**IMAGINE for better diabetes management: modifying delay discounting and physical activity via episodic future thinking**

**(IMAGINE)**

**UTN:** **U1111-1300-8986**

**ANZCTR:** To be inserted

# RESEARCH TEAM

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# SUMMARY

**Table1.** Summary of the CIRCUIT study

| ****Protocol Title (Short Title)**** | IMAGINE |
| --- | --- |
| ****Protocol Number**** | V1.0 |
| ****Study Design**** | This is a two-arm, proof-of-concept feasibility study, with randomisation |
| ****Study Duration**** | 6 months  |
| ****Setting**** | Diabetes clinics in South Western Sydney Local Health District |
| ****Sample Size**** | 60 |
| ****Inclusion Criteria**** | * Type 2 diabetes diagnosis (with HbA1c >= 7.0%)
* Aged over 18 years
* No Conditions that preclude physical activity
* Access and ability to use smartphone;
* No psychiatric conditions
 |
| ****Exclusion Criteria**** | * Pregnancy
* cognitive impairment precluding consent;
 |
| ****Primary Outcome(s):**** | Primary outcome: Change in physical activity, i.e., energy expenditure and physical activity-related cognitions (e.g., intention, planning), delay discounting.Secondary outcome: Diabetes distress, and diabetes self-care behaviours |
| ****Secondary Outcome(s):**** | Secondary outcome: Diabetes distress, and diabetes self-care behaviours |
| ****Statistical Analysis:**** | Descriptive statistics will be used to summarise baseline characteristics and rates of drop-outs and completion. An intention-to-treat method will be adopted. Longitudinal physical activity data for each group will be analysed using Linear Mixed Modelling. |

# GLOSSARY

HbA1c Glycated haemoglobin (HbA1c)

EFT Episodic Future Thinking

REDCap Research Electronic Data Capture

SWSLHD South Western Sydney Local Health District

T2D Type 2 diabetes mellitus

# BACKGROUND AND RATIONALE

This study document is the protocol for research involving human participants. This study is to be conducted according to Australian and international standards, and in compliance with the protocol, International Conference on Harmonisation Good Clinical Practice E6 (ICH-GCP), World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Participants, as well as applicable regulatory and institutional requirements and research policies.

## Summary

### Physical Activity and Type 2 Diabetes Management

Substantial evidence has demonstrated the importance of physical activity in promoting physical and mental health (see Warburton & Bredin, 2017 for a review). Physical activity improves physical health by influencing bodily mechanisms via blood lipids, body weight, blood pressure, metabolic changes, glucose tolerance, insulin resistance, immunologic functions and hormonal regulation. It also helps alleviate stress and fatigue and enhance self-confidence, satisfaction and general wellbeing, with evidence for reducing depression and psychological distress.

Physical activity is central to the prevention and control of Type 2 diabetes mellitus (T2D) and requires active engagement and commitment from the individual. To minimise complications associated with diabetes, it is advised that people engage in a minimum of 150 minutes of moderate intensity physical activity per week (Australian Government Department of Health, 2021). Over 50% of Australians with diabetes do not meet this recommended guideline for physical activity and those with complications do worse (Nolan, Raynor, Berry, & May, 2016).

### Delay Discounting is Associated with Poorer Diabetes Self-Management Behaviours

Delay discounting (an immediacy bias suggesting *a tendency to discount future consequences and overvalue present rewards*), is a psychological barrier that may contribute to the low levels of self-management see in people with T2D **CI Skinner** has recently published a systematic review with 12 studies demonstrating the associations between time preferences and diabetes self-management behaviours, with higher discount rates predicting less diabetes-related self-care and worse clinical outcomes, highlighting delay discounting as a significant potential barrier for engaging in health behaviours (Madsen, Kjær, **Skinner**, & Willaing, 2019). Applying delay discounting to physical activity means that greater value is placed on immediate gratification (e.g., watching television on a sofa) over the future goal of improved health (e.g., better blood glucose level) by engaging in physical activity. Evidence has shown that people with T2D discount the future (Lebeau et al., 2016). Further evidence supports that delay discounting is a significant predictor of obesity and poorer glycemic control for individuals with prediabetes (Epstein et al., 2019). Moreover, higher delay discounting is associated with lower engagement in self-care behaviours among those with T2D (Campbell, Williams, & Egede, 2021). This raises the question as to how one can reduce delay discounting to modify this risk factor, in order to help people with T2D focus on future benefits rather than immediate rewards. Delay discounting represents a novel target for diabetes management interventions.

