#### **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)

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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) with a cardiac condition and found to have a type 2 Diabetes Mellitus(T2DM) comorbidity. 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. 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 readmission of people with T2DM to the Lyell McEwin Hospital; (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 (March 2020) 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. <sup>10</sup> 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. <sup>11</sup> 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 <sup>10-13</sup>.

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<sup>10</sup>.

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<sup>14</sup>.

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. <sup>15</sup> 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<sup>15</sup> and 25% of people with T2DM in SA are re-admitted to hospital within 30 days, especially if they have co-morbid Cardio Vascular Disease (CVD)<sup>7</sup>

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. <sup>16-18</sup> 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<sup>19,20</sup>, diabetes education<sup>21,22</sup>, role of medical specialists<sup>23,24</sup>, medication adherence<sup>25,26</sup>, healthy lifestyle activities<sup>27,28</sup> diet and exercise interventions <sup>22</sup> as well as substantial empirical evidence of the contribution of social and behavioural factors to functional status and the onset and progression of disease<sup>28-30</sup>.

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-centred 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, socioeconomic 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 with a cardiac condition and found to also have T2DM.
- Determine whether a treatment package targeted at people admitted to LMH for a cardiac indication and who have comorbid T2DM will improve glycaemic control at 6 weeks and reduce hospital admission or if re-admitted, reduce length of stay.

The objective of the in-hospital treatment package is to:

Commence a pilot study to determine the benefit of a treatment focused on improvement of diabetes related health literacy and self-management skills compared to a control group including:

- 1. Proactively manage high risk patients with T2DM associated with a cardiac condition in collaboration with hospital services and primary health care providers commencing with the identification of high-risk patients at time of admission.
- 2. Provide a holistic, and patient-centered approach to improve health outcomes for patients and ultimately reduce length of stay and hospital readmissions.

#### **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 <sup>17</sup>. 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)

#### 6. STUDY POPULATION AND SETTING

The participants will be drawn from patients admitted to the Lyell McEwin hospital in Adelaide, South Australia with a cardiac condition and Type 2 Diabetes Mellitus (T2DM).

From July 2017 to June 2018 there were 734 separations in the target group. Assuming a similar accrual rate during the proposed REMIT-2-DS2 project and 2/3 of the patients providing consent, we anticipate randomising 10- 12 patients per week.

# 7. ELIGIBILITY CRITERIA

#### a. Inclusion criteria

- 1. Non-Indigenous and Indigenous peoples of age 18 years and over.
- 2. Patients with Type 2 DM with an underlying cardiac condition admitted to LMH.

## 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.

#### 8. STUDY OUTCOMES

# a. Quantitative

## i. Primary Outcome

o 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 with a primary diagnosis of a cardiac condition with a comorbid diagnosis of Type 2 Diabetes Mellitus (T2DM) will be enrolled.

# b. Study procedures

#### **Care Coordinator role:**

- Ask resident, registrar or nursing staff on cardiology or medical wards each weekday morning to identify any patients with a cardiac diagnosis + Type 2 Diabetes
- 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)
- Help patients to complete questionnaires (includes clinical, psychological, knowledge, literacy, access to appropriate health services and medical history) which may take up to 1.5 hours with or without a break if the patient requires. (Figure)
  - 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) Ask patients if they would like a friend or relative with them and/or, for Aboriginal patients, an Aboriginal health worker.

The questionnaires include(Figure):

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

# Pittsburgh Sleep Quality Index<sup>34</sup>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 2)

#### 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: <a href="https://www.ndss.com.au/">https://www.ndss.com.au/</a>

- 1. NDSS\_Understanding Type 2 Diabetes<sup>35</sup>
- 2. NDSS Healthy Food Choices<sup>36</sup>
- 3. NDSS Physical Activity<sup>37</sup>

The randomisation study groups are as follows(Figure):

## 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.

At 6 weeks the project manager will contact participants and send them a pathology form to have a blood test for HbA1C (haemoglobin A1c test measures average level of blood sugar) and triglycerides. In addition, we will repeat the Diabetes Distress Scale (DDS) questionnaire. The Care Coordinator will provide the patients with pathology forms at discharge and they will receive a phone call to remind them to have their blood test and to deliver the DDS at 6 weeks.

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).

