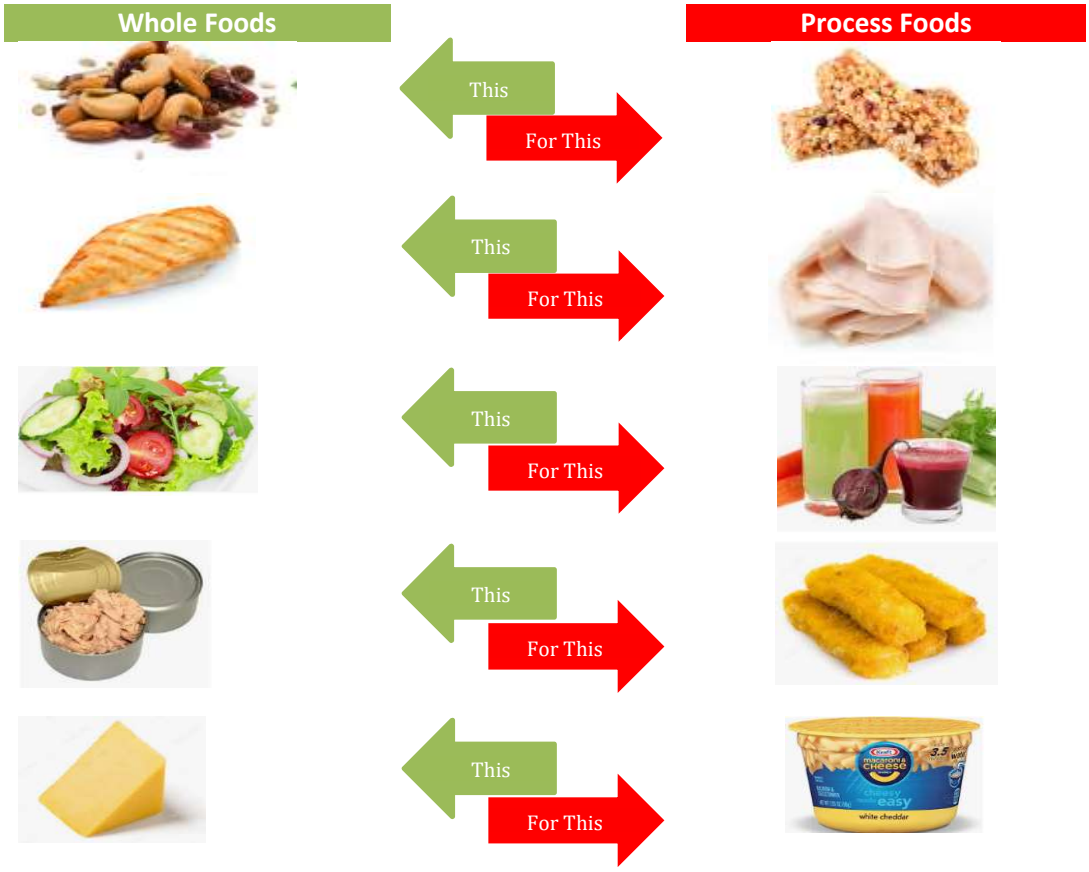
IMPROVE SKIN

Eat Fresh Whole Foods especially Plant Based Food

Eating well is not difficult, but understanding what foods are important can sometimes be confusing. The following information provides you with tips and cues on how to improve your diet and get the benefits you are looking for.

Eat whole foods in quick steps:

- Choose Whole foods, have a look at the following and if you are choose more in the red zone, focus on changing to the green zone (some examples of swaps):



- Eat more plant foods. Does your lunch or dinner plate look like this? If not, maybe adding more fresh or frozen veggies is your first step.

- Time your meals: Avoid grazing aim to have 3 MEAL TIMES a Day and in between HYDRATE.
- Avoid Night Time Eating: Eating late at night is usually related to boredom eating. Try not eating after 8pm or at least 3 hrs before going to bed. If you get hungry, try water first, then some of your plant-based foods if you are still feeling hungry – fibre can make you feel fuller than a sweet!

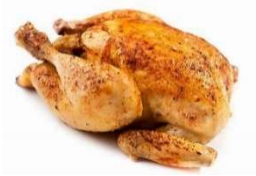
Shopping Trolley Quiz

Place a number by the foods in order of what you would add to your shopping trolley.