### Episodic Future Thinking (EFT) Reduces Delay Discounting

Episodic future thinking is a conceptual tool simulating the experience of the future. By cognitively simulating future outcomes and making them salient, it can motivate goal-directed health behaviours through enhanced consideration and valuation of the future. Through the process of EFT, individuals are more likely to make choices that focus on long-term outcomes. **Lead investigator CI Chan** has conducted a randomised controlled trial using a type of EFT know as future-oriented imagery and successfully increased physical activity among inactive adults in the general population compared to control group over a 4-week period (Chan & Cameron, 2012). *EFT* has been used as an innovative strategy to *reduce delay discounting* among those at risk of T2D (Bickel et al., 2020). Focusing on desired future events, individuals engage in episodic future thinking via a mental simulation demonstrated reduced delay discounting (Stein et al., 2021). It remains an empirical question if such strategy can be applied to T2D populations in real-life settings.

**CI Gordon** has conducted physical activity interventions with success in increasing activity levels, however, these strategies are often labour-intensive to deliver, requiring a lot of staff time to follow-up, and hence with limited adoption in real-life settings (Hunter, Gordon, Huynh, & Benson, 2021). Addressing an immediacy bias where greater focus is on immediate rewards over the future goal of improved health is a contemporary approach for behaviour change. Therefore, EFT has several potential advantages over current approaches and can be scalable in communities.

## Rationale

This project presents a novel intervention combining mental imagery and episodic future thinking in diabetes management, targeting T2D. There is a substantial need to target value and decision-making in diabetes management interventions as evidence has shown that health behaviour change can be overwhelming and is associated with distress. Modifying delay discounting to help people with T2D focus on the future rather than immediate rewards is an innovative and low-cost approach which can be adopted by individuals easily once they have learnt to generate the future-oriented mental pictures.

# STUDY AIMS AND HYPOTHESES

## Research Aims

Firstly, this study seeks to confirm the relationship between delay discounting and self-reported physical activity specifically among diabetes patients. Additionally, building on CI Chan's earlier work using an EFT mental imagery intervention to increase physical activity among inactive adults in the general population (Chan & Cameron, 2012), the present study will instill episodic future thinking through mental imagery, with the aim to reduce delay discounting and enhance the performance of physical activity which can lead to improved glycemic control in the long run. CI Persson has developed a mobile application based on Epstein et al’s (2019) work to measure delay discounting and incorporated the prompts for EFT in the program. The present study will apply EFT and mental imagery to people with diabetes (with the support of a mobile application to measure delay discounting) and assess the feasibility, acceptability, and potential impact of offering an intervention that guides people with diabetes to 'imagine the future' using mental imagery.

## Hypotheses

We hypothesise that:

1) in general, individuals with lower delay discounting scores would also report lower engagement in physical activity compared to those with higher delay discounting scores.

2) 70% of practice compliance would be obtained and that participants would rate the EFT simulation as easy and beneficial.

3) Individuals in the EFT mental imagery condition reporting reduced delay discounting, greater behavioural intentions, increased action planning and increased physical activity at 1-, 3- and 6-month follow ups.

# RESEARCH DESIGN

## Research Project Setting and Ethical Considerations

### Research Setting

The study will be based in South-Western Sydney Local Health District, New South Wales. T2D patients who attend the Campbelltown and Camden Hospitals and Macarthur Diabetes Endocrinology and Metabolism Services. Eligible consenting participants will attend a mental imagery intervention either in-person at Western Sydney University Campbelltown campus or virtually via zoom to learn imagery techniques led by a psychologist.

### Ethical Considerations

#### Recruitment and Selection of Participants

Direct recruitment will occur in the clinic waiting area, which is a standard approach. Participants will have ample time to consider, and participation will be voluntary. No dual relationships, conflicting concerns, coercion will exist.

#### Informed Consent

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

#### Confidentiality and privacy

All screening data will be stored securely by the research nurses. All hard copy material (consent forms, survey forms) will be stored in locked facilities and all soft copy materials such as the transcripts and data will be stored on the WSU secure password protected Australia's Academic and Research Network (AARNet). All individuals recruited in the clinic will be approached by the researcher in a clinical setting and guidelines around patient privacy adhered to. All questionnaire derived data will be collected using RedCap an online secure custom built study database which will run on a La Trobe University governed server. The platform uses a top-down authorisation system that can restrict users to only viewing project data that they need to and only allowing data input if needed. Data blinding can also be enabled whereby a password is required to retrieve and view restricted content.