## 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
  - o Date of birth (replaced with the calculated field age)
  - o Hospital URN
  - Separation date/time and admission date/time (replaced by length of stay hours)

# ii) During the Project

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 1**) 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

## i. Sample size and statistical power

It is anticipated that 10 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 study groups (three experimental and one 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, with an average accrual of 10 patients per week this will be achieved after 14 weeks. With an additional 6 weeks follow-up we anticipate an interim analysis at 22 weeks after which the two worse performing experimental interventions will be dropped. Accrual will continue during the first stage's 8-week follow-up period, thereby shortening the overall study length. At 10 patients per week 80 patients are expected to be accrued, of which 40 will be in the final two arms. The second stage requires a further 66 patients, thereby we anticipate accrual (and treatment) end after 25 weeks with final analysis at 31 weeks after study start. The difference in means with control arm as common reference are multivariate normally distributed allowing for strong control of the type I error rate. 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.

#### 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 and data management 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 1**) 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, 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), 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 1**) 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 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.

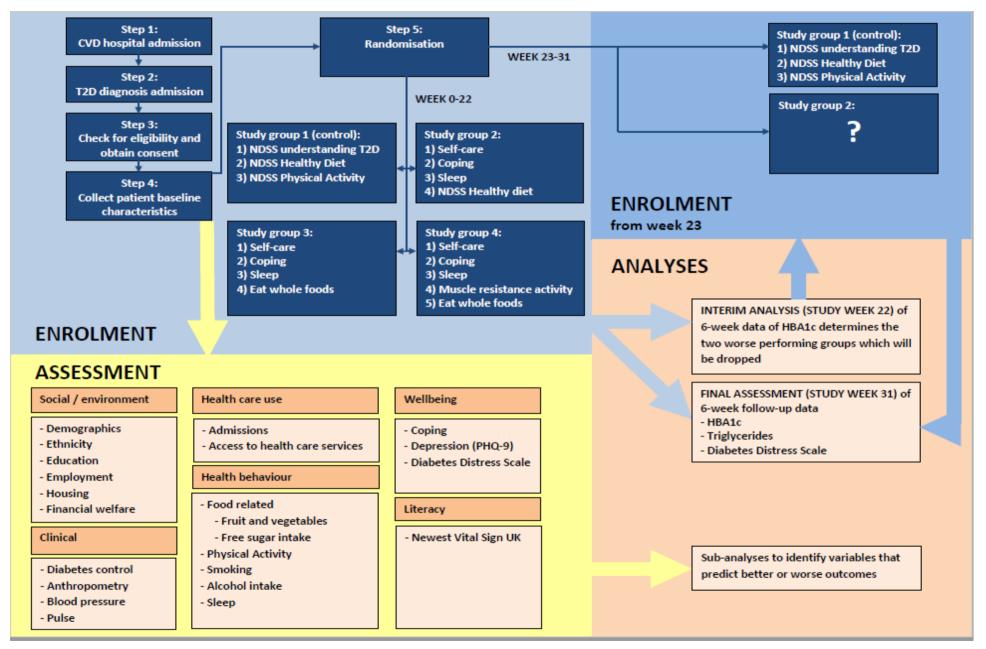
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  - https://www.ndss.com.au/physical-activity

Figure. Study Flow chart

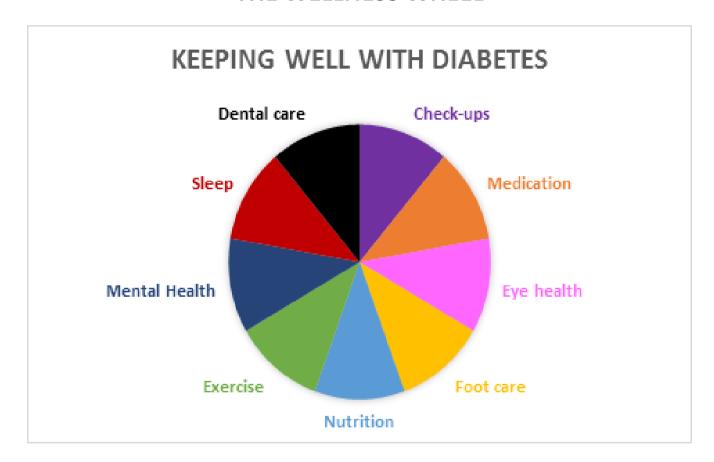


# Appendix 1. REMIT-2D Expert Advisory Group

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 Zimmerman	LMH		
Dr Peak Mann Mah	Endocrinologist, LMH		
Dr Isuru Ranasinghe	Cardiology, CAHLN		
Dr Elaine Pretorius	Director Medicine, 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)		

# **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/medicalinfo/consumer-info/managing-yourmedicines

# **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: <a href="https://www.heartfoundation.org.au/healthy-eating">https://www.heartfoundation.org.au/healthy-eating</a>

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: <a href="http://healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/content/home">http://healthstarrating.gov.au/internet/healthstarrating/publishing.nsf/content/home</a>



