

## **Trial Registration Data Set**

### **Trial ID**

ACTRN12618000412235

### **Date registered**

21 March 2018

### **Health condition**

Type 2 diabetes

### **Recruitment countries**

Australia

### **Recruitment site location(s) (State)**

Queensland

### **Recruitment status**

Not yet recruiting

### **Anticipated date of first participant enrolment**

02 April 2018

### **Ethics application status**

Approved

### **Brief summary**

Insulin initiation and/or titration for type 2 diabetes (T2DM) is a resource intensive process requiring a referral to a credentialed diabetes educator (CDE) for insulin dose adjustment (IDA). To address the challenges in IDA, we have developed an innovative mobile health (mhealth) based model of care to support the patients and clinicians in diabetes specialist outreach and telehealth clinics (REMODEL-IDA: REthinking MOdel of Diabetes care utilising EhealTh – Insulin Dose Adjustment). Advances in mhealth have enabled to redesign traditional models of healthcare delivery. This model aims to improve glycaemic management, improve healthcare service delivery efficiency and improve the patients' experience. A two-arm pilot randomised controlled trial will be conducted for 3 months with 44 participants, randomised at a 1:1 ratio to receive either the mhealth-based model of care (intervention) or routine care (control), in diabetes specialist outreach and telehealth clinics. The intervention arm will exchange glycaemic management information via a Mobile-based Disease Management System (MDMS) developed for T2DM outpatients. They will receive

advice for insulin titration from the CDE via the mobile-app and receive automated text-message prompts for better self-management based on their glycaemic management. The routine care arm will be followed up via telephone calls. The primary outcome is change in HbA1c, a marker of glycaemic management, at 3 months. Patient and healthcare provider satisfaction, and time required by health care providers in both arms will be collected. This study will guide the conduct of a large-scale implementation study.

### **Key inclusion criteria**

Type 2 Diabetes Mellitus ( diagnosed for at least 6 months) attending the telehealth clinic at the Princess Alexandra Hospital (PAH) or specialist outreach clinics run by PAH

HbA1c > 8% ( done within 4 weeks of the trial)

Age > 16 yrs

Using a smartphone/tablet

Able to communicate in English

### **Minimum age**

16 Years

### **Maximum age**

No limit

### **Gender**

Both males and females

### **Key exclusion criteria**

No access to reliable internet connection (3G/4G/Wi-Fi)

Pregnant

Type 1 DM

### **Primary Sponsor**

Type: Individual

Name: Anish Menon

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## **Contact person for information and recruitment**

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