**TITLE**: Impact of Mobile Phone Diabetes Application Intervention on Diabetes Patients: a Randomized Controlled Trial

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**STUDY SITES:** Townsville Teaching Hospital and Community Health Services, Kirwan

**BACKGROUND**

Diabetes Mellitus (especially type 1 and 2) remains an emerging epidemic. Diabetes is the fastest growing chronic condition across all ages in Australia (Australian, 2017), with 1.2 million (5.1%) of the population haven some type of diabetes in 2014-2015 and this indicates a 1.5 % increase over the 3.6% in 2004-2005, the majority (85%) of these are type 2 (ABS 2015). Type 2 diabetes contributed about 4% of the disease burden in 2014-2015, indicating a 2.3% increase from 1.7% in 2000-2001 (ABS 2006; ABS 2015). A 10 year (2002-2012) period of analysis, shows that the annual incidence of type 2 diabetes among people aged 10 years and over; fluctuated between 200 to 264 new cases per 100,000 population while from 2000-2013, there are 31,895 new cases of type 1 diabetes with an average of 2,300 cases annually (AIHW, 2014). The latest available national data on insulin treated diabetes in Australia shows that in 2015, there are 28,775 people with diabetes who began using insulin treatment; 63% of this had type 2 diabetes while 9% are type 1 (AIHW, 2017).

According to the latest estimates of the International Diabetes Federations (IDF), there is a global prevalence of 415 million adults with diabetes, where the majority are type 1 or 2. This figure is likely to increase to 642 million in 2040 if without any intervention (IDF, 2015). Also, it is estimated that 37% of all adults with type 1 or 2 diabetes live in the Western pacific region which includes Australia (IDF, 2015).

When diabetes is not well managed, complications develop that threatens health, endanger life and greatly increase economic burden. Moreover, it has been observed that Australians who live in rural/remote areas have a disproportionately higher risk of prevalence, complications and mortality due to diabetes than those living in major cities (Minges et al., 2011; ABS, 2006; AIHW, 2016). The prominent features of these excess risks are limited access to care and the necessary diabetes support services; due to inadequate resources at the community health care level (Bailie et al., 2007; Peiris, Wirtanen, & Hall, 2006; Condon, Warman & Arnold, 2001). Such complications are significant contributor to mortality and poor quality of life. They may be inform of hypoglycaemia, diabetic ketoacidosis and hyperosmolar coma (Atlas 2015). Over time, diabetes can damage the eyes (retinopathy), kidney (nephropathy), nerves (neuropathy) as well as increase in the risk of heart disease, stroke and poor blood supply to the limbs (Albert & Zimmet, 1998; Papatheodorou et al., 2015).

This salient public health pandemic has continued to impose substantial burden on the health care systems as well as the economy of nations. A systematic review conducted by Seuring et al. (2015) reported that the direct annual cost of diabetes to the world is more than US$827. In 2015, 12% of global health expenditure was spent on diabetes (USD$673 billion) with a proposed estimate exceeding $802 billion by 2040 (Atlas 2015). Beside the burden on the nations and health care system, diabetes poses a significant economic impact on its victims and their families in terms of higher out- of- pocket health care payments, reduced productivity, absence from work and premature death (WHO 2016). In Australia, health care cost directly attributed to diabetes cost was $14.6 billion in 2016, an average of 97% increase from $1,507 million in 2008-09 (AIHW 2013, Diabetes Australia 2017). In Australian, there is a direct annual cost of $9645 compared with $4025 among type 2 diabetics without complications (Colaguiri et al., 2003) and $16,698 compared to $3,468 among type 1 diabetics without complications (Colaguiri et al., 2009).

The increasing prevalence of diabetes in combination with increasing years of life span in many world populations signifies a need for improved management of the disease and its risk factors in order to prevent complications. Reduction in the risk of developing complications from diabetes and improved quality of life can be attained through self-care behaviours which ensures disciplined or tight control of important risk factors such as blood glucose, blood pressure and lipid levels (UK Prospective Diabetes Study Group, 1998a; 1998b; Gaede et al., 2008).