Granola cereals ____. 	2 Minute Noodles ____ 	Frozen pies or sausage rolls _____ 	Pre-cut and packed salad mixes ____ 
Potato Crisps ___ 	Canned Tomatos  _____	Rotisserie Chicken ____ 	Cereal and Nut Bars ____ 
Regular Dressings OR sauces (BBQ or Tomato) _____ 	Sauces (Meal) ___ 	Pre Made Lasagne _____ 	Crumpets ___ 
Wholemeal Bread ____ 	Mixed Rice Crackers _____ 	Salt-reduced Stock ___ 	Fruit Juice ___ 
Dried Herbs and Spices _____ 	Deli style Metwurst or Pepperoni ____ 	Frozen Vegetables ____ __ 	Milk coffee sachets ____ 
Frozen Waffles ____ 	Chuck Steak _____ 	Hazelnut Chocolate Spread _____ 	Shredded wheat cereals ____ 

Shopping Trolley Quiz

Outcome: Those highlighted RED are NO GO foods, best not to add them to the Trolley and the GREEN are the GO TO foods.

Granola cereals ____. 	2 Minute Noodles ____ 	Frozen pies or sausage rolls _____ 	Pre-cut and packed salad mixes ____ 
Potato Crisps ___ 	Canned Tomatoes _____ 	Rotisserie Chicken ____ 	Cereal and Nut Bars ____ 
Regular Dressings OR sauces (BBQ or Tomato) _____ 	Sauces (Meal) ___ 	Pre Made Lasagne _____ 	Crumpets ___ 
Wholemeal Bread ____ 	Mixed Rice Crackers _____ 	Salt-reduced Stock ___ 	Fruit Juice ___ 
Dried Herbs and Spices _____ 	Deli style Metwurst or Pepperoni ____ 	Frozen Vegetables ____ 	Milk coffee sachets ____ 
Frozen Waffles ____ 	Chuck Steak _____ 	Hazelnut Chocolate Spread _____ 	Shredded wheat cereals ____ 

Sample Time	Meal Occasion	Meal Suggestions		Average Cost ($)
7-8am	Meal 1	**1-2 boiled eggs + 1 cup grilled veggies** (i.e. carrot, capsicum, tomato, spinach, mushroom whatever is left in your fridge) 	**150-200g plain or vanilla yoghurt + 40g nuts/seed mix** added to the yoghurt for taste and crunch. 	$2.50
	Hydration	*Carolyn can they have a coffee no sugar?		
1230-1pm	Meal 2	Small tin flavoured Tuna + 2 cups of salad mixed in a bowl (30g cheese optional) 		$4.00
	Hydration			
6-7pm	Meal 3	150-200g of cooked meat, fish, chicken and 2 Cups of salad + 30g Cheese (optional) mixed into a tossed salad + veg (add 40ml of Free salad Dressing or Oil and vinegar for dressing) 		$5.70
	Hydration			
Nothing after 8 pm				

