“THE IMPACT OF A MOBILE APPLICATIONS FOR KIDNEY TRANSPLANT PATIENTS ON IMPROVED MEDICATION ADHERENCE, BLOOD PRESSURE CONTROL, AND PATIENT ENGAGEMENT”.

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Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics.

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Abstract

The purpose of this study was to evaluate the effectiveness of mobile app used for renal transplant patients on improved medication adherence, blood pressure control and patient engagement. Secondary outcome was to understand patient experience using the app. The study was conducted in the Beaumont Hospital Transplant Clinic.

The researcher used a retrospective quantitative study with matched control group to meet the objectives of the study. There were total 25 patients participate in the intervention group. All the selected patients in the intervention group were downloaded the ‘patientmpower’ app and provided a Bluetooth enabled blood pressure monitor. They were expected to use the app for medication reminder, Home BP monitor and tracking their lab values. There were 30 patients in control group who were matched with app users in terms of age and gender.

The outcome measures include IS medication adherence, blood pressure control and patient engagement. The anonymised patient clinical data were collected from renal clinical management system, eMed. Further, a survey conducted in the app users to understand patients experience using the app. The study duration was three months from March 2017 to May 2017.

The result of the study shows app users have significant improvement in the Immunosuppressant medication adherence with higher number of participants in therapeutic range. The app users had less variability in Tacrolimus level as compared to control group. However, there were no significant improvement in blood pressure control and patient engagement in app users. Overall, positive

response from the survey and device usage data show the app is easy to use and accepted by patients to support the post-transplant care.

The result suggests that the app can improve medication adherence in renal transplant patients. However, in the aspects of blood pressure control and patient engagement the app users are similar to control group. This study also pointed to the importance of healthcare provider's communication and feedback via app to improve the clinical outcome and sustain users. As this is the first study of this kind to evaluate the outcome of the app in kidney transplant patients a prospective study with large sample size will be needed.

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Abbreviations

ACO	Accountable Care Organization
BP	Blood Pressure
Cr	Creatinine
DBP	Diastolic Blood Pressure
eHealth	Electronic Health
ESRD	End Stage Renal Disease
EU	European Union
HTN	Hypertension
IKA	Irish Kidney Association
IS	Immunosuppressant
JNC	Joint National Committee
KIDGO	Kidney Disease Improvement Global Outcome
KDCPMS	Kidney Disease Clinical Patient Management System
mHealth	Mobile Health
RCT	Randomized Control Trial
RFID	Radio Frequency Identification
SBP	Systolic Blood Pressure
WHO	Word Health Organization

Glossary of term

Term	Description
End stage renal disease	End stage Renal disease is the last stage of chronic Kidney Disease presented by loss of renal function required dialysis or kidney transplant to survive (Levey and Coresh, 2012).
Graft Kidney	Transplanted Kidney generally termed graft kidney, or graft
Graft rejection	Failure of transplanted kidney.
Adherence	The extent to which a person's behavior-taking medication, following diet and or executing life style changes correspondence with agreed recommendation from health care providers"(Sabatae' E, 2003)
Non Adherence	"Deviation from the prescribed medication regimen sufficient to adversely influence the regimen's intended effect"(Fine *et al.*, 2009).
Immunosuppressant medication	These are the medication that diminish the body's ability to reject a transplant organ.
Hypertension	BP higher than 140/90mmHg (Wadei and Textor, 2010)

Blood pressure Control	Maintain blood pressure within the desired target range
Smartphone	Smartphone is an internet capable mobile phone
Apps	Apps are software programme specifically designed to run on smartphone (Wang *et al.*, 2013).
Self-management apps	Software programme designed on smart phones or tablet aim to support self –management skill to manage the key disease marker and symptoms.
mHealth Technology	Medical and public health practice supported by mobile devices such as smartphone, tablet, patient monitoring devices, or personal digital assistant (World Health Organization, 2011).
EHR	A computerized system for patient health data storage and retrieval. It allow reporting of data related to patient health information and facilitate electronic communication between providers, patient support and administrative support (Navaneethan *et al.*, 2013).
Patient registries	Disease specific patient archives for aggregation patient data for quality improvement and clinical research (Navaneethan *et al.*, 2013).

Patient portal	Patient portal are secure health information system that provides patient access to personal health record and typically allow functionality such as secure messaging with providers, appointment schedule, prescription refill and self-management programme (Otte-Trojel *et al.*, 2016).
eMed*Renal*	eMed*Renal* is software designed for integrated renal patient management. Implemented in Ireland renal centres under the HSE project, Kidney Disease Clinical Patient Management System (KDCPMSProject, 2010).
Therapeutic Range	Drug dosage or serum concentration usually expected to achieve desired therapeutic effects.
Tacrolimus	A immunosuppressant drugs commonly used for transplant patients to prevent rejection of transplant organ.

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Chapter 1 **INTRODUCTION**

This chapter introduce the research. It first provides brief outline about the study, background information about kidney transplantation in Ireland and the problems that occur in terms of post-kidney transplant management and patient engagement. The importance of mobile health technology for post-kidney transplant patients' self-management is explored and provide the motivation for this study. This chapter also includes a brief outline of the main aspects of the study, which are the research question, study design, study setting, and an overview of each chapter.

1.1 Kidney Transplant in Ireland

National Kidney Transplant Services in Ireland was initiated with the first diseased donor kidney transplant in Ireland in 1964. Initially, transplant activities grew slowly in Ireland, with approximately 20 transplants per year in the first decade. Gradually, activities grew and matured until they reached an average of 140 transplants per year, and the number currently in the kidney transplant waiting pool is 568. Over 50 years of National Kidney Transplant Services, 4500 kidney transplants have been performed in Ireland, and over 2000 patients are currently living with and enjoying the benefits of a functioning kidney transplant (National Kidney Transplant Services, 2016). According to National Kidney Transplant annual report (2016) the overall five year graft survival rate in Ireland is 89%, which is highest among all European countries and the world. However, in Ireland 10% of rejection occurred in the first year of the post-transplant period.

Patients who receive successful transplants without any complications are discharged home within two weeks. Afterward, the patient is followed up in the

renal clinic. At each clinic visit, the patient is routinely monitored in terms of BP, heart rate, temperature, weight, and lab analysis, including full blood count, renal profile, and Immunosuppressant (IS) level. Post-transplant patients attend the renal clinic once weekly for the first three weeks and every two weeks for following three weeks; then, based on their vital signs and lab values, the number of clinic visits gradually decreases. Three months after the transplant, the patient is seen in the clinic every two months, and after six months, every three months. However, the frequency of clinic visits also depends on patient's lab values and symptoms. Evidence from the studies showed non-adherence and poor patient engagement increase as clinic visits decrease (Weng *et al.*, 2013), (Loghman-adham, 2015). Thus, the first year of the post-transplant period demonstrates increasing non-adherence behaviour and poor patient engagement.

1.2 Background

Although kidney transplantation offers better outcomes for patients with end-stage renal disease, patients must adhere to complex self-management regimens. Immunosuppressant non-adherence is the leading cause of transplant failure (Butler *et al.*, 2004). A systematic review in ten cohort studies, a median of 36.4% transplant failure primary related immunosuppressant nonadherence. Additionally, systematic review in ten cross-sectional studies showed a median 26.4% renal transplant patients are non-adherent to Immunosuppressant medication (Butler *et al.*, 2004). The lack of patient engagement and poor blood pressure control undermine transplantation, which has a negative impact on quality of life, morbidity, and mortality. Medical resources have been devoted in an effort to find a solution such as medication therapy management, electronic

pill monitoring, and home BP measurement to improve medication adherence, blood pressure control, and patient engagement (De Geest *et al.*, 2006). However, the costs associated with the maintenance of these efforts and direct patient care are increasing health care cost (Bryant *et.al*, 2013).

Despite many efforts, management of post-kidney transplant patients remains challenging. Medication adherence, blood pressure control, and patient engagement are always varying and suspect. Furthermore, poor communication between patients and healthcare providers and decreasing numbers of clinic visits six months after post-transplant can exacerbate these issues. The end result of these clinical consequences are increasing graft failures, returns to dialysis, utilization of inpatient treatments, emergency room visits, and increasing readmissions.

Understanding today's lack of support for patient self-management in chronic conditions and ubiquitous smartphones and other computing platforms in daily life, numerous device manufacturers have developed biomedical sensors for patients to monitor their physiological metrics. These sensors often utilize smartphones to display information and transmit data to storage or analytics. The World Health Organization (WHO) defines mHealth technology '*as the medical and public health practice supported by mobile device such as mobile phones, patient monitoring devices, personal digital assistant and other wireless devices*'(World Health Organization, 2011). Individuals appropriately using this technology can monitor their conditions in real world settings and obtain more personalized and engaged management of their diseases. Despite the promising results of mHealth apps (Kardas, *et.al,* 2016), (Triantafyllidis *et al.*, 2015),

(Williams *et al.*, 2014), the current literature supporting the use of mHealth technology implementation and the evaluation of such technology is limited.

1.3 Motivation of the study

The researcher is a renal nurse working in the one of the university hospitals in Dublin. Dealing with daily issues such as lack of adherence and knowledge about complex post-transplant medication regimens and poor blood pressure control, patients are unable track their clinical data, such as blood results and blood pressure measurements. Additionally, patients may forget to bring their post-transplant diaries, called “renal passports” (where the health care providers normally record patients’ blood results, blood pressure measurements, and other clinical data at their clinical visits), which makes it difficult for healthcare providers to update clinical data in a timely manner and to track clinical data over time.

These challenges highlight the need for a mobile app to empower eligible patients in their post-kidney transplant care and to improve medication adherence, blood pressure control, and patient engagement in post-transplant. Based on these needs, the National Kidney Transplant Centre in Ireland has introduced a mobile application called the ‘patientMpower’ app. It can assist in monitoring blood pressure, reminding, patients about medication and appointments, and monitor daily activity steps. Any transplant patient who interested to use the app to support their post-transplant self-management can download the app from any App store. Additionally a Bluetooth enabled blood pressure monitor is given to all patients. The screen shot of the app presented in Appendix A. Key features of the app are described below (www.patientMpower.com).

a) Export of clinic data from eMED(Renal system) to the app via bar code scanning technology.
b) Offline storage;
c) Traffic signal alert of threshold value based on guideline;
d) Encrypted database and support;
e) Personalized threshold for patients;
f) Patient activity monitor;
g) Patient reminders regarding medication and appointments;
h) Home blood pressure monitoring and real-time recording via Bluetooth-enabled BP monitor;
i) Graphic display of all clinical data over time.

Post Transplanted patients have been offered this app since 2016.The goal of this research is to evaluate the whether its use improve key metrics such as medication adherence, blood pressure control and patient engagement. By evaluating this app researcher interested to introduce the app in researcher's workplace and also to initiate development of the app to support the patient's self-management with chronic kidney disease and long term intermittent dialysis.

1.4 Research Question and Study Aims

This research study based on the mobile app will address the following research question:

- Does the use of 'patientMpower' app improve outcomes for renal transplant patients?

The sub-questions are:

- Does use of the app improve medication adherence in renal transplant patients?
- Does the app generate better control of blood pressure in transplant patients?
- Does use of the mobile app enhance patient engagement in post-transplant care?

The aims of this study are to:

1. To measure the IS medication adherence in transplant patients using the app as compared to the control group;
2. To determine the level of blood pressure control in transplant patients using the app as compared to the control group;
3. To identify levels of patient engagement in transplant patients using the app as compared to the control group;
4. To understand the patients' experience of by using the 'patientMpower' app.

1.5 Overview of the Research

This is a preliminary study to evaluate the patientMpower, as the number of patientMpower app users are too small so far to allow a full randomizied controlled trail (RCT) at this stage. The research question was addressed primarily by an intervention study using a matched historical control group to examine the effectiveness of the mobile app and a survey conducted among post-

transplant patients using the app to understand patient experience with using the app. This study also contributes to the evaluation of mHealth app technology.

First a literature review was conducted to establish the state of the art in the management of kidney transplant patients and the limitations of current solutions for that management. This literature review also extended to evidence of emerging mHealth technologies for supporting the management of chronic conditions and identifying the literature gap in studies regarding in the implementation and evaluation of mHealth technology.

1.6 Overview of the Dissertation

This dissertation is organized into six chapters. Chapter one is the introduction, which provides an overview of the research topic and its content. Furthermore, this chapter also provided background information and examines the significance of the study.

Chapter Two is an organized literature review of studies regarding the importance of medication adherence, blood pressure control, and patient engagement in kidney transplant care, as well as different measures to manage these factors and issues that arise with managing these factors. In addition, this chapter deals with evidence regarding emerging mHealth technology to support self-management and patient engagement in those with chronic conditions. It also identifies the literature gap regarding the evaluation of mHealth technologies.

Chapter Three describes the study site, sampling method, study participants, and data collection. In addition, it addresses a description of the methodology, the rationale behind the methodology, and the methodology's limitations.

Chapter Four explains the quantitative data analysis and the study findings. It also analyses the survey questionnaire results.

Chapter Five discusses the findings. The implications of the study and suggestions for future research in the area are also presented.

Chapter Six is the final chapter of the dissertation and includes the conclusion. This chapter also discusses the recommendations and limitations of the study. Additionally, it includes the researcher's reflections on the research process.

Chapter 2 **STATE OF THE ART**

2.1 Introduction

This chapter presents the literature on importance of kidney transplantation and the role of medication adherence, blood pressure control, and patient engagement in the context of kidney transplant and emerging mobile health (mHealth) technology. It also explains mobile health app in chronic disease self-management and also identify literature gap related to research topic.

The chapter starts by outlining the search criteria followed by importance of management of post kidney transplant and next sections 2.4, 2.5, and 2.6 provide information about main attributes such as medication adherence, blood pressure control and patient engagement related to kidney transplant. The last section of this chapter provide information on mobile health technology and its role to enhance these attributes.

2.2 Search Strategy

The literature search covers from 2002 to 2017.The data bases used for literature search are ACM digital library, Science Direct, Scopus, PubMed and Google scholar. The search includes all type of studies including qualitative, quantitative, systematic review and integrative literature review to understand three key issues such medication adherence, blood pressure control and patient engagement and limitations of current post kidney transplant management. The search also extend to understand the importance of mHealth technologies (mobile apps), and its challenges and implementation and evaluation of mHealth technologies for the effective management of post kidney transplant and in other chronic conditions. However, the literature review revealed that there was limited evidence of

effective evaluation of mobile apps for the management of chronic conditions. The appropriate articles were also selected from citations and references from reviewed literature or articles. The total number of articles resulted from using the keywords and the number of articles used for review after removing the duplicate and not relevant to this study are given below Table 2.1.

Table 2. 1 Summary of articles identified during the literature search

Key words	Database (s)	Total Result	Total articles chosen after removing duplicate
Kidney transplant/medication adherence/Hypertension/patient engagement/ mobile health apps/ health technology	PubMed /Scopus/science direct/	o	Kidney transplant -5
Kidney transplant/medication adherence/blood pressure control/patient engagement	PubMed Science direct Scopus	18,68	IS medication adherence in renal transplant patients - 25
Kidney transplantation/ mHealth apps	PubMed/ Scopus/ACM	892	
Kidney transplant/patient engagement	PubMed/ Science Direct Scopus	9137	Hypertension in renal transplant -25
Kidney transplant/ Immunosuppressant medication adherence	PubMed/ Scopus	3435	
Kidney transplant/ hypertension	PubMed 73557 Scopus - 9009	82.566	Patient engagement-15
mHeatlh apps /chronic conditions	PubMed- 16542 Scopus 1295	17837	mHealth Technology in chronic disease management - 20
mHealth app/medication adherence/Hypertension/patient engagement	PubMed/ Scopus	1,721	

2.3 Importance of Kidney transplantation

A kidney transplant is a successful treatment option for eligible patients with End Stage Renal Disease which improves the quality of life and frees the patient from expensive and time consuming dialysis and its complications. Although medical and surgical care are advanced for transplant recipient, the considerable improvements in long-term graft survival have not been achieved yet. The current 3-year graft survival rate around the world is only 81% and graft half- life is only 9years (McGillicuddy *et al.*, 2015). Key patient related factors which negatively affect the long-term graft survival are lack medication adherence and poor control of comorbid medical conditions and poor patient engagement with post-transplant care. Non-adherence to prescribed medical regimens have been identified as a most significant risk factor for graft rejection, morbidity and mortality. Even in the absence of rejection, non-adherent result a more fast loss of renal function over time (McGillicuddy *et al.*, 2015). Moreover, growing transplant expenses, long waiting list for transplant candidate, availability of limited donors are few of the social and clinical imperatives for maximizing the success of a kidney that is transplanted (Aberger *et al.*, 2014).

Immunosuppressant medication adherence, blood pressure control, and patient engagement are the key important attributes for long-term graft and patient survival. These are the three primary goals of the ‘patientMpower’ app and hence the factors being evaluated by this research. The following section will provide a detailed explanation of these characteristics in general and in the context of the kidney transplant.

2.4 Medication Adherence

Adherence to medication and medical regimen is a major factor for a wide range of chronic and complex medical conditions. Medication adherence by patient involves three action (1) Initiation of therapy which means filling the prescription and taking the medications, (2) Implementation (Correspondence with prescribed regimen) (3) Persistent with recommended dosing (Breckenridge *et al.*, 2017). Nonadherence to medication is the leading cause of morbidity and mortality in many conditions (Lieber, Helcer *et al.,* 2015).

2.4.1 Definition of Non adherence

Non-adherence is defined as "*the extent to which patient's behavior in medication taking following a diet or executing a life style change diverges from agreed health care providers recommendation* " (Berben *et al.*, 2015).

The poor adherence or non-adherence to treatment adversely affects the patient's physical and psychological condition, reduces their quality of life, intensifies the likelihood in developing drug resistance, wastes resources, and also compromises the efforts of the health system to improve the health of the population (Crawford *et al.*, 2015). Thus, measuring adherence is imperative to determine the magnitude of the problem and to identify the contributing factors.

2.4.2 Immunosuppressant medication adherence in kidney transplant

Following renal transplantation, adherence to immunosuppressant therapy (IS) is essential to optimize long-term graft survival (Doyle *et al.*, 2016). Immunosuppressant nonadherence is a leading cause of graft failure in kidney transplant patients (Lieber, Helcer *et al.*, 2015). A systematic review on the

impact of IS medication adherence on the kidney transplant patient indicates that a 36% graft rejection rate is associated with IST nonadherence and rejection rate in nonadherence patient is seven-fold higher than the adherent patient (Butler *et al.*, 2004). Furthermore, this review also highlighted the requirement of an effective interventions to improve medication adherence for long term graft survival in kidney transplant patients (Butler *et al.*, 2004). Another study suggests that even slight deviation from immunosuppressant regimen (3-5%) can contribute to poor clinical outcome (Takemoto *et al.*, 2007).

Additionally, a low adherence rate also increases healthcare utilization such as hospitalization, re-admissions and emergency room visits (Chisholm-Burns *et al.*, 2013). Pinsky *et al.*(2009)'s study on the economic cost and transplant outcome associated with non-compliance on IS, found that insistent low adherence in immunosuppressant is related to increased medication cost in the individual as compared with high adherence.

2.4.3 Risk factors for adherence

The factors associated with non-adherence among patients are varying, and can be divided into unintentional and intentional. Unintentional nonadherence results when a patient intends to take medications as prescribed but fails to do so due to forgetfulness. Intentional nonadherence occurs when a patient consciously makes the decision not to take the medications (Doyle *et al.*, 2016).

Furthermore, non-adherence is a very dense issue which includes a number of modifiable and non-modifiable factors. The modifiable factors include patient busy-ness, work related barriers, low self-efficacy, mental distress. Non-

modifiable factors associated with nonadherence include young age, long-time after transplant (Doyle *et al.*, 2016).

Based on the World Health Organization World Health Organization (2003) the risk factors for post-transplant nonadherence are divided into five groups which are:

1. Patient-related factors
2. Post-transplant related factors
3. Therapy-related factor
4. Healthcare related factor
5. Sociodemographic factors

- *Patient-related factors*

Patient's concepts, belief about therapy and medication is a significant threat to medication adherence behaviour. A transplant patient who thinks maintenance of transplant life is a burden and too risky as well as very seldom benefits from the transplant tends more to engage in nonadherence behaviour (Chisholm-Burns *et al.*, 2012) (Chisholm, 2002). Massey *et al.*, (2013) in their cohort study demonstrated patients' belief, the concept of disease and treatment have a significant role in adherence. Another study found that lower self-efficacy, not using pill box, being male, young age are the primary risk factor associated with nonadherence (Denhaerynck *et al.*, 2007).

- *Post-transplant related factors*

Patient's nonadherence rate is inversely related to frequency of clinic visit. When the frequency of hospital visit decreases, the nonadherence rate increases. Patient adherence is high early after transplant, and it declines as the time elapse

(Obi *et al.*, 2013). A qualitative study on self-report adherence after kidney transplant, found a, high level of adherence (around 83%) in first six weeks post-transplant and same declined by 10%(73%) after six months of transplant (Massey *et al.*, 2013).

- *Therapy-related factors*

Fear of experiencing side-effects, complex medical regimen inconvenient to patient and lack of immediate clinical effect are the therapy related factors associated with nonadherence(Chisholm, 2002).

- *Healthcare related factors*

De Fátima Cruz de Morais *et al.*(2016) in their review found that lack of time for more efficient monitoring as well as the shortage of staff and lack of the instrument to access adherence impact medication adherence. Lack of patient involvement in clinical decision making and treatment plan makes patient believe that they have no control over or responsibility for the treatment outcome and tend to be more non-adherent to medication therapy. Chisholm (2002) maintains that it is the responsibility of healthcare providers to reinforce the patient recognition of benefits of adherence behaviour. Active patient participation when design therapy help to enhance the self-efficacy.(Chisholm, 2002).

- *Sociodemographic factors*

Low health literacy and poor sociodemographic factors can also result in nonadherence. De Fátima Cruz de Morais *et al.*, (2016) reported that young age population is at more risk of nonadherence. High social life and busy professional life are the common reason for non-adherence in young age. Similarly a

comparative study by Chisholm-Burns *et al.*, (2012) found that non-adherence is higher in younger group (18-29) as compared with older population group (46-64). The various studies of risk factors for non-adherence are summerised in Table 2.1. So mHealth intervention such as mobile app which provide reminders and are easy to use by young people and support behavioural change can be a solution for non-adherence. Section 2.7 will elaborate about mHealth technology.

Table 2.2 Risk factors for non-adherence

Therapy related	Healthcare relate	Socio-demographics	Pearson related
Complex medical regimen Fear of side-effects Lack of immediate effect	Lack of patient involvement in disease process	Busy life High social life Poor social support	Forgetfulness, young age Distraction Intentionally not taking

2.4.4 Monitoring and measuring of medication adherence

Measuring medication adherence is always a difficult task, and each method has limitations. Although there is no golden standard for measuring medication adherence, the methods divide into two groups, direct methods, and indirect methods (Hansen, *et al*, 2007).

Direct Method

The direct methods of measuring adherence include observing medication intake and drug metabolite level. Even though the direct methods are more accurate and relevant measures of IS medication there are some shortcomings of these methods such as it is often expensive and inconvenient (Hansen *et al*, 2007) . Another main limitation of testing metabolite level is that patient may increase their medication dose before the measuring which may cause a false positive result of medication adherence in patients (white coat effect) (Hansen *et al*,

2007). Furthermore, laboratory errors such as the timing of the sample and accuracy of the assay are also the possible limitation of direct serum tests (Chisholm, 2002).

Indirect Method

Indirect ways of measuring adherence include patient self-report, prescription refill rate, and electronic monitoring. However, each of these methods has limitations and also they are not adequately validated (Lieber, Helcer *et al.*, 2015).

Self-report

Attaining a good medication history from the patient is an indirect measure of medication adherence. The main advantages of obtaining patient self-report medication history is that it is inexpensive and it gives awareness to the patient about the health provider's care and their attitude towards the patient. These interview can also reveal the fact that the patient is not adhering to their medication (Chisholm, 2002).

However, the information obtained from the patient may be inaccurate. Most of the time patient may not reveal the medication taking behaviour clearly or not admit the misbehavior (Chisholm, 2002)

Electronic monitoring

Numerous studies reported that electronic measures are the golden standard and most accurate measurement of IS medication adherence(Butler *et al.*, 2004), (Takemoto *et al.*, 2007), (Fine *et al.*, 2009), (Russell *et al.*, 2013). The electronic measures include electronic pill bottle cap and ingestible electronic sensor.

Electronic Pill monitoring which records when prescription bottles are opened and measures the accurate medication adherence. However it will only indicate medication source and not indicate actual medication intake (Hansen *et al.*, 2007).

Another electronic monitoring measure is the ingestion of RFID microchips. This device activates upon ingestion and send signals to a patch on the patient and also to an adherence database (Eisenberger *et al.*, 2013). A study of 20 transplant patients found that the use of RFID chips coated in Immunosuppressant is 99.4% effective to detected the ingestion of drug as prescribed (Eisenberger *et al.*, 2013).

Although electronic monitoring such as electronic pill bottle, electric sensors are reliable and valid methods for monitoring drug adherence, it is not easily available as well as expensive to use (Doyle *et al.*, 2016). Moreover, non-adherent patients by definition may not accept this technique(Hansen et al., 2007).See table 2.3

Furthermore, a number of studies of medication adherence in kidney transplantation found that a combination of measurements such as electronic pill monitoring, drug assay, patient self-report and physician's collateral report are better for the diagnostic accuracy of medication adherence (Chisholm, 2002), (Schmid-Mohler *et al.*, 2010), (Griva *et al.*, 2012), (Lieber *et al.*, 2015) (Doyle *et al.*, 2016).