**Diabetes self – care education (DSCE) and its effect on complication reduction**

Knowledge and skills on targeted self-care behaviours can only be impacted through a process of education; that is making self-care education an essential component in the prevention and early detection of diabetes complications. This process is known as Diabetes Self Care Education (DSCE). The overall objective of DSCE is to foster informed decision-making, self-care behaviours, problem solving and active collaboration with the health care team; leading to improved clinical outcome, heath status and quality of life (Funnell et al., 2009). According to Shrivastava et al. (2013), there are seven essential self-care behaviours in people with diabetes which predict good health outcomes namely; healthy eating, being physically active, monitoring of blood sugar, compliance with medications, good problem-solving skills, healthy coping skills and risk-reduction behaviours. These seven behaviours have been found to be positively correlated with good glycemic, cholesterol and blood pressure control, reduction of onset and/or advancement of complications to improve quality of life (Shrivastava et al. 2013).

Studies from around the world have shown the positive effects of the educational process on diabetes, with a meta-analysis reporting that patients present improvements in glycemic control, and in the prevention and control of acute and chronic complications, when they receive effective treatment, self-care support and regular monitoring (Jarvis, Skinner, Carey, & Davies, 2010). Kang et al. (2014) reported that self-care education could improve diabetes management behaviour in type 1 diabetics. A study by Mensing et al. (2003) revealed a four-fold increase in complications for individuals with diabetes who had not received education concerning self-care practices. A review of DSCE revealed that education is successful in lowering glycosylated haemoglobin levels (HbA1c) (Norris, Lau, Smith, Schmid, & Engelgau, 2002). Another meta-analysis of self-care education for adults with type-2 diabetes reported improvement in the control of blood glucose levels at immediate follow-up. However, the benefit decreased one to three months after the intervention was terminated, suggesting the need for continued educational support (Williams, Freedman, & Deci, 1998).

Despite the proven benefits of DSCE, the majority of people with diabetes do not receive DSCE. Johnson et al., 2015 revealed that 52.1% of adults with type 1 or type 2 received no DSCE. In another study, Li et al., 2014 reported that only 6.8% of individual with newly diagnosed type 2 diabetes who have private health insurance participated in DSCE within 12 months of diagnosis and only 4% of Medicare patients received DSCE (Ellis et al., 2004). This low number is attributed to many barriers including factors associated with access to the health system and health care professionals; limited community resources and; the behaviour of individuals with diabetes (Peyrot, Rubin, Funnel, & Siminero, 2009; Remler et al., 2011). Barriers can also include limited access to the recommended DSCE because of financial burdens and limited speciality provider resources, especially in rural/remote communities (Scrimgeour & Scrimgeour, 2008). Furthermore, assessing DSCE does not in itself guarantee effective and sustained long term self-care in diabetic patients. Most patients need ongoing education to sustain the level of self-management needed on long term basis.

It is advocated that educational support on self-care should go beyond the present recommendation of occurrence at diagnosis, annually, when new complication sets in or during transition in care (Powers et al., 2017); but more regularly. This is essential to promote awareness of the importance of self-management, build the resilience needed to overcome barriers, cope with the ongoing demands, and facilitate required behavioural changes during the course of treatment and life transitions (Coyle, Francis, & Chapman, 2013; Shrivastava et al., 2013).

 **Self-care education via mobile technology-based applications (apps)**

According to the World Health Organisation, the use of mobile technologies can support the achievement of health outcomes, which have the potential to transform health service delivery globally (WHO 2011). The prevention and management of chronic conditions such as diabetes present serious problems for the patients and the health care system; because patients’ ongoing compliance to self-care is a difficult challenge (Tam, Sharma, & Amirfar, 2013). However, with advancing technology, mobile communication devices are widely accessible and it is therefore possible to apply mobile apps technology to empower patients through improved self-monitoring and disease mangement programs (Mickan, Tilson, Atherton, Roberts, & Heneghan, 2013).