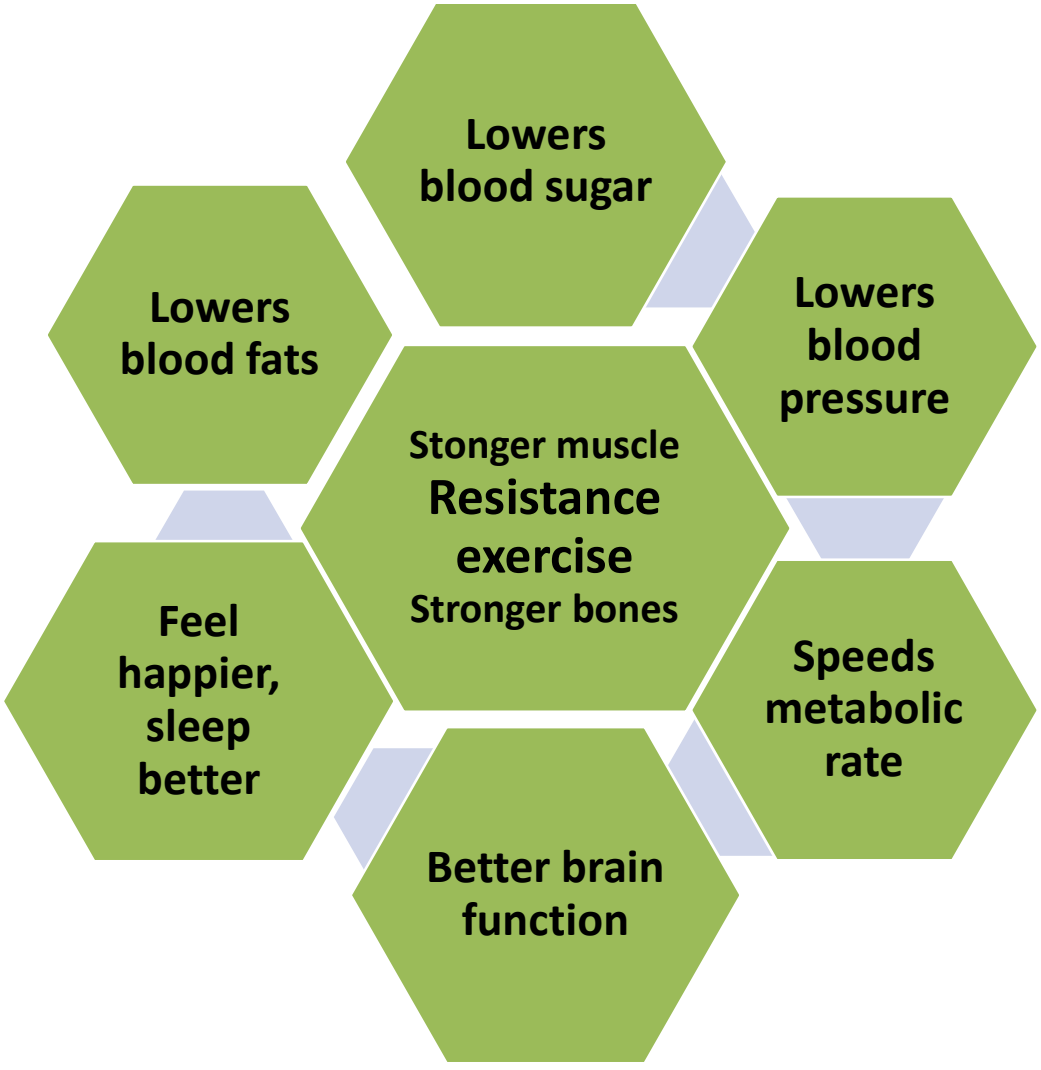
MUSCLE RESISTANCE ACTIVITY

THE WELLNESS WHEEL

PHYSICAL ACTIVITY IS LIKE TOOTHBRUSHING FOR THE WHOLE BODY

- We do it everyday
- Use every opportunity to Move, **Move**, **Move**
- Try tracking your activity using a Fitbit, phone app. or simple pedometer (aim for 10,000 steps/day).

BENEFITS OF MUSCLE RESISTANCE ACTIVITY



And let's do some Resistance Activity.

Resistance exercise can be done at home, even while watching your favourite TV show. It is easy, fun, free and suitable for anyone

Here are 4 movements for your upper body and 4 for your lower body

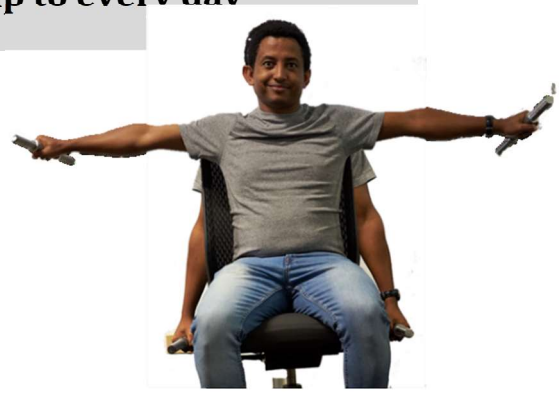
Upper Body

- **Sit in a high back chair**
- **Make sure your bottom is right at the back of the chair and your back is straight**
- **Hold a 1 kg weight (see resource list) in each hand. If 1kg is too heavy use a can of sweetcorn or similar ~450 grams**
- **Do 20 repetitions of each of the movements pictured below. Rest briefly for 1-2 minutes then do another 20 of each movement. If you cannot manage 20, do as many as you can and gradually build up to 20.**
- **Do the movements slowly breathing in and out with each.**
- **Do these at least 3 days of the week. Build up to every day**