Table 2.3 Methods of measuring medication adherence

Method	Advantage	Disadvantage
Direct Method Direct observation Serum metabolite level	Accurate Objective methods	Impractical for routine Expensive, white coat effects
Indirect method Patient self-report Prescription refill rate Electronic monitor	Easy to perform	Data can easily manipulated Required pharmacy system Expensive

2.4.5 Interventions for improving medication adherence

A wide range of different interventions are available to improve medication adherence. These interventions fall into two broad self-management strategies. 1. Educational interventions and 2.Behavioural interventions (Hansen *et al.*, 2007). Studies show a combination of interventions are more effective for improving medication adherence (De Bleser *et al.*, 2009). See table 2.4

Table 2.4 Interventions for medication adherence

Behavioral	Educational
Communication and counselling	Written and oral education
Simplify medication regimen	Health education programme
Motivation Interview	Follow-up, Answering the queries
Technology assisted monitoring	

Educational interventions

Educational interventions include providing written and oral education about chronic condition, benefits of treatment, importance of medication adherence and complications of non-adherence. Health education program about self-

management in post-transplant care help to promote medication adherence in transplant patients (Hansen *et al*., 2007).

Behavioural interventions

Behavioural contracts intervention includes identifying target behaviours and factors associated with the particular behaviour and then proposing strategies to improve behaviour to reach the desired outcome (Chisholm-Burns *et al.*, 2013). Behavioural interventions enhance the development of self-efficacy in renal transplant patients. When self-efficacy increases, patients are more motivated and capable to perform adherence behaviour (Chisholm-Burns *et al.*, 2013). In regards to behavioural interventions, the health care providers adjust the therapy according to patients need and preference to achieve highest adherence rate (Hansen *et al.*, 2007),(Chisholm-Burns *et al.*, 2013). These methods include:

- Communication and counselling such as investigating patient choice, automated phone call, follow up, family and social support, computer assisted monitoring, motivational interview (de Fátima Cruz de Morais *et al* 2016).
- Improve conveniences such as simplifing medication regimen, reducing the frequency and dose, and medication management services such as medication review, medication related action plan and follow-up will increase medication taking behaviour in transplant patients (Chisholm-Burns *et al.*, 2016).
- Providing reminder, special reminder package, appointment and prescription refill reminders, etc (de Fátima Cruz de Morais *et al* 2016).

A randomized controlled study by Chisholm-Burns *et al.*,(2013) and a crossectional study done by same authors in 2016 indicate that behaviour interventions such as pharmacy refill record, pharmacy linked medication management services improve medication adherence and reduce the health care utilization in renal transplant patients (Chisholm-Burns *et al*.,2016). Evidence from many studies proved that behavioural interventions are effective, but sustaining emotional and behavioural change over time is difficult (de Fátima Cruz de Morais *et al.*, 2016),(Lieber *et al*., 2015).

Furthermore, a systematic review and meta-analysis of interventions to improve medication adherence in solid organ transplant recipients indicates, out of 12 interventions identified and reviewed, not any one of intervention demonstrated to be superior for enhancing medication adherence. The study concluded that a combination of interventions in a team approach is effective for improving of medication adherence (De Bleser *et al.*, 2009).

2.4.5 Mobile apps for medication adherence

Smartphone apps are a novel technology to support and monitor behavioural change which enhances medication adherence. Many medication apps are available in the app centers which can be easily downloaded free or for low cost. Apps enable to store health information and provide the reminders for medication. Some apps display adherence information and notify health providers when the patient misses the medication(McGillicuddy *et al.*, 2013). However, there is a lack of evidence in the literature that mobile app improves medication adherence and relevant clinical outcomes (Dayer *et al.*, 2013). Section 2.7 will give details about the use of mobile apps for medication adherence.

Same as IS medication adherence, blood pressure control is also another key important factor in kidney transplant patient for long-term graft survival and reducing cardiovascular morbidity. The next section will provide more detail about hypertension in renal transplants patients and challenges and interventions to achieve better blood pressure control.

2.5 Hypertension in kidney transplant patients

Hypertension is the one of the most important non-immunological factors predicting long-term graft survival (Kokado *et al,*. 1996). Furthermore, use of immunosuppressant drugs such as Tacrolimus and Calcitonin induce hypertension in 90% of post-Kidney Transplant patients (Kokado, *et al,*. 1996). Persistent long-term hypertension also amplifies cardiovascular risk in renal transplant patient which is 50 fold higher than the general population (Wadei and Textor, 2010).

An estimated 70-90% post-transplant individuals develop hypertension and take at least one antihypertensive medication to maintain blood pressure value (Thomas *et al*., 2013). In post-transplant patient, an elevated systolic blood pressure of 5mmHg can lead to graft loss and death (Aberger *et al.*, 2014). Another study showed that over four years post-transplant patients with controlled blood pressure value has significantly increased long-term graft survival (Midtvedt and Hartmann, 2002). Even though hypertension is a curable risk factor evidence from the studies indicate that arterial hypertension is poorly controlled in renal transplant patients (Wadei and Textor, 2010). A retrospective cohort study of 1666 renal transplant patients found that only 55% patients had Systolic BP less than 140mmHg one year post transplant (Kasiske *et al.*, 2004).

2.5.1 Definition of post-transplant hypertension

According to seventh report of Joint National Committee, Hypertension is define as blood pressure is greater than 140/90 mmHg and is treated by any antihypertensive medication(James *et al.*, 2014),(Mangray and Vella, 2011). Based on KIDGO guideline target BP in renal transplant patients are less than 130/80 mmHg (National Kidney Foundation, 2012)

2.5.2 Interventions to achieve blood pressure control

A study reported that inadequate blood pressure control noticed when only clinic blood pressure is used as the only method of measurement and hypertensive dose adjustment (Agena *et al.*, 2011). There are number of intervention has been in place to achieve better blood pressure control in transplant patients. The following interventions are given below.

a).Pharmacy control medication therapy management

In pharmacy control medication therapy pharmacist is monitoring the medication adherence by reminder phone call, patient counselling, follow-up calls, and patient's reminder for prescription refill time. Studies showed that MTM therapy is associated with substantial improvement in blood pressure control, increase patient satisfaction, reduced the adverse reaction and decreased the health care utilization (Migliozzi *et al.*, 2015).

b).Home blood pressure monitoring

With the extensive availability of electronic blood pressure monitors, it is easy to monitor and evaluate blood pressure at home which results in better adherence to antihypertensive medication, and also easy to identify masked hypertension.

A systematic review and meta-analysis of 37 studies of home blood pressure monitoring to overcome therapeutic inertia and better blood pressure indicate that home blood pressure monitoring patients have 95% better control of blood pressure than the patients monitoring blood pressure at clinic only. Home blood pressure monitoring also resulted in frequent reduction in antihypertensive medication and less therapeutic inertia (Agarwal *et al.*, 2011).

C).Technology based hypertension interventions

I. *eHealth intervention*.

eHealth tools promise to monitor patient remotely patient for chronic conditions (Mancia and Parati, 2011). Persistent blood pressure control has been reported in combined telemonitoring and pharmacy management (Weber, 2010).

A telehealth system was developed and implemented in a renal transplant clinic with the aim of improving blood pressure control in post renal transplant patients (Aberger *et al.*, 2014). Patients were given electronic upload able blood pressure monitors, and were also taught how to upload and send the reading to the clinic from home computer. Total, participants recruited was 66 of which 75% monitored once daily and 69% achieved minimum six reading to achieve average blood pressure. After 30 days of enrolment, the average blood pressures were found to be significantly low. The early result of this telehealth was promising to the management of blood pressure and better patient engagement (Aberger *et al.*, 2014)

II. mHealth interventions

Emerging mHealth technologies, such as mobile apps, are supporting remote monitoring and provide strategies for effective communication between patient and providers (Sivakumaran and Earle, 2014). A three months randomized controlled study on mHealth intervention for the management of hypertension and medication adherence in kidney transplant patients shows improved medication adherence and 90-95% better control of blood pressure than usual care group (McGillicuddy *et al.*, 2015). The intervention provided in this program include electronic medication monitoring, blood pressure reminder, motivational and reinforcement messages for adherence, visual feedback for blood pressure control and adherence (McGillicuddy *et al.*, 2015).

Although the results of mHealth technologies are promising, they are still in the early stage and there is a lack of evidence for the sustainability of mHealth technology to improve behavioral change in long-term (Stellefson *et al.*, 2013), (McGillicuddy *et al.*, 2015), (Chandak and Joshi, 2015). Section 2.7 will give more detail about mHealth technology. Next section will discuss about patient engagement in chronic conditions, its challenges and strategies to improve patient engagement for the management of chronic conditions.

2.6 Patient engagement

With growing number of patients with chronic diseases and healthcare cost inflation, there is always demand for new strategies to achieve high quality, easily accessible and efficient healthcare system. This demand drives the introduction of patient-centred care model from the traditional physician-centred care model. There is an increasing evidence indicating that patients who are actively involved

in their health care management achieve better health outcomes and procure low costs (James, 2013). This growing concern motivates towards the "patient engagement" strategies to promote patients actively participating in their health and healthcare activity. Patient engagement means overall behavioral, cognitive and emotional presentation of an individual towards the disease condition and the management (Graffigna *et al.*, 2015). The "triple aim "of patient engagement strategies are to improve health outcome, better patient care, and lower costs (Bloomrosen and Sennett, 2015),(James, 2013).

To leverage patient engagement, the patient needs information about diagnosis, treatment, and self-management. Physician and organization plays a crucial role to create an environment that is more supportive of patient engagement. Patient engagement is not only related to completing the health care task but also the self-efficacy to engage in this task. Self-efficacy means an individual believes in their capacity to organize and execute action required to produce the desired result (Khuntia *et al.*, 2016). Individual with low self-efficacy may find difficult to manage their health due to stress and excessive burden (Khuntia *et al.*, 2016). Research findings show that when a patient is more empowered, they develop a greater sense of self-efficacy by seeking more information about the disease and treatment-related behaviour (Khuntia *et al.*, 2016).

2.6.1. Concept of patient engagement

There are two different terms mainly used in the concept of patient engagement which include "*patient activation"* and "*patient empowerment".*

Patient Activation

Patient activation refers to patients understanding of their active role in managing their own health and extend to which they accomplish that role (Hibbard and Mahoney, 2010). Patient and clinician relationship is also required for active engagement of patient (Jenerette and Mayer, 2016). Additionally, patient activation refers to engagement in healthy behaviour, adhere to guidelines and screening and effective communication (Kinney *et al.*, 2015). Patient activation is the key role of all strategies used for patient self-management in chronic disease which means personal knowledge, confidence and ability to take a self-management role in their own health and health care. Knowledgeable and skilled patients are more likely to engage in activities which promote their own their own self-care (Kinney *et al.*, 2015).

Patient Empowerment

Empowerment means having the knowledge, support, and skill along with mutual trust and autonomy*"* (Jenerette and Mayer, 2016). The empowered patient believes they can play an active role in managing their own health condition and to make a decision and experience greater control in health management. A sense of empowering could lead the patient to take the necessary steps for treatment and management (Jenerette and Mayer, 2016).

Regardless of these terms, an important aspect of all these definitions includes having the knowledge to foster the patient relationship and to communicate effectively for patient centred care (Jenerette and Mayer, 2016). Figure2.1 shows patient engagement concepts in patient-centered care model.

In short, a better engagement in the self-management improves health care outcome and reduces the cost (Jenerette and Mayer, 2016).

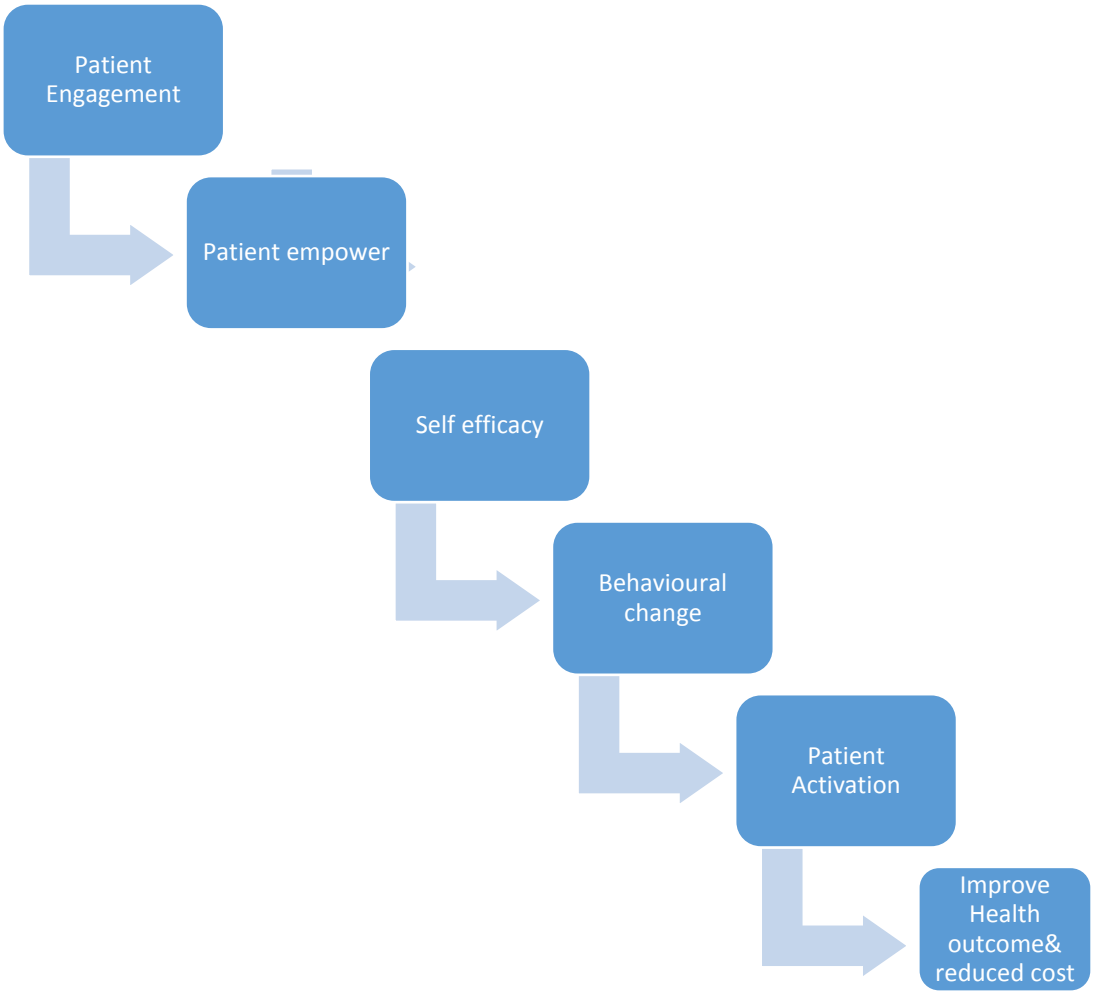


Figure 2.1 patient engagement concept

2.6.2 HealthCare Utilization and patient engagement

According to Williams, (2016) hospitalization account for 43% of an Accountable Care Organization's medical cost (ACO). With patient engagement strategies, more than ten percent of hospitalization in chronic conditions are avoidable.

Evidence suggests that patient activation is a critical factor in reducing health care utilization such as emergency room visits, hospital admission and

medication adherence in chronic conditions (Hibbard and Greene, 2013). Conversely, a systematic review on the association between patient activation and healthcare utilization in chronically ill patients demonstrated that poor patient activation results in increased health care utilization such hospitalization and emergency room visits (Kinney *et al.*, 2015).

2.6.3 Barriers to patient engagement

Powell *et al.*,(2016), in their qualitative study on interprofessional perception on patient's barriers related to patient engagement in health care classified the barrier into three major obstacles for health care engagement. These are, social system factor, health care system and patient trust in the health system. Social barriers contain financial issues, substance abuse, mental health and patient transport related issues. Health care system factors embraces poor care coordination, poor communication, and lack of clarity in the discharge summary. Patient trust in health system consists of mistrusting the patient, distress of receiving serious diagnosis or prognosis. Identifying the barriers related to patient engagement provide an insight to strategies and interventions to improve patient engagement (Powell *et al.*, 2016).See table 2.5

Table 2.5 Factors to patient engagement barrier

Social Factors	Healthcare Factors	Patient Factors
• Financial issues • Substance abuse • Mental health • Patient transport	• Poor care coordination • Poor communication • Lack of clarity in discharge summary	• Lack of trust • Distress of disease and prognosis

2.6.3 Behavioral principle in patient engagement

Implementing patient engagement strategies requires understanding human behaviour and what initiatives make a change in individual (Williams, 2016). Based on Fogg (2009) conception model map there are three key elements to behavioral change which are motivation, ability, and trigger. If the expected behavior is not occurring, it means that one of those three key elements is missing. In his model, harder changes require a higher level of motivation and stronger trigger. He argued that rather than teaching new behavior simplifying the task for example a sensors technology for health monitoring which may increase the ability. Providing triggers such as reminder help to initiate behavior on the appropriate time, and motivation which include, feedback, update status, overview of the results overtime might help to continue the preferred behavior overtime (Fogg, 2009). Figure 2.2 explain the three elements of Fogg's behavioral model. Fogg's behavioral model (FBM) is directly adapted to patient engagement programmers and technology intervention. For an example 'Endogoal' is a mobile app developed by using three elements FBM theory for the management of Diabetic. The main goal of the app is to sustain the positive healthy behavior for people with diabetic. The behavioral goal is self-entering of glucose reading in a designated time. The *ability* features is the reward system, when completing designated four reading in a day the user achieve a fincial reward. The *motivating* features is virtual pet dog who is being fed each time users check their glucose and remain hungry if they do not. *Trigger* features are reminder alarm, to monitor the glucose and barking virtual dog if the users did not entry the glucose reading (Dyer, 2013). So the health technology using FBM theory trying to achieve

required behavior from the patient to improve patient engagement with his/her disease conditions

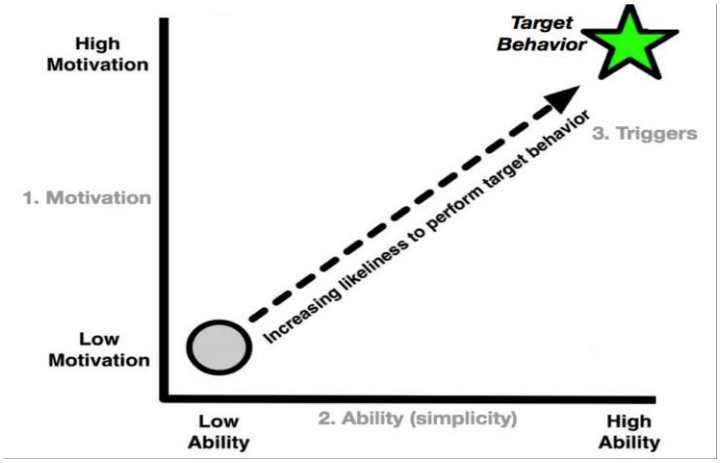


Figure 2.2 Fogg's Behavioral model

Source: Fourth international conference of persuasive technology (2009)

2.6.4 Technology based intervention for patient engagement

There is a pragmatic shift of information exchange from traditional face to face communication to web-based and smartphone-based intervention such as telehealth, eHealth, and mHealth. Increasing web-based intervention plays a major role in providing information, developing skills and patient empowerment in self-management (Jenerette and Mayer, 2016). A recent systematic review indicate physical activity in chronic condition has increased with using many web-based interventions (Kuijpers *et al.*, 2013).

Furthermore, Patient engagement is also facilitated by interactive patient portal to the EHR.The patient portal has a wide variety of application such as access to Electronic Medical Record, eConsultation, collection and sharing patient generated data, online patient social support. Evidence supported that the patient portal is promising for both patients and healthcare providers (Kuijpers *et*

al., 2015). Additionally, many healthcare organizations have introduced electronic clinic data and patient registries to track their illness, compare treatment and support one another. Moreover, these registries are a valid tool to understand variation in treatment and outcome, to examines factors influencing prognosis and quality of life (Bloomrosen and Sennett, 2015). A study on patient direct access to test results through EHR patient portal demonstrated that direct access to the test result is strongly valued by the patient and increased patient engagement (Pillemer *et al.*, 2016).

Furthermore, widespread adoption of smartphone app allows fast data collection and information delivery to the patient within no time. Additionally, the use of wearable devices helps to track health data and to transfer the data to health care providers in real time (Bloomrosen and Sennett, 2015).

Patient engagement is now recognized as an important elements of chronic care. Mobile technology, the subject of the next section has a role to play in patient engagement and also in blood pressure control and medication adherence

2.7 Mobile Health technology

In today's era, mobile technology is ubiquitous. Along with popularity and wide utilization of smartphone, the number of mobile apps is increasing rapidly (Blodt et al., 2014). Mobile apps are downloadable software applications that run on a smartphone, tablet or other mobile communication devices. They are typically available through app distribution platforms such as Google Play, Apple Store, Windows phone store (Doyle, 2014).

A systematic review by Zapata *et al.*, (2015) on usability of mobile health apps reported that there are more than 8000 mobile health (mHealth) app available in

Google Play Application and 20,000 in tha Apple App store. Furthermore, an estimated 500 million smartphone users around the world are using mobile health app. Currently apps are available to support people with various health problems (Blodt et al., 2014). In addition to that, nowadays many health care organizations are introducing mobile health application for monitoring diseases and assisting self-management in chroinic diseases (Zapata *et al.*, 2015).

2.7.1 mHealth technologies in Healthcare

mHealth is one of the biggest technology innovations in healthcare (Malvey and Slovensky 2014). mHealth technologies mean use of primarily wireless technologies such as mobile phone and tablet computer to improve access to and delivery of healthcare services and finally improving health care outcomes (Free *et al*., 2013). With the advance of mHealth technologies, the health-care industry is expected to transform into personalized, collabrative, preventive and less expensive care. An industry report indicates that emerging market shows incredible strength and growth with mHealth technologies (Malvey and Slovensky, 2014). The primary drivers of mHealth technology is the increasing number of chronic disease that require regular care rather than episodal care. Mobile health technology offers to manage the care outside the hospital, reduce hospitalization and improve quality of life (Malvey and Slovensky, 2014).

Smartphone apps are available for health care providers as well as consumers. For health care providers, health-related apps assist them in patient care and work-related responsibilities. These apps include decision support tools, drug dosing, medication interaction, international classification of diseases coding information as well as guidelines for the management of disease. Whereas, for

healthcare consumer they are mainly designed to monitor and track medication dose, adherence, record blood pressure, heart rate as well as designed for the management of diseases such as diabetic, asthma or chronic kidney disease

(Bryant *et al.*, 2013), (Doyle 2014).

2.7.2 Smartphone app for health behavioral intervention.

According to a review by (Dennison *et al.*, 2013) there are many reason smartphone used for behavioural intervention. Which are given below.

- Portable remains with person all the time, and high value
- The device is cheaper, more convenient, less stigmatize intervention which not available anywhere,
- Facilitate sharing health care data and communicate with health care providers

2.7.3 mHealth technologies for chronic disease management

Despite the substantial advances in biomedical sciences to improve diagnosis, treatment, prevention and the management of diseases, the patient engagement, medication adherence and strategies to improve treatment are still varying and challenging (Brayant *et al*., 2013). In addition to, lack of communication between patient and their health care providers can also accelerate these issues. These may end up in clinical consequence and also increase healthcare utilization of inpatient resources such as emergency departments and readmission (Bloss *et al.*, 2016).

To compensate today's poor health care management a number of manufacturers developed sensor design connected with the smartphone for

individuals to monitor their physiological parameters and also to track their health care data. The smartphones often displays the data, transmit the data to remote server, store and analyse the data (Bloss *et al*., 2016). Individuals who appropriately use this device can monitor their condition in their real world and engage more and get personalized with their disease management. However, this monitoring may potentially increase short- term health care utilization until the patient learns to recognize which readings constitute normal or required medical attention (Bloss *et al*., 2016).

However, evidence from a prospective randomized study on digital and smartphone technology used for the management of three chronic diseases shows there is little or no increase of short-term health care utilization; secondary analyses also shows improved patient engagement in self-management by the intervention group using mobile health technologies (Bloss *et al.*, 2016). Additionally secure electronic messaging between patient and health care providers reduces the primary care utilization such as primary care office visits and telephone contacts (Brzan, 2016).

Furthermore, there is only one study found that an mHealth technology is used for achieving three main goals such as medication adherence, blood pressure control and patient engagement which shows promising (McGillicuddy *et al.*, 2015). However, studies are still not out to evaluate long-term improved outcomes of mobile health and digital technology on chronic disease management (Bloss *et al*., 2016),(Steven and Steinhubl, 2013).

2.7.4 Examples of mobile app used for chronic disease management

"COMMODITY" is an mHealth system developed and implemented for the management of Type 2 Diabetes Mellitus. A study to assess the feasibility and user experience indicates that the technology is well accepted by the patients for the management of diabetes (Kardas *et al*, 2016).

Furthermore,"*Poket PATH*" is another mobile app developed for lung transplant recepients. A study to understand the degree that *poket path* users respond to the decision support for reporting critical values showed the mobile technology with decision support system is promising and effective to bring behavioural changes in lung tranplant patients (Jiang *et al.*, 2016).

Next,"SMASK" (Smartphone Medication Adherence and Save Kidney) is a smartphone app programme developed for renal transplant patients for better blood pressure control and improved medication adherence (McGillicuddy *et al.*, 2015). A randomized pilot study on patient attitude ,and acceptance to mobile technology found that the intervention group has better blood pressure control than control group (McGillicuddy *et al.*, 2015).

Moreover, 'Heartmaap' is also another smartphone app devloped fot the mangement of heartfailure patients a descriptive study by Athilingam *et al.*,(2016) the system is promising and easy to use and accepted by the patients. Lastly 'Medplan' is an another smartphone app devloped for medication management in chronic coditions. Pre and post intervention study indicate the app is promising to improve medication adherence(Anglada-martínez *et al.*, 2016) See Table 2.6.