## Method

### Design

This is a two-arm, proof-of-concept feasibility study, with randomisation. The 2 x 3 randomised control trial involves 1, 3 and 6 month follow-up. The intervention condition uses imagery to instil episodic future thinking and the control condition is neutral imagery (i.e., no episodic future thinking).

### Screening for eligible participants

People with T2D will be asked to complete a screening questionnaire including measures on study criteria to determine their eligibility.

Ineligible participants will not proceed and will be automatically directed to a survey thank-you page informing them of their ineligibility. Their data will not be retained.

Those who are deemed eligible will be sent a separate Participant Information and Consent Form. Consenting volunteers will be sent the baseline questionnaire (online or hardcopy) to complete. The baseline questionnaire includes measures on demographics (age, gender, relationship status, living arrangement, ethnicity, educational qualifications, employment status), physical activity, delay discounting, diabetes distress, and diabetes self-care behaviours.

### Intervention

After the first week of baseline physical activity measurement, participants will be randomised to one of two conditions (EFT imagery (A) vs Non-EFT imagery control (B)) plus standard care. As participant recruitment will occur at different stages, simple randomisation will be performed using an ‘envelope’ method. The envelope will contain equal amounts of paper A and B’s. Researchers will randomly choose from the envelope when conducting intervention with participants. The EFT condition focuses on thinking about future personalised events that participants look forward to and can imagine at different timeframes. These events may be linked directly or indirectly to their participation in regular physical activity. The control group will generate mental imagery of past events in the last 7 days timeframe. Both groups will experience the positive effect of feeling relaxed. Participants will be contacted by the research team to schedule an in-person (at Western Sydney University) or virtual appointment (of their choice) which they will attend a psychologist-led session and learn a mental imagery technique and generate the corresponding imagery. Both groups will be prompted to practice their respective imageries 3 times a day for 1 month. They will be offered a mobile application to be installed to their smartphone with details of the imagery instructions and reminders to practice after the intervention session. One week after the initial imagery session, each participant will be followed up via telephone call to check their imagery generation progress. At 1-, 3- and 6-months participants will be contacted again by telephone with instructions on how to complete a short follow-up questionnaire.

### Proof-of-concept:

As a pilot/feasibility study, measures of success will focus on the following:

1. Feasibility and acceptability will be assessed by rates of dropout, proportion of sessions completed and the proportion of participants complying to the imagery practice recommendation. Recruitment will be active in the New South Wales and Greater City of Bendigo region (ethics approval has been granted for the Bendigo arm of the study under Non-National Mutual Acceptance HREC) until the target sample size is reached. The number of people referred and the number of people agreeing to participate will be used to calculate the participation rate. For feasibility, a priori thresholds of 80% retention, completion of 70% of practice compliance and completion of telephone follow-up by more than 60% of participants will be set. Usage and engagement data will also be obtained from the mobile application. Participants’ reports of ease and utility (provided via 0-10 Likert scales with 10 being very easy/helpful) of the initial session will be assessed. A threshold of mean participant ratings of 7.0/10 will be used.
2. Potential impact of the program will be based on the study outcomes at 6 months:

(i) Delay discounting is measured by the gold-standard method, using a computerised adjusting amount task (Johnson & Bickel, 2008) which involves two theoretical delayed monetary rewards ($100 and $1000). In the task, participants will decide if they wanted either a fraction of the total delayed amount of money now or the full amount at different delays. The program calculates a delay discount score based on participants’ responses, with higher values representing lower discounting of the future.

(i) Diabetes distress is measured by the 20-item Problem Areas In Diabetes scale. The scale assesses a range of issues that may cause emotional distress for a person with diabetes, with higher scores indicating greater diabetes distress.

(iii) Diabetes self-care behaviours will be assessed by the Summary of Diabetes Self-Care Activities (SDSCA) which assesses physical activity, diet, glucose monitoring and medication taking behaviours for T2D.

3) Sample size: Part of the goal of the proof-of-concept study is to generate estimates of effect sizes. We will aim to recruit a total of 60 participants with 30 in each condition.