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: <a href="https://www.sleephealthfoundation.org.au/obstructive-sleep-apnea.html">https://www.sleephealthfoundation.org.au/obstructive-sleep-apnea.html</a>

**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: <a href="http://sacommunity.org/org/197186Centre">http://sacommunity.org/org/197186Centre</a> for Physical Activity in Ageing

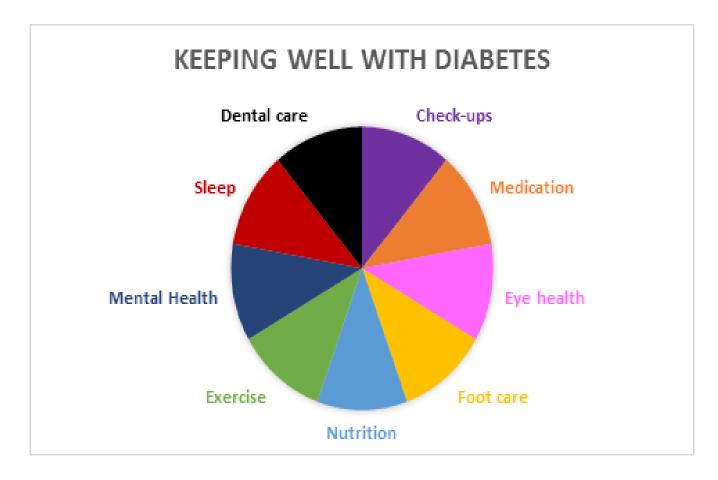
Active Ageing Australia, 118 Richmond Rd Marleston SA 5033, Ph: 08 8423 0960, email: admin@activeageing.org.au, website: https://activeageing.org.au/

**Depression and Anxiety** 

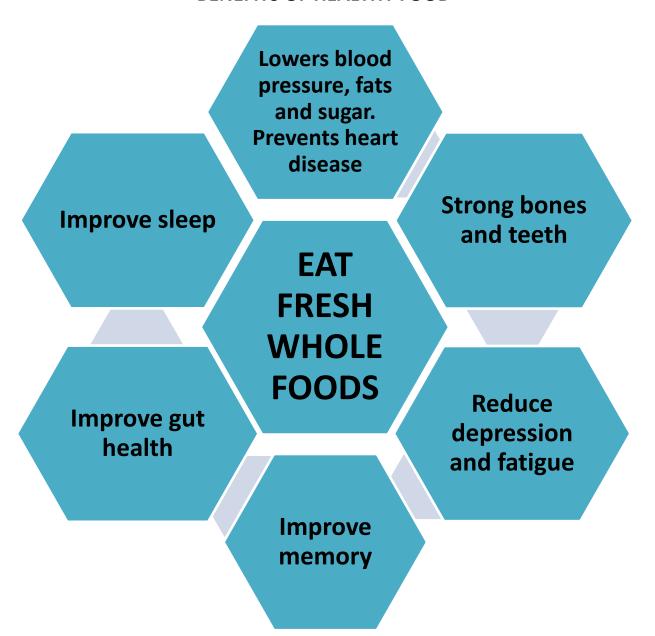
Beyond Blue, P: 1300 224 636, Website: https://www.beyondblue.org.au/