Table 2.6 mHealth technologies for chronic disease management

mHealthTechonology	Study/Author	Disease	Features	outcome
COMODITY 2	RCT /(Kardas *et al.*, 2016)	Diabetic	Smartphone Bluetooth enable glucometer, blood pressure reader, scale Adherence monitor	Improved health related quality of life Improve medication adherence
PoketPATH	Cross-sectional/(Jiang *et al.*, 2016)	Lung transplant recipient	Smartphone, Bluetooth enabled spirometry, Thermometer, Direct entry of all health data, Graphic display of data over time, Automatic decision support based on critical value	Effective in interpreting and reporting critical value to the healthcare providers
SMASK	RCT/ (McGillicuddy *et al.*, 2015)	Renal transplant patient	Smartphone, Bluetooth enable blood pressure monitor, Medication reminders, Feedback from healthcare provider	Improve medication adherence Improved blood pressure control. Highly accepted by the patients
Heartmaap	Descriptive survey/(Athilingam *et al.*, 2016)	Heart failure patient	Smartphone app, Bluetooth sensor weight monitor, real-time vitals monitoring using wearable sensor, daily Symptoms monitoring, feedback message based on symptoms breathing exercise	Promising and may motivate patient engagement in self-management
Medplan	Pre and post intervention study/(Anglada-martínez *et al.*, 2016)	Chronic disease patients	Web and smartphone app, Medication reminder, Health advice, Bidirectional communication between healthcare provider's and patient data	Improved medication adherence.

2.7.5 Mobile health apps for medication adherence

Mobile health apps allow medication adherence monitoring and management in real-time.This may reduce the limitation associated with the traditional method of patient recall of memory after an extended period.More precisely it may allow missed dose identified as it occurs and facilitating timely medical consultation or intervention if needed (Bryant *et al.,* 2013). A smartphone and web based application developed to improve medication adherence in chronic conditions shown to be feasble and found promising tool in medication adherence (Anglada-martínez *et al.*, 2016).

2.7.6 Mobile health apps for blood pressure control

Smartphone based apps can facilitate self-management of hypertension. A cross-sectional study about medical apps for the management of hypertension revealed that consumer has greater tendency to download and rate the app which measure BP and heart rate despite a lack validation for these apps (Kumar *et al.*, 2015). Another randomized control study on mobile apps for the management of hypertension showed, in intervention group blood-pressures decreased by 10mmHg than control group (Moore *et al.*, 2014).

2.7.7 Mobile health apps for patient engagement

A recent review by Alberti and Nannini (2013) reported that traditional patient education using printed material does not demonstrate to support self-management skill development (Alberti and Nannini, 2013). Thus it illustrates the need for new patient teaching strategy for prolonged patient engagement to support self-management (Athilingam *et al.,* 2016), (Dickson and Riegel, 2009).

Advances in mobile health technology provides new opportunities for the self-management of chronic diseases (Athilingam *et al.*, 2016). Studies suggest that older people even with no experiences of technology have also used mobile phone applications for daily self-management of their chronic diseases (Athilingam *et al.*, 2016) (Dickson and Riegel, 2009). Saranummi *et al*.,(2013) in their review reported that persistent engagement in older adults has shown to improve overall health and wellbeing. By automated coaching, feedback, and evidence-based interventions, mobile phone applications may empower older patient to get engaged in their self-management (Heron and Smyth, 2010). However a Pew internet survey on 2014 and another study about mHealth technology revealed that most the smartphone and technology users are younger population (less than 45 years) (Smith, 2014) (McGillicuddy *et al.*, 2013).

Several studies assessed patient's satisfaction and acceptance using mobile health applications. Patient-centred mobile health technologies have emerged in such a way that they actively engage patients in their decision making which tend to make them healthier and even have better outcomes (Athilingam et al. 2016). A recent study about usability and feasibility assessment of a mobile application called "HeartMaap" for self-management indicates its potential feasibility for congestive heart failure patients including elderly patients with no experience of using the mobile phone (Athilingam *et al.*, 2016). Furthermore, a systematic review conducted by Bryant *et al.(2013)* showed that mobile apps are supporting self-management in diabetics by providing reminders for blood sugar monitoring, insulin therapy, meals and physical activity.

Furthermore, a qualitative study about mobile apps users' experiences to facilitate self-care indicate that mobile apps can sustain positive behaviour changes in individual that can enhance self-management of the chronic conditions (Anderson *et al.*, 2016). The study also highlighted that use of health apps improves self-awareness in one's condition, and easy adoption of self-management in daily life, easy to view historic data as well as sending the data to health-care providers without repeated visits (Anderson *et al*., 2016).

Conversely, Dennison *et al.,* (2013) conducted a qualitative study in young adults to explore the user's experience and views on health apps related to health behaviour changes. The findings indicate that mobile health application encourage healthy behavioural changes in young people. The features of the mobile app that influence the users include accuracy, legibility, ability to record and track the behaviour goal and easy to acquire advice and information from the app. However, the majority of participants reported that sensing capability and social media features considered to be unnecessary in any health app (Dennison *et al.*, 2013).

2.7.8 Impact of mobile health technology on clinical outcome.

The impact of mobile health technology on clinical outcome are mixed. A systematic review by Whitehead *et al* (2016) to examine mobile health intervention on chronic disease management, demonstrated, of the nine studies they examined only six studies reported significant improvement in clinic outcome. Five of these studies mentioned mHealth technology for the management of diabeties. In addition to that another RCT study on smartphone technology combined with diabetic educator feedback to support diabetic self-

management showed significant improvement in HbA1c in app uses (Kirwan *et al.*, 2013). Furthermore, another mHealth system developed for post kidney transplant management self-management and promote communication with health care provider showed significant improvement in blood pressure control and medication adherence (McGillicuddy *et al.*, 2013). Furthermore, mobile phone based self-management system for asthma found significant control on asthma(Liu *et al.*, 2011). However, there are a few studies reported not any significant improvement in clinical outcome. A mobile application called *t+ asthma* was developed for asthma control, and facilitate healthcare provider communication and ongoing support through secure password protected web. However, RCT showed there was no significant improvement in asthma control (Ryan *et al.*, 2012). COMODITY is an application developed for diabetic patients also show no significant improvement in clinical outcome with regard of blood pressure control (Kardas *et al,* 2016). Another systematic review that evaluated clinical outcome of mHealth intervention on chronic disease management illustrated that of 41 studies examined only 16 studies reported a disease specific clinical outcome (Hamine *et al.*, 2015).

2.7.9 Challenges in using mobile health apps

Despite the effectiveness of mobile health apps for the management of chronic conditions, there is some substantive side of apps which affect the widespread implementation of app for the management of chronic diseases. Brzan et al (2016) in their review stated that as per the latest report of institute for Healthcare Informatics, more than 165,000 health apps are available in the market. However, the majority of apps are focusing on the area of wellness, diet, and exercise.

Almost a quarter apps are only concentrating on treatment and disease management. Many physicians do not trust or recommende apps due to lack of supporting evidence (Brzan, 2016). Furthermore, the vast majority of apps have limited functionality beyond displayed information (Malvey and Slovensky, 2014).

Moreover, there are some concerns about privacy, accuracy and safety of the mobile health apps. Users do not know what companies do with the data that they entered (Brzan, 2016).

Lastly, difficulty to sustain the users for long-term is also a major challenges. Brazan (2016) in his review showed that difficulties to use the smartphone are the most common reason for quitting the app. For that reason, the author also suggested that significant amount of patient training is needed for the easy and continuous usage of the app. The next common reason for ending the app usage is the need of time for entering the data. Lack of acceptance by patient is another major obstacle for the widespread implementation of mHealth technology (Kardas *et al*, 2016). Furthermore, review by reported that most direct to consumer health care app was not developed by health care professional or academic do not draw on behaviour change theory or techniques or not underline the clinical guideline for the condition (Dennison *et al.*, 2013).

2.8 Conclusion to State of the Art

In summary, kidney transplant is the successful treatment for eligible patients with End Stage Renal Disease (ESRD). However, lack of medication adherence, poor blood pressure control and patient engagement are the frequent causes for graft rejection. A systematic review showed 26.4% renal transplant patients are non-adherent to IS medication and 36% transplant rejection occurred due to IS

medication non-adherence (Butler *et al*., 2004). Furthermore, it is estimated that 70 - 90 % renal transplant patients have uncontrolled blood pressure (Thomas *et al.,* 2013). Additionally lack of patient engagement reduce the quality of life and also increase healthcare utilization. Non-adherence rate high in first year of post-transplant and it increase with decreasing clinic visit. Although Ireland has the highest kidney transplant survival rate in Europe and world, in Ireland 10% transplant rejection occurred in the first year of transplant (National Kidney Transplant Services annual report 2016).

There are various intervention for improving medication adherence, blood pressure control and patient engagement such as, behavioral intervention, pharmacy based intervention, electronic pill monitoring, home blood pressure monitoring, technology based intervention etc. However, there are many downside of these intervention, such as expensive, lack of follow up, may not be convenient for patients, short of healthcare providers as well as patient may not follow these intervention in long-term basis.

A rapid adoption of smartphone technologies makes it an attractive platform for improving medication adherence, blood pressure control and patient engagement (Kumar *et al.*, 2015). Evidence from some of the studies shows mHealth apps are promising technology for the management of chronic conditions. Study shows there could be 1.7milliions mobile health app users around the world by 2018 however, a very few have been tested adequately (Morawski *et al.*, 2017). A smartphone based mHealth technology can increase patient engagement, medication adherence and blood pressure control.

Despite the advantage of mHealth app there are some challenges of mHealth apps such interoperability issues, privacy and security concern and lack of evidence supporting the mHealth technologies*(Brzan, 2016)*. A review on 2012 showed 147 unique medication adherence apps are available however the data on its effectiveness was missing (Dayer *et al.*, 2013). Although the number of mHealth apps are increasing considerably, the evidence supporting their impact on health care quality is limited (Dayer *et al.*, 2013). Therefore, this research study will support the evaluation of effectiveness of mHealth apps on improving clinical outcome. Next chapter discuss about the research design and methodology and data collection.

Chapter 3 **RESEARCH DESIGN / METHODOLOGY**

3.1 Introduction

This chapter outlines the methodological approach used when attempting to answer the research questions. The chapter starts with the purpose of the study, followed by the research question, aims, and objective of the study. Additionally, the chapter will elaborate on the research design and the rationale for the research design, incorporating the sampling method, data collection measures, data analysis, and ethical considerations.

3.2 The purpose of the study

The purpose of this study is to examine the effectiveness of the mobile app patientMpower, which is used for kidney transplant patients to improve medication adherence, blood pressure control, and patient engagement. In addition, this study seeks to understand the patients' experience with using the app.

3.3 Research Question

The National kidney transplant center in Beaumont recently launched a mobile health application called 'patientMpower' for newly transplanted patients to improve their medication adherence and blood pressure control and to enhance patient engagement in their treatment and self-management.

This research study based on this mobile app will address the following research questions:

- Does the use of 'patientMpower' app improve outcomes for renal transplant patients?

The sub-questions are:

- Does the use of the app improve medication adherence in renal transplant patients?
- Does the app generate better control of blood pressure in transplant patients?
- Does the use of the mobile app enhance patient engagement post-transplant care?

A subsidiary question is: How do patients feel about the use of the 'patientMpower' app?

3.4 Aims and objective of the study

The overall aim of the study is to examine the effectiveness of the mobile app used for kidney transplant patients.

The objectives of the study are:

- To measure the Immunosuppressant (IS)medication adherence in transplant patients using the app as compared to the control group;
- To determine blood pressure control in transplant patients using the app as compared to the control group;
- To identify levels of patient engagement with using the app as compared to the control group;
- To understand the patients' experience of the use of the 'patientMpower' app.

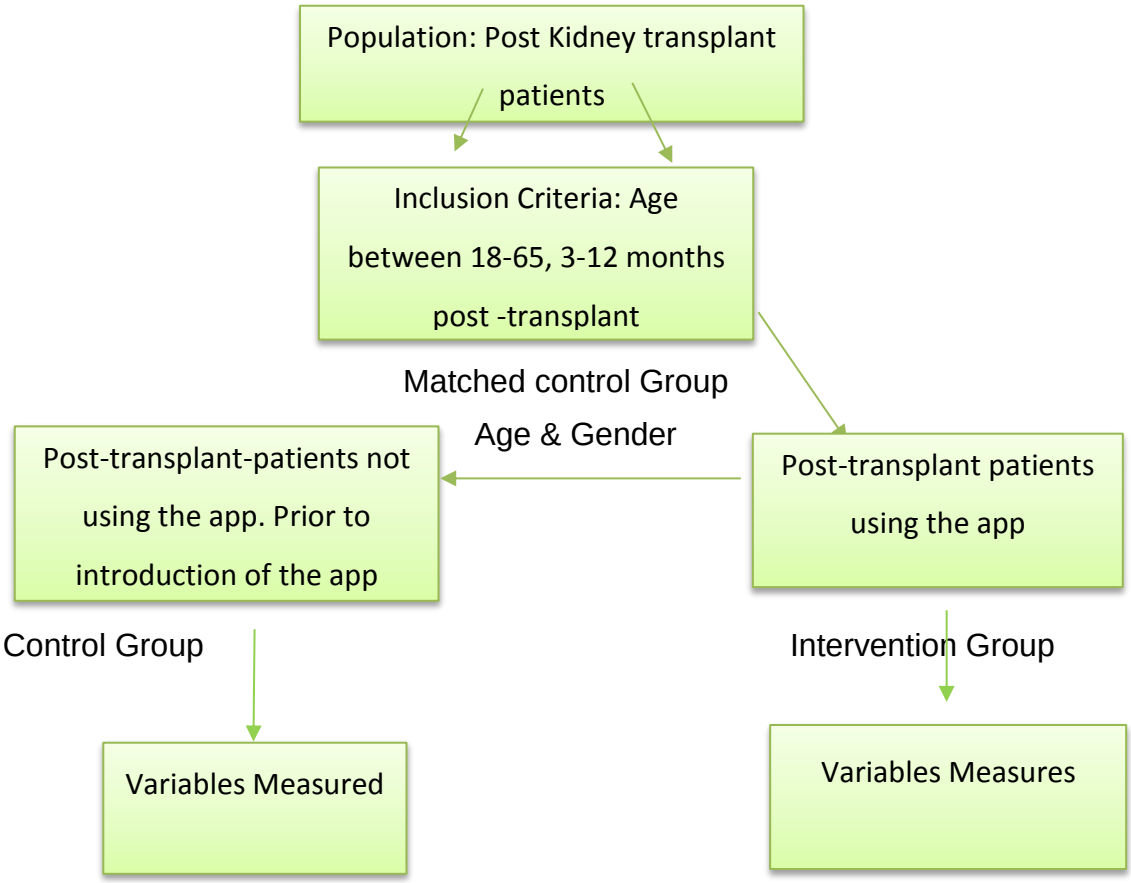
3.5 Research Design

According to Burn *et al (*2012) a research design is a blueprint for conducting the study. The purpose of the design is to format the situation that exploits the possibility of obtaining accurate response to research question. There are three types of research, which includes qualitative research, quantitative research and mixed method research.

Quantitative research is defined as a 'formal, objective, systematic process in which numerical data are used to obtain information about the world' (Curtis *et al.,* 2013, p.19*).* A quantitative experimental study is needed to measure the outcome of individuals who receiving the treatment and to compare with individual not received the treatment (Bowling, 2009, p.237). Bowling (2009) suggested that, for the accurate assessment of the outcome or the effect of an intervention, measurement of the variable in controlled conditions and a comparison of the group receiving the intervention with an equivalent control group are necessary. A true experiment study includes a group of participants receiving the intervention, and an equivalent control group not receiving the intervention and random selection of participants group. The true experiment study also called Randomized control study (Bowling, 2009). However, this study lack of equivalent control group for randomization as intervention already in place since 2016. Hence this study is a quantitative non-randomized study with a matched historical control group. Figure 3.1 explains the research design.

Additionally, a survey of the intervention group was conducted to assess the patients' experience and the usefulness of the 'patientMpower' mobile app. Bowling (2009) indicated that a survey can be designed to measure certain

phenomena in the population of interest. Surveys are mainly conducted to measure attitudes, knowledge, and behaviour and to collect information as accurately and precisely as possible (Bowling, 2009, p.214).



Variables: 1. Immunosuppressant Medication adherence
2. Blood pressure control
3. Patient engagement

Figure 3.1 Study Design

3.6 Rationale for Research Design

Randomized control trials are the most common method used to evaluate the effectiveness of a mobile health app as shown in research studies (Ledford *et al.*, 2016), (Anglada-martínez *et al.*, 2016), (McGillicuddy *et al.*, 2015). However, this method is not appropriate for this study situation due to limitations such as small sample size (only 30 patients meet the inclusion criteria for the intervention group) and lack of reliable controlled group in the same time period as the intervention. Black (1996) argued that RCT is not appropriate in situations that involve inadequate sample size, rare outcome measurement, and/or ethical or legal objection. He also pointed out that when randomized trials cannot be conducted, it is feasible to use other well-designed methods.

The app was introduced in 2016 and was given to all eligible patients, who are using the smartphone and interested to use the app to support their post-transplant self-management. So among the 2016 transplanted patients, those who have not downloaded the app may be due to non-compliance with the treatment, reluctance to use the app, or not having a smartphone. Thus, patients transplanted in 2016 who are not using the app are not a reliable control group. Therefore, for this research study examining the effectiveness of the 'patientMpower' app, the researcher chose patients transplanted in 2015 using mobile phone and matched with intervention group in terms of age and gender. They are a more reliable control group than 2016 patients because they are using mobilephones and may be more inclined to use the app if it had been introduced in earlier.

The purpose of matching is to ensure subjects in control groups are equivalent to intervention group. According to Faresjö , (2010) matching increase the efficiency of the study. Matching is usually done to avoid the confounding factors in the study and reduce selection bias. Peat et al (2002) explain matching means selecting the control group that matches the case on main confounders such as age and sex. Theoretically any variables other than independent variable which affect the dependent variable can be matched. In this study, 2015 transplant patients who meet the inclusion criteria (age 18-65,3-12 months post-transplant, using mobile phone) may demographically different from the app users. So the researcher randomly matched the control groups with intervention group based on age and gender

3.6.1Study Duration

Total study duration is October 2016 to June 2017, and Data collection is from March 2017 to May 2017.

3.7 Variables Measured

The variables used to measure data in this study include IS medication adherence, blood pressure control, and patient engagement. The main variable and attributes used to measure are described below and shown in table 3.1.

Table 3.1: Variable and attribute measured

Variables	Attributes to measure
IS medication adherence	• Serum tacrolimus level • Adherence score from the app (for app users)
Blood pressure control	• Clinic blood pressure reading • Home blood pressure monitoring record (for app users only)
Patient engagement	• Number of missed appointment • hospital admission, • A & E visit, • Creatinine level

3.7.1 Variable 1: Immunosuppressant medication adherence

Although there is no golden standard for measuring non adherence, variability of immunosuppressant drug (IS) level variability (Lieber, *et.al*, 2015), (Liu *et al.*, 2015) and target range of IS level are the objective way of measuring immunosuppressant adherence (Takemoto *et al.*, 2007). Non-adherence can be a reason for high variability of immunosuppressant (IS) levels (Pabst *et al.*, 2015), (Slatinska *et al.*, 2013). Tacrolimus is a primary immunosuppressant therapy well established for kidney and liver transplant. It is a therapeutic alternative for Cyclosporin. Evidence from the studies showed that graft survival rate is higher in tacrolimus as compared to other form of immunosuppressant therapy (Plosker and Foster, 2000). To assess IS medication adherence, four consecutive lab values of Tacrolimus levels have been collected from the computerized renal medical record called (eMed) for each patients at their 3-12 months post-transplant clinical visits. Variability was measured by calculating coefficient variation for each patient's tacrolimus level. For this mean and standard deviation of each patient computed and then coefficient variation (CV) calculated by dividing SD by mean (Pabst *et al.*, 2015). The target level of

Tacrolimus level in 3 – 12 months post-renal transplant period is 6- 10 ng/ml. (Ben Fredj *et al.*, 2013), (Wallemacq *et al.*, 2009). If two or more values outside the target value is consider the patient can be nonadherence to IS medication. However patient therapeutic drug level may be affected by patient's current drug dosage and regimen can be affect the tacrolimus level (Ben Fredj *et al.*, 2013). The variability and number of samples outside the target level of Tacrolimus for both groups was calculated using IBM version 24 SPSS statistic software.

3.7.2 Variable 2: Blood pressure control

Blood pressure readings have been obtained from four consecutive clinic visits during the 3-12 months following the kidney transplant. Based on Kidney Disease Improvement Global Outcome (KDIGO) guidelines, a systolic blood pressure of less than 130mmHg and diastolic less than 80mmHg in a post-transplant patient is seen as blood pressure under control (National Kidney Foundation, 2012). According to seventh National Joint Committee report hypertension is consider BP greater than 140/90mmHg (James *et al.*, 2014). For each patients 4 consecutive BP reading was collected. If two or more value outside the target value (greater than 140/90 mmHg) is consider patient is hypertensive.

For the intervention group, additional data about the number of times they monitor and record their blood pressure at home has also been collected from the app.

3.7.3 Variable3: Patient engagement

Patient engagement is determined by the number of missed appointments at the clinic, any hospitalizations and A&E visit during the period, and any signs of transplant rejection. High Creatinine level (above 150) is an indication of poor

graft function and sign of rejection. Four consecutive lab values of the Creatinine (Cr) levels have been measured at 3-12 months post-transplant clinic visit.

For the intervention group, along with all the above data, additional data such as how often the patient used the app, how often they recorded taking their medication, and how often they monitored blood pressure at home has also been collected from the 'patientMpower' app as marker of patient engagement.

3.7.4 Patient experience survey

The Likert scale was used to determine the opinions or attitude of the study subjects (Burns *et al.*, 2011). The researcher also designed and used a Likert scale questionnaire for the intervention group to understand patients' experiences of using the 'patientMpower' app. The Likert scale contains 10 items the scale range from strongly disagree (1) to strongly agree (5). The questions are adapted from Zhang *et al.*, (2016) from the study of users acceptance of mobile health technology and Mcgillicuddy *et al.*, (2013) patient attitude towards mobile health technology. Questions from Zhang et al (2016) and Mcgillicuddy *et al* (2013) were made specific to the 'patientMpower app'. The researcher also add a free text comment box at the end of the survey to allow patients to write any additional comment or opinion about using the app. Table 4.2 shows the survey questionnaire

Table 3.2 survey questions

No	Literature	Modified question
1.	It is easy to me use mobile health services(Zhang *et al.*, 2016)	'patientMpower' app is easy to use
2.	mHealth app are effective in keeping me healthy Zhang *et al.*, 2016).	The app making me more confident in post-transplant management
3.	If someone available to answer my questions I would like to use it Zhang *et al.*, 2016).	The app answer my queries related to post -transplant management
4.	Mobile technology allow doctor to change my medication (Mcgillicuddy *et al.*, 2013).	The app allows doctor to track my BP
5.	Remind me to take my medication (Mcgillicuddy *et al.*, 2013).	The app helps me to take my medication as directed
6.	Remind me about appointment (Mcgillicuddy *et al.*, 2013).	Remind me about my appointment
7.	a)Using mobile health service is for more healthcare convenience b)My health is more likely good (Zhang *et al.*, 2016).	The app reduces me frequency of seeking medical advice
8	Mobile health services useful in my life (Zhang *et al.*, 2016).	The app helps me to track my blood result
9		Helps regular monitoring of my blood pressure
10		Helps better understanding of my medication

3.8 Study setting and Context

Beaumont Hospital is the national centre for kidney transplant and renal excellence in Ireland. This study was conducted in the Beaumont Renal Transplant Clinic. Support for the study and written permission were obtained from the Beaumont Nephrology and Transplant consultant and Transplant Urology and Nephrology (TUN) nursing director before the study was conducted.

As the researcher is not an employee of Beaumont Hospital, the researcher does not have direct access to the hospital medical record and information system, so the data was extracted with the help of a Renal System Administrator in the hospital. All data was extracted from eMed Renal. It is a national system implemented at all renal centers in Ireland as part of the Kidney Disease Clinical Patient Management System (KDCPMS) project.

PatientMpower' app was implemented in Beaumont Hospital on 2016. All the eligible patients who are post-transplanted in 2016 were downloaded the app from the app store. Additionally, a Bluetooth-enabled blood pressure device was provided to all the app users. This allows direct real- time entry of BP record into the app. Furthermore, a bar code scanning technology used to enter clinic data from the eMed to the app. Patients can add all their medication list into the app and the app also provides medication reminder. Moreover, the app also presents graphic display of all the data over time. Training and support provided to all the app users. Finally, the app included education and information tools for post-transplant care. All the patients who downloaded the app were expected use app regularly to monitor home BP, marking their daily adherence score and tracking the lab result. The main feature of the app is, there is no manual entry of any data by the patient.

3.9 Population and Sampling

The study population is post-kidney transplant patients who are attending the Beaumont Renal Clinic. There are two population target groups. The first group is the intervention group. This group consists of a population who have been using the mobile app since it was launched in 2016. The second target group is

a control group who received transplants in 2015 before the app was available and who have a mobile phone thereby omitting people who would be unlikely to have used the app if it had been available.

Sampling involves selecting a group of people, events, behaviours, or other elements with which to conduct a study (Grove *et al*., 2013). Every research study has certain eligibility criteria to be included in the target population, which are referred as exclusion and inclusion criteria (Grove *et al*., 2013). In this study, the inclusion and exclusion

Table 3.3: Inclusion and exclusion criteria

Study Group	Inclusion criteria	Exclusion criteria
Intervention Group	• Age between 18-65 • 3-12 months post-transplant in 2016 • Using patientMpower app	• Age below 18 or 65 • Not using the app
Control Group	• Age and gender matched with Intervention group • 3-12 months post-transplant in 2015 • Having mobile phone in medical record	• Age and gender not matched with intervention group • Not having mobile number on medical record.