Bicep

Overhead shoulder

Straight arm



Side arm

When you have completed the 2 lots of 20 repetitions of each of the 4 movements (or as many as you can do) stand and go for a walk for 10 minutes. Even if it is just around the house.
Now you are set to do the lower body

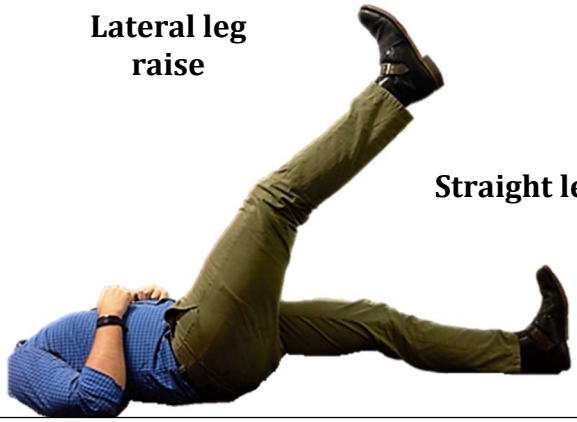
Lower Body

- **For these you need 1kg strips of lead that are covered with material and have Velcro straps to fasten them around your ankles. Your can also fill a small pouch with 1kg or 500 grams of course sand, attach some ties or Velcro straps so that one can be strapped around each ankle**
- **In the pictures below, you will see one of these exercises is done sitting in the chair as you for the upper body exercises. Two are done standing behind the chair and holding on. The final one is done lying on the bed. Maybe leave this one for last.**
- **Do 20 repetitions of each of the movements pictured below. Rest briefly for 1-2 minutes then do another 20 of each movement. If you cannot manage 20, do as many as you can and gradually build up to 20.**
- **Do the movements slowly breathing in and out with each.**
- **Do these at least 3 days of the week. Build up to every day.**

Knee flexion/extensio

Lateral leg raise

Toe lift



Straight leg raise

When you have completed the 2 lots of 20 repetitions of each of the 4 movements (or as many as you can do) stand and go for a walk for 10 minutes. Even if it is just around the house.

IF AT ANY TIME YOU EXPERIENCE PAIN IN JOINTS OR THESE EXERCISES FEEL DIFFICULT, PLEASE DISCUSS WITH YOUR HEALTH PROFESSIONAL.

Here are some other ideas to help get you moving moving moving

Heart Foundation walking group join a group in your local area for free; phone 131112 or 08 8224 2888 or go online at;
Website: https://www.heartfoundation.org.au/support/heart-foundation-helpline

Centre for Physical Activity and Ageing, 207-255 Hampstead Rd, Northfield Ph 08 8222 1891, website:
http://sacommunity.org/org/197186Centre_for_Physical_Activity_in_Ageing

Active Ageing Australia, 118 Richmond Rd Marleston SA 5033, Ph: 08 8423 0960, email: admin@activeageing.org.au, website: https://activeageing.org.au/

Exercise is Medicine- Australia- ESSA, Ph: 07 3171 3335, Email: info@exerciseismediciane.org.au, Website: http://exerciseismedicine.com.au/

Department of Health Be Active: a physical activity guide for older Australians.
Ph 1800 500 853 or 08 8168 8776 or 1800 636 368- country

COTA SA: Ph 08 8232 0422 or 1800 182 324 website: www.cotasa.org.au

Purchase 1 kg weights:
Rebel Sports: Gepps Cross 750 Main North Rd, Gepps Cross, ph 08 8465 0009 or Tea Tree Plus, 15 Main North East Rd, Modbury ph 08 8464 0005 or online.
Gym and Fitness online: ph 1800 614 491 or
https://www.gymandfitness.com.au/products/