### Participants

Participants will include English-speaking adults (aged above 18) with T2D

Participants will include English-speaking adults (aged above 18) with T2D who a) attend the South-Western Sydney Local Health District, Campbelltown and Camden Hospitals, and Macarthur Diabetes Endocrinology and Metabolism Services; b) self-identified after seeing the advertisement flyer or c) self-identified via word of mouth through patients or clinicians. CI Simmons and Piya are endocrinologists who have oversight in the specialist clinics at the specified health services.

Screening phase: People with T2D will be invited to participate in a screening survey to assess eligibility to participate in the intervention.

#### Inclusion Criteria

Participants will be eligible if they meet the following criteria:

1. T2D diagnosis (with haemoglobin A1c >= 7.0%)
2. Aged over 18 years
3. No cognitive impairment precluding consent
4. No Conditions that preclude physical activity
5. Access and ability to use smartphone
6. Are not pregnant
7. No psychiatric conditions

#### Exclusion Criteria

1. Cognitive impairment precluding consent
2. Pregnancy

#### Sample Size

 At least 60 participants will be recruited. The purpose of a feasibility study is to generate estimates of effect size. So that future studies will be able to calculate accurate sample sizes.

### Participant Recruitment

* Participants who attend the endocrinology and footcare service at South Western Sydney Local Health District, Campbelltown and Camden Hospitals and Macarthur Diabetes Endocrinology and Metabolism Service.
* Self-identified participants who see the advertisement flyer posted at the General Practice that they attend will complete the screening survey either online or if they prefer a hardcopy they can contact the research team.
* Self-identified participants who see the advertisement flyer on social media will complete the screening survey online.
* Bendigo Health Specialist Waitlist - The Manager of the Specialist Clinics will generate the list of patients with T2D from the iPM. For those who have provided an email address, a letter from the endocrinology clinic and the advertisement flyer with the link to the screening survey will be sent to them. For those who have not provided an email address, the research assistant on the team will call the participant using the contact phone number provided to explain the reason for calling [see script] and ask patients if they would be happy to receive the invitation to the study via email or text message on their phone. If neither is possible, then a hardcopy of the letter and screening survey will be posted out to them.
* CI Triay, CI Savage, CI Harding and CI Vijayanand are experienced endocrinologists who consult at Bendigo Health and have access to T2D patients through their practices. Recruitment will occur in partnership with Bendigo Health who will provide the support and access to patients who attend the clinic. A research team member will attend the Bendigo Health Endocrinology and foot clinic to recruit participants while they attend their clinic appointments. Patients will be shown the advertisement flyer and/or invited by the research team on site and asked to complete the screening survey.

### Participant Consent

After screening, eligible volunteers will be sent a copy of the Participant Information and Consent Form. Informed consent will be obtained via the physical or virtual signed consent form.

After screening, ineligible people will be asked for their permission to retain their screening data for research purpose and their data will be made anonymous. Physical or virtual signed consent form represents informed consent to release their data.

### Research Activities

This study will take place over six months inclusive of both baseline, intervention, and follow-ups. Participants will first be screened for their eligibility to take part in the intervention.

Ineligible participants will be automatically directed to a survey thank-you page informing them of their ineligibility. Their data will not be retained.

Eligible consenting participants will be asked to complete baseline assessment via a questionnaire. After baseline assessment, they will be randomly allocated to one of two imagery conditions. Participants will be scheduled to attend either an in-person or virtual appointment (of their choice) led by a psychologist and will be taught the EFT imagery technique. They will be asked to commit to engaging in the mental imagery 3 times per day for 1 month. At each follow-up phase participants will be contacted by a researcher who will re-explain these requirements.

# Project data

## Screening

* Identification/Contact Details: Phone number; email address
* Study criteria (Age; language spoken; diabetes diagnosis; HbA1c level; conditions limiting physical activity; smartphone access; pregnancy; participation in wellness programs).

## Baseline

* Demographics (age, gender, relationship status, living arrangement, ethnicity, educational qualifications, employment status)
* Self-reported physical activity Craigh et al. (2003), Ajzen, (2002), Norman & Conner (2005)
* Delay discounting – Clare (2010)
* Diabetes self-care behaviours - Summary of Diabetes Self-Care Activities (SDSCA) which assesses physical activity, diet, glucose monitoring and medication taking behaviours for T2D (Toobert et al., 2000).
* Personality- (BFI-10) - Rammstedt, B. & John, O.P. (2007)
* Diabetes distress - the 20-item Problem Areas In Diabetes (PAID) scale (Polonsky et al., 1995).

## Intervention

* Intervention Feasibility - (provided via 0-10 Likert scales with 10 being very easy/helpful) of the initial EFT session and ongoing EFT practice through the mobile application.
* Vividness of imagery & Practice – Chan & Cameron (2012)
* Mobile application measuring: delay discounting (Johnson & Bickel, 2008); Usage and engagement data.

## Follow-up

* Self-reported physical activity levels – Craig et al. (2003); Ajzen (2002); Norman & Conner (2005).
* Motivational readiness – Marcus et al. (1992) Intervention Feasibility - (provided via 0-10 Likert scales with 10 being very easy/helpful) of the initial EFT session and ongoing EFT practice through the mobile application.
* Diabetes self-care behaviours - Summary of Diabetes Self-Care Activities (SDSCA) which assesses physical activity, diet, glucose monitoring and medication taking behaviours for T2D (Toobert et al., 2000).
* Diabetes distress - the 20-item Problem Areas In Diabetes (PAID) scale (Polonsky et al., 1995).
* Vividness of imagery & Practice – Chan & Cameron (2012)

# Data collection , MANAGEMENT AND ANALYSIS

## Data Collection

Depending on the method of recruitment, the screening questionnaire will be in online format or hard copy upon request. Participants can choose their preferred method of completion. Participants at Camden and Campbelltown Hospitals and Macarthur Diabetes Endocrinology and Metabolism Services will complete the online questionnaire using iPad/s or pen/paper while they wait for their appointment at the health facilities. Data collected form the online questionnaires will be obtained using Research Electronic Data Capture (REDCap), an online secure study database which will run on a La Trobe University governed server. The platform uses a top-down authorisation system that can restrict users to only viewing project data that they need to and only allowing data input if needed.

Waitlist patients will be emailed and invitation to do a screening survey online.

Potential participants at local General Practices will complete the screening survey online.

During intervention, follow-up questionnaires will re-assess diabetes distress, diabetes self-care and physical Activity (Self-report) as well as obtain information on ease and utility, use and engagement and proof-of-concept.

Participant engagement with EFT imagery will be measured using self-reported measures.

Participants are permitted to withdraw at any time during the project. Participant attrition will also help to accurately answer the feasibility and acceptability of EFT aspect of this study.

## Data management

All collected data will be stored on password protected drive at La Trobe University. NSW collaborator will be provided with secure access to shared research drives. Any hard copies will be shredded once data are entered into the computer. Any email transfer of data between researchers will be via secure University and/or Bendigo Health and Western Sydney University’s email systems (if there is any need to transfer data files). All Data and information collected will be retained for a period of 7 seven years then deleted. Only deidentified data will be publish and no personally identifiable information will be disclosed.

## Data Analysis

Descriptive statistics will be used to summarise baseline characteristics and rates of drop-outs and completion. An intention-to-treat method will be adopted. Longitudinal physical activity data for each group will be analysed using Linear Mixed Modelling. This technique intrinsically accounts for missing data and attrition in longitudinal studies by modelling trajectories for each participant from available data.

To take a conservative approach, it will be assumed that non-completers do not show further gains after the last data point available.

The longitudinal association between DD and physical activity will be analysed with a cross-lagged longitudinal structural equation model which will account for autoregression between variables at a particular time-point and the same variable at a subsequent timepoint. Significance level of hypothesis testing will be set at 0.05.

# Outcome Measures

Definition: The World Health Organization defines an outcome measure as a “change in the health of an individual, group of people, or population that is attributable to an intervention or series of interventions.” Outcome measures (mortality, readmission, patient experience, etc.) are the quality and cost targets healthcare organizations are trying to improve.

## Primary Outcome

Change in physical activity, i.e., energy expenditure and physical activity-related cognitions (e.g., intention, planning), delay discounting

## Secondary Outcome

Secondary outcome: Diabetes distress, and diabetes self-care behaviours

# Results, Outcomes and Future Plans

* Results summary will be sent to participants upon completion via email or post depending on their preference.
* Findings will be disseminated in peer-reviewed scientific journals, conferences, general public (via media)
* Data from the feasibility study will provide preliminary evidence for future larger-scale trials in real-world settings.
* Data from the screening survey will allow the study of delay discounting within a T2D cohort and comparisons between active and inactive individuals on delay discounting.
* After 7 years, collected data will be deleted.

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