3.9.1 Sampling Method

The sampling method refers to the process of selecting and recruiting the participants. It is important to use careful sampling procedures and to adhere strictly to any inclusion and exclusion criteria so that the characteristics of the study sample can be described precisely and the generalisability of the results

can be accurately described (Curtis and Drennan, 2013). Burns et al. (2011) state that the sampling method is designed to increase the representativeness of the population and to reduce systematic variation or bias. Stratified random sampling is mainly used in situations where some variables in the population are critical for achieving representativeness (Grove *et al.*, 2013). Thus, this study used a stratified random sampling of 3-12 months post-transplant patients and age between 18 and 65 years from the app users list to select the patients in the intervention group. The next, matched sampling technique used to select participants in the intervention group. Matching is done based on age and gender, which is described in section 3.10.2.

3.9.2 Justification of sample

Sample size is the most critical factor of any research study (Peat, 2002). The size of the sample group affects all aspects regarding conducting the study and interpreting the result. Burns et al. (2011), in their textbook about understanding nursing research, stated that, 'a research study needs to be large enough to ensure the generalisability and accuracy of the results, but small enough so that the study question can be answered within the research resources that are available'. Additionally, if the sample size is too small, clinically important differences between the study groups may not be statstically significant. These are categorised as type two statistical errors (Peat, 2002).

In this study, total 37 app users in 2016 of those 30 were available for the intervention group who met the inclusion criteria. For the control group the researcher included all patients who matched with intervention group in terms of age and gender and who met with inclusion criteria (having mobile number in

the medical record and 3 -12 months post transplanted) which leaves total samples in control group is n= 30.

3.10 Procedure

The study involves four main steps. The initial step was obtaining ethical approval from both Trinity College, Dublin and Beaumont Hospital. After being granted ethical approval by both organizations, the researcher contacted the nephrology consultant and the line manager in the Renal Transplant Clinic to recruit participants. Patients were randomly selected in the intervention group from the app users list who met with inclusion criteria. A matched control group was selected based on age and gender. The third step was the relevant clinical data extraction from Beaumont. The Beaumont Renal System Administrator assisted in extracting the relevant clinical data from eMed to examine the variables, and additional data from the app was collected from the app database with the help of the 'patientMpower' company director. Finally, a survey was conducted among the intervention group using a Likert scale questionnaire at their renal clinic visit. Consent from all participants in the intervention group obtained before the survey.

3.10.1 Ethical Approval

Research ethics always places the rights and welfare of the subjects above the needs of the investigator (Peat, 2002). The researcher has an obligation to safeguard study participants (Burns *et al,* 2011). All research performed within

this study was carried out after obtaining ethical approval from the Beaumont Research Ethics Committee and Trinity College, Dublin's School of Computer and Statistics Research Ethics Committee. The initial application for ethical approval was submitted to Beaumont Hospital in November 2016, and a further clarification letter was issued from the committee in December 2016 seeking information about data collection, participant recruitment, and researcher access to the data. This letter also asked for modifications to the patient information leaflet. These issues were addressed, and ethical approval was granted in January 2017 (see Appendix B). The application for ethical approval from Trinity College was submitted in January 2017 and was approved in February 2017 (see Appendix C).

The letter of invitation to all participants and patient information leaflet was reviewed by the Renal Clinic manager and nephrology consultant prior to distribution to each potential participant. The patient information leaflet described the purpose of the study and provided information on confidentiality and anonymity and the participant's right to withdraw from the study at any stage throughout the study. More importantly, it stated that their level of treatment and care would not be affected in any way, irrespective of whether or not they partook in the study. The letter included the researcher's email address and phone number so she could be contacted if the participant had any queries or wanted to opt out of the study. By signing the consent form, the participants consented to the researcher obtaining their medical information and clinical data. A copy of the patient information leaflet and consent form are attached in the Appendix H and I.

Participants were given assurance that all information collected during the study would be de-identified and stored securely, would only be available to the researcher and academic supervisor, and would be analysed in accordance with the guidelines set out by Trinity College, Dublin. All data on computers was encrypted and stored in a password-protected computer.

3.10.2 Participants Recruitment

Selection of the control and intervention group is the most important aspect of any study design. For this study, both the intervention and control group were selected from Beaumont Renal Transplant computerized medical record. Total patients selected in the study was n=60.

Intervention group (App users)

For the intervention group, out of 37 total app users only 30 who met with inclusion criteria were selected from computerized medical record. All these 30 patients are post-transplanted in 2016, have downloaded and are using the app, within the time frame of 3-12 months post-transplant and age between 18 and 65. Of those, 22 patients, had clinic visits during the study period (March – May) they were approached and study was explained to them. Of those 22 participants one declined to participate in the study. Of those 21 agreed to participate, signed the consent and completed the questionnaire. For the remaining 8 patients who did not have clinic visit during the study period an invitation letter, consent form and questionnaire were sent by post. Of those four responded and sent back the signed consent and completed questionnaire. So the total participants in the intervention group is n= 25. See figure 3.2 study flow diagram

Control group

After selecting the participants in the intervention group the researcher select the patients in the control group. For the control group, 30 patients were randomly selected who were matched with the same demographics properties of intervention group (age and gender), 3-12 months post-transplant in 2015 and having mobile phone in their medical record, from the computerized medical record of 2015 transplant patients. Patients having mobile phone in their medical record used as a proxy for they are using the smartphone.

After randomly select 30 patients who matched with intervention group in terms of age and gender, the researcher extracted the clinic visits date for control group with the help of the Renal System Administrator and renal clinic staff. However, a few patients in the control group had a clinic appointment during the study period, therefore, an amendment requested from Beaumont research ethics committee to collect the anonymised clinic data without patient consent. According to the Beaumont ethics guidance manual irrevocably anonymised clinic data is no longer consider as a personal data therefore, consent is not required from control group to collect anonymised data. Amendment was granted on 6th April 2017 and researcher collected the anonymised clinical data with the help of Beaumont renal system administrator. A copy of the amendment letter attached in the appendix F. The Renal system Administrator was a Gate Keeper for extracting irrevocably anonymized clinical data to the researcher.

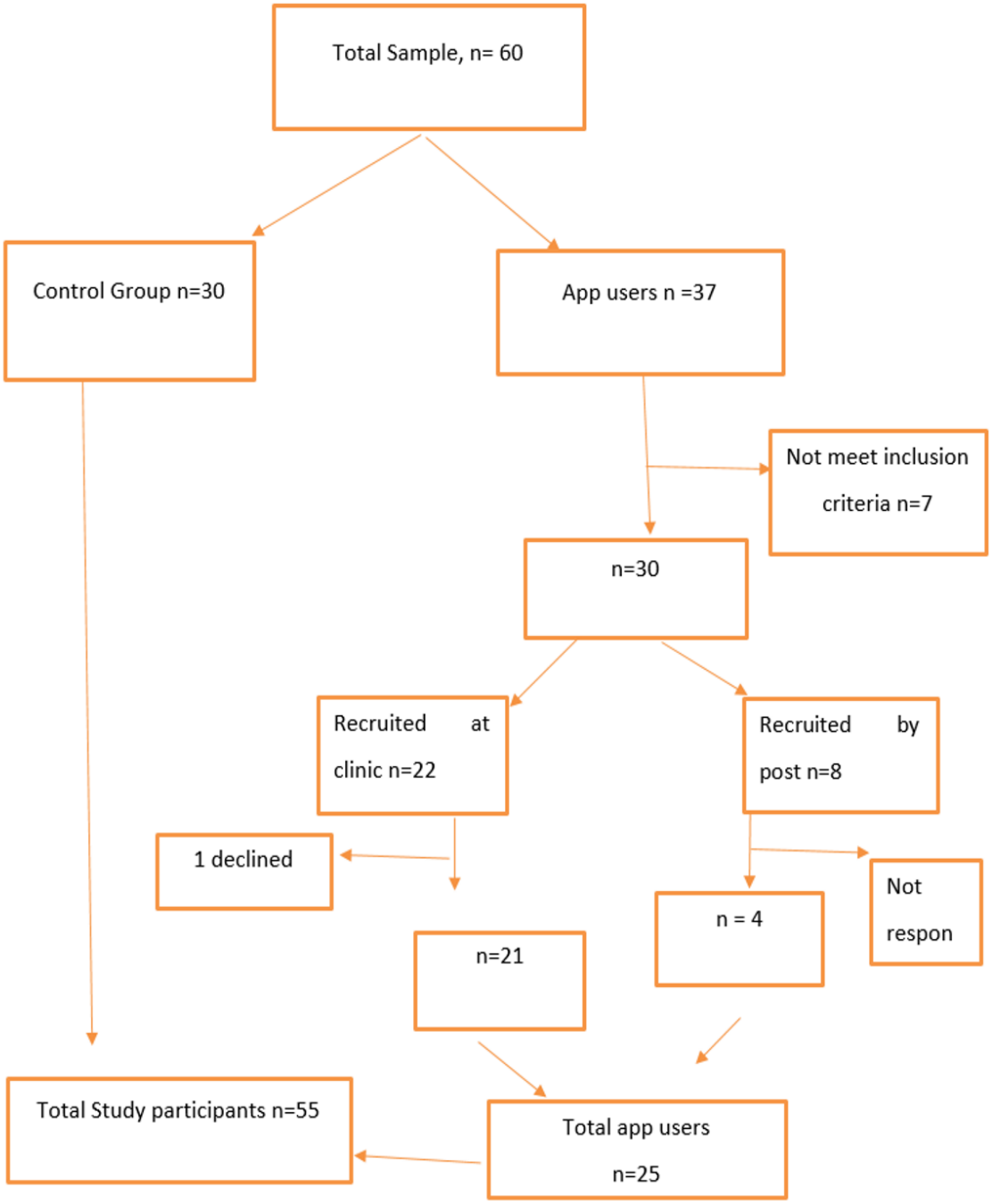


Figure 3.2 study flow diagram

3.10.3 Data Collection

Data collection is the process of selecting the subjects and gathering data from those subjects. Data may be collected on subjects by observing, testing, measuring, recording, questioning, or any combination of these methods (Grove *et al*., 2013). In research studies, variables are measured with the best possible measurement method available to produce trustworthy data that can be used in statistical analyses (Burns *et al*., 2011). In 1946, Stevens established different hierarchical levels of measurement in quantitative data collection. These levels of measurement are classified into four types: the nominal level of measurement, ordinal level, interval level, and ratio level of measurement. Variables measured at the interval or ratio level are more effective in identifying relationships among variables or determining differences between groups (Grove *et. al*., 2013, p.387). For the purpose of this study, interval and ratio level were utilized to measure the variables to examine the effectiveness of the 'patientMpower' app, and a Likert scale questionnaire was used for the survey among the intervention group to understand how patients feel about using the 'patientMpower' app.

The data was collected from the computerized renal clinical management system, eMed, and from the participants among the intervention group at the Beaumont Renal Clinic. All data was collected by the researcher and the Beaumont Renal System Administrator, who assisted in extracting the data from eMed. Efficacy data was collected on medication adherence (IS level), blood pressure control (clinic blood pressure reading, frequency of home BP measurement), and patient

engagement (number of hospital admissions, missed appointment, how often the app was used) using a data collection form. For the app users an additional data about device usage collected from the app data base. A pilot test of the data collection form was undertaken to test the usability and reliability of the data collection form. Four consecutive clinical measurements were collected at the participants' 3-12 months post-transplant visits.

3.10.4 Survey using Likert scale

A survey was conducted among app users using a 10 item Likert scale questionnaire. The survey was conducted when recruiting the patients for study at the renal transplant clinic. Participant took approximately 5 – 15 minutes to complete the questionnaire. Before a questionnaire was finalized, a small number of pilot studies are required to identify problems with the questionnaire and data collection form (Peat, 2002). A pilot test of the Likert scale was carried out with three patients from the sample group to ensure the questions were clear and beneficial and obtained the level of information needed. There was not any modification made in the questionnaire after the pilot study. The questionnaire was formatted in a simple and easy to read by research participants. Due to short of sample pilot study samples also included in the actual study.

3.10.4 Data Analysis

All the anonymized data was collected in a MS Excel spreadsheet and export into SPSS statistics software. All the statistics analysis was done using SPSS software. Descriptive statistics were used to reveal the characteristics of the data set. Inferential statistics was used to compute and gain the information about the population being studied. The statistical analysis used to mean standard

deviation and coefficient variation, frequency and range of the variable. Indepedent t –test and Pearson Chi-square test used to compare the difference variables between control group and intervention group. The next Chapter will provide more detail about data analysis and result.

- Hypothesis testing

Hypothesis is statistical test for interpreting the result. A research hypothesis can be alternative hypothesis to the null hypothesis (Burns *et al., 2*012).

Ho- A null hypothesis states that there is no relationship between the variables studied.

H1- Alternative hypothesis is that, there is a significant relationship between the variables studies

In data analysis a statistical significance relationship between the variables at the specified level of significance the null hypothesis is rejected. Rejection of statistical hypothesis means accepting research hypothesis. *p* value of less than .005 is consider significance(Burns *et al., 2*012).

The *alternative* hypothesis guiding to this research study are;

- There is a statistical deference in IS medication adherence between intervention group (app users) and control group
- There is statistical significance in blood pressure control between intervention group (app users) and control group
- There is a statistical significance in patient engagement between intervention group and control group.

3.11 Methodology Limitations

- Selection bias:

Control group patients using smartphones might represent all demographics, having mobile number in their medical record was considered as a proxy they were using smartphone and an indication they would have been eligible to use the ‘patientMpower’ app if it had been available in 2015.

- Information bias:

As all data has been collected retrospectively, there i some data may be missed which may lead to less accuracy and competency.

- Inappropriate control group:

Selection of an appropriate control group is also another limitation of the study. In this study, 2016 post-transplant patients not using the app were not considered for the control group because they were not using the app. This may be due to lack of computer literacy, not using smartphones, or fear of technology. Consequently, the intervention group may be more educated, younger, and more motivated than the control group. However, the researcher attempted to minimize this bias by stratifying the historical control group with key demographic variables.

- Small sample size:

Lastly, a small sample size is also a limitation. As the mobile app was introduced in 2016, the maximum available sample size who met the inclusion criteria and responded to participate in the intervention group was only 25 and the participant who matched with control group in terms of age and gender is only 30. Small

sample size can cause type 2 statistical error. It means clinically significant difference may not show any statistical difference.

- Lack of effective method for assessing IS medication adherence.

The researcher used a Tacrolimus viability and outside therapeutic range as an indication for nonadherence. However, therapeutic drug level can be affected by patient's recent drug dosage and the time patient took the medication.

3.12 Conclusion

This research design / methodology chapter enclosed all the elements involved in the planning of the research study and included the approach to the research, methodology, population and sampling, data collection and analysis and ethical considerations. The results of the analysis of the 'patientMpower' app users and control group are outlined in the next chapter.

Chapter 4 **DATA ANALYSIS AND RESULTS**

4.1. Introduction

The purpose of the study is to evaluate the effectiveness of a mobile app used for post kidney transplant patients. The chapter organizes and discusses the study's main findings. The chapter starts with main aim and objective of the study, statistics of total participants and demographics characteristics of the sample analysed. This chapter then analyses each outcome: medication adherence, blood pressure control, and patient engagement. Appropriate figures and tables are used to enhance the understanding of all who read this chapter.

4.2 Aim and Objective

The main objective of the study is to examine the effectiveness of mobile app used for kidney transplant patients on improved medication adherence, blood pressure control, and patient engagement and also to understand patient's experience of using the mobile app for the post kidney transplant management.

The study used a quantitative design using a matched historical control group. Matching was done to improve the efficiency of the study and an unmatched control group from 2015 (ie 3-12 months post-transplant, 18-65 years, with mobile numbers) was demographically very different from the intervention group. Hence, patients transplanted in 2016, 3-12 months post-transplant, using the mobile app were compared with matched patients in 2015 was not using the app. Matching was done in terms of age and gender without looking any clinical parameters and using stratified sampling technique.. Retrospective clinical data was collected from eMed (a computerised renal clinical system) for the 3 -12 months post transplanted period in both groups. The reason that, the researcher did not

choose 2016 transplant patients not using the app as they are not the reliable control group. In 2016 the app was offered to all eligible patients transplanted in 2016. The 2016 patients were not using the app is likely to be because they don't have a smartphone or they are reluctant to use the technology or noncompliant by nature. On the other hand, all the selected patients in 2015 are using a mobile phone, could have to use the app if it was introduced earlier. Additionally, a survey was conducted among app users to understand how they experience with using the app for their post-transplant care.

4.3 Statistics used for the data analysis

- *Statistical Package for Social Sciences (SPSS)* and word Excel were used to analyse the data.
- Descriptive statistics were used to reveal the characteristics of the sample and to describe study variable.
- The exploratory data analysis helped to identify the key differences in comparative figures among the intervention group and control group. This includes percentage, mean, and standard deviations.
- Variability of Tacrolimus for each participant calculated using coefficient variation formula in word Excel. Then Tacrolimus variability is expressed in percentage.
- Inferential statistical methods were applied to test the difference in key values between intervention and control group. Independent t-test is used for comparing the mean values of the age.

- Categorical values like gender and occupation are tested using nonparametric Pearson chi-square test, and the differences are established by analyzing the significance values.
- To analyse dependent variables such as Tacrolimus, level, blood pressure, creatinine level, participants are divided into two group within normal range or outside normal rage. Then categorical variables are expressed in percentage and compared using Pearson Chi-Square test.
- All the statistical tests assumed 95% confidence interval i.e with a significance value *p* less than 0.05.

4.4 Comparison of control and intervention group

A Total 60 patients were selected for this study. Each group has 30 patients selected. Beaumont Hospital Ethics approved to collect anonymised clinical data for control group without patient consent.

For the intervention group from the total 37 app users in 2016, 30 selected who met the inclusion criteria. After selecting the patients in the intervention group, the researcher selected patients in the control group from post transplanted patients in 2015 who are matched with intervention group in terms of age, sex and transplant period (3-12 months). The matching was done randomly without visibility of clinical data. All the participants were selected from the eMed. In the intervention group, of 30 patients approached one declined and four did not return the consent and questionnaire. This leaves total participants in the intervention group is 25. See Table 4.1 and 4.

Table 4.1 Total participants in the study

	Control Group (%)	App users
Total Patients selected	30 (100%)	30 (100 %)
Not responded	0 (0)	5 (5%)
Total participants	30 (100%)	25 (95%)

Table 4.2 Sample size by group

Group	Total Participants	percentage
Total	55	100%
Intervention Group	25	45%
Control group	55	55%

4.5 Demographic characteristics of participants

Baseline demographics characteristics and clinical outcomes are explained and compared between the two groups using the descriptive statistics. Frequency tables were also plotted for independent variables like age, gender, occupation. Independent t-test was used to compare the age and Pearson chi-square test used to compare gender and occupation between the groups.

4.5.1 Age distribution

The percentage and frequency of age distribution in both groups are shown in Table 4.3. The mean age in both groups is 36. In the app users, 84% were in the younger category (less than 45) with an average age of 36. In the app users group, only 12% (n=3) falls into the older age group. In the control group is 76.7% (n=23) are younger and 23 % (n = 7) are older. It reveals that the majority of

participants using the mobile app users are young. As expected given that control group was matched on age.

Table 4.3 Frequency distribution of age

Age	Control Group % (n)	Intervention group (%) (n)	P value
18 -45year(Younger)	76.7% (23)	84% (21)	0.852
46 -65 year (Older)	23% (7)	16% (4)	
Range	18 – 58 years.	18 -58 years	
Mean (SD)	35.93 (10.7)	36.44 9.3)	

4.5.2 Gender distribution

Gender classification of both control and intervention group was shown in Table 4.4. Male proportion in the total samples is 85% and the female proportion is only 14%. 83.3% of the participants in the control group are male and 16.7 % are female whereas, in the mobile app users 88% are male and females are 12%. Hence it can be interpreted that most of the participants in the mobile app users were male and very few females 12% (n=3) only using the app.

Table 4.4 Gender distribution

Gender	Control Group% (n)	Intervention group %(n)	Total n=55	P
Female	16.7% (5)	12% (3)	14% (8)	.458
Male	83.3% (25)	88% (22)	85% (47)	

4.5.3 Occupation

Table 4.5 shows the frequency distribution of occupation in both control group and intervention group. Overall n = 41 (75%) are working and n=14 (25%) are not working. In control group, 73% are working, and 27% are not working. In the app users' most of the participants (76%) are working.

Table 4.5 Frequency distribution of Occupation

Occupation	Control Group(n=30)		app users(n=25)		Total		P value
	n	%	n	%	n	%	
Working	22	73%	19	76%	41	75%	P= 462
Not working	8	27%	6	24%	14	25%	

4.6 Immunosuppressant medication adherence outcome

Studies are reported that there is no golden standard for measuring medication adherence (Anglada-martínez *et al.*, 2016), (Lieber *et al*., 2015). Each method has advantages and downsides. Tacrolimus is an immunosuppressant (IS) drug most commonly used in renal transplant patients. Serum Tacrolimus level is an objective way of measuring IS medication adherence. It is important to maintain the therapeutic level of tacrolimus to improve graft function and delay graft rejection. The Serum therapeutic level for 3 – 12 months post-transplant patients are 6-10ng/ml. Tacrolimus outside the target level and high variability in tacrolimus level are an indication poor medication adherence. So to examine the immunosuppressant adherence the researcher used Tacrolimus target level and variability over time.

To measure the IS adherence, the researcher categorized the participants within therapeutic range and presented in percentage. Pearson chi-square test used to compare the group .See Table 4.6 and figure 4.1.

To examine the Tacrolimus variability, researcher calculated each participant's coefficient variation and presented in percentage. Then the participants are categorised into following groups <15%, 15-25%, 25-35 %,< 35%. See table 4.7 and figure 4.2.

4.6.1 Percentage of participants within therapeutic range in both groups

As shown in figure 4.1 and table 4.6 three quarters of the participants (76%) in the intervention group falls in the tacrolimus target level of 6-10 mg/ml. Whereas in control group only half of the (50%) subject within target range. This group difference is tested using Chi-Square, and it is significant with p value .048. Hence it can be interpreted that, participants within the range of therapeutic drug level significantly high intervention group (among app users) than the control group. The mobile app users have better control of their Tacrolimus therapeutic level.

Table 4.6 Percentage of participant in target level in both groups

Tacrolimus level	Control group		app group		*P* value
	n	%	n	%	
Therapeutic range (6-10)	15	50%	19	76%	*P=.048*
Outside range	15	50	6	24%	

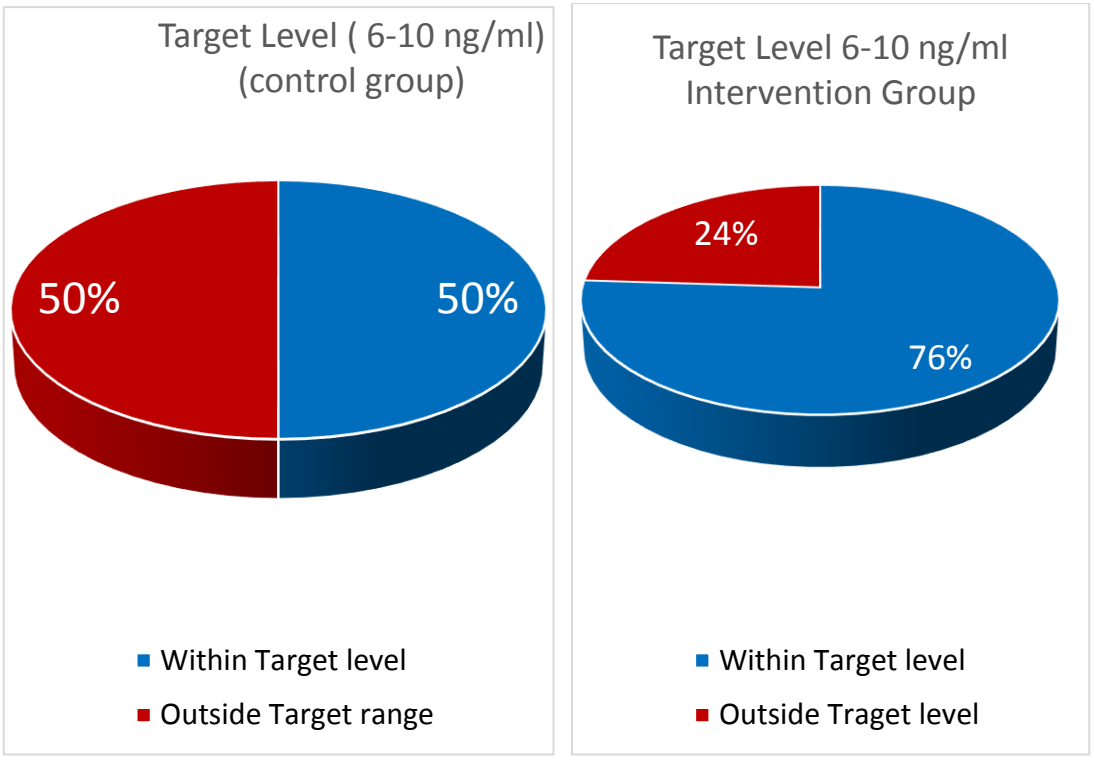


Figure 4.1 Percentage of participants in target range in both groups

4.6.2. Tacrolimus variability among the group

To measure variability, each participant's coefficient variation value measured from the four clinic visit value using Coefficient variation in MS Excel. Based on the percentage of coefficient variability patients are categorised into different groups. The high variability is noticed in control group than the intervention group. In control group, the six participants variability was more than 35% however, in the intervention group only one participant fall under highest variability. More than half of the participant's variability is less than 15%.Hence it can be interpreted that Tacrolimus variability is lower for app users compared to the control group.