# EAT FRESH, WHOLE FOODS

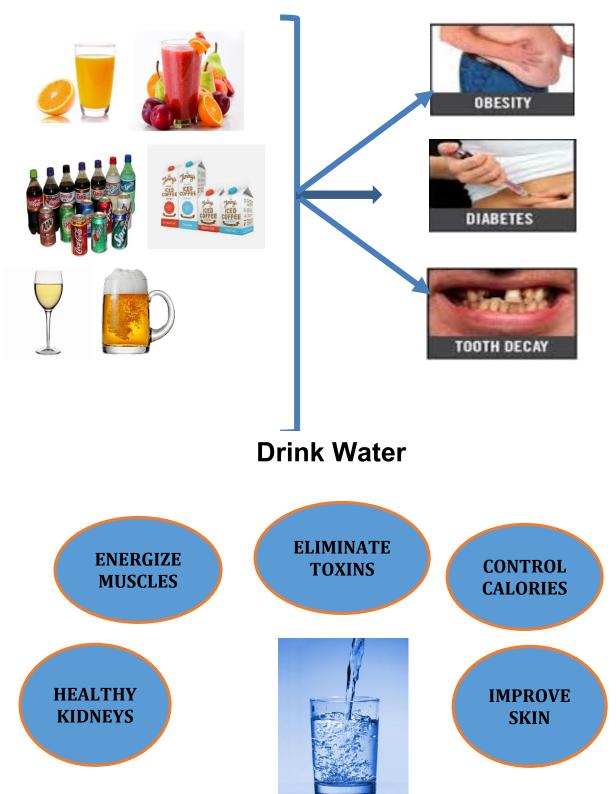
# THE WELLNESS WHEEL



# **BENEFITS OF HEALTHY FOOD**



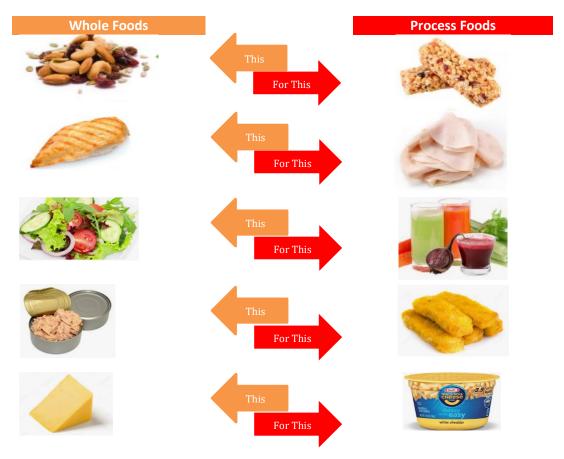
# THINK BEFORE YOU DRINK



# 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):



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



- <u>Time your meals:</u> 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.

		what you would add to y	
Granola cereals	2 Minute Noodles	Frozen pies or sausage	Pre-cut and packed
		rolls	salad mixes
Potato Crisps	Canned Tomatos	Rotisserie Chicken	Cereal and Nut Bars
	Ardmon Diesel Tomortoes		
Regular Dressings OR	Sauces (Meal)	Pre Made Lasagne	Crumpets
sauces (BBQ or Tomato) ———	Tonight  This sure  This sure	BEEF LASAGNE Was and a second of the control of the	Golden
Wholemeal Bread	Mixed Rice Crackers	Salt-reduced Stock	Fruit Juice
		Campbells REAL STOCK	
Dried Herbs and Spices	Deli style Metwurst or	Frozen Vegetables	Milk coffee sachets
- Valor	Pepperoni		NESCAFE Vandla
Frozen Waffles	Chuck Steak	Hazelnut Chocolate	Shredded wheat
		Spread	cereals

# **Shopping Trolley Quiz**

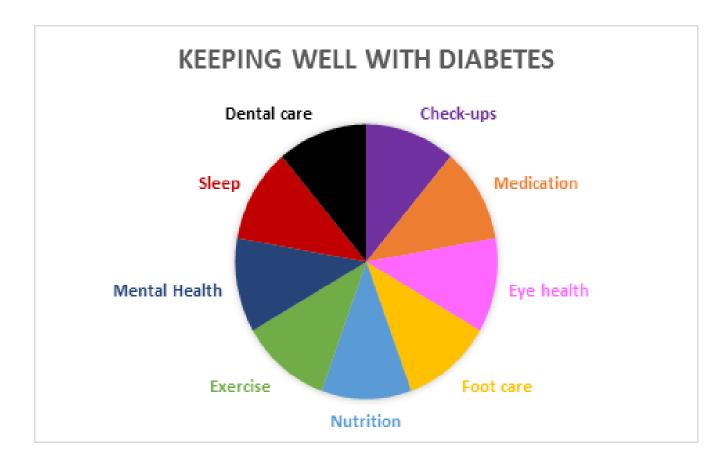
Outcome: Those highlighted RED are NO GO foods, best not to add them to the Trolley and the GREEN are the GO TO foods.

	GO TO	10003.	
Granola cereals	2 Minute Noodles	Frozen pies or sausage rolls	Pre-cut and packed salad mixes
			A Sand Pills
Potato Crisps	Canned Tomatos	Rotisserie Chicken	Cereal and Nut Bars
	Dead Tomorres		
Regular Dressings OR	Sauces (Meal)	Pre Made Lasagne	Crumpets
sauces (BBQ or Tomato) ———	Tonight Has Batter	BEEF LASAGNE  Have designed to the state of	Golden
Wholemeal Bread	Mixed Rice Crackers	Salt-reduced Stock	Fruit Juice
		Campbells REAL STOCK	
Dried Herbs and Spices	Deli style Metwurst or Pepperoni	Frozen Vegetables	Milk coffee sachets
	T C C C C C C C C C C C C C C C C C C C		NESCAFE Vonulla
Frozen Waffles	Chuck Steak	Hazelnut Chocolate Spread	Shredded wheat cereals
		nutella	CEIEdIS

