Division of Biomedical Engineering

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Project Title:

Improving Diabetes Management of Pregnant Women in Under-Served Communities of South Africa by Using a Mobile Phone

Full Dissertation

In fulfilment of the requirements for the degree:

Master of Science in Biomedical Engineering: Dissertation

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Abstract

Background

Diabetes has been reported as being the tenth leading cause of death in South Africa, and can affect a person's livelihood, productivity and physical ability. In particular, gestational diabetes mellitus (GDM) affects 7-10% of pregnancies worldwide and greatly increases the risk of developing Type II diabetes after pregnancy, particularly if the patient has a high Body Mass Index.

Research suggests that accurate education and proper management regarding diabetes can have a positive impact on the quality of patient life, as well as the country's healthcare system. One such disease management platform exists as mHealth, which is the acronym for mobile health, and is best described to be the use of mobile communication for health services and information. This report intends to

Method

The information for this report was gathered by means of a combination of Internet research, already-existing knowledge of the subject, textbooks, journal articles, and thoughtful direction from the project supervisor. The research consisted of three studies: a systematic review, prototype design, and a user survey.

The systematic review collected and analysed existing literature related to the knowledge and impact of mHealth among pregnant women with or at risk of GDM in underserved communities. The use of mHealth was analysed by focusing on its impact on outcomes related to glycaemic control, pregnancy and delivery, and behaviour and knowledge. This information was then used to develop a suitable mobile health platform targeted at a specific user: a pregnant woman. Design methods were used to identify the most effective solution, and a prototype was built using the online software Proto.io. User feedback on the produced prototype was received through an interview questionnaire, which was hosted by the online survey system *SurveyMonkey*.

Results

By paying close attention to parameters limited to under-served communities, the systematic review included four articles relevant to the scope of the research. Through the outcome analysis, the review

revealed that two of the more common reasons for the development of GDM is a newly-pregnant woman being unaware of the risk, as well as lack of immediate access to available information on how to self-manage her pregnancy. It was identified that patient follow-up played a major role in helping them maintain weight and glucose goals, which is one of the driving factors behind the design of the intervention.

Based on the requirements and specifications of the solution, a mobile application was chosen to be developed, in order to be able to develop a solution with the capability to meet a list of functions and features identified through the collected literature and user-based design.

From the 33 respondents to the survey, it was discovered that majority (81.82%) of the respondents expressed competence in the use of mobile technology and had access to the internet and a smartphone. Most respondents (60.61%) specified that they preferred receiving knowledge in a 'hands-on' capacity. Majority of the findings lined up with the collected literature as it was determined that the respondents believed having access to key medical and health information has a positive effect on the health outcomes of both mother and baby.

Conclusions

The investigation concluded that providing women with access to information and self-management platforms generally results in an increase in positive health outcomes for both women and their babies, during pregnancy and later in life. From the systematic review results, mobile health has a significant and positive impact on a patient's quality of life, as well as the healthcare industry. The results indicated technology can improve patient knowledge, understanding and management of GDM, though more research and controlled trials are required to support this deduction.

Glossary of Terms

List of Abbreviations

AHEAD	Action for Health in Diabetes
BMI	Body Mass Index
FHS	Faculty of Health Sciences
GDM	Gestational Diabetes Mellitus
GDP	Gross Domestic Product
LMIC	Low and/or Middle-Income Country
MeSH	Medical Subject Headings
MMS	Multimedia Messaging Service
PDA	Personal Digital Assistants
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised Control Trial
SMS	Short Message Service
UCT	University of Cape Town
USSD	Unstructured Supplementary Service Data
VOIP	Voice Over Internet Protocol
WHO	World Health Organization

List of Definitions

Qualitative Research	Research that is usually not pre-emptive in that it is taken as a measure against what is already anticipated (Richards, 2005).
Quantitative Research	Research that starts with an understanding to be tested (Kelley et al., 2003).

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1. Introduction

1.1 Subject and Motivation of Report

This report describes the investigation into the use of mobile health in improving knowledge among pregnant women, particularly in relation to the disease gestational diabetes mellitus (GDM), and specifically in under-served communities. The report details the development of a mobile health prototype, and explains the process behind the design choices. It also describes the conducting of a survey on selected women, to provide comment on existing knowledge of GDM, as well as feedback on the suggested prototype.

The motivation for this report stems from knowledge that pregnant women can and do suffer from GDM and at an alarming prevalence, which poses a threat to the lives of both mothers and their unborn babies. GDM also increases the risk of developing diabetes at a later stage in life, and so places significant importance placed on screening, educating and treating of the disease. This investigation will play close attention to the stage of 'educating,' in an effort to take preventive measures against this disease, as knowledge and awareness is a key factor in reducing the incidence of GDM.

1.2 Background to Investigation

Diabetes has been reported as being the tenth leading cause of death in South Africa, and can affect a person's livelihood, productivity and physical ability (Baleta et al., 2014). Diabetes also places immense burden on a country's healthcare system, particularly in terms of the three metrics found in the Healthcare Triangle: cost, access and quality (Katz et al., 2012).

Research suggests that accurate education and proper management regarding diabetes and its risk factors can have a positive impact on the quality of patient life, as well as the country's healthcare system (Katz et al., 2012). As a result, there is clearly a need to develop low-cost, accessible and innovative solutions to address the management and health outcomes of various diseases. The use of modern technologies, such as mobile phones, can go a long way towards providing a platform for improved health outcomes.

One such disease management platform is mHealth, which is the acronym for mobile health, and is best described as the use of mobile communication for health services and information (Klonoff,

2013). Mobile and electronic health methods have proven to be effective methods of disease management by encouraging patients to get involved in their own treatment (Klonoff, 2013).

This study aims to improve on this by disseminating health information in an interactive, personalised manner that is both effective and affordable. The theory is that, with improved knowledge, patients' behaviour will improve and so impact positively on health outcomes. Similar studies are common in higher income countries, but this is a relative first for low and middle income countries (LMICs), particularly in Africa (Hall et al., 2014).

This specific study intends to improve GDM knowledge in under-served communities using a mobile phone by focusing on the background, planning, development, and the evaluation of the intervention. The research presented consists of three main studies: a systematic review, a conceptual framework and prototype design, and an evaluation of the developed prototype.

1.3 Method of Investigation

The main aim of this research is to determine the effectiveness of an mHealth platform among pregnant women in relation to GDM. The research intends to discover whether a patient's gestational diabetes knowledge, understanding and management is improved in under-served communities with the use of a mobile health intervention.

The objectives of this research are, therefore, to:

- Document the use and impact of mHealth in GDM by conducting a detailed systematic review of the existing literature.
- Develop and design a low-fidelity prototype based on a conceptualised framework for the proposed mHealth intervention.
- Collate and analyse feedback on the prototype based on the conducted electronic survey.

These objectives were reached by conducting three separate studies, which formed the plan of development for the investigation. These studies, therefore, were able to cover the scope of the research by:

- Explaining the types of diabetes mellitus and describing the direct and indirect implications associated with the disease on human health and healthcare.
- Discussing various texts of literature focused on the effects of mobile health on disease management and patient health outcomes.

- Describing the methodology of the investigation, going into detail about the strategy of performing the research in relation to pregnant women.
- Explaining the process of establishing the conceptual framework for the intervention to be implemented and presenting the prototype for evaluation.
- Describing and analysing the attained results.
- Drawing conclusions based on the interpreted results.
- Recommending strategies to improve the strength of the project.

2. Literature Review

The following literature review explains aspects of diabetes, such as its causes, implications and required management options and treatments before it goes on to discuss the factors responsible for poor health outcomes predominantly found in under-served communities.

It touches on the definition and usefulness of mobile health as a tool to facilitate proper healthcare management, and highlights both the advantages and disadvantages of using technology-based interventions in the field of medicine. It also mentions pregnant women as the participants for this research, before offering examples of interventions currently being implemented worldwide.

2.1 Diabetes Mellitus

Globally, by 2014, there was an estimated 422 million people suffering from diabetes, resulting in up to 8.5% of the world's adult population affected by what can be a preventable disease in some cases (Shaw et al., 2010). As an LMIC, South Africa's statistic on diabetes is rising rapidly and will continue to do so unless properly addressed (Roglic et al., 2016).

2.1.1 Types and Aetiology of Diabetes

As of the late 1970s, diabetes exists in four major forms: Type I, Type II, Other (Type III) and Gestational, which occur in varying frequencies through populations (Alberti et al., 1998). The diagnostic criteria for diabetes is classified through the body's blood glucose levels and its ability to produce and use the necessary insulin (Shaw et al., 2010).

Owing to the growth levels of urbanisation and recent changes in peoples' eating habits and lifestyles, there has been a significant upsurge in the prevalence of diabetes over the last two decades, with the risk of developing the disease increasing tenfold as people age (Shaw et al., 2010). There are a number of factors that contribute to the development of diabetes, which includes a person's diet and level of physical exercise, resulting in symptoms of increased urine production, heightened thirst, and fatigue (Shaw et al., 2010).

Type I is classified through the body's deficiency in producing insulin, and requires that insulin be administered in an external capacity (Shaw et al., 2010). Typically, Type I diabetes is not a hereditary disease but can be developed through an inherited genetic predisposition (Roglic et al., 2016).

As the number one growing type of diabetes, Type II is largely presented as being preventable. It is the most commonly found form and is referred to as insulin-resistant, as the body is unable to make proper use of the insulin it has already produced (Alberti et al., 1998). There is no genetic cause for Type II diabetes, though certain people are more inclined to develop the disease if it exists in their family's medical history (Shaw et al., 2010).

Other (Type III) can refer to pancreatogenic diabetes (Type 3c), or the proposed description for the link between insulin resistance and the triggering of Alzheimer's disease (Alberti et al., 1998). Gestational diabetes mellitus (GDM) is discussed further in Section 2.1.3 Gestational Diabetes Mellitus.

2.1.2 Treatment and Control of Diabetes

If left untreated, diabetes has very serious short and long-term consequences to a patient's health, livelihood and physical ability (Roglic et al., 2016). Not only can it result in damage to vital organs (eyes, heart and kidneys) but it can also have irreversible effects on vital nerves and blood vessels (Alberti et al., 1998). Diabetes can lead to severe cardiovascular disease, possible limb amputation and even death if not properly treated, which is why it is imperative to ensure patients are involved in their own disease maintenance (Wang et al., 2018). Proper diabetes management optimises a patient's quality of life, prevents morbidity and reduces the rate of premature mortality (Fisher et al., 2012). Worldwide, diabetes was estimated to be responsible for 1.6 million deaths in 2016, and has been growing exponentially (WHO, 2017).

The treatment plan for diabetes can include oral medication, daily injections, a proper diet, frequent exercise, and various combinations of these (Roglic et al., 2016). There is currently a large effort to prevent or delay early-onset diabetes among adults by putting great emphasis on maintaining a healthier lifestyle. This encourages those at risk to make good eating choices and participate in regular physical exercise in order to maintain safe blood glucose levels and a suitable body weight (Sarwar et al., 2010). Types I and II require constant monitoring and possible insulin to be administered, in order to sustain appropriate blood glucose levels (Sarwar et al., 2010).

2.1.3 Gestational Diabetes Mellitus

Gestational diabetes mellitus (GDM), which is the primary focus of this research, is a type of diabetes that affects only pregnant women, where a woman's blood glucose is considerably high enough to require caution, but generally not to the levels prompting full treatment (Roglic et al., 2016). This type

of diabetes is especially dangerous, as there is an increased risk of complications to both mother and baby during the pregnancy, during delivery and later in life (Roglic et al., 2016).

GDM is typically diagnosed during the second or third trimester of pregnancy and is a result of the placenta producing hormones that impede the body's ability to use insulin (Karuranga et al., 2017). This condition affects 7-10% of pregnancies worldwide and greatly increases the risk of developing Type II diabetes after pregnancy, particularly if the pregnant woman has a high BMI (Gandevani et al., 2019). Babies born of mothers with GDM are also more susceptible to have high birth-weights and develop Type II diabetes later in life, which poses a considerable health risk (Karuranga et al., 2017).

Combinations of treatments can provide the best health outcomes for patients, if carefully adhered to, as it has been found that proper disease management through constant monitoring, sustainable exercise and a well-balanced, prescribed diet can have both positive and substantial effects on the health outcomes of diabetic patients (Society of Endocrinology Metabolism and Diabetes of South Africa, 2017). This is especially vital when concerning expectant mothers, as some women will respond differently to the provided medication, and this can have short and long-term effects on both baby and mother (Roglic et al., 2016).

2.2 Under-Served Communities

The World Health Organization (WHO) recognises countries as low and/or middle income countries based on their respective Gross Domestic Product (GDP) according to the World Bank (World Health Organization, 2017). The United Nations describes an under-served community, particularly in regard to health services, as an area that suffers from a shortage of primary medical and healthcare services (Blanc et al., 2016).

The importance of literacy levels and decent communication and technology is paramount and has the ability to correlate directly to the quality of healthcare available in those geographical areas (Roglic et al., 2016). With the rapidly rising statistics in prevalence of diabetes in LMICs, proper education and higher quality of healthcare are especially needed to tackle the global pandemic (Roglic et al., 2016).

2.2.1 Prevalence of Diabetes

In South Africa alone, there is an estimated 3.85 million people affected by the chronic disease, which is close to 7% of the total population (Roglic et al., 2016). GDM has an incidence rate of 7-10% in all pregnancies (Gandevani et al., 2019).

Alarmingly, rural areas show increased levels of diabetes compared to urban areas, and this is attributed to low quality healthcare facilities, lack of nutritional education, and poor eating habits largely credited to limiting household incomes (Roglic et al., 2016). As a result, WHO has spent considerable time and effort to create and bolster sufficient awareness surrounding the disease, as well as present specific guidelines regarding diagnosis and treatment of diabetes to pregnant women and healthcare professionals (WHO, 2004).

Additionally, Zhu et al. conducted a comprehensive review of available date to determine the prevalence of GDM globally, by region. Their findings, between 2005 and 2015, are found in Figure 1 below, and indicate that the burden of disease remains substantial in developing countries, and particularly Africa.

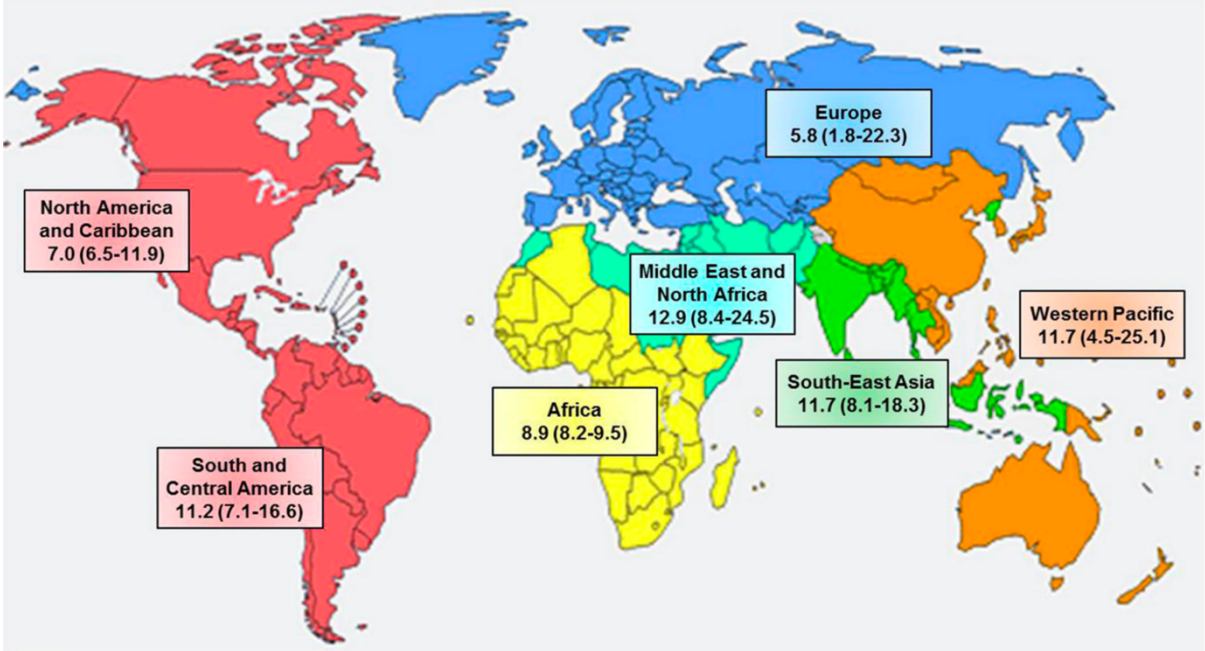


Figure 1: Prevalence (%) of GDM by Global Region (Zhu et al., 2019)

2.2.2 Impact of Diabetes

Already, the economic cost of diabetes is a heavy burden on the country's health system and will only rise if not properly and promptly addressed (Mutyambizi et al., 2018). South Africa's healthcare services are unequipped to shoulder the demand of the burden of multiple diseases, as it has limited resources compared to those found in developed countries (Steyn et al., 2006). Mitigating unhealthy lifestyles, along with promoting early diagnosis and self-management remain low priorities but are critical to moderating the burden on the public health sector (Steyn et al., 2006). Prevention of chronic

diseases, such as diabetes, by promoting cost-effective health interventions would aid South Africa's health system utilise its limited resources in an optimal way (Steyn et al., 2006).

Diabetes has been shown to affect quality of life by impacting patients physically, mentally, psychologically and socially (Trikkalinou et al., 2017). With the disease, comorbidities and additional complications exist, which cause further deterioration of a patient's ability, mobility and mental health (Trikkalinou et al., 2017). Psychometric tools are being developed to aid in increasing a patient's evaluated quality of life, to which this project could contribute.

2.3 mHealth

The acronym, mHealth, refers to the use of various forms of mobile communication to assist with delivering health services and information (Klonoff, 2013). Other names include telemedicine, eHealth and telehealth, which also make use of telephonic and online forms of communication (Klonoff, 2013). In a world where technology is constantly evolving, its use in healthcare is becoming more and more difficult to ignore, and there has already been concerted effort towards successful integration in recent years (Klonoff, 2013).

2.3.1 Overview

mHealth is an effective and efficient tool for facilitating healthcare management. It offers a means to impact positively on the country's healthcare system and an individual patient's health outcomes through increased access to knowledge, better quality of healthcare and minimised cost of health services (Free et al., 2013). mHealth makes use of electronic devices that have the capability to communicate wirelessly, such as mobile phones, tablets and personal digital assistants (Hall et al., 2014).

General use of mobile phones is estimated at 93% globally, with South Africa having approximately 59 million devices in circulation, which actually exceeds the country's population of 56 million people (Aranda-Jan et al., 2014). While there exists a substantial mobile gender gap, the numbers in women's mobile phone ownership and women's mobile internet use are increasing significantly by year (Rowntree, 2019). The statistics regarding the abundance of mobile phones present in the country can be used to consolidate the idea that mobile phones can and will be an essential and viable tool to adopt in terms of healthcare.

The technology involved in mHealth and telemedicine exists in a variety of modalities, and their respective uses are dependent on the specified user requirements of the intervention being developed (Hall et al., 2014). For this particular research, registration and event tracking, and data collection and reporting are just two of the purposes required of the intervention, and examples of the necessary mobile device functions are listed below, as adapted from Labrique et al., 2013:

- Short Message Service (SMS)
- Multimedia Messaging Service (MMS)
- Voice Communication/Audio Clips
- Images
- Digital Forms

2.3.2 Usefulness

mHealth has already had a positive impact on healthcare in South Africa, by encouraging self-management of illnesses through the reminding of appointments, the monitoring of chronic medication, the providing of psychological support, and various other ways (de Tolly et al., 2012). mHealth has the advantage of promoting self-care, allowing patients to follow their own treatments and self-monitor (Hamine et al., 2015).

By encouraging patients to participate in self-management, mHealth has the ability to save medical aid insurers, government and individuals significant amounts of money. It can also go a long way to aiding expectant mothers by efficiently and easily tracking the various stages of their pregnancy and monitoring their daily food intake, physical activity and blood glucose levels (Kennelly et al., 2016).

2.4 Case Studies: mHealth

In recent years, mHealth and telemedicine have been implemented in a number of settings, both nationally and internationally. This section discusses such studies relating to mHealth being used in diabetes, pregnancy and GDM.

2.4.1 mHealth Used in Diabetes: Look AHEAD (Action for Health in Diabetes)

As part of a pilot comparative effectiveness trial conducted in Texas, USA, involving a sample group of participants who are overweight, suffering from Type II diabetes and living in an under-served community, the theory of Look AHEAD (Action for Health in Diabetes) was tested (Wang et al., 2018).

This trial involved three separate randomised control groups: paper-based care, mobile-based care and one involving the usual, standard care, and each group was monitored for weight loss at three and six months after commencement of the trial (Wang et al., 2018). Through this trial, it was found that the delivery of behavioural change intervention through the use of mobile health to this type of community is, indeed, both practicable and achievable when taking into account the efficiency of mobile self-monitoring compared to paper-based monitoring (Wang et al., 2018).

2.4.2 mHealth Used in Pregnancy: MomConnect

South Africa's very own *MomConnect*, driven by the National Department of Health South Africa, was nationally launched in August 2014 with the aim of delivering specific and timely information related to health and proper management to pregnant women (National Department of Health South Africa, 2014). Figure 2 found below shows a brief overview of how the initiative works.

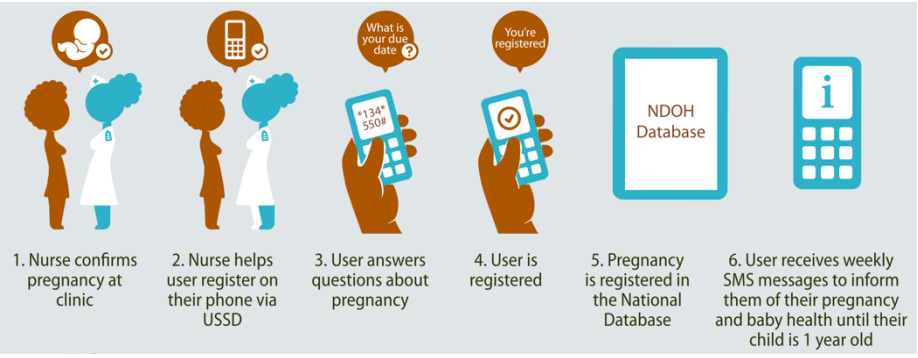


Figure 2: MomConnect: How It Works (World Health Organization, 2016)

It was designed and implemented with the sole intention of reducing the rates of preventable maternal and infant mortality among low and/or middle-income women. This is done by providing a programme capable of reaching a large number of women and providing them with access to quality healthcare and information about the stages of pregnancy (National Department of Health South Africa, 2014).

This initiative is one of many paving the way for increasing the presence of technology in healthcare in Africa, and it is from an existing platform such as this one that the GDM mobile health service can be adapted.

2.4.3 mHealth Used in Gestational Diabetes: MODIAB-Web

In 2014, a randomised control trial was conducted in Sweden, which involved the evaluation of the impact of a web-based intervention on pregnant women or women who recently gave birth suffering from GDM (Adolfsson et al., 2014). It made use of two separate groups – one making use of the intervention and the other as the control group - to determine the effectiveness of the intervention (Adolfsson et al., 2014).

While the control group participated in manual (paper-based) self-management, the intervention group had access to web support that offered information on GDM, techniques for proper self-care and peer-to-peer communication (Adolfsson et al., 2014). It was expected that the web support would increase the women's capacity to self-manage their GDM and pregnancy, as well as improve their general attitude throughout the various stages of pregnancy and early motherhood while managing their disease (Adolfsson et al., 2014).

2.5 Conclusion

This literature review discussed the disease, diabetes, its implications on patient health and the healthcare system, and health outcomes related to patient knowledge. It also discussed mHealth and the effects of its use on both the patient's knowledge about diabetes and his or her health outcome.

Diabetes is a major public health challenge that impacts negatively on the health system, both globally and locally, and this research study is a first phase in providing justification for the use of mHealth in the management of GDM in South Africa.

3. Study One: Systematic Review

3.1 Introduction

This study includes the systematic review, the purpose of which was to determine how mHealth impacts on patient knowledge, understanding and management of GDM. It provides a comprehensive overview of the methodology used. In addition, the systematic review also reports on the results and discusses these results in relation to the aim of the study.

3.2 Methodology

This section describes the search strategy used to obtain the relevant articles required to conduct the systematic review, and the methods involved in identifying and selecting studies for inclusion. It also identifies the measured outcomes used for the analysis found in Section 3.3 Results and Analysis.

Prior to commencing the review, a brief protocol was prepared, in order to guide and control the review, as well as to allow the review to be replicated, and has been included as Appendix A – Systematic Review Protocol.

3.2.1 Preliminary Study Design

The primary outcome in this review was to determine how mHealth impacts on patient knowledge, understanding and management of GDM in under-served communities, and was assessed in the systematic review by:

1. Identifying whether GDM knowledge, understanding and management was improved.
2. Monitoring the clinical outcomes of pregnancy.

In order to garner this information, the review interpreted data from studies where conventional healthcare methods were adopted and where mHealth was used in an experimental capacity, and the results were compared. The success or failure of the intervention was then determined by the level of improved knowledge and patient attitude, which was additionally evidenced by the resulting health results.

The type of research included in the review was mainly qualitative in nature. It made use of both randomised and non-randomised studies, with a dominant focus on studies with case-controlled

mHealth as the principal implemented intervention, as well as pilot projects. It did not include studies where mobile phones were used in the study, but not in the capacity of mHealth. The selected participants were pregnant women above the age of 18 who live in countries or communities considered to be low to middle income, as stipulated by the World Bank, and not limited to the continent of Africa.

The type of intervention for implementation included mobile phones with only limited mobile use functionalities. It excluded MMS, Personal Digital Assistants (PDA), various forms of social media (e.g. *Facebook* and *Twitter*), and Voice Over Internet Protocol (VOIP), and included text-based SMS, Unstructured Supplementary Service Data (USSD) and smartphone applications not limited to a specific operating system (e.g. Android and iOS).

3.2.2 Search Strategy and Criteria for Study Selection

An electronic systematic literature search was conducted using databases that included PubMed, Cochrane Library, Scopus, EBSCOhost (Academic Search Premier, Africa-Wide Information, MEDLINE and PsycInfo), Web of Science and Google Scholar. The studies were selected by using relevant search parameters, chosen with regard to the research question. An Information Sciences Specialist was consulted regarding these parameters, and both Medical Subject Headings (MeSH) found in National Institute of Health, 2018, and free-text language were used when conducting the searches.

The searches were limited to articles published in English, involving human beings (women) and published during the period between the beginning of 2015 and the end of 2019. This period was chosen to accommodate more recent articles, where mHealth has been more prevalent in this setting. The searches were performed on 9-11 January 2020 by one author (SA), and then reviewed by an independent (JL). All the relevant studies were retrieved and saved in the reference management software, EndNote, which allowed for automatic removal of all duplicated articles. From there, a manual revision was further completed for verification (SA).

From the remaining search results, all potential abstracts were screened, and studies where selected for full-text review. Manual searches were conducted in digital sources, and studies were excluded based on availability of full-text articles. Further studies were identified by checking the reference lists of originally-included studies and data was extracted from these findings. To avoid selection bias, two independent reviewers (JL and JFA) evaluated the bias in the study according to the standards predetermined by the International Cochrane Collaboration.

All study designs (pilot projects and randomised control trials etc.) were included in the final selection, except for project protocols. Other exclusion criteria chosen were: investigation not located within an LMIC or in a low to middle income setting, implementation not rooted in mHealth as it is described in this project, disease not GDM, study conducted postpartum, and mobile use unrelated to healthcare.

3.2.3 Study Selection

The research question of, 'Does mHealth improve diabetes' knowledge, understanding and management among pregnant women compared to conventional healthcare methods currently being used with regards to gestational diabetes mellitus in under-served communities?' was established and divided into workable terms. The PICO method was adopted, which determined the Population, Intervention, Comparison and Outcome, and is shown in Table 1 found below.

Table 1: Populated PICO

Population	Pregnant women with GDM (who live in low-to-middle-income countries and under-served communities).
Intervention	mHealth platform.
Comparison	Conventional healthcare methods.
Outcome	To determine if mHealth improves patient knowledge and understanding of diabetes.

These factors were used to populate the parameters for the actual search, which can be found in Appendix B – Search Parameters and Strategy. These keywords were used in each of the databases, through advanced search principles or adopting Boolean operators. At completion, the various databases produced a total of 325 search results, which were then screened for any duplicates, before their titles and abstracts were reviewed. The remaining 67 studies were further and critically sifted based on strict inclusion criteria to be included in the final review, and the identification of these articles are shown in Figure 3 below.

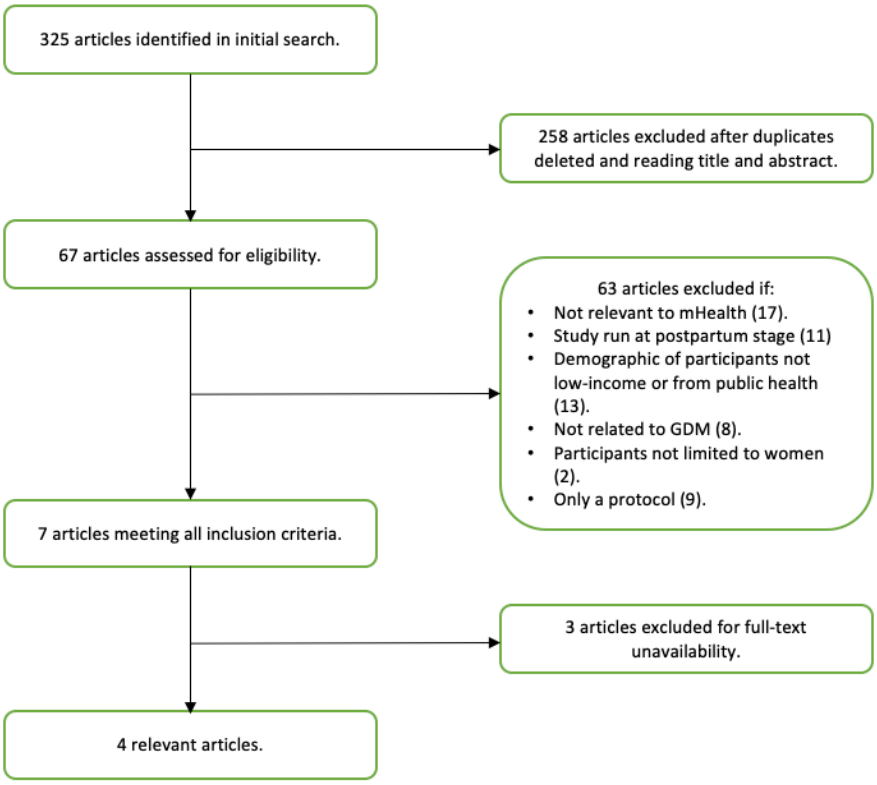


Figure 3: Identification of Relevant Articles

The single largest exclusion factor proved to be the socio-economic setting of the studies. Upon search and exclusion completion, only four studies were included in the final review. Of these studies, three were RCTs and one was a one-group pre-test/post-test. The studies were all qualitative in design and peer-reviewed, each featuring relatively small sample sizes (range of 21 to 157). The studies included in the review can be found in Table 2 below.

Table 2: Included Studies by Type, Author, Year and Country

Type of Study	Author	Year of Publication	Country
Randomised Controlled Trial	Eslami et al.	2017	Iran
	Guo, H. et al.	2019	China
	Yang, P. et al.	2018	China
Basic One-Group Pre-Test/Post-Test Design	Carolan-Olah, M. et al.	2015	Low-Income Community in Australia

3.2.4 Data Extraction

The data extraction form specified in Table 3 was adopted, in order to keep the relevant data from each selected study properly organized and simply accessible for ease of analysis. Only the following key information was tabulated with the intention of increasing the efficiency of data collection. An expanded and completed table can be found as Appendix C – Extracted Key Information.

Table 3: Extracted Key Information

Author/s	
Year of Study	
Country of Study Setting	
Environment of Study/Type of Facility (e.g. hospital, clinic, community)	
Author Affiliation	
Demographic Traits of Study Population/Type of Participants (e.g. age, annual income, ethnicity)	
Type of mHealth Intervention Employed	
Type of Study (i.e. design)	
Type of Outcomes and How They Are Measured	
Findings/Results	
Conclusions	

This format is borrowed from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Checklist, which forms part of the PRISMA Statement (Moher et al., 2009). The checklist covered topics pertaining to the research, which included, and was not limited to the title, abstract, methods and results.

Table 4 was used to identify and present the measured outcomes shared by each of the studies included in the review. This information remained useful when the data was analysed in Section 3.3 Results and Analysis.

Table 4: Shared Measured Outcomes in the Studies

Author	Study Population [Intervention Group:Control Group]	mHealth Intervention	Measured Outcomes										
			Compl-iance	Blood Glucose Levels	Gestational Age at Delivery	Vaginal Delivery	Instru-mental Delivery	C-Section	Birth Weight	Hypo-glycaemia	Premature Delivery	Macrosomia	Neonatal NICU
Carolan-Olah, M. et al.	21 Women with GDM.	Information Website											
Eslami, E et al.	140 Women at Risk of GDM. [70:70]	Educational Text Messages and Booklets		X									
Guo, H. et al.	124 Women. [64:60]	Mobile Application	X		X	X	X	X		X		X	
Yang, P. et al.	107 Women with GDM + 50 With Normal Glucose Response as Control Cohort. [57:50] + [50]	WeChat Platform		X	X	X	X	X	X	X	X	X	X

3.3 Results and Analysis

The results section explains the assessment and analysis of the findings. The review manager, RevMan Version 5.3, was used to perform the meta-analysis of the data found in the studies. This data was extracted and inputted into the review manager, with the subsequent comparisons divided into two measured outcome groups: Glycaemic Control, and Pregnancy and Delivery. Included are also outcomes relating to behaviour and knowledge, as well as to the design and functionality of the mHealth intervention.

3.3.1 Types of Analysis

For the purpose of this entire meta-analysis, it was decided that dichotomous data type (numbers of events occurring) outcomes would use the Mantel-Haenszel statistical method and the risk ratio effect measure. For continuous data type (e.g. ages and blood glucose readings) outcomes, the inverse variance statistical method was used with the mean difference effect measure. All results were considered at a 95% confidence interval.

The assessment of clinical heterogeneity involved the examination of each study, with respect to the measured outcomes. The studies were generally found to have an acceptable amount of heterogeneity, according to the studies' participants, types of intervention, and settings. This allowed for the application of the analysis model of random effects. According to Higgins et al., an I^2 value higher than 50% represents significant heterogeneity.

For the statistical analysis, it was also stated a P value lower than 0.05 displays statistical significance (Higgins et al., 2003). Owing to the limited studies involved in the measurable outcomes indicated in Table 4, the results were found not to be statistically significant in majority of the meta-analyses. The review manager enabled these I^2 and P values to be calculated and presented, and are clinically assessed for each explored outcome.

3.3.2 Assessing Risk of Bias

In order for the review to be deemed more credible, the risk of bias was assessed. All four included studies were assessed and the results are displayed in the graph found in Figure 4 below, all with possible methodological bias.

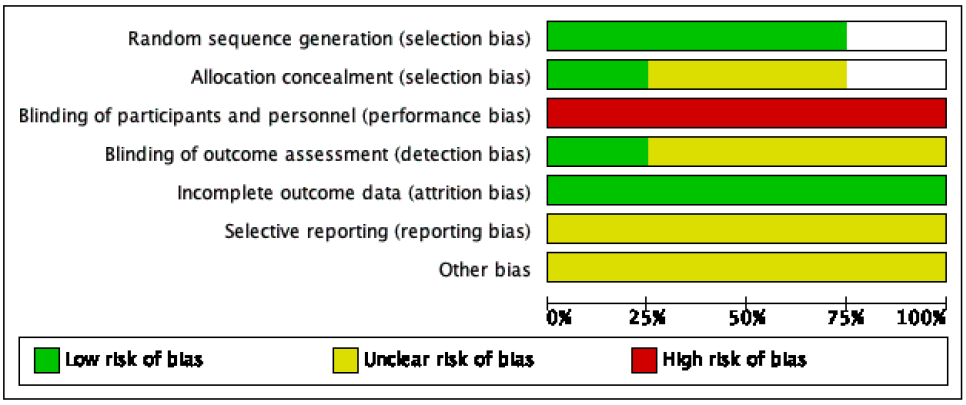


Figure 4: Risk of Bias Graph

Of the four studies, only three had adequate generation of a randomised sequence, as one is not an RCT. Only one of the studies displayed any clear allocation concealment or selection bias. Blinding of the participants and personnel was not possible in all the studies, as all participants had knowledge of the allocated groups. Only one study indicated evidence into the blinding of outcome assessment or detection bias. There remained a low risk of attrition bias in all the studies owing to the handling of incomplete outcome data, and all the studies maintained an unclear risk of selective reporting. These indicators are summarised in Figure 5.

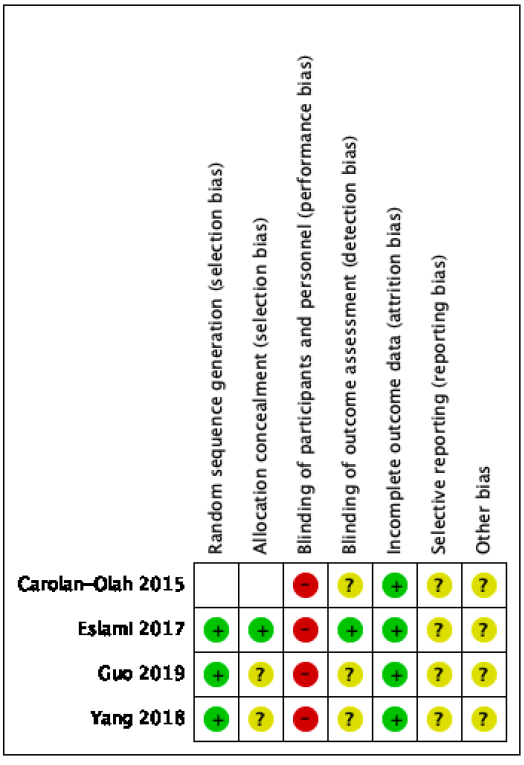


Figure 5: Risk of Bias Summary

3.3.3 Glycaemic Control Outcomes

The outcomes in this section refer to the values related to blood glucose and patient compliance.

There were two studies (Eslami et al., 2017 and Yang et al., 2018) that evaluated the blood glucose levels of the control and intervention groups. For this meta-analysis, the fasting blood glucose values post-intervention were used, each from an oral glucose tolerance test (fasting blood glucose, and 1-hour and 2-hour postprandial). The results shown in Figure 6 indicated there was improvement between pre and post intervention values in the intervention group, with a risk ratio of 0.45. These results were at a high level of heterogeneity (I^2 = 95%) and were not statistically significant (P = 0.39).

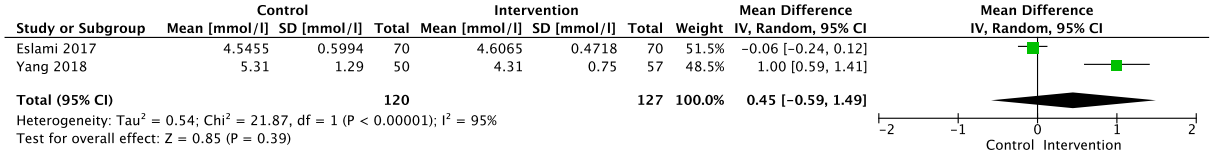


Figure 6: Forest Plot of Blood Glucose Levels

Compliance was calculated as the actual blood glucose measurements divided by the instructed measurements, and was indicated as a percentage by Guo et al. It provided a numerical indication of the patient's inclination to follow treatment and maintain self-monitoring. In the single study, it was found that women in the control group were 12.90% less compliant than women in the intervention group, and these results were considered statistically significant with a P value < 0.001 (Guo et al., 2019).

3.3.4 Pregnancy and Delivery Outcomes

The outcomes in this section refer to the data collected relating to maternal and perinatal health during pregnancy and delivery. They include gestational age at delivery, vaginal delivery, instrumental delivery, Caesarean section, birthweights, hypoglycaemia, premature delivery, macrosomia and neonatal admissions.

There were two studies (Guo et al., 2019 and Yang et al., 2018) that reported the gestational age at delivery in weeks. In the forest plot shown in Figure 7 below, it was found that there was a higher probability of giving birth at an advanced gestational age among the women in the intervention group,

as shown by the risk ratio of -0.38. The data was homogeneous (I^2 = 0%) and was not statistically significant (P = 0.10).

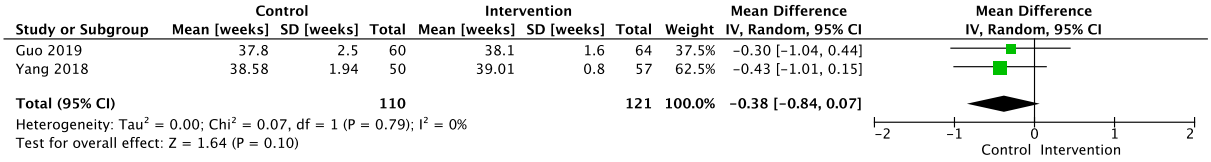


Figure 7: Forest Plot of Gestational Age at Delivery

The numbers reported in Guo et al. and Yang et al. in relation to vaginal deliveries indicated that the differences in vaginal delivery between the control and intervention groups was minimal (risk ratio of 1.05). The I^2 value of 74% found in the forest plot in Figure 8 below shows that the results were noticeably heterogeneous, and not statistically significant (P = 0.79).

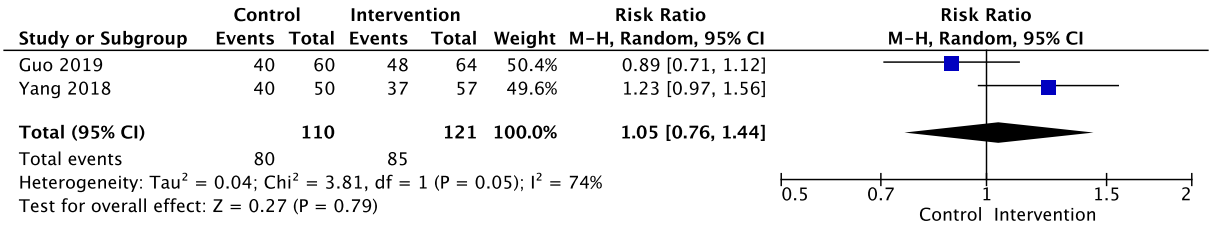


Figure 8: Forest Plot of Normal Vaginal Deliveries

There were two studies that informed statistics on instrumental delivery, which refers to births assisted by the use of forceps or a suction cup (Aliyu et al., 2011). The meta-analysis of Guo et al. and Yang et al., found in Figure 9 below, specified that women in the control group were more likely to have an assisted delivery, with a risk ratio of 1.89. These results were homogeneous (I^2 = 0%) and were not statistically significant (P = 0.24).

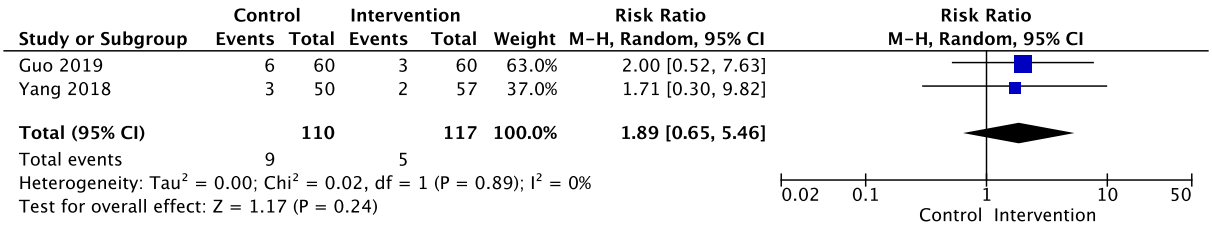


Figure 9: Forest Plot of Instrumental Deliveries

Guo et al. and Yang et al. also reported on the number of Caesarean sections in their respective studies. The results shown in Figure 10 below indicated that the probability of having a Caesarean section was actually higher among women in the intervention group than in the control group (risk ratio of 0.80). The results were substantially heterogenous (I^2 = 80%) and were not statistically significant (P = 0.68).

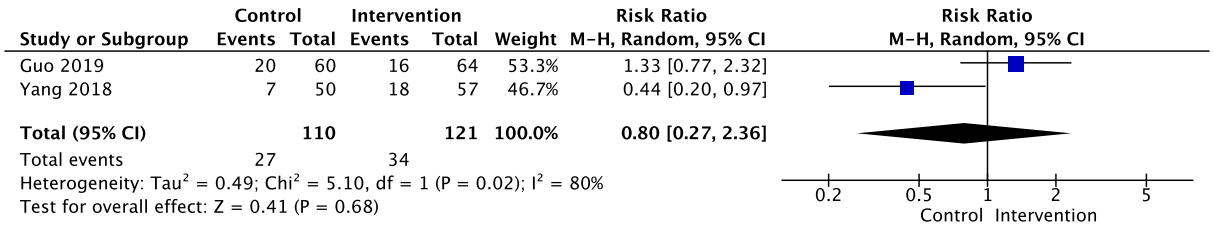


Figure 10: Forest Plot of Deliveries by Caesarean

Only one study (Yang et al., 2018) assessed the birthweights upon delivery of the new-borns. The results found that calculated mean birthweights in the intervention group was 29.87 g higher than in the control group. In the study, the results were stated not to be statistically significant (P = 0.737).

Cases of hypoglycaemia were reported by two studies (Guo et al., 2019 and Yang et al., 2018), and the results of the meta-analysis showed that it was considerably more likely for hypoglycaemia cases to occur in the control group than the intervention one (risk ratio of 3.11). The results found in Figure 11 below were homogeneous (I^2 = 0%) and were not statistically significant (P = 0.23).

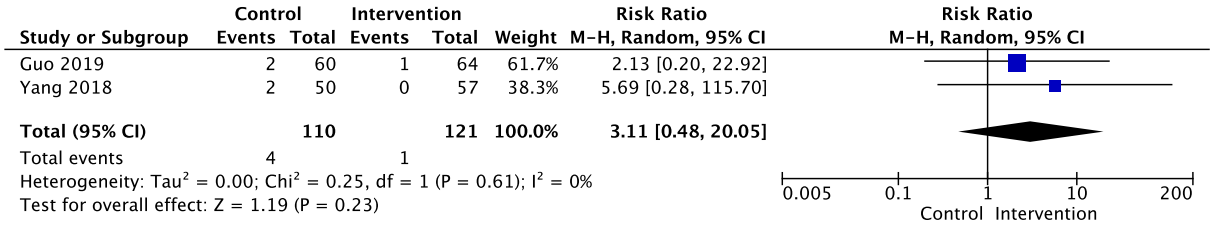


Figure 11: Forest Plot of Hypoglycaemia Cases

Premature delivery was reported on by only one study (Yang et al., 2018), and revealed that the probability of delivering prematurely is substantially higher among women in the control group. In this particular study, these results were considered statistically significant (P = 0.032).

Guo et al. and Yang et al. both reported on the number of cases of macrosomia and the results are shown in Figure 12 below. The studies indicated that macrosomia was more likely to be found in new-

borns in the control group, shown by a risk ratio of 1.45. The results were homogeneous (I^2 = 0%) and were not statistically significant (P = 0.48).

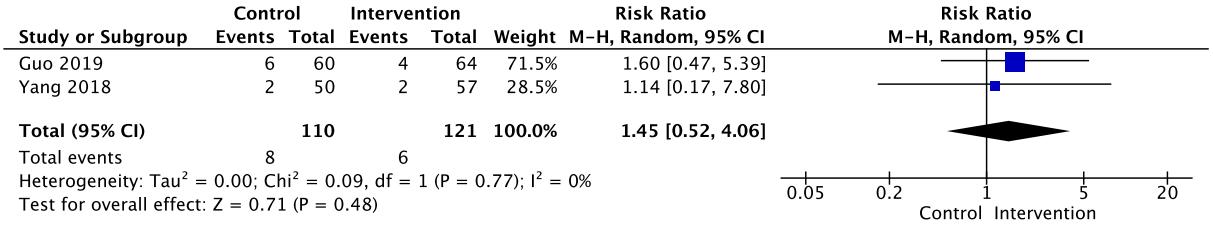


Figure 12: Forest Plot of Macrosomia Cases

Neonatal admissions were reported by Yang et al. The results found within the study show that there was a higher probability of new-borns being admitted to neonatal intensive care in the control group, and were not deemed statistically significant (P = 0.314).

3.3.5 Behaviour and Knowledge Outcomes

The outcomes in this section refer to the information learned from the studies in relation to patient knowledge and understanding of GDM, as well as their motivation to participate actively in self-management of GDM. Carolan-Olah et al. evaluated the knowledge and understanding of types of diabetes, food's calorific values and blood glucose monitoring using the Diabetes Knowledge Scale. It was largely found that the mHealth intervention used improved patient knowledge.

Key findings from the included studies found that, in order to improve knowledge and self-efficacy, the intervention should:

- Include larger pictures, especially if levels of literacy are low in the community (Carolan-Olah et al., 2015).
- Incorporate more ethnic-specific foods and recipes (Carolan-Olah et al., 2015).
- Include recipes suitable for women with GDM (Carolan-Olah et al., 2015).
- Provide examples of items to make up a healthy shopping list (Carolan-Olah et al., 2015).
- Have tips on how to manage cravings (Carolan-Olah et al., 2015).
- Give access to sufficient, complete information that is user specific (Carolan-Olah et al., 2015).
- Have a list of food beliefs, myths and taboos surrounding nutrition during pregnancy, and how to combat them (Carolan-Olah et al., 2015).

- Use clear and precise language that cannot easily be misinterpreted (Carolan-Olah et al., 2015).
- Use tactics that include sending educational messages (Eslami et al., 2018), motivational messages, and the setting of weight and blood glucose goals (Carolan-Olah et al., 2015).
- Deliver health education sessions tailored towards women with GDM (Eslami et al., 2018).

3.3.6 Design of mHealth Intervention Outcomes

The outcomes in this section refer to what was learned regarding the design and implementation of the mHealth interventions found in each of the included studies. This data was not measurable and, thus, not able to be statistically analysed in the review manager. Instead, it has been reviewed to identify that a successful GDM platform should:

- Input initial patient demographics and personal information (Yang et al., 2018).
- Allow daily communication between patients and their health caretakers (Yang et al., 2018).
- Distribute customised patient treatment and dietary plans (Yang et al., 2018).
- Record the patient's daily food intake and frequency, duration and intensity of physical activity, as well as body weight, ketone, Haemoglobin A1C and blood glucose (Guo et al., 2019; Yang et al., 2018).
- Allow healthcare workers to view collected data for external monitoring and support (Guo et al., 2019).
- Allow the patient to set goals for body weight, exercise and daily food intake (Carolan-Olah et al., 2015; Guo et al., 2019).
- Graphically display all recorded data (Guo et al., 2019).
- Provide the patient with messages, reminders and alerts (Guo et al., 2019).

3.4 Discussion

3.4.1 Self-Monitoring and Compliance

The outcomes related to glycaemic control suggest that, collectively, the blood glucose levels improved in the women in the intervention groups, though they maintain a high level of heterogeneity and are not statistically significant, which is evident in Figure 6: Forest Plot of Blood Glucose Levels.

Guo et al. found that patient compliance improved among the women in the intervention group within its study, which is in alliance with the conclusion that there is insufficient evidence of improvement

found in previous reviews (Ming et al., 2016). Additionally, another study not included in the review found that enhanced compliance is linked to the patient's performance at maintaining blood glucose monitoring, which was greatly improved by the mHealth platform's feedback system and ability to maintain daily communication (Miremberg et al., 2018).

Additional motivational messages and scheduled reminders could be credited for this trend, as they work to encourage the patient's self-management. The compliance calculation is dependent on the actual blood glucose measurements reported in Guo et al., and correlates to the individual results that the mHealth platform has a positive effect on blood glucose levels, particularly at the fasting blood glucose measurement.

3.4.2 Effect on Pregnancy and Delivery Outcomes

The results in Section 3.3.4 indicated that the probability of delivering at a later gestational age was higher among women in the intervention group. Yang et al. does state that an important factor affecting this statistic included a reduced levels of fasting blood glucose, which was positively affected by the intervention.

At substantial heterogeneity, it was found that there was minimal difference in data regarding vaginal delivery, while the probability of delivery by Caesarean was reduced (P = 0.92) in the intervention group. Both results not considered to be statistically significant. This was in correlation with the findings in previous systematic reviews, namely Ming at al., which reported an increase in the probability of a Caesarean section instead. The results also found the probability of an instrumental delivery to be higher among the control group, though not statistically significant.

The meta-analysis showed that the results of the cases of hypoglycaemia and macrosomia were not statistically significant, which is in line with the evidence presented in Ming et al. Based on homogeneous data (I^2 = 0%), the results showed that the rates of hypoglycaemia and macrosomia cases were substantially reduced with use of an mHealth platform.

Yang et al. maintained findings of improvements in the numbers of premature deliveries among the intervention groups to a statistically significant number (P = 0.032), and presented that the probability of neonatal admissions was lower among the control group. The fact that these results could be found in only one of the studies indicates that more studies are needed, with an increased number of outcomes assessed.

3.4.3 External Monitoring and Support

Yang et al. found that it is essential to have a live, external system of monitoring blood glucose levels in patients with GDM. Nutrition therapy and guidance on exercises that are safe to do during pregnancy are able to be administered through mHealth platforms, and indicate a positive effect on blood glucose values.

Providing patients with daily communicable access to healthcare workers in lieu of basic and conventional care (e.g. fortnightly visits to the hospital and limited monitoring of blood glucose readings) allows patients to have immediate access to targeted health information, which would increase knowledge and understanding of GDM. Also, giving physicians and nurses remote access to the patient's collected data (body weight, blood glucose levels, etc.) aids in customising treatment and dietary plans for the individual on a case-by-case basis.

3.4.4 Health Education and Patient Understanding

There are structural (knowledge of disease), demographic (age, ethnicity, socio-economic status and level of education) and psychosocial (personality) factors that affect behaviour, particularly in a health setting (Bandura, 1982). Information on GDM that includes pictures and targeted language were found to be essential in improving disease and food knowledge (Carolan-Olah et al., 2015).

While the implementation of lifestyle-based training with regards to nutrition and physical exercise in Eslami et al. did not offer statistically significant results on improvement (partly owed to the shortness of the intervention duration and small sample size), it was recommended that the intervention would be more credible if presented at onset of pregnancy and for a longer period of time. Both these changes would work towards avoiding diagnosis of GDM and manage weight gain.

3.5 Limitations of Review

Upon completion of the review, several limitations were identified. The search strategy paid specific attention to studies conducted in LMICs and low-income settings, which largely excluded studies with additional evidence relating to the successful implementation of mHealth among pregnant women with or at risk of GDM in high-income settings. While the information gathered from these excluded studies would not necessarily apply to developing countries, there is a lot to be learned from similar projects conducted in developed ones.

Further exclusion criteria omitted articles not written in English, which discounted majority of the additional studies referenced in Yang et al. The publication dates being set between 2015 and 2019 also placed limitations on the numbers of studies identified, though this filter remained relevant to ensure only recent technology was present as the executed mHealth intervention.

Owing to the low numbers of participants involved in the studies (a range of 21 to 157), the meta-analysis of the measured outcomes was determined to be underpowered and unlikely to report significant numbers on additional pregnancy outcomes. More RCTs with larger population sizes in under-served communities would go a long way towards better informing the implementation of mHealth interventions. Another limitation was found in the social and economic background of the participants, as this statistic was only briefly reported on by one study during initial recruitment.

3.6 Conclusion

While all of the studies included in the review indicate that technology can make a difference in improving pregnancy outcomes to some degree, there remains professional consensus that there is currently insufficient literature to support technology-based care on a much larger scale, particularly in low-income settings.

mHealth has a positive effect on patient knowledge, understanding and management of GDM, as evidenced through the maternal and perinatal health outcomes.

4. Study Two: Prototype Design

4.1 Introduction

This study describes the methods used to transform the information and outcomes determined from the Literature Review and Study One: Systematic Review into workable deliverables in the form of a conceptualised prototype for the prescribed intervention. This research project's scope is limited to the theoretical framework required to build a low-level prototype of a mHealth platform for GDM, designed with the intention of presenting a simple and feasible final intervention capable of meeting the requirements to be a successful project.

4.2 Methodology

The conclusions of the systematic review and the knowledge learned in the literature review formed the foundation for determining the most effective and worthwhile intervention design for the participants involved in this research. This section showcases the design methods adopted for the investigation, and describes how they were implemented. This was done with the focal idea that the intervention was to be designed for a specific user, who would act as the main stakeholder: a pregnant woman.

This section also details the proposed intervention and attempts to rationalise the design choices made to produce the presented prototype. It also briefly specifies the predicted flow of the intervention, as well as explains the moving parts of the final prototype.

4.2.1 Background to the Design Processes

The research followed a blend of design processes, namely d.school bootcamp bootleg and Biodesign: The Process of Innovating Medical Technologies. Ultimately, it was decided that the investigation would draw from both processes in order to determine the best eventual solution. It was initially proposed that bootcamp bootleg be the primary method, but the research plan was altered owing to the delay in Ethics approval and subsequent and ongoing COVID-19 pandemic. As such, an increased number of design principles for the design process were drawn from Biodesign.

The first design process, bootcamp bootleg, places significant emphasis on designing with a specific user in mind, which was chosen to be pregnant women. It was adopted, owing to the fact that it was

considered to be a more interactive design toolkit, encouraging open-mindedness, collaboration and a creative mindset (d.school, 2010). This design process is depicted in Figure 13. The five components of the design process are to empathise, define, ideate, prototype and test, which were linearly used to tackle the research problem (d.school, 2010).

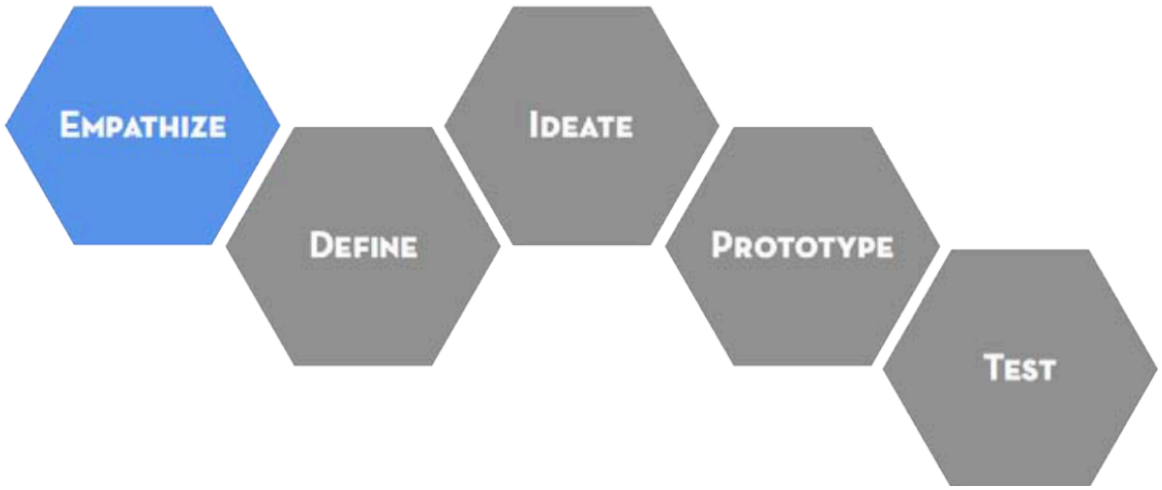


Figure 13: d.school Modes of the Design Process (Stanford d.school, 2010)

The bootcamp bootleg approach is rather linear in design, as it promotes following a step-by-step process, with a very clear starting point referred to as the "beginner's mindset" (d.school, 2010). This requires the designer be non-judgmental, pay avid attention and ask appropriate questions. This is especially important, as the questions 'What?,' 'How?' and 'Why?' are intrinsic to the success of this form of design thinking. Rethinking and redesigning is encouraged and receiving feedback from users and other external sources (e.g. healthcare professionals) goes a long way towards filtering out undesirable concepts in order to produce the best final solution (d.school, 2010).

The second design method is described in Biodesign: The Process of Innovating Medical Technologies and is a three-part process: Identify, Invent and Implement (Zenios et al., 2010). This design method is depicted in Figure 14 found below, and gives a clear indication of the stages found in each of the phases.

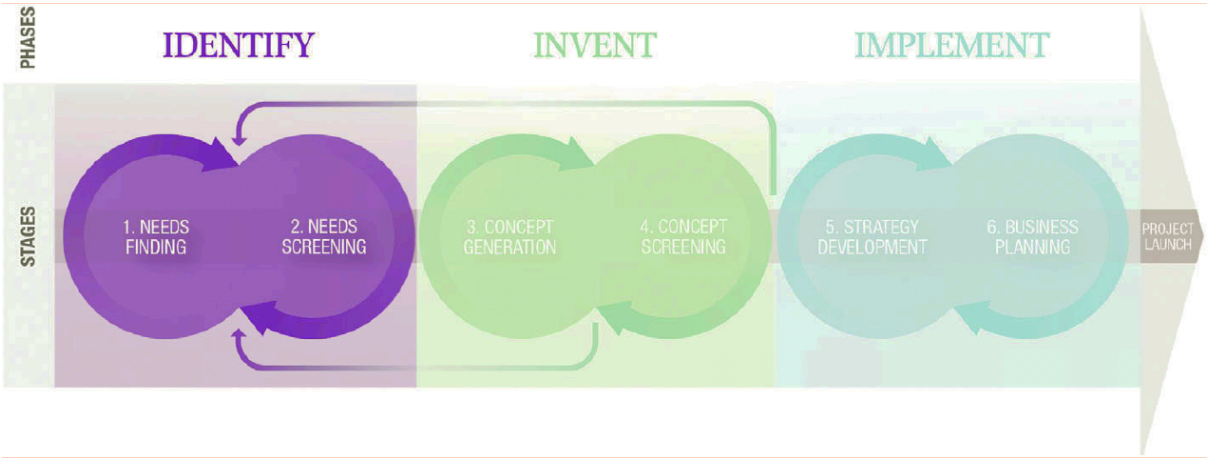


Figure 14: Biodesign Innovation Process (Zenios et al., 2010)

The primary driving factor behind Biodesign innovation is "a compelling need," and places increased significance on the needs of the various identified stakeholders (Zenios et al., 2010). The idea is to identify the more important needs and design the solution with the primary intention of meeting the highest ranked needs. For the purpose of this research, only the 'Identify' and select parts of the 'Invent' phases were used in the design process, as the 'Implement' phase was considered to be beyond the scope of this investigation.

4.2.2 Design Mode: Empathise

In its attempt to remain sincere to the human aspect of design, the first of bootcamp bootleg's modes, titled 'Empathise,' is believed to be the very foundation of human-centred design, and encompasses the three acts of observing, engaging with and immersing in the potential users of the intervention (d.school, 2010).

As part of the design method, this mode would have required the researchers speak directly to the target market of the investigation. This would have been accomplished by liaising with and questioning pregnant women in maternal wards and clinics to determine the best ways to offer knowledge, access, and assistance through a mobile health platform. However, owing to delays on ethics clearance and the pandemic, information was rather collated only from the systematic review and literature review, and so formed the basis for the user data going forward.

4.2.3 Design Mode: Define

In the 'Define' mode of bootcamp bootleg, the design process is more dedicated, and produces a suitable problem statement and the all-important Point of View, which takes note of the specific user, his or her specific need, and insight into the reason for this need.

The Point of View was thus stated as: pregnant women in underserved communities need a suitable way to access health information, owing to the increased numbers in the diabetes among them, particularly during pregnancy and later in life. It was from this Point of View that the User Experience found in Section 4.2.6.1 was compiled.

Given the information gathered, the main problem was described as being that the rates of GDM in under-served communities is rising, and this creates a health risk to women and their babies, during pregnancy and later in life. With the documented increase in mobile use, mHealth remained a viable and feasible platform through which to provide health services to these communities. As such, a suitable mobile intervention was needed, in order to educate women on pregnancy and GDM, as well as aid in self-management.

At this stage in the design process, there were no possible solutions presented, or any assumptions and inferences made. Both design methods use the process of identifying stakeholders, which kept a specific spotlight on all the primary patrons standing to benefit from the success of the investigation. The main user, and thus the primary stakeholder, was identified as a pregnant woman, as she would be assured more favourable health outcomes with the realisation of the project.

Additional stakeholders were identified because they stood to benefit from the success of this project, thereby eliciting a positive net impact. The burden of diabetes, particularly Type II diabetes, is significant on the **public health sector**, and introducing platforms to aid in self-management can meaningfully reduce the impact of diabetes. Equipping patients with the means to access health information and monitor their own diseases also decreases the demand on **healthcare workers**. **Health insurance companies** would also experience less claims related to diabetes for processing.

4.2.4 Design Mode: Ideate

Next, there was bootcamp bootleg's 'Ideate' mode, during which the ideas are generated by the design team based on reaching a solution to the problem (d.school, 2010). This was done in tandem with the Biodesign's directive of needs finding and screening in the 'Identify' phase, and used to populate a modified driver analysis, which aided in determining the concepts with the most telling

impacts on patient outcomes. This was specific to the user's health and knowledge of the disease and likelihood of complying to treatment regimens or even being able to make use of the intervention.

For this investigation, the drivers were identified as factors that could act as hinderances or barriers to the user's ability to make proper use of the intervention. These drivers were collected from the literature review and systematic review, and summarised in Table 5, along with the impacts these factors would have on the user's ease of use.

Table 5: Impact Breakdown of Affecting Factors

Factor	Impact
Literacy Level of User	If the user has a low literacy level, this could have significant impact on her ability to read and understand the information offered on and by the solution.
Preferred Language of User	If the user's preferred language is different to the intervention's proffered language, this could create a substantial barrier for any user wanting to make use of the solution.
Affordability of Intervention	Considering the desired community of users, the pricing of the purchase and use of the solution is critically important to evaluate, as it would likely create avoidance of the solution.
Compatibility with Various Operating Systems	If the user possesses a mobile device with an operating system different to the intervention's, this would hinder her capacity to use the solution on her own individual device.
Ability of User to Use a Mobile Device	The user's ability to use her mobile device effectively could hinder the way in which she makes use of the offered intervention to its full potential.
Aesthetic Appeal to the User	The visual representation of the intervention plays a critical role in actually prompting the user to get involved with the solution.
Simplicity of Intervention Operation	If the intervention is complex in design when in operation, this would affect the user's capacity to use the solution as it is presented.
User Privacy	If the intervention does not offer the user strict confidentiality and data privacy, it is unlikely she would offer true information needed to reach the best outcomes, let alone even use the solution.

Adherence to Intervention Regulations	If the intervention does not comply to mobile health regulations, the solution would not be successful.

Therefore, based on the content supplied in Table 5 and previously gathered information; a list of solution criteria was created and determined to be as follows:

- The final solution must be affordable to acquire and use.
- The design must be able to be used by all types of users, regardless of demographic.
- The design must be compatible with numerous operating systems.
- The final product must be simple and safe to use, independent of confidence in phone use.
- The design must be aesthetically pleasing.
- The design must keep gathered data confidential.
- The eventual solution must adhere to all health standards and regulations.

The above criteria gave an expansive understanding of what was required of the intervention and became the building blocks on which the prototype was designed.

4.2.6 Design Mode: Prototype

The 'Prototype' mode finds its importance in the notion of giving ideas a physical form, in order for the 'Test' mode to be effectively performed, though this last mode goes beyond the scope of this research. The systematic review and literature review provided a number of existing solutions as well additional useful information, which were all used to generate the final prototype.

At this point in the Biodesign innovation process, several concepts would have been generated and compared using a selection matrix, depending on how closely they adhered to the specified solution criteria (Zenios et al., 2010). Owing to both expected and unexpected delays, only one final solution was designed based on assessments gathered from reviewing other solutions, as well as considering the desired functionality and ability expected from the intervention. These processes are described in the following sections.

4.2.6.1 User Experience

Based on learnings from the systematic review, the user experience – or user journey – was carefully catered for, in order to provide the best suitable service and comfort when using the proposed

intervention. Through this, critical potential user input assisted in making major decisions regarding the intervention's aesthetics and capabilities.

In order to cater for the individual user's specific needs, particular and personal information from the user would be required. The initial reasons for use of the intervention and the user's stage of pregnancy are both essential considerations, as they both inform the requirements for ensuring a satisfied and healthy user. During the user's initial profile completion with the intervention, the user would be asked important questions pertaining to her physical traits, particulars of her pregnancy, her general health, and her overall weight, exercise and glucose expectancies, in order to cater properly to the user's desires and achieve the best possible health outcomes.

Figure 15 below tracks the user's journey from learning of her pregnancy through potential scenarios where knowledge of the existence of GDM or methods on how to manage the disease are not immediately available. It was concluded an unfavourable journey for both mother and baby, and could have lasting consequences beyond birth that would contribute additional strain to the healthcare system.

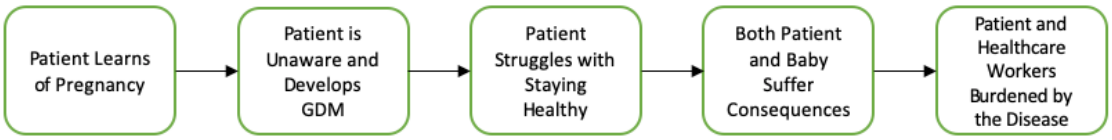


Figure 15: User Journey Without Intervention

In contrast, Figure 16 represents the user's journey where only one thing is immediately changed - the patient is made aware of the intervention – and it is predicted to have a significant impact. It was theorised that supplying pregnant women with awareness and access to information would vastly improve the statistics surrounding the prevalence of GDM. From the potential user journey alone, the implication of a lack of timely intervention is immediately apparent.

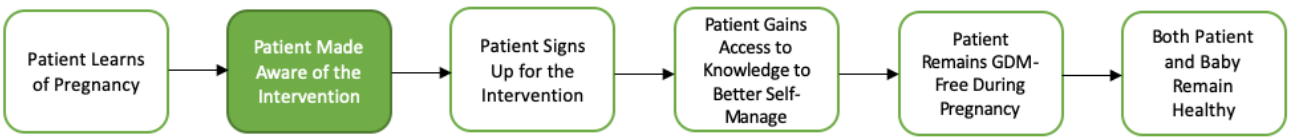


Figure 16: User Journey With Intervention

4.2.6.2 User Interface

When faced with the decision on which platform would be the most suitable for the prototype, it was important to note that USSD has certain limitations that a smartphone application does not. This is based on knowledge gathered from the literature, and these restrictions had to be strongly considered before moving forward with the platform.

Furthermore, the prototype required the use of an interface that would have the capability to provide the features needed to present a feasible, appropriate and relevant product. These features are listed below:

- Tracking of the user's waist circumference through the various stages of pregnancy.
- Following fluctuations in weight and BMI.
- Uploading of pictures documenting progress of pregnancy.
- Keeping of a food, glucose and exercise diary.
- Receiving timely reminders to keep active and stay hydrated.
- Participating in a comprehensive user forum.
- Creating a personal profile tailored for each individual.
- Providing access to published information on health and nutrition.

With all these potential features in mind, it became apparent that the only way forward was to make use of a platform that would be able to support the required features. The concept was, therefore, designed with the capabilities of a smartphone application in consideration. By identifying, deciding on and mapping out the most important functions expected of the intervention, a concept prototype was thoroughly developed and is further described in Section 4.3 Final Prototype.

4.2.6.3 Designing the Prototype

As part of the scope of this project, a prototype of the proposed mHealth platform was developed using the information gathered from both the literature review and systematic review. This required that a design layout be chosen and customised to meet the user's needs, with added features that reflected the required services noted in Section 4.2.2 User Interface. The prototype was designed to be aesthetically pleasing and simple to use.

To create the prototype, an online web service was used to showcase the potential user interface, as well as the platform's proposed capabilities. Some of the online services looked into for this purpose

included InVisionApp and Panacea Mobile, which provide both application development abilities and USSD gateway representation, respectively. Other online services considered included Appery.io and Proto.io, which both provided a lower-level structure. Ultimately, Proto.io was chosen to satisfy the scope of this particular project, and a subscription was purchased for the duration of the project.

Proto.io proved a worthy choice as it was quickly and easily mastered by the researcher. It offered templates specific to operating systems and supplied stock pictures to create better visual appeal to the proposed prototype, which is further explained in the following section.

4.3 Final Prototype

Taking into consideration previous learnings including the concept generation phase, the prototype was successfully built and compiled on Proto.io. It consisted of ten individual screens, which provided a surface idea of the general aesthetics and proposed features. The flow of the application was designed with simplicity in mind, to ensure even those users who weren't necessarily confident in being able to use their phone would not struggle. Figure 17 found below provides a bird's eye view of the navigational flow of the prototype.

Figure 17: Navigational Flow of Prototype

The following sections expand on each of the screens in more detail, explaining the design choices and available features, so as to meet the guidelines mentioned in Section 4.2.6.2 User Interface.

4.3.1 Welcome Screen

The screen capture found in Figure 18 below represents the initial display when the mobile application, Jelly Bean, is first opened from the thumbnail on the user's device.

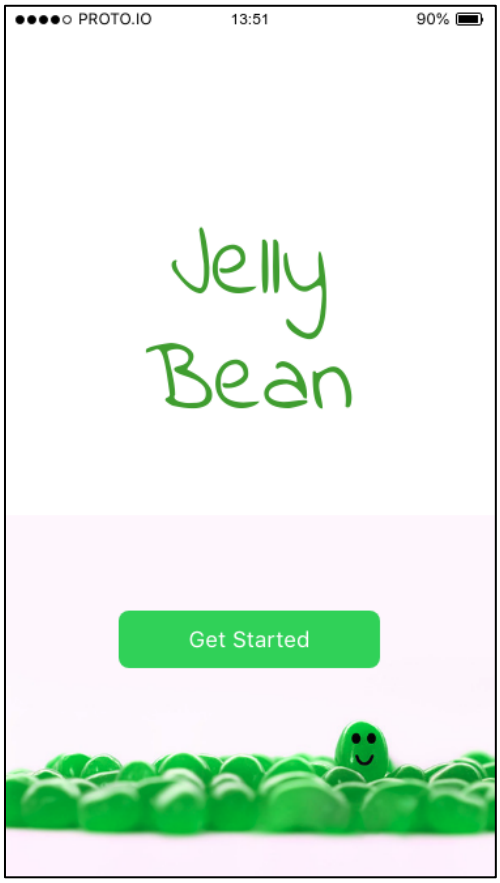


Figure 18: Welcome Screen

The display is meant to comfort and welcome the user, and bring a smile to her face. The name of the prototype was picked in relation to the crude idea that, during the early stages of a pregnancy, the foetus resembles a bean in size and shape. The colour green is considered an integral part of nature, and is known to symbolise good health and new beginnings, and so was chosen as the principal colour scheme for the application (Corey, 2018). The jelly bean image was sourced from an online image database (kelxkel, 2015).

4.3.2 Sign-Up/Sign-In Screens

The sign-up and sign-in functions are displayed on the screens in Figure 19 and Figure 20 located below. They represent the mandatory set-up stage when initially beginning to use the application, as a registered account is required in order to access the other features of the application.

Ideally, these screens will be utilised only once by the user on a single device. The application would remain 'logged in' to the user's account on the individual device, unless otherwise specified. In that

regard, beyond the initial account registration, the application would then open to the Home Screen found in Section 4.3.3 instead of the screen found in Section 4.3.1.

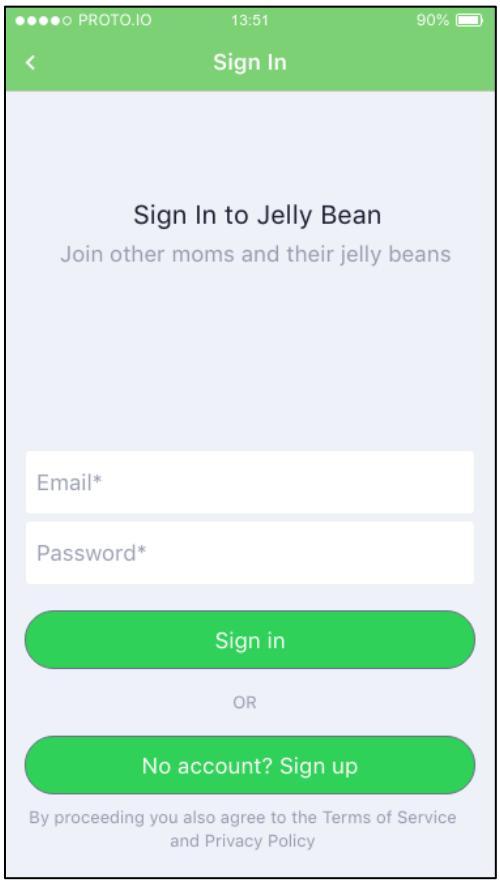


Figure 19: Sign-In Screen

Figure 19 offers the options to sign into an already existing account, or sign up as a new user. For the former option, the application navigates to the Home Screen found in Section 4.3.3, while the latter directs the user to the Sign-Up screen found in Figure 20 (Left) below. This screen asks the registering user for her first and last name, email address, chosen password and birthday as part of the basic information required to set up an account. The ability to personalise any profile is granted once the account has been confirmed and access to the application has been granted.

Figure 20 (Right) shows the screen once the sign-up for the Jelly Bean service has been deemed successful, and so finally allows the user to make use of the application as it is intended.

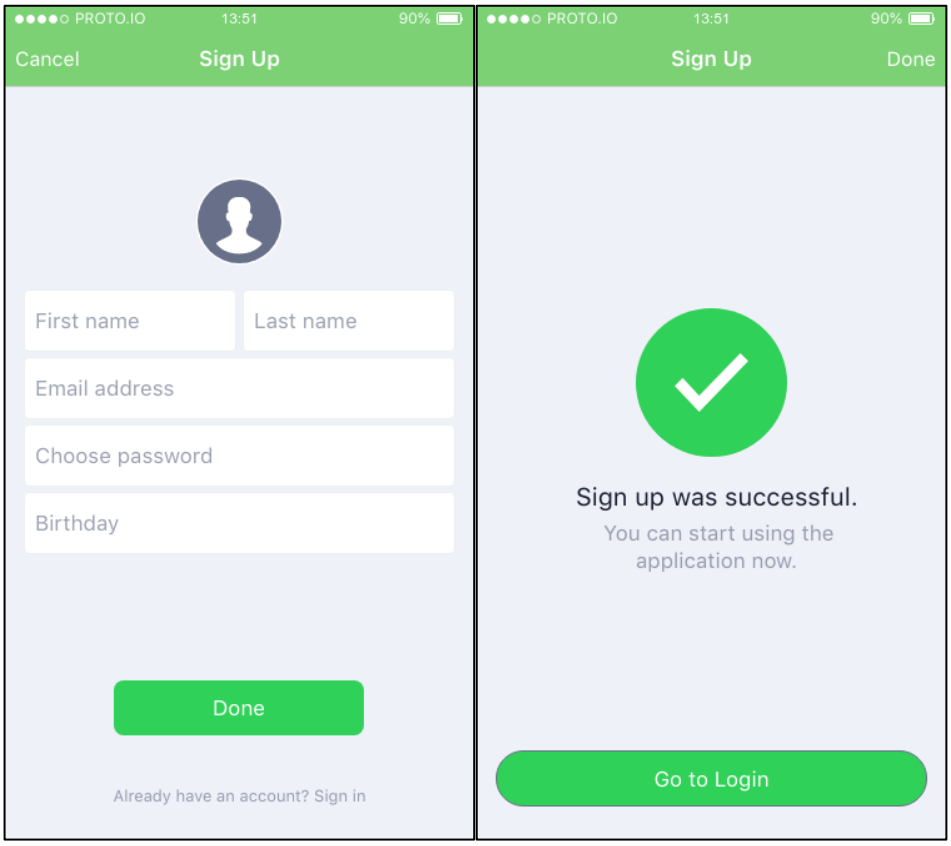


Figure 20: Sign-Up Screens

4.3.3 Home Screen

Beyond the initial registration for the application, the Home Screen found in Figure 21 below will be the first screen shown when the application is opened. The display centres around the user's personal profile, which includes a profile picture, header and any additional biographical information of her choice. This feature contributes to the platform's ability to customise to the individual user.

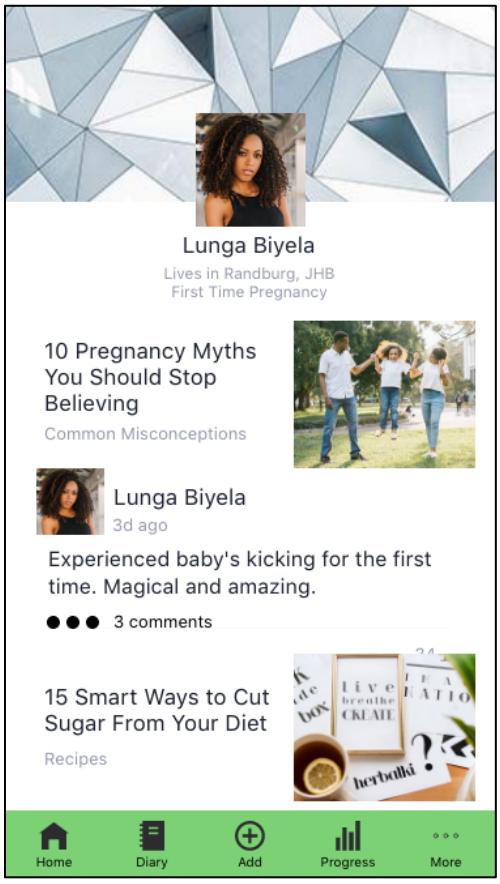


Figure 21: Home Screen

This screen aids in meeting the feature of being able to personalise the user's dashboard specific to the individual. Considerably the most important screen, it also allows easy navigation to the various application features on offer, marked with the toolbar found at the bottom of the screen. The Home Screen also acts as the news feed, supplying the user with published articles on nutrition, pregnancy and other health practices, as well as a platform to publish her own updates and interact with other users.

4.3.4 Diary Screen

The Diary Screen found in Figure 22 below shows the screen where food consumption, exercise performed and glucose readings are manually entered, stored, and simply displayed, which is one of the identified features. From this inputted information, the application is able to provide a visual representation of progress throughout the day and helps keep track of calories consumed, minutes of active exercise and inputted glucose readings throughout each day of the pregnancy.

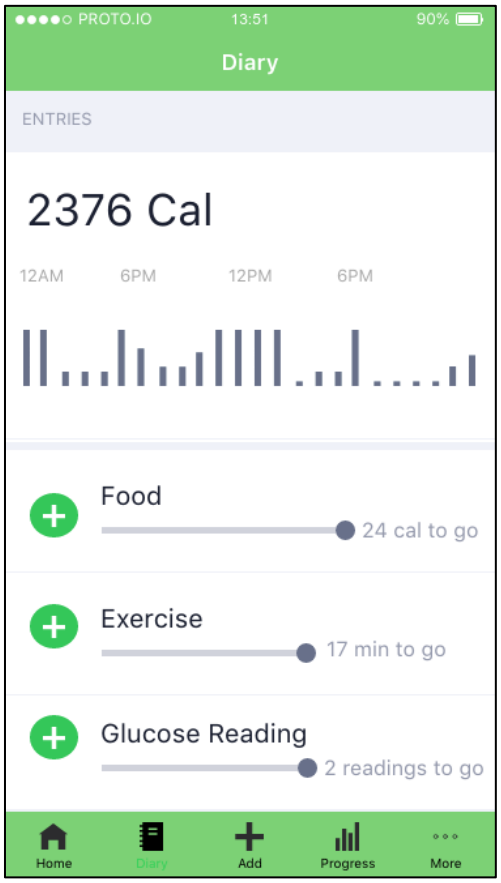


Figure 22: Diary Screen

This visual representation of the user's daily intake and activity offers constant access to her progress in meeting her everyday goals. The simple illustration also gives a clear picture of what has been achieved and what is expected, which can better promote self-discipline required for self-management.

4.3.5 Add Screens

The input functions of the application include various forms of diary entries (food consumed, active exercise and glucose readings), setting up reminders and posting updates to the user's profile. The gateway to be able to perform any one of these actions is shown in the screen capture found in Figure 23 below. It is navigated to from the Home Screen found in Section 4.3.3, and contains further navigation capabilities of its own.

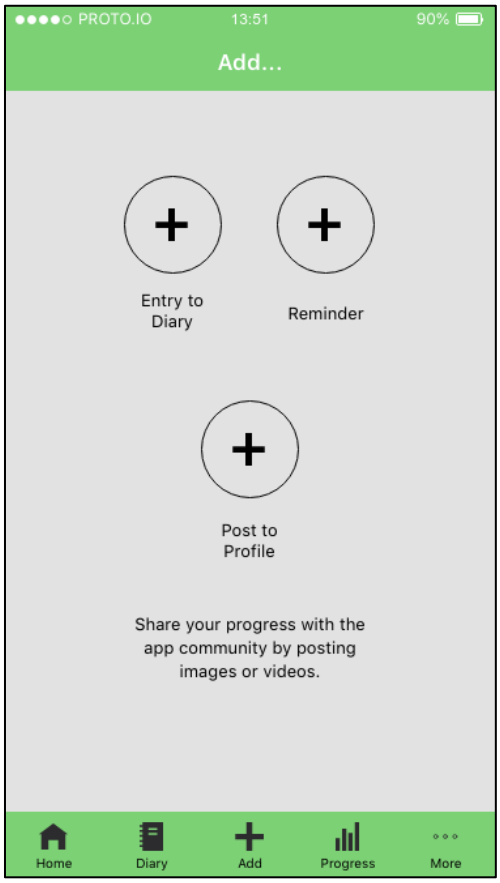


Figure 23: Add Screen

The action of posting to the user's profile meets the feature of being able to upload pictures and statuses documenting the user's pregnancy progress, which would then be displayed on the Home Screen found in Section 4.3.3.

While Figure 23 acts as a bridge from the Home Screen to the input actions, the screen capture shown in Figure 24 below goes on to display the icons for manually setting reminders for the user to eat, drink water, get some exercise, take a glucose reading or even just update the entry log for the day's diary – which is actually a second way to accomplish the action.

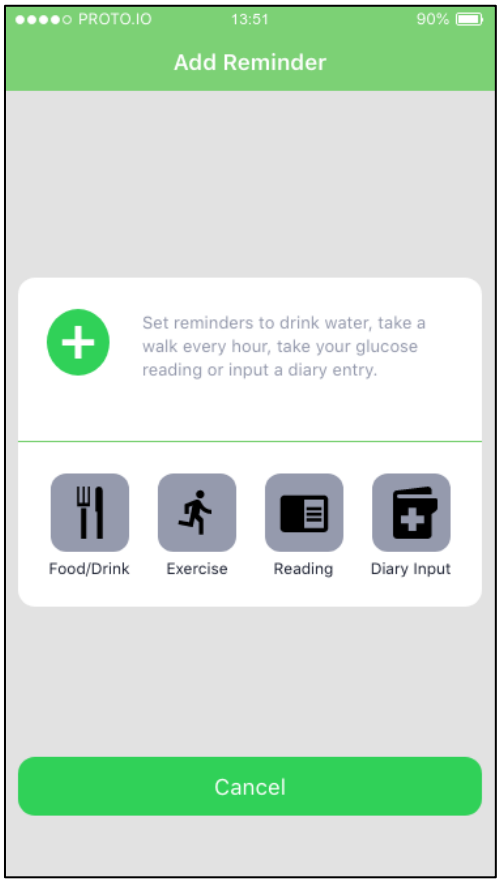


Figure 24: Add Reminder Screen

The ability to add and maintain reminders is a feature that is especially essential, because one of the more common reasons for not taking medication in a timely manner or taking a regular glucose reading is that the user usually forgets. Having the ability to set a reminder negates the excuse and provides the user with the capability to create an entry timetable tailored specific to her schedule, and was identified as a critical feature expected of the final solution.

4.3.6 Progress Screen

In contrast to the user's hourly and daily progress displayed on the Diary Screen found in Figure 22, Figure 25 found below shows a weekly – and monthly – representation of the user's progress. It tracks and displays the user's BMI, weight, waist circumference measurement, blood glucose and stage of pregnancy at that current moment in time.

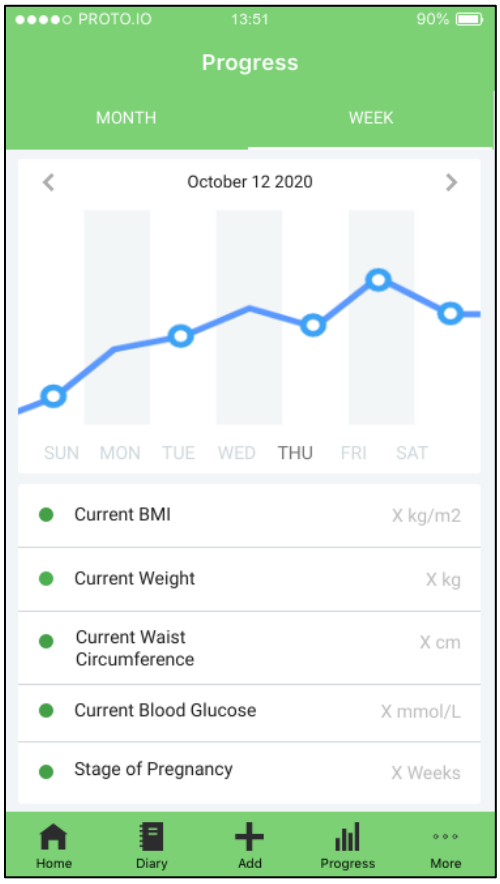


Figure 25: Progress Screen

This screen, essentially, provides a zoomed-out, clear and concise picture of the transformation the user's body goes through during her pregnancy. It also allows the user to follow any fluctuations in weight and BMI, which is one of the identified features, along with being able to track the user's waist circumference measurement through the stages of pregnancy.

4.3.7 More Screen

In order for the application to provide extra features beyond the ones already identified as key, an additional tab in the bottom toolbar was needed, which led to the More Screen shown in Figure 26 below. It gives the user the opportunity to personalise her profile more extensively and maintain her nutrition, weight and glucose goals.

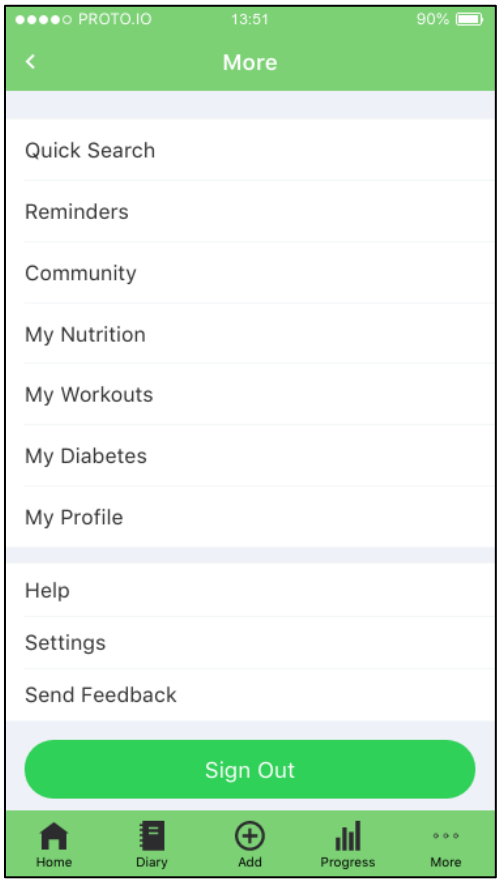


Figure 26: More Screen

This screen allows the application to provide access to published information on health and nutrition, and encourages the user to participate in a community of other expectant mothers. These are both features identified in the User Interface, and are important to the successful implementation of the solution.

4.4 Beyond the Prototype

Further development and testing of the final intervention is beyond the scope of this research. Past this project, any gathered information and the final deliverable of the low-level prototype would be used to commence with technical and physical development. This would include testing of the intervention through external or separate means, which would round off the last mode of the Stanford d.school bootcamp bootleg design methodology: Test as well as fit into the 'Implement' phase of Biodesign's innovation process.

4.5 Conclusion

This section of the document included the steps that were taken to transform the key points found in Study One: Systematic Review and the literature review into a comprehensive conceptual prototype of the mHealth intervention. From this section's deliverables, a selection of women were surveyed about their impression of the prototype, and the results are found in the following study.

5. Study Three: Post-Prototype Survey

5.1 Introduction

This study describes the process behind developing and conducting a survey on the developed prototype, and was completed by women working or studying in the Division of Biomedical Engineering at the University of Cape Town.

It explores the methods behind preparing questions for the survey, running a mock survey within the Digital Health research group, distributing to specified participants, conducting follow-ups, and collating and analysing any results. The results of the survey inform on the recommendations to improve the investigation and the solution.

5.2 Methodology

This research was considered to be mainly quantitative. The survey focused on the aesthetic and usability of the proof-of-concept. A small sample size was considered appropriate, as this was a conceptual design. The survey was intended towards women above the age of eighteen, regardless of their pregnancy or diabetic status. The answers were collected and tabulated using an online survey tool, and proved to be useful for a potential further development, which did not fall within the scope of this project. This section describes the steps taken to develop, conduct and roll out the survey.

5.2.1 Sampling

A survey was conducted among a chosen target group: 63 women in the Division of Biomedical Engineering in the Faculty of Health Sciences at the University of Cape Town. The interview questionnaire was designed to determine the levels of knowledge of GDM before, during and after pregnancy, as well as establish the general impression of the produced low-level prototype.

The participants for the survey were screened for eligibility based on inclusion and exclusion criteria, that included and was not limited to their ages and willingness to discuss what could be considered a sensitive topic, regardless of assured anonymity.

5.2.2 Data Collection

The survey questionnaire was electronically disseminated to the 63 participants via the online service of SurveyMonkey, using email addresses located on the web pages of the Division of Biomedical Engineering. Owing to its simplicity and compatibility, this online platform allowed for ease of distribution, completion and subsequent collection and representation of the responses to the survey.

5.2.2.1 Preparing Questions

The questions used in the survey were required to be clear, succinct and concise and were, therefore, carefully phrased and arranged in a way so as to avoid unnecessary confusion (Kelley et al., 2003). Simple questions were also able to be answered easily, which made obtaining results more efficient. The survey included both open and closed-ended questions, which sought to learn and understand about any existing knowledge on GDM.

In order for the survey to be engaging and not to become tiresome, it did not consist of too many questions (Kelley et al., 2003). If the survey was made too long, the response rate would greatly diminish. It was also verbose, but still maintained the required amount of respect and professionalism. The survey made use of a range of types of questions, which included: long opinion-based questions, single and multiple Likert scale questions, checking boxes type questions and single-answer questions. An example of a five-point Likert scale type question is indicated in Figure 27 below, which is largely a psychometric scale (Richards, 2005).

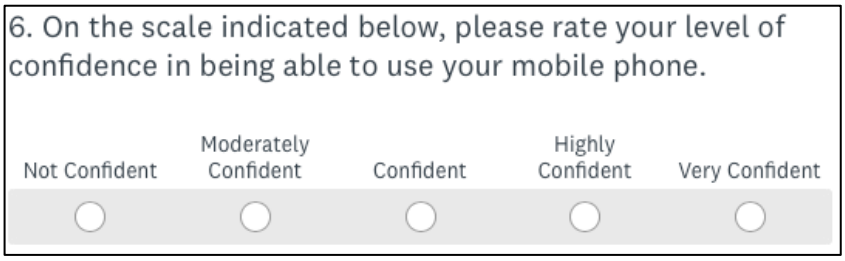


Figure 27: Example of a Linkert Scale in Use

Owing to the nature of the research, there was no predicted result of any one question. Questions, though, could be asked in both an open and closed way (Kelley, et al., 2003). Open questions allowed for the respondent to respond in her own words, while closed questions limited the respondent to certain options for response. All questions were considered optional, with none of them marked with

an asterisk to indicate that they are compulsory. This collected data formed the basis for the analysis on the investigation.

5.2.2.3 Survey Layout

The final survey consisted of three main sections of questions, namely: Preliminary Information, Pregnancy and Diabetes, and Prototype Questions.

The survey began by providing background information behind the proposed investigation and explained why the survey was being conducted. It also confirmed that the survey would remain confidential and anonymous throughout the entirety of the investigation, as this was important information to convey to respondents, in order to achieve honest responses.

The first section of the survey dealt with questions specifically about the respondent, typically questions about her age, access to and ability to use technology, and whether or not she had ever been pregnant.

The second section involved questions primarily focused on the participant's experiences with pregnancy, particularly in terms of her knowledge regarding GDM. This section also aided in identifying what other methods of getting information were utilised during pregnancy. This section was skipped by those respondents who had not yet experienced pregnancy.

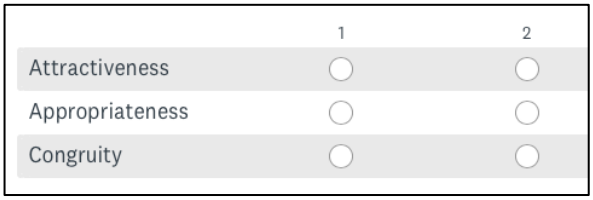
The third section asked questions in regards to the presented proof-of-concept prototype, particularly about the aesthetics, general layout and features. It also ascertained whether the use of mHealth would be considered in any future pregnancies or worthy of recommendation.

Majority of the data collected by the survey will be able to be used in further research beyond the scope of this project.

5.2.2.4 Running the Mock Survey

Prior to finalising the survey, a mock trial was run within the Digital Health research group in the Division of Biomedical Engineering, to gather insight from colleagues not limited by gender. The mock survey can be found attached as Appendix D – Mock Survey. From the responses received, the final survey was adjusted accordingly and deemed ready to be completed for mass completion. They offered questions, comments and suggestions, as well as the subsequent alterations made to the survey are explained in Table 6 found below.

Table 6: Comments from the Mock Survey

Comment	Alteration
'One thing while I was busy completing the survey, I almost missed the second set of questions in white (now marked with yellow), I instinctively wanted to start completing the next grey question.'  *Figure 28: Comment on Mock Survey*	This comment prompted the addition of a third option for the Likert scale question, which was successful in drawing attention to the second option that all responders would fill in the complete question.  *Figure 29: Successful Alteration to Survey*
'I am just thinking that maybe the text can be one shade darker to make reading easier?'	This comment prompted an important change in the text by initiating a darker shading, thereby making it easier to read.

5.2.2.5 Running the Final Survey

Careful consideration went into the wording of the cover letter that was sent to potential respondents, and presented as part of the invitation to participate. It gave sufficient background information on the researcher, the investigation being conducted, and the reasons behind the chosen investigation. This letter also represented the participant's consent, and explained that any responses to the survey would remain confidential and anonymous if they chose to participate in the research.

The final email sent to all potential participants can be found attached as Appendix E – Email Invitation. A complete and final survey of questions can be found attached as Appendix F – Final Survey.

The survey was disseminated on 12th October 2020, and was sent via web link to 63 email addresses of students and staff members as potential participants identified through various pages found on the Division of Biomedical Engineering website. The survey ran for five weeks, ending on 16th November 2020, with a total of 33 responses, all of which were used in the subsequent analysis of results found in Section 5.3 Survey Results and Response Analysis.

5.2.2.6 Analysis of Collected Data

Owing to the nature of the data, there was significant importance placed on the actual results of the questionnaires, as opposed to the number of acquired results. The survey, itself, had no predicted or predetermined result of any one question, and rather aimed to learn as much from the respondents as possible.

In order to collect the results of the survey and properly analyse them, a simple and suitable method would be required, namely an online-based survey website. This provided an easy and efficient way not only to track survey responses but also to count and evaluate them. The online tool allowed for the results of the survey questions to be carefully categorised, analysed, and eventually presented in the form of clear answer tables and various chart types, which are presented in Section 5.3 Survey Results and Response Analysis.

5.2.3 Ethical Considerations

Piloting a survey involves the collection of data from or about living people and, therefore, had to undergo a review of ethics from the Human Ethics Research Committee of the University of Cape Town. The survey remained entirely anonymous and completely confidential, and the responses were collected and analysed as impartially as could be maintained. All answers provided by respondents were accepted as they were, and no results were tampered with or altered in any way to fit any predictions of the survey. Ethical clearance for this research can be found under Appendix G – Ethical Clearance.

5.3 Survey Results and Response Analysis

This section shows the results of the survey, including critical analyses and brief discussions on the responses as they were submitted, and so reported in relation to the research question. An overview of demographic characteristics is reported, thereafter a descriptive analysis of the results is presented.

Of the survey, Section 1: Preliminary Questions was answered by all 33 respondents, while Section 2: Gestational Diabetes Mellitus was answered by 9 respondents. The last section, Prototype Questions, was completed by 22 of the total respondents. Figure 30 found below provides additional insight into a selection of response statistics.

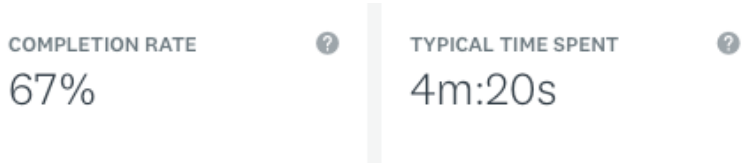


Figure 30: Insight into Response Rate

The typical time spent on the survey proved to be below the expected time during planning, and this was attributed to the number of respondents who ended up exempt from filling in the second section of the survey. The completion rate of 67%, with only 22 of the original 33 respondents finishing the survey until the end proved disappointing. For this response analysis, all of the answers were accepted and, therefore, included.

5.3.1 Participant Demographics

This section conveys details on the demographics established in the first section of the survey. These results informed on the expected target market of the prototype.

32 of the 33 surveyed women indicated their preferred language was English, which accounted for 96.97% of respondents. This was an overwhelming majority over the single response of Afrikaans, which remained a reminder to consider other languages in the design – particularly in South Africa where there are eleven official languages – when considering taking the application to market.

Figure 31 below indicates the responses to the question of age of the participants, which provided insight into the potential amount of years the participants have had access to more technologically-advanced methods of obtaining health information.

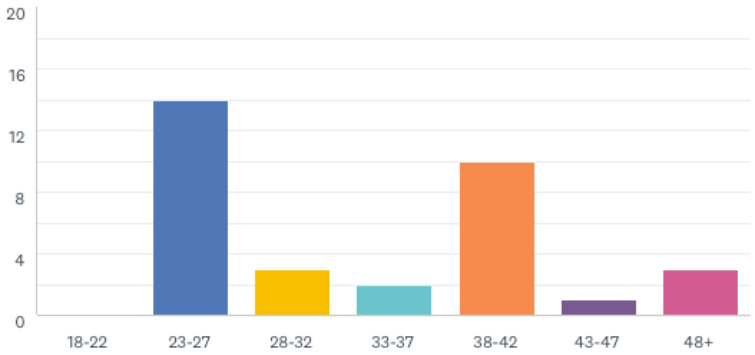


Figure 31: Age of Participants (in years)

The results revealed that the largest number of respondents (14) indicated they were between 23 and 27 in age, followed by 10 respondents between the ages of 38 and 42. These two age divisions accounted for more than 70% of all the respondents. This result was almost expected, given the knowledge of the relative ages of the sample group, which was made up exclusively of students and staff of the Division of Biomedical Engineering.

Next, the question was asked of how best the participants believed they learned new information, which was intended to identify how best information on pregnancy and GDM could be presented within the mobile health platform. The results are found in Figure 32 below.

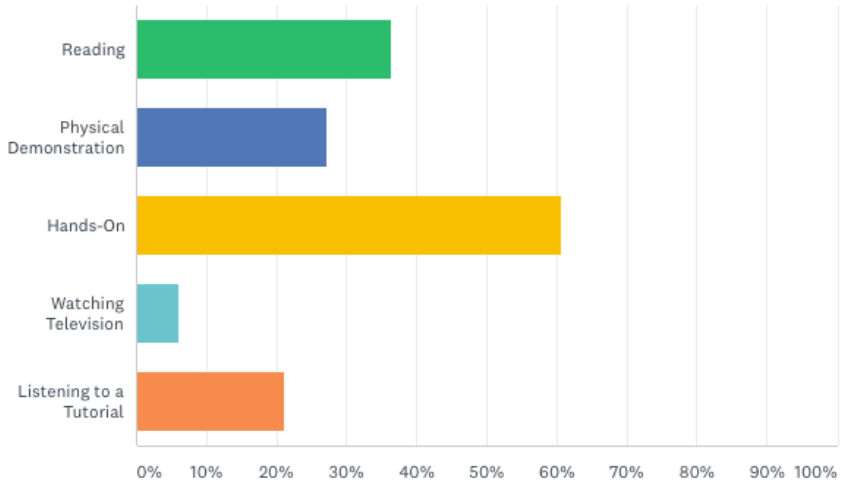


Figure 32: Preferred Learning Method

Despite the 33 participants who responded to the question of preferred learning method, a total of 50 options were checked. All the available possibilities were accounted for, with a majority (60.61%) choosing the option 'Hands-On.' The option is, however, admittedly difficult to implement using a mobile application, but the platform would provide an appropriate and efficient medium for the second highest option of 'Reading,' which approximated to 36.36% of the selected options. The option 'Other' was checked by seven respondents, with six commenting "Practice" and one stating "Infographics" as alternate methods through which they learn.

5.3.2 Mobile and Internet Usage

The results in this section report on the feasibility of implementing an mHealth application within this demographic. All the respondents specified they did have access to the Internet as well as to a smartphone, which went a long way towards supporting the decision to pursue a mobile application as the chosen platform, instead of the other potential options.

In addition to having access to connectivity, over half (51.52%) of the respondents indicated they considered themselves to be 'Very Confident' with the use of a mobile phone, with 10 respondents stating they considered themselves 'Highly Confident.' These numbers, found in Figure 33 below, promoted the conclusion that using a mobile health platform is a feasible and appropriate method to provide health information.

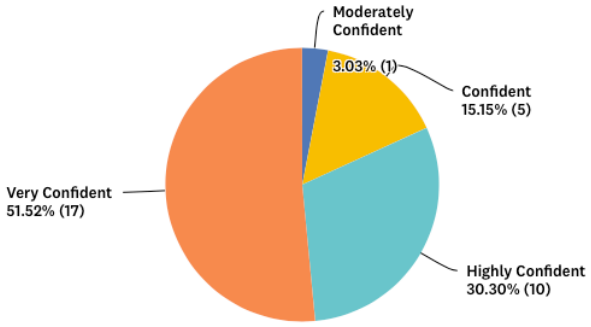


Figure 33: Confidence in Use of Mobile Phone

5.3.3 Pregnancy and GDM

As the project was aimed at pregnant women and identifying their general knowledge surrounding GDM, it was especially important to establish the respondents' history of pregnancy. From the ages previously specified by the participants, the lower number of positive pregnancies among the sample (9 of 33) was expected, based on natural likelihood of having experienced pregnancy increasing with age.

This question of pregnancy also acted as the qualifier for whether the respondent continued on with the second section of the survey, or if they moved straight to the third section to answer questions on the prototype. The nine women proceeding through the second section were asked to refer to their first pregnancy when responding to the upcoming questions, if they had experienced multiple pregnancies.

Prior to taking the survey, all of the women indicated they were aware of the existence and the possibility of developing GDM. Given the fields in which the respondents were known to work and study, the blanket affirmation was expected and worked in the researcher's favour, as it allowed for more information to be gained on **how** and **when** the women learned of the disease. Figure 34 below provides a simple and visual representation of the spread of responses from the participants among the given options.

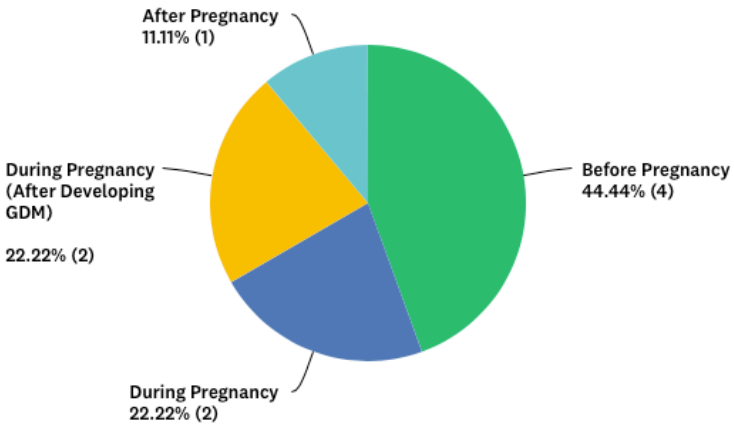


Figure 34: Stage of GDM Awareness

The results show that 4 of the 9 responders were aware of GDM prior to falling pregnant for the first time. It was, however, the number of respondents (2) that learned about GDM only after developing the disease that advocated for improved pregnancy management. Despite the small sample size answering questions in the second part of the survey, this number of women developing GDM at all should have been zero, which can be accomplished through awareness of and education on the potential complications of pregnancy.

The pie chart in Figure 35 below offers a rather telling impression of the methods by which the women learned of GDM. Majority of the participants (55.56%) learned of GDM through a nurse or a doctor, with a third of participants stating they learned about the disease through 'Word of Mouth,' which implied non-medical professionals.

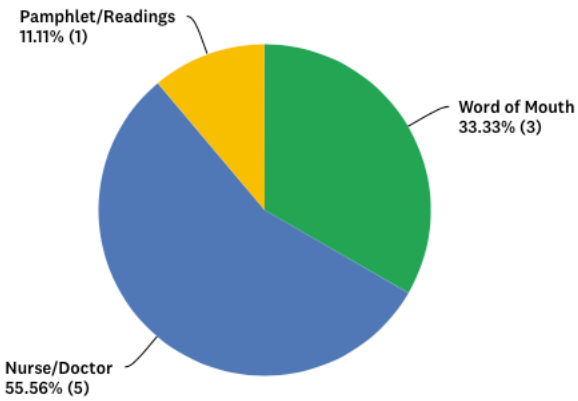


Figure 35: Method of GDM Awareness

None of the respondents chose 'Mobile Health' as an option, which was relevant in ascertaining the other ways in which the women received medical information. This statistic was considered to be the by-product of the relatively recent implementation of mobile-based platforms in healthcare, particularly in developing countries. It also strengthened the idea that there is a place for mobile health to do good work in providing access to disease information, and so reducing the risk of women not receiving crucial health information about their pregnancies in a timely manner.

An overwhelming majority (88.89%) of the participants responded that they did believe mobile health could play a critical role in preventing pregnant women from developing GDM. It was especially meaningful to note that none of the responses were in the negative, with only one of the participants remaining on the fence. Additionally, nearly all (8 of 9) of the participants responded that they did not use any form of technological healthcare during their first pregnancies, which was attributed to the known ages of the participants. It was previously acknowledged that ten of the initial responders were within the 38-42 age bracket and the prevalence of mHealth would have been limited at the time of a first pregnancy.

These results presented a compelling case for the use of mobile health in this particular lane, as the opinion of women who have experienced pregnancy carries significant weight.

5.3.4 Commentary on Prototype

This section details the respondents' thoughts and opinions on the prototype, and was not dependent on their history of pregnancy. There were only 22 respondents who answered questions in the third section of the survey, which reduced the sample size in the remainder of the questions.

The participants were asked to rate the colour palette and the layout (blueprint and visual framework) of the prototype on a scale of 1 to 5. From the results shown in Figure 36 below, the colour palette was largely considered acceptable, with popular ratings for each of the colour descriptor options: Attractiveness, Appropriateness and Congruity, with weighted averages calculated as 3.95, 4.18 and 3.91 out of 5, respectively.

	1	2	3	4	5	TOTAL	WEIGHTED AVERAGE
Attractiveness	0.00% 0	4.55% 1	22.73% 5	45.45% 10	27.27% 6	22	3.95
Appropriateness	0.00% 0	0.00% 0	9.09% 2	63.64% 14	27.27% 6	22	4.18
Congruity	0.00% 0	4.55% 1	22.73% 5	50.00% 11	22.73% 5	22	3.91

Figure 36: Prototype Colours

Most of the sample strongly agreed to the prototype layout with 45.45% fully supporting the Position and Spacing, 40.91% wholly approving Readability and 45.45% indicating that there was sufficient Clarity of Navigation. These results are depicted in Figure 37 below, and it was concluded that the layout of the prototype proved to be suitable for its designed purpose, though there remains room for alterations and adjustments.

	1	2	3	4	5	TOTAL	WEIGHTED AVERAGE
Position and Spacing	0.00% 0	4.55% 1	4.55% 1	45.45% 10	45.45% 10	22	4.32
Readability	0.00% 0	0.00% 0	4.55% 1	54.55% 12	40.91% 9	22	4.36
Clarity of Navigation	0.00% 0	0.00% 0	18.18% 4	36.36% 8	45.45% 10	22	4.27

Figure 37: Prototype Layout

The question of which feature or function the participants thought was the most important in the intervention was designed to establish which application feature was deemed the most essential by potential users. The results are shown in a tabulated form in Figure 38 found below.

	NOT IMPORTANT	MODERATELY IMPORTANT	IMPORTANT	HIGHLY IMPORTANT	EXTREMELY IMPORTANT	TOTAL	WEIGHTED AVERAGE
Home Screen (featuring a graphical display of progress and health trends)	0.00% 0	9.09% 2	40.91% 9	36.36% 8	13.64% 3	22	3.55
Reminders/Alarms (ability to receive notifications on testing blood glucose and regularly meals)	0.00% 0	0.00% 0	31.82% 7	31.82% 7	36.36% 8	22	4.05
Data Capture (ability to input and track blood glucose levels, exercise and food consumption)	4.55% 1	4.55% 1	9.09% 2	22.73% 5	59.09% 13	22	4.27
Access to Appropriate Nutrition and Health Information	0.00% 0	18.18% 4	22.73% 5	22.73% 5	36.36% 8	22	3.77
Access to a Comprehensive User Forum	4.55% 1	36.36% 8	22.73% 5	22.73% 5	13.64% 3	22	3.05

Figure 38: Features of Prototype Table

The aforementioned design features of the prototype were made options owing to the application criteria recognised in the User Interface. The features were ranked in order of importance, with 'Data Capture (ability to input and track blood glucose levels, exercise and food consumption)' regarded as the most vital feature with a weighted average of 4.27. The feature of 'Reminders/Alarms (ability to receive notifications on testing blood glucose and regular meals)' came in second, with a slim majority believing it was an 'Extremely Important' feature. 'Access to a Comprehensive User Forum' was rated the least important overall with a weighted average of 3.05. A broad visual representation of the order of importance of each of the features can be found in Figure 39 below, allowing for simple evaluation and ranking of the responses.

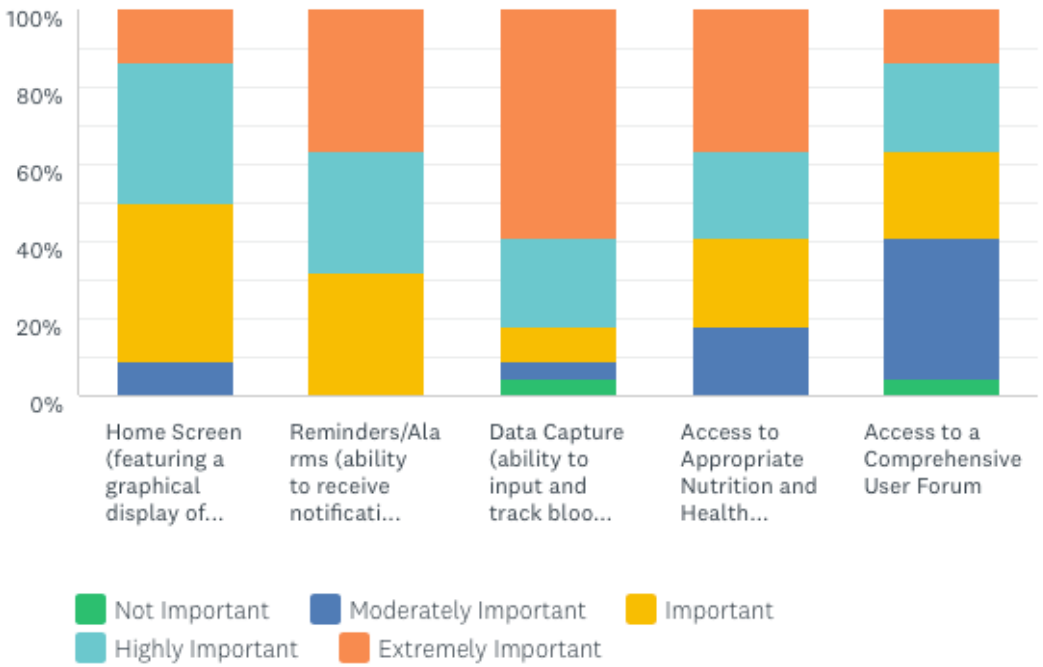


Figure 39: Features of Prototype Graph

The participants were able to submit additional comments on the aesthetic and layout of the prototype, which offered insight into the user's thoughts on both the colour selections and overall arrangement of the prototype, by allowing them the space and opportunity to give long, more detailed replies. The comments are found in Table 7 below.

Table 7: Comments on Prototype Aesthetic and Features

	Responses
1	"I really like the name, I think it is cute in relation to babies. It's just a bit ironic for diabetes. Green just doesn't say diabetes or babies for me. Blue may be common, but it says both "babies" and "diabetes" (since it is the awareness ribbon colour). I was unsure what the difference between congruity and appropriateness is for the colour palette question (so I just answered them as both appropriateness for the gestational diabetes. So you may ignore my answer for congruity.) Layout is 5-star."
2	"The colour palette makes it easy to read since the colour white is paired with neu[t]ral grey. Also, the green colour is not too light nor too bright. Easy on the eyes."
3	"I think a slightly softer more pastel green would be more welcoming, esp. on the first screen."

4	"I like the green, it is a soothing and natural colour. The whole feeling about the site is calm - I love the Jelly Bean :)"
5	"It would be great if the app can allow women (if they want) to interact and engage more on the app. Perhaps share their struggles and progress."
6	"None."
7	"Maybe a progress bar of how far along in their pregnancy they are or keeping track of their due date or something."
8	"Is there a place where the person can save photos of themselves? Can the information within the app be shared with anyone like a healthcare provider or a friend/partner?"

From the responses, it was clear there were mixed reviews regarding some of the shades of green used in the prototype and with the use of the name Jelly Bean, particularly in regard to its connection to GDM. One responder also mentioned she was unsure of the difference between appropriateness and congruity in this context, which proved on oversight by the researcher when designing the survey, as it was not properly explained in the question.

From these responses, it became increasingly clear that additional information was required to be sent along with the link to the preview of the prototype: perhaps a separate document that explained the features more clearly for the respondents. It would eliminate the fifth response, as there is an 'Add' feature explained in Section 4.3.5 Add Screens that does allow the user to post updates to her profile, as further pressed upon by said responder suggesting the user be able to "share their struggles and progress."

As the seventh responder alluded to, there is already a progress bar found on the Progress Screen, which is explained in Section 4.3.6, though the comment remains relevant as the progress bar could become a central feature of the application. As the eighth responder commented, a working prototype would have a user forum available, as well as a 'Data Capture' feature, also found on the More Screen explained in Section 4.3.7.

5.3.5 Commentary on mHealth Platform

A noteworthy majority (77.27%) of respondents indicated they would likely use some kind of mHealth technology in any future pregnancies, with the rest of the respondents opting for the option of 'Not Applicable.' This breakdown in responses correlated with what was learned of the spread of ages making up the sample size, as ten respondents specified they were within the age bracket of 38 and

42, and would likely not experience any further pregnancies. An important takeaway was that there were no negative responses, which worked in favour of mHealth becoming a fixture in future healthcare practices.

When asked whether mHealth in any form would be something to be endorsed among other pregnant women, 18 of the 22 participants stated they would recommend mHealth to other pregnant women, with the remaining four claiming they were unsure. This was attributed to there not being enough information provided about the prototype or even mHealth in general within the links to the survey and the prototype. It was also important to note that no responders indicated they would not endorse mHealth, which presented a positive statistic when considering the future of mHealth among this particular demographic.

In Table 8 below, the comments provided by the respondents as to the reasons why they weren't sure if they would recommend any kind of mHealth platform to other women are found.

Table 8: Comments on Use of mHealth Platform

	Responses
1	"I am not interested in pregnancy in any way and would not see it as my place to recommend anything. that is the job of their health professional."
2	"I think it depends if there are any complications or difficulties to their pregnancy which they might need to monitor -- else if things are moving straightforwardly it might not add a lot of information to their experience."

The first commenter expressed disinterest in anything related to pregnancy, and would likely not mention it to other women, while the second stated she would hesitate to recommend mHealth if a woman's pregnancy didn't appear to have any complications, as the application might not be needed, otherwise. The second respondent's comment was critical as it highlighted that women need access to the available information before there is a chance for any difficulties to arise, as prevention goes a long way to ensuring maternal and perinatal health.

5.4 Conclusions

This section collates what was learned in Section 5.3 Survey Results and Response Analysis, and summarises the boundaries of the survey delivery and critiques of the prototype. It was based on the above results that the following conclusions were drawn:

5.4.1 Limitation of Sample Size

Of the 63 survey links sent out to potential participants, 33 responses were received, with only 22 actually reaching the end of the survey. Ideally, the aim was to receive a more complimentary response and completion rate, but the results remain valid. This could be explained by the fact that the third section of the survey required the participant to open the prototype through a separate web link, and likely contributed to the respondent's reluctance to continue with the survey.

5.4.2 Limitation of Demographic of Sample

As mentioned briefly in Section 4.2.2 Design Mode: Empathise, the initial design plan was meant to include solely pregnant women identified within maternal wards and clinics. Ethics delays and COVID-19 related restrictions, however, necessitated that the target group remain technologically and ethically accessible within the allotted time. Levels of education and similar fields of study created limitations on the diversity of responses by targeting women solely in the Division of Biomedical Engineering.

5.4.3 Barriers Created by Language

The survey indicated that languages other than English were preferred, which highlighted a need to offer additional language options, in order to reach a greater market size.

5.4.4 Mixed Reviews on Colour Choices

The survey revealed conflicting comments on the colour choices, with some respondents in favour and others questioning the brightness of the green colour on specific screens. The prototype's success or failure is highly dependent on its visual appeal, and so these comments hold significant weight.

5.4.5 Appropriateness of Prototype Name

The decision to name the prototype Jelly Bean created some confusion, particularly in relation to the prototype's desire to aid in GDM self-management, as jelly beans are considered a prohibited food for people with glucose irregularities. In that regard, the name was viewed unfitting, but considered

appropriate in relation to pregnant women, where a jelly bean can be used to describe the size and shape of an unborn baby during the early stages of pregnancy.

5.4.6 Lack of Focus on Pregnancy Progress

Several respondents queried the prototype's ability to track the stages of the user's pregnancy through a progress bar and a pictorial timeline. As the target market group was established as pregnant women, this should be a central focus.

5.4.7 Misconception on Prototype's Target Market Group

Responses in the survey indicated that the prototype was thought not to be useful to pregnant women if they were not experiencing any difficulties during their pregnancies, which is not the case at all.

5.5 Recommendations

On the basis of the above drawn conclusions, the following recommendations were made:

5.5.1 Adjust the Sample Group

A greater number of responses could be received by increasing the target group to include women studying and working not only within the Division of Biomedical Engineering, but also within other divisions in the Department of Human Biology. To combat the low response rate, the prototype preview could have rather been embedded within the survey itself, thereby urging the respondents to click through it instead of having to open a separate link. A higher response rate would add value to the collected results.

5.5.2 Expand the Demographic of the Sample Size

If the survey were to be run again, the target group should include women from a more diverse background. By broadening the inclusion criteria of participants, the survey could provide better context and improve the range of results, as responses would be coming from women from different walks of life.

5.5.3 Ensure Option for Additional Languages

South Africa alone has an abundance of official languages, and it would work in the researcher's favour to accommodate as many national languages as possible, in order to appeal to an increased number of users if taking the prototype to market.

5.5.4 Consider Different/Lighter Shades of Green

Owing to the mixed feedback on the chosen colour palette of the prototype, lighter or more neutral shades of green should be considered as alternates. The visual presentation could prove critical in attracting pregnant women to use the application.

5.5.5 Explain the Decision Behind the Application Name

The decision behind naming the application Jelly Bean should be made immediately apparent to all prospective users of the prototype. It should be made clear the 'jelly bean' refers to the user's unborn baby, and presents a running theme of the prototype. By ensuring this information is immediately provided, it should limit confusion as well as attract users.

5.5.6 Make the User's Pregnancy Progress More Prominent

The prototype should put additional focus on the user's pregnancy timeline, through a more-dominant visual representation of her advancing through the stages of pregnancy. This should also include the ability to capture pictures - not only her increasing waist circumference - of the changes in her body as the weeks progress.

5.5.7 Clarify the Target Market Group for the Prototype

The prototype is meant for pregnant women, with or without GDM or any other complications related to pregnancy. The aim of the application is to provide access to healthcare information, and educate the users before there is a chance to develop a preventable pregnancy complication. This should be made abundantly clear when marketing the prototype, should it be taken further.

6. Conclusion

The aim of this research was to determine the effectiveness of an mHealth platform among pregnant women in relation to GDM in under-served communities. It was met through three objectives: conducting a systematic review, developing a low-fidelity prototype and receiving feedback on the prototype. These objectives were separated into three separate studies.

The first study obtained knowledge on the use and impact of mHealth among pregnant women with or at risk of GDM by conducting a systematic review. Within the chosen publication dates, an alarmingly small number of articles met the inclusion criteria, which emphasised the need for more rigorous mHealth intervention studies to be conducted in low-income settings. The evidence highlighted that diabetes statistics are higher and still rising in rural areas compared to that of urban areas, and so have an increased need for timely intervention that is easy to use and cost-effective. The studies found that mHealth is a viable solution.

The second study focused on developing a suitable mHealth platform targeted at pregnant women. In order to meet the design functions and features identified in the literature to produce a successful intervention, the solution was chosen to be prototyped as a mobile application. While this remained the preferred platform, an avenue to determine a way to include a text-based component into the intervention should remain open, in order to accommodate women without a smartphone or confident mobile-use skills.

The third study successfully conducted a survey on pregnancy, technology and the prototype, and it discovered that majority of the respondents believed having access to key medical and health information has and will have a positive effect on pregnancy health outcomes. While the results of the survey remained promising, a larger and more diverse sample population is required in any further surveys, to ensure a more impactful indication of the collective opinions of women.

The project achieved its aim and found that mHealth has a positive impact on knowledge, understanding and management of GDM among women in under-served communities. Further research is required, consisting of a larger and more diverse sample, within communities from LMICs, especially in Sub-Saharan Africa.

This concluded the scope of the investigation.

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8. Appendices

Appendix A – Systematic Review Protocol

Research Question	Does mHealth improve diabetes' knowledge, understanding and management among pregnant women compared to conventional healthcare methods currently being used with regards to gestational diabetes mellitus in under-served communities?
Objectives	1. Identify whether GDM knowledge, understanding and management was improved in the studies. 2. Monitor the clinical outcomes of pregnancy in the studies.
PICO	• **Population**: pregnant women with GDM (who live in low-to-middle-income countries and under-served communities). • **Intervention**: mHealth platform. • **Comparison**: conventional healthcare methods. • **Outcome**: to determine if mHealth improves patient knowledge and understanding of diabetes.
Setting	Any setting.
Study Designs	Any study design, excluding project protocols.
Primary Exclusion Criteria	• mHealth used in a non-healthcare capacity. • mHealth intervention is MMS, PDA, social media or VOIP – essentially not text-based or a mobile application.
Search Databases	• PubMed • Cochrane Library • Scopus • EBSCOhost (Academic Search Premier, Africa-Wide Information, MEDLINE and PsycInfo) • Web of Science • Google Scholar
Search Filters	• Language: English • Publication Date: 2015 – 2019 • Species: Human Beings (Women)

Secondary Exclusion Criteria	• Study not set in LMIC or under-served community. • mHealth not used specifically for healthcare. • Disease intervention not targeted at GDM. • Study conducted postpartum. • Full-text availability.
Additional Searching	Reference checking of included studies and manual searches of these.
Reviewers	• JL for study relevance. • JL and JFA for selection bias.
Data Collection	Reference Manager: EndNote.
Data Extraction	Key data extraction form in Word document.
Meta-analysis	Review Manager: RevMan Version 5.3.
Measured Outcomes	• Glycaemic Control • Pregnancy and Delivery • Behaviour and Knowledge • mHealth Functions and Features
Types of Analysis	Assessment of heterogeneity. Statistical analysis. Risk of bias assessment.
Outputs	Forest Plots Results and Discussion

Appendix B – Search Parameters and Strategy

Population: Pregnant women with GDM (who live in low-to-middle-income countries and communities).

#1	MeSH Terms	Pregnant Women OR Pregnancy OR Prenatal Care
#2	Free Language	Gravid OR Prenatal OR Pregnant OR Pregnancy OR Pregnancies OR Expectant Mothers
#3		#1 OR #2
#4	MeSH Terms	Diabetes Mellitus OR Insulin Resistance
#5	Free Language	Increased Sugar Levels OR Increased Glucose Levels OR Diabetes OR Gestational Diabetes
#6		#4 OR #5
Intervention**: mHealth platform.**		
#7	MeSH Terms	Telemedicine OR Cell Phone OR Computers, Handheld OR Mobile Applications
#8	Free Language	mHealth OR eHealth OR Mobile Health OR Telehealth OR SMS OR Smart Phone OR Texting OR Web-Based OR Online OR Computer OR USSD OR Wireless Technology OR Reminder System OR Cell Phones OR Self-Monitoring OR Handheld Computers OR Mobile Application OR Computer Tablet OR iPad OR Reminder System OR Medical Informatics OR Android OR Blog OR Cellular Phones OR Digital Health Interventions OR e-counselling OR eHealth OR e-health OR iPhone OR Internet-Based OR Messaging OR m-Health OR Mobile-Based OR Mobile Devices OR Mobile Phones OR Mobile Technology OR Portable Electronic Applications OR Telecommunication in Medicine OR Telecare OR Telephone-Based OR Web Site OR Website
#9		#7 OR #8
#10	MeSH Terms	Behavior Therapy OR Models, Theoretical OR Behavioral Medicine OR Health Behavior
#11	Free Language	Health Behavior OR Health Behaviour OR Knowledge OR Attitude OR Awareness OR Understanding OR Health Literacy OR Education OR Communication OR Instruction OR Training
#12		#10 OR #11
#13		#3 AND #6 AND #9 AND #12
#14		Deprived Countries OR Deprived Population OR Deprived Populations OR Developing Countries OR Developing Country OR Developing Economies OR Developing Economy OR Developing Nation OR Developing Nations OR Developing Population OR Developing Populations OR Developing World OR LAMI Countries OR LAMI Country OR Less Developed Countries OR Less Developed Country OR Less Developed Economies OR Less Developed Nation OR Less Developed Nations OR Less Developed World OR Lesser Developed Countries OR Lesser Developed Nations OR LMIC OR LMICS OR Low GDP OR Low GNP OR Low Gross Domestic OR Low Gross National OR Low Income Countries OR Low Income Country OR Low Income Economies OR Low Income Economy OR Low Income Nations OR Low Income Population OR Low Income Populations OR Lower GDP OR lower gross domestic OR Lower Income Countries OR Lower Income Country OR Lower Income Nations OR Lower Income Population OR Lower Income Populations OR Middle Income

		Countries OR Middle Income Country OR Middle Income Economies OR Middle Income Nation OR Middle Income Nations OR Middle Income Population OR Middle Income Populations OR Poor Countries OR Poor Country OR Poor Economies OR Poor Economy OR Poor Nation OR Poor Nations OR Poor Population OR Poor Populations OR poor world OR Poorer Countries OR Poorer Economies OR Poorer Economy OR Poorer Nations OR Poorer Population OR Poorer Populations OR Third World OR Transitional Countries OR Transitional Country OR Transitional Economies OR Transitional Economy OR Under Developed Countries OR Under Developed Country OR under developed nations OR Under Developed World OR Under Served Population OR Under Served Populations OR Underdeveloped Countries OR Underdeveloped Country OR Underdeveloped Economies OR Underdeveloped Nations OR Underdeveloped Population OR Underdeveloped World OR Underserved Countries OR Underserved Nations OR Underserved Population OR Underserved Populations
#15		Afghanistan OR Albania OR Algeria OR American Samoa OR Angola OR Armenia OR Azerbaijan OR Bangladesh OR Belarus OR Byelarus OR Belorussia OR Belize OR Benin OR Bhutan OR Bolivia OR Bosnia OR Botswana OR Brazil OR Bulgaria OR Burma OR Burkina Faso OR Burundi OR Cabo Verde OR Cape Verde OR Cambodia OR Cameroon OR Central African Republic OR Chad OR China OR Colombia OR Comoros OR Comores OR Comoro OR Congo OR Costa Rica OR Côte d'Ivoire OR Cuba OR Djibouti OR Dominica OR Dominican Republic OR Ecuador OR Egypt OR El Salvador OR Equatorial Guinea OR Eritrea OR Ethiopia OR Fiji OR Gabon OR Gambia OR Gaza OR Georgia OR Georgia Republic OR Ghana OR Grenada OR Grenadines OR Guatemala OR Guinea OR Guinea- Bissau OR Guyana OR Haiti OR Herzegovina OR Hercegovina OR Honduras OR India OR Indonesia OR Iran OR Iraq OR Jamaica OR Jordan OR Kazakhstan OR Kenya OR Kiribati OR Democratic People's Republic of Korea OR Kosovo OR Kyrgyz OR Kirghizia OR Kirghiz OR Kyrgyzstan OR Lao PDR OR Laos OR Lebanon OR Lesotho OR Liberia OR Libya OR Macedonia OR Madagascar OR Malawi OR Malay OR Malaya OR Malaysia OR Maldives OR Mali OR Marshall Islands OR Mauritania OR Mauritius OR Mexico OR Micronesia OR Moldova OR Mongolia OR Montenegro OR Morocco OR Mozambique OR Myanmar OR Namibia OR Nepal OR Nicaragua OR Niger OR Nigeria OR Pakistan OR Palau OR Panama OR Papua New Guinea OR Paraguay OR Peru OR Philippines OR Principe OR Romania OR Ruanda OR Rwanda OR Samoa OR Sao Tome OR Senegal OR Serbia OR Sierra Leone OR Solomon Islands OR Somalia OR South Africa OR South Sudan OR Sri Lanka OR St Lucia OR St Vincent OR Sudan OR Surinam OR Suriname OR Swaziland OR Syria OR Syrian Arab Republic OR Tajikistan OR Tadzhikistan OR Tajikistan OR Tadzhik OR Tanzania OR Thailand OR Timor OR Togo OR Tonga OR Tunisia OR Turkey OR Turkmen OR Turkmenistan OR Tuvalu OR Uganda OR Ukraine OR Uzbek OR Uzbekistan OR Vanuatu OR Venezuela OR Vietnam OR West Bank OR Yemen OR Zambia OR Zimbabwe
#16	#14 OR #15	
#17	#13 AND #16	
	Filters	Language: English
		Species: Human
		Publication Date: 2015 - 2019
#18		Final Search: **325**

Appendix C – Extracted Key Information

	Author	Year of Study	Country of Study Setting	Environment of Study/Type of Facility	Author Affiliation	Demographic Traits of Study Population/Type of Participants	Type of mHealth Intervention Employed	Type of Study	Type of Outcomes and How They Are Measured	Findings/Results	Conclusions
1	**Carolan-Olah, M**. ; Steele, C.; Krenzin, G.	2015	Melbourne, Australia	Hospital Diabetes Clinic	Nursing and Midwifery, College of Health and Biomedicine	21 women with GDM, from multi-ethnic backgrounds, over 18 and English-competent.	Web-based intervention.	Basic one-group pre-test/post-test design.	Explore the impact of the intervention in 3 domains: knowledge of GDM, food values, and GDM self-management principles. Questionnaire data was used and analysed using Statistical Package of the Social Sciences and Fisher's Exact Test.	The intervention was effective at improving knowledge scores in the first domain, but produced numbers lower than expected in the second and third. This may be linked to misunderstandings in interpretation of the service.	Initial results look promising and suggest the intervention could be further useful with improvements in certain areas - namely the type of language used.
2	**Eslami, E**; Mohammad, S; Charandabi, A; Khalili, A; Jafarabadi, M; Mirghafourvand, M	April 2016 - February 2017	Tehran, Iran	12 Health Centres in Tehran	Tabriz University of Medical Sciences	140 women at risk of GDM, over 18, 16 to 20 weeks' gestation and BMI > 25 kg/m^3.	Lifestyle training through information sessions and booklets, as well as educational text messages.	RCT	To identify the effect a lifestyle-based training program that includes info sessions and educational text messages has on blood glucose levels and weight gain during pregnancy. Masses of the participants were recorded, pre and post intervention, and the blood glucose levels measured using an oral glucose tolerance test.	There was no statistically significant difference identified in the mean weight gain between the control and intervention group after the intervention. It was also found lifestyle training programs were ineffective in reducing the prevalence of GDM and gestational weight gain.	Although the results did not favour the intervention group, they were not considered statistically significant, possibly owing to the size of the sample. Further studies are recommended with larger sample sizes.

3	**Guo, H**.; Zhang, Y.; Li, P.; Zhou, P.; Chen, L. M.; Li, S. Y.	December 2015 - December 2017	Tianjin, China	Metabolic Disease Hospital of Tianjin Medical University	Tianjin Medical University	124 singleton pregnant woman between 21 and 45, skilled at using a smartphone, and over 18.	Nurse's online guidance and a mobile medical application.	RCT	To explore the effects of an mHealth intervention on pregnancy weight management, blood glucose control and pregnancy outcomes. Patients were treated for 13 weeks, with the control group received standard care and the other group had access to the intervention, and were tested for compliance, frequency of outpatient service and weight gain.	The mHealth group showed higher levels of compliance, lower blood glucose measurements and less weight gain than the control group.	mHealth intervention management of GDM improves patient compliance, blood glucose control and reduces weight gain. These all minimise complications during pregnancy and birth, for both mother and child.
4	**Yang, P**.; Lo, W.; He, Z. L.; Xiao, X. M.	March 2016 - August 2016	Guangzhou, China	1st Affiliated Hospital of Jinan University in China	Department of Obstetrics and Gynaecology, 1st Affiliated Hospital of Jinan University	107 women with GDM (divided into two groups), and 50 women with normal glucose tolerance, with a gestational stage of 24-28 weeks. All over 18.	WeChat platform-based treatment, and access to health education articles.	RCT	Data regarding various blood glucose levels and maternal and foetal outcomes was analysed using t-test, variance analysis, chi-square test and multiple linear regression.	Blood glucose levels were significantly lower in the intervention group, with premature delivery less likely than in the control group. Numbers of women experiencing hypertension was also lower in the intervention group.	The intervention effectively reduced the levels of fasting blood glucose and 2-h postprandial blood glucose, but 1-h was not affected. It was accepted that the treatment may improve pregnancy outcomes.

Appendix D – Mock Survey

Section 1: Preliminary Questions

This section involves questions that provide the research team with a general idea of your demography.

1. What is your preferred language?

- ◯ English
- ◯ Afrikaans
- ◯ Xhosa

Other (please specify)

2. What is your age?

- ◯ 18-22
- ◯ 23-27
- ◯ 28-32
- ◯ 33-37
- ◯ 38-42
- ◯ 43-47
- ◯ 48+

3. How best do you believe you learn (Check all options that apply)?

- ☐ Reading
- ☐ Physical Demonstration
- ☐ Hands-On
- ☐ Watching Television
- ☐ Listening to a Tutorial

Other (please specify)

4. Do you have access to the Internet?

- ◯ Yes
- ◯ No
- ◯ Maybe

5. Do you have access to a smartphone?

- ◯ Yes
- ◯ No
- ◯ Maybe

6. On the scale indicated below, please rate your level of confidence in being able to use your mobile phone.

Not Confident	Moderately Confident	Confident	Highly Confident	Very Confident
◯	◯	◯	◯	◯

7. Have you ever been pregnant?

- ◯ Yes
- ◯ No
- ◯ Unsure

Section 2: Gestational Diabetes Mellitus

This section involves questions primarily focused on your experience with pregnancy, and knowledge regarding Gestational Diabetes Mellitus (GDM), which is a type of Diabetes developed during pregnancy.

For the upcoming questions, please answer based on your experiences during your first pregnancy, if you've had multiple.

8. Prior to this survey, were you aware of the existence of the disease known as GDM?

- ◯ Yes
- ◯ No
- ◯ Vaguely

9. Are you aware of the possibility of developing GDM during pregnancy?

- ◯ Yes
- ◯ No
- ◯ Maybe

10. If you answered 'Yes' to the previous question, at what stage were you made aware of this possibility?

- ◯ Before Pregnancy
- ◯ During Pregnancy
- ◯ During Pregnancy (After Developing GDM)
- ◯ After Pregnancy

11. How were you made aware of GDM? Please specify if you choose 'Other.'

- ◯ Word of Mouth
- ◯ Nurse/Doctor
- ◯ Pamphlet/Readings
- ◯ Television/Radio
- ◯ Mobile Health

Other (please specify)

12. Do you believe GDM and other pregnancy-related health complications can be prevented with convenient access to information?

- ◯ Yes
- ◯ No
- ◯ Maybe

13. During your pregnancy, did you make use of any technology (call centres, health applications) to aid in keeping track of your progress?

- ◯ Yes
- ◯ No
- ◯ Maybe

14. If you answered 'Yes' to the previous question, please provide examples, if you are able to.

Section 3: Prototype Questions

Before completing this section, please take a moment to open the link to the live version of the proof-of-concept prototype, as this section includes questions pertaining to it.

15. Using a scale of 1-5, how would you rate the colour palette of the prototype?

	1	2	3	4	5
Attractiveness	○	○	○	○	○
Appropriateness	○	○	○	○	○

16. Using a scale of 1-5, how would you rate the general layout of the prototype?

	1	2	3	4	5
Position and Spacing	○	○	○	○	○
Readability	○	○	○	○	○

17. Please offer any comments you might have on the colour palette and general layout.

18. Which feature do you think presents as the most important?

	Not Important	Moderately Important	Important	Highly Important	Extremely Important
Home Screen (featuring a graphical display of progress and health trends)	○	○	○	○	○
Reminders/Alarms (ability to receive notifications on testing blood glucose and regularly meals)	○	○	○	○	○
Data Capture (ability to input and track blood glucose levels, exercise and food consumption)	○	○	○	○	○
Access to Appropriate Nutrition and Health Information	○	○	○	○	○
Access to a Comprehensive User Forum	○	○	○	○	○

19. If you can think of any other features not displayed that you believe could be important, please specify.

20. Are you likely to make use of a mobile health platform should you have any future pregnancies?

- ○ Yes
- ○ No
- ○ Not Applicable

21. Would you recommend that pregnant women make use of a mobile health platform similar to this prototype?

- ○ Yes
- ○ No
- ○ Maybe

22. If you answered 'Maybe' or 'No' to the previous question, please provide any reasons why.

Appendix E – Email Invitation

Dear Ma'am,

My name is Shameela Arbi and I am currently a Masters' student in the Division of Biomedical Engineering at the University of Cape Town. As part of my thesis project, I am conducting a survey on knowledge among women regarding Gestational Diabetes Mellitus (a type of diabetes that affects women during pregnancy), and on the general impression and usability of a low-level prototype. It would greatly contribute to my research if you could please complete it.

This survey is aimed at women within the Division, and is intent on being as sensitive as possible. The survey should take between 4-7 minutes, and can be accessed via the link: https://www.surveymonkey.com/r/92H8V5Y.

The survey is completely anonymous and no names will be associated with any responses. Confidentiality is guaranteed, so please respond to each question honestly and accurately. Part of the survey includes questions pertaining to a designed low-level prototype, a preview of which can be accessed through the link: https://pr.to/IT4UEM/.

Thank you for your time. Your participation is deeply appreciated.

Kind regards,

Shameela Arbi

Appendix F – Final Survey

Section 1: Preliminary Questions

This section involves questions that provide the research team with a general idea of your demography.

1. What is your preferred language?

- English
- Afrikaans
- Xhosa

Other (please specify)

2. What is your age?

- 18-22
- 23-27
- 28-32
- 33-37
- 38-42
- 43-47
- 48+

3. How best do you believe you learn (Check all options that apply)?

- Reading
- Physical Demonstration
- Hands-On
- Watching Television
- Listening to a Tutorial

Other (please specify)

4. Do you have access to the Internet?

- Yes
- No
- Maybe

5. Do you have access to a smartphone?

- Yes
- No
- Maybe

6. On the scale indicated below, please rate your level of confidence in being able to use your mobile phone.

Not Confident	Moderately Confident	Confident	Highly Confident	Very Confident

7. Have you ever been pregnant?

- Yes
- No
- Unsure

Section 2: Gestational Diabetes Mellitus

This section involves questions primarily focused on your experience with pregnancy, and knowledge regarding Gestational Diabetes Mellitus (GDM), which is a type of Diabetes developed during pregnancy.

For the upcoming questions, please answer based on your experiences during your first pregnancy, if you've had multiple.

8. Prior to this survey, were you aware of the existence of the disease known as GDM?

- ◯ Yes
- ◯ No
- ◯ Vaguely

9. Are you aware of the possibility of developing GDM during pregnancy?

- ◯ Yes
- ◯ No
- ◯ Maybe

10. If you answered 'Yes' to the previous question, at what stage were you made aware of this possibility

- ◯ Before Pregnancy
- ◯ During Pregnancy
- ◯ During Pregnancy (After Developing GDM)
- ◯ After Pregnancy

11. How were you made aware of GDM? Please specify if you choose 'Other.'

- ◯ Word of Mouth
- ◯ Nurse/Doctor
- ◯ Pamphlet/Readings
- ◯ Television/Radio
- ◯ Mobile Health

Other (please specify)

12. Do you believe GDM and other pregnancy-related health complications can be prevented with convenient access to information?

- ◯ Yes
- ◯ No
- ◯ Maybe

13. During your pregnancy, did you make use of any technology (call centres, health applications) to aid in keeping track of your progress?

- ◯ Yes
- ◯ No
- ◯ Maybe

14. If you answered 'Yes' to the previous question, please provide examples, if you are able to.

Section 3: Prototype Questions

Before completing this section, please take a moment to open the link to the live version of the proof-of-concept prototype, as this section includes questions pertaining to it.

15. Using a scale of 1-5, how would you rate the colour palette of the prototype?

	1	2	3	4	5
Attractiveness	○	○	○	○	○
Appropriateness	○	○	○	○	○
Congruity	○	○	○	○	○

16. Using a scale of 1-5, how would you rate the general layout of the prototype?

	1	2	3	4	5
Position and Spacing	○	○	○	○	○
Readability	○	○	○	○	○
Clarity of Navigation	○	○	○	○	○

17. Please offer any comments you might have on the colour palette and general layout.

18. Which feature do you think presents as the most important?

	Not Important	Moderately Important	Important	Highly Important	Extremely Important
Home Screen (featuring a graphical display of progress and health trends)	○	○	○	○	○
Reminders/Alarms (ability to receive notifications on testing blood glucose and regularly meals)	○	○	○	○	○
Data Capture (ability to input and track blood glucose levels, exercise and food consumption)	○	○	○	○	○
Access to Appropriate Nutrition and Health Information	○	○	○	○	○
Access to a Comprehensive User Forum	○	○	○	○	○

19. If you can think of any other features not displayed that you believe could be important, please specify.

20. Are you likely to make use of a mobile health platform should you have any future pregnancies?

- ○ Yes
- ○ No
- ○ Not Applicable

21. Would you recommend that pregnant women make use of a mobile health platform similar to this prototype?

- ○ Yes
- ○ No
- ○ Maybe

22. If you answered 'Maybe' or 'No' to the previous question, please provide any reasons why.

Appendix G – Ethical Clearance

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

24 February 2020

HREC REF: 765/2018

Dr Jill F Abrahams
Division of Biomedical Engineering
Room 7.23, Anatomy Building
FHS

Dear Dr Abrahams

PROJECT TITLE: IMPROVING DIABETES MANAGEMENT OF PREGNANT WOMEN IN UNDER-SERVED COMMUNITIES OF SOUTH AFRICA BY USING A MOBILE PHONE (MSc Candidate - Ms S Arbi)

Thank you for your response letter dated 19 November 2019, addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 28 February 2021

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: - Ms Shameela Arbi will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.