Table 4.7 Tacrolimus variability

Percentage of coefficient variability	Control group(n=30)		App users(n=25)	
	n	%	n	%
<15%	13	45%	13	52%
16-25%	15	24%	8	32%
26-35%	3	10%	3	12%
36-40%	6	21%	1	5%

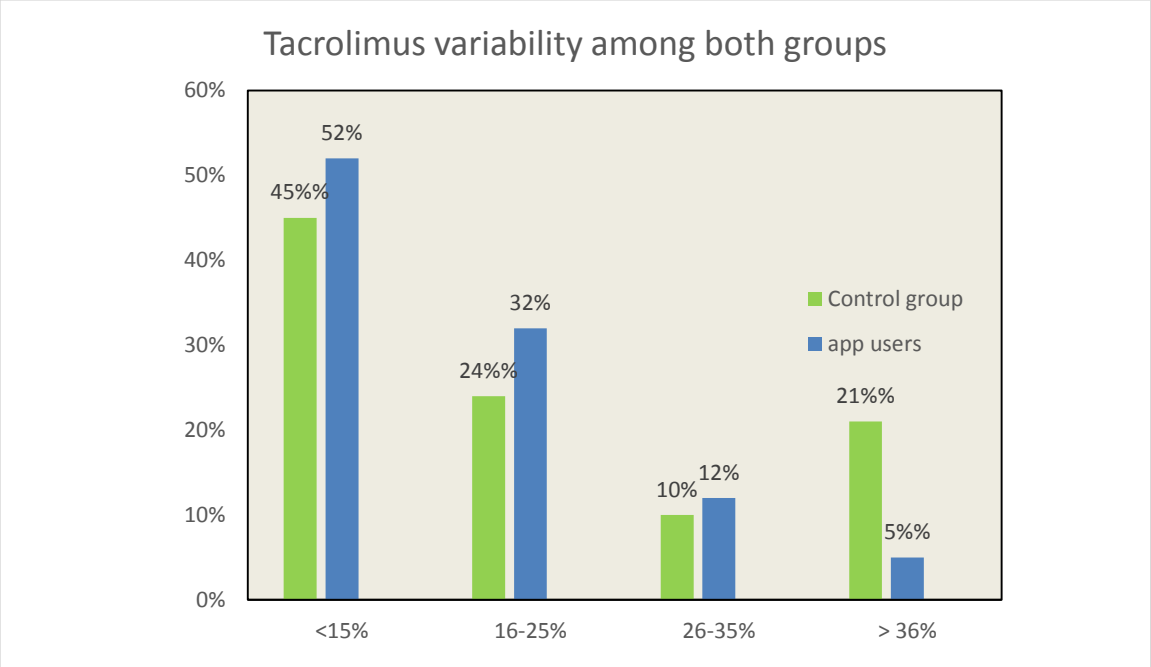


Figure 4.2 Tacrolimus variability among both groups

4.6.3. Immunosuppressant medication adherence over time among both groups

Table 4.8 and figure 4.3 illustrate the Tacrolimus values in their clinic visits. It can be seen that number of participants within the target level is increasing over time in the intervention group as compared to control to control group. The mobile

app users have better control of their tacrolimus level over time as compared to control group, but not statistically significant

Table 4.8 Participants within therapeutic level in each clinic visit

Clinic visit	Control group (n=30)		App users (n=25)	
	n	%	n	%
Clinic visit 1	17	56.7%	16	60%
Clinic visit 2	16	44.8%	20	80%
Clinic visit 3	18	60%	20	80%
Clinic visit 4	13	53.3%	22	88%

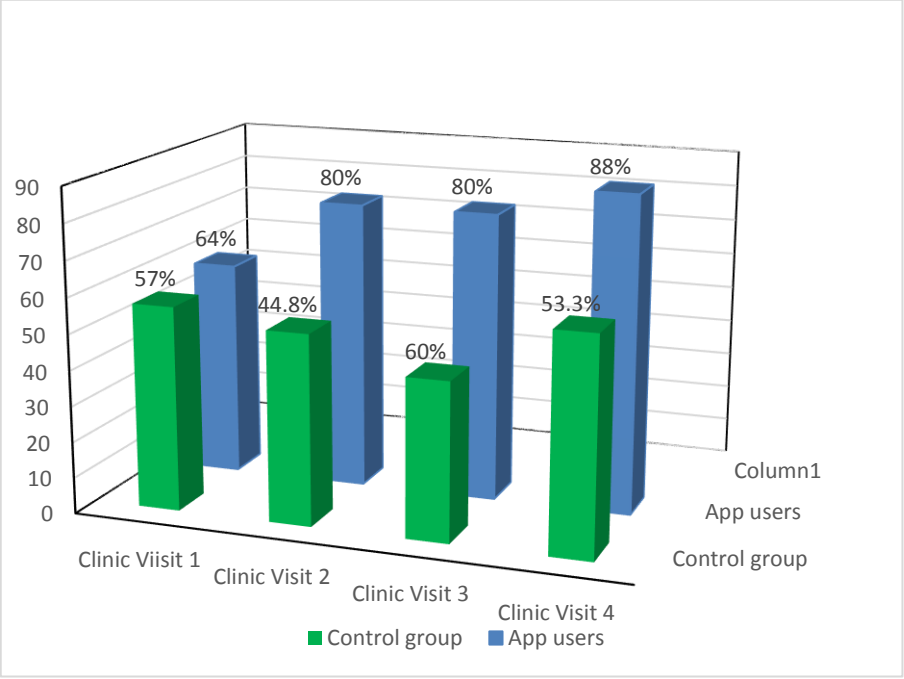


Figure 4.3 Bar chart showing tacrolimus value in each visit.

4.7 Blood pressure control

Better blood pressure control is crucial to long-term graft success. According to KIDGO guidelines, the target blood pressure for renal transplant patients is less than 130/80 mmHg (National Kidney Foundation, 2012). However, only a few participants among both groups achieved this target. See figure 4.4. According to Seventh Joint National Committee hypertension is defined as BP greater than 140/90mmHg (James *et al.*, 2014). Based on this guideline the researcher set a target BP less than 140/90 mmHg as better blood pressure control. The researcher categorised each participant as a BP controlled or not based on two or more than values within normal range. Table 4.9 show number of participants in each group BP less than140/90 mmHg.

4.7.1 *Blood pressure less than 140/90mmHg*

As shown in Table 4.9, and figure 4.4 systolic BP in control group is 46.7% (n=14) which is slightly greater than app users group (40.4%). The mean systolic BP in control group is 140 mmHg and in app users is 141.5mmHg. However the highest standard deviation is noticed in control group (12.4).

The diastolic BP slightly better in app users (76%) than the control group (66.7%). The mean diastolic BP in both groups are 83.mmHg, and standard deviation (SD) marginally high in app users than the control group (See Table 4.9 andSee figure 4.5.) There is no statistical significance in BP between both groups. More than half of the participants in both groups are hypertensive.

Table 4.9 participant's systolic BP less than 140/90mmHg

Range	Control group (total n=30)		Intervention group (total n-=25)		p
	n	(%)	n	%	
SBP<140 mmHg	14	46.7%	10	40%	.629
DBP < 90mmHg	20	66.7%	19	76%	.448
SBP mean (SD)	140	(12.4)	141.5	(8.9)	
DBP mean (SD)	83.13	(7.04)	83.1	(9.5)	

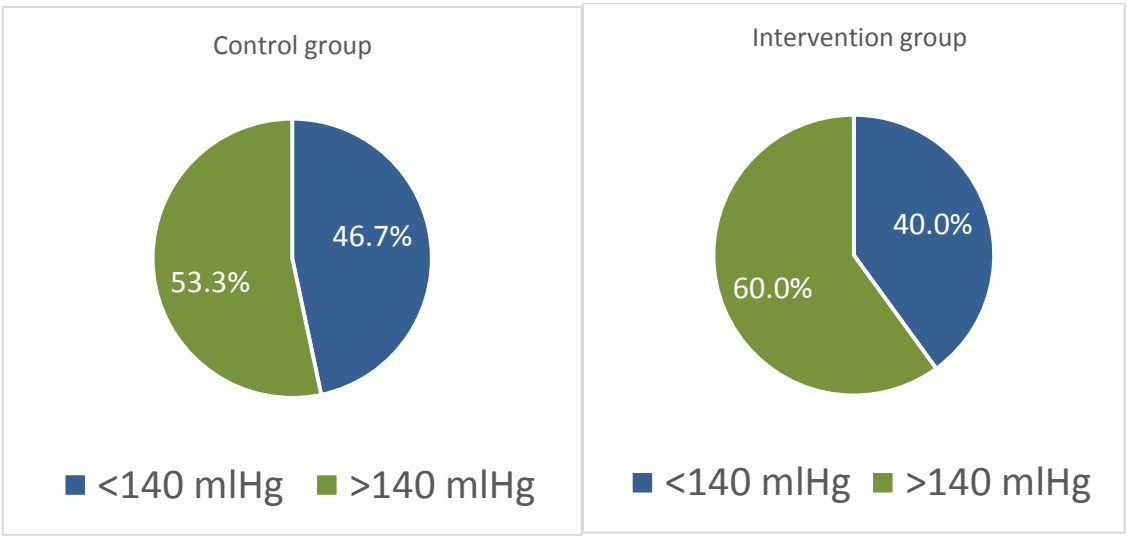


Figure 4.4 BP less than 140mmHg

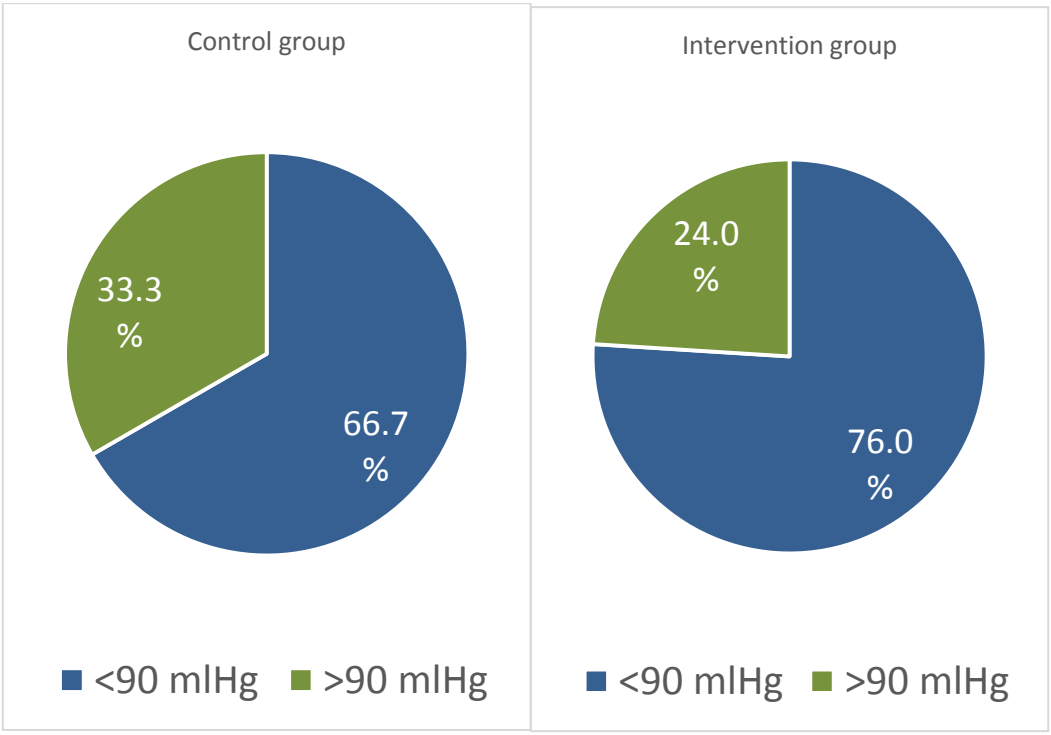


Figure 4.5 Diastolic BP<90mmHg

4.7.2 Baseline mean BP

Table 4.10 and Figure 4.6 presented the mean base line systolic BP in each group. It can be seen that only a few participants BP is less than 130mmHg. According to KIDGO guideline target Systolic BP is less than130mmHg. Morethan two-third of the participants BP above the target level.

Table 4.10 Mean Baseline systolic blood pressure in both groups

Systolic BP	Control group n=30		app users n=25	
	n	%	n	%
<130mmHg	9	30%	4	16%
130-140	5	16.7%	8	32%
>140mmHg	16	53.3%	13	52%

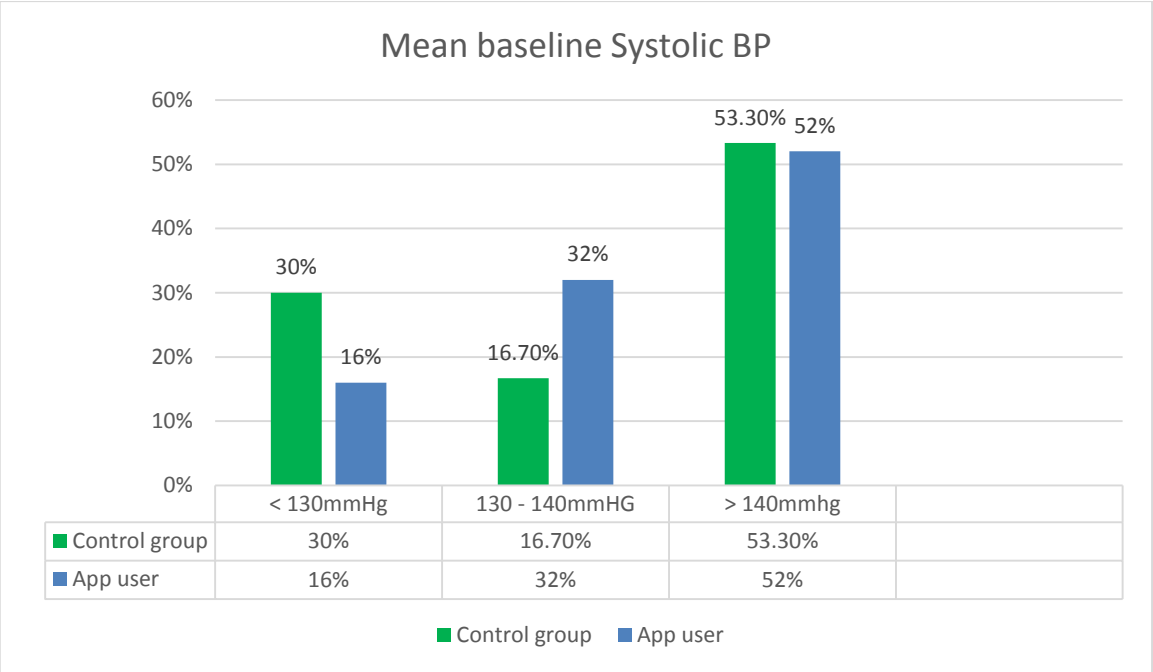


Figure 4.6 baseline SBP

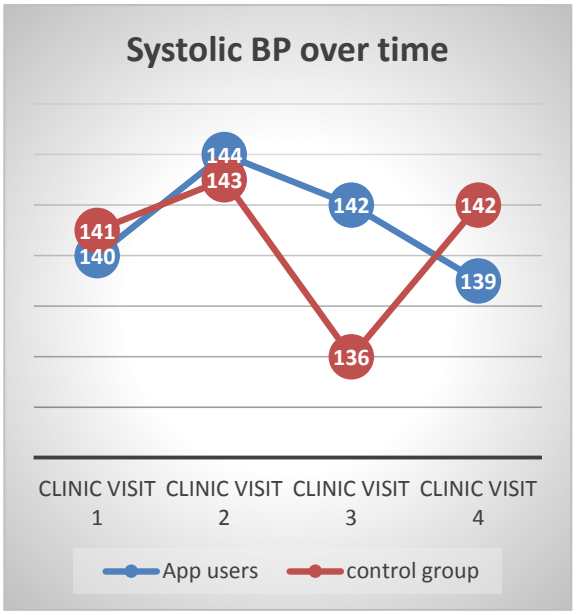
4.7.3 Blood Pressure over time

The Table 4.11 and Figure 4.7 are shown mean BP over time in both groups. For the app users the mean SBP at the first clinic visit was 142 mmHg which decreased to 139mmHg at the last clinic visit. Whereas in control group mean SBP at the first clinic visit was 141mmHg, same remain almost stable throughout the period. BP at the last clinic visit was 142mmHg and the standard deviation was high in control group as compared to app users.

The mean diastolic BP slightly increased in control group over time. For the control group mean diastolic BP at the first clinic visit was 80mmHg which increased to 86 mmHg at the last clinic visit. For the app users mean BP increased by only 1 mmHg from first visit to last visit. In the app users diastolic BP remains same throughout the period. Standard deviation of diastolic BP at each visit is almost same in both groups.

Table 4.11 Mean BP over time

Clinic visit	Control Group				App user			
	Mean SBP mmHg	SD	Mean DBP mmHg	SD	Mean SBP mmHg	SD	Mean DBP mmHg	SD
Clinic Visit 1	141	16.9	80	12	140	10.5	82	9.7
Clinic visit 2	143	15.9	86	11.3	144	12.9	83	11.3
Clinic Visit 3	136	14.9	84	9	142	11.5	83	12
Clinic Visit 4	142	13.0	86	9.4	139	10.4	83	9.5



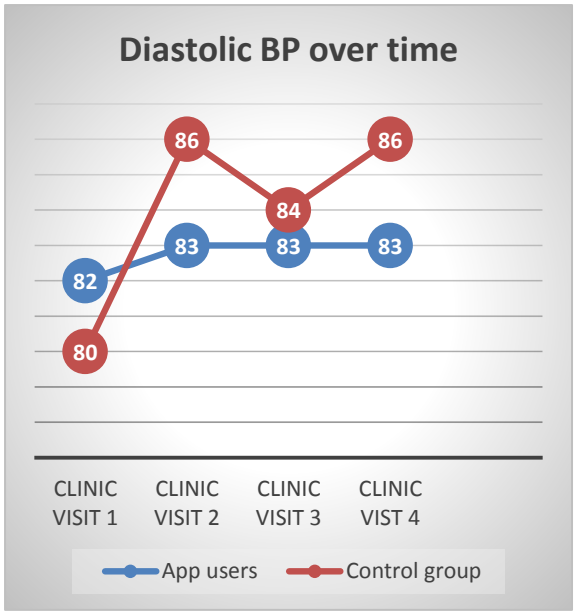


Figure 4.7 BP overtime

By analyzing the systolic and diastolic BP, within target range, mean base line BP and BP over time, none of the values are shows any statistical significance. Hence it can be interpreted that both groups are marginally hypertensive. Although better control of diastolic BP noticed in app users and slight decreasing

systolic BP over time among app users, the app users did not show any significant improvement in blood pressure control.

4.8 Patient engagement

Patient engagement means overall behavioral, cognitive and emotional presentation of individual towards the disease condition and the management (Graffigna *et al.*, 2015). Poor patient engagement leads to the medication nonadherence, poor disease control, inadequate monitoring of health conditions and also reduces the quality of life (Cramm and Nieboer, 2015) and increase readmission and missed the appointments (Hardinge *et al.*, 2015). To measure patient engagement, the researcher collects the data about a number of missed appointments and number of A&E visits. Missed appointments and A&E visits is an indication of poor patient engagement. In addition, the researcher also collected lab data about creatinine value. Target Creatinine value is less than 150mmg/dl. Increasing creatinine level is a sign of detoreating graft function. It may also be an indication for poor patient engagement.

In addition for the intervention group, the researcher collects the data about app usage to analyse patient engagement in self-management with app. However, researcher were not able to link app data to clinical data so the researcher could not look for correlation between usage and impact.

4.8.1 Missed appointment

As shown in Table 4.12 there is no significant difference in missed appointment or creatinine level among both groups. Missed appointment is relatively less in the intervention group than control group. However, this is not show any statistics significance.

Table 4.12 missed appointment

Feature	Control group n=30		Intervention group n=25		Chi- square p
	n	%	n	%	
Missed appointment/ A&E Visit	7	23%	3	12%	.278

4.8.2 Creatinine level

As shown in Table 4.13 majority of participants in both groups creatinine level is less than 150mg/dl. Mean creatinine value is 131 and 132 for the control group and intervention group respectively. Variability in creatinine high in the control group. As shown in figure 4.8 the number of participants with the target value was increasing over time.

Table 4.13 Creatinine level

Creatinine	Control group		Intervention group		P value
	N	%	N	%	
Creatinine <150	23	77%	19	76%	.954
Creatinine mean (SD)	131.2 (54.4)		132 (40.9)		

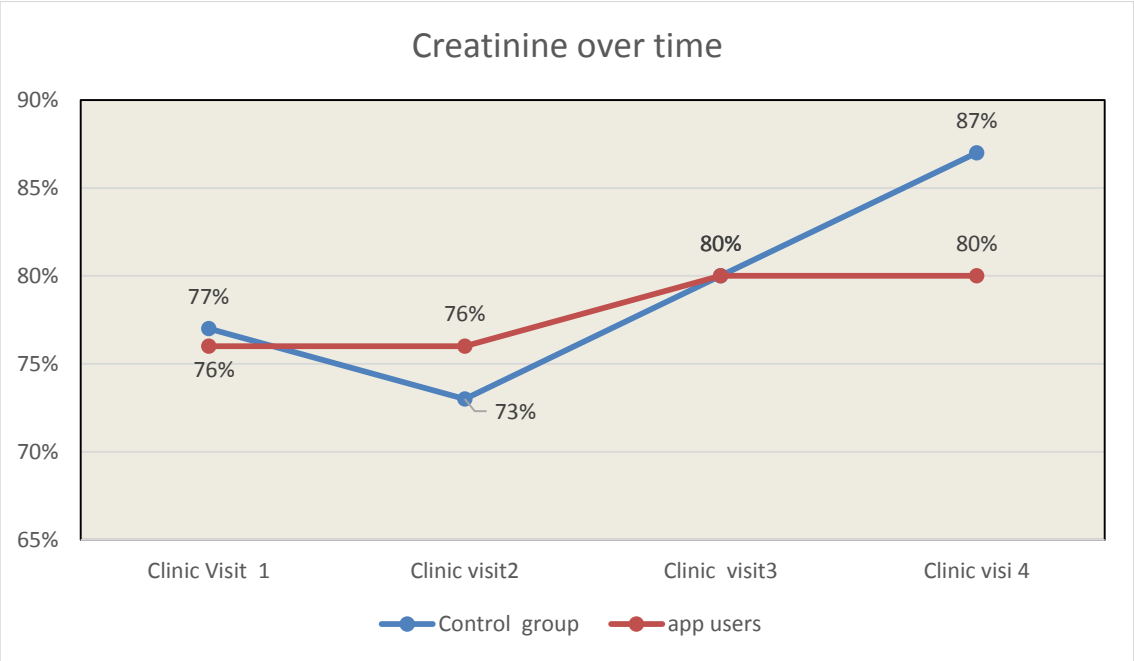


Figure 4.8 Participant within target creatinine level over time

4.8.3 Device usage data of app users

To measure the patient engagement in self-management with additional data was collected from the app database. It shows that 52% of the users of app use the app daily, while 16% are not using the app. Nearly 52% participants are marking the adherence daily, 16% of participants marking 2nd day or weekly, and 8% of participants are recording occasionally. However, 24% participants are not marking adherence. These results are presented in figure 4.9.

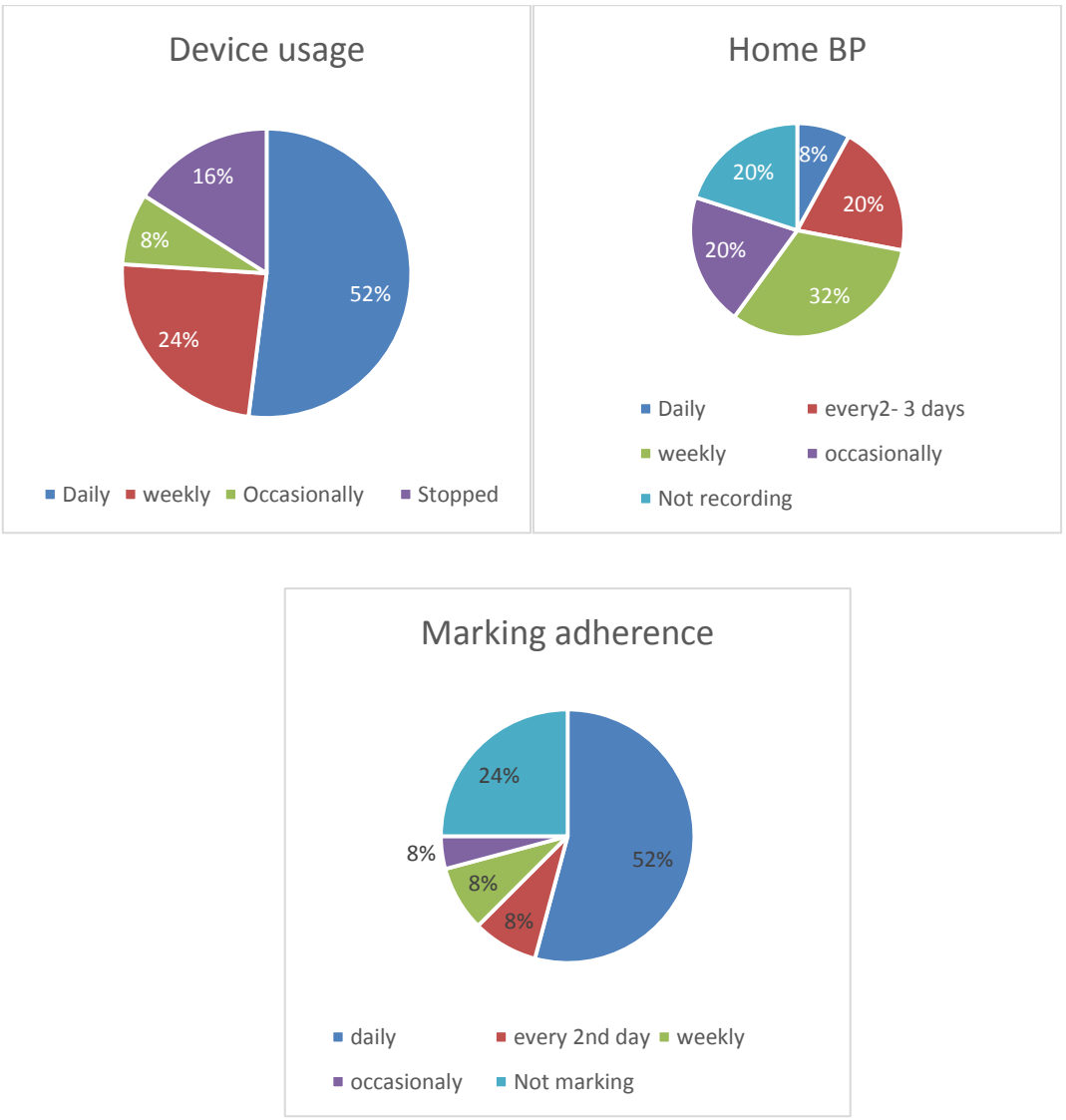


Figure 4.9 device usage data

4.9 App user's experience survey

The results of mobile app usage depend on the perception of mobile user's satisfaction across different journey points on the application. A customer satisfaction survey to assess the usage patterns was conducted by the researcher and strongly believes it is a great way to make sure that the customer's views are involved the further development of this application. The in-app experience is crucially important in assessing the outcome caused by usage.