SLEEP

WELLNESS WHEEL

GOOD SLEEP = GOOD HEALTH
Some benefits

Getting a Good Night's Sleep – Top Tips

A good night's sleep starts before bedtime

Don't nap during the day

Keep the room cool

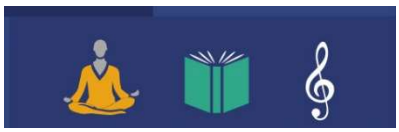
Stop caffeine after noon
Stop alcohol 3 hrs before
Avoid big meals and finish 2-3 hrs before

A comfortable room without distractions

***Wear ear plugs if its* noisy**

Have a regular bedtime

Have regular routine and relaxation rituals



Keep technology out of the bedroom

Stop working and turn off computer and TV screens 1 hour before

Meditate, read or listen to music

IS YOUR SLEEP AFFECTED BY ANY OF THESE?

1. **OBSTRUCTIVE SLEEP APNOEA (OSA):**

What is it? OSA is where the airways block off during sleep, depriving the person of oxygen and can occur several times per night.
When should I seek help? if you're experiencing snoring along with waking up gasping and choking, the need to frequently urinate during the night, erectile dysfunction, feeling sleepy and fatigued during the day, dozing off in the afternoon or early evening, irritability and mood changes.

2. **INSOMNIA:**

What is it? Insomnia is when you can't sleep or can't sleep enough. It can be caused from medications or other drugs, alcohol, caffeine, chronic pain, stress or anxiety.
When should I seek help? if you have regular problems falling asleep, staying asleep, waking too early in the morning or worrying about being able to sleep.

3. **SHIFT WORK:**

Getting enough quality sleep can be difficult for people who work shift work.
What can I do?

- ensure your bedroom is dark and quiet, or wear ear plugs
- turn you phone off and let people know not to disturb you,
- avoid caffeine, alcohol and large meals,
- avoid exercise and bright sunshine just before going to sleep
- sleep before work instead of immediately afterwards,
- try to establish regular sleep routines,

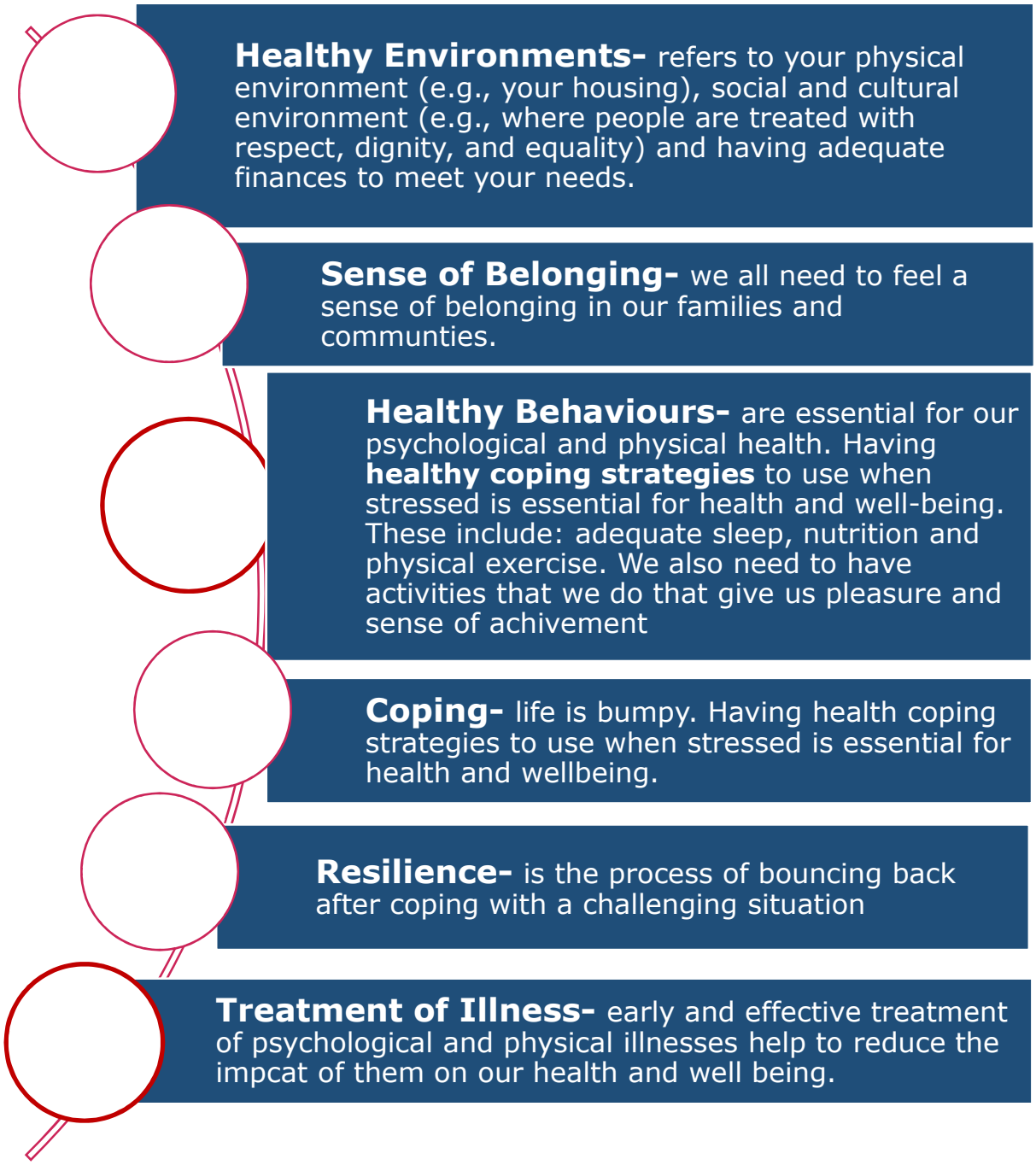
RESOURCES
The Sleep Health Foundation, P: 02 8814 865,**E**:admin@sleephealthfoundation.org.au, Website: https://www.sleephealthfoundation.org.au/obstructive-sleep-apnea.html