Sample Time	Meal Occasion	Meal Suggestions		
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**

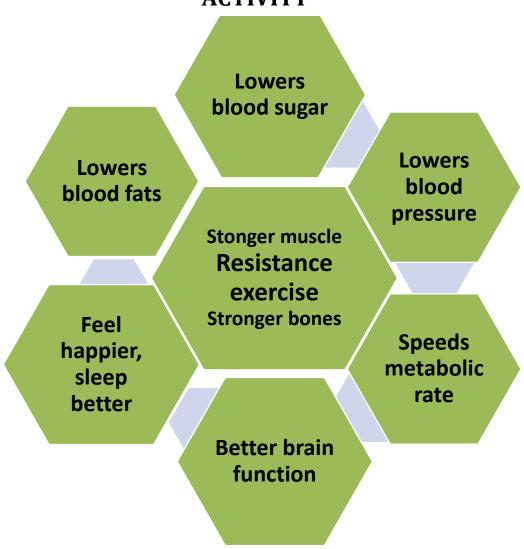
# THE WELLNESS WHEEL



# 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 t leasts 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.



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: <a href="mailto:info@exerciseismediciane.org.au">info@exerciseismediciane.org.au</a>, Website: <a href="http://exerciseismediciane.com.au/">http://exerciseismediciane.com.au/</a>

**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: <u>www.cotasa.org.au</u>

# 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/

# **WELLNESS WHEEL**



# GOOD SLEEP = GOOD HEALTH Some benefits



Getting a Good Night's Sleep - Top Tips

A good night's sleep starts before hadtime

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



Meditate, read or listen to music



Keep technology out of the bedroom



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

# 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: <a href="https://www.sleephealthfoundation.org.au/obstructive-sleep-apnea.html">https://www.sleephealthfoundation.org.au/obstructive-sleep-apnea.html</a>

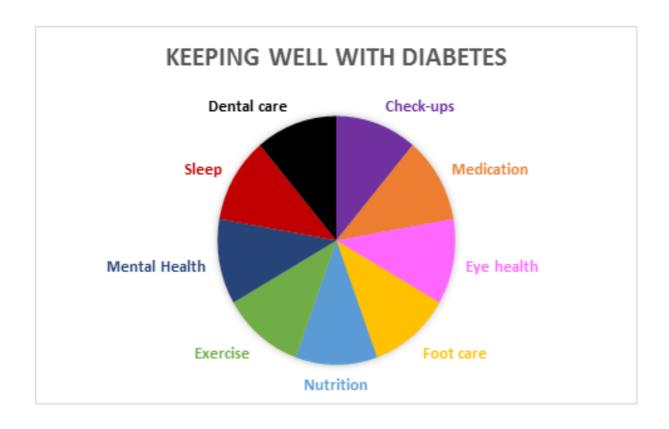
## Sleep Health Service Clinics, SA Health, Locations:

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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**

**Healthy Environments-** refers to your physical environment (e.g., your housing), social and cultural environment (e.g., where people are treated with respect, dignity, and equality) and having adequate finances to meet your needs.

**Sense of Belonging-** we all need to feel a sense of belonging in our families and communities.

Healthy Behaviours- are essential for our psychological and physical health. Having healthy coping strategies to use when stressed is essential for health and well-being. These include: adequate sleep, nutrition and physical exercise. We also need to have activities that we do that give us pleasure and sense of achivement

**Coping-** life is bumpy. Having health coping strategies to use when stressed is essential for health and wellbeing.

**Resilience-** is the process of bouncing back after coping with a challenging situation

**Treatment of Illness-** early and effective treatment of psychological and physical illnesses help to reduce the import of them on our health and well being.

# 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.

# **App Store** Preview

This app is only available on the App Store for iOS devices.



# My Coping Plan 4+

University of South Australia

\*\*\*\* 3.7, 6 Ratings

Free

# **MY COPING PLAN**

Self-soothing Self-soothing
Things I can do on my own
People who can support me
Professionals who can support me
In an emergency
©University of South 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
- a 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





# 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:

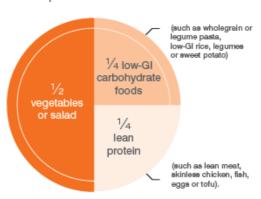
- eat regular meals to assist with managing energy and blood glucose levels
- » choose high-fibre, lower glycaemic index (GI) carbohydrate foods
- limit foods that are high in saturated fat and choose healthy fats
- include lean protein foods with your meals
- choose foods low in added salt (sodium)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



NDSS Helpline 1300 136 588

ndss.com.au





# 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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