The claim of mobile app users increased control over clinical values depends on usage patterns.

The mobile app usage experience survey is established to assess different aspects of the mobile app in view of typical users experience survey, where participants are requested to respond to the touchpoints using a Likert scale from strongly agree to strongly disagree. With a Likert scale, respondents have the option to indicate the degree of agreement or disagreement in a multiple choice format.

The survey showed a positive response to ease of use of the app. The satisfaction ratings from this survey are presented using the Likert scale as combined score of agree and strongly agree as a proxy of satisfaction. The overall results from this satisfaction survey are presented in figure 4.10

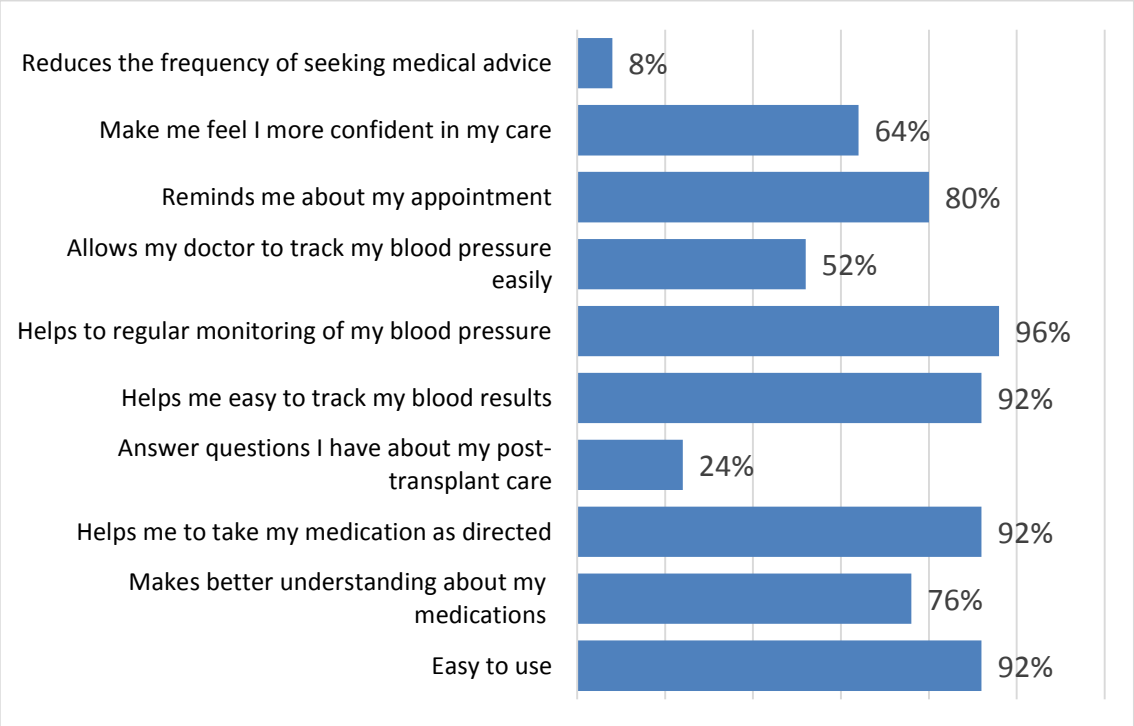


Figure 4.10 Overall patient experience ratings in using the app.

Overall 92% agreed and strongly agreed that the app functionality is easy and user friendly. Adoption of mobile health app depends on the perception of ease of use as it is critical from a user's point of view that technology should facilitate ease of use. Overall 76% participants agreed and strongly agreed that the app provides a better understanding of the medication and most of the participants (92%) agreed that the app helps them to take their medication as directed. Considering the high values of these satisfaction ratings, the ease of use and directions on medication helps the app users in the daily routines of a post-transplant patient.

The majority of the participants had negative response when they were asked the app-assisted them about queries related to post-transplant care. Only 24% participants agreed that the app help to understand queries related to post-transplant care, with over a half being neutral to this statement. This could be because they either haven't used this app as trustable source for post -transplant queries.

It is evident from the users that most of the users of app use it for tracking their clinical values and using the app as a tracking record in their clinical values, which needed routine scrutiny. Most of the participant suggested 92% the app helps them to track their blood results and as expected 96% reported that the app helps the regular monitoring of BP. 52 % of participants were reported that doctors are tracking their home BP measurement and 86% of the app users respond that the app provides a reminder for their appointment.

64% of the app users feel the app makes them confident about their post-transplant care while 14% disagree and 52% neutral to that the app helps them in reducing the frequency of seeking medical advice.

A few participants (30%) wrote as an additional comment they are facing technical issues while using the app. This includes downloading problem, getting graphic display over time, errors and technical issues related to automatic transferring the data.

4.10 Conclusion

In summary, findings from the study show the target level of Tacrolimus level is significantly higher and less variability Tacrolimus in app users than the control group. This is an indication of a better medication adherence. Although less deviation in systolic BP and better control of diastolic BP was noticed among app users, there is no significance improvement in blood pressure control in-app users. Patient engagement is moderately same in both groups regarding missed appointment, A&E visits. Both groups showed decreasing trend of creatinine value over time. However, it does not show any statistics significance. Device usage from the app database showed the majority of the participants (72%) using the daily or weekly. However, a small number of participants stopped using the app recently. More than half of the participants (52%) record the adherence daily. Most of the patients monitoring the BP weekly, every second or third day. However, there is no BP record for 20% participants.

The survey showed an overall positive response from the participants. The majority of the participant respond that app is easy to use and they felt app help

them to track the lab value, monitoring and recording the BP, better understanding of the medication.

However, the majority felt the app does not answer queries related to their post-transplant care, and does not reduce the frequency of seeking medical advice. In the additional comments, a few participants raised concern about the technical issues while using the app.

Next chapter will discuss the findings of the results linked with findings from the literature review.

Chapter 5 **CHAPTER 5 DISCUSSION**

5.1 Introduction

This chapter discusses the findings of the result analysis in the previous chapter. The purpose of the study is to evaluate the effectiveness of the mobile health app used by kidney transplant patients with regard to improving medication adherence, blood pressure control, and patient engagement. This chapter discusses the results of the analysis based on the objectives of the study and links them to the literature review.

5.2 Overview of the findings

The development of effective and efficient aids to support self-management and monitoring is crucial to the success of graft function (McGillicuddy *et al.*, 2013). Furthermore, shortage of healthcare professionals, growing number of renal disease and renal transplant patients, there are increasing demands for healthcare delivery via mobile health technology to support patients with chronic diseases (McGillicuddy *et al.*, 2013).

In this research study, a retrospective quantitative analysis with a matched control group was used to answer the research question. Overall findings from the study indicate that mobile health app intervention significantly improves medication adherence. However, there is no evidence of a significant improvement in blood pressure control and patient engagement from the study. The majority of intervention group patients use the app daily or weekly. Overall survey response showed the app is easy to use.

The total sample size for this study was 55. For the intervention group, almost 83% (25/30) of patients approached agreed to participate in the study. Of the remaining five, one declined as he was not using the app, although he had downloaded it. The remaining four patients were approached by mail as they had no clinical appointments during the study period (March-May), and they did not respond. For the control group, patients who matched with intervention group in terms of age and gender were randomly selected from the computerised medical record (n=30). The high rate of participation (83%), positive responses on the surveys, and 72% high-to-moderate (daily or weekly) use of the application showed that mobile app is a promising tool to support self-management in renal transplant patients.

5.3 Demographic characteristics of the participants

A study by Chisholm-Burns et al. (2012) highlighted the common risk factors associated with non-adherence in renal transplant patients; these were youth, being male, and having a busy professional life. General analysis of the baseline demographic characteristics of participants found that the app users were younger, more likely to be employed, and more likely to be male than those in the control group. These findings showed that the mobile health app can support and improve behavioural changes in the young as well as those patients who lead busy professional lives. These findings are also consistent with many other studies that have demonstrated most health app users are young (Kirwan *et al.*, 2013, McGillicuddy *et al.*, 2015) and employed (Bhuyan *et al.*, 2016). There was only one participant in the intervention group aged over 45 years. A study included in the literature review showed that older populations are less likely to

use health apps for medication reminders, communication with healthcare providers, and appointment reminders (Bhuyan *et al.*, 2016). Furthermore, a Pew research survey on older adults using technology in 2014 found that only 18% people over 65 years are using a smartphone (Smith, 2014).

Findings from the study also indicated that fewer females are using the app (n=3) than males (22). However, this finding was contradictory to the results of the study by Jiang et al, (2016), who in their study about a mobile app-supported decision support system for reporting critical values for lung transplant patients found that females are better at using the technology than males. Another study related to a mobile app used for asthma care also showed that the majority of participants were female (Ryan *et al.*, 2012). No other studies located in the literature search discussed the gender difference with regard to the adoption of mobile apps.

The main objectives and findings of the study will be discussed in light of the existing literature in the following sessions.

5.4 Objective of the study

5.4.1 Objective 1: To measure IS medication adherence in transplant patients using the mobile app as compared to those in the control group

As an indication of Immunosuppressant medication adherence this study used achieving target level of Tacrolimus and less variability in Tacrolimus. The target Tacrolimus range in the 3-12 month post-transplant period is 6-10 ng/ml. The study shows three quarters of app users achieved the target level of Tacrolimus level compared to control group. App users also had less variability in Tacrolimus levels than the control group participants. These findings are consistent with

those of McGillicuddy et al. (2015), who found that a mobile health technology improved medication adherence in renal transplant patients.

According to Chisholm-Burns *et al*., (2016) and de Fátima Cruz de Morais *et al* (2016) behavioural interventions such as reminders and feedback can improve medication adherence in renal transplant patients. In this study, data from the app showed that more than half of the participants marked adherence daily (52%) or weekly (16%). Findings from the survey also showed 80% of patients felt the app helped them to better understand their medication and to take medication as directed.

Findings from the other studies also highlighted mobile app support with regard to behavioural changes to improve medication adherence by providing reminders, feedback, and a graphic display of adherence over time (Zhang *et al.*, 2016, Grundy, Wang, and Bero, 2016). The study by McGillicuddy et al. (2015) suggested that mobile apps can help to improve self-efficacy in medication adherence by being easy to use and inexpensive and by providing reminders and real-time feedback to motivate the patient. From these findings, and the result from this study, it is clear that mobile health app support improves medication adherence in transplant patients by providing reminders and feedback.

5.4.2 To determine the blood pressure control in transplant patients using the app as compared to control group

The study identified that the majority of the participants (87%, n= 75/87) were hypertensive, with a mean (SD) systolic BP among app users of 143mmHg (12.01) and among control group of 140mmHg (9.04). This was consistent with the findings of the study by Thomas et al. (2013), which stated that 70-90% of

renal transplant patients are hypertensive and taking antihypertensive medication. Mean systolic BP in app users at the second visit was 144mmHg and in the fourth visit the mean had reduce by 5mmHg whereas in the control group the mean BP remain almost same from first clinic visit(141mmHg) to fourth clinic visit 142mmHg). The study also found that the app users showed less variability in systolic blood pressure and better control of systolic BP than the control group. However these difference fell short of statistical significance. McGillicuddy *et al.*,(2015) suggested that less variability of BP is an indication of a patient's adherence to blood pressure medication.

The study findings emphasise the importance of home blood pressure monitoring in renal transplant patients for better control of BP and hypertensive dose adjustment. Although this study did not find any statistical significance in blood pressure control among app users, a randomized control trial by McGillicuddy et al. (2013) proved that home BP monitoring using mobile health intervention offered better control of BP in renal transplant patients. Additionally, Monitoring BP regularly at home motivates the patient to adhere to their BP medication.

Home BP monitoring helps patients to track their BP regularly and to show the readings to clinicians at their clinic visits. It also helps clinicians to compare clinic readings with home readings and effectively adjust doses. Surprisingly, in the survey, only 52% of participants responded that doctors review their home BP readings along with clinical readings to adjust antihypertensive medication. A systematic review by Agarwal et al.(2011) suggested that home BP monitoring has no relevance unless physicians review and act on it. Hence, the study results and evidence from the literature review indicate the importance of reviewing

home BP measurements at each clinic visit for improved hypertension management.

5.4.3 Objective 3. To identify levels of patient engagement for those using the app as compared to the control group

The study did not find any significant difference in patient engagement between those using and not using the app. Both groups were similar with regard to patient engagement in terms of A&E visits, missed appointments, and inpatient admissions. Creatinine levels decreased in both groups over time. The mean and (SD) creatinine value in those using the app was 133 (40.11) and in the control group was 118.2 (46.7). Increasing Creatinine values greater than 150 are an early indication of poor graft function.

The data analysed regarding device usage demonstrated that 70% of participants were using the app daily or weekly. Nearly 8% rarely used it, and 16% stopped using the app. These findings are consistent with those of the study by Krebs and Duncan (2015) found that 58.2% participants downloaded the health app at some point, and that 45.7% of app users stopped using the health app. In some respects, this also corresponds with the findings of the earlier study by (Bhuyan *et al.*, 2016), who found that it is hard to sustain use of the app. Furthermore, a review by Whitehead et al. (2016) also highlighted that frequency of data entry and app usage decreased over time.

Although this study found significant improvement in medication adherence, the app usage data from the last three months indicates that a few participants using the app rarely and stop using the app. Consequently, it is important to identify the factors associated with the decreasing use of the app and barriers associated

with usage of the app. The researcher anticipates that app usage can be increased through clinician input and patient-provider communication in the form of feedback reinforcement messages from the app, phone calls or text messages, and occasional health advice to improve efficacy of the app to motivate behavioural changes in patients. When they feel that their health is being looked after by care providers even outside the hospital, the patients' mobile health app usage will increase. The key conceptual framework for patient engagement is information, motivation, and behavioural change (Athilingam *et al.*, 2016). Most of the studies reported using mobile health technology for supporting the self-management for chronic diseases can facilitate communication with health care provider, and able to transfer patient generated data into the corresponding physician via secure email or web server (Jiang *et al.*, 2016),(Kirwan *et al.*, 2013),(Liu *et al.*, 2011).

5.4.4 Objective 4: To understand the patients' experience of the use of the 'patientMpower' app

The overall survey shows a positive response from the participants. Ninety-two percent of participants responded that the app is easy to use. Most of the participants felt that the app was helping them to take medication as directed, monitor BP regularly, and track lab results. These findings are consistent with those of other studies that evaluated mHealth technology for chronic diseases (Mcgillicuddy *et al.*, 2015, Whitehead, Seaton and Hons, 2016). Surprisingly, a limited percentage of participants felt that the app helped to answer queries related to post-transplant care, provide health advice, and improve confidence in care. This may indicate that patients expect some sort of educational tool or

communication with healthcare providers to answer queries related to post-transplant care. It would be helpful to conduct future studies to understand patients' views, acceptance, and expectations; this will be further discussed in the next chapter.

In the additional comments section of the survey, a few participants (30%) raised technical issues related to the app, such as the inability to use the app off-line, downloading problems, errors in graphical display of lab values and BP over time, errors in transferring BP data due to Bluetooth paring issues, and technical issues regarding the automatic transmission of lab results from eMed to the app. According to the Technology Acceptance Model (TAM) theory, technology factors are a key variable in the acceptance of the adoption of technology (Zhang *et al.*, 2016). Findings from the survey suggest the need for better technical support to solve the technical issues encountered by app users in order to sustain the use of the mobile app.

5.5 Summary

The findings of the study were discussed in detail in this chapter. The study found that mobile health app intervention in transplant patients promises to improve clinical outcomes, medication adherence, and blood pressure control among app users and to aid self-management. The app was seen to be easy to use and helped patients to take medication as directed, better understand their medication, and track blood pressure and lab values. However, the study did not show any evidence of improvement in patient engagement in terms of missed appointments and A&E visits. Although the data from the app found that the

majority of participants using the app used it daily or weekly, a few participants ceased using or rarely used the app.

The survey showed an overall positive response to the mobile app. The majority reported that the app is easy to use. However, factors such as technical issues, lack of features to answer queries related to self-management, and lack of health providers-patient communication may be potential barriers to adoption of the mobile health app and to long-term use.

The findings also emphasized the need to sustain the users by improving app features through gamification, communication with healthcare providers, and real-time technical support. The recommendations drawn up as a result of the study and strengths and limitations of the study will be discussed in the next chapter.

Chapter 6 CONCLUSION

6.1 Introduction

The aim of this study was to evaluate the effectiveness of a mobile app used for kidney transplant patients on clinical outcome such as medication adherence, blood pressure control and patient engagement. This chapter firstly presents with summary and key findings of the research study, followed by strengths and limitation of the study. Then it presents recommendations for future work. In conclusion the researcher reflect experience and knowledge gained by this study.

6.2 Summary

The widespread increasing in smartphone health app creates better media for the management of chronic disease. A mobile app was recently implemented in national renal transplant Centre to support the self-management of kidney transplant patients. The researcher took an opportunity to examine the effectiveness of mobile app and to understand patient's experience using the app. The study setting is Beaumont Hospital National Centre for Renal Transplant which provides care for renal transplant patients. A literature review identified the importance of and challenges related to post-transplant medication adherence, blood pressure control and patient engagement. Further it also identified that mobile health app are used to support self-management in many chronic diseases and renal transplant patients. Based on the literature review a methodology was drawn up to answer the research question. The research questions, study method and answers will discuss in next section.

6.2.1 Does the app improve clinical outcome in renal transplant patients?

Primary focus of the study was to examine the effectiveness of the app on improved IS medication adherence, blood pressure control and patient engagement. A quantitative study approach using a matched control group was used to answer the research question. For that, clinical data are retrospectively collected from renal data base called eMed. Also app usage data was collected from the app database.

6.2.2 Key Findings related to clinical outcome

- The number of participants reaching therapeutic level of Tacrolimus level is significantly higher for app users. Further, app users had less variability in Tacrolimus level than the control group. Achieving therapeutic of Tacrolimus and less variability in Tacrolimus level is a clinical indication for better adherence.
- Slightly better blood pressure control over time was identified in app users compared to control group. However, the difference was not statistically significant.
- Patient engagement was the same in both groups in terms of A&E visits, missed appointment and inpatient admission. Although 72% participants were using the app daily or weekly, a few patients stopped using the app in last three months.

6.2.3 What is the patient experience of using the app?

A survey was conducted in app users to understand patient experience using the app.

6.2.4 Key findings from the survey

- Majority of the patients positively respond to the survey, that the app is easy to use, reminds them about the medication and helps to track their home BP and lab values. However, comparatively fewer participants felt that the app supports self-management through answering queries, providing medical advice to make them feel confident in self-management. In addition to that, a few participants reported technical issues while using the app.

6.3 Implication of the study

- The findings provide evidence of the impact of the mobile health app in renal transplant team, and the App developer.
- The findings also help the app developer and lead renal transplant consultant and team to identify areas of concern, address the issues of the app users as well as take the measures to sustain the users.
- The findings from the study suggest that the mobile health application is easy to use and a promising tool for patients with any chronic disease in terms of supporting self-management behaviour and tracking their lab result, monitoring and automated recording clinical data.
- The results from the study motivated the researcher to implement mobile app technology in her workplace and also to support patients with renal diseases.
- The study also suggest the importance of health provider's communication and involvement via app to support self-management.

- Overall positive impact of the study was to motivate the organization to develop or implement mobile app to support self-management different chronic disease.

6.4 Strengths and Limitations of the study

The study help to understand the effectives and limitations of the 'patientMpower' app. The recommendations will be based on the findings, anticipated improvement in the app to provide technical support and healthcare provider's communication to sustain the users. The enthusiastic, positive attitudes and willing to participate in the research by all the participants were valuable. The support, consideration and encouragement from all the renal department staff, managers and consultant, patientMpower app developer for the study was greatly appreciated.

This study was the first attempt to examine the effectiveness of the app on improved clinical outcome on renal transplant patients. Hence, the study has several limitation which are outlined below.

- The size of the sample in the app users were small. There were only 30 patients who the inclusion criteria; of those, one declined and four did not return the consent and questionnaire. Due to small sample size the study did not have statistical power to find statistical significance
- Lack of appropriate control group. The app was introduced in 2016 and was given to all the eligible patients in 2016. The patients transplanted in 2016 who are not using the app are likely to be different from app users in being not having smartphone, non -compliant or having a fear of technology. So the researcher used a historical control group (those transplanted in 2015) to

answer the research question. Hence, the benefits from the intervention are impossible to determine whether observed benefits were from mobile app intervention or enhanced clinical care.

- To measure IS medication adherence the researcher used a proxy (i.e., therapeutic range and variability). However, the variability and attaining the therapeutic level may be depend on the drug regimen and drug dosage.
- Having mobile phone number on the medical record used as a proxy that patients were using the smartphone in the control group. But, it is not necessary that all of them are using a smartphone. The alternative would have required contacting control group participants to ascertain wheater they use a smartphone. But the study design did not require contacting control group patients (see section 3.10.2).
- As this was a preliminary study to evaluate the effectiveness of the app on clinical outcomes and patient experience. The users adoption, behavioural intention and technology acceptance was not tested.

6.6. Recommendation for future work

The further work proposed based on this study result are

- A prospective randomized control trial with using large sample is needed to examine the long-term outcome of the mobile app.
- The success of the any mobile health intervention is depends on the adoption and effectively utilizing the technology by the target population. Hence, it is important to do a qualitative study to explore patient experience, views, and concerns using the app
- Providing a mobile app interface to the renal database called eMed.

This will facilitate communication to the healthcare providers in terms of real time reporting of critical values and sending feedback, reinforce message, advice from healthcare providers.

- Bluetooth attached medication tray.

The current way medication monitoring adherence monitoring is patients' response to a prompt message of medication of reminder. Even though, the patient marked adherence when the prompt appears. It may not provide the evidence that they are taking the medication at right time. A wireless Bluetooth attached medication tray for all the medication dispensing would be beneficial and would also facilitate real time tracking of adherence (Mcgillicuddy *et al.*, no date).

- Recommendation to other renal centers in the Ireland.

The researcher recommended to implement a single app across all the renal centers in Ireland. This will provide unity and support post-transplant self-management support and patient portal to the development of a national renal registry.

- The researcher strongly wish to expand the mobile health technology into the other area of renal diseases to support the patient self-management such as chronic kidney disease, hemodialysis and peritoneal dialysis.

6.7 Dissemination of the findings

The researcher submitting this report to Transplant Urology and Nephrology Department in Beaumont. The study also going to be submitted to the Nephrology directorate, and IT department at the researcher hospital.

Furthermore, the author plans to publish and present at HISI conference. In addition to that, the author wishes to present the findings at Irish Nephrology Nurses Association conference and National Nephrology conference.

6.8 Reflection of the study

The researcher was very anxious initially to conduct the research study. Ongoing support from the supervisor gave encouragement and motivation to complete the project. The researcher had to face many challenges during the project such as ethical approval and data collection. The researcher went to Beaumont go every day off from March to May to recruit the participants. However, it was interesting to communicate to patients and understanding their expectations and concerns. Lectures from the course helped to understanding of each steps of the research project. The researcher achieved deeper knowledge in SPSS and different statistical analysis methods.

A research study need commitment and enthusiasm. A research study needs contact and support from many people directly or indirectly. The knowledge and experience gained from doing the study will help to participating in any studies in future and especially evaluating any healthcare IT projects. The researcher felt that she has competency in partake any health IT research project.

6.9 Conclusion

The aim of the study was to evaluate the effectiveness of mobile app on improved clinical outcome such as medication adherence, blood pressure control and patient engagement. The secondary aim of the study was to understand patients experience using the app. All the objectives of the study were identified, the study showed a positive impact on medication adherence in terms of less variability and

higher number of participants within target level of Tacrolimus level. However, the study did not show any significant improvement patient blood pressure control and patient engagement. Overall positive response from the survey and device usage data showed the app is easy to use and accepted by the patients.

This was the preliminary study to look at the outcome of mobile app for kidney transplant patients. I hope the outcome of the study will give recommendation to the app developer and to the renal team to look at the areas that need consideration. Further study with a large sample is necessary to understand long-term outcome, patient's acceptance and sustainability of using the app.