Persuasive technology which refers to a computing device or application intentionally designed to change users’ attitude or behaviour in a predetermined way (Fogg 2003) have the ability to motivate and support healthy lifestyle decisions, which could prevent or delay the onset of complications in chronic diseases and improve the quality of life. Persuasive strategies include text messaging and mobile phone applications, and they have been shown to; be valid tools for behaviour change (Coles-Lewis & Kershaw, 2010) and are essential techniques for cost-effective delivery of patient education to rural populations (Thaker, Monypenny, Olver, & Sabesan, 2013). These strategies proffer an approach to deliver health care outside the clinical environment and also provide ongoing support especially in resources constrained areas. A study revealed that text messaging for 6 months reduced HbA1C in diabetic patients to 7.04% at 3 months and 6.94% at 6 months compared to 8.09% at baseline (Kim & Jeong, 2007). Kirwan et al., (2013) reported the effectiveness of smart phone application combined with text messaging for improved glycemic control from baseline (8.47%) to 6 months intervention and 3 months follow up (7.80%) compared to control group 8.47% at baseline and 8.58% follow up. A review paper reported that apps positively support diabetes self-management tasks such as blood glucose testing, diet monitoring, physical exercise and medication reminder (EL-Gayar, Timsina, Nawar, & Eid, 2013). Another systematic review gave evidence of improvement in glycemic control among those using a diabetes mobile apps (Kitsiou, Pare, Jaana, & Gerber, 2017).

Receiving diabetes self-care education through the use of text messaging on mobile diabetes apps is becoming more available with increased access (Power et al., 2015). It is a cheap, convenient and effective mechanism to implement diabetes health education, medication and clinic appointment reminders and for building awareness about the disease D**é**glise, Suggs, & Odermatt, 2012). It is a viable and acceptable pathway of improving knowledge and promoting daily self-management activities and preventing risk of complications in patients with chronic diseases such as diabetes (Boren et al., 2006; Déglise et al., 2012; Vervloet et al., 2012) and also allows for more frequent communication between patient and health care providers (Goyal & Cafazzo, 2013; Hanauer, Wentzell, Laffel, & Laffel, 2009). Mobile diabetes apps are tools to monitor patients’ conditions outside the doctors’ offices (Chomutare, Fernandez-Luque, Årsand, & Hartvigsen, 2011; Martínez-Pérez, De La Torre-Díez, & López-Coronado, 2013).

However, to the best of my knowledge, there is no information, on the impact of using such an approach to deliver diabetes self-care education on the prevention of complications in diabetic patients living in rural settings of developed nations like Australia. Additionally, diabetes patients living in rural and remote areas of Australia do not have regular access to education on self-care due to inadequate staff numbers and high staff turnover rates in community health centres (Condon et al., 2001). Use of app on mobile phones to deliver regular information on how patients can care for themselves would bridge these gaps.

Therefore, this study aims to use a randomised controlled clinical trial to promote diabetes patients’ self-care education through diabetes app and text messaging on mobile phones. This approach will support diabetes patient in making informed decisions and sustained behavioural health changes in managing their conditions to reduce the risk of developing complications. The study will also explore cost-effectiveness of the intervention in relation to its impact on acute complication / sick days, emergency hospital visits and quality of life years gained.

**The specific aims are:**

1. To investigate the impact of diabetes self-care educational intervention using a mobile app, in a randomised controlled trial with two participant groups (intervention and control groups), on hyperglycaemia, hypoglycaemia, HbA1c, Albumin/Creatinine ratio and Blood Pressure levels, lipid control and anthropometric measurements.
2. To estimate changes in: knowledge, ability to perform self-care for diabetes, medication adherence and self-perceived quality of life pre and post intervention.
3. To determine the cost effectiveness of the intervention relative to standard care.

**Research Hypotheses**

1. Use of mobile phone diabetes app text messaging for self-care education can improve clinical health outcomes in diabetes patients
2. Use of mobile phone diabetes app text messaging for self-care education can improve knowledge, ability to perform self-care activities, medication adherence and quality of life in diabetes patients.
3. Receiving self-care education through mobile diabetes application text messaging is more cost effective than the standard care.