Sleep Health Service Clinics, SA Health, Locations:
Clinic B, level 2, Flinders Medical Centre, **P:** (08) 8204 5193 or First Floor, Noarlunga GP Plus Super Clinic **P:** (08) 8164 9131

Adelaide Sleep Clinic, Wellington Centre, 3a/2 Portrush Rd, Payneham,
P: 1300 075 337 **E**: **info@sleepclinic.com.au**
COPING with diabetes and reducing distress

WELLNESS WHEEL

HEALTH AND WELLBEING



Make a coping plan with your health professional

We all get upset and distressed from time to time. When we're feeling upset, it can be hard to think clearly and make good decisions. Coping Planning helps you think ahead to plan healthy coping strategies to use to feel calmer. Your coping plan can be a reminder to use these strategies when you're upset.
Make a list of coping strategies using the My Coping Worksheet
Ask your health professional for any extra support contacts so you have it handy if you need it
Download

My Coping Plan App for Apple or Android phones or tablets and add these details so that you can keep a copy of your plan with you.

MY COPING PLAN

Self-soothing

Things I can do on my own

People who can support me

Professionals who can support me

In an emergency

- Go to the nearest hospital emergency department
- Telephone emergency services - Triple Zero

Appendix 4. Diabetes Australia Fact sheets

NDSS_ Understanding T2 Diabetes

ndss national diabetes services scheme

diabetes australia

Understanding type 2 diabetes

Type 2 diabetes is the most common form of diabetes. It affects 85–90% of all people with diabetes.

What is type 2 diabetes?

Diabetes is a condition where there is too much glucose (sugar) in the bloodstream. Glucose is an important source of energy for your body. It comes from carbohydrate foods that you eat, such as bread, pasta, rice, cereals, fruits, starchy vegetables, milk and yoghurt. Your body breaks down carbohydrates into glucose, which then enters your bloodstream.

Insulin is made in your body by the pancreas. Insulin is needed to allow glucose from the bloodstream to enter the body cells and be used for energy.

Type 2 diabetes occurs when the body resists the effects of insulin and cannot make enough insulin to maintain blood glucose levels within the target range. This leads to high blood glucose levels.

Who is at risk of type 2 diabetes?

Type 2 diabetes usually occurs in adults, but younger people – and even children – are now developing this type of diabetes.

Risk factors for type 2 diabetes include:

- having a family history of type 2 diabetes
- having pre-diabetes
- being above the healthy weight range
- having an inactive lifestyle
- increasing age
- having an Aboriginal or Torres Strait Islander background
- being from a Melanesian, Polynesian, Chinese, Southeast Asian, Middle Eastern or Indian background
- having prior gestational diabetes
- having polycystic ovary syndrome
- taking some types of antipsychotic or steroid medications.

Can type 2 diabetes be prevented or cured?

People who are at risk of type 2 diabetes can delay and, in some cases, even prevent developing diabetes by adopting a healthy lifestyle. This includes regular physical activity, making healthy food choices, and being a healthy weight.

NDSS Helpline 1300 136 588 **ndss.com.au**

NDSS_Healthy Food

ndss
national diabetes services scheme

diabetes australia

Making healthy food choices

Healthy eating, along with regular physical activity, can help you look after your diabetes. It can also help you manage other risk factors like high blood pressure, or unhealthy cholesterol and triglyceride levels.

Healthy eating for people with diabetes is no different from what is recommended for everyone else. There is no need to prepare separate meals or buy special foods – the whole family can enjoy the same healthy meals.

There are various dietary approaches that may be suitable for people with diabetes. These include Mediterranean-style diets, low fat plant-based diets or lower carbohydrate eating plans.

The following guidelines are general recommendations suitable for most people with diabetes. However, a dietitian can help you to develop an eating plan to meet your food preferences and nutritional needs.

To make healthy food choices:

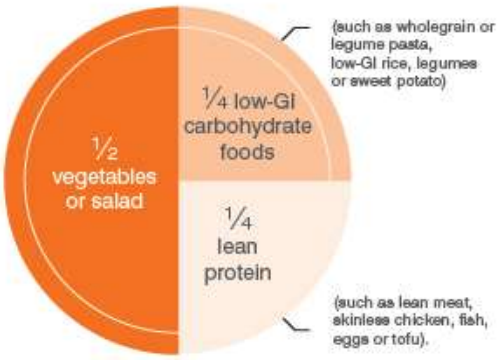
- eat regular meals to assist with managing energy and blood glucose levels
- choose high-fibre, lower glycaemic index (GI) carbohydrate foods
- limit foods that are high in saturated fat and choose healthy fats
- include lean protein foods with your meals
- choose foods low in added salt (sodium) and avoid adding salt to your food.

Eat regular meals in the right amounts

Aim to eat three meals during the day and choose serving sizes to meet your energy needs. Talk to your dietitian for advice about your individual needs and the serving sizes that are right for you.

When preparing a healthy meal aim to:

- fill half of your plate with a variety of non-starchy vegetables or salad
- fill a quarter of your plate (a palm-sized serving) with a lean protein source, such as lean meat, skinless poultry, fish, seafood, tempeh, legumes or eggs
- fill a quarter of your plate with a nutritious carbohydrate food that has a lower GI, such as wholegrain or legume pasta or noodles, brown, basmati or Doongara™ rice, quinoa, soba or mung bean noodles, legumes (such as chickpeas, kidney beans, lentils), barley, freekeh, corn, low-GI potato or sweet potato.



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national diabetes services scheme

diabetes australia

Physical activity

Regular physical activity is one of the most important things you can do to improve your health and help manage your diabetes.

The more physically active you are, the greater the health benefits will be. However, any activity, even at a slow pace, can have health benefits, and some activity is better than none at all.

Benefits of physical activity

Physical activity plays a vital role in helping the body use glucose as fuel for the working muscles, which in turn lowers blood glucose levels.

When the body starts to exercise, the muscles need energy to move. This energy comes from glucose in the blood as well as glucose stored in the muscles and, occasionally, from stores in the liver.

There are plenty of other benefits of regular physical activity, including:

- reducing the risk of heart disease and stroke
- lowering cholesterol levels
- helping to lower blood pressure
- assisting with weight loss and maintaining a healthy weight
- slowing age-related loss of muscle mass
- preventing osteoporosis and risk of falls
- increasing strength, power and balance
- improving mood
- helping circulation in lower limbs.

Types of physical activity

Doing a combination of different types of physical activity has proven benefits for managing diabetes. There are two main types of physical activity: aerobic exercise and resistance exercise.

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