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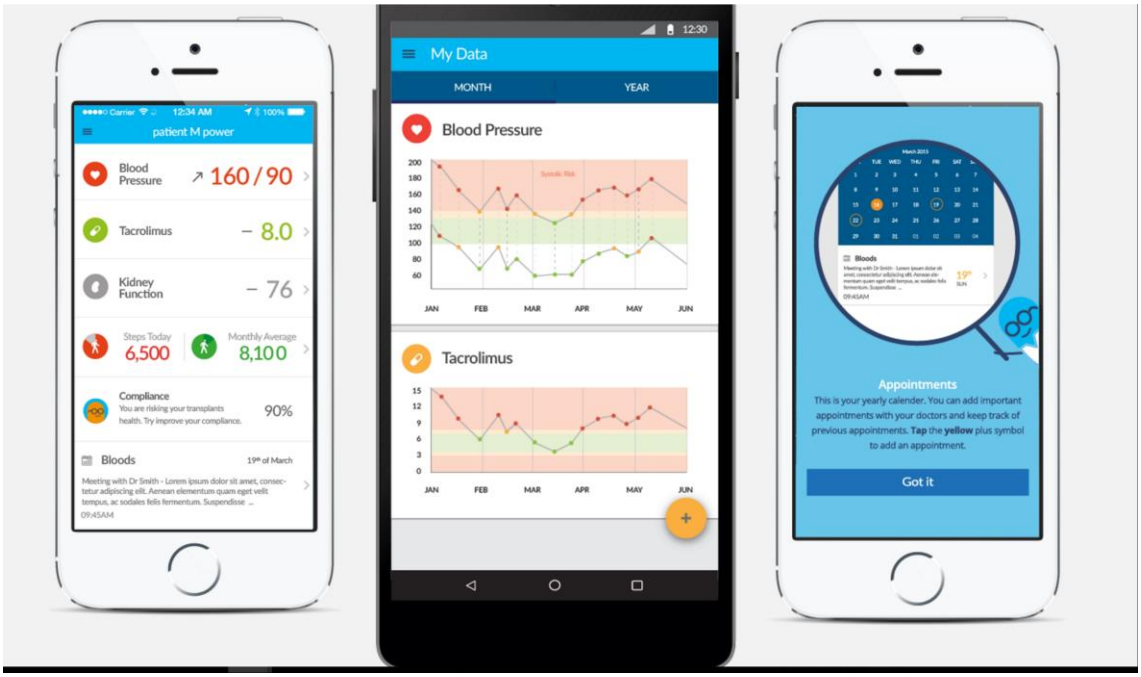
Appendix A: 'PatientMpower' app screen shot



1.App dash board displaying home BP, latest Tacrolimus level, Kidney Function, patient activity explain steps achieved today average estimated ,below it shows the medication adherence score, The bottom of the dash show the reminder for bloods.

2. Graphic display of the data over time

3. Reminders for the appointment.

Appendix B Ethical Approval from Beaumont

Beaumont Hospital
Ethics (Medical Research) Committee

Chairperson: Professor Gerry McElvaney / Gillian Vale
Convenor: Dr. Peter Branagan

Admin: Phil Oglesby

20th January 2017

REC reference: 16/91

Ms. Simi Kannumkula Mathew
Department of Nephrology
Mater Misericordiae Hospital
Eccles Street
Dublin 7

To: mathews1@tcd.ie

Dear Ms. Mathew

RE: 16/91 Study Title: "The Impact of Mobile applications for Kidney Transplant Patients to improve medication adherence, Blood Pressure control and patient engagement in Beaumont Hospital Dublin"

Principal Investigator: Ms. Simi Mathew

The Beaumont Ethics Committee has reviewed the requested amendments to the above study and is now happy to provide Ethical Approval for this study.

With best regards

Yours sincerely

Dr. Peter Branagan
Convenor
Beaumont Ethics (Medical Research) Committee

Appendix C Trinity College Ethics

rec-app-help@tchpc.tcd.ie 20 Feb

The status of '"The impact of a mobile applications for Kidney transplant patients on improved medication adherence, blood pressure control, and patient engagement"' has been updated by the Committee.

Title: '"The impact of a mobile applications for Kidney transplant patients on improved medication adherence, blood pressure control, and patient engagement"'
Applicant Name: Simi Kannumkulampil Mathew
Submitted by: Simi Kannumkulampil Mathew
Academic Supervisor: Lucy Hederman
Application Number: 20170201

Result of the REC Meeting: Approved

The Feedback from the Committee is as follows:
This study may proceed.

Appendix D Letter from TUN directorate

Suíomh Gréasáin: Website: www.beaumont.ie

OSPIDÉAL BEAUMONT
Bosca O.P. 1297 Bóthar Beaumont Baile Átha Cliath 9

BEAUMONT HOSPITAL
P. O. Box 1297 Beaumont Road Dublin 9
Guthán: Telephone: 8093000 / 8377755 Facs: Facsimile: 837 6982

Ms. Simi Kannumkula Mathew
Department of Nephrology
Mater Misericordiae Hospital
Eccles Street
Dublin 7

RE: 16/91 Study Title: "The Impact of Mobile applications for Kidney Transplant Patients to improve medication adherence, Blood Pressure control and patient engagement in Beaumont Hospital Dublin"

Dear Simi,

I am writing to you to confirm I have reviewed your request use the Beaumont Renal Clinic's to recruit participant and collect data for your study and am happy to approve same.

Kind Regards

Ms Melanie McDonnell
Directorate Nurse Manager
TUN Directorate
Beaumont Hospital
Ph: 8092297
Email: melaniemcdonnell@beaumont.ie

Appendix E Letter from Gate Keeper

Website: www.beaumont.ie

Ospidéal Beaumont

BEAUMONT HOSPITAL
P. O. Box 1297 Beaumont Road Dublin 9
Telephone: 809 3000 / 837 7755 Facsimile: 837 6982

From,

Binu Vasu,
Renal IT Support CNM 2,
TUN Directorate,
Beaumont Hospital,
Dublin 9.

To,

Simi K. Mathew
Renal Nurse,
Department of Nephrology,
Mater Misericordiae University Hospital,
Dublin 7

Dear Simi

I would like to acknowledge that your request to carry out a study on renal transplant patient on the impact of the mobile application in Dublin hospital. I am more than happy to provide any support you need and fully assist you with this study as I feel it is a valuable research initiative for renal transplant care and the future of the transplant Application.

Yours Sincerely

Binu Vasu

Place: Dublin
Date: 08/12/2016

Appendix F: Amendment letter from Beaumont Ethics

Beaumont Hospital
Ethics (Medical Research) Committee

Chairperson: Professor Gerry McElvaney
Convenor: Dr. Peter Branagan

Admin: Phil Oglesby / Gillian Vale

6th April 2017

REC reference: 16/91

Ms. Simi Kannumkula Mathew
Department of Nephrology
Mater Misericordiae Hospital
Eccles Street
Dublin 7

To: mathews1@tcd.ie

Dear Ms. Mathew

RE: 16/91 - Ms. Simi Mathew (Nursing / Mater) - The Impact of Mobile applications for Kidney Transplant Patients to improve medication adherence, Blood Pressure control and patient engagement in Beaumont Hospital Dublin

Consultant Co-investigator: Mr. C. O'Seadhga

I confirm I have reviewed amendment #1, 15/3/17, to this study, and that the requested change in study design has now been approved.

Documents Reviewed:

Amendment #1, 15/3/17
Application RECSAF 5.6, Version 3 15/3/17 (replaces Version 3, 18/1/17)

With best regards

Yours sincerely

Gillian Vale

Ms. Gillian Vale
IRB Specialist
Beaumont Ethics (Medical Research) Committee

"The REC must be satisfied with the scientific quality of the research proposal"
- Council of Europe (2011) Guide for Research Ethics Committee Members

Ethics (Medical Research) Committee Beaumont Hospital Dublin 9
Tel: 353-1-809 2680 Email: beaumontethics@rcsi.ie www.beaumontethics.ie

Appendix G: Letter to participants in the 'patientMpower' app users

Website: www.beaumont.ie

Ospidéal Beaumont

BEAUMONT HOSPITAL
P. O. Box 1297 Beaumont Road Dublin 9
Telephone: 809 3000 / 837 7755 Facsimile: 837 6982

Dear Patient

Kindly see letter below by Simi Mathew.

I am supporting Simi in Beaumont Hospital for her study in the evaluation of the Mobile App.

Yours Sincerely

_____

Dr. Conall O'Seaghdha
Consultant Nephrologist/Renal Transplant Physician

Invitation letter to Research Participants

Date …..

Dear ……..,

I am currently undertaking the Master Programme in Health Informatics in Trinity College Dublin and I am required to complete a research dissertation in fulfilment of this qualification. My research study is to evaluate the Mobile app introduced in Beaumont hospital to improve medication adherence, blood pressure control and patient engagement in post kidney transplant patients. For the study I am comparing post transplanted patients in 2016 and using the app with post transplanted patient either in 2015 not used the app.

As part of my work I have identified you are transplanted in 2016 and using the app and I am invite you to take part in study. For the study I would like to get your anonymised data about clinic blood pressure reading, serum tacrolimus value, serum creatinine, and some addition data from the app such as how often you are using the app, recording medication adherence, recording and monitoring blood pressure. And also I am invite you to participate in a survey to understand how you experience with the app.

I would like you to contact me as soon as possible if you are interested in participating in the interview kindly contact me by email or phone for the consent and survey or would you please fill the consent and survey questionnaire and send to me the stamped envelope enclose with this letter. I am hoping that you will be able to assist in this research and your anticipated support is much appreciated.

Kind Regards,

_____

Simi K. Mathew

Email: mathews1@tcd.ie

Phone no 0851375219

Appendix H: Patient information leaflet

Website: www.beaumont.ie

Ospidéal Beaumont

BEAUMONT HOSPITAL
P. O. Box 1297 Beaumont Road Dublin 9
Telephone: 809 3000 / 837 7755 Facsimile: 837 6982

Patient Information Leaflet

Study title: **"**The impact of a mobile applications for Kidney Transplant Patients on improved medication adherence, blood pressure control and patient engagement"

Principal investigator's name:	**Simi K. Mathew**
Principal investigator's title:	**Registered Nurse**
Telephone number of principal investigator:	**0851375219**
Consultant co-investigator's name:	**Conall O' Seaghdha**
Consultant co-investigator's title:	**Nephrologist**

You are being invited to take part in a clinical research study to be carried out at Beaumont Hospital.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

The research study is taking place to find out whether the use of the mobile application "patientMpower" by kidney transplant patients improves medication adherence, blood pressure control and patient engagement

Who is organising and funding this study?

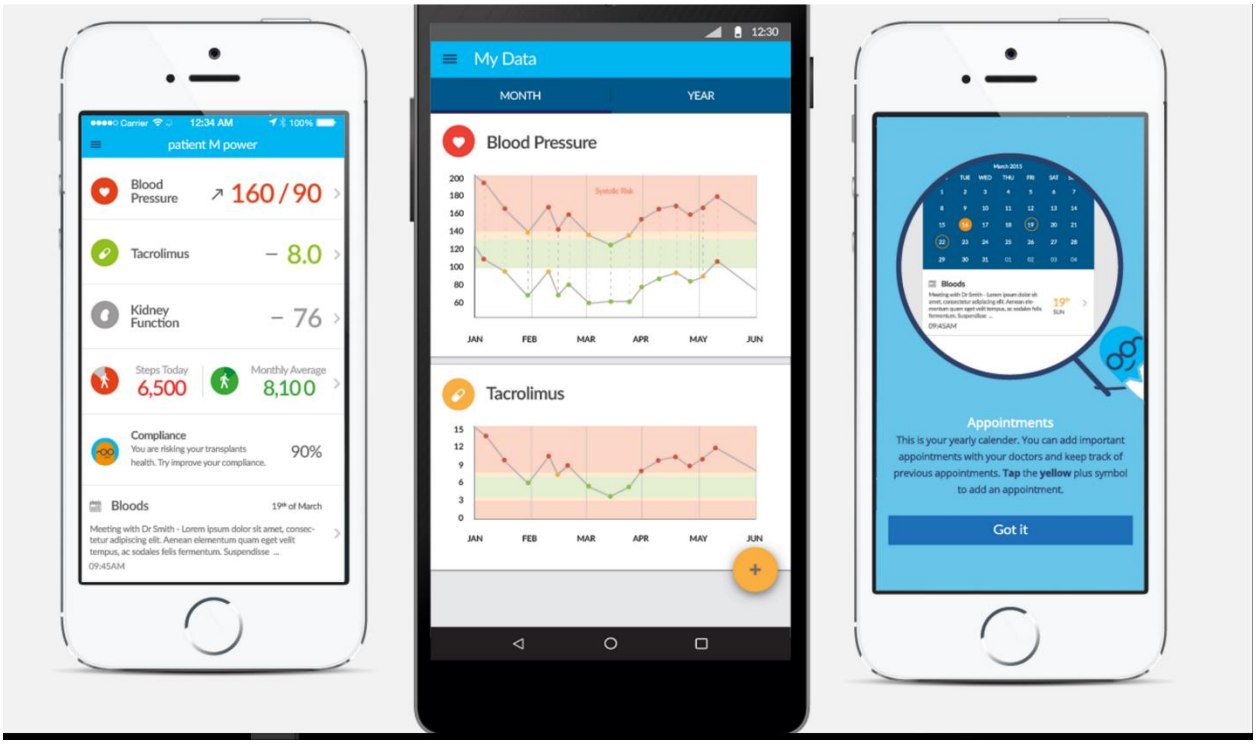
This study is conducted by Simi K Mathew an MSc in Health Informatics student in Trinity College Dublin as part of my dissertation research project. By the successful completion of study I will be obtained academic qualification of Masters in Health Informatics. I am thankful to you for being part of my study.

Why am I being asked to take part?

You are being asked to take part because you have had a kidney transplant and you are using the patientMPower app

How will the study be carried out?

This study will take place from January to April 2017 and total number of participant estimated is 60.The purpose of the study to evaluate the usefulness of a "patientMpower app" which recently launched in Beaumont transplant clinic. This app will provide reminders for medication and hospital appointments, assist in monitoring and recording blood pressure at home, track your health data such as tacrolimus level and kidney functions. It is hoped that the app increases patient compliance with medication and patient engagement in self-management and better control of blood pressure. This study aims to determine if that is true. Screenshots of app are given below.



What will happen to me if I agree to take part?

For the study I will access your medical record at the Beaumont Kidney Transplant Clinic to obtain the relevant data such as your Immunosuppressant level, blood pressure readings and related data at 6 clinic visits from the time 3-12 months transplanted.

As part of the study if you are using the app I will also collect the additional data such as how often you used the app, recorded the blood pressure and responded to medication reminder and also you will be asked to complete a questionnaire. The purpose of the questionnaire is to understand how people feel about patientMpower app. Before participating in the study, I request you to sign the attached consent form after reading it thoroughly**.**

The researcher will maintain the extracted data in such a way that you cannot be identified from it, so your name or other personal information that could identify yow will be removed. All data collected will be solely for the purpose of the study only and will be destroyed after the completion of this study. In addition the data will be stored securely and will only be accessed by the researcher and her supervisor. You are simply being asked to give permission for the researcher to access your relevant data for the study.

What are the benefits?

There is no material benefit from taking part in the study however, it is hoped that the findings will be of benefits to the organisation and the Kidney Transplant Patients as a whole.

What are the risks?

There won't be any risk for participating in this study

Is the study confidential?

In this study all the information about you will be kept private and confidential. The result of this study will be published as a Trinity College MSc dissertation and also may be presented in a presentation or conference. The result of the study will be informed to your consultant. But any of the information within the result will not be capable of identifying any participants in the study.

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please contact:

Name Simi Mathew

Address Registered Nurse

Nephrology Department

Mater Public Hospital

Dublin 7

Phone No 01 8032400. Mob : 0851375219

Appendix I: Patient Consent form

Website: www.beaumont.ie

Ospidéal Beaumont

BEAUMONT HOSPITAL
P. O. Box 1297 Beaumont Road Dublin 9
Telephone: 809 3000 / 837 7755 Facsimile: 837 6982

Patient Consent Form

Study title: The impact of a mobile application for Kidney Transplant Patients on improved medication adherence, blood pressure control, and patient engagement

I have read and understood the **Information Leaflet** about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	**Yes** ☐	**No** ☐
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my future medical care.	**Yes** ☐	**No** ☐
I am aware of the potential risks of this research study.	**Yes** ☐	**No** ☐
I give permission for researchers to look at my medical records to get information. I have been assured that information about me will be kept private and confidential.	**Yes** ☐	**No** ☐
I have been given a copy of the Information Leaflet and this completed consent form for my records.	**Yes** ☐	**No** ☐
Storage and future use of information: I give my permission for information collected about me to be stored or electronically processed for the purpose of scientific research and to be used in <u>related studies or other studies in the future</u> but only if the research is approved by a Research Ethics Committee.	**Yes** ☐	**No** ☐

| |

Patient Name (Block Capitals) | Patient Signature | Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

SIMI MATHEW | MSc Health Informatics | /|

---------Name (Block Capitals) | Qualifications | Signature | Date

Appendix J: patientMpower app Survey questions

1.’ PatientMpwer’ app easy to use

1	2	3	4	5
Strongly Disagree	disagree	neutral	Agree	Strongly Agree

2. PatientMpower App makes better understanding about my medications

1	2	3	4	5
Strongly Disagree	disagree	neutral	Agree	Strongly Agree

3. PatientMpower helps me to take my medication as directed

1	2	3	4	5
Strongly Disagree	disagree	neutral	Agree	Strongly Agree

4. PatientMpower app answer questions I have about my post-transplant care

1	2	3	4	5
Strongly Disagree	disagree	neutral	Agree	Strongly Agree

5. PatientMpower helps me easy to track my blood results

1	2	3	4	5
Strongly Disagree	disagree	neutral	Agree	Strongly Agree

6. PatientMpower app helps to regular monitoring of my blood pressure

1	2	3	4	5

Strongly Disagree	disagree	neutral	Agree	Strongly Agree

7. PatientMpower app allows my doctor to track my blood pressure easily

1	2	3	4	5
Strongly Disagree	disagree	neutral	Agree	Strongly Agree

8. PatientMpower app reminds me about my appointment

1	2	3	4	5
Strongly Disagree	disagree	neutral	Agree	Strongly Agree

9. PatientMpower make me feel I more confident in my care

1	2	3	4	5
Strongly Disagree	disagree	neutral	Agree	Strongly Agree

10. PatientMpower app reduces the frequency of seeking medical advice

1	2	3	4	5
Strongly Disagree	disagree	neutral	Agree	Strongly Agree

Any Comments

Appendix K: Letter to Transplant Urology Nephrology Nursing Directorate

Dear Melanie,

I am Simi Mathew, an MSc Health Informatics student in Trinity College Dublin. I am writing to ask you permission to carry out a study within your department. The proposed study is titled "The Impact of mobile health application on improved medication adherence, blood pressure control, and patient engagement in kidney transplant patients."
The objective of the study is to evaluate the outcome of the mobile app on medication adherence, blood pressure control, and patient engagement. Duration of the study will be three months from February to April .All data collection will be carried out by the researcher with no interference to the staff and their normal duties. The renal consultant Dr. Conall O' Seadgha happy to supervise me in Beaumont Hospital.

Confidentiality will be maintained at all times, and all hospital policies and regulations will be followed.I have submitted the applications for ethical approval.

I would be grateful if could give me the permission to do research study.

Thanking you

Simi K Mathew
Renal Nurse
Department of Nephrology
Mater Misericordiae University Hospital
Dublin 7

Appendix L: A letter to Renal Consultant

Request for Supporting research study in Beaumont

To

Conall O'Seaghdha

Consultant in Nephrology Department

Beaumont

Dublin 9

Re: Request for supporting and supervising my research project in Beaumont Hospital.

Dear Dr. Conall

I am Simi k. Mathew registered nurse working in the Mater Dialysis Unit, and currently, doing MSc Health Informatics in Trinity College Dublin. As part of my MSc Dissertation, I planned to do a research project on patientMpower- a mobile app used for kidney transplant patients in Beaumont. The title of the study is "The impact of a mobile application for kidney transplant patients on improved medication adherence, blood pressure control, and patient engagement". For my study, I need to recruit the eligible participants from Beaumont renal clinic and to get access to the selected kidney transplant patient's health record to collect the required data and also to survey among post transplanted patients using patientMpower app to understand how patient's experience with using app. Along with this letter I am attaching my research proposal.

It would be grateful if you could support and supervise me with this project as a Co-Investigator in Beaumont Hospital.

Thanking You

Yours Faithfully

Simi K Mathew

Appendix M: Letter to gate keeper

To

Binu Vasu

Renal System Administrator

Nephrology Department

Beaumont

Dublin 9

Re: Request for supporting my research project in Beaumont Hospital.

Dear Binu

I am Simi k. Mathew registered nurse working in the Mater Dialysis Unit, and currently, doing MSc Health Informatics in Trinity College Dublin. As part of my MSc Dissertation, I planned to do a research project on patientMpower- a mobile app used for kidney transplant patients in Beaumont. The title of the study is "The impact of a mobile application for kidney transplant patients on improved medication adherence, blood pressure control, and patient engagement". For my study, I need to recruit the eligible participants from Beaumont renal clinic and to get access to the selected kidney transplant patient's health record to collect the required data and also to survey among post transplanted patients using patientMpower app to understand how patient's experience with using app. Along with this letter I am attaching my research proposal.

I would be grateful if you could support me for the project as a Gatekeeper in Beaumont Hospital.

Thanking You

Yours Faithfully

Simi K Mathew

Appending N: Beaumont Research ethics Application Form

STANDARD APPLICATION FORM

For the Ethical Review of
Health-Related Research Studies, which are not Clinical Trials of Medicinal Products
For Human Use
as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study: "The impact of mobile applications for kidney transplant patients to improve medication adherence, blood pressure control and patient engagement in Beaumont Hospital Dublin."

Application Version No: RECSAF V5.,VERSION 3,REF:16/91

Application Date: 09/11/2016

For Official Use Only – Date Stamp of Receipt by REC:

SECTION A GENERAL INFORMATION	MANDATORY*
SECTION B STUDY DESCRIPTORS	MANDATORY*
SECTION C STUDY PARTICIPANTS	MANDATORY*
SECTION D RESEARCH PROCEDURES	MANDATORY*
SECTION E DATA PROTECTION	MANDATORY*
SECTION F HUMAN BIOLOGICAL MATERIAL	(OPTIONAL)
SECTION G RADIATION	(OPTIONAL)
SECTION H MEDICAL DEVICES	(OPTIONAL)
SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS	(OPTIONAL)
SECTION J INDEMNITY AND INSURANCE	MANDATORY*
SECTION K COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS	MANDATORY*
SECTION L ADDITIONAL ETHICAL ISSUES	(OPTIONAL)

This Application Form is divided into Sections.

*Sections A, B, C, D, E, J and K are **Mandatory.**

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

IMPORTANT NOTE: Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

IMPORTANT NOTE: This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL WHEN COMPLETING THIS APPLICATION FORM

SECTION A GENERAL INFORMATION

SECTION A IS MANDATORY

A1 TITLE OF THE RESEARCH STUDY:

"The impact of mobile application for kidney transplant patients to improve medication adherence, blood pressure control and patient engagement in Beaumont Hospital Dublin"

A2 (a) Is this a multi-site study? No

IF YOU CHOSE 'YES', PLEASE DELETE QUESTIONS A2 (E) AND (F), IF YOU CHOSE 'NO' PLEASE DELETE QUESTIONS A2 (B) (C) AND D)

A2 (e) If no, please name the principal investigator with overall responsibility for the conduct of this single-site study.

Title: Ms. **Name:** Simi Kannumkulampil Mathew
Qualifications: BSc (Hons) Nursing
Position: Registered Nurse
Dept: Nephrology
Organisation: Mater Misericordiae University Hospital
Address: Eccles Street, Dublin 7
TEL: 085 137 5219 **E-MAIL:** mathews1@tcd.ie

A2 (f) For single-site studies, please name the only site where this study will take place.

Kidney Transplant Clinic in Beaumont Hospital

A3. DETAILS OF CO-INVESTIGATORS:

Name of site (if applicable): same as abobe
Title: Dr. **Name:** Conall O' Seaghdh
Qualifications: , Speciality in General Nephrologist and Transplantation
Position: Conusultant
Dept : Nephology department
Organisation: Beaumont
Address: Nephrology Department,Beaumont Hospital,Dublin9
Tel: Answer **E-mail:** conalloseaghdha@beaumont.ie
Role in Research e.g. statistical / data / laboratory analysis: Supervisor in Beaumont Hospital

Name of site (if applicable): same as abobe
Title: Mr. **Name:** Binu Vasu
Qualifications: BSc Nursing, Post Graduate in Informatics
Position: Renal IT nurse (System Administrator)
Dept : Nephology department
Organisation: Beaumont
Address: Nephrology Department, Beaumont Hospital, Dublin9
Tel: 0876770008 **E-mail:** binuvasu@beaumont.ie
Role in Research e.g. statistical / data / laboratory analysis: Selection, recruitment, consent form and assist in sample collection

A4. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.

Name: Simi Kannumkulampil Mathew
POSITION: Registered Nurse
ORGANISATION: Mater Misericordiae University Hospital
Address for Correspondence: 155,Hamptonwood Avenue, St.Margaret's Road Dublin11
TEL (WORK): 01803 2400 **TEL (MOB.):** 085 137 5219 **E-MAIL:** Mathews1@tcd.ie

A5 (A) IS THIS STUDY BEING UNDERTAKEN AS PART OF AN ACADEMIC QUALIFICATION? Yes

A5 (b) IF YES, please complete the following:

Student Name(s): Simi Kannumukulampil Mathew

Academic Course: MSc Health Informatics

Academic Institution: Trinity College Dublin

A5 (c) Academic Supervisor(s):

Title: Prof. **Name: Lucy Hederman**
Qualifications: PhD

Position: Director of the Centre for Health Informatics
Dept: School of Computer Science and Statistics
Organisation: Trinity College Dublin
Address: The University of Dublin, Dublin2.
TEL: 01 896 1765 **E-MAIL:** hederman@scss.tcd.ieSECTION B STUDY DESCRIPTORS

SECTION B IS MANDATORY

B1. What is the anticipated start date of this study?

January 2017

B2. What is the anticipated duration of this study?

3 months

B3. Please provide a brief lay (plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.

About this study
This study will take place in the Beaumont Hospital Renal clinic. The aim of the study is to understand how useful the mobile app-patientMpower post kidney transplant to improve patients' compliance with medication and appointments and better control of blood pressure.