**Significance and Innovation of Research:**

This project will provide better health for regional Queensland communities though excellent and innovative educational intervention that is networked, collaborative and engaged locally with communities. The educational and healthcare delivery model is intended to be patient-centred and community-focused, utilising best practice and emerging educational methods and persuasive technologies to maximise improved health outcomes. The strength of this research include its targeted approach at meeting priority community needs and its connection to clinical practice to foster better health outcomes and quality of life for diabetic patients in tropical and regional Northern Queensland.

The results of this study will promote diabetes patients’ self-care management via consistent and effective education, communication and care in order to reduce their risk of developing complications. Furthermore, it is hoped that the outcome of this study will help to reduce the huge burden of diabetes on the health system by providing diabetics with a better quality of life as well as decreased patient lost years of life and health care cost. Ultimately the outcomes will contribute to meeting the goal of the Australia National Diabetes Strategy 2016 – 2020; which is to “reduce the occurrence of diabetes-related complications and improve the quality of life among people with diabetes” (AGDH 2015).

**RESEARCH PLAN AND METHOD**

**Study sites:** Diabetes Clinics of the Townsville Teaching Hospital (TTH) and Community Health Service, Kirwan.

**Study design:** This will be a randomized controlled intervention trial (RCT) comparing standard-of-care alone with a standard-of-care plus a mobile diabetes app based text messaging educational intervention for 12 months. RCT trial allows for rigorous research to determine cause-effect relationship between intervention and outcomes and ensure that there are no systemic differences between both groups which may affect results (Sibbald & Roland, 1998).

**Study population**: Patients with type 1 and type 2 diabetes attending the diabetes clinics at the Townsville Teaching Hospital (TTH) and Community Health Service, Kirwan.

***Inclusion criteria: Diagnosed with type 1 or 2 diabetes,***  using insulin therapy with or without oral antidiabetic agents, ≥ 18 years old, living in North Queensland, using a smart phone, willing to return for follow up at 4, 8 and 12 months.

***Exclusion criteria:*** Type 1 and 2 diabetes patients’ with major diabetes complications (such as kidney failure and lower limb amputation), pregnancy and psychiatric co-morbidity.

**Intervention*:*** This will be a mobile phone-based diabetes app text messages on diabetes self-care. The app was specifically developed for this study based on needs analysis of diabetes patients in terms of perceived functionalities an app should entail and how best diabetes patients can be constantly motivated to perform the daily self-care essential for diabetes management. The use of this approach for development of the proposed intervention was based on these facts. Firstly, previous studies revealed that despite the investments that has gone into the technological process of diabetes app development and its proven effectiveness; optimal use has been limited by high attrition rate (Catherine et al., 2014). This low level of acceptance has been attributed to insufficient consideration of its usability requirements by users (Demidowich, Lu, Tamler, & Bloomgarden, 2012; Mallenius, Rossi, & Tuunaunen, 2007). User-centred development processes that engages users’ in the conceptualisation, design and production of technologically advanced tools will increase the appeal and functionality of such devices (Buller et al., 2013; LeRouge, Ma, Sneha, & Tolle, 2013). Additionally, it has been reported that health education is an under represented feature in majority of the available diabetes mobile apps in the market (Chomutare et al., 2011). These highlights the essence of using a mobile diabetes app intervention that was developed based on needs analysis of diabetes patients. This may provide an effective approach to increasing motivation and compliance to self-care education, which will ultimately improve health outcomes, quality of life and prevent or delay the onset of diabetes complications.

The major functionality of the app includes blood glucose log, exercise management, food calorie tracker and task reminders (e.g reminder for medication intake and clinic appointments). Once app is installed on mobile phone, there will be a generation of computed algorithm feedback of text messages in response to patients’ imputed data on some required parameters for self-management such as blood glucose levels, diet and physical exercise. This is necessary to personalise the intervention to match individual needs and characteristics. General messages will also be provided in addition to the personalised automated text messages. All messages will deliver information on the seven essential self-care behaviours in people with diabetes which predict good outcomes namely; lifestyle modifications (healthy eating and improved physical activity), monitoring of blood sugar, compliance with medications, good problem-solving skills, healthy coping skills, and risk-reduction behaviours (such as smoking caseation and reduction in alcohol intake). The proposed duration of intervention is 12 months; this time span is necessary to examine short and medium term impacts of the intervention on blood glucose, HbA1c, ACR, lipid and BP levels and anthropometrics and on the development of complications.

**Sample size determination:** A prior power analyses was computed using G-power to determine the sample size. The power analysis indicated that 150 participants will be needed to have 80% power for detecting differences in the outcomes of interest between control and intervention groups with a statistical criterion level of 0.05. The sample size has taken into account a drop out of 10%. Computer-generated random numbers will be used to randomize subjects into the two groups and will provide 1:1 of participants in each stratum.

**Participant recruitment strategy**

1. A trial nurse who is familiar with the clinic records of type 1 and 2 diabetes patients attending the study sites will screen for eligible potential participants, in collaboration with the booking officer to obtain the mailing address. A detailed information sheet on the conduct of the study will be mailed to eligible participants 2 weeks prior to their clinic appointments. This is to give them a prior information about the study and allow eligible participants ample time to make decision on whether to participate or not.

The information sheet assures the potential participants of their right to participate or decline participation in the study without any negative impact on their relationship with the Townsville Teaching Hospital or Community Health Services, Kirwan. Additionally, the information sheet will include detailed description of the study protocols, benefits, confidentiality and data security procedures. Contact details of the principal investigator will also be provided in case prospective participants require some participation about the study.

1. On the clinic days, the principal investigator will provide eligible participants with verbal information about the study and also offer them time to ask any questions they may have.
2. Eligible and interested participants will then be offered the informed consent form to sign.

**Data Collection***:*

*Aim 1:*

To ensure this aim is attained, there will be a retrospective check of all respondents’ hospital clinical records at the end of the intervention. Relevant clinical record will include Plasma Glucose, blood pressure, lipid levels and glycosylated haemoglobin (HbA1c), urine albumin/creatinine ratio (ACR), weight, height, waist circumference and medication history, events of emergency hospital visits for the duration they were in the study.

*Aim 2*: Collection of data to achieve this aim will be through administration of structured questionnaire to all participants at baseline and 12 months post intervention. Data will be gathered on socio-demographic and economic status, medical and family history of disease, knowledge of diabetes management, perception on ability to perform self-care, and medication adherence. Information on self-perceived quality of life would also be elucidated.

*Aim 3*: Data collection will capture both direct and indirect health care costs. Direct costs of implementing the intervention will be: cost of personnel, operating cost, materials and supplies, maintenance cost, utilities, capital costs, cost of hospital visits due to emergency (acute) complications as well as predicted long term health care cost incurred related to chronic complication development. Indirect health cost will entail transportation to clinic appointments due to emergency complication and loss of productivity from being absent from work or usual activity due to such complication. Cost for standard care will also be elucidated for comparative cost analysis.

**Data Analysis:** All data collected will be imported into SPSS v23 (IBM, USA) for analysis.

Aim 1: The primary clinical outcome are frequency and degree of hypoglycaemia, hyperglycaemia, HbA1c, lipids, ACR, FPG and BP levels, and anthropometry. These parameters will be analysed as continuous variables and dichotomised variables, and the mean values compared between the exposed and control groups using Bonferroni pair-wise comparison test from multivariate analysis. Furthermore, adjusted group comparisons using multilinear and logistic regressions will be performed. Goodness of fit model will be checked using graphical techniques and Hosmer-Lemeshow test will be performed for binary outcomes. The extent to which improvement in Fasting Plasma Glucose, HbA1c,  lipids, BP and ACR levels mediate reduction in complication development will be assessed by fitting two linear/logistic regression models, one including only group characteristics (such as age, sex, baseline HbA1c level) and the others incorporating both group effect and the intervention as covariates. The degree to which group characteristics are abated after adding the intervention into the model provides an indication of the mediating effect (Lin, Fleming, & De Gruttola, 1997).

***Aim 2: Knowledge and behavioural change analysis:*** Knowledge of diabetes management, medication intake and adherence, self-care practices, perceived ability to perform self-care and quality of life will be reported using descriptive statistics. Any changes in these parameters and socio-demographics will be accessed using Multivariate Analysis of Variance (MANOVA) while Pearson Correlation Coefficient will be utilized to assess the strength of the relationship between the continuous variables.

***Aim 3: Cost-effectiveness*** will be expressed as an Incremental Cost-Effectiveness Ratio (ICER) and calculated as incremental costs divided by incremental effects. Results will be presented in cost-effectiveness planes and cost-effectiveness acceptability curves (CEACs). Prospective cost-savings from use of the intervention in rural areas will be analysed using a one-way sensitivity to test the robustness of findings in net savings. Savings in this model will be attributed to: (a) avoiding travel by the patients and escorts to a tertiary centre due to emergency complication (b) avoiding overnight accommodation for patients and escorts in Townsville. Savings from avoiding travel by patients to a tertiary centre will be calculated by multiplying return travel cost for two people (the patient and one escort) by the number of consultations as determined and fully reimbursed by the Queensland Health Patient Subsidy Scheme (PTSS).

***Cost Effectiveness Analysis*:**

* Assign monetary value to tangible costs
	+ physical resources (hardware & software)
	+ human resources (training)
	+ Patient health service emergency use from trial entry to 1 year follow up.
* Assign monetary value to intangible costs
	+ cost of setting up process and developing assessment items
	+ cost of adjusting established routine procedures
* Outcomes
	+ changes in HbA1c, BP, lipid, ACR levels
	+ effect on quality of life (measured by AQoL8D survey instrument)
	+ Predict Quality of life years gains (QALY’s) through impact of changes in clinical outcomes on future rates of chronic complication development
* Compare costs and benefits for intervention and control groups.

**Data Management**

* Data collected on hard copy forms such as questionnaires will be entered into password protected electronic spread sheets on a password-protected personal drive of the principal investigator.
* Electronic data will utilise participants’ assigned three digit identification numbers only, and will contain no personal details of participants.
* Computer and hard drive containing electronic data will be backed up. James Cook University’s personal drives undergo automatic daily back-ups, which will update and protect all data collected during the study.
* Hard copy documents will be securely stored in a locked filing cabinet in the office of the principal investigator and destroyed after 5 years.
* Electronic data will retained at the college of the principal investigator and stored for at least 15 years as required by the Australian Code for the Responsible conduct of research.
* The disposal of data collection instruments will be in accordance with James Cook University’s record disposal procedure; which follows the Queensland State Archives Health Sector Retention and Disposal Schedule. Papers will be shredded prior to disposal while electronic data will be deleted from the computer.

**Ethical and Safety Consideration**

***Confidentiality and Anonymity of data will be guided through;***

* Method of protocol design ensures that participants’ information is re-identified with an assigned identification number.
* Publications and reports from the study will be in an aggregated format and participants will not be in any way identified with it
* Participation in the study will be totally voluntary

***Avoidance of harm***

* There are no anticipated risk or adverse effects associated with participation in this study because all study participants will continue with their usual standard of clinical care.

**Duration of Project**

Anticipated start date: 1st October 2017

Anticipated finish date: 1st December 2021

**Project Time Line**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Activities** | 2017 | 2018 | 2019 | 2020 | 2021 |
|  | 6 | 12 | 18 | 24 | 30 | 36 | 42 | 48 |
| Recruitment/ Pre-intervention data collection |   |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| Intervention |   |  |  |  |  |
|  |   |   |  |  |  |  |  |  |  |
| Post intervention-data collection |   |   |   |  |  |
|  |   |   |   |  |  |  |  |  |  |
| Data Analysis |   |   |   |
|  |   |   |   |  |  |  |  |  |  |
| Manuscript writing and Publications |  |  |   |

**Dissemination of Project Findings**

The knowledge gained from this study will be communicated to the research community through presentations at scientific conferences, and publications in peer reviewed journals.

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