In this study the researcher is comparing the patient who are post transplanted 3-12 months in 2016 and using the app with patients who are 3-12 months transplanted either in 2015 are not using the app

For the study the researcher needs to access the relevant data such as participants' clinic blood pressure reading, Tacrolimus level, number of missed appointment and number of hospital readmission in a patient no identifiable format(patient name age, sex, other demographic detail won't be identified in extracted data.

Along with the above data for the patients who are using the app the researcher needs some additional data from the app such as how often they used the app,record their blood pressure and respond to medication reminder.

Additionally the post transplanted patient using the app also need to complete the questionnaire to understand patients experience with using the app.

B4. Provide brief information on the study background.

Kidney transplant is a successful treatment option for eligible patients with End Stage Renal Disease. However, remediable factors like poor medication adherence, blood pressure control and lack of patient engagement may negatively impact kidney transplant outcomes.

Nonadherence to prescribed medication regimens has been identified as one of the risk factors for graft rejection. There is lack of an established programme to ensure medication adherence and blood pressure control in kidney transplant patients.

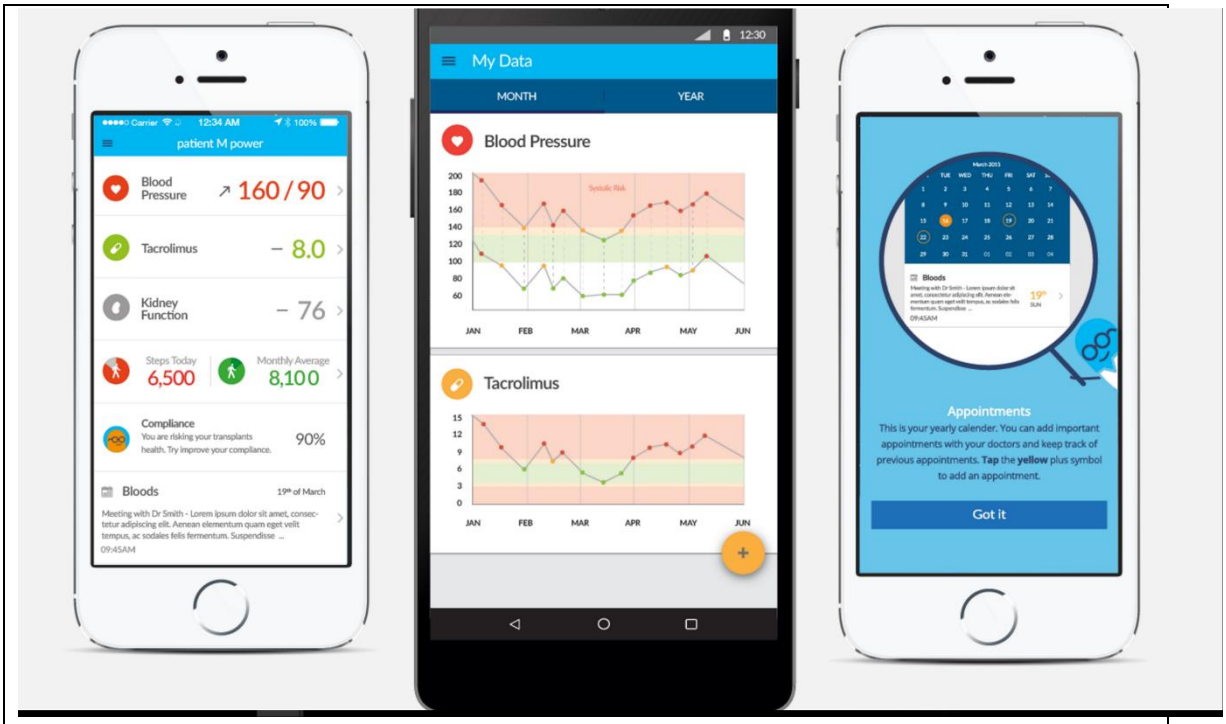
Recently Kidney Transplant clinic in Beaumont Hospital launched a mobile health application called “patientMpower” for kidney transplant patients in Beaumont to improve patient medication adherence, Blood Pressure control and engagement of patients in their own healthcare and management through using the app.

The main interventions of patientMpower app are the following:

1. The App provides medication reminders which improves post -transplant patient compliance with medication adherence.

2. The post-transplant patients using the app are provided with a Bluetooth attached Blood pressure monitor which enhance the patient blood pressure monitoring at the home. All the home blood pressure readings will be directly entered into the app via Bluetooth connection. Traffic light signals (green, amber, red) used to highlight the blood pressure reading from normal to abnormal

3.The app also supports patient engagement with post transplant self-management, the app provides reminder about appointments as well as track their health data, such as Tacrolimus level, kidney functions and daily activities, .The main features of the app is direct entry of the all health data, as well as both logged and graphical display of the data over time.



Screen shot of patientMpower App.

B5. List the study aims and objectives.

The overall aim of the study is to:
-Evaluate the outcome of mobile app intervention – PatientMpower – on helping kidney transplant patients with medication adherence, Blood Pressure control and, engagement in their health management.
-asses patients experience with the mobile application

The specific objectives are to:
-Estimated 60 participants for the study from kidney transplant patients who had their transplant in 2015 and 2016 and attending Beaumont Renal Clinic.

This study going to assess the hypothesis
- Interventional group(using mobile app) will have more medication adherence, better blood pressure control and grater patient engagement than usual care group(Control group those who are not using the app) .

B6. List the study endpoints / measurable outcomes (if applicable).

80 participants involved in the study

Information on the value of the app used in terms of helping patients to follow their medication, control their BP and patient engagement with post kidney transplant self-management.

Report on the impact of the app on the above three areas – to include recommendations

B7. Provide information on the study design.

Non-Randomised study design using matched historical control group patient who are transplanted in 2016 and using the app as intervention group and patient who are transplanted in 2015 who are not using the app as a control group. 30 participants in intervention group using the app and 30 participants in control group who are receiving usual care. Total participants is 60.

Retrospective analysis of the variables from chart review or Hospital Information Systems or from eMED renal system. The variables:

Variable 1: For Medication adherence, the immunosuppressant trough level is the measures of medication adherence,

Variable 2: Blood pressure Control which includes Blood pressure reading from eMED (Electronic Patient Record) at their clinic visit.

Variable 3: Patient Engagement: number of missed appointments, number of hospital admissions (if any), any kidney biopsy at the study period.

Likert scale questionnaire will be given to the participants in the intervention group to understand patient experience with using mobile app

.

B8. Provide information on the study methodology.

30 patients in intervention groups, 3-12 months post transplanted in 2016 who are using the mobile app.
30 patients in control group, 3-12 months post transplanted in 2015 or 2014 and received usual care.

For both groups, collect the data which includes 4 consecutive values of Immunosuppressant trough level, blood pressure, number of medications, number of missed admission, and Hospital admission at their 3-12months post-transplant clinic visits time.
All these data are collected either from eMed Renal(EPR) system or chart review or hospital computer System.

Likert scale questionnaire with 10 items 5 point scale strongly disagree to strongly agree will be given to all participants in the intervention group to understand patients experience with app

Intervention group additional limited data from mobile app about how often they use the app, how often they open it, how often they record taking their medication and monitor blood pressure

B9. Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.

Variables will be described, as appropriate, in terms of means and standard deviations or percentages. Comparisons between groups, particularly between those using the smart-phone app and the 2015 control group, will be made using, as appropriate, the parametric t-test, the non-parametric Wilcoxon Rank Sum test, or the chi-square test. A 5% (two sided) level of significance will be taken. Relationships between numerical variables will be examined using Pearson correlation coefficient. Statistical advice from School of Computer Sciences and Statistics Department, Trinity College Dublin.

B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).

Total number of sample size is 60. 30 participants in intervention group, and 30 participants control group. As the mobile app launched 2016 the maximum no of app users with all the eligibility criteria incudes only 30.

It is not possible to use 2016 transplant patients who are not using the mobile app as the control group, as these patients, by choosing not to use the app, show themselves to be different from those using the smartphone app.

B10 (b) Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.

Answered in question 10 a

B11. How many research participants are to be recruited in total?

total 60 participants involved in study

B12 (a) How many research participants are to be recruited in each study group (where applicable)? Please complete the following table (where applicable).

Name of Study Group:	**Name of Study Group:**	**Name of Study Group:**	**Name of Study Group:**	**Name of Study Group:**
Intervention group (chart review)	Control group (chart review)	survey of interventional group	Answer	Answer
Number of Participants in this Study Group:	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**	**Number of Participants in this Study Group:**
30	30	20	Answer	Answer

B12 (b) Please provide details on the method of randomisation (where applicable).

Not applicable

B13. How many research participants are to be recruited at each study site (where applicable)? Please complete the following table.

Site:	Number of Research Participants at this site:
BEAUMONUT RENAL CLINIC	60 PARTICIPANTS

SECTION C IS MANDATORY

C1 PARTICIPANTS – SELECTION AND RECRUITMENT

C1.1 HOW will the participants in the study be selected?

Both intervention and control group will be selected from Beaumont hospital post-transplant clinic. For intervention group, all patients who have downloaded the app with inclusion criteria will be invited to participate,. For control group, patient who transplanted either 2015 and having mobile number in their record and attending Beaumont renal clinic will be selected until 30 are recruited,

C1.2 HOW will the participants in the study be recruited?

For intervention group, the invitation letter will be sent to all the patients using the app by the principle investigator to find their interest to participate in the study; patient information leaflet and informed consent will be obtained at their next earliest clinic visit for both data and for survey about their experience with using app, by the principal investigator.
There is no additional hospital visit required for the study.
For Control group irrevocably anonymised data will be collected from eMed by renal system administrator

C1.3 what are the inclusion criteria for research participants? (Please justify, where necessary)

Case Group (Intervention) : Age 18-65, 3-12 months post transplanted in 2016,Using mobile app
Control group: age 18-65, 3-12 months post transplanted in either in 2015, having mobile number in their record.

C1.4 what are the exclusion criteria for research participants? (Please justify, where necessary)

Patients less than 18 or more than 65, or not using smartphone.

C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project? Not to my knowledge C2 PARTICIPANTS – INFORMED CONSENT

C2.1 (a) Will informed consent be obtained? Yes, Patient informed consent will be obtained from intervention group only by principal investigator

C2.1 (b) If no, please justify. You must provide a full and detailed explanation as to why informed consent will not be obtained.

C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)

Principle investigator will contact the patient on their clinic appointment date and explain about the study and obtain informed consent if patients are interested. if the appointment is late or not having any appointment in data collection period an invitation letter and leaflet will be sent by post providing researcher mobile no and email, if they are interested to contact the research by phone or email, and then, consent form and questionnaire will be sent to the participant with free postal envelope and stamp enclosed.
If principle investigator unable to attend the clinic the consent will be obtained by Beaumont co-investigator Binu Vasu

C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study? Yes

C2.2 (b) If no, please justify.

C2.3 (a) Will there be a time interval between giving information and seeking consent? Yes

C2.3 (b) If yes, please elaborate.

The information will be provide on their clinic visit and consent will obtained if patient happy to give consent on same day. However, If they want to discuss with someone the time will be given as they required. Patient have right to decide about the consent and participating the study. If patient has no clinic appointment on data collection period the invitation letter and leaflet will be sent by post, consent form and questionnaire will be sent based on their respond with enclosing free envelop and post stamp enclosed.

C2.3 (c) If no, please justify and explain why an instantaneous decision is reasonable having regard to the rights of the prospective research participants and the risks of the study.C3 adult participants (AGED 18 or over) - CAPACITY

C3.1 (a) Will all adult research participants have the capacity to give informed consent? YES

If answer is Yes, please delete remaining questions in Section C3

c4 participants under the age of 18

C4.1 (a) Will any research participants be under the age of 18 i.e. Children? No

C5 PARTICIPANTS - CHECKLIST

C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special arrangements, if any, have been made to deal with

issues of consent. It is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE's National Consent Policy, particularly Part 3, Section 5.

Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.

(a) Healthy Volunteers No

(b) Patients Yes

- **Unconscious patients** No
- **Current psychiatric in-patients** No
- **Patients in an emergency medical setting** No

(c) Relatives / Carers of patients No

(d) Persons in dependent or unequal relationships No

- **Students** No
- **Employees / staff members** No
- **Persons in residential care** No
- **Persons highly dependent on medical care** No

(e) Intellectually impaired persons No

(f) Persons with a life-limiting condition No
(Please refer to guidance manual for definition)

(g) Persons with an acquired brain injury No

C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).

Answer

C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.

No

SECTION D research PROCEDURES

SECTION D IS MANDATORY

D1 (A) what activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?

Likert scale questionnaire with 10 items will be given to intervention group to understand how they experience with patientMpower app (Already mentioned in B3,B7 and B8)

D1 (B) WHAT OTHER ACTIVITIES (IF ANY) ARE TAKING PLACE FOR THE PURPOSES OF THIS RESEARCH STUDY E.G. CHART REVIEW, SAMPLE ANALYSIS ETC?

Patient chart review or eMED renal (EPR) to get information about the Blood pressure readings and Immunosuppressant trough level, no. of missed appointment, no. of hospital admission at the time period of study.

D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.

There is no harm or risk to participants.

D3. What is the potential benefit that may occur as a result of this study?

Understand the impact of mobile applications used for renal kidney transplant patients

D4 (A) WILL THE STUDY INVOLVE THE WITHHOLDING OF TREATMENT?
NO

D4 (B) WILL THERE BE ANY HARMS THAT COULD RESULT FROM WITHHOLDING TREATMENT? NO

D4 (C) IF YES, PLEASE ELABORATE.

Not Applicable

D5 (A) HOW WILL THE HEALTH OF PARTICIPANTS BE MONITORED DURING THE STUDY, AND WHO WILL BE RESPONSIBLE FOR THIS?

Not Applicable

D5 (B) HOW WILL THE HEALTH OF PARTICIPANTS BE MONITORED AFTER THE STUDY, AND WHO WILL BE RESPONSIBLE FOR THIS?

Not Applicable

D6 (A) WILL THE INTERVENTIONS PROVIDED DURING THE STUDY BE AVAILABLE IF NEEDED AFTER THE TERMINATION OF THE STUDY? THE STUDY IS NOT PROVIDING ANY INTERVENTION, IN THE STUDY THE RESEARCHER WILL RETROSPECTIVELY COLLECT THE PATIENT DATA

ABOUT CLINIC BLOOD PRESSURE DATA, IMMUNOSUPPRESSANT VALUES TO CHECK THE HYPOTHESIS AS MENTIONED IN B5.

D6 (B) IF YES, PLEASE STATE THE INTERVENTION YOU ARE REFERRING TO AND STATE WHO WILL BEAR THE COST OF PROVISION OF THIS INTERVENTION?

This study is not providing any intervention. Retrospectively analyse the data to evaluate the app users with control group.

D7. PLEASE COMMENT ON HOW INDIVIDUAL RESULTS WILL BE MANAGED.

The mean value of intervention group and control group will be used to evaluate the impact of patientMpower app

D8. PLEASE COMMENT ON HOW AGGREGATED STUDY RESULTS WILL BE MADE AVAILABLE.

Answered. Trinity college MSc dissertation and Health Informatics conference

D9. WILL THE RESEARCH PARTICIPANT'S GENERAL PRACTITIONER BE INFORMED THAT THE RESEARCH PARTICIPANT IS TAKING PART IN THE STUDY (IF APPROPRIATE)? NO

D10. WILL THE RESEARCH PARTICIPANT'S HOSPITAL CONSULTANT BE INFORMED THAT THE RESEARCH PARTICIPANT IS TAKING PART IN THE STUDY (IF APPROPRIATE)? NO

SECTION E data protection

SECTION E IS MANDATORYE1 data processing - consent

E1.1 (A) WILL CONSENT BE SOUGHT FOR THE PROCESSING OF DATA? NO

E1.1 (B) IF NO, PLEASE ELABORATE.

Answer: The researcher need only an irrevocably anonymised data from the control group. The researcher is not directly involving with control group participants for any kind of interview or questionnaire and renal system administrator will extract the relevant data for the study.

E2 data processing - GENERAL

E2.1 WHO WILL HAVE ACCESS TO THE DATA WHICH IS COLLECTED?

Beaumont Co-Investigators, Principle investigator and supervisor

E2.2 WHAT MEDIA OF DATA WILL BE COLLECTED?

Electronic media from either Emed Renal system or Hospital Information system or chart review

E2.3 (A) WOULD YOU CLASS THE DATA COLLECTED IN THIS STUDY AS anonymous, irrevocably anonymised, pseudonymised, coded or identifiable data?

For control group all the relevant data will be anonymised and give unique data collection number prior to being transferred to the principal investigator,
For case group the data collected will be de-identified and coded, with last 4 digits of Medical Record Number(MRN) because to get some additional data from the app such as how often they use the app, how of the participants record their blood pressure and to respond to the medication reminder. However, patient name age, sex and other demographics won't be in an identifiable format.

E2.3 (B) IF 'CODED', PLEASE CONFIRM WHO WILL RETAIN THE 'KEY' TO RE-IDENTIFY THE DATA?

The key to re-identify the data will be remain at the Renal clinic Beaumont, The Co-Investigator at the Beaumont clinic Dr. Conall O'Seaghdha will hold the key to re-identify the data.

E2.4 WHERE WILL DATA WHICH IS COLLECTED BE STORED?

On encrypted computer file and Stored in encrypted secured computer file system in School of Computer Science and Statistics, Trinity College Dublin.

E2.5 PLEASE COMMENT ON SECURITY MEASURES WHICH HAVE BEEN PUT IN PLACE TO ENSURE THE SECURITY OF COLLECTED DATA.

Encrypted, stored on secured School of Computer Science and Statistics file system in Trinity College Dublin

E2.6 (A) WILL DATA COLLECTED BE AT ANY STAGE LEAVING THE SITE(S) OF ORIGIN?

YES

E2.6 (B) IF YES, PLEASE ELABORATE.

Data Encrypted and stored in School of Computer Sciences and Statistics Department

E2.7 WHERE WILL DATA ANALYSIS TAKE PLACE AND WHO WILL PERFORM DATA ANALYSIS (IF KNOWN)?

At School of Computer Sciences and Statistics Department the principle investigator and supervisor

E2.8 (A) AFTER DATA ANALYSIS HAS TAKEN PLACE, WILL DATA BE DESTROYED OR RETAINED?

It will be kept until the Examination of MSc dissertations.

E2.8 (B) PLEASE ELABORATE.

MSc Dissertation examination is on September, all the data destroyed after the examination

E2.8 (C) IF DESTROYED, HOW, WHEN AND BY WHOM WILL IT BE DESTROYED?

It will be destroyed by the principle Investigator, under the university or with hospital policy by the end of September 2017.

E2.8 (D) IF RETAINED, FOR HOW LONG, FOR WHAT PURPOSE, AND WHERE WILL IT BE RETAINED?

Not Applicable

E2.9 PLEASE COMMENT ON THE CONFIDENTIALITY OF COLLECTED DATA.

Information leaflet will provide to all participants about the study, Informed consent obtain for the study and data will not disclose to any third parties, and data will not be disclosed to third parties

E2.10 (A) WILL ANY OF THE INTERVIEW DATA COLLECTED CONSIST OF AUDIO RECORDINGS / VIDEO RECORDINGS? NO

E2.10 (B) IF YES, WILL PARTICIPANTS BE GIVEN THE OPPORTUNITY TO REVIEW AND AMEND TRANSCRIPTS OF THE TAPES?

N/A

E2.11 (A) WILL ANY OF THE STUDY DATA COLLECTED CONSIST OF PHOTOGRAPHS/ VIDEO RECORDINGS? NO

E2.11 (B) IF YES, PLEASE ELABORATE.3 ACCESS TO HEALTHCARE RECORDS

E3.1 (A) DOES THE STUDY INVOLVE ACCESS TO HEALTHCARE RECORDS (HARD COPY / ELECTRONIC)? YES

If answer is No, please delete remaining questions in Section E3

E3.1 (B) IF YES, PLEASE ELABORATE.

Need to access to the hospital computer System or Hospital medical record, to get the required data, which include, lab value of Serum Immunosuppressant level, blood pressure readings, no. of hospital admission, any missed appointment at the time period,

patient demographic details such age, gender, occupation, education. For post intervention group, the researcher need permission to get limited data about their use of the app such as how often they open it, how often they record taking their medication.

E3.1 (C) WHO WILL ACCESS THESE HEALTHCARE RECORDS?

The Beaumont co-Investigators Nephrology consultant Dr.Conall O' Seaghdha and Renal System administrator Mr. Binu Vasu will access the health record. And will provide the relevant data to principal investigator within the scope of study in a patient non-identifiable format.

E3.1 (D) WILL CONSENT BE SOUGHT FROM PATIENTS FOR RESEARCH TEAM MEMBERS TO ACCESS THEIR HEALTHCARE RECORDS? NO CONSENT SOUGHT FROM CONTROL GROUP, RESEARCHER IS NOT DIRECTLY ACCESSING THE PERSONAL DATA OF ANY PARTICIPANTS. BUT CONSENT SOUGHT FROM INTERVENTION GROUP AS THE RESEARCHER IS DOING SURVEY USING LIKERT SCALE QUESTIONNAIRE IN THE INTERVENTION GROUP.

If answer is Yes, please delete remaining questions in Section E3

E3.2 (A) WHO OR WHAT LEGAL ENTITY IS THE DATA CONTROLLER IN RESPECT OF THE HEALTHCARE RECORDS?

[RENAL CONSULTANTS AND RENAL SYSTEM ADMINISTRATOR. THE RENAL SYSTEM ADMINISTRATOR WILL EXTRACT AND PROVIDE THE IRREVOCABLY ANONYMIZED DATA ON BEHALF OF RESEARCHER]

E3.2 (B) WHAT MEASURES HAVE BEEN PUT IN PLACE BY THE DATA CONTROLLER WHICH MAY MAKE ACCESS TO HEALTHCARE RECORDS PERMISSIBLE WITHOUT CONSENT?

[The Beaumont co-investigators act as a gatekeeper to select, recruit and extract irrevocably non-anonymized data on behalf of researcher]

SECTION f HUMAN BIOLOGICAL MATERIAL
1 Bodily Tissue / Bodily Fluid Samples - general

F1 1 (a) Does this study involve human biological material? NO

If the answer is No, please delete Section F

section G radiationG1 radiation – general

G1.1 (a) Does this study/trial involve exposure to radiation? NO

If answer is No, please delete remaining questions in Section G SECTION H
MEDICAL DEVICES

H1 (A) IS THE FOCUS OF THIS STUDY/TRIAL TO INVESTIGATE/EVALUATE A MEDICAL DEVICE? NO

If answer is No, please delete remaining questions in Section H.

SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOOD STUFFS
1.1 NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

I1.1 (a) Does this study involve a medicinal product? No

If the answer is No, please delete remaining questions in subsection 1I.2
COSMETICS

I2.1 (a) Does this study involve a cosmetic? No

If the answer is No, please delete remaining questions in subsection I2
I.3 FOOD AND FOOD SUPPLEMENTS

I3.1 (a) Does this study involve food or food supplements? No

If the answer is No, please delete remaining questions in subsection I3
SECTION j INDEMNITY and insurance

SECTION J IS MANDATORY

J1 PLEASE CONFIRM AND PROVIDE EVIDENCE THAT APPROPRIATE INSURANCE/INDEMNITY IS IN PLACE FOR THIS RESEARCH STUDY AT EACH SITE.

State sponsored Clinical Indemnity Scheme or IRISH NURSE AND MIDWIFERY ORGANISATION,

J2 PLEASE CONFIRM AND PROVIDE EVIDENCE THAT APPROPRIATE INSURANCE/INDEMNITY IS IN PLACE FOR THIS RESEARCH STUDY FOR EACH INVESTIGATOR.

yes

J3.1 Please give the name and address of the organisation / or individual legally responsible for this research study?

School of Computer Science and Statistics Department, Trinity College Dublin

J3.2 Where an organisation is legally responsible, please specify if this organisation is:

A pharmaceutical company NO
A medical device company NO
A university YES
A registered charity NO
Other NO **If yes, please specify:** Answer

J3.3 PLEASE CONFIRM AND PROVIDE EVIDENCE OF ANY SPECIFIC ADDITIONAL INSURANCE / INDEMNITY ARRANGEMENTS WHICH HAVE BEEN PUT IN PLACE, IF ANY, BY THIS ORGANISATION / OR INDIVIDUAL FOR THIS RESEARCH STUDY?

Currently working in Mater Public Hospital so I am eligible for state sponsored Clinical Indemnity Scheme. and IRISH NURSES AND MIDWIFERY ORGANISATION indemnity scheme

SECTION k COST AND RESOURCE IMPLICATIONS, funding and payments

SECTION K IS MANDATORY

K1 COST AND RESOURCE IMPLICATIONS

K1.1 PLEASE PROVIDE DETAILS OF ALL COST / RESOURCE IMPLICATIONS RELATED TO THIS STUDY (E.G. STAFF TIME, OFFICE USE, TELEPHONE / PRINTING COSTS ETC.)

I will need to use Beaumont Renal office to collect the data on January to April few hours, and also need support from Beaumont Staff for the data collection.

k2 funding

K2.1 (a) Is funding in place to conduct this study?

NO

K2.1 (b) If no, has funding been sought to conduct this study? From where? Please elaborate.

ALL EXPENSE FOR THE STUDY WILL RESPONSIBLE BY PRINCIPLE RESEARCHER

K2.1(d) Please provide additional details in relation to management of funds.

Answer

K2.1(e) Is the study funded by a 'for profit' organisation? NO

K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding? NO

K2.2 (b) If yes, please elaborate.k3 payments to investigators

K3.1 (a) Will any payments (monetary or otherwise) be made to investigators? NO

K3.1 (b) If yes, please provide details of payments (including amount).

NA

K 4 payments to PARTICIPANTS

K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants? NO

K4.1 (b) If yes, please provide details of payments / reimbursements (including amount).

SECTION L additional ethical ISSUES

L1 (a) Does this project raise any additional ethical issues? NO

If answer is No, please delete remaining questions in Section